

# 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](mailto:hhsdeputycfo@hhs.gov) or at:

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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 100<sup>th</sup> 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

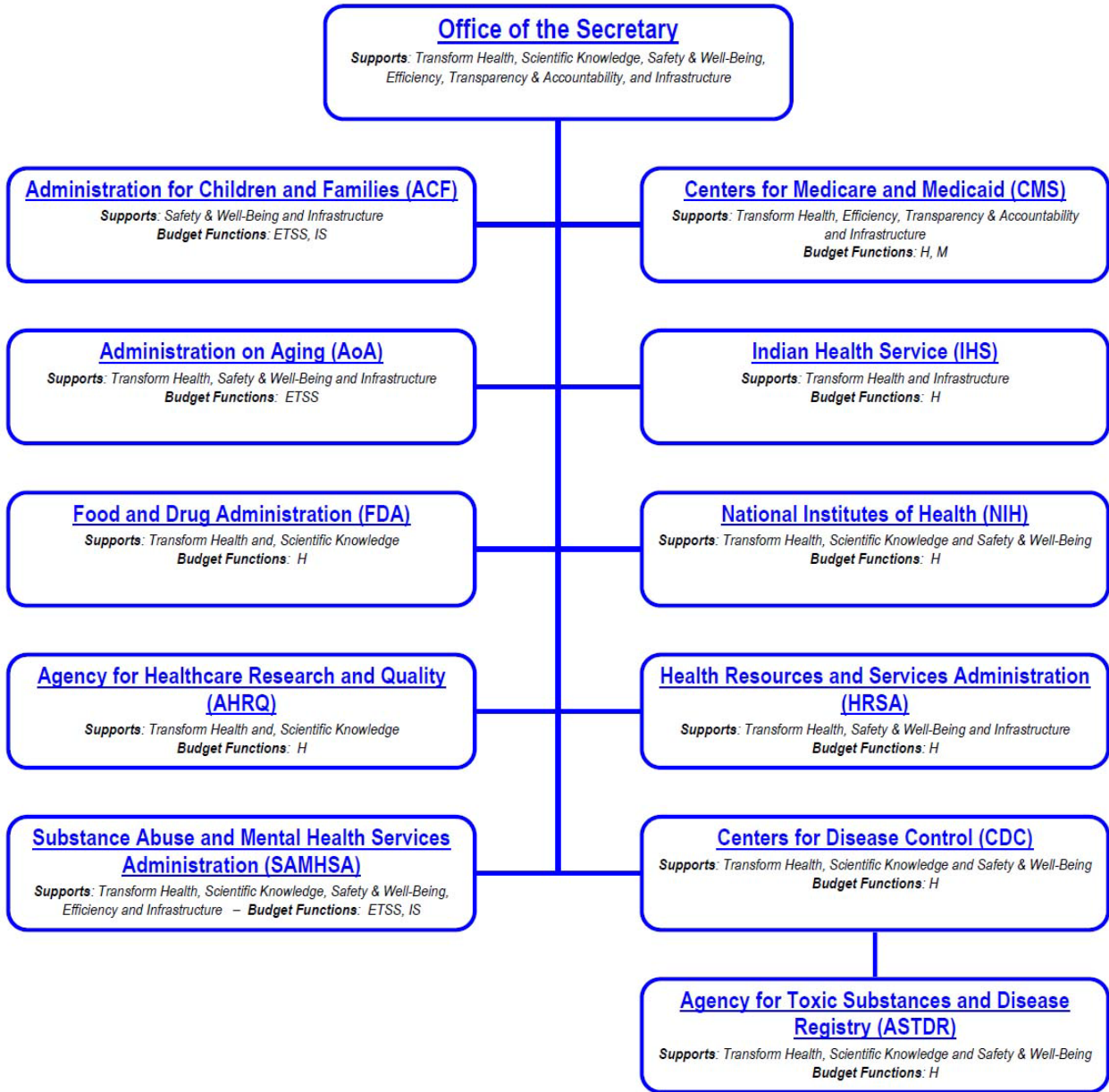
America's communities. The SAMHSA accomplishes its mission by providing leadership, developing service capacity, communicating with the public, setting standards; and improving practice in communities and in primary and specialty care settings.

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 expenditures<sup>1</sup> 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

<sup>1</sup> 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.

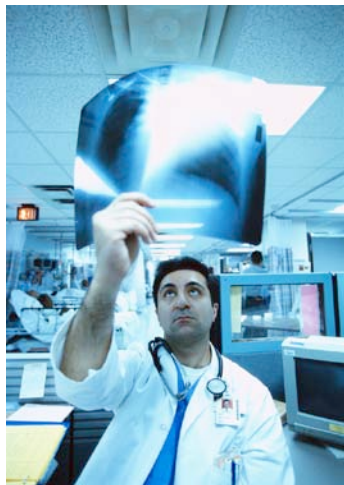
## Strategic Goal 2: Advance Scientific Knowledge and Innovation

### 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/ophs/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 100<sup>th</sup> 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<br>(Decrease) | % Change      |
|---|----------------|----------------|----------------|----------------|----------------|------------------------|---------------|
| <b>Total Assets</b>                       | <b>\$513.9</b> | <b>\$503.8</b> | <b>\$529.3</b> | <b>\$562.8</b> | <b>\$563.7</b> | <b>\$0.9</b>           | <b>0.2%</b>   |
| 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%          |
| <b>Total Liabilities</b>                  | <b>\$78.4</b>  | <b>\$81.9</b>  | <b>\$86.6</b>  | <b>\$94.4</b>  | <b>\$99.2</b>  | <b>\$4.8</b>           | <b>5.1%</b>   |
| 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%         |
| <b>Net Position</b>                       | <b>\$435.5</b> | <b>\$421.9</b> | <b>\$442.7</b> | <b>\$468.4</b> | <b>\$464.5</b> | <b>\$(3.9)</b>         | <b>(0.8)%</b> |
| <b>Total Liabilities and Net Position</b> | <b>\$513.9</b> | <b>\$503.8</b> | <b>\$529.3</b> | <b>\$562.8</b> | <b>\$563.7</b> | <b>\$0.9</b>           | <b>0.2%</b>   |

### 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.

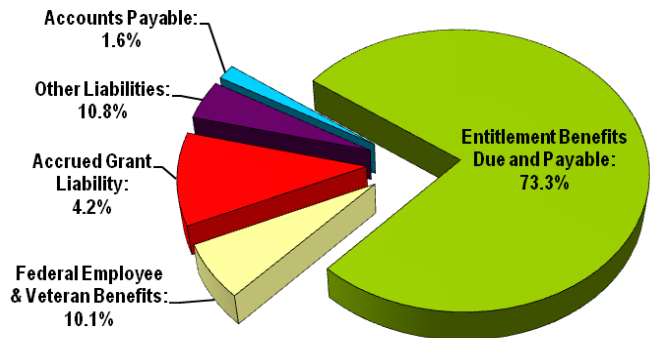
Liabilities – What Do We Owe?

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



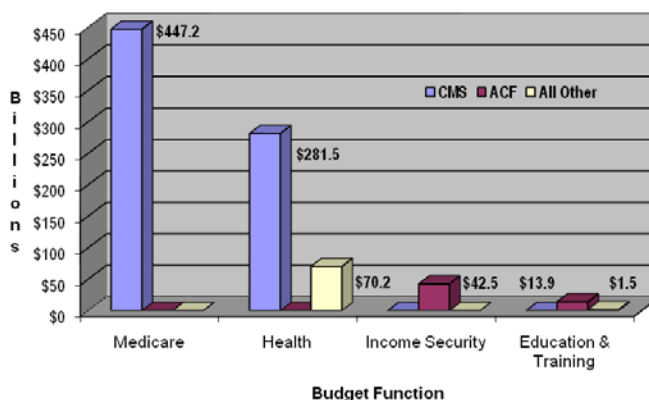
FY 2010, the Health and Medicare budget functions experienced growth of 9.8 percent (\$31.4 billion) and 4.0 percent (\$17.1 billion), respectively. The growth in the Health budget function is primarily attributable to normal increases in Entitlement Benefits of \$13.9 billion and *Recovery Act* extension 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       |
|---|----------------|----------------|----------------|----------------|----------------|---------------|-------------|
| <b>Responsibility Segments</b>                              |                |                |                |                |                |               |             |
| 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%        |
| <b>Other Segments:</b>                                      |                |                |                |                |                |               |             |
| 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%       |
| <b>Net Cost of Operations</b>                               | <b>\$623.9</b> | <b>\$664.6</b> | <b>\$709.1</b> | <b>\$803.9</b> | <b>\$856.7</b> | <b>\$52.8</b> | <b>6.6%</b> |

**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.

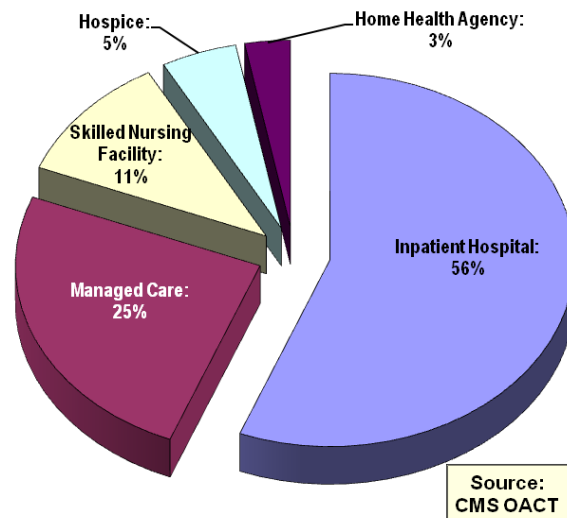
In December 2003, *Medicare Prescription Drug, Improvement & Modernization Act of 2003 (P.L. 108-173)* was enacted, which included the addition of a drug benefit (Part D). The Medicare Prescription Drug Benefit program represents one of the largest changes to Medicare since its enactment in 1965, and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

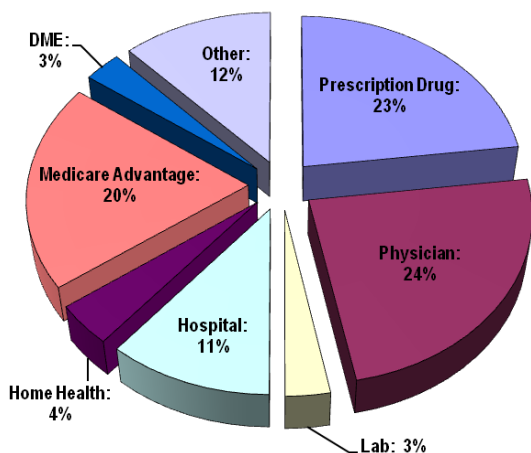


Under the Trustees' intermediate set of assumptions, as displayed in the Statement of Social Insurance, as of January 1, 2010, the Hospital Insurance Trust Fund will incur an actuarial deficit of nearly \$2.7 trillion over the 75-year projection period, as compared with \$13.8 trillion in the FY 2009 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<br>(As of 9/30/2010) | Compliance<br>(As of 9/30/2010) | Financial<br>Reporting<br>(As of 6/30/2010) | Systems<br>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

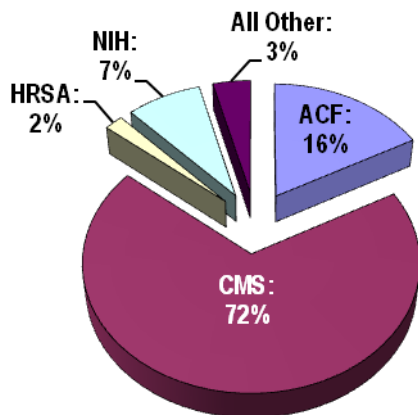
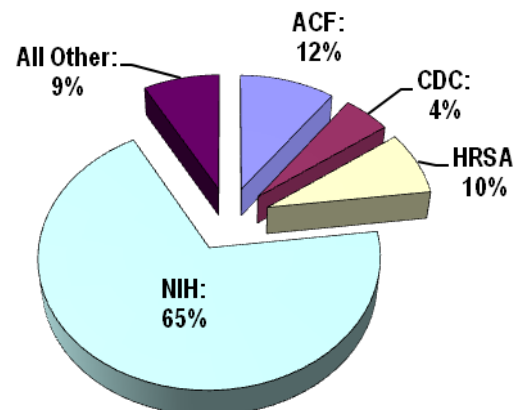


Figure 6: FY09 Grant Volume by Component



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.

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### *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.

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### *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.

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### *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**

| <b>2. Integrity of Provider and Supplier Enrollment</b>  | <b>3. Integrity of Federal Health Care Program Payment Methodologies</b>   | <b>4. Promoting Compliance With Federal Health Care Program Requirements</b>  |
|--|--|---|
| <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"> <li>• Implementing the provisions of the <i>Affordable Care Act</i> using additional tools to evaluate and monitor providers and suppliers;</li> <li>• Ensuring adequate and appropriate provider and supplier enrollment standards and screening;</li> <li>• Streamlining variations in Medicaid provider and supplier enrollment standards, both across States and for providing within a State; and</li> <li>• Increasing nursing home ownership transparency.</li> </ul> | <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"> <li>• 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;</li> <li>• Examining payments under Medicare Part D to determine whether risk-sharing percentages are appropriate; and</li> <li>• Establishing and maintaining the integrity of payment methodologies so that resources are not lost to fraud, waste, and abuse.</li> </ul> | <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"> <li>• Ensuring providers and the supplier community are well informed about rules and engaged in compliance;</li> <li>• 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</li> <li>• 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.</li> </ul> |

**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"> <li>• Improving collection, analysis, and monitoring of data to better prevent, detect and respond to fraud, waste, and abuse;</li> <li>• Enhancing the availability of data to monitor payment accuracy and integrity across Medicare Parts A, B, C, and D and Medicaid; and</li> <li>• Implementing provider compliance education efforts to help ensure expanded and redefined roles under the <i>Affordable Care Act</i>.</li> </ul> | <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"> <li>• Prioritizing and responding to the most serious vulnerabilities;</li> <li>• Responding to detected vulnerabilities by suspending payments to providers upon credible evidence of fraud; and</li> <li>• 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>.</li> </ul> | <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"> <li>• Overseeing provider compliance using existing quality standards;</li> <li>• Protecting beneficiaries from sub-standard care and from abuse and neglect by providers;</li> <li>• Adopting beliefs of the patient safety movement, focusing on quality improvement, measurement, root cause analysis, and public reporting;</li> <li>• Working with various types of health care providers to ensure they are knowledgeable about and consistently implement quality improvement processes; and</li> <li>• Ensuring enhanced quality of care as mandated by the <i>Affordable Care Act</i>.</li> </ul> |

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

| <b>8. Oversight of Food, Drugs, and Medical Devices</b>  | <b>9. Emergency Preparedness and Response</b>   | <b>10. Grants and Contract Management</b>   |
|--|---|---|
| <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"> <li>• Responding to emergencies related to food safety, which often involves multiple State and Federal public health agencies;</li> <li>• Ensuring the safety and security of the nation’s food supply, human and veterinary drugs, and medical devices;</li> <li>• Protecting the rights, safety, and well-being of human subjects who participate in clinical trials; and</li> <li>• Making certain that products, once proven safe and effective, are marketed appropriately.</li> </ul> | <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"> <li>• Providing continued guidance to help improve the public and private sectors’ preparedness and response to public health emergencies;</li> <li>• 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</li> <li>• Safeguarding our nation’s laboratory system.</li> </ul> | <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"> <li>• Monitoring of grants and contracts management because of the size and scope of grant and contract expenditures;</li> <li>• Ensuring the appropriate use of grants and contracts funds; and</li> <li>• Making sure of the integrity of the grants award processes and grantee compliance with program requirements.</li> </ul> |

**Part IV: Cross-Cutting Issues that Span the Department**

| <p><b>11. American Recovery and Reinvestment Act</b></p>   | <p><b>12. Health Information Technology and Integrity of Information Systems</b></p>  | <p><b>13. Ethics Program Oversight and Enforcement</b></p>   |
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| <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"> <li>• Implementing and overseeing <i>Recovery Act</i> funding to ensure accountability and transparency;</li> <li>• Assessing whether the Department is using <i>Recovery Act</i> funds in accordance with legal and administrative requirements; and</li> <li>• Using systems associated with <i>Recovery Act</i> reporting requirements to ensure funds are accurately tracked and reported.</li> </ul> | <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"> <li>• Developing and maintaining adequate internal controls over its information systems to protect the security and privacy of health plans;</li> <li>• 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;</li> <li>• Ensuring the confidentiality, integrity, and availability of critical systems and data; and</li> <li>• Proving oversight and monitoring of security controls for our networks, as well as those of its contractors and grantees.</li> </ul> | <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"> <li>• Overseeing ethics considerations in grants and contracts management and research and regulatory oversight;</li> <li>• 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</li> <li>• Monitoring potential conflict-of-interest issues related to non-Federal entities and participants in our programs (grantees, clinical investigators, contractors).</li> </ul> |