

Department of Health and Human Services



FY 2010 Agency Financial Report

November 15, 2010

FY 2010 Agency Financial Report

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GLOSSARY

INTRODUCTION

Purpose of This Report

Our fiscal year (FY) 2010 *Agency Financial Report* provides fiscal and high-level performance results that enable the President, Congress, and American people to assess our accomplishments for the reporting period October 1, 2009 through September 30, 2010. This report provides an overview of our programs, accomplishments, challenges, and management's accountability for the resources entrusted to us. We have prepared this report in accordance with the requirements of the Office of Management and Budget's (OMB) Circular A-136, *Financial Reporting Requirements*.

How This Report is Organized

This report includes a message from the Secretary, followed by three sections:

Section I: Management's Discussion and Analysis contains information on our mission and organizational structure; strategic goals and highlights of our accomplishments; analysis of the financial statements and stewardship information; systems, legal compliance and controls; and other management information and initiatives.

Section II: Financial Reports contains a message from the Chief Financial Officer, the independent auditor reports, the financial statements and notes, required supplementary stewardship information, and required supplementary information.

Section III: Other Accompanying Information includes other annually required reports, *Improper Payments Information Act of 2002 (Public Law (P.L.) 107-300)* reporting details, the management report on final action, the summary of financial statement audit and management assurance findings, the Office of Inspector General's summary of top management challenges and our response to those challenges.

We Welcome Your Comments

Thank you for your interest in the Department of Health and Human Services. We welcome your comments and questions regarding this *Agency Financial Report* and appreciate any suggestions for improving this report for our readers. Please contact us at hhsdeputycfo@hhs.gov or at:

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Office of Finance/DFMP
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MESSAGE FROM THE SECRETARY



Kathleen Sebelius

I am pleased to issue this *Fiscal Year 2010 Agency Financial Report* for the Department of Health and Human Services.

The Department of Health and Human Services helps provide the building blocks that Americans need to live healthy, successful lives. We fulfill that mission every day by providing millions of children, families, and seniors with access to high-quality health care, by helping people find jobs and parents find affordable childcare, by keeping food safe and infectious diseases at bay, and by pushing the boundaries of how we diagnose and treat disease.

New laws are helping us give Americans more control over their health care. The *Patient Protection and Affordable Care Act* (P.L. 111-148) and the *Health Care and Education Reconciliation Act* (P.L. 111-152), collectively known as the *Affordable Care Act*, include comprehensive health insurance reforms that will hold insurance companies more accountable, lower health care costs, guarantee more health care choices, and enhance the quality of health care for all Americans.

I am also proud of our continued efforts to implement the *American Recovery and Reinvestment Act of 2009* (*Recovery Act*, P.L. 111-5). Because of the *Recovery Act*, we have been able to expand comprehensive prevention and wellness efforts, make new investments in cures and treatments for the future, provide relief to States and families struggling in the recession, and strengthen our primary care workforce.

In FY 2010, we had a number of other significant accomplishments.

Improving the Quality of and Access to Health Care

Thanks to the *Affordable Care Act*, millions of Americans are already enjoying better access to health care. As part of the law, we established a new Pre-Existing Condition Insurance Plan (PCIP) offering coverage to uninsured Americans previously unable to obtain health coverage because of a pre-existing condition. We also created an Early Retiree Reinsurance Program to shore up the health coverage of retirees, while making American businesses more competitive. In addition, we sent \$250 checks to more than one million seniors and people with disabilities to supplement their medication expenses.

These efforts build on the foundation laid by the *Recovery Act*. Through that law, we made an historic investment in health information technology – helping put tools in the hands of doctors and other health professionals so they can help their patients make informed decisions about their health care. Altogether, we announced awards to help make health information technology available to hospitals and primary care physicians, and trained thousands of people for careers in health care and information technology. In addition, through enactment of the *Indian Health Care Improvement Act of 2010*, we continued critical efforts to reduce health disparities for American Indians and Alaska Natives.

Promoting Public Health

The new Communities Putting Prevention to Work initiative helped support efforts to decrease smoking and obesity, increase physical activity, and improve nutrition. We also unveiled innovative new online tools to help consumers take control of their health care by connecting them to new information and resources to help access quality, affordable health care coverage. In addition, we funded projects to fight costly and dangerous health care-associated infections, and launched a new national strategy to prevent and treat HIV/AIDS here in the United States. We also continued our efforts to fight infectious diseases abroad, marking the approval of the 100th antiretroviral drug aimed at the treatment and care of people living with HIV/AIDS worldwide, in cooperation with the President's Emergency Plan for AIDS Relief.

Reducing Health Care Fraud

We are committed to responsibly managing every dollar in our budget and are accountable to America's hard-working citizens for results with honest disclosure of potential conflicts of interest and no tolerance for waste or abuse. Our anti-fraud efforts include plans to increase investments in programs with a proven record of preventing fraud, reduce payment errors, and return recovered funds to the Trust Funds. We will continue to fight health care fraud by strengthening program integrity for Medicare, Medicaid, and other significant programs. We anticipate that anti-fraud efforts, building on accomplishments of the Health Care Fraud Prevention and Enforcement Action Team, will save billions over the next 10 years.

Stewardship

During FY 2010, we continued in our role as stewards of the public trust. This year we obtained a clean opinion on our Consolidated Balance Sheet, Statement of Net Cost, Statement of Changes in Net Position, and the Combined Statement of Budgetary Resources. The auditors did not express an opinion on the Statement of Social Insurance, which is developed using information from the annual report of the Medicare trust funds. The FY 2010 Statement of Social Insurance projections contained in this report incorporate the effects of the *Affordable Care Act* and are prepared in accordance with the standards issued by the Federal Accounting Standards Advisory Board and reflect current law. Please refer to the auditor's reports, the financial statements, and notes contained in Section II of this *Agency Financial Report*.

FY 2010 Agency Financial Report

As required by the *Federal Managers' Financial Integrity Act of 1982 (FMFIA)* and the Office of Management and Budget's (OMB) Circular A-123, *Management's Responsibility for Internal Control*, we evaluated our internal controls and financial management systems. Section I of this report includes the Department's qualified assurance statement, which again describes two material weaknesses in the Department: 1) Financial Reporting Systems and Processes, and 2) Information Systems Control and Security. These weaknesses also constitute system non-conformances under Section 4 of the *FMFIA*. Sections II and III of this report provide further, detailed information on our weaknesses and the corrective actions we are taking.

Looking to the Future

The U.S. Department of Health and Human Services manages one of the largest budgets in the world. The investments we make in health care, disease prevention, social services, and scientific research represent a vast contribution to the health and quality of life of every American and play a large part in building a healthier, more prosperous America. Our accomplishments would not be possible without the dedication and commitment of our employees and the strong support of our State, local, and nonprofit partners. I am proud of the incredible work this Department does to improve the health and well-being of all Americans, especially those who are least able to help themselves.

/Kathleen Sebelius/

Kathleen Sebelius
Secretary
November 15, 2010

Section I: Management's Discussion and Analysis

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MISSION AND ORGANIZATIONAL STRUCTURE

Our mission is to enhance the health and well-being of Americans by providing for effective health and human services and by fostering sound, sustained advances in the sciences, underlying medicine, public health, and social services. Our vision is to provide the building blocks that Americans need to live healthy, successful lives. We fulfill our mission and vision daily by providing millions of children, families, and seniors with access to high-quality health care, helping people find jobs, assisting parents to find affordable childcare, keeping the food on Americans' shelves safe, and pushing the boundaries of how we diagnose and treat disease. Each of our components contributes to our mission and vision in the following ways.

- The Administration for Children and Families (ACF) is responsible for Federal programs that promote the economic and social well-being of families, children, individuals, and communities.
- The Administration on Aging (AoA) is responsible for developing a comprehensive, coordinated, and cost-effective system of home- and community-based services that help elderly individuals maintain health and independence in their homes and communities. The AoA serves as the primary Federal focal point and advocacy agent for older Americans via State and area agency networks on aging, as well as providing grants to States, Tribal organizations, and other community services.
- The Agency for Healthcare Research and Quality (AHRQ) improves the quality, safety, efficiency, and effectiveness of health care for all Americans. The AHRQ fulfills this mission by conducting health services research in order to identify the most effective ways to organize, manage, finance, and deliver high quality healthcare, reduce medical errors, and improve patient safety.
- The Agency for Toxic Substances and Disease Registry (ATSDR) serves the public by using the best science, taking responsive public health actions, and providing trusted health information to prevent harmful exposures or disease-related exposures to toxic substances.
- The Centers for Disease Control and Prevention (CDC) collaborates to create the expertise, information, and tools that people and communities need to protect their health – through health promotion; prevention of disease, injury and disability; and preparedness for new health threats.
- The Centers for Medicare and Medicaid Services (CMS) administers public insurance programs, which serve as the primary sources of health care coverage for seniors and a large population of medically vulnerable individuals, and act as a catalyst for enormous changes in the availability and quality of health care for all Americans. In addition to these programs, CMS has the responsibility to ensure effective, up-to-date health care coverage, and promote quality care for beneficiaries.
- The Food and Drug Administration (FDA) is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation. The FDA is also responsible for advancing the public health by helping to speed innovations that make medicines and foods effective, affordable, and safer; and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health.
- The Health Resources and Services Administration (HRSA) is responsible for improving health care and achieving health care equity through access to quality services, a skilled health workforce and innovative programs. The HRSA focuses on uninsured, underserved, and special needs populations in its goals and program activities.
- The Indian Health Service (IHS) raises the physical, mental, social, and spiritual health of American Indians and Alaska Natives to the highest level.
- The National Institutes of Health (NIH) are the stewards of medical and behavioral research for the nation. The NIH promotes science in pursuit of fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to extend healthy life and reduce the burdens of illness and disability.
- The Substance Abuse and Mental Health Services Administration (SAMHSA) is responsible for reducing the impact of substance abuse and mental illness on

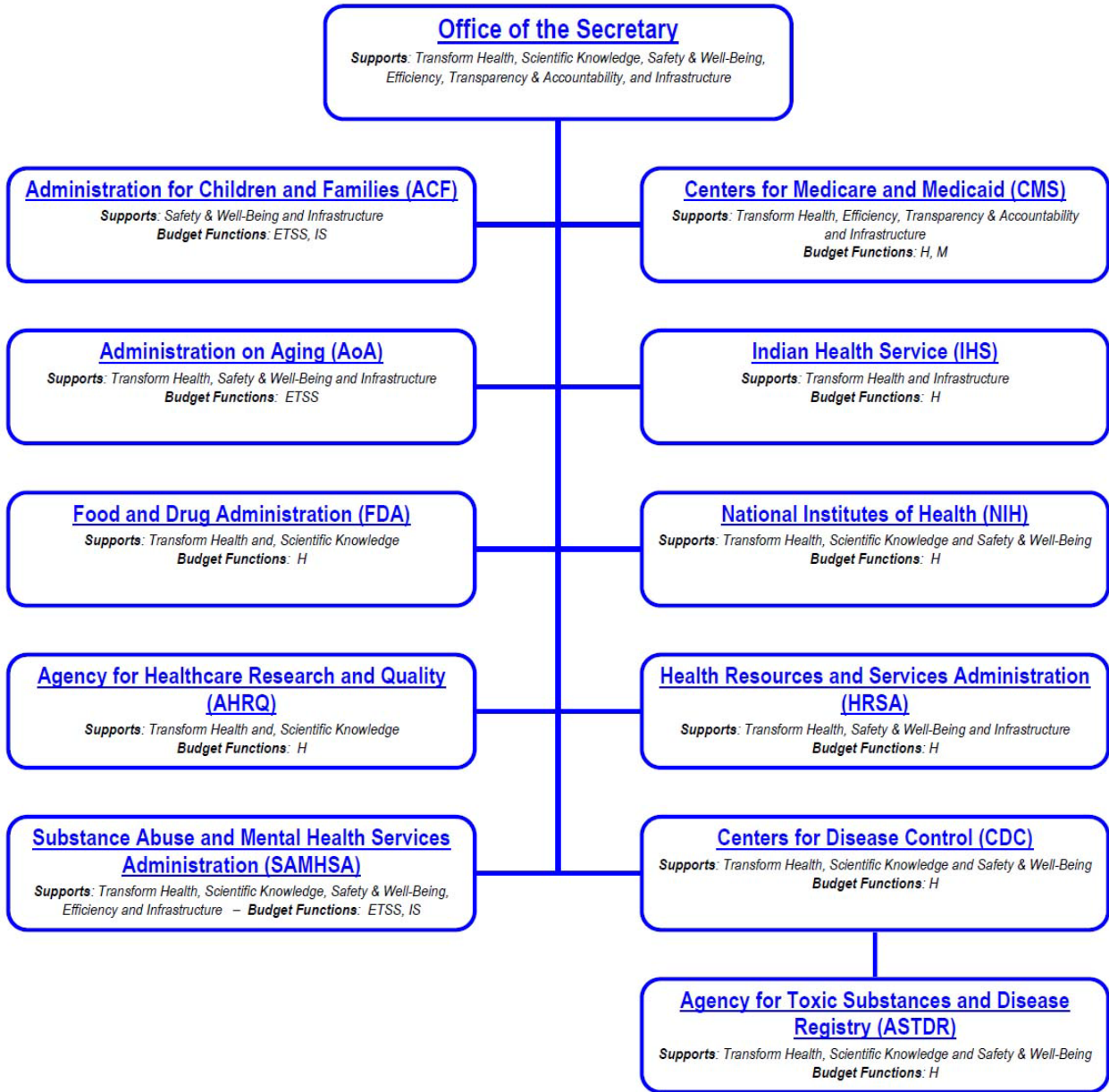
America's communities. The SAMHSA accomplishes its mission by providing leadership, developing service capacity, communicating with the public, setting standards; and improving practice in communities and in primary and specialty care settings.

Our Secretary leads our components to provide a wide range of services and benefits to the American people. In addition, the following staff offices report directly to the Secretary, and support the operating components in carrying out our mission. They are:

- Office of the Assistant Secretary for Health (ASH)
- Office of the Assistant Secretary for Administration (ASA)
- Office of the Assistant Secretary for Financial Resources (ASFR)
- Office of the Assistant Secretary for Legislation (ASL)
- Office of the Assistant Secretary for Planning and Evaluation (ASPE)
- Office of the Assistant Secretary for Public Affairs (ASPA)
- Office of the Assistant Secretary for Preparedness and Response (ASPR)

- Center for Faith-Based and Neighborhood Partnerships (CFBNP)
- Departmental Appeals Board (DAB)
- Office for Civil Rights (OCR)
- Office of Consumer Information and Insurance Oversight (OCIIO)
- Office on Disability (OD)
- Office of the General Counsel (OGC)
- Office of Global Health Affairs (OGHA)
- Office of Health Reform (OHR)
- Office of the Inspector General (OIG)
- Office of Intergovernmental Affairs (IGA)
- Office of Medicare Hearings and Appeals (OMHA)
- Office of the National Coordinator for Health Information Technology (ONC)

We present our organizational chart, which consists of the Office of the Secretary and 10 operating components, and further details concerning each component's role in the accomplishment of our overall mission and strategic goals, incorporating those of the staff offices, in the chart below. To find further information regarding our organization, components, and programs, visit our website at <http://www.hhs.gov>.



Budget Functions: ETSS = Education, Training and Social Services; H = Health; IS = Income Security; M = Medicare

STRATEGIC GOALS

We strive for continuous improvement to enhance the health and well-being of Americans. We achieve our vision for a healthier and more hopeful America through leadership in medical sciences, and public health and human services programs.

We accomplish our mission through several hundred programs and initiatives that cover a wide spectrum of activities, serving the American public at every stage of life. We are responsible for approximately a quarter of all Federal expenditures¹ and administer more grant dollars than all other Federal agencies combined. Our FY 2010 direct budget authority was approximately \$845 billion. Through our programs and other activities, we work closely with State, local, U.S. Territories, Tribal Governments and the private sector to improve the health and well-being of Americans.

Many of our programs meet the objectives of the *American Recovery and Reinvestment Act of 2009 (P.L. 111-5) (Recovery Act)*, which provides an estimated \$141.4 billion over 11 years to achieve and support the objectives of the *Recovery Act*. In addition to funding in the direct provisions, the *Recovery Act* provides for additional fiscal relief to the States, in the form of reduced contributions for prescription drug costs of approximately \$4.3 billion over the same period. For specific accountability and transparency information concerning our *Recovery Act* efforts and expenditures, visit <http://www.hhs.gov/recovery>. For government-wide information concerning the *Recovery Act*, visit <http://www.recovery.gov>.

Every three years, we update our Strategic Plan, which describes our work to address complex, multifaceted, and ever-evolving health and human service issues. An agency strategic plan is one of three main elements required by the *Government Performance and Results Act of 1993 (P.L. 103-62) (GPRA)*. Our Strategic Plan defines our mission, goals, and the means by which we will measure our progress in addressing specific national problems, needs or

challenges related to our mission over the course of five years.

Goal 1. Transform Health Care. Make coverage more secure and affordable while promoting high-value, effective care.

Goal 2. Advance Scientific Knowledge and Innovations. Improve patient care, food safety, and medical product safety through scientific discovery, innovation for shared solutions, and investment in the regulatory sciences.

Goal 3. Advance the Health, Safety, and Well-Being of Our People. Ensure the health, safety and well-being of our people through improved accessibility and quality of supportive services, promotion of prevention and wellness, reduction of infectious diseases, and protection of health and safety during emergencies.

Goal 4. Increase Efficiency, Transparency, and Accountability of HHS Programs. Ensure program integrity and responsible stewardship of resources by fighting fraud and working to eliminate improper payments. Improve the health and well-being of the American people by providing and leveraging available data. Promote sustainability through improving HHS environmental, energy, and economic performance.

Goal 5. Strengthen the Nation's Health and Human Service Infrastructure and Workforce. Enhance the ability and capacity of the health care workforce, strengthen the Nation's human service workforce, and improve National, State, local and Tribal surveillance and epidemiology capacity.

We are in the process of updating our Strategic Plan for fiscal years (FY) 2010 through 2015. The plan will contain our five updated strategic goals related to each of our operating components, and is summarized below. The primary responsibility for our strategic efforts, by component, is included in our organizational chart on the previous page.

Each of our operating and staff divisions contributed to the development of our Strategic Plan, as reflected in our goals, objectives, strategies, evaluations, and performance

¹ Calculated using data from the *FY 2011 President's Budget*, Historical Table 4.2 *Outlays by Agency*

indicators. The process emphasized creating alignment between the long-range Strategic Plan and annual GPRAs reporting in our *Congressional Budget Justifications* and the *Summary of Performance and Financial Information*, which together fulfill our GPRAs annual performance reporting requirements.

We discuss our strategic highlights in the *Strategic Goal Highlights* section, beginning on Page 6. Additionally, the table on the next page summarizes the latest information available relating to our performance targets and results for FY 2007 through FY 2010.

SUMMARY OF DEPARTMENT OF HEALTH AND HUMAN SERVICES PERFORMANCE RESULTS

Through our 10 Operating Divisions and 20 Staff Divisions, we managed over 300 programs affecting the health, safety, and welfare of every American. Detailed information about each of our programs and its associated performance measures can be found at: <http://www.hhs.gov/budget>.

We gauge our success by hundreds of performance measures. Information on our performance measures is included in the *On-line Performance Appendices* (available at: <http://www.hhs.gov/budget>). We do not yet have FY 2010 data for many programs' measures due to the expected data lag that results from the timing of the reporting requirements for our grantees at the State and local levels.

Table 1 shows our overall progress in meeting 1,033 performance measures for FY 2007 through FY 2010. These data are preliminary; more complete data will be presented in the FY 2010 *Summary of Performance and Financial Information* that will be available in February 2011. Data for FY 2010 are currently available for 2 percent of our performance measures. Out of the 25 targets currently reported in FY 2010, 76 percent met or exceeded the targets. Our continued ability to meet a large percentage of our targets is notable, considering our size and the scope of our programs.

Table 1: Summary of Performance Targets and Results (Preliminary)

Fiscal Year	Total Targets	Targets with Results Reported	Percent of Targets with Results Reported	Total Reported Targets Met	Percent of Reported Targets Met
2007	870	851	98%	661	78%
2008	932	875	94%	675	77%
2009	968	766	79%	593	77%
2010	1,033	25	2%	19	76%

STRATEGIC GOAL HIGHLIGHTS

We accomplish our Strategic Goals by managing hundreds of programs across several disciplines. As a major, grant-making agency, our grantees influence our outcomes. We publicly report our progress toward achievement of our mission and Strategic Goals through more than 1,000 performance measures contained in our *On-Line Performance Appendices* (at <http://www.hhs.gov/budget>). More than half of these measures track outcomes versus outputs. An example of an outcome rate is the adoption rate for children involved in the Child Welfare System. One-fifth of our performance measures track the efficiency with which we provide our services, reflecting our goal of getting better value for each dollar spent.

Based on available data, in FY 2010 we met or exceeded 76 percent of our reported performance targets. Detailed performance results are available in our *FY 2010 Annual Performance Report*, which will be available in our *FY 2012 Congressional Justification*, in February 2011 at <http://www.hhs.gov/budget>. In addition, a synopsis of performance information will be contained in the *FY 2010 Summary of Performance and Financial Information*, also available at <http://www.hhs.gov> by February 2011.

The accomplishments described below, related to our five updated strategic goals, represent highlights of our accomplishments. These selected accomplishments demonstrate progress toward the achievement of our mission and strategic goals. For a discussion of our financial and program challenges, please see *Looking Ahead*, included later in this Section, on Page 5.

Strategic Goal 1: Transform Health Care

Giving Americans Control over Health Care

On March 23, 2010, President Obama signed health insurance reform legislation giving Americans more control of their health care. This important legislation strengthens insurance coverage for Americans and makes coverage more affordable for families and small business owners. The *Affordable Care Act* ensures that all Americans have access to quality, affordable health care. The non-

partisan Congressional Budget Office (CBO) determined that the *Affordable Care Act* provides health care coverage to an additional 32 million Americans.



Covering the Uninsured with Pre-existing Conditions

We announced the establishment of the new \$5 billion Pre-existing Condition Insurance Plan (PCIP), created under the *Affordable Care Act*. This program offers coverage to uninsured Americans who have been unable to obtain health coverage because of a pre-existing health condition. Plans are administered through two processes: supporting State run programs, or providing insurance coverage directly to individuals in States where States have not established their own program. This program was established to enable coverage until the Health Benefit Exchange program is operational and ends on January 1, 2014. For more information on this program, visit <http://www.HealthCare.gov>.

Promoting the Adoption of Health Information Technology

In FY 2009, under the *Health Information Technology for Economic and Clinical Health Act (HITECH Act)*, we began a \$2 billion effort to achieve widespread, meaningful use of health information technology (HIT). The majority of the \$2 billion investment supports new cooperative agreement programs awarded in FY 2010.

The Office of the National Coordinator also worked extensively with the Centers for Medicare and Medicaid Services and the Regional Extension Centers to develop the policies and regulations required to implement the Medicare and Medicaid Electronic Health Records (EHRs) Incentive Programs. This effort included stakeholders across the health care system as well as recommendations from the two Federal Advisory Committees (the HIT Policy and Standards Committees).

The HIT Extension Program provided \$774 million to establish a network of 62 Regional Extension Centers that will offer technical assistance and guidance to providers as they adopt and work toward achieving meaningful use of EHRs. This Program provides funding to create the HIT Research Centers. The HIT Research Centers, will collect and disseminate information on best practices to support and accelerate healthcare providers' use of electronic health records.

We awarded \$564 million in State Health Information Exchange cooperative agreements to support States or State Designated Entities in establishing health information exchange capability among healthcare providers and hospitals in their jurisdictions. This effort is critical to enabling care coordination and improving the quality and efficiency of health care.

To demonstrate the potential impact of HIT on improved health care outcomes, the Beacon Community Program has funded 17 cities that will demonstrate the vision of a future where hospitals, clinicians, and patients are meaningful users of health IT electronic health records. Together, this community achieves measurable improvements in health care quality, safety, efficiency, and population health.

To ensure that individuals are trained to support and sustain the investments of the HIT Initiative, the HIT Workforce Program provided awards totaling \$84 million to 16 universities and junior colleges to support training and development of more than 50,000 new health IT professionals. We also provided \$60 million for Strategic Health IT Advanced Research Projects (SHARP) awards to four advanced research institutions to focus on solving current and future challenges that represent barriers to the adoption and meaningful use of health IT. In addition to the new cooperative agreement

program, funds were awarded to support privacy security, standards and interoperability, and communication activities.

More information on the HIT Initiative is available at <http://healthit.hhs.gov>. This website also includes *HIT Buzz*, our new blog that provides information about health IT and a forum for consumers, providers, policymakers, and technology experts to share their ideas and concerns regarding health IT.

Connecting Consumers to Quality Affordable Health Care Coverage

We unveiled several innovative new on-line tools that help consumers take control of their health care by connecting them to new information and resources to help access quality, affordable health care coverage.

One such tool, <http://www.HealthCare.gov>, is the first website to provide consumers with both public and private health coverage options – tailored specifically for their needs – in a single, easy-to-use tool. The website combines information about our programs with information from more than 1,000 private insurance plans. The website also provides information about the implementation of the *Affordable Care Act* and other health care resources, including important new information about the quality of care available in America's outpatient and emergency departments.

We also unveiled <http://www.CuidadodeSalud.gov>, a partner site to [HealthCare.gov](http://www.HealthCare.gov). It is the first website in Spanish of its kind to help consumers take control of their health care by connecting them to new information and resources that will help them access quality, affordable health care coverage. [CuidadodeSalud.gov](http://www.CuidadodeSalud.gov) is particularly important for Latinos, who have the highest rates of un-insurance in the nation—more than one in three Latinos are uninsured.

Medicare Prescription Drug Cost Relief



Provisions of the *Affordable Care Act* are designed to make prescription drug costs more affordable. One particular program provided more than one million eligible seniors and people with disabilities with a tax-free, one-time rebate check for \$250. In 2011, the *Affordable Care Act* will provide eligible beneficiaries with a 50 percent discount on their Medicare Part D covered brand name medications for drugs purchased in the coverage gap.

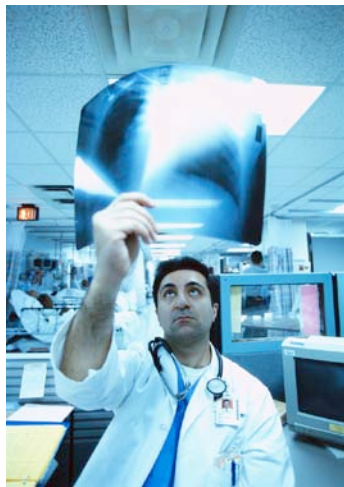
Strategic Goal 2: Advance Scientific Knowledge and Innovation

Innovation Supporting Transparent and Open Government

We developed three innovative ideas in direct response to the "[Memorandum on Transparency and Open Government](#)," issued by President Obama on January 21, 2009, his first full day in office.

Information Streaming, *IdeaLab*, and *YouTube Know What to Do About the Flu and Prevention PSA Contest* implement the President's three principles for promoting a transparent and open government: transparency, participation, and collaboration. Our initiatives help to facilitate ways for the public and private sector to find the information they need and receive real-time updates. Websites with further innovation information include *Information Streaming*, found at <http://www.whitehouse.gov/open/commitments> and *IdeaLab and YouTube Know What to Do about the Flu and Prevention PSA Contest*, found at <http://www.whitehouse.gov/open/innovations>.

Preparing the Nation's Response to Radiological Emergencies



We awarded nine contracts under the Biomedical Advanced Research and Development Authority (BARDA) for the advanced research and development of more effective tests and devices to determine the level of

radiation a person has absorbed after a nuclear or radiological incident. These contracts total \$35 million for the initial phase and up to \$400 million over five years.

Each contractor has identified particular physical or biological characteristics, known as biomarkers, to indicate how much radiation a person has absorbed. The contractors will initially conduct studies to

test the accuracy of the biomarkers as an indicator for the level of absorbed radiation. In addition, they will determine if their proposed devices measure these biomarkers effectively.

Upon successful completion of these studies, the contractors will develop prototypes of portable devices that can be used in the field by responders to test for radiation absorption. Knowing a more precise measure of radiation exposure will help health care responders determine the most appropriate treatment for patients exposed to damaging ionizing radiation, which can destroy the body's cells.

Providing for Development of Cell-based Viral Vaccines

We issued final guidance to help manufacturers who are developing safe and effective cell-based viral vaccines to address emerging and pandemic threats.

The document, "[Guidance for Industry: Characterization and Qualification of Cell Substrates and Other Biological Materials Used in the Production of Viral Vaccines for Infectious Disease Indications](#)," will aid manufacturers who wish to use new cell substrates for vaccine production, such as for influenza vaccines. Currently, all licensed manufacturers use chicken eggs to produce influenza vaccines. In addition to providing advice to manufacturers about the scientific principles of cell substrate development, the guidance describes tests that may be used to evaluate cell substrates intended for use in viral vaccine production.

Progressing in Prevention of Healthcare-Associated Infections

We released a report showing our nation is making progress toward eliminating healthcare-associated infections that kill almost 100,000 Americans each year. The report focuses on central line-associated bloodstream infections (CLABSI), serious infections that can cause death in hospitalized patients and an estimated \$2.7 billion added costs to the U.S. healthcare system.

The *First State-Specific Healthcare-Associated Infections Summary Data Report* (available at <http://www.cdc.gov/hai/statesummary.html>), demonstrates steps take to reduce these often-preventable infections are working. The data in the report shows an 18 percent decrease in national CLABSI incidence. This report is also a benchmark for progress on the national goals outlined in the our *Action Plan to Prevent Healthcare-Associated Infections* (<http://www.hhs.gov/ophis/initiatives/hai/>).

Implementing Food Safety Working Group Recommendations

The U.S. Department of Agriculture (USDA) Secretary, Tom Vilsack, and the Health and Human Services Secretary, Kathleen Sebelius, commended Federal food safety agencies for their accomplishments supporting President Obama's Food Safety Working Group. The Food Safety Working Group, co-chaired by Secretaries Vilsack and Sebelius, recommended a public health-focused approach to food safety based on three core principles: prioritizing prevention; strengthening inspection and enforcement; and improving response and recovery.

The following are a few of the highlights of the progress and accomplishments achieved during the year:

Prioritizing Prevention

- **Salmonella in poultry and eggs:** USDA issued revised draft standards for the presence of Salmonella to reduce consumers' exposure to this pathogen in raw poultry products. We issued a rule to control Salmonella contamination of eggs during production, storage, and transportation. By July 9, 2010, approximately 82 percent of shell eggs were expected to be covered under the new requirements.
- **Produce safety:** We issued commodity-specific draft guidance documents to industry on agricultural practices to reduce the risk of microbial contamination in the production and distribution of tomatoes, melons and leafy greens. We are developing a proposed rule on produce safety.

Strengthening Inspection and Enforcement

- **Reportable Food Registry:** We launched the Reportable Food Registry (RFR), an electronic portal for industry and public health officials to report when there is reasonable probability that a food item will cause serious adverse health consequences.
- **Environmental assessments:** The workgroup is developing a training program for environmental health specialists on how to conduct an

environmental assessment properly during a food-borne outbreak investigation.

Improving Response and Recovery

- **Improving disease surveillance:** This workgroup launched a new web-based surveillance platform to enhance the speed and completeness of food-borne outbreak reports, and developed an on-line database to make data more easily accessible by the public. We also published the first joint executive report on antimicrobial resistance among pathogens in food animals, retail meats and human clinical cases based on data up to 2007.
- **Collaborative investigation or identification of outbreaks:** Since July 2009, we coordinated or led more than 15 major multi-state outbreak, food-related investigations. These investigations have identified new food vehicles, including peppered Italian-style deli meat, and a new food-borne pathogen (Shiga-toxin producing *E. coli* O145), and have led to major product recalls. All involved close collaboration among Federal agencies.

Enhancing the Evidence Base for Health Care Decisions

We conducted a landmark clinical trial comparing two stroke prevention procedures, which showed that surgery and stenting are equally safe and effective treatments for patients at risk for stroke. A trial of 2,502 participants compared carotid endarterectomy (CEA) to carotid artery stenting (CAS). CEA is a surgical procedure to clear blocked blood flow and considered the gold standard prevention treatment. CAS is a newer and less invasive procedure that involves threading a stent and expanding a small protective device in the artery to widen the blocked area and capture any dislodged plaque.

The overall safety and efficacy of the two procedures was largely the same with equal benefits for both men and for women, and for patients who had previously had a stroke and for those who had not. However, when investigators looked at the numbers of heart attacks and strokes, they found differences. The investigators found that there were more heart attacks in the surgical group, 2.3 percent compared to 1.1 percent in the stenting group; and more strokes in the stenting group, 4.1 percent versus 2.3 percent for the surgical group in the weeks following the procedure. The long-term investment in patient-centered health research informs

clinicians, consumers, and policymakers on the effectiveness of different treatment options.

Strategic Goal 3: Advance the Health, Safety and Well-Being of the American People



Promoting Early Childhood Health and Development

One year after enactment of the *Children's Health Insurance Program Reauthorization Act*, we collaborated with the USDA and jointly released a comprehensive review of the past year's accomplishments in finding and enrolling children in health coverage, *The Children's Health Insurance Program Reauthorization Act One Year Later: Connecting Kids to Coverage*.

We announced that 2.6 million more children were served by Medicaid or the Children's Health Insurance Program (CHIP) over the past year. Our goal is to enroll the nearly 5 million more children who are eligible for coverage. In conjunction with these efforts, we announced \$100 million in Federal grant funds to improve health care quality and delivery systems for children enrolled in CHIP. This includes \$10 million in awards specifically for Indian Health providers to reach out in new ways to American Indian and Alaska Native children and families.

To further promote early childhood health and development, we are increasing access to, and improving the quality of early childhood education programs such as Head Start. These efforts reinforce the Administration's goal of serving more low-income children in safe, healthy, and nurturing childcare settings that promote learning, child development, and school readiness.

Over 45,000 additional Head Start and Early Head Start slots were created because of *Recovery Act* funding, which provided \$2 billion in child care funding. We also are on track to implement revised program performance standards for Head Start programs and expand the number of States with Quality Rating and Improvement Systems (QRIS) that meet high quality benchmarks for childcare and other early childhood education programs. These benchmarks were developed by us in coordination with the U.S. Department of Education.

Supporting the National HIV/AIDS Strategy

We approved the 100th antiretroviral drug in association with the President's Emergency Plan for AIDS Relief (PEPFAR), aimed at the prevention, treatment, and care of people infected with and affected by HIV/AIDS worldwide. The PEPFAR program is a cooperative effort that involves many of our components, the State Department's Office of the U.S. Global AIDS Coordinator, the U.S. Department of Defense, other Federal agencies, host country governments, and other international partners. The goal of PEPFAR is to work with host nations to support treatment of at least 3 million people, prevention of 12 million new infections, and providing care for more than 12 million HIV-infected and affected people by 2013. In addition, PEPFAR supports training of at least 140,000 health care workers in HIV/AIDS prevention, treatment, and care.



We also announced the release of grant awards totaling more than \$1.84 billion to ensure that people living with HIV/AIDS continue to have access to life-saving health care and medications. The grants are funded through the [Ryan White HIV/AIDS Program](#), which helps more than half a million individuals every year obtain clinical care, treatment and social support services. The Health Resources and Services Administration (HRSA), one of our components, oversees the Ryan White HIV/AIDS Program, which provides funding for health services for people who lack sufficient health care coverage or financial resources to cope with HIV disease. Federal funds are awarded to agencies located around the country, which in turn deliver care to eligible individuals.

Supporting Pregnant and Parenting Teens and Women

We awarded grants of \$182 million in States and tribes across the country to support pregnant and

parenting teens and women. Of the total awards, \$100 million came from the Teen Pregnancy Prevention Program, \$55 million was from the Personal Responsibility Education Program, \$24 million was from the Pregnancy Assistance Fund, and \$3 million was from the Tribal Maternal, Infant, and Early Childhood Home Visiting Grant Program.

Each of these programs provides States and tribes with assistance to support vulnerable teens and women who are pregnant and parents. These grants help support the replication of teen pregnancy prevention programs that have shown to be effective, and provide rigorous research as well as the testing of new, innovative approaches to combating teen pregnancy. In addition, States will use these funds to link these families to health, education, child care, and other support mechanisms that can help brighten the futures of parents and their children. States are also encouraged to use the funds to address violence against pregnant and parenting women.

Protecting the Health and Safety of Americans in Public Health Emergencies

We released *The National Health Security Strategy*, the nation's first comprehensive strategy focused on protecting people's health during a large-scale emergency. The strategy sets priorities for government and non-government activities over the next four years.

National health security means that the nation and its people are prepared for, protected from, and resilient in the face of health threats or incidents with potentially negative health consequences such as bioterrorism and natural disasters. The strategy provides a framework for actions that will build community resilience, strengthen and sustain health emergency response systems, and fill current gaps.

Among the initial actions for the Federal Government is conducting a review to improve the system for developing and delivering countermeasures – medications, vaccines, supplies and equipment for health emergencies; coordinating across government and with communities to identify and prioritize the capabilities, research, and investments needed to achieve national health security; and evaluating the impact of these investments.

Responding to the Haiti Earthquake Emergency

When the devastating earthquake first struck Haiti on January 12, 2010, President Obama called on Americans to unite and respond to this tragedy. Our personnel were among the first to answer that call. We worked closely with the U.S. Department of State, which notified us of specific requests from Haiti for medical and public health support in the disaster zone. We also launched a website for media and the public, to provide real-time updates on the Department's response to the earthquake in Haiti.

Our medical teams traveled with medicine, medical supplies, and equipment to help save lives during the critical post-earthquake timeframe. Doctors, nurses, paramedics, emergency medical technicians, and other medical personnel in our National Disaster Medical System (NDMS) and U.S. Public Health Service provided immediate medical care to the injured, while public health experts assessed the scope of the earthquake's damage to water and food supplies.

We also helped U.S. citizens returning from Haiti, assessing their needs upon arrival. These needs included medical care, short-term shelter, and transportation to their destinations in the United States. We also worked to unite Haitian children who arrived in the United States with their prospective parents, who filed for their adoption. These children are now all in the care of their new families.

In the aftermath of the earthquake our personnel assisted the Haitian Government with mental health services, disaster and public health assessments, environmental health and safety testing, and the critical reconstruction of health care infrastructure.

Helping Americans Lead Healthier Lives

First Lady Michelle Obama, Secretary Kathleen Sebelius and U.S. Surgeon General Regina Benjamin announced plans to help Americans lead healthier lives through better nutrition, regular physical activity, and by encouraging communities to support healthy choices.

The First Lady launched the *Let's Move!* campaign on childhood obesity and asked us to play a key role. To assist, Secretary Sebelius launched the *Let's Move Cities and Towns* component of the *Let's Move!* campaign encouraging adoption of a long-term, sustainable and holistic approach to fight child obesity in their communities. We also released *The Surgeon General's Vision for a Healthy and Fit Nation*, which highlights the alarming trend of overweight and obese

Americans, and the changes that promote the health and wellness of our families and communities. To view *The Surgeon General's Vision for a Healthy and Fit Nation*, visit <http://www.surgeongeneral.gov>.

To further fight the prevalence of obesity, we awarded more than \$650 million to support public health efforts to reduce obesity, increase physical activity, improve nutrition, and decrease smoking—the four most important actions for combating chronic diseases and promoting health in communities, States, and U.S. territories. This money supports several components in the Department's comprehensive prevention and wellness initiative, Communities Putting Prevention to Work (CPPW), which is funded under the *Recovery Act*. CPPW awards to cities, towns, and tribes across the country will provide communities with the resources to create healthy choices for residents, such as increasing availability of healthy foods and beverages, improving access to safe places for physical activity, discouraging tobacco use, and encouraging smoke-free environments. To learn more about *Communities Putting Prevention to Work*, visit <http://www.cdc.gov/chronicdisease/recovery>.



In addition, we partnered with the Departments of Treasury and Agriculture on the Healthy Food Financing Initiative to bring grocery stores and other healthy food retailers to under-served urban

and rural communities across America. The Healthy Food Financing Initiative will promote a range of interventions that expand access to nutritious foods, including developing and equipping grocery stores and other small businesses and retailers selling healthy food in communities that currently lack these options.

Strategic Goal 4: Increase Efficiency, Transparency, and Accountability of Our Programs

Implementing the Program Integrity Initiative

We launched a Department-wide program integrity initiative to ensure that every one of our programs and offices prioritizes the identification of systemic vulnerabilities and opportunities for waste and exploitation, and implements heightened oversight. Because each dollar wasted or stolen is a dollar taken away from a family whose health and well-being may depend on it, we are obligated to ensure our program dollars are being spent in the way they were intended. Accordingly, we created the Secretary's Council on Program Integrity.

The Council on Program Integrity is looking at all areas within our organization to conduct risk assessments of programs or operations most vulnerable to waste, fraud, or abuse; enhance existing program integrity initiatives or create new ones; share best program integrity practices throughout our organization; and measure the results of our efforts. Programs or operations that the Council is looking at include Medicare, Medicaid, Head Start, Low-Income Home Energy Assistance Program, medical research, and the public health grants. While the initiative was established just months ago, we have already re-designed our risk assessment tool and are in the process of putting the first group of programs through the new risk assessment process. That will be followed by successive rounds of program risk assessments across our organization until all of our programs have strong program integrity practices built into their operations.

Preventing Medical Identity Theft and Medicare Fraud

In early FY 2010, Secretary Kathleen Sebelius and Assistant Attorney General Tony West highlighted the Obama Administration's work to fight Medicare Fraud and released new tips and information to help seniors and Medicare beneficiaries deter, detect and defend against Medical identity theft.

Medical identity theft occurs when someone steals a patient's personal information, such as his or her name and Medicare number, and uses the information to obtain medical care, to buy drugs or supplies, or to bill Medicare fraudulently using that patient's stolen identity. The new tips and a printable brochure were produced by our Office of the Inspector General (OIG) and are available now at <http://www.StopMedicareFraud.gov> and <http://www.oig.hhs.gov/fraud/idtheft>.

The materials include practical steps to help “deter, detect, and defend” against medical identity theft. Beneficiaries are reminded to beware of offers of free medical equipment, services, or goods in exchange for their Medicare numbers. Beneficiaries are also encouraged to review their Medicare Summary Notices, Explanations of Benefits statements, and medical bills regularly for suspicious charges and to report suspected problems.

“When criminals steal from Medicare, they are stealing from all of us. That’s why fighting Medicare fraud is one of the Obama Administration’s top priorities.”

Secretary Kathleen Sebelius

Expanding the Medicare Fraud Strike Force

In December 2009, CMS announced that as part of the continuous operations of the Medicare Fraud Strike Force, thirty people were indicted in three cities for their alleged roles in schemes to submit more than \$61 million in false Medicare claims.

In conjunction with the indictments, we jointly announced with the Department of Justice (DOJ) the expansion of Medicare Fraud Strike Force operations from four cities in the United States (Miami, Los Angeles, Detroit, and Houston) to seven cities (Brooklyn, Tampa and Baton Rouge added). The DOJ-HHS Medicare Fraud Strike Force is a multi-agency team of Federal, State and local investigators designed to combat Medicare fraud using Medicare data analysis techniques and an increased focus on community policing.

The Strike Force Team operations are another important step of the Health Care Fraud Prevention and Enforcement Action Team (HEAT), an initiative announced in May 2009 between the DOJ and us to focus our joint efforts to reduce and prevent Medicare and Medicaid fraud through enhanced cooperation. In the three years since they were created, Medicare Fraud Strike Forces have charged more than 810 defendants with defrauding Medicare of nearly \$1.9 billion taxpayer dollars. Since

announcing HEAT in May 2009, the Medicare Fraud Strike Forces have charged 465 defendants with defrauding Medicare of more than \$830 million taxpayer dollars.

Strategic Goal 5: Strengthen the Nation’s Health and Human Services Infrastructure and Workforce

Providing Indian Health Care Improvements

The *Indian Health Care Improvement Act (IHCIA)*, the cornerstone legal authority for the provision of health care to American Indians and Alaska Natives, was made permanent when President Obama signed the bill on March 23, as part of the *Affordable Care Act*. The version of the *IHCIA* signed into law provides a comprehensive health service delivery system for approximately 1.9 million of the nation’s estimated 3.3 million American Indians and Alaska Natives.

We also announced our compliance with President Obama’s memorandum on Tribal consultation and Executive Order 13175 by submitting a detailed tribal consultation plan to improve services, outreach, and consultation efforts to American Indian and Alaska Natives.

In conjunction with our plan, Secretary Sebelius convened a Tribal-Federal Work Group whose task it will be to review tribal comments, regional consultation reports and develop recommendations to improving our Tribal consultation policy. Secretary Sebelius will also create a Tribal Advisory Committee, the first of its kind established by any Cabinet official in the Administration.



Constructing or Improving Biomedical Research Facilities

We awarded \$1 billion dollars of *Recovery Act* funds to construct, repair and renovate scientific research laboratories and related facilities across the country. Environmental impact was a prominent theme of the related construction application and awards process to ensure energy

efficiency, reduction of the environmental impact of building materials, and minimized use of compounds that deplete the ozone.

These awards are part of the Administration's \$100 billion investment in science, innovation and technology to spur domestic job creation in emerging industries and create a long-term foundation for economic growth, which helps to foster scientific advances that may lead to improved human health.

Investing to Train and Develop New Health Care Providers

We invested \$250 million to increase the number of health care providers and strengthen the primary care workforce. The investments in the primary care workforce are the first allocation from the new \$500 million Prevention and Public Health Fund for fiscal year 2010, created by the *Affordable Care Act*. These funds will be used to creating additional primary care residency slots, support physician assistant training in primary care, encouraging students to pursue full-time nursing careers, establishing new nurse practitioner-led clinics, and encouraging States to plan for and address health professional workforce needs.

Communities across the country have long suffered from a shortage of primary care providers. Without action, experts project a continued primary care shortfall due to the needs of an aging population and a decline in the number of medical students choosing

one primary care specialty. The Association of American Medical Colleges estimated that the nation would have a shortage of approximately 21,000 primary care physicians in 2015. Building on the earlier investments made by the *Recovery Act*, the *Affordable Care Act* investments, particularly for the National Health Service Corps, will support the training and development of more than 16,000 new primary care providers over the next five years.

Supporting Public Health Training Centers

We awarded \$16.8 million to support 27 Public Health Training Centers at schools of public health and other public or non-profit institutions across the country. The program helps improve the public health system by enhancing skills of the current and future public health workforce. Institutions accredited to provide graduate or specialized training in public health are eligible for funding. Most of the funding – \$15.4 million – is made available by the *Prevention and Public Health Fund* authorized by the *Affordable Care Act*.

Funded organizations (1) plan, develop, operate and evaluate projects that support goals established by the Secretary in preventive medicine, health promotion and disease prevention; or (2) improve access to and quality of health services in medically underserved communities. Other Public Health Training Centers activities include assessing the learning needs of the public health workforce; providing accessible training; and working with organizations to meet strategic planning, education, and resource needs.

ANALYSIS OF FINANCIAL STATEMENTS AND STEWARDSHIP INFORMATION

The financial statements were prepared in accordance with Federal accounting standards and audited by the independent accounting firm of Ernst & Young LLP under the direction of our Inspector General. The *Chief Financial Officers Act of 1990 (P.L. 101-576)* requires the preparation and audit of these statements, which are part of our efforts for continuous improvement of financial management. The production of accurate and reliable financial information is necessary for making sound decisions, assessing performance, and allocating resources. Section II of the report presents our audited financial statements and notes.

Limitations of the Principal Financial Statements

The principal financial statements in Section II of this report have been prepared to report our financial position and results of operations, pursuant to the requirements of 31 U.S.C. §3515 (b). Although the statements have been prepared from our books and records in accordance with generally accepted accounting principles for Federal entities and the formats prescribed by the OMB, the statements are in addition to the financial reports used to monitor and control budgetary resources, which are prepared from the same books and records. These statements should be read with the realization that they are for a component of the U.S. Government, a sovereign entity. One implication of this is that liabilities cannot be liquidated without legislation providing us with resources and budget authority.

Table 2: Summary of Financial Condition Trends
(in Billions)

	FY2006	FY2007	FY2008	FY2009	FY2010	Increase (Decrease)	% Change
Total Assets	\$513.9	\$503.8	\$529.3	\$562.8	\$563.7	\$0.9	0.2%
Fund Balance with Treasury	159.9	114.8	124.3	162.0	182.2	20.2	12.5%
Investments, Net	342.0	365.9	385.4	381.1	359.9	(21.2)	(5.6)%
Other Assets	12.0	23.1	19.6	19.7	21.6	1.9	9.6%
Total Liabilities	\$78.4	\$81.9	\$86.6	\$94.4	\$99.2	\$4.8	5.1%
Accounts Payable	1.2	1.0	1.0	1.1	1.6	0.5	45.5%
Entitlement Benefits Due and Payable	61.2	61.5	65.9	72.2	72.7	0.5	0.7%
Accrued Grant Liabilities	3.8	3.9	3.9	4.0	4.2	0.2	5.0%
Federal Employee and Veterans Benefits	7.5	8.4	8.8	9.7	10.0	0.3	3.1%
Other Liabilities	4.7	7.1	7.0	7.4	10.7	3.3	44.6%
Net Position	\$435.5	\$421.9	\$442.7	\$468.4	\$464.5	\$(3.9)	(0.8)%
Total Liabilities and Net Position	\$513.9	\$503.8	\$529.3	\$562.8	\$563.7	\$0.9	0.2%

Financial Condition – What is Our Financial Picture?

The table above summarizes trend information concerning components of our financial condition – assets, liabilities, and net position. The Consolidated Balance Sheet presents a snapshot of our financial condition as of September 30, 2010, compared to FY 2009, and displays assets, liabilities and net position. Another component of our financial picture is our Consolidated Statement of Net Cost. Each of these components are discussed below, and in

further detail in Financial Statements and Notes, Section II, of this report.

Assets—What Do We Own and Manage?

Assets represent the value of what we own or manage. Our total assets were \$563.7 billion on September 30, 2010. This amount represents an increase of \$0.9 billion or 0.2 percent above the last year's assets. This increase is largely attributable to the net effect of an increase of \$20.2 billion in Fund Balance with Treasury and a decrease of \$21.2 billion in Net Investments. The Fund Balance with Treasury increase of

\$20.2 billion resulted primarily from increases of \$20.8 billion in various HHS appropriations. The increases of \$20.8 billion include \$8.9 billion in unobligated balances; \$10.3 billion in obligations that have not yet been disbursed; and \$1.0 billion in non-budgetary funds with Treasury. The increase in unobligated balances includes funds that are restricted for future use and not apportioned for current use. The restricted amount is primarily for the *Affordable Care Act* programs, Children’s Health Insurance Program, CMS Program Management, State Grants and Demonstrations, and the *Recovery Act* Health Information Technology Program. In FY 2010, the HHS received \$18.7 billion under the *Affordable Care Act* of which \$16 billion is restricted for future use. The majority of the \$21.2 billion decrease in Net Investments resulted from a decline of \$21.3 billion in Medicare Non-Marketable, Par Value bonds carried at face value.

Fund Balance with Treasury and Net Investments together comprise 96.2 percent of our total assets. The remaining assets totaling \$21.6 billion or 3.8 percent consist of Accounts Receivable, Inventory and Related Property, General Property, Plant, and Equipment, and Other Assets.

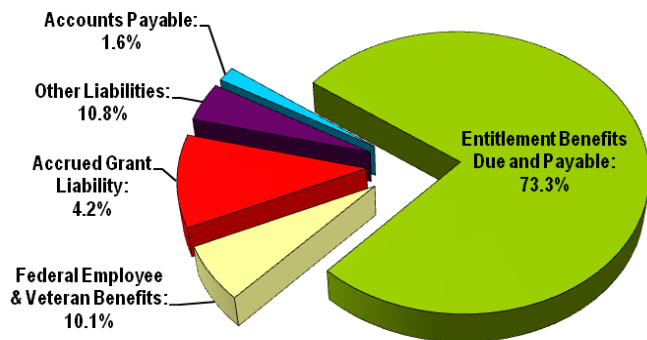
Liabilities – What Do We Owe?

Our liabilities, amounts that we owe from past transactions or events, were \$99.2 billion on September 30, 2010. This represents an increase of \$4.8 billion, or 5.1 percent above the last year’s liabilities. Entitlement benefits due and payable to the public from the Medicare and Medicaid insurance programs in the amount of \$72.7 billion represent 73.3 percent of our liabilities.

Of the \$4.8 billion increase, \$2.0 billion relates to increases in contingent liabilities and the remaining \$2.8 billion relates to increases in all other liabilities. Contingent liabilities have been established for Medicaid audit and program disallowances that are currently being appealed by the States. Consistent with Federal accounting standards, we recognize the responsibility for future program participants of Medicare as a social insurance program, rather than a pension program. Accordingly, we have not recognized a liability for future payments to current and future program participants. The estimated long-term cost is included in the Statement of Social Insurance and discussed

further in the associated financial statement notes included in Section II of this report.

Figure 1: FY 2010 Liabilities by Type



Ending Net Position—What Have We Done Over Time?

Our net position represents the difference between assets and liabilities. Changes in our net position resulted from changes that occur within cumulative results of operations and unexpended appropriations. At the end of FY 2010, our net position was \$464.5 billion, a decrease of \$3.9 billion, or 0.8 percent from the previous year. Of the \$464.5 billion, \$319.0 billion was for earmarked funds and \$145.5 billion was for all other funds. The decrease of \$3.9 billion was due to the net effect of an increase of \$14.6 billion in unexpended appropriations, offset by a decrease of \$18.5 billion in cumulative results of operations. Net position is the sum of the cumulative results of operations since inception and unexpended appropriations, those appropriations provided to HHS that remain unused at the end of the fiscal year.

Net Cost of Operations—What Are Our Sources and Uses of Funds?

Our net cost of operations represents the difference between the costs incurred by our programs less associated revenues. We receive the majority of our funding through Congressional appropriations and reimbursement for the provision of goods or services to other Federal agencies. Our net cost of operations for the year ended September 30, 2010 totalled \$856.7 billion.

The chart to the right depicts our’ FY 2010 net cost of operations by major budget function and component. The majority of FY 2010 net costs relate to Medicare (\$447.2 billion) and Health (\$351.8 billion) programs, or more than 93 percent of our annual net costs. During

FY 2010, the Health and Medicare budget functions experienced growth of 9.8 percent (\$31.4 billion) and 4.0 percent (\$17.1 billion), respectively. The growth in the Health budget function is primarily attributable to normal increases in Entitlement Benefits of \$13.9 billion and *Recovery Act* extension of Federal Medical Assistance Percentage (FMAP) expenditures of \$8.2 billion. The growth in Medicare is primarily attributed to an increase in the Hospital Insurance (HI) and Supplementary Medical Insurance (SMI) benefits of \$8.6 billion and \$5.0 billion, respectively. There was also an increase in Part D benefits of approximately \$6.6 billion and a reduction in the net cost related to an increase in the SMI premiums of \$3.1 billion.

The FY 2010 net cost represents an increase of \$52.8 billion or 6.6 percent more than the FY 2009 net cost. Approximately 85 percent of the net cost of operations relates to Medicare, Medicaid, the Children's Health

Insurance Program (CHIP), and other health programs managed by the Centers for Medicare and Medicaid Services.

The table below depicts our net cost of operations by major component for the last five years.

Figure 2: FY 2010 Net Cost

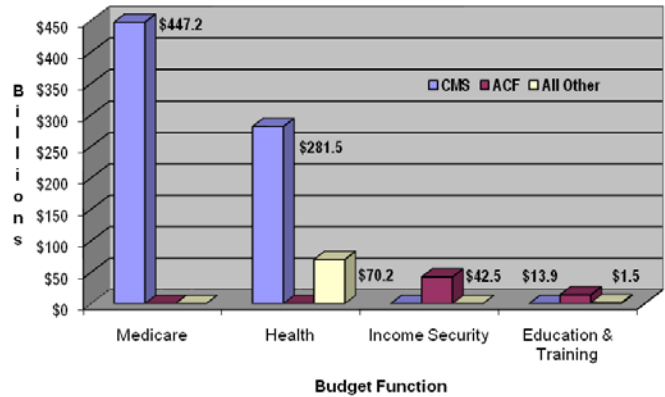


Table 3: Net Cost of Operations
(in Billions)

	2006	2007	2008	2009	2010	\$ Chg	% Chg
Responsibility Segments							
Centers for Medicare and Medicaid Services (CMS) Gross Cost	\$574.2	\$ 612.4	\$657.9	\$749.0	\$789.7	\$40.7	5.4%
CMS Exchange Revenue	(49.8)	(50.3)	(54.1)	(57.3)	(60.7)	(3.4)	5.9%
CMS Net Cost of Operations	524.4	562.1	603.8	691.7	729.0	37.3	5.4%
Other Segments:							
Other Segments Gross Cost of Operations	102.2	105.4	108.4	116.0	130.9	14.9	12.8%
Exchange Revenue	(2.7)	(2.9)	(3.1)	(3.8)	(3.2)	0.6	15.8%
Other Segments Net Cost of Operations	99.5	102.5	105.3	112.2	127.7	15.5	13.8%
Net Cost of Operations	\$623.9	\$664.6	\$709.1	\$803.9	\$856.7	\$52.8	6.6%

Budget Resources - What Were Our Resources and the Status of Funds?

The Combined Statement of Budgetary Resources provides information on availability of budgetary resources and the status at the end of the year. FY 2010 total resources were \$1.3 trillion, representing an increase of \$73.7 billion, or 6.2 percent, over FY 2009. Fiscal year obligations of \$1.2 trillion increased \$64.7 billion, or 5.7 percent, over FY 2009. Our year-end resources were \$59.3 billion, of which \$16.6 billion were not available for expenditure. Total net outlays (cash disbursed for the Department’s obligations) of \$854.1 billion increased \$56.8 billion or 7.1 percent from FY 2009 net outlays of \$797.3 billion.

Social Insurance

The Statement of Social Insurance is presented as a principal financial statement, in accordance with Statement of Federal Financial Accounting Standards No. 25, *Reclassification of Stewardship Responsibilities and Eliminating the Current Services Assessments*. This statement presents the 75-year actuarial present value projection of the income and expenditures of the Hospital Insurance and Supplementary Medical Insurance trust funds. Future expenditures are expected to arise from the formulae specified in current law for current and future program participations. These projections are considered important information regarding the potential future cost of the Medicare program.

Medicare Trust Funds

Medicare is a combination of four programs: HI, SMI, Medicare Advantage, and Medicare Prescription Drug Benefit. At the end of FY 2010, approximately \$354.5 billion or 98.5 percent of HHS investments were in Treasury securities to support the Medicare Trust Funds.

Established in 1965 as Title XVIII of the *Social Security Act (42 U.S.C. Ch. 7)*, Medicare was legislated as a complement to Social Security retirement, survivors, and disability benefits and originally covered people age 65 and older. In 1972, the program was expanded to cover the disabled, people with end-stage renal disease requiring dialysis or kidney transplant, and people age 65 or older who elect Medicare coverage. Since 1966,

Medicare enrollment has increased from 19 million to approximately 47 million beneficiaries.

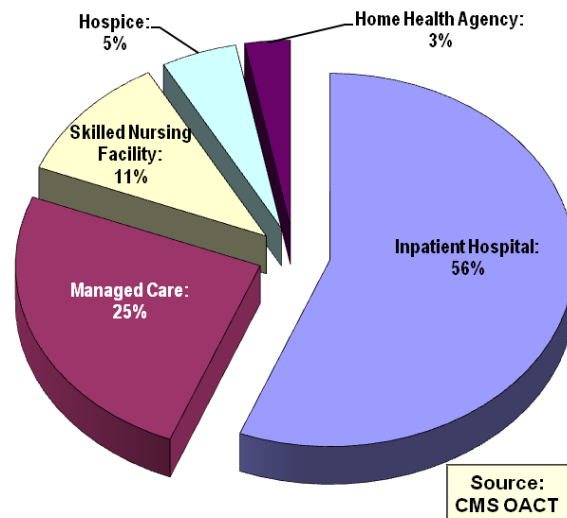
In December 2003, *Medicare Prescription Drug, Improvement & Modernization Act of 2003 (P.L. 108-173)* was enacted, which included the addition of a drug benefit (Part D). The Medicare Prescription Drug Benefit program represents one of the largest changes to Medicare since its enactment in 1965, and FY 2007 was the first year to reflect a full year of costs.

Hospital Insurance

Hospital Insurance (HI), or Medicare Part A, is usually available automatically to people age 65 and older, who have worked long enough to qualify for Social Security benefits, and to most disabled people entitled to Social Security, or Railroad Retirement benefits. The program, financed primarily by payroll taxes paid by workers and employers, pays for in-patient hospital, skilled nursing facility, home health, hospice, and managed care. The annual payroll taxes fund benefits for current beneficiaries. The Hospital Insurance Trust Fund invests in Treasury securities for funds not currently needed to pay benefits and related expenses.

Based on estimates from the *Midsession Review of the FY 2011 President’s Budget*, in-patient hospital spending accounted for 56 percent of HI benefit outlays in FY 2010 and managed care spending comprised about 25 percent. Total HI benefit outlays grew by 3.9 percent during 2010, and HI benefit outlays per enrollee were projected to increase by 1.7 percent, to \$5,210.

Figure 3: HI Medicare Benefit Payments

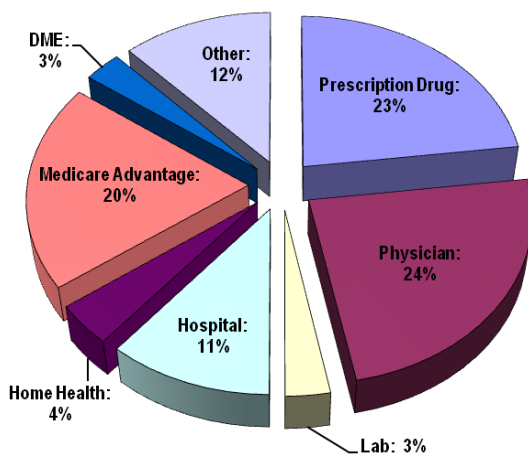


Under the Trustees' intermediate set of assumptions, as displayed in the Statement of Social Insurance, as of January 1, 2010, the Hospital Insurance Trust Fund will incur an actuarial deficit of nearly \$2.7 trillion over the 75-year projection period, as compared with \$13.8 trillion in the FY 2009 financial report. To bring the HI Trust Fund into actuarial balance over the next 75 years, substantial increases in revenues and/or reductions to benefits will be required.

Supplementary Medical Insurance

Supplementary Medical Insurance, or Medicare Part B and Medicare Part D, is available to nearly all people age 65 and older, the disabled, and people with end-stage renal disease who are entitled to Part A benefits.

Figure 4: SMI Medicare Benefit Payments



The program pays for physician, out-patient hospital, home health, laboratory tests, durable medical equipment, designated therapy, out-patient prescription drugs, and other services not covered by Hospital Insurance. The coverage is optional and beneficiaries are subject to monthly premium payments. Approximately 93 percent of Hospital Insurance enrollees elect to enroll in Supplementary Medical Insurance.

The SMI program is financed primarily by transfers from the Treasury General Fund and by the monthly premiums. As with Part A, funds not needed to pay benefits and related expenses are held in the SMI Trust Fund and invested in Treasury securities.

Based on estimates from the Midsession Review of the *FY 2011 President's Budget*, SMI benefit outlays grew by 7.2 percent during FY 2010. Physician services, the largest component of SMI, accounted for 24 percent of SMI benefit outlays. During FY 2010, total SMI benefit outlay projections indicate an estimated increase of 4.5 percent, to \$6,300 per enrollee.

As reported in the Required Supplementary Information Section of this report, income (including interest on Treasury securities) is very close to expenditures. Expenditures include benefit payments as well as administrative expenses. This is because SMI funding differs fundamentally from HI. Parts B and D are not based on payroll taxes, but rather on a combination of monthly beneficiary premiums and interest income from the Treasury. Both are established annually to cover the following year's expenditures, thus the B and D accounts are automatically in financial balance every year, regardless of future economic and other conditions.

Under the Trustees' intermediate set of assumptions, and as displayed in the Statement of Social Insurance, the situation over the 75-year period is entirely different from HI projections because of the program financing. The projected future expenditures for Part B will be \$17.7 trillion or \$5.5 trillion less than the FY 2009 projection. The projected future expenditures for Part D will be \$9.7 trillion, or \$.3 trillion more than the FY 2009 projection. A substantial level of uncertainty surrounds these projections pending the availability of sufficient data, especially on Part D expenditures, to help establish a trend baseline. The Trustees' estimates assume that the Trust Fund will continue to operate without change in current law.

SYSTEMS, LEGAL COMPLIANCE, AND MANAGEMENT ASSURANCES

Our overall goals for financial management systems focus on ensuring effective internal controls, systems integration, and the ability to produce timely and reliable financial and performance data for reporting. One of management's immediate priorities is to address weaknesses previously identified in audits, evaluations, and assessments of our financial management controls, systems, and processes.

The cornerstone to improving our financial management practices is the ability to maintain management systems, processes, and controls that ensure accountability and transparency; provide useful management information; and meet requirements of Federal laws, regulations, and guidance. We seek to comply with Federal financial management systems requirements, including the:

- *Federal Managers' Financial Integrity Act of 1982 (P.L. 97-255)*
- *Chief Financial Officers Act of 1990 (P.L. 101-576)*
- *Government Management Reform Act of 1994 (P.L. 103-356)*
- *Federal Financial Management Improvement Act of 1996 (P.L. 104-208)*
- *Clinger-Cohen Act of 1996 (P.L. 104-106)*
- *Federal Information Security Management Act of 2002 (P.L. 107-347)*
- OMB Regulations related to these laws.

This Section provides an overview of our current key systems.

Goals and Strategies

Our financial system is a web-based, commercial off-the-shelf product that serves as the foundation for integrated financial management across our organization. The system requires a unified approach for enhancing financial management performance by eliminating duplication, streamlining processes, producing consolidated reports, and establishing a common IT infrastructure across the enterprise.

Our current financial system replaced various legacy accounting systems with one modern technology system with three major components: the Healthcare Integrated General Ledger Accounting System supporting

the Centers for Medicare and Medicaid Services; the National Institutes of Health Business System supporting the National Institutes of Health; and Unified Financial Management System (UFMS) serving the rest of our organization.

Our financial management goals seek to provide decision-makers with timely, accurate, and useful financial and program information; and ensure that our resources are used appropriately, efficiently, and effectively. We continue to strive for improvements in financial management and reporting by streamlining and integrating our financial management systems to ensure transparency and accountability.

We established the Financial Management System Program (FMSP) to provide central management direction and oversight of financial management systems across the Department. We facilitate collaboration between business owners and information technology professionals to maximize our investments and reduce redundancies. We plan to strengthen governance by engaging the business owners and the information technology professionals throughout the life cycle of the HHS financial management system. We will continue to enhance our systems to strengthen control, improve operating performance, and reporting capabilities.

We developed the Consolidated Financial Reporting System (CFRS) to generate our consolidated financial statements. We have run parallel testing during FY 2010. CFRS will become our system of record for FY 2011 and beyond. In addition, during FY 2010, the FDA piloted the Oracle Business Intelligence Enterprise Edition – a reporting dashboard for managers – to enhance the availability of financial management information.

Statement on Auditing Standards (SAS) 70 Reviews

Annually, independent examinations of our internal controls are completed. The auditors completed their examinations for our service providers for FY 2010 under the guidelines of the American Institute of Certified Public Accountants' SAS-Number 70, *Service Organizations*, as amended. The annual examination is a "Type 2" report providing an opinion on the internal controls placed in operation and includes tests of operating effectiveness.

During FY 2010, independent accountants performed SAS 70 examinations on the

Program Support Center's Payment Management System and the National Institutes of Health's Center for Information Technology (CIT) service organizations for periods from July 1, 2009 to June 30, 2010. In the examiner's opinion, the controls that were tested were operating with sufficient effectiveness to provide reasonable, but not absolute, assurance that the control objectives were achieved during that period, with the exception of access and change controls at the CIT, as noted by the examiners. We are developing and implementing plans to address the deficiencies identified in these examinations.

LEGAL COMPLIANCE

Anti-Deficiency Act

As noted in our FY 2009 *Agency Financial Report*, we indicated we were investigating potential reportable violations. During FY 2010, we determined an issue related to a *Recovery Act* contract for the Indian Health Service (IHS) was reportable. The IHS signed a contract in excess of *Recovery Act* funds apportioned for the project. The IHS re-negotiated the contract and we complied with the reporting requirements as required by the *Anti-Deficiency Act* in July 2010.

With respect to a second issue we were investigating, further assessment is necessary. We are committed to resolving this matter appropriately and complying with all aspects of the law.

Improper Payments Information Act (IPIA)

The *Improper Payments Elimination and Recovery Act (IPERA, P.L. 111-204)*, signed into law on July 22, 2010, amends the *Improper Payments Information Act of 2002 (IPIA, P.L. 107-300)* and repeals the *Recovery Auditing Act (Section 831, Defense Authorization Act of 2002, P.L. 107-107)*. The *IPERA*, like *IPIA*, requires each Federal agency to annually review all programs and activities that it administers and identify all such programs and activities that may be susceptible to improper payments. For high-risk programs, the *IPERA* requires that we report improper payment estimates and various other related data. In addition, the *IPERA* significantly increases our recovery auditing efforts, by expanding the definition of payments recovered to include program payments. Section III of this report contains detailed information on our *IPIA* and *IPERA* activities.

MANAGEMENT ASSURANCE

Department-wide Assurance Statement

The Department of Health and Human Services' (HHS) management is responsible for establishing and maintaining effective internal control and financial management systems that meet the objectives of the *Federal Managers' Financial Integrity Act (FMFIA)* and Office of Management and Budget (OMB) Circular A-123, *Management's Responsibility for Internal Control*, dated December 21, 2004. These objectives are to ensure (1) effective and efficient operations; (2) compliance with applicable laws and regulations; and (3) reliable financial reporting.

As required by OMB Circular A-123, *Management's Responsibility for Internal Control*, HHS has evaluated its internal control and financial management systems to determine whether these objectives are being met. Accordingly, HHS provides a qualified statement of reasonable assurance that its internal control and financial systems meet the objectives of *FMFIA*. This statement is qualified due to the following *two* material weaknesses (noted in Table I), which also constitute non-conformances under Section 4 of *FMFIA*:

1. Financial Reporting Systems and Processes
2. Information System Controls and Security

Internal Control over Financial Reporting

HHS conducted its assessment of the effectiveness of internal control over financial reporting, which includes safeguarding of assets and compliance with applicable laws and regulations, in accordance with the requirements of Appendix A, OMB Circular A-123, *Management's Responsibility for Internal Control*. Based on the results of this assessment, HHS identified *one* material weakness in its internal control over financial reporting as of June 30, 2010, relating to the Department's financial reporting systems and processes (identified as #1 above), which also constitutes a non-conformance under Section 4 of *FMFIA*. Other than the exception (identified as #1 above) and described in Table 1, the internal controls over financial reporting as of June 30, 2010, were operating effectively and no other material weaknesses were found in the design or execution of the internal controls over financial reporting.

Internal Control over Operations and Compliance

HHS conducted its assessment of internal control over the effectiveness and efficiency of operations and compliance with applicable laws and regulations, in accordance with OMB Circular A-123, *Management's Responsibility for Internal Control*. Based on the results of this evaluation, HHS identified *one* material weakness in its internal control over the effectiveness and efficiency of operations under Section 2 of *FMFIA* relating to the Department's information system controls and security (identified as #2 above), which also constitutes a non-conformance under Section 4 of *FMFIA* as of September 30, 2010. Other than the exception (identified as #2 above) and described in Table 1, the Department provides reasonable assurance that internal controls over operations and compliance with applicable laws and regulations as of September 30, 2010, were operating effectively and no other material weaknesses were found in the design or execution of the internal controls over operations and compliance.

/Kathleen Sebelius/

Kathleen Sebelius
November 15, 2010

Table 1
Summary of Material Weaknesses and System Non-Conformances

Control Area	FMFIA Section 2			FMFIA Section 4
	Operations (As of 9/30/2010)	Compliance (As of 9/30/2010)	Financial Reporting (As of 6/30/2010)	Systems Non-Conformance
1. Financial Reporting Systems and Processes	-	X	X	X
2. Information System Controls and Security	X	-	-	X

1. Financial Reporting Systems and Processes

HHS' financial management systems are not in substantial compliance with the requirements of the *Federal Financial Management Improvement Act* (FFMIA) because they do not yet fully comply with the Federal financial management systems requirements of OMB Circular A-127, *Financial Management Systems*, and the United States Government Standard General Ledger at the transaction level.

As in prior years, HHS continues to have internal control weaknesses in its financial reporting systems and processes for producing financial statements. While progress has been made over the last few years, the lack of a fully integrated financial management system, and weaknesses in internal control make it difficult for HHS to prepare timely and reliable financial statements. Substantial manual reporting processes, significant adjustments to reported balances, and numerous accounting entries recorded outside the general ledger system are necessary to produce the consolidated financial statements.

HHS completed the Unified Financial Management System (UFMS) implementation for all applicable components and the Department is in the process of integrating the component reporting into a consolidated reporting system. The consolidated reporting system will also include the National Institutes of Health Business System and the Healthcare Integrated General Ledger Accounting System. The consolidated reporting system will be implemented in FY 2011 and is intended to strengthen controls over financial reporting.

In addition to the matters described above, HHS conducted an extensive review across the Operating Divisions of contract funding activities in an effort to assess compliance with existing Departmental guidance and the Federal Acquisition Regulation applicable to funding contracts exceeding one year of performance and to identify avenues to strengthen controls over compliance for such contracts, as needed, within the framework of those requirements. The internal review identified significant compliance concerns and indicated that there were misunderstandings of appropriation-related guidance and its applicability to planning, awarding and funding HHS contracts exceeding one year of performance. The Department is committed to notify appropriate authorities of violations as soon as possible. Corrective actions have been developed to ensure compliance in FY 2011 and beyond.

2. Information System Controls and Security

HHS acknowledges internal control weaknesses for system security, including general and application controls in our financial management systems. Although no one financial management system had a material weakness, the pervasive nature of the findings across our organization leads management to conclude that these findings warrant classification as a material weakness. Significant progress has been made in the remediation of the financial management systems' findings significant progress. However, the financial management systems are not yet in conformance with the appropriate legal and regulatory guidelines as established by the appropriate governing bodies with respect to overall system security. Due to the sensitive nature of information security controls, detailed findings and corrective actions are submitted separately through the governance of the *Federal Information Security Management Act (FISMA)*.

Table 2

Corrective Action Plan and Impact of Material Weaknesses

The following table lists the corrective action dates for the control weaknesses and the impacts of the material weaknesses on the Financial Statements.

Material Weakness	Corrective Action Date	Impact of Material Weakness on Financial Statements
1. Financial Reporting Systems and Processes	FY 2011	Through significant manual effort and compensating controls, the risk of misstating the Financial Statements is mitigated.
2. Information System Controls and Security	FY 2012	Sufficient compensating controls exist through manual efforts that the risk of misstating the Financial Statements is mitigated.

OTHER MANAGEMENT INFORMATION AND INITIATIVES

Grants Management

We are the principal Federal agency for protecting the health of all Americans and providing essential human services to those in need. As the largest Federal agency, the nation's largest health insurer, and the largest grant-making agency, HHS represents more than a quarter of all Federal outlays and administers more grant dollars than all other Federal agencies combined. We manage an array of grant programs in basic and applied science, public health, income support, child development, and health and social services. Through these programs, we awarded more than 96,000 grants totaling more than \$363 billion in FY 2009.

Collectively, these programs are our primary means to achieve our Strategic Goals and objectives, and are described in our new Strategic Plan for fiscal years 2010 to 2015. To achieve our goals, we form partnerships with other Federal departments; State, local, and Tribal governments; academic institutions; hospitals; the business community; nonprofit and volunteer organizations including faith- and community-based organizations; foreign countries, and international organizations. The primary funding vehicle used in these partnerships is a grant. Grants are financial assistance awards that provide support or stimulation to accomplish a public purpose authorized by Federal statute. The primary beneficiary under a grant or cooperative agreement is the public, as opposed to the Government.

The Division of Grants (within the Office of Grants and Acquisition Policy and Accountability), in addition to providing Department-wide policy oversight and guidance for our grant portfolio, has primary responsibility for two systems that support our grant activity. The Tracking Accountability in Government Grants System (TAGGS), a comprehensive Department-wide database designed to track our obligated grant awards at the transaction level on behalf of our operating divisions, offers full search capabilities (<http://taggs.hhs.gov>) for all of our awards, including grants and cooperative agreements. TAGGS supports our compliance with *The Federal Funding Accountability and Transparency Act of 2006 (P.L. 109-282)* by collecting agency grant data and transmitting the data to the Federal web site, <http://www.USASpending.gov>.

We also continue to serve as the managing partner for <http://www.Grants.gov>, which is the Federal Government's central portal for the public to find and apply for Federal assistance awards. As of the end of FY 2009, <http://www.Grants.gov> posted 3,946 grant opportunities and processed approximately 309,771 grant applications Government-wide. We posted 1,647 grant opportunities on <http://www.Grants.gov>, and processed more than 200,000 applications.

We manage several types of grants including formula, block, entitlement, and discretionary. As was the case in prior years, the largest number of grant awards were discretionary (92 percent of total grant volume awarded), yet most of the dollars associated with our grants were awarded through formula, block, or entitlement grants (86 percent of the total dollars awards).

Figure 5: FY09 Grant Dollars by Component

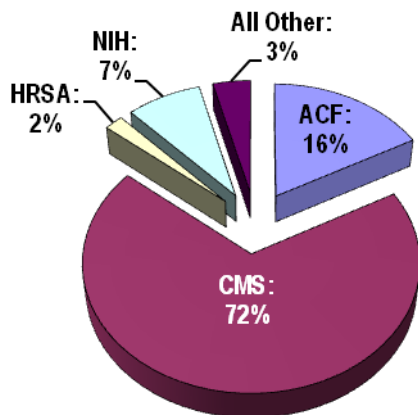
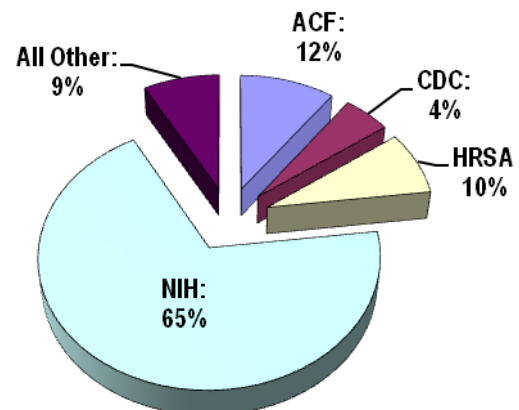


Figure 6: FY09 Grant Volume by Component



The data presented in this section are based on the latest available at the time of this report. The majority of our total FY 2009 grant dollars were awarded by the Centers for Medicare and Medicaid Services (71.4 percent) and the Administration for Children and Families (15.6 percent). By volume, the National Institutes of Health awarded 65.2 percent of the grants, whereas the Administration for Children and Families awarded 11.7 percent.

LOOKING AHEAD TO 2011 - MANAGEMENT CHALLENGES AND HIGH-RISK AREAS

Financial Management Challenges

We are the largest agency in the Federal Government. Our FY 2010 direct budget authority of nearly \$845 billion represents more than a quarter of all Federal expenditures. We are one of the largest financial organizations in the world. Our total net cost of operations is almost double the revenues of the largest *Fortune 500* companies. The sheer magnitude and size, combined with the diverse nature of our operating components, constantly challenges our efforts to standardize and improve financial management across our organization. We have found that a cohesive, coordinated, and unified approach makes these challenges less difficult to overcome, as discussed in the Strategic Planning Section below.

Health Reform Implementation

We have been entrusted with the responsibility for implementing many major provisions of the historic *Affordable Care Act*. Reforming health care is a key goal of the Administration. We established a structure of cross-component subject matter working groups to promote effective collaboration during the implementation phase to ensure goals are met.

Our Office of Health Reform is working in tandem with the White House Office of Health Reform to advance legislation and take actions to cut consumer costs, assure quality and affordable health care for all Americans, and make certain Americans can choose their doctor and health plan.

In conjunction with our health reform efforts, the Office of Consumer Information and Insurance Oversight (OCIIO) was established on April 14, 2010, to implement many of the private health insurance provisions of the

Affordable Care Act. OCIIO is responsible for ensuring compliance with the new insurance market rules, such as the prohibitions on rescissions and on pre-existing condition exclusions for children that took effect this year.

During FY 2010 and beyond, OCIIO will oversee the new medical loss ratio rules and will assist States in reviewing insurance rates. It will also provide guidance and oversight for the State-based health insurance exchanges and administer the Temporary National Pre-existing Condition Insurance and the Early Retiree Reinsurance programs. OCIIO will also compile and maintain an Internet portal providing public information on health insurance options.

Our Office of Health Reform and the Office of Consumer Information and Insurance Oversight will continue to work closely with State Insurance Commissioners and governors, consumers, and stakeholders throughout the implementation process to ensure the new law best serves the American people.

Recovery Act Challenges and Opportunities

The unprecedented accountability and transparency requirements of the *Recovery Act* continue to pose important opportunities and challenges for us. Although we have made significant strides in the development of sophisticated financial systems, work remains to consolidate financial information and to provide more timely and meaningful management reports.

Implementation and oversight of the *Recovery Act* funding presents significant challenges. The awarding and distribution of funds within short timeframes created challenges for us. Among them were ensuring funds were not only distributed to qualified recipients, but also used appropriately and effectively. In addition, the creation and expansion of programs increased the number of new recipients that lack experience with Federal requirements for grantees and contractors. We have had to institute greater monitoring and review at the program level.

The *Recovery Act* and its subsequent regulation required agencies to report data at a level previously unheard of in the Federal

Government. This greater transparency requirement provided us an opportunity to enhance further our financial and management reporting capabilities. The lessons learned from the implementation of the *Recovery Act* and its unprecedented accountability requirements, provides the foundation for a successful implementation of the *Affordable Care Act*.

We continue to face challenges ensuring the accountability and transparency of *Recovery Act* funds; and ensuring the funds are used for designated purposes and for the benefit of the beneficiaries served under the programs receiving enhanced resources. As a result, during FY 2010, Secretary Sebelius initiated a Council on Program Integrity, which strengthens our commitment to ensure that taxpayer dollars are managed and used for the purpose they were intended.

Overseeing and protecting the integrity of *Recovery Act* funds requires even greater coordination among agencies within the Department and with States and other entities.

Strategic Planning

During FY 2010, our CFO Community rallied to use the critical lessons learned implementing the *Recovery Act* to ensure that we would be able to provide appropriate transparency for funds provided under the *Affordable Care Act* and all other appropriations. We continue to conduct business in a collaborative and cross-organizational manner, promote accountability for all of our programs and ensure that our initiatives support our missions and fiscal responsibilities.

Our key initiative for FY 2010 was the development and testing of our Consolidated Financial Reporting System. This integration of our three key accounting systems provides the foundation for data availability and improves our ability to provide consolidated information at more detailed levels and more timely. The success of this effort required not only cross-functional collaboration, but also cross-departmental collaboration. We will produce the first quarter financial statements from this system in January 2011, and anticipate enhancing our management reporting during FY 2011.

Corrective Action Plans

In FY 2010, we continued our work on the corrective action plans developed in FY 2009 and earlier. In addition, we built upon lessons

learned during the implementation of the *Recovery Act* to implement the *Affordable Care Act*.

We also continued our focus upon those Strategic Goals and objectives supporting our Strategic Plan in FY 2010. We maintained our process whereby key Department financial managers collaborated to address management challenges across the organization, leveraging capabilities to improve our business processes. Although work remains, we expect to continue strengthening controls in the years ahead.

As we carry out our efforts to promote and improve financial accountability, transparency, compliance, and risk management across HHS, this collaboration provides a solid foundation for progress. Coming together as a community ensures a balanced approach and the ultimate achievement of our distinct organizational goals. This coordinated pursuit fosters financial management improvement and excellence throughout HHS.

Program Challenges

The breadth of essential human services we deliver to fulfill the President's vision of a healthier, safer, and more hopeful America creates a number of management challenges. To ensure effective stewardship of the taxpayer's resources, we are committed to make improvements related to these challenges.

The enactment of the *Recovery Act* required us to release millions of dollars rapidly to State and local recipients to improve the lives of Americans through protection of health coverage, improved public health, and targeted needed assistance to families who struggled during the economic downturn. Since its enactment in FY 2009, we have obligated \$106.3 billion, or 75.2 percent of the \$141.4 billion in total *Recovery Act* estimated outlays for FY 2009 - 2019.

We are committed to meeting our new responsibilities under the *Affordable Care Act* to ensure that our programs operate efficiently and effectively, while protecting the dollars entrusted to us from fraud and abuse. To achieve this, we will implement clear and effective communication with program beneficiaries, private citizens, and health care industry stakeholders to maintain, develop and oversee our grant and loan programs. We will collaborate with partners to respond to vulnerabilities in current Federal health care programs.

In recent years, we made significant strides to improve the lives of Americans through the efforts of all our components. Breakthroughs in health information technology accelerated the development and adoption of this promising resource. Medicare beneficiaries have greater access to their medications because of the Medicare prescription drug benefit. Medicaid modernization efforts improved and reformed programs, resulting in streamlined eligibility processes. We expanded access to health care for America's low-income, underserved, and medically vulnerable populations, with unprecedented growth in the health care center system.

Although we made great progress, we must continue our current efforts to sustain positive outcomes and augment them with new, innovative strategies to continue to improve the nation's health and well-being. A *Summary of Top Management Challenges Identified by the Inspector General* follows this section. We present the full text of the Inspector General's assessment and our management's response to these challenges in Section III, Other Accompanying Information. Additionally, Section III includes further information concerning our efforts and actions to resolve Office of Inspector General audit findings in the FY 2010 *Management's Report on Final Action*.

SUMMARY OF TOP MANAGEMENT CHALLENGES IDENTIFIED BY THE INSPECTOR GENERAL

Part I: Health Care Reform

1. Incorporating Integrity into Health Care Reform Implementation

Affordable Care Act program integrity is essential to preventing fraud, waste, and abuse in the programs as implementation continues to impact providers, insurers, employers, and beneficiaries.

Challenges include:

- Developing new programs, while issuing and overseeing billions of dollars awarded for grants and loans and benefit payments;
- Implementing clear and effective communication with program beneficiaries, private citizens, and health care industry stakeholders;
- Identifying and mitigating key vulnerabilities and prioritizing oversight resources;
- Collaborating with partners to respond to vulnerabilities in current Federal health care programs, in addition to those established by the *Affordable Care Act*; and
- Building an infrastructure to support continued implementation of the *Affordable Care Act*.

Part II: Integrity of Medicare, Medicaid, and the Children’s Health Insurance Program

2. Integrity of Provider and Supplier Enrollment	3. Integrity of Federal Health Care Program Payment Methodologies	4. Promoting Compliance With Federal Health Care Program Requirements
<p>Medicare and Medicaid programs draw individuals and other groups wishing to exploit the health care system for their own financial gain.</p> <p>Challenges include:</p> <ul style="list-style-type: none"> • Implementing the provisions of the <i>Affordable Care Act</i> using additional tools to evaluate and monitor providers and suppliers; • Ensuring adequate and appropriate provider and supplier enrollment standards and screening; • Streamlining variations in Medicaid provider and supplier enrollment standards, both across States and for providing within a State; and • Increasing nursing home ownership transparency. 	<p>Medicare and Medicaid program methodologies should make certain access to quality care is available without wasteful overspending.</p> <p>Challenges include:</p> <ul style="list-style-type: none"> • Ensuring new payment models under the <i>Affordable Care Act</i> bring balance between protecting the integrity of health care programs and fostering innovation that increases quality, efficiency, and cost effectiveness; • Examining payments under Medicare Part D to determine whether risk-sharing percentages are appropriate; and • Establishing and maintaining the integrity of payment methodologies so that resources are not lost to fraud, waste, and abuse. 	<p>Medicare and Medicaid program compliance is essential to preventing fraud, waste, and abuse in the programs and promoting efficiency and economy.</p> <p>Challenges include:</p> <ul style="list-style-type: none"> • Ensuring providers and the supplier community are well informed about rules and engaged in compliance; • Determining which tools and approaches are the most cost effective, in addition to being the best fit for a diverse and rapidly changing health care industry, to produce the greatest benefit for increasing compliance; and • Implementing a comprehensive safeguard strategy for Medicare and Medicaid as new mandates in the <i>Affordable Care Act</i> expand and redefine roles for compliance programs.

Part II: Integrity of Medicare, Medicaid, and the Children’s Health Insurance Program (Continued)

5. Oversight and Monitoring of Federal Health Care Programs	6. Response to Fraud and Vulnerabilities in Federal Health Care Programs	7. Quality of Care
<p>Trust is the foundation of the Department’s health care programs. Although most providers are honest, a trust-based system requires oversight and monitoring to detect potential fraud, waste, and abuse by a minority or providers.</p> <p>Challenges include:</p> <ul style="list-style-type: none"> • Improving collection, analysis, and monitoring of data to better prevent, detect and respond to fraud, waste, and abuse; • Enhancing the availability of data to monitor payment accuracy and integrity across Medicare Parts A, B, C, and D and Medicaid; and • Implementing provider compliance education efforts to help ensure expanded and redefined roles under the <i>Affordable Care Act</i>. 	<p>A high degree of coordination and collaboration between Federal and State agencies and contractors is necessary to respond to fraud and program vulnerabilities. The complexity of Medicare, Medicaid, and CHIP makes implementing a comprehensive and swift response to fraud and vulnerabilities difficult.</p> <p>Challenges include:</p> <ul style="list-style-type: none"> • Prioritizing and responding to the most serious vulnerabilities; • Responding to detected vulnerabilities by suspending payments to providers upon credible evidence of fraud; and • Strengthening the Government’s ability to detect fraud and abuse, and to respond rapidly to health care fraud under the <i>Affordable Care Act</i>. 	<p>Ensuring the quality of care provided to beneficiaries of Federal health care programs continues to be a high priority.</p> <p>Challenges include:</p> <ul style="list-style-type: none"> • Overseeing provider compliance using existing quality standards; • Protecting beneficiaries from sub-standard care and from abuse and neglect by providers; • Adopting beliefs of the patient safety movement, focusing on quality improvement, measurement, root cause analysis, and public reporting; • Working with various types of health care providers to ensure they are knowledgeable about and consistently implement quality improvement processes; and • Ensuring enhanced quality of care as mandated by the <i>Affordable Care Act</i>.

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

<p>8. Oversight of Food, Drugs, and Medical Devices</p>	<p>9. Emergency Preparedness and Response</p>	<p>10. Grants and Contract Management</p>
<p>The Food and Drug Administration ensures the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, food supply, cosmetics, and products that emit radiation. The National Institutes of Health acquires knowledge to help prevent, diagnose, and treat disease and disability.</p> <p>Challenges include:</p> <ul style="list-style-type: none"> • Responding to emergencies related to food safety, which often involves multiple State and Federal public health agencies; • Ensuring the safety and security of the nation’s food supply, human and veterinary drugs, and medical devices; • Protecting the rights, safety, and well-being of human subjects who participate in clinical trials; and • Making certain that products, once proven safe and effective, are marketed appropriately. 	<p>Events like the outbreak of the H1N1 virus highlight the importance of a comprehensive public health infrastructure that is prepared to respond rapidly and capably to public health emergencies. This infrastructure requires planning, coordination, and communication across a wide range of entities to include: Federal agencies; States, localities, and Tribal organizations; the private sector; individuals and families; and international partners.</p> <p>Challenges include:</p> <ul style="list-style-type: none"> • Providing continued guidance to help improve the public and private sectors’ preparedness and response to public health emergencies; • Ensuring early and accurate detection and reporting of biological agents that pose a national threat, as well as ensuring the drugs used to treat these agents, are available and effective; and • Safeguarding our nation’s laboratory system. 	<p>We are the largest grant-awarding Federal agency. Our 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 addition, we awarded over \$20 billion in contracts in FY 2009. The top five products or services purchased with these contracts were drugs and biologics, professional services, information technology and telecommunications, operations of Government facilities, and research.</p> <p>Challenges include:</p> <ul style="list-style-type: none"> • Monitoring of grants and contracts management because of the size and scope of grant and contract expenditures; • Ensuring the appropriate use of grants and contracts funds; and • Making sure of the integrity of the grants award processes and grantee compliance with program requirements.

Part IV: Cross-Cutting Issues that Span the Department

<p>11. American Recovery and Reinvestment Act</p>	<p>12. Health Information Technology and Integrity of Information Systems</p>	<p>13. Ethics Program Oversight and Enforcement</p>
<p>The <i>Recovery Act</i> was enacted to promote economic recovery and improve the affects of the recession. The <i>Recovery Act's</i> combined spending and tax provisions are expected to cost \$141.4 billion over 10 years. In addition to the funding in direct provisions, the <i>Recovery Act</i> provides for additional fiscal relief to the States, in the form of reduced contributions for prescription drug costs, in the amount of \$4.3 billion. The <i>Recovery Act's</i> objectives include preserving and maintaining jobs, assisting those most affected by the recession, increasing economic efficiency by investing in technological advances in science and health, and stabilizing State and local budgets.</p> <p>Challenges include:</p> <ul style="list-style-type: none"> • Implementing and overseeing <i>Recovery Act</i> funding to ensure accountability and transparency; • Assessing whether the Department is using <i>Recovery Act</i> funds in accordance with legal and administrative requirements; and • Using systems associated with <i>Recovery Act</i> reporting requirements to ensure funds are accurately tracked and reported. 	<p>The development and implementation of interoperable health IT has become a national priority. We must continue to ensure the integrity of information systems and promote health information (IT) technology infrastructure.</p> <p>Challenges include:</p> <ul style="list-style-type: none"> • Developing and maintaining adequate internal controls over its information systems to protect the security and privacy of health plans; • Coordinating among HHS organizations to ensure the privacy and security of health information by enforcing standards and monitoring security control for health IT at the provider level; • Ensuring the confidentiality, integrity, and availability of critical systems and data; and • Proving oversight and monitoring of security controls for our networks, as well as those of its contractors and grantees. 	<p>OIG is involved in oversight of our ethics program. OIG's activities range from evaluating agency ethics programs to investigating allegations of criminal ethics violations by current and former HHS employees. OIG's activities related to ethics issues have increased steadily since 2005.</p> <p>Challenges include:</p> <ul style="list-style-type: none"> • Overseeing ethics considerations in grants and contracts management and research and regulatory oversight; • Ensuring that Federal employees are not compromised by conflicts of interest when performing their official duties (employees cannot participate in official matters in which they and related parties have a financial interest); and • Monitoring potential conflict-of-interest issues related to non-Federal entities and participants in our programs (grantees, clinical investigators, contractors).

Section II: Financial Reports

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MESSAGE FROM THE CHIEF FINANCIAL OFFICER



As the Chief Financial Officer (CFO) of the Department of Health and Human Services (HHS), I recognize we are accountable to our ultimate stakeholders -- the American Public. We are vigilant to use taxpayer resources wisely to carry out the Department's mission to enhance the health and well-being of Americans. With an annual budget in excess of \$845 billion in fiscal year (FY) 2010, we are one of the largest, most complex financial organizations in the world. Through collaboration, our CFO community manages financial accountability, compliance, and risk across HHS by maximizing resources to drive results.

This *Agency Financial Report* represents our accountability report for FY 2010. We will issue the *FY 2010 Annual Performance Report*, the *Congressional Budget Justification*, and the *Summary of Performance and Financial Information* in February 2011. During FY 2010, the Department successfully sustained its standards for reporting and management controls. We have improved our reporting processes and successfully performed our fourth annual, more rigorous internal control assessment as required by OMB Circular A-123, *Management's Responsibility for Internal Control*. The Secretary's annual Statement of Assurance reflecting the results of our assessment is presented in Section I of this report. During FY 2010, we continued in our role as stewards of the public trust. This year we obtained a clean opinion on our Consolidated Balance Sheet, Statement of Net Cost, Statement of Changes in Net Position, and the Combined Statement of Budgetary Resources. However, the auditors did not express an opinion on the Statement of Social Insurance, which is developed using information from the annual report of the Medicare trust funds. The FY 2010 Statement of Social Insurance projections contained in this report incorporate the effects of the *Affordable Care Act*, and are prepared in accordance with the standards issued by the Federal Accounting Standards Advisory Board and reflect current law. Please refer to the auditor's reports, the financial statements, and notes contained in Section II of this *Agency Financial Report*.

The FY 2010 independent auditors' report on controls identifies two internal control material weaknesses that must be corrected relating to: (1) financial reporting systems, analyses, and oversight, and (2) financial management information systems. The Department recognizes the importance of effective internal control and is committed to resolving these material weaknesses promptly. During FY 2011, we plan to continue our collaborative efforts to improve our financial management and to further enhance information available through the implementation of a consolidated reporting solution.

With respect to our financial reporting capabilities, the Department continues to convert Medicare contractor systems and fully implement our consolidated reporting system, which will substantially comply with the *Federal Financial Management Improvement Act (FFMIA)* in early FY 2011. During FY 2010, our CFO executives throughout the Department worked together as a community to provide the public with transparent information concerning our continued implementation of the *American Recovery and Reinvestment Act of 2009* and first year of implementation of the *Affordable Care Act of 2010*. While work remains, we are committed towards resolving long-standing issues to strengthen our internal control structure. Many of these improvements resulted from our strong commitment to accountability, transparency, and effective stewardship.

Finally, I want to thank our employees and partners who work each day to achieve our Nation's noblest human aspirations for safety, compassion, and trust. This report, and the accomplishments it describes, is a reflection of their extraordinary dedication to our mission. Together we look forward to tackling our ambitious agenda for the future in 2011.

/Ellen G. Murray/

Ellen G. Murray
Assistant Secretary for Financial Resources, and
Chief Financial Officer
November 15, 2010

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AUDIT REPORTS

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Washington, D.C. 20201

NOV 15 2010

TO: The Secretary
 Through: DS _____
 COS _____
 ES _____

FROM: Inspector General

SUBJECT: Report on the Financial Statement Audit of the Department of Health & Human Services for Fiscal Year 2010 (A-17-10-00001)

This memorandum transmits the independent auditors' reports on the Department of Health & Human Services (HHS) fiscal year (FY) 2010 financial statements, conclusions about the effectiveness of internal controls, and compliance with laws and regulations. The Chief Financial Officers Act of 1990 (P.L. No. 101-576), as amended, requires the Office of Inspector General (OIG) or an independent external auditor, as determined by OIG, to audit the HHS financial statements in accordance with applicable standards.

We contracted with the independent certified public accounting firm of Ernst & Young, LLP (E&Y), to audit the HHS consolidated balance sheet as of September 30, 2010, and the related consolidated statements of net cost and changes in net position, the combined statement of budgetary resources for the year then ended, and the statement of social insurance as of January 1, 2010. The contract required that the audit be performed in accordance with auditing standards generally accepted in the United States of America; the standards applicable to financial audits contained in the *Government Auditing Standards*, issued by the Comptroller General of the United States; and Office of Management and Budget (OMB) Bulletin 07-04, as amended, *Audit Requirements for Federal Financial Statements*.

Results of Independent Audit

Based on its audit, E&Y found that the FY 2010 HHS consolidated balance sheet and the related consolidated statements of net cost and changes in net position and the combined statement of budgetary resources were fairly presented, in all material respects in conformity with accounting principles generally accepted in the United States of America. E&Y was unable to determine whether the statement of social insurance was fairly presented because of the uncertainties reported by the Chief Actuary in the *2010 Annual Report of The Board of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds*. E&Y also noted two matters involving internal controls over financial reporting that were considered to be

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material weaknesses under standards established by the American Institute of Certified Public Accountants:

- *Financial Reporting Systems, Analyses, and Oversight* - HHS's financial management systems are not compliant with the Federal Financial Management Improvement Act (FFMIA.) of 1996. More specifically, the FFMIA requires Federal agencies to have an integrated financial management system that provides effective and efficient interrelationships among software, hardware, personnel, procedures, controls, and data contained within the systems and compliance with the United States Standard General Ledger at the transaction level and applicable Federal accounting standards. HHS's lack of an integrated financial management system continues to impair its ability to support and analyze account balances reported. Because of continued weaknesses in the financial management systems, management must compensate for the weaknesses by implementing and strengthening additional controls to ensure that errors and irregularities are detected in a timely manner. Review of internal controls disclosed a series of weaknesses that impact HHS's ability to report accurate financial information on a timely basis. For example, the audit found that HHS did not have adequate controls in place to monitor undelivered orders which represent remaining amounts of obligated funds that had not been delivered or appropriately deobligated. As of September 30, 2010, the audit identified approximately 102,500 transactions totaling an approximate \$1.8 billion that were more than 2 year s old without activity. Additionally, during FY 2010, OIG, the Office of General Counsel, and management from HHS and the operating divisions completed reviews of various multiyear contracts and found contracts reviewed were funded inconsistent with the legal requirements.
- *Financial Information Systems* - Issues in the design and the operation of key controls in both general and application controls were noted. In particular, weaknesses were identified in information security program and application configuration management. For example, external and internal system vulnerabilities such as weak password configurations, insecure system configuration, and unnecessary system services continue to exist and pose a significant risk, and change management procedures were insufficient to ensure that only properly authorized changes were implemented into production systems. In addition, audit log monitoring and contingency management were identified as deficiencies that warrant attention.

Evaluation and Monitoring of Audit Performance

In accordance with the requirements of OMB Bulletin 07-04, we reviewed E&Y's audit of the HHS financial statements by:

- evaluating the independence, objectivity, and qualifications of the auditors and specialists;
- reviewing the approach and planning of the audit:
- attending key meetings with auditors and HHS officials:

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- monitoring the progress of the audit;
- examining audit documentation related to the review of internal controls over financial reporting;
- reviewing the auditors' reports; and
- reviewing the HHS Management Discussion and Analysis, Financial Statements and Footnotes, and Supplementary Information.

E&Y is responsible for the attached reports dated November 15, 2010, and the conclusions expressed in those reports. Our review, as differentiated from an audit in accordance with U.S. generally accepted government auditing standards, was not intended to enable us to express, and accordingly we do not express, an opinion on HHS's financial statements, the effectiveness of internal controls, whether HHS's financial management systems substantially complied with the FFMIA, or compliance with laws and regulations. However, our monitoring review, as limited to the procedures listed above, disclosed no instances in which E&Y did not comply, in all material respects, with U.S. generally accepted government auditing standards.

If you have any questions or comments about this report, please do not hesitate to call me, or your staff may contact George M. Reeb, Acting Deputy Inspector General for Audit Services, at (202) 619-3155 or through e-mail at George.Reeb@oig.hhs.gov. Please refer to report number A-17-10-00001.

/Daniel R. Levinson/

Daniel R. Levinson

Attachment

cc:
Ellen Murray
Assistant Secretary for Financial Resources
and Chief Financial Officer

Sheila Conley,
Deputy Assistant Secretary, Finance
and Deputy Chief Financial Officer

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Report of Independent Auditors

To the Secretary and the Inspector General of the
U.S. Department of Health and Human Services

We have audited the accompanying consolidated balance sheets of the U.S. Department of Health and Human Services (DHHS) as of September 30, 2010 and 2009, and the related consolidated statements of net cost and changes in net position, and the combined statement of budgetary resources for the fiscal years then ended, and the statements of social insurance as of January 1, 2009 and 2008. We were engaged to audit the statement of social insurance as of January 1, 2010. These financial statements are the responsibility of DHHS's management. Our responsibility is to express an opinion on these financial statements based on our audits. The statements of social insurance as of January 1, 2007 and 2006, were audited by other auditors whose report dated November 14, 2007, expressed an unqualified opinion on those statements.

Except as discussed in the following paragraphs with respect to the accompanying statement of social insurance as of January 1, 2010, we conducted our audits in accordance with auditing standards generally accepted in the United States, the standards applicable to financial audits contained in *Government Auditing Standards*, issued by the Comptroller General of the United States, and Office of Management and Budget (OMB) Bulletin No. 07-04, *Audit Requirements for Federal Financial Statements*, as amended. Those standards and bulletin require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of DHHS's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of DHHS's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

As discussed in Note 24 to the financial statements, the statement of social insurance presents the actuarial present value of the Centers for Medicare and Medicaid Services' (CMS) Hospital Insurance (HI) and Supplementary Medical Insurance (SMI) trust funds' estimated future income to be received from or on behalf of the participants and estimated future expenditures to be paid to or on behalf of participants during a projection period sufficient to illustrate long-term sustainability of the social insurance program. In preparing the statement of social insurance, management considers and selects assumptions and data that it believes provide a reasonable basis for the assertions in the statement. However, because of the large number of factors that

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Report of Independent Auditors
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affect the statement of social insurance and the fact that future events and circumstances cannot be known with certainty, there will be differences between the estimates in the statement of social insurance and the actual results, and those differences may be material. In addition to the inherent variability that underlies the expenditure projections prepared for all parts of Medicare, the SMI Part D projections have an added uncertainty in that they were prepared using very little program data upon which to base the estimates, and as discussed below, significant additional variability has been introduced by the passage of recent legislation as well as issues regarding the sustainability of the underlying assumptions under current law.

As further described in Note 25 to the financial statements, with respect to the estimates for the DHHS social insurance program presented as of January 1, 2010, management has reflected in the projections of the program the direct impact, but not the secondary impacts, if any, of productivity adjustments (reductions in anticipated rates of increase) and reductions in Medicare payment rates for physician services mandated in the Patient Protection and Affordable Care Act (ACA), and current law. Prior legislation mandating reductions in provider payments has been overridden in whole or in part by new legislation, including frequent adjustments to scheduled reductions in physician payments and to prior efforts to adjust payments for inpatient hospital services. Management has noted that actual future costs for Medicare are likely to exceed those shown by the current-law projections, and has developed illustrative alternative scenarios and projections intended to provide additional context to users of the actuarial estimates regarding the long-term sustainability of the social insurance program. As a result of these limitations, we were unable to obtain sufficient evidential support for the amounts presented in the statement of social insurance as of January 1, 2010.

Because of the matters discussed in the preceding paragraph, the scope of our work was not sufficient to enable us to express, and we do not express, an opinion on the financial condition of the DHHS social insurance program as of January 1, 2010.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of DHHS as of September 30, 2010 and 2009, and its net cost, changes in net position, and budgetary resources for the years then ended, and the financial condition of its social insurance program as of January 1, 2009 and 2008, in conformity with accounting principles generally accepted in the United States.

In accordance with *Government Auditing Standards*, we also have issued our reports dated November 15, 2010, on our consideration of DHHS's internal control over financial reporting and on our tests of its compliance with certain provisions of laws and regulations and other matters. The purpose of those reports is to describe the scope of our testing of internal control over financial reporting and compliance and the results of that testing, and not to provide an opinion on the internal control over financial reporting or on compliance. Those reports are an integral part of an audit performed in accordance with *Government Auditing Standards* and should be considered in assessing the results of our audit.



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Our audits were conducted for the purpose of forming an opinion on the 2010 and 2009 basic financial statements taken as a whole. The information presented in Management's Discussion and Analysis, required supplementary stewardship information, required supplementary information, and other accompanying information is not a required part of the basic financial statements but is supplementary information required by OMB Circular No. A-136. The other accompanying information has not been subjected to the auditing procedures applied in our audits of the basic financial statements and, accordingly, we express no opinion on it. For the remaining information, we have applied certain limited procedures, which consisted principally of inquiries of management regarding the methods of measurement and presentation of the supplementary information. However, we did not audit the information and express no opinion on it.

/Ernst & Young LLP/

November 15, 2010
McLean, VA.

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Report on Internal Control Over Financial Reporting Based on an Audit of the Financial Statements Performed in Accordance with *Government Auditing Standards*

To the Inspector General and Secretary of the
U.S. Department of Health and Human Services

We have audited the financial statements of the U.S. Department of Health and Human Services (DHHS) as of and for the year ended September 30, 2010, and we were engaged to audit the statement of social insurance as of January 1, 2010, and have issued our Report on Independent Auditor, therein dated November 15, 2010. That report states that because of the matters discussed therein, the scope of our work was not sufficient to enable us to express, and we do not express, an opinion on the statement of social insurance as of January 1, 2010. Except for the matters discussed in the fourth paragraph of the Report of Independent Auditors, we conducted our audit in accordance with auditing standards generally accepted in the United States, the standards applicable to financial audits contained in *Government Auditing Standards*, issued by the Comptroller General of the United States, and Office of Management and Budget (OMB) Bulletin No. 07-04, *Audit Requirements for Federal Financial Statements*, as amended.

In planning and performing our audit, we considered the Department's internal control over financial reporting as a basis for designing our auditing procedures for the purpose of expressing our opinion on the financial statements, but not for the purpose of expressing an opinion on the effectiveness of the Department's internal control over financial reporting. Accordingly, we do not express an opinion on the effectiveness of the Department's internal control over financial reporting. We limited our internal control testing to those controls necessary to achieve the objectives described in OMB Bulletin No. 07-04, as amended. We did not test all internal controls relevant to operating objectives as broadly defined by the Federal Managers' Financial Integrity Act of 1982 (FMFIA), such as those controls relevant to ensuring efficient operations.

A *deficiency in internal control* exists when the design or operation of a control does not allow management or employees, in the normal course of performing their assigned functions, to prevent, or detect and correct misstatements on a timely basis. A *material weakness* is a deficiency, or a combination of deficiencies, in internal control such that there is a reasonable possibility that a material misstatement of the entity's financial statements will not be prevented, or detected and corrected on a timely basis.

Our consideration of internal control over financial reporting was for the limited purpose described in the second paragraph and was not designed to identify all deficiencies in internal control that might be deficiencies, significant deficiencies or material weaknesses and, therefore, there can be no assurance that all deficiencies, significant deficiencies, or material weaknesses have been identified. However, as discussed below, we identified certain deficiencies in internal control that we consider to be material weaknesses.

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Material Weaknesses

Financial Reporting Systems, Analyses, and Oversight

Overview

In Fiscal Year (FY) 2010, DHHS continued its efforts in remediating significant weaknesses that impact DHHS and its operating division (OPDIV) financial management processes. However, the passage of significant legislation and other challenges, including resource limitations, the decentralized nature and complexities within the organization, and the need for training to address policy changes, have impacted the pace of progress.

As reported in FY 2009, the American Recovery and Reinvestment Act (Recovery Act), which was established on February 17, 2009, increased DHHS budgets by approximately \$141 billion over ten years and provided for strict guidelines on how and exactly when those funds should be distributed, accounted for, monitored, and reported to OMB and Congress. These funds were distributed among most of DHHS's operating divisions and required new processes to be developed or modified within a very short time frame under DHHS's American Recovery and Reinvestment Implementation Plan to ensure compliance with the Act and OMB regulation. During FY 2010, DHHS expended approximately \$55.4 billion related to the Recovery Act. Total Recovery Act expenditures to date are \$88.3 billion.

In addition to ARRA, effective March 23, 2010, DHHS was entrusted with the responsibility for implementing many major provisions of the health reform bill, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (combined known as Affordable Care Act or ACA). For FY 2010, the ACA included appropriated funding for approximately 34 provisions. Of the 34 provisions, Congress appropriated approximately \$18.7 billion for 32 provisions, and "such sums as may be necessary" for 2 provisions. This amount includes funding that was appropriated in FY 2010 to be available for one or for multiple years and excludes amounts appropriated to other Departments or Agencies. Congress also authorized, but did not appropriate, funding for over 100 provisions in FY 2010.

The implementation of such significant legislation required much focus and significant resources across the Department. Our testing of internal control continued to identify significant internal control weaknesses in financial systems and processes for producing financial statements, including lack of integrated financial management systems and inability to reconcile certain significant account balances which impaired DHHS's ability to report accurate and timely financial information. Within the context of the approximately \$854 billion in departmental net outlays, the ultimate resolution of such amounts is not material to the financial statements taken as a whole. However, these matters are indicative of serious systemic issues that must continue to be resolved.



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Lack of Integrated Financial Management System

In FY 2004, DHHS began its implementation of a commercial web-based off-the-shelf product modified to replace five legacy accounting systems and numerous subsidiary systems with one modern accounting system with three components. The three components include:

- Healthcare Integrated General Ledger Accounting System (HIGLAS) - developed to support the financial activities of the Centers for Medicare & Medicaid Services (CMS) and its Medicare contractors by integrating the CMS contractors' standard claims processing system and eventually replace the CMS current mainframe-based financial system with a web-based accounting system (currently, the web-based accounting system has been placed "on top" of the current mainframe-based financial system). Based on the ability to generate financial statements, CMS named HIGLAS as its official financial management system of record. Although initiated in FY 2005, full implementation is not expected until FY 2013.
- National Institutes of Health (NIH) Business System (NBS) - developed to support the financial activities at NIH. NIH completed certain aspects of its implementation in FY 2008 with more ancillary modules expected to be implemented over the next few years.
- Unified Financial Management System (UFMS) - developed to support the financial activities at the remaining OPDIVs with full implementation completed in FY 2008. Certain processes to refine the implementation and address systemic issues are ongoing.

Although progress to fully implement the new financial systems is underway, DHHS's financial management systems are not compliant with the Federal Financial Management Improvement Act (FFMIA) of 1996. FFMIA requires agencies to implement and maintain financial management systems that comply with federal financial management systems requirements. More specifically, FFMIA requires federal agencies to have an integrated financial management system that provides effective and efficient interrelationships between software, hardware, personnel, procedures, controls, and data contained within the systems and compliance with the United States Standard General Ledger (USSGL) at the transaction level and applicable federal accounting standards. The lack of an integrated financial management system continues to impair DHHS's and its OPDIVs' abilities to adequately support and analyze account balances reported.

Although DHHS implemented a commercial off-the-shelf product, approved by the former Joint Financial Management Improvement Program (JFMIP), DHHS's accounting systems lack integration and do not conform to the requirements. DHHS's management has identified configuration issues that result in inappropriate transactional postings. Finally, the financial systems are not fully integrated and are not expected to have full integration until FY 2012. Specific weaknesses noted include the following:



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- Although progress was made during FY 2010, thousands of manual journal vouchers in excess of \$621 billion in absolute value were required to be recorded in UFMS and NBS to post certain types of transactions - including transactions to record certain proprietary and budgetary entries, record accruals, perform adjustments between governmental and nongovernmental accounts, perform adjustments to agree budgetary to proprietary accounts, perform other reconciliation adjustments at period end, and correct errors identified related to configuration issues within UFMS and NBS. These entries are nonstandard postings to UFMS and NBS to record both the proprietary and budgetary effects of certain financial activities for which the financial system is not configured properly to post automatically. Although these entries are required to be posted to the general ledger in order for the financial statements to be accurate, many of these entries should have been configured as routine systematic entries within the systems.
- By the end of FY 2010, certain Medicare contractors have not implemented HIGLAS and continue to rely on a combination of claims processing systems, personal computer-based software applications and other ad hoc systems to tabulate, summarize and prepare information that is reported to CMS on the 750 - *Statement of Financial Position Reports*, the 751 - *Status of Accounts Receivable Reports*, and the reporting of funds expended, the 1522 - *Monthly Contractor Financial Report*. The accuracy of these reports remains heavily dependent on inefficient, labor-intensive, manual processes that are also subject to an increased risk of inconsistent, incomplete, or inaccurate information being submitted to CMS. Although CMS has begun preparing financial statements using HIGLAS, full functionality of the HIGLAS system has not been implemented.
- As discussed in further detail below, reviews of general and application controls over financial management systems identified certain departures from requirements specified in OMB Circulars A-127, *Financial Management Systems*, and A-130, *Management of Federal Information Resources*. Additionally, we identified certain issues, including access control deficiencies related to systems, as part of our Federal Information Security Management Act and other Office of Inspector General (OIG) engagements. Finally, DHHS management has identified financial management information systems as a material weakness as a result of its OMB Circular A-123 and FMFIA assessments discussed within the Management Discussion & Analysis of the Department's FY 2010 Annual Financial Report.
- Although the OPDIVs are using UFMS, HIGLAS or NBS to account for financial activities within the OPDIVs, DHHS is utilizing the Automated Financial Statements System (AFS) to compile the consolidated financial statements. AFS, a spreadsheet macro-driven process, requires the OPDIVs to manually enter their trial balances and footnote disclosures for DHHS to compile the Department-level consolidated financial statements. The key entry process can be error-prone if effective controls are not in place. The Department is expected to implement a reporting tool that will automate its consolidation in FY 2011.



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- Due to certain configuration issues within UFMS, NBS and HIGLAS, certain financial statement balances on the Statement of Budgetary Resources (SBR) require analysis of other accounts to derive/estimate the amounts reported. For example, financial accounting and reporting standards require that DHHS record prior year recoveries in a separate general ledger account and report these amounts on the SF-133 and the SBR. These items are currently not being captured. As a result, most OPDIVs are required to analyze transactions in other accounts to derive the balance.

Resource limitations and other priorities were noted as causes for delays in upgrading certain system and financial internal control processes limiting DHHS's ability to comply with requirements under FFMIA.

Financial Analysis and Oversight

The U.S. Government Accountability Office's (GAO) *Standards for Internal Control in the Federal Government* states that internal control activities help ensure that management's directives are carried out. The control activities should be effective and efficient in accomplishing the organization's control objectives. Examples of control activities include: top-level reviews, reviews by management at the functional or activity level, segregation of duties, proper execution of transactions and events, accurate and timely recording of transactions and events, and appropriate documentation of transactions and internal control.

Because weaknesses continue to exist in the financial management systems, management must compensate for the weaknesses by implementing and strengthening additional controls to ensure that errors and irregularities are detected in a timely manner. Our review of internal control disclosed a series of weaknesses that impact DHHS's ability to report accurate financial information on a timely basis. Consistent with prior years, during FY 2010, we found that certain controls were not adequately performed to ensure differences were properly identified, researched, and resolved in a timely manner, and that account balances were complete and accurate. We noted the following items in the current year audit that indicate additional improvements in the financial reporting systems and processes are required:

Department/Operating Division Periodic Analysis and Reconciliation

When weaknesses exist in financial systems, as discussed above, management must compensate by implementing and strengthening other manual or compensating controls to ensure that errors and irregularities are detected in a timely manner. These manual and compensating controls would include monitoring of budgets, reconciliations of accounts, analyses of fluctuations, and aging of accounts. During our audit, we found that certain controls were not adequately performed. The following represent specific areas we noted that need enhanced periodic reconciliation and analysis procedures:



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- Fund Balance with Treasury (FBWT) - Treasury regulations require that each federal entity ensure that it reconciles, on a monthly basis, its financial records with Treasury's records and that it promptly resolves differences. If this reconciliation is not adequately performed, loss, fraud, and irregularities could occur and not be promptly detected, and/or financial reports that are inaccurate may be prepared and used in decision-making. On a monthly basis, DHHS is responsible for reconciling approximately 500 Treasury appropriation symbols. As of June 30, 2010, the general ledger and Treasury's records differed by more than an approximate absolute value of \$3 billion. This primarily relates to three OPDIVs that did not adequately research and clear differences noted in the Suspense Account Reconciliation. The differences were primarily caused by a backlog of differences dating back to 2004. During the fourth quarter, management focused additional efforts on its suspense account reconciliations which resulted in progress in reducing differences at September 30, 2010, to an approximate \$400 million. Additionally, management was not fully compliant with the U.S. Treasury FBWT Suspense Waiver according to all terms and conditions. Certain disbursements were not related to allowable transactions within the waiver, and differences in the Suspense Account Reconciliation were not properly cleared within the 60 days required timeframe.
- Indian Health Service's (IHS) Financial Management Environment - During our testing of internal controls surrounding cash receipts, cash disbursements other than compacts and contracts, fund balance with Treasury and suspense account reconciliations, IHS was unable to provide sufficient documentation to assess the effectiveness of internal controls surrounding such account activity. IHS management represented that due to resource limitations, timing for hiring contractors, strategy decisions that would ultimately resolve underlying causes, and the decentralized nature of the entity, it had not taken corrective actions to remediate certain control issues identified in FY 2009. As such, interim testing was not conducted over internal controls surrounding fund balance with Treasury and suspense reconciliations, cash receipts and cash disbursements other than compacts and contracts. During the fourth quarter of FY 2010, significant efforts were taken to reduce the reconciling items in the fund balance with Treasury and suspense account reconciliations and to resolve \$525 million of data integrity issues dating back several years identified in the preparation of reconciliation between certain budgetary and proprietary accounts. The fund balance with Treasury difference at September 30, 2010, was \$209 million. We assessed the differences in fund balance with Treasury, suspense account reconciliations and proprietary and budgetary tie-point reconciliations at year end and found differences not to be significant to the financial statements taken as a whole. However, efforts are ongoing and are not expected to be completed until mid-2011.
- OPDIV Financial Reconciliation Activity Certifications - As part of the accounting centers' monthly processes, the Department has instituted a policy whereby the accounting centers certify the status of completing required periodic reconciliations. For each required reconciliation, the preparer and approver sign off and provide a date of completion. On a monthly basis, the document is forwarded to the Department. No supporting documentation is required to be provided as part of the submission. Our



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- review of the OPDIVs' submissions and the supporting documentation maintained at the OPDIVs identified inconsistencies in the procedures performed, the reports utilized, and the results provided among the various OPDIVs. Our review of prepared certifications identified that although certain reconciliations were signed off and dated, the reconciliation had not been completed as differences within the reconciliation had not been identified on a timely basis. Further, we noted that although the financial statements are submitted to OMB on the 21st day after the end of the quarter and we received draft financial statements on October 22, reconciliations were not required to be completed and certified until the end of the month. Finally, we noted that although desk officers have been assigned the responsibility of reviewing specific OPDIV financial reporting, the desk officers do not consistently review the supporting documentation to ensure that the submissions are accurate. During our review of the September 30, 2010 financial statements, we identified over \$400 million of unsupported adjustments or differences in the financial statements.
- Undelivered Orders - As reported in the past, DHHS does not have adequate controls in place to monitor undelivered orders which represent remaining amounts of obligated funds that have not been delivered or appropriately de-obligated. As of September 30, 2010, we noted approximately 102,500 transactions totaling an approximate \$1.8 billion which were over two years old without activity. Many of these transactions represented travel, grants, and contracts awaiting close-out. Additionally, for grants, although progress was noted, during our review of FY 2010 grant activity provided from the Payment Management System (PMS) as of March 31, 2010, we noted approximately 1,750 grant obligations totaling \$165 million that were dated prior to FY 2004 that had not been closed out. We continue to note that these grants were already beyond a reasonable timeframe for close-out. In prior years, a lack of resources was noted as the cause of backlog in closing out expired grants. Management needs to increase emphasis on close-out to reduce the backlog and ensure consistency between PMS and the OPDIVs' official subsidiary systems.
- Budgetary Analyses - Within the federal government, the budget is a primary financial planning and control tool. OMB Circular A-11, *Preparation, Submission and Execution of the Budget*, establishes the requirements of budget formulation and execution including requirements related to apportionments, accounting systems to control spending, proper recording of obligations, and closing accounts. For internal control purposes, budgetary monitoring is a key management control that, if implemented correctly, identifies cost overruns and potential material misstatements in a timely fashion. Currently, DHHS has completed its investigation and will be reporting to appropriate authorities a series of violations as discussed in the Procurement Activities section below. To ensure these violations do not continue, enhanced budgetary monitoring processes are required. Additionally, in our review of the Statement of Budgetary Resources, we compared balances in budgetary accounts to their related proprietary accounts. Based on our review and discussions with management, we noted differences of \$794 million that could not be explained.



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- **Procurement Activities** - During FY 2008, the Senior Procurement Executive (SPE) of the DHHS performed an extensive review across all OPDIVs of its multiple year contract funding activities, to (a) assess compliance with pertinent requirements of the Federal Acquisition Regulation (FAR), HHS Acquisition Regulation (HHSAR) and “Bona Fide Needs” rule; and (b) identify avenues to improve multiple year contracting and funding strategies within the framework of those requirements. The report on the SPE review, issued in July 2009, identified significant compliance concerns including a misunderstanding of the above appropriation-related guidance and its applicability to planning, awarding and funding DHHS contracts. In August 2009, DHHS management contracted for an independent assessment which generally confirmed apparent deviations from such guidance. During FY 2010, DHHS OIG, Office of General Counsel (OGC), and Departmental and OPDIV management continued their reviews of the affected contracts and found contracts reviewed were funded inconsistent with legal requirements. We understand that the Department is committed to notifying the appropriate authorities of violations of the Anti-Deficiency Act. DHHS management indicated that it has also taken, or is taking, the following actions to prevent future problems:
 - issued comprehensive guidance in June 2010,
 - enhanced DHHS’ standard acquisition plan template to reinforce the need for (a) program and contracting officials to consider appropriation issues as early as possible in the acquisition cycle, and (b) proper, informed funds reviews and certifications,
 - developed an appropriation law decision tree for the DHHS acquisition workforce, with plans to web-enable it for user-friendly linkage to pertinent guidance,
 - developing and requiring training courses on appropriations law and contract funding, and committing – at all levels within the Department – to the proper funding of all DHHS contracts in FY2011 and beyond.
- **Monitoring of Financial Operations**
GAO’s *Standards for Internal Control in the Federal Government* states that “...information should be recorded and communicated to management and others within the entity who need it and in a form and within a time frame that enables them to carry out their internal control and other responsibilities.” Further, the standard indicates that financial statement information is needed not only on a periodic basis for external reporting but also on a day-to-day basis to make operating decisions, monitor performance, and allocate resources. Within a decentralized complex organization like DHHS, a single integrated financial system with strong internal controls is required for up-to-date accurate financial information needed for certain decision-making responsibilities. Currently, due to the number of manual correcting entries, evolving internal control, and outdated policies and procedures, accurate information needed for decision-making at all levels of the organization may not be readily available on a day-to-day or even monthly basis as required by FFMIA. Currently, except for the compilation of quarterly financial statements, there is limited available reporting of accurate financial activities at the program, OPDIV, and/or consolidated department level. During FY 2010, it is our



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understanding that certain OPDIVs have moved to a monthly close process; however, full implementation is not expected until FY 2011 with the implementation of the automated reporting process.

Policies and Procedures and Additional Training of Personnel

DHHS's formalized policies and procedures are out of date and may be inconsistent with actual processes taking place. During our internal control documentation and testing phases, we noted that, although various internal control processes had been changed or updated, the Department had not completed its updating of procedural manuals or provided sufficient formalized guidance/training to personnel to ensure sufficient knowledge of financial management systems/processes or consistency, and adequacy of internal control. For example, we noted that certain policies and procedures, including certain accrual processes, had not been updated since the mid-1980s. Further, we noted additional training on the financial systems was needed to enable DHHS personnel in their ability to access needed information from the system to complete their day-to-day responsibilities - including the preparation of reconciliations, research of differences noted, and the ability to identify and clear older "stale" transactions dating back several years.

It is our understanding that the Department and its OPDIVs are currently updating their procedures and developing further training for their personnel in the use of Oracle and other financial related systems and processes. Further training is expected to include training on Government-wide (including OMB and Treasury), DHHS, and OPDIV level policies and procedures; the use of UFMS and other subsidiary systems; the preparation of financial statements and related analysis and reconciliations; and system security.

In addition, the implementation of the ACA, including the Community Living Assistance Services and Support Act (CLASS), Health Benefit State Exchanges, Temporary Insurance for early retirees, the Qualified High Risk Pool for Preexisting Conditions, and other significant programs, will have significant impacts with financial activity totaling in the billions to the Department over the next several years. The ACA will require extensive coordination, numerous resources, policy development, and training across the various OPDIVs to ensure the programs are operating and monitored effectively and accounted for correctly in accordance with Federal Accounting requirements.

CMS Required Coordination, Communication and Collaboration to Facilitate an Effective Financial Management System

Considering the recent realignment of the Agency and the passage of significant legislation in the current year, CMS should critically assess its process for managing the cross-functional teams of financial management, information technology, actuarial, general counsel, operations, and other personnel to better monitor business activities, generate and share financial and other information and identify situations where accounting evaluation or decision-making may be required to arrive at and document an appropriate conclusion in a timely manner. Critical accounting matters such as accruals and contingencies require a robust process on a quarterly



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basis including the documentation of these critical accounting matters through a series of white papers. Albeit that CMS has strengthened its ability to identify contingencies on a quarterly basis, these white papers supporting the conclusions on several critical accounting matters had not been timely prepared and approved to effectuate a change in policies or procedures. In addition, the white papers were either not finalized or not available for review until after the fiscal year end. The dispersed nature of the environment leaves CMS vulnerable to delays in the financial management implications of issues being recognized and addressed. Additional examples of these include:

- While the most significant legal matters are recorded, CMS does not ensure that the legal accrual is recorded in accordance with generally accepted accounting principles in the United States.
- During the FY 2009 budgetary closing process, CMS did not return \$8.1 billion in indefinite authority related to its Medicaid ARRA funds. CMS and Department of Health and Human Services (DHHS) management indicated that the authority had not been returned due to several miscommunications between the CMS budget and finance offices, DHHS and OMB. In January 2010, through and after discussions with OMB and Treasury, DHHS requested a negative warrant to be processed to return the funds. For the FY 2009 financial statement purposes, no restatement of balances was required as they represented the actual relative positions of the entities, as they stood at the time. Although CMS drafted a white paper document to address financial and budgetary accounting and reporting issues, the document never was finalized and no documentation was prepared to support the concurrence by the various entities of the corrective actions to be taken. During FY 2010, CMS identified and implemented corrective actions, including reviews of subsequent period apportionments to ensure that funds not available for carryover would be returned during the year-end closing process.
- Insufficient communications within the organization resulted in understatement/overstatement of accounts receivable and related interest from, and payables to, the States for Medicaid and ARRA advances. For example, in the prior year a state was in an overdrawn position that should have resulted in an accounts receivable; however, it was not reflected in the financial statement until the current fiscal year. In addition, the finalization of grant awards is not performed consistently or timely for all States. Efforts to continuously monitor State draws and reinforce applicable cash management and grant oversight activities, including working to resolve issues with disclaimed or qualified opinions reflected in grantee compliance audit reports (States' A-133 compliance reports) merit continued focus.
- Contemporaneously addressing the financial reporting implications in connection with the deliberations ultimately reflected in the Trustees Report and accompanying Office of the Actuary (OACT) reports and projections might have been useful in mitigating the impact on the Statement of Social Insurance reporting.



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- As CMS continues to enhance its data analyses capability, further improvement can be made by developing robust analytical procedures or measures against benchmarks to monitor and mitigate risks associated with the decentralized nature of CMS operations. To the extent more robust analysis occurs within Centers and Offices, cataloging and reviewing such analysis would assist in ensuring that a perspective which incorporates a financial reporting point of view is captured and considered.

CMS Financial Management Analysis Function

The dispersed nature of the financial management environment requires a high degree of coordination between the financial and program management personnel to ensure the effective operation of the controls. The decentralized nature of the organization results in a significant number of controls being performed at the contractors, regional offices, Centers and Offices outside of OFM. Critical accounting matters identified within the organization require a robust review process, including timely documentation to capture CMS' considerations, analyses and ultimate conclusions.

Consistent with the prior years, we noted that CMS does not perform a claims-level detailed look-back analysis for the Medicaid Entitlement Benefits Due and Payable (EBDP) to determine the reasonableness of the various state calculations of incurred but not reported (i.e., unpaid claims) liability. The Medicaid EBDP is approximately \$27.0 billion as of September 30, 2010, and is a significant liability on the financial statements. Currently, CMS is not able to validate its methodology in a manner similar to the Medicare methodology by using a claims-based approach. CMS continues to rely on its estimation methodology (which is based on using a historical three-year average) to record the Medicaid EBDP without the ability to confirm the reasonableness of its methodology.

All individuals within the organization are responsible for establishing, managing and maintaining an effective control environment. A good control environment not only ensures accountability but also provides oversight and reasonable assurance that the organization's goals are met. During the internal control tests, errors were noted that were not detected by the organization's monitoring and review function, and accordingly, the control was not functioning as designed or intended. The errors identified by our audit procedures at the central office, regional offices and Medicare contractor locations may be summarized, including an example for each category, as follows: (i) activity or accounts for which no formal, documented review or monitoring function was established (identified as a design deficiency) (for example, no documentation or certification of the review that the premium calculation spreadsheets are reviewed for accuracy prior to publication of the premium); (ii) review or monitoring function was established but was not performed or effective (for example, reconciling items identified in the benefit payment reconciliation were not investigated and resolved timely); and (iii) the review or monitoring function was not performed timely (for example, the monthly National Claims History (NCH) validation process, which compares the NCH paid claims to the Medicare contractor reported draws, was not performed in the current fiscal year).



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CMS Business Partner Risk Management

CMS administers an extensive internal control program to protect the Agency's resources from fraud, waste and mismanagement. CMS also relies heavily on third-party contractors as it outsources substantially all the day-to-day operations for its information technology systems, the payment of Medicare fee-for-service and Medicaid claims and certain services related to the Medicare Advantage (Part C) and Part D Drug programs.

CMS has developed internal controls that help prevent fraud and waste from occurring such as edits in the claims processing systems that attempt to identify and filter inappropriate claims. CMS also has developed internal controls that will help detect fraud and waste that may have occurred. Any strong control environment will have a combination of both prevent and detect controls with a greater emphasis on prevent controls.

While we noted during the current year audit that CMS had both prevent and detect controls in operation, we noted several examples of areas where improvements could be made in the overall control environment. This is especially true of CMS' relationships with its third-party contractors referred to herein as "contractors."

- The contracts between CMS and its Medicare contractors include provisions that require the Medicare contractor to develop and follow policies and procedures or objectives established by CMS, as described more fully in the CMS Medicare Financial Reporting Management Manual (Chapter 5). The specific objectives followed at each location are to be documented by the Medicare contractors, supporting documentation must be maintained and available for review and audit, all shared systems must be able to produce any system report required by Medicare contractors on a month-end basis and the Medicare contractor must be able to support all summary amounts reported on any system report with transaction level detail. In addition, Medicare contractors are required to periodically (e.g., monthly) certify to the completeness and accuracy of the financial information transmitted to CMS for their responsible workloads. Through its A-123 process, CMS tests the Medicare contractors' compliance with its policies and procedures and the financial controls established.

While this approach to financial integrity supports monitoring of the Medicare contractors' financial controls, the monitoring process has not been fully effective in identifying and resolving financial recording and reporting issues or ensuring that they are timely remediated by the Medicare contractors. As CMS continues their efforts to transition to the Healthcare Integrated General Ledger Accounting System (HIGLAS) and to implement the provisions of ACA, there will be a greater significance placed on monitoring the Medicare and other contractors, accentuating not only the value, but the consequences, to the Agency. During our audit activities, we identified weaknesses in financial reporting oversight, including:

- Neither CMS nor the Medicare contractors were able to provide a system-generated subsidiary ledger or detail schedule for the amounts payable to providers or beneficiaries (or amounts owed to CMS) for certain ancillary accounts (e.g., accounts payable other, refunds payable or custodial liabilities) as of a balance sheet date. While account



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reconciliations are performed for the primary claims payable accounts, because there was no subsidiary ledger available for these ancillary accounts, neither CMS nor the Medicare contractors were able to fully reconcile these accounts on a periodic basis.

- For one Medicare contractor and two workloads, initially neither CMS nor the Medicare contractor were able to provide a system-generated subsidiary report for the adjudicated claims balances reported to CMS because the volume of transactions was greater than the HIGLAS capabilities and the report could not be successfully generated. Ultimately, CMS was able to provide a number of system-generated subsidiary reports by open year and fund (i.e., HI, SMI and general) to support the adjudicated claims balance. These reports reconciled to the balances reported by the Medicare contractor.
- Undelivered Medicare Summary Notices (MSNs) returned to the Medicare contractor were shredded by the Medicare contractor and are not being investigated as there is no existing CMS policy that addresses the actions in this circumstance. The result of the beneficiary not being able to review the MSN and notifying CMS of unusual services or charges may lead to improper payments going undetected.
- The Medicare contractors did not perform a periodic review of claims held (i.e., "invoices on hold" or payables held for specific reasons) and CMS did not monitor that the outstanding balances are properly and timely resolved. If the aged claims are not tracked or monitored by the Medicare contractor periodically, the claims may not be paid or disposed of in a timely manner and the payable balances reported by the Medicare contractor at the end of each reporting period may not be correct. We understand that CMS is in process of developing a policy or guidance that will require the Medicare contractors to perform a periodic review.
- During 2007, CMS transferred a majority of the Medicare Secondary Payor recovery process to a single contractor. This contractor is responsible for initiating collection of several hundred million dollars on an annual basis. Although some additional procedures were implemented, we continued to note several instances where internal controls related to this contractor were not designed or operating effectively, including lack of, or an ineffective level of, review and the untimely application of cash receipts.
- The processes designed to prevent errors should be supplemented by controls and analyses that highlight any material errors that may or could occur. In this regard, errors or abuses within the Medicare fee-for-service claim data, if material, should be detected in the annual Comprehensive Error Rate Testing (CERT) process, while for Medicaid the Payment Error Rate Measurement (PERM) process can be useful in this regard. These processes, which are primarily outsourced to contractors, are designed to assess accuracy rates as applicable. Similar processes are used to monitor Part C and D plans, particularly prescription drug event data. These processes continue to evolve and the error rate development processes developed to date, and further steps being taken to verify that only appropriate providers and beneficiaries participate in the programs are important steps forward in this regard. To be fully effective in compensating for inherent risks in the programs, the monitoring activities must be well understood, susceptible to replication and highly credible. We reviewed these



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error analyses and these analyses quantify the challenges that CMS has regarding improper payments. Our audit procedures also consider the audit activities performed by the OIG and others for the Part C and D programs. Findings, such as timeliness of the plan audits and the accumulation of True-Out-of-Pocket costs (TROOP) and Prescription Drug Event (PDE) data, are inherent risks of the programs.

In 2008, the OIG recommended revisions to the error rate review methodology, which were implemented by CMS during fiscal year 2009 which resulted in higher projected error rates. Similarly, ensuring that a fully reconciled population of claims is susceptible to testing is an important starting point in the development of PERM error rates. The work previously performed by the OIG in reconciling such populations indicates that further focus on this area is needed.

Statement of Social Insurance (SOSI)

The Statement of Social Insurance (SOSI) for CMS presents a long-term projection of the present value, spanning a 75-year time horizon, of the benefits to be paid for the closed and open groups of existing and future participants of the Medicare social insurance programs, less the inflows to be received from or on behalf of those same individuals. The presentation assumes the programs will continue in their current form under current law, albeit with certain economic assumptions that serve to constrain growth of the programs and imply refinements in response to the burden of the programs on economic activity. Departure from the current law construct also is made in assuming that the programs would continue to provide substantially consistent benefits after exhaustion of the Trust Funds, while under current law payment reductions would otherwise reduce or defer such payments. This approach allows for illustration of the excess of payments beneficiaries may expect over the related funding streams.

The presentation includes estimates not only of the payroll taxes, premiums, and other contributions to be made directly by the participants, but also estimates of general fund contributions on their behalf to help finance the programs for which this funding mechanism exists. In contrast, the presentation included in the consolidated annual financial statements of the U. S. government excludes such intragovernmental transfers. The process for preparing the SOSI must comply with appropriate financial reporting internal control requirements and is intended to provide information useful in assessing the financial condition of the programs and related Trust Funds.

In FY 2010, the passage of the Affordable Care Act significantly impacted the projections embodied in the Trustees Report and SOSI. The application of the current law formulation to development of the SOSI projection created significant challenges in applying this legislation. These challenges included considering the impacts of an estimated 165 provisions affecting the Medicare program, including modeling significant changes in provider payments arising from legislative limitations to constrain growth in the cost of the programs, and considering potentially



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wide ranging impacts from investments in combating fraud and abuse, initiating a major program of research and development, and implementing accountable care organizations to assist in coordinating care.

The projections always have been complex and need considerable care in interpreting the resulting SOSI. The degree of uncertainty regarding the projections increased in FY 2010 and certain matters called into question, and we were unable to assess, whether the presentation of the SOSI was fairly presented and fully useful for its intended purpose. Management has noted that the effects of some of ACA's provisions on Medicare are not known at this time, and the long-range feasibility of certain of the provisions is doubtful. The Trustees Report, related Actuarial Opinion and other materials incorporated by reference in the Trustees Report reflect uncertainty regarding the projections and reflect concerns that certain current law provisions are not sustainable or will, based on prior patterns, likely be modified. The extent to which the SOSI projections as presented are anchored in the current law formulation, are subject to additional uncertainty this year and may not reflect management's reasonable estimate of the ultimate cash flows of the social insurance programs, is discussed in the footnotes to the FY 2010 SOSI.

The disclosure steps taken by management appear to have been reasoned judgments to aid users of the financial statements in interpreting the information pending further refinement of the projections and a more fundamental reexamination of the assumptions underlying the development of the SOSI and Trustees Report. The efforts needed in modeling the impacts of the ACA include work which management anticipates regarding potentially refining the assumptions and narrowing the range of the projected outcomes for the cash flow models and seeking further input in comprehensively considering the secondary impacts of price changes mandated by current law on access and utilization. Enhancing the utility of the projections will require addressing systemic issues regarding patterns of legislative changes in the programs, including for example the physicians' payment update reduction deferrals of the last several years. It also may require positing sustainable operating models for the programs, their providers and beneficiaries, some of which may require postulating future changes in the legislative or regulatory formulations of the programs needed to sustain the programs. Developing auditable estimates for SOSI that fairly present the financial condition of the Trust Funds may require revisiting provisions of federal accounting standards and potentially reformulating the assumptions used in SOSI and the Trustees Report to help improve the usefulness of the estimates provided.

Certain efforts already underway within CMS will assist in narrowing areas of concern. While appointment of public trustees and a panel of advisors to assist in reviewing the projections and related assumptions came too late for the FY 2010 SOSI presentation and Trustee Report development, these measures will assist CMS during the refinement of future projections and in considering the appropriate response to concerns about the sustainability of current law provisions over the projection period, which are significant enhancements. The investment made by the Office of the Actuary in formulating alternative illustrative scenarios will help inform the process. Similarly, the Federal Accounting Standards Advisory Board departed from a current



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law formulation when formulating guidance regarding developing analogous projections for sustainability reporting. The work devoted to this effort may also facilitate developing appropriate responses to the unique challenges faced by CMS in developing projections for SOSI under the current law construct referenced in applicable Federal reporting standards.

In addition to the overarching concerns, our work in review of the internal controls for the related models noted continue improvement, considering the magnitude of changes in the current fiscal year, with some areas warranting continued focus. The SOSI models are complex, 75-year projections that contain a high degree of estimation. The lack of robust controls over spreadsheet changes and inputs, and complexity of the models may result in output that varies from management's intentions. We noted the following deficiencies that, if improved, would enhance the reliability and credibility of the SOSI model and process:

- The SOSI model is password protected to ensure that only authorized access and changes are made to the analyses within the model. During our testing, we noted that four spreadsheets were not password protected, which could allow unauthorized access and changes to the SOSI model.
- CMS has developed and implemented a change management process over the SOSI model, which applies to significant changes or changes in methodology of the model. During our testing, we noted that certain spreadsheets were removed from the models and the reasons for being removed were not documented or tracked through the change management process.

Management Corrective Actions

During FY 2010, DHHS OPDIVs performed their annual OMB Circular No. A-123, *Management's Responsibility for Internal Control*, assessment procedures in support of the Department's annual FMFIA process. OMB Circular No. A-123 provides internal control standards and specific requirements for conducting management's assessment of the effectiveness of internal control over financial reporting. As part of these assessments, the various OPDIVs identified instances of non-compliance with federal accounting requirements and the Department's own policies - many of which had been identified in prior years. Consistent with the OMB No. A-123 assessment, our procedures identified a number of specific instances of deficiencies in application of DHHS' internal control.

In some cases, the DHHS management has not properly implemented corrective actions for long-standing deficiencies in internal controls. Certain deficiencies have been continuously identified and reported to management over the past decade. These include:

- untimely and incomplete suspense reconciliation processes;
- cleanup of old "stale" account balances;
- extensive manual adjustments in financial reporting; and



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- significant weaknesses surrounding the various information technology systems upon which DHHS relies heavily for its operations and financial reporting.

This insufficient progress of implementing corrective actions has resulted in limited improvement and continues to impair DHHS's capability to support and report accurate financial information. In other cases, actions to address weaknesses are documented late in the fiscal year with limited or no documentation that the controls were placed in operation during the period under audit. To the extent circumstances such as resource constraints and implementation of new financial systems occur which can lead to multiple years of efforts in addressing issues, some delays may be unavoidable. A more robust process to assess ongoing risks and adopt strategies to mitigate control risks pending overarching solutions can assist in assuring stakeholders that management is systemically addressing control deficiencies and fostering a tone at the top to address audit findings on a timely basis.

* * * * *

Recommendations

We recommend that DHHS continue to develop and refine its financial management systems and processes to improve its accounting, analysis, and oversight of financial management activity. Specifically, we recommend that DHHS:

- Continue to strengthen controls related to its entity-wide structure for account reconciliation, analyses, and oversight by providing more in-depth on-site quality reviews of OPDIV and headquarters financial functions, periodically requesting the supporting documentation to compare to the results communicated, and improving communications between the various parties so that issues may be identified and resolved in a more timely manner. Additionally, we believe continued focus is especially needed in the areas of Fund Balance with Treasury reconciliations and related suspense accounts. Further, we recommend that the OPDIVs allocate adequate resources to perform the required account reconciliations and analyses on a timely basis.
- Continue to improve its financial reporting and internal quality review procedures to reasonably assure that information presented in the interim financial statements and Annual Financial Report are accurate, supported fully, and completed timely and consistently with the requirements of OMB Circular A-136, *Financial Reporting Requirements*, including rigorous use of checklists and enhanced supervisory review processes.
- Continue to improve its process to timely close out "stale" or old account balances, including undelivered orders, accounts receivable, accounts payable, and grants.



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- Continue to devise short-term and long-term resolutions to systematic and integration issues that complicate use of UFMS and NBS. DHHS should continue to assess whether systems used to prepare the financial statements are working effectively and have been sufficiently tested prior to year-end reporting dates.
- Continue to offer updated guidance and training to personnel to ensure specific guidelines are documented as to the source of data, required follow-up with timetables, and documentation retention policies. Further, training should be provided to OPDIV and headquarters personnel to ensure a complete understanding of the financial management systems and the available reports to perform certain tasks.
- Consider moving to a monthly departmental close of financial data to provide for a more timely compilation of accurate data that may be needed for decision-makers at all levels. The monthly consolidation of financial statements will be more feasible with management's complete implementation of Hyperion to consolidate its financial statements, for which initial pilots occurred during FY 2009 and complete implementation is expected during the first quarter of FY 2011.
- Ascertain whether the OPDIVs, in conjunction with DHHS, properly track and implement corrective actions to mitigate deficiencies that impair the capability to support and report accurate financial information.
- Complete its implementation of corrective actions related to contracting activities to ensure compliance with Federal acquisition requirements.

Additionally, in regard to CMS, we recommend that CMS continue to develop, enhance, refine, and provide robust analyses over its financial reporting systems and processes. Specifically, CMS should:

- Establish specific policies, procedures and a protocol to address situations or transactions that require cross-functional involvement to ensure interim and year-end financial statements are accurate and complete. This includes policies and procedures to ensure changes to critical systems outputs are appropriately discussed and reviewed with all users. The financial management function should serve as the primary coordinator to facilitate the input and involvement of the other cross-functional units whose involvement and input are important factors to consider in formulating accounting treatment and financial reporting implications.
- Continue to enhance its process related to the development, documentation and validation of critical accounting matters and the timeliness of its white papers.
- Delegate to and ensure that the Centers or Offices provide robust analytical analyses to OFM on a periodic basis (e.g., quarterly) that would be analyzed and reconciled by OFM in connection with the preparation of the quarterly CMS financial reports and available for use throughout the Agency.



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- Establish a process to perform a claims-level detailed look-back analysis on the Medicaid EBDP to determine the reasonableness of the methodology utilized to record the \$27.0 billion accrual. One potential method to verify the reasonableness of the Medicaid EBDP balance would be to use the detail claims data from the PERM process to calculate the average days outstanding or sample the largest states and determine if information is available for subsequent analysis.
- Evaluate the monitoring and review function to determine the reason the reviews are not performed effectively. Reinforce the importance of the detect control within the internal control structure, the accountability of the control and the oversight required to maintain an effective control environment.
- Continue to implement an integrated financial management system for use by Medicare contractors and CMS to promote consistency and reliability in accounting and financial reporting.
- Regularly evaluate its overall directives to contractors to ensure that adequate controls are in place and that appropriate documentation is maintained to support the conduct of those controls. As CMS transitions the contractors to HIGLAS or implements new legislation, CMS should challenge its current policies, procedures and methodologies to determine if such implementation has impacted the financial reporting and internal control processes (examples include generation and reconciliation of subsidiary ledgers, MSNs and HIGLAS reporting). If current methods are impacted, CMS should provide updated and relevant guidance and communication to, and collaborate with, the contractor to facilitate and properly incorporate the changes.
- Continue the process of enhancing the integrity, improving the process and capturing the benefits of the CERT, PERM, Part C and Part D error rate development and analysis tools. Error rate results should be developed at a sufficient level of detail to analyze, scrutinize and classify errors and identify anomalies to begin separate investigations or studies of the root causes of the errors and appropriate prevention, mitigation and recovery plans. Continue the efforts to further develop the eligibility processes to ensure only appropriate parties participate and use the periodic error rate processes to comprehensively test for eligibility and improper payments.
- Critically assess findings from OIG and other reviews of the Part C and D programs to ensure that the evolving nature of these programs are accompanied by robust internal control processes utilized by CMS to address the inherent risks of these programs. Continue to consider and implement the recommended audit results and modify the processes to hold plan sponsors more accountable for the findings identified. The financial management group should ensure it monitors and maintains oversight over the programs and its activities to identify the appropriate financial statement impact and disclosure. In light of the extraordinary financial crisis that existed in 2008, 2009 and continues in 2010, and the pattern of advances to Part D drug plans and states, we believe that CMS should continue to evaluate its risks with respect to all its grantees, contractors and providers to ensure that the Agency is appropriately protecting its resources.



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Developing SOSI projections for use in general purpose financial statements which represent management's reasonable estimate of the cash flows for the programs over a 75-year projection period will continue to be a challenge. The fact pattern presented in FY 2010 in developing the projections raises important issues regarding the role of SOSI reporting, and the merits of departing further from a current law formulation in instances in which management believes that legislative or regulatory changes will be needed to sustain the programs throughout the projection period. Pending resolution of these issues, the disclosures help to partially mitigate the potential adverse impact from presenting information management does not believe will actually occur. In pursuing the ultimate resolution of these matters, we suggest management consider the following:

- Continue efforts initiated late in FY 2010 to engage a panel of advisors to assist in addressing the challenges presented by the passage of ACA in developing and presenting projections for the Medicare programs which are reasonable estimates of the program cash flows.
- Continue and broaden discussions with key stakeholders and standard setting bodies, including the Federal Accounting Standards Advisory Board, to codevelop appropriate recommendations for potential revisions to the approaches used in presenting projections for the programs in the Trustees Report and standards applicable to presentation of the SOSI to aid in ensuring that the SOSI projection is meaningful and presents fairly the financial condition of the Trust Funds. These consultations should address how patterns of revisions to law, and situations in which a continuation of current law is anticipated to potentially not be feasible should be addressed, if at all, in the projections.
- Verify that all spreadsheets are password protected to avoid unauthorized access or changes.
- Adhere to established policies and procedures to ensure that the SOSI model methodology and related calculations and estimates are consistently documented. Adherence to these policies will ensure that the model is evaluated to verify that the input/output data is appropriate based on the expected results of the data and spreadsheet changes.
- Adhere to the established policies and procedures to ensure that the verification, review and approval process for the SOSI model occurs in a timely manner.



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Financial Information Systems

Overview

HHS is a highly decentralized organization with currently six separate accounting offices and numerous regional offices, contractors, and area offices with access to various components of the financial management system. In addition, although HHS has begun efforts to consolidate the accounting systems, separate accounting systems are still used to support the financial statements in FY 2010. They include: Unified Financial Management System (UFMS) for Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), Administration for Children and Family (ACF), Health Resources and Services Administration (HRSA), Substance Abuse and Mental Health Services Administration (SAMHSA), Program Support Center (PSC), Administration on Aging (AOA), Agency for Healthcare Research and Quality (AHRQ), Office of the Secretary (OS), and Indian Health Service (IHS); National Institute of Health's (NIH) Business System (NBS) for NIH; and the Healthcare Integrated General Ledger Accounting System (HIGLAS) for CMS. Although CMS maintains only one of the six separate accounting offices, the CMS'S HIGLAS system and its ancillary systems are responsible for over \$ 729 billion or 85% of the Department's total net cost. As a result, we have discussed our results for CMS separately below.

CMS Information Systems Controls

During FY 2010, CMS made investments in additional processes, personnel, and technology to strengthen internal controls over information technology and continues to take proactive steps to improve information assurance at both the Central Office and its business partners, principally Fiscal Intermediaries (FIs) Carriers, Medicare Administrative Contractors (MACs), and Enterprise Data Centers (EDCs), collectively referred to as Medicare contractors. Examples of improvements are described in the context of these investments.

- CMS has strengthened the oversight of its Medicare contractors through improvements to existing and the introduction of new control activities. As such, CMS has:
 - Established the requirement for Medicare contractors to report in compliance with baseline security settings. When exceptions are reported, CMS determines whether the exception can be granted or requires the contractor to communicate a remediation plan.
 - Improved communication of roles and responsibilities between Medicare claims processors and Medicare data centers by requiring the execution of Joint Operating Agreements. These agreements between the data center and claims processor define the roles of each for information security controls and monitoring.

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- Initiated the monitoring of compliance with edit settings for shared system applications by Medicare contractors. Contractors are required to submit reports quarterly and provide business justification for non-compliance.
- Developed new guidance on compliance requirements for access control over shared systems.
- Continued efforts to monitor compliance with Medicare data access by contractor personnel.
- Increased staffing at Central Office to support the monitoring of contractor security compliance reports.
- Strengthened the change control process through further formalization of change control boards for Central Office-managed applications.
- Reinforced enterprise IT vulnerability management through the implementation of new technologies that allows for vulnerability monitoring on a continuous basis.
- Increased awareness and collaboration around information assurance throughout CMS through monthly Security of Excellence meetings and other related activities.

In conjunction with the ongoing consolidation of the overall information processing environment, these activities have helped to reduce CMS' overall exposure to potential information security configuration and access deficiencies.

CMS' Business Environment Overview

Extensive information systems operations are necessary to support CMS' large size and decentralized business model. Substantially all of CMS' Medicare fee-for-service claims and related data are processed by geographically dispersed contractors. Additional key systems are processed at CMS' Central Office. These operations support numerous Medicare and Medicare-related application programs that are intended to assure consistency in administering the Medicare program, in addition to processing, accounting for, and reporting on Medicare expenditures and related assets and liabilities. Internal controls over these operations are essential to manage the integrity, confidentiality, and reliability of Medicare data and application programs and to reduce the risk of errors, frauds, or other illegal acts.

For Medicare fee-for-service claims, CMS has entered into contracts with several organizations known as Fiscal Intermediaries (FIs), Carriers, and Medicare Administrative Contractors (MACs) for claims processing software administration, claims payment, and audit/reimbursement services. CMS also has continued to centralize its ongoing data processing needs into three Enterprise Data Centers (EDCs). Other contractors known as software system maintainers make and test changes to the claims processing software to meet Congressional mandates and/or other business needs as defined by CMS. CMS maintains multiple claims processing systems depending on the type of claim. These systems include the Fiscal Intermediary Shared System (FISS), the Multi-Carrier System (MCS), the ViPS Medicare



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System (VMS), and the Common Working File (CWF). Collectively these systems are referred to as shared systems. Other important financial systems processed by the CMS Central Office include the Financial Accounting and Control System (FACS), the Healthcare Integrated General Ledger Accounting System (HIGLAS), and the Medicare Advantage and Prescription Drug System (MARx).

CMS is subject to various federal information security and application software management guidelines. Primary guidance is included in the National Institute of Standards and Technology (NIST) Special Publication 800-53, *Recommended Security Controls for Federal Information Systems*, and NIST Special Publication 800-37, *Guide for Applying the Risk Management Framework to Federal Information Systems*. An independent assessment of CMS' compliance with the NIST guidance is in part accomplished through the performance of an annual review conducted by the HHS Office of Inspector General under the *Federal Information Security Management (FISMA) Act of 2002*.

CMS maintains a Business Partners Systems Security Manual (BPSSM) based on federal guidelines for its application software systems used to direct the information security activities at the Medicare contractors. CMS communicates the requirements of their information assurance program through the requirements of the BPSSM; monitoring compliance with the BPSSM is accomplished through the CMS Certification and Accreditation (C&A) program. Each contractor is required to maintain a System Security Plan (SSP) developed in accordance with the BPSSM that outlines the contractor's plan for maintaining a secure environment for the shared systems. Central Office and contractor personnel are required to receive annual security awareness training.

CMS principally monitors the compliance with its standards through the following processes:

- (1) Evaluations of the implementation of information security requirements outlined in Section 912 of the Medicare Modernization Act of 2003,
- (2) Annual reports on the MACs' controls placed in operation and tests of operating effectiveness issued by independent auditors in accordance with the AICPA's Statement on Auditing Standards No. 70, *Service Organizations*,
- (3) Annual reviews in accordance with Office of Management and Budget (OMB) Circular No. A-123, *Management's Responsibility for Internal Control*, which provides updated internal control standards and specific requirements for conducting management's assessment of the effectiveness of internal control over financial reporting, and
- (4) Additional monitoring procedures performed by CMS including ongoing contractor management assessments and regular reviews of computer security configurations submitted by the MACs and the EDCs.



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These enterprise-wide CMS activities and our procedures continue to identify instances of non-compliance with CMS IT security and other requirements. While CMS continues to remediate identified findings and weaknesses, these monitoring activities also revealed a number of instances in which the remediation had not been timely implemented.

The complexity of the CMS environment, fast paced technological changes, and the evolution of threats pose a significant challenge to CMS. The age of the mainframe systems and associated software that CMS employs in its processing of Medicare, Medicaid and financially significant data will become more difficult to maintain and modify when integrating future changes in the Medicare program. CMS also requires constant vigilance in managing information security risks to ensure that weaknesses are identified and remediated timely.

CMS Information Security

When properly designed and implemented, access controls ensure that critical system assets are physically and logically protected from unauthorized usage and that only authorized personnel are granted access to data and programs; such controls include active monitoring of security events for proper assessment and timely remediation.

We identified the following weaknesses in information security that merit continued focus:

- CMS did not ensure that all Medicare contractors performed periodic reviews of user access to sensitive Medicare data and the related application systems. This condition continued at two MACs. Such periodic reviews are essential to ensure that all access continues to be appropriate and authorized.
- Unauthorized wireless access to Medicare networks was observed at the single testing contractor who completes testing on the four shared systems supported by the software maintainers. Such access introduces a vulnerability into the CMS network that is not consistent with the information security control standards of CMS and potentially permits non-authorized external users to access sensitive Medicare data and systems.
- Vulnerabilities in system configurations for contractor networks used to transport Medicare data were identified at two MACs. Providers and other health-care related organizations use these networks for transmission of claims data and other information using Electronic Data Interchange (EDI). These vulnerabilities could result in inappropriate network access and access to application systems connected to the network. At one MAC, the vulnerability identified permitted update access to the server supporting the Medicare EDI application.
- One EDC and one shared system maintainer had not completed their implementation of CMS-required computer system security configuration settings. At the EDC that processes claims for multiple MACs, security is managed using IBM's Resource Access Control Facility (RACF) software for which security settings were not set in accordance with the CMS security standards for RACF. Without full implementation of these settings, unauthorized access and usage of Medicare data and systems could occur.



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- User security administration for access to shared systems was not effectively performed at three MACs. This could result in potentially unauthorized access to Medicare data and systems.
- SSPs for the single testing contractor and one MAC were incomplete. In addition, the single testing contractor's SSP had not been timely reviewed or approved by CMS.
- Data backup tapes managed by the EDCs contain unencrypted personally identifiable information (PII) related to Medicare information. CMS has not fully implemented HHS Standard for Encryption 2008-0007.001S, dated December 23, 2008. Such encryption is also required by OMB Memorandum No. M-06-16, *Protection of Sensitive Agency Information*. CMS has not obtained a waiver from OMB related to this weakness.
- Pending the decommissioning of FACS and the full implementation of HIGLAS, segregation of duties conflicts continued to exist at Central Office between the business *function and information security administration* function of CMS' Office of Financial Management (OFM) for FACS. OFM has assigned personnel the function of system and security administrators; these personnel also were able to grant access to the FACS application and perform and process business transactions.
- CMS has not provided guidance to the MACs on how to establish segregation of duties between business processes for the shared systems applications. Since the systems are developed by the shared system maintainers and tested by the STC, the MACs do not have sufficient knowledge of the application processing to design appropriate segregation of duties controls. These controls are key to the effective administration of user access to the shared systems that process Medicare claims and are required by the NIST standards.

CMS Application Configuration Management

Configuration management is the process used to ensure that the Medicare applications used by the Central Office and Medicare contractors operate as intended by CMS. Configuration management depends on the consistent application of program change management processes and policies to the Medicare systems to ensure the continued integrity and security of financial and claims data.

CMS has contracted with several software system maintainers to provide software development and testing support for the majority of the systems used to process Medicare claims. Some of these maintainers provide services for the shared systems that include system development, system documentation, training, and testing. The MACs that use the shared systems are responsible for the configuration of programmed edits (e.g., a valid provider type was entered for the medical service rendered), the customization of automated adjudication software (AAS or "scripts"), and local information security user administration procedures.



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We identified the following weaknesses:

- Change control boards are important in an organization as complex as CMS to oversee the interfacing of Medicare and financial data across numerous applications. While CMS has instituted several change control boards for these applications, there is no overall change control board or process to coordinate efforts to integrate necessary application interfaces. Further, CMS has developed a process requiring Interface Control Documents (ICDs) but these are not standardized in content and not used by all relevant programming groups. Without appropriate integration and proper data interfacing among the many business applications used by CMS, the accuracy and reporting of financial and beneficiary data may be impacted.
- Automated Adjudication Software (AAS) scripts and configurable edits implement the business rules for processing Medicare claims. MACs have the ability to develop and implement AAS scripts. MACs are also responsible for ensuring the configuration edits are set to CMS standards. We noted at two MACs that AAS scripts are not being tested when the programs that process these scripts change by the shared systems maintainer. We also noted at two MACs that configurable edits are not being managed in accordance with CMS requirements. If these tools for implementing business claims processing policies are not tested and configured in accordance with CMS policy, the exposure exists that claims will not be processed correctly resulting in improper payments.
- The shared systems (FISS, MCS, and VMS) use thousands of data edits to adjudicate claims against Medicare policies. However, CMS has not identified all the data edits that should be activated and accurately functioning in accordance with Medicare policies. This deficiency may result in inaccurate adjudication of Medicare claims.
- CMS has implemented a quarterly edit compliance process for all FIs, Carriers, and MACs. We found that for one quarter, the compliance process did not function properly and such errors were not identified timely. CMS was not able to determine the monetary impact of the edit compliance process not functioning for the quarter.

Recommendations

Through its added oversight procedures, CMS has made progress in identifying, monitoring, and remediating specific control weaknesses related to information security and its business applications. CMS should continue its efforts to increase contractor compliance by enhancing and consistently applying oversight activities, including proactive monitoring of contractor compliance with security settings and related directives for data access and the shared systems. A particular focus should be placed on reviewing and evaluating instances of non-compliance with stated Medicare policies, including the documentation of conclusions and approvals of instances of non-compliance and evaluating their impact on the financial statements.



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To achieve these objectives, CMS should continue to coordinate and implement control processes that will enhance the overall integrity of the Medicare information systems. Such coordination will require further integration of efforts by the Office of Financial Management (OFM), the Office of Information Services (OIS), and those charged with governance over the MACs in the Center for Medicare (CM).

We recommend that CMS:

- Further the implementation of enhanced and required information security policies and techniques developed by OIS over the Medicare information systems, including:
 - Periodic and timely information system user access reviews at the Central Office, FIs, Carriers, MACs, and EDCs.
 - Increased oversight of contractors' use of newer technologies, including wireless access and publicly accessible networks.
 - Consistent and enforceable policies for the encryption of PII on its information systems, including portable devices, as required by OMB and HHS.
 - Consistent and complete system security plans prepared by all system owners, MACs, EDCs, and software system maintainers.
 - Continued implementation of system and security settings at the Central Office and the EDCs in accordance with CMS policies, related monitoring procedures, and timely remediation of identified errors.
- Oversee an integrated effort by OIS and CM to ensure that:
 - Appropriate segregation of duties is established in all systems that support Medicare and financial processing at the FIs, Carriers, and MACs to prevent excessive or inappropriate access. In addition, access to all systems should be periodically reviewed to ensure that access remains appropriate and no incompatible duties exist.
 - Compliance detection systems for the timely implementation and activation of new Medicare claims edits are monitored timely and appropriate system corrections are made for identified errors.
 - All application changes to the Medicare systems, including FISS, MCS, VMS, and CWF, are tested adequately and completely.
 - All AAS programs (scripts), new or old, are documented, validated as to business need, and adequately tested prior to implementation at the MACs or whenever the Medicare applications that use the scripts are changed.
- Continue efforts by all three organizations (OFM, OIS, CM) to require that all changes to Medicare and related financial applications be subject to review by a designated enterprise-wide change control board. System interfaces should be identified and ICDs should be consistently completed and used for all systems. In addition, relevant NIST

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guidance should be applied in the review and approval of changes. Documentation should be prepared for all phases of the change management process.

Non-CMS Financial Management Information Systems

Similar to CMS, the Department's OPDIVs initiated efforts in FY 2010 to improve IT infrastructure and financial application systems to support the program. Examples of these improvements are:

- HHS continued its implementation of Hyperion, consolidating reporting module, to automate the preparation of Department-level consolidated and individual operating division financial statements.
- NIH implemented logical access authentication to NIHNet using HHS PIV-cards.
- NIH provided IT security awareness training to 100% of their staff.
- NIH consolidated and improved monitoring of Windows servers and developed a continuous monitoring process aligned to NIST guidelines to support the annual assessment of one-third of FISMA system security controls.
- OS awarded a new multi-year IT Service contract that serves several OPDIVs, including ACF, AHRQ, AoA, SAMHSA, OS, and the regional offices of HRSA. The contract includes task order awards for computer and infrastructure support, for business application hosting, and for continuity of operations and disaster recovery planning. In addition, the contract contains new service level agreements for IT security.
- HHS established the Computer Security Incident Response Capability to perform a number of important Department-wide security incident response coordination functions.
- OS's acting CIO set a fiscal year goal to achieve a 50% reduction in the number of open/delayed weaknesses. On October 1, 2009, there were 866 open Plan of Action and Milestones (POA&M) items, and as of July 15, 2010, there were 458 open POA&M items.
- GATES remediated 70% of the weaknesses identified during the 2009 audit.
- UFMS management implemented the User Provisioning Automation (UPA) system to centralize and automate the provisioning process.
- NBS management implemented a rigorous compensating manual process for managing system changes.

Although progress was noted in remediating system vulnerabilities and refining financial IT processes, our audit results continued to show significant infrastructure and financial application system weaknesses. Our procedures noted issues in both the design and the operations of key controls in both general and application controls. The scope of audit included general controls



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testing for the National Institutes of Health's (NIH) Center for Information Technology (CIT). In addition, we reviewed the Unified Financial Management System (UFMS), NIH Business System (NBS); Grants Administration, Tracking and Evaluation System (GATES); HHS Consolidated Application System (HCAS); Enterprise Human Resources and Payroll (EHRP) System; Information for Management, Planning, Analysis, and Coordination (IMPACII); Automated Financial Statements System (AFS); and Commissioned Corps Personnel and Payroll System (CCP). The following represents a number of specific instances of deficiencies identified during our procedures.

Non-CMS Information Security Program

The security program is intended to ensure that security threats are identified, risks are assessed, control objectives are appropriately designed and formulated, relevant control techniques are developed and implemented, and managerial oversight is consistently applied to provide for the overall effectiveness of security measures. Our procedures identified the following issues:

- Vulnerability Management - The vulnerability scanning process in one OPDIV is in transition, and no formal policies and/or procedures were in place at the time of our review.
- Background Investigation - Management at one OPDIV has not fully implemented an information technology new hire personnel security program for new employee background investigation.
- Remote Access - Users may access the DHHS network using their own personal home computers; however, there is currently no monitoring or ability to enforce or confirm that minimum security requirements or authentication requirements are met for personal computers logging onto DHHS network.
- Penetration Testing - One OPDIV continues to decrease the total number of external and internal system vulnerabilities; however, the vulnerabilities that continues to exist pose a significant risk. Categories of these risks are 1) weak password configurations, 2) insecure system configuration, and 3) unnecessary system services. Specific examples of these weaknesses are:
 - Two external web applications allowed privileged system access with the default usernames and passwords;
 - Databases with default user names and passwords;
 - 30 instances of anonymous file transfer protocols; and
 - Outdated software such as secure mail transfer protocol, domain name services, and secure shell.
- Application User Access Management - For some users, access to key financial systems such as AFS, EHRP, GATES, HCAS, and UFMS was not appropriately granted, reviewed, recertified, or removed.



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- User IDs and Passwords: - Application users on key financial systems such as EHRP, GATES, HCAS, IMPACII, and UFMS utilized generic shared system IDs or had multiple IDs associated to accounts. Sharing of user IDs eliminates personal accountability for any system activity. A number of other system password configurations do not comply with DHHS standards.
- Security Management - Documentation to support corrective actions is not complete or not provided for the POA&M items for GATES and HCAS.
- Certification & Accreditation - Compliance with the C&A policies and procedures has not been formalized for HCAS. Documentation is not complete or contains inconsistent language for EHRP, GATES, HCAS, IMPACII, and UFMS.

Non-CMS Application Configuration Management

Elements of sound CM programs consist of a wide range of activities starting with the a formal change management process, authorization and approval of all configuration changes, a comprehensive testing and an audit trail that clearly documents and tracks the configuration changes. For the majority of the significant financial applications, the framework of a sound CM program exists; however, the CM program has not fully matured nor been integrated.

- Change Management - Change management procedures for UFMS, NBS, HCAS, IMPACII, GATES, and EHRP were insufficient to ensure only properly authorized changes were implemented into production systems. For NBS as an example, they lacked an automated tool to manage the CM process. As a result, NBS management established a cumbersome manual compensating process that is prone to error. In the case of UFMS, the application users have the system capability to apply configuration changes. This level of system access poses a significant risk without an effective monitoring tool. Due to this concern, UFMS initiated the implementation of a system monitoring tool, which will provide the automated capability to monitor the system for all changes. For FY2010, however, we were unable to determine the appropriateness of these system changes.
- Segregation of Duties - Access assignments were excessive for UFMS, NBS, IMPACII, HCAS, GATES, EHRP, and AFS systems and did not provide an adequate segregation of duties. Assignment conflicts represent instances whereby access assigned may have allowed users to perform all phases of transactions without intervention by other users or approvers. In addition, application developers had full access to both development and production system.

Other deficiencies that warrant attention include the following:

- Audit Log Monitoring - For the AFS, HCAS, and UFMS systems, audit log monitoring procedures were not documented. Further, audit trails that were generated were not being monitored or reviewed.



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- **Contingency Management** - Contingency plans for HCAS could be enhanced. Plans did not include effective scenarios to address business resumption or address effective testing.

Due to the pervasive nature of general and application controls, the cumulative effect of these significant deficiencies represents a material weakness in the overall design and operation of internal controls. DHHS should take a department-wide view in developing a top-down strategy in implementing information security programs to drive information security control design and operations in accordance with standards established by DHHS and other Federal government standards promulgated by NIST and OMB. Detailed descriptions of control weaknesses may be found in the management letters issued on information technology general controls and audited applications.

Recommendations

To provide a secure computing environment for critical applications throughout the Department, HHS should:

- Develop a top down approach to system and information management where support and functional personnel work in collaboration to support the HHS and OPDIV missions while maintaining focus on integrated security and information management through defined directives and initiatives from executive level Departmental management.
- Enhance overall security management programs to update documentation and review certification & accreditation, plan of action and milestones, vulnerability management, and background investigations.
- Develop safeguards around access controls to limit unauthorized access to system assets, including controls around remote access and penetration testing.
- Develop and implement effective tools, policies, and procedures to review platform security settings for all components on a continuing basis.
- Develop an overall HHS platform configuration security standards for all operating platforms and databases, following the guidance issued by NIST, for all components
- Continue to test, track, and authorize all system changes planned for released into the live environment.
- Continue to review segregation of duties logs to ensure least privilege access is granted to users with significant security and change management responsibilities.
- Review and update contingency plans for the applications and critical processing locations and ensure proper testing is performed.
- Continue to review verify that user access to critical financial applications is properly granted and to recertify or remove access on a periodic basis.



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- Maintain updated system security plans for all critical applications and validate that information is accurate.
- Develop an effective data management program to establish optimal security settings on the database.



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STATUS OF PRIOR YEAR FINDINGS

In the reports on the results of the FY 2009 audit of the DHHS financial statements, a number of issues were raised relating to internal control. The chart below summarizes the current status of the prior year items:

Material Weaknesses		
Issue Area	Summary Control Issue	FY 2010 Status
Financial Reporting Systems, Analyses, and Oversight	<ul style="list-style-type: none"> • Lack of Integrated Financial Management System • Financial Analysis and Oversight • Management Corrective Actions 	Certain progress noted; certain issues need continued focus. Repeat Condition
Financial Management Information Systems	<ul style="list-style-type: none"> • Security Management • Access Control • Configuration Management • Segregation of Duties • Contingency Planning • Financial Application Specific Concerns 	Certain progress noted, certain issues need continued focus. Modified Repeat Condition

We have reviewed our findings and recommendations with DHHS management. Management generally concurs with our findings and recommendations and will provide a corrective action plan to address the findings identified in this report. We did not audit DHHS's response and, accordingly, we express no opinion on it.

This report is intended solely for the information and use of the management and the Office of Inspector General of DHHS, OMB, GAO, and Congress. The report is not intended to be and should not be used by anyone other than these specified parties.

/Ernst & Young LLP/

November 15, 2010
McLean, VA

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Report on Compliance and Other Matters Based on an Audit of the Financial Statements Performed in Accordance with *Government Auditing Standards*

To the Secretary and the Inspector General
of the U.S. Department of Health and Human Services

We have audited the financial statements of the U.S. Department of Health and Human Services (DHHS) as of and for the year ended September 30, 2010, and we were engaged to audit the statement of social insurance as of January 1, 2010, and have issued our Report of Independent Auditors therein dated November 15, 2010. That report states that because of the matters discussed therein, the scope of our work was not sufficient to enable us to express, and we do not express, an opinion on the statement of social insurance as of January 1, 2010. Except for the matters discussed in the fourth paragraph of the Report of Independent Auditors, we conducted our audit in accordance with auditing standards generally accepted in the United States, the standards applicable to financial audits contained in *Government Auditing Standards*, issued by the Comptroller General of the United States, and Office of Management and Budget (OMB) Bulletin No. 07-04, *Audit Requirements for Federal Financial Statements*, as amended.

As part of obtaining reasonable assurance about whether DHHS's financial statements are free of material misstatement, we performed tests of its compliance with certain provisions of laws and regulations, noncompliance with which could have a direct and material effect on the determination of financial statement amounts, and certain other laws and regulations specified in OMB Bulletin No. 07-04, as amended, including the requirements referred to in the Federal Financial Management Improvement Act of 1996 (FFMIA). We limited our tests of compliance to these provisions, and we did not test compliance with all laws and regulations applicable to DHHS.

The results of our tests of compliance with the laws and regulations described in the second paragraph of this report disclosed instances of noncompliance with the following laws and regulations or other matters that are required to be reported under *Government Auditing Standards* and OMB Bulletin No. 07-04, as amended, as described below.

DHHS's management is investigating potential violations of certain provisions of the Anti-Deficiency Act (31 U.S.C. §1341-1342, 1349-1351, and 1517-1519) and OMB Circular A-11.

Additionally, the Improper Payments Information Act (IPIA) of 2002 and the Improper Payment Eliminations and Recovery Act (IPERA) of 2010 (hereinafter the Acts) require federal agencies to identify the program and activities that may be susceptible to significant improper payments and estimate the amount of the improper payments. While DHHS is not in full compliance with the requirements of the Acts, it has developed and reported error rates for each of its seven high-



Report on Compliance and Other Matters
Page 2

risk programs, or components of such programs. DHHS continues its efforts to fully implement the Acts and OMB's implementing regulation.

Under FFMIA, we are required to report whether DHHS's financial management systems substantially comply with federal financial management systems requirements, applicable federal accounting standards, and the United States Standard General Ledger (USSGL) at the transaction level. To meet this requirement, we performed tests of compliance with FFMIA Section 803(a) requirements. The results of our tests disclosed instances in which DHHS's financial management systems did not substantially comply with certain requirements as discussed above. We have identified the following instances of noncompliance:

- Certain subsidiary systems are not integrated with the Unified Financial Management System (UFMS) and are not complemented by sufficient manual preventative and detective type controls. For example, although operational at some of the Medicare Contractors, DHHS has not yet completed the implementation of the HIGLAS general ledger system. Additionally, manual key input continues to be required for each Operation Division (OPDIV) to upload trial balances into the Automated Financial Statements System for consolidation in preparation of the departmental consolidated financial statements. Further, certain OPDIV-level reconciliations/analyses were not performed on a timely basis.
- Certain reconciliations and clearance of differences are not completed timely due to the use of ad hoc inquiries and system limitations on matching debits and credits to resolve certain issues.
- During fiscal year 2010, hundreds of manual journal vouchers were required to be recorded in UFMS to post certain types of transactions - including budgetary and proprietary, not currently configured correctly within UFMS and for the purpose of developing quarterly financial statements.
- Reviews of general and application controls over financial management systems identified certain departures from requirements specified in OMB Circulars A-127, *Financial Management Systems*, and A-130, *Management of Federal Information Resources*. Additionally, the Office of Inspector General (OIG) identified certain issues, including access control deficiencies related to systems as part of its Federal Information Security Management Act and other OIG engagements. Finally, DHHS management has identified certain weaknesses within its information technology general and application controls during its assessment of corrective action status and its OMB A-123 processes.

* * * * *

Our Report on Internal Control dated November 15, 2010, includes additional information related to the financial management systems that were found not to comply with the



Report on Compliance and Other Matters
Page 3

requirements, relevant facts pertaining to the noncompliance to FFMA, and our recommendations related to the specific issues presented. It is our understanding that management agrees with the facts as presented and that relevant comments from DHHS's management responsible for addressing the noncompliance are provided as an attachment to its report. We did not audit management's comments and, accordingly, we express no opinion on them. Additionally, DHHS is updating its agency-wide corrective action plan to address FFMA and other financial management issues.

Providing an opinion on compliance with certain provisions of laws and regulations was not an objective of our audit and, accordingly, we do not express such an opinion.

This report is intended solely for the information and use of management and the Office of Inspector of General of the DHHS, OMB, and Congress, and is not intended to be and should not be used by anyone other than these specified parties.

/Ernst & Young LLP/

November 15, 2010
McLean, VA

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DEPARTMENT'S RESPONSE TO THE AUDIT



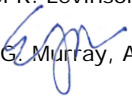
DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Washington, D.C. 20201

November 12, 2010

To: Daniel R. Levinson, Inspector General

From:  Ellen G. Murray, Assistant Secretary for Financial Resources and Chief Financial Officer

Subject: FY2010 Financial Statement Audit

We would like to thank the Office of Inspector General and your contractors, Ernst & Young LLP for your efforts on our behalf. We appreciate the professionalism exhibited by your staff and contractors during the audit.

We appreciate the opportunity to comment on the draft reports provided to us on November 5, 2010. We generally concur with the findings identified in the draft Report on Internal Control. The final reports will be included in our FY 2010 Agency Financial Report. In response to your reports, we will prepare corrective action plans to address the identified findings within the next 60 days.

HHS management is committed to working toward resolving these challenges. We look forward to continued collaboration with the OIG to improve our stewardship of taxpayer funds.

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FINANCIAL STATEMENTS

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES CONSOLIDATED BALANCE SHEET As of September 30, 2010 and 2009 (in Millions)

	2010	2009
Assets (Note 2)		
Intragovernmental		
Fund Balance with Treasury (Note 3)	\$ 182,235	\$ 161,962
Investments, Net (Note 4)	359,882	381,116
Accounts Receivable, Net (Note 5)	1,137	913
Other (Note 8)	99	92
Total Intragovernmental	<u>543,353</u>	<u>544,083</u>
Accounts Receivable, Net (Note 5)	7,394	5,504
Inventory and Related Property, Net (Note 6)	6,077	5,604
General Property, Plant & Equipment, Net (Note 7)	5,263	5,047
Other (Note 8)	1,652	2,542
Total Assets	<u><u>\$ 563,739</u></u>	<u><u>\$ 562,780</u></u>
Stewardship PP&E (Note 1)		
Liabilities (Note 9)		
Intragovernmental		
Accounts Payable	\$ 906	\$ 566
Other (Note 13)	1,572	1,182
Total Intragovernmental	<u>2,478</u>	<u>1,748</u>
Accounts Payable	673	554
Entitlement Benefits Due and Payable (Note 10)	72,712	72,218
Accrued Grant Liability (Note 12)	4,204	4,040
Federal Employee & Veterans' Benefits (Note 11)	9,985	9,690
Contingencies & Commitments (Note 14)	6,079	4,048
Other (Note 13)	3,082	2,069
Total Liabilities	<u><u>99,213</u></u>	<u><u>94,367</u></u>
Net Position		
Unexpended Appropriations - Earmarked funds	1,675	3,492
Unexpended Appropriations - Other funds	140,468	124,037
Unexpended Appropriations, Total	<u>142,143</u>	<u>127,529</u>
Cumulative Results of Operations - Earmarked funds	317,334	336,811
Cumulative Results of Operations - Other funds	5,049	4,073
Cumulative Results of Operations, Total	<u>322,383</u>	<u>340,884</u>
Total Net Position	<u><u>464,526</u></u>	<u><u>468,413</u></u>
Total Liabilities & Net Position	<u><u>\$ 563,739</u></u>	<u><u>\$ 562,780</u></u>

The accompanying "Notes to the Financial Statements" are an integral part of these statements.

**U. S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
CONSOLIDATED STATEMENT OF NET COST
For the Years Ended September 30, 2010 and 2009
(in Millions)**

	2010	2009
Responsibility Segments		
Centers for Medicare & Medicaid Services (CMS)		
Gross Cost	\$ 789,713	\$ 749,004
Exchange Revenue (Note 16 & 17)	(60,717)	(57,294)
CMS Net Cost of Operations	<u>728,996</u>	<u>691,710</u>
Other Segments:		
Administration for Children and Families (ACF)	56,369	52,326
Administration on Aging (AoA)	1,530	1,441
Agency for Healthcare Research and Quality (AHRQ)	86	(55)
Centers for Disease Control and Prevention (CDC)	10,482	9,274
Food and Drug Administration (FDA)	3,130	2,629
Health Resources and Services Administration (HRSA)	9,222	7,314
Indian Health Service (IHS)	5,262	5,225
National Institutes of Health (NIH)	33,776	30,369
Office of the Secretary (OS)	6,720	2,341
Program Support Center (PSC)	1,063	975
Substance Abuse and Mental Health Services Administration (SAMHSA)	<u>3,362</u>	<u>3,501</u>
Other Segments Gross Cost of Operations before Actuarial Gains and Losses	131,002	115,340
Actuarial (Gains) and Losses Commissioned Corp Retirement System and Commissioned Corps Post Retirement Medical Plan	<u>(77)</u>	<u>675</u>
Other Segments Gross Cost of Operations after Actuarial Gains and Losses	130,925	116,015
Exchange Revenue (Note 16 and 17)	<u>(3,193)</u>	<u>(3,820)</u>
Other Segments Net Cost of Operations	127,732	112,195
Net Cost of Operations	<u><u>\$ 856,728</u></u>	<u><u>\$ 803,905</u></u>

The accompanying "Notes to the Financial Statements" are an integral part of these statements.

U. S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
CONSOLIDATED STATEMENT OF CHANGES IN NET POSITION
For the Year Ended September 30, 2010
(in Millions)

	2010			Consolidated Total
	Earmarked Funds	All Other Funds	Eliminations	
Cumulative Results of Operations:				
Beginning Balances	\$ 336,811	\$ 4,073	\$ -	\$ 340,884
Budgetary Financing Sources:				
Appropriations Used	228,883	408,384	-	637,267
Nonexchange Revenue				
Non-exchange Revenue - Tax Revenue	183,812	-	-	183,812
Non-exchange Revenue - Investment Revenue	17,349	4	-	17,353
Non-exchange Revenue - Other	619	(9)	90	700
Donations and Forfeitures of Cash and Cash Equivalents	83	2	-	85
Transfers-in/out without Reimbursement	(3,290)	1,746	-	(1,544)
Other Financing Sources (Non-Exchange):				
Donations and Forfeitures of Property	-	5	-	5
Transfers-in/out Without Reimbursement (+/-)	-	1	-	1
Imputed Financing	39	667	(166)	540
Other (+/-)	-	8	-	8
Total Financing Sources	427,495	410,808	(76)	838,227
Net Cost of Operations (+/-)	446,972	409,832	(76)	856,728
Net Change	(19,477)	976	-	(18,501)
Cumulative Results of Operations	317,334	5,049	-	322,383
Unexpended Appropriations				
Beginning Balances	3,492	124,037	-	127,529
Budgetary Financing Sources				
Appropriations Received	230,499	427,065	-	657,564
Appropriations Transferred in/out	-	(544)	-	(544)
Other Adjustments	(3,433)	(1,706)	-	(5,139)
Appropriations Used	(228,883)	(408,384)	-	(637,267)
Total Budgetary Financing Sources	(1,817)	16,431	-	14,614
Total Unexpended Appropriations	1,675	140,468	-	142,143
Net Position	\$ 319,009	\$ 145,517	\$ -	\$ 464,526

The accompanying "Notes to the Financial Statements" are an integral part of these statements.

**U. S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
 CONSOLIDATED STATEMENT OF CHANGES IN NET POSITION
 For the Year Ended September 30, 2009
 (in Millions)**

	2009			Consolidated Total
	Earmarked Funds	All Other Funds	Eliminations	
Cumulative Results of Operations:				
Beginning Balances	\$ 346,287	\$ 2,868	\$ -	\$ 349,155
Budgetary Financing Sources:				
Appropriations Used	209,273	373,868	-	583,141
Nonexchange Revenue				
Non-exchange Revenue - Tax Revenue	194,330	-	-	194,330
Non-exchange Revenue - Investment Revenue	18,686	1	-	18,687
Non-exchange Revenue - Other	503	(9)	(127)	367
Donations and Forfeitures of Cash and Cash Equivalents	128	3	-	131
Transfers-in/out Without Reimbursement	(2,918)	1,465	4	(1,449)
Other Financing Sources (Non-Exchange):				
Donations and Forfeitures of Property	-	5	-	5
Transfers-in/out Without Reimbursement (+/-)	-	9	(2)	7
Imputed Financing	32	498	(105)	425
Other (+/-)	-	(10)	-	(10)
Total Financing Sources	420,034	375,830	(230)	795,634
Net Cost of Operations (+/-)	429,510	374,625	(230)	803,905
Net Change	(9,476)	1,205	-	(8,271)
Cumulative Results of Operations	336,811	4,073	-	340,884
Unexpended Appropriations				
Beginning Balances	12,172	81,350	-	93,522
Budgetary Financing Sources				
Appropriations Received	213,023	431,868	-	644,891
Appropriations Transferred in/out	-	1,854	-	1,854
Other Adjustments	(12,430)	(17,167)	-	(29,597)
Appropriations Used	(209,273)	(373,868)	-	(583,141)
Total Budgetary Financing Sources	(8,680)	42,687	-	34,007
Total Unexpended Appropriations	3,492	124,037	-	127,529
Net Position	\$ 340,303	\$ 128,110	\$ -	\$ 468,413

The accompanying "Notes to the Financial Statements" are an integral part of these statements.

**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
COMBINED STATEMENT OF BUDGETARY RESOURCES
For the Years Ended September 30, 2010 and 2009
(in Millions)**

	2010		2009	
	Budgetary	Non-Budgetary Credit Program Financing Accounts	Budgetary	Non-Budgetary Credit Program Financing Accounts
Budgetary Resources:				
Unobligated Balance, Brought Forward, October 1:	\$ 50,305	\$ 73	\$ 34,349	\$ 95
Recoveries of Prior Year Unpaid Obligations				
Actual	17,682	-	12,719	-
Budget Authority				
Appropriation	1,194,294	-	1,153,357	1
Borrowing Authority	-	-	-	2
Spending Authority from Offsetting Collections				
Collected	9,020	18	10,449	19
Change in Receivables from Federal Sources	290	-	(263)	-
Change in Unfilled Customer Orders				
Advance Received	279	-	154	-
Without Advance from Federal Sources	(102)	-	(766)	-
Previously Unavailable	293	-	306	-
Expenditure Transfers from Trust Funds				
Actual	3,721	-	3,512	-
Change in Receivables from Trust Funds	313	-	515	-
Subtotal	1,208,108	18	1,167,264	22
Nonexpenditure Transfers, Net, Anticipated and Actual	(663)	-	2,100	-
Temporarily not available pursuant to Public Law	(11,296)	-	(1,515)	-
Permanently not available (-)	(5,281)	(16)	(29,731)	-
Total Budgetary Resources	\$ 1,258,855	\$ 75	\$ 1,185,186	\$ 117
Status of Budgetary Resources:				
Obligations Incurred				
Direct	\$ 1,191,984	\$ 25	\$ 1,127,560	\$ 44
Reimbursable	7,596	-	7,321	-
Subtotal	1,199,580	25	1,134,881	44
Unobligated Balances Available				
Apportioned	48,476	50	40,647	72
Exempt from Apportionment	354	-	389	-
Subtotal	48,830	50	41,036	72
Unobligated Balances Not Available	10,445	-	9,269	1
Total Status of Budgetary Resources	\$ 1,258,855	\$ 75	\$ 1,185,186	\$ 117
Change in Obligated Balance:				
Obligated Balance, Net				
Unpaid Obligations, brought forward, October 1	\$ 171,739	\$ -	\$ 145,222	\$ -
Uncollected Customer Payments from Federal Sources, brought forward, October 1	(6,678)	-	(7,192)	-
Total unpaid Obligated Balance, Net	165,061	-	138,030	-
Obligations Incurred Net	1,199,580	25	1,134,881	44
Gross Outlays	(1,171,097)	(25)	(1,095,645)	(44)
Recoveries of Prior Year Unpaid Obligations, Actual	(17,682)	-	(12,719)	-
Change in Uncollected Customer Payments from Federal Sources	(501)	-	514	-
Obligated Balance, Net, End of Period				
Unpaid Obligations	182,540	-	171,739	-
Uncollected Customer Payments from Federal Sources	(7,179)	-	(6,678)	-
Total, Unpaid Obligated Balance, Net, End of Period	175,361	-	165,061	-
Net Outlays				
Gross Outlays	1,171,097	25	1,095,645	44
Offsetting Collections	(13,020)	(18)	(14,115)	(19)
Distributed Offsetting Receipts	(303,967)	(10)	(284,264)	(28)
Net Outlays	\$ 854,110	\$ (3)	\$ 797,266	\$ (3)

The accompanying "Notes to the Financial Statements" are an integral part of these statements.

**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
STATEMENT OF SOCIAL INSURANCE
75-Year Projection as of January 1, 2010 and Prior Base Years
(in Billions)**

	2010 <i>unaudited</i>	Estimates from Prior Years			
		2009	2008	2007	2006
Actuarial present value for the 75-year projection period of estimated future income (excluding interest) received from or on behalf of: (Notes 24 and 25)					
Current participants who, in the starting year of the projection period:					
Have not yet attained eligibility age					
HI	\$ 7,216	\$ 6,348	\$ 6,320	\$ 5,975	\$ 5,685
SMI Part B	12,688	16,323	14,932	12,112	12,446
SMI Part D	6,355	6,144	6,527	7,285	7,366
Have attained eligibility age (age 65 and over)					
HI	248	209	202	178	192
SMI Part B	1,972	1,924	1,785	1,648	1,606
SMI Part D	646	595	581	746	750
Those expected to become participants					
HI	6,944	5,451	5,361	4,870	4,767
SMI Part B	3,077	4,909	4,480	4,460	3,562
SMI Part D	2,714	2,632	2,856	2,735	2,134
All current and future participants:					
HI	14,408	12,008	11,883	11,023	10,644
SMI Part B	17,737	23,156	21,197	18,221	17,613
SMI Part D	9,715	9,371	9,964	10,766	10,250
Actuarial present value for the 75-year projection period of estimated future expenditures for or on behalf of: (Notes 24 and 25)					
Current participants who, in the starting year of the projection period:					
Have not yet attained eligibility age					
HI	12,032	18,147	17,365	15,639	15,633
SMI Part B	12,587	16,342	14,949	12,130	12,433
SMI Part D	6,355	6,144	6,527	7,273	7,338
Have attained eligibility age (age 65 and over)					
HI	2,648	2,958	2,747	2,558	2,397
SMI Part B	2,166	2,142	1,986	1,834	1,773
SMI Part D	646	595	581	794	792
Those expected to become participants					
HI	2,411	4,673	4,506	5,118	3,904
SMI Part B	2,984	4,672	4,262	4,257	3,407
SMI Part D	2,714	2,632	2,856	2,699	2,121
All current and future participants:					
HI	17,090	25,778	24,619	23,315	21,934
SMI Part B	17,737	23,156	21,197	18,221	17,613
SMI Part D	9,715	9,371	9,964	10,766	10,250
Actuarial present values for the 75-year projection period of estimated future excess of income (excluding interest) over expenditures (Notes 24 and 25)					
HI	\$ (2,683)	\$ (13,770)	\$ (12,737)	\$ (12,292)	\$ (11,290)
SMI Part B	-	-	-	-	-
SMI Part D	-	-	-	-	-
Additional Information					
Actuarial present values for the 75-year projection period of estimated future excess of income (excluding interest) over expenditures (Notes 24 and 25)					
HI	\$ (2,683)	\$ (13,770)	\$ (12,737)	\$ (12,292)	\$ (11,290)
SMI Part B	-	-	-	-	-
SMI Part D	-	-	-	-	-
Trust fund assets at start of period					
HI	304	321	312	300	285
SMI Part B	76	59	53	38	23
SMI Part D	1	1	3	1	-
Actuarial present value for the 75-year projection of estimated future excess of income (excluding interest) and Trust Fund assets at start of period over expenditures (Notes 24 and 25)					
HI	\$ (2,378)	\$ (13,449)	\$ (12,425)	\$ (11,993)	\$ (11,006)
SMI Part B	76	59	53	38	23
SMI Part D	1	1	3	1	-

Note: Totals do not necessarily equal the sums of rounded components.

With the exception of the 2007 projections presented, current participants are assumed to be the "closed group" of individuals who are at least age 15 at the start of the projection period, and are participating in the program as either taxpayers, beneficiaries, or both. For the 2007 projections, the "closed group" are assumed to be individuals who are at least 18 at the start of the projection period, and are participating in the program as either taxpayers, beneficiaries, or both.

The accompanying "Notes to the Financial Statements" are an integral part of these statements.

NOTES TO THE PRINCIPAL FINANCIAL STATEMENTS FOR THE YEARS ENDED SEPTEMBER 30, 2010 AND 2009

Note 1. Summary of Significant Accounting Policies

Reporting Entity

The Department of Health and Human Services (HHS) is a Cabinet-level agency of the Executive Branch of the Federal Government. Its predecessor, the Department of Health, Education and Welfare (HEW), was officially established on April 11, 1953. In 1979, the *Department of Education Organization Act of 1979 (Public Law (P.L.) 96-88)* was signed into law, providing for a separate Department of Education. The HEW officially became the HHS on May 4, 1980. The HHS is responsible for protecting the health of all Americans and providing essential human services, especially for those who are least able to help themselves.

Organization and Structure of the HHS

The HHS is comprised of the Office of the Secretary and 10 other Operating Divisions (OPDIVs) with diverse missions and programs. The Office of the Secretary and the OPDIVs are each responsible for carrying out a mission, conducting a major line of activity, or producing one or a group of related products or services. Although organizationally located within the Office of the Secretary, the Program Support Center reports on its activity separately because its business activities encompass offering services to other Federal agencies and the HHS OPDIVs. The Agency for Toxic Substances and Disease Registry is combined with the Centers for Disease Control and Prevention for financial reporting purposes; therefore, these footnotes will refer to them as one responsibility segment. Managers of the responsibility segments report directly to the entity's top management, and the resources and results of operations can be clearly distinguished from those of other responsibility segments.

The 12 responsibility segments are:

1. Administration for Children and Families (ACF)
2. Administration on Aging (AoA)
3. Agency for Healthcare Research and Quality (AHRQ)
4. Centers for Disease Control and Prevention and
Agency for Toxic Substances and Disease Registry (CDC)
5. Centers for Medicare and Medicaid Services (CMS)
6. Food and Drug Administration (FDA)
7. Health Resources and Services Administration (HRSA)
8. Indian Health Service (IHS)
9. National Institutes of Health (NIH)
10. Office of the Secretary (OS) – excluding the Program Support Center
11. Program Support Center (PSC)
12. Substance Abuse and Mental Health Services Administration (SAMHSA)

The HHS partners with other governmental agencies to accomplish its mission. One such partnership is with the Department of Homeland Security for the Biodefense Countermeasures Fund, which is reported on the HHS financial statements under the Office of the Secretary responsibility segment.

Basis of Accounting and Presentation

The HHS financial statements have been prepared to report the financial position and results of operations of the Department, pursuant to the requirements of 31 U.S. Code 3515(b), the *Chief Financial Officers (CFO) Act of 1990 (P.L. 101-576)*, as amended by the *Government Management Reform Act of 1994 (P.L. 103-356)*, and presented in accordance with the requirements in the Office of Management and Budget (OMB) Circular No. A-136, *Financial Reporting Requirements* (OMB Circular A-136). These statements have been prepared from the Department's financial records using an accrual basis in

conformity with accounting principles generally accepted in the United States. The generally accepted accounting principles (GAAP) for Federal entities are the standards prescribed by the Federal Accounting Standards Advisory Board (FASAB) and recognized by the American Institute of Certified Public Accountants as Federal GAAP. These statements are, therefore, different from financial reports prepared pursuant to other OMB directives that are primarily used to monitor and control the use of budgetary resources.

Transactions are recorded on an accrual and budgetary basis of accounting. Under the accrual method of accounting, revenues are recognized when earned, and expenses are recognized when resources are consumed, without regard to the payment of cash. Budgetary accounting principles, on the other hand, are designed to recognize the obligation of funds according to legal requirements, which, in many cases, is prior to the occurrence of an accrual-based transaction. The recognition of budgetary accounting transactions is essential for compliance with legal constraints and controls over the use of Federal funds.

The financial statements consolidate the balances of approximately 200 appropriations and fund accounts. The fund accounts include accounts used for suspense, collection of receipts, and general government functions. Transactions and balances within the HHS have been eliminated in the presentation of the Consolidated Balance Sheet and Statements of Net Cost and Changes in Net Position. The Combined Statements of Budgetary Resources are presented on a combined basis; therefore, transactions and balances within the HHS have not been eliminated from these statements. Supplemental information is accumulated from the OPDIV reports, regulatory reports, and other sources within the HHS. These statements should be read with the realization that they are for a component of the U.S. Government, a sovereign entity. One implication of this is that liabilities cannot be liquidated without legislation providing resources and budget authority for the HHS.

Financial Management Systems Program

The HHS' financial management goals seek to (a) provide decision-makers with timely, accurate, and useful financial and program information and (b) ensure that the HHS resources are used appropriately, efficiently, and effectively. The HHS continues to strive for improvements in financial management and reporting by streamlining and integrating its financial management systems to ensure transparency and accountability.

The HHS established the Financial Management Systems Program to provide central management direction and oversight of financial management systems across the Department. The HHS facilitates collaboration between business owners and information technology professionals to maximize the HHS investment and reduce redundancies. The goal is to strengthen governance by engaging the business owners and the information technology professionals throughout the life cycle of the HHS financial management system.

Three major systems support HHS programs: the Healthcare Integrated General Ledger Accounting System (HIGLAS), the Unified Financial Management System (UFMS), and the NIH Business Systems (NBS). The HHS will continue its reporting and system enhancements to strengthen controls, operating performance, and reporting capabilities.

The Consolidated Financial Reporting System (CFRS) is under development to generate automated consolidated financial statements, and will be deployed for the first quarter of fiscal year 2011. CFRS addresses the Department's recurring *CFO Act* audit findings and the *Federal Financial Management Improvement Act of 1996 (P.L. 104-208)* system non-compliance. The system will eliminate the OPDIVs' manual intervention for the consolidation process. During FY 2010, the FDA piloted the Oracle Business Intelligence Enterprise Edition – a reporting dashboard for managers – to enhance the availability of financial management information.

Use of Estimates in Preparing Financial Statements

Preparation of financial statements in accordance with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect reported amounts of assets and liabilities, and the disclosure of contingent liabilities as of the date of the financial statements. Estimates and assumptions also affect revenues and expenses accrued and reported in the financial statements. Actual results may differ from estimates.

Parent/Child Reporting

Allocation transfers are legal delegations by one agency of its authority to obligate budget authority and outlay funds to another agency. The HHS is party to allocation transfers with other Federal agencies as both a transferring (parent) entity and a receiving (child) entity.

A separate fund account (allocation account) is created in the Department of the Treasury (Treasury) as a subset of the parent fund account for tracking and reporting purposes. All allocation transfers of balances are credited to this account, and subsequent obligations and outlays incurred by the child entity are charged to this allocation account as they execute the delegated activity on behalf of the parent entity. Generally, all financial activity related to these allocation transfers (e.g., budget authority, obligations, outlays) is reported in the financial statements of the parent entity from which the underlying legislative authority, appropriations and budget apportionments are derived.

In FY 2008, the HHS received an exception to the Parent/Child reporting requirements of OMB Circular No. A-136 as it pertains to the allocation transfer from the Department of Homeland Security (DHS) to the HHS for the Biodefense Countermeasures Fund for FY 2008 and beyond. Per this exception, the HHS, as the child, assumed the financial statement reporting responsibilities of this fund. Also, due to the revised definition of Parent/Child reporting, and revised Treasury Appropriation Codes made by Treasury in FY 2009, the Treasury-managed Trust Funds Supplementary Medical Insurance (SMI) Trust Fund, the Hospital Insurance (HI) Trust Fund, the Vaccine Injury Compensation Program (VICP) Trust Fund and the Health Care Fraud and Abuse Control Account, are no longer considered as Parent/Child reporting. These changes have no impact on the HHS reporting of the Treasury-managed Trust Funds.

In addition to these funds, the HHS allocates funds, as the parent, to the Department of Interior, Bureau of Indian Affairs and Department of Treasury, Internal Revenue Service. The HHS receives allocation transfers, as the child, from the Departments of Agriculture, Justice and State.

Reclassifications

Certain FY 2009 balances have been reclassified to conform to FY 2010 financial statement presentations, the effects of which are immaterial.

Earmarked Funds

Earmarked funds are financed by specifically identified revenues often supplemented by other financing sources, or other specific financing sources, which remain available over time. Earmarked funds must meet the following criteria:

- A statute committing the Federal Government to use specifically identified revenues and other financing sources only for designated activities, benefits or purposes;
- Explicit authority for the earmarked fund to retain revenues and other financing sources not used in the current period for future use to finance the designated activities, benefits, or purposes; and
- A requirement to account for and report on the receipt, use, and retention of the revenues and other financing sources that distinguishes the earmarked fund from the Government's general revenues.

The HHS' major earmarked funds are described below:

Medicare Hospital Insurance (HI) Trust Fund – Part A

Section 1817 of the *Social Security Act* (P.L. Ch. 531, 49 Stat. 620, now codified as 42 U.S.C. Ch. 7, P.L. 104-191) established the Medicare HI Trust Fund. Medicare contractors are paid by the HHS to process Medicare claims for hospital in-patient services, hospice, and certain skilled nursing and home health services. Benefit payments made by the Medicare contractors for these services, as well as administrative costs, are charged to the HI Trust Fund. A portion of HHS payments to Medicare Advantage Plans (previously known as Managed Care plans) are also charged to this fund. The financial statements include the HI Trust Fund activities administered by the Treasury. The HI Trust Fund has permanent indefinite authority.

Employment tax revenue is the primary source of financing for the Medicare HI program. Medicare's portion of payroll and self-employment taxes is collected under the *Federal Insurance Contributions Act (FICA)* (26 U.S.C. Ch 21) and *Self Employment Contributions Act (SECA) of 1954* (Chapter 2 of Subtitle A of the *Internal Revenue Code*, 26 U.S.C. §1401 through §1403). Employees and employers are both

required to contribute 1.45 percent of earnings, with no limitation, to the HI Trust Fund. Self-employed individuals contribute the full 2.9 percent of their net income. The *Social Security Act* requires the transfer of these contributions from the Treasury General Fund to the HI Trust Fund based on the amount of wages certified by the Commissioner of Social Security from the Social Security Administration (SSA) records of wages. The SSA uses the wage totals reported by employers via the quarterly Internal Revenue Service, *Employer's Quarterly Federal Tax Return*, as the basis for conducting quarterly certification of regular wages.

Medicare Supplementary Medical Insurance (SMI) Trust Fund – Part B

Section 1841 of the *Social Security Act* established the Medicare SMI Trust Fund. Medicare contractors are paid by the HHS to process Medicare claims for physicians, medical suppliers, hospital out-patient services and rehabilitation, end-stage renal disease treatment, rural health clinics, laboratory services, and certain skilled nursing and home health services. Benefit payments made by the Medicare contractors for these services, as well as administrative costs, are charged to the SMI Trust Fund. A portion of HHS payments to Medicare Advantage Plans are also charged to this fund. The financial statements include SMI Trust Fund activities administered by the Treasury. The SMI Trust Fund has permanent indefinite authority.

SMI benefits and administrative expenses are financed by monthly premiums paid by Medicare beneficiaries and are matched by the Federal Government through the General Fund appropriation, Payments to the Health Care Trust Funds. Section 1844 of the *Social Security Act* authorizes appropriated funds to match SMI premiums collected and prescribes the ratio for the match as well as the method to fully compensate the Trust Fund if insufficient funds are available in the appropriation to match all premiums received in the fiscal year.

Medicare Supplementary Medical Insurance Trust Fund – Part D

The Medicare Supplementary Medical Insurance Trust Fund – Part D, (Prescription Drug Benefit) was established by the *Medicare Prescription Drug, Improvement, and Modernization Act of 2003* (known as the *Medicare Modernization Act, or MMA*) (P.L. 108-173). The Prescription Drug Benefit is available to all Medicare beneficiaries and provides a prescription drug benefit to those who opt into the program (beneficiaries eligible for Medicaid are automatically enrolled unless they have other credible drug coverage). The Prescription Drug Benefit is part of the SMI Trust Fund and is reported in the Medicare column of the financial statements where required. Drug plans are offered by insurance companies and other private companies approved by Medicare and are of two types: Medicare Prescription Drug Plans, which add coverage to fee-for-service Medicare and Medicare Advantage Prescription Drug Plans and other Medicare Health Plans in which drug coverage is offered as part of a benefit package that includes Part A and Part B services. Medicare helps employers and unions continue to provide retiree drug coverage that meets Medicare's standards through the Retiree Drug Subsidy. The Low Income Subsidy helps those with limited income and resources.

Medicare Integrity Program

The *Health Insurance Portability and Accountability Act of 1996 (HIPAA)* (P.L. 104-191) established the Medicare Integrity Program and codified the Medicare Integrity Program activities previously known as "payment safeguards." The HIPAA also established the Health Care Fraud and Abuse Control Account, which provides a dedicated appropriation for carrying out the Medicare Integrity Program. Through the Medicare Integrity Program, the HHS contracts with eligible entities to perform such activities as medical and utilization reviews, fraud reviews, cost report audits. In addition, the Department will educate providers and beneficiaries, with respect to payment integrity and benefit quality assurance issues. The Medicare Integrity Program is funded by the HI Trust Fund.

Revenue and Financing Sources

The HHS receives the majority of funding needed to support its discretionary programs through Congressional appropriation and through reimbursement for the provision of goods or services to other Federal agencies. The United States Constitution prescribes that no money may be expended by a Federal agency unless and until funds have been made available by Congressional appropriation. Appropriations are recognized as financing sources when related expenses are incurred or assets are purchased. Revenues from reimbursable agreements are recognized when the goods or services are provided by the HHS. Other financing sources, such as donations and transfers of assets without reimbursements, are also recognized on the Consolidated Statement of Changes in Net Position.

Appropriations

The HHS receives annual, multi-year, and no-year appropriations that may be used within statutory limits. For example, funds for general operations are normally made available for one fiscal year; funds for long-term projects such as major construction will be available for the expected life of the project and funds used to establish revolving fund operations are generally available indefinitely (i.e., no-year funds).

Borrowing Authority

The HHS uses indefinite borrowing authority under the *Federal Credit Reform Act of 1990 (FCRA)*, (P.L. 101-508, as amended) for its loan programs. Borrowing authority increases budgetary resources and enables costs to be financed by borrowing from Treasury. Any unobligated borrowing authority does not carry forward to the next fiscal year. The HHS has several existing programs with borrowing authority: the Health Care Loan Program and the Health Education Assistance Loan Program.

In FY 2010, HHS received borrowing authority under the *Patient Protection and Affordable Care Act* (P.L. 111-148, § 1322) to support the Consumer Operated and Oriented Plan (CO-OP) Program. The Act requires HHS to provide loans for start-up costs. This provision fosters the creation of qualified, non-profit health insurance issuers who will offer qualified health plans in the individual- and small-group markets of each State. These loans will be repaid in a manner consistent with State solvency and reserve requirements. These program awards are to be made no later than July 1, 2013.

- *Direct Loans*

The Health Care Infrastructure Improvement Program (enacted into law as part of the *Medicare Modernization Act of 2003*, P.L. 108-173) provides direct loans to hospitals or entities engaged in research of causes, prevention, and treatment of cancer. These entities are designated as cancer centers by the National Cancer Institute, or by the State legislature as the official cancer institute of the State. Such State designation must have occurred prior to December 8, 2003 to qualify for payment of capital costs for eligible projects.

- *Loan Guarantees*

The HHS administers guaranteed loan programs for the Health Center and the Health Education Assistance Loan Programs. Loans receivable represent defaulted guaranteed loans which have been paid to lenders under these programs and also include interest due to the HHS on the defaulted loans. The liabilities for loan guarantees are valued at the present value of the cash outflows from the HHS less the present value of related inflows. Due to the immateriality of these Direct Loans and Loan Guarantees, the related receivables and liabilities are reported in Other Assets and Other Liabilities, respectively.

Exchange Revenue

Exchange revenue is recognized when earned (i.e., when goods have been delivered or services have been rendered). These revenues reduce the cost of operations.

The HHS' pricing policy for reimbursable agreements is to recover full cost and to incur no profit or loss. In addition to revenues related to reimbursable agreements, the HHS collects various user fees to offset the cost of its programs. Certain fees charged by the HHS are based on an amount set by law or regulation and may not represent full cost.

With minor exceptions, all receipts of revenues by Federal agencies are processed through the Treasury's central accounting system. Regardless of whether they derive from exchange or non-exchange transactions, all receipts not earmarked by Congressional appropriation for immediate HHS use are deposited in the General or Special funds of the Treasury. Amounts not retained for use by the HHS are reported as transfers to other Government agencies on the HHS Consolidated Statement of Changes in Net Position.

Non-Exchange Revenue

Non-exchange revenues result from donations to the government and from the Government's sovereign right to demand payment, including taxes. Non-exchange revenues are recognized when a specifically identifiable, legally enforceable claim to resources arises, but only to the extent that collection is

probable and the amount is reasonably estimable. Non-exchange revenues are not considered to reduce the cost of the Department's operations and are reported in the Consolidated Statement of Changes in Net

Position. Employment tax revenue collected under *FICA* and *SECA* is considered non-exchange revenue. See Medicare Hospital Insurance Trust Fund – Part A for descriptions of this revenue.

Imputed Financing Sources

In certain instances, the HHS' operating costs are paid out of funds appropriated to other Federal agencies. For example, by law, certain costs of retirement programs are paid by the Office of Personnel Management, and certain legal judgments against the HHS are paid from the Judgment Fund maintained by the Treasury. When costs that are identifiable to the HHS and directly attributable to the Department's operations are paid by other agencies, the Department recognizes these amounts as imputed costs on the Consolidated Statement of Net Cost and as an imputed financing source on the Consolidated Statement of Changes in Net Position.

Intragovernmental Transactions and Relationships

Intragovernmental transactions are transactions between Federal entities, meaning both the buyer and seller are Federal entities. Transactions with the public are transactions in which the buyer or seller of the goods or services is a non-Federal entity and the other party is a Federal entity.

If a Federal entity purchases goods or services from another Federal entity and sells them to the public, the exchange revenue would be classified as with the public but the related costs would be classified as intragovernmental. The purpose of the classifications is to enable the Federal Government to provide consolidated financial statements and not to match public and intragovernmental revenue with costs that are incurred to produce public and intragovernmental revenue.

In the course of its operations, the HHS has relationships and financial transactions with numerous Federal agencies. The more prominent of these are with the SSA and the Treasury. The SSA determines eligibility for Medicare programs and also deducts Medicare Part B premiums from Social Security benefit payments and allocates those funds to the Medicare Part B Trust Fund for Social Security beneficiaries who elect to enroll in the Medicare Part B program. The Treasury receives the cumulative excess of Medicare receipts and other financing over outlays and issues interest-bearing securities in exchange for the use of those monies. Medicare Part D is primarily financed by the General Fund of the Treasury and beneficiary premiums.

Entity and Non-Entity Assets

Entity assets are assets the reporting entity has authority to use in its operations (i.e., management has the authority to decide how the funds are used) or management is legally obligated to use to meet entity obligations.

Non-entity assets are those assets held by the reporting entity, but not available for use. An example of a non-entity asset is the interest accrued on overpayments and cost settlements reported by the Medicare contractors.

Fund Balance with Treasury (FBWT)

The HHS maintains its available funds with the Treasury. The FBWT is available to pay current liabilities and finance authorized purchases. Cash receipts and disbursements are processed by the Treasury, and the HHS FBWT accounts are reconciled with those of Treasury on a regular basis.

Custodial Activity

Following OMB Circular A-136 guidance, the HHS now reports custodial activities on its Balance Sheet. However, the HHS does not prepare a separate Statement of Custodial Activity since custodial activities are incidental to its operations and the amounts collected are immaterial.

The ACF receives funding from the Internal Revenue Service for outlay to the States for child support. This funding represents delinquent child support payments withheld from Federal tax refunds. The FDA custodial activity involves collections of civil monetary penalties (CMP) assessed by the Department of Justice on behalf of FDA. Penalties are assessed for violations in areas such as illegally manufactured, marketed, and distributed animal food and drug products. The CDC custodial activity consists of collections of interest on outstanding receivables and funds received from debts in collection status.

Investments, Net

The HHS invests entity Medicare Trust Fund balances in excess of current needs in U.S. securities. The Treasury acts as the fiscal agent for the U.S. Government's investments in securities. Section 1817 for the HI Trust Fund and Section 1841 for the SMI Trust Fund of the *Social Security Act* require that Trust Funds not necessary to meet current expenditures be invested in interest-bearing obligations, or in obligations guaranteed as to both principal and interest by the U.S. Government. The cash receipts collected from the public, for the earmarked funds, are deposited with the Treasury, which uses the cash for general government purposes. Treasury securities are issued by Bureau of Public Debt to the HI and SMI Trust Funds as evidence of their receipt and are an asset to the Trust Funds and a liability of the Treasury. The Federal Government does not set aside assets to pay future benefits or other expenditures associated with the HI or SMI Trust Funds.

The Treasury securities provide the HI and SMI Trust Funds with authority to draw upon the U.S. Treasury to make future benefit payments or other expenditures. When the Trust Funds require redemption of these securities to make expenditures, the government finances the expenditures by (a) raising taxes, (b) raising other receipts, (c) borrowing from the public or repaying less debt, or (d) curtailing other expenditures. This is the same way that the Government finances all expenditures.

The Treasury securities issued and redeemed to the HI and SMI Trust Funds are Non-Marketable (Par Value) securities. These investments are carried at face value as determined by Treasury. Interest income is compounded semiannually (June and December) by Treasury and at year end is adjusted to include an accrual for interest earned from July 1 to September 30 (See Note 4).

The Vaccine Injury Compensation Trust Fund, an earmarked trust fund similar to the HI and SMI Trust Funds, invests in Non-Marketable Market Based securities issued by Bureau of Public Debt in the form of One Day Certificates and Market-Based Bills, Notes and Bonds.

The NIH Gift Funds are invested in Non-Marketable Market Based Bills issued by the Bureau of Public Debt. Funds are invested for either a 90 day or 180 day period based on the need for funds – no provision is made for unrealized gains or losses on these securities since it is the HHS' intent to hold investments to maturity.

The *Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA, P.L. 111-3)* established a Child Enrollment Contingency Fund to cover shortfalls in funding for the States' Children's Health Insurance Program (CHIP). The *Affordable Care Act* extended the availability of the fund through 2015. This fund is invested in Non-Marketable Market-Based Bills issued by Bureau of Public Debt. These investments will be redeemed as funds are needed by the States to cover short-term shortfalls in the program.

Accounts Receivable, Net

Accounts Receivable, Net consist of the amounts owed to the HHS by other Federal agencies and the public as the result of the provision of goods and services less an allowance for uncollectible amounts. Intragovernmental accounts receivable arise generally from the provision of reimbursable work to other Federal agencies and no allowance for uncollectible amounts is established as they are considered fully collectible. Accounts receivable from the public are primarily composed of provider and beneficiary overpayments, Medicare Prescription Drug overpayments, Medicare premiums, and Medicaid audit disallowances.

Accounts Receivable are presented net of an allowance for uncollectible amounts. The allowance is based on past collection experience and an analysis of outstanding balances. For Medicare accounts receivable, the HHS calculates the allowance for uncollectible amounts based on the collection activity and the age of the debt for the most current fiscal year, while taking into consideration the average uncollectible percentage for the preceding five years. The Medicaid accounts receivable has been recorded at a net realizable amount based on historical analyses of actual recoveries and the rate of disallowances found in favor of the States.

Advances to Grantees and Accrued Grant Liability

The HHS awards grants to various grantees and provides advance payments to meet grantees' cash needs to carry out the HHS programs. Advance payments are recorded as "Advances to Grantees" and are liquidated upon grantees' reporting expenditures on the quarterly *Federal Financial Report*. In some instances, grantees incur expenditures before drawing down funds that, when claimed, would reduce the

“Advances to Grantees” account to a negative balance. An “Accrued Grant Liability” occurs when the accrued grant expenses exceed the outstanding advances to grantees.

The HHS grants are classified into two categories: “Grants Not Subject to Grant Expense Accrual” and “Grants Subject to Grant Expense Accrual.” “Grants Not Subject to Grant Expense Accrual” represents formula grants (also referred to as “block grants”) under which grantees provide a variety of services or payments to individuals and local agencies. Expenses are recorded as the grantees draw funds. These grants are funded on an allocation basis determined by budgets and agreements approved by the sponsoring OPDIV. Therefore, they are not subject to grant expense accrual.

For “Grants Subject to Grant Expense Accrual,” commonly referred to as “non-block grants,” grantees draw funds (recorded as Advances to Grantees) based on their estimated cash needs. As grantees report their actual disbursements quarterly, the amounts are recorded as expenses, and their advance balances are reduced. At year-end, the OPDIVs report both actual payments made through the fourth quarter and an unreported grant expenditure estimate for the fourth quarter based on historical spending patterns of the grantees. The year-end accrual estimate equals the estimate of fourth quarter disbursements plus an average of two weeks annual expenditures for expenses incurred prior to the cash being drawn down.

Exceptions to the definition of “block” or “non-block” grants for reporting purposes are the Temporary Assistance for Needy Families Program and the Child Care Development Fund Program. These two programs are referred to as “block” grants but, since the programs report expenses to the HHS, they are treated as “non-block” grants for the estimate of the grant accrual.

Inventory and Related Property, Net

Inventory and Related Property primarily consist of Inventory Held for Sale, Operating Materials and Supplies, and Stockpile Materials.

Inventory Held for Sale consists of small equipment and supplies held by the Service and Supply Fund for sale to the HHS components and other Federal entities. Inventories Held for Sale are valued at historical cost using the weighted average valuation method for the PSC inventories and using the moving average valuation method for the NIH inventories.

Operating Materials and Supplies include pharmaceuticals, biological products, and other medical supplies used to provide medical services and conduct medical research. They are recorded as assets when purchased and are expensed when consumed. Operating Materials and Supplies are valued at historical cost using the first-in/first-out (FIFO) cost flow assumption.

Stockpile Materials are held in reserve to respond to local and national emergencies. The HHS maintains several stockpiles for emergency response purposes, which include the Strategic National Stockpile (SNS), Vaccines for Children (VFC) and Avian Influenza (H5N1). The pre-pandemic H5N1 Avian Influenza vaccine stockpile is held in reserve to respond to an avian pandemic declaration. The stockpile contains several million doses of vaccine in bulk which is stored and maintained for possible use. Project BioShield has increased the preparedness of the nation by procuring medical countermeasures that include anthrax vaccine, anthrax antitoxins, botulinum antitoxins, and blocking and decorporation agents for a radiological event. The cost value of the stockpile is vast and the importance of the vaccine stockpile is incalculable. All stockpiles are valued at historical cost, using various cost flow assumptions, including the FIFO for SNS and specific identification for VFC and Avian Influenza.

General Property, Plant and Equipment (PP&E), Net

The General PP&E consists of buildings, structures, and facilities used for general operations; land acquired for general operating purposes; equipment; assets under capital lease; leasehold improvements; construction-in-progress; and internal use software. The basis for recording purchased PP&E is full cost, including all costs incurred to bring the PP&E to a form and location suitable for its intended use, and is shown net of accumulated depreciation.

The cost of PP&E acquired under a capital lease is the amount recognized as a liability for the capital lease at its inception; or when acquired through a donation is the estimated fair market value when acquired. The cost of PP&E transferred from other Federal entities is the transferring entity’s net book value. All PP&E with an initial acquisition cost of \$25,000 or more and an estimated useful life of two years or more are capitalized, except for internal use software discussed below.

The PP&E is depreciated using the straight-line method over the estimated useful life of the asset. Land and land rights, including permanent improvements, are not depreciated. Normal maintenance and repair costs are expensed as incurred.

The Statement of Federal Financial Accounting Standards (SFFAS) No. 10, *Accounting for Internal Use Software*, requires that the capitalization of internally developed, contractor-developed and commercial off-the-shelf (COTS) software begin in the software development phase. The estimated useful life for internal use software is three to ten years for amortization purposes. The HHS begins amortization when the internal use software is placed in use. Capitalized costs include all direct and indirect costs.

The HHS' capitalization threshold for internal use software costs for appropriated fund accounts is \$1 million and the threshold for revolving funds is \$500 thousand. Costs below the threshold levels are expensed. The software is depreciated for a period of time consistent with the estimated useful life used for planning and acquisition purposes.

Stewardship Property, Plant & Equipment

Stewardship PP&E consists of stewardship land whose physical properties resemble those of General PP&E that are traditionally capitalized in the financial statements. Based on SFFAS No. 29, *Heritage Assets and Stewardship Land*, and due to the immateriality of these assets, the HHS does not report a related amount on the balance sheet.

The HHS' stewardship assets support the day-to-day operations of providing health care to American Indians and Alaskan Natives in remote areas of the country where no other facilities exist.

Indian Trust lands do not meet the definition of Stewardship land (i.e., land other than that acquired for or used in connection with capitalized General PP&E), but have always been held by the U.S. Government as separate and distinct because of its long-term trust responsibility. The Indian Health Service (IHS) has built health care facilities on these Trust lands. Trust lands, when no longer needed by the IHS in connection with its general use PP&E, must be returned to the Department of the Interior's Bureau of Indian Affairs for continuing trust responsibilities and oversight.

The HHS asset accountability reports differentiate Indian Trust land parcels from General PP&E situated thereon. The Required Supplementary Information (RSI) section provides additional information for Stewardship PP&E.

Liabilities

Liabilities are recognized for amounts of probable and measurable future outflows or other sacrifices of resources as a result of past transactions or events. Since the HHS is a component of the U.S. Government, a sovereign entity, its liabilities cannot be liquidated without legislation that provides resources to do so. Payments of all liabilities other than contracts can be abrogated by the sovereign entity. In accordance with public law and existing Federal accounting standards, no liability is recognized for future payments to be made on behalf of current workers contributing to the Medicare HI Trust Fund, since liabilities are only those items that are present obligations of the Government. The Department's liabilities are classified as covered by budgetary resources or not covered by budgetary resources.

Liabilities Covered by Budgetary Resources

Available budgetary resources include: (a) new budget authority, (b) spending authority from offsetting collections, (c) recoveries of expired budget authority, (d) unobligated balances of budgetary resources at the beginning of the year, and (e) permanent indefinite appropriation or borrowing authority.

Liabilities Not Covered by Budgetary Resources

Sometimes funding has not yet been made available through Congressional appropriation or current earnings. The major liabilities in this category include employee annual leave earned but not taken, and amounts billed by the Department of Labor (DOL) for the *Federal Employees' Compensation Act (FECA) of 1916 (5 U.S.C. 751)* disability payments. Also included in this category is the actuarial FECA liability determined by DOL but not yet billed.

Accounts Payable

Accounts Payable primarily consists of amounts due for goods and services received, progress in contract performance, interest due on accounts payable, and other miscellaneous payables.

Fiduciary Activities

Effective FY 2009, the SFFAS No. 31, *Accounting for Fiduciary Activities* requires Federal entities to distinguish the information relating to fiduciary activities of the Federal entity from all other activities. The fiduciary activities are those Federal Government activities that relate to the collection or receipt, and the subsequent management, protection, accounting, investment and disposition of cash or other assets in which non-Federal individuals or entities have an ownership interest that the Federal Government must uphold. The HHS does not have reportable activities as defined by SFFAS No. 31.

Accrued Payroll and Benefits

Accrued Payroll and Benefits consists of salaries, wages, leave and benefits earned by employees but not disbursed at the end of the reporting period. A liability for annual and other vested compensatory leave is accrued as earned and reduced when taken. At the end of each fiscal year, the balance in the accrued annual leave liability account is adjusted to reflect current pay rates. Annual leave earned but not taken is considered an unfunded liability since it will be funded from future appropriations when it is actually taken by employees. Sick leave and other types of leave are not accrued and are expensed when taken. Intragovernmental Accrued Payroll and Benefits consists primarily of the HHS FECA liability.

Entitlement Benefits Due and Payable

Entitlement Benefits Due and Payable represents a liability for Medicare and Medicaid owed to the public for medical services incurred but not reported (IBNR) as of the end of the reporting period. The Medicare and Medicaid programs are the largest entitlement programs in the HHS.

Medicare

The Medicare liability is developed by the CMS Office of the Actuary and includes:

- (a) An estimate of claims incurred that may or may not have been submitted to the Medicare contractors but were not yet approved for payment.
- (b) Actual claims approved for payment by the Medicare contractors for which checks have not yet been issued.
- (c) Checks issued by the Medicare contractors in payment of claims that have not yet been cashed by payees.
- (d) Periodic interim payments for services rendered in the current fiscal year but paid in the subsequent fiscal year.
- (e) An estimate of retroactive settlements of cost reports submitted to the Medicare contractors by health care providers.

The HHS develops estimates for medical costs IBNR using an actuarial process that is consistently applied, centrally controlled, and automated. The actuarial models consider factors such as time from date of service to claim receipt, claim backlogs, medical care professional contract rate changes, medical care consumption, and other medical cost trends. The HHS estimates liabilities for physician, hospital, and other medical cost disputes based upon an analysis of potential outcomes, assuming a combination of litigation and settlement strategies. Each period, the HHS re-examines previously established medical cost payable estimates based on actual claim submissions and other changes in facts and circumstances. As the liability estimates recorded in prior periods become more exact, the HHS adjusts the amount of the estimates, and includes the changes in estimates in medical costs in the period in which the change is identified. In every reporting period, the HHS operating results include the effects of more completely developed Medicare benefits payable estimates associated with previously reported periods.

Medicaid

The Medicaid estimate represents the net Federal share of expenses incurred by the States but not yet reported to the HHS. This estimate is developed based on historical relationships between prior Medicaid net payables and current Medicaid activity.

The American Recovery and Reinvestment Act of 2009 (Recovery Act, P.L. 111-5) provides additional Federal funding for the States through a temporary increase in the Federal Medical Assistance Percentages through the first quarter of FY 2011. *P.L. 111-226* extended this additional assistance, at phased down levels, through the third quarter of FY 2011. *P.L. 111-226, Title II, Subtitle A - State Fiscal Relief and Other Provisions, Sec. 201*, extends this additional assistance, at phased down levels, through the third quarter of FY 2011.

Federal Employee and Veterans' Benefits

The HHS administers the Public Health Service (PHS) Commissioned Corps Retirement System (authorized by the *Public Health Service Act, P.L. 78-410*), a defined noncontributory benefit plan, for its active duty officers, retiree annuitants and survivors. The plan does not have accumulated assets, and funding is provided entirely on a pay-as-you-go basis by Congressional appropriation. The HHS records the present value of the Commissioned Corps pension and post-retirement health benefits.

The liability for Federal Employee and Veterans' Benefits also includes a liability for actual and estimated future payments for workers' compensation pursuant to the *FECA*. The *FECA* provides income and medical cost protection to Federal employees injured on the job or who sustained a work-related occupational disease, and beneficiaries of employees whose deaths are attributable to job-related injury or occupational disease. The *FECA* program is administered by the Department of Labor (DOL) which pays valid claims and subsequently bills the employing Federal agency. The *FECA* liability consists of two components: (a) actual claims paid by the DOL but not yet billed to agencies and (b) an estimated liability for future benefit payments as a result of past events such as death, disability, and medical costs.

Most HHS employees participate in the Civil Service Retirement System (CSRS), a defined benefit plan, or the Federal Employees' Retirement System (FERS), a defined benefit and contribution plan. For employees covered under CSRS, the Department contributes a fixed percentage of pay. Most employees hired after December 31, 1983, are automatically covered by the FERS. For employees covered under FERS, the Department contributes the employer's matching share for Social Security and Medicare Insurance. FERS offers a Thrift Savings Plan into which the Department automatically contributes one percent of employee pay and matches the first 3 percent of employee contributions dollar for dollar. Each dollar of the employee's next 2 percent of basic pay is matched 50 cents on the dollar.

The Office of Personnel Management is the administering agency for both of these benefit plans and, thus, reports CSRS and FERS assets, accumulated plan benefits, and unfunded liabilities applicable to Federal employees. Therefore, the HHS does not recognize any liability on its Consolidated Balance Sheet for pensions, other retirement benefits, and other post-employment benefits of its Federal employees with the exception of the PHS Commissioned Corps. The HHS does, however, recognize an expense in the Consolidated Statement of Net Cost and an imputed financing source for the annualized unfunded portion of pension and post-retirement benefits in the Consolidated Statement of Changes in Net Position. Gains or losses from changes in assumptions in the PHS Commissioned Corps retirement benefits are recognized at year end.

Contingencies

A loss contingency is an existing condition, situation, or set of circumstances involving uncertainty as to possible loss to the HHS. The uncertainty should ultimately be resolved when one or more future events occur or fail to occur. The likelihood that the future event or events will confirm the loss or the incurrence of a liability can range from probable to remote. SFFAS No. 5, *Accounting for Liabilities of the Federal Government*, as amended by SFFAS No. 12, *Recognition of Contingent Liabilities from Litigation*, contains the criteria for recognition and disclosure of contingent liabilities.

The HHS and its components could be parties to various administrative proceedings, legal actions, and claims brought by or against it. With the exception of pending, threatened, or potential litigation, a contingent liability is recognized when a past transaction or event has occurred, a future outflow or other sacrifice of resources is more likely than not to occur, and the related future outflow or sacrifice of resources is measurable. For pending, threatened, or potential litigation, a contingent liability is recognized

when a past transaction or event has occurred, a future outflow or other sacrifice of resources is likely to occur, and the related future outflow or sacrifice of resources is measurable.

Statement of Social Insurance

The SOSI presents the projected 75-year actuarial present values of the income and expenditures of the HI and SMI Trust Funds. Future expenditures are expected to arise from the health care payment provisions specified in current law for current and future program participants and from associated administrative expenses. Actuarial present values are computed on the basis of the intermediate set of assumptions specified in the *Annual Report of the Medicare Board of Trustees*. These assumptions represent the Trustees' best estimate of likely future economic, demographic, and health care-specific conditions. The projected potential future income and expenditures under current law are not included in the accompanying Consolidated Balance Sheet, Statements of Net Cost, and Changes in Net Position, or Combined Statement of Budgetary Resources.

In order to make projections regarding the future financial status of the HI and SMI Trust Funds, various assumptions have to be made. As stated previously, the estimates presented here are based on the assumption that the Trust Funds will continue to operate under the law in effect August 5, 2010. In addition, the estimates depend on many economic, demographic, and health care-specific assumptions, including changes in per beneficiary health care cost, wages, the gross domestic product (GDP), the consumer price index (CPI), fertility rates, mortality rates, immigration rates, and interest rates. In most cases, these assumptions vary from year to year during the first 5 to 30 years before reaching their ultimate values for the remainder of the 75-year projection period. The assumed growth rates for per beneficiary health care costs vary throughout the projection period.

The assumptions underlying the SOSI actuarial projections are drawn from the Social Security and Medicare Trustees Reports for 2010. Specific assumptions are made for each of the different types of service provided by the Medicare program (for example, hospital care and physician services). These assumptions include changes in the payment rates, utilization, and intensity of each type of service.

American Recovery and Reinvestment Act of 2009

The *American Recovery and Reinvestment Act of 2009 (Recovery Act, P.L. 111-5)* was signed into law on February 17, 2009. It was an extraordinary response to an economic crisis that included measures to modernize our nation's infrastructure, enhance energy independence, expand educational opportunities, preserve and improve affordable health care, provide tax relief, and protect those in greatest need.

The *Recovery Act* provides an estimated \$141 billion to the HHS from 2009 through 2019, to fund Health Information Technology, Comparative Effectiveness Research, Prevention and Wellness, Scientific Research, Social Services, and Medicaid relief to the States. For further information concerning HHS obligations and expenditures related to the *Recovery Act*, see Note 27.

Affordable Care Act of 2010

During FY 2010, President Obama signed health insurance reform legislation giving Americans more control over their health care. The *Patient Protection and Affordable Care Act (P.L. 111-148)* and the *Health Care and Education Reconciliation Act (P.L. 111-152)* collectively referred to as the *Affordable Care Act* ensures that all Americans have access to quality, affordable health care, while significantly reducing long-term health care costs. Further information is available at <http://www.healthcare.gov/>.

For FY 2010, the *Affordable Care Act* included appropriated funding to the HHS for approximately 34 provisions. Of the 34 provisions, Congress appropriated approximately \$18.7 billion for 32 provisions, and such sums as may be necessary for two provisions. This amount includes funding that was appropriated in FY 2010 to be available for one or multiple years and excludes amounts appropriated to other Departments or Agencies. Congress also authorized, but did not appropriate, funding for over 100 provisions in FY 2010.

Under the *Affordable Care Act*, the HHS was authorized to execute several new programs, which include: Qualified High Risk Pool for Pre-existing Conditions, Early Retiree Reinsurance Programs, American Health Benefit Exchanges (the "Exchanges"), Consumer Operated and Oriented Plan (CO-OP) Program, and the *Community Living Assistance Services and Support (CLASS) Act*. A brief description of these programs and their impact on the HHS financial statements is presented below.

Qualified High Risk Pool for Pre-existing Conditions

This plan is also known as the Pre-existing Condition Insurance Plan Program and offers coverage to uninsured Americans who have been unable to obtain health coverage because of a pre-existing health condition. Plans are administered through two processes: supporting State-run programs, or providing insurance coverage directly to individuals in States where States do not run their own programs. This program was established to enable coverage until the Exchanges programs are operational. Congress appropriated \$5 billion for the life of this interim program.

The *Affordable Care Act* provides the HHS Secretary significant authorities to ensure the financial sustainability of this program, including, under Section 1101 Paragraph (g) (2), the authority to eliminate deficits under the program if available funds are less than estimated expenses. The Secretary also has the authority under Paragraph (g) (4) to stop taking applications to comply with funding limitations. This program ends on January 1, 2014. For FY 2010, the HHS recognized a liability at September 30 to cover the anticipated subsidy costs associated with applications received prior to year end.

Early Retiree Reinsurance Program

Under the *Affordable Care Act*, the HHS established a temporary reinsurance program to reimburse a portion of the employer cost of providing health insurance coverage for early retirees. Under the Act, limitations on the amounts of such reimbursements per claim have been established. Congress appropriated \$5 billion for the life of this program. The Act authorizes the HHS Secretary to stop taking applications for participation in the program based on the availability of funding. On June 29, 2010 the HHS began accepting applications from employers. The program permits approved applicants to submit for reimbursement expenses incurred after June 1, 2010. As a result, the HHS recognized a liability at September 30, 2010 for those anticipated reimbursement requests. The program is scheduled to terminate on January 1, 2014.

American Health Benefit Exchanges

The HHS will provide grants to the States to establish American Health Benefit Exchanges, better known as Health Benefit Insurance Exchanges. These grants are to be made by the HHS to the States "not later than one (1) year after the date of enactment." Thus, the HHS is required to make the initial grants by March 23, 2011. As of September 30, 2010, the HHS had no liability under this program.

Consumer Operated and Oriented Plan (CO-OP) Program

The CO-OP Program was established to foster the creation of qualified nonprofit health insurance issuers to offer qualified health plans to the individual and small group markets in each State. Under this program, the HHS provides assistance to persons applying to become qualified, nonprofit health insurance issuers through loans to assist in meeting start-up costs, and grants to assist the applicant meet State solvency requirements. In accordance with regulations to be developed by HHS not later than July 1, 2013, as well as legislative requirements, loans shall be repaid within five years and the grants repaid in 15 years, considering State reserve requirements and solvency regulations. Congress appropriated \$6 billion to carry out this assistance program under the *Affordable Care Act*. At this time, the HHS does not anticipate awarding any loans or grants prior to FY 2012, and has no liability under this program. The loans and grants must be awarded before July 1, 2013.

Community Living Assistance Services and Support (CLASS) Act

The *CLASS Act* establishes a national voluntary insurance program for purchasing community living assistance services and supports in order to 1) provide individuals with functional limitations with tools that will allow them to maintain their personal and financial independence and live in the community through a new financing strategy for community living assistance services and supports; 2) establish an infrastructure that will help address the nation's community living assistance services and supports needs; 3) alleviate burdens on family caregivers; and 4) address institutional bias by providing a financing mechanism that supports personal choice and independence to live in the community. This program has not been implemented as of September 30, 2010, and the financial statements do not reflect any impact of the program at this time.

Note 2. Entity and Non-Entity Assets

(in Millions)

	2010	2009
Intragovernmental:		
Fund Balance with Treasury	\$ 19	\$ 29
Accounts receivable	6	14
Total Intragovernmental	25	43
Accounts receivable	21	21
Total Non-Entity Assets	46	64
Total Entity Assets	563,693	562,716
Total Assets	\$ 563,739	\$ 562,780

Note 3. Fund Balance with Treasury

(in Millions)

	2010	2009
Fund Balance with Treasury		
Trust Funds	\$ 2,265	\$ 3,525
Revolving Funds	954	989
Appropriated Funds	177,852	156,469
Other Funds	1,164	979
Total	\$ 182,235	\$ 161,962
Status of Fund Balance with Treasury		
Unobligated Balance		
Available	\$ 48,880	\$ 41,108
Unavailable	10,445	9,270
Obligated Balance not yet Disbursed	175,361	165,061
Non-Budgetary Fund Balance with Treasury	(52,451)	(53,477)
Total	\$ 182,235	\$ 161,962

Other Funds include balances in deposit, suspense and related non-spending accounts. The Unobligated Balance includes funds that are restricted for future use and not apportioned for current use of \$24.4 billion and \$3.7 billion as of September 30, 2010 and September 30, 2009, respectively. The restricted amount is primarily for the *Affordable Care Act* programs, Children's Health Insurance Program, CMS Program Management, State Grants and Demonstrations, and the *Recovery Act* Health Information Technology Program. In FY 2010 the HHS received \$18.7 billion under the *Affordable Care Act* of which \$16 billion is restricted for future use. The Non-Budgetary FBWT negative balances reported for September 30, 2010 and September 30, 2009, are primarily due to CMS Medicare Trust Funds temporarily precluded from obligation.

Note 4. Investments, Net

(in Millions)	2010				
	Cost	Unamortized Discount	Interest Receivable	Investments, Net	Market Value Disclosure
Intragovernmental Securities					
Non-Marketable: Par Value	\$ 350,457	\$ -	\$ 4,046	\$ 354,503	\$ 354,503
Non-Marketable: Market-Based	5,098	249	32	5,379	5,379
Total, Intragovernmental	\$ 355,555	\$ 249	\$ 4,078	\$ 359,882	\$ 359,882

(in Millions)	2009				
	Cost	Unamortized Discount	Interest Receivable	Investments, Net	Market Value Disclosure
Intragovernmental Securities					
Non-Marketable: Par Value	\$ 371,466	\$ -	\$ 4,369	\$ 375,835	\$ 375,835
Non-Marketable: Market-Based	5,046	207	28	5,281	5,281
Total, Intragovernmental	\$ 376,512	\$ 207	\$ 4,397	\$ 381,116	\$ 381,116

The HHS investments consist primarily of Medicare Trust Fund earmarked investments. Medicare Non-Marketable: Par Value Bonds are carried at face value and have maturity dates ranging from June 30, 2011, through June 30, 2025, with interest rates ranging from 3.25 percent to 6.5 percent. Medicare Non-Marketable: Par Value Certificates of Indebtedness mature on June 30, 2011, with interest rates ranging from 2.125 percent to 2.5 percent.

Securities held by the Vaccine Injury Compensation Trust Fund will mature in fiscal years 2010 through 2018. The Market-Based Notes paid from 3.125 percent to 5.0 percent during October 1, 2009, to September 30, 2010, and October 1, 2008, to September 30, 2009. The Market-Based Bonds pay 9.125 percent through FY 2018.

The Market Based Bills held in the NIH gift funds during the fiscal year ended September 30, 2010, yielded from 0.04 percent to 0.32 percent depending on the date purchased and the time to maturity.

The non-earmarked investments held by the CHIP Child Enrollment Contingency Fund in the amount of \$2.1 billion as of September 30, 2010, are short term Non-Marketable Market-Based Bills purchased at a discount which are fully amortized at the maturity date.

Note 5. Accounts Receivable, Net

		2010				
(in Millions)	Accounts Receivable Principal	Interest Receivable	Penalties, Fines, & Admin Fees Receivable	Accounts Receivable, Gross	Allowance	Net HHS Receivables
Intragovernmental						
Entity	\$ 1,131	\$ -	\$ -	\$ 1,131	\$ -	\$ 1,131
Non-Entity	6	-	-	6	-	6
Total	\$ 1,137	\$ -	\$ -	\$ 1,137	\$ -	\$ 1,137
With the Public						
Entity						
Medicare	\$ 5,801	\$ 2	\$ -	\$ 5,803	\$ (1,426)	\$ 4,377
Other	3,738	-	3	3,741	(745)	2,996
Non-Entity	46	9	-	55	(34)	21
Total	\$ 9,585	\$ 11	\$ 3	\$ 9,599	\$ (2,205)	\$ 7,394

		2009				
(in Millions)	Accounts Receivable Principal	Interest Receivable	Penalties, Fines, & Admin Fees Receivable	Accounts Receivable, Gross	Allowance	Net HHS Receivables
Intragovernmental						
Entity	\$ 898	\$ -	\$ 1	\$ 899	\$ -	\$ 899
Non-Entity	14	-	-	14	-	14
Total	\$ 912	\$ -	\$ 1	\$ 913	\$ -	\$ 913
With the Public						
Entity						
Medicare	\$ 4,859	\$ -	\$ -	\$ 4,859	\$ (1,852)	\$ 3,007
Other	3,123	-	3	3,126	(650)	2,476
Non-Entity	12	46	-	58	(37)	21
Total	\$ 7,994	\$ 46	\$ 3	\$ 8,043	\$ (2,539)	\$ 5,504

Accounts receivable are composed of various program related overpayments and other recoverable payments. The increase in the Medicare accounts receivable with the public is primarily attributable to the Medicare Prescription Drug (MPD) Program. The MPD accounts receivable of \$1.4 billion (\$0.3 billion in FY 2009) consists of amounts due CMS after completion of the Part D payment reconciliation for calendar year 2009.

Note 6. Inventory and Related Property, Net

(in Millions)	2010	2009
Inventory Held for Sale:		
Inventory Held for Current Sale	\$ 34	\$ 13
Operating Materials and Supplies:		
Operating Materials and Supplies Held for Use	15	86
Operating Materials and Supplies Reserved for Future Use	282	434
Total Operating Materials and Supplies	297	520
Stockpile Materials Held for Emergency or Contingency	5,746	5,071
Inventory and Related Property, Net	\$ 6,077	\$ 5,604

Note 7. General Property, Plant and Equipment, Net

(in Millions)	Depreciation Method	Estimated Useful Lives	2010		
			Acquisition Cost	Accumulated Depreciation	Net Book Value
Land & Land Rights	-	-	\$ 51	\$ -	\$ 51
Construction in Progress	-	-	592	-	592
Buildings, Facilities & Other Structures	Straight Line	5-50 Yrs	5,349	(2,012)	3,337
Equipment	Straight Line	3-20 Yrs	1,644	(926)	718
Internal Use Software	Straight Line	5-10 Yrs	1,059	(602)	457
Assets Under Capital Lease	Straight Line	1-20 Yrs	132	(52)	80
Leasehold Improvements	Straight Line	*Life of Lease	49	(21)	28
Totals			\$ 8,876	\$ (3,613)	\$ 5,263

(in Millions)	Depreciation Method	Estimated Useful Lives	2009		
			Acquisition Cost	Accumulated Depreciation	Net Book Value
Land & Land Rights	-	-	\$ 51	\$ -	\$ 51
Construction in Progress	-	-	665	-	665
Buildings, Facilities & Other Structures	Straight Line	5-50 Yrs	5,000	(1,858)	3,142
Equipment	Straight Line	3-20 Yrs	1,515	(943)	572
Internal Use Software	Straight Line	5-10 Yrs	1,002	(499)	503
Assets Under Capital Lease	Straight Line	1-20 Yrs	136	(53)	83
Leasehold Improvements	Straight Line	*Life of Lease	49	(18)	31
Totals			\$ 8,418	\$ (3,371)	\$ 5,047

*7 to 15 years or the life of the lease.

Note 8. Other Assets

(in Millions)	2010	2009
Intragovernmental		
Advances to Other Federal Entities	\$ 99	\$ 92
With the Public		
Travel Advances & Emergency Employee Salary Advances	3	6
Cash and Other Monetary Assets	-	357
Other	1,649	2,179
Total With the Public	\$ 1,652	\$ 2,542

Other Assets with the public primarily consist of \$1.0 billion, as of September 30, 2010 (\$1.6 billion in FY 2009), of prepayment advances outstanding related to the CMS SMI Part D Program.

Note 9. Liabilities Not Covered by Budgetary Resources

<u>(in Millions)</u>	<u>2010</u>	<u>2009</u>
Intragovernmental		
Accrued Payroll and Benefits	\$ 61	\$ 40
Other	890	621
Total Intragovernmental	<u>951</u>	<u>661</u>
Accounts Payable	1	-
Federal Employee and Veterans' Benefits (Note 11)	9,985	9,690
Accrued Payroll and Benefits	554	517
Contingencies (Note 14)	6,079	4,048
Other	56	71
Total Liabilities Not Covered by Budgetary Resources	<u>\$ 17,626</u>	<u>\$ 14,987</u>
Total Liabilities Covered by Budgetary Resources	<u>81,587</u>	<u>79,380</u>
Total Liabilities	<u>\$ 99,213</u>	<u>\$ 94,367</u>

Note 10. Entitlement Benefits Due and Payable

<u>(in Millions)</u>	<u>2010</u>	<u>2009</u>
Medicare	\$ 45,007	\$ 46,772
Medicaid	27,215	24,977
Other	490	469
Totals	<u>\$ 72,712</u>	<u>\$ 72,218</u>

Medicare benefits payable consists of a \$39.7 billion estimate (\$39.6 billion in FY 2009) of Medicare services incurred, but not paid as of September 30, 2010, calculated by the CMS Office of the Actuary.

Medicare Advantage and Prescription Drug Program benefits payable consists of \$2.4 billion (\$2.5 billion in FY 2009) for amounts owed to plans relating to risk and other payment related adjustments, \$0.9 billion in FY 2010 (\$2.6 billion in FY 2009) owed to plans after the completion of the Prescription Drug payment reconciliation, and \$0.1 billion for amounts owed to beneficiaries that have qualified for the Part D coverage gap as of the end of the fiscal year.

The Medicare Retiree Drug Subsidy (RDS) consists of a \$1.9 billion estimate (\$2.1 billion in FY 2009) of payments to plan sponsors of retiree prescription drug coverage incurred but not paid as of September 30, 2010. As part of the *Medicare Modernization Act (MMA)*, the RDS program makes subsidy payments available to sponsors of retiree prescription drug coverage. The program is designed to strengthen employer- and union-based retiree prescription drug plans.

Medicaid benefits payable of \$27.2 billion as of September 30, 2010 (\$25.0 billion in FY 2009) is an estimate of the net Federal share of expenses that have been incurred by the States but not yet reported to the HHS. This estimate incorporates claim activity tracked under *Recovery Act* of \$4.0 billion (\$3.2 billion in FY2009). An estimated CHIP benefits payable of \$0.4 billion has been recorded as of September 30, 2010 (\$0.4 billion in FY 2009) for the net Federal share of expenses that have been incurred by the States but not yet reported to the HHS.

Note 11. Federal Employee and Veterans' Benefits

<u>(in Millions)</u>	<u>2010</u>	<u>2009</u>
With the Public		
Liabilities Not Covered by Budgetary Resources		
PHS Commissioned Corp Pension Liability	\$ 9,075	\$ 8,817
PHS Commissioned Corp Post-retirement Health Benefits	651	619
Workers' Compensation Benefits (Actuarial FECA Liability)	259	254
Total, Federal Employee and Veterans' Benefits	<u>\$ 9,985</u>	<u>\$ 9,690</u>

Public Health Service (PHS) Commissioned Corps

The HHS administers the PHS Commissioned Corps Retirement System for 6,540 active duty officers and 5,872 retiree annuitants and survivors. As of September 30, 2010, the actuarial accrued liability for the retirement benefit plan was \$9.7 billion, of which \$0.7 billion was for non-Medicare coverage.

On October 14, 2008, the Federal Accounting Standards Advisory Board issued Statement of Federal Financial Accounting Standards (SFFAS) No. 33. This standard covers Federal Pensions, Other Retirement Benefits (ORB) and Other Post Employment Benefits (OPEB), previously covered by SFFAS No.5, and is effective for fiscal years beginning after September 30, 2009.

In FY 2010, this new standard affects the selection of discount rates used for present value measurements of Federal employee pension, ORB and OPEB liabilities. The Commission Corp Retirement System and Post-Retirement Benefits are not funded. Therefore, the standard indicates the discount rate should be based on long-term assumptions, for marketable securities (such as Treasury marketable securities) of similar maturity to the period over which the payments are to be made. The discount rates should be matched with the expected timing of the associated expected cash flow. A single discount rate may be used for all the projected cash flows, if the resulting present value is not materially different than the resulting present value using multiple rates.

The significant assumptions used in the calculation of the pension and medical program liability, as of September 30, 2010, and September 30, 2009, were:

	<u>2010</u>	<u>2009</u>
Interest on Federal securities	5.16 percent	5.75 percent
Annual basic pay scale increase	3.25 percent	3.75 percent
Annual inflation	2.50 percent	3.00 percent

The following shows key valuation results as of September 30, 2010 and 2009, in conformance with the actuarial reporting standards set forth in the SFFAS No. 5, *Accounting for Liabilities of the Federal Government* and SFFAS No. 33, *Pensions, Other Retirement Benefits, and Other Postemployment Benefits: Reporting the Gains and Losses from Changes in Assumptions and Selecting Discount Rates and Valuation Dates*. The valuation is based upon the current plan provisions, membership data collected as of June 30, 2010, and actuarial assumptions. The September 30, 2010 valuation includes an increase in liabilities of \$290 million resulting from an increase in costs offset by actuarial gain from changes in assumptions and experience. Volatility of the discount rate significantly affects the liabilities for these benefits. Therefore, to mitigate the impact of this volatility, SFFAS No. 33 also provides for these of historical average rates to prevent the undue influence of current or near term rates.

<u>(in Millions)</u>	<u>2010</u>	<u>2009</u>
Beginning Liability Balance	\$ 9,436	\$ 8,462
Expense		
Normal Cost	235	183
Interest on the liability balance	527	496
Actuarial (Gain)/Loss		
From experience	(101)	169
From assumption changes		
Change in discount rate assumption	850	315
Change in inflation/salary increase assumption	(720)	-
Change in Others	(106)	191
Net Actuarial (Gain)/Loss	<u>(77)</u>	<u>675</u>
Total expense	685	1,354
Less amounts paid	(395)	(380)
Ending Liability Balance	<u>\$ 9,726</u>	<u>\$ 9,436</u>

Workers' Compensation Benefits

The actuarial liability for future workers' compensation benefits includes the expected liability for death, disability, medical, and miscellaneous costs for approved compensation cases, plus a component for incurred but not reported claims. The liability utilizes historical benefit payment patterns to predict the ultimate payment related to that period. Consistent with past practice, these projected annual benefit payments have been discounted to present value using the OMB's economic assumptions for 10-year Treasury notes and bonds. Interest rate assumptions utilized for discounting as of September 30, 2010 and September 30, 2009 appear below.

FY 2010	FY 2009
3.653% in Year 1	4.223% in Year 1
4.300% in Year 2 and thereafter	4.715% in Year 2 and thereafter

To provide specifically for the effects of inflation on the liability for future workers' compensation benefits, wage inflation factors (cost of living adjustments (COLA)) and medical inflation factors (consumer price index-medical (CPIM)) are applied to the calculations for projected future benefits. These factors are also used to adjust historical payments to current year dollars. The anticipated percentages for COLA and CPIM used in projections are:

FY	COLA	CPIM
2010	N/A	N/A
2011	2.23%	3.45%
2012	1.13%	3.43%
2013	1.70%	3.64%
2014	1.90%	3.66%
2015	1.93%	3.73%

Note 12. Accrued Grant Liability

<u>(in Millions)</u>	2010	2009
Grant Advances Outstanding (before year end grant accrual)	\$ 20,202	\$ 17,427
Less: Estimated Accrual for Amounts Due to Grantees	(24,406)	(21,467)
Net Grant Liability	\$ (4,204)	\$ (4,040)

Note 13. Other Liabilities

<u>(in Millions)</u>	2010		2009	
	Intra- governmental	With the Public	Intra- governmental	With the Public
Accrued Payroll & Benefits	\$ 139	\$ 907	\$ 111	\$ 851
Advances from Others	591	369	474	160
Deferred Revenue	-	409	-	392
Capital Lease Liability (Note 15)	72	22	74	23
Custodial Liabilities	745	21	469	35
Other	25	1,354	54	608
Consolidated HHS Totals	\$ 1,572	\$ 3,082	\$ 1,182	\$ 2,069

Note 14. Contingencies and Commitments

The HHS is a party in various administrative proceedings, legal actions, and tort claims which may ultimately result in settlements or decisions adverse to the Federal Government. The HHS has accrued contingent liabilities where a loss is determined to be probable and the amount can be estimated. Other contingencies exist where losses are reasonably possible, and an estimate can be determined or an estimate of the range of possible liability has been determined.

(in Millions)	2010	2009
Medicaid Audit and Program Disallowances	\$ 5,391	\$ 3,793
Vaccine Injury Compensation Program	688	255
Total Contingencies	\$ 6,079	\$ 4,048

Medicaid Audit and Program Disallowances

The Medicaid amount for FY 2010 of \$5.4 billion (\$3.8 billion in FY 2009) consists of Medicaid audit and program disallowances of \$0.9 billion (\$1 billion in FY 2009) and of \$4.5 billion (\$2.8 billion in FY 2009) for reimbursement of State Plan amendments. Contingent liabilities have been established as a result of Medicaid audit and program disallowances that are currently being appealed by the States. In all cases, the funds have been returned to the HHS. The HHS will be required to pay these amounts if the appeals are decided in favor of the States. In addition, certain amounts for payment have been deferred under the Medicaid program when there is a reasonable doubt as to the legitimacy of expenditures claimed by a State. There are also outstanding reviews of the State expenditures in which a final determination has not been made.

Vaccine Injury Compensation Program (VICP)

The VICP is administered by HRSA and provides compensation for vaccine-related injury or death. The \$688 million (\$255 million in FY 2009) VICP liability represents the estimated future payment value of injury claims outstanding for VICP as of September 30, 2010.

Obligations Related to Cancelled Appropriations

Payments may be required of up to one percent of current year appropriations for valid obligations incurred against prior year appropriations that have been cancelled pursuant to the *National Defense Authorization Act of 1991 (P.L. 101-150)*. The total payments related to cancelled appropriations are estimated at \$1.3 billion and \$1.5 billion as of September 30, 2010 and 2009, respectively.

Appeals at the Provider Reimbursement Review Board

Other liabilities do not include all provider cost reports under appeal at the Provider Reimbursement Review Board (PRRB). The monetary effect of those appeals is generally not known until a decision is rendered. However, historical cases that have been appealed and settled by the PRRB are considered in the development of the actuarial Medicare incurred, but not reported (IBNR) liability, resulting in a projected liability for the 7,833 cases (7,984 in FY 2009) remaining on appeal as of September 30, 2010. In FY 2010, a total of 1,384 new cases were filed (2,312 in FY 2009). The PRRB rendered decisions on 144 cases in FY 2010 (93 in FY 2009); and 1,395 additional cases (1,947 in FY 2009) were dismissed, withdrawn, or settled prior to an appeal hearing. The PRRB receives no information on the value of these cases that are settled prior to a hearing.

Note 15. Leases

Capital Leases

The HHS has entered into various capital leases with private entities and with the General Services Administration (GSA) for office and warehouse space. Lease terms vary from 1 to 30 years. Capitalized assets acquired under capital lease agreements and the related liabilities are reported at the present value of the minimum lease payments. Assets under Capital Lease amounts are reported in Note 7, General Property, Plant and Equipment.

Summary of Net Assets under Capital Lease

(in Millions)

	2010	2009
Land and Building	\$ 132	\$ 136
Accumulated Amortization	(52)	(53)
Assets under Capital Lease	<u>\$ 80</u>	<u>\$ 83</u>

Future Minimum Payments

(in Millions)

	2010	2009
Year 1	\$ 11	\$ 12
Year 2	10	10
Year 3	10	10
Year 4	10	10
Year 5	11	10
Later Years	<u>91</u>	<u>103</u>
Total Minimum Lease Payments	143	155
Imputed Interest	<u>(49)</u>	<u>(58)</u>
Total Capital Lease Liability	<u>\$ 94</u>	<u>\$ 97</u>

Operating Leases

The HHS has commitments under various operating leases with private entities and GSA for offices, laboratory space, and land. Leases with private entities have initial or remaining non-cancellable lease terms from 1 to 20 years. The GSA leases, in general, are cancelable with 120 days notice. Under an operating lease, the cost of the lease is expensed as incurred.

Future Minimum Payments

(in Millions)

	2010	2009
Year 1	\$ 383	\$ 344
Year 2	379	380
Year 3	377	382
Year 4	355	359
Year 5	377	317
Later Years	<u>1,217</u>	<u>1,002</u>
Total Operating Lease Liability	<u>\$ 3,088</u>	<u>\$ 2,784</u>

Note 16. Consolidated Gross Cost and Earned Revenue by Budget Function Classification

2010							
(in Millions)	Education Training & Social Services	Health	Medicare	Income Security	OPDIV Combined Totals	Intra-HHS Eliminations	Consolidated Totals
Gross Cost	\$ 137	\$ 5,428	\$ 863	\$ 43	\$ 6,471	\$ (2,161)	\$ 4,310
Earned Revenue	(26)	(3,240)	(16)	(20)	(3,302)	2,085	(1,217)
Net Cost, Intragovernmental	\$ 111	\$ 2,188	\$ 847	\$ 23	\$ 3,169	\$ (76)	\$ 3,093
With the Public							
Gross Cost	\$ 15,282	\$ 351,482	\$ 507,112	\$ 42,452	\$ 916,328	\$ -	\$ 916,328
Earned Revenue	-	(1,888)	(60,797)	(8)	(62,693)	-	(62,693)
Net Cost, With the Public	\$ 15,282	\$ 349,594	\$ 446,315	\$ 42,444	\$ 853,635	\$ -	\$ 853,635
Totals							
Gross Cost	\$ 15,419	\$ 356,910	\$ 507,975	\$ 42,495	\$ 922,799	\$ (2,161)	\$ 920,638
Earned Revenue	(26)	(5,128)	(60,813)	(28)	(65,995)	2,085	(63,910)
Net Cost of Operations	\$ 15,393	\$ 351,782	\$ 447,162	\$ 42,467	\$ 856,804	\$ (76)	\$ 856,728
2009							
(in Millions)	Education Training & Social Services	Health	Medicare	Income Security	OPDIV Combined Totals	Intra-HHS Eliminations	Consolidated Totals
Gross Cost	\$ 157	\$ 5,169	\$ 777	\$ 36	\$ 6,139	\$ (2,077)	\$ 4,062
Earned Revenue	(27)	(3,419)	(10)	(2)	(3,458)	1,847	(1,611)
Net Cost, Intragovernmental	\$ 130	\$ 1,750	\$ 767	\$ 34	\$ 2,681	\$ (230)	\$ 2,451
With the Public							
Gross Cost	\$ 13,098	\$ 320,781	\$ 486,580	\$ 40,498	\$ 860,957	\$ -	\$ 860,957
Earned Revenue	(1)	(2,179)	(57,322)	(1)	(59,503)	-	(59,503)
Net Cost, With the Public	\$ 13,097	\$ 318,602	\$ 429,258	\$ 40,497	\$ 801,454	\$ -	\$ 801,454
Totals							
Gross Cost	\$ 13,255	\$ 325,950	\$ 487,357	\$ 40,534	\$ 867,096	\$ (2,077)	\$ 865,019
Earned Revenue	(28)	(5,598)	(57,332)	(3)	(62,961)	1,847	(61,114)
Net Cost of Operations	\$ 13,227	\$ 320,352	\$ 430,025	\$ 40,531	\$ 804,135	\$ (230)	\$ 803,905

During FY 2010, the Health and Medicare budget functions experienced growth of 9.8% (\$31.4 billion) and 4.0% (\$17.1 billion), respectively. The growth in the Health budget function is primarily attributable to normal increases in Entitlement Benefits of \$13.9 billion, and *Recovery Act* expenditures of \$8.2 billion, which includes \$6 billion for the extension of the Federal Medical Assistance Percentage. The growth in Medicare is primarily attributed to an increase in the HI and SMI benefits of \$8.6 billion and \$5.0 billion, respectively. There was also an increase in Part D benefits of approximately \$6.6 billion and a reduction in the net cost related to an increase in the SMI premiums of \$3.1 billion.

Note 17. Exchange Revenue

The HHS recognizes its revenue from exchange transactions when goods and services are provided. Total exchange revenue was \$64 billion and \$61 billion through September 30, 2010 and September 30, 2009, respectively. The HHS' exchange revenue consists primarily of Medicare premiums collected from beneficiaries. The HHS also charges user fees and collects revenues related to reimbursable agreements with other government entities.

Note 18. Apportionment Categories of Obligations Incurred

(in Millions)	2010		
	Direct	Reimbursable	Total
Category A (Distributed by Quarter)	\$ 102,622	\$ 7,106	\$ 109,728
Category B (Restricted and Distributed by Activity)	610,334	490	610,824
Exempt from Apportionment	479,053	-	479,053
Total Obligations Incurred	\$ 1,192,009	\$ 7,596	\$ 1,199,605

(in Millions)	2009		
	Direct	Reimbursable	Total
Category A (Distributed by Quarter)	\$ 158,031	\$ 6,785	\$ 164,816
Category B (Restricted and Distributed by Activity)	507,428	536	507,964
Exempt from Apportionment	462,145	-	462,145
Total Obligations Incurred	\$ 1,127,604	\$ 7,321	\$ 1,134,925

Obligations incurred consist of expended authority and the change in undelivered orders. OMB has exempted CMS from the Circular No. A-11, *Preparation, Submission and Execution of the Budget*, requirement to report Medicare's refunds of prior year obligations separately from refunds of current year obligations on the SF-133, *Report on Budget Execution and Budgetary Resources*.

Note 19. Legal Arrangements Affecting Use of Unobligated Balances

The unobligated balances consist of appropriated funds, revolving funds, management funds, Trust Funds, Cooperative Research and Development Agreement (CRADA) funds and royalty funds. Annual appropriations are available for sponsoring and conducting medical research and are available for new obligations in the year of appropriation and for adjustments to valid obligations for five subsequent years.

All Trust Fund receipts collected by the HHS during the fiscal year are reported as new budget authority in the Combined Statement of Budgetary Resources. The portion of the Trust Fund receipts collected in the fiscal year that exceeds the amount needed to pay benefits and other valid obligations in that fiscal year is precluded by law from being available for obligation. This excess of receipts over obligations is reported as Temporarily Not Available Pursuant to Public Law in the Statement of Budgetary Resources and, therefore, is not classified as budgetary resources in the fiscal year collected. However, all such excess receipts are assets of the Trust Funds and currently become available for obligation as needed. The entire Trust Fund balances in the amount of \$300.5 billion as of September 30, 2010, and \$320.1 billion as of September 30, 2009 are included as Investments in the Consolidated Balance Sheet.

The NIH Funds consist of the following:

- (a) The revolving and management funds available for centralized research support services and administrative activities.
 1. Revolving funds are no-year funds available until expended.
 2. The management fund is available for two fiscal years.

- (b) The Gift Funds consist of the Conditional, Unconditional, and Patient Emergency Funds, and are also available until expended.
1. The Unconditional Gift Fund is available for any authorized purpose in the performance of NIH functions.
 2. The Conditional Gift Fund is restricted to a specific purpose determined by the donor.
 3. The Patient Emergency Fund is intended solely for the benefit of patients.
- (c) The CRADA funds received are available for the performance of the contractual agreement, and are available for the term of the agreement.
- (d) Royalty funds are available for obligation for two fiscal years after the fiscal year in which the funds are received. These funds are available for a variety of purposes, such as rewards to scientific, engineering, and technical employees of the laboratory; education and training of employees; and payment of expenses incidental to the administration of intellectual property by the entity.

The NIH is not authorized to spend the Gift Funds to support functions not encompassed within the terms of the conditions. However, for conditional monetary gifts, upon completion of the stipulated conditions, or circumstances rendering completion of the conditions impossible, any remaining unobligated conditional funds are transferred to the Unconditional Gift Fund for the support of any other objectives of the recipient organization.

Note 20. Explanation of Differences between the Statement of Budgetary Resources (SBR) and the Budget of the United States Government

The *FY 2011 President's Budget*, with actual amounts for FY 2010, has not yet been published, and, therefore, no comparisons can be made between FY 2010 amounts presented in the SBR with amounts reported in the Actual column of the *President's Budget*. The *FY 2012 President's Budget* is expected to be released in February 2011, and may be obtained from the Office of Management and Budget's website <http://www.whitehouse.gov/omb/budget> or from the Government Printing Office.

The *Budget of the United States Government, FY 2011 – Appendix* was used as the reference for the HHS total budgetary resources amount. Information contained in the "Federal Programs by Agency and Account" in the FY 2011 Analytical Perspectives volume of the *Budget of the United States Government* was used as the reference for the net outlays (gross outlays less offsetting collections) amount in the following reconciliation of the SBR to the *President's Budget* for FY 2009.

(in Millions)	2009			
	Budgetary Resources	Obligations Incurred	Offsetting Receipts	Net Outlays (Gross Outlays less Offsetting Collections)
Statement of Budgetary Resources	\$ 1,185,303	\$ 1,134,925	\$ 284,292	\$ 1,081,555
Unobligated Balances – Not Available	(5,623)	-	-	-
Other	(2,457)	(1,800)	22	(740)
Budget of the U.S. Government	<u>\$ 1,177,223</u>	<u>\$ 1,133,125</u>	<u>\$ 284,314</u>	<u>\$ 1,080,815</u>

For the budgetary resources reconciliation, the amount used from the *President's Budget* was the total budgetary resources available for obligation. Therefore, a reconciling item that is contained in the SBR and not in the *President's Budget* is the budgetary resources that were not available. The Unobligated Balances – Not Available line in the above schedule includes expired authority, recoveries, and other amounts included in the SBR that are not included in the *President's Budget*. The Other differences primarily consist of activities performed by the HHS for the Department of Homeland Security (DHS) for Project Bioshield. The resources, obligations and outlays are reported on the HHS' SBR and included in the DHS *President's Budget*. The Other amounts in Obligations Incurred also consist of obligations for expired accounts that are appropriately reported on the SBR but not included in the *President's Budget*.

Note 21. Permanent Indefinite Appropriations

The HHS permanent indefinite appropriations are open-ended; that is, the dollar amount is unknown at the time the authority is granted. These appropriations are available for specific purposes without current year action by Congress.

Note 22. Undelivered Orders at the End of the Period

Undelivered Orders include grants that have been issued and obligated but not yet drawn down by the grantee, and goods and services ordered that have not been received. The HHS reported \$99.9 billion of budgetary resources obligated for undelivered orders as of September 30, 2010, and \$91.5 billion as of September 30, 2009.

Note 23. Earmarked Funds

Medicare is the largest earmarked fund group managed by the Department and is presented in a separate column in the schedule below. The Medicare programs include: (a) the Medicare Hospital Insurance (HI) Trust Fund, (b) the Medicare Supplementary Medical Insurance (SMI) Trust Fund, (c) the Medicare Prescription Drug Benefit – Part D, and (d) the Medicare Integrity Program. See Note 1 for a description of each fund's purpose and how the HHS accounts for and reports the fund. Portions of the Program Management appropriation have been allocated to the HI and SMI Trust Funds. SMI benefits and administrative expenses are financed by monthly premiums paid by Medicare beneficiaries and are matched by the Federal Government through the General Fund Appropriation, Payments to the Health Care Trust Funds.

The standard monthly SMI premium per beneficiary was \$96.40 from October 1, 2009, through December 31, 2009, and \$110.50 for January 1, 2010, through September 30, 2010. However, as a result of the zero cost-of-living adjustment (COLA) for Social Security beneficiaries effective for December 2009, about three-fourths of Part B enrollees are "held harmless" and do not have to pay the higher premium amount in 2010. New beneficiaries enrolling on January 1, 2010, and beyond, enrollees subject to an income-related additional premium, and individuals who do not have their premiums deducted from their Social Security benefit, including Medicare-Medicaid "dual-eligible beneficiaries," must pay a monthly premium based on the standard premium of \$110.50. (Premiums for dual-eligible beneficiaries are paid by the State Medicaid programs.)

(in Millions)	2010		
	Medicare	Other	Total
Balance Sheet as of September 30, 2010			
Fund Balance with Treasury	\$ 1,996	\$ 1,217	\$ 3,213
Investments	354,503	3,261	357,764
Other Assets	6,073	172	6,245
Total Assets	<u>\$ 362,572</u>	<u>\$ 4,650</u>	<u>\$ 367,222</u>
Entitlement Benefits Due and Payable	\$ 45,007	\$ -	\$ 45,007
Other Liabilities	2,342	864	3,206
Total Liabilities	<u>47,349</u>	<u>864</u>	<u>48,213</u>
Unexpended Appropriations	1,776	(101)	1,675
Cumulative Results of Operations	313,447	3,887	317,334
Total Liabilities and Net Position	<u>\$ 362,572</u>	<u>\$ 4,650</u>	<u>\$ 367,222</u>
Statement of Net Cost			
For the Period Ended September 30, 2010			
Gross Program Costs	\$ 507,975	\$ 909	\$ 508,884
Less: Earned Revenues	60,813	1,099	61,912
Net Cost of Operations	<u>\$ 447,162</u>	<u>\$ (190)</u>	<u>\$ 446,972</u>
Statement of Changes in Net Position			
For the Period Ended September 30, 2010			
Net Position Beginning of Period	\$ 336,342	\$ 3,961	\$ 340,303
Non-Exchange Revenue	201,482	298	201,780
Other Financing Sources	224,561	(663)	223,898
Net Cost of Operations	(447,162)	190	(446,972)
Change in Net Position	<u>(21,119)</u>	<u>(175)</u>	<u>(21,294)</u>
Net Position End of Period	<u>\$ 315,223</u>	<u>\$ 3,786</u>	<u>\$ 319,009</u>
2009			
(in Millions)	Medicare	Other	Total
Balance Sheet as of September 30, 2009			
Fund Balance with Treasury	\$ 3,265	\$ 1,100	\$ 4,365
Investments	375,835	3,168	379,003
Other Assets	5,689	92	5,781
Total Assets	<u>\$ 384,789</u>	<u>\$ 4,360</u>	<u>\$ 389,149</u>
Entitlement Benefits Due and Payable	\$ 46,772	\$ -	\$ 46,772
Other Liabilities	1,675	399	2,074
Total Liabilities	<u>48,447</u>	<u>399</u>	<u>48,846</u>
Unexpended Appropriations	3,590	(98)	3,492
Cumulative Results of Operations	332,752	4,059	336,811
Total Liabilities and Net Position	<u>\$ 384,789</u>	<u>\$ 4,360</u>	<u>\$ 389,149</u>
Statement of Net Cost			
For the Period Ended September 30, 2009			
Gross Program Costs	\$ 487,357	\$ 327	\$ 487,684
Less: Earned Revenues	57,332	842	58,174
Net Cost of Operations	<u>\$ 430,025</u>	<u>\$ (515)</u>	<u>\$ 429,510</u>
Statement of Changes in Net Position			
For the Period Ended September 30, 2009			
Net Position Beginning of Period	\$ 354,907	\$ 3,552	\$ 358,459
Non-Exchange Revenue	213,177	342	213,519
Other Financing Sources	198,283	(448)	197,835
Net Cost of Operations	(430,025)	515	(429,510)
Change in Net Position	<u>(18,565)</u>	<u>409</u>	<u>(18,156)</u>
Net Position End of Period	<u>\$ 336,342</u>	<u>\$ 3,961</u>	<u>\$ 340,303</u>

Note 24. Statement of Social Insurance Disclosures (Unaudited)

The Statement of Social Insurance (SOSI) presents the projected 75-year actuarial present values of the income and expenditures of the Hospital Insurance (HI) and Supplementary Medical Insurance (SMI) Trust Funds. Future expenditures are expected to arise from the health care payment provisions specified in current law for current and future program participants and from associated administrative expenses. Actuarial present values are computed on the basis of the intermediate set of assumptions specified in the *Annual Report of the Medicare Board of Trustees*. These assumptions represent the Trustees' best estimate of likely future economic, demographic, and health care-specific conditions.

The SOSI projections are based on current law, and reflect the effects of the *Patient Protection and Affordable Care Act*, as amended by the *Health Care and Education Reconciliation Act of 2010*. This legislation, referred to collectively as the "*Affordable Care Act*" contains roughly 165 provisions affecting the Medicare program by reducing costs, increasing revenues, improving certain benefits, combating fraud and abuse, and initiating a major program of research and development.

The *Affordable Care Act* improves the financial outlook for Medicare substantially; however, the full effects of some of the new law's provisions on Medicare are not known at this time, with the result that the projections are much more uncertain than normal, especially in the long-range future. It is important to note that the substantially improved results for HI and SMI Part B depend, in part, on the long-range feasibility of lower increases in Medicare payment rates to most categories of health care providers, as mandated by the *Affordable Care Act*. Moreover, in the context of today's health care system, these adjustments would probably not be viable indefinitely into the future. As a result, the actual future costs for Medicare are likely to exceed those shown by the current-law projections shown in the SOSI. Please see Note 25 for further information on the impact of the *Affordable Care Act*.

Actuarial present values are computed as of the year shown and over the 75-year projection period, beginning January 1 of that year. The Trustees' projections are based on the current Medicare laws, regulations, and policies in effect on August 5, 2010, and do not reflect any actual or anticipated changes subsequent to that date. The present values are calculated by discounting the future annual amounts of non-interest income and expenditures (including benefit payments as well as administrative expenses) at the projected average rates of interest credited to the HI Trust Fund. HI income includes the portion of *FICA* and *SECA* payroll taxes allocated to the HI Trust Fund, the portion of Federal income taxes paid on Social Security benefits that is allocated to the HI Trust Fund, and receipts from fraud and abuse control activities. SMI income includes premiums paid by, or on behalf of, beneficiaries and general revenue contributions made on behalf of beneficiaries. Fees related to brand-name prescription drugs, required by the *Affordable Care Act*, are included as income for Part B of SMI, and transfers from State governments are included as income for Part D of SMI. Since all major sources of income to the Trust Funds are reflected, the actuarial projections can be used to assess the financial condition of each Trust Fund.

The Part A present values in the SOSI exclude the income and expenditures for the roughly one percent of beneficiaries who are 65 or over, but are "uninsured" because they do not meet the normal insured status or related requirements to qualify for entitlement to Part A benefits. The primary purpose of the SOSI is to compare the projected future costs of Medicare with the program's scheduled revenues. Since costs for the uninsured are separately funded either through general revenue appropriations or through premium payments, the exclusion of such amounts does not materially affect the financial balance of Part A. In addition, such individuals are granted coverage outside of the social insurance framework underlying Medicare Part A. For these reasons, it is appropriate to exclude their income and expenditures from the statement of social insurance.

Actuarial present values of estimated future income (excluding interest) and estimated future expenditures are presented for three different groups of participants: (1) current participants who have not yet attained eligibility age; (2) current participants who have attained eligibility age; and (3) new entrants, those who are expected to become participants in the future. With the exception of the 2007 projections presented, current participants are the "closed group" of individuals who are at least age 15 at the start of the projection period, and are participating in the program as either taxpayers, beneficiaries, or both. For the 2007 projections, the "closed group" of individuals includes individuals who are at least 18 at the start of the projection period. Since the projection period consists of 75 years, the period covers virtually all of the current participants' working and retirement years.

The SOSI sets forth, for each of these three groups, the projected actuarial present values of all future HI (Part A) and SMI (Parts B and D) expenditures and of all future non-interest income for the next 75 years.

The SOSI also presents the net present values of future net cash flows for each fund, which are calculated by subtracting the actuarial present value of future expenditures from the actuarial present value of future income. The existence of an actuarial deficit for the HI Trust Fund indicates that, under these assumptions as to economic, demographic, and health care cost trends for the future, HI income is expected to fall short of expenditures over the next 75 years. Neither Part B nor Part D of SMI has similar problems because each account is automatically in financial balance every year due to its statutory financing mechanism.

In addition to the actuarial present value of the estimated future excess of income (excluding interest) over expenditures for the open group of participants, it is possible to make an analogous calculation for the "closed group" of participants. The "closed group" of participants consists of those who, in the starting year of the projection period, have attained retirement eligibility age or have attained ages 15 through 64 (18 through 64 in the case of the 2007 projections). In order to calculate the actuarial net present value of the excess of future income over future expenditures for the closed group, the actuarial present value of estimated future expenditures for or on behalf of current participants is subtracted from the actuarial present value of future income (excluding interest) for current participants.

Since its enactment in 1965, the Medicare program has experienced substantial variability in expenditure growth rates. These different rates of growth have reflected new developments in medical care, demographic factors affecting the relative number and average age of beneficiaries and covered workers, and numerous economic factors. The future cost of Medicare will also be affected by further changes in these factors that are inherently uncertain. Consequently, Medicare's actual cost over time, especially for periods as long as 75 years, cannot be predicted with certainty and such actual cost could differ materially from the projections shown in the SOSI. Moreover, these differences could affect the long-term sustainability of this social insurance program. Please see Note 25 below for important information on the further uncertainty, resulting from the provisions in the *Affordable Care Act*, associated with the current-law projections presented in the SOSI. In order to make projections regarding the future financial status of the HI and SMI Trust Funds, various assumptions have to be made. As stated previously, the estimates presented here are based on the assumption that the Trust Funds will continue to operate under the law in effect on August 5, 2010. In addition, the estimates depend on many economic, demographic, and health care-specific assumptions, including changes in per beneficiary health care cost, wages, the consumer price index (CPI), fertility rates, mortality rates, immigration rates, and interest rates. In most cases, these assumptions vary from year to year during the first 5 to 30 years before reaching their ultimate values for the remainder of the 75-year projection period. The assumed growth rates for per beneficiary health care costs vary throughout the projection period.

The most significant underlying assumptions based on current law, used in the projections of Medicare spending displayed in this section, are included in the following table. The assumptions underlying the 2010 SOSI actuarial projections are drawn from the Social Security and Medicare Trustees Reports for 2010. Specific assumptions are made for each of the different types of service provided by the Medicare program (for example, hospital care and physician services). These assumptions include changes in the payment rates, utilization, and intensity of each type of service. The projected beneficiary cost increases summarized below reflect the overall impact of these more detailed assumptions. Detailed information, similar to that denoted within Table 1, for the prior years is publicly available on the CMS website at: www.cms.hhs.gov/CFORepor/.

**Table 1: Significant Assumptions and Summary Measures
Used for the Statement of Social Insurance 2010**

	Fertility rate ¹	Net immigration ²	Mortality rate ³	Real-wage differential ⁴	Annual percentage change in:						Real-interest rate ⁹
					Wages ⁵	CPI ⁶	Real GDP ⁷	Per beneficiary cost ⁸			
								HI	SMI		
								B	D		
2010	2.08	1,215,000	784.4	3.1	5.1	2.0	2.3	1.1	3.8	4.3	0.9
2020	2.05	1,125,000	723.8	1.1	3.9	2.8	2.2	3.5	5.0	7.3	2.9
2030	2.01	1,085,000	661.8	1.2	4.0	2.8	2.1	4.7	4.8	5.9	2.9
2040	2.00	1,050,000	606.8	1.2	4.0	2.8	2.2	4.8	4.5	5.3	2.9
2050	2.00	1,035,000	558.6	1.2	4.0	2.8	2.1	3.9	4.1	5.1	2.9
2060	2.00	1,030,000	516.4	1.1	3.9	2.8	2.1	3.7	4.1	4.8	2.9
2070	2.00	1,025,000	479.1	1.1	3.9	2.8	2.1	3.6	3.9	4.6	2.9
2080	2.00	1,025,000	446.1	1.2	4.0	2.8	2.1	3.3	3.8	4.4	2.9

¹Average number of children per woman.

²Includes legal immigration, net of emigration, as well as other, non-legal, immigration.

³The age-sex-adjusted death rate per 100,000 that would occur in the enumerated population as of April 1, 2000, if that population were to experience the death rates by age and sex observed in, or assumed for, the selected year.

⁴Difference between percentage increases in wages and the CPI.

⁵Average annual wage in covered employment.

⁶Consumer price index represents a measure of the average change in prices over time in a fixed group of goods and services.

⁷The total dollar value of all goods and services produced in the United States, adjusted to remove the impact of assumed inflation growth.

⁸These increases reflect the overall impact of more detailed assumptions that are made for each of the different types of service provided by the Medicare program (for example, hospital care, physician services, and pharmaceutical costs). These assumptions include changes in the payment rates, utilization, and intensity of each type of service.

⁹Average rate of interest earned on new Trust Fund securities, above and beyond rate of inflation.

The ultimate values of the above-specified assumptions used in determining the estimates for each of the five years presented in the Statement of Social Insurance are listed within Table 2 below. They are based on the intermediate assumptions of the respective Medicare Trustees Reports.

**Table 2: Significant Ultimate Assumptions Used for the Statement of Social Insurance,
FY 2010 - 2006**

	Fertility rate ¹	Net immigration ²	Mortality rate ³	Real-wage differential ⁴	Annual percentage change in:						Real-interest rate ⁹
					Wages ⁵	CPI ⁶	Real GDP ⁷	Per beneficiary cost ⁸			
								HI	B	D	
FY 2010	2.0	1,025,000	446.1	1.2	4.0	2.8	2.1	3.3	3.8	4.4	2.9
FY 2009	2.0	1,025,000	458.2	1.1	3.9	2.8	2.1	4.4	4.3	4.3	2.9
FY 2008	2.0	1,025,000	476.8	1.1	3.9	2.8	2.1	4.4	4.3	4.4	2.9
FY 2007	2.0	900,000	496.8	1.1	3.9	2.8	1.9	4.3	4.3	4.3	2.9
FY 2006	2.0	900,000	497.6	1.1	3.9	2.8	1.9	4.3	4.3	4.3	2.9

¹Average number of children per woman. The ultimate fertility rate is assumed to be reached by the 25th year of the projection period.

²Includes legal immigration, net of emigration, as well as other, non-legal, immigration. For 2008-2010, the ultimate level of net legal immigration was increased from 600,000 to 750,000 persons per year. In addition, the method for projecting annual net other immigration was changed and it now varies throughout the projection period. So for 2008-2010, the assumption presented is the value assumed in the year 2080. For 2006-2007, the ultimate assumption is displayed and is reached by the 20th year of each projection period.

³The age-sex-adjusted death rate per 100,000 that would occur in the enumerated population as of April 1, 2000, if that population were to experience the death rates by age and sex observed in, or assumed for, the selected year. The annual rate declines gradually during the entire period so no ultimate rate is achieved. The assumption presented is the value assumed in the year 2080.

⁴Difference between percentage increases in wages and the CPI. Except for minor fluctuations, the ultimate assumption is reached within the first 10 years of the projection period.

⁵Average annual wage in covered employment. Except for minor fluctuations, the ultimate assumption is reached within the first 10 years of the projection period.

⁶Consumer price index represents a measure of the average change in prices over time in a fixed group of goods and services. The ultimate assumption is reached within the first 10 years of the projection period.

⁷The total dollar value of all goods and services produced in the United States, adjusted to remove the impact of assumed inflation growth. The annual rate declines gradually during the entire period so no ultimate rate is achieved. The assumption presented is the value assumed in the year 2080.

⁸These increases reflect the overall impact of more detailed assumptions that are made for each of the different types of service provided by the Medicare program (for example, hospital care, physician services, and pharmaceutical costs). These assumptions include changes in the payment rates, utilization, and intensity of each type of service. The annual rate of growth declines gradually during the entire period so no ultimate rate is achieved. The assumption presented is the value assumed in the year 2080.

⁹Average rate of interest earned on new trust fund securities, above and beyond rate of inflation. The ultimate assumption is reached within the first 10 years of each projection period.

Part D Projections

In addition to the inherent variability that underlies the expenditure projections prepared for all parts of Medicare, the Part D program is still relatively new (having begun operations in January 2006), with relatively little actual program data currently available. The actual 2006 through 2010 bid submissions by the private plans offering this coverage, together with actual data on beneficiary enrollment and program spending through 2009, have been used in the current projections. Nevertheless, there remains a high level of uncertainty surrounding these cost projections, pending the availability of sufficient data on actual Part D expenditures to establish a trend baseline.

Note 25. Affordable Care Act and SMI Part B Physician Payment Update Factor (Unaudited)

The *Affordable Care Act* improves the financial outlook for Medicare substantially; however, the full effects of some of the new law's provisions on Medicare are not known at this time, with the result that the projections are much more uncertain than normal, especially in the longer-range future. For example, the *Affordable Care Act* initiative for aggressive research and development has the potential to reduce Medicare costs in the future; however, as specific reforms have not yet been designed, tested, or evaluated, their ability to reduce costs cannot be estimated at this time, and thus no specific savings have been reflected in the projections for the initiative.

Another important example involves lower payment rate updates to most categories of Medicare providers in 2011 and later. These updates will be adjusted downward by the increase in productivity experienced in the economy overall. Since the provision of health services tends to be labor-intensive and is often customized to match individuals' specific needs, most categories of health providers have not been able to improve their productivity to the same extent as the economy at large. Over time, the productivity adjustments mean that the prices paid for health services by Medicare will grow about 1.1 percent per year more slowly than the increase in prices that providers must pay to purchase the goods and services they use to provide health care services. Unless providers could reduce their cost per service correspondingly, through productivity improvements, or other steps, they would eventually become unwilling or unable to treat Medicare beneficiaries.

It is possible that providers can improve their productivity, reduce wasteful expenditures, and take other steps to keep their cost growth within the bounds imposed by the Medicare price limitations. Similarly, the implementation of payment and delivery system reforms, facilitated by the *Affordable Care Act* research and development program, could help constrain cost growth to a level consistent with the lower Medicare payments. These outcomes are far from certain, however. Many experts doubt the feasibility of such sustained improvements and anticipate that over time the Medicare price constraints would become unworkable and that Congress would likely override them, much as they have done to prevent the reductions in physician payment rates otherwise required by the sustainable growth rate formula in current law.

The reductions in provider payments reflected in these updates, if implemented for all future years as required under current law, could have secondary impacts, for beneficiary access to care; utilization, intensity and quality of services; and other factors. These possible impacts are speculative, and at present there is no consensus among experts as to their potential scope. Further research and analysis will help to better inform this issue and may enable the development of specific projections of secondary effects under current law in the future.

The SOSI projections must be based on current law. Therefore, the productivity adjustments are assumed to occur in all future years, as required by the *Affordable Care Act*. In addition, reductions in Medicare payment rates for physician services, totaling 30 percent over the next three years, are assumed to be implemented as required under current law, despite the virtual certainty that Congress will continue to override these latter reductions. Therefore, it is important to note that the actual future costs for Medicare are likely to exceed those shown by these current-law projections.

Illustrative Scenario

The Medicare Board of Trustees, in their annual report to Congress, references an alternative scenario to illustrate, where possible, the potential understatement of Medicare costs and projection results. This alternative scenario assumes that the productivity adjustments are gradually phased out over the 15 years, starting in 2020, and that the physician fee reductions are overridden. These examples were developed for illustrative purposes only; the calculations have not been audited; no endorsement of the illustrative alternative to current law by the Trustees, CMS, or the Office of the Actuary should be inferred; and the examples do not attempt to portray likely or recommended future outcomes. Thus, the illustrations are useful only as general indicators of the substantial impacts that could result from future legislation affecting the productivity adjustments and physician payments under Medicare and of the broad range of uncertainty associated with such impacts. The table below contains a comparison of the Medicare 75-year present values of income and expenditures under current law with those under the alternative scenario illustration.

Medicare Present Values (in Billions)		
	Current law (unaudited)	Illustrative Alternative Scenario ^{1,2} (unaudited)
Income		
<i>Part A</i>	\$14,408	\$14,408
<i>Part B</i>	17,737	28,284
<i>Part D</i>	9,715	9,715
Expenditures		
<i>Part A</i>	17,090	21,745
<i>Part B</i>	17,737	28,284
<i>Part D</i>	9,715	9,715
Income Less Expenditures		
<i>Part A</i>	(2,683)	(7,337)
<i>Part B</i>	0	0
<i>Part D</i>	0	0
¹ These amounts are not presented in the 2010 Trustees' Report. ² At the request of the Trustees, the Office of the Actuary at CMS has prepared an illustrative set of Medicare Trust Fund projections that differ from current law. No endorsement of the illustrative alternative to current law by the Trustees, CMS, or the Office of the Actuary should be inferred.		

As expected, the differences between the current-law projections and the illustrative alternative are substantial, although both represent a sizeable improvement in the financial outlook for Medicare compared to law in effect prior to the *Affordable Care Act*. This difference in outlook serves as a compelling reminder of the importance of developing and implementing further means of reducing health care cost growth in the coming years. All Part A fee-for-service providers are affected by the productivity adjustments, so the current law projections reflect an estimated 1.1 percent reduction in annual Part A cost growth each year. If the productivity adjustments were gradually phased out, as illustrated under the alternative scenario, the present value of Part A expenditures is estimated to be roughly 27 percent higher than the current-law projection. As indicated above, the present value of Part A income is unchanged under the alternative scenario.

The Part B expenditure projections are significantly higher under the alternative scenario than under current law, both because of the assumed gradual phase-out of the productivity adjustments and the assumption that the scheduled physician fee reductions would be overridden and based on annual increases in the Medicare Economic Index. The productivity adjustments are estimated to affect more than half of Part B expenditures at the time their phase-out is assumed to begin. Similarly, physician fee schedule services are assumed to be roughly 30 percent higher under the alternative scenario than under current law at that time. The combined effect of these two factors results in a present value of Part B expenditures under the alternative scenario that is approximately 59 percent higher than the current-law projection.

The Part D projections are unaffected under the alternative projection because the services are not impacted by the productivity adjustments or the physician fee schedule reductions.

The extent to which actual future Part A and Part B costs exceed the projected current-law amounts due to changes to the productivity adjustments and physician payments depends on both the specific changes that might be legislated and on whether Congress would pass further provisions to help offset such costs. As noted, these examples only reflect hypothetical changes to provider payment rates.

It is likely that in the coming years Congress will consider, and pass, numerous other legislative proposals affecting Medicare. Many of these will likely be designed to reduce costs in an effort to make the program more affordable. In practice, it is not possible to anticipate what actions Congress might take, either in the near term or over longer periods.

Note 26. Reconciliation of Net Cost of Operations (Proprietary) to Budget *(in Millions)*

	2010	2009
RESOURCES USED TO FINANCE ACTIVITIES:		
BUDGETARY RESOURCES OBLIGATED		
Obligations Incurred	\$ 1,199,605	\$ 1,134,925
Spending Authority from Offsetting Collections and Recoveries	(31,221)	(26,339)
Obligations Net of Offsetting Collections and Recoveries	1,168,384	1,108,586
Offsetting Receipts	(303,977)	(284,292)
Net Obligations	864,407	824,294
OTHER RESOURCES		
Net Non-Budgetary Resources Used to Finance Activities	554	427
Total Resources Used to Finance Activities	864,961	824,721
RESOURCES USED TO FINANCE ITEMS NOT PART OF THE NET COST OF OPERATIONS:		
Change in Budgetary Resources Obligated for Goods, Services and Benefits		
Ordered but Not Yet Provided	7,249	21,396
Resources That Fund Expenses Recognized in Prior Periods	3	17
Budgetary Offsetting Collections and Receipts That Do Not Affect		
Net Cost of Operations	(110)	(89)
Resources That Finance the Acquisition of Assets or Liquidations of Liabilities	903	1,565
Other Resources or Adjustments to Net Obligated Resources That Do Not Affect		
Net Cost of Operations	1,468	1,138
Total Resources Used to Finance Items Not Part of the Net Cost of Operations	9,513	24,027
Total Resources Used to Finance the Net Cost of Operations	855,448	800,694
COMPONENTS OF NET COST OF OPERATIONS THAT WILL NOT REQUIRE OR GENERATE RESOURCES IN THE CURRENT PERIOD		
Components Requiring or Generating Resources in Future Periods	483	3,686
Components Not Requiring or Generating Resources	797	(475)
Total Components of Net Cost of Operations That Will Not Require or Generate Resources in the Current Period	1,280	3,211
NET COST OF OPERATIONS	\$ 856,728	\$ 803,905

Note 27. American Recovery and Reinvestment Act Obligations and Net Outlays *(in Millions)*

	2010	2009	Inception to September 30, 2010
OBLIGATIONS	\$ 59,800	\$ 46,512	\$ 106,312
NET OUTLAYS	\$ 55,248	\$ 33,048	\$ 88,296

These funds were distributed among most of the HHS' responsibility segments and required new processes to be developed or modified within a very short timeframe to ensure compliance with the *Recovery Act* and OMB regulations.

REQUIRED SUPPLEMENTARY STEWARDSHIP INFORMATION

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INVESTMENT IN HUMAN CAPITAL
For the Year Ended September 30, 2010
(in Millions)

Responsibility Segment Program	2010	2009	2008	2007	2006
Administration for Children and Families					
Administration on Developmental Disabilities	\$ 9	\$ 10	\$ 8	\$ 8	\$ 7
National Institutes of Health					
Research Training and Career Development	1,915	1,862	1,792	1,756	1,747
Totals	\$ 1,924	\$ 1,872	\$ 1,800	\$ 1,764	\$ 1,754

Investments in Human Capital are expenses incurred by Federal education and training programs for the public, which are intended to maintain or increase national productive capacity. Two operating divisions of the Department conduct education and training programs under this category: Administration for Children and Families (ACF) and National Institutes of Health (NIH).

Administration for Children and Families

The ACF is able to estimate Investment in Human Capital for the Administration for Developmental Disabilities (ADD) using existing data collection activities. Under ADD, 34 grants are anticipated to be awarded for Projects of National Significance (PNS). As of September 30, 2010, all of the 34 PNS grants have been awarded for FY 2010. PNS grants are awarded to public or private, non-profit institutions to enhance the independence, productivity, integration and inclusion into the community of people with developmental disabilities. These monies also support the development of national and State policy to serve this community. Grants awarded total \$9 million as of September 30, 2010.

National Institutes of Health

The NIH Research Training and Career Development Program addresses the need for trained personnel to conduct medical research. The primary goal of the support that NIH provides for graduate training and career development is to produce new, highly trained investigators who are likely to perform research that will benefit the nation's health. NIH's ability to maintain the momentum of recent scientific progress and international leadership in medical research depends upon the continued development of new, highly trained investigators.

INVESTMENT IN RESEARCH AND DEVELOPMENT
As of September 30, 2010
 (in Millions)

Responsibility Segments	2010				Total				Grand Total
	Basic	Applied	Develop-mental	Total	2009	2008	2007	2006	
ACF	\$ -	\$ 9	\$ -	\$ 9	\$ 16	\$ 25	\$ 16	\$ 39	\$ 105
AHRQ	263	-	-	263	203	184	198	175	1,023
CDC	-	465	-	465	755	440	563	478	2,701
FDA	42	-	6	48	36	67	40	37	228
HRSA	-	-	-	-	-	-	-	28	28
NIH	18,805	12,537	-	31,342	27,889	27,302	26,131	25,780	138,444
Totals	\$ 19,110	\$ 13,011	\$ 6	\$ 32,127	\$ 28,899	\$ 28,018	\$ 26,948	\$ 26,537	\$ 142,529

The many research and development programs in the HHS include the following:

Administration for Children and Families

The ACF oversees research and development programs that contribute to a better understanding of how to improve the economic and social well-being of families and children, so that they may lead healthier and more productive lives.

Agency for Healthcare Research and Quality (AHRQ)

The AHRQ is the lead Federal agency charged with improving the quality, safety, efficiency, and effectiveness of health care for all Americans. AHRQ supports health services research that will improve the quality of health care and promote evidence-based decision making.

Food and Drug Administration (FDA)

The FDA has two programs that meet the requirements of research and development investments: Orphan Products Development (OPD) Program and FDA Research Grants Program. While the FDA's center components conduct scientific studies, FDA does not consider this type of research as "research and development" because it is used to support FDA's regulatory policy and decision making processes.

The OPD Program was established by the *Orphan Drug Act (P.L. 97-414, as amended)* with the purpose of identifying orphan products and facilitating their development. An orphan product is a drug, biological product, medical device, or medical food that is intended to treat a rare disease or condition (i.e., one with a prevalence of fewer than 200,000 people in the United States).

The FDA Research Grants Program is a grants program whose purpose is to assist public and non-public institutions and for-profit organizations to establish, expand, and improve research, demonstration, education, and information dissemination activities concerned with a wide variety of FDA areas.

Centers for Disease Control and Prevention (CDC)

Infectious Diseases, Occupational Safety and Health, Health Promotion, and Environmental Health and Injury Prevention were the primary areas where CDC's research and development was invested.

National Institutes of Health (NIH)

The NIH Research Program includes all aspects of the medical research continuum, including basic and disease-oriented research, observational and population-based research, behavioral research, and clinical research, including research to understand both health and disease states, to move laboratory findings into medical applications, to assess new treatments or compare different treatment approaches; and health services research. NIH regards the expeditious transfer of the results of its medical research for further development and commercialization of products of immediate benefit to improved health as an important mandate.

REQUIRED SUPPLEMENTARY INFORMATION

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COMBINING STATEMENT OF BUDGETARY RESOURCES
For the Year Ended September 30, 2010
(in Millions)

	CMS			Other Agency Budgetary Accounts ¹	Agency Combined Totals
	Medicare HI	Medicare SMI	Medicaid		
Budgetary Resources:					
Unobligated Balance, Brought Forward, Oct 1	\$ 54	\$ 54	\$ 8,163	\$ 42,107	\$ 50,378
Recoveries of Prior Year Unpaid Obligations	755	158	14,010	2,759	17,682
Budget Authority	252,321	224,644	285,272	445,889	1,208,126
Nonexpenditure Transfers, Net, Anticipated & Actual	(22)	(73)	(3,744)	3,176	(663)
Temporarily not available pursuant to Public Law	-	(11,238)	-	(58)	(11,296)
Permanently not available (-)	5	7	-	(5,309)	(5,297)
Total Budgetary Resources	\$ 253,113	\$ 213,552	\$ 303,701	\$ 488,564	\$ 1,258,930
Status of Budgetary Resources:					
Obligations Incurred	\$ 253,113	\$ 213,552	\$ 286,701	\$ 446,239	\$ 1,199,605
Unobligated Balances – Available	-	-	14,240	34,640	48,880
Unobligated Balances – Not Available	-	-	2,760	7,685	10,445
Total Status of Budgetary Resources	\$ 253,113	\$ 213,552	\$ 303,701	\$ 488,564	\$ 1,258,930
Relationship of Obligations to Outlays:					
Obligated Balance, Net	\$ 23,707	\$ 21,202	\$ 24,977	\$ 95,175	\$ 165,061
Obligations Incurred, Net (+/-)	253,113	213,552	\$ 286,701	446,239	1,199,605
Less: Gross Outlays	(252,697)	(212,466)	(269,781)	(436,178)	(1,171,122)
Less: Recoveries of Prior Year Unpaid Obligations	(755)	(158)	(14,010)	(2,759)	(17,682)
Change in Uncollected Customer Payments	54	54	-	(609)	(501)
Obligated Balance, Net, End of Period	23,422	22,184	27,887	101,868	175,361
Net Outlays	\$ 229,125	\$ (67,135)	\$ 269,009	\$ 423,108	\$ 854,107

Summary of Other Agency Budgetary Accounts

	Budgetary Resources	Status of Budgetary Resources	Net Outlays
ACF	\$ 59,757	\$ 59,757	\$ 55,561
AoA	1,561	1,561	1,511
AHRO	1,141	1,141	83
CDC	12,556	12,556	10,711
CMS	317,606	317,606	298,057
FDA	3,794	3,794	2,039
HRSA	9,538	9,538	8,410
IHS	6,597	6,597	4,270
NIH	41,263	41,263	32,926
OS	29,326	29,326	5,759
PSC	1,638	1,638	464
SAMHSA	3,787	3,787	3,317
	\$ 488,564	\$ 488,564	\$ 423,108

¹ "Other Agency Budgetary Accounts" includes the budgetary accounts of the 11 HHS agencies other than CMS, as well as the remaining budgetary accounts not reported by CMS under Medicare and Medicaid. This includes budgetary resources of \$3.77 billion and net outlays of \$3.76 billion for the Vaccine for Children Program which are appropriated to the Medicaid program and transferred to the CDC.

DEFERRED MAINTENANCE

For the Years Ended September 30, 2010 and 2009

Deferred maintenance is maintenance that was not performed when it should have been, was scheduled and not performed, or was delayed for a future period. Maintenance is the act of keeping fixed assets in acceptable condition, including preventive maintenance, normal repairs, replacement of parts and structural components and other activities needed to preserve the asset so that it continues to provide acceptable services and achieves its expected life. Maintenance does not include activities aimed at expanding the capacity of an asset or otherwise upgrading it to serve needs different from, or significantly greater than, those originally intended. Maintenance expense is recognized as incurred. The Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), and the Food and Drug Administration (FDA) all use the condition assessment survey for all classes of property. The Indian Health Service (IHS) uses two types of surveys to assess installations – annual general inspections and deep look surveys.

Category of Asset (in Millions)	Condition	Estimated Cost to Return to Acceptable Condition	
		2010	2009
General PP&E			
Buildings	1 - 4	\$ 1,940	\$ 2,012
Equipment	4	12	12
Other Structures	1 - 4	34	47
Total		\$ 1,986	\$ 2,071

Asset condition is assessed on a scale of 1-5 as follows: Excellent-1; Good-2; Fair-3; Poor-4; Very Poor-5. A "fair" or 3 rating is considered acceptable operating condition. Although PP&E categories may be rated as acceptable, individual assets within a category may require maintenance work to return them to acceptable operating condition. Therefore, asset categories with an overall rating of "fair" or above may still report necessary costs to return them to acceptable condition.

STEWARDSHIP PROPERTY, PLANT, AND EQUIPMENT

As of September 30, 2010

The HHS has Indian Trust Lands that are considered a type of property, plant, and equipment (PP&E) for stewardship reporting purposes. Indian Trust Lands are those lands that do not meet the definition of stewardship land (i.e., land other than those acquired for or used in connection with general (capitalized) PP&E), but have always been held by IHS as separate and distinct, because of the Government's long-term trust responsibility. All Trust Lands, when no longer needed by the IHS in connection with its general use PP&E, must be returned to the Department of the Interior's Bureau of Indian Affairs, for continuing Trust responsibilities and oversight.

For the purpose of Statements of Federal Financial Accounting Standards No. 29, *Heritage Assets and Stewardship Land*, heritage assets are any real property assets that are individually listed on the National Register of Historic Places. As of September 30, 2010, IHS has no individually listed properties.

The IHS accountability reports differentiate Indian Trust Land parcels from general PP&E situated thereon. The IHS Trust Land balances are removed from the HHS FY 2010 Balance Sheet and reported as Stewardship Assets - Indian Trust Lands.

The Distribution of Stewardship Assets by Type and Area, as of September 30, 2010, is summarized below:

Distribution of Stewardship Assets by Type and Area

	Indian Trust Lands	
	Number of Sites	Total Hectares
Aberdeen	9	75
Albuquerque	4	4
Bemidji	2	9
Billings	7	48
Navajo	35	255
Oklahoma City	1	2
Phoenix	11	14
Portland	3	1
Tucson	5	12
Total	77	420

SOCIAL INSURANCE

As of September 30, 2010

Medicare, the largest health insurance program in the country, has helped fund medical care for the nation's aged and disabled for over four decades. A brief description of the provisions of Medicare's Hospital Insurance (HI, or Part A) Trust Fund and Supplementary Medical Insurance (SMI, or Parts B and D) Trust Fund is included in this financial report.

The Required Supplementary Information (RSI) contained in this section is based on current law, and is presented in accordance with the requirements of the Federal Accounting Standards Advisory Board (FASAB). Included are descriptions of long-term sustainability and financial condition of the program, and a discussion of trends revealed in the data.

RSI material is generally drawn from the *2010 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds*, which represents the official government evaluation of the financial and actuarial status of the Medicare Trust Funds. Unless otherwise noted, all data are for calendar years, and all projections are based on the Trustees' intermediate set of assumptions.

The projections shown here incorporate the effects of the *Patient Protection and Affordable Care Act*, as amended by the *Health Care and Education Reconciliation Act of 2010*. This legislation, referred to collectively as the "*Affordable Care Act*," contains roughly 165 provisions affecting the Medicare program by reducing costs, increasing revenues, improving certain benefits, combating fraud and abuse, and initiating a major program of research and development for alternative provider payment mechanisms, health care delivery systems, and other changes intended to improve the quality of health care and/or reduce its costs to Medicare.

The *Affordable Care Act* improved the financial outlook for Medicare substantially, mainly as a result of permanent price update reductions for most fee-for-service providers, substantial reductions in payments to private health plans, and an increase in the Part A payroll tax rate for high-income earners. It is possible that providers can improve their productivity, reduce wasteful expenditures, and take other steps to keep their cost growth within the bounds imposed by the Medicare price limitations. These outcomes are far from certain, however, many experts doubt the feasibility of such sustained improvements and anticipate that over time the Medicare price constraints would become unworkable and Congress would likely override them, much as they have done to prevent the reductions in physician payment rates otherwise required by the sustainable growth rate formula in current law. However, the effects of some of the new law's provisions on Medicare are not known at this time, with the result that the projections are much more uncertain than normal, especially in the longer-range future.

As stated previously, the projections in this section are drawn from the annual Medicare Trustees report, which must be based on current law. In addition, the FASAB rules governing the Statement of Social Insurance (SOSI) also require use of projections based on current law. Accordingly, the permanent payment update reductions are assumed to occur in all future years, as required by the *Affordable Care Act*. In addition, reductions in Medicare payment rates for physician services, totaling 30 percent over the next three years, are assumed to be implemented as required under current law, despite the virtual certainty that Congress will continue to override these latter reductions.

In view of the factors described above, it is important to note that the actual future costs for Medicare are likely to exceed those shown by the current-law projections. Therefore, the Medicare Board of Trustees, in their annual report to Congress, references an alternative scenario to illustrate, where possible, the potential understatement of Medicare costs and projections results. At the request of the Trustees, the Office of the Actuary at CMS has prepared an illustrative set of Medicare Trust Fund projections under this theoretical alternative to current law. No endorsement of the illustrative alternative to current law by the Trustees, CMS, or the Office of the Actuary should be inferred. Additional information on this theoretical alternative to current law is provided in Note 25 in these financial statements, and in an auxiliary memorandum prepared by the CMS Office of the Actuary at the request of the Board of Trustees.

Printed copies of the Trustees Report and auxiliary memorandum may be obtained from the CMS Office of the Actuary (410-786-6386) or can be downloaded from <http://www.cms.hhs.gov/ReportsTrustFunds/>.

ACTUARIAL PROJECTIONS

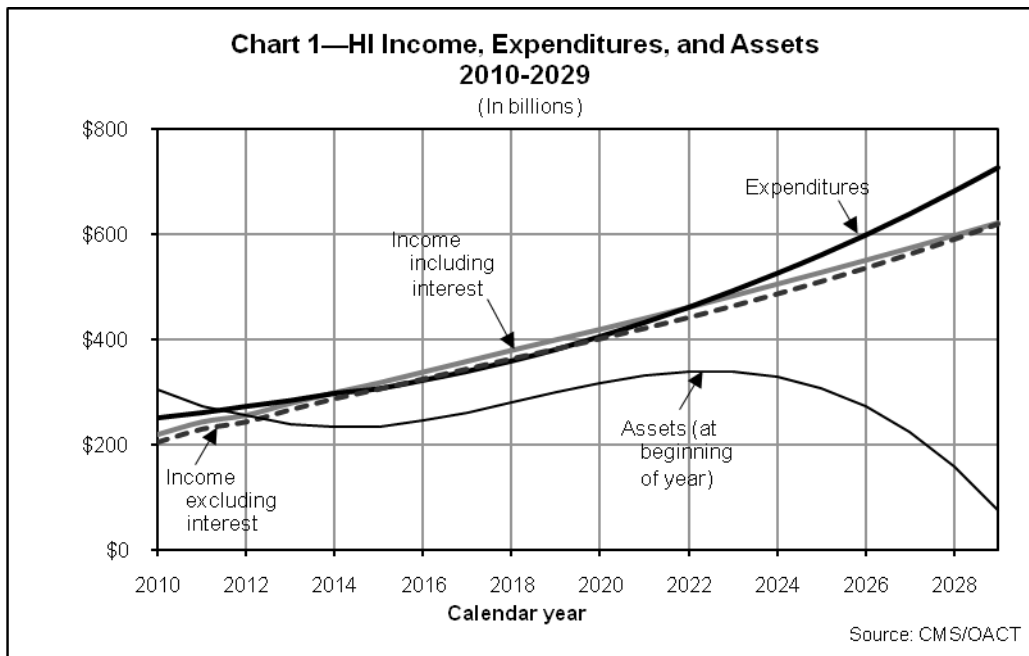
Cashflow in Nominal Dollars

Using nominal dollars for short-term projections paints a reasonably clear picture of expected performance with particular attention on cashflow and trust fund balances.² Over longer periods, however, the changing value of the dollar can complicate efforts to compare dollar amounts in different periods and can create severe barriers to interpretation, since projections must be linked to something that can be reasonably comprehended in today's experience.

For this reason, long-range (75-year) Medicare projections in nominal dollars are seldom used and are not presented in this section. Instead, nominal-dollar estimates for the HI Trust Fund are displayed only through the projected date of asset depletion, currently the year 2029. Corresponding estimates for SMI Parts B and D are presented only for the next 10 years, primarily due to the fact that under present law, the SMI Trust Fund is automatically in financial balance every year.

- *HI*

Chart 1 shows the actuarial estimates of HI income, expenditures, and assets for each of the years 2010 through 2029, in nominal dollars. Income includes payroll taxes, income from the taxation of Social Security benefits, interest earned on the U.S. Treasury securities held by the HI Trust Fund, and other miscellaneous revenue. Expenditures include benefit payments and administrative expenses. The estimates are for the "open group" population - all persons who will participate during the period as either HI taxpayers or beneficiaries, or both - and consist of payments from, and on behalf of, employees now in the workforce, as well as those who are expected to enter the workforce through 2029. The estimates also include income and expenditures attributable to these current and future workers, in addition to current beneficiaries.



HI expenditures initially exceeded income in 2008. As Chart 1 shows, they are expected to continue to do so through 2013, but then are projected to fall just below income each year through 2021 under the intermediate assumptions. This situation arises due to lower expenditures and additional revenues instituted by the *Affordable Care Act*. The HI Trust Fund is estimated to again start redeeming its assets in 2022; by the end of 2029, the assets would be depleted. Despite this improvement, the HI Trust Fund does

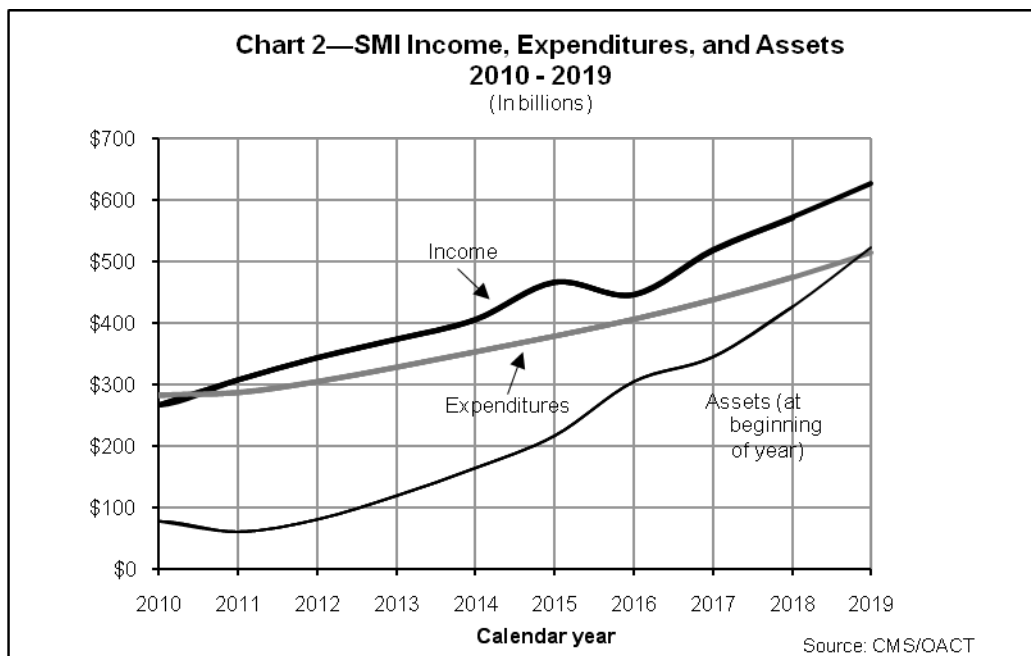
² Dollar amounts that are not adjusted for inflation or other factors are referred to as "nominal."

not meet an explicit test of short-range financial adequacy for the seventh year in a row, since assets are predicted to fall below expenditures within the next 10 years.

The projected year of depletion of the HI Trust Fund is very sensitive to assumed future economic and other trends. Under less favorable conditions the magnitude of the deficits could be greater and thereby accelerate asset exhaustion.

- *SMI*

Chart 2 shows the actuarial estimates of SMI income, expenditures, and assets, for Parts B and D combined, for each of the years 2010 through 2019, in nominal dollars. Income includes monthly premiums paid by, or on behalf of, beneficiaries, transfers from the general fund of the U.S. Treasury, certain payments by the States to the Part D account, fees related to brand-name prescription drugs, and interest earned on the U.S. Treasury securities held by the SMI Trust Fund.^{3,4} Chart 2 displays only total income; it does not separately show income excluding interest. The difference between the two depictions of income is not visible graphically since interest is not a significant source of income.⁵ Expenditures include benefit payments as well as administrative expenses.



SMI income is normally very close to expenditures because of the financing mechanism for Parts B and D. In particular, income for SMI Part B and Part D includes a combination of monthly beneficiary premiums and transfers from the general fund of the U.S. Treasury - both of which are established annually to cover the following year's expenditures. Under present law, both SMI accounts are automatically in financial balance every year, regardless of future economic and other conditions. The current-law projections shown in Chart 2 reflect the 30-percent reduction in Medicare payment rates for physician services that would be

³ Delivery of Social Security benefit checks normally due January 3, 2016 is expected to occur on December 31, 2015. Consequently, the Part B premiums withheld from the checks and the associated general revenue contributions are expected to be added to the Part B account on December 31, 2015. These amounts are excluded from the premium income and general revenue income for 2016, resulting in the income pattern shown in Chart 2.

⁴ Special payments from the States to the Part D account represent a portion of the States' forgone Medicaid expenditures attributable to the Medicare drug benefit. Beginning in 2011, the *Affordable Care Act* imposes fees on manufacturers and importers of brand-name prescription drugs; the revenue from these fees is allocated to the Part B account of the SMI Trust Fund.

⁵ Interest income is generally about one to two percent of total SMI income.

required in 2010-2012. Due to the high probability that these reductions will be overridden by new legislation, it is necessary to maintain a Part B contingency reserve that is much larger than normally required. The projected level of Part B income required for this purpose is significantly larger than the projected level of expenditures under current law, thus leading to the imbalance shown in Chart 2. In practice, either the physician reductions will occur (and a larger contingency reserve will be unnecessary) or, more likely, the reductions will not occur (and actual expenditures will be roughly in line with the projected income amounts shown above).

Maintaining adequate Part B premium and general revenue income, despite the impact of the premium "hold-harmless" provision, would require substantial premium increases for the roughly 25 percent of beneficiaries who are not subject to this provision. Such increases are assumed to occur, since no other mechanism is available under current law to ensure adequate income. The 2010 Medicare Trustees Report provides additional information on this issue.

HI Cashflow as a Percentage of Taxable Payroll

Each year, estimates of the financial and actuarial status of the HI Trust Fund are prepared for the next 75 years. It is difficult to meaningfully compare dollar values for different periods without some type of relative scale, therefore income and expenditure amounts are shown relative to the earnings in covered employment that are taxable under HI (referred to as "taxable payroll").

Chart 3 illustrates income (excluding interest) and expenditures as a percentage of taxable payroll over the next 75 years. Prior to the 2006 Trustees Report, the long-range increase in average expenditures per beneficiary was assumed to equal growth in per capita gross domestic product (GDP) plus one percentage point. Beginning with the 2006 report, the Board of Trustees adopted a refinement of these long-range growth assumptions. The refinement provides a smoother and more realistic transition from current Medicare cost growth rates, which have been significantly above the level of GDP growth, to the ultimate assumed level of GDP plus zero percent for the indefinite future.

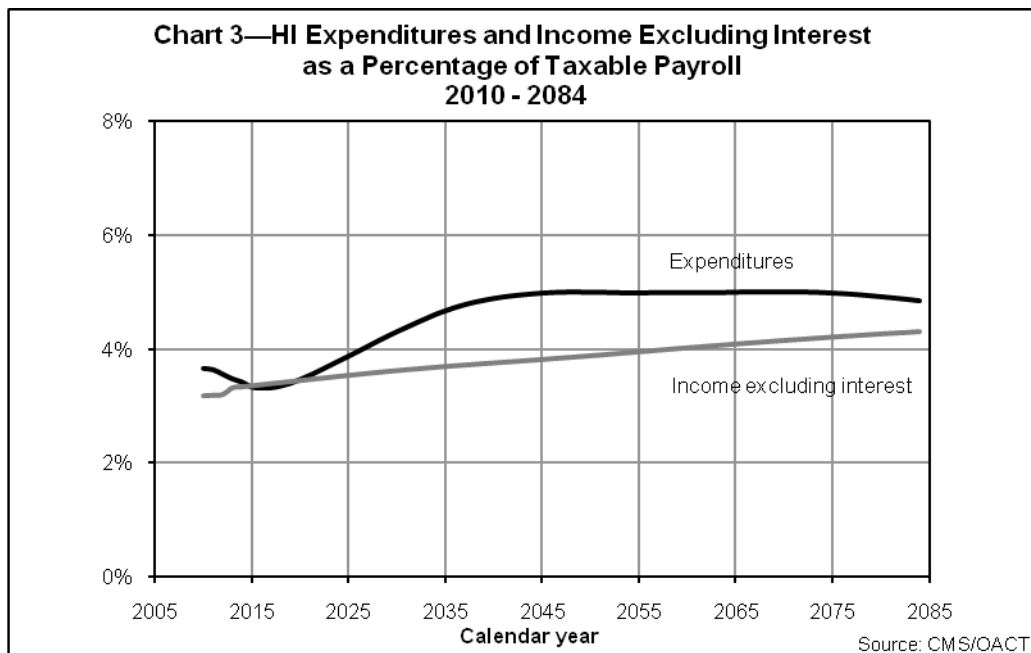
This same approach was used to establish "baseline" long-range growth rate assumptions for the 2010 Medicare Trustees Report, prior to the incorporation of the provisions in the *Affordable Care Act*. Under the Office of the Actuary's economic model, in 2034 the pre-*Affordable Care Act* growth rate for all Medicare services is assumed to be about 1.3 percentage points above the rate of GDP growth for that year (before demographic impacts). This differential gradually declines to about 0.8 percentage point in 2054 and to 0.3 percentage point in 2084. Compared to a constant "GDP plus one percent" assumption, the pre-*Affordable Care Act* baseline growth assumption is initially higher, but subsequently lower.

In order to incorporate the effects of the permanent Medicare price update reductions required by the *Affordable Care Act*, adjustments were made to the per capita growth rates produced by the economic model for Parts A and B.⁶ Since all Part A fee-for-service providers are affected, the assumed adjustment in each year is the full update reduction (1.1 percent).

For SMI Part B, only certain provider categories - for example, outpatient hospitals, ambulatory surgical centers, diagnostic laboratories, and most other non-physician services - are affected by the price update reductions. Accordingly, these services are subject to the same assumed long-range growth rate as Part A services. In contrast, Part B physician expenditures per beneficiary are increased at approximately the rate of per capita GDP growth, as required by the sustainable growth rate formula in current law. All other Part B outlays, which constitute an estimated 16.8 percent of total Part B expenditures in 2019, have an assumed average growth rate of per capita GDP plus 1 percent (adjusted by the economic model), as determined for the pre-*Affordable Care Act* "baseline" growth trend.

Based on these projections, the Medicare Trustees apply a formal test of "long-range close actuarial balance." The HI Trust Fund fails this test, as it has for many years.

⁶ The price update reductions do not affect Part D, and therefore the growth assumption for this account continues to be based on the pre-*Affordable Care Act* baseline growth of GDP plus one percent, as adjusted by the economic model.



Since the standard HI payroll tax rates are not scheduled to change in the future under present law, most payroll tax income as a percentage of taxable payroll is estimated to remain constant at 2.90 percent. Under the *Affordable Care Act*, however, high-income workers will pay an additional 0.9 percent of their earnings above \$200,000 (for single workers) or \$250,000 (for married couples filing joint income tax returns) in 2013 and later. Because these income thresholds are not indexed, over time an increasing proportion of workers will become subject to the additional HI tax rate, and consequently, total HI payroll tax revenues will increase steadily as a percentage of taxable payroll. Income from taxation of benefits will also increase as a greater proportion of Social Security beneficiaries become subject to such taxation, since the income thresholds determining taxable benefits are not indexed for price inflation. Thus, as Chart 3 shows, the income rate is expected to gradually increase over current levels.

As indicated in Chart 3, the cost rate will initially decline as the economy recovers from the recent recession and as the savings provisions of the *Affordable Care Act* take effect. Subsequently, the cost rate will increase significantly due to retirements of those in the baby boom generation and continuing health services cost growth. The effect of these factors will be largely offset in 2045 and later under current law by the accumulating effect of the reduction in provider price updates, which will reduce annual HI cost growth by an estimated 1.1 percent per year. If the slower price updates are not feasible in the long range, and are phased out during 2020-2034, then the HI cost rate would be 4.5 percent in 2030 and 8.9 percent in 2080. These levels are about 5 percent and 80 percent higher, respectively, than the current-law estimates under the intermediate assumptions, illustrating the very strong impact of the market basket reductions scheduled in current law.

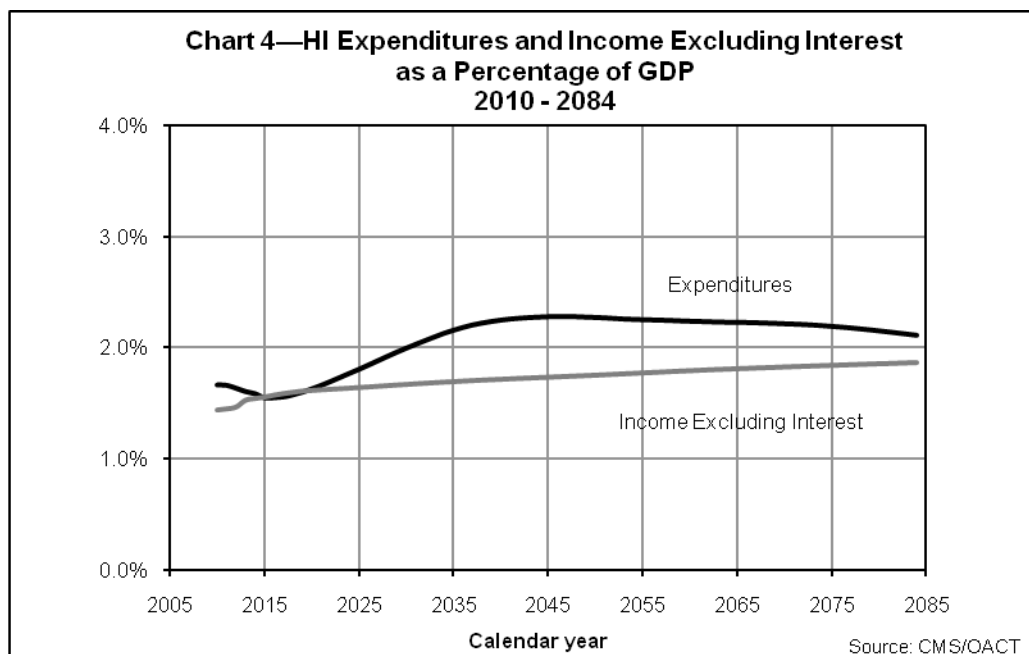
HI and SMI Cashflow as a Percentage of GDP

Expressing Medicare incurred expenditures as a percentage of GDP gives a relative measure of the size of the Medicare program compared to the general economy. The GDP represents the total value of goods and services produced in the United States. This measure provides an idea of the relative financial resources that will be necessary to pay for Medicare services.

- *HI*

Chart 4 shows HI income (excluding interest) and expenditures over the next 75 years expressed as a percentage of GDP. In 2009, the expenditures were \$242.5 billion, which was 1.7 percent of GDP. This percentage is projected to increase steadily through 2046 and then decrease throughout the remainder of the 75-year period, as the accumulated effects of the price update reductions are realized. Based on the

illustrative alternative projections⁷, HI costs as a percentage of GDP would increase steadily throughout the long-range projection period, reaching 4.0 percent in 2084.



- *SMI*

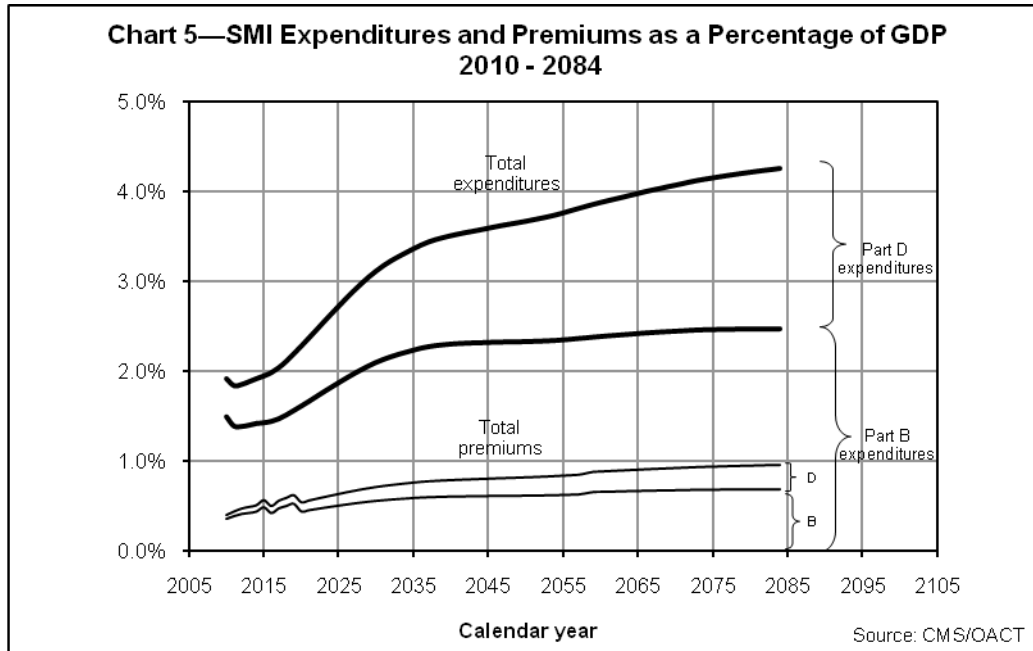
Because of the Part B and Part D financing mechanism in which income mirrors expenditures, it is not necessary to test for long-range imbalances between income and expenditures. Rather, it is more important to examine the projected rise in expenditures and the implications for beneficiary premiums and Federal general revenue payments.

Chart 5 shows projected total SMI (Part B and Part D) expenditures and premium income as a percentage of GDP. As in the projections for HI, the assumed long-range increase in average expenditures per beneficiary incorporates the effects of the *Affordable Care Act*. The growth rates are estimated year by year for the next 10 years, reflecting the impact of specific statutory provisions. Expenditure growth for years 11 to 25 is assumed to grade smoothly into the long-range assumption described previously.

Under the intermediate assumptions, annual SMI expenditures were \$266.5 billion, or about 1.9 percent of GDP, in 2009. Then, in about 25 years, they would grow to roughly 3.3 percent of GDP and to approximately 4.3 percent by the end of the projection period. Total SMI expenditures in 2084 would be almost 7 percent of GDP under the illustrative alternative projection⁸.

⁷ At the request of the Trustees, the Office of the Actuary at CMS has prepared an illustrative set of Medicare Trust Fund projections under this theoretical alternative to current law. No endorsement of the illustrative alternative to current law by the Trustees, CMS, or the Office of the Actuary should be inferred.

⁸ At the request of the Trustees, the Office of the Actuary at CMS has prepared an illustrative set of Medicare Trust Fund projections under this theoretical alternative to current law, which assumes that the (i) physician payment rates would be updated using the Medicare economic index, rather than through the sustainable growth rate (SGR) process; and (ii) the productivity adjustments would be gradually phased out starting in 2020. No endorsement of the illustrative alternative to current law by the Trustees, CMS, or the Office of the Actuary should be inferred.

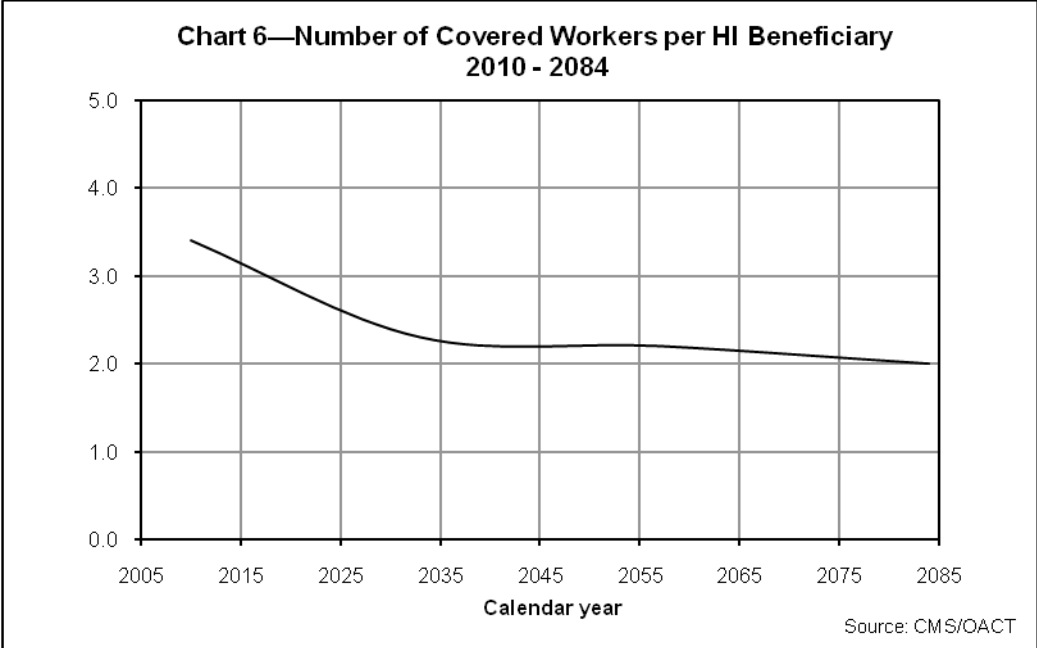


To match the faster growth rates for SMI expenditures, beneficiary premiums, along with general revenue contributions, would increase more rapidly than GDP over time. In fact, average per-beneficiary costs for Part B and Part D benefits are projected to increase after 2011 by about 4.3 percent annually. The associated beneficiary premiums—and general revenue financing—would increase by approximately the same rate. The special State payments to the Part D account are set by law at a declining portion of the States’ forgone Medicaid expenditures attributable to the Medicare drug benefit. The percentage was 90 percent in 2006, phasing down to 75 percent in 2015 and later. Then, after 2015, the State payments are also expected to increase faster than GDP.

Worker-to-Beneficiary Ratio

- *HI*

Another way to evaluate the long-range outlook of the HI Trust Fund is to examine the projected number of workers per HI beneficiary. Chart 6 illustrates this ratio over the next 75 years. For the most part, current benefits are paid for by current workers. The retirement of the baby boom generation will therefore be financed by the relatively smaller number of persons born after the baby boom. In 2009, every beneficiary had 3.5 workers to pay for his or her benefit. In 2030, however, after the last baby boomer turns 65, there will be only about 2.3 workers per beneficiary. The projected ratio continues to decline until there are just 2.0 workers per beneficiary by 2084.



SENSITIVITY ANALYSIS

In order to make projections regarding the future financial status of the HI and SMI Trust Funds, various assumptions have to be made. First and foremost, the estimates presented here are based on the assumption that both trust funds will continue under present law. In addition, the estimates depend on many economic and demographic assumptions. Because of revisions to these assumptions, due to either changed conditions or updated information, estimates sometimes change substantially compared to those made in prior years. Furthermore, it is important to recognize that actual conditions may likely differ from the projections presented here, since the future cannot be anticipated with certainty.

In order to illustrate the sensitivity of the long-range projections, six of the key assumptions were varied individually to determine the impact on the HI actuarial present values and net cashflows.⁹ The assumptions varied are the health care cost factors, real-wage differential, consumer price index (CPI), real-interest rate, fertility rate, and net immigration.¹⁰

For this analysis, the intermediate economic and demographic assumptions in the *2010 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds* are used as the reference point. Each selected assumption is varied individually to produce three scenarios. All present values are calculated as of January 1, 2010, and are based on estimates of income and expenditures during the 75-year projection period.

Charts 7 through 12 show the net annual HI cashflow in nominal dollars and the present value of this net cashflow for each assumption varied.¹¹ The charts depicting the estimated net cashflow indicate that, for the most part, net cashflow decreases through 2084 under both the intermediate assumptions and the more pessimistic assumptions. However, under the more optimistic assumptions, net cashflow begins to increase at different times throughout the projection period, depending on the assumptions being varied. This increase is the result of the combined effect of (i) lower expenditures due to the continued provider payment update reductions required by the *Affordable Care Act*, and (ii) higher income as more and more workers become subject to the additional HI payroll tax rate, which is also mandated by the new legislation.

On the present value charts, under all three scenarios the present values initially increase, as the effects of the *Affordable Care Act* result in trust fund surpluses, and then decrease until about 2040 when they start to increase (or become less negative) once again. This pattern occurs in part because of the discounting process used for computing present values, which is used to help interpret the net cashflow deficit in terms of today's dollar. In other words, the amount required to cover this deficit, if made available and invested today, begins to decrease at the end of the 75-year period, reflecting the long period of interest accumulation that would occur. The pattern is also affected by the accumulating impact of the lower Medicare price updates over time and the greater proportion of workers who will be subject to the higher HI payroll tax rate, as noted above.

Health Care Cost Factors

Table 1 shows the net present value of cashflow during the 75-year projection period under three alternative assumptions for the annual growth rate in the aggregate cost of providing covered health care services to beneficiaries. These assumptions are that the ultimate annual growth rate in such costs, relative to taxable payroll, will be one percent slower than the intermediate assumptions, the same as the intermediate assumptions, and one percent faster than the intermediate assumptions. In each case, the taxable payroll will be the same as that which was assumed for the intermediate assumptions.

⁹ Sensitivity analysis is not done for Parts B or D of the SMI Trust Fund due to the financing mechanism for each account. Any change in assumptions would have a negligible impact on the net cashflow, since the change would affect income and expenditures equally.

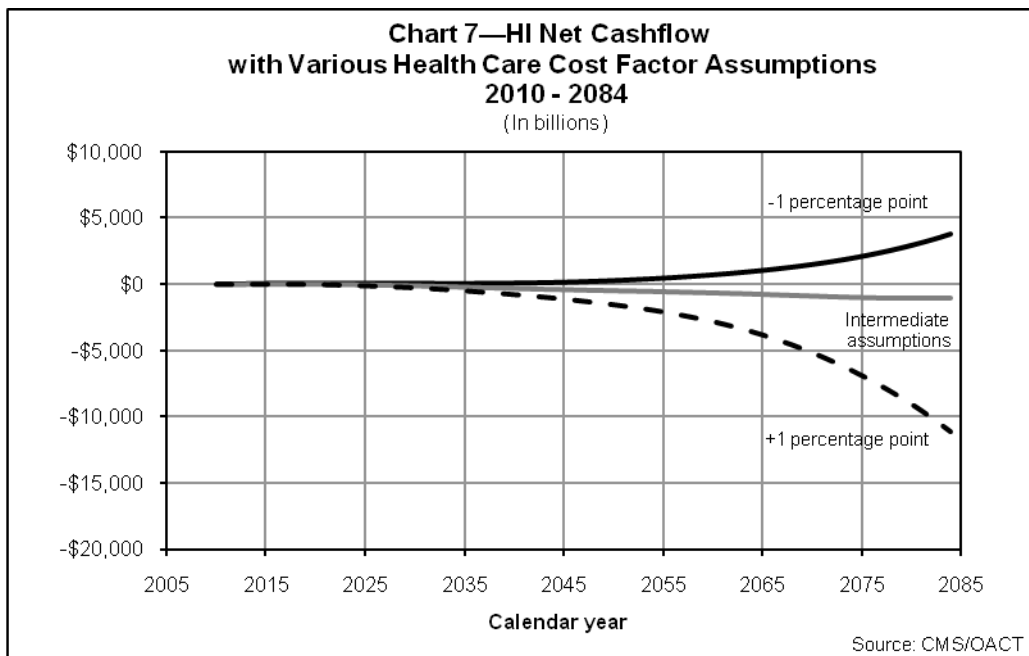
¹⁰ The sensitivity of the projected HI net cash flow to variations in future mortality rates is also of interest. At this time, however, relatively little is known about the relationship between improvements in life expectancy and the associated changes in health status and per beneficiary health expenditures. As a result, it is not possible at present to prepare meaningful estimates of the HI mortality sensitivity.

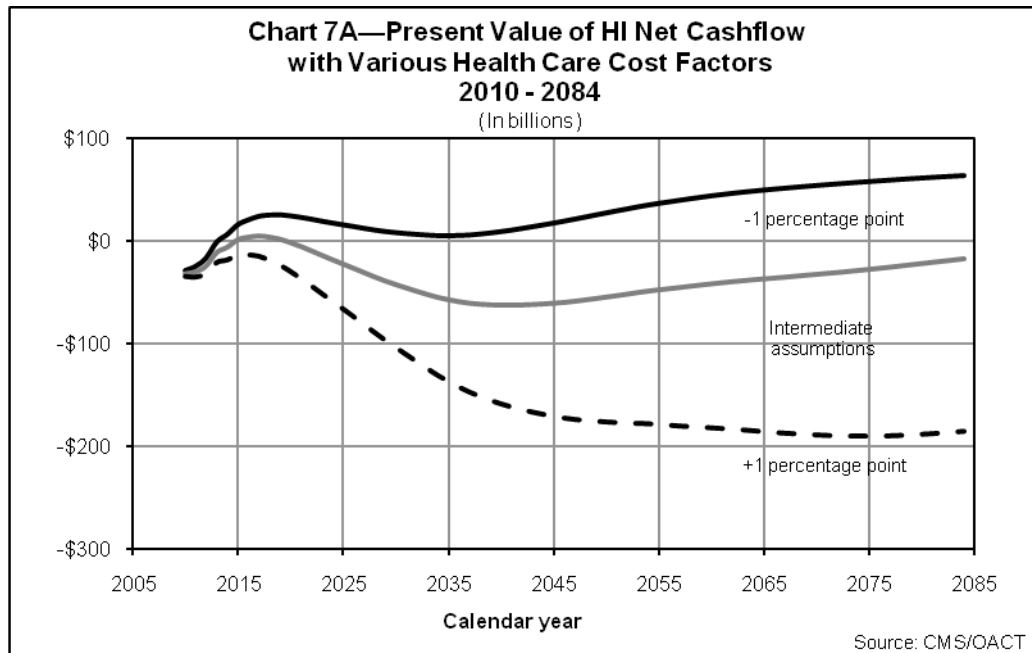
¹¹ As noted previously, long-range projections expressed in nominal dollar amounts can be very difficult to interpret, due to the changing value of the dollar over time. Amounts expressed in present values are less subject to this difficulty.

Table 1 demonstrates that if the ultimate growth rate assumption is one percentage point lower than the intermediate assumptions, the deficit decreases by \$4,829 billion. On the other hand, if the ultimate growth rate assumption is one percentage point higher than the intermediate assumptions, the deficit increases substantially, by \$7,663 billion.

Table 1—Present Value of Estimated HI Income Less Expenditures Under Various Health Care Cost Growth Rate Assumptions			
Annual cost/payroll relative growth rate	-1 percentage point	Intermediate assumptions	+1 percentage point
Income minus expenditures (in billions)	\$2,146	\$(2,683)	\$(10,346)

Charts 7 and 7A show projections of the net cashflow in nominal and present value dollars, respectively, under the three alternative annual growth rate assumptions presented in Table 1.





This assumption has a dramatic impact on projected HI cashflow. The net cashflow under the ultimate growth rate assumption of one percentage point lower than the intermediate assumption actually becomes a surplus and remains positive throughout the entire period, due to the improved financial outlook for the HI Trust Fund as a result of the *Affordable Care Act*. Several factors, such as the utilization of services by beneficiaries or the relative complexity of services provided, can affect costs without affecting tax income. As charts 7 and 7A indicate, the financial status of the HI Trust Fund is extremely sensitive to the relative growth rates for health care service costs.

Real-Wage Differential

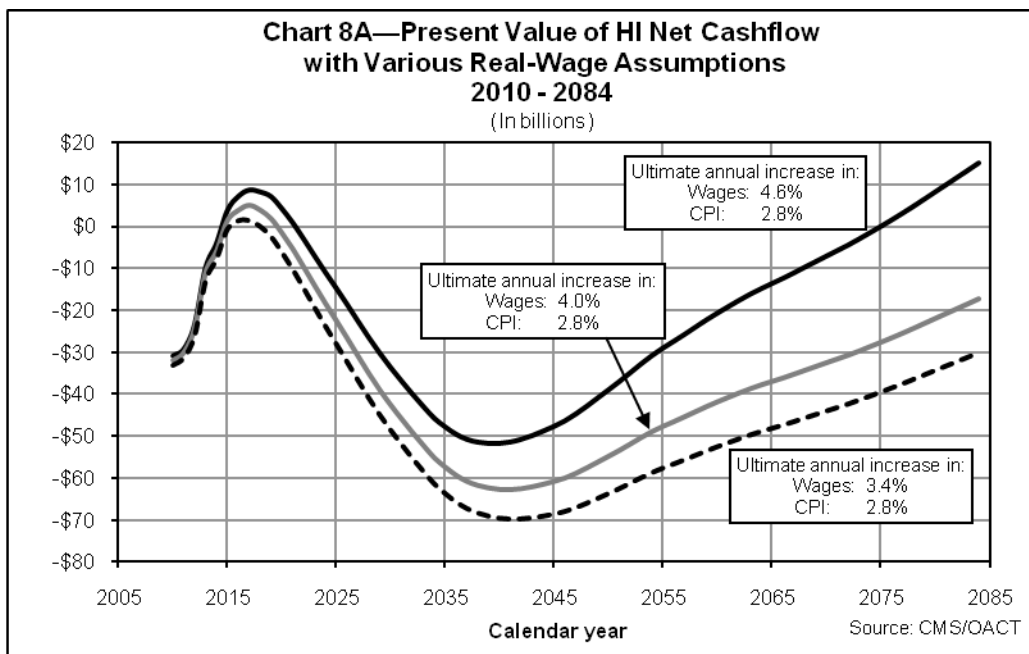
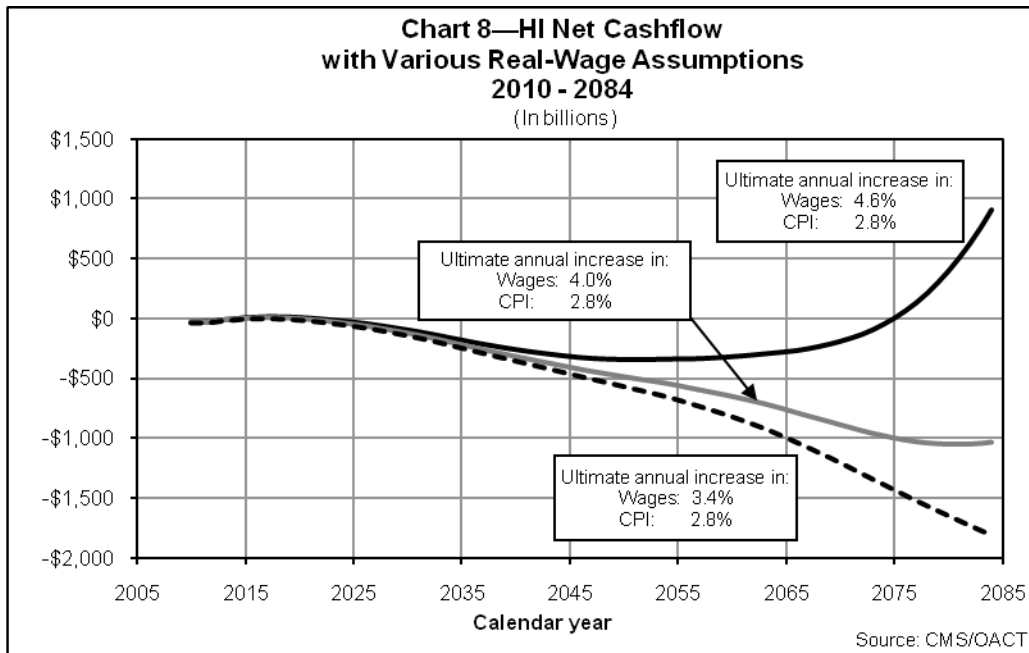
Table 2 shows the net present value of cashflow during the 75-year projection period under three alternative ultimate real-wage differential assumptions: 0.6, 1.2, and 1.8 percentage points.¹² In each case, the ultimate CPI increase is assumed to be 2.8 percent, yielding ultimate percentage increases in average annual wages in covered employment of 3.4, 4.0, and 4.6 percent, respectively.

	3.4 - 2.8	4.0 - 2.8	4.6 - 2.8
Ultimate percentage increase in wages - CPI	3.4 - 2.8	4.0 - 2.8	4.6 - 2.8
Ultimate percentage increase in real-wage differential	0.6	1.2	1.8
Income minus expenditures (in billions)	\$(3,284)	\$(2,683)	\$(1,507)

As indicated in Table 2, for a half-point increase in the ultimate real-wage differential assumption, the deficit - expressed in present-value dollars - increases by approximately \$740 billion.

Charts 8 and 8A show projections of the net cashflow under the three alternative real-wage differential assumptions presented in Table 2.

¹² The real-wage differential is the difference between the percentage increases in the average annual wage in covered employment and the average annual CPI.



As illustrated in Charts 8 and 8A, faster real-wage growth results in smaller HI cashflow deficits, when expressed in either nominal or present-value dollars. A higher real-wage differential immediately increases both HI expenditures for health care and wages for all workers. There is a full effect on wages and payroll taxes, but the effect on benefits is only partial, since not all health care costs are wage-related. These results are different than in past reports mainly due to the much closer financial balance under the *Affordable Care Act*. In prior reports, the deficit was increased under the higher real-wage assumptions on both a nominal-dollar and present-value basis, since the dollar impact on expenditures was higher than the dollar impact on income. This is not the case with this year's projections because (i) expenditures are substantially reduced from last year due to the continued payment update reductions for all HI fee-for-service providers that are required by the new legislation, and (ii) income is higher than last year's projection as a result of the additional HI tax rate for high-income earners, which is also required by the

Affordable Care Act. This reversal in the direction of the impact of higher real-wage growth illustrates a limitation of the use of nominal or present-value cashflows as a measure of financial status; in practice, faster real-wage growth always improves the financial status of the HI Trust Fund, regardless of whether there is a small or large imbalance between income and expenditures. Also, as noted previously, the closer financial balance for the HI Trust Fund under the *Affordable Care Act* depends on the long-range feasibility of the lower Medicare price updates for hospitals and other HI providers. There is a strong likelihood that certain of these changes will not be viable in the long range. Specifically, the annual price updates for most categories of non-physician health services will be adjusted downward each year by the growth in the economy-wide productivity.

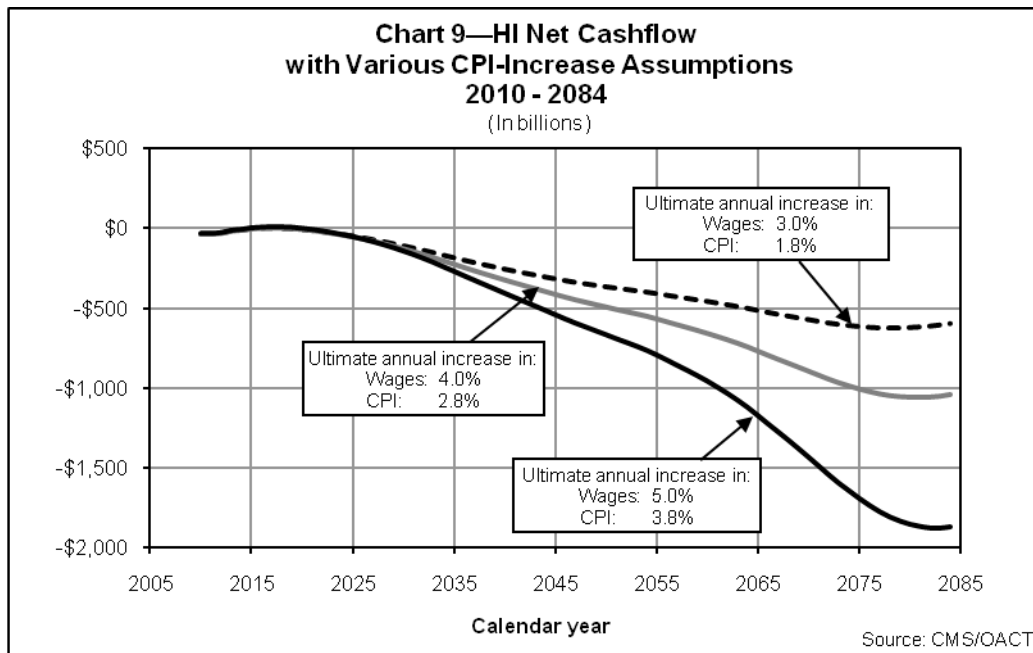
Consumer Price Index

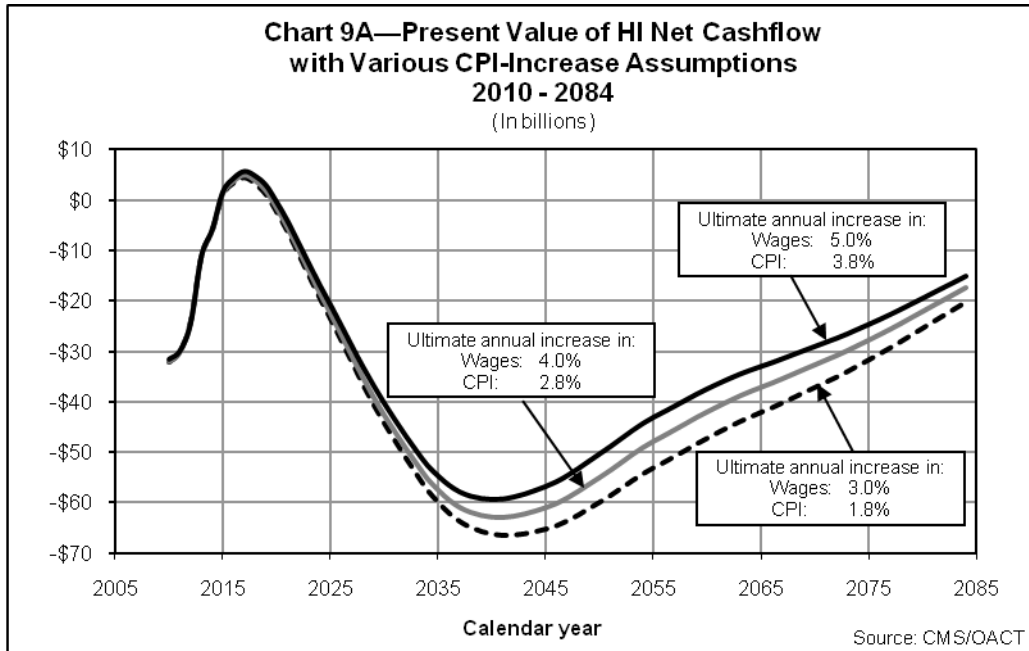
Table 3 shows the net present value of cashflow during the 75-year projection period under three alternative ultimate CPI rate-of-increase assumptions: 1.8, 2.8, and 3.8 percent. In each case, the ultimate real-wage differential is assumed to be 1.2 percent, yielding ultimate percentage increases in average annual wages in covered employment of 3.0, 4.0, and 5.0 percent, respectively.

Table 3—Present Value of Estimated HI Income Less Expenditures under Various CPI-Increase Assumptions			
Ultimate percentage increase in wages - CPI	3.0 - 1.8	4.0 - 2.8	5.0 - 3.8
Income minus expenditures (in Billions)	\$(2,924)	\$(2,683)	\$(2,466)

Table 3 demonstrates that if the ultimate CPI-increase assumption is 1.8 percent, the deficit increases by \$241 billion. On the other hand, if the ultimate CPI-increase assumption is 3.8 percent, the deficit decreases by \$217 billion.

Charts 9 and 9A show projections of the net cashflow under the three alternative CPI rate-of-increase assumptions presented in Table 3.





As Charts 9 and 9A indicate, this assumption has a large impact on projected HI cashflow in nominal dollars and a much smaller impact when the cashflow is expressed as present values. For the nominal cashflow, Chart 9 appears to suggest that the outlook for the HI Trust Fund worsens substantially with faster CPI growth. In practice, however, higher or lower long-term trends in inflation have only a modest impact on the financial status of the trust fund. Moreover, the impact is in the opposite direction of that suggested by the nominal cashflow sensitivity. In this instance, the results expressed in nominal dollar terms do not reveal the full implications of faster or slower growth in inflation. That is, under high-inflation conditions, a given deficit “looks bigger” in nominal dollars but is much smaller when expressed as a present value or relative to taxable payroll. This sensitivity test serves as a useful example of the limitations of nominal-dollar projections over long periods. The relative insensitivity of the projected present values of HI cashflow to different levels of general inflation occurs because inflation tends to affect both income and costs in a similar manner. In present value terms, a smaller deficit results under high-inflation conditions because the present values of HI expenditures are not significantly different under the various CPI scenarios, but under high-inflation conditions the present value of HI income increases as more people become subject to the additional 0.9-percent HI tax rate required by the *Affordable Care Act* for workers with earnings above \$200,000 or \$250,000 (for single and joint income-tax filers, respectively). Since the thresholds are not indexed, additional workers become subject to the additional tax more quickly under conditions of faster inflation, and vice-versa.

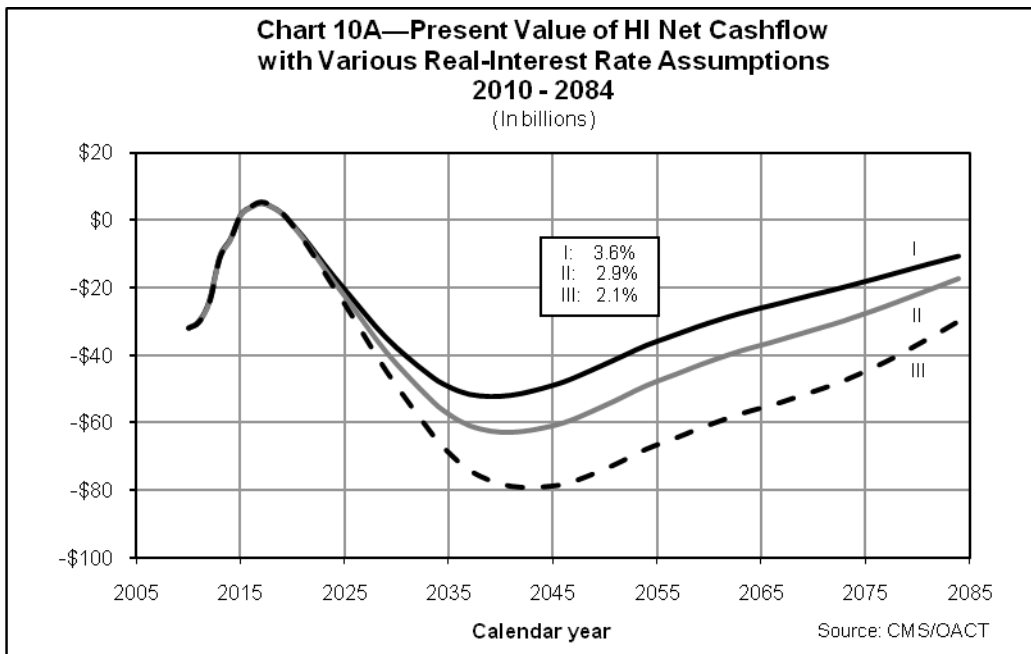
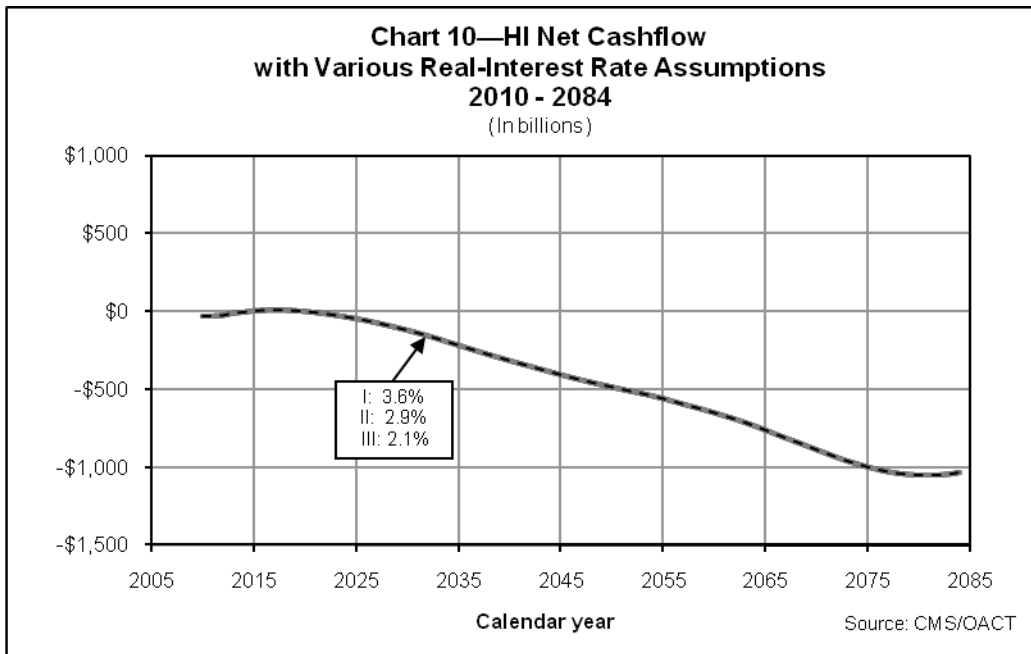
Real-Interest Rate

Table 4 shows the net present value of cashflow during the 75-year projection period under three alternative ultimate real-interest assumptions: 2.1, 2.9, and 3.6 percent. In each case, the ultimate annual increase in the CPI is assumed to be 2.8 percent, resulting in ultimate nominal annual yields of 4.9, 5.7, and 6.4 percent, respectively.

Table 4—Present Value of Estimated HI Income Less Expenditures under Various Real-Interest Assumptions			
Ultimate real-interest rate	2.1 percent	2.9 percent	3.6 percent
Income minus expenditures (in Billions)	\$(3,603)	\$(2,683)	\$(2,107)

As illustrated in Table 4, for every increase of 0.1 percentage point in the ultimate real-interest rate, the deficit decreases by approximately \$100 billion.

Charts 10 and 10A show projections of the net cashflow under the three alternative real-interest assumptions presented in Table 4.



As shown in Charts 10 and 10A, the projected HI cashflow when expressed in present values is more sensitive to the interest assumption than when it is expressed in nominal dollars. This is not an indication of the actual role that interest plays in HI financing. In actuality, interest finances very little of the cost of the HI Trust Fund because, under the intermediate assumptions, the fund is projected to be relatively low and exhausted by 2029. These results illustrate the substantial sensitivity of present value measures to different interest rate assumptions. With higher assumed interest, the very large deficits in the more

distant future are discounted more heavily (that is, are given less weight), resulting in a smaller overall net present value.

Compared to past reports, however, the sensitivity of present values to different real-interest rate assumptions is substantially reduced as a result of the *Affordable Care Act*. Under the new legislation, annual deficits would decrease due to the compounding effects of the price update reductions for HI fee-for-service providers. Discounting a relatively level series by high or low interest factors has much less effect than when the series is increasing rapidly, as with the pre-*Affordable Care Act* projections.

Fertility Rate

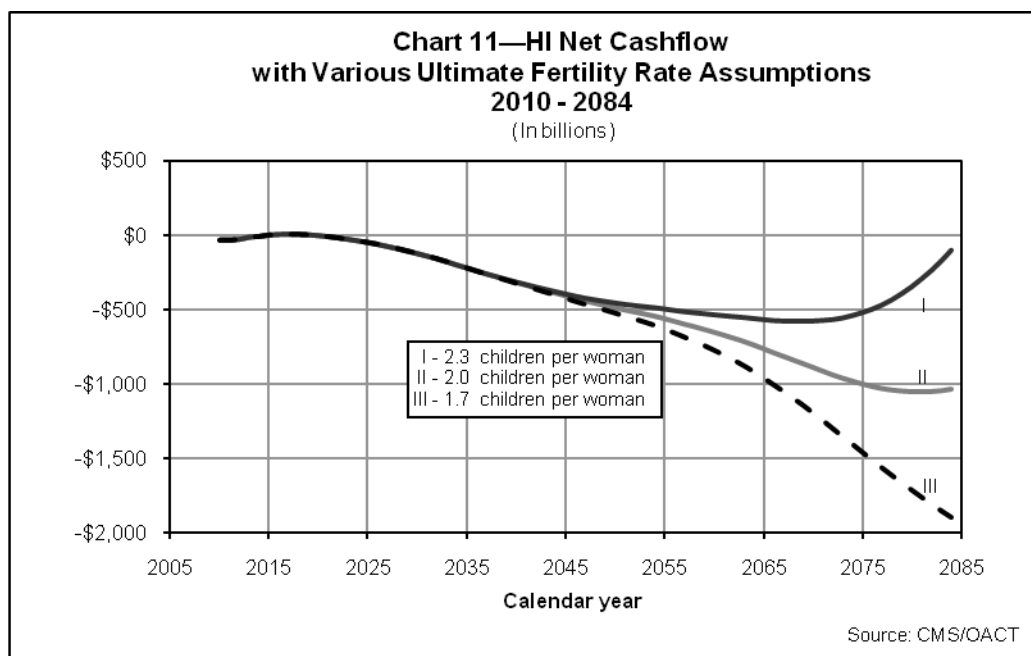
Table 5 shows the net present value of cashflow during the 75-year projection period under three alternative ultimate fertility rate assumptions: 1.7, 2.0, and 2.3 children per woman.

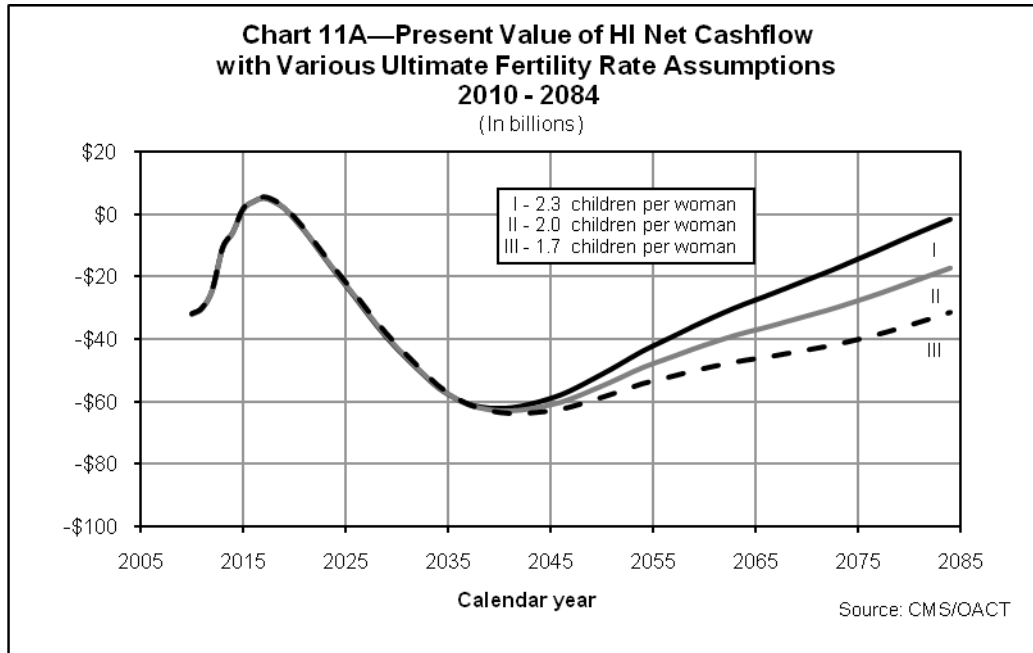
Table 5—Present Value of Estimated HI Income Less Expenditures Under Various Fertility Rate Assumptions			
Ultimate fertility rate ¹	1.7	2.0	2.3
Income minus expenditures (in Billions)	\$(3,035)	\$(2,683)	\$(2,308)

¹The total fertility rate for any year is the average number of children who would be born to a woman in her lifetime if she were to experience the birth rates by age observed in, or assumed for, the selected year and if she were to survive the entire childbearing period.

As Table 5 demonstrates, for an increase of 0.3 in the assumed ultimate fertility rate, the projected present value of the HI deficit decreases by approximately \$360 billion.

Charts 11 and 11A show projections of the net cashflow under the three alternative fertility rate assumptions presented in Table 5.





As Charts 11 and 11A indicate, the fertility rate assumption has a fairly large impact on projected HI cashflows. This result is different than in past reports mainly due to the additional HI tax on high-income earners required by the *Affordable Care Act*. Under the higher fertility rate assumptions, there will be additional workers in the labor force after 20 years, as in past reports, but their impact on future HI taxes will be relatively greater, since many will become subject to the additional HI tax, thereby lowering the deficit proportionately more on both a nominal- and present-value-dollar basis. Under the lower fertility rate assumptions, on the other hand, there will be fewer workers in the workforce with a smaller number subject to the additional tax, in turn raising the HI deficit.

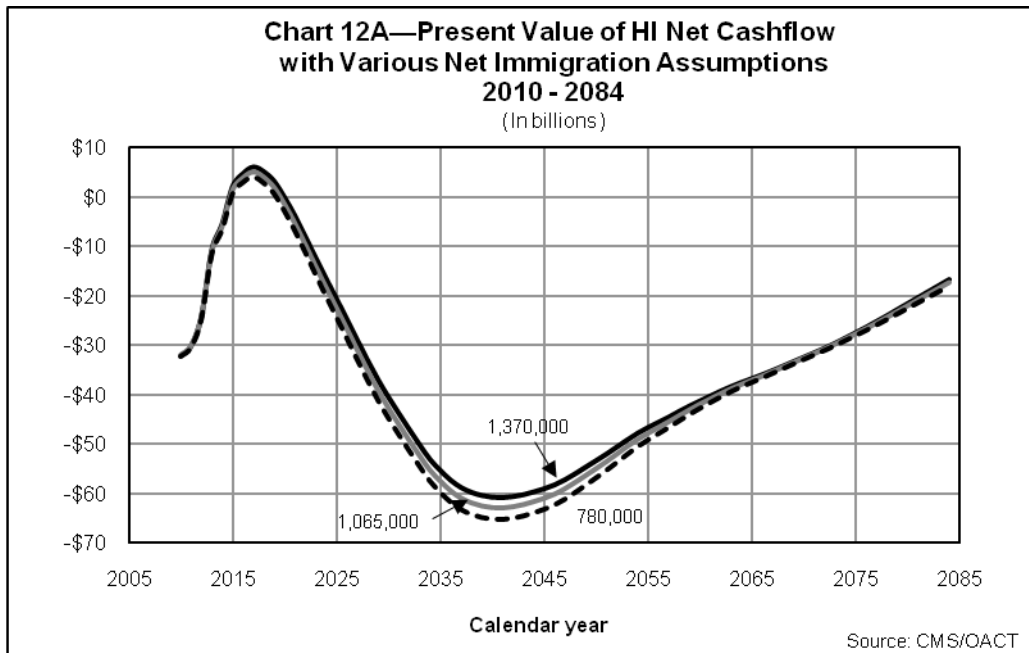
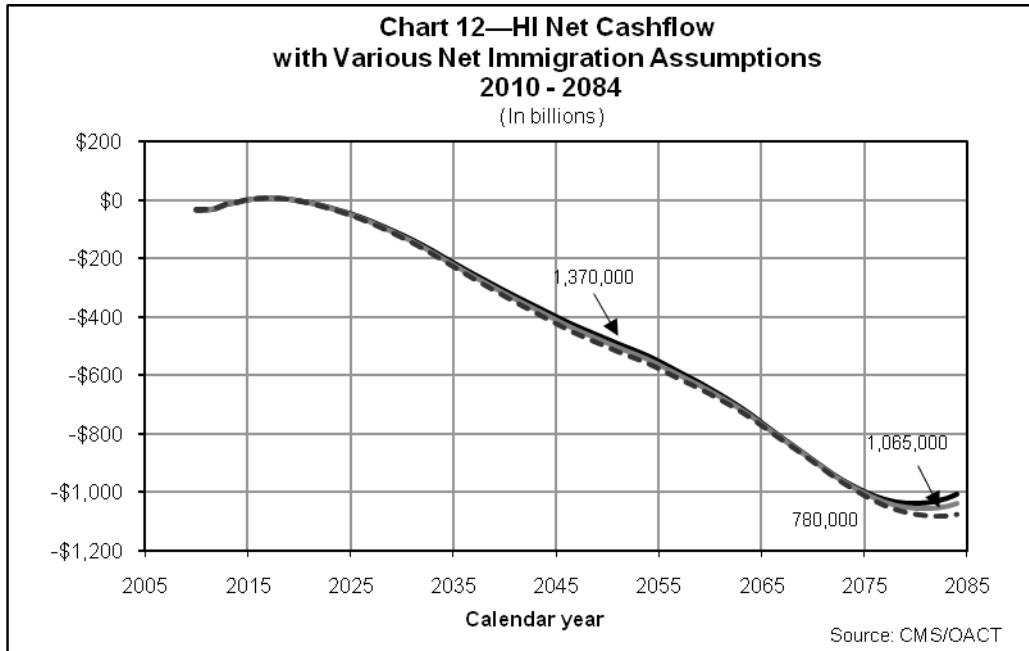
Net Immigration

Table 6 shows the net present value of cashflow during the 75-year projection period under three alternative average annual net immigration assumptions: 780,000 persons, 1,065,000 persons, and 1,370,000 persons per year.

Average annual net immigration	780,000	1,065,000	1,370,000
Income minus expenditures (in billions)	\$(2,774)	\$(2,683)	\$(2,605)

As indicated in Table 6, if the average annual net immigration assumption is 780,000 persons, the deficit - expressed in present-value dollars - increases by \$91 billion. Conversely, if the assumption is 1,370,000 persons, the deficit decreases by \$78 billion.

Charts 12 and 12A show projections of the net cashflow under the three alternative average annual net immigration assumptions presented in Table 6.



As illustrated in Charts 12 and 12A, higher net immigration results in smaller HI cashflow deficits, when expressed in either nominal or present-value dollars. Since immigration tends to occur most often among people at working ages, who work and pay taxes into the HI system, a change in the net immigration assumption affects revenues from payroll taxes almost immediately. However, the impact on expenditures occurs later as those individuals age and become beneficiaries.

These results are different than in past reports mainly due to the various provisions in the *Affordable Care Act*. In prior reports, the deficit was increased under the higher-net immigration assumptions on both a nominal-dollar and present-value basis, since the cost of HI benefits for the additional participants was substantially greater than their HI taxes. This is not the case with this year's projections because (i) expenditures are substantially reduced from last year due to the continued payment update reductions

for all HI fee-for-service providers required by the *Affordable Care Act*, and (ii) income is higher than last year's projection as a result of the additional HI tax for high-income earners, which is also mandated by the new health-reform law. As shown in the SOSI, the value of the additional HI payroll taxes paid by new participants in the future, on average, will be greater than the cost of their benefits, assuming that the lower HI price updates can be continued indefinitely. As noted previously, there is a significant likelihood that the reductions in Medicare provider payment updates will not be feasible indefinitely.

TRUST FUND FINANCES AND SUSTAINABILITY

HI

The financial status of the HI Trust Fund is substantially improved by the lower expenditures and additional tax revenues instituted by the *Affordable Care Act*. These changes are estimated to postpone the exhaustion of trust fund assets from 2017 under the prior law to 2029 under current law. Despite this significant improvement, however, the fund is still not adequately financed over the next 10 years. HI expenditures have exceeded income annually since 2008 and are expected to continue to do so under current law through 2013 and again after 2021. The shortfalls can be met with increasing reliance on the redemption of trust fund assets, thereby adding to the draw on the Federal Budget. In the absence of corrective legislation, a depleted HI Trust Fund would initially produce payment delays, but very quickly lead to a curtailment of health care services to beneficiaries. In practice, Congress has never allowed a Medicare or Social Security Trust Fund to become fully depleted.

It is important to note that the improved outlook for the HI Trust Fund depends in part on the feasibility of the provider payment update reductions. There is a significant likelihood that these providers would not be able to reduce their cost growth rates sufficiently during this period to match the slower increases in Medicare payments per service, and in which case they would eventually become unable to continue providing health care services to Medicare beneficiaries. If such a situation occurred, and Congress overrode the productivity adjustments, then actual costs would be higher and the HI Trust Fund would be depleted somewhat sooner.

The HI Trust Fund remains out of financial balance in the long range. Bringing the fund into actuarial balance over the next 75 years under the intermediate assumptions would require significant increases in revenues and/or reductions in benefits. These changes are needed partially as a result of the impending retirement of the baby boom generation. If the productivity adjustments to HI provider price updates cannot be continued in the long run, then the actuarial deficit would be much greater.

SMI

Under current law, the SMI Trust Fund will remain adequate, both in the near term and into the indefinite future, because of the automatic financing established for Parts B and D. There is no authority to transfer assets between the Part D and Part B accounts, therefore, it is necessary to evaluate each account's financial adequacy separately.

The financing established for the Part B account for calendar year 2010 is adequate to cover 2010 expected expenditures and to maintain the financial status of the account in 2010 at a satisfactory level. The Part B cost projections are understated as a result of the substantial reductions in physician payments that would be required under current law and are further understated if the reductions in future price updates for most other Part B providers are not feasible. Actual future Part B costs will depend on the steps that Congress might choose to take to address these situations.

No financial imbalance is anticipated for the Part D account, since the general revenue subsidy for this benefit is drawn on a daily, as-needed basis. The projected Part D costs shown in this section are somewhat lower than previously estimated, primarily due to lower assumed growth rates for prescription drug expenditures in the U.S. overall.

For both the Part B and Part D accounts, beneficiary premiums and general revenue transfers will be set to meet expected costs each year. Such financing, however, would have to increase faster than the economy to match expected expenditure growth under current law. Absent legislation, it will probably be necessary to significantly raise Part B premiums for a subset of beneficiaries in 2011 and 2012 to ensure adequate program financing. A critical issue for the SMI Trust Fund continues to be the impact of the past and expected rapid growth of SMI costs, which place gradually increasing demands on beneficiaries, the Federal Budget, and society at large.

Medicare Overall

The *Medicare Modernization Act* requires the Board of Trustees to determine whether the difference between Medicare outlays and "dedicated financing sources" is projected to exceed 45 percent of total

Medicare outlays within the next 7 fiscal years (2010-2016).¹³ This difference first exceeded 45 percent of total expenditures at the end of calendar year 2009 and is expected to do so in fiscal year 2010, which is the first year of the 7-year test period. Consequently, the Trustees issued a determination of projected “excess general revenue Medicare funding,” as required by law. Similar determinations were made in their 2006-2009 annual reports to Congress. With this fifth consecutive finding, another “Medicare funding warning” is triggered this year, indicating that the general revenues provided to Medicare under current law are becoming a substantial proportion of total program costs. This finding requires the President to submit to Congress, within 15 days after the release of the next budget, proposed legislation to respond to the warning. Congress is then required to consider this legislation on an expedited basis.¹⁴ This requirement helps to call attention to Medicare’s impact on the Federal Budget.

The Medicare financial projections shown in this section represent a substantial, but very uncertain, improvement over those in recent years because of the far-reaching provisions of the *Affordable Care Act*. In the long range, much of this improvement depends on the feasibility of the *Affordable Care Act*’s downward adjustments to future increases in Medicare prices for most categories of health care providers. Although these projections show substantially improved results over last year’s, they continue to demonstrate the need for timely and effective action to address the remaining financial challenges facing Medicare—including the projected exhaustion of the HI Trust Fund, this fund’s long-range financial imbalance, and the issue of rapid growth in Medicare expenditures. Furthermore, if the lower prices payable for health services under Medicare are overridden, the financial challenges in the long range would be much more severe. In their 2010 annual report to Congress, the Medicare Boards of Trustees emphasized the seriousness of these concerns and urged the nation’s policymakers to take “prompt action ... to address these challenges.” They also stated: “Consideration of ... further reforms should occur in the near future.”

¹³ Dedicated Medicare financing sources include HI payroll taxes; income from taxation of Social Security benefits; State transfers for the prescription drug benefit; premiums paid under Parts A, B, and D; fees allocated to Part B related to brand-name prescription drugs; and any gifts received by the Medicare Trust Funds.

¹⁴ In January 2009, the House of Representatives passed a resolution (H. Res.5, section 3(e)) stating that section 803 of the Medicare Modernization Act, governing action required by the House in response to a funding warning, would not apply to the 111th Congress.

Section III: Other Accompanying Information

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Section III: Other Accompanying Information

This section contains other financial information, HHS' detailed *Improper Payments Information Act of 2002 Report*, summary of financial statement audit and management assurance findings, the HHS Inspector General's summary of the most significant management and performance challenges facing the Department, and the Department's response to the Inspector General's assessment.

OTHER FINANCIAL INFORMATION

CONSOLIDATING BALANCE SHEET BY BUDGET FUNCTION As of September 30, 2010 (in Millions)

	Education, Training & Social Services	Health	Medicare	Income Security	Agency Combined Totals	Intra-HHS Eliminations	HHS Consolidated Totals
Assets (Note 2)							
Intragovernmental							
Fund Balance with Treasury (Note 3)	\$ 10,024	\$ 154,917	\$ 1,996	\$ 15,298	\$ 182,235	\$ -	\$ 182,235
Investments, Net (Note 4)	-	5,379	354,503	-	359,882	-	359,882
Accounts Receivable, Net (Note 5)	57	1,309	50,015	7	51,388	(50,251)	1,137
Other (Note 8)	-	299	4	-	303	(204)	99
Total Intragovernmental	10,081	161,904	406,518	15,305	593,808	(50,455)	543,353
Accounts Receivable, Net (Note 5)	-	3,017	4,377	-	7,394	-	7,394
Inventory and Related Property, Net (Note 6)	-	6,077	-	-	6,077	-	6,077
General Property, Plant & Equipment, Net (Note 7)	-	4,891	372	-	5,263	-	5,263
Other (Note 8)	-	489	1,163	-	1,652	-	1,652
Total Assets	\$ 10,081	\$ 176,378	\$ 412,430	\$ 15,305	\$ 614,194	\$ (50,455)	\$ 563,739
Stewardship PP&E (Note 1)							
Liabilities							
Intragovernmental							
Accounts Payable	\$ 5	\$ 107	\$ 50,810	\$ -	\$ 50,922	\$ (50,016)	\$ 906
Other (Note 13)	35	1,181	777	18	2,011	(439)	1,572
Total Intragovernmental	40	1,288	51,587	18	52,933	(50,455)	2,478
Accounts Payable	15	657	-	1	673	-	673
Entitlement Benefits Due and Payable (Note 10)	-	27,705	45,007	-	72,712	-	72,712
Accrued Grant Liability (Note 12)	898	2,514	-	792	4,204	-	4,204
Federal Employee and Veterans Benefits (Note 11)	5	9,968	12	-	9,985	-	9,985
Other	26	8,517	601	17	9,161	-	9,161
Total Liabilities	984	50,649	97,207	828	149,668	(50,455)	99,213
Net Position							
Unexpended Appropriations - Earmarked funds	-	(101)	1,776	-	1,675	-	1,675
Unexpended Appropriations - Other funds	9,074	116,908	-	14,486	140,468	-	140,468
Unexpended Appropriations, Total	9,074	116,807	1,776	14,486	142,143	-	142,143
Cumulative Results of Operations - Earmarked funds	-	3,887	313,447	-	317,334	-	317,334
Cumulative Results of Operations - Other funds	23	5,035	-	(9)	5,049	-	5,049
Cumulative Results of Operations, Total	23	8,922	313,447	(9)	322,383	-	322,383
Total Net Position	9,097	125,729	315,223	14,477	464,526	-	464,526
Total Liabilities and Net Position	\$ 10,081	\$ 176,378	\$ 412,430	\$ 15,305	\$ 614,194	\$ (50,455)	\$ 563,739

CONSOLIDATED BALANCE SHEET BY OPERATING DIVISION
As of September 30, 2010
(in Millions)

	ACF	AoA	AHRQ	CDC	CMS	FDA	HRSA	IHS	NIH	OS	PSC	SAMHSA	Agency Consolidated Totals	Intra-HHS Eliminations	HHS Consolidated Totals
Assets (Note 2)															
Intragovernmental															
Fund Balance with Treasury (Note 3)	\$ 24,620	\$ 702	\$ 724	\$ 7,371	\$ 64,841	\$ 1,986	\$ 7,332	\$ 2,185	\$ 39,326	\$ 30,178	\$ 207	\$ 2,763	\$ 182,235	\$ -	\$ 182,235
Investments, Net (Note 4)	-	-	-	-	356,621	-	3,222	-	39	-	-	-	359,882	-	359,882
Accounts Receivable, Net (Note 5)	21	43	22	91	493	7	39	39	1	296	362	100	1,514	(377)	1,137
Other (Note 8)	-	-	-	-	5	-	-	-	1	-	1	94	101	(2)	99
Total Intragovernmental	24,641	745	746	7,462	421,960	1,993	10,593	2,224	39,367	30,474	570	2,957	543,732	(379)	543,353
Accounts Receivable, Net (Note 5)	-	-	1	6	7,046	160	4	158	3	8	8	-	7,394	-	7,394
Inventory and Related Property, Net (Note 6)	-	-	-	1,795	-	1	2	11	30	4,233	5	-	6,077	-	6,077
General Property, Plant & Equipment, Net (Note 7)	-	-	-	1,420	398	385	-	875	1,920	262	3	-	5,263	-	5,263
Other (Note 8)	-	-	-	-	1,309	10	330	1	2	-	-	-	1,652	-	1,652
Total Assets	\$ 24,641	\$ 745	\$ 747	\$ 10,683	\$ 430,713	\$ 2,549	\$ 10,929	\$ 3,269	\$ 41,322	\$ 34,977	\$ 586	\$ 2,957	\$ 564,118	\$ (379)	\$ 563,739
Stewardship PP&E (Note 1)															
Liabilities (Note 9)															
Intragovernmental															
Accounts Payable	\$ 5	\$ -	\$ 2	\$ -	\$ 959	\$ 13	\$ 25	\$ 3	\$ 18	\$ 21	\$ -	\$ 2	\$ 1,048	\$ (142)	\$ 906
Other (Note 13)	52	1	49	128	811	33	86	332	84	48	4	181	1,809	(237)	1,572
Total Intragovernmental	57	1	51	128	1,770	46	111	335	102	69	4	183	2,857	(379)	2,478
Accounts Payable	15	1	10	-	-	5	45	36	376	147	28	10	673	-	673
Entitlement Benefits Due and Payable (Note 10)	-	-	-	-	72,712	-	-	-	-	-	-	-	72,712	-	72,712
Accrued Grant Liability (Note 12)	1,594	96	11	360	-	9	397	23	1,667	79	-	(32)	4,204	-	4,204
Federal Employee and Veterans Benefits (Note 11)	5	-	-	34	13	22	20	77	56	17	9,729	12	9,985	-	9,985
Other (Note 13)	41	2	13	192	6,009	263	769	594	423	796	54	5	9,161	-	9,161
Total Liabilities	1,712	100	85	714	80,504	345	1,342	1,065	2,624	1,108	9,815	178	99,592	(379)	99,213
Net Position															
Unexpended Appropriations - Earmarked funds	-	-	-	-	1,776	(97)	(4)	-	-	-	-	-	1,675	-	1,675
Unexpended Appropriations - Other funds	22,954	606	659	6,924	34,377	(1,572)	6,646	1,425	36,330	29,367	49	2,703	140,468	-	140,468
Unexpended Appropriations, Total	22,954	606	659	6,924	36,153	(1,669)	6,642	1,425	36,330	29,367	49	2,703	142,143	-	142,143
Cumulative Results of Operations - Earmarked funds	-	-	2	36	313,447	925	2,531	11	375	-	-	7	317,334	-	317,334
Cumulative Results of Operations - Other funds	(25)	39	1	3,009	609	2,948	414	768	1,993	4,502	(9,278)	69	5,049	-	5,049
Cumulative Results of Operations, Total	(25)	39	3	3,045	314,056	3,873	2,945	779	2,368	4,502	(9,278)	76	322,383	-	322,383
Total Net Position	22,929	645	662	9,969	350,209	2,204	9,587	2,204	38,698	33,869	(9,229)	2,779	464,526	-	464,526
Total Liabilities and Net Position	\$ 24,641	\$ 745	\$ 747	\$ 10,683	\$ 430,713	\$ 2,549	\$ 10,929	\$ 3,269	\$ 41,322	\$ 34,977	\$ 586	\$ 2,957	\$ 564,118	\$ (379)	\$ 563,739

NET COST OF TOP 20 PROGRAMS
For The Year Ended September 30, 2010 and 2009
(in Millions)

HHS Program	HHS Net Cost (\$)		Rank by (\$)		Budget Function	HHS Component Responsible for Program
	FY 2010	FY 2009	FY 2010	FY 2009		
Medicare	\$447,162	\$ 430,025	1	1	Medicare	CMS
Medicaid	272,995	253,352	2	2	Health	CMS
Research	33,476	29,985	3	3	Health	NIH
Temporary Assistance to Needy Families	20,307	19,058	4	4	Education, Training & Social Services / Income Security	ACF
Head Start	8,262	7,074	5	7	Education, Training & Social Services / Income Security	ACF
Children's Health Insurance Program (CHIP)	7,968	7,610	6	6	Health	CMS
Child Welfare	7,883	7,915	7	5	Education, Training & Social Services / Income Security	ACF
Child Care	5,972	5,262	8	8	Education, Training & Social Services / Income Security	ACF
Infectious Diseases	5,970	5,153	9	9	Health	CDC
Public Health and Social Services	5,057	1,355	10	18	Health	OS
Low-Income Home Energy Assistance	4,599	4,537	11	10	Education, Training & Social Services / Income Security	ACF
Child Support Enforcement	4,408	4,430	12	11	Education, Training & Social Services / Income Security	ACF
Primary Care	3,103	2,358	13	12	Health	HRSA
HIV/AIDS Programs	2,448	2,353	14	13	Health	HRSA
Clinical Services	2,188	2,148	15	14	Health	IHS
Social Services Block Grant	1,991	1,840	16	15	Education, Training & Social Services / Income Security	ACF
Substance Abuse Prevention and Treatment Block Grant	1,727	1,749	17	16	Education, Training & Social Services / Income Security	SAMHSA
Community Services	1,500	834	18	23	Education, Training & Social Services / Income Security	ACF
State and Community Based Services	1,395	1,331	19	19	Education, Training & Social Services	AOA
Health Promotion	1,193	994	20	21	Health	CDC
Total, Top 20 Programs	839,604	789,363				
All Other HHS Programs	17,124	14,542			Various Functions	Various Components
Total Net Costs	\$856,728	\$ 803,905				

SUPPLEMENTAL STATEMENT OF NET COST
For The Years Ended September 30, 2010 and 2009
(in Millions)

Responsibility Segments	2010			
	Agency Consolidated Totals	Inter-Agency Eliminations		Consolidated Totals
		Costs (-)	Earned/Exchange Revenues (+) ¹	
ACF	\$ 56,331	\$ (13)	\$ 51	\$ 56,369
AoA	1,529	(2)	5	1,532
AHRQ	57	(361)	13	(291)
CDC	10,356	(378)	200	10,178
CMS	728,704	(6)	298	728,996
FDA	2,153	(26)	140	2,267
HRSA	9,158	(24)	151	9,285
IHS	4,390	(33)	55	4,412
NIH	33,476	(188)	921	34,209
OS	6,513	(342)	191	6,362
PSC	738	(631)	30	137
SAMHSA	3,399	(157)	30	3,272
Net Cost of Operations	\$ 856,804	\$ (2,161)	\$ 2,085	\$ 856,728

Responsibility Segments	2009			
	Agency Consolidated Totals	Inter-Agency Eliminations		Consolidated Totals
		Costs (-)	Earned/Exchange Revenues (+) ¹	
ACF	\$ 52,318	\$ (18)	\$ 48	\$ 52,348
AoA	1,440	(4)	5	1,441
AHRQ	(6)	(393)	11	(388)
CDC	9,124	(351)	170	8,943
CMS	691,452	(2)	260	691,710
FDA	1,939	(28)	127	2,038
HRSA	7,311	(56)	173	7,428
IHS	3,952	(29)	56	3,979
NIH	29,985	(127)	753	30,611
OS	1,913	(428)	182	1,667
PSC	1,406	(607)	22	821
SAMHSA	3,301	(34)	40	3,307
Net Cost of Operations	\$ 804,135	\$ (2,077)	\$ 1,847	\$ 803,905

¹Eliminations for non-exchange revenue are reported in the Statement of Changes in Net Position

CONSOLIDATING STATEMENT OF NET COST BY BUDGET FUNCTION
For The Year Ended September 30, 2010
(in Millions)

Responsibility Segments	Education, Training, & Social Services	Health	Medicare	Income Security	Agency Combined Totals	Intra-HHS Eliminations		Consolidated Totals
						Cost (-)	Revenue	
ACF	\$ 13,864	\$ -	\$ -	\$ 42,467	\$ 56,331	\$ (13)	\$ 51	\$ 56,369
AoA	1,529	-	-	-	1,529	(2)	5	1,532
AHRQ	-	57	-	-	57	(361)	13	(291)
CDC	-	10,356	-	-	10,356	(378)	200	10,178
CMS	-	281,542	447,162	-	728,704	(6)	298	728,996
FDA	-	2,153	-	-	2,153	(26)	140	2,267
HRSA	-	9,158	-	-	9,158	(24)	151	9,285
IHS	-	4,390	-	-	4,390	(33)	55	4,412
NIH	-	33,476	-	-	33,476	(188)	921	34,209
OS	-	6,513	-	-	6,513	(342)	191	6,362
PSC	-	738	-	-	738	(631)	30	137
SAMHSA	-	3,399	-	-	3,399	(157)	30	3,272
Net Cost of Operations	\$ 15,393	\$ 351,782	\$ 447,162	\$ 42,467	\$ 856,804	\$(2,161)	\$ 2,085	\$ 856,728

GROSS COST AND EXCHANGE REVENUE
For The Year Ended September 30, 2010
(in Millions)

Responsibility Segments	Intragovernmental						With the Public		Consolidated Net Cost of Operations
	Gross Cost			Less: Exchange Revenue			Gross Cost	Less: Exchange Revenue	
	Combined	Eliminations	Consolidated	Combined	Eliminations	Consolidated			
ACF	\$ 179	\$ (23)	\$ 156	\$ 53	\$ (61)	\$ (8)	\$ 56,213	\$ 8	\$ 56,369
AoA	11	(2)	9	3	(5)	(2)	1,521	-	1,532
AHRQ	38	(361)	(323)	394	(13)	381	409	(4)	(291)
CDC	949	(418)	531	535	(240)	295	9,951	9	10,178
CMS	942	(6)	936	17	(298)	(281)	788,777	60,998	728,996
FDA	917	(26)	891	41	(140)	(99)	2,239	962	2,267
HRSA	296	(35)	261	59	(162)	(103)	8,961	40	9,285
IHS	601	(33)	568	330	(55)	275	4,694	575	4,412
NIH	4,478	(2,960)	1,518	3,147	(3,693)	(546)	32,258	113	34,209
OS	657	(357)	300	573	(206)	367	6,420	(9)	6,362
PSC	126	(631)	(505)	871	(30)	841	1,491	8	137
SAMHSA	132	(164)	(32)	134	(37)	97	3,394	(7)	3,272
Totals	\$ 9,326	\$ (5,016)	\$ 4,310	\$ 6,157	\$ (4,940)	\$ 1,217	\$ 916,328	\$ 62,693	\$ 856,728

IMPROPER PAYMENTS INFORMATION ACT REPORT

1.0 Overview

Our FY 2010 *Improper Payments Information Act* Report includes a discussion of the following information, as required by the *Improper Payments Information Act of 2002 (IPIA)*, OMB Circular A-136 and OMB Circular A-123, Appendix C.

- Program Descriptions (Section 1.10)
- Risk Assessments (Section 2.0)
- Statistical Sampling Process (Section 3.0)
- Corrective Action Plans (Section 4.0)
- Recovery Auditing Reporting (Section 5.0)
- Accountability in Reducing and Recovering Improper Payments (Section 6.0)
- Information Systems and Other Infrastructure (Section 7.0)
- Mitigation Efforts Related to Statutory or Regulatory Barriers (Section 8.0)
- Progress and Achievements (Section 9.0)
- Improper Payment Reduction Outlook (Section 10.0)
- Program Specific Reporting Information (Section 11.0)
 - Medicare Fee-for-Service (FFS) Program (Section 11.10)
 - Medicare Advantage (Section 11.20)
 - Medicare Prescription Drug Benefit (Section 11.30)
 - Medicaid (Section 11.40)
 - Children's Health Insurance Program (Section 11.50)
 - Temporary Assistance for Needy Families (Section 11.60)
 - Foster Care (Section 11.70)
 - Head Start (Section 11.80)
 - Child Care (Section 11.90)

- 4) Medicaid - A joint Federal/State program, administered by the States that provides health insurance to certain low income individuals.
- 5) Children's Health Insurance Program (CHIP) - A joint Federal/State program, administered by the States that provides health insurance for qualifying children.
- 6) Temporary Assistance for Needy Families (TANF) - A joint Federal/State program, administered by the States that provides time-limited assistance to needy families with children to promote work, responsibility and self-sufficiency.
- 7) Foster Care - A joint Federal/State program, administered by the States for children who need placement outside their homes in a foster family home or a child care facility.
- 8) Head Start - A Federal program that provides comprehensive developmental services for America's low-income, preschool children ages three to five and their families.
- 9) The Child Care Development Fund (CCDF) - A joint Federal/State program, administered by the States that provides child care financial assistance to low-income working families.

2.0 Risk Assessments

In addition to the nine programs deemed by OMB to be susceptible to significant improper payments, HHS conducts risk assessments on 23 additional high-dollar programs. OMB Circular A-123, Appendix C requires HHS to perform risk assessments once every three years on these programs. In the most recent review cycle, all 23 of these programs were deemed non-high-risk programs.

3.0 Statistical Sampling Process

The statistical sampling process conducted to estimate the improper payment rate for each program identified in our program description section is discussed in the Program-Specific Reporting Information section. Eight of our programs that report error rates use a statistical contractor. Unless otherwise stated in the Program-Specific Reporting Information section, all programs also comply with *IPIA* guidance that requires that all estimates be based on the equivalent of a statistically valid random sample of sufficient size to yield an estimate with a 90-percent confidence interval of plus or minus 2.5 percentage points around the estimate of the percentage of erroneous payments.

1.10 Program Descriptions

The following is a brief description of the nine programs that will be discussed in this report.

- 1) Medicare Fee-for-Service (Medicare Parts A and B) - A Federal health insurance program for: people age 65 or older, people younger than age 65 with certain disabilities, and people of all ages with End-Stage Renal Disease.
- 2) Medicare Advantage (Medicare Part C) - A Federal health insurance program that allows beneficiaries to receive their Medicare benefits through a private health plan.
- 3) Medicare Prescription Drug Benefit (Medicare Part D) - A Federal prescription drug benefit program for Medicare beneficiaries.

4.0 Corrective Action Plans

Corrective Action Plans for reducing the estimated rate of improper payments for each program are included in the Program-Specific Reporting Information section. There are two important aspects to the corrective action plans: (1) setting aggressive, but realistic, goals and targets and (2) achieving the targets according to the timetable in the plan. Corrective Action Plans are reviewed each year to ensure that they are focused on the root causes of the errors and that the targets are being met. If targets are not being met, remediation will take place that can include employing new strategies, adjusting staffing and other resources, and possibly revising targets.

5.0 Recovery Auditing Reporting

In July 2004, HHS awarded a contingency fee contract to a recovery auditing firm to review FY 2002 and FY 2003 contract payments. During FY 2006, HHS exercised an option under the contract for review of FY 2004 and FY 2005 contract payments. As previously reported, our recovery auditors have found the HHS payment systems to be without major program integrity issues. HHS has recovered \$74,401 out of more than \$24 billion of contracts reviewed. We have not sought a contractor to attempt to recover funds beyond FY 2005 because our efforts to date have produced such small recoveries.

The table below displays full results for FY 2002-FY 2005.

AGENCY COMPONENT	HHS
Amount Subject to Review for CY + PY Reporting	\$24.2 billion
Actual Amount Reviewed and Reported CY + PY	\$24.2 billion
Amounts Identified for Recovery CY	0
Amounts Recovered CY	0
Amounts Identified for Recovery PYs	\$1,586,643
Amounts Recovered PYs	\$74,401
Cumulative Amounts Identified for Recovery (CY + PYs)	\$1,586,643
Cumulative Amounts Recovered (CY + PYs)	\$74,401

NOTE: PY= Prior Year, CY= Current Year

6.0 Accountability in Reducing and Recovering Improper Payments

HHS has shown tremendous leadership in the improper payments arena. We have been publishing an error rate for Medicare Fee-for-Service (FFS) since FY 1996, which was one of the first error rates published across government.

HHS has also been reporting Foster Care and Head Start error rates since FY 2004. Last year, we reported at least one error component for seven of our high risk programs. HHS continues to implement corrective action plans to reduce future error rates.

In addition, HHS management performance plan objectives hold agency managers, beginning with leadership and cascading down through HHS Senior Executives (including component heads) to the lowest accountable program official, responsible for achieving progress on this initiative. As part of the semiannual and annual performance evaluation, HHS Senior Executives and program officials are evaluated on the progress the agency achieves toward this and other goals.

7.0 Information Systems and Other Infrastructure

Reporting requirements related to information systems and other infrastructure is discussed by program within the Program-Specific Reporting Information section.

8.0 Mitigation Efforts Related to Statutory or Regulatory Barriers

Reporting requirements related to whether there are any statutory or regulatory barriers to reducing improper payments are discussed by program within the Program-Specific Reporting Information section.

9.0 Progress and Achievements

9.10 FY 2010 Progress

HHS currently has nine programs that have been deemed risk susceptible: Medicare Fee-for-Service, Medicare Advantage, Medicare Prescription Drug Benefit, Medicaid, Children's Health Insurance Program (CHIP), Temporary Assistance for Needy Families (TANF), Head Start, Child Care, and Foster Care. HHS expects to report a comprehensive error rate for the Medicare Prescription Drug Benefit program next year.

HHS works with OMB to put approved measurement plans in place for all risk-susceptible programs as well as a corrective action plan with OMB-approved targets for all programs that have established baseline measurements.

9.20 Achievements

9.21 Improving Program Integrity in Medicare and Medicaid

- Medicare:

Section 302 of the *Tax Relief and Health Care Act of 2006* required HHS to implement a Recovery Audit Contractor (RAC) program in all 50 States no later than January 1, 2010. In February 2009, HHS awarded contracts to four RACs. Each RAC is responsible for identifying and correcting improper payments in approximately 25 percent of the country. HHS completed the nationwide implementation effort in October 2009.

FY 2010 was the first year for the national RAC program. During FY 2010 HHS focused on education and outreach, and establishing an infrastructure for managing and overseeing the RACs. As of September 30, 2010, the RAC program has demanded approximately \$135 million and recovered \$75.4 million. HHS expects collections to continue to increase as the RACs expand their reviews.

- Medicaid:

Section 6411 of the *Affordable Care Act* requires States to establish Medicaid RAC programs. HHS has required States to submit State plan amendments by December 31, 2010, on how they will establish their RAC program. Medicaid RACs will be paid by the States on a contingency basis. They will review Medicaid provider claims to identify and recover overpayments and identify underpayments made for services provided under Medicaid State plans and Medicaid waivers. HHS is in the process of developing a proposed rule that outlines requirements States must meet for this program.

9.22 Head Start Signed Statement Template Form

HHS has developed a standard signed statement template form for Head Start, which was made available to all grantees in FY 2009. Since OMB clearance (OMB 0907-0374) was obtained in FY 2010, the use of the form is optional, but grantees are strongly encouraged to use it. The standard signed statement form helps guide grantees on the type of information they need to collect from prospective families during the enrollment process and provides them with a structure for recording this information.

9.23 Public Assistance Reporting Information System

The Public Assistance Reporting Information System (PARIS) is a voluntary project that

enables participating States' public assistance data to be matched against several databases to help maintain program integrity and detect and deter improper payments in several programs (TANF, Medicaid and the Supplemental Nutritional Assistance Program). The August 2010 data match was the largest to date in terms of number of agencies (50) participating.

HHS engaged in a number of activities to improve data-match capabilities and usefulness to increase State utilization of PARIS. These activities included engaging in outreach activities to encourage States to participate in the PARIS match process; providing HHS training to States in utilizing the PARIS to its fullest capability; conducting an evaluation of the PARIS; formulating recommendations for improving and enhancing its usefulness; and developing a uniform reporting format.

On October 10, 2008, the *QI Program Supplemental Funding Act of 2008* was signed. The *Act* stated that in order to receive Medicaid Federal matching funds for automated data systems to administer the Medicaid State plan, the provision requires States to have an operational Medicaid eligibility determination system that provides for data matching through PARIS (or any successor system), including matching with medical assistance programs operated by other States. HHS issued a State Medicaid Directors Letter dated June 21, 2010 to promulgate this information to the States

10.0 Improper Payment Reduction Outlook FY 2009 through 2013

The chart on the following page shows our *IPIA* results for the current year (CY) 2010, the prior year (PY) 2009, as well as the targets for the years 2011 through 2013. For each year we show, for each program, outlays for that fiscal year (FY), an error rate or target (IP%), and the dollars paid improperly (IP\$). Table notes are defined in Section 10.1, after the table.

IMPROPER PAYMENT REDUCTION OUTLOOK FY 2009 - FY 2013 (in Millions)

Program	PY Outlay \$	PY %	PY \$	CY Outlay \$	CY IP %	CY IP \$	CY+1 Est Outlay \$	CY+1 IP %	CY+1 IP \$	CY+2 Est Outlay \$	CY+2 IP %	CY+2 IP \$	CY+3 Est Outlay \$	CY+3 IP %	CY+3 IP \$
Medicare FFS	308,418 Note (a)	12.4 Note (1)	\$35,400	326,400 Note (b)	10.5	34,300	355,956 Note (c)	8.5	30,300	372,303	6.2	23,100	399,112	5.8	23,100
Medicare MC	77,985 Note (d)	15.4	12,010	96,437 Note (e)	14.1	13,600	129,213 Note (f)	13.7	17,700	111,802	13.2	14,800	120,581	12.9	15,600
Medicare Drug	54,869 Note (g)	N/A	N/A	58,822	N/A Note (2)	N/A	68,458	N/A	N/A	66,065	N/A	N/A	77,333	N/A	N/A
Medicaid	188,286 Note (h)	9.6	18,075	239,012 Note (i)	9.4 Note (3)	22,500	258,706 Note (j)	8.4	21,700	261,284	7.4	19,300	282,831	6.4	18,100
CHIP	7,855 Note (k)	N/A Note (4)	N/A	8,909	N/A	N/A	10,292	N/A	N/A	11,605	N/A	N/A	12,885	N/A	N/A
TANF	20,727	N/A	N/A	17,320	N/A Note (5)	N/A	17,191	N/A	NA	17,061	NA	NA	17,148	NA	N/A
Head Start	7,113	3.0	213.4	7,234	1.7	123	8,234	1.7 Note (6)	140	8,646	1.7	147	9,077	1.7	154.3
Foster Care	1,610	4.7	75.7	1,483	4.9	72.7	1,306	4.7	61.4	1,224	4.5	55.1	1,190	4.3	51.2
Child Care	5,245	11.9	624	6,091	13.3 Note (7)	810	6,239	13.1	817.3	5,722	12.8	732.4	5,583	12.4	692.3

Note: The CY+1, CY+2 and CY+3 estimated dollars paid improperly (IP\$) is calculated based on the target error rate and estimated outlays for each year, respectively. However, it is important to note that the measurement periods for each program vary. Therefore, the future outlay estimates presented are not the actual amounts against which the target error rates will be applied to compute the dollars paid improperly in future years. To illustrate, the CY outlays for Medicaid, \$239,012 million, is actually based on FY 2009 claims data, as explained in note (i), whereas the CY+1 outlays of \$258,706 million reflects FY 2011 estimated outlays. When determining the amount of dollars paid improperly next year, the target error rate of 8.4% will be applied to the FY 2010 claims data.

10.10 Improper Payment Reduction Outlook Notes

(a) – PY benefit outlays for Medicare FFS are from the November 2009 Improper Medicare FFS Payments Report (based on claims from April 2008 – March 2009).

(b) – CY benefit outlays for Medicare FFS are from the November 2010 Improper Medicare FFS Payments Report (based on claims from April 2009 – March 2010).

(c) – Medicare FFS CY+1, CY+2, CY+3 benefit outlay numbers are based on the FY 2011 Midsession Review (Medicare Benefit Outlays current law (CL)).

(d) – Medicare Advantage PY benefit outlays are from the Medicare Part C Payment Error Final Report 2009 (based on CY 2007 data).

(e) – Medicare Advantage CY benefit outlays are from the Medicare Part C Payment Error Final Report 2010 (based on CY 2008 data).

(f) – Medicare Advantage CY+1, CY+2, CY+3 benefit outlay numbers are based on the FY 2011 Midsession Review (Medicare Benefit Outlays (CL)).

(g) – Medicare Prescription Drug Benefit PY, CY, CY+1, CY+2, CY+3 outlay numbers are based on the FY 2011 Midsession Review (Medicare Benefit Outlays (CL)).

(h) – PY benefit outlays for Medicaid are from the 2009 Medicaid Annual Error Rate Report (based on FY 2008 claims).

(i) – CY benefit outlays for Medicaid are from the 2010 Medicaid Annual Error Rate Report (based on FY 2009 claims).

(j) – Medicaid CY+1, CY+2, CY+3 benefit outlay numbers are based on the FY 2011 Midsession Review (Medicaid Net Benefit Outlays (CL), excluding CDC Program Vaccine for Children obligations).

(k) – CHIP PY, CY, CY+1, CY+2, CY+3 benefit outlays are based on the FY 2011 Midsession Review (CHIP Total Benefit Outlays with CHIPRA Bonus and Health Care Quality Provisions (CL)).

(1) – The FY 2009 Agency Financial Report (AFR) reported the Medicare FFS error rate as 7.8 percent with \$24.1 billion in improper payments. HHS changed its error rate measurement methodology during the FY 2009 review year. Thus, the 7.8 percent represents a combination of review results using two different methodologies. The

original methodology, under which most of the claims were reviewed, was less stringent than the new methodology. The error rate based on the subsample of claims using the new stricter methodology was 12.4 percent with \$35.4 billion in error (the amount of \$35.4 billion in improper payments was derived from statistical calculations based on the subsample reviewed). Given the change in methodology, and that HHS is now using the new methodology, HHS is reporting the prior year error rate as 12.4 percent rather than 7.8 percent.

(2) – For FY 2010 *IPIA* reporting for the Medicare Prescription Drug Benefit, HHS calculated four components of payment error: (1) the Medicare Advantage and Prescription Drug System (MARx) Payment Error (MPE): the measurement reflects errors in Part D payments caused by errors in the transfer/interpretation of source data and errors in payment calculations in the MARx payment system; (2) payment error relating to Low Income Subsidy status (PELS): the measurement reflects errors in Low Income Cost sharing Subsidy (LICS) payments; (3) Payment Error Related to Incorrect Medicaid Status (PEMS): the measurement reflects errors in LICS and two other Low Income Subsidy-related payments: the Low Income Premium Subsidy and Direct Subsidy amounts; where the FY 2009 Payment Error Rate Measurement (PERM) national Medicaid eligibility case error rate is applied to Part D payments to calculate a PEMS error rate for *IPIA* reporting; and (4) Payment Error Related to Prescription Drug Event Data Validation (PEPV): the measurement reflects errors due to invalid and/or inaccurate Prescription Drug Event (PDE) records that impact Part D LICS and reinsurance payments. The MPE, PELS, and PEMS measures are based on CY 2008 payments, and the PEPV measure is based on CY 2007 payments. Note that the four Part D estimates of gross dollars in error reported for FY 2010 are not mutually exclusive, and therefore, cannot be summed. HHS calculated a Part D MPE rate of 0.1 percent for payments made from January 1, 2008 through December 31, 2008, and estimated a gross amount of payment error totaling \$45.0 million. Estimated Part D MPE underpayments were \$20.0 million and estimated overpayments were \$25.0 million. HHS calculated a Part D PELS error rate of 0.1 percent for payments made from January 1, 2008 through December 31, 2008, and estimated a gross amount of payment error totaling \$54.0 million. Estimated Part D PELS underpayments were \$33.0 million and estimated overpayments were \$21.0 million. HHS calculated a

Part D PEMS error rate of 1.7 percent for payments made from January 1, 2008 through December 31, 2008, and estimated a gross amount of payment error totaling \$785.0 million (all errors are overpayments). HHS calculated a Part D PEPV error rate of 12.7 percent for payments from January 1, 2007 through December 31, 2007, and estimated a gross amount of payment error totaling \$5.4 billion. Estimated Part D PEPV underpayments were \$3.0 million and estimated overpayments were \$5.4 billion.

(3) – HHS calculated and is reporting the three-year weighted average national error rate that includes data reported in the *AFR* for FYs 2008, 2009, 2010. The weighted national error components rates are as follows: Medicaid FFS: 4.4 percent; Medicaid managed care: 1.0 percent; and Medicaid eligibility: 5.9 percent. However, as required under Section 601 of the *Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA P.L. 111-3)*, HHS published a final rule on August 11, 2010, which required the eligibility reviews to be consistent with the State's eligibility verification policy rather than reviewing eligibility against a uniform methodology, which was done in the past. Based on current regulations, certain cases from FYs 2008-2010 would no longer be considered as errors.

(4) – The Payment Error Rate Measurement final rule (75 FR 48816), the methodology used to measure the Medicaid and Children's Health Insurance Program, was published on August 11, 2010, and became effective September 10, 2010. This final rule implements provisions from the *Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA)* with regard to the PERM program. Section 601 of *CHIPRA* prohibits HHS from calculating or publishing any national or state-specific error rates for CHIP until six months after the new PERM final rule is effective. HHS did not report a national error rate for CHIP in the FY 2009 *AFR* and due to timing of the published PERM final rule, will not be reporting a national error rate for CHIP in the FY 2010 *AFR*. However, HHS will begin conducting the CHIP error rate measurement in FY 2011, with the results being published in the FY 2012 *AFR*. Due to the recent publication of the PERM final rule, setting out-year target rates for CHIP is not applicable at this time.

(5) – The TANF program is not reporting an error rate for FY 2010. Statutory limitations prohibit HHS from requiring States to participate in a TANF improper payment measurement. Despite statutory limitations, HHS continues to explore options that will allow for a future error rate measurement.

(6) – HHS is engaged in a number of efforts to reduce erroneous determinations in the Head Start eligibility process and to improve our detection and measurement of errors. Until HHS determines how these efforts will impact error rates, HHS will be maintaining our FY 2010 rates as our out-year targets.

(7) – Since States measure once every three years, this is the first year that HHS is reporting a baseline error rate for Child Care. The error rate is based on a three year weighted average of error rates.

11.0 Program-Specific Reporting Information

Within this section we discuss each program's methodology for complying with *IPIA*, the results and future plans. For each program we discuss:

- How they performed their sampling, including sample sizes and methodology;
- Plans for corrective action, including a breakdown of most common error types;
- Recovery Actions taken as a result of identifying improper payments;
- Whether there are statutory, regulatory, or information systems barriers that limit potential corrective actions and;
- Best practices that have been incorporated in each error rate process.

11.10 Medicare Fee-for-Service Program - A Federal health insurance program for: people age 65 or older, people under age 65 with certain disabilities, and people of all ages with End-Stage Renal Disease.

11.11 Statistical Sampling Process

The Medicare Fee-for-Service (FFS) improper payment estimate is calculated under the Comprehensive Error Rate Testing (CERT) Program.

The Medicare FFS improper payment methodology begins with a random sample of claims. This year approximately 82,000 claims were sampled. Next, for each sampled claim, HHS obtains medical records from providers and additional claim detail from its shared systems. This information is

reviewed for compliance with Medicare coverage, coding and billing rules. When a provider does not provide the requested medical record documentation or the information submitted does not meet the Medicare requirements, the claim is counted as an error.

The Medicare FFS error rate for FY 2010 is 10.5 percent, or \$34.3 billion.

During the analysis of improper payments identified in 2010, CMS found that the improper payments error rate for inpatient hospital claims had increased significantly from last year. A large number of the payment errors were due to clinical care and procedures provided in an acute inpatient hospital that should have been provided in an outpatient hospital or other less intensive setting, meaning the clinical service was medically necessary but the place of service was incorrect. Under current Medicare statute, these claims must be denied in full. These inappropriate "place of service" errors accounted for projected improper payments of \$5.1 billion.

11.12 Medicare FFS Corrective Action Plans

The primary causes of improper payments, as identified in the FY 2010 Medicare FFS Improper Payments report, were insufficient documentation errors (Administrative and Documentation), medically unnecessary services (Authentication and Medical Necessity), and to a lesser extent, coding errors (Administrative and Documentation). When the errors are analyzed based on the setting in which the service took place, the data shows that the most improper payments are due to medically unnecessary errors for durable medical equipment (DME) and inpatient hospitals services. Physicians and inpatient hospitals contribute substantially to the amount of improper payments due to insufficient documentation and incorrect coding errors.

HHS developed an Error Rate Reduction Plan (ERRP) that outlines actions the agency will implement in an effort to prevent/reduce improper payments for all categories of error.

Administrative and Documentation Errors - Corrective Actions:

HHS has implemented safeguards to better ensure that only legitimate providers and suppliers receive Medicare payments:

- HHS undertook numerous aggressive actions to strengthen the provider enrollment process; provided more rigorous oversight and monitoring once a provider/supplier enrolled in the program; and strengthened the provider revocation process. HHS implemented a durable medical equipment accreditation program to

ensure the legitimacy of the DME suppliers that bill Medicare and to ensure those suppliers meet all the requirements for participation in the Medicare program.

- HHS implemented surety bond requirements for most suppliers of durable medical equipment, prosthetics and orthotics.
- HHS published an Interim Final Rule with Comment (IFC) regulation titled, "Medicare and Medicaid Programs; Changes in Provider and Supplier Enrollment, Ordering and Referring, and Documentation Requirements; and Changes in Provider Agreements" in the Federal Register on May 5, 2010. This IFC implemented several provider enrollment enhancements as required by the *Patient Protection and Affordable Care Act (Affordable Care Act) (P. L. 111-148)* designed to support the Administration's efforts to prevent and detect fraud, waste, and abuse in the Medicare and Medicaid programs, and to ensure quality care for beneficiaries.
- HHS published a final rule titled, "Medicare Program; Establishing Additional Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Supplier Enrollment Safeguards" (CMS-6036-F) in the Federal Register on August 27, 2010. This final rule clarified and expanded on the existing enrollment requirements that DMEPOS suppliers must meet to establish and maintain billing privileges in the Medicare program.
- HHS initiated the realignment of the Program Safeguard Contractors (PSC) with the Medicare Administrative Contractors (MACs). When the realignment is completed, there will be seven zones to address fraud "hot spots" in the United States, thereby concentrating on areas of high fraud occurrence. The name for this entity is being changed from PSCs to Zone Program Integrity Contractor (ZPIC). Four ZPIC awards have already been made.
- HHS took steps to fight durable medical equipment, prosthetics and orthotics (DMEPOS) fraud in the "high risk" states of Florida, California, Texas, Illinois, Michigan, North Carolina and New York. These efforts include more stringent reviews of new suppliers' applications; unannounced site visits; extensive pre- and post-payment review of claims; interviews with high volume ordering/referring physicians; and visits to high risk beneficiaries to ensure they are appropriately receiving items and services for which Medicare is being billed.
- HHS implemented the DME competitive bidding program which will have a gradual impact on the DME error rate.

HHS implemented improvements and continues to improve upon the Medicare FFS error rate measurement program to ensure that providers and suppliers submit the required documentation, as follows:

- HHS commenced DME and MAC task forces. These task forces consist of contractor medical review professionals that meet regularly to develop strategies for provider education in error prone areas. One potential strategy involves the task forces writing informational articles that will be distributed on an as-needed basis to promote education among providers. The articles would be maintained on the Medical Learning Network (MLN).
- When a supplier is contacted for documentation, HHS contacts the ordering provider and advises them that they may be contacted by the supplier.
- HHS conducted calls with contractors and sent notices to providers to advise them of the special studies, measures, the associated documentation requests they may receive, and what they are required to provide.
- HHS continuously revises the medical record request letters to clarify the components of the medical record that are required for a CERT review.
- HHS contacts third party providers to request documentation when the billing provider indicated that a portion of the medical record is possessed by a third party.
- HHS conducts ongoing education to inform providers about the importance of submitting thorough and complete documentation. This involves national training sessions, individual meetings with providers with high error rates, presentations at industry association meetings, and the dissemination of educational materials.

Authentication and Medical Necessity Errors - Corrective Actions:

- HHS continually updates its review manuals to clarify requirements for reviewing documentation to promote uniform interpretation of our policies across all medical reviews performed by Medicare contractors.
- The HHS implementation of the Electronic Submission of Medical Documentation (ESMD) into the CERT review process will create greater program efficiencies, allow a quicker response time to documentation requests, and provide better communication between the provider, the CERT contractors, and HHS.

- HHS developed Comparative Billing Reports (CBRs) to help Medicare non-hospital providers analyze administrative claims data. CBRs compare a provider's billing pattern for various procedures or services to their peers on a state and national level. HHS also developed the Program for Evaluating Payment Patterns Electronic Report (PEPPER). The PEPPER allows Medicare inpatient hospital providers to also analyze their billing patterns through a comparison to other providers in their state and in the nation.
- HHS is developing a Vulnerability Tracking System (VTS) which will track and analyze vulnerabilities identified by internal and external sources.
- HHS is conducting a competition to procure private sector edits to implement within the Medicare program. As part of this effort HHS will evaluate the accuracy of commercial products and determine whether these products are feasible in the Medicare FFS environment and whether they can reduce improper payments in the Medicare FFS program. HHS posted two requests for proposals (RFPs) during FY 2010. The first RFP, for the automated edit integration contractor, was awarded in September 2010. The second RFP, for the automated edit module contractor, was posted August 2010 and will be awarded late second quarter FY 2011.
- HHS will explore conducting probe samples on providers to identify potential problem areas. Based on the probe results, additional corrective actions will be taken.
- HHS is increasing medical review. The findings shall be used to target additional medical review in those areas with high rates of error.
- HHS will allow RACs to review additional provider types and will closely monitor the decisions made by the RACs.
- HHS tasked each Carrier, FI, and MAC with developing an Error Rate Reduction Plan (ERRP) that targets medical necessity errors in their jurisdiction.
- HHS requires the Carriers, FIs, and MACs to review and validate the CERT results for their jurisdiction to determine the education needed to reduce medical necessity and incorrect coding errors.
- HHS developed medically unlikely auto-deny edits to catch services where the level billed falls beyond a specified limit. These edits are updated quarterly.

- HHS increased and refined educational contacts with providers who are billing in error.
- HHS developed and installed new correct coding edits.

11.13 Medicare FFS Improper Payment Recovery

The actual overpayments identified in the FY 2010 Medicare FFS Improper Payments Report were \$5,057,759. The identified overpayments are to be recovered by the Medicare contractors via the standard payment recovery methods. As of the report publication date, Medicare contractors reported collecting \$3,297,479 of the actual overpayment dollars identified in the report.

HHS traditionally has been able to recover 85 percent of identified Medicare overpayments over the last five years. Specifically, in FY 2009, HHS recovered 89 percent or \$4,202,977 of the total actual identified Medicare overpayments of \$4,729,993.

11.14 Medicare FFS Information Systems and Other Infrastructure

HHS has the information systems and other infrastructure it needs to reduce improper Medicare FFS payments to the levels that we have targeted. HHS' systems have the ability to identify developing and continuing aberrant billing patterns based upon a comparison of local payment rates with national rates. The systems at both the Medicare contractor level and the central office level are tied together by a high-speed secure network that allows rapid transmission of large data sets between systems. No other systems or infrastructure are needed at this time.

11.15 Medicare FFS Statutory or Regulatory Barriers that could limit Corrective Actions

No statutory or regulatory barriers that could limit corrective actions have been identified at this time.

11.16 Medicare FFS Best Practices

The following best practices have been incorporated into the overall CERT process to ensure the highest degree of efficiency for the program:

- CERT offers many educational forums for providers to gain additional knowledge about the CERT program, and to give providers the latest up-to-date information. Such educational resources include several CERT-related websites, a toll-free CERT contractor customer service line, CERT provider calls, and on-line manuals.

- HHS holds weekly calls with all CERT contractors in order to facilitate communication and problem solving and to improve the CERT process.

11.20 Medicare Advantage or Medicare Part C - A Medicare health insurance program that allows beneficiaries to receive their Medicare benefits through a private health plan.

11.21 Part C Medicare Advantage Statistical Sampling Process

For FY 2010, HHS is reporting a composite error estimate for the Medicare Advantage Program (Part C), based on CY 2008 payments. The CY 2008 Part C Composite Payment Error Rate combines two component payment error measures: the Medicare Advantage Prescription Drug (MARx) Payment Error (MPE) estimate and the Risk Adjustment Error (RAE) estimate.

The Part C MPE estimate captures errors in prospective Part C payments caused by errors in the transfer of data, interpretation of data, and payment calculations in the MARx system. The methodology consists of:

- Selection of a random three percent sample of beneficiaries for whom HHS made payments to plans, for each month of CY 2008.
- Computation of the prospective payment error amount for sampled beneficiaries.
- Extrapolation of the sample payment error to the population, resulting in a Part C gross payment error amount.

The RAE estimate captures payment errors due to the application of incorrect beneficiary risk scores. The primary component of a beneficiary's risk score is based on clinical diagnoses submitted by plans. If diagnoses submitted to HHS by the plans are not supported by medical records, the risk scores will be inaccurate and result in payment errors. The RAE estimate is based on medical record reviews conducted under HHS' annual Risk Adjustment Data Validation (RADV) process, where unsupported diagnoses are identified and corrected risk scores are calculated.

The CY 2008 RAE methodology consists of:

- Selection of a stratified random sample of 600 beneficiaries for whom a risk adjusted payment was made in CY 2008, where the strata are high, medium, and low risk scores.
- Medical record review of the diagnoses submitted by plans for the 600 sampled beneficiaries.

- Calculation of beneficiary-level payment error for the sample.
- Extrapolation of the sample payment error to the population subject to risk adjustment, resulting in a Part C gross payment error amount.

The CY 2008 Part C composite payment error amount is the sum of the MPE and RAE gross payment error amounts described above. The Part C composite payment error rate is this sum divided by the CY 2008 total final Part C payments.

The Part C composite error rate for CY 2008 is 14.1 percent.

11.22 Medicare Advantage Corrective Action Plans

The root cause of improper payments in the Part C program for CY 2008 is Administrative and Documentation errors. The majority of the payment error estimate results from insufficient documentation to support the diagnoses submitted by plans for payment, measured by the RAE. The remainder of the payment error in the program is related to transfer of data, interpretation of data, and payment calculations within the MARx payment system, reflected in the MPE estimate. HHS is taking steps to address the error measured by both the MPE and RAE.

For the MPE error estimate, HHS will continue to routinely implement payment controls in the MARx payment system to ensure accurate and timely payments, including monthly payment validation and authorization processes. MARx payment errors are corrected and payment adjustments are made on a flow basis, including payment adjustments applied as part of the final Part C risk score reconciliation. These steps have been successful, as the MPE rate has declined from that reported in the *FY 2009 Agency Financial Report*.

For the RAE error estimate, HHS has implemented a corrective action plan. HHS is proceeding with the RADV process to estimate payment error at the contract level for the purposes of recovering overpayments. HHS has also conducted national training sessions for Medicare Advantage plans that provided comprehensive information on the processes for submitting accurate risk adjustment data. This training reviewed RADV procedures based on medical record review and payment error associated with inaccurate risk adjustment data. Additionally, outreach to plans is conducted regularly through a monthly user group call, during which any questions pertaining to risk adjustment may be addressed. Finally, HHS is developing a method for identifying risk adjustment diagnoses that are more likely to be associated with payment error. This study will examine the reasons these

diagnoses are problematic. HHS will use these findings to conduct outreach and education to plans.

11.23 Medicare Advantage Program Improper Payment Recovery

The MARx payment system error rate is based on analysis of prospective payments. MARx payment system errors are fixed continuously throughout the payment year. The resulting payment adjustments are regularly corrected in the MARx system, including payment adjustments due to the final Part C risk score reconciliation. Therefore, recovery of MPE errors occurs as part of the routine operation of the MARx payment system.

Regarding the risk adjustment error, the CY 2008 Medical Record Review was based on a national sample of beneficiaries, and no payment recovery has been conducted at this point. However, HHS is proceeding with the RADV process to estimate CY 2007 payment error at the contract level for the purposes of recovering overpayments.

11.24 Medicare Advantage Information Systems and Other Infrastructure

HHS has the information systems and other infrastructure needed to reduce improper Part C Medicare Advantage payments. HHS uses the following internal Medicare systems to make and validate the Part C payments: the Medicare Beneficiary Database, the Risk Adjustment System, the Health Plan Management System, and the MARx payment system. No other systems or infrastructure are needed at this time.

11.25 Medicare Advantage Statutory or Regulatory Barriers that could limit Corrective Actions

No statutory or regulatory barriers that could limit corrective actions have been identified at this time.

11.26 Medicare Advantage Program Best Practices

HHS has taken several steps to ensure payment accuracy in the Medicare Advantage program. HHS performs a monthly evaluation of the MARx payment system, as represented in the MPE estimate, which has led to system refinement and more accurate prospective payment to plans.

11.30 Medicare Prescription Drug Benefit or Part D - A Federal prescription drug benefit program for Medicare beneficiaries.

11.31 Part D Statistical Sampling Process

In FY 2009, HHS implemented two methodologies developed in prior years to estimate improper payments for two components of Part D payment:

the Medicare Advantage Prescription Drug (MARx) Payment Error (MPE) and the Payment Error related to Low Income Subsidy (LIS) status (PELS). HHS also reported for the first time the Part D Payment Error related to incorrect Medicaid Status (PEMS). In FY 2010, in addition to reporting the MPE, PELS, and PEMS estimates, HHS is reporting for the first time the Part D Payment Error related to Prescription Drug Event Data Validation (PEPV).

The Part D MPE estimate captures errors in prospective Part D payments caused by errors in the transfer of data, interpretation of data, and payment calculations in the MARx system. The MPE methodology consists of:

- Selection of a random three percent sample of beneficiaries for whom HHS made payments to plans, for each month of CY 2008.
- Computation of the prospective payment error amount for sampled beneficiaries.
- Extrapolation of the sample payment error to the population, resulting in a Part D MPE gross payment error amount and an MPE rate.

For FY 2010, the MPE rate is 0.10 percent.

The Part D PELS estimate captures payment errors due to inconsistent HHS data on beneficiary LIS status and the related low income cost sharing subsidy (LICS) payments. The payment error may occur when a State Medicaid agency or the SSA submit to HHS' systems an update on a beneficiary's level of LIS after a Prescription Drug Event (PDE) record has been accepted. The PELS methodology consists of:

- Identification of the population subject to PELS.
- For this population, identification of discrepancies between LIS status in HHS' systems at the time of reconciliation and LIS status in the PDE record generated on the date of service, and computation of the LICS payment amount based on the corrected LIS status.
- Computation of: (1) the gross payment amount in error (the absolute difference between actual and corrected LICS payments for accepted PDE records), and (2) the PELS rate.

For FY 2010, the PELS rate is 0.12 percent.

The Part D PEMS estimate captures payment errors due to incorrect assignment of Medicaid status, which results in incorrect LIS-related payments. Full benefit dually-eligible beneficiaries (eligible for Medicare and Title XIX benefits -- comprehensive health benefits and/or the Medicare Savings

Program) are also eligible for the Part D full LIS. If a beneficiary were incorrectly assigned Medicaid eligibility, all or part of HHS' LIS-related payment to the Part D sponsor would be in error. The CY 2008 PEMS estimate is based on the 2008 national Medicaid eligibility case error rate determined by another of HHS' *IPIA* error rate measurement programs, the Payment Error Rate Measurement (PERM) program. For the PEMS estimate, this PERM rate (representing incorrect status for the entire Medicaid population) is assumed to be a proxy for the eligibility error rate for a subset of Medicaid beneficiaries, those also eligible for Medicare. The PEMS rate reflects overpayments only. The PEMS methodology consists of:

- Application of the PERM eligibility active case error rate to 100 percent of dual-eligible beneficiaries, by dividing them into three groups: (1) those who would remain eligible for the Part D full LIS even without dual eligible status; (2) those who would become eligible for the Part D partial LIS; and (3) those who would no longer be LIS-eligible.
- Computation of: (1) the PEMS gross payment error amount as the sum of the LIS payment amounts in error for the three groups, and (2) the PEMS rate.

For FY 2010, the PEMS error rate is 1.76 percent.

The Payment Error related to PEPV captures errors in payment due to invalid and/or inaccurate PDE records that result in adjustments to the benefit phase assignment of beneficiaries' PDE records, thus changing Part D LICS and reinsurance payments. The PEPV methodology consists of:

- Validation of the accuracy of 2,000 sampled PDE records using hard copy prescriptions and other claims documentation submitted by plan sponsors, and the creation of a corrected PDE record for all sampled records with discrepancies.
- Imputation of PDE sample validation findings onto the PDE records for a random five percent sample of the Part D population.
- Calculation of a payment error estimate for the sample of beneficiaries. The simulation measures the change in LICS and reinsurance payments as they relate to the changes in gross drug costs.
- Extrapolation of the sample payment error to the entire Part D population resulting in a PEPV gross payment error amount and PEPV rate.

For FY 2010, the PEPV error rate is 12.74 percent.

11.32 Corrective Action Plan

The root cause of improper payments in the Part D program is Administrative and Documentation errors. For the MPE component, HHS will continue to routinely implement payment controls in the MARx payment system to ensure accurate and timely payments, including monthly payment validation and authorization processes. MARx payment errors are corrected and future payments adjustments are made on a flow basis, including the payment adjustments applied to the final Part D risk score reconciliation.

The corrective action steps identified in Medicaid Section 11.42 will also assist in addressing the PEMS error estimate, which is driven by the PERM findings. HHS will conduct more in depth analyses on the PELS error estimate to further describe the PELS population and assist in identifying the subsequent steps that could be taken to address improper payment issues.

A significant portion of the FY 2010 PEPV payment error was driven by missing prescription documentation. For FY 2011 *IPIA* reporting, HHS will conduct validation of CY 2009 PDE records, thus shortening the gap between the date of service and the collection period and likely reducing the volume of missing prescription documentation.

11.33 Medicare Prescription Drug Benefit Improper Payment Recovery

The MARx payment system error rate is based on analysis of prospective payments. MARx payment system errors are fixed on a flow basis throughout the payment year. The resulting payment adjustments are also implemented on a flow basis in the MARx system, including the round of payment adjustments due to the final Part D risk score reconciliation. Therefore, recovery of MPE errors occurs on a flow basis as part of the routine operation of the MARx payment system.

Regarding the PELS estimate, further investigation must be done to better understand the inconsistencies identified by this analysis in order to determine how to conduct payment recovery.

Regarding the PEMS estimate, application of the aggregate national active case eligibility error rate from another program (PERM) to Part D payments in order to estimate PEMS does not allow HHS to identify which dual eligible beneficiaries actually had incorrect Medicaid status. Thus, it is not possible to identify any beneficiary-level payments for which HHS should pursue recovery.

Regarding the PEPV error, the CY 2007 PDE validation was based on a national sample of PDEs and the imputation of these results onto the Part D

population, therefore payment errors cannot be linked to specific beneficiaries for payment recovery purposes.

11.34 Medicare Prescription Drug Benefit Information Systems and Other Infrastructure

The information systems and other infrastructure that would be valuable to HHS in reducing errors in the Part D program cannot be identified with certainty until this measurement is fully implemented. However, for the four components that we have measured, HHS has the information systems and other infrastructure needed to reduce improper Medicare Prescription Drug Benefit payments. HHS uses the following internal Medicare systems to make and validate the Part D payments: the Medicare Beneficiary Database, the Risk Adjustment System, the Health Plan Management System, the MARx payment system, and the Integrated Data Repository. No other systems or infrastructure are needed at this time.

11.35 Medicare Prescription Drug Benefit Statutory or Regulatory Barriers that could limit Corrective Actions

No statutory or regulatory barriers that could limit corrective actions have been identified at this time. Statutory or regulatory barriers for limiting corrective actions will not be known until full implementation is complete and results are available.

11.36 Medicare Prescription Drug Benefit Program Best Practices

HHS has taken several steps to ensure payment accuracy in the Medicare Prescription Drug program. Monthly validation of the MARx generated prospective payments, as represented in the MPE estimate, has led to system refinement and robust monitoring of prospective payments to plans. Outreach to plans before and during the PEPV data collection and validation process provides an open forum for improving instructions for data submission, and extending the collection period will allow for increased response rates and decreased improper payment estimates over time.

11.40 Medicaid - A joint Federal/State program, administered by the States that provides health insurance to certain low income individuals.

11.41 Medicaid Statistical Sampling Process

The Payment Error Rate Measurement (PERM) program uses a 17 State three-year rotation for measuring Medicaid improper payments. To select the 17 States for the three-year cycle, States were ranked by size based on their past Federal FFS

expenditures and grouped into three major strata with 17 States in each stratum. The expenditure data showed that nine States represent the major portion (approximately 50 percent) of total Federal Fee-for-Service (FFS) expenditures. To get a precise estimate for the national rate, it was important to make these nine high-expenditure States their own stratum. Therefore, the 17 States in Strata - 1 were further divided into two substrata – Strata - 1A (consisting of the nine States with the highest Federal FFS expenditures) and Strata - 1B (consisting of the eight remaining high-expenditure States). The States were sampled such that three States were selected from Strata - 1A each year. Given the criterion that each State be sampled exactly once over a three-year cycle, each stratum will have one year in which only five States are sampled. That is, the pattern will resemble the sample distribution shown in Table 1.

Table 1: Number of States to be Selected from Each Stratum in Each Year

Strata	Year 1	Year 2	Year 3
1A	3	3	3
1B	3	3	2
2	6	5	6
3	5	6	6

Medicaid improper payments are estimated on a Federal fiscal year basis and measure three component error rates: FFS, managed care, and eligibility. HHS, through its use of Federal contractors, measures the FFS and managed care components and States perform the eligibility component measurement.

FFS and Managed Care Component:

States submit quarterly adjudicated claims data from which a randomly selected sample of FFS claims and managed care claims are drawn each quarter. Each selected FFS claim is subjected to a medical and data processing review. Managed care claims are subject only to a data processing review. For States reporting in FY 2010, the average FFS sample size was 500 claims and the average managed care sample size was 250 claims per State.

Eligibility Component:

For FY 2010, States conducted an eligibility review on a randomly selected sample of 504 active and 204 negative Medicaid cases over a 12-month period.

- Active cases contain information on a beneficiary who is enrolled in the Medicaid program in the month that eligibility is reviewed.

- Negative cases contain information on a beneficiary who applied for benefits and was denied, or whose program benefits were terminated based on the State agency’s eligibility determination in the month eligibility was reviewed.

Each State calculated two error rates for active cases, a payment error rate and a case error rate.

- The payment error rate is calculated using the dollar value of payments made for services provided to beneficiaries who were ineligible, divided by the dollar value of claims for the sample of beneficiaries, i.e., dollars in error over total dollars in the sample. HHS combines the State reported eligibility component payment error rates to develop a national eligibility error rate for Medicaid.
- The case error rate is calculated by dividing the number of ineligible beneficiaries by the total number of beneficiaries in the sample. States calculate only a case error rate for negative cases because no payments were made. For the active and negative case error rates, the errors are not dollar weighted.

Since there was no historical eligibility error rate data, the initial sample size was calculated under the assumption that the error rate would be five percent. This means that the desired precision requirements will be achieved with a high probability if the actual error rate is five percent or less. For this reason, an annual sample of 504 active cases should meet the desired State-level precision with a high probability. In subsequent years, if the State’s actual error rate is lower, the State may demonstrate that a smaller sample size based on the documented lower error rate is sufficient. Conversely, if a State’s actual error rate is higher, the State may need to select a larger sample.

Calculations and Findings:

All payment error rate calculations for the Medicaid program (the FFS component, managed care component, eligibility component, and national Medicaid error rate) are based on the ratio of estimated dollars of improper payments to the estimated dollars of total payments. Individual State error rate components are combined to calculate the national component error rates. The national Medicaid program error rate is calculated by combining the individual State error rates. National component error rates and the Medicaid program error rate are weighted by State size, so that a State with a \$10 billion program “counts” 10 times more toward the national rate than a State with a one billion dollar program. The national program error rate represents the combination of

Medicaid FFS, Medicaid managed care, and Medicaid eligibility error rates. A small correction factor ensures that Medicaid eligibility errors do not get "double-counted."

HHS calculated and is reporting the three-year weighted average national error rate that includes data from FYs 2008, 2009, and 2010. The three-year rolling error rate is 9.4 percent or \$22.5 billion. The weighted national error components rates are as follows: Medicaid FFS: 4.4 percent; Medicaid managed care: 1.0 percent; and Medicaid eligibility: 5.9 percent. However, as required under Section 601 of the *Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA P.L. 111-3)*, HHS published a final rule on August 11, 2010, which requires the eligibility reviews to be consistent with the State's eligibility verification policy rather than reviewing eligibility against a uniform methodology, which was done in the past. Based on current regulations, certain cases from FYs 2008-2010 would no longer be considered as errors.

The active case error rate for Medicaid is 8.9 percent; the negative case error rate is 8.1 percent.

11.42 Medicaid Corrective Action Plans

Overall, the majority of the FY 2010 errors were a result of cases reviewed for eligibility that were either not eligible or their eligibility status could not be determined, thus they were considered errors (Verification errors). The most common cause of cases in error for the Medicaid FFS medical review was insufficient documentation (Administrative and Documentation errors).

For FY 2010, the most common causes of improper payments were:

- Administrative and Documentation:
 - Insufficient documentation
 - No documentation
 - Administrative/other
- Authentication and Medical Necessity:
 - Diagnosis coding error
 - Number of units error
 - Medically unnecessary services
 - Policy violation
 - Procedure coding error
 - Unbundling
- Verification:
 - Eligibility Errors

- Duplicate item
- FFS claim for a managed care service
- Pricing error
- Logic edit
- Third party liability
- Non-covered service
- Data entry error
- Rate cell error (wrong managed care payment amount)
- Managed care payment error

HHS works closely with States to develop State-specific Corrective Action Plans (CAPs). States are responsible for implementing, monitoring, and evaluating the effectiveness of their CAPs. HHS received CAPs from all States whose Medicaid programs were measured and reported in FY 2009. States continue to take steps to reduce errors identified during the measurement.

Because much of the error rate in the past was due to missing or insufficient documentation, the majority of States focused on provider education and communication methods to improve the responsiveness and timeliness of submission of requested documentation. These methods included provider training sessions; meetings with provider associations; notices, bulletins and provider alerts; provider surveys; improvements and clarifications to written State policies emphasizing documentation requirements; and performing more provider audits.

States focus their efforts on major causes of error where HHS and the State can identify clear patterns. For example, States have found that particular provider types, such as pharmacies or long-term care facilities, repeatedly fail to comply with documentation requirements and may find that a targeted corrective action for these providers is cost-effective and likely to reduce future improper payments. When States have pricing and logic errors occur in their processing system, they work to ensure that those systems are fixed to avoid improper payments.

For eligibility errors, specific corrective action strategies implemented by the States to reduce eligibility errors have included leveraging technology and available databases to obtain eligibility verification information without client contact; providing additional caseworker training, particularly in areas determined by the PERM review to be error-prone; and providing additional eligibility policy resources through a consolidated manual and web-based training.

The States reviewed for the FY 2010 AFR will also be reviewed and have error rates reported again in the FY 2013 AFR. The re-measurement audit will document effectiveness of prior years' corrective actions and HHS expects to see improvement in the State and national component payment error rates. HHS is also developing an error rate reduction plan at the Federal level based on its analysis of the FY 2010 improper payments.

In addition to the development, execution, and evaluation of the State-specific CAPS, HHS has also made significant efforts to lower error rates:

- A significant portion of medical review errors in previous measurements resulted from providers failing to submit necessary documentation. It is possible that some of these claims were accurate, but HHS could not verify their validity in the absence of sufficient documentation. The claims were therefore considered to be fully in error. HHS increased its efforts to reach out to providers and to obtain medical records to help resolve this problem. This activity had a significant impact on reducing the no documentation errors. HHS also advanced a pilot program to give States more information on the potential impact of these documentation errors and more time for the States to work with providers to resolve them.
- HHS sponsored a series of provider open forum calls from May 2010 through August 2010 for all States in the next PERM review cycle. HHS also enhanced the CMS PERM website with up-to-date information, included a separate web page for providers, and an email account for providers to communicate directly with HHS.
- HHS is working to reduce the State burden and align PERM data collection more closely with other HHS program integrity data collection processes. Over the past two years, HHS developed and pilot tested a new, streamlined methodology (referred to as "PERM Plus") to collect data required for PERM. When implemented, this approach will position HHS to integrate PERM data collection with other emerging HHS program integrity initiatives.
- HHS is exploring the development of an eligibility measurement methodology that would combine the requirements of section 1903(u) of the Medicaid statute for Medicaid Eligibility Quality Control (MEQC) with the requirement of *IPIA*. The *CHIPRA* regulation requires HHS to review the requirements of the MEQC and PERM programs and coordinate the implementation of the requirements to reduce redundancies between the measurements. The eventual goal is to allow one measurement to meet the quality control requirements of MEQC and the

improper payment requirements of PERM. Harmonization would benefit States by reducing workload for conducting eligibility reviews, providing meaningful results for corrective actions, and allowing HHS to recover identified erroneous payments based on Medicaid eligibility determinations.

- States have historically struggled to include "aggregate payments" (ie., payments that cannot be identified by an individual claim transaction) in the PERM review. HHS has developed a theoretical framework to address this issue and has pilot tested the approach with three States. HHS is applying the aggregate payment framework to all States in the next year's review.

As an additional program corrective action, HHS formed a State systems workgroup to address individual State system problems that may cause payment errors. The workgroup includes representatives from HHS and State staff.

11.43 Medicaid Program Improper Payment Recovery

For FY 2008, the actual improper payments identified for the Medicaid program in the sample were \$1,258,525.

For FY 2009, the actual improper payments identified for the Medicaid program in the sample were \$1,095,473.

For FY 2010, the actual Medicaid improper payments identified for the Medicaid program in the sample were \$784,877.

The recoveries of Medicaid improper payments are governed by Section 1903(d)(2) of the *Social Security Act* and related regulations at Part 433, Subpart F under which States must return the Federal share of overpayments. States reimburse the Federal share on the CMS-64 expenditure report for Medicaid which contains a line item for program collections.

As of January 2010, PERM Recoveries are reported on Form CMS 64.90 PERM, which will automatically transfer to the CMS-64 Summary Form on Line 10D, specifically created for PERM. HHS continues to work with the States to collect recoveries. Our efforts are ongoing. Due to our continued efforts, HHS will be able to report on Medicaid recoveries in the future.

11.44 Medicaid Information Systems and Other Infrastructure

Since Medicaid payments occur at the State level, information systems and other infrastructure needed to reduce Medicaid improper payments would need to be implemented at the State level.

PERM faced many challenges with State payment systems that had paper only and aggregate claims; changes in information systems at the State level during the course of the measurement cycle; and a wide variation of systems designs and capabilities from State to State. HHS has been active in encouraging and supporting States in their efforts to modernize and improve State Medicaid Management Information Systems (MMIS). Such improvements will produce greater efficiencies in the PERM measurement and strengthen program integrity. Recently, HHS formed a State systems workgroup consisting of State and HHS representatives. This group meets regularly to identify and discuss State system vulnerabilities and the impact on the measurement of improper payments. In addition, HHS developed a methodology to measure aggregate claims that will be incorporated into future PERM processes.

Also, HHS is developing a comprehensive plan to modernize Children's Health Insurance Program (CHIP) and Medicaid data systems. The primary goal of this plan is to leverage technologies to create an authoritative and comprehensive Medicaid and CHIP data structure so that HHS can provide effective oversight of its programs. The plan will also result in a reduction in State burden and more robust data available for the PERM measurement.

11.45 Medicaid Statutory or Regulatory Barriers that could limit Corrective Actions

No statutory or regulatory barriers that could limit corrective actions have been identified at this time.

11.46 Medicaid Program Best Practices

Based on lessons learned through previous PERM cycles and in an effort to address challenges faced by the States, HHS implemented a pre-cycle aspect of the PERM measurement starting with FY 2009. The pre-cycle phase occurs prior to the first submission of data, and allows HHS to disseminate information on changes in the program and conduct individual orientation and education sessions with the States. The following additional measures have been incorporated into the overall process:

- States receive further education on the PERM process through HHS-initiated cycle calls and website activity.
- HHS has designated a cycle manager as the lead for a fiscal year measurement and the main point of contact at HHS for that year.
- HHS utilizes dashboards, a compilation of the contractors' and States' work, to monitor the progress of the measurement. The dashboards enable HHS to monitor problems in the measurement earlier and provide assistance to

resolve issues delaying the measurement progress.

- The use of biweekly all-contractor meetings has been employed to facilitate communication and problem solving between HHS and its contractors to improve the PERM process.
- For States having difficulty providing complete data, HHS has provided on-site technical assistance.

11.50 Children's Health Insurance Program (CHIP) - A Joint Federal/State program administered by the States that provides health insurance for qualifying children.

11.51 CHIP Statistical Sampling Process

On August 11, 2010, as part of enhanced efforts to reduce improper payments in Federal programs, HHS issued the final regulations (PERM final rule) that will fully implement improvements to the Payment Error Rate Measurement (PERM) program for Medicaid and the Children's Health Insurance Program (CHIP). Section 601 of the *Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA P.L. 111-3)* prohibited HHS from calculating or publishing any national or State-specific error rates for CHIP until six months after a new PERM final rule is in effect. HHS did not report a national error rate for CHIP in the FY 2009 AFR and, due to timing of the published PERM final rule, will not be reporting a national error rate for CHIP in the FY 2010 AFR. However, HHS will begin conducting the CHIP error rate measurement in FY 2011, with the results being published in the FY 2012 AFR.

Prior to the passage of *CHIPRA* and the statutory requirement prohibiting the calculation or publication of a CHIP error rate, Medicaid and CHIP employed the same State sampling process. HHS determined that CHIP can be measured in the same States selected for Medicaid review each fiscal year with a high probability that the CHIP error rate will meet the *IPIA* required confidence and precision levels. Since CHIP and Medicaid will be measured in the selected States at the same time, each State will be measured for CHIP once and only once every three years. For detailed information on the State sampling process implemented prior to passage of *CHIPRA*, please read Section 11.41, Medicaid Statistical Sampling Process.

CHIP improper payments are estimated on a Federal fiscal year basis and measure three component error rates: FFS, managed care, and eligibility. HHS, through its use of Federal contractors, measures the FFS and managed care components and States perform the eligibility component measurement.

11.52 CHIP Corrective Action Plans

Since HHS is not reporting a national CHIP FY 2010 error rate, the affected States were not required to submit a corrective action plan.

States will submit and implement corrective action plans in FY 2012 when we report a CHIP error rate. That corrective action plan will include the following:

- Data analysis - an analysis of the findings to identify where and why errors are occurring.
- Program analysis - an analysis of the findings to determine the causes of errors in program operations.
- Corrective action planning - steps taken to determine cost-effective actions that can be implemented to correct error causes.
- Implementation - plans to operationalize the corrective actions, including milestones and a timeframe for achieving error reduction.
- Monitoring and evaluation – assessment of whether the corrective actions are in place and are effective at reducing or eliminating error causes.

HHS will monitor States' implemented corrective actions to determine whether the actions are effective and whether milestones are being reached.

11.53 CHIP Program Improper Payment Recovery

Improper payments identified in FY 2009, prior to the passage of *CHIPRA*, are subject to recovery, as detailed at 42 Code of Federal Regulations (CFR) §§ 431.1002 and 457.232. For FY 2009, the actual improper payments identified for the CHIP program in the sample, prior to the passage of *CHIPRA*, was \$4,570.

For FY 2010, no improper payments were identified for the CHIP program due to the reasons stated above.

The recoveries of CHIP improper payments are governed by Section 1903(d)(2) of the *Social Security Act* and related regulations at Part 433, Subpart F under which States must return the Federal share of overpayments. States reimburse the Federal share on the CMS-21 form for CHIP which contains a line item for program collections. Historically, the CMS-21 expenditure report did not include space for States to separately report PERM recoveries. In January 2010, CMS added a new section in the CMS-21 financial report where States separately reported PERM recoveries for the first time. Due to our continued efforts, HHS will be able to report on CHIP recoveries in the future.

11.54 CHIP Information Systems and Other Infrastructure

Since CHIP payments occur at the State level, information systems and other infrastructure needed to reduce CHIP improper payments would need to be implemented at the State level. PERM faced many challenges with State payment systems that had paper only and aggregate claims; changes in information systems at the State level during the course of the measurement cycle; and a wide variation of systems designs and capabilities from State to State. HHS has been active in encouraging and supporting States in their efforts to modernize and improve State Medicaid Management Information Systems (MMIS). Such improvements will produce greater efficiencies in the PERM measurement and strengthen program integrity. Recently, HHS formed a State systems workgroup consisting of State and HHS representatives. This group meets regularly to identify and discuss State system vulnerabilities and the impact on the measurement of improper payments. In addition, HHS developed a methodology to measure aggregate claims that will be incorporated into future PERM processes.

Also, HHS is developing a comprehensive plan to modernize CHIP and Medicaid data systems. The primary goal of this plan is to leverage technologies to create an authoritative and comprehensive Medicaid and CHIP data structure so that HHS can provide effective oversight of its programs. The plan will also result in a reduction in State burden and more robust data available for the PERM measurement.

11.55 CHIP Statutory or Regulatory Barriers that could limit Corrective Actions

Section 601 of the *Children's Health Insurance Program Reauthorization Act (CHIPRA) of 2009 (P.L. 111-3)* prohibited HHS from calculating or publishing any national or State-specific error rates for CHIP until six months after a new PERM final rule is in effect. The new final rule for PERM became effective September 10, 2010; therefore, for FY 2009 and FY 2010, HHS did not report a national CHIP error rate. However, HHS will begin the CHIP measurement in FY 2011 and report an error rate in the FY 2012 AFR.

11.56 CHIP Best Practices

This section is not currently applicable to the program as the CHIP error rate has only been calculated and measured once, and HHS is not reporting a CHIP error rate for FY 2010.

11.60 Temporary Assistance for Needy Families (TANF) - A joint Federal/State program administered by the States that provides time-limited assistance to needy families with children to promote work, responsibility and self-sufficiency.

11.61 TANF Statistical Sampling Process

Statutory limitations prohibit HHS from requiring States to participate in a TANF improper payment measurement. As a result, the TANF program is not reporting an error rate for FY 2010.

Despite statutory limitations, HHS continues to explore options that will allow for a future error rate measurement.

11.62 TANF Corrective Action Plans

Since TANF is a state administered program, corrective actions that could help reduce improper payments would have to be implemented at the State level. The TANF statute prohibits HHS from requiring State TANF agencies to implement and report on corrective actions. Despite the limitations, HHS annually submits a letter to all TANF States with recommendations for potential corrective actions based on the past reviews done by OIG. The reviews show that the primary causes of error are ineligible recipients, incorrect payment amounts and insufficient documentation. States may employ these recommendations voluntarily in their corrective action efforts to reduce future improper payments.

11.63 TANF Improper Payments Recovery

Statutory limitations prohibit HHS from requiring States to participate in a TANF improper payment measurement. As a result, the TANF program is not reporting an error rate for FY 2010.

Despite statutory limitations, HHS continues to explore options that will allow for a future error rate measurement and improper payment recoveries.

11.64 TANF Information Systems and Other Infrastructure

Since TANF payments occur at the State level, information systems and other infrastructure needed to reduce TANF improper payments would need to be implemented at the State level. States utilize the Public Assistance Reporting Information System (PARIS), the National Directory of New Hires (NDNH), and the Income Eligibility Verification System (IEVS), to help ensure that improper payments are minimized. No other systems or infrastructure are needed at this time.

11.65 TANF Statutory or Regulatory Barriers

Statutory limitations prohibit HHS from requiring States to participate in a TANF improper payment measurement. As a result, the TANF program is not reporting an error rate for FY 2010.

Despite statutory limitations, HHS continues to explore options that will allow for a future error rate measurement.

11.66 TANF Program Best Practices

We encourage States to stress the importance of payment accuracy for TANF cases and seriously consider measures that will reduce the incidence of erroneous payments in their States. Actions that may prove beneficial in this area include but are not limited to, the following:

- Conduct local office quality control reviews at both the initial intake and redetermination stages of case development for basic assistance eligibility and payment processes.
- Consider payment accuracy as proper case documentation measures or elements of staff performance.
- Develop and maintain a reminder system for critical follow-up actions on cases such as responding to reports of non-cooperation with child support, IEVS "hits", redeterminations of eligibility, or failure to fulfill work requirements.
- Establish a process for the collection of TANF overpayments from the applicable recipients.
- Periodically remind TANF recipients of their responsibility to accurately report income, resources, and other family circumstances to the local TANF agency on a timely basis.
- Conduct training on investigative interviewing techniques for intake workers and case managers.
- Perform periodic "checks" of case records, paying particular attention to documentation that includes a current application and facts supporting income, household composition, participation in work activities, and cooperation with child support enforcement.
- Establish and monitor internal procedures to ensure that TANF payments are adjusted on a timely basis when family circumstances change and affect case eligibility or the amount of payment.

States may also improve the integrity of their programs by participating in the Public Assistance

Reporting Information System (PARIS) and/or by using information available through the National Directory of New Hires (NDNH). PARIS is a federal-state partnership which provides all fifty States, D.C., and Puerto Rico detailed information and data to assist them in maintaining program integrity and detecting duplicate or other improper payments by public assistance programs such as TANF, Medicaid, Supplemental Nutritional Assistance Program, and Child Care.

State TANF agencies can use NDNH information to verify the eligibility of adult TANF recipients residing in the State and, once the information is verified, it can be used to modify benefits or close the case if the individual is not eligible for assistance. States using NDNH information have reported that it has been a valuable tool in improving payment accuracy. By using NDNH information, States have uncovered previously unknown employment, improved TANF program integrity by evaluating benefit accuracy, and even uncovered identity theft.

HHS will issue a TANF Information Memorandum providing technical assistance to States in the form of recommendations gleaned from OIG reports and other activities undertaken by HHS that can reduce improper payments. The TANF Information Memorandum will be posted on the HHS TANF website and distributed via our listserv to all States and to the other TANF stakeholders on our listserv.

HHS Regional Offices will follow-up with the States regarding the TANF Information Memorandum on strategies to reduce improper payments to respond to questions and to provide further information and/or technical assistance.

11.70 Foster Care - A joint Federal/State program administered by the States for children who need placement outside their homes in a foster family home or a child care facility.

11.71 Foster Care Statistical Sampling Process

There have been no changes to the statistical sampling process for Title IV-E Foster Care during the current year. Under the regulatory review promulgated at 45 CFR 1356.71, Foster Care Eligibility Reviews are conducted systematically in each State (the 50 States, the District of Columbia and Puerto Rico) every three years. During these reviews, a team comprised of Federal and State staff review 80 cases selected from the State's Title IV-E Foster Care population to determine a State's level of compliance in meeting the Federal eligibility requirements for the Foster Care program and to validate the accuracy of a State's claim for Federal reimbursement of Foster Care payments. Each regulatory review identifies the number of error cases and amount of payment errors

determined from the review of a sample drawn from the State's overall Title IV-E caseload for its six-month Period Under Review (PUR). The sample is a random sample drawn from the universe of cases having at least one Title IV-E Foster Care maintenance payment during the PUR. An error case is defined as a case in which a Title IV-E Foster Care maintenance payment is made on behalf of an ineligible child during the PUR. Payment errors may include payments for error cases, payments made for non-error cases which failed to meet an eligibility criterion outside the PUR, and payments for services not covered by Title IV-E or its regulatory provisions (e.g. therapy). If any payment errors are identified during a primary review, HHS imposes a disallowance in the total amount of all identified payment errors.

HHS employs a 10 percent error threshold to determine the level of State compliance in meeting the Federal requirements in the Foster Care program. If during a primary review a State exceeds the error threshold, (a) HHS takes a disallowance as described above, (b) the State is required to develop and implement a Program Improvement Plan (PIP) and, (c) following PIP implementation (which generally is completed within a year), the State is subjected to a secondary review where 150 cases are selected for review. If a State exceeds the error threshold for the case and dollar error rates in a secondary review, the State is assessed an additional extrapolated disallowance, which is equal to the lower limit of a 90 percent confidence interval for the State Foster Care population's total dollars in error during the six-month PUR. The extrapolation increases geometrically the resulting disallowance. Since FY 2000, HHS has systematically conducted more than 155 regulatory Foster Care reviews, with over 14,500 Foster Care cases reviewed.

The Foster Care error rate and national estimates of improper payments are calculated each year using data collected in the most recent eligibility review for each of 50 States, the District of Columbia, and Puerto Rico. Since each State is reviewed every three years, each year's "composite sample" of data from 52 State reviews incorporates new review data for about one-third of the States. While each State sample represents a distinct six-month PUR, the national "composite" sample reflects a composite PUR. Consequently, the resulting error rate is referred to as a "rolling" estimate, since about one-third of the review data are replaced with new data each year. To arrive at the national estimates of improper payments and payment error rate, data from each State review sample are used to develop an estimate of State improper payments for the PUR. This estimate considers both under- and overpayments in accordance with the *IPIA*. State

estimates are then aggregated to estimate national improper payments for the composite PUR. The national estimate is divided by the sum of payments received during respective PURs to determine the national payment error rate for the program. The FY 2008 and FY 2009 estimates reflected a transition from case-based estimation to a refined dollar-based methodology for estimating State improper payments. Continued application of the new, refined methodology to eligibility review data for this year indicates that, for FY 2010, the Foster Care estimated national payment error rate is 4.9 percent. This represents a slight increase compared to the FY 2009 error rate of 4.7 percent; however, current performance still represents a decrease of over 50 percent from the baseline rate of 10.33 percent. The slight increase in the error rate does not represent a regular pattern across States reviewed but appears to be more of an artifact of mixed individual State review performance relative to the size of the States. Specifically, those States that demonstrated substantively improved performances, as indicated by lower error rates, were relatively small, so the improvements had minimal impact on the national rate. Only one large State demonstrated a substantial drop in its payment error rate. Additionally, a few relatively large States reported slightly higher payment error rates than in their previous review. Due to these circumstances, the net national result was a slightly higher overall program error rate.

11.72 Foster Care Corrective Action Plans

All payment errors in the Title IV-E Foster Care Program are “Administrative and Documentation” errors because they all reflect incorrect classifying or processing of payments by State agencies or third parties who are not the beneficiaries. Thus, all corrective action plans are targeted to improving processing of IV-E claims by State and local agencies. Corrective action plans instituted by HHS to address improper payments in the Foster Care program have been designed to help States address those payment errors (e.g., underpayments) that have contributed most to improper payments made by the IV-E program to State agencies. In FY 2010, the most common payment errors made by States involving IV-E Foster Care funds included the following:

- Underpayments (19 percent of errors)
- Provider not licensed or approved (16 percent of errors)
- Ineligible payment (e.g., therapy) (14 percent of errors)
- Not AFDC eligible at time of removal (11 percent of errors)
- Criminal records check not completed (9 percent of errors)
- Judicial determination regarding reasonable efforts to finalize permanency plan not timely (6 percent of errors)
- Duplicate or excessive maintenance payments to providers (6 percent of errors)
- No judicial determination of reasonable efforts to prevent removal (4 percent of errors)

Together these eight items account for nearly 85 percent of payment errors for Foster Care. The overall frequency of all types of payment errors in the composite Foster Care sample (i.e., across all States) decreased by about 19 percent from FY 2009 to 2010. This decrease may have been fueled in part due to the drop in underpayments. While underpayments are the most frequent payment error occurring in the composite sample, the total frequency dropped considerably from FY 2009 (down from 176 or 28 percent of all errors last year to 96 or 19 percent of all errors this year). This occurred because several States with high numbers of underpayments in earlier reviews were reviewed again this year and were found to have fewer or no underpayment errors.

It is of interest to note that over the course of efforts to reduce improper payments, the overall number of payment errors has dropped substantially and the composition of error types identified has changed as well. When reporting commenced in FY 2004, the most prevalent errors were errors associated with the requirement for a judicial determination in finalizing the permanency plan. However, these errors have been reduced from a frequency of 286 in FY 2004 to only 30 in FY 2010. Currently, underpayments, rather than overpayments are the largest component of a much smaller universe of payment errors in the program. While the overall impact of payment errors has been reduced between FY 2009 and FY 2010, this reduction highlights the importance of maintaining diligence in corrective action efforts. Key features of HHS’s corrective action strategies include the following:

- HHS conducts on-site and post-site review activities to effectively validate the accuracy of a State’s claim for reimbursement of payments made on behalf of children and their Foster Care providers. Specific feedback is provided on-site to the State agency to directly impact the

proper and efficient administration and implementation of the State's Title IV-E Foster Care programs. Further, a comprehensive report is issued to the State agency to confirm the final findings of the on-site review. The final report serves as the basis for the development of a Program Improvement Plan (PIP) for States that exceed the error threshold.

- States are required to develop and execute State-specific PIPs that target corrective action to the root cause of payment errors in the State. The PIP is developed by State staff in consultation with Federal staff and is required to include: (1) Specific goals or outcomes for program improvement; (2) Measurable action steps required to correct each identified weakness or deficiency; (3) Target date for completing each action step; (4) Description of how progress will be evaluated by the State and reported to HHS, including the frequency and format of the evaluation procedures; and (5) Description of how the State will report to HHS when an action step has been achieved.
- The PIP is designed to lead to measurable changes in State program operations and is required to identify the specific action steps developed to attain the desired outcomes and correct program deficiencies. Each action strategy has a projected completion date that will not extend more than one year from the date the PIP is approved by HHS. This assures that proper attention is given to correcting deficiencies in a timely manner. HHS believes that the development and implementation of the PIP is the key to identifying the reasons why cases are in error and motivating States to correct the identified problems. Requiring States to implement PIPs has proven to be an effective solution in addressing eligibility errors as reflected in the decrease in the national error rate since FY 2004.
- HHS provides onsite training and technical assistance to States to develop and implement program improvement strategies.
- HHS works toward heightening judicial awareness and monitoring of reviews. In past years, three of the six most frequently occurring errors have involved the judiciary. In FY 2010, none of the five most frequent payment errors involved the judiciary. HHS continues to share the results of the Foster Care reviews with judicial organizations and offers training and technical assistance to educate and inform the judiciary in areas pertaining to their role directly impacting the State agency's performance on the eligibility factors.

- HHS works closely with the Court Improvement Program in States where judges require training and court orders warrant modification to maintain the gains in reducing improper payments related to the judiciary.
- HHS conducts secondary reviews (as applicable) and takes appropriate disallowances consistent with the review findings. HHS's expectation is that these disallowances, in conjunction with the development and implementation of the PIP, will serve as strong encouragement to the States to improve their programs to the extent that when a secondary review is conducted they will be determined to be in substantial compliance.
- HHS provides technical guidance to ensure reliable identification of underpayments by (1) discussing any underpayments identified during a Title IV-E eligibility review at the exit conference with State agency senior management; (2) identifying underpayments in final reports issued to States following Title IV-E eligibility reviews; and (3) including language in the *Title IV-E Foster Care Eligibility Review Guide* clarifying what constitutes an "underpayment" to ensure that Federal and State agency staff accurately identify underpayments.
- Also, HHS provides training and technical assistance tailored to assist States and Tribes in improving their child welfare systems and to conform to outcomes and systemic factors identified in the results of the regulatory Foster Care monitoring reviews. The aim is to refine their management and operations, expand organizational capacity, and foster effective and consistent practice while improving outcomes for children, youth, and families.

Through implementation of its comprehensive corrective action plan, HHS reduced the national Foster Care error rate below target levels and demonstrated steady progress in reducing the error rate in FY 2005, FY 2006, and FY 2007. The error rate decreased from 10.33 percent in FY 2004 (baseline) to 8.60 percent (FY 2005) to 7.68 percent (FY 2006) to 3.30 percent (FY 2007). Although the rate increased in FY 2008 to 6.42 percent, that change still represented a reduction of the rate by over one-third since establishing the baseline for FY 2004. In addition, the FY 2008 error rate estimate reflected a transition from a case-based estimation to a refined dollar-based methodology for estimating State improper payments. Subsequent rulings by the Departmental Appeals Board reversed some errors for one of three States contributing to the increase in FY 2008. In 2009, the error rate decreased to

4.7 percent, and in 2010, the error rate remained low at 4.9 percent; thus, the IV-E Foster Care program continues to maintain a payment error rate that is less than half the baseline rate.

11.73 Foster Care Improper Payment Recovery

As a result of its conducting Foster Care eligibility reviews in 18 States during the 12-month period of August 2009 – July 2010, HHS has recovered over \$1.7 million in Title IV-E improper payments. The funds recovered are comprised of \$966,556 disallowed maintenance payments and \$798,076 disallowed administrative payments. The following table shows over \$12.2 million improper payments recovered through IV-E Foster Care Eligibility Reviews from FY 2004 through FY 2010.

**Recovery of Improper Payments Table
(in Millions)**

FY	Reporting Period	# Reviews	Amount Identified = Amount Recovered		
			Maintenance Disallowances	Administrative Disallowances	Total Disallowances
2004	10/2003-9/2004	20	\$.949	\$.652	\$ 1.601
2005	10/2004-9/2005	13	.611	.405	1.017
2006	10/2005-7/2006	9	.371	.333	.704
2007	8/2006-7/2007	24	2.104	1.587	3.691
2008	8/2007-7/2008	14	1.420	.729	2.150
2009	8/2008-7/2009	17	.535	.751	1.287
2010	8/2009-7/2010	18	.967	.798	1.765

Recovery of Improper Payments through Title IV-E Foster Care Eligibility Reviews

The recovery of improper payments through eligibility reviews is most aptly classified as occurring through *post-payment reviews*. HHS does not systematically track cost recovery through the Office of Inspector General reviews and Single Audit Reports; however, such information has been obtained from HHS reports generated as part of the audit clearance process. Specifically, audit findings where the audit has been closed and a recommended cost recovery has been sustained for the Title IV-E Foster Care program were identified and tabulated.

These amounts are in addition to amounts identified through the eligibility reviews and are presumed as recovered in the fiscal year, when the audit is closed.

Recoveries of improper payments through audits can include Title IV-E Foster Care maintenance assistance payments, administration, and training and automated systems development costs. Thus, the following table summarizes the recovery of improper payments – as monitored by HHS – for Title IV-E Foster Care:

**Title IV-E Foster Care:
Costs Identified and Recovered
(in Millions)**

Source	2004	2005	2006	2007	2008	2009	2010**	TOTAL
Eligibility Reviews	\$ 1.6	\$ 1.0	\$ 0.7	\$ 3.7	\$ 2.1	\$ 1.3	\$ 12.2	\$ 10.4
OIG Reviews	40.0	3.0	11.7	32.0	12.4	0.0	2.8	102.0
Single Audits	5.5	1.7	5.2	1.6	6.4	5.3	0.3	26.1

** FY 2010 amount contains data through 07/31/2010

11.74 Foster Care Information Systems and Other Infrastructure

HHS uses the Adoption and Foster Care Analysis and Reporting System for the regulatory reviews. Utilizing this existing source of data reduces the burden on States to draw their own samples, promotes uniformity in sample selection, and employs the database in a practical and beneficial manner.

Since Foster Care payments occur at the State level, information systems and other infrastructure needed to reduce Foster Care improper payments would need to be implemented at the State level. No other systems or infrastructure are needed at this time.

11.75 Foster Care Statutory or Regulatory Barriers that could limit Corrective Actions

No statutory or regulatory barriers that could limit corrective actions have been identified at this time.

11.76 Foster Care Best Practices

Since the inception of its improper payment reporting, HHS has maintained a diligent focus on improper payment identification and reduction efforts in the Foster Care program. Over the past five years, HHS has consistently received positive feedback from OMB for its original, sound methodology for estimating improper payments from existing data sources as well as for continued

refinements of the methodology to accurately identify improper payments and maximize adherence to *IPIA* requirements. These refinements have included steps to ensure systematic examination and consideration of underpayments in eligibility reviews and modifying data retention practices to permit shifting from case-based extrapolation to dollar-based extrapolation.

Concurrent with these efforts to continually refine its identification and reporting on improper payments, HHS has worked successfully to reduce improper payments across the Foster Care program. Working on dual fronts with States to improve administrative procedures for tracking and documenting eligibility and with the judiciary to support adherence to requirements for timely and thoroughly documented case hearings and court orders has yielded reductions in eligibility errors and resulting improper payments nearly each year since baseline reporting in FY 2004. The payment error rate has been reduced from a baseline rate of 10.33 percent of payments in FY 2004 to a rate of 4.9 percent in FY 2010. Furthermore, in the years since baseline reporting commenced, the Title IV-E Foster Care Program has recovered a total of \$12.2 million in improper payments.

In addition to the ongoing efforts to address improper payments outlined above, in FY 2010 the Foster Care program has continued to lay the groundwork for and move towards future implementation of a new methodology to review administrative payments for Title IV-E Foster Care (i.e., Administrative Cost Review, or ACR). The methodology has been recognized by OMB for its innovative approach to examining and testing the allocation and assignment of administrative costs to Title IV-E Foster Care. In FYs 2009 and 2010, HHS conducted two additional pilot tests of the ACR methodology, and shared the findings with the participating States for their consideration and implementation in improving the administrative cost allocation and the assignment to Title IV-E Foster Care.

11.80 Head Start - A Federal program that provides comprehensive developmental services for America's low-income, preschool children ages three to five and their families.

11.81 Head Start Statistical Sampling Process

HHS is legislatively required to perform reviews of each Head Start program every three years. The design of the sample for the Erroneous Payments Study of Head Start programs is a three-stage element sample. Since each program is reviewed once every three years, the first stage of the sample is to identify the programs up for review. The second stage of the sample is to select the

programs to be reviewed. As was done in the previous Erroneous Payments studies, the FY 2010 study selected 50 programs and several alternates. Programs were selected through a stratified random sample, where programs were divided into five strata by size of enrollment. The number of programs sampled within each stratum is roughly proportional to the number of children represented in each stratum, based on the most recent Program Information Report funded enrollment data. The third stage of the sample is to select the records to be reviewed in each selected program, using a systematic sampling scheme.

For the FY 2010 Erroneous Payments Study, 50 Head Start programs from 21 States and Puerto Rico were reviewed. Approximately 10,748 records were examined. The objective of the reviews is to produce a national error rate of enrolled children who are ineligible for Head Start or Early Head Start services according to Head Start's income eligibility guidelines.

A payment error in the Head Start program is defined as a payment for an enrolled child from a family whose income exceeds the allowable limit (in excess of the 10.0 percent program allowance for families above the income limit). To make this determination, reviewers were required to look at each sample child's folder and determine if the child was ineligible. A child was deemed ineligible if (1) there was not, as required by 45 CFR Part 1305.4(e), a signed statement by a Head Start employee stating the child was eligible to participate or (2) there was income documentation in the child's folder that, in the reviewer's judgment, suggested the child was not Head Start eligible. Reviewers are also asked to review income documentation regardless of whether there was a signed statement in the file.

The FY 2010 error rate is 1.7 percent, a decrease from the FY 2009 rate which was 3.0 percent. Included this year was a formal examination of the 2007 *Head Start Act* requirement regarding the eligibility of children whose families fall between 100 and 130 percent poverty. On-site examination shows that programs are beginning to include children in that category, and no programs exceeded the allowed 35 percent enrollment threshold for that group of children.

11.82 Head Start Corrective Action Plans

The statistical analysis indicates that approximately 99 percent of the FY 2010 Head Start Erroneous Payments error rate is due to Administrative and Documentation errors and Verification errors.

In May 2010, HHS issued a Program Instruction (ACF-PI-HS-10-02) reminding programs that they are required to verify family income before

determining a child is eligible to participate in the program. The Program Instruction also encouraged programs to maintain copies of the eligibility documents with the eligibility verification form in the child's official record and to provide annual training to employees responsible for determining and verifying income eligibility.

To further reduce Administrative and Documentation errors, HHS has developed a standard signed statement template form for Head Start. Since OMB clearance (OMB 0907-0374) was obtained in FY 2010, the use of the form is optional, but grantees are strongly encouraged to use it. The standard signed statement form helps guide grantees on the type of information they need to collect from prospective families during the enrollment process and provides them with a structure for recording this information.

In FY 2011, HHS will expand the Erroneous Payments study to review more child files while onsite. In addition, during monitoring reviews for all programs, additional files will be sampled to verify age/income eligibility requirements and information will be collected on how many programs maintain source documentation with the child's record. If available, a review of source documentation will be used to better understand whether the program is accurately determining eligibility status. Maintaining source documentation is currently not a requirement.

11.83 Head Start Improper Payments Recovery

HHS has determined that no program reviewed as part of the FY 2010 Erroneous Payment study will be subject to a disallowance. Since 99 percent of the error rate is due to Administrative and Documentation errors and Verification errors, HHS is concentrating its efforts on instructing and training their employees to reduce these correctable errors. In addition, HHS will continue to concentrate on improper payment recovery wherever necessary.

11.84 Head Start Information Systems and Other Infrastructure

HHS has the information systems and infrastructure needed to reduce improper Head Start payments to the levels that HHS has targeted. HHS has two systems in place that identify grantees that are not complying with Head Start's income eligibility requirements. First, all review reports are processed centrally by HHS as part of Head Start monitoring. Secondly, Head Start is using the Risk Management System, implemented in each region, to help identify and manage grantee compliance with eligibility requirements. Both systems allow HHS to identify grantees that fail to comply with income

eligibility requirements. No other systems or infrastructure are needed at this time.

11.85 Head Start Statutory or Regulatory Barriers

Currently, HHS cannot require programs to maintain source documentation that supports the determination of income eligibility.

11.86 Head Start Program Best Practices

HHS continues to explore ways as to how to improve the Head Start error rate process and address the Administrative and Documentation errors.

11.90 Child Care - A Joint Federal/State program, administered by the States that provides child care financial assistance to low-income working families.

11.91 Child Care Statistical Sampling Process.

The Child Care and Development Fund (CCDF) Error Rate methodology is conducted on a three-year cycle, beginning with Year One and Year Two States whose baseline data was reported in the FY 2008 and FY 2009 *Agency Financial Report (AFR)*. For the FY 2010 *AFR*, Year One, Year Two, and Year Three States' data have been combined to generate the complete baseline payment error rate and related findings reported below.

The CCDF program baseline payment error rate or percentage of improper authorizations for payment is 13.3 percent. The national over-authorization error rate, or the percentage of authorizations in excess of the amounts for which cases are eligible, is 12.6 percent. The percentage of under-authorization is equal to 0.7 percent.

HHS uses a three-year rotation for measuring CCDF improper authorizations for payments. A stratified random sampling method was used for selecting States. One third of the total of 52 States (50 States plus the District of Columbia and Puerto Rico) was selected to participate each year of a three-year cycle in the error rate measurement methodology. The sample of States was stratified by region (10 total), with the regions randomly ordered. States were sorted within each region by caseload, from the most to the least. Every third State on the list was then selected, using a random start number for the first and second years. The third year included those States not selected in year one or year two. Each year this sample yields a mix of county-administered and State-administered programs and States serving small and large numbers of children.

The CCDF error rate methodology employs a case record review process to determine whether child

care subsidies were properly authorized to eligible families. The methodology focuses on administrative errors and improper authorizations for payment made during the client eligibility determination process. It is important to note that the CCDF methodology distinguishes between authorizations for payment and actual payments made to providers for child care services rendered. Because States were estimating improper *authorizations* for payment, the authorization amounts do not represent what was actually paid. In general, the amount of actual payments is lower, computed to be about 17 percent lower. Reporting the amount of improper authorizations for payment in the CCDF program is more stringent than the *IPIA* requirements.

CCDF improper authorizations for payment are estimated on a fiscal year basis. States select a random statewide sample of cases for each month of the fiscal year. States may choose to sample either 271 or 276 cases for the 12-month review period which provides a representative estimate of the annualized amount of improper authorizations for payments. This sample size is projected to allow the CCDF program at the national level to achieve a precision level of 5 percent at the 90 percent confidence interval. CCDF was granted an exception by OMB allowing CCDF to meet the 5 percent precision rather than the required 2.5 percent. States generate a list of all active cases authorized to receive a child care payment during the review month. The list is subsequently sorted by county and caseload size, listing counties with the largest caseload first to counties with the smallest caseload. States utilize a random number generator of their choice to calculate a sampling interval based on the size of the sampling frame and the sample cases that are selected. This process is repeated to allow States to select the monthly sample cases and replacement cases.

States conduct reviews of sampled cases using the ACF-400 *Record Review Worksheet* template. As a block grant, CCDF devolves a great deal of flexibility to States to determine administrative rules and eligibility requirements within broad Federal guidelines. Therefore, States have the option to customize the *Record Review Worksheet* to incorporate State eligibility policies in effect at the time of the case record review. The template consists of four sections designed for review of the following areas:

- Section I: State Child Care Program Forms – Review the presence and completeness of application/ re-determination forms.
- Section II: Priority Group Placement – Review if the child met the criteria of State-designated priority groups.

- Section III: General Program Requirements – Review if the client met the State's definition of parent, residency requirements, and if the client was working or attending job training or educational program or other eligible activity. Review the child's eligibility for a subsidy, the number of hours of care authorized, and if the child care provider regulatory requirements were met.
- Section IV: Income and Authorizations – Review if the household income met State requirements and if the computation of the amount authorized was accurate based on income and family size the State's payment rate schedule, and the sliding fee schedule (parent co-pay requirement).

The Year Three States conducted case record reviews and calculated State-specific error measures for reporting to HHS. The payment error rate, which is the improper authorizations for payment rate for purposes of CCDF, is estimated by applying the percentage of improper authorizations for payment derived from the sampled cases to the annual amount of authorizations for payment. HHS combines the State-reported payment authorization error rates to develop a weighted national improper authorization for payment error rate for the CCDF program for the three year cycle.

11.92 Child Care Corrective Action Plans

Administrative and Documentation Errors accounted for 55 percent of the improper authorization for payment errors primarily due to missing or insufficient documentation. The most frequently cited reasons for errors due to missing or insufficient documentation included: (1) insufficient documentation of earned income, unearned income and income deductions; (2) inability to locate the case record, missing or incomplete application or recertification forms, missing pages or forms without signatures; (3) missing or incomplete documentation about the work/educational/training activity of the head of household; (4) insufficient documentation of the hours of care needed; and (5) while less common, States also cited lack of documentation for the child's immigration status; correct household size/composition; and provider materials.

The next highest error rate category consisted of *Verification Errors* caused by the failure or inability to verify recipient information including: (1) income calculation errors: inability to determine income calculation method, failure to include all income, and use of an incorrect monthly conversion factor; (2) co-pay calculations, including incorrect use of the fee schedule; (3) parents' work/training/educational hours did not meet the minimum

requirement; and (4) incorrect inclusion or exclusion of household members.

Corrective actions targeting *Administrative and Documentation Errors* include efforts by both the States administering the program as well as HHS.

States' efforts include:

- Conducting ongoing case record reviews.
- Increasing program monitoring to incorporate performance improvement plans, increased awareness through review of results, and targeted corrective actions to managers.
- Evaluating and revising program policies and procedures.
- Additional training, policy clarification, calculation tools and checklists for workers to ensure accuracy in the application process.
- Modifying contracts with local agencies to include measures on payment accuracy rates, annual management reviews, and corrective action plans.

HHS corrective actions include:

- Providing technical assistance by HHS, specifically designed to help States focus on staff training, eligibility determination procedures, documentation requirements, and routine case reviews.
- Conducting on-site visits to assist States in the implementation of the Error Rate Review methodology.
- Providing guidance as States explore technological avenues to reduce Administrative and Documentation errors.
- Initiating a series of conference calls on accountability topics which include addressing fraud, using assessments to monitor risk and error, developing an inter-disciplinary team that addresses fraud, waste, and abuse.
- Sharing information regarding errors identified and the major causes of those errors with participants attending the annual State and Territories Administrators' Meeting.
- Revising the CCDF Plan Pre-Print to require specific information regarding reducing administrative errors, fraud, waste, and abuse. State Plan summaries are made available to the public in the spring following the year of submission. The next summary will be available in FY 2012.

- Designing a comprehensive Accountability Framework for CCDF which includes the Error Rate Review process, monitoring audit processes, addressing potential fraud, waste, and abuse in administration of CCDF.
- Delivering targeted technical assistance to States to meet their individual needs within a block grant format.
- Providing States with an opportunity for peer-to-peer sharing of both error causes and program improvements to reduce and/or eliminate errors and improper payments.
- Providing technical assistance through Regional training opportunities with States in conjunction with efforts that address overall program administration with the benefit of reducing errors and improper payments.
- Convening conference calls with all stakeholders regarding promising practices, sharing of tools and information, and concerns around fraud, waste, and abuse.
- Assigning contracted technical assistance specialists to work with individual States on implementing the Error Rate Review process. This added support was in addition to the technical assistance provided through the HHS Regional and Central Offices.
- Planning technical assistance and training opportunities to encourage States to begin their next review early, through examining current policies and procedures and automating their case review tool.
- Streamlining the review tool for ease of implementation, avoiding duplications, and eliminating errata.
- Determining additional means to ascertain data on the scope of administrative errors, fraud, waste, and abuse.

Corrective actions that target *Verification Errors* include both State and HHS efforts.

States' efforts include:

- Developing an aggressive training plan to provide one-on-one training for eligibility workers.
- Additional monitoring for verification accuracy.
- Including income, co-payment and rate calculators used by caseworkers as part of the automated eligibility system.

HHS efforts include:

- Providing technical assistance to the States including individualized webinar training, site visits, conference calls, peer-to-peer sharing.
- Developing the technical assistance tool *State Internal Control Self-Assessment Instrument*, which is under revision and will be implemented with targeted programs early next year. States will assess their internal control system, identify areas of risk, develop a program improvement plan based on the results, and receive technical assistance as they implement the plan. The tool will also be available on the Child Care Bureau website for any program to use.
- Developing targeted technical assistance to aid States specifically with concerns over potential fraud in the CCDF program. This includes sharing documents and other best practices, as well as, sharing tools and information to reduce fraud, waste, and abuse.
- Providing an Information Technology Guide, currently under revision, that will provide up-to-date information to assist States in their plans to upgrade and enhance IT needs.
- Planning information briefs to outline promising practices regarding reducing Administrative and Documentation errors as well as Verification errors. Many programs have offered to share tools developed for program monitoring, designing corrective actions, IT enhancements, and training tools.

11.93 Child Care Program Improper Payment Recovery

As reported in FY 2010, the actual CCDF improper authorizations for payment identified in the sample baseline review cycle was \$774,833, consisting of \$175,610 for Year One, \$214,475 for Year Two States, and \$384,748 for Year Three States.

The CCDF methodology distinguishes between authorizations for payment and actual payments made to providers. Therefore, the amount of improper authorizations for payment identified during the review process does not represent actual improper payments. In general, the amount of payments is lower, computed to be on average about 17 percent lower. Any actual improper payments related to a specific case that was included in the sample during the case review process will be recovered from States by HHS through the disallowance process as set forth at 45 CFR 98.86 of CCDF regulations.

States also may take their own action to pursue recovery from the appropriate party (e.g., client or child care provider), however pursuant to CCDF

regulations at 45 CFR 98.60 (i), States are required to recover child care payments that are the result of fraud. States have discretion as to whether to recover misspent funds that were not the result of fraud, such as in cases of administrative error. Improperly spent funds are subject to disallowance by HHS regardless of whether the State pursues recovery.

Guidance is under development that will provide information to Lead Agencies regarding those sampled cases found to be in error. Programs will have an opportunity to verify if identified cases with improper authorizations were in fact improperly paid. In the event that improper payments are identified it is expected that they will be recovered in accordance with 45 CFR 98.60 (g) which provides that such payments shall 1) if received by the Lead Agency during the applicable obligation period be used for activities specified in the Lead Agency's approved plan and must be obligated by the end of the obligation period or 2) if received after the end of the applicable obligation period, be returned to the Treasury.

Single State Audits reported the following information regarding closed audit findings that resulted in a sustained amount of disallowance (dollars in thousands).

Closed Audit Findings

FY	Number of Sustained Audits	Total Dollars from Sustained Audits
2005	8	747,040
2006	5	65,610
2007	3	59,948
2008	4	201,207
2009	8	3,894,640
2010	3 (to date)	173,563

11.94. Child Care Program Information Systems and Other Infrastructure

Since CCDF program payments occur at the State level, information systems and other infrastructure needed to reduce CCDF improper payments would need to be implemented at the State level. State investments in information systems for administering the CCDF program vary widely and there are large disparities in the capacity and capabilities of State systems. The majority of States report having sufficient infrastructure to meet designated targets. Eighteen States report actively working toward updating their computer data systems and ten States plan to have new systems in place before their next review cycle.

While the majority of States have statewide automated systems and the necessary infrastructure to meet targets to reduce improper

authorizations in their next reporting cycle, States reported a variety of areas in which improvements to information systems are still needed:

- Integrating systems to enhance the application for child care benefits and to build the child care authorization spreadsheet into the application system.
- Incorporating alerts into the child care application system to remind eligibility workers to check completeness and accuracy of case files.
- Enhancing child care information systems to include capacity for automated calculation of authorization amounts given family income, hours of care needed, provider payment rate and co-pay requirements.

In addition, HHS has been active in encouraging and supporting States in their efforts to modernize and improve Information Systems. Such improvements would produce greater efficiencies in the CCDF measurement and strengthen program integrity. Recently, HHS formed a State systems workgroup consisting of State and HHS representatives. This group meets regularly to identify and discuss State system vulnerabilities and the impact on the measurement of improper payments.

11.95 Child Care Program Statutory or Regulatory Barriers.

No statutory or regulatory barriers that would limit corrective actions have been identified at this time.

11.96 Child Care Program Best Practices

Many Lead Agencies have shown reductions in errors by implementing strategic measures determined from review results. Additional highlights from the implementation of the Error Rate Review include:

- Several States that participated in pilots as part of the development of the Error Rate methodology had lower error rates when conducting their first cycle *IPIA* reviews. Reductions in errors were noted after implementing corrective actions based on the pilot review results. Similar reductions are anticipated as all States conduct the next cycle of reviews.
- During the first cycle of reviews, States with existing monitoring processes in place tended to have lower initial error rates.
- Implementation of a new tool for caseworkers resulted in a 30 percent reduction in errors in one State.

Reports have included rich information as well. We have included the following quotes from several reports as highlights of key lessons learned from the reviews:

"...learning from peers by arranging visits to neighboring States to learn about their information system..."

"...implement an Error Reduction Conference to discuss root causes of errors and potential options for reductions..."

"...revisions to policies and procedures were recommended as a result of common errors found on reviews..."

"...most important thing we do to reduce errors is implementation of an ongoing monitoring program..."

"...developing an aggressive training plan to provide regional or one-on-one training for all eligibility workers..."

MANAGEMENT REPORT ON FINAL ACTION

October 1, 2009 - September 30, 2010

Background

The Inspector General Act Amendments of 1988 (P.L. 100-504) require Departments and Agencies to report to Congress on the actions they have taken and the amount of funds recovered or saved in response to the Office of Inspector General's (OIG) audit recommendations. This annual management report provides the status of OIG A-133 audit reports in the Department and summarizes the results of actions taken to implement OIG audit recommendations during the reporting period. As part of the U.S. Chief Financial Officer Council's Streamlining Effort of FY 1996, the Management Report on Final Action has been incorporated in the Agency Financial Report.

Status of Audits in the Department

In general, HHS Agencies follow-up on OIG recommendations effectively and within regulatory time limits. The HHS Agencies usually reach a management decision within the 6-month period that is prescribed by P.L. 100-504 and OMB Circular A-50, *Audit Follow-up*. For the most part, they also complete their final actions on OIG reports, including collecting disallowed costs and carrying out corrective action plans, within a reasonable amount of time. However, the Department continues to monitor this area to improve procedures and ensure compliance with corrective action plans.

Departmental Conflict Resolution

In the event that HHS agencies and OIG staff cannot resolve differences on specific report recommendations, a conflict resolution mechanism is available. During FY 2010, there were no disagreements requiring the convening of the Conflict Resolution Council.

Final Action Tables and Departmental Findings

Table I – Management Action on Costs Disallowed in OIG Reports. Disallowed costs are those costs that are challenged by HHS because a grantee has violated a law, regulation, grant term, or condition.

The HHS Process

Four Key Elements to the HHS Audit Resolution and Follow-up Process

- The HHS Agencies have a lead responsibility for implementation and follow-up on OIG and independent auditor recommendations;
 - The Assistant Secretary for Resources and Technology establishes policy and monitors HHS Agencies' compliance with audit follow-up requirements;
 - The audit resolution process includes the ability to appeal disallowances administratively under such programs as Head Start, Foster Care and Medicaid pursuant to the Departmental Grant Appeals Board's regulations in 45 C.F.R. Part 16; and
 - If necessary, the Conflict Resolution Council resolves conflicts between the HHS Agencies and the OIG.
- In FY 2010, HHS initiated Recovery Action, through collection, offset or other means, on 308 cases for a total of \$1,105,989,201.
 - In FY 2010, HHS completed Recovery Action, through collection, offset or other means, on 328 cases for a total of \$726,476,325.
 - As of September 30, 2010, HHS reports 170 outstanding balances over one year old totaling \$1,741,756,232. Forty-one percent of these accounts receivable are currently being pursued for collection. These accounts receivable are owed by State and local governments (72), hospital and medical related organizations (52), nonprofit organizations (18), Indian tribes (18), and educational institutions (10). A detailed list of reports over one year old with outstanding balances to be collected can be found at: <http://www.hhs.gov/asfr/of/finpollibrary/financialpolicies/outstandingbalances2010.html>.

TABLE I
MANAGEMENT ACTION ON COSTS DISALLOWED IN OIG REPORTS
 As of September 30, 2010
 (in Thousands)

	Number	Disallowed Costs
A. Reports for which final action had not been taken by the commencement of the reporting period. See Note 1.	269	\$2,242,413
B. Reports on which management decisions were made during the reporting period. See Note 2.	308	1,105,989
Subtotal (A+B)	577	3,348,402
C. Reports for which final action was taken during the reporting period:		
i. The dollar value of disallowed costs were recovered through collection, offset, property in lieu of cash, or otherwise.	328	726,476
ii. The dollar value of disallowed costs that were written off by management.	15	1,615
Subtotal (i+ii)	343	728,091
D. Reports for which no final action has been taken by the end of the reporting period. See Note 3.	234	\$2,620,311

Notes:

1. Includes adjustments of amended disallowance and disallowance excluded from the previous reporting period.
2. Represents the amount of management concurrence with the OIG's recommendations. For this fiscal year, the OIG's reconciliation with the HHS Agencies showed a variance that represents the three organizations having different cut-off dates.
3. In addition to current unresolved cases, this figure includes audits over 1 year old with outstanding balances totaling \$1,741,756,232 (e.g., audits under current collection schedule, or audits under administrative or judicial appeal).

TABLE II
MANAGEMENT ACTION ON OIG REPORTS
with Recommendations That Funds Be Put to Better Use
As of September 30, 2010
(in Thousands)

	Number	Disallowed Costs
A. Reports for which final action had not been taken by the commencement of the reporting period. See Note 1.	12	\$14,880
B. Reports on which management decisions were made during the reporting period.	8	412,567
Subtotal (A+B)	20	427,447
C. Reports for which final action was taken during the reporting period:		
i. The dollar value of recommendations that were actually completed based on management action or legislative action.	9	414,377
ii. The dollar value of recommendations that management has subsequently concluded should not or could not be implemented or completed.	0	-
Subtotal (i+ii)	9	414,377
D. Reports for which no final action has been taken by the end of the reporting period.	11	\$13,069
Notes:		
1. Includes adjustments of amended disallowance and disallowance excluded from the previous reporting period.		

Table II – Management Action on OIG Reports with Recommendations that Funds Be Put to Better Use. “Funds to be put to better use” relates to those costs associated with cost avoidances, budget savings, etc.

- In FY 2010, HHS initiated action on \$412,566,811 in OIG recommendations to put funds to better use.
- In FY 2010, HHS completed action on \$414,377,233 in OIG recommendations to put funds to better use.

SUMMARY OF FINANCIAL STATEMENT AUDIT AND MANAGEMENT ASSURANCES

TABLE 1 SUMMARY OF FINANCIAL STATEMENT AUDIT					
Audit Opinion			Unqualified for Four Financial Statements. No Opinion Expressed on Statement of Social Insurance		
Restatement			No		
Material Weaknesses	Beginning Balance	New	Resolved	Consolidated	Ending Balance
Financial Reporting, Systems, Analyses & Oversight	<input checked="" type="checkbox"/>				<input checked="" type="checkbox"/>
Financial Management Information Systems	<input checked="" type="checkbox"/>				<input checked="" type="checkbox"/>
Total Material Weaknesses	<i>2</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>2</i>

Definition of Terms – Tables 1 and 2

Beginning Balance: The beginning balance shall agree with the ending balance of material weaknesses from the prior year.

Resolved: The total number of material weaknesses that have dropped below the level of materiality in the current year.

Consolidated: The combining of two or more findings.

Reassessed: The removal of any finding not attributable to corrective actions (e.g., management has re-evaluated and determined a material weakness does not meet the criteria for materiality or is redefined as more correctly classified under another heading (e.g., Section 2 to a Section 4 and vice versa).

Ending: The agency's year-end balance.

**TABLE 2
SUMMARY OF MANAGEMENT ASSURANCES**

Effectiveness of Internal Control over Financial Reporting (FMFIA #2)

Statement of Assurance	Qualified					
Material Weaknesses	Beginning Balance	New	Resolved	Consolidated	Reassessed	Ending Balance
Financial Reporting Systems & Processes	<input checked="" type="checkbox"/>					<input checked="" type="checkbox"/>
<i>Total Material Weaknesses</i>	<i>1</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>1</i>

Effectiveness of Internal Control over Operations (FMFIA #2)

Statement of Assurance	Qualified					
Material Weaknesses	Beginning Balance	New	Resolved	Consolidated	Reassessed	Ending Balance
Information System Controls and Security	<input checked="" type="checkbox"/>					<input checked="" type="checkbox"/>
<i>Total Material Weaknesses</i>	<i>1</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>1</i>

Conformance with Financial Management System Requirements (FMFIA #4)

Statement of Assurance	Non-conformance					
Non-Conformances	Beginning Balance	New	Resolved	Consolidated	Reassessed	Ending Balance
Financial Reporting Systems & Processes	<input checked="" type="checkbox"/>					<input checked="" type="checkbox"/>
Information System Controls and Security	<input checked="" type="checkbox"/>					<input checked="" type="checkbox"/>
<i>Total Non-Conformances</i>	<i>2</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>2</i>

Compliance with Federal Financial Management Improvement Act (FFMIA)

	Agency	Auditor
Overall Substantial Compliance	No	No
1. System Requirements	No	
2. Accounting Standards	Yes	
2. USSGL at Transaction Level	No	

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**OIG TRANSMITTAL OF
FY 2010 TOP MANAGEMENT AND PERFORMANCE CHALLENGES**

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Washington, D.C. 20201

NOV 12 2010

TO: The Secretary
 Through: DS _____
 COS _____
 ES _____

FROM: Inspector General

SUBJECT: Top Management and Performance Challenges facing the Department of Health and Human Services in Fiscal Year 2011

This memorandum transmits the Office of Inspector General's (OIG) list of top management and performance challenges facing the Department of Health and Human Services (Department) in fiscal year (FY) 2011. The Reports Consolidation Act of 2000, Public Law 106-531, requires OIG to identify these management challenges, assess the Department's progress in addressing each challenge, and submit this statement to the Department annually.

OIG's list of top management and performance challenges for FY 2011 includes the following:

- Part I: Health Care Reform
 - Incorporating Integrity into Health Care Reform Implementation
- Part II : Integrity of Medicare, Medicaid, and the Children's Health Insurance Program
 - Integrity of Provider and Supplier Enrollment
 - Integrity of Federal Health Care Program Payment Methodologies
 - Promoting Compliance With Federal Health Care Program Requirements
 - Oversight and Monitoring of Federal Health Care Programs
 - Response to Fraud and Vulnerabilities in Federal Health Care Programs
 - Quality of Care
- Part III: Integrity of the Department's Public Health and Human Services Programs
 - Oversight of Food, Drugs, and Medical Devices
 - Public Health Emergency Preparedness and Response
 - Grants and Contracts Management
- Part IV: Cross-Cutting Issues
 - American Recovery and Reinvestment Act Accountability and Transparency
 - Health Information Technology and Integrity of Information Systems
 - Ethics Program Oversight and Enforcement

Page 2 - The Secretary

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

/Daniel R. Levinson/

Daniel R. Levinson

Attachment

FY 2010 TOP MANAGEMENT AND PERFORMANCE CHALLENGES IDENTIFIED BY OFFICE OF THE INSPECTOR GENERAL

Pursuant to the *Reports Consolidation Act of 2000* (P.L. No. 106-531), each year the Office of Inspector General (OIG) summarizes what the Office considers to be the most significant management and performance challenges facing the Department of Health & Human Services (the Department or HHS) and the Department's progress in addressing those challenges. In 2010, the Office identified the following top management challenges for fiscal year (FY) 2011. This document is divided into four parts: (1) health care reform; integrity of the Medicare, Medicaid and the Children's Health Insurance Program (CHIP); (2) integrity of the Department's public health and human services programs; and (3) cross-cutting issues that span the Department.

PART I: Health Care Reform

The *Patient Protection and Affordable Care Act*, as amended by the *Health Care and Education Reconciliation Act of 2010* (collectively, the *Affordable Care Act* or the *Act*) sets forth the most comprehensive changes to Federal health care programs and the national health insurance system since the inception of the Medicare program in 1965.

Management Issue 1: Incorporating Integrity into Health Care Reform Implementation

MANAGEMENT CHALLENGE AND ASSESSMENT OF PROGRESS IN ADDRESSING THE CHALLENGE:

The *Act's* 10 titles include private insurance market reforms, Medicare and Medicaid amendments, quality and efficiency of care, public health, the health care workforce, and *Community Living Assistance Services and Support (CLASS)*. The Congressional Budget Office (CBO) has estimated the costs of the new programs to be \$940 billion over the next 10 years. The magnitude of expenditures and impact on providers, insurers, employers, and beneficiaries from financial and health perspectives make it critical that *Affordable Care Act* programs operate efficiently and effectively and are protected from fraud and abuse.

Under the *Affordable Care Act*, the Department has broad new responsibilities. It will manage the significant modification and expansion of many existing programs, develop and implement new programs, promulgate regulations, issue and oversee billions of dollars in grants and loans,

develop strategic plans, conduct a variety of studies, prepare reports for Congress, and enforce program rules. Much of this has occurred and will continue to occur with short implementation timelines.

Many components within the Department are responsible for implementing the *Affordable Care Act*, including the new Office of Consumer Information and Insurance Oversight (OCIO), Centers for Medicare & Medicaid Services (CMS), Food and Drug Administration (FDA), National Institutes of Health (NIH), Indian Health Service (IHS), Centers for Disease Control and Prevention (CDC), Administration on Aging (AoA), Agency for Healthcare Research and Quality (AHRQ), and the Office of Inspector General. In addition, implementing the *Act* requires that the Department work closely with other Federal agencies, including the Department of Labor and the Department of the Treasury. Successful implementation depends on extensive intra-agency and inter-agency collaboration and coordination.

Successful implementation of the *Affordable Care Act* also requires clear and effective communication with program beneficiaries, private citizens, and health care industry stakeholders. For example, the Department has substantial new involvement with the private insurance markets, requiring subject-matter expertise, new oversight strategies, and new technologies and approaches in generating and disseminating consumer information.

Implementation of the law merits thoroughness, scrutiny, and oversight. A significant challenge for the Department will be identifying key vulnerabilities and prioritizing oversight resources. Based on the Office's experience in auditing, evaluating, and investigating fraud, waste, and abuse, areas that warrant vigilant HHS oversight include:

- Programs implemented under expedited timeframes. The Department can draw upon experience gained in two recent programs that were implemented with short timeframes - the Medicare Prescription Drug Benefit and the *American Recovery and Reinvestment Act (Recovery Act) of 2009* (P.L. No. 111-5).
- Programs involving data collection to ensure accuracy and completeness of data.

- Grant programs.
- Ensuring accuracy of payments involving risk corridors, reconciliation payments, or similar payment structures.
- Changes to Part D and other Medicare and Medicaid payments.
- Activities, such as insurance scams, that may put beneficiaries at risk. Already, OIG has received reports that criminals, preying on the fears and confusion that surround the new program, are offering fake insurance policies.

The Department has taken many steps to address the challenges posed by implementation of the *Act*. For example, to address internal coordination challenges, the Department has established a structure of cross-component subject matter working groups to promote effective collaboration. To ensure timely and complete implementation, the Department has engaged dedicated staff to maintain a database with a dashboard feature to track implementation milestones and deliverables. Representatives from HHS components confer regularly to monitor progress in meeting the implementation goals. In addition, the management of individual components meets regularly to discuss and track policy development and implementation of the *Act* as it pertains to their components.

The Department is also building infrastructure to support implementation of the *Act*. For example, the Department created and is staffing up OCIO to focus on private insurance issues (including enforcement), CMS created the new Center for Medicare and Medicaid Innovation to focus on innovative delivery models and established the Center for Program Integrity to strengthen its oversight of the Medicare and Medicaid programs. The Department is also devoting additional resources and effort to enhance the use of information technology to foster effective implementation of the *Act*, including the use of sophisticated performance tracking tools.

Finally, the Department has provided guidance about new requirements to affected stakeholders by issuing many proposed and final regulations implementing *Affordable Care Act* provisions and a variety of subregulatory guidance documents. More remains to be done as implementation proceeds.

The Department, including OIG, must work with its partners to respond to vulnerabilities in current Federal health care programs and in the expanded and new programs established through the

Affordable Care Act. The Department, including OIG, must identify new risks posed by the changing dynamics of Federal health care programs and the evolving nature of fraud and abuse schemes and respond effectively to those risks.

PART II: INTEGRITY OF MEDICARE, MEDICAID, AND THE CHILDREN'S HEALTH INSURANCE PROGRAM

For Federal health care programs to best serve beneficiaries and remain solvent for future generations, the Government must pursue a comprehensive strategy to prevent, detect, and correct fraud, waste, and abuse. Based on its experience in combating health care fraud, waste, and abuse, OIG has identified five principles that it believes should guide the Department's integrity strategy for Medicare, Medicaid, and CHIP. These principles offer a framework for implementing programs, as well as designing integrity safeguards and putting them into practice.

- **Enrollment** – Scrutinize individuals and entities that seek to participate as providers and suppliers before they enroll in health care programs.
- **Payment** – Establish payment methodologies that are reasonable and responsive to changes in the marketplace.
- **Compliance** – Assist health care providers and suppliers in adopting practices that promote compliance with program requirements, including quality and safety standards.
- **Oversight** – Vigilantly monitor programs for evidence of fraud, waste, and abuse.
- **Response** – Respond swiftly to fraud, impose appropriate punishment to deter others, and promptly eliminate program vulnerabilities.

Consistent with these principles, OIG has applied this framework to identify the top management challenges that the Department faces in protecting the integrity of its health care programs, meeting the needs of beneficiaries, and keeping Federal health care programs solvent.

Ensuring that the beneficiaries receive quality health care has many dimensions, including overseeing providers' compliance with quality-of-care standards, ensuring patient safety, and identifying opportunities for improvements in quality of care.

Management Issue 2: Integrity of Provider and Supplier Enrollment

Management Challenge and Assessment of Progress in Addressing the Challenge:

Large Federal Government expenditures on the Medicare and Medicaid programs attract certain individuals and entities that may seek to exploit the health care system for financial gain. Although the vast majority of health care providers and suppliers are honest and well intentioned, the Department faces challenges in ensuring the integrity of the programs' provider and supplier enrollment processes. A small percentage of providers and suppliers intent on defrauding these programs has exploited weaknesses in the enrollment process, causing significant harm. These providers and suppliers drain resources that should be spent on providing care to beneficiaries. OIG's oversight and enforcement work identified weaknesses in provider and supplier enrollment that enable unqualified, dishonest, and unethical individuals and entities to access a system they can easily exploit. OIG also identified weaknesses in the oversight of provider and supplier eligibility to receive payments under Medicare and Medicaid.

A number of OIG's concerns have been addressed in the *Affordable Care Act*. Provisions of the *Act* require the Secretary, in consultation with OIG, to establish more rigorous enrollment and screening processes and to provide for enhanced oversight measures, disclosure requirements, enrollment moratoriums, and requirements for developing compliance programs. The *Act* also requires that any home health or durable medical equipment (DME) prescription or referral covered by Medicare Parts A or B be written by a Medicare-enrolled physician or nonphysician practitioner and authorizes the Secretary to extend this requirement to other Medicare-covered items and services. The *Act* also requires any agents, clearinghouses, or other alternate payees that submit claims on behalf of Medicaid health care providers to register with the State and the Secretary in a form and manner specified by the Secretary.

In the area of enforcement, the *Affordable Care Act* introduces new civil monetary penalties (CMP) for certain types of infractions, including falsifying information on provider enrollment applications. The *Act* also expands the Inspector General's discretionary authority to exclude individuals and entities from participation in Medicare, Medicaid, and all other Federal health care programs to include situations in which an individual or entity makes a false statement or misrepresentation on an enrollment application.

All these provisions, when implemented, will help the Government to better know and control with whom it is doing business. Protecting programs and beneficiaries from unqualified, fraudulent, or abusive providers and suppliers upfront is more effective than trying to recover payments or redress fraud or abuse after it occurs.

Enrollment Process and Oversight Activities

Ensuring adequate and appropriate provider and supplier enrollment standards and screening is an essential first step to strengthening the integrity of the Medicare and Medicaid programs. OIG identified certain characteristics that may indicate a provider's increased potential for fraud, including interest in or ownership of other health services providers and related businesses with Medicare or Medicaid debt; other evidence of financial instability; no evidence of a physical business facility; previous criminal history, suspension, or exclusion from participation in Federal health care programs; or sanctions by State Medicaid agencies or other health care organizations. The *Affordable Care Act* requires the Secretary to implement screening procedures for different categories of providers and suppliers based on the risk of fraud, waste, and abuse. The screening must be applied to all new enrollments starting March 23, 2011, and all providers and suppliers must be subject to the same process by March 23, 2013.

The *Affordable Care Act* has several additional provisions aimed at reducing vulnerabilities in provider and supplier enrollment, including subjecting new providers and suppliers to enhanced oversight, such as prepayment review for 30 days to 1 year after enrollment. Providers or suppliers applying for enrollment on or after March 23, 2011, must disclose any direct or indirect, current, or previous affiliation with a provider or supplier that has uncollected debt or that has been subject to a payment suspension, program exclusion, or revocation or denial of its billing privileges under a Federal health care program. The Secretary may also impose a temporary moratorium on enrollment of providers and suppliers or on enrollment of certain categories of providers and suppliers, if necessary, to prevent or combat fraud, waste, and abuse. The Secretary's authority was expanded to impose surety bond requirements on DME and home health providers by allowing the imposition of a larger requirement based on the suppliers' or providers' volume of billing, as well as by allowing the extension of the surety bond requirements to other types of providers. Finally, the Secretary has the authority to require that providers and suppliers maintain compliance programs as a condition of

enrollment. Effective use of these new tools and authorities will be critical to addressing fraud, waste, and abuse in the future.

The Department has responded to vulnerabilities in provider and supplier enrollment with measures to enhance enrollment standards for DME suppliers. The response includes a final rule published August 2010 (CMS-6036-F) which clarifies and expands the existing enrollment requirements for DME suppliers. The Department also initiated a demonstration project requiring reenrollment of DME suppliers in south Florida and southern California as a condition for remaining enrolled in the Medicare program. OIG recognizes the Department's progress and continues to recommend further improvements to oversight and enforcement of provider enrollment standards. OIG will also monitor progress under the competitive bidding program for DME suppliers once it is fully implemented in 2011 to determine whether the application and enrollment process is sufficiently rigorous to prevent suppliers prone to fraud, waste, and abuse from receiving contracts.

In other work, OIG investigations identified a fraud scheme involving foreign nationals who obtained Medicare provider numbers that they used to submit fraudulent claims. Unknown individuals recruit foreign nationals who are in the United States on student visas to obtain Medicare provider numbers. These provider numbers are used to fraudulently bill Medicare while the foreign nationals return to their home countries. OIG alerted CMS to this fraud scheme and recommended that CMS adopt guidelines with regard to foreign nationals' obtaining Medicare provider numbers. CMS responded that it was unclear whether it had the authority to implement the recommended actions and noted that when conducting reviews, surveyors examine the Employment Eligibility Verification document (Form I-9) for facility owners and key employees as part of the accreditation process. While surveyor reviews may identify some schemes, until the vulnerabilities brought to light by this fraud scheme are addressed, Medicare continues to risk exposure to fraudulent claims by ineligible providers.

The Department also faced challenges stemming from the variation in Medicaid provider and supplier enrollment standards, which can differ across States and for providers within a State. For example, an OIG evaluation of State Medicaid enrollment requirements for personal care attendants found that State Medicaid programs established multiple sets of provider requirements that often vary among programs and by delivery models within programs, resulting in 300 sets of provider requirements nationwide for personal care

attendants. OIG is examining whether States enforce their requirements for personal care attendants. The *Affordable Care Act* requirements, when implemented, should create a more consistent approach to the enrollment and screening process.

OIG has identified challenges related to nursing home ownership transparency. (See Management Issue 7 for more information on this topic.) Greater transparency in the enrollment process for nursing homes would help the Government know with whom it is doing business and whom to hold accountable in cases of noncompliance, fraud, or abuse. Congress recognized this in enacting the *Affordable Care Act*, which requires nursing homes to disclose information about the identity of parties with an ownership or management interest. This information will be made public. OIG will monitor implementation of this provision to ensure that it addresses vulnerabilities in nursing home enrollment.

Provider and Supplier Eligibility for Certain Payments

The *Affordable Care Act* includes provisions that address program vulnerabilities to prevent ineligible providers from enrolling in the Medicare and Medicaid programs. The *Act* also includes provisions to enhance OIG's authority to obtain any information necessary from any individual or entity to validate claims for payment under Titles XVIII or XIX for evaluation of the economy, efficiency, or effectiveness of these programs. Together, these provisions should help the Department oversee the programs and prevent providers that are improperly enrolled from participating in the programs or receiving payments for which they are not eligible.

OIG identified instances in which Medicare and Medicaid made payments to providers that were improperly enrolled or were not eligible to receive payments. For example, OIG found that between FYs 2000 and 2006, 397 hospitals received \$21.9 million in capital disproportionate share hospital (DSH) payments for which they were not eligible. Further, OIG reviewed States' compliance with Medicaid DSH payment requirements and found that from July 2000 through June 2003, one State paid \$142.3 million (\$88.2 million Federal share) to three State-owned psychiatric hospitals that were not eligible for such payments.

OIG also determined that from July 1, 1996, through June 30, 2007, one State paid \$26.2 million (\$16.3 million Federal share) to a hospital that was not eligible to receive Medicaid payments for inpatient psychiatric services because it did not show compliance with certain Medicare Conditions of Participation requirements. OIG audits at

numerous Medicare fiscal intermediaries (FI) found that unallowable payments of about \$4.9 million were made to providers that were not eligible for payment because the services were provided on or after the dates that the providers were terminated from the Medicare program.

The Department responded to these vulnerabilities by directing the Medicare administrative contractors (MAC) and FIs to assess capital DSH eligibility as part of their review processes. CMS will also include an edit to the hospital cost report software to prevent ineligible hospitals from claiming capital DSH payments on their cost reports.

OIG continues to encourage the Department to implement payment safeguards to ensure that payments are made only to eligible providers and suppliers. As described above, the *Affordable Care Act* authorizes the Department to establish procedures to strengthen provider and supplier enrollment standards. Fully implementing the new procedures should lessen the risk of improper enrollments or payments for which providers are not eligible.

Management Issue 3: Integrity of Federal Health Care Program Payment Methodologies

Management Challenge and Assessment of Progress in Addressing the Challenge:

The Federal Government must act as a prudent purchaser of health care. Medicare and Medicaid payment methodologies must ensure access to quality care without wasteful spending. Achieving this objective is critical to maintaining an effective and efficient health care delivery system. The challenges associated with meeting this objective are complex and are evolving, especially in the context of implementing health care reform. Initial payment methodologies must be set to reimburse providers and suppliers fairly for appropriate care. Payment methodologies must also be responsive to ensure that they remain reasonable and appropriate as the health care marketplace and medical practice evolve. Finally, CMS must be nimble enough to safeguard against the financial incentives and fraud and abuse risks associated with each payment methodology that is established.

Setting Initial Payment Methodologies

As Federal health care programs are created, expanded, or revised under the *Affordable Care Act*, which creates new payment methods and updates existing payment methods, it is critical to establish initial payment rates based on the most accurate data available and on reasonable assumptions and projections. OIG has identified instances in which issues with the data used in the development of initial payment methodologies have resulted in

increased expenditures by Medicare and its beneficiaries. For example, because of earlier work, OIG is concerned that the Part A prospective payment systems (PPS) for home health services, Skilled Nursing Facility (SNF) services, and Part B PPS for hospital outpatient department services were based on data known to be problematic, which may have resulted in inaccurate payment rates. CMS will need to address this challenge when it rebases the home health PPS, as required by the *Affordable Care Act*. With the new and expanded programs enacted under health care reform, it is important to strengthen oversight of these programs.

Setting proper payment rates for Medicare Part B services has also proved challenging. OIG reviews have determined that Medicare payments for certain categories of DME do not accurately reflect the costs of these products because the payment rates are based on historical average prices and do not reflect current market prices. For example, in 2006, OIG found that Medicare allowed more than \$7,000 for 36 months of rental payments for oxygen concentrators that cost \$587, on average, to purchase. OIG also found that Medicare allowed an average of \$4,018 to purchase standard power wheelchairs and \$11,507 for complex rehabilitation power wheelchair packages, compared with supplier acquisition costs of \$1,048 and \$5,880, respectively. OIG has recommended that CMS determine whether these amounts should be adjusted using its inherent reasonableness authority, using information from the Competitive Bidding Acquisition Program, or seeking legislation to ensure that fee schedule amounts are reasonable and responsive to market changes. OIG's 2009 findings that more than half of power wheelchair claims submitted by suppliers do not meet the requirements for payments underscores the need to closely align the amount Medicare pays for power wheelchairs with the costs to suppliers.

The Competitive Bidding Acquisition Program is CMS's main initiative to reduce beneficiary costs and improve the accuracy of Medicare payments for certain categories of DME. Legislation delayed its implementation, and contracts under the program's first round of bidding are to become effective on January 1, 2011, and CMS plans to expand the program.

Payments to Medicare Advantage (MA) organizations under Part C may also be higher than necessary. Based on numerous reviews of the Medicare + Choice program (MA's predecessor), OIG concluded that the data and estimates used to calculate monthly capitation payments were flawed, resulting in higher payments. The inflated base-year data continue to affect MA payments, which have not been adjusted to take into account problems

with Medicare + Choice data that OIG had identified. OIG plans to further examine the accuracy of the data used to adjust capitation payments to MA organizations. In addition, the *Affordable Care Act* will reduce payments to MA organizations in 2012.

Appropriate payment rates for Medicare Part D continue to be a challenge. OIG is examining the extent to which Part D Plans report all rebates and direct and indirect remuneration they receive. In earlier work, OIG found that estimated costs in sponsors' bids were higher than their actual costs, which resulted in higher Medicare payments and premiums. In response, CMS agreed to ensure that sponsors' bids accurately reflect the cost of providing benefits and noted that it incorporates data submitted to CMS for reconciliation of prior years into its bid review process.

Responding to Changes in the Marketplace and Health Care Practices

The Department faces a substantial challenge in reacting swiftly and appropriately to changes in health care delivery systems and standards of care so that the programs continue to effectively reimburse for quality care. OIG has conducted reviews of Medicare and Medicaid payment methodologies and found that when reimbursement methodologies do not respond to such changes, the programs and their beneficiaries bear the cost.

Medicare Part B payments for new wound therapy pumps provide one example of the costs of failing to update payments in response to market changes. When Medicare first covered wound pumps, it covered only one model and Medicare based the payment on that model's purchase price. As new models became eligible for coverage, Medicare continued to reimburse suppliers based on the original model's purchase price, which OIG found is more than four times the average price currently paid by suppliers for new pumps.

Another example is demonstrated in OIG work, which found that Medicare has paid physicians for evaluation and management (E&M) services that were included in global fees for eye surgery but were not provided during the global surgery periods. The misalignments in global eye surgery payments are attributable, in part, to CMS's not updating payments to reflect changes in medical practice. Over time, the average number of E&M services provided during the global period has decreased, but payments continue to be based on estimates that a higher number of E&M services are provided.

Other examples include Medicare Part B payments for laboratory tests and for certain drugs. OIG

found that Medicare Part B payments for laboratory tests, which were established over 20 years ago, vary within and between Medicare contractors. The variances did not appear to reflect geographic differences in costs. OIG recommended that CMS seek legislation to establish a new process for setting accurate and reasonable payment rates. CMS stated that it would consider OIG's recommendation as the agency continues to monitor the effects of its current payment policies. OIG work has also shown that Medicare payments for certain Part B drugs are higher than actual costs in the marketplace when newly available generic versions first enter the market.

Payment methodologies for other benefits also present challenges in responding to marketplace changes. The average manufacturer price (AMP), which is used in calculations of both Medicaid drug rebates and the Federal Upper Limit (FUL), has been redefined in the *Affordable Care Act*. This change may resolve the disparity between what Medicaid pays for drugs and the prices available in the marketplace.

Payment Incentives and Risks of Fraud and Abuse

Payment methodologies inherently create incentives and risks for fraud. Fee-for-service (FFS) payments create financial incentives to provide excessive, complex, or unnecessary services. Conversely, under capitated or bundled payment systems, financial incentives may encourage providers to stint on needed care. The *Affordable Care Act* introduces several new payment models, such as accountable care organizations, medical homes, and shared savings programs. A key challenge for the Department will be ensuring that it strikes the right balance between protecting the integrity of the health care programs and fostering innovation that increases quality, efficiency, and cost effectiveness. Because fraud schemes develop and multiply quickly, it is crucial that the Department rapidly identify and address the risks inherent in new payment models.

OIG's work on Medicare and Medicaid outlier payments highlights the importance of addressing the integrity of payment methodologies. Recent investigations have identified abuses of CMS's home health outlier payment methodology, which has resulted in providers' receiving significant outlier payments to which they were not entitled. In response to evidence of abuse in this area, CMS caps outlier payments to individual home health agencies. Continuing OIG work is examining vulnerabilities linked to this payment methodology.

Similarly, OIG found in previous work that Medicare payment methodologies for inpatient outlier payments had loopholes whereby inflated charges submitted by hospitals and delays in FI financial analysis of hospital data resulted in hundreds of millions of dollars of wasteful spending. Policy changes were made, and financial settlements with several hospital groups were reached. OIG work in several States has shown that if the State Medicaid programs modified their outlier payment policies to mirror changes made in the Medicare program, they could save tens of millions of dollars.

OIG has also found other instances in which payment methodologies have created incentives for providers to alter their practices to maximize reimbursement. For example, ongoing OIG work has found that the current SNF payment methodology gives SNFs an incentive to fraudulently increase the level of services and therapy needed by each beneficiary to qualify for higher per diem rates. This has resulted in severe overutilization of SNF therapy services, including therapy for patients for whom any therapy is inappropriate.

Certain types of services may be vulnerable to abuses such as upcoding, or billing a higher complexity code than the one appropriate for the service performed. OIG has observed that Medicare payments for E&M services increased by over \$9 billion between 2000 and 2009, in part because of a trend of increased billing for high-complexity E&M codes. E&M services may be particularly vulnerable to abuse because the differences among complexity levels are less distinct than the differences in other services and because monitoring by CMS and contractors is lacking.

Medicaid's reliance on published prices as the basis for drug reimbursement also creates fraud vulnerabilities. OIG investigations of allegations that pharmaceutical manufacturers have manipulated prices to decrease Medicaid rebate payments and increase Medicaid drug reimbursement have resulted in significant *False Claims Act* (FCA) settlements. In late 2009, Mylan Pharmaceuticals, Inc., paid \$118 million to resolve allegations that it misclassified drugs in informational filings to the Government to reduce the amounts it paid under the Medicaid Rebate Program. AstraZeneca Pharmaceuticals LP and Ortho MacNeil Pharmaceuticals, Inc., each settled similar allegations in 2007. In 2007, Aventis Pharmaceuticals, Inc., paid \$182.8 million to resolve allegations that it inflated its prices for products paid for by Federal health care programs. Because of the alleged illegal pricing, programs, including Medicaid, overpaid for Aventis's drug, Anzemet.

The Department's challenge to react to payment methodology vulnerabilities is not limited to abuses by providers and suppliers. OIG has found problems with States' implementation of financing mechanisms involving certain intergovernmental transfer of funds, which resulted in an inappropriate inflation of the Federal share of Medicaid payments. Through these arrangements, States often retained funds that were intended to reimburse Medicaid providers. Another way in which States have inappropriately increased the Federal share of Medicaid payments is requiring hospitals to return larger portions of their disproportionate share payments to the States. This practice is contrary to the program's purpose, which is to compensate hospitals that care for large percentages of Medicaid beneficiaries and uninsured patients.

As the Medicare and Medicaid populations grow, the importance of establishing and maintaining the integrity of payment methodologies becomes more critical so that scarce resources are not lost to fraud, waste, and abuse, and beneficiary care is not diminished.

Management Issue 4: Promoting Compliance with Federal Health Care Program Requirements

MANAGEMENT CHALLENGE AND ASSESSMENT OF PROGRESS IN ADDRESSING THE CHALLENGE:

Provider compliance with Federal health care program requirements is essential to the integrity of the Medicare and Medicaid programs. Compliance prevents fraud, waste, and abuse and promotes efficiency and economy. To ensure compliance, the Department must partner with health care providers. The Medicare program pays for health care services for about 47 million beneficiaries rendered by 1.2 million participating providers and suppliers, including hospitals, nursing homes, physicians and other practitioners, DME companies, and others. An estimated 1.2 billion Medicare FFS claims are processed by CMS annually, amounting to an average 4.6 million claims processed each working day. In FY 2009, Medicare FFS payments totaled \$327.8 billion. Medicare is required to process and pay electronically submitted claims within 30 days of receipt. The Medicaid Federal Medical Assistance Percentage (FMAP) payment totaled \$252.9 billion in FY 2009, helping to address the care needs for about 51 million Medicaid recipients.

The Medicare and Medicaid programs rely on the premise that providers and suppliers submit legitimate and accurate claims by providers and suppliers. Although most providers and suppliers are honest and well intentioned, even honest providers and suppliers can make mistakes or fail to

comply with the rules. Though small in number, dishonest providers and suppliers attempt to game the system by exploiting or circumventing payment and coverage rules. The challenge facing the programs is illustrated by a December 2009 OIG study, which found that 60 percent of claims for standard and complex rehabilitation power wheelchairs did not meet Medicare documentation requirements and that error rates varied by power wheelchair type and supplier volume during the first half of 2007, with greater documentation error rates accompanying claims for complex rehabilitation wheelchairs than for standard models. CMS concurred with all of OIG's recommendations for improving documentation processes to reduce improper payments in this area and noted multiple efforts underway to improve compliance. For example, a contract was recently awarded to a Program Safeguard Contractor (PSC) to conduct medical review on power mobility claims submitted by certain providers. In addition, CMS will instruct MACs to examine whether beneficiaries were receiving the correct wheelchairs for their conditions and whether correct documentation was present.

A June 2010 OIG report reveals how noncompliance with even the most basic documentation safeguards challenges Federal health care programs. Medicare Part D sponsors and beneficiaries paid pharmacies \$1.2 billion in 2007 for claims in which the listed prescriber identifiers did not correspond to practicing physicians. Without a valid prescriber identifier, CMS and its contractors cannot determine whether a physician actually prescribed the drug or whether the physician was validly licensed and had not been excluded from the Medicare program. Furthermore, invalid prescriber identifiers inhibit OIG investigations by making it more difficult to identify questionable prescribing patterns and the parties responsible for potential fraud.

Effectively combating fraud, waste, and abuse includes ensuring that a provider and supplier community is well informed about program rules and is actively engaged in compliance efforts.

The Costs of Noncompliance

Assisting health care providers and suppliers in adopting practices that promote compliance with program coverage, payment, and quality requirements must be an integral part of the Department's program integrity strategy. The benefits of industry compliance include reduced risk of fraud and abuse, as well as fewer billing and payment errors; better quality of care; and the fostering of an ethical culture that enhances public confidence in the system.

The risks associated with failing to create a culture of compliance and the costs of noncompliance are

significant. CMS estimated that in FY 2009, improper FFS payments cost Medicare \$24.1 billion (7.8-percent error rate). Changes were implemented during FY 2009 review year and, as a result, the 7.8 percent was a combined error rate using two different methodologies. The revised methodology is more stringent. The national paid claims error rate for those claims reviewed under the strictest criteria, when applied to the entire year, is 12.4% or \$35.4 billion. CMS estimated that in FY 2008, improper Medicaid State and Federal payments cost \$28.7 billion (8.71-percent error rate). OIG has identified inappropriate Medicare payments for specific services and products. (See also management issues 2, 3, 5, and 6.) OIG recently found that certain DME claims did not meet Medicare program requirements, resulting in potentially more than \$200 million in improper payments. OIG found that New York's Medicaid program paid more than \$414.5 million (\$207.6 million Federal share) to providers in New York City for rehabilitation services claims that did not meet program requirements. Error rates and improper payment estimates include paid claims that do not meet program rules, whether because of error, fraud, or other factors.

OIG has also identified fraud and abuse that have resulted in substantial costs to Federal health care programs: expected OIG recoveries for the 6 months that ended March 2010 include about \$667 million in audit receivables and \$2.5 billion in investigative receivables. In addition, noncompliance with standards of care can be so egregious as to constitute a failure of care and jeopardize patient health and safety. (See Management Issue 7.) When settling allegations of fraud and abuse, OIG often requires health care providers to enter into Corporate Integrity Agreements (CIA) in exchange for OIG's agreement not to exclude the provider from participation in Federal health programs. OIG tailors CIAs according to the conduct and circumstances of each case. However, CIAs generally require providers to implement compliance programs that include a compliance officer or committee, written standards and policies, employee training programs, confidential disclosure mechanisms, reviews by an independent reviewer, and various reporting requirements.

Education and Guidance Efforts

Provider education and guidance are important tools for fostering compliance. However, several factors create challenges in promoting industry compliance with program rules through education. Federal health care programs are governed by complex statutes, regulations, and subregulatory guidance.

There are national rules, such as statutes, regulations, and national coverage determinations, and local rules, including local medical review policies. These rules and regulations are frequently updated or changed by law or by administrative action. In a complex programmatic environment, it is a challenge to ensure that guidance is clear, informed, complete, and audience appropriate.

The audience for compliance education is diverse in terms of sophistication, size, and resources. Medicare providers range from health care corporations that hire top legal and management advisors to small operations with minimal legal or regulatory expertise. Some are integrated delivery systems that need to master the rules and regulations for multiple benefit categories, while others are purveyors of only one item or a few items and services. Some providers may have limited resources to devote to compliance, which competes with other priorities, such as providing care, managing business operations, and earning a profit. Others are affiliated with well-established, large, multi-facility organizations with a widely dispersed workforce and significant resources to devote to compliance.

To address these challenges, the Department must work to ensure that it is providing guidance that assists providers and suppliers in understanding and complying with program requirements, educating providers and suppliers effectively about program requirements, and promoting industry adoption of effective internal controls and other compliance measures. The Department must also ensure that its claims-processing contractors are knowledgeable about program requirements, that the contractors provide useful guidance on their policies, and that they offer adequate education for the providers and suppliers whose claims they process.

The Department has a variety of tools and approaches available for this effort. These include regulatory and subregulatory issuances (including manuals, frequently asked questions, advisory opinions, and other materials), provider listservs, Web sites (such as the Medicare Learning Network), and live educational opportunities (such as open-door forums and sponsored education programs on requirements of the *Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 (P.L. No. 108-173)*). CMS is also exploring the use of new media, such as podcasts and RSS feeds, to reach provider and supplier audiences. It recently launched a series of national listening sessions related to OIG reports in an effort to educate provider and suppliers on specific vulnerabilities that exist in DME, Part A, Part B, and home health and hospice settings.

A National Health Care Fraud Summit was held in Washington, DC, in January 2010. The Department is working with the Department of Justice (DOJ) on additional live educational opportunities, such as Regional Fraud Prevention Summits; summits have been held in Miami and Los Angeles. At this point, additional summits have been planned for New York, Detroit, Boston, and Philadelphia. The summits bring together representatives from Federal, State, and local law enforcement agencies and representatives from the private sector, including health care providers, hospitals, and doctors for a day of panels and training sessions that facilitate the sharing of information about trends in health care fraud that will ensure effective referral mechanisms and procedures.

The Department also works with the private sector to promote compliance. For example, CMS has a Provider Partnership Program through which it shares Medicare FFS information with national organizations that are Medicare billers or serve as intermediaries for Medicare billers. Through the Medicaid Integrity Program, CMS funds contracts for educating health care providers and suppliers, managed care entities, and beneficiaries to promote payment integrity and quality of care.

OIG also collaborates with health care providers to promote compliance. As discussed more fully in Management Issue 7, OIG has worked with nursing home providers through roundtables that focus on how boards of directors can better monitor and ensure quality of care. Another collaborative live educational opportunity will be represented by the OIG's Provider Compliance Training initiative, to begin in 2011. The Provider Compliance Training Initiative will bring together representatives from a variety of government agencies to provide compliance training at no cost to local provider, legal, and compliance communities in Medicare Strike Force cities and other locations across the country. Strike Forces are multiagency teams of prosecutors and investigators that use real-time analysis of Medicare billing data to assist in the identification, investigation, and prosecution of individuals and entities that have committed fraud.

The continuing challenge is determining which tools and approaches are most cost effective, which are best suited to a diverse and rapidly evolving health care industry, and which produce the greatest benefit for increasing compliance.

Provider and Supplier Adoption of Compliance Programs

Implementation of effective compliance programs is another method of fostering an industry culture of compliance and a continuing commitment to

delivering quality health care. Successful compliance programs should establish internal controls to decrease providers' and suppliers' risk of practices that result in billing errors, fraud, and abuse. Quality assurance and improvement programs should ensure compliance with Federal health care program requirements and result in tangible benefits to the organization and the beneficiaries it serves.

One challenge, historically, is that the implementation of compliance programs has been largely voluntary. Before enactment of the *Affordable Care Act*, most Medicare and Medicaid providers were not required to adopt compliance programs. Compliance programs have been required only among certain categories of providers and suppliers, including Medicare Part D drug plan sponsors and MA organizations, which are required by statute to implement compliance plans and individuals and entities that have entered into CIAs with OIG. In addition, Medicaid providers in New York have been required by the State to implement effective compliance plans as a condition of Medicaid participation. Several other States besides New York have imposed compliance plan requirements on certain types of health care providers or entities. In some sectors of the health care industry, such as hospitals, voluntary compliance programs have been widespread and sophisticated; other sectors were slower to adopt internal compliance practices and may have had fewer resources to devote to compliance. As discussed below, the *Affordable Care Act* promises improvements because it contains provisions that effectively mandate compliance programs across provider categories.

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

OIG has recommended that all Medicare and Medicaid providers and suppliers be required to adopt compliance programs as a condition of participating in the Medicare and Medicaid programs. Passage of the *Affordable Care Act* entails major changes in the role of provider and supplier compliance plans in Federal health care programs. Section 6102 of the *Act* requires, among other things, that nursing homes develop effective

compliance and ethics programs to be in place by March 2013. More broadly, section 6401 of the *Act* sets out provider screening and enrollment requirements for Medicare, Medicaid, and CHIP, which include compliance program mandates for providers and suppliers. The compliance programs for providers and suppliers within a "particular industry or category" will need to meet certain core elements to be developed by the Department in consultation with OIG. Implementation timelines for the compliance program requirements are to be determined by the Secretary.

Even where compliance programs have been required, however, the Department has faced challenges in implementing a comprehensive safeguard strategy. OIG's reviews of the Part D program indicate that CMS's program integrity efforts have been limited in scope and may not sufficiently protect the program. While some of CMS's safeguards are functional, other critical safeguards have been implemented to a limited extent or have not been put in place. OIG found, for example, that CMS relied largely on complaints to identify potential fraud in Part D and that not all complaints were investigated in a timely manner.

OIG recently completed an indepth audit of one plan sponsor's internal controls for the Part D program during 2007 and 2008 and found that although most of the sponsor's internal controls were adequate, they had several weaknesses that compromised the sponsor's ability to detect, correct, and prevent fraud, waste, and abuse. In another report, issued in 2008, OIG found that plan sponsors vary widely in the identification of potential fraud. Although sponsors are the initial gatekeepers for protecting the Part D program, OIG found that not all of them identified potential fraud and abuse, conducted inquiries, initiated corrective actions, or made referrals for further investigation.

Failure to implement effective compliance programs can be a contributing factor that enables fraud and abuse to go unaddressed. CMS's task is to determine what Part D sponsors can do to improve program safeguards based on the information collected in audits of individual sponsors. After Medicare Drug Integrity Contractors (MEDIC) conducted 16 desk-review compliance plan audits, however, CMS found that these audits were of only limited value in monitoring and oversight efforts. As a result, in 2009, CMS revised its approach to compliance audits, changing from reliance on desk review, to on-site review.

CMS also found that it needed to develop more comprehensive, meaningful, and robust compliance plan audit protocols focused on evaluating and

validating the effectiveness of compliance programs, including measures to prevent, detect, and correct fraud, waste, and abuse. The new audit protocols were piloted in 2009 and early 2010, and changes were made based on lessons learned.

The benefits of promoting compliance, and highlighting the costs of noncompliance, will grow as beneficiary populations and health care costs increase. The Department must assist an ever larger and more diverse population of Medicare and Medicaid providers and suppliers in complying with program requirements.

The new mandates in the *Affordable Care Act* should ensure an expanded and redefined role for compliance programs. The Department is implementing several provider compliance education efforts and exploring many others. OIG will continue to provide compliance tools and resources to the provider and supplier community and work closely with the Department to meet this essential but difficult challenge.

Management Issue 5: Oversight and Monitoring of Federal Health Care Programs

MANAGEMENT CHALLENGE AND ASSESSMENT OF PROGRESS IN ADDRESSING THE CHALLENGE:

The Department's health care programs have been founded largely on a system of trust. Although most providers are honest and well intentioned, a system based on trust is vulnerable to exploitation by a minority of providers intent on gaming or defrauding the system. Thus, oversight and monitoring to detect potential fraud, waste, and abuse are critical. However, tension exists between the dual goals of implementing measures preventing and detecting fraud, waste, and abuse, and making timely payments to legitimate providers.

The Department is further challenged to provide effective oversight and monitoring of Federal health care programs because the programs are large and complex, with increasing expenditures and growing numbers of beneficiaries. The size of the programs means that fraud, waste, and abuse in claim submission and payments can result in substantial financial losses. Schemes have become increasingly sophisticated, and criminals adapt to oversight efforts.

Analysis of claims data is a key method of identifying fraud, waste, and abuse. Each program compiles an enormous amount of data on beneficiaries, providers, and the delivery of services. Processing, managing, and analyzing these vast and varied types of data is challenging. These challenges will grow with the additional data

collection and reporting required under the *Affordable Care Act*. The Department often fails to use these data effectively for oversight and monitoring, resulting in the loss of Federal health care dollars. Claims-processing and payment systems have traditionally relied on claim-by-claim review. However, in many cases, fraud or abuse can be detected only by reviewing aggregated claims and billing patterns because each claim may appear on its face to be legitimate. OIG has identified opportunities for the Department to improve its collection, analysis, and monitoring of data to better fight fraud, waste, and abuse. As will be discussed in more detail later, CMS plans to enhance the data available to monitor payment accuracy and integrity across the Medicare and Medicaid programs.

Measuring Error Rates

Measuring error rates is key to monitoring program integrity and the scope of inappropriate payments. In its reviews of CMS's annual Comprehensive Error Rate Testing (CERT) program, OIG has raised concerns that the Medicare error rates for certain provider types may be understated. To address these problems, CMS in 2009 made substantial changes in the CERT medical record review process, including revising the *Program Integrity Manual* to clarify requirements and promote uniform interpretation of its policies. As a result of the changes and a more complete accounting of improper payments, the FY 2009 national paid claim error rate was 7.8 percent, compared with the FY 2008 error rate of 3.6 percent. The changes were implemented during the FY 2009 review year, and as a result, the 7.8 percent was a combined error rate using two different methodologies. The revised methodology is more stringent. If the results from the revised methodology were annualized, the error rate would have been 12.4 percent. The Department has reported the 12.4 percent error rate and has set out-year targets based on that rate.

Measuring payment errors and their causes in the Medicaid and CHIP programs is particularly challenging because of the diversity of State programs and the variation in their administrative and control systems. CMS's Payment Error Rate Measurement (PERM) program was designed to measure error rates for three components of Medicaid and CHIP: FFS, managed care, and eligibility. OIG is performing audit work to determine whether problems similar to those discovered in the CERT program exist in the PERM program.

Improper payments are also a significant problem across Federal programs. In November 2009, the President signed *Executive Order 13520, Reducing Improper Payments*, and in July 2010, the *Improper*

Payments Elimination and Recovery Act (IPERA) was enacted. The purpose of the Executive Order and *IPERA* is to reduce improper payments by intensifying efforts to eliminate payment error, waste, fraud, and abuse in the major programs administered by the Federal Government, including the Department's health care programs, while continuing to ensure that Federal programs serve and provide access to their intended beneficiaries. The requirements of the Executive Order and *IPERA* will further help to reduce improper payments by boosting transparency, holding agencies accountable for reducing improper payments, and creating incentives for States and other entities to reduce improper payments and increasing penalties for contractors who fail to disclose improper payments in a timely manner. The Department and OIG are working together to implement requirements of both the Executive Order and *IPERA*.

Oversight through Effective Analysis of Data

The health care system compiles an enormous amount of data on patients, providers, and the delivery of health care items and services. However, OIG has found numerous examples in which Federal health care programs have failed to use claims-processing edits and other information technology effectively to prevent improper claims. The following are examples of how vigilant claims analysis could assist the Department in monitoring programs for fraud, waste, and abuse.

Claims analysis can reveal instances in which providers bill for medically unnecessary services to defraud programs. In December 2008, a Miami physician was sentenced to 30 years in prison and ordered to pay more than \$8.2 million in joint and several restitution in connection with her role in an HIV infusion fraud scheme. In another example, at the Saint Jude Rehabilitation Center, Inc., HIV-positive Medicare patients were paid cash kickbacks in exchange for allowing the physician and her co-conspirators to prescribe medically unnecessary infusion treatments; the case was brought by the Medicare Strike Force (see Management Issue 6).

Claims analysis can also reveal instances in which providers bill for more services than are physically possible. In one of the largest civil fraud recoveries ever against a single U.S. hospital, Staten Island University Hospital agreed to pay \$88.9 million in a global settlement resolving allegations that it defrauded Medicare and Medicaid. OIG identified potentially fraudulent billing, among other allegations, for inpatient alcohol and substance abuse detoxification treatment for more beds than the facility was authorized by the State of New York.

Claims analysis can also identify service areas in which providers submit questionable claims. OIG found that providers in a south Florida county accounted for more home health outlier payments in 2008 than the rest of the counties in the Nation combined. Twenty-three more counties nationwide also exhibited aberrant home health payment patterns similar to that of the Florida county but to a lesser extent. CMS has taken steps to address widespread abuse of Medicare outlier payments to home health providers.

Challenges in Using Data Effectively

In some cases, program data are insufficient to support effective oversight and monitoring. OIG found that Medicare data are insufficient to determine consistently whether Medicare Part B chemotherapy administration payments are appropriate. Part B data do not identify drugs that are not billed to the program even when their administration is billed to Part B. In these cases, when there is no matching drug claim, the data alone cannot be used to determine whether the administration fee has been appropriately billed for administering a qualifying drug.

In other cases, CMS does not effectively use the safeguards available to monitor claims. Unique provider identifiers are a primary tool for ensuring that Medicare services and products are ordered by qualified, legitimate providers. However, OIG work has uncovered vulnerabilities related to the misuse of physician identifiers. OIG found that more than 18 million Medicare Part D prescription drug claims accounting for \$1.2 billion contained invalid prescriber identifiers in 2007. These identifiers either were not listed as valid identifiers in the National Provider Identification (NPI), Drug Enforcement Administration (DEA) number, or Unique Physician Identification Number (UPIN) registry databases or had been deactivated or retired before January 1, 2006. In another review, OIG found that Medicare Part B allowed almost \$28 million for claims with inactive referring physician UPINs, including \$5 million for claims with dates of services after the dates of death of the referring physicians. In 2008, CMS completed its transition from UPINs to a new NPI system for Medicare claims processing. However, OIG has concerns that the vulnerabilities associated with the UPIN system may also affect the integrity of the NPI system.

The Medicaid program has unique data challenges because key program operations occur in States, rather than on a national level. The Medicaid Statistical Information System (MSIS) is the only source of nationwide Medicaid claims information, and weaknesses in MSIS data limit its usefulness for

oversight and monitoring of the program. OIG determined that during FYs 2004 through 2006, MSIS data were an average of 1.5 years old when CMS released the data to users for data analysis purposes. And MSIS did not capture many of the data elements that can assist in fraud, waste, and abuse detection. CMS did not fully disclose or document information about the accuracy of MSIS data; however, CMS maintains a Data Anomalies/State Issues document, which identifies State-specific data issues by file type and year.

The effective use of data is critical to the Department's oversight and monitoring activities and in turn will support the overall success of the Department's anti-fraud efforts.

Recent and Planned Oversight Enhancements

The Department is making progress in improving the oversight and monitoring of Federal health care programs. CMS is augmenting its oversight capabilities by contracting with outside entities to perform many oversight and monitoring functions for Medicare and Medicaid. CMS is also acting to enhance data systems available for use by these contractors. The *Affordable Care Act* creates new implementation challenges in directives requiring the Department to collect, use, and share data. The *Act* requires the Department to expand CMS's Integrated Data Repository to include claims and payment data from Medicaid, the Department of Veterans Affairs (VA), the Department of Defense (DOD), the Social Security Administration (SSA), and IHS. The *Act* also contemplates real-time access by law enforcement to Medicare claims data. To facilitate oversight, the *Act* exempts OIG from prohibitions against matching data across programs. The *Act* also provides OIG with more streamlined access to data and will improve its ability to oversee the integrity of Federal health care programs.

For Medicare, CMS is transitioning program safeguard functions from PSCs and MEDICs to Zone Program Integrity Contractors (ZPIC). These new contractors will be responsible for ensuring the integrity of all Medicare-related claims under Parts A and B (e.g., hospital, skilled nursing, home health, physician, and DME claims); Part C (MA health plans); and Part D (prescription drug data) and for coordinating Medicare-Medicaid data matches (Medi-Medi). As of November 2010, CMS had awarded four ZPIC contracts, with three more contracts planned. With the transition to ZPICs, determining whether the change in contractors has brought about improvement in the use of proactive methods in analyzing claims data will be important. OIG is examining ZPICs' efforts to identify program vulnerabilities and detect and investigate fraud and abuse.

In 2003, Congress authorized the Department to establish a demonstration program for Recovery Audit Contractors (RAC) to identify underpayments and overpayments and to recoup overpayments under Part A or B of the Medicare program. Under this authority, Congress provided for payments to RACs on a contingent basis for detecting and correcting overpayments and underpayments. In 2006, Congress mandated that the Department implement RACs on a nationwide and permanent basis. As of October 2009, CMS completed implementation of the national RAC program in all 50 States. CMS reported that the RAC demonstration project successfully returned almost a billion dollars to Medicare, which represented a new mechanism for detecting improper payments, and provided CMS with a tool for preventing and reducing future improper payments. CMS will require RACs to help develop plans designed to address vulnerabilities found during their reviews. RACs are also responsible for referring to CMS any cases of potential fraud that are found during their reviews. However, OIG noted that over the 3-year demonstration period, RACs referred only two cases of potential fraud to CMS. OIG and CMS are working together to ensure appropriate referrals of suspected fraud under the national RAC program. CMS has agreed to implement a system to track fraud referrals and to require RACs to receive mandatory training on the identification and referral of fraud. Section 6411 of the *Affordable Care Act* expands the RAC program, giving it additional responsibilities to address improper payments in Medicaid and Medicare Parts D and C.

As part of the Medicaid Integrity Program, CMS has hired contractors to perform data analysis to detect aberrant billing patterns and to audit claims to identify improper payments. OIG is examining the contractors' work. The Medicaid Integrity Group developed a data engine, a central component of its data strategy and information technology infrastructure. The data engine combines State Medicaid claims data to facilitate detection of fraud, waste, and abuse. The need for an accurate and comprehensive Medicaid claims database that can be used at the national level for data mining and fraud detection is important.

In 2009, OIG formed a cross-disciplinary, interdepartmental Advanced Data Intelligence and Analytics Team (Data Team) to support the work of the Health Care Fraud Prevention and Enforcement Action Team (HEAT) initiative and the Medicare Fraud Strike Forces. (See Management Issue 6 for further discussion of this issue.) The Data Team consists of investigators, auditors, and evaluators from OIG as well as DOJ personnel; the team combines sophisticated data analysis with criminal intelligence gathered through traditional law

enforcement techniques to identify fraud trends. Using Data Team analysis, in December 2009 the HEAT Operations Committee announced several metropolitan “hot spots” for new Strike Force operations. In April 2010, the Data Team provided additional national-level analysis in support of the planned expansion of HEAT operations.

Despite the progress described and plans for enhancements, the Department needs to make continued improvements in oversight and monitoring to meet the challenges that have been outlined. As fraud schemes become more sophisticated and migratory, the use of advanced data analysis to monitor claims and provider characteristics becomes even more important. (See Management Issue 6 for further discussion of this issue.) Needed improvements in using data analysis to support program oversight include sufficient access to data for investigations and analysis; uniform, comprehensive data elements; more timely collection and validation of data; robust reporting of program data by States and others; interoperability of systems; consistent data extraction methods; and the ability to select and analyze claims and provider data across Medicare Parts A, B, C, and D and Medicaid.

Management Issue 6: Response to Fraud and Vulnerabilities in Federal Health Care Programs

MANAGEMENT CHALLENGE AND ASSESSMENT OF PROGRESS IN ADDRESSING THE CHALLENGE:

Responding to fraud and program vulnerabilities requires a high degree of coordination and collaboration between multiple Federal and State agencies and contractors. Federal health care programs are built on a range of regulations, program requirements, and payment methodologies that are often the result of detailed rulemaking and programmatic balancing of competing stakeholder interests. The size and complexity of Federal health care programs also make implementing a comprehensive and swift response to fraud and vulnerabilities difficult. Adding to this complexity, the Medicare administration and program integrity responsibilities are divided among a variety of contractors, and Medicaid and CHIP have their own systems and contractors. The programs compile an enormous amount of data on patients, providers, and the delivery of health care items and services, which are often housed in many locations with different data infrastructures. Operating within this complex framework, it is often difficult for the programs to respond nimbly in the face of a vulnerability, which can result in a significant monetary loss before a remedy or sanction is applied.

OIG work has identified fraud and vulnerabilities across the Department’s health care programs. (See also Management Issues 2-5 and 7.) It is a challenge for the Department to prioritize and respond to the most serious vulnerabilities in the face of limited resources to implement the response. Further, once perfected, many fraudulent schemes are easily replicated and move quickly through communities and across the country. Law enforcement may respond with criminal prosecutions in one jurisdiction only to see the scheme replicated in another part of the country. Fraud schemes are also becoming increasingly sophisticated and often evolve in response to Government’s detection and enforcement efforts. An effective response must be swift; too often, program funds are lost and unrecoverable by the time data are analyzed and the fraud scheme is detected.

These and other factors create conditions that are ripe for those who would take advantage of Federal health care programs. In the face of this significant challenge, the Department brings to bear a law enforcement response through OIG and a programmatic response through CMS.

Law Enforcement Response

The law enforcement response to fraud and program vulnerabilities falls into three categories: criminal prosecution, civil litigation, and administrative remedies. Challenges in these three areas are described below.

While most health care providers submit legitimate claims, a minority abuse the system. Adding to this are an increasing number of criminals whose sole purpose is to defraud the program. These are often career criminals running sophisticated and organized criminal enterprises, and the most appropriate response is criminal prosecution. Of particular concern has been the increase in medical identity theft in a broad range of cases. Medical identity thieves often sell and resell beneficiary information. It is not unusual for physicians or beneficiaries to have their identities compromised multiple times.

In response, HHS and DOJ took strong and decisive enforcement action through the creation of Medicare Fraud Strike Forces as part of the HEAT initiative to combat health care waste, fraud, and abuse. HEAT built on the successful Medicare Fraud Strike Force (Strike Force) initiated in south Florida by expanding Strike Forces to other metropolitan areas across the country. These Strike Forces use advanced data analysis techniques (see Management Issue 5) to identify criminals operating as health care providers and detect emerging or

migrating fraud schemes. Strike Force teams operate in Miami, Los Angeles, Detroit, Houston, Brooklyn, Baton Rouge, and Tampa, and 13 more teams are to be established in other cities as resources permit. As of September 30, 2010, Strike Force efforts have resulted in charges against approximately 625 individuals or entities, more than 300 convictions, and approximately \$315 million in investigative receivables. Strike Forces have been successful, but the teams require sufficient staffing and resources to respond effectively to health care fraud schemes.

The *Affordable Care Act* increases criminal penalties for health care offenses under the Federal Sentencing Guidelines, and it expands the types of conduct that constitute Federal health care fraud offenses under Title 18 of the United States Code. As a result, those who commit health care fraud will serve longer prison terms and face larger criminal fines, and the government will have a broader range of tools to address criminal health care fraud schemes.

In addition to criminal prosecution, civil litigation continues to be an important response to fraud and program vulnerabilities. Complex corporate fraud and other matters can be resolved through civil litigation in addition to or as an alternative to criminal enforcement. Despite multimillion-dollar, and even billion-dollar civil settlements, corporations often write checks and continue their abuse of the system. Large corporations that engage in health care fraud often resolve a criminal case through a guilty plea of a nonoperating subsidiary. In those cases, which involve admitted criminal conduct, OIG may have no basis to exclude the parent-company defendant or any other operating company from future participation in the Federal health care programs based on the criminal conviction. Even when there may be a basis for a permissive exclusion of the parent company or when a company has engaged in multiple schemes and its subsidiary has been convicted in more than one criminal case, OIG must carefully consider how beneficiary access to vital medical products and services could be affected by any such exclusion of the parent company.

A comprehensive law enforcement response to fraud must use all tools available to the Government. In addition to criminal and civil actions, the appropriate response in a particular case may include alternate remedies, such as OIG's use of targeted CMPs and program exclusions. For example, where DOJ might pursue civil litigation against a large corporate defendant that paid health care kickbacks, OIG might bring a parallel case under the CMP Law against the individual recipients of the kickbacks. Where a health care fraud case involves potential harm to program beneficiaries,

the most appropriate response will often include OIG's exclusion of the defendant from future participation in the programs. Wherever possible, OIG works with its law enforcement partners to tailor the response to a given scheme in a way that maximizes the use of resources and effectively utilizes administrative tools, in addition to criminal and civil remedies.

Federal Health Care Program Responses

Law enforcement actions alone will not eliminate fraud and abuse; and yet where vulnerabilities are accurately identified, it can be a significant challenge for the Department to respond effectively and ensure that the problems are corrected. During a series of unannounced site visits to DME suppliers in south Florida in 2007, OIG found that 491 of 1,581 suppliers failed to meet Medicare standards; CMS revoked their billing privileges. Nearly half of these suppliers appealed the revocations and received hearings, and 91 percent had their billing privileges reinstated. Two-thirds of those suppliers who were reinstated have since had their privileges revoked again, and some individuals connected with reinstated suppliers have been indicted. In a report on DME supplier appeals, OIG found that because there are no criteria for the types of evidence necessary to reinstate providers' billing privileges, hearing officers made decisions based on a variety of evidence, which resulted in inconsistencies. CMS agreed that it should consider establishing consistent guidelines on the evaluation of evidence that a hearing officer will review during the appeal process. Establishing consistent guidelines will continue to be a challenge for the Department.

OIG is assessing other Medicare contractors' use of enrollment-screening mechanisms and post-enrollment monitoring to identify DME and home health agency applicants that pose a risk of fraud to Medicare and will determine the extent to which applicants omitted ownership information on enrollment applications, potentially circumventing the program's safeguards. (See Management Issue 2.)

Despite CMS's and its contractors attempts to address billing problems in high-risk areas, aberrant billing problems persist. In a 2009 review, OIG's analysis of Medicare billing patterns in south Florida for inhalation drugs used with DME uncovered evidence of abusive billing. Medicare paid almost \$143 million for inhalation drugs in Miami-Dade County alone, an amount 20 times greater than was paid in Cook County, Illinois, the jurisdiction (outside south Florida) with the next-highest total payments. However, according to Medicare enrollment data, Cook County is home to almost twice as many Medicare beneficiaries as Miami-Dade County.

In response to this scheme, CMS reported that its contractor had implemented a “medically unlikely” edit for the inhalation drug, budesonide, and after the edit there was an immediate 50-percent decrease in allowed and billed amounts for budesonide in Miami-Dade and Broward Counties in October 2008. Although CMS response was an important first step, experience tells us that this alone will not solve the problem. The same criminals who were exploiting the system with respect to budesonide will attempt to circumvent this response by billing for other items or services.

Therefore, it is important to use analytic tools such as data mining to monitor whether and how criminals are adapting their fraud schemes in response to the Government’s program integrity efforts. CMS is developing such tools through its Integrated Data Repository (see also Management Issue 5). OIG’s experience tells us that such approaches can be effective in identifying and responding to fraud. For example, in the coming months, OIG will issue a report analyzing how use of certain inhalation drugs may have changed in the wake of Medicare program integrity efforts relating to budesonide. OIG is also using a combination of claims and sales data to determine whether the amount of a different inhalation drug billed by south Florida suppliers and paid for by Medicare exceeded the total amount of the drug distributed for sale in the area. By using innovative data analysis to detect unusual patterns, OIG is able to target high-risk services and geographic regions and make recommendations for a more comprehensive approach to address systemic vulnerabilities.

As described above, the programs rely on contractors to pay claims and to administer the response to fraud and vulnerabilities. This dual reliance on contractors presents a unique challenge for CMS. In February 2010, OIG evaluated the results of CMS’s 3-year RAC demonstration project. Three RACs participated in the project. Although they were not responsible for reviewing claims for fraudulent activity, they were responsible for referring to CMS any instances of suspected fraud found during their reviews. However, the RACs have a disincentive for referring instances of suspected fraud because they are paid through contingency fees based on overpayments collected. In case of suspected fraud, overpayments are generally not collected while the fraud is being investigated. Despite their identification of more than \$1.03 billion in Medicare improper payments, between 2005 and 2008, the RACs referred only two cases of potential fraud to CMS. As the RAC demonstration shows, it will continue to be a challenge for the Department to ensure that its response to program vulnerabilities captures not

only improper payments but also fraud and that the contractors on which it relies have the tools, training, resources, and incentive to appropriately address improper payments and make appropriate fraud referrals.

In addition, CMS contracts with MEDICs to perform integrity functions, such as identifying and investigating potential fraud, waste, and abuse in the Part D program. OIG found that CMS’s program integrity efforts have been limited in scope and that major challenges remain to sufficiently protect the Part D program. One of the key aspects of CMS’s strategy to combat fraud in Part D was the MEDICs’ use of innovative techniques for proactive data analysis. While proactive data analysis is a key element of MEDICs’ responsibility, OIG found in a 2009 review that MEDICs identified most incidents of potential fraud through external sources, such as beneficiary complaints, rather than proactive data analysis. MEDICs may not have been aware of some potential fraud and abuse incidents because Part D plan sponsors are not required to refer them. Finally, CMS did not give MEDICs approval to conduct audits of sponsors’ compliance plans in FY 2008. In November, 2009, after the issuance of this report, CMS restructured the MEDIC program. However, CMS indicated that it does not have the regulatory authority to require sponsors to report these incidents.

Given the significant expenditures at issue, responding quickly and comprehensively to identified weaknesses in the Part D program is imperative. Ensuring that Part D and its beneficiaries are paying appropriately for the benefit will remain a significant challenge for the Department. OIG is performing reviews on questionable billing patterns, sponsors’ anti-fraud training, the status and results of all audits of sponsors, Part D electronic-prescribing initiatives, invalid prescriber identifiers on prescription drug data, payments made to excluded providers, reconciliation calculations, and Part D rebates and pharmacy discounts.

OIG has also found that challenges remain in the programs’ efforts to respond to fraud, waste, and abuse vulnerabilities in home health and personal care services similar to those described above for DME. OIG analyzed all Medicare home health claims that were submitted and fully paid in 2008 to identify geographic areas that exhibited aberrant Medicare home health outlier payment patterns. OIG’s review found that Miami-Dade County, Florida, accounted for more home health outlier payments in 2008 than the rest of the Nation combined. OIG also found that 23 other counties nationwide exhibited aberrant home health outlier

payment patterns similar to that of Miami-Dade County. Despite the programs' focus in this area, these findings demonstrate that home health services in Miami-Dade County, as well as in other counties nationwide, warrant additional attention as part of continuing anti-fraud activities, such as HEAT.

Another challenge for the Department is to respond to detected vulnerabilities by suspending payments to providers upon credible evidence of fraud. This is critical in an environment in which claims are submitted and paid electronically, with potentially large sums of money being paid by the Government in a very short period if the payment suspension is not implemented in a timely manner. The *Affordable Care Act* expressly authorizes the Secretary to suspend payments to providers if the Secretary determines, in consultation with OIG, that there is a credible allegation of fraud. To mount a comprehensive response to fraud and program vulnerabilities, the Department must use the payment-suspension authority wherever it is warranted to protect the programs while also protecting the rights of providers.

As discussed in other sections, the *Affordable Care Act* strengthens the Government's ability to detect fraud and abuse and to respond rapidly to health care fraud. The law also requires the Department to expand CMS's integrated data repository to include claims and payment data from Medicaid, VA, DOD, SSA, and IHS and fosters data-matching agreements among Federal agencies. These agreements will make it easier for the Federal Government to identify fraud, waste, and abuse. It will then be a challenge for the Department to integrate all of this data into its systems for analysis and response. The challenge remains to obtain real-time information across all areas of the programs, which will enable the government to respond to fraud more quickly, bring criminals to justice, and recoup stolen funds. Timely data are also essential to responding with agility as criminals shift their schemes and locations to avoid detection.

By using the new tools described above to meet these challenges, the Department, including OIG, must continue to work with its many partners to respond to vulnerabilities in Federal health care programs. The Department must work to reduce improper Medicare and Medicaid payments resulting from fraud, waste, and abuse across all service areas by addressing vulnerabilities and weaknesses with all available tools.

OIG's *Compendium of Unimplemented Recommendations* identifies many significant vulnerabilities and provides recommended responses requiring action by the Department or Congress. The Department, including OIG, must

also identify new risks posed by the changing dynamics of Federal health care programs and the resulting evolving nature of fraud and abuse schemes and act promptly and effectively.

Management Issue 7: Quality of Care

MANAGEMENT CHALLENGE AND ASSESSMENT OF PROGRESS IN ADDRESSING THE CHALLENGE:

Ensuring quality of care for beneficiaries of Federal health care programs continues to be a significant challenge for the Department. This challenge has many facets, such as ensuring that the Department adequately oversees health care providers' compliance with quality-of-care standards and ensuring that beneficiaries do not receive substandard care and are not abused or neglected. The Department also faces challenges in adopting tenets of the patient-safety movement, which focuses on improving care through quality improvement initiatives, measurement, and reporting.

Oversight of Compliance with Existing Quality Standards

Overseeing compliance with quality standards represents a challenge for the Department. The growing number of beneficiaries receiving care in hospitals, in nursing facilities, and from home health agencies underscores the need to ensure beneficiaries receive quality care and to enforce quality standards.

Ensuring quality care for nursing home residents remains a significant challenge. OIG is examining whether atypical antipsychotic drugs provided to residents are in compliance with CMS standards for unnecessary drugs. OIG is also examining SNFs' compliance with Federal requirements for quality of care by reviewing their plans of care and discharge planning. In addition, OIG is updating its 2006 review of SNF compliance with emergency preparedness planning standards. In future work, OIG will review poorly performing nursing homes. (See Management Issue 9 for further discussion of emergency preparedness in nursing homes.)

OIG will also examine quality of care in Medicaid home- and community-based settings, such as assisted-living facilities and adult day health centers. This work will determine whether the care provided follows the plans of care and will assess the extent of CMS's oversight of quality of care in these settings.

The Department has made progress on its oversight of quality standards. For example, CMS expanded its oversight of accreditation organizations and effective mid-2010, it approved the Joint Commission's deeming authority for hospitals. The

Joint Commission previously held a unique statutory status that allowed it permanent deeming authority, but now this authority must be periodically reapproved by CMS. CMS also proposed rules that would require unannounced and extended surveys of home health agencies and the imposition of sanctions when they are found to be out of compliance with Federal standards.

Protecting Beneficiaries from Substandard Care and from Abuse and Neglect

Protecting beneficiaries is an ever-present challenge for the Department. Identifying and addressing instances of substandard care are central to this challenge.

OIG investigations and enforcement cases demonstrate that some beneficiaries receive substandard care or are abused or neglected by providers. In January 2010, five Cathedral Rock Corporation nursing homes pleaded guilty to felony health care fraud, and Cathedral Rock Corporation's chief executive officer (CEO) entered into a 2-year deferred prosecution agreement for submitting claims for worthless care resulting in serious harm and patient death. The five homes and the CEO were jointly assessed a \$1 million criminal penalty. Cathedral Rock Corporation paid \$628,000 to resolve its civil FCA liability and entered into a 5-year CIA requiring Cathedral Rock to retain an independent quality monitor selected by OIG.

As cases resolved in 2010 indicate, these problems exist across provider types. In January 2010, FORBA holdings paid \$24 million to resolve allegations that it provided substandard and medically unnecessary dental services to Medicaid patients at its pediatric dental clinics. In April 2010, Harbor Senior Concepts, an assisted-living facility chain, paid \$258,000 to resolve allegations that it provided substandard care to Medicaid beneficiaries resulting in patient harm.

Other OIG work has also identified instances of patient abuse and neglect. For example, OIG found serious quality-of-care issues in the delivery of Medicaid personal care services, which are delivered in beneficiaries' homes. Beneficiaries alleged that they were abused, neglected, and mistreated, and that personal care attendants stole their property. OIG recommended that States improve monitoring. In future work, OIG will examine hospital reports of restraint-related deaths and subsequent investigations by State agencies.

Complex ownership arrangements that include multiple entities present a particular challenge for holding nursing home owners accountable for substandard care. Pursuant to the *Affordable Care*

Act, the Department must promulgate regulations within 2 years requiring nursing homes to report their ownership in a standard format and, within 3 years, to make it public. Promulgating these regulations promptly and making effective use of the new authority provided by the *Affordable Care Act* poses a continuing challenge for the Department. Collection and publication of this information should facilitate more effective oversight and response to quality-of-care problems.

Medicare's primary program for addressing substandard care is the Quality Improvement Organization (QIO) program, which was established to promote the effective, efficient, and economical delivery of Medicare health care services and ensure the quality of those services. However, in 2007, OIG found that only 11 percent of cases reviewed by QIOs were for quality-of-care concerns and that sanction referrals were rare. Moreover, QIOs routinely failed to respond to OIG referrals on beneficiary care. CMS has improved the QIO program, adding the use of management information tools, such as milestone and project tracking. The use of these tools is intended to ensure that QIOs' services improve beneficiary care.

The Department also relies, in part, on the State Medicaid Fraud Control Units to investigate and address abuse and neglect in State-regulated Medicaid facilities. In addition, as part of the *Affordable Care Act*, the *Elder Justice Act* will improve reporting and investigation of allegations of abuse, neglect, and misappropriation of funds of residents in nursing homes. It requires nursing facility owners, operators, employees, managers, and contractors to report a reasonable suspicion of a crime against residents in nursing facilities to the Department and to law enforcement officers. Failure to report may result in significant penalties and, in cases where further harm occurred after the failure to report, exclusion from participation in the Federal health care programs. In addition, the Federal Elder Justice Interagency Working Group provides a forum for the exchange of current agency activities, emerging trends in policy and research, promising practices, and legislative developments related to elder justice.

The Patient Safety Movement and Incentives for Quality Improvement

The Department, which represents a major purchaser of health care, faces challenges in adopting tenets of the expanding patient-safety movement, which focuses on quality improvement, measurement, root-cause analysis, transparency, and public reporting.

The OIG's recent work on adverse events underscores the significance of this challenge. OIG reported that 13.5 percent of hospitalized Medicare beneficiaries experienced serious adverse medical events that prolonged a hospitalization, required life-sustaining intervention, or contributed to permanent harm or death and that another 13.5 percent of beneficiaries experienced temporary-harm events requiring medical intervention. These events, nearly half of which (44 percent) were preventable, cost the Medicare program \$324 million in additional costs in a single month. OIG is reviewing the extent to which internal hospital incident-reporting systems capture adverse events, report the information to external patient-safety entities, and use the information to improve practices. OIG also is assessing CMS's response to adverse events in hospitals.

The Department faces a challenge in working with health care providers to ensure that they are knowledgeable about and consistently implement quality-improvement processes. OIG has sponsored roundtables with hospital and nursing home representatives to explore involving boards of directors and trustees in quality-improvement matters. In 2010, OIG began incorporating requirements for board and trustee members' increased involvement in quality-of-care CIAs.

The Department has implemented a number of programs as part of the challenge to ensure patient safety and become a more prudent purchaser of health care. It established the Office of Healthcare Quality, which is leading and coordinating an initiative on preventing health-care-associated infections. Also, CMS continues to fund demonstrations on value-based purchasing and gain-sharing to provide payments to improve quality and efficiency. And it continues to have its QIOs work with providers to improve their performance on clinical measures related to patient safety and disease prevention.

The Department continues to make hospital, nursing home, and dialysis facility ratings available to consumers. AHRQ has also made considerable progress in implementing Patient Safety Organizations (PSO), which encourage clinicians and health care organizations to voluntarily report and share quality and patient safety information without fear of legal discovery. PSOs play an important role in collecting and studying data regarding adverse events.

OIG will examine hospitals' controls regarding the accuracy of quality-related data reported to CMS. OIG will also determine whether States have sufficient controls in place to ensure appropriate incentive payments in Medicaid programs aimed at rewarding high-quality care.

Related Challenge of Health Care Reform

The *Affordable Care Act* further underscores the importance of the challenges associated with ensuring quality of care. It creates an interagency workgroup on quality and calls for developing a national strategy to improve health care delivery. It calls for new models for patient care while focusing on greater transparency and accountability. In addition, it links payment to health care outcomes. It also requires background checks for those who will be working directly with patients in long-term care facilities. The successful implementation of these and other quality mandates in the *Act* will ensure enhanced quality of care in the health care delivery system, but the magnitude, complexity, and timely implementation of these changes present a challenge for the Department.

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

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

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

MANAGEMENT CHALLENGE AND ASSESSMENT OF PROGRESS IN ADDRESSING THE CHALLENGE:

Recent outbreaks of foodborne illness and increased drug and medical device recalls underscore the importance of ensuring the safety and security of the Nation's food supply, human and veterinary drugs, biologics, and medical devices. However, the Department's oversight responsibilities for these products are vast, creating a number of management challenges. For instance, responding to food safety emergencies often involves multiple State and Federal public health agencies, which makes coordination difficult. Likewise, ensuring that medical products, once proven to be safe and effective, are labeled and advertised appropriately is more demanding than ever given technological advances in the media used to promote such products. In the increasingly globalized market for food, drugs, biologics, and medical devices, these challenges -- combined with new statutory authorities that expand the Department's oversight role to include new products, such as tobacco -- elevate the significance of the Department's oversight function.

Despite these difficulties, the Department has made progress in addressing challenges in the oversight of food, drugs, biologics, and medical devices. FDA opened field offices in China, India, and Costa Rica to conduct more inspections and work with local officials to improve the safety of foods exported to the United States. In September 2009, FDA also required food facilities to report in a new registry all instances in which an article of food might cause serious health consequences and to investigate the causes of any adulteration reported. The Department has also made efforts to improve the safety of drugs and biologics through initiatives such as a new Risk Evaluation and Mitigation Strategy, which is designed to ensure that the benefits of a drug or biologic outweigh its risk. Although these efforts highlight the strides the Department has made, OIG work in the areas of food, drugs, biologics, and medical devices illustrates that more effort needs to be made to ensure quality and safety.

Oversight of Food Safety

More than 300,000 Americans are hospitalized and 5,000 die annually after consuming contaminated food and beverages. FDA is responsible for finding the contamination source during a food emergency and overseeing the voluntary removal by manufacturers of these products from the market. Yet recent OIG reports found that recordkeeping issues, inspection coverage, and recall problems impair FDA's ability to effectively resolve food emergencies.

Food facilities' failure to comply with FDA's recordkeeping requirements is a vulnerability that impedes the Department's ability to ensure the safety of the Nation's food supply. FDA requires some food facilities to maintain information about their product sources, recipients, and transporters. However, in a food traceability study, OIG found that only 5 of the 40 products purchased could be traced through each stage of the food supply chain back to a farm or a border. Fifty-nine percent of selected food facilities did not comply with FDA's recordkeeping requirements. Twenty-five percent of the facilities were not aware of such requirements. In another report, OIG found that 5 percent of selected facilities failed to register with FDA as required. Of those that did register, almost half failed to provide accurate and complete information.

The absence of guidelines establishing a minimum frequency with which FDA should conduct food facility inspections is problematic. OIG found that FDA inspects less than a quarter of food facilities each year and that more than half of food facilities have gone 5 or more years without an FDA

inspection. Furthermore, because FDA lacks adequate internal inspection procedures, the agency took actions against less than half of the food facilities where inspectors found objectionable conditions that warranted FDA's most severe inspection classification.

OIG also identified vulnerabilities in FDA's oversight of pet food recalls. OIG found that FDA lacks the statutory authority to require manufacturers to initiate pet food recalls and did not always follow its own procedures in overseeing the recall of pet food tainted with melamine. Nor were FDA's procedures always adequate for monitoring recalls as large as those required in the pet food incident of 2007.

OIG will continue to oversee the Department's management of food safety issues. As part of that oversight, OIG is reviewing FDA's monitoring of State agencies that contract with FDA to conduct food facility inspections; food facilities' compliance with requirements of FDA's Reportable Food Registry; FDA oversight and operations related to imported pet food and feed products; and the extent to which it tested human food for contamination from melamine and other contaminants.

Oversight of Drugs, Biologics, and Medical Devices

The Department is responsible for ensuring that all drugs, biologics, and medical devices are safe and effective. The Department must also ensure that once a drug, biologic, or device has been approved for use, it is marketed appropriately. However, OIG work in this area has exposed weaknesses in FDA's ability to adequately oversee the safety of drugs, biologics, and medical devices. In particular, OIG work found vulnerabilities in FDA's ability to ensure the timeliness of drug application reviews, the adequate monitoring of adverse-event reporting, and the prevention of off-label marketing of drugs, biologics, and medical devices.

FDA faces challenges in approving generic drug applications in a timely manner. In its June 2008 report, OIG found that FDA exceeded the 180-day review for nearly half of the original generic drug applications. FDA has implemented some changes that are consistent with OIG's recommendations to improve the generic drug approval process. In July 2008, FDA published a final rule that required it to review generic drug applications and describe all deficiencies to the applicant within 180 days. FDA also issued additional guidance on what information to include in generic drug applications. The *Affordable Care Act* expanded FDA's authority to include approval of biosimilars (generic biologics). Because of the unique nature of biologics research

and production, FDA faces additional challenges in implementing this new responsibility.

Providing adequate oversight of adverse events associated with the use of medical devices is a challenge for FDA. The agency receives about 200,000 adverse-event reports each year about medical devices. However, OIG found that FDA did not use the reports in a systematic manner to detect and address safety concerns. In a 2009 report, OIG found that FDA did not document followup on adverse events nor did it consistently read adverse-event reports in a timely manner. FDA has since developed a new database that will enable it to more effectively review adverse-event reports and conduct followup.

Although this is a step in the right direction, the Department still faces a number of obstacles in its oversight of medical device safety. For example, preventing the use of unapproved medical devices and the illegal marketing of potentially harmful devices continues to be a challenge. In December 2009, Spectranetics Corporation agreed to pay \$4.9 million in civil damages plus a \$100,000 forfeiture to resolve allegations that the company illegally imported unapproved medical devices and provided them to physicians for use in patients, conducted a clinical study in a manner that failed to comply with Federal regulations, and promoted certain products for procedures for which the company had not received FDA approval or clearance.

Among the Department's challenges is ensuring that drugs, once they have been determined to be safe and effective, are marketed appropriately. OIG has investigated a number of cases involving the illegal promotion of drugs by pharmaceutical manufacturers. In September 2009, Pfizer, Inc., and its subsidiary Pharmacia & Upjohn, Inc., agreed to pay \$2.3 billion to resolve criminal and civil liability arising from alleged illegal promotion of Bextra, an anti-inflammatory drug pulled from the market in 2005, and three other drugs. In April 2010, AstraZeneca LP and AstraZeneca Pharmaceuticals LP entered into a \$520 million civil and administrative settlement to resolve allegations that it illegally marketed the antipsychotic drug Seroquel. In January 2009, Eli Lilly and Company entered a \$1.4 billion global criminal, civil, and administrative settlement to resolve allegations that it illegally marketed its antipsychotic drug Zyprexa.

OIG is investigating many more allegations of fraudulent marketing and promotional practices in the pharmaceutical and medical device industries and is reviewing over 100 sealed *qui tam* complaints involving pharmaceutical and medical device fraud and abuse. Also, OIG is increasingly using its administrative authorities to sanction

individuals and entities engaged in fraudulent and abusive practices in the pharmaceutical and medical device industries. Even as cases are investigated and enforcement remedies are pursued, the Department faces the task of identifying systemic responses that can reduce illegal off-label marketing.

Oversight of Human Subject Protections in Clinical Trials

The Department's ability to protect human subjects enrolled in clinical trials and to ensure the identity and security of data collected in those trials remains a challenge that OIG continues to monitor. In 2007, OIG found that the lack of a clinical trial registry and inconsistencies in inspection classifications inhibited FDA's ability to manage its oversight of clinical trials. OIG also found that FDA inspected only about 1 percent of clinical trial sites during fiscal years 2000-2005. A recent OIG report found that sponsors relied heavily on foreign clinical trial data to support their marketing applications for drugs and biologics. OIG found that FDA inspected clinical investigator facilities at less than 1 percent of foreign sites. Logistical and jurisdictional challenges in conducting foreign inspections and data limitations also inhibited FDA's ability to monitor foreign clinical trials. FDA has taken steps to improve its oversight of foreign clinical trials. To leverage its inspection resources, FDA reached an agreement with the European Medicines Agency to share inspection-related data and other information. FDA is also piloting a data analysis tool to identify foreign and clinical investigator sites for inspection.

As the agency tasked with ensuring the safety and efficacy of food, cosmetics, drugs, biological products, medical devices, and products that emit radiation, the Department faces important challenges with respect to increasingly globalized markets. These challenges will only be exacerbated with new legislative mandates increasing the Department's oversight responsibilities, such as new authority to regulate the content, marketing, and sale of tobacco products. Despite making progress and plans for improvement, the Department must make strides in its oversight efforts to meet those challenges.

Management Issue 9: Public Health Emergency Preparedness and Response

MANAGEMENT CHALLENGE AND ASSESSMENT OF PROGRESS IN ADDRESSING THE CHALLENGE:

Recent natural disasters, such as hurricanes, wildfires, floods, and the outbreak of the H1N1 virus, highlight the importance of a comprehensive national public health infrastructure that is prepared to respond rapidly and capably to emergencies. The

ability to effectively prepare for and respond to a public health emergency requires planning, coordination, and communication across a range of entities, including Federal agencies; States, localities, and tribal organizations; the private sector; individuals and families; and international partners. This combination of organizations with significantly different roles and structures poses unique and unprecedented demands on the Department.

In its FY 2010 budget, the Department requested over \$5.1 billion to fund programs to enhance the Nation's emergency preparedness activities to better respond to large-scale public health emergencies, such as natural disasters, infectious disease outbreaks, or acts of bioterrorism. (See Management Issue 8 for discussions of preparedness for and response to foodborne illness and related emergencies.)

The Department has continued to work with States and selected localities to improve their public health emergency preparedness and response capacity. However, OIG work assessing preparedness as recently as June 2010 shows both progress and the need for significant improvements in the public and private sectors' preparedness and response capabilities during public health emergencies.

State and Local Public Health Emergency Preparedness Planning

Documented emergency preparedness plans that are current and cohesive and contain sufficient detail are critical for ensuring that States and localities are prepared for a public health emergency. The Department provides guidance to States and localities on the development of emergency preparedness plans. However, variations in State and local health department structures and the size of the populations they serve make it challenging to provide Federal guidance that is tailored to an individual jurisdiction's needs.

In its evaluation of the Nation's pandemic influenza preparedness, OIG found that most selected States and localities had begun emergency preparedness planning but had not addressed in planning documents most of the items in departmental guidance. States and localities also varied in the extent to which they exercised their emergency response plans and addressed lessons learned. OIG recommended that the Department (1) work with States to help localities improve preparedness and (2) ensure that States and localities consistently document their exercises and lessons learned. In response to these recommendations, the Office of the Assistant Secretary for Preparedness and

Response (ASPR) and CDC have developed guidance for States and localities that addresses the gaps found by OIG. ASPR implemented a new standardized reporting template to improve documentation of emergency preparedness exercises in health care systems and data collection. CDC now requires that grantees develop and submit mass vaccination after-action reports and improvement plans as a part of the Public Health Emergency Response grant application and the Public Health Emergency Preparedness cooperative agreement.

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

OIG is reviewing State and local preparedness for radiological and nuclear incidents. In its review, OIG will determine the extent to which selected States and localities are prepared to respond to the public health challenges of a radiological and nuclear incident and how they have used Department guidance in their preparedness efforts.

Federal and State Drug Storage and Laboratory Capability and Security

Early and accurate detection and reporting of biological and chemical agents are critical components of a national public health response. These threats include anthrax, influenza, nerve agents, and foodborne pathogens that cause outbreaks such as E. coli and salmonella. It is also important that the drugs used to treat these agents be available and effective during a public health emergency. However, OIG's findings reveal vulnerabilities in the Nation's preparedness to respond to potential biological and chemical threats.

For example, weaknesses exist in the Nation's laboratory system capability and security. CDC provides funds to States, in part, to improve public health laboratory preparedness. State public health laboratories rely on private clinical laboratories, which are not under the authority of the State, to perform diagnostic tests ordered by physicians. Yet in its review of laboratory capacity, OIG found that not all clinical laboratories have the ability to conduct initial screenings and refer suspicious specimens to a State laboratory, which could confirm the presence of public health threats. OIG

recommended that CDC continue to assist States in meeting the requirement to decrease the time needed to detect and report biological public health threats, and CDC concurred with that overall recommendation.

OIG reviewed Department and external laboratories to determine their compliance with the regulations governing select agents (i.e., pathogens or biological toxins that pose a severe threat to public health and safety) and found that some laboratories did not adequately safeguard the agents against theft or loss. In its recent audits at six departmental laboratories, OIG found problems with access controls, training, and/or recordkeeping, among other findings. These problems mirrored those found during earlier work at universities and public and private laboratories. Through its authority to impose CMPs against persons or entities who violate select agent regulations, including universities and nonpublic laboratories, OIG has collected over \$2 million for such violations as conducting unauthorized research with select agents, conducting unauthorized select agent transfers, failing to secure select agents against unauthorized access, and allowing unauthorized individuals access to select agents.

OIG also reviewed CDC's CHEMPACK project, which places nerve agent antidotes in monitored storage containers in multiple State locations for immediate use in the event of a nerve agent release. In its review, OIG determined the extent to which nerve agent antidotes were stored at the temperatures required by FDA. OIG also reviewed the extent to which CDC implemented procedures to ensure the quality of nerve agent antidotes and the extent to which antidotes appropriately received extended expiration dates under the Shelf Life Extension Program (SLEP). OIG found that CDC's policies for CHEMPACK drug storage did not meet FDA's temperature and quality requirements and that CDC did not monitor and store containers appropriately. Also, CDC allowed CHEMPACK drugs to inappropriately receive extended expiration dates under SLEP. OIG recommended that CDC revise its policies and procedures regarding CHEMPACK drug storage and SLEP to comply with FDA requirements. CDC concurred with all OIG's recommendations.

Lessons Learned From Real-Life Public Health Emergency Responses

It is important that the public and private sectors prepare for large-scale public health emergencies, and it is equally important that they effectively execute their plans in response to an emergency. Therefore, it is essential that Federal, State, and local entities identify vulnerabilities in, and determine the lessons learned from, responses to real-life public health emergencies.

For example, during the 2009 H1N1 influenza pandemic, OIG conducted onsite evaluations of selected localities' administration of H1N1 vaccine at School-Located Vaccination (SLV) sites. OIG found that SLV programs can be a viable strategy for vaccinating a large number of students in a short time. However, SLV programs require significant planning and resources, and selected localities had difficulty implementing SLV programs. OIG's report identified challenges and lessons learned and provided Federal, State, and local planning considerations for future SLV programs.

After the 2005 Gulf Coast hurricanes, OIG examined selected public health disaster responses to these events to highlight potential vulnerabilities and lessons learned. OIG reviewed the emergency plans of nursing homes in five Gulf Coast States and found that all had problems in implementing their emergency plans or with impromptu decisionmaking. OIG recommended that CMS consider strengthening Federal certification standards for nursing home emergency plans and encourage communication and collaboration between States and localities and nursing homes. CMS concurred with OIG's recommendations and issued Federal guidance and requirements as a result. OIG is conducting a followup evaluation that reexamines nursing home emergency preparedness and evacuation during recent hurricanes, wildfires, and floods. OIG will assess the use of the new tools that CMS developed and now requires as a result of the first OIG report. OIG will also describe the experiences of selected nursing homes, including challenges, successes, and lessons learned when they implemented their plans during natural disasters. (See Management Issue 7 for discussion of preparedness within nursing homes as it relates to quality of care.)

Overall, the Department has made progress in implementing some of OIG's recommendations for improvements to the Nation's preparedness for and response to public health emergencies. However, to mitigate the vulnerabilities noted in this management issue, the Department should continue to focus on providing additional guidance to States and localities to improve their public health emergency preparedness capability.

Management Issue 10: Grants and Contracts Management

MANAGEMENT CHALLENGE AND ASSESSMENT OF PROGRESS IN ADDRESSING THE CHALLENGE:

In FY 2009, the Department awarded over \$364 billion in grants, making it the largest grant-awarding Department in the Federal Government. Almost 71 percent of the money was for health care

coverage under Medicaid and CHIP. The remaining 29 percent funded health and social service programs administered by the Administration for Children & Families (ACF), the Health Resources and Services Administration, (HRSA) NIH, CDC, and other Department agencies. The *Recovery Act* provided \$27 billion for the temporary expansion of these health and social service programs for FYs 2009 and 2010.

The size and scope of the Department's grant expenditures make grants management a significant challenge for the Department. New legislative mandates, such as the *Recovery Act* and the *Affordable Care Act*, that increase the Department's portfolio of grants and oversight responsibilities exacerbate this challenge. For instance, the *Affordable Care Act* establishes an \$11 billion Community Health Center Fund to be administered through the Department. (See also Management Issue 11 for a discussion of broader departmental challenges related to the oversight and implementation of the *Recovery Act* and OIG reviews specifically focused on grants management issues related to *Recovery Act* funding. Broad challenges related to implementation of the *Affordable Care Act* are discussed in Management Issue 1. Challenges related to the Medicaid and CHIP programs are discussed in Management Issues 2 through 7.)

Adding to this challenge is that the primary responsibility for performance and management of a grant rests with the grantee, with limited Federal involvement in the funded activity. However, the grant-awarding agency retains oversight responsibility for ensuring that funds are awarded and used appropriately and that grantees comply with grant requirements. Recent statutory changes, most notably through the *Recovery Act*, have increased Federal agencies' responsibilities for grantee oversight. OIG's work in reviewing grant programs administered by ACF, CDC, HRSA, and NIH has highlighted grants management vulnerabilities and opportunities for improvements in the Department's oversight of grant funds and grantee compliance.

In addition to awarding grants, the Department awarded over \$20 billion in contracts in FY 2009. The top five products or services purchased with these contracts were drugs and biologics, professional services, information technology and telecommunications, operations of Government facilities, and research. The scope and size of these contracts are significant and pose a challenge to effective oversight. OIG's work in reviewing the award and management of contracts at NIH and

CDC found problems with compliance with appropriations and acquisition laws and regulations.

Grant Oversight

OIG has identified risks related to grantee noncompliance in departmental grants programs at ACF and NIH. Funding from both the *Recovery Act* and the *Affordable Care Act* for community health centers increases the challenge HRSA faces in ensuring that Federal grant awards to health centers are used in accordance with Federal regulations. OIG performed a series of audits to assess the financial capability of community health centers receiving *Recovery Act* funds to account for and manage Federal funds. The assessments identified problems with inventory, cash management, and financial systems controls. In response, HRSA has increased its efforts in monitoring, assisting grantees, and ensuring program integrity.

OIG performed a series of reviews in one State to determine whether the State agency claimed foster care costs to ACF in accordance with Federal regulations. Title IV-E of the *Social Security Act*, as amended, authorizes Federal funds for States to provide foster care for children under an approved State plan. For children who meet Title IV-E Foster Care requirements, Federal funds are available to States for maintenance, administrative, and training costs. HHS must ensure that costs claimed by a State are in accordance with Federal regulations. In 2008, OIG found that one State agency claimed costs for children in unlicensed facilities and for ineligible services. As of November 2010, ACF had not responded to more than \$56 million in questioned costs in this report. In a 2009 review of the same State, OIG found that the State agency inappropriately claimed costs of over \$1.6 million for children after they turned 19.

In another example, OIG found that although NIH's National Cancer Institute had implemented processes to ensure the completeness and accuracy of grantees' progress reports, 41 percent of progress reports were received late. OIG also identified deficiencies in NIH's financial oversight of grants, including delays in closing out some grants. NIH agreed with OIG's recommendations to initiate earlier and more frequent followup with grantees to obtain required documents and to improve its grants monitoring, including conducting a pilot study to verify grantees' self-reported fund balances by contacting external sources. OIG is evaluating the NIH National Center for Research Resources' management of the Clinical and Translational Science Awards, which are expected to award 60 grantees with annual funding of \$500 million by 2012.

Without proper controls to ensure the appropriate use of Federal funds and to oversee grantees, the Department's grant programs are at risk of fraud, waste, abuse, and ineffectiveness. Expansions in the number and size of grants awarded by the Department magnify grant oversight vulnerabilities facing the programs. OIG will continue to monitor grants management challenges and recommend improvements to the Department's grants oversight, as warranted.

Contract Oversight

OIG conducted a series of contracting audits at NIH and CDC, which found that both improperly funded contracts. CDC administered one contract improperly. An HHS "Tiger Team" initially identified Departmentwide concerns about potential improper contracting, including at NIH. A key concern was the improper partial funding of long-term high-dollar-value research contracts. Federal appropriations statutes require that agency fiscal year funds may be obligated or used only for legitimate needs (including through contracts) of that fiscal year; fiscal year funds cannot generally be used for agency needs of prior or future years. Failure to comply with this statute may result in agencies' not being able to fund or pay outstanding contracts.

OIG is reviewing 21 NIH contracts identified by the Tiger Team to determine whether the contracts were awarded in compliance with Federal appropriations laws. While some of these audits are still in process, OIG's work thus far indicates that at least some of the contracts were improperly funded.

OIG also performed a series of contract audits at CDC. One contract was improperly administered as a personal services contract. In this same contract, CDC was using fiscal year funds after their periods of availability. OIG recommended that CDC determine whether these contract actions violated the *Anti-Deficiency Act* and take action to correct such violations. OIG plans to continue its contract audit work at CDC, NIH, and throughout the Department.

NIH and CDC stated that they have taken action to correct problems identified in the audit reports. NIH and CDC provided appropriations law training to their acquisition workforce. HHS is developing a training course that specifically addresses the issues identified in the OIG audits. CDC stated that they reviewed all FY 2010 contracts for adherence to contract funding regulations.

HHS acknowledged the appropriations-related acquisition challenges identified by OIG and has informed OIG that it is taking the necessary steps to address those challenges. The Department noted that while achieving full compliance with

appropriation law will involve adjustments to its budgetary, program planning, financial, and contracting processes, it is confident that its business process improvement effort will succeed.

PART IV: CROSS-CUTTING ISSUES

OIG has identified three more Departmentwide issues as top management challenges: assessing whether the Department is using *Recovery Act* funds in accordance with legal and administrative requirements and is meeting the accountability objectives defined by the Office of Management and Budget (OMB); developing and maintaining adequate internal controls over its information systems to protect the security and privacy of health data; and effectively overseeing its ethics program.

Management Issue 11: American Recovery and Reinvestment Act Accountability and Transparency

MANAGEMENT CHALLENGE AND ASSESSMENT OF PROGRESS IN ADDRESSING THE CHALLENGE:

As the nation faced what is generally reported to be the most serious economic crisis since the Great Depression, the *Recovery Act* was enacted in 2009 to promote economic recovery and minimize the impact of the recession. The Congressional Budget Office (CBO) originally projected that the *Recovery Act's* combined spending and tax provisions would cost \$787 billion over 10 years, including more than \$499 billion in additional Federal spending and \$288 billion in tax relief. The objectives of the *Recovery Act* include preserving and creating jobs, assisting those most affected by the recession; increasing economic efficiency by investing in technological advances in science and health; investing in transportation, environmental protection, and other infrastructure that will provide long-term economic benefits; and stabilizing State and local budgets.

The *Recovery Act* provides \$141.4 billion to the Department to provide additional Federal assistance for health care, public health and human services programs, and to invest in research and health information technology (health IT), as estimated in the 2011 President's Budget. This amount includes \$4.3 billion in the form of reduced contributions for prescription drug costs for additional fiscal relief to the States in addition to the funding in direct provisions from the *Recovery Act*. The magnitude of expenditures and the potential impact of this funding on the economy, Federal and State budgets, program beneficiaries, and taxpayers make it critical that *Recovery Act* funds be used efficiently and effectively and be protected from fraud, waste, and abuse.

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

- **Medicaid** – improving and preserving health care by providing an estimated \$84.5 billion temporary increase in the FMAP.
- **Health IT** – accelerating the adoption of health IT by (1) providing the Office of the National Coordinator with \$2 billion for Health Information Technology to coordinate Federal health IT policy and programs and foster the electronic use and exchange of health information, and (2) by providing CMS with an estimated \$25 billion to make incentive payments to encourage physicians and hospitals to adopt “meaningful use” of certified electronic health records starting in 2011. (“Meaningful use” of health IT is the standard established in the *Recovery Act*, and defined by CMS, that must be met for a hospital or eligible professional to receive incentive payments.)
- **Children and Families** – improving services to children and communities by providing ACF with more than \$13.2 billion to temporarily expand the Temporary Assistance for Needy Families Program (TANF), Child Support Enforcement, Foster Care FMAP, Head Start and Early Head Start, Child Care Development, and community services programs.
- **Research** – strengthening scientific research and facilities by providing \$10.4 billion to NIH.
- **Health Care** – strengthening community health care services by providing HRSA with \$2.5 billion to renovate and construct new centers, to expand health care services, and to train health care professionals.

Most of the Department's *Recovery Act* funds are increases in Federal funding for existing programs. OIG has conducted extensive work and identified management challenges specific to these programs. (Challenges related to Medicaid are discussed in Management Issues 2 through 7. Challenges related to programs and grants administered by ACF, CDC, NIH, and HRSA are discussed in detail in Management Issue 10. Finally, challenges related to health IT are discussed in Management Issue 12.)

Implementation and oversight to ensure accountability and transparency of *Recovery Act* funding present significant challenges. *Recovery Act* funds are to be awarded and distributed within short timeframes to stimulate economic growth and minimize the impact of the recession. Expediting

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

The *Recovery Act* also established new reporting requirements for the awarding and use of funds to promote transparency and accountability. Challenges associated with the new reporting requirements include developing systems and infrastructure for collecting and reporting the required information, educating recipients about the reporting requirements, validating the reported information, and using the collected information effectively to monitor and oversee *Recovery Act* programs and performance. The new reporting requirements for *Recovery Act* funds are in addition to reporting requirements that some grantees must also provide for similar activities funded outside the *Recovery Act*; this can create multiple and inconsistent reporting rules.

Overseeing and protecting the integrity of *Recovery Act* funds requires coordination among agencies within the Department and with States and other entities. The Department has established the Office of Recovery Act Coordination, headed by the Deputy Assistant Secretary for Recovery Act Coordination. Department agencies administering programs and activities funded by the *Recovery Act* are responsible for ensuring the appropriate awarding, distribution, use, and reporting of *Recovery Act* funds. OIG is charged with overseeing the Department's execution of these responsibilities and with preventing and detecting fraud, waste, and abuse. The *Recovery Act* also established the Recovery Accountability and Transparency Board (RATB), consisting of 12 Inspectors General, including the HHS Inspector General, to coordinate and conduct oversight of *Recovery Act* funds; prevent fraud, waste, and abuse; and promote accountability and transparency.

State agencies also have roles in overseeing *Recovery Act* funds, particularly those that increase Federal contributions to State-administered programs, such as Medicaid, TANF, and Community Services programs. Some States have raised concerns about having adequate funds for the administrative costs associated with meeting *Recovery Act* oversight and reporting requirements.

At the request of RATB, OIG completed a series of reviews to assess the Department's process, oversight, and effectiveness in performing data-quality reviews of information reported by recipients

of *Recovery Act* funds. OIG found that the Department has designed an adequate process for performing limited data-quality reviews that identify material omissions and significant errors in recipient-reported *Recovery Act* information. In another RATB-requested review, OIG reviewed the staffing, training, and qualifications of Department personnel responsible for overseeing *Recovery Act* funds; the overall results of the review based on our findings and those reported by other OIGs concluded that staffing qualifications at the largest Federal agencies, including HHS, were inadequate.

In addition, a series of OIG risk assessments was conducted that covered \$72.7 billion of the \$76.4 billion allocated to health IT and non-Medicaid programs to determine which *Recovery Act* programs to review. As a result, OIG performed 127 reviews of grant applicants and new or existing grantees to determine whether the entities were financially viable and had financial management systems in place to adequately manage and account for the additional *Recovery Act* funds in accordance with Federal regulations. Consequently, OIG identified entities that were not capable of handling *Recovery Act* grant funds or required increased HHS oversight and guidance. For example, OIG conducted limited-scope audits on 83 Early Head Start applicants for grant funds and based on those audits, ACF decided not to award 15 applicants \$31 million in *Recovery Act* funds. In addition, 60 Early Head Start applicants received funds with increased HHS oversight.

The *Recovery Act* provided an additional \$2.1 billion for the Head Start and Early Head Start programs during FYs 2009 and 2010. OIG has identified risks related to grantee compliance with health and safety requirements at Head Start facilities. OIG initiated a series of reviews to determine whether grantees could provide a safe environment for children. In the multiple reviews performed, OIG found instances of noncompliance with regulations that jeopardized the health and safety of children. OIG has made recommendations to the grantees to address the deficiencies.

As for *Recovery Act* oversight of Medicaid programs, OIG conducted two reviews to determine whether the Department and CMS had correctly calculated the temporary increase in the FMAP awarded under the *Recovery Act*, in accordance with the applicable provisions. OIG also conducted 17 reviews of various States and determined that States were generally in compliance with the requirements for Medicaid funding under Section 5001 of the *Recovery Act*.

OIG has also increased investigative efforts related to programs affected by the *Recovery Act*. A

screening process has been developed to identify applicants for *Recovery Act* funds that are under investigation by OIG. OIG has developed and implemented processes for addressing allegations related to the fraudulent use of *Recovery Act* funds and allegations of retaliation against whistleblowers who disclosed instances of the improper use of *Recovery Act* funds. OIG has also provided training to OIG agents on the *Recovery Act* and its whistleblower protection provisions.

The *Recovery Act* provides explicit protections for certain individuals who make specified disclosures relating to these funds. OIG receives allegations of fraud, waste, and mismanagement of *Recovery Act* funds from various sources, including the RATB and OIG hotline. OIG has received 50 complaints alleging inappropriate use of *Recovery Act* funds. These complaints have resulted in several investigations and some cases have entered the judicial process. To date, OIG has received one whistleblower-retaliation complaint related to HHS *Recovery Act* funds.

In addition to steps taken to oversee and protect the integrity of *Recovery Act* funds, examples of OIG's efforts include reviewing *Recovery Act* grantees' compliance with the recipient reporting requirements under section 1512 of the *Recovery Act*; reviewing agencies' progress toward implementing *Recovery Act* incentive payments for electronic health records and other funded health IT initiatives; reviewing CMS policies and procedures for protecting against IT breaches and medical identity theft involving Medicare identification numbers and determining whether responses to any breaches complied with notification requirements; reconciling the CMS-64, the standard form States use to claim FMAP, to claims-level data and identifying high-risk areas and providers for increased audit scrutiny; and performing audits of *Recovery Act* spending for recipients receiving HHS *Recovery Act* funding to ensure that awards are being used for authorized purposes and program goals are achieved.

OIG and the Department will continue to work to ensure that the Department meets its *Recovery Act* responsibilities. The Department continues to face challenges to ensuring the accountability and transparency of *Recovery Act* funds and ensuring that the funds are used for designated purposes and for the benefit of the beneficiaries served under the programs receiving enhanced resources. Continuing activities include minimizing risk; assessing controls for preventing fraud, waste, and abuse; and ensuring program goals are achieved and *Recovery Act* funds are accurately tracked and reported. The Department's and OIG's efforts in

overseeing the awarding and effective use of funds will have long-term benefits for Department programs beyond the expenditure of *Recovery Act* funding.

Management Issue 12: Health Information Technology and Integrity of Information Systems

MANAGEMENT CHALLENGE AND ASSESSMENT OF PROGRESS IN ADDRESSING THE CHALLENGE:

The *Health Information Technology for Economic and Clinical Health Act (HITECH Act)* established the Office of the National Coordinator for Health Information Technology (ONC) within the Department and tasked it with leading the development of an interoperable national health information network that allows for the electronic exchange of health information while, among other things, protecting the security and privacy of health data. OIG has divided health IT management challenges into two categories: (1) ensuring the integrity of information systems through which health information is transmitted and stored to prevent fraud, waste, and abuse and (2) ensuring the integrity of the Department's programs to promote health IT. Protecting sensitive health data is a challenge because a patchwork of authorities establishes, and agencies oversee, such data.

Within the Department, CMS, ONC, and the Office for Civil Rights (OCR) are responsible for ensuring the privacy and security of health information. One challenge is coordinating among HHS agencies to ensure the privacy and security of health information by enforcing standards and monitoring security controls for health IT at the provider level. Ineffective or inadequate management processes, controls, or IT security put data and systems at risk. With the enactment of the *HITECH Act*, HHS initiatives promoting the use of health IT include:

- The adoption of interoperability standards by the Secretary;
- Payment of Medicare and Medicaid incentives for providers engaged in the "meaningful use" of health IT;
- HRSA grants for the acquisition of health IT;
- ONC programs to facilitate the adoption of health IT through extension center programs; and
- State grants for health information exchange and development of a health IT workforce.

As electronic medical records become more prevalent and the exchange of personal health data

over expanding networks becomes more pervasive – and as Federal and State health and human services programs implement the requirement in section 1561 of the *Affordable Care Act* to facilitate electronic enrollment of beneficiaries - we identify the risk for a rise in medical identity theft. The Department must quickly identify and address vulnerabilities in each of its health IT initiatives. It is also imperative that *Recovery Act* funds to support the widespread adoption of health IT be used efficiently and effectively. The Department's challenge is to balance the need to meet its health IT development goals with its obligation to oversee the expenditure of *Recovery Act* funds; an estimated \$30 billion over the next several years in pursuit of health IT objectives. Comprehensive guidance to all health care providers is needed to ensure robust IT security that supports health information systems and the underlying network infrastructures to protect health information as it is created, transmitted, and stored.

Integrity of Information Systems

The Department administers its programs through a mix of grants, contracts, and cooperative agreements and as a payer of health benefits through Medicare, Medicaid, CHIP, and IHS. To accomplish its mission, the Department relies on a network environment that includes Federal agencies, State and local governments, grantees and contractors, health care providers, and colleges and universities. A significant challenge for the Department is to establish an information security program that protects critical infrastructure and assets and creates, monitors, and maintains an enterprisewide baseline of core security requirements.

OIG has monitored the ability to meet this challenge by determining whether the Department's information system security controls are adequate. OIG has also examined departmental oversight of health care providers' compliance with the *Health Insurance Portability and Accountability Act (HIPAA) Security Rule* (the applicability of which the *HITECH Act* has expanded and enforcement of which has been transferred from CMS to OCR).

OIG has performed dozens of independent audits of departmental agencies, as well as audits of State and local governments, contractors, and hospitals. The audits have identified vulnerabilities in the areas of:

- Network access and management;
- Security program infrastructure, which includes security program documentation, contingency plan documentation, accuracy

of system inventory, and acknowledgment of management responsibilities;

- Security training;
- Personnel security, such as background checks and user account management;
- Contractor oversight; and
- Integration of security into major applications, which includes certification and accreditation, contingency plan testing, privacy impact statements, and annual self-assessments.

With the push for increased adoption of health IT, there is heightened public concern about the security of personal health information. Accordingly, OIG has increasingly focused on combating medical identity theft. OIG investigations have uncovered a growing number of fraud schemes involving stolen provider and beneficiary identification numbers. In response, OIG issued a consumer education brochure that provides tips and resources to help beneficiaries protect themselves and Medicare from medical identity theft and fraud. OIG is also reviewing CMS's policies and procedures regarding information security breaches and medical identity theft involving Medicare identification numbers. OIG will continue its work in this area and make recommendations to the Department, as appropriate, about safeguards for personally identifiable information.

Integrity of Health Information Technology Programs

Like all grants and contracts, Federal health IT initiatives are susceptible to fraud, noncompliance, and inefficiency. Even before the enactment of the *HITECH Act*, OIG monitored Federal health IT initiatives. In 2009, OIG assessed Medicare Part D plan sponsors' implementation of CMS-mandated e-prescribing standards. OIG found that most sponsors had implemented some of the standards but that few had implemented all of them. Another study in 2008 examined the State Medicaid agencies' health IT initiatives. OIG recommended that States work with other Federal agencies and offices in developing policies to protect patient privacy and data security and coordinate State Medicaid initiatives with Federal health IT activities to ensure consistency with national goals.

OIG has developed a work plan to ensure that the estimated \$49 billion in incentive payments and health IT program funds are used in ways consistent with the requirements in the *HITECH Act* and the Department's implementing regulations and policies. (See Management Issue 11 for further

discussion of challenges associated with the *Recovery Act*.)

Looking forward, OIG is considering ways in which the design and function of electronic health records and health IT systems can help prevent and detect fraud, waste, and abuse and ways in which these tools can be misused to facilitate fraud, waste, and abuse and impede their detection.

Management Issue 13: Ethics Program Oversight and Enforcement

MANAGEMENT CHALLENGE AND ASSESSMENT OF PROGRESS IN ADDRESSING THE CHALLENGE:

During the past year, conflicts of interest in the health care system generally, and specifically in the Department, have been the subject of scrutiny, raising the issue of which stakeholders should be responsible for monitoring and managing conflicts of interest: individuals, government, or institutions.

Government Ethics Programs and Conflicts of Interest of Department Employees

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

Monitoring for conflicts of interest continues to be a challenge for the Department. In December 2009, OIG determined the extent to which CDC and its Special Government Employees (SGE) on Federal Advisory Committees complied with ethics requirements. SGEs on Federal Advisory Committees provide expert advice to the Federal Government on important public health topics, such as breast and cervical cancer, immunization, smoking, tuberculosis, and clinical laboratory improvement. SGEs are temporary Federal employees who are typically involved in work outside the Government in the same areas as their committees' work. SGEs must comply with essentially the same OGE financial disclosure and conflict-of-interest regulations issued by OGE as Federal employees while performing their temporary work. OIG determined that CDC did not require SGEs to disclose their interests completely before participating in meetings, and CDC did not identify or resolve all SGE potential conflicts of interest, even when adequate information identifying a conflict was provided. CDC concurred with all seven of OIG's recommendations. Since the

OIG report was issued, CDC has worked with the General Services Administration and the OGC Ethics Division to provide specialized training for all staff with advisory committee responsibilities to address conflict-of-interest issues identified by OIG.

OIG is reviewing HHS waivers and analyzing the extent to which the waivers are being created and used across the Department. Most HHS waivers are limited in nature and contain certain recusal requirements. OIG is examining the HHS waiver process to ensure that recusals within waivers are clear to the employees receiving the waivers and to ensure that higher level managers inform employees not to engage in matters from which they are recused. Another challenge for the Department is monitoring for conflicts of interest in a workforce that has become increasingly reliant on contract workers. For example, a recent audit of a CDC service contract found CDC managers "maintained relatively continuous supervision and control of contractor personnel who worked onsite at CDC," effectively treating these contractors as if they were operating under personal services contracts, which is a prohibited practice. (See also Management Issue 10, for further discussion of this issue as it relates to service contracts.)

In a July 2009 memorandum, the OMB director recognized the formidable task agencies face in appropriately and effectively managing a multi-sector workforce of both Federal employees and contractors to deliver important services. Since December 2007, OIG has maintained hotline posters on its Web site for use by departmental contractors and their employees to encourage reporting fraud to OIG. The OGE is releasing guidance on conflict-of-interest considerations of contractor employees in the workplace and OIG is developing internal training to prepare supervisors to address emerging issues involving contractors.

OIG continues to consult with the Department about the number and quality of conflict-of-interest referrals from divisions in the Department. Since OIG created a form for referrals of conflict-of-interest cases, OIG has seen a significant improvement in the quality of information received on such cases, resulting in reduced evaluation time. OIG's relations with the Office of General Counsel (OGC) Ethics Division, as well as regular interactions by OIG staff with the operating and staff divisions, continue to yield positive results. Departmental management appears to have a greater understanding of what constitutes potential ethics and conflict-of-interest violations as evidenced by an increase in reporting potential violations, in the quality of the referrals, and in the number of contacts by departmental officials

seeking input and guidance on conflict-of-interest matters.

OIG's enforcement efforts are often measured in convictions. In 2009, an employee of the National Library of Medicine at NIH failed to receive required prior approval for outside activities and to report income from them. The employee admitted receiving as much as \$500,000 in unauthorized income after testifying as an expert witness on toxicology issues in legal proceedings. As a result, he was sentenced to 1 year of probation and 160 hours of community service and was ordered to pay a \$200,000 fine.

As important as convictions are for redressing serious violations, it is more important to prevent employees from violating criminal conflict-of-interest statutes and to protect the integrity of departmental programs. In 2010, in cooperation with the OGC Ethics Division, OIG examined allegations of conflict of interest involving high-level Department officials and determined that no conflict-of-interest violations had occurred. OIG confirmed that the OGC Ethics Division's efforts to work with HHS employees, focusing on incoming high-level officials to reduce and prevent conflict-of-interest violations from occurring, were successful. New employees were encouraged to seek counsel to get advice, and avoid actions that could violate criminal conflict-of-interest statutes.

Oversight of Department Grantee, Researcher and Contractor Conflicts of Interest

In addition to departmental employees and contractors, Federal grantees and non-Federal researchers play important roles in departmental programs, and their conflicts of interest could also bias these programs and ultimately affect the public's health and safety. Eighty percent of NIH research funding goes to extramural grantees, primarily to research universities that undertake grant and contract work. Conflicts of interest among extramural grantees could compromise the integrity of the research that the Department funds. Therefore, in addition to performing work focused on departmental employees, OIG also examined potential conflicts of interest of Federal grantees and non-Federal researchers.

In 2008, OIG identified vulnerabilities associated with NIH's monitoring of conflict-of-interest reports submitted by external grantees for FYs 2004 through 2006. OIG found that NIH's Institutes and the Office of Extramural Research (OER) were unable to provide all the conflict-of-interest reports they received from grantee institutions and did not follow up with grantee institutions about reported conflicts of interest. OIG recommended that NIH

increase oversight of grantee institutions and require them to provide details about the nature of financial conflicts of interest and the ways in which they are managed, reduced, or eliminated and ensure that OER's conflict-of-interest database contains information on all conflict-of-interest reports provided by grantee institutions. In July 2009, NIH began requiring that all financial conflict-of-interest reports from grantees be submitted electronically to NIH's system, using a uniform format.

In its followup work, OIG examined the nature of financial conflicts of interest reported by grantee institutions to NIH and the ways in which grantee institutions managed, reduced, or eliminated these conflicts. OIG identified vulnerabilities, including grantee institutions' reliance on researchers' discretion in reporting conflicts, failure to require researchers to report amounts of compensation in financial disclosures, and failure to routinely verify information submitted by researchers. OIG continues to recommend that NIH ask grantee institutions to provide it with details on the nature of all reported financial conflicts of interest and ways in which they are managed, reduced, or eliminated. OIG also recommended that NIH (1) require grantee institutions to collect all information on significant financial interests held by researchers, (2) require grantee institutions to collect from researchers information on specific amounts of equity and compensation, (3) increase oversight of grantee institutions to ensure that financial conflicts of interest are reported and managed appropriately, and (4) develop regulations that address institutional financial conflicts of interest. OIG is undertaking a review to determine what policies and procedures NIH grantee institutions have in place to address researchers' conflicts of interest.

In response to concerns about these vulnerabilities, NIH sought input from the public and from the research community on modifying Federal regulations by publishing an Advance Notice of Proposed Rulemaking (NPRM) on Promoting Objectivity in Research in May 2009. NIH invited public comments on all aspects of potential regulation in this area, particularly on the following issues: (1) expanding the scope of the regulation and the disclosure of conflicts of interest, (2) the definition of "significant financial interest," (3) identification and management of conflicts by grantee institutions, (4) assuring grantee institution compliance, (5) requiring grantee institutions to

provide additional information to NIH, and (6) broadening the regulations to address institutional conflicts of interest. The NPRM was published in May 2010 and the comment period closed on August 19, 2010. The NPRM also proposed regulations for revising conflict-of-interest policies for contractors in 45 CFR Part 94.

OIG has also identified departmental conflict-of-interest vulnerabilities affecting other agencies. In 2009, OIG reported on vulnerabilities in FDA oversight of clinical investigators' financial interests. Clinical investigators lead clinical trials, recruit subjects, supervise trials, and analyze and report clinical trial results that are submitted to FDA in new drug applications. OIG identified vulnerabilities in the disclosure process and in FDA's review of the disclosed financial interests. OIG recommended that FDA ensure that new drug sponsors submit complete financial information for all clinical investigators and that FDA consistently review and take action in response to disclosed financial interests. OIG also recommended that sponsors submit financial information for their clinical investigators earlier in the process. In its response to the report, FDA agreed with most of our recommendations. FDA is currently in the process of revising its *Guidance for Industry: Financial Disclosure by Clinical Investigators*. It also updated its *Compliance Program Guidance Manual* chapter on Clinical Investigator Inspections to ensure that clinical investigators submit required financial information to sponsors.

Recent decisions by the Government Accountability Office (GAO) have highlighted the issue of organizational conflicts of interest of Government contractors. GAO sustained two bid protests under the CMS ZPIC program, agreeing that CMS had failed to reasonably consider the awardee's plan to mitigate its impaired objectivity. OIG is also evaluating how CMS oversees potential ZPIC organizational conflicts of interest. In addition, OIG is evaluating the oversight of potential conflicts of interest within the pharmacy and therapeutics committees within Part D plans.

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

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



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Washington, D.C. 20201

November 15, 2010

To: Daniel R. Levinson, Inspector General

From:  Ellen G. Murray, Assistant Secretary for Financial Resources and Chief Financial Officer

Subject: FY 2010 Top Management and Performance Challenges Identified by the Office of the Inspector General

This memorandum is in response to OIG's *FY 2010 Top Management and Performance Challenges*, which summarized the top management and performance challenges that the Department has faced over recent years.

We concur with OIG's findings concerning the HHS top management and performance challenges. In response to OIG's report, we are providing the attached table which includes a brief summary of the top management challenges, management's response, and future plans to address these challenges during FY 2011.

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

FY 2010 Top Management and Performance Challenges Summary

Part I: Health Care Reform

Management Challenge Identified by the OIG	OIG Progress Assessment	Management Response	Future Plans to Address the Challenge
1. Incorporating Integrity into Health Care Reform Implementation	HHS is working to successfully implement the numerous provisions of the <i>Affordable Care Act</i> . This will continue to require clear and effective communication with program beneficiaries, private citizens, and health care industry leaders. The Department will need to identify key vulnerabilities and prioritize oversight resources to address the new risks posed by the changing dynamics of evolving Federal health care programs. Effective collaboration is necessary to monitor progress in meeting implementation goals, while building infrastructure to support implementation of the <i>Affordable Care Act</i> .	HHS is building infrastructure to address the challenges posed by the implementation of the <i>Affordable Care Act</i> , and engaged a staff to maintain a database with a dashboard feature to track implementation. In addition, the Department created the Office of Consumer Information and Insurance Oversight (OCIIO) to focus on private insurance issues. Also, the Centers for Medicare and Medicaid (CMS) created the new Center of Medicare and Medicaid Innovation to focus on innovative delivery models and the Center for Program Integrity to strengthen its oversight of the Medicare and Medicaid programs.	The OIG and the Department will work together to ensure we meet our <i>Affordable Care Act</i> responsibilities. In addition, we will continue to work with our partners to respond to vulnerabilities in current Federal health care programs. We will strive to work with the OIG and identify new risks posed by the changing dynamics of Federal health care programs and the evolving nature of fraud.

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

Management Challenge Identified by the OIG	OIG Progress Assessment	Management Response	Future Plans to Address the Challenge
2. Integrity of Provider and Supplier Enrollment	CMS has made continued progress in responding to enrollment vulnerabilities, including implementing some measures aimed at enhancing enrollment standards for durable medical equipment suppliers. The <i>Affordable Care Act</i> contains several provisions, including subjecting new providers and suppliers to enhanced oversight, such as prepayment review for 30 days to 1 year after enrollment, aimed at reducing vulnerabilities in provider and supplier enrollment.	We agree with the OIG and have made significant progress responding to vulnerabilities to strengthen the integrity of the Medicare program. CMS has taken steps to tighten the provider enrollment process, provide more oversight and monitoring once a provider/supplier enrolls in the program, and strengthen the provider revocation process. These steps include claims specialty editing to ensure suppliers are only paid for items they are properly licensed to provide, and increasing the number of random site visits.	CMS will continue to clarify and expand on existing enrollment requirements that durable medical equipment, orthotics, prosthetics, and supplies (DMEPOS) suppliers must meet to establish and maintain billing privileges in the Medicare program. CMS will also look at future ways to improve the Medicare enrollment process, including enhanced monitoring of a provider or supplier once it has entered the program.

Part II: Integrity of Medicare, Medicaid, Children’s Health Insurance Program (Continued)

Management Challenge Identified by the OIG	OIG Progress Assessment	Management Response	Future Plans to Address the Challenge
<p>3. Integrity of Federal Health Care Program Payment Methodologies</p>	<p>CMS continues efforts to ensure payments are based on accurate data, responds to changes in the marketplace and medical practice, and limit the risk of fraud. While many of the payment issues identified by the OIG have not been resolved, the Department faces the challenge of developing new payment models under <i>the Affordable Care Act</i>, to bring balance between protecting the integrity of health care programs and fostering innovation that increases quality, efficiency, and cost effectiveness.</p>	<p>CMS continues making progress to aggressively identify those payment methodologies that create fraudulent incentives in Medicare and Medicaid, as well as address vulnerabilities, which includes steps to address widespread abuse of outlier payments to Medicare-certified Home Health Agencies (HHAs).</p>	<p>The Department is reacting to ongoing changes in the marketplace and medical practices. In this regard, CMS is escalating its recent efforts to review and adjust the relative values upon which payments for physicians’ services rely to reflect contemporary medical practice.</p>
<p>4. Promoting Compliance With Federal Health Care Program Requirements</p>	<p>CMS program and contract efforts, such as the Medicaid Integrity Program, provide education for health care providers and suppliers, managed care entities, and beneficiaries to promote payment integrity and quality of care. The Department faces the challenge of implementing a comprehensive safeguard strategy for Medicare and Medicaid as new mandates in the <i>Affordable Care Act</i> expand and redefine roles for compliance programs.</p>	<p>CMS recognizes the importance of clear guidance and the need for broad access to that guidance. Because of the diversity of Medicare providers, CMS has an extensive inventory of Medicare Learning Network educational products. Efforts are ongoing to continually evaluate provider outreach, education, and inquiry support.</p>	<p>CMS will continue its efforts to create a robust education, training, and outreach campaign, which is designed to improve the plan sponsor’s compliance with Medicare program requirement. Recognizing the importance of program integrity, CMS will devote additional resources to the Medicare Drug Integrity Contractors (MEDICs) to address new complexities, including routine compliance and enforcement tracking.</p>
<p>5. Oversight and Monitoring of Federal Health Care Programs</p>	<p>CMS is making progress in developing oversight tools and monitoring of Federal Health Programs. The <i>Affordable Care Act</i> will challenge the Department by requiring CMS to expand its Integrated Data Repository to include claims from Medicaid and other Federal entities, including the Social Security Administration.</p>	<p>CMS continues to strive and eliminate improper payments in the Medicare program to maintain the Medicare trust funds and protect beneficiaries. CMS altered the Comprehensive Error Rate Testing (CERT) program and called for a more strict enforcement of its policies.</p>	<p>CMS understands the importance of having complete and timely data for use in oversight and monitoring of its programs. CMS remains committed to leveraging innovative technology and techniques to better identify excessive payments early.</p>

Part II: Integrity of Medicare, Medicaid, Children’s Health Insurance Program (Continued)

Management Challenge Identified by the OIG	OIG Progress Assessment	Management Response	Future Plans to Address the Challenge
<p>6. Respond to Fraud and Vulnerabilities in Federal Health Care Programs</p>	<p>Progress continues in the Department’s efforts to respond to fraud through law enforcement (through OIG, in partnership with the Department of Justice) and by addressing program vulnerabilities (through CMS). Under the <i>Affordable Care Act</i>, the Department is further challenged with its efforts to work and reduce improper Medicare and Medicaid payments resulting from fraud, waste, and abuse across all service areas.</p>	<p>CMS agrees that responding to fraud and program vulnerabilities requires a high degree of coordination and collaboration between multiple Federal and State agencies. CMS agrees that access to real-time information across all areas is critical towards meeting the challenges and demands of its programs. A proven industry best practice, Master Data Management (MDM), will be put in place at CMS to focus on eliminating redundancy, inconsistency, and fragmentation of information.</p>	<p>CMS will continue to work with its partners to respond to health care waste, fraud, and abuse. CMS will also strive to implement additional tools to provide access to real-time information, which is critical to the Department’s data analytical environment.</p>
<p>7. Quality of Care</p>	<p>HHS continues making progress in ensuring that providers comply with quality standards, developing initiative to protect beneficiaries from abuse or neglect, and implementing payment incentives linked to quality. The Department is challenged by the <i>Affordable Care Act</i> to provide enhanced quality of care in the health care delivery system.</p>	<p>CMS continues to improve its oversight of accrediting organizations (AOs) through increased use of validation surveys and analysis of AO data. AHRQ has made considerable progress expanding its influence on health care provider practices to improve health care quality and patient safety. It collaborated within HHS to develop <i>Common Formats</i> for reporting patient safety events to Patient Safety Organizations.</p>	<p>The Department will continue to implement programs, and work with providers to enhance the quality of care in the health care delivery system.</p>

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

Management Challenge Identified by the OIG	OIG Progress Assessment	Management Response	Future Plans to Address the Challenge
8. Oversight of Food, Drugs, and Medical Devices	FDA continues making progress in ensuring the timely approval and oversight of drugs and medical devices. The Department; however, faces challenges with respect to increasingly globalized markets and new legislative mandates increasing oversight responsibilities, such as new authority to regulate tobacco product.	FDA remains committed to the work of the Food Safety Working Group, and it focus on a new public health-focused approach to food safety, which includes prioritizing prevention. FDA expanded the availability of high-quality generic drug products and provided consumers and health care providers with information on both safety and effectiveness.	FDA will continue to collaborate with sponsors and contract research organizations as part of its on-going improvement of the generic drug process. It will also strive to expand its training of employees in foreign posts as part of its multifaceted and collaborative approach to the oversight of clinical trials..
9. Emergency Preparedness and Response	The Department continues working with State and local health officials to make progress in preparing for and responding to public health emergencies, and in the development of emergency preparedness and detention plans for pandemic influenza, bioterrorist attacks, and natural disasters.	HHS continues its work with experts to develop guidance on developing emergency preparedness plans for States, local and territorial public health departments. Progress also is being made to improve the Nation's preparedness for and response to public health emergencies.	On-going progress is being made to provide additional guidance to States and localities to improve their public health emergency preparedness capability. This includes specifically targeting high-risk populations, minority and hard-to reach populations, and underserved and vulnerable populations.
10. Grants and Contract Management	HHS continues its progress in developing consistent policies and procedures to oversee Federal grantees and has maintained its key leadership role in the temporary expansion of health and social programs under the <i>Recovery Act</i> , due to the Department's significant grant expenditures as the largest grant-awarding agency in the Federal Government. HHS is challenged with increasing its contracting training and clarifying guidance on the use of annual appropriated funds throughout the Department.	The Department continued its oversight responsibility for ensuring that grant funds are awarded and used appropriately by grantees. HHS resolved concerns regarding whether one State agency claimed foster care costs under the Title IV-E Foster Care program in accordance with Federal regulations. HHS is developing on-line and instructor –led acquisition appropriation law courses to further educate appropriate parties on acquisition policy.	The Department will continue coordinating the expeditious financial closeout of ended projects. HHS is establishing internal policy workgroups to foster greater consistency and accountability in the application of its grant and management policies. In addition, HHS plans to institute greater management oversight of the use of contractor support and the related acquisition practices.

Part IV: Cross-Cutting Issues that Span the Department

Management Challenge Identified by the OIG	OIG Progress Assessment	Management Response	Future Plans to Address the Challenge
<p>11. <i>American Recovery and Reinvestment Act.</i></p>	<p>The <i>Recovery Act</i> provided an estimated \$141.4 billion over 11 years to the Department to provide Federal assistance for health care, public health, and human services programs, as well as to invest in research and health information technology (health IT). In addition to the funding in direct provisions, the <i>Recovery Act</i> provides for additional fiscal relief to the States, in the form of reduced contributions for prescription drug costs, in the amount of \$4.3 billion. It is critical that <i>Recovery Act</i> funds are used efficiently and effectively and are protected from fraud, waste, and abuse.</p>	<p>The Office of Recovery Act Coordination continues to ensure the appropriate awarding, distributing, use, and reporting of <i>Recovery Act</i> funds. In addition, the <i>Recovery Act</i>, established by the Recovery Accountability and Transparency Board (RATB), consisting of 12 Inspectors General, including the HHS Inspector General, coordinates and conducts oversight of <i>Recovery Act</i> funds; prevent fraud, waste, and abuse; and promote accountability and transparency.</p>	<p>The OIG and the Department will continue to work together to ensure HHS meets its <i>Recovery Act</i> responsibilities. This includes ensuring the accountability and transparency of <i>Recovery Act</i> funds. In addition, activities will continue to focus on minimizing risk, assessing controls for preventing fraud, waste and abuse; and ensuring program goals are achieved and <i>Recovery Act</i> funds are tracked and reported.</p>
<p>12. Health Information Technology and Integrity of Information Systems</p>	<p>The Department continues to make progress in ensuring the integrity of the Department's programs to promote health information technology, in addition to ensuring the integrity of information systems through which health information is transmitted and stored.</p>	<p>The Office of the National Coordinator for Health IT (ONC) continues to provide national leadership in health IT adoption and electronic health information exchange. Under the ONC, we identified potential approaches for addressing medical identity theft in a comprehensive manner through research and stakeholder "town hall" meetings.</p>	<p>ONC and the Department are well aware of privacy and security challenges as we transition to wide adoption and use of electronic health records and secure electronic health information exchange. We will be seeking recommendations on additional security capabilities from our Federal advisory committees that may be incorporated into future phases of the transition processes.</p>

Part IV: Cross-Cutting Issues that Span the Department (Continued)

Management Challenge Identified by the OIG	OIG Progress Assessment	Management Response	Future Plans to Address the Challenge
<p>13. Ethics Program Oversight and Enforcement</p>	<p>NIH and FDA continue implementing additional measures to strengthen their processes for reviewing and approving outside activities. The OGC Ethics Division continued its ethics program oversight.</p>	<p>The OGC Ethics Division has responsibility for administering the Department's ethics program as it pertains to HHS employees (including special Government employees). It continued to conduct internal reviews of OPDIV and STAFFDIV ethics programs to ensure that these programs function effectively and that conflicts of interest on the part of HHS employees are identified and resolved.</p>	<p>The DAEO and the OGC Ethics Division will continue to work closely with the OIG in identifying and addressing areas of improvement within HHS' ethics program and the handling of referrals of conflict of interest violations.</p>

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Glossary

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GLOSSARY

ACRONYM	DESCRIPTION
ACF	Administration for Children and Families
AFR	Agency Financial Report
AHIC	American Health Information Community
AHRQ	Agency for Healthcare Research and Quality
AIDS.....	Acquired Immunodeficiency Syndrome
AoA	Administration on Aging
AMP.....	Average Manufacturer Price
ASA	Assistant Secretary for Administration
ASFR	Assistant Secretary for Financial Resources
ASH.....	Assistant Secretary for Health
ASL	Assistant Secretary for Legislation
ASPA	Assistant Secretary for Public Affairs
ASPE	Assistant Secretary for Planning and Evaluation
ASPR	Assistant Secretary for Preparedness and Response
ATSDR	Agency for Toxic Substances and Disease Registry
BARDA.....	Biomedical Advanced Research and Development Authority
CAS	Carotid Artery Stenting
CBO.....	Congressional Budget Office
CCB	Child Care Bureau
CCDF	Child Care Development Fund
CDC.....	Centers for Disease Control and Prevention
CEA	Carotid Endarterectomy
CERT	Comprehensive Error Rate Testing
CFBNP	Center for Faith-Based and Neighborhood Partnerships
CFO	Chief Financial Officer
CFR	Code of Federal Regulations
CFRS	Consolidated Financial Reporting System
CHIP.....	Children's Health Insurance Program
CHIPRA.....	<i>Children's Health Insurance Program Reauthorization Act of 2009</i>
CIA	Corporate Integrity Agreement
CIT.....	Center for Information Technology
CLABSI	Central Line-Associated Bloodstream Infections
CLASS	<i>Community Living Assistance Services and Support Act</i>

ACRONYM DESCRIPTION

CMP	Civil Monetary Penalties
CMS.....	Centers for Medicare and Medicaid Services
COLA	Cost of Living Adjustment
COTS	Commercial-off-the-shelf
CPG	Compliance Program Guidance
CPI	Consumer Price Index
CPIM.....	Consumer Price Index-Medical
CPPW.....	Communities Putting Prevention to Work
CRADA	Cooperative Research and Development Agreement
CSRS	Civil Service Retirement System
CY	Current Year
DAB.....	Departmental Appeals Board
DAEO	Designated Agency Ethics Officer
DC	District of Columbia
DHS.....	Department of Homeland Security
DME.....	Durable Medical Equipment
DMEPOS	Durable Medical Equipment, Prosthetics, Orthotics, and Supplies
DOJ	Department of Justice
DOL.....	Department of Labor
DSH.....	Disproportionate Share Hospital
E&M	Evaluation and Management
EHR	Electronic Health Records
EY	Ernst & Young LLP
FASAB.....	Federal Accounting Standards Advisory Board
FBWT.....	Fund Balance with Treasury
FCA	False Claims Act
FDA	Food and Drug Administration
<i>FECA</i>	<i>Federal Employees' Compensation Act</i>
FERS.....	Federal Employees' Retirement System
<i>FFMIA</i>	<i>Federal Financial Management Improvement Act of 1996</i>
FFS.....	Fee-for-Service
<i>FICA</i>	<i>Federal Insurance Contributions Act</i>
FIFO	First-in/first-out
<i>FISMA.....</i>	<i>Federal Information Security Management Act of 2002</i>
<i>FMFIA</i>	<i>Federal Managers' Financial Integrity Act of 1982</i>
FUL	Federal Upper Limit

ACRONYM DESCRIPTION

FMAP	Federal Medical Assistance Percentage
FMSP	Financial Management System Program
FY	Fiscal Year
GAAP	Generally Accepted Accounting Principles
GDP.....	Gross Domestic Product
<i>GMRA</i>	<i>Government Management Reform Act of 1994</i>
<i>GPRA</i>	<i>Government Performance and Results Act of 1993</i>
GSA.....	General Services Administration
HEAT	Health Care Fraud Prevention and Enforcement Action Team
HEW	Department of Health, Education and Welfare (now HHS)
HHAs	Home Health Agencies
HHS	Department of Health and Human Services
HI	Hospital Insurance
HIGLAS	Healthcare Integrated General Ledger Accounting System
<i>HIPAA.....</i>	<i>Health Insurance Portability and Accountability Act of 1996</i>
HIT.....	Health Information Technology
HITECH	Health Information Technology for Economic and Clinical Health Act
HIV	Human Immunodeficiency Virus
HRSA	Health Resources and Services Administration
H5N1	Avian Influenza
IBNR.....	Incurred But Not Reported
IEVS	Income Eligibility Verification System
IGA	Intergovernmental Affairs
<i>IHCIA</i>	<i>Indian Health Care Improvement Act</i>
IHS	Indian Health Service
<i>IPERA</i>	<i>Improper Payments Elimination and Recovery Act of 2010</i>
<i>IPIA</i>	<i>Improper Payments Information Act of 2002</i>
IT.....	Information Technology
J3.....	Jurisdiction 3
LICS	Low Income Cost Sharing Subsidy
LIPS	Low Income Premium Subsidy
LIS	Low-Income Subsidy
LLP.....	Limited Liability Partnership
MA	Medicare Advantage
MACs	Medicare Administrative Contractors

ACRONYM DESCRIPTION

MARx	Medicare Advantage Prescription Drug
MC.....	Managed Care
MEDIC	Medicare Drug Integrity Contractors
<i>MMA</i>	<i>Medicare Prescription Drug, Improvement and Modernization Act of 2003</i>
MPD	Medicare Prescription Drug
MMIS	Medicaid Management Information Systems
MPE	MARx Payment Error
MSIS	Medicaid Statistical Information Systems
N/A.....	Not Applicable
NBS	NIH Business Systems
NCI.....	National Cancer Institute
NDMS	National Disaster Medical System
NDNH	National Directory of New Hires
NHIN	Nationwide Health Information Network
NIH	National Institutes of Health
NPI	National Provider Identification
NPRM.....	Notice of Proposed Rulemaking
OACT	Office of the Actuary
OCIIO	Office of Consumer Information and Insurance Oversight
OCR.....	Office for Civil Rights
OD.....	Office on Disability
OER	Office of Extramural Research
OGC	Office of the General Counsel
OGE	Office of Government Ethics
OGHA	Office of Global Health Affairs
OHR	Office of Health Reform
OIG	Office of the Inspector General
OMB	Office of Management and Budget
OMHA	Office of Medicare Hearings and Appeals
ONC	Office of the National Coordinator for Health Information Technology
OPDIV.....	Operating Division
OPEB	Other Post Employment Benefits
ORB.....	Other Retirement Benefits
OS	Office of the Secretary
<i>PAHPA.....</i>	<i>Pandemic and All-Hazards Preparedness Act</i>
PARIS	Public Assistance Reporting Information System
PCIP	Pre-Existing Condition Insurance Plan

ACRONYM DESCRIPTION

PDE	Prescription Drug Event
PELS.....	Payment Error related to Low-Income Subsidy
PEMS	Payment Error related to incorrect Medicaid Status
PEPFAR	President's Emergency Plan for AIDS Relief
PEPV.....	Prescription Drug Event Validation
PERM	Payment Error Rate Measurement
PHS	Public Health Service
PIP	Program Improvement Plan
P.L.	Public Law
PP&E	Property, Plant and Equipment
PPS	Prospective Payment System
PRRB	Provider Reimbursement Review Board
PSC	Program Support Center or Program Safeguard Contractor
PUR	Period Under Review
PY	Prior Year
QI	Qualifying Individual
QIO	Quality Improvement Organization
QRIS	Quality Rating and Improvement Systems
RAC	Recovery Audit Contractor
RADV.....	Risk Adjustment Data Validation
RAE	Risk Adjustment Error
RATB	Recovery Accountability and Transparency Board
RDS	Retiree Drug Subsidy
RFR	Reportable Food Registry
RSI.....	Required Supplementary Information
RSSI.....	Required Supplementary Stewardship Information
SAMHSA	Substance Abuse and Mental Health Services Administration
SAS	Statement on Auditing Standards
SBR	Statement of Budgetary Resources
SECA	<i>Self-Employment Contribution Act of 1954</i>
SFFAS.....	Statement of Federal Financial Accounting Standards
SGE	Special Government Employees
SHARP	Strategic Health IT Advanced Research Projects
SLEP.....	Shelf Life Extension Program
SLV	School-Located Vaccination

ACRONYM	DESCRIPTION
SMI	Supplementary Medical Insurance
SNF	Skilled Nursing Facility
SNS	Strategic National Stockpile
SOSI	Statement of Social Insurance
SSA	Social Security Administration
SSN	Social Security Number
STAFFDIV	Staff Division
TAGGS	Tracking Accountability in Government Grants System
TANF.....	Temporary Assistance for Needy Families
Treasury.....	Department of the Treasury
UFMS	Unified Financial Management System
UPIN	Unique Physician Identification Number
U.S.	United States
VFC	Vaccines for Children
VICP	Vaccine Injury Compensation Program
ZPIC	Zone Program Integrity Contractor

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