

## Department of Health and Human Services



## FY 2009 Agency Financial Report

November 16, 2009

***FY 2009 AGENCY FINANCIAL REPORT***

# CONTENTS

|                                                                                   |     |
|-----------------------------------------------------------------------------------|-----|
| INTRODUCTION .....                                                                | ii  |
| MESSAGE FROM THE SECRETARY .....                                                  | iii |
| <b>SECTION I: MANAGEMENT’S DISCUSSION AND ANALYSIS</b>                            |     |
| Agency Financial Report Acknowledgment.....                                       | 1   |
| Mission and Organizational Structure .....                                        | 1   |
| Strategic Goals .....                                                             | 3   |
| Analysis of Financial Statements and Stewardship Information .....                | 10  |
| Systems, Legal Compliance, and Internal Controls.....                             | 15  |
| Other Management Information and Initiatives.....                                 | 20  |
| Looking Ahead to 2010—Department’s Management Challenges and High-Risk Areas..... | 21  |
| <b>SECTION II: FINANCIAL REPORTS</b>                                              |     |
| Message From the Chief Financial Officer .....                                    | 3   |
| Independent Audit Reports.....                                                    | 5   |
| Financial Statements and Notes.....                                               | 51  |
| Required Supplementary Stewardship Information.....                               | 92  |
| Required Supplementary Information .....                                          | 96  |
| <b>SECTION III: OTHER ACCOMPANYING INFORMATION</b>                                |     |
| Other Financial Information .....                                                 | 4   |
| <i>Improper Payments Information Act</i> Report .....                             | 9   |
| Management Report on Final Action .....                                           | 32  |
| Summary of Financial Statement Audit and Management Assurances.....               | 35  |
| OIG Top Management and Performance Challenges .....                               | 37  |
| Department’s Response to the Top Management and Performance Challenges .....      | 65  |

## GLOSSARY

## INTRODUCTION

### Purpose of This Report

Our fiscal year (FY) 2009 *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, 2008 through September 30, 2009. 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 (P.L. 107-300)* reporting details, 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 identified.

### 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:

Department of Health and Human Services  
Office of Finance/DFMP  
Mail Stop 522D  
200 Independence Avenue, SW  
Washington, DC 20201

## MESSAGE FROM THE SECRETARY

I am pleased to transmit this *Fiscal Year (FY) 2009 Agency Financial Report* for the Department of Health and Human Services.

HHS has made tremendous strides in FY 2009 toward protecting our nation's health and providing essential human services—especially for those who are least able to help themselves. This report enumerates our accomplishments, and although you can read the details in the pages that follow, I want to point out some of our highlights of the past year.



### Health Insurance Reform

This year, President Obama articulated a vision of an America where everyone, regardless of income or health status, has access to health coverage that meets their needs and they can afford. In FY 2009, the Department of Health and Human Services began laying the foundation for comprehensive health insurance reform.

Early in the year, we played a key role in the White House Forum on Health Reform and regional forums, to examine the need for affordable health coverage across the country and set the stage for solutions moving forward.

We are working to improve efficiency, innovation, accountability, and transparency in our programs, including expanding the Hospital Quality Improvement program, raising the level of post-hospital care, reducing readmission rates, and bringing down drug prices and Medicare overpayments to private insurers.

We charted a new course for safety-net programs, including making it possible for States to offer health coverage to working-poor families under the Children's Health Insurance Program (CHIP), and working with the Department of Labor to improve coordination of group health plans with Medicaid and CHIP coverage.

### The Recovery Act

In 2009, HHS helped millions of Americans recover from the recession and invest in the future. The *American Recovery and Reinvestment Act (Recovery Act)* provided an estimated \$167 billion in additional funding over ten years to HHS programs, making a difference in the lives of millions of Americans hit hard by the economic downturn. These programs helped preserve health insurance coverage, maintain access to health care, and target critical human services to families.

Thanks to HHS' *Recovery Act* funding, hospitals that served a disproportionate share of uninsured and low-income Americans could keep their doors open and States had the resources to administer vaccines—the best protection we have against influenza. *Recovery Act* funds also invest in the future of our people, by enabling parents in low-income communities to continue enrolling their children in quality early childhood education programs like Head Start and Early Head Start. Additionally, *Recovery Act* funds enabled Community Health Centers to serve more Americans in need and States could extend families' Medicaid coverage as parents transitioned back into the workforce.

Finally, with a significant new investment in health information technology, we accelerated the nation's progress toward a twenty-first century, interoperable health system for every patient and provider across the United States.

In addition to the details provided in this report, additional information on *Recovery Act* investments are available on the [www.recovery.gov](http://www.recovery.gov) website.

## Public Health Initiatives

HHS worked tirelessly to improve public health for every American. We took aggressive action to fight the spread of the 2009 H1N1 flu virus as soon as it appeared in the United States last spring, and worked against the clock to ready a vaccine for the fall. We launched the *Act Against AIDS* initiative, which expanded our efforts to limit transmission of this deadly disease that continues to infect far too many Americans. Moreover, when the peanuts and pistachios were recalled following reports of bacterial contamination, we reached out with new media, creating—among other tools—a widget e-mailed to websites and inboxes to alert consumers with public health updates.

## Stewardship

In FY 2009, we continuously sought to improve in our role as stewards of the public trust. For the eleventh consecutive year, HHS obtained an unqualified or “clean” audit opinion on our consolidated financial statements from our independent auditor Ernst & Young LLP. This demonstrates our continued commitment to better reporting and greater transparency.

Our third year of participation in the Office of Management and Budget’s Performance and Accountability Report Pilot Program is part of our commitment to provide better, more transparent financial and performance reporting. The Program requires a number of reports, including the *FY 2009 Agency Financial Report* we are issuing today, as well as the *FY 2009 Annual Performance Report*, the *Congressional Budget Justification*, and the summary of performance and financial information, which we will issue in February 2010. These reports will be available at [www.hhs.gov](http://www.hhs.gov).

Our managers use the financial information summarized in the reports to improve the quality and effectiveness of our services to the American people. The financial and performance data presented in this report are reliable, complete, and provide the latest data available.

## FY 2009 Agency Financial Report

As required by the *Federal Managers’ Financial Integrity Act of 1982 (FMFIA)* and Office of Management and Budget Circular’s A-123, *Management’s Responsibility for Internal Control*, we have evaluated our internal controls and financial management systems. Section I of this report includes the Department’s qualified assurance statement that describes two material weaknesses in the Department: 1) Financial Reporting System and Processes, and 2) Information Systems Control and Security. These weaknesses also constitute system non-conformances under Section 4 of the *FMFIA*. Sections I 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 improve the lives of children, families, and older people; and represent an immeasurable contribution to the health and quality of life of every American moving forward. Our accomplishments would not have been possible without the dedication and commitment of our employees and the strong support of our partners. I am proud of the positive impact of this Department on the well-being of all Americans.



Secretary Kathleen Sebelius  
November 16, 2009

## Section I: Management's Discussion and Analysis

*[Page Left Intentionally Blank]*



## AGENCY FINANCIAL REPORT ACKNOWLEDGEMENT

We chose to participate, for the third year, in the Performance and Accountability Report pilot, as defined in the Office of Management and Budget's (OMB's) Circular A-136, *Financial Reporting Requirements*. We believe this format provides the reader and decision-makers more transparent and enhanced financial and performance reporting. We produced an alternative to the consolidated *Performance and Accountability Report* called an *Agency Financial Report*. The *FY 2009 Performance Report* and the *FY 2011 Congressional Budget Justification* will be available in February 2010, as will the *Summary of Performance and Financial Information*. These reports will be available on our website at [www.hhs.gov](http://www.hhs.gov) at that time.

## 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 strong, sustained advances in the sciences, underlying medicine, public health, and social services. Each of our components contributes to our mission 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) helps elderly individuals maintain their dignity and independence in their homes and communities through comprehensive, coordinated, and cost effective systems of long-term care, and livable communities across the country.
- The Agency for Healthcare Research and Quality (AHRQ) improves the quality, safety, efficiency, and effectiveness of health care for all Americans. Information from AHRQ's research helps inform decisions and improves the quality of health care services.
- 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 and 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), one of the largest purchasers of health care, administers the Medicare program and works in partnership with the States to administer the Medicaid program and the Children's Health Insurance Program (CHIP). In addition to these programs, CMS has other responsibilities that ensures effective, up-to-date health care coverage and promotes 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) provides national leadership, program resources, and services needed to improve access to culturally competent, quality health care.
- 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. They promote 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) builds resilience and facilitates recovery for people with or at risk for mental or substance use disorders. SAMHSA is gearing all of its resources – programs, policies and grants – toward that outcome.

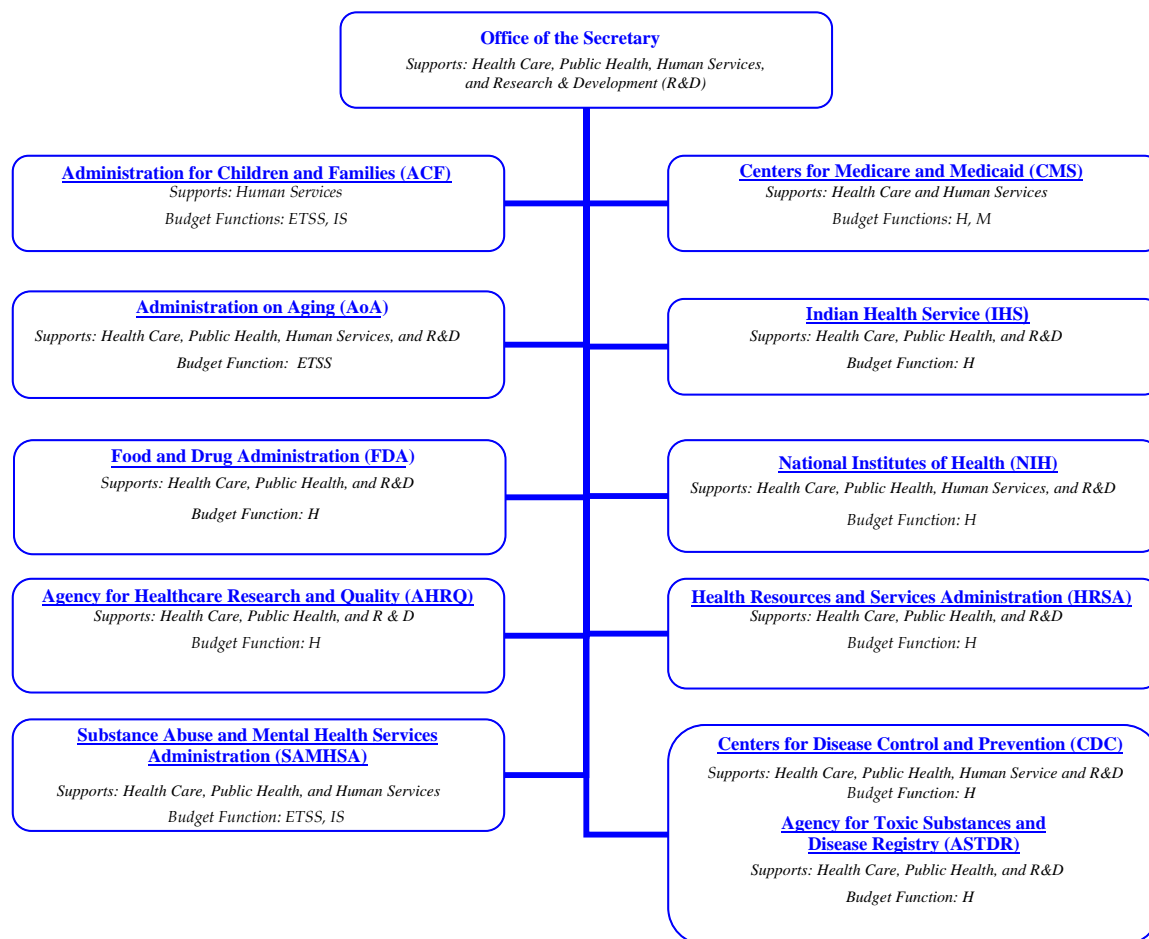
Our Secretary leads our components to provide a wide range of services and benefits to the American people. In addition, the following staff offices report directly to the Secretary, and support the operating components in carrying out our mission. They are:

- Office of Intergovernmental Affairs and Regional Representatives (IGA)
- Office of Public Health and Science (PHS)

- Office of the Assistant Secretary for Administration (ASA)
- Office of the Assistant Secretary for Financial Resources (ASFR)
- Office of the Assistant Secretary for Planning and Evaluation (ASPE)
- Office of the Assistant Secretary for Preparedness and Response (ASPR)
- Office of the Assistant Secretary for Legislation (ASL)
- Office of the Assistant Secretary for Public Affairs (ASPA)
- Office of the General Counsel (OGC)
- Office of Medicare Hearings and Appeals (OMHA)
- Office for Civil Rights (OCR)

- Office of Inspector General (OIG)
- Office of Global Health Affairs (OGHA)
- Departmental Appeals Board (DAB)
- Office of the National Coordinator for Health Information Technology (ONC)
- Center for Faith-Based and Community Initiatives (CFBCI)

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 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 [www.hhs.gov](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 more than 300 programs and initiatives that cover a wide spectrum of activities. Our FY 2009 direct budget authority of nearly \$841 billion represented more than a quarter of all Federal expenditures. In addition, we administer more grant dollars than all other Federal agencies combined.

Many of our programs meet the objectives of the *American Recovery and Reinvestment Act (Recovery Act, P.L. 111-5)*, which the President signed into law on February 17, 2009. The *Recovery Act* is an unprecedented effort to jumpstart our economy, create or save millions of jobs, and begin to address challenges so that the country can thrive in the 21st century. Overseeing and protecting the integrity of *Recovery Act* funds is a shared responsibility within the Department and with States and other entities.

The *Recovery Act* provided an estimated \$167 billion over 10 years to achieve and support the objectives of the *Recovery Act*. For specific accountability and transparency information concerning our *Recovery Act* efforts, visit [www.hhs.gov/recovery](http://www.hhs.gov/recovery). For government-wide information concerning the *Recovery Act*, visit [www.recovery.gov](http://www.recovery.gov).

Our four strategic goals relate to each of our operating components. Primary responsibility for these efforts by component is included in our organizational chart on the previous page. The *FY 2007–2012 Strategic Plan*,

**Goal 1. Health Care.** Improve the safety, quality, affordability, and accessibility of health care, including behavioral health care and long-term care.

**Goal 2. Public Health Promotion and Protection, Disease Prevention, and Emergency Preparedness.** Prevent and control disease, injury, illness, and disability across the lifespan, and protect the public from infectious, occupational, environmental and terrorist threats.

**Goal 3. Human Services.** Promote the economic and social well-being of individuals, families, and communities.

**Goal 4. Scientific Research and Development.** Advance scientific and biomedical research and development related to health and human services.

available at [www.hhs.gov/strategic\\_plan](http://www.hhs.gov/strategic_plan), articulates the strategic goals designed to accomplish our mission.

On April 29, 2009, Secretary Sebelius released our progress report of the first 100 days of the Administration, including progress under the *Recovery Act*. We discussed many of our programs and initiatives in the accompanying Strategic Goal Highlights. Additionally, the following table summarizes our performance results for FY 2008, which is the latest performance information available, except for the Medicare FFS error rate. The FY 2009 actual rates are presented in Section III of this report.

## SUMMARY OF DEPARTMENT OF HEALTH AND HUMAN SERVICES FY 2008 PERFORMANCE RESULTS

**Strategic Goal One - Health Care:** Improve the safety, quality, affordability, and accessibility of health care, including behavioral health care and long-term care.

| PERFORMANCE MEASURES*                                                                                                                                                              | 2006 RESULTS | 2007 RESULTS | 2008 TARGET | 2008 RESULTS | 2009 TARGET |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|--------------|-------------|--------------|-------------|
| Increase the number of states that have the ability to assess improvements in access and quality of health care through implementation of the Medicaid Quality Improvement Program | N/A          | 0            | 8           | 8            | 9           |
| Reduce the percentage of improper payments made under the Medicare fee-for-service (FFS) programs                                                                                  | 4.4%         | 3.9%         | 3.8%        | 3.6%         | 3.5%        |
| Implement the Medicare Prescription Drug Benefit – Increase the percentage of Medicare beneficiaries with prescription drug coverage from Part D or other sources                  | N/A          | 90%          | N/A         | 90%          | 91%         |

**Strategic Goal Two - Public Health Promotion and Protection, Disease Prevention, and Emergency Preparedness:** Prevent and control disease, injury, illness, and disability across the lifespan, and protect the public from occupational, environmental and terrorist threats.

| PERFORMANCE MEASURES*                                                                                                                                                               | 2006 RESULTS    | 2007 RESULTS    | 2008 TARGET     | 2008 RESULTS    | 2009 TARGET     |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| Reduce complications of diabetes by increasing the proportion of American Indian/Alaska Native patients with diagnosed diabetes that have achieved blood pressure control (<130/80) | 38%             | 38%             | 38%             | 36%             | 38%             |
| Reduce fatal work-related injuries among youth ages 15 to 17                                                                                                                        | 3.2/100,000 FTE | 2.0/100,000 FTE | 2.5/100,000 FTE | 2.0/100,000 FTE | 3.0/100,000 FTE |

**Strategic Goal Three - Human Services:** Protect the economic and social well-being of individuals, families, and communities.

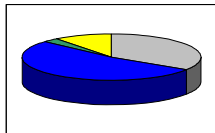
| PERFORMANCE MEASURE*                                                         | 2006 RESULTS | 2007 RESULTS | 2008 TARGET | 2008 RESULTS | 2009 TARGET |
|------------------------------------------------------------------------------|--------------|--------------|-------------|--------------|-------------|
| Increase the adoption rate for children involved in the Child Welfare System | 9.91%        | 10.00%       | 10.00%      | 11.02%       | 10.10%      |

**Strategic Goal Four - Scientific Research and Development:** Advance scientific and biomedical research and development related to health and human services.

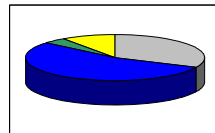
| PERFORMANCE MEASURES*                                                                                                                                                                         | 2006 RESULTS | 2007 RESULTS | 2008 TARGET | 2008 RESULTS | 2009 TARGET |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|--------------|-------------|--------------|-------------|
| Through the National Research Service Award Program, increase the probability that scientists continue participation in NIH-funded research within the following years (Postdoctoral Fellows) | 13%          | 13%          | 12%         | 13%          | 12%         |
| Reduce the financial cost (or burden) of upper gastrointestinal (GI) hospital admissions by implementing known research findings, as measured by per capita charges for GI bleeding           | \$93.36      | \$91.81      | \$91.71     | \$87.10      | \$90.75     |

\*We selected these measures from a number of performance measures aimed at the specific strategic goal represented.

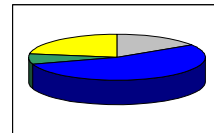
Goal 1



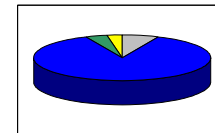
Goal 2



Goal 3



Goal 4



### FY 2008 Performance Results per Strategic Goal

■ Target met/exceeded    
 ■ Target not met but improved over prior years    
 ■ Target not met    
 ■ Data not yet available

## STRATEGIC GOAL HIGHLIGHTS

We accomplish our strategic goals by managing and delivering hundreds of programs across several disciplines. As a major grant-making agency, in many cases outside parties and partnership efforts with State and local governments, and private organizations influence our outcomes. We publicly report our progress toward achievement of our mission and strategic goals by featuring nearly 700 program-specific performance measures at [www.ExpectMore.gov](http://www.ExpectMore.gov). More than half of these measures track *outcomes*, for example, 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.

Each year, we set performance targets for our measures, and we publicly report on whether we met our performance targets. In 2008, we met or exceeded 78% of our performance targets. For this report, we are providing the latest information available. More detailed performance results will be published in our *FY 2009 Annual Performance Report*, available in our FY 2011 *Congressional Justification* in February 2010 at [www.hhs.gov](http://www.hhs.gov). In addition, a synopsis of performance information will be contained in the *FY 2009 Summary of Performance and Financial Information*, planned for publication on [www.hhs.gov](http://www.hhs.gov) by February 2010.

Our ability to meet the health and human service needs of Americans is tied directly to the commitment, cooperation, and success generated by our employees and partners, such as other Federal agencies, State and local governments, U.S. territories, Tribal organizations, community-based organizations, faith-based organizations, and the business community. The accomplishments described below, related to our four 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.

### Strategic Goal 1: Health Care

**Helping People Living With HIV/AIDS.** We released \$1.8 billion in grants to ensure that people living with HIV/AIDS continue to have access to life-saving health

care and medications. The Ryan White HIV/AIDS Program, which helps more than 529,000 individuals each year obtain the care and services they need to live longer, healthier lives, funds the grants. The Health Resources and Services Administration (HRSA), an agency within HHS, oversees the Ryan White HIV/AIDS Program. For information about HIV/AIDS prevention, testing, treatment, research, and use of new media, visit [www.aids.gov](http://www.aids.gov).

**Interagency Health Care Fraud Prevention and Enforcement Action Team.** In a joint effort with the Department of Justice, we announced the creation of a new interagency effort, the Health Care Fraud Prevention and Enforcement Action Team (HEAT), to combat Medicare fraud. We jointly announced the expansion of Strike Force team sites from two (South Florida and Los Angeles) to four sites (Detroit and Houston added). Further information may be found at [www.hhs.gov/stopmedicarefraud](http://www.hhs.gov/stopmedicarefraud) or call 1-800-HHS-TIPS (1-800-447-8477) to report suspected Medicare fraud.

*“Today, we are turning up the heat on perpetrators who steal from taxpayers and threaten the future of Medicare and Medicaid.”*  
Secretary Kathleen Sebelius

**Increasing Child Health Care Access.** Federal funds totaling \$68.9 billion will be made available to States and U.S. territories to provide health care to millions of children across America through the Children’s Health Insurance Program (CHIP) through FY 2013. The new funds for CHIP were made available by the *Children’s Health Insurance Program Reauthorization Act of 2009* (CHIPRA, P.L. 111 -3). Of the available \$68.9 billion, the Act appropriated \$10.6 billion to States for FY 2009.

CHIPRA’s additional funding helps States and U.S. territories maintain existing CHIP enrollment and expand their programs. CHIP provides health insurance for children of working families whose incomes are too high for traditional Medicaid, but too low for either employer-sponsored family plans or other private coverage. CHIP is jointly funded by States and the Federal government. A list of funding by State for CHIP programs can be viewed at [www.insurekidsnow.gov](http://www.insurekidsnow.gov).





**“Meaningful Use” of Electronic Health Records.** The *Recovery Act* provided incentive and discretionary payments from Medicare and Medicaid to further the national adoption and implementation of health information technology (HIT). HIT is an essential tool that will modernize the health care system and bring about improved health care for all Americans. The *Recovery Act* provides Medicare and Medicaid incentive payments to eligible providers, such as physicians and hospitals, in order to increase the adoption and meaningful use of Electronic Health Records (EHR). Starting in 2015, providers are subject to penalties on their Medicare payments if they cannot demonstrate “meaningful use” of EHR.

**Improving Health and Support Services at the Nation’s Health Centers.** More than \$25.7 million in grants was provided to increase and improve health and support services at the nation’s health centers. Overseen by HRSA, the Health Center system served more than 17 million medically underserved people in 2008, up from 10 million patients served in 2001.

Since the economic downturn began, the health center patient population has grown by another million people – a third of them children. A total of 180 grants, more than \$21.9 million, will give existing health centers the funds to add or increase support services related to mental health/substance abuse, oral health pharmacy services, and other support services. Additionally, 48 planning grants totaling more than \$3.8 million will be distributed to

organizations in hard hit areas that do not have health centers to help them develop new service delivery sites.

**Largest Health Care Fraud Settlement in its History.** In the largest civil fraud settlement in history, a pharmaceutical giant and its subsidiary agreed to pay \$2.3 billion to resolve criminal and civil liability arising from the illegal promotion of certain pharmaceutical products. The company agreed to plead guilty to a felony violation of the *Federal Food, Drug and Cosmetic*

*Act of 1938 (FFDCA)* for misbranding an anti-inflammatory drug with the intent to defraud or mislead. The sale of this product was promoted for several uses and dosages that the FDA specifically declined to approve due to safety concerns; the product was pulled from the market in 2005.

**“This historic settlement will return nearly \$1 billion to Medicare, Medicaid, and other government insurance programs, securing their future for the Americans who depend on these programs”**

**Secretary Kathleen Sebelius**

*Act of 1938 (FFDCA)* for misbranding an anti-inflammatory drug with the intent to defraud or mislead. The sale of this product was promoted for several uses and dosages that the FDA specifically declined to approve due to safety concerns; the product was pulled from the market in 2005.

The company will pay a criminal fine of \$1.2 billion, the largest criminal fine ever imposed in the United States for any matter. The company also forfeits \$105 million, for a total criminal resolution of \$1.3 billion. This settlement is in addition to agreeing to pay \$1 billion to resolve allegations under the civil *False Claims Act (P.L. 99-562)* that the company illegally promoted four drugs and caused false claims to be submitted to government health care programs for uses that were not medically accepted indications and therefore not covered by those programs.

**Strategic Goal 2: Public Health Promotion and Protection, Disease Prevention, and Emergency Preparedness**

**Significant Improvement in Local Hospitals’ Disaster Preparedness.** American hospitals are significantly better prepared for disasters and public health emergencies now than they were in 2001. However, challenges remain according to a University of Pittsburgh Medical Center study. The university’s Center for Biosecurity conducted an independent evaluation of our Hospital Preparedness Program (HPP), including the program’s impact on health care preparedness for mass casualty disasters. The study evaluated the first 5 years of the program (2002 to 2007), and the study showed HPP has been the catalyst for new health care coalitions throughout the country.

Through these coalitions, hospitals are now working collaboratively on disaster preparedness with other hospitals, public health departments and emergency

managers. The report also stated that health care planning for catastrophic emergencies at the individual hospital level is still in the early stages and that a large-scale emergency could “overwhelm the medical capabilities of communities, regions or the entire country and require drastic departures from customary health care practices.” The report concluded that bridging this gap would require significant changes in the way health care is delivered. The full report is available at [www.upmc-biosecurity.org/HPPreport](http://www.upmc-biosecurity.org/HPPreport).

**H1N1 Influenza Virus.** At a national summit at the National Institutes of Health, government officials outlined a coordinated response to a potential flu pandemic. They announced new funding to enhance States preparedness and response activities, and a new nation-wide flu information campaign at [www.flu.gov](http://www.flu.gov).

*“Preparation and planning are critical to keep Americans safe in the face of a potential pandemic.*

*Our goal throughout this new H1N1 outbreak has been to stay one step ahead of the virus.”*

**Secretary Kathleen Sebelius**

As part of the coordinated response, we met jointly with the White House, the Department of Homeland Security, the Department of Education, and delegations from 54 States, Tribes and U.S. territories to kick off the government's nation-wide flu preparedness efforts. At the summit, we announced preparedness grants for State and local governments worth a total of \$350 million.

Since the summit, HHS has provided almost \$1.1 billion in additional funding for preparedness and response grants. HHS has also worked with manufacturers, CDC, FDA, and NIH to purchase enough doses of an H1N1 vaccine to protect the American people.

In the spring, we had stockpiled nearly 50 million courses of antiviral drugs in the Strategic National Stockpile (SNS), and State stockpiles across the country include an additional 23 million more treatment courses. In June 2009, HHS procured 13 million treatment courses of antivirals to replenish the SNS, which deployed antiviral drugs to States in May 2009 at the advent of the first wave of the 2009 H1N1 virus. In September 2009, HHS procured an additional 16 million treatment courses of antivirals for the SNS to address the disproportionate effects of the 2009 H1N1 virus on children and to help mitigate other potential resistant strains of the virus.

**Food Safety Working Group.** Responding to President Obama's directive to upgrade the nation's food safety system, the White House Food Safety Working Group, led by Agriculture Secretary Tom Vilsack and HHS Secretary

Kathleen Sebelius, launched two websites to provide information about the group's activities and progress. The Web site, [www.foodsafetyworkinggroup.gov](http://www.foodsafetyworkinggroup.gov), is an important resource for people who want to stay apprised of the Working Group's progress, learn about food safety tools and practices, and share their views on how to improve the food safety system.

A comprehensive approach to an improved national food safety system links statutory modernization to regulatory actions and public health outcomes. The website, [www.foodsafety.gov](http://www.foodsafety.gov), provides food safety and recall information in one convenient place. The new site features information from all the agencies across the Federal government that deal with critical food and food safety information, including preventive tips about how to handle food safely, alerts on life-saving food recalls, and the latest news from the key agencies.

### Strategic Goal 3: Human Services

**Year of Community Living.** To affirm our commitment to addressing isolation and discrimination against people with disabilities that still exists today, President Obama designated this as a “Year of Community Living.” To begin this Year of Community Living, our operating components are undertaking the task of aggressively addressing barriers that prevent some Americans with disabilities from enjoying a meaningful life as part of their community. For example, an AoA funding opportunity makes it easier for older people, younger adults, and their families to learn about and access health and long-term care options through Aging and Disability Resource Center (ADRC) programs. ADRCs provide “one-stop shop” sources of information, one-on-one counseling, and streamlined access to programs and services that can enable people to remain in their own homes and communities. In conjunction with these efforts, HHS is proud to support the Convention on the Rights of Persons with Disabilities, the first new United Nations human rights convention of the 21st century. We look forward to advancing dignity, autonomy, full inclusion, and equality of opportunity for Americans, and for people with disabilities around the world.

**Child Support Enforcement.** We announced the availability of *Recovery Act* funds for State programs that establish, enforce, collect and distribute child support. Currently, the Federal Government provides incentive payments to States based on the strength of their child support enforcement programs. States are required to use these incentive payments to strengthen their Child Support Enforcement Programs. Under a new provision in the *Recovery Act*, these incentive payments will be matched by the Federal government. The change will make approximately \$1 billion in new resources available to

States across the country for child support enforcement. This will help parents make ends meet, while ensuring children receive the money they are due.



**Head Start and Early Head Start Programs.** Head Start and Early Head Start programs received funding and recipients are eligible to apply for grants worth \$2.1 billion under the *Recovery Act*. Head Start was established in 1965 to promote school readiness and provide a comprehensive array of health, nutritional and social services to eligible 4- and 5-year old preschoolers and their families. The program has enrolled more than 25 million children since its inception. The Early Head Start program was established in 1995 for children from birth to 3 years of age and pregnant women to promote healthy development in the early years.

Head Start received \$1 billion from the *Recovery Act*, whereas \$1.1 billion from the *Recovery Act* benefits Early Head Start. Head Start also benefits from a separate \$235 million increase in funding for fiscal year 2009, bringing the total funding increase for Head Start and Early Head Start to more than \$2.3 billion. The increased number of children and families served by these grants will create new jobs at Head Start and Early Head Start centers to handle increased enrollment.

**Temporary Assistance for Needy Families.** We announced \$5 billion in emergency funding for the Temporary Assistance for Needy Families (TANF) program. The Emergency Fund, established by the *Recovery Act*, helps States serve more families seeking

employment opportunities and other forms of assistance during the economic downturn. In order to be eligible to receive resources from the Emergency Fund, a State must demonstrate an increase in the number of families receiving assistance from the TANF program or an increase in employment subsidy expenditures or short-term, one-time benefits in at least one quarter during fiscal year 2009 or 2010. The *Recovery Act* also continues a supplemental grant program that provides additional support to 17 States with growing populations.

#### **Strategic Goal 4: Scientific Research and Development**

**Health Information Technology (IT) Advisory Panels.** The American Health Information Community (AHIC), a Federal advisory committee established in 2005 to offer recommendations to HHS, formally concluded its work. Over 3 years, AHIC brought together more than 160 public and private sector health IT experts to develop recommendations for advancing health IT. Seven dedicated workgroups addressed diverse health IT topics ranging from patient and population needs to standards harmonization necessary to advance the use of health IT.

The *Recovery Act* also created two new panels, the Health IT Policy Committee and the Health IT Standards Committee. These committees, which first convened in May 2009, are charged with making recommendations to HHS on policies and standards related to the development and adoption of a nation-wide health information infrastructure, including standards for the exchange and use of patient medical information.

**Federal Coordinating Council for Comparative Effectiveness Research.** We appointed members to the Federal Coordinating Council for Comparative Effectiveness Research to help coordinate research and guide investments in patient-centered research. The Council identified key areas in which funding could make the greatest impact to improve health outcomes for our nation in a report released in June 2009. The research provides information on the relative benefits and risks of various medical interventions to help clinicians and patients choose the treatment that is best for their individual needs and improve the performance of the nation's health care system.

**Family Health Portrait Tool.** We released an updated and improved version of the Surgeon General's My Family Health Portrait Tool, found at the website <https://familyhistory.hhs.gov>. The revised tool makes it easier for consumers to assemble and share family health history information. It can also help practitioners make better use of health history information so that they can provide more



informed and personalized care for their patients. The revised tool helps consumers and clinicians, and serves as a platform for developing new risk assessment software that helps in screening and prevention of cancer, heart disease, diabetes, and other conditions. The first adopter of the tool is the National Institute of Genomic Medicine of Mexico. The Mexican family health history tool is available on the website, <http://www.inmegen.gob.mx>. The Indian Health Service (IHS), an agency of HHS that was instrumental in developing the new Surgeon General tool, also adopted into the IHS health care system.

**Health Information Technology (IT) Systems.** The Nationwide Health Information Network (NHIN) is a Federal initiative led by the Office of the National Coordinator for Health Information Technology (ONC). NHIN facilitates the electronic exchange of health information among health stakeholders throughout the country. It includes standards, agreements, policies and core services that allow health data to be securely exchanged across the Internet. The benefits of widespread health information exchange include up-to-date records available at the point of care; enhanced population health screening; and the ability to collect information faster to facilitate disability claims.

The Federal Health Architecture (FHA) is making software available to help public and private organizations participate in health information exchanges using NHIN specifications and governance. Twenty Federal agencies participate in FHA, an electronic government initiative also led by ONC, and together, the agencies created an open source software called Connect that any organization can use to set up and participate in NHIN-enabled health information exchange. Connect facilitates NHIN participation among integrated delivery networks, pharmacies, government health facilities, payers, laboratories, providers, and other stakeholders. Numerous public and private organizations have already demonstrated the ability to share data securely with each other using Connect. The software is being used by the Social Security Administration, and MedVirginia, a regional health information organization, to support long-term disability claims. Connect is available to the entire health care industry, with the goal of speeding widespread NHIN adoption. The software and its supporting documentation are available at [www.connectopensource.org](http://www.connectopensource.org).

**Childhood Overweight and Obesity Prevention.** HHS launched a new series of public service advertisements (PSAs) designed to address childhood overweight and obesity. The PSAs are an extension of our Childhood Overweight and Obesity Prevention campaign with the Ad Council, which encourages children and families to lead healthy lifestyles. The ads are being distributed to media outlets nation-wide this week. According to CDC, the percentage of young people in the United States who are overweight has more than tripled since 1980, with more than 9 million school-age children older than the age of 6 considered overweight. In addition to the psychological and social issues of stigmatization, overweight children are at far greater risk of growing into adults who have cardiovascular disease, Type 2 diabetes, and other chronic diseases that may reduce the length and quality of their lives. A recent report also illustrated that the health cost of obesity in the United States is as high as \$147 billion annually.

**United States and Four Latin American Countries Partner To Battle Cancer.** The National Cancer Institute (NCI), part of the NIH, formalized bilateral partnerships with the governments of Argentina, Brazil, Mexico, and Uruguay to accelerate progress against cancer in Hispanic populations in the United States and Latin America, and improve cancer research. These countries, along with Chile and the United States, comprise the United States-Latin America Cancer Research Network, which is committed to developing a comprehensive understanding of the cancer burden among Hispanic populations in Latin America and the United States.

Spearheaded by NCI's Office of Latin American Cancer Program Development, this partnership supports the co-development of programs in three broad scientific areas: cancer research and clinical trials; multi-national and multi-disciplinary training programs; technology and capacity building. In Latin America, cancer is among the top three deadliest diseases, and its incidence in these countries continues to rise.

## ANALYSIS OF FINANCIAL STATEMENTS AND STEWARDSHIP INFORMATION

For the eleventh consecutive year, HHS obtained an unqualified or “clean” audit opinion on its financial statements. 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 the Department’s 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 the Department’s 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 the Department’s 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 the financial position and results of operations of HHS, pursuant to the requirements of 31 U.S.C. §3515 (b). Although the

statements have been prepared from the books and records of HHS 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. The statements should be read with the realization that they are for a component of the U.S. Government, a sovereign entity. One implication of this is that liabilities cannot be liquidated without legislation providing resources and budget authority for HHS.

### Financial Condition – What is Our Financial Picture?

The following chart summarizes trend information concerning components of our financial condition –assets, liabilities, and net position. The Consolidated Balance Sheets presents a snapshot of our financial condition as of September 30, 2009, compared to FY 2008, and displays assets, liabilities and net position. Another component of our financial picture is our Consolidated Statements of Net Cost. Each of these components is discussed below, and in detail in Section II of this document.

| FINANCIAL CONDITION<br>(Dollars in Billions) | FY 2005        | FY 2006        | FY 2007        | FY 2008        | FY 2009        | Increase<br>(Decrease) | %<br>Change |
|----------------------------------------------|----------------|----------------|----------------|----------------|----------------|------------------------|-------------|
| <b>Total Assets</b>                          | <b>\$428.5</b> | <b>\$513.9</b> | <b>\$503.8</b> | <b>\$529.3</b> | <b>\$562.8</b> | <b>\$33.5</b>          | <b>6.3%</b> |
| Fund Balance with Treasury                   | \$99.6         | \$159.9        | \$114.8        | \$124.3        | \$162.0        | \$37.7                 | 30.3%       |
| Investments, Net                             | \$300.7        | \$342.0        | \$365.9        | \$385.4        | \$381.1        | \$(4.3)                | (1.1)%      |
| Other Assets                                 | \$28.2         | \$12.0         | \$23.1         | \$19.6         | \$19.7         | \$0.1                  | 0.5%        |
| <b>Total Liabilities</b>                     | <b>\$71.0</b>  | <b>\$78.4</b>  | <b>\$81.9</b>  | <b>\$86.6</b>  | <b>\$94.4</b>  | <b>\$7.8</b>           | <b>9.0%</b> |
| Accounts Payable                             | \$1.1          | \$1.2          | \$1.0          | \$1.0          | \$1.1          | \$0.1                  | 10.0%       |
| Entitlement Benefits Due and Payable         | \$53.8         | \$61.2         | \$61.5         | \$65.9         | \$72.2         | \$6.3                  | 9.6%        |
| Accrued Grant Liabilities                    | \$3.8          | \$3.8          | \$3.9          | \$3.9          | \$4.0          | \$0.1                  | 2.6%        |
| Federal Employee and Veterans Benefits       | \$7.2          | \$7.5          | \$8.4          | \$8.8          | \$9.7          | \$0.9                  | 10.2%       |
| Other Liabilities                            | \$5.1          | \$4.7          | \$7.1          | \$7.0          | \$7.4          | \$0.4                  | 5.7%        |
| <b>Net Position</b>                          | <b>\$357.5</b> | <b>\$435.5</b> | <b>\$421.9</b> | <b>\$442.7</b> | <b>\$468.4</b> | <b>\$25.7</b>          | <b>5.8%</b> |
| <b>Total Liabilities and Net Position</b>    | <b>\$428.5</b> | <b>\$513.9</b> | <b>\$503.8</b> | <b>\$529.3</b> | <b>\$562.8</b> | <b>\$33.5</b>          | <b>6.3%</b> |

### Assets—What Do We Own and Manage?

Assets represent the amounts that we own or manage. Our assets were \$562.8 billion on September 30, 2009. This amount represents an increase of \$33.5 billion or 6.3 percent above the prior year’s assets. This increase is largely attributable to the net effect of an increase of \$37.7 billion in Fund Balance with Treasury and a decrease of \$4.3 billion in Net Investments. The Fund Balance with Treasury increase of \$37.7 billion resulted primarily from increases of \$46.9 billion in various HHS appropriations

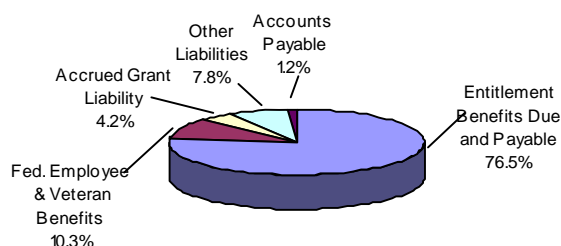
offset by a decrease of \$9.4 billion in Supplementary Medical Insurance (SMI). Of the \$46.9 billion increases in various HHS appropriations, \$31.7 billion related to the *Recovery Act*, \$6.2 billion related to CHIP, \$6.0 billion related to Public Health and Social Services Emergency Fund, and \$2.5 billion related to the Low Income Home Energy Program. The majority of the \$4.3 billion decrease in Net Investments resulted from a decline of \$9.3 billion in Health Insurance (HI) offset by increases in the Medicare SMI Trust Fund of \$2.7 billion and CHIP Contingency Fund of \$2.1 billion. In addition, net

investments in other market-based securities increased by \$2.4 billion. The majority of the HI decrease relates to a \$8.9 billion decrease in investments in bonds. Separate trust funds hold assets not currently needed to pay Medicare benefits and related expenses. We invest these funds in Treasury securities.

Fund Balance with Treasury and Net Investments together comprise 96.5 percent of total assets. The remaining assets totaling \$19.7 billion or 3.5 percent consist of Accounts Receivable, Cash and Other Monetary Assets, Inventory and Related Property, General Property, Plant, and Equipment, and Other Assets.

Liabilities – What Do We Owe?

**FY 2009 Liabilities by Type**



Our liabilities, amounts that we owe from past transactions or events, were \$94.4 billion on September 30, 2009. This represents an increase of

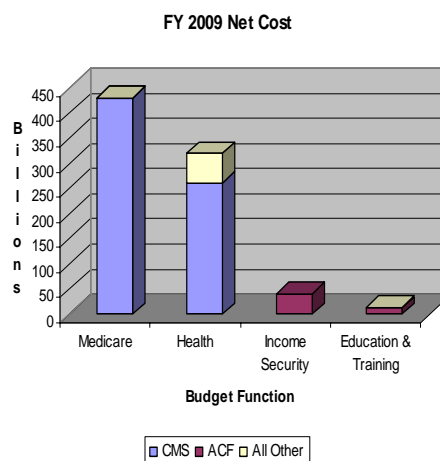
\$7.8 billion, or 9.0 percent above the prior year’s liabilities. Entitlement benefits due and payable to the public from the Medicare and Medicaid insurance programs represent 76.5 percent of the liabilities. The \$6.3 billion increase in FY 2009 entitlements include an increase of \$1.8 billion related to the Medicare program and an increase of \$4.6 billion related to the Medicaid program. Of the \$4.6 billion related to the Medicaid program, \$3.2 billion related to *Recovery Act* increases. 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.

Ending Net Position—What Have We Done Over Time?

Our net position represents the difference between assets and liabilities. Changes to our net position resulted from changes that occur within cumulative results of operations and unexpended appropriations. At the end of FY 2009, our net position was \$468.4 billion, an increase of \$25.7 billion or 5.8 percent from the previous year. Of the \$468.4 billion, \$340.3 billion was for earmarked funds and \$128.1 billion was for all other funds. The increase of \$25.7 billion was due to the net effect of an increase of \$34.0 billion in unexpended appropriations offset by a decrease of \$8.3 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 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, 2009 totalled \$803.9 billion. The chart to the right depicts HHS' FY 2009 net cost of operations by major budget function and component. The majority of our FY 2009 net costs relate to Medicare (\$430.0 billion) and Health (\$320.4 billion) programs, or nearly 93 percent of our annual costs.



The table below depicts our net cost of operations by major component for the last 5 years.

| <b>NET COST OF OPERATIONS<br/>(Dollars in Billions)</b> | <b>2005</b>    | <b>2006</b>    | <b>2007</b>    | <b>2008</b>    | <b>2009</b>    | <b>Chg</b>    | <b>% Chg</b> |
|---------------------------------------------------------|----------------|----------------|----------------|----------------|----------------|---------------|--------------|
| <b>Responsibility Segments</b>                          |                |                |                |                |                |               |              |
| Centers for Medicare and Medicaid Services (CMS)        |                |                |                |                |                |               |              |
| Gross Cost                                              | \$521.7        | \$574.2        | \$ 612.4       | \$657.9        | \$749.0        | \$91.1        | 13.8%        |
| CMS Exchange Revenue                                    | (38.1)         | (49.8)         | (50.3)         | (54.0)         | (57.3)         | (3.3)         | 6.1%         |
| CMS Net Cost of Operations                              | \$483.6        | \$524.4        | \$562.1        | \$603.9        | \$691.7        | 87.8          | 14.5%        |
| <b>Other Segments:</b>                                  |                |                |                |                |                |               |              |
| Other Segments Gross Cost of Operations                 | \$100.3        | \$102.2        | \$105.4        | \$108.3        | \$116.0        | \$7.7         | 7.1%         |
| Exchange Revenue                                        | (2.6)          | (2.7)          | (2.9)          | (3.1)          | (3.8)          | (0.7)         | 22.6%        |
| Other Segments Net Cost of Operations                   | \$97.7         | \$99.5         | \$102.5        | \$105.2        | \$112.2        | 7.0           | 6.7%         |
| <b>Net Cost of Operations</b>                           | <b>\$581.3</b> | <b>\$623.9</b> | <b>\$664.6</b> | <b>\$709.1</b> | <b>\$803.9</b> | <b>\$94.8</b> | <b>13.4%</b> |

The FY 2009 net cost represents an increase of \$94.8 billion or 13.4 percent more than the FY 2008 net cost. Approximately 86 percent of the net cost of operations relates to Medicare, Medicaid, State Children's Health Insurance Program (CHIP), and other health programs managed by the Centers for Medicare and Medicaid Services.

14.7 percent, over FY 2008. Fiscal year obligations of \$1.1 trillion increased \$136.1 billion, or 13.6 percent, over FY 2008. Resources at year-end were \$50.4 billion, of which \$9.3 billion were not available for expenditure. Total net outlays (cash disbursed for the Department's obligations) of \$797.3 billion increased \$96.3 billion or 13.7 percent from FY 2008 net outlays of \$701.0 billion.

**Budget Resources – What Were Our Resources and the Status of Funds?**

The Combined Statements of Budgetary Resources provide information on availability of budgetary resources and the status at the end of the year. Total resources of \$1.2 trillion for FY 2009 represented an increase of \$152.0 billion, or

**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 to be 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 2009, approximately \$375.8 billion or 98.6 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 45 million beneficiaries.

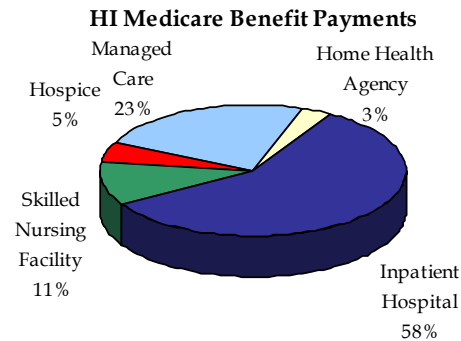
In December 2003, *Medicare Prescription Drug, Improvement & Modernization Act of 2003 (P.L. 108-173)* was enacted, which included the addition of a drug benefit (Part D). The Medicare Prescription Drug Benefit program represents the largest change to Medicare since its enactment in 1965, and FY 2007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

Hospital Insurance

Hospital Insurance (HI), or Medicare Part A, usually is 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 *FY 2010 President's Budget*, in-patient hospital spending accounted for roughly 58 percent of

HI benefit outlays in FY 2009 and managed care spending comprised about 23 percent. Total HI benefit outlays grew by 8.7 percent during 2009, and HI benefit outlays per enrollee grew by 6.9 percent, to \$5,220.

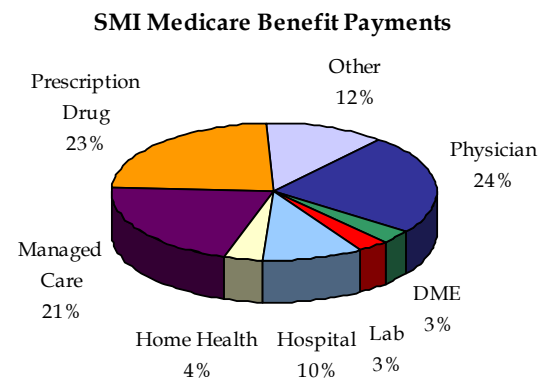


Source: CMS/OACT

Under the Trustees' intermediate set of assumptions, as displayed in the Statement of Social Insurance, as of January 1, 2009, the Hospital Insurance Trust Fund will incur an actuarial deficit of nearly \$13.8 trillion over the 75-year projection period, as compared with \$12.7 trillion in the FY 2008 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.



Source: CMS/OACT

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.

The 10-year spending projections for Medicare and Medicaid included in the Mid-Session Review of *FY 2010 President's Budget* remain unchanged from last year. Based on estimates from the *FY 2010 President's Budget*, SMI benefit outlays grew by 10.6 percent during FY 2009. Physician services, the largest component of SMI, accounted for 24 percent of SMI benefit outlays. During FY 2009, total SMI benefit outlay projections indicate an estimated increase of 8.8 percent, to \$6,000 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 program financing. The projected future expenditures for Part B will be \$23.2 trillion or \$2.0 trillion more than the FY 2008 projection. The projected future expenditures for Part D will be \$9.4 trillion, or \$.6 billion less than the FY 2008 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 INTERNAL CONTROLS

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 and our implementation of the Unified Financial Management System (UFMS).

### 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 UFMS serving the rest of our organization. The

core of these three components is a Financial Systems Integration Office (FSIO) federally certified commercial off-the-shelf financial management system.

During FY 2008, we completed the UFMS implementation at all of our operating divisions. The National Institutes of Health Business System has been deploying modules since 2004 and completed deployment of the electronic travel module in FY 2009. The Healthcare Integrated General Ledger Accounting System made significant progress during FY 2009 and 62 percent of its components have implemented. Full implementation of these three systems facilitates integration for our consolidated reporting and greatly enhances the goal of achieving a Department-wide concept.

During FY 2009, we began a phased approach to our consolidated reporting efforts. Beginning with the UFMS-served components, we developed the initial code, and performed limited consolidations. During FY 2010, we will continue our efforts, and expect to run parallel consolidation in the 3rd and 4th quarters. The consolidated reporting effort will continue through 2010.

### Statement on Auditing Standards (SAS) 70 Reviews

Independent examinations of HHS internal controls are completed annually. The auditors completed their examinations for our service providers for FY 2009 under the guidelines of the American Institute of Certified Public Accountants' Statement on Auditing Standards (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 2009, 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, 2008 to June 30, 2009. 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 CIT 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 2008 report, we discovered a potential *Anti-Deficiency Act* violation. Based on further management investigation and Office of General Counsel review, this matter is not considered a reportable item and is closed.

During FY 2009, several other potentially reportable items were discovered that are currently under investigation by management. As further information becomes available, management will review these matters with the Office of General Counsel to determine whether further reporting is required. We are committed to resolving these matters appropriately and complying with all aspects of the law.

### Improper Payments Information Act (IPIA)

The *Improper Payments Information Act of 2002* requires that the Department 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 *IPIA* requires that the Department report improper payment estimates and various other related data. During FY 2009, the Department made progress toward compliance with the *IPIA* by conducting reviews of its programs and activities and by continuing to develop and/or implement methodologies to estimate improper payments for several of its programs. Detailed information on the Department's *IPIA* activities is found in Section III of this document.



## INTERNAL CONTROLS

### 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

### Assurance for 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, which also constitutes a non-conformance under Section 4 of *FMFIA* as of September 30, 2009. Other than the exception noted above and described in Table I, the Department provides reasonable assurance that internal controls over operations and compliance with applicable laws and regulations as of September 30, 2009, were operating effectively and no other material weaknesses were found in the design or operation of these internal controls.

### Assurance for 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 of 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, 2009, relating to the Department's financial reporting systems and processes, which also constitutes a non-conformance under Section 4 of *FMFIA*. Other than the exception noted above and described in Table I, the internal controls over financial reporting as of June 30, 2009, were operating effectively and no other material weaknesses were found in the design or operation of the internal control over financial reporting.



Kathleen Sebelius

November 16, 2009

**Table I**  
**Summary of Material Weaknesses and System Non-Conformances**

| Control Area                              | FMFIA Section 2                 |                                 |                                          | FMFIA Section 4 |
|-------------------------------------------|---------------------------------|---------------------------------|------------------------------------------|-----------------|
|                                           | Operations<br>(As of 9/30/2009) | Compliance<br>(As of 9/30/2009) | Financial Reporting<br>(As of 6/30/2009) | Non-Conformance |
| Financial Reporting Systems and Processes | -                               | -                               | X                                        | X               |
| Information System Controls and Security  | X                               | -                               | -                                        | X               |

**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.

We completed the Unified Financial Management System (UFMS) implementation for all of our components and we are 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.

**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 ascertain that these findings warrant classification as a material weakness. 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 governance of the *Financial Information Security Management Act (FISMA)*.

**Table II**  
**Corrective Action Plan and Impact of Material Weaknesses**

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

| Material Weakness and Corrective Action Plan  | 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

HHS is 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. HHS manages 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 nearly 75,700 grants totaling more than \$264 billion in FY 2008. Collectively, these programs are our primary means to achieve our strategic goals and objectives, described in our *FY 2007-2012 Strategic Plan*, available at [www.hhs.gov/strategic\\_plan](http://www.hhs.gov/strategic_plan).

To achieve our goals, HHS forms partnerships with other Federal departments; State, local, and Tribal governments; academic institutions; hospitals; the business community; non-profit and volunteer organizations including faith-based and community-based organizations; and 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.

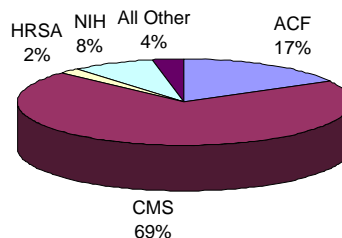
Last year, the Office of Grants implemented a grants forecast system for announcing potential areas for funding through grants, thereby assisting applicants in their yearly planning. Supporting these efforts is the Tracking Accountability in Government Grants System (TAGGS), a comprehensive Department-wide database with full search capabilities ([www.taggs.hhs.gov](http://www.taggs.hhs.gov)) for all awards, including grants and cooperative agreements. The TAGGS program also gathers agency data to comply with the *Federal Funding Accountability and Transparency Act of 2006* (P.L. 109-282) and forwards that data to the national program system. We continue to serve as the managing partner for [www.grants.gov](http://www.grants.gov), which is the Federal Government's central storehouse for information on more than 1,000 grant programs and access to approximately \$500 billion in annual awards.

We manage two types of grants: mandatory and discretionary. Mandatory programs are those that a Federal agency is required by statute to award if the eligible recipient submits an application that meets the program requirements. Discretionary grants permit the Federal Government, according to specific legislation, to exercise judgment in selecting the project or proposal to be supported and selecting the recipient organization. The Federal agency may use discretionary funds for both unsolicited proposals and those announced opportunities that require a competitive process.

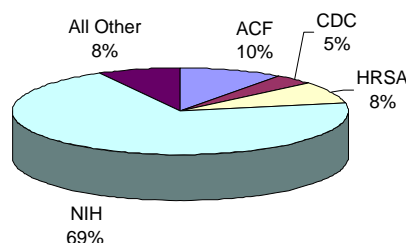
As in the case with prior years, most of our grants awards were discretionary (94 percent of total grant volume awarded), yet most dollars associated with Departmental grants were mandatory (85 percent of total dollars awarded).

The majority of our total FY 2008 grant dollars were awarded by the Centers for Medicare and Medicaid Services (69 percent) and the Administration for Children and Families (17 percent). By volume, the National Institutes of Health awarded 69 percent of the grants, whereas the Administration for Children and Families awarded 10 percent.

FY08 Grant Dollars by Component



FY08 Grant Volume by Component



## LOOKING AHEAD TO 2010— DEPARTMENT'S MANAGEMENT CHALLENGES AND HIGH-RISK AREAS -

### Financial Management Challenges

We are the largest agency in the Federal Government. Our FY 2009 direct budget authority of nearly \$841 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.

---

### *Recovery Act Challenges and Opportunities*

---

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

The transparency requirements of the *Recovery Act* have caused us to reconsider our financial management strategy and to review data repositories and reporting methods. The accountability provisions of the *Recovery Act* brought challenges and opportunities to better mitigate risks intrinsic to effective stewardship of taxpayer dollars.

The *Recovery Act* and its subsequent regulation require agencies to report data at a level previously unheard of in the Federal Government. In addition, the regulation requires regular program risk assessment and the development of risk mitigation strategies by program. These two challenges have become opportunities to drive improvements in financial management across the Department.

---

### *Strategic Planning*

---

During FY 2008, we achieved a financial management paradigm shift in the way HHS' Chief Financial Officer (CFO) Community works together to solve Departmental challenges, which resulted in the development of a *CFO Community Strategic Plan* to chart a course for the future. Rather than executing a traditional strategic planning exercise to develop individual, component-specific plans, the HHS CFO Community came together with an integrated perspective to build the foundation of a "strategic thinking" culture across our organization.

During FY 2009, we revised and enhanced our strategic planning process to incorporate the flexibility to address external events such as the *Recovery Act*. The guiding principles for the future of the CFO Community are:

- Conduct business in a cross-organizational, collaborative and transparent manner.
- Implement the strategic course for the future as outlined in the *CFO Community Strategic Plan*.
- Revisit the *CFO Community Strategic Plan* on a regular basis to ensure applicability to short- and long-term issues.
- Promote the value of financial accountability in supporting HHS' mission.

The process of the CFO Community pulling together in FY 2008 established the example for the Department, and enabled us to address the significant challenges related to the *Recovery Act*.

---

### *Corrective Action Plans*

---

In FY 2009, we continued our work on the corrective action plans developed in FY 2008. In addition, we discovered while implementing the *Recovery Act* that we could strategically improve the same corrective actions to incorporate the newly identified risks and challenges.

We also continued our focus upon those strategic goals and objectives supporting our strategic plan in FY 2009. We maintained our FY 2008 process whereby key Department financial managers collaborated to address key management challenges across the organization, leveraging capabilities to improve our business processes. Although much work remains, we expect to continue strengthening controls in the years ahead.

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

### **Program Challenges**

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

The enactment of the *Recovery Act* required us to release millions of dollars rapidly to State and local recipients to improve the lives of Americans through protection of health coverage, improved public health, and targeted needed assistance to families who struggled during the economic downturn. In FY 2009, we obligated \$49.0 billion, or 76.3 percent of the \$64.2 billion in FY 2009 *Recovery Act* budget authority. Total expenditures of \$35.1 billion, represented 79.1 percent of the \$44.4 billion in total *Recovery Act* gross outlays.

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. The full text of the Inspector General's assessment and HHS management's response to these challenges are presented 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 2009 *Management's Report on Final Action*.

## SUMMARY OF TOP MANAGEMENT CHALLENGES IDENTIFIED BY THE INSPECTOR GENERAL

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

| 1. Integrity of Provider and Supplier Enrollment                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 2. Integrity of Federal Health Care Program Payment Methodologies                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 3. Promoting Compliance With Federal Health Care Program Requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>Medicare and Medicaid programs draw individuals and other groups wishing to exploit the health care system for their own financial gain.</p> <p>Challenges include:</p> <ul style="list-style-type: none"> <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>• Examining payments under Medicare Part D to determine whether risk-sharing percentages are appropriate;</li> <li>• Exploring changes in the marketplace and medical practices so that programs continue to effectively reimburse for quality care; 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; and</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.</li> </ul>                                                                                                                    |
| 4. Oversight and Monitoring of Federal Health Care Programs                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 5. Response to Fraud and Vulnerabilities in Federal Health Care Programs                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | 6. 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; and</li> <li>• Enhancing the availability of data to monitor payment accuracy and integrity across Medicare Parts A, B, C, and D and Medicaid.</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 due to limited responses; and</li> <li>• Responding to detected vulnerabilities by suspending payments to providers upon credible evidence of fraud.</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 with 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; and</li> <li>• Working with various types of health care providers to ensure they are knowledgeable about and consistently implement quality improvement processes.</li> </ul> |



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

| 7. Emergency Preparedness and Response                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 8. Oversight of Food, Drugs, and Medical Devices                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | 9. Grants Management                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>Events like the recent 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 that includes 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>● Improving 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>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>● 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>HHS is 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.</p> <p>Challenges include:</p> <ul style="list-style-type: none"> <li>● Monitoring of grants management because of the size and scope of grant expenditures;</li> <li>● Ensuring the appropriate use of grants funds; and</li> <li>● Making sure of the integrity of the grants award processes and grantee compliance with program requirements.</li> </ul> |

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

| 10. American Recovery and Reinvestment Act.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 11. Health Information Technology and Integrity of Information Systems                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 12. Ethics Program Oversight and Enforcement                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <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 \$787 billion over 10 years. 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; and</li> <li>● Developing systems associated with <i>Recovery Act</i> reporting requirements, which includes educating recipients about those reporting requirements as well as providing program performance information.</li> </ul> | <p>The development and implementation of interoperable health IT has become a national priority. HHS 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>● Enacting components of the <i>Health Information Technology for Economic and Clinical Health (HITECH)</i> Act to promote the use of health IT;</li> <li>● Ensuring the confidentiality, integrity, and availability of critical systems and data; and</li> <li>● Proving oversight and monitoring of security controls of HHS’ 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 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> |