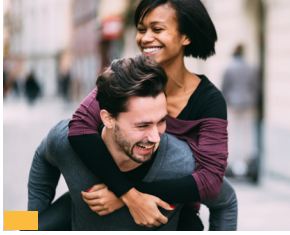
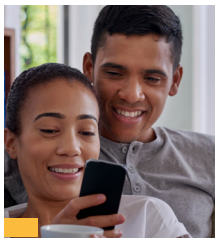
Department of Health and Human Services

Advancing the health, safety, and well-being of the nation



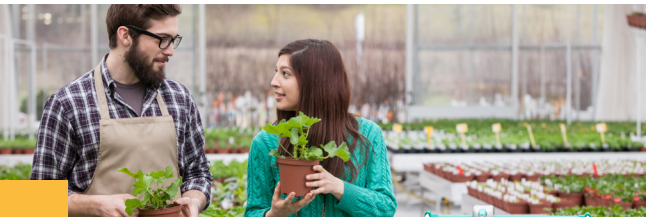










FY 2016

Agency Financial Report

Certificate of Excellence in Accountability Reporting

In May 2016, the U.S. Department of Health and Human Services (HHS) received the Certificate of Excellence in Accountability Reporting (CEAR) from the Association of Government Accountants (AGA) for its Fiscal Year (FY) 2015 Agency Financial Report. The CEAR Program was established by the AGA in collaboration with the Chief Financial Officers Council and the U.S. Office of Management and Budget to further performance and accountability reporting. Through the program, agencies improve accountability by streamlining reporting and improving the effectiveness of such reports to clearly show what an agency accomplished with taxpayer dollars and the challenges that remain. FY 2015 marked the third consecutive year the Department received this prestigious award.

AGA also presented HHS with a Best in Class Award for the Best Improper Payments Elimination and Recovery Act Detail.

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An electronic copy of the FY 2016 *Agency Financial Report* is available at: www.hhs.gov/afr

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MESSAGE FROM THE SECRETARY

Sylvia M. Burwell

Our mission at the U.S. Department of Health and Human Services (HHS) is to enhance and protect the health and well-being of all Americans. We fulfill that mission by providing effective services and fostering advances in medicine, public health, and social services. We are committed to ensuring that every American has access to the building blocks for healthy and productive lives.

I am pleased to present HHS's Fiscal Year 2016 Agency Financial Report. This report highlights our major accomplishments, illustrates how we manage our resources, and outlines our plans to address the challenges we face. At HHS, we are dedicated to meeting high standards of government reporting and accountability.

HHS administers more than 300 programs that enhance the well-being of others. The HHS FY 2014-2018 Strategic Plan helps guide the Department's programs within the context of four strategic goals:

- Strengthen health care
- Advance scientific knowledge and innovation
- Advance the health, safety and well-being of the American people
- Ensure efficiency, transparency, accountability and effectiveness of HHS programs

Together, these goals form our vision for how HHS can contribute to a stronger, healthier, and more prosperous America, both today and for many years to come.

FY 2016 Significant Activities

The provisions of the *Affordable Care Act*, and our efforts to strengthen our health care system, have helped an estimated 20 million people gain health coverage since the passage of the law in 2010, a historic reduction in the uninsured. We are committed to reaching even more Americans during the fourth open enrollment of the Health Insurance Marketplace and making it easier for them to access affordable, quality health coverage. Today, no American can be denied health coverage because of a pre-existing condition, young adults can stay on a parent's plan until they turn 26, and we have strengthened the quality of coverage.

We are also committed to advancing the health, safety, and well-being of the American people by detecting global health threats early, responding quickly, working with partners across the globe, and building the capacity necessary to deal with these threats. This commitment, and our network of global partners, helped to resolve the Ebola crisis, and it is guiding our efforts to fight the Zika virus today.

More than 50 countries and territories have active Zika virus transmission, and in February 2016, the World Health Organization declared that the clusters of microcephaly and other neurological complications associated with the Zika virus constituted a Public Health Emergency of International Concern. Tens of thousands of Zika cases have been reported in the United States and its territories, including thousands of pregnant women who are at particular risk because of the severe birth defects that Zika infection can cause. HHS is working with states and territories to improve mosquito control and increase laboratory capacity, and working with private sector partners to accelerate the development of diagnostic tests as well as a Zika vaccine. Researchers at the National Institutes of Health have been working tirelessly to develop a safe and effective Zika vaccine, and thanks to their work, NIH recently began human trials of a vaccine candidate – an important milestone they reached nearly a decade faster than with typical vaccines. It will take some time before a vaccine is commercially available, but the launch of this study is an important step forward.

To better serve the American people, we need to constantly search for new ideas and innovative ways to improve

how we do business. That is where the HHS Innovation, Design, Entrepreneurship and Action (IDEA) Lab comes in. The IDEA Lab promotes the use of innovation across HHS, taking advantage of the talent of the workforce at HHS and removing the barriers that stand in their way. One of the greatest impacts we have seen has come from the Health Data Initiative, which aims to improve health and the delivery of human services by harnessing the power of data in public and private sector institutions, communities, and research groups. The initiative has liberated more than 2,100 health data sets, helping to power the growth of the health care start-up ecosystem. Unlocking health care data and information is part of the Department's strategy to build a health care delivery system that is better, smarter, and healthier and ultimately puts patients in the center of their care.

Financial Management

As responsible stewards of the resources the American taxpayers and Congress entrust to us, one of our most important duties is to practice fiscal responsibility and transparency. To that end, our independent Department-wide financial statement audit is one of our most important tools. This year, we obtained an unmodified (clean) opinion on the Consolidated Balance Sheets, Statement of Net Cost, Statement of Changes in Net Position, and the Combined Statement of Budgetary Resources. The auditors disclaimed providing an opinion on the Statement of Social Insurance and the Statement of Changes in Social Insurance Amounts, primarily due to the uncertainties surrounding provisions of the *Affordable Care Act* and the impact of potential changes in law that would impact underlying assumptions of financial projections. These statements were developed based upon current law using information from the *2016 Medicare Trustees Report*, as required by standards issued by the Federal Accounting Standards Advisory Board. The "Financial Section" of this report includes more detailed information.

As required by the *Federal Managers' Financial Integrity Act of 1982* (FMFIA) and the Office of Management and Budget's Circular A-123, *Management's Responsibility for Enterprise Risk Management and Internal Control*, we also evaluated our internal controls and financial management systems. We identified one material weakness relating to Information System Controls and Security. We also identified two material noncompliances relating to Error Rate Measurement and the Medicare appeals process. Our senior leadership continues efforts to improve our financial reports and systems. The "Management's Discussion and Analysis" section of this report includes further details. Based on our internal assessments and the auditors' report, I believe that our financial and performance data are reliable and complete.

Management Opportunities and Challenges

Despite our successes, HHS still faces opportunities for improvement. We have worked closely with the Office of Inspector General to gain its perspective about our most significant management and performance challenges, which are presented in the "Other Information" section under *FY 2016 Top Management and Performance Challenges Identified by the Office of Inspector General*. The HHS Inspector General identified 10 performance challenges that present opportunities for improvement. These challenges, which we are committed to overcoming, include delivering quality services and benefits, exercising sound fiscal management, safeguarding public health and safety, and enhancing cybersecurity.

Conclusion

As it has for many decades now, our Department will continue to protect the health and well-being of the American people, and of people around the globe. I have no doubt that well after this Administration concludes, the dedicated public servants here at HHS will continue to strengthen existing relationships and forge new ones with people and organizations committed to helping Americans access the building blocks for healthy and productive lives. I look forward to seeing the impact that HHS will deliver for many decades to come.

/Sylvia M. Burwell/

Sylvia M. Burwell
Secretary
November 14, 2016

ABOUT THE AGENCY FINANCIAL REPORT

The HHS FY 2016 AFR provides fiscal and summary performance results that enable the President, Congress, and the American people to assess our accomplishments for the reporting period October 1, 2015, through September 30, 2016. This report provides an overview of our programs, accomplishments, challenges, and management's accountability for the resources entrusted to us. We prepared this report in accordance with the requirements of the Office of Management and Budget (OMB) Circular A-136, *Financial Reporting Requirements.* This document consists of three primary sections and appendices:

Section 1: Management's Discussion and Analysis

The Management's Discussion and Analysis section provides an overview of the Department's performance and financial information. It introduces its mission, and describes the Department's organizational structure. This section highlights HHS's goals and priorities and summarizes the results for select key performance measures. It also highlights the Department's financial results and provides management's assurances on HHS's internal controls.

Section 2: Financial Section

The Financial Section begins with a message from the Chief Financial Officer. It details the Department's finances and includes the audit transmittal letter from the Inspector General, the independent auditors' report, and the principal financial statements and notes. The required supplementary information included in this section provides the Combining Statement of Budgetary Resources, and Deferred Maintenance and Repairs, and Social Insurance information.

Section 3: Other Information

The Other Information section begins with the Combined Schedule of Spending, Freeze the Footprint baseline square footage cost and data, and Civil Monetary Penalty Adjustment for Inflation information. It also includes the Improper Payments Information Act Report, a summary of the results of the Department's financial statement audit and management assurances, and the Inspector General's assessment of the Department's management and performance challenges.

Appendices

The appendices include data that support the main sections of the AFR. This includes a glossary of acronyms used in the report and resources for connecting with the Department.

The Department has chosen to produce an AFR and *Annual Performance Plan and Report*. In February 2017, additional reports that will be available on HHS/About HHS/Budget & Performance (www.hhs.gov/about/budget) include:

1. FY 2018 *Annual Performance Plan and Report*
2. FY 2018 *Congressional Budget Justification*

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Management's Discussion and Analysis

1

In This Section

- About the Department of Health and Human Services
- Performance Goals, Objectives, and Results
- Systems, Legal Compliance, and Internal Control
- Management Assurances
- Looking Ahead to 2017
- Financial Summary and Highlights

Did you know?

This year marks the Centers for Disease Control and Prevention's (CDC) 70th Anniversary. For 70 years, CDC has put proven science into action to keep Americans safe from health threats. Its forerunner, the Communicable Disease Center was established on July 1, 1946, focusing on the fight against malaria. Today, CDC is the nation's premier promotion, disease prevention and emergency preparedness agency and a global leader in public health.

CDC, circa 1946

CDC Today

HHS Historical Highlights

1798 — A federal network of hospitals for the care of merchant seamen, forerunner to today's U.S. Public Health Service, was established by the passage of an act for the relief of sick and disabled seamen.

1862 — President Lincoln appointed a chemist to serve in the new Department of Agriculture. This was the beginning of the Bureau of Chemistry, forerunner to the Food and Drug Administration.

1871 — The first Supervising Surgeon (later called the Surgeon General) for the Marine Hospital service was appointed.

1887 — The federal government opened a one-room laboratory on Staten Island for research on disease, a very early forerunner to the National Institutes of Health.

1921 — The Bureau of Indian Affairs Health Division, forerunner to the Indian Health Service, was created.

1930 — The National Institute (later Institutes) of Health was created out of the Public Health Service's Hygienic Laboratory.

1946 — Communicable Disease Center was established, forerunner to the Centers for Disease Control and Prevention.

1953 — The Department of Health, Education, and Welfare was created under President Eisenhower.

ABOUT THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

Mission Statement

The mission of the United States (U.S.) Department of Health and Human Services (HHS) is to enhance the health and well-being of Americans by providing for effective health and human services and by fostering sound, sustained advances in the sciences, underlying medicine, public health, and social services.

Vision Statement

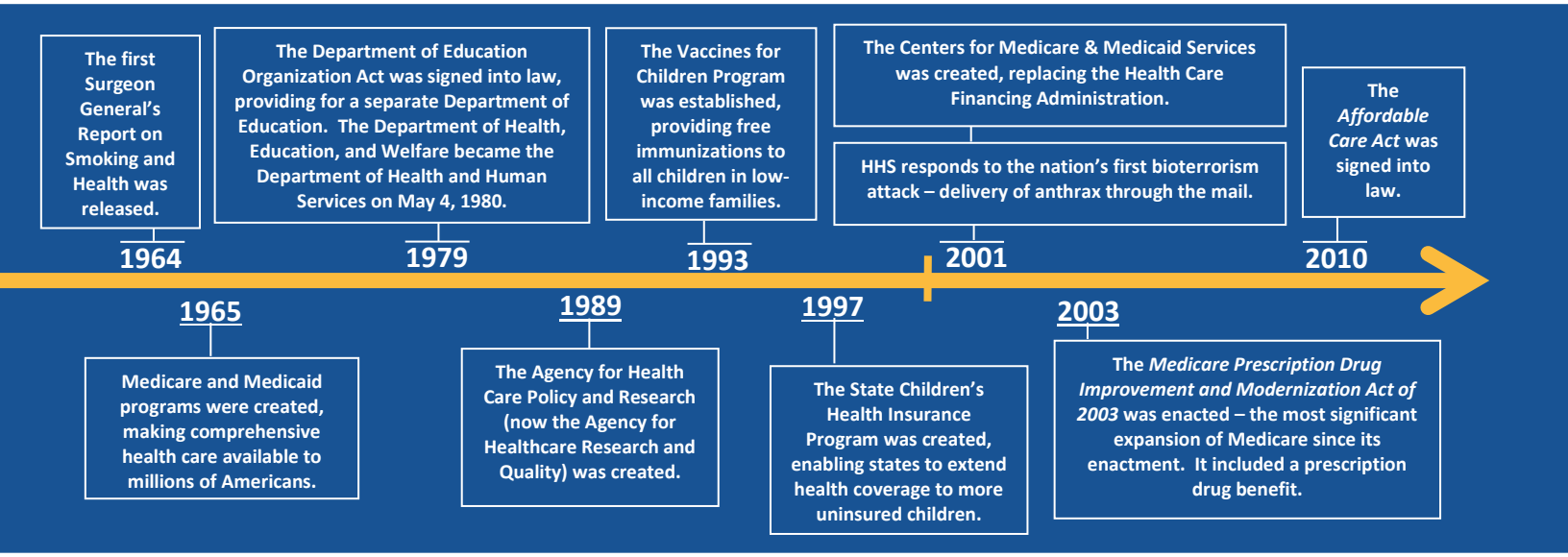
The vision of HHS is to provide the building blocks that Americans need to live healthy, successful lives.

Purpose

HHS is the U.S. government's principal agency for protecting the health of all Americans, providing essential human services, and promoting economic and social well-being for individuals, families, and communities, including seniors and individuals with disabilities. HHS is responsible for almost a quarter of all federal outlays and administers more grant dollars than all other federal agencies combined. HHS's Medicare program is the nation's largest health insurer, handling more than one billion claims per year. Medicare and Medicaid together provide health care insurance for 1 in 3 Americans.

HHS works closely with state and local governments, and many HHS-funded services are provided at the local level by state or county agencies, or through private sector grantees. The HHS Office of the Secretary and its 11 Operating Divisions (OpDivs) administer more than 300 programs covering a wide spectrum of activities. In addition to the services they deliver, HHS programs provide for equitable treatment of beneficiaries nationwide and enable the collection of national health and other data. HHS, through its programs and partnerships:

- Provides health care coverage to more than 100 million people through Medicare, Medicaid, the Children's Health Insurance Program, and the Health Insurance Marketplace;
- Promotes patient safety and health care quality in health care settings and by health care providers, by assuring the safety, effectiveness, quality, and security of foods, drugs, vaccines, and medical devices;



- Eliminates disparities in health, as well as health care access and quality, and protects vulnerable individuals and communities from poor health and human services outcomes;
- Conducts health and social science research with the largest source of funding for medical research in the world, while creating hundreds of thousands of high-quality jobs for scientists in universities and research institutions in every state across America and around the globe;
- Leverages health information technology to improve the quality of care and to use HHS data to drive innovative solutions to health, public health, and human services challenges;
- Improves maternal and infant health; promotes the safety, well-being, and healthy development of children and youth; and supports young people's successful transition to adulthood;
- Promotes economic and social well-being for individuals, families, and communities, including seniors and individuals with disabilities;
- Supports wellness efforts across the life span, from protecting mental health, to preventing risky behaviors such as tobacco use and substance abuse, to promoting better nutrition and physical activity;
- Prevents and manages the impacts of infectious diseases and chronic diseases and conditions, including the top causes of disease, disability, and death;
- Prepares Americans for, protects Americans from, and provides comprehensive responses to health, safety, and security threats, both foreign and domestic, whether natural or man-made; and
- Serves as responsible stewards of the public's investments.

Organizational Structure

HHS's organizational structure is designed to accomplish its mission and provide a framework for sound business operations and management controls. The Office of the Secretary, with the Secretary, provides the overarching vision and strategic direction for the Department, and leads HHS and its 11 OpDivs to provide a wide range of services and benefits to the American people. Each OpDiv contributes to our mission and vision as follows:

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. ACF programs aim to empower families and individuals to increase their economic independence and productivity, and encourage strong, healthy, supportive communities that have a positive impact on quality of life and the development of children. For more information, visit www.acf.hhs.gov.

Administration for Community Living (ACL) was created around the fundamental principle that all people, regardless of age or disability, should be able to live where they choose, with the people they choose, and fully participate in their communities. By advocating for older adults and people with disabilities, and the families and caregivers of both across the federal government; funding services and supports provided by networks of community-based organizations; and investments in research and innovation, ACL helps makes this principle a reality for millions of Americans. For more information, visit www.acl.gov.

Agency for Healthcare Research and Quality (AHRQ) produces evidence to make health care safer, higher quality, more accessible, equitable, and affordable, and to work within HHS and with other partners to make sure that the evidence is understood and used. This mission is supported by focusing on (1) improving health care quality, (2) making health care safer, (3) increasing accessibility, and (4) improving health care affordability, efficiency, and cost transparency. For more information, visit www.ahrq.gov.

Agency for Toxic Substances and Disease Registry (ATSDR) is charged with the prevention of exposure to toxic substances and the prevention of the adverse health effects and diminished quality of life associated with exposure to hazardous substances from waste sites, unplanned releases, and other sources of pollution present in the environment. For more information, visit www.atsdr.cdc.gov.

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. CDC works to protect America from health, safety, and security threats, both foreign and domestic. Whether diseases start at home or abroad, are chronic or acute, curable or preventable, human error or deliberate attack, CDC fights diseases and supports communities and citizens to do the same. For more information, visit www.cdc.gov.

Centers for Medicare & Medicaid Services (CMS) administers public insurance programs that serve as the primary sources of health care coverage for seniors and a large population of medically vulnerable individuals. CMS acts as a catalyst for enormous changes in the availability and quality of health care for all Americans. In addition to these programs, CMS has the responsibility to ensure effective, up-to-date health care coverage, and to promote quality care for beneficiaries. CMS is also responsible for helping to implement many provisions of the *Patient Protection and Affordable Care Act* (*Affordable Care Act*), such as the establishment of the Federally Facilitated Marketplace. For more information, visit www.cms.gov.

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.

FDA is also responsible for advancing the public health by helping to speed innovations that make medicines more effective, safer, and more affordable and by helping the public get the accurate, science-based information it needs to use medicines and foods to maintain and improve their health. FDA also has responsibility for regulating the manufacturing, marketing, and distribution of tobacco products to protect the public health and to reduce tobacco use by minors.

Finally, FDA plays a significant role in the nation's counterterrorism capability. FDA fulfills this responsibility by ensuring the security of the food supply and by fostering development of medical products to respond to deliberate and naturally emerging public health threats. For more information, visit www.fda.gov.

Health Resources and Services Administration (HRSA) is responsible for improving access to health care by strengthening the health care workforce, building healthy communities, and achieving health equity. HRSA's programs provide health care to people who are geographically isolated, and economically, or medically vulnerable. For more information, visit www.hrsa.gov.

Indian Health Service (IHS) is responsible for providing federal health services to American Indians and Alaska Natives. The provision of health services to members of federally recognized tribes grew out of the special government-to-government relationship between the federal government and Indian tribes. IHS is the principal federal health care provider and health advocate for the Indian people, with the goal of raising Indian health status to the highest possible level. IHS provides a comprehensive health service delivery system for approximately 2.2 million American Indians and Alaska Natives who belong to 567 federally recognized tribes in 36 states. For more information, visit www.ihs.gov.

National Institutes of Health (NIH) seeks fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability. For more information, visit www.nih.gov.

Substance Abuse and Mental Health Services Administration (SAMHSA) is responsible for reducing the impact of substance abuse and mental illness on America's communities. SAMHSA accomplishes its mission by providing leadership, developing service capacity, communicating with the public, setting standards, and improving behavioral health practice in communities, in both primary and specialty care settings. For more information, visit www.samhsa.gov.

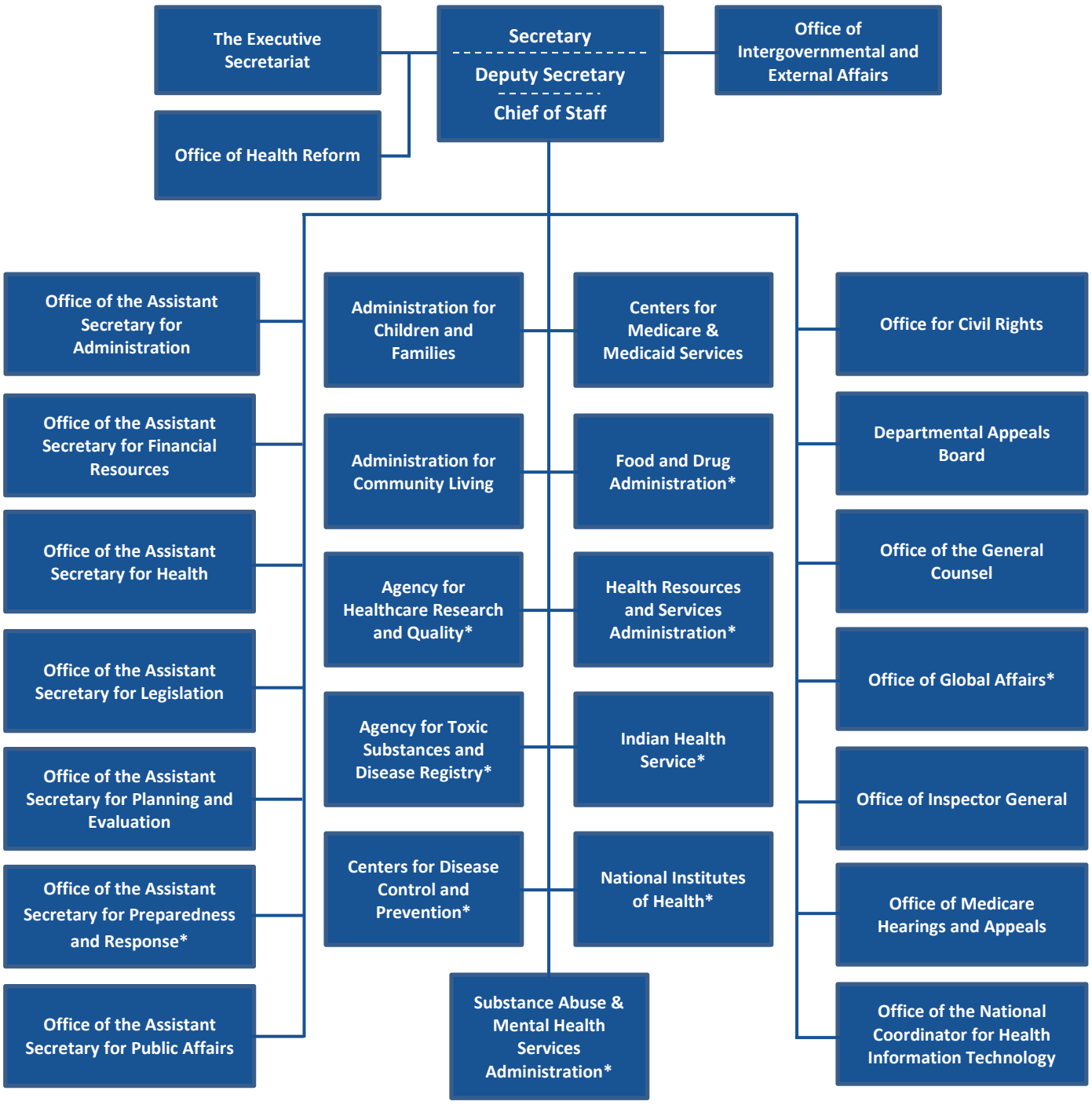
In addition, the following Staff Divisions (StaffDivs) report directly to the Secretary, managing programs and supporting the OpDivs in carrying out the Department's mission. The primary goal of the Department's StaffDivs is to provide leadership, direction, and policy and management guidance to the Department. The StaffDivs are:

- Immediate Office of the Secretary (www.hhs.gov/about/agencies/staff-divisions/immediate-office-secretary)
  - The Executive Secretariat (www.hhs.gov/about/agencies/staff-divisions/immediate-office-secretary/executive-secretariat/index.html)
  - Office of Health Reform
  - Office of Intergovernmental and External Affairs (www.hhs.gov/about/agencies/iea/index.html)
- Office of the Assistant Secretary for Administration (www.hhs.gov/asa/index.html)
  - Program Support Center (www.psc.gov/)
- Office of the Assistant Secretary for Financial Resources (www.hhs.gov/about/agencies/asfr/index.html)
- Office of the Assistant Secretary for Health (www.hhs.gov/ash)
- Office of the Assistant Secretary for Legislation (www.hhs.gov/asl/)
- Office of the Assistant Secretary for Planning and Evaluation (www.aspe.hhs.gov/)
- Office of the Assistant Secretary for Preparedness and Response (www.phe.gov/about/pages/default.aspx)
- Office of the Assistant Secretary for Public Affairs (www.hhs.gov/about/agencies/aspa/index.html)
- Office for Civil Rights (www.hhs.gov/ocr)
- Departmental Appeals Board (www.hhs.gov/dab/)
- Office of the General Counsel (www.hhs.gov/about/agencies/ogc/index.html)
- Office of Global Affairs (www.hhs.gov/about/agencies/oga)
- Office of Inspector General (www.oig.hhs.gov/)
- Office of Medicare Hearings and Appeals (www.hhs.gov/about/agencies/omha/index.html)
- Office of the National Coordinator for Health Information Technology (www.healthit.gov/newsroom/about-onc)

The HHS organizational chart, which consists of the Office of the Secretary and the noted StaffDivs and OpDivs, is presented on the next page. For further information regarding our organization, components, and programs, visit our website at www.hhs.gov.

Office of the Assistant Secretary for Preparedness and Response operations experts prepare for Hurricane Matthew.

ABOUT THE DEPARTMENT OF HEALTH AND HUMAN SERVICES



*Component of the Public Health Service

PERFORMANCE GOALS, OBJECTIVES, AND RESULTS

Overview of Strategic and Agency Priority Goals

Every 4 years HHS updates its strategic plan, which describes its work to address complex, multifaceted, and evolving health and human services issues. An agency strategic plan is 1 of 3 main elements required by the *Government Performance and Results Act of 1993* (GPRA) and the *GPRA Modernization Act of 2010*. The Department's Strategic Plan (Plan) defines its mission, goals, and the means by which it will measure its progress in addressing specific national problems over a four-year period. In addition, each of the Department's OpDivs and StaffDivs contribute to the development of the strategic plan, as reflected in the Plan's strategic goals, objectives, strategies, and performance goals.

Strategic Goals

The HHS Strategic Plan FY 2014 – 2018 (www.hhs.gov/about/strategic-plan/index.html) describes the Department's efforts within the context of broad strategic goals. This Plan identifies 4 strategic goals and 21 related objectives. The four strategic goals are:

Goal 1: Strengthen Health Care

Goal 2: Advance Scientific Knowledge and Innovation

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

Goal 4: Ensure Efficiency, Transparency, Accountability, and Effectiveness of HHS Programs

The strategic goals and associated objectives focus on the major functions of HHS. Although the strategic goals and objectives in the Plan are presented as separate sections, they are interrelated, and successful achievement of one strategic goal or objective can influence the success of others. For example, the application of a promising new scientific discovery (Strategic Goal 2) can affect the quality of health care patients receive (Strategic Goal 1) and/or the success of human service programs (Strategic Goal 3). Improving economic well-being and other social determinants of health (Strategic Goal 3) can improve health outcomes (Strategic Goal 1). Responsible management and stewardship of federal resources (Strategic Goal 4) can create efficiencies the Department can leverage to advance its health, public health, research, and human services goals. For the third consecutive year, HHS conducted an annual Strategic Review, which consisted of various senior Department leaders reviewing performance data, evidence, and other factors for the 21 objectives. The annual review allows HHS leadership to undertake a high-level look at results, challenges, and future initiatives across the Department.

Agency Priority Goals

HHS uses Agency Priority Goals (APGs) to improve performance and accountability. HHS developed APGs by collaborating across the Department to identify activities that would reflect HHS priorities and benefit from the focus of the APG process. These goals are a set of ambitious but realistic performance objectives that the Department will strive to achieve within a 24-month period. For FY 2016 – FY 2017, HHS developed a new set of APGs. Altogether, these APGs involve work from 14 OpDivs and StaffDivs, combined. HHS is currently engaged in the following APGs that support the achievement of our strategic goals:

APG 1: Shift Medicare health care payments from volume to value

APG 2: Improve the quality of early childhood programs for low-income children

APG 3: Improve the timeliness of initiation into treatment for individuals with serious mental illness
APG 4: Combating antibiotic-resistant bacteria
APG 5: Reduce opioid-related morbidity and mortality
APG 6: Reduce foodborne illness
APG 7: Reduce the annual adult combustible tobacco consumption in the U.S.

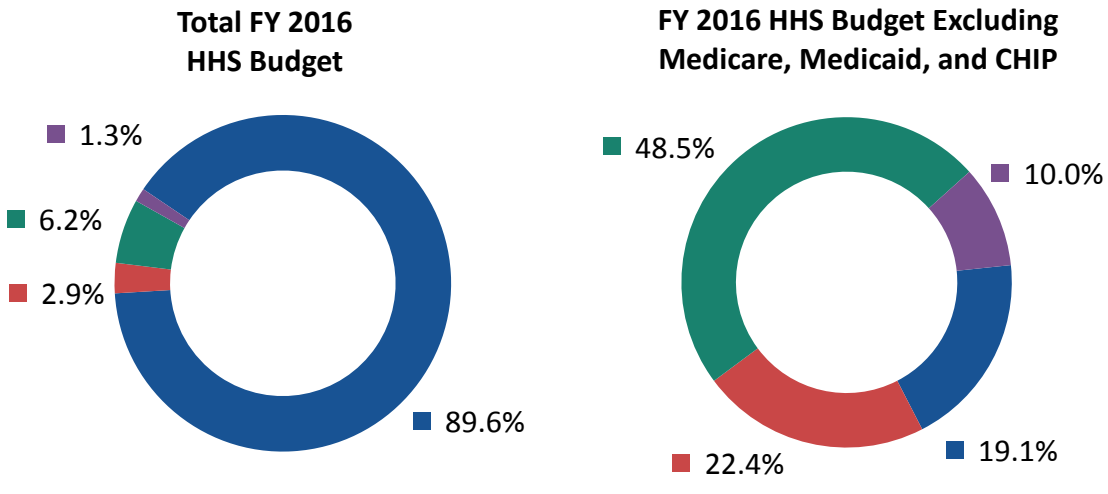
The knowledge gained through collaboration and during data-driven reviews has supported the development of our APGs. For more information on HHS's APGs, please visit Performance.gov (www.performance.gov/agency/department-health-and-human-services?view=public#apg). HHS performance initiatives, including APGs, continue to influence plans and policies as demonstrated in the Department's Strategic Plan, which guides our efforts into the future.

Looking Back at FY 2016 Performance and Budget

It is helpful to look at how HHS invests resources toward fulfilling the Department's mission through its strategic goals. Below are two charts that show the proportion of financial resources that are primarily dedicated to achieving each strategic goal.

Although HHS funding is categorized here by strategic goals, many of the programs in HHS are crosscutting in nature and support a number of strategic goals. The chart on the left provides the breakdown of the HHS budget by strategic goal. The majority of the Department's funding was primarily associated with Goal 1 because of the large amount of money invested in delivering quality care and services through Medicare, Medicaid, and the Children's Health Insurance Program (CHIP). For FY 2016, of the four strategic goals, 89.6 percent of funding was spent on Goal 1, 2.9 percent on Goal 2, 6.2 percent on Goal 3, and 1.3 percent on Goal 4.

The chart on the right illustrates the HHS FY 2016 budget excluding the costs of Medicare, Medicaid, and CHIP. Of the four strategic goals excluding Medicare, Medicaid, and CHIP, 19.1 percent was spent on Goal 1, 22.4 percent on Goal 2, 48.5 percent on Goal 3, and 10.0 percent on Goal 4.



Performance Management

HHS continues to engage with individuals across the federal performance management community to implement best practices and refine processes. These refinements and lessons learned have also influenced future plans and priorities. Refer to the "Looking Ahead to 2017" section for further details. HHS will actively monitor progress and work toward achieving our APGs through quarterly data-driven reviews and other mechanisms. The most recent data, accomplishments, and future actions on HHS APGs as well as information on previous APG cycles, can be found on Performance.gov (www.performance.gov/agency/department-health-and-human-services). The website provides information on the measures and milestones used by HHS to track progress toward these goals.

In addition to the APGs and strategic reviews, HHS reported data on 144 performance measures in its FY 2017 *HHS Annual Performance Plan and Report*. These measures represent important issue areas being addressed by the health care and human services communities. The performance measures present a powerful tool to improve HHS operations and help to advance an effective, efficient, and productive government. HHS regularly collects and analyzes performance data to inform decisions. While HHS does not yet have FY 2016 data available for all measures due to the lag associated with data collection and reporting of results in the FY 2016 AFR, HHS's OpDivs and StaffDivs constantly strive to find lower-cost ways to achieve positive impacts in addition to sustaining and fostering the replication of effective and efficient government programs. For more information on results from FY 2016 and earlier, please consult the *HHS Annual Performance Plan and Report* (www.hhs.gov/about/budget/fy2017/performance/index.html), released annually along with the *President's Budget*.

Performance Results

The performance results in this section represent key measures and performance highlights demonstrating progress toward each HHS strategic goal.

The accomplishments and performance trends, including progress on HHS APGs, underscore HHS's dedication to sustained performance improvement and emphasis on working to meet the Department's four strategic goals. Targets presented within the tables represent performance expectations based on a number of factors and may not exceed the previous years' results, although they may represent an improvement over previous years' targets. The status row within each performance measure table indicates whether or not targets that were met or exceeded for the applicable period. Some results were not available at the time of this report due to the lag associated with data collection requirements. The target is displayed to show planned progress. More updated information will be available in the *FY 2018 Annual Performance Plan and Report* (www.hhs.gov/about/budget).

Strategic Goal 1
Strengthen Health Care

Objectives

- **1.A. Make coverage more secure for those who have insurance and extend affordable coverage to the uninsured**
- **1.B. Improve health care quality and patient safety**
- **1.C. Emphasize primary and preventive care, linked with community prevention services**
- **1.D. Reduce the growth of health care costs while promoting high-value, effective care**
- **1.E. Ensure access to quality, culturally competent care, including long-term services and support, for vulnerable populations**
- **1.F. Improve health care and population health through meaningful use of health information technology**

Strategic Goal 1: Strengthen Health Care

The intent of the *Affordable Care Act* was to transform and modernize the American health care system. As 2016 draws to a close, HHS continues to drive the effort to strengthen and modernize health care to improve patient outcomes. Through its programs, HHS also promotes efficiency and accountability, ensures patient safety, encourages shared responsibility, and works toward high-value health care. In addition to addressing these responsibilities, HHS is improving access to culturally competent, quality health care for uninsured, underserved, and vulnerable populations.

Health Care Payment Reform. To build a health care system that delivers better care, that is smarter about how dollars are spent, and that makes people healthier, the *Affordable Care Act* created a number of new programs and payment models with goals of rewarding value and quality. These models include Accountable Care Organization models, medical home models focused on primary care, and new models of bundling payments for episodes of care. In these alternative payment models, health care providers are accountable for the quality and cost of the care they deliver to patients and have a financial incentive to coordinate care for their patients – who are therefore more likely to receive high quality, team-based care. In March 2016, HHS announced that we were on track to meet the 2016 target ahead of schedule. However, HHS cannot calculate the percentage of Medicare Fee-For-Service (FFS) payments tied to quality and value until reconciled claims data are available 9 months after the end of each calendar year, leading to the significant time gap between the end of the calendar year and when results are available.

APG 1 – Shift Medicare health care payments from volume to value
Performance Measure: Percent of Medicare FFS payments tied to Quality and Value in Alternative Payment Models
Unit of Measurement: Percent

	2012	2013	2014	2015	2016	2017
Target			-	26%	30%	40%
Result			22%	Nov 30, 2016	Nov 30, 2017	Nov 30, 2018
Status			Baseline	Pending	Pending	Pending

Serious Mental Illness. Individuals with serious mental illness are a high-need, high-cost population. They are frequent utilizers of emergency departments and have high rates of readmission to inpatient care, especially when co-occurring substance use disorders are present. In addition, people with serious mental illness often have co-morbid physical health conditions and shorter life expectancies than people without serious mental illness, primarily due to co-occurring physical health conditions that too often go unaddressed. Individuals with serious mental illness often experience barriers to treatment, including difficulty accessing and initiating treatment. Significant delays in the identification and treatment of serious mental illness are common; for example, research has repeatedly found that individuals with psychosis in the U.S. often do not receive

appropriate treatment for that condition for 1 to 3 years. HHS's Serious Mental Illness Initiative builds on activities that are currently underway in various HHS agencies; these activities are coordinated through the HHS Behavioral Health Coordinating Council (BHCC). The BHCC subcommittee on serious mental illness is critical to the implementation of the Initiative, which is also oriented toward achievement of this APG on serious mental illness.

APG 3 – Improve the timeliness of initiation into treatment for individuals with serious mental illness

Performance Measure: Increase access to early intervention services by increasing the number of states with early intervention programs

Unit of Measurement: States

	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Target				-	-	20 states
Result				13 states	25 states	Sept 30, 2017
Status				Baseline	Baseline	Pending

Combating Antibiotic-Resistant Bacteria. Antibiotics have been a critical public health tool since the discovery of penicillin in 1928, saving the lives of millions of people around the world. Today, however, the emergence of drug resistance in bacteria is reversing the miracles of the past 80 years, with drug choices for the treatment of many bacterial infections becoming increasingly limited, expensive, and, in some cases, nonexistent. CDC estimates that drug-resistant bacteria cause two million illnesses and approximately 23,000 deaths each year in the U.S. alone. At least one-third of antibiotics used in inpatient settings are either unnecessary or inappropriately prescribed. Implementation of antibiotic stewardship programs in hospitals will help ensure that hospitalized patients receive the right antibiotic, at the right dose, at the right time, and for the right duration. Improved antibiotic use leads to reduced mortality, reduced risk of Clostridium difficile-associated diarrhea, shorter hospital stays, reduced overall antibiotic resistance within the hospital, and increased cost savings.

Did you know?

Antibiotics are among the most commonly prescribed drugs used in human medicine, and can often be lifesaving. However, up to 50 percent of the time antibiotics are not optimally prescribed, often done so when not needed, or with an incorrect dosage or duration.

APG 4 – Combating Antibiotic-Resistant Bacteria

Performance Measure: Increasing the percent of hospitals that report implementation of antibiotic stewardship programs that comply with all of the CDC Core Elements for Hospital Antibiotic Stewardship Programs

Unit of Measurement: Percent

	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Target			-	-	50.0%	59.0%
Result			39.2%	40.9%	July 31, 2017	July 31, 2018
Status			Baseline	Baseline	Pending	Pending

Opioid Morbidity and Mortality. Opioid misuse and overdose present a nationwide public health challenge. Death by drug overdose is the leading cause of injury death in the U.S., with deaths from opioids in particular increasing precipitously in the twenty-first century. Overdose deaths from prescription opioids, such as oxycodone, hydrocodone, and morphine, have more than quadrupled over the period 1999 – 2013. Overdose deaths involving heroin have increased significantly in recent years, more than tripling from 2010 – 2014. Agencies across HHS recognize the urgency of halting the rise of opioid use disorder and overdose, and are working to

develop and implement the most effective interventions, from prevention through treatment. By September 30, 2017, opioid-related overdose death and opioid use disorder will be addressed through the three priority areas of reforming opioid prescribing practices, increasing the use of naloxone, and expanding access to and use of medication-assisted treatment for opioid use disorders.

APG 5 – Reduce opioid-related morbidity and mortality

Performance Measure: Decrease the total morphine milligram equivalents (MMEs) dispensed

Unit of Measurement: MMEs

	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Target	N/A	N/A	N/A	N/A	53,237,426,263	50,435,456,459
Result	62,835,579,985	60,493,554,681	59,352,680,649	55,734,326,020	Nov 30, 2016	Nov 30, 2017
Status	Historical Actual	Historical Actual	Historical Actual	Historical Actual	Pending	Pending

Performance Measure: Increase the number of prescriptions dispensed for naloxone

Unit of Measurement: Prescriptions

	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Target	N/A	N/A	N/A	N/A	4,771	5,104
Result	396	351	2,038	7,658	Nov 30, 2016	Nov 30, 2017
Status	Historical Actual	Historical Actual	Historical Actual	Historical Actual	Pending	Pending

Performance Measure: Increase the number of unique patients receiving prescriptions for buprenorphine (BUP) and naltrexone (NAL) in a retail setting

Unit of Measurement: Patients

	FY 2012	FY 2013	FY 2014 (BUP)	FY 2014 (NAL)	FY 2015 (BUP)	FY 2015 (NAL)	FY 2016 (BUP)	FY 2016 (NAL)	FY 2017 (BUP)	FY 2017 (NAL)
Target			N/A	N/A	N/A	N/A	915,207	112,398	958,788	117,750
Result			807,555	85,494	909,656	121,067	Nov 30, 2016	Nov 30, 2016	Nov 30, 2017	Nov 30, 2017
Status			Historical Actual	Historical Actual	Historical Actual	Historical Actual	Pending	Pending	Pending	Pending

Did you know?

In 2015, nearly 2.4 million Americans had an opioid use disorder, and close to 80 percent of them did not receive treatment.

AHRQ's Patient Safety Network (PSNet). AHRQ PSNet (psnet.ahrq.gov) is a web-based resource featuring the latest news and essential information on patient safety. In 2001, AHRQ launched a web-based morbidity and mortality conference called WebM&M to facilitate the posting of anonymous cases of medical errors or near misses, accompanied by commentaries written by experts that articulated lessons learned in a thoughtful, evidence-based, and engaging way. Over the nearly 15-year existence of WebM&M, the site has received millions of visits, awarded nearly 70,000 hours of CME credit, and published over 360 cases which have been widely used in teaching.

In the first 6 months of 2016, the new AHRQ PSNet has already received almost 600,000 visits. User responses to the site's last satisfaction survey are overwhelmingly positive: 92 percent of PSNet and 86 percent of WebM&M respondents stated they were likely to recommend these sites as resources on patient safety. Supported by a robust patient safety taxonomy and web architecture, AHRQ PSNet provides powerful searching and browsing capability, as well as the ability for diverse users to customize the site around their interests.

Strategic Goal 2: Advance Scientific Knowledge and Innovation

HHS is expanding its scientific understanding of how best to advance health care, public health, human services, and biomedical research, and to ensure the availability of safe medical and food products. Chief among these efforts is the identification, implementation, and rigorous evaluation of new approaches in science, health care, public health, and human services. These efforts encourage efficiency, effectiveness, sustainability, and sharing or translating that knowledge into better products and services.

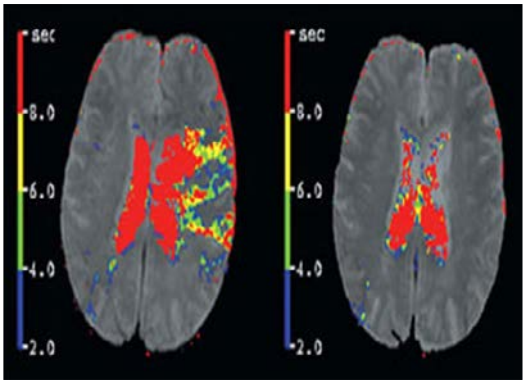
Strategic Goal 2
Advance Scientific Knowledge and Innovation

Objectives

- **2.A Accelerate the process of scientific discovery to improve health**
- **2.B Foster and apply innovative solutions to health, public health, and human services challenges**
- **2.C Advance the regulatory sciences to enhance food safety, improve medical product development, and support tobacco regulation**
- **2.D Increase our understanding of what works in public health and human services practice**
- **2.E Improve laboratory, surveillance, and epidemiology capacity**

Data for evidence-based decision making. In FY 2015, CDC published over 250 Morbidity and Mortality Weekly Reports (MMWRs) and increased total electronic media reach to 23.0 million potential viewings. The MMWR series provides critical epidemiological data and recommendations to clinicians, epidemiologists, laboratorians, and other public health professionals. Fifty-two reports were published regarding Ebola, with the publications serving as critical CDC tools for disseminating scientific and public health information about the international Ebola response. CDC also published several MMWRs regarding laboratory practices and capacity, including Competency Guidelines for Public Health Laboratory Professionals. In FY 2016, in support of the international Zika response, CDC published 34 reports regarding Zika, serving as critical CDC tools for disseminating guidance and scientific and public health information. Also in FY 2016, the MMWR publication received its first Journal Impact Factor, which measures the impact of a publication based on the frequency articles are cited. It was ranked second of the 170 journals in the category of Public, Environmental and Occupational Health. Since January 2016, CDC has released 26 scientific resources and guidance documents related to transmission, control, and treatment of the Zika virus disease in the MMWR.

CDC microbiologist works with a test developed for the Zika virus response.



NIH DEFUSE-2 MRI brain scans from a stroke patient, illustrating improved blood flow. The MRI helps doctors determine the most effective therapy approach; over the next month, this patient made a nearly complete recovery.

New imaging methods for post-stroke care. The blood-brain barrier is a layer of cells that protects the brain from harmful molecules passing through the bloodstream. After stroke, the barrier is disrupted, becoming permeable and losing control over what gets into the brain. In a study of stroke patients, NIH investigators confirmed through magnetic resonance imaging (MRI) brain scans that there was an association between the extent of disruption to the blood-brain barrier and the severity of bleeding following invasive stroke therapy. These findings are part of the Diffusion and Perfusion Imaging Evaluation for Understanding Stroke Evolution (DEFUSE)-2 Study, which was designed to see how MRIs can help determine which patients undergo endovascular therapy (removing a blood clot or breaking it up with a stent) following ischemic stroke. Ischemic stroke patients are increasingly receiving combination therapy, endovascular treatment along with an intravenous drug known as tissue plasminogen activator (t-PA), to effectively break up clots in the brain. However, bleeding into the damaged brain tissue is a serious complication of both acute stroke therapies. This research has led to a large phase III clinical trial, currently being conducted in the NIH Stroke Network, to evaluate the role of these imaging techniques in identifying patients likely to benefit from new approaches to endovascular therapy.

International Field Epidemiology Training Programs. Since 1980, CDC has developed international Field Epidemiology Training Programs (FETPs) serving over 70 countries that have graduated over 3,600 epidemiologists. Through FETPs, CDC helps establish a network of disease detectives around the globe that are the first line of defense in detecting and responding to outbreaks in their respective countries as well as neighboring countries. In FY 2015, CDC exceeded its target for new residents by more than 20 percent over FY 2014, a nearly 75 percent increase since FY 2012. On average, over 80 percent of FETP graduates work within their Ministry of Health after graduation and many assume key leadership positions, such as the National Director of Tuberculosis program and National Director of Chronic Disease program in the Dominican Republic. The total number of new FETP residents increased in FY 2015 to 483, strengthening global health ministries' ability to detect and respond to outbreaks. Their presence enhances sustainable public health capacity in these countries, which is critical in transitioning U.S.-led global health investments to long-term host-country ownership. CDC is planning for a level number of new residents in FY 2017 based on current participation and funding considerations. FETP activities are supported by funding from CDC appropriations and inter-agency agreements with the Department of Defense, Department of State, and the U.S. Agency for International Development. Policy changes within those agencies may affect the future number of FETPs supported, which may require adjustments to targets.

Performance Measure: Increase epidemiology and laboratory capacity within global health ministries through the FETP New Residents

Unit of Measurement: New Residents

	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Target	179	255	430	430	430	430
Result	280	300	402	483	June 30, 2017	June 30, 2018
Status	Target Exceeded	Target Exceeded	Target Not Met but Improved	Target Exceeded	Pending	Pending

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

HHS strives to promote the health, economic, and social well-being of children, people with disabilities, and older adults while improving wellness for all. To meet this goal, the Department is employing evidence-based strategies to strengthen families and to improve outcomes for children, adults, and communities. A focus on prevention underlies each objective and strategy associated with this goal.

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

Objectives

- **3.A Promote the safety, well-being, resilience, and healthy development of children and youth**
- **3.B Promote economic and social well-being for individuals, families, and communities**
- **3.C Improve the accessibility and quality of supportive services for people with disabilities and older adults**
- **3.D Promote prevention and wellness across the life span**
- **3.E Reduce the occurrence of infectious diseases**
- **3.F Protect Americans' health and safety during emergencies, and foster resilience to withstand and respond to emergencies**

Quality Rating and Improvement Systems with High-Quality Benchmarks. The "Improve the quality of early childhood programs for low-income children" APG (www.performance.gov/content/improve-quality-early-childhood-programs-low-income-children) calls for actions to improve the quality of programs for children of low-income families, namely Head Start and Child Care. For the Child Care program, the aim is to increase the number of states with Quality Rating and Improvement Systems (QRIS) that meet the seven high quality benchmarks for child care and other early childhood programs developed by HHS. QRIS is a mechanism used to improve the quality of child care available in communities and to increase parents' knowledge and understanding of available child care options. Through FY 2015, 32 states had a QRIS that met high-quality benchmarks, meeting the APG target. States expanded from pilot programs to state-wide systems, added financial incentives for child care providers, and increased availability of quality information, leading them to meet more components of the QRIS measure.

APG 2 - Improve the quality of early childhood programs for low-income children
Performance Measure: Increase the number of states with QRIS that meet high quality benchmarks for child care and other early childhood programs developed by HHS
Unit of Measurement: States

	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Target	20 states	25 states	29 states	32 states	35 states	37 states
Result	19 states	27 states	29 states	32 states	June 30, 2017	June 30, 2018
Status	Target Not Met but Improved	Target Exceeded	Target Met	Target Met	Pending	Pending

Reduction in Head Start Grantees Receiving a Low Score on the Classroom Assessment Scoring System (CLASS: Pre-K). In support of this APG, ACF is striving to increase the percentage of Head Start children in high quality classrooms. Progress is measured by reducing the proportion of Head Start grantees that score in the low range on any of the three domains of the CLASS: Pre-K, a research-based tool that measures teacher-child interaction on a seven-point scale in three broad domains: Emotional Support, Classroom Organization, and Instructional Support. An analysis of CLASS scores for FY 2016 indicates that 24 percent of grantees scored in the low range, exceeding the target of 25 percent. All grantees scoring in the low range did so on the Instructional Support domain.

ACF continues to invest in building its CLASS related resources and making those resources available to grantees. In response to the data from the FY 2013 CLASS reviews, ACF provides more intentional targeted assistance to those grantees that score in the low range on CLASS. ACF continues to conduct more analysis on the specific dimensions that are particularly challenging for those grantees, such as concept development and language modeling, and tailor the technical assistance for grantees based on their specific needs.

A recent analysis of data from the Family and Child Experience Survey (FACES), a federally funded nationally representative survey of Head Start programs, provides some evidence that grantee scores on domains of the CLASS have improved over time. This analysis demonstrates that over time fewer classrooms scored in the "low" range and more classrooms scored in the "mid" to "high" range on Instructional Support. FACES data also shows a statistically significant increase in the average score and the percentage of Head Start classrooms scoring 3 or higher on Instructional Support between 2006 and 2014. Overall, Head Start classrooms regularly score above a 5 in Emotional Support and Classroom Organization. The FACES data analysis showed that over time fewer classrooms scored in the "mid" range and more classrooms scored in the "high" range on Emotional Support.

APG 2 - Improve the quality of early childhood programs for low-income children

Performance Measure: Reduce the proportion of Head Start grantees receiving a score in the low range on the basis of CLASS: Pre-K

Unit of Measurement: Percent

	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Target	-	23%	27%	26%	25%	24%
Result	25%	31%	23%	22%	24%	Jan 31, 2018
Status	Baseline	Target Not Met	Target Exceeded	Target Exceeded	Target Exceeded	Pending

Did you know?

Head Start helps families obtain health insurance, find services for children with disabilities, secure adequate housing, participate in job training, and more.

Head Start Teachers with Degrees in Early Childhood Education. In addition to looking at classroom quality through the CLASS measure, the ACF Office of Head Start (OHS) is also emphasizing the credentials of classroom teachers by striving to increase the percentage of Head Start and Early Head Start teachers with a Bachelor's Degree (BA) degree. In doing so, OHS is prioritizing a distinct but complementary goal in boosting the quality of Head Start programs. This measure is distinct in that it looks at credentials for both Head Start and Early Head Start teachers, rather than focusing on the credentials of Head Start pre-school teachers. The most recent results for this performance measure indicate that in FY 2016, 55 percent of Head Start and Early Head Start teachers have a BA or higher, missing the target of 62 percent.

Analysis of the data indicates that a key reason for the decrease relative to the prior year is that a lower percentage of teachers in Early Head Start-Child Care partnership (EHS-CCP) programs have BA degrees. This year is the first year the Program Information Report, the annual survey of Head Start grantees, collects data on these teachers, which has an effect on our national average. The purpose of the EHS-CCP grants is to improve the care of infants and toddlers through partnerships with Early Head Start programs and child care programs that agree to

meet the Head Start Program Performance Standards, which includes requirements for teacher qualifications. We anticipate qualifications will increase through these continued partnerships.

To continue the trend of increasing the number of teachers with a BA or higher, ACF is investing in an initiative called Early EdU, which is a higher education alliance working to advance early childhood teaching by providing online courses for early childhood educators so they can pursue a BA. ACF is also working within states to strengthen early care and education professional development systems and promote articulation agreements within and across institutions of higher education. Articulation agreements allow students to apply credits earned in one program toward another program, which facilitates them moving along their educational pathway toward a BA.

APG 2 - Improve the quality of early childhood programs for low-income children
Performance Measure: Increase the percentage of teachers in Head Start and Early Head Start that have a BA or higher
Unit of Measurement: Percent

	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Target	N/A	N/A	N/A	N/A	62%	57%
Result	52%	55%	58%	60%	55%	Jan 31, 2018
Status	Historical Actual	Historical Actual	Historical Actual	Historical Actual	Target Not Met	Pending

Reduce Foodborne Illness. Listeria monocytogenes (L.m.) infections are one of the leading causes of death from foodborne illness in the U.S., resulting in an estimated 1,600 illnesses and 260 deaths each year. Outbreak investigations determine which foods are responsible for illness and can lead to important food safety improvements. For example, recent investigations identified previously unknown sources of L.m. illnesses—cantaloupe, ice cream, and caramel apples—and focused attention on preventing contamination of these products. However, finding the source of clusters of L.m. illnesses is difficult. Determining if the same strain of L.m. is making people sick, meaning the illnesses likely came from the same food source, requires intensive investigation. Clusters of illnesses caused by L.m. strains with the same genetic fingerprint are often small. Figuring out what ill persons ate in common is often very difficult; especially when some are too sick for interviews or have died and the long incubation period makes it more difficult for patients to remember what and where they ate. More complete information from patient interviews, information about isolations of L.m. from food and the environment, and whole genome sequencing of strains can all help to identify the source of outbreaks. When food sources and the cause of contamination are identified, food safety changes can be implemented throughout an industry and prevent future outbreaks.

A member of the FDA Whole Genome Sequencing Team in a lab.

APG 6 – Reduce Foodborne Illness

Performance Measure: Reduce the incidence rate of Listeria

Unit of Measurement: Reported Cases per 100,000 population per year

	CY 2012	CY 2013	CY 2014	CY 2015	CY 2016	CY 2017
Target	-	-	-	-	-	.22 cases/100,000
Result	.26 cases/100,000	.25 cases/100,000	.24 cases/100,000	.24 cases/100,000	March 31, 2017	March 31, 2018
Status	Baseline	Baseline	Baseline	Baseline	Pending	Pending

Combustible Tobacco Consumption (Cigarette Equivalents). Smoking and secondhand smoke kill an estimated 480,000 people in the U.S. each year. For every smoker who dies from a smoking-attributable disease, another 30 live with a serious smoking-related disease. Smoking costs the U.S. $170 billion in medical costs and $156 billion in lost productivity each year. An estimated 58 million nonsmoking Americans are exposed to secondhand smoke, which causes more than 41,000 deaths in non-smoking adults each year. While smoking among adults in the U.S. has decreased significantly from a decade ago, the decline in adult smoking rates has slowed, concurrent with reductions in state investments in tobacco control programs. In addition, the coordinated efforts of the APG to reduce tobacco use (www.performance.gov/content/reduce-annual-adult-combustible-tobacco-consumption-united-states) have resulted in reductions in adult cigarette consumption, based on FY 2013 results (reported in June 2014). For FY 2015, the annual per capita adult cigarette consumption fell to 1,211 cigarettes, but missed the FY 2015 target of 1,174 (37 cigarette equivalents). However, the FY 2014 results (the most recent available data) of other combustible tobacco use indicators are tracking lower usage across both adults and youth:

- Percentage of adult smokers – 16.8 percent; exceeding the FY 2014 target of 18 percent (National Health Interview Survey)
- Percentage of adult smokers who last smoked 6 months to 1 year ago – 7.6 percent; exceeding the FY 2014 target of 7.2 percent (National Health Interview Survey)
- Percentage of children/adolescents initiation – 3.8 percent; exceeding the FY 2014 target of 4.7 percent (National Survey on Drug Use and Health)
- Percentage of young adults initiation – 7.2 percent; exceeding the FY 2014 target of 7.5 percent (National Survey on Drug Use and Health)

CDC plans to continue conducting applied research on the health effects and patterns of use of emerging tobacco products to inform the American public as well as decision makers. CDC is also modifying its surveillance systems to ensure it is able to capture relevant data on new products and shifting patterns of use. CDC will continue to communicate about these evolving issues to the American public, through media, such as the Tips from Former Smokers national education campaign.

APG 7 - Reduce the annual adult combustible tobacco consumption in the United States

Performance Measure: Annual Per Capita Combustible Tobacco Consumption by Adults in the U.S.

Unit of Measurement: Cigarette Equivalents per Capita

	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Target	-	1,259 per capita	1,212 per capita	1,174 per capita	1,145 per capita	1,127 per capita
Result	N/A	1,277 per capita	1,216 per capita	1,211 per capita	July 31, 2017	July 31, 2018
Status	Set Baseline	Target Not Met	Target Not Met but Improved	Target Not Met but Improved	Pending	Pending

National Family Caregiver Support Program. Families are the nation's primary provider of long-term care, but a number of factors including financial constraints, work and family demands, and the many challenges of providing care places great pressure on family caregivers. Better support for informal caregivers is critical because often it is their availability that determines whether an older person can remain in his or her home. In 2013, approximately 34.2 million adult caregivers provided uncompensated care to those 50 years and older. The economic cost of replacing unpaid caregiving of elderly adults is estimated to be between $470 billion and $522 billion annually. ACL's Administration on Aging Family Caregiver Support Program provides services and supports that lessen the strain and make caregiving easier for family caregivers, such as information, counseling and training, respite care and supplemental services. Since 2008, program participants have rated services good to excellent consistently above the target level of 90 percent. Nearly 75 percent of program participants reported that services enabled them to provide care longer than otherwise would have been possible and the same percent report feeling less stressed due to services. It should also be noted that results of an ACL evaluation of the National Family Caregiver Support Program (NFCSP) show that states reported being able to serve greater numbers of family caregivers as a result of the NFCSP. This includes a 260 percent increase, from before the NFCSP was implemented, in support group services (an increase from 15 to 54 states) and a 227 percent increase in training and education services for caregivers (an increase from 15 to 49 states). Of 53 reporting states, about half (45 percent) answered that the NFCSP is the only state-administered caregiver program.

Performance Measure: Maintain at 90% or higher the percentage of NFCSP clients who rate services good to excellent

Unit of Measurement: Percent

	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Target	90%	90%	90%	90%	90%	90%
Result	93.8%	94.6%	93.6%	Dec 31, 2016	Dec 31, 2017	Dec 31, 2018
Status	Target Exceeded	Target Exceeded	Target Exceeded	Pending	Pending	Pending

Caregiver with family member. The *Older Americans Act Reauthorization Act of 2016* was signed into law in April 2016. It includes a key change to NFCSP, allowing the program to be more inclusive in serving older-relative caregivers, including people who are age 55 or older and parents of individuals with disabilities.

Strategic Goal 4
Ensure Efficiency, Transparency, Accountability, and Effectiveness of HHS Programs

Objectives

4.A Strengthen program integrity and responsible stewardship by reducing improper payments, fighting fraud, and integrating financial, performance, and risk management
4.B Enhance access to and use of data to improve HHS programs and to support improvements in the health and well-being of the American people
4.C Invest in the HHS workforce to help meet America's health and human services needs
4.D Improve HHS environmental, energy, and economic performance to promote sustainability

Strategic Goal 4: Ensure Efficiency, Transparency, and Accountability of HHS Programs

As the largest grant-awarding agency in the federal government and the nation's largest health insurer, HHS places a high priority on ensuring the integrity of its expenditures. HHS manages hundreds of programs in basic and applied science, public health, income support, child development, and health and social services, which award over 75,000 grants annually. The Department has robust processes in place to manage the resources and information employed to support programs and activities.

Medicare, Medicaid, and CHIP Improper Payment Rates. One of CMS's key goals is to pay Medicare claims properly the first time. This means paying the right amount, to legitimate providers, for covered, reasonable, and necessary services provided to eligible beneficiaries. Paying correctly the first time saves resources required to recover improper payments and ensures the proper expenditure of valuable dollars. The primary cause of improper payments is Documentation and Administrative Errors, in large part due to insufficient documentation. Other notable causes include Authentication and Medical Necessity Errors, caused by medically unnecessary services, and to a lesser extent, incorrect diagnosis coding. Between FY 2009 and FY 2012, the improper payment rate for Medicare FFS consistently improved. Data from FY 2013 and FY 2014 indicate an increase in this improper payment rate and efforts are currently in progress to investigate and resolve the drivers causing this increase. However, the improper payment rate for Medicare FFS decreased from FY 2014 through FY 2016.

Since roughly one third of the states are measured each year to calculate the Medicaid and CHIP error rates, these measures are calculated as a rolling rate that includes the reporting year and the previous two. In an attempt to reduce the national Medicaid error rates, states are required to develop and submit corrective action plans. The FY 2016 Medicaid error rate is 10.48 percent, and the FY 2016 CHIP error rate is 7.99 percent. Similar to recent years, the increase was due to state difficulties bringing systems into compliance with new requirements for: (1) all referring or ordering providers to be enrolled in Medicaid, (2) states to screen providers under a risk-based screening process prior to enrollment, and (3) the inclusion of the attending provider National Provider Identifier (NPI) on all electronically filed institutional claims. While these requirements will ultimately strengthen the integrity of the program, they require systems changes and, therefore, many states had not fully implemented these new requirements. CMS is working with states to improve compliance with the additional state requirements that contributed to the increase in error rates.

Performance Measure: Estimate of the Improper Payment Rate in the Medicaid Program

Unit of Measure: Percent

	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Target	7.4%	6.4%	5.6%	6.70%	11.53%	9.57%
Result	7.1%	5.8%	6.7%	9.78%	10.48%	Nov 15, 2017
Status	Target Exceeded	Target Exceeded	Target Not Met	Target Not Met	Target Exceeded	Pending

Performance Measure: Reduce the Percentage of Improper Payments Made Under the Medicare FFS Program

Unit of Measurement: Percent

	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Target	5.4%	8.3%	9.9%	12.50%	11.50%	10.40%
Result	8.5%	10.1%	12.7%	12.09%	11.00%	Nov 15, 2017
Status	Target Not Met but Improved	Target Not Met	Target Not Met	Target Exceeded	Target Exceeded	Pending

Performance Measure: Estimate the Percentage of Improper Payments in the CHIP Program

Unit of Measurement: Percent

	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Target				6.50%	6.81%	7.38%
Result				6.80%	7.99%	Nov 15, 2017
Status				Target Not Met	Target Not Met	Pending

Clients Served by Home and Community-Based Services. A foundation of ACL's program success is access to Home and Community-based Services. In FY 2014, the Aging Services Network served 8,930 clients per million dollars of *Older Americans Act* funding, exceeding the target of 8,600 clients per million dollars. Performance has largely trended upward and performance targets have been consistently achieved. This reflects strong partnerships with state and local governments, philanthropic organizations, and private donors that contribute funding (leveraging resources of two to three dollars for every federal dollar) and the success of ongoing initiatives to improve program management and expand options for home and community-based care. Aging and Disability Resource Centers, along with increased commitments and partnerships at the state and local levels, have all had positive impacts on program efficiency. Between FY 2008 and FY 2013 performance has improved by 18.3 percent, without benefit of adjustment for inflation. The FY 2014 results showed a decline while still exceeding the target. This variation between FY 2014 and FY 2017 is anticipated as delayed effects of sequestration may occur.

Performance Measure: For Home and Community-based Services including Nutrition and Caregiver services increase the number of clients served per million dollars of Title III *Older Americans Act* funding

Unit of Measurement: Number of Clients

	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Target	8,600 clients	8,700 clients	8,600 clients	9,250 clients	8,700 clients	9,000 clients
Result	9,206 clients	9,753 clients	8,930 clients	Dec 31, 2016	Dec 31, 2017	Dec 31, 2018
Status	Target Exceeded	Target Exceeded	Target Exceeded	Pending	Pending	Pending

Head Start Enrollment Rate. ACF's Head Start program works to ensure that the maximum number of children are served and that federal funds are used appropriately and efficiently by measuring under-enrollment across programs. Since Head Start grantees range in size from super-grantees with multiple delegate agencies serving up to 20,000 children to individual centers that serve as few as 15 children, a national under-enrollment rate better captures the under-enrollment than the proportion of grantees that meet under-enrollment targets. An un-enrolled space or vacancy in Head Start is defined as a funded space that is vacant for over 30 days.

ACF continues to focus on improvements to reduce Head Start under-enrollment. Though each Head Start program is required to keep a wait list to fill vacancies as they occur, there are a number of reasons that it may be difficult to fill vacancies quickly. Low-income families are often mobile and eligible families on the waiting list may have moved out of the service area. In addition, as state pre-kindergarten programs have grown, parents may choose to send their children to those programs. The most recent data available indicate that, during the 2014 –

2015 program year, Head Start grantees had, on average, not enrolled 1.84 percent of the children they were funded to serve. This represents approximately 16,700 children who could have been served using the Head Start funds appropriated and awarded to grantees.

Children at a Head Start Program.

There are three factors that contributed to the increased rate of under-enrollment in Head Start in FY 2015: (1) a period of under-enrollment as more programs become Birth-to-Five through competition and renovate facilities, train staff and recruit infants and toddlers; (2) competitive transitions which can result in a period of under-enrollment as programs become fully operational; and (3) under-enrollment within some very large grantees. The ACF OHS is following up and providing technical assistance to ensure these grantees become fully enrolled as soon as possible. Per the 2007 reauthorization of the *Head Start Act*, ACF now collects online enrollment data on a monthly basis from all Head Start grantees through the Head Start Enterprise System. The Head Start Enterprise System provides a system-generated alert when grantees are under-enrolled, and Regional Offices have procedures in place, consistent with the *Head Start Act*, to begin technical assistance and to establish improvement plans with clear timetables if the under-enrollment persists.

Performance Measure: Decrease under-enrollment in Head Start programs, thereby increasing the number of children served per dollar

Unit of Measurement: Percent

	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Target	0.7%	0.7%	0.6%	0.8%	1.2%	1.1%
Result	0.8%	0.7%	0.9%	1.84%	Jan 31, 2017	Jan 31, 2018
Status	Target Not Met	Target Met	Target Not Met	Target Not Met	Pending	Pending

Cross-Agency Priority Goals

Cross-Agency Priority goals address the longstanding challenge of tackling horizontal problems across vertical organizational silos. In the 2015 *President's Budget*, 15 Cross-Agency Priority Goals were announced – 7 mission-oriented and 8 management-focused goals with a 4-year time horizon. Established by the *GPRA Modernization Act of 2010*, these Cross-Agency Priority Goals are a tool used by federal leadership to accelerate progress on a limited number of Presidential priority areas where implementation requires active collaboration between multiple agencies. HHS contributes to Cross-Agency Priority Goals with other federal agencies in the mission-oriented goals of Science, Technology, Engineering and Mathematics Education; and Service Members and Veterans Mental Health. We are also maximizing federal spending through participation in the management-focused goals of Shared Services; Benchmark and Improve Mission-Support Operations; and Customer Service. For more information on HHS's contributions to Cross-Agency Priority Goals and progress, refer to www.performance.gov/cap-goals-list.

SYSTEMS, LEGAL COMPLIANCE, AND INTERNAL CONTROL

Systems

Financial Systems Environment

HHS's Chief Financial Officer (CFO) Community strives to provide effective stewardship of taxpayer funds through transparency and accountability in support of the Department's mission and programs. The HHS financial systems environment forms the financial and accounting foundation for managing the $1.7 trillion in budgetary resources entrusted to the Department in FY 2016. These resources represent about a quarter of all federal outlays and encompass more grant dollars than all other federal agencies combined.

The robust financial systems environment supports HHS's diverse portfolio of mission-oriented programs, as well as business operations. Its purpose is to: efficiently process financial transactions in support of program activities and HHS's mission; provide complete and accurate financial information for decision-making; improve data integrity; strengthen internal controls; and mitigate risk.

The HHS financial systems environment consists of a core financial system (with three instances) and two Department-wide reporting systems used for financial and managerial reporting that – taken together – satisfy the Department's financial accounting and reporting needs.

Core Financial System

The core financial system operates on a commercial off-the-shelf (COTS) platform to support data standardization and facilitate Department-wide reporting. Each of the instances operates the same COTS solution.

- The Healthcare Integrated General Ledger Accounting System (HIGLAS) supports CMS. HIGLAS serves CMS's Medicare Administrative Contractor organizations, Administrative Program Accounting, and the Center for Consumer Information and Insurance Oversight. It processes an average of five million transactions daily.

- The NIH Business System (NBS) serves NIH's 27 research institutes and supports grant funding to more than 300,000 researchers at more than 2,500 universities, medical schools, and other research institutions in every state and around the world.

- The Unified Financial Management System (UFMS) serves 10 OpDivs (including the OS) and 18 StaffDivs across the Department. The following accounting centers utilize UFMS: CDC, FDA, IHS, and PSC. PSC provides shared service accounting support for the rest of the Department.

Reporting Systems

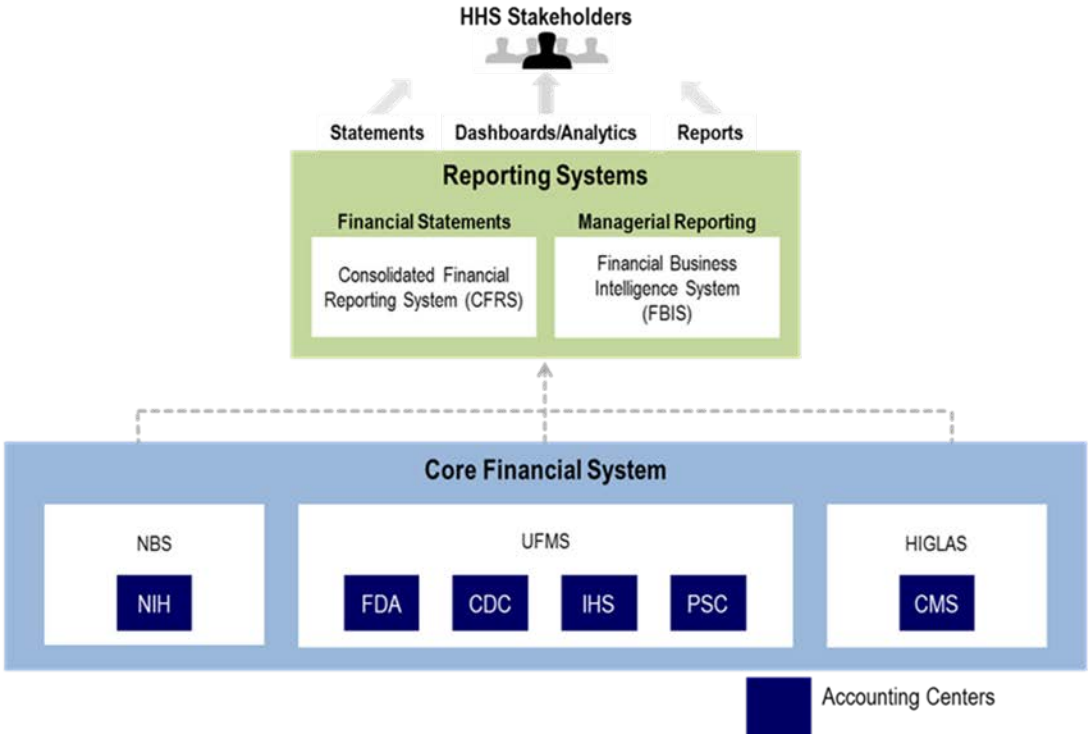
Reporting components within the HHS financial systems environment consist of two Department-wide applications: the Consolidated Financial Reporting System (CFRS) and the Financial Business Intelligence System (FBIS). These reporting systems facilitate data reconciliation, financial and managerial reporting, and data analysis.

- CFRS systematically consolidates information from all three instances of the core financial system. It generates Departmental quarterly and year-end consolidated financial statements on a consistent and timely basis, while supporting HHS in meeting regulatory reporting requirements.

- FBIS is the financial business intelligence application that supports the information needs of HHS stakeholders at all levels by retrieving, combining, and consolidating data from the core financial system. It contains a set of techniques and tools for analyzing data and presenting actionable information

including metrics and key performance indicators, dashboards with graphical displays, interactive reports, and ad-hoc reporting. FBIS allows executives, managers, and operational end users, to make informed business decisions to support their organization's mission.

The illustration below depicts the current financial systems environment.



The HHS financial systems environment is required to comply with all relevant federal laws, regulations, and authoritative guidance. In addition, HHS must conform to federal financial management and systems requirements including:

- *Federal Managers' Financial Integrity Act of 1982* (FMFIA)
- *Chief Financial Officers Act of 1990* (CFO Act)
- *Government Management Reform Act of 1994*
- *Federal Financial Management Improvement Act of 1996* (FFMIA)
- *Clinger-Cohen Act of 1996*
- *Federal Information Security Management Act of 2002,* as amended by the *Federal Information Security Modernization Act of 2014* (FISMA)
- *Digital Accountability and Transparency Act of 2014* (DATA Act)
- *Federal Information Technology Acquisition Reform Act of 2014* (FITARA)
- Office of Management and Budget (OMB) directives and U.S. Department of the Treasury (Treasury) guidance related to these laws

Financial Systems Environment Improvement Strategy

HHS continues to implement a Department-wide strategy to advance its financial systems environment through the Financial Systems Improvement Program (FSIP) and Financial Business Intelligence Program (FBIP). The portfolio of projects within these programs addresses immediate business needs and positions the Department to

take advantage of state-of-the-art tools and technology. The goals of the strategy are to improve the effectiveness and efficiency of the Department's financial management capabilities, mature the overall financial systems environment, and strengthen accountability and financial stewardship. This is a multi-year initiative, and the Department is making significant progress in each of the following key strategic areas.

Financial Systems Modernization

- *Strategy*: A critical component of the multi-year FSIP initiative is upgrading the core financial system to the most current version of the COTS software to maintain a secure and reliable financial systems environment. Concurrently, HHS also plans to transition key financial systems to a cloud service provider for hosting and application management. Benefits of the upgrade and cloud transition include: safeguarding system security and privacy; enhancing information access; complying with and implementing evolving federal requirements; achieving efficiencies and promoting standardization; eliminating security and control vulnerabilities; and maximizing the return on existing system investments. Following the upgrade, additional modernization projects and enhancements to further mature the HHS financial systems environment will be pursued incrementally.

- *Progress*: HHS completed the major upgrade of its core financial system in December 2015 – on-time, on-budget, fully functional, and in-line with the federal government's broader financial management and information technology (IT) priorities. The upgrade represents one of the largest successful financial systems modernization efforts across the entire federal government. UFMS, FBIS, and CFRS were transitioned to a FedRAMP-certified cloud service provider as part of the upgrade, with plans to transition additional systems in future years, supporting both the *Federal Cloud Computing Strategy* and the *Federal Information Technology Shared Services Strategy*. The upgrade and cloud transition increase system security, scalability, reliability, and availability, and establish a shared platform configured to HHS's business needs. Further, as part of the upgrade, HHS implemented a Department-wide Accounting Treatment Manual (ATM) to improve financial reporting and fiscal accountability. With the upgrade complete, HHS is progressing on its financial systems modernization roadmap, having initiated projects to develop a Department-wide electronic invoicing solution and an automated, sustainable solution for implementing DATA Act reporting requirements.

Business Intelligence and Analytics

- *Strategy*: Leveraging the FBIS platform, HHS is expanding the use of business intelligence and analytics across the Department to establish an information-driven financial management environment in which stakeholders at all levels have access to timely and accurate information required for measuring performance, increasing transparency, and enhancing decision-making. This will allow the Department to more effectively and efficiently meet evolving information demands for fiscal accountability, performance improvement, and external compliance requirements in a sustainable manner.

- *Progress*: Since it was first deployed in FY 2012, FBIS has been providing operational and business intelligence to users across the HHS finance, budget, grants, and acquisition communities. FBIS includes accurate, consistent, near real-time data from UFMS, and summary data from HIGLAS and NBS. FBIS now supports over 2,000 users across the Department. In FY 2016, HHS successfully consolidated several legacy managerial reporting solutions into FBIS, allowing the Department to retire three systems as reports and users were brought onto the FBIS platform. The transition to the cloud environment will facilitate further system growth, enabling FBIS to incorporate data from additional systems and business domains and generate actionable insights.

Systems Policy, Security, and Controls

- *Strategy*: The reliability, availability, and security of HHS's financial systems are of paramount importance. As such, HHS has placed a high-priority on maturing and enhancing its financial systems control environment, strengthening policy, proactively monitoring emerging issues, and ensuring progress toward remediating the Department's IT Material Weakness. HHS is implementing a policy management program to standardize development, implementation, and monitoring of financial systems policies.

- *Progress*: HHS is addressing the Department's IT material weakness by analyzing audit findings, identifying root causes, and implementing solutions collaboratively. The Financial Management Governance Board (FGB) chartered an IT Material Weakness Working Group (MWWG), with members from OpDiv CFO, Chief Information Officer (CIO), and Chief Information Security Officer (CISO) communities. The IT MWWG meets monthly and has developed a roadmap to address pervasive issues, recommend comprehensive remediation approaches, and monitor implementation progress. Working on two fronts – coordinating responsive efforts to address current audit findings, as well as proactive efforts to mature the security and controls environment going forward – HHS initiated projects to address and minimize vulnerabilities and risks related to data and system security, access management, configuration management, and segregation of duties. Supporting these efforts, HHS developed a Financial Systems Policy Development framework, outlining an updated approach to reviewing, refining, and creating financial systems policies and monitoring compliance.

Governance

- *Strategy*: In November 2013, the Department established the FGB to address enterprise-wide issues, including those related to financial policies and procedures, financial data, and technology. The FGB's goals include establishing HHS financial management governance; providing people, processes, and technology to support governance; engaging stakeholders through effective communication and management strategies; and supporting project alignment with federal mandates and priorities.

- *Progress*: Since its inception, the FGB has met monthly and facilitated executive-level oversight of financial management related areas. It promotes collaboration among stakeholders from the different disciplines within the financial management community by engaging senior leadership from HHS OpDivs and StaffDivs, and across functions such as finance, budget, grants, and IT. The FGB has effectively transformed the way in which financial management initiatives and activities are accomplished in HHS, moving from a Division-specific, vertical focus to a more enterprise-wide approach to solving problems and implementing standards for financial management excellence. This has improved collaboration and strengthened oversight across HHS's financial management and systems environment.

Program Management

- *Strategy*: To support FSIP and FBIP, HHS established a Department-wide program management framework to facilitate effective implementation of projects and to enhance collaboration across project teams. This includes the Financial Systems Consortium: a body of contractors, federal project managers, and federal contracting officers representing NBS, UFMS, and HIGLAS, that fosters communication and implementation of best practices.

- *Progress*: Department-wide program management and the Financial Systems Consortium played critical roles in coordinating the successful upgrade of the HHS core financial system. Within this framework, project teams were able to share industry best practices, lessons learned, and risks identified during the

upgrade while minimizing overall costs. This included sharing solutions across system upgrade teams to streamline implementation, as well as coordinating vendor support to resolve software issues. Effective program management also reduced duplication of effort and costs by identifying potential sharing opportunities and improvements. Though developed initially to facilitate the major financial systems upgrade, both the Enterprise Program Management Office and the Financial Systems Consortium are continuing post-upgrade as forums to support on-going collaboration and coordination across the financial systems environment and modernization initiatives.

Sharing Opportunities

- *Strategy*: As a key FSIP component, HHS is actively pursuing multiple initiatives to generate efficiencies and improve effectiveness through implementing shared solutions. The Department has also established a framework for continuously identifying sharing opportunities in its financial systems environment.

- *Progress*: Examples of sharing opportunities pursued to date include transitioning key financial systems to a cloud service provider; the use of shared acquisition contracts and streamlining of system operations and maintenance contracts; the development and implementation of a Department-wide ATM; consolidation of three legacy managerial reporting systems into FBIS; and sharing solutions across the HHS financial community. Currently, the HHS finance, acquisition, and IT communities are collaboratively pursuing a Department-wide solution for electronic invoicing, supporting both compliance with OMB direction as well as specific business needs identified across HHS. The FGB continues to assess future sharing opportunities across the enterprise to further align with financial management and system policies, business processes and operations, and the overall financial system vision and architecture.

HHS functions collaborate daily to deliver beneficial results to our stakeholders.

Legal Compliance

Anti-Deficiency Act

The *Anti-Deficiency Act* (ADA) prohibits federal employees from obligating in excess of an appropriation, or before funds are available, or from accepting voluntary services. As required by the ADA, HHS notifies all appropriate authorities of any ADA violations. ADA reports can be found at www.gao.gov/legal/anti-deficiency-act/about.

HHS management is taking necessary steps to prevent future violations. On August 1, 2016, the Director of OMB approved HHS's updated Administrative Control of Funds policy, as required by United States Code, Title 31, *Money and Finance*, Section 1514, "Administrative Division of Apportionments." This policy provides HHS's guidelines to follow in budget execution and to specify basic fund control principles and concepts, including the administrative control of all funds for HHS and its OpDivs, StaffDivs, and Accounting Centers. With respect to two possible issues, we are working through investigations and further assessment where necessary. We remain fully committed to resolving these matters appropriately and complying with all aspects of the law.

Digital Accountability and Transparency Act of 2014

The *Digital Accountability and Transparency Act of 2014* (DATA Act) expands the *Federal Funding Accountability and Transparency Act of 2006* to increase accountability and transparency in federal spending, making federal expenditure information more accessible to the public. It directs the federal government to use governmentwide data standards for developing and publishing reports, and to make more information, including award-related data, available on www.USAspending.gov. Among other goals, the DATA Act aims to improve the quality of the information on www.USAspending.gov, as verified through regular reviews of the posted data, and to streamline and simplify reporting requirements through clear data standards. Additionally, the DATA Act accelerated the referral of delinquent debt owed to the federal government to the Treasury's Offset Program after 120 days of delinquency.

HHS has played an integral role in the iterative development of data requirements and policy, utilizing internal and governmentwide working groups to analyze and provide feedback to the Treasury. HHS provided feedback on policy guidance through formal OMB policy review periods and by actively participating in various forums such as OMB Office Hours and Open Beta design studios to help shape the evolution of the governmentwide DATA Act implementation and enhance compliance. HHS also collaborated extensively within the Interagency Advisory Committee, which represents the federal communities impacted by the DATA Act, to provide substantive community-specific and cross-cutting feedback to OMB and Treasury in support of governmentwide standardization and related policy considerations.

HHS has revised its DATA Act implementation plan to account for updated requirements from Treasury and additional policy guidance from OMB, as well as the current state of operations and known technical and schedule constraints. HHS implementation is concentrating on reporting mechanisms for May 2017 that minimize changes to existing systems or reporting tools.

To support the initial DATA Act reporting requirements for May 2017, HHS has established file solution teams aligned with the Financial Management, Financial Assistance and Acquisition business lines that will be operationally responsible for generating and validating submissions to ensure transparency, consistency, and compliance. HHS has also established and continued targeted working groups to address specific challenges such as Award ID linkage, Aggregated Data, and Activity Address Code. The DATA Act Program Management Office (DAP) works closely with these file solution teams and working groups to coordinate overall activities and track progress towards meeting key HHS milestone dates. These efforts have enabled HHS to begin compiling data consistent with submission requirements and to iteratively test this data using the most current version of the Treasury broker available on its new DATA Act www.USAspending.gov site to support initial compliance with the

DATA Act. Finally, HHS is developing a strategy to leverage existing processes for data validation, error handling, and internal controls in order to effectively identify and address data discrepancies in a timely manner and build the certification process for DATA Act reporting in May 2017.

The DATA Act aims to standardize data and make it more transparent to the public by requiring the federal government to establish governmentwide data standards and publish all federal spending data so that it is accessible, searchable, and reliable. To help meet this goal, the legislation contains Section 5, which calls for a grants Pilot to help inform recommendations to Congress on methods for (1) standardized reporting; (2) elimination of duplication; and (3) reduction of compliance costs.

Since May 2015, HHS has been working in partnership with OMB, as its executing agent for the Grants Section 5 Pilot, to develop and execute pilot test models that focus on finding ways to promote government efficiency and improve the public's experience throughout the grants lifecycle. Test Models include the Common Data Element Repository Library (www.hhs.gov/about/agencies/asfr/data-act-program-management-office/common-data-element-repository/index.html), Consolidated Federal Financial Reporting (www.hhs.gov/about/agencies/asfr/data-act-program-management-office/consolidated-federal-financial-reporting/index.html), Single Audit (www.hhs.gov/about/agencies/asfr/data-act-program-management-office/single-audit/index.html), Notice of Award – Proof of Concept (www.hhs.gov/about/agencies/asfr/data-act-program-management-office/notice-of-award/index.html), and Learn Grants (www.hhs.gov/about/agencies/asfr/data-act-program-management-office/learn-grants/index.html). DAP is using these existing tools, forms, and/or processes to collaborate with stakeholders and ascertain if recipient burden may be reduced.

HHS will continue to engage the public in this area through May 2017. The test model results collected by HHS between May 2016 and May 2017 will be reported to OMB for inclusion in the statutorily required report to Congress for legislative action including, but not limited to, consolidating/automating aspects of the federal financial reporting process, simplifying reporting requirements for federal awards, and improving financial transparency.

Improper Payments Information Act of 2002, Improper Payments Elimination and Recovery Act of 2010, and Improper Payments Elimination and Recovery Improvement Act of 2012

An improper payment occurs when a payment should not have been made, federal funds go to the wrong recipient, the recipient receives an incorrect amount of funds, the recipient uses the funds in an improper manner, or documentation is not available to verify the appropriateness of the payment. The *Improper Payments Information Act of 2002* (IPIA), as amended by the *Improper Payments Elimination and Recovery Act of 2010* (IPERA) and the *Improper Payments Elimination and Recovery Improvement Act of 2012* (IPERIA), requires federal agencies to review their programs and activities to identify programs that may be susceptible to significant improper payments, test high risk programs, and develop and implement corrective action plans for high risk programs. HHS is striving to better detect and prevent improper payments through close review of our programs and activities using sound risk models, statistical estimates, and internal controls.

HHS has shown tremendous leadership in the improper payments arena. HHS has a robust improper payments estimation and reporting process that has been in place for many years, and developed and implemented many corrective actions to prevent and reduce improper payments in our programs. In compliance with the IPIA as amended, HHS completed 35 improper payment risk assessments in FY 2016 (representing risk assessments of programs, employee pay, charge cards, and *Affordable Care Act* Marketplace and related programs), and determined that two programs are high risk and must develop improper payment estimation methodologies. In addition, HHS is publishing improper payment estimates and associated information for 12 high risk programs in this year's AFR, of which six programs reported lower improper payment rates in FY 2016 compared to FY 2015. Lastly, HHS also utilizes the Do Not Pay portal to check payments and awardees to identify potential

improper payments or ineligible recipients. In FY 2016, HHS screened more than $385 billion in Treasury-disbursed payments through the Do Not Pay portal; HHS identified no improper payments. A detailed report of HHS's improper payment activities and performance is presented in the "Other Information" section of this AFR, under "Improper Payments Information Act Report."

Patient Protection and Affordable Care Act

The *Affordable Care Act* implements comprehensive health care reform to make quality health care more affordable and accessible. The *Affordable Care Act* includes provisions for a patient's bill of rights, a Health Insurance Marketplace, financial assistance for low and moderate-income Americans to purchase health insurance coverage, incentives for high-quality care from physicians, and expansion of the Medicaid program, helping to provide access to affordable health insurance options for all Americans.

The *Affordable Care Act* also aims to reduce health care fraud, waste and abuse by toughening the sentences for perpetrators of fraud, employing enhanced screening procedures, improving the monitoring of providers, and using predictive modeling technology to target suspect behaviors. These efforts have enabled the government to recover billions of dollars related to improper payments over the last 5 years. For detailed information on improper payment recovery efforts, see the "Program-Specific Reporting Information" section of the "Improper Payments Information Act Report."

A key aspect of the *Affordable Care Act* allows eligible Americans to receive a premium tax credit when purchasing their health insurance coverage through the Health Insurance Marketplace. The amount of the credit can be paid in advance directly to the consumer's health insurer. Consumers then claim the premium tax credit on their federal tax returns, reconciling the credit allowed with any advance payments made throughout the tax year. HHS coordinates closely with the Internal Revenue Service (IRS) on this process.

HHS has implemented many provisions of the *Affordable Care Act*. For more information about implementation of the many *Affordable Care Act* provisions, visit the "Key Features" page at www.hhs.gov/healthcare/facts-and-features/key-features-of-aca-by-year/index.html.

Did you know?

As of September 2016, 20 million individuals have gained coverage thanks to the *Affordable Care Act*. Today, the uninsured rate is the lowest it has been in history.

Federal Information Technology Acquisition Reform Act

The *Federal Information Technology Acquisition Reform Act* (FITARA) established an enterprise-wide approach to federal IT investments and provides the Chief Information Officer (CIO) of CFO Act agencies with greater authority over IT investments, including authoritative oversight of IT budgets and budget execution, and IT-related personnel practices and decisions.

Since OMB approved the HHS FITARA Implementation Plan in March 2016, the Agency completed 18 of 39 elements and actions from HHS FITARA Implementation Plan. The CIO reviewed the IT governance policies and procedures for all the OpDivs, published an updated Capital Planning and Investment Control Policy and an addendum to the Enterprise Performance Life Cycle policy, and with the CFO, conducted annual reviews of all IT budgets. In addition, the CIO made progress on the Data Center Optimization Initiative Strategic Plan. FITARA

implementation has strengthened relationships with the OpDivs as well as the CFO, Chief Human Capital Officer, and the Chief Acquisition Officer. These are just a few of the FITARA highlights for FY 2016. Over the next year, the CIO will continue to advance the FITARA goals in HHS.

Federal Managers' Financial Integrity Act of 1982 and Federal Financial Management Improvement Act of 1996

The *Federal Managers' Financial Integrity Act of 1982* (FMFIA) requires federal agencies to annually evaluate and assert on the effectiveness and efficiency of their internal control and financial management systems. Agency heads must annually provide a statement on whether there is reasonable assurance that the agency's internal controls are achieving their intended objectives and the agency's financial management systems conform to governmentwide requirements. Section 2 of FMFIA outlines compliance with internal control requirements, while Section 4 dictates conformance with systems requirements. Additionally, agencies must report on any identified material weaknesses and provide a plan and schedule for correcting the weaknesses.

In September 2014, the U.S. Government Accountability Office (GAO) released an updated edition of its *Standards of Internal Control in the Federal Government*, effective FY 2016. The document takes a principles-based approach to internal control, with a balanced focus over operations, reporting, and compliance. In July 2016, OMB released revised Circular A-123, *Management's Responsibility for Enterprise Risk Management and Internal Control*. The new Circular complements GAO's *Standards*, and it implements requirements of the FMFIA with the intent to improve accountability in federal programs and increase federal agencies' consideration of ERM. The Department with its OpDiv and StaffDiv stakeholders are working together to implement the new requirements.

The *Federal Financial Management Improvement Act of 1996* (FFMIA) requires federal agency heads to assess the conformance of their financial management information systems to mandated requirements. FFMIA expanded upon FMFIA by requiring that agencies implement and maintain financial management systems that substantially comply with federal financial management systems requirements, applicable federal accounting standards, and the U.S. Standard General Ledger at the transaction level. Guidance for determining compliance with FFMIA is provided in OMB Circular A-123, Appendix D, *Compliance with the FFMIA of 1996*.

HHS is fully focused on the requirements of FMFIA and FFMIA through its internal control program and a Department-wide approach to risk management. Based on thorough ongoing internal assessments and FY 2016 audit findings, HHS provides reasonable assurance that controls are operating effectively. For further information, see the "Management Assurances" section. We are actively engaged with our OpDivs to correct the identified material weaknesses through a corrective action process focused on addressing the true root cause of deficiencies, and supported by active management oversight. More information on the Department's internal control efforts and the HHS Statement of Assurance follows.

Internal Control

FMFIA requires agency heads to annually evaluate and report on the internal control and financial systems that protect the integrity of federal programs. This evaluation aims to provide reasonable assurance that internal controls are achieving the objectives of effective and efficient operations, reliable financial reporting, and compliance with applicable laws and regulations. The safeguarding of assets is a subset of these objectives. HHS performs rigorous, risk-based evaluations of its internal controls in compliance with OMB Circular A-123, *Management's Responsibility for Enterprise Risk Management and Internal Control*.

HHS management is directly responsible for establishing and maintaining effective internal controls in their respective areas of responsibility. As part of this responsibility, management regularly evaluates internal control and HHS executive leadership provides annual assurance statements reporting on the effectiveness of controls at meeting objectives. The HHS Risk Management and Financial Oversight Board (RMFOB) evaluates the OpDivs' management assurances and recommends a Department assurance for the Secretary's consideration and approval, resulting in the Secretary's annual Statement of Assurance.

HHS aims to strengthen its internal control assessment and reporting process to more effectively identify key risks, develop effective risk responses, and implement timely corrective actions. The HHS FY 2016 OMB Circular A-123 assessment and the financial statement audit reported one material weakness in Information System Controls and Security. Additionally, HHS recognizes one material noncompliance with IPIA regarding Error Rate Measurement and one material noncompliance with the *Social Security Act* related to the Medicare appeals process.

Maintaining integrity and accountability in all programs and operations is critical to HHS's mission and demonstrates responsible stewardship over assets and resources. It also promotes responsible leadership, ensures the effective delivery of high quality services to the American people, and maximizes desired program outcomes.

President Obama designated HHS as the lead federal agency responsible for coordinating the Administration's response and recovery efforts in Flint, Michigan.

MANAGEMENT ASSURANCES

Statement of Assurance

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary
Washington, DC 20201

The Department of Health and Human Services' (HHS or the Department) management is responsible for managing risks and maintaining effective internal control to meet the objectives of Sections 2 and 4 of the *Federal Managers' Financial Integrity Act of 1982* (FMFIA). These objectives are to ensure (1) effective and efficient operations; (2) reliable financial reporting; and (3) compliance with applicable laws and regulations. The safeguarding of assets is a subset of these objectives.

HHS conducted its assessment of risk and internal control in accordance with OMB Circular A-123, *Management's Responsibility for Enterprise Risk Management and Internal Control*. Based on the results of the assessment, the Department provides reasonable assurance that internal controls over operations, reporting, and compliance were operating effectively as of September 30, 2016, with the exception of one material weakness related to Information System Controls and Security, and two material noncompliances: one involving noncompliance with the *Improper Payments Information Act* (IPIA) related to Error Rate Measurement, and the second involving noncompliance with the *Social Security Act* related to the Medicare appeals process.

HHS is taking steps to address the material weakness related to Information System Controls and Security and the material noncompliance related to the Medicare appeals process, as described in the "Corrective Action Plans for Material Weaknesses" section. Remediation for the material noncompliance related to Error Rate Measurement relies on a modification to legislation to require states to participate in an improper payment rate measurement.

The *Federal Financial Management Improvement Act of 1996* (FFMIA) requires agencies to implement and maintain financial management systems that substantially comply with federal financial management system requirements, federal accounting standards, and the United States Standard General Ledger (USSGL) at the transaction level. HHS conducted its evaluation of financial management systems for compliance with FFMIA in accordance with OMB Circular A-123, Appendix D. Based on the results of this assessment, HHS provides reasonable assurance that its overall financial management systems substantially comply with the FFMIA and substantially conform to the objectives of FMFIA, Section 4.

HHS will continue to ensure accountability and transparency over the management of taxpayer dollars, and strive for the continuing progress and enhancement of its internal control and financial management programs.

/Sylvia M. Burwell/

Sylvia M. Burwell
Secretary
November 14, 2016

Summary of Material Weaknesses

1. Information System Controls and Security

HHS acknowledges a material weakness related to Information System Controls and Security. This material weakness includes general and application controls weaknesses specifically related to segregation of duties, access controls, and configuration management, as well as other information system security weaknesses that were identified through the annual Chief Financial Officer (CFO) Audit (*Federal Information Systems Control Audit Manual*), annual *Federal Information Security Management Act* (FISMA) assessment, and other internal management reviews. While no single financial management system had a material weakness, the nature of the deficiencies throughout the Department leads management to conclude that these aggregate deficiencies warrant classification as a material weakness under Section 2 of FMFIA.

2. Error Rate Measurement

HHS reports a statutory limitation relating to the Temporary Assistance for Needy Families (TANF) program that results in a material noncompliance with IPIA. The TANF program is not reporting an error rate for FY 2016, as required by IPIA, because statutory limitations currently prohibit HHS from requiring states to provide information needed for determining a TANF improper payment measurement.

3. Medicare Appeals Process

Several factors, including the growth in Medicare claims and HHS's continued investment and focus on ensuring program integrity, have led to more appeals than Levels 3 and 4 of the Medicare appeals process can adjudicate within the timeframes required by the *Social Security Act*.

From FY 2010 through FY 2015, the HHS Office of Medicare Hearings and Appeals (OMHA) experienced an overall 442 percent increase in the number of Level 3 appeals received annually. During the same timeframe, the HHS Departmental Appeals Board (DAB) experienced an overall 267 percent increase in the number of Level 4 appeals it received annually. However, while the volume of appeals has increased dramatically, funding has remained comparatively stagnant for the relevant OMHA and DAB operations. As a result, at the end of FY 2016, 658,307 appeals were waiting to be adjudicated by OMHA and 22,707 appeals were waiting to be reviewed at the DAB Medicare Appeals Council. This has led to the inability to meet statutory decisional timeframes of 90 days at Levels 3 and 4 of the Medicare appeals process.

Under current resources (and without any additional appeals), it would take several years for both OMHA and the DAB Medicare Appeals Council to process their respective backlogs.

Corrective Action Plans for Material Weaknesses

1. Information System Controls and Security

HHS has placed a high priority on maturing its financial systems controls environment and remediating the Information System Controls and Security material weakness through strengthening policy management, proactively monitoring emerging issues, and ensuring progress toward correcting deficiencies contributing to the material weakness. A Department-wide IT Material Weakness Working Group (MWWG) was established in FY 2015 with members from the CFO, Chief Information Officer, and Chief Information Security Officer Communities to collaboratively identify challenges, conduct root cause analyses, and jointly implement comprehensive solutions. The IT MWWG developed a roadmap to proactively improve the financial systems in the areas of segregation of duties, access controls, configuration management, and FISMA weaknesses that contribute to the Information System Controls and Security material weakness. In FY 2016, HHS has:

- Analyzed FY 2014 and FY 2015 IT audit results to understand the factors contributing to the Information System Controls and Security material weakness;
- Evaluated Federal Information System Controls Audit Manual (FISCAM) system controls gaps based on evaluation criteria derived from National Institute of Standards and Technology (NIST) standards and HHS policies;
- Identified cross-cutting issues and developed preliminary recommendations to address Department-wide and system level challenges; and
- Developed a Financial Systems Policy Management framework, outlining an updated approach to creating, implementing, and monitoring financial systems policies. Further, a pilot program to monitor policy compliance for a core accounting system was established with plans to roll out the program more broadly across the financial systems environment.

In addition to proactive efforts, HHS has made significant progress in remediating audit findings as part of the responsive efforts to address the Information System Controls and Security material weakness.

In the first quarter of FY 2016, HHS completed its major financial management systems upgrade and transitioned the hosting services for key financial systems to a Cloud Service Environment certified by the Federal Risk and Authorization Management Program (FedRAMP), enhancing systems security, scalability, reliability, and availability.

In FY 2017, HHS will continue its collaborative efforts to identify high risk areas within the HHS financial systems environment, develop and implement comprehensive solutions to address department-wide and system level controls gaps in the areas of policy, business application and infrastructure, and monitor corrective action implementation to meet the Department's objectives. HHS will continue to report remediation progress to the Risk Management and Financial Oversight Board and maintain accountability and commitment to strengthen the HHS financial systems environment.

2. Error Rate Measurement

Current statutory limitations restrict corrective actions HHS can take to develop an error rate for TANF. HHS plans to encourage Congress to consider statutory modifications that would allow for greater accountability, including a reliable error rate measurement if appropriate when legislation is considered to reauthorize TANF.

3. Medicare Appeals Process

HHS has a three-pronged strategy to improve the Medicare appeals process:

1) Invest new resources at all levels of appeal to increase adjudication capacity and implement new strategies to alleviate the current backlog;
2) Take administrative actions to reduce the number of pending appeals and encourage resolution of cases earlier in the process; and
3) Propose legislative reforms that provide additional funding and new authorities to address the appeals volume.

The *FY 2017 President's Budget* request includes a comprehensive legislative package aimed at both helping the Department process a greater number of appeals and reducing the number of appeals that reach OMHA. Accounting for current administrative actions and the enactment of proposed funding increases and legislative actions outlined in the *FY 2017 President's Budget*, HHS projects that the backlog could potentially be reduced to 240,810 appeals by the end of FY 2018 and may be eliminated by FY 2019.

LOOKING AHEAD TO 2017

HHS is the U.S. government's principal agency for protecting the health of all Americans, providing essential human services, and promoting economic and social well-being for individuals, families, and communities, including vulnerable populations. Our OpDivs and StaffDivs strive each day to help more Americans acquire affordable health care, to protect and enhance the health of the people of this country and the world, and to assist those who are least able to help themselves. These daily achievements support the Department's existing strategic goals and objectives. In 2017, HHS will update its Strategic Plan to align with the priorities of the next Presidential Administration.

Strengthen Health Care

HHS is responsible for implementing many of the provisions of the *Affordable Care Act,* which makes health insurance coverage more secure and reliable for Americans, makes coverage more affordable and accessible for families and small business owners, and helps bring down health care costs. The *Affordable Care Act* also expands consumer choice, supports informed decision making and increases health insurance coverage for low-income populations, partly through the expansion of Medicaid eligibility and the advent of the Health Insurance Marketplace.

Advance Scientific Knowledge and Innovation

HHS is working to advance scientific knowledge and innovation to prevent, diagnose, and treat diseases and disorders, as well as address emerging health threats, and sustain a vital and cutting edge workforce and scientific infrastructure. Medical breakthroughs, fueled by scientific discovery, have made the difference between life and death for countless Americans. Nevertheless, the need for better health interventions remains. Continuing to improve the health and well-being of Americans requires ongoing investments, with goals that range from improving our understanding of fundamental biological processes to identifying the best modes of prevention and treatment. HHS investments have improved the health of many Americans, but the path from basic discovery into safe, effective patient care can be long.

Advance the Health, Safety, and Well-Being of the American People

HHS focuses on creating environments that promote healthy behaviors to prevent chronic disease and health conditions, including those related to tobacco use and substance abuse, being overweight or obese, and mental disorders. These conditions result in the most deaths, disability, and substantial human and fiscal costs for Americans. HHS works to promote prevention and wellness across its programs and with a variety of partner stakeholders.

HHS partners with state, local, tribal, urban Indian, and other service providers to sustain an essential safety net of services that protect children and youth, promote their resilience in the face of adversity, and ensure their healthy development from birth through the transition to adulthood. Health and early intervention services ensure children get off to a good start from infancy. Early childhood programs, including Head Start, enhance the school readiness of preschool children. Child welfare programs, including child abuse prevention, foster care, and adoption assistance, target those families in which there are safety or neglect concerns. Services for children exposed to trauma or challenged with mental or substance use disorders provide support for those with behavioral health care needs. Several HHS programs also promote positive youth development and seek to prevent risky behaviors in youth.

Promoting economic and social well-being requires attention to a complex set of factors, through the collaborative efforts of agencies, policymakers, researchers, community members, and providers. HHS OpDivs work together and collaborate across departments to maximize the potential benefits of various programs, services, and policies designed to improve the well-being of individuals, families, and communities.

Over the past decade, our nation has renewed its efforts to address large-scale incidents that have threatened human health, such as natural disasters, disease outbreaks, and terrorism. Working with its federal, state, local, tribal, and international partners, as well as industry in public-private partnerships, HHS has improved and exercised response capabilities and developed medical countermeasures.

Did you know?

Injuries are the leading cause of death among American Indians and Alaska Natives ages 1 to 44. The IHS Injury Prevention Program aims to decrease the incidence of injuries and increase the ability of tribes to prevent injuries within their communities.

Ensure Efficiency, Transparency, Accountability, and Effectiveness of HHS Programs

Stewardship of federal funds involves more than ensuring that resources are allocated and expended responsibly. Managing federal health care related investments with integrity and vigilance will safeguard taxpayer dollars as well as benefit the public through improved health and enhanced well-being. Responsible stewardship involves allocating these resources effectively—and for activities that generate the highest benefits. HHS has placed a strong emphasis on protecting program integrity and the well-being of program beneficiaries by identifying opportunities to improve program efficiency and effectiveness. HHS is making every effort to ensure that the right recipient is receiving the right payment for the right reason at the right time.

HHS is strongly committed to data security and the protection of personal privacy and confidentiality as a fundamental principle governing the collection and use of data. HHS protects the confidentiality of individually identifiable information in all public data releases, including publication of datasets on the Web. By employing state-of-the-art processes for data prioritization, release, and monitoring, HHS increases the value derived from information in several ways. Consumers are able to access information and benefit directly from using it personally. Public administrators can use these information resources to enhance service delivery and improve customer satisfaction.

As we near the end of this Administration, HHS leadership is committed to leaving the Department in a strong position to continue its vital work. To do this, HHS will stay committed to developing effective systems, workforce, and infrastructure that can address complicated and emerging challenges. These efforts will allow HHS to continue toward its goal of improved health and well-being among Americans.

FINANCIAL SUMMARY AND HIGHLIGHTS

Once again, HHS received an unmodified audit opinion on its financial statements and notes[1] for the year ending September 30, 2016. We present these in the "Financial Section" of this report. At HHS, we take pride in the preparation of our financial statements, yet it can sometimes be difficult to draw the relationships between the information in the statements and the overall performance of an agency. This section is presented as an interpretation of the financial statements, which include the Consolidated Balance Sheets, Consolidated Statement of Net Cost, Consolidated Statement of Changes in Net Position, Combined Statement of Budgetary Resources, Statement of Social Insurance, and the Statement of Changes in Social Insurance Amounts, as well as selected Notes to the Principal Financial Statements. Included in this analysis is a year-over-year summary of key financial balances, nature of significant changes, and highlights of key financial events to assist our readers in establishing the relevance of the financial statements to the operations of HHS.

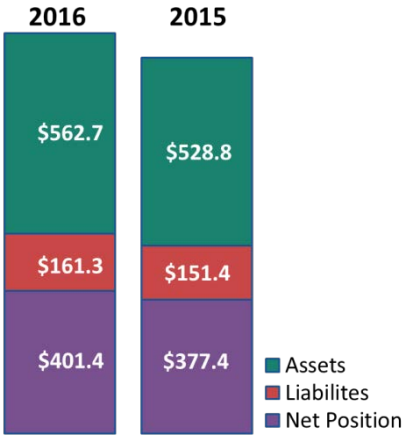
As a federal entity, HHS's financial position and activities are significant to the governmentwide statements. Based on the FY 2015 *Financial Report of the United States Government*, our net operating cost was larger than any single agency across the entire federal government[2]. A similar relationship exists within HHS, where the Department is significantly represented by one OpDiv. CMS alone consistently stewards the largest share of our resources. Therefore, noteworthy changes in HHS balances are primarily related to fluctuations in CMS program activity.

Balance Sheets

To communicate performance for HHS at fiscal year-end, the Consolidated Balance Sheets show the resources available to HHS (Assets) and claims against those assets (Liabilities). The remainder represents the equity retained by the government (Net Position). The table below summarizes the major components of the FY 2016 and FY 2015 year-end balances of HHS's assets available for use, the liabilities owed by HHS, and the equity retained by HHS as represented by the Net Position.

Financial Condition Summary (in Billions)	2016	2015	Change (2016-15) $	Change (2016-15) %
Fund Balance with Treasury	$ 237.8	$ 219.5	$ 18.3	8%
Investments, Net	262.1	269.7	(7.6)	(3)%
Accounts Receivable	25.2	22.9	2.3	10%
Other Assets	37.6	16.7	20.9	125%
Total Assets	**$ 562.7**	**$ 528.8**	**$ 33.9**	**6%**
Accounts Payable	$ 1.3	$ 0.9	$ 0.4	44%
Entitlement Benefits Due and Payable	108.2	108.1	0.1	0%*
Accrued Liabilities	14.4	14.3	0.1	1%
Federal Employee and Veterans' Benefits	12.9	12.1	0.8	7%
Other Liabilities	24.5	16.0	8.5	53%
Total Liabilities	**$ 161.3**	**$ 151.4**	**$ 9.9**	**7%**
Net Position	**$ 401.4**	**$ 377.4**	**$ 24.0**	**6%**
Total Liabilities & Net Position	**$ 562.7**	**$ 528.8**	**$ 33.9**	**6%**

***Change is less than one percent**



[1] Due to the uncertainty of the long-range assumptions used in the Statement of Social Insurance model, our auditors were not able to express an opinion on the Statement of Social Insurance and the Statement of Social Insurance Amounts and associated footnotes.

[2] HHS's net costs are 27 percent of the federal government's total costs; the Social Security Administration costs are 24 percent, Department of Defense are 15 percent, Treasury's Interest on Treasury Security Held by the Public are 6 percent, and the Department of Veterans Affairs are 4 percent. All remaining agencies combined only represent 24 percent.

Source: FY 2015 Financial Report of the United States Government fiscal.treasury.gov/fsreports/rpt/finrep/fr/fr_index.html

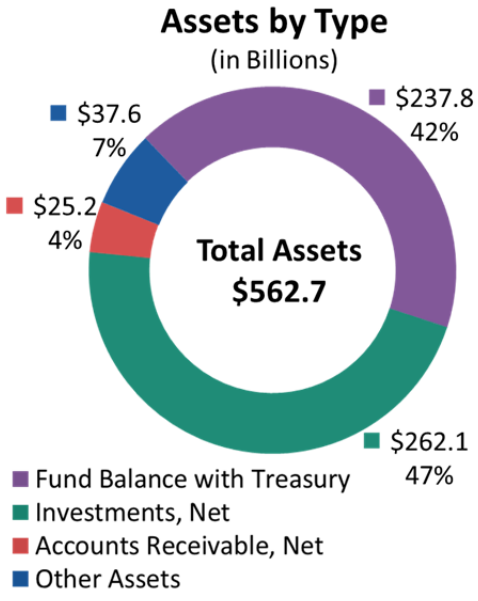
Assets

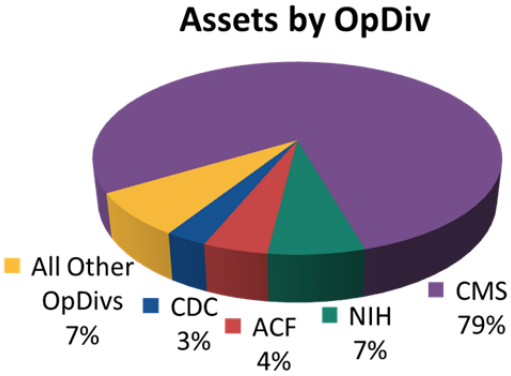
The total Assets for HHS were $562.7 billion at year-end, representing the value of what we own and manage. This is an increase of 6 percent or approximately $33.9 billion over September 30, 2015.

The Other Assets line contains the largest net change between FY 2016 and FY 2015 at $20.9 billion. This is primarily represented by a $21.5 billion increase in advances, including a $14.6 billion increase for the Supplemental Medical Insurance (SMI) Prescription Drug and Medicare Advantage Benefits advances and a $6.9 billion increase in Medicare Hospital Insurance (HI) advances.

Net Investments and the Fund Balance with Treasury (FBwT) together comprise 89 percent of our total assets, which is a 4 percent decrease from 93 percent in FY 2015. Of the $18.3 billion FBwT increase, 63 percent was within CMS. The CMS increase includes FBwT increases for SMI of $8.3 billion and for the Children's Health Insurance Program (CHIP) of $5.6 billion, offset by FBwT decreases in other CMS programs.

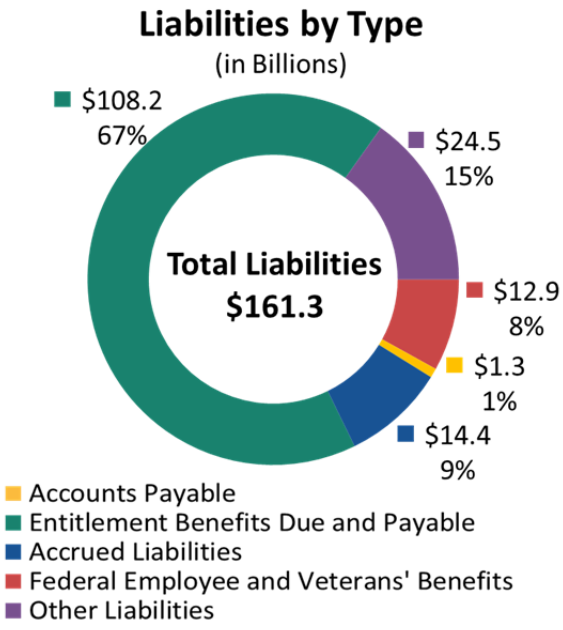
The chart to the right, "Assets by OpDiv," demonstrates asset distribution within the Department. The OpDiv asset balances ranged from $323.0 million at AHRQ to $445.7 billion at CMS. ACF had one of the largest percentile and dollar value asset increases (at 8 percent and $1.8 billion) over FY 2015 due to an expansion of the Temporary Assistance for Needy Families (TANF) program of $1.1 billion and additional resources provided to Head Start of $0.5 billion.

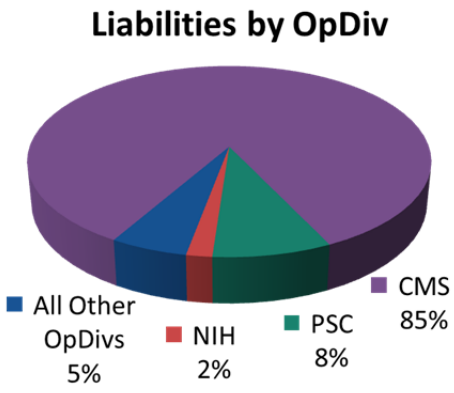




Liabilities

Our Liabilities, or amounts that we owe from past transactions or events, were $161.3 billion on September 30, 2016. This represents an increase of $9.9 billion, or 7 percent more than the FY 2015 liabilities. The driving factor behind this increase can be found in the Other Liabilities line, which increased 53 percent ($8.5 billion) over FY 2015. A major contributor to this change is the result of the *Bipartisan Budget Act of 2015 (Section 601)* which authorized a transfer from the General Fund to SMI. The mandatory repayment of the General Fund transfer created the increased liability. *Section 601* also created an additional premium, which will be charged together with the regular Medicare Part B monthly premiums and will be used to pay back the General Fund without interest.

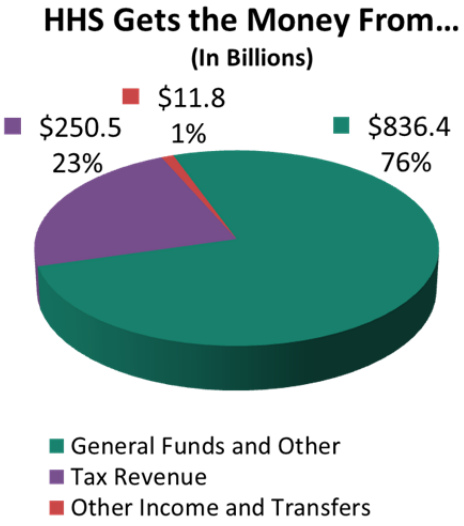




The OpDivs with the largest and smallest asset balances are also the OpDivs with the largest and smallest liabilities. With the majority share, CMS reports $136.9 billion and 85 percent of the HHS liabilities, while AHRQ (shown in All Other OpDivs on the chart to the left) has liabilities around $25.0 million. Other than CMS, PSC had the largest OpDiv dollar value increase in liabilities over FY 2015 of $959.2 million. Of this PSC increase, $819.0 million is an increase to the Pension Liability to capture updated estimates based on mid-year and year-end reviews of their Pension Liability.

Statement of Changes in Net Position

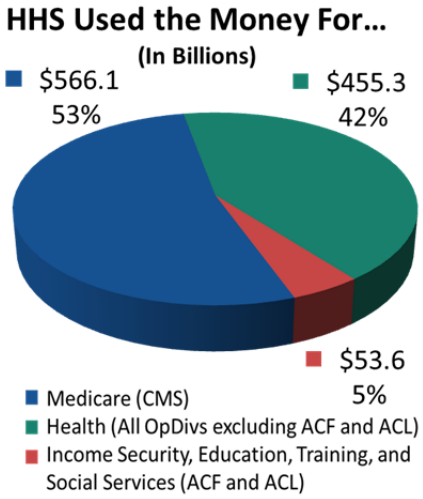
The Consolidated Statement of Changes in Net Position displays the activities affecting the difference between the beginning net position and ending net position, as shown on our Consolidated Balance Sheets. This is also represented as the difference between assets and liabilities.



Changes in assets are shown by breaking out where HHS gets the money from, known as our financing sources. Total financing sources includes both the Total Financing Sources and Total Budgetary Sources lines from the Statement of Changes in Net Position.

We receive the majority of our funding through Congressional appropriations and reimbursement for the provision of goods or services to other federal agencies. HHS's largest financing source, our General Funds and Other, increased over FY 2015 by 5 percent ($39.0 billion) from $797.4 billion to $836.4 billion. Fluctuations in tax revenue collected are due to legislative changes. The increase in tax revenue of 5 percent is comparable to the prior year 4 percent increase in tax revenue.

Statement of Net Cost



The Consolidated Statement of Net Cost represents how we spent the money. This can also be stated as the difference between the costs incurred by our programs less associated revenues. Our Net Cost of Operations for the year ended September 30, 2016, totaled approximately $1.1 trillion. The chart on the left shows consolidating HHS costs by Major Budget Function[3], which are the categories displayed in the federal budget. Most agencies have one or two budget functions, where HHS has many.

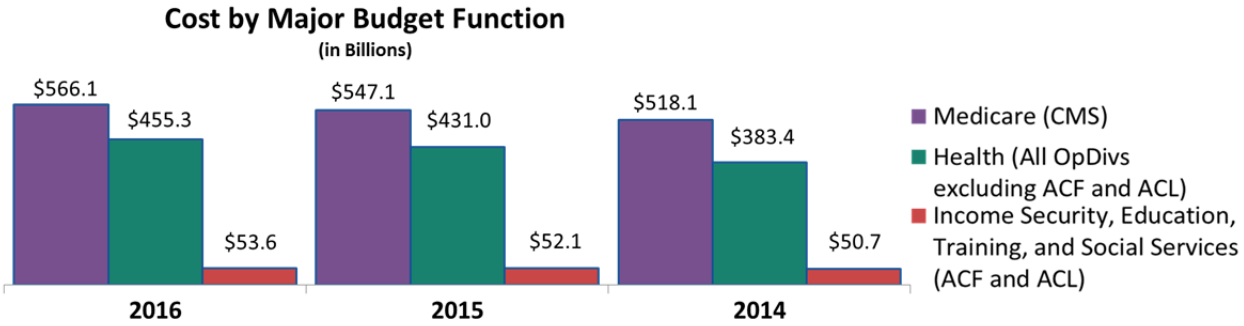
[3] Totals in the chart are exclusive of Intra-HHS Eliminations from the Consolidating Statement of Net Cost by Budget Function.

The table below presents our FY 2016 Consolidated Net Cost of Operations, which we break out into Responsibility Segments between CMS and the remaining OpDivs (Other Segments). Net cost for CMS increased by $39.4 billion between FY 2016 and FY 2015. The majority of this increase relates to benefit expenses reflecting an expansion of Medicaid (with increases of costs approximately totaling $13.9 billion), as well as benefit expense increases for the Medicare SMI of $12.2 billion, and increases of $7.4 billion for Medicare Part D. There was a nominal increase in total Net Cost of Operations for the remaining HHS segments at around $5.4 billion.

Net Cost of Operations (in Billions)	2016	2015	Change (2016-15) $	Change (2016-15) %
Responsibility Segments:				
CMS Gross Cost	$ 1,044.6	$ 1,011.3	$ 33.3	3%
CMS Exchange Revenue	(91.9)	(98.0)	6.1	(6)%
CMS Net Cost of Operations	**$ 952.7**	**$ 913.3**	**$ 39.4**	**4%**
Other Segments:				
Other Segments Gross Cost	$ 127.2	$ 120.7	$ 6.5	5%
Other Segments Exchange Revenue	(5.1)	(4.0)	(1.1)	28%
Other Segments Net Cost of Operations	**$ 122.1**	**$ 116.7**	**$ 5.4**	**5%**
Net Cost of Operations	**$ 1,074.8**	**$ 1,030.0**	**$ 44.8**	**4%**

Rounding in CMS Exchange Revenue

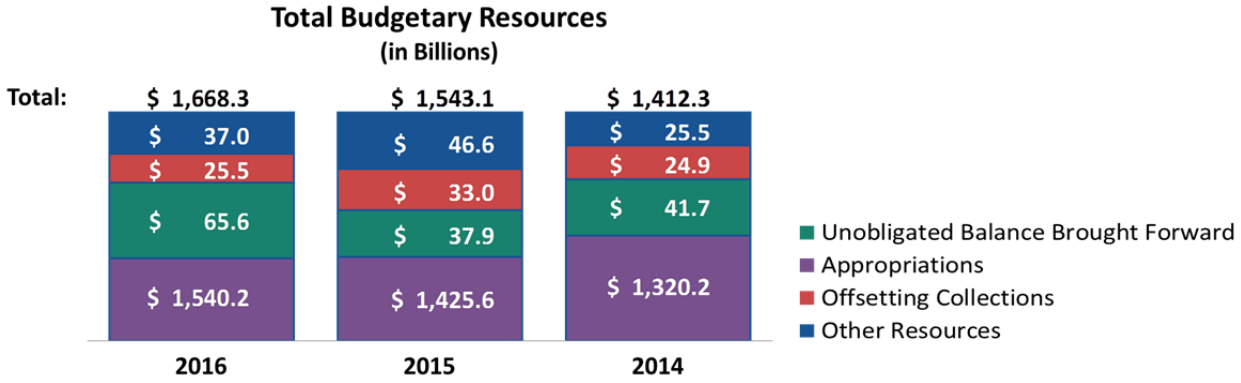
As stated previously, HHS classifies costs by Major Budget Function such as Medicare, Health, Income Security, and Education. This is shown on the Consolidating Statement of Net Cost by Budget Function in the "Other Information" section of this report. Below are the three-year cost trends for these Major Budget Functions[4]. Total net costs for Medicare $566.1 billion and Health $455.3 billion Budget Functions account for 95 percent of our annual net costs.



Statement of Budgetary Resources

The Combined Statement of Budgetary Resources displays the budgetary resources available to HHS throughout 2016 and 2015, and the status of those resources at the fiscal year-end. The primary components of our resources, totaling approximately $1.7 trillion for FY 2016, are appropriations from Congress, resources not yet used from previous years (unobligated balances brought forward), spending authority from offsetting collections, and other budgetary resources. This represents an increase of $125.2 billion, or 8 percent, over FY 2015. The following chart highlights trends in these balances over the past three fiscal years.

[4] Totals in the chart are exclusive of Intra-HHS Eliminations from the Consolidating Statement of Net Cost by Budget Function.



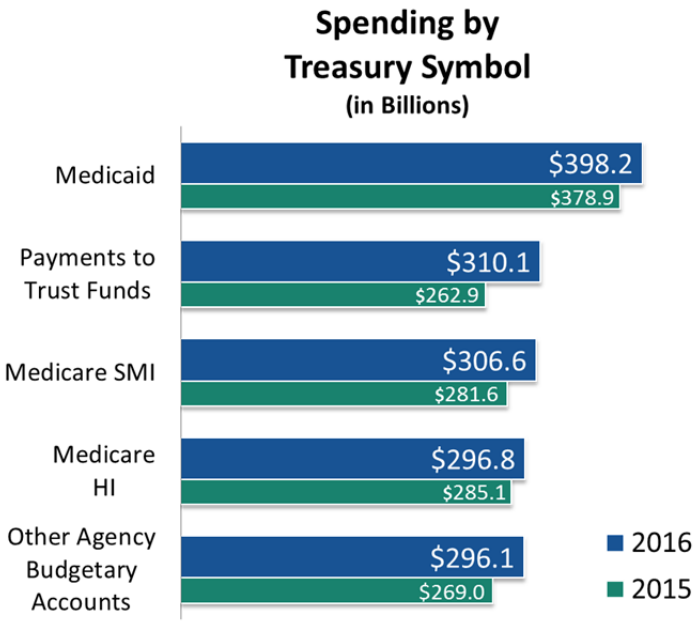
The increase in appropriations are primarily related to increases in the Payments to Trust Funds of $44.6 billion, Medicare SMI of $43.6 billion, Medicare HI of $11.8 billion, Medicaid of $11.2 billion, and CHIP of $1.7 billion. For further details, see the Combining Statement of Budgetary Resources in the "Financial Section" of this report.

Schedule of Spending

HHS has elected to present our trends in spending in the audited Notes to the Principal Financial Statements titled, Combined Schedule of Spending. The chart below illustrates this spending as of September 30, 2016 and 2015 for the top four Treasury Account Symbols (TAS). The remaining TAS are presented in Other Agency Budgetary Accounts.

The New Obligations and Upward Adjustments line on the Combined Statement of Budgetary Resources is the same as Total Amounts Agreed to be Spent line on the Combined Schedule of Spending. Total obligations for FY 2016 were approximately $1.6 trillion, a 9 percent increase over the approximately $1.5 trillion in obligations for FY 2015.

The Department's total spending is once again significantly represented by four of CMS's TAS; Medicaid, Medicare HI, Medicare SMI, and Payments to Trust Funds; at 82 percent of HHS total obligations.



As the American public will soon be able to see more clearly on the new USAspending.gov website[5], the majority (47 percent) of all HHS spending was made through Grants, Subsidies, and Contributions at $749.2 billion. We are the largest grant-making agency in the federal government. Additionally, HHS has incurred obligations for Federal Assistance Direct Payments (44 percent) totaling $704.0 billion. We classify obligations by items or services provided into categories known as object classes. For more information on object classes, see the Combined Schedule of Spending by Object Class in the "Other Information" section of this report.

[5] The goal date for go-live DATA Act reporting is May 2017.

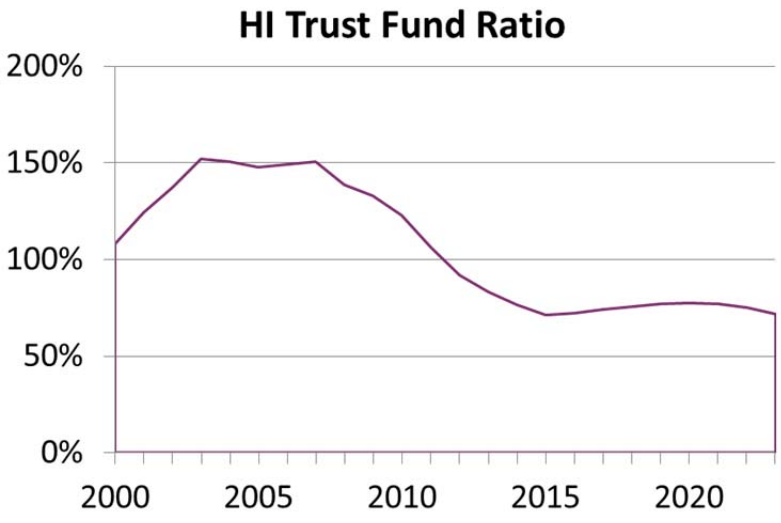
Statement of Social Insurance

The Statement of Social Insurance presents the 75-year actuarial present value of the income and expenditures of the HI and SMI Trust Funds. Future expenditures are expected to arise for current and future program participants. This projection is considered to be important information regarding the potential future cost of the program. These projected potential future obligations are not included in the Consolidated Balance Sheets, Statements of Net Cost and Changes in Net Position, or Combined Statement of Budgetary Resources.

Actuarial present values are computed under the intermediate set of assumptions specified in the *2016 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds*.

The Statement of Social Insurance presents the following estimates:

- The present value of future income (income excluding interest) to be received from or on behalf of current participants who have attained eligibility age and the future cost of providing benefits to those same individuals;
- The present value of future income to be received from or on behalf of current participants who have not yet attained eligibility age and the future cost of providing benefits to those same individuals;
- The present value of future income less future cost for the closed group, which represents all current participants who attain age 15 or older in the first year of the projection period, *plus* the assets in the combined HI and SMI Trust Funds as of the beginning of the valuation period;
- The present value of income to be received from or on behalf of future participants and the cost of providing benefits to those same individuals;
- The present value of future income less future cost for the open group, which represents all current and future participants (including those born during the projection period) who are now participating or are expected to eventually participate in the Medicare program, plus the assets in the combined HI and SMI Trust Funds as of the beginning of the valuation period; and
- The present value of future cash flows for all current and future participants over the next 75 years (open group measure) increased from $(3.2) trillion, determined as of January 1, 2015, to $(3.8) trillion, determined as of January 1, 2016.



Including the combined HI and SMI Trust Fund assets increases the present value, as of January 1, 2016, of future cash flow for all current and future participants to $(3.6) trillion for the 75-year valuation period. The comparable closed group of participants, including the combined HI and SMI Trust Fund assets, is $(10.2) trillion.

HI TRUST FUND SOLVENCY

Pay-as-you-go Financing

The HI Trust Fund is deemed to be solvent as long as assets are sufficient to finance program obligations. Such solvency is indicated, for any point in time, by the maintenance of positive trust fund assets. In recent years, current expenditures have exceeded program income for the HI program, and thus, the HI Trust Fund assets have been declining. The following table shows that HI Trust Fund assets[6], expressed as a ratio of the assets at the beginning of the fiscal year to the expenditures for the year. This ratio has steadily dropped from 95 percent at the beginning of FY 2012 to 67 percent at the beginning of FY 2016.

Trust Fund Ratio Beginning of Fiscal Year					
	2016	2015	2014	2013	2012
HI	67%	73%	77%	86%	95%

Short-Term Financing

The HI Trust Fund is deemed adequately financed for the short term when actuarial estimates of trust fund assets for the beginning of each calendar year are at least as large as program obligations for the year. Estimates in the 2016 Trustees Report indicate that the HI Trust Fund is not adequately financed over the next 10 years. Under the intermediate assumptions of the 2016 Trustees Report, the HI Trust Fund ratio is estimated to continue decreasing through 2025 and remain at approximately 70 percent through 2022. From the end of 2015 to the end of 2020, assets are expected to increase, from $193.8 billion to $216.6 billion, but then decrease to $137.7 billion by the end of 2025.

Long-Term Financing

The short-range outlook for the HI Trust Fund has worsened as compared to what was projected last year. After 2020, the trust fund ratio starts to decline quickly until the fund is depleted in 2028, two years earlier than projected last year. HI financing is not projected to be sustainable over the long term with the tax rates and expenditure levels projected. Program cost is expected to exceed total income in all years. When the HI Trust Fund is exhausted, full benefits cannot be paid on a timely basis. The percentage of expenditures covered by tax revenues is projected to decrease from 87 percent in 2028 to 79 percent in 2040 and then to increase to about 86 percent by the end of the projection period.

The primary reasons for the projected long-term inadequacy of financing under current law relate to the fact that the ratio of the number of workers paying taxes relative to the number of beneficiaries eligible for benefits drops from 3.1 in 2015 to about 2.1 by 2090. In addition, health care costs continue to

Did you know?

Only four federal benefit programs meet the criteria to report a Statement of Social Insurance. They are the Medicare, Social Security, Railroad Retirement, and Black Lung programs.

[6] Assets at the beginning of the year to expenditures during the year.

rise faster than the taxable wages used to support the program. In present value terms, the 75-year shortfall is $3.6 trillion, which is 0.7 percent of taxable payroll and 0.3 percent of Gross Domestic Product (GDP) over the same period.

Significant uncertainty surrounds the estimates for the Statement of Social Insurance. In particular, the actual future values of demographic, economic, and programmatic factors are likely to be different from the near-term and ultimate assumptions used in the projections. For more information, please refer to the *Required Supplementary Information: Social Insurance* disclosures required by the Federal Accounting Standards Advisory Board.

Did you know?

Based on the latest 2016 projections, Medicare and Medicaid (including state funding) represent 38 cents of every dollar spent on health care in the U.S.—or looking at it from three other perspectives: 54 cents of every dollar spent on nursing homes, 44 cents of every dollar received by U.S. hospitals, and 34 cents of every dollar spent on physician services.

SMI TRUST FUND SOLVENCY

The SMI Trust Fund consists of two accounts – Part B and Part D. In order to evaluate the financial status of the SMI Trust Fund, each account needs to be assessed individually, since financing rates for each part are established separately, and their program benefits are quite different in nature.

While differences between the two accounts exist, the financing mechanism for each part is similar in that the financing is determined on a yearly basis. The Part B account is generally financed by premiums and general revenue matching appropriations determined annually to cover projected program expenditures and to provide a contingency for unexpected program variation. The Part D account is financed by premiums, general revenues, and transfers from state governments. Unlike the Part B account, the appropriation for Part D general revenues has generally been set such that amounts can be transferred to the Part D account on an as-needed basis; under this process, there is no need to maintain a contingency reserve. In September 2015, a new policy was implemented to transfer amounts from the Treasury into the account five business days before the benefit payments to the plans. This transfer occurred again in February 2016 and is expected to occur consistently thereafter. As a result, the Trustees expect the Part D account to include a more substantial balance at the end of most months to reflect the new policy.

Since both the Part B and Part D programs are financed on a yearly basis, from a program perspective, there is no unfunded liability in the short or long-range. Therefore, in this financial statement the present value of estimated future excess of income over expenditures for current and future participants over the next 75 years is $0. However, from a government wide perspective, general fund transfers as well as interest payments to the Medicare Trust Funds and asset redemption, represent a draw on other federal resources for which there is no earmarked source of revenue from the public. Hence, from a government wide perspective, the corresponding estimate of future income less expenditures for the 75-year projection period is $(28.6) trillion.

Even though from a program perspective, the unfunded liability is $0, there is concern over the rapid increase in cost of the SMI program as a percent of GDP. In 2015, SMI expenditures were 2.1 percent of GDP. By 2090, SMI expenditures are projected to grow to 3.8 percent of the GDP.

The following table[7] presents key amounts from our basic financial statements for fiscal year 2014 through 2016.

Table of Key Measures

Financial Condition Summary (in Billions)	2016	2015	2014
Net Position (end of fiscal year)			
Assets	$ 446.0	$ 418.6	$ 380.0
Less Total Liabilities	137.3	129.1	104.7
Net Position (assets net of liabilities)	**$ 308.7**	**$ 289.5**	**$ 275.3**
Change in Net Position (end of fiscal year)			
Net Costs	$ 953.1	$ 913.8	$ 837.8
Total Financing Sources	960.1	910.3	820.4
Change in Net Position	**$ 7.0**	**$ (3.5)**	**$ (17.4)**
Statement of Social Insurance (calendar year basis)			
Present value of estimated future income (excluding interest) less expenditures for current and future participants over the next 75 years (open group), current year valuation	$(3,821.7)	$(3,187.0)	$(3,822.9)
Present value of estimated future income (excluding interest) less expenditures for current and future participants over the next 75 years (open group), prior year valuation	$(3,187.0)	$(3,822.9)	$(4,771.8)
Change in Present Value	**$ (634.7)**	**$ 635.9**	**$ 948.9**

Statement of Changes in Social Insurance Amounts

The Statement of Changes in Social Insurance Amounts reconciles the change (between the current valuation period and the prior valuation period) in the present value of future tax income less future cost for current and future participants (the open group measure) over the next 75 years. This reconciliation identifies those components of the change that are significant and provides reasons for the changes. In general, an increase in the present value of net cash flow represents a positive change (improving financing), while a decrease in the present value of net cash flow represents a negative change (worsening financing).

The present value as of January 1, 2016, decreased by $168.6 billion due to advancing the valuation date by one year and including the additional year 2090, by $288.7 billion due to changes in the projection base, and by $366.1 billion due to the changes in economic and health care assumptions. However, changes in demographic assumptions and legislation changes increased the present value of future cash flows by $182.4 billion and $6.4 billion, respectively.

[7] The table or other singular presentation showing the measures described above. Although, the closed group measure is not required to be presented in the table or other singular presentation, the CMS presents the closed group measure and open group measure.

Required Supplementary Information

As required by Statement of Federal Financial Accounting Standards (SFFAS) Number 17, Accounting for Social Insurance (as amended by *SFFAS Number 37, Social Insurance: Additional Requirements for Management Discussion and Analysis and Basic Financial Statements*), HHS has included information about the Medicare trust funds – HI and SMI. The Required Supplementary Information (RSI) presents required long-range cash-flow projections, the long-range projections of the ratio of contributors to beneficiaries (dependency ratio), and the sensitivity analysis illustrating the effect of the changes in the most significant assumptions on the actuarial projections and present values. The SFFAS 37 does not eliminate or otherwise affect the SFFAS 17 requirements for the supplementary information, except that actuarial projections of annual cash flow in nominal dollars are no longer required; as such, it will not be reported in the RSI. The RSI assesses the sufficiency of future budgetary resources to sustain program services and meet program obligations as they come due. The information is drawn from the *2016 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds*, which represents the official government evaluation of the financial and actuarial status of the Medicare Trust Funds.

Limitation of the Principal Financial Statements

The principal financial statements in the "Financial Section" have been prepared to report our financial position and results of operations, pursuant to the requirements of 31 U.S.C. §3515(b). Although the statements have been prepared from our books and records in accordance with generally accepted accounting principles for federal entities and the formats prescribed by the OMB, the statements are in addition to the financial reports used to monitor and control budgetary resources, which are prepared from the same books and records.

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 HHS with resources and budget authority.

Financial Section

2

In This Section

- Message from the Chief Financial Officer
- Report of the Independent Auditors
- Department's Response to the Report of the Independent Auditors
- Principal Financial Statements
- Notes to the Principal Financial Statements
- Required Supplementary Stewardship Information
- Required Supplementary Information

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MESSAGE FROM THE CHIEF FINANCIAL OFFICER

I am pleased to join the Secretary in presenting the Department of Health and Human Services' (HHS) Fiscal Year (FY) 2016 Agency Financial Report. HHS oversees one of the largest budgets in the world, managing one of every four dollars spent by the federal government. Serving as effective stewards of public funds is an integral component of achieving our mission.

This year, we obtained an unmodified (clean) opinion on the Consolidated Balance Sheets, Statement of Net Cost, Statement of Changes in Net Position, and the Combined Statement of Budgetary Resources. The auditors identified one material weakness and two significant deficiencies. The auditors disclaimed providing an opinion on the Statement of Social Insurance and the Statement of Changes in Social Insurance Amounts, primarily due to the uncertainties surrounding provisions of the *Affordable Care Act* and the impact of potential changes in law that would impact underlying assumptions of financial projections. These statements were developed based upon current law using information from the *2016 Medicare Trustees Report*, as required by standards issued by the Federal Accounting Standards Advisory Board.

During FY 2016, HHS continued to make progress in executing its multi-year financial systems modernization initiative to strengthen system security, reliability, and availability, as well as target remediation of the Department's material weakness pertaining to information technology (IT). Our efforts included:

- Completing the major upgrade of our core financial system in December 2015 – on-time, on-budget, and fully functional – enabling HHS to mitigate mission risk, improve functionality and performance, and strengthen overall system controls and security.
- Transitioning key financial systems to a Federal Risk and Authorization Management Program certified cloud service provider, supporting governmentwide IT priorities and further enhancing system security, reliability, availability, performance, and scalability.
- Maturing the overall financial systems security and controls environment, including strengthening policy development and monitoring; proactively monitoring emerging issues; and coordinating a Department-wide initiative to systematically address HHS's IT material weakness by defining the complete problems, identifying root causes, and implementing collaborative solutions.

We also made significant progress in remediating significant deficiencies related to Financial Reporting Systems, Analyses, and Oversight; and the Financial Management Close and Review Process. Our remediation efforts included:

- Continuing to review, update, and develop HHS policies in financial management, grants, and acquisitions to ensure compliance with applicable federal regulations and guidance.
- Establishing a mature and structured corrective action planning process, consisting of increased Operating Division (OpDiv) communication and support through a standardized approach, policy, guidance, training, and on-site technical assistance.

HHS also achieved significant accomplishments in several additional areas that strengthen Department management:

- Continued implementation of Enterprise Risk Management across the Department and in its OpDivs, consistent with the July 2016 release of OMB Circular A-123, *Management's Responsibility for Enterprise Risk Management and Internal Control*.
- Established a strategy, cross-functional governance structure, and implementation teams to support the *Digital Accountability and Transparency Act* reporting requirements by May 2017.
- Expanded HHS's business intelligence and analytics capabilities through the Financial Business Intelligence System – enhancing access to financial management information, supporting internal and external reporting requirements, and facilitating effective stewardship and decision making.
- Continued to improve governance through the Financial Management Governance Board, allowing HHS to effectively address enterprise-wide financial management issues related to policies, data, and technology, and enhance collaboration across the Department's financial management community.

Our Chief Financial Officer (CFO) community is dedicated to working together to improve Department-wide operations, financial reporting and systems, while focusing our efforts on strengthening internal control, maintaining data integrity, increasing data transparency, and reporting reliable information to support effective internal and external decision making.

The Association of Government Accountants presented HHS with the *Certificate of Excellence in Accountability Reporting* award for our FY 2015 AFR, the third consecutive year we earned recognition for our financial report. The award is given to federal agencies following a rigorous, independent review against a comprehensive set of standards. We were also presented with a Best in Class award for our Improper Payments and Elimination Act Reporting Detail.

The achievements depicted in this report are a reflection of the earnest effort and diligent dedication of our employees and partners who collaborate throughout the year to serve our mission and the American people. We will continue to conscientiously serve our stakeholders in an accountable and transparent manner.

/Ellen G. Murray/

Ellen G. Murray
Assistant Secretary for Financial Resources and
Chief Financial Officer
November 14, 2016

REPORT OF THE INDEPENDENT AUDITORS

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201

TO: The Secretary NOV 14 2016
Through: DS _____
COS _____
ES _____

FROM: Inspector General Daniel R. Levinson

DATE: November 14, 2016

SUBJECT: OIG Report on the Financial Statement Audit of the Department of Health and Human Services for Fiscal Year 2016 (A-17-16-00001)

This memorandum transmits the independent auditors' reports on the Department of Health and Human Services (HHS) fiscal year (FY) 2016 financial statements, conclusions about the effectiveness of internal controls, and compliance with laws and other matters. The Chief Financial Officers Act of 1990 (P.L. No. 101-576), as amended, requires the Office of Inspector General (OIG) or an independent external auditor, as determined by OIG, to audit the HHS financial statements in accordance with applicable standards.

We contracted with the independent certified public accounting firm of Ernst & Young, LLP, to audit the HHS (1) consolidated balance sheets as of September 30, 2016 and 2015, and the related consolidated statements of net cost and changes in net position; (2) the combined statements of budgetary resources for the years then ended; and (3) the statement of social insurance as of January 1, 2016, and the related statement of changes in social insurance amounts. The contract required that the audit be performed in accordance with auditing standards generally accepted in the United States of America; the standards applicable to financial audits contained in *Government Auditing Standards,* issued by the Comptroller General of the United States; and Office of Management and Budget (OMB) Bulletin 15-02, *Audit Requirements for Federal Financial Statements*.

Results of the Independent Audit

On the basis of its audit, Ernst & Young found that the FY 2016 HHS consolidated balance sheets and the related consolidated statements of net cost and changes in net position and combined statements of budgetary resources were presented fairly, in all material respects, in conformity with U.S. generally accepted accounting principles. With respect to the estimates for the statement of social insurance as of January 1, 2016 and 2015, and the related Statement of Changes in Social Insurance Amounts, HHS management described in the financial statement footnotes the Medicare Board of Trustees alternative scenario that illustrates, when possible, the

potential understatement of Medicare cost and projection results. This scenario assumes that the various cost-reduction measures will occur as current law requires. The most important of these measures are the reduction in the annual payment rate updates for most categories of Medicare providers by the growth in economy-wide multifactor productivity and the specified physician updates put in place by the Medicare Access and CHIP[1] Reauthorization Act of 2015 (MACRA) (P.L. No. 114-10)—will occur as current law requires. Also, the Medicare Board of Trustees, in its annual report to Congress, stated:

> The Trustees are hopeful that U.S. health care practices are in the process of becoming more efficient as providers anticipate more modest rates of reimbursement growth, in both the public and private sectors, than those experienced in recent decades. The methodology for projecting Medicare finances assumes a substantial long-term reduction in per capita health expenditure growth rates relative to historical experience, to which the cost-reduction provisions of the Affordable Care Act[2] and MACRA would add substantial savings. Notwithstanding recent favorable developments, current-law projections indicate that Medicare still faces a substantial financial shortfall that will need to be addressed with further legislation.

The range of the social insurance liability estimates in the various scenarios is significant. As a result, Ernst & Young was unable to obtain sufficient audit evidence for the particular amounts presented in the statements of social insurance as of January 1, 2016, 2015, 2014, 2013, and 2012, and the related statements of changes in social insurance amounts for the periods ended January 1, 2016 and 2015. Ernst & Young was not able to, and did not, express an opinion on the financial condition of the HHS social insurance program and related changes in the social insurance program for the specified periods.

Ernst & Young also noted three matters involving internal controls with respect to financial reporting. Under the standards established by the American Institute of Certified Public Accountants and *Government Auditing Standards*, issued by the Comptroller General of the United States, Ernst & Young identified a material weakness in HHS's Financial Information Systems and significant deficiencies in both its Financial Reporting Systems, Analyses, and Oversight and the National Institutes of Health (NIH) Financial Management Systems and Review Processes:

- *Financial Information Systems*—Ernst & Young noted that HHS had continued to make strides to improve controls that support the information technology (IT) infrastructure and financial application system. The Material Weakness Working Group has continued to take a leadership role in monitoring activities across all HHS IT systems in scope for the consolidated financial statement audit and the Federal Information Security Modernization Act of 2014. Ernst & Young noted improvements occurred as a result of investments in the key financial systems' underlying infrastructure, proactive remediation of issues identified that allowed the risk to be modified, and the strengthening of the

[1] Children's Health Insurance Program.

[2] The Patient Protection and Affordable Care Act (P.L. No. 111-148) as amended by the Health Care and Education Reconciliation Act of 2010 (P.L. No. 111-152) are collectively referred to as the Affordable Care Act."

departmentwide Plan of Actions and Milestone process that has led to the remediation of a number of prior-year findings. As in previous fiscal years, Ernst & Young indicated a focused effort is still needed to completely remediate long outstanding deficiencies related to segregation of duties, configuration management, and access to HHS financial systems. The deficiencies continue to represent a material weakness in internal control.

- *Financial Reporting Systems, Analyses, and Oversight*—During the FY 2016 audit, Ernst & Young continued to note progress in certain areas to improve HHS's and its Operating Divisions' financial management processes. While progress has continued, the FY 2016 audit, as in prior years, identified internal control deficiencies in financial systems and processes for producing financial statements, including a lack of integrated financial management systems and insufficient analysis of certain accounts. Ernst & Young continued to note that HHS did not consistently perform controls to ensure that differences were properly identified, researched, and resolved in a timely manner, and account balances were complete and accurate. Ernst & Young concluded that additional improvements in the financial reporting systems and processes are required. These deficiencies collectively constitute a significant deficiency in internal control.

- *NIH Financial Management System and Review Processes*—In FY 2016, Ernst & Young noted that the National Institutes of Health (NIH) performed additional analysis of its balances and invested resources to overcome certain deficiencies in its internal controls supporting IT infrastructure and financial application systems. Ernst & Young, however, continued to identify deficiencies that require additional focus. It identified deficiencies in the financial reporting process in which certain transactions are not reported consistently, resulting in differences that require research and manual posting of entries to ensure the financial information is synchronized between NIH and U.S. Treasury financial records, manual journal entries had improper or no approvals or insufficient support, and the lack of specific NIH procedures for its period-end closing to ensure all entries had been recorded appropriately or were complete. The deficiencies collectively constitute a separate significant deficiency in internal control.

Ernst & Young identified several instances of noncompliance with laws and other matters. During FY 2016, HHS was not in full compliance with the requirements of the Improper Payments Information Act of 2002 (P.L. No. 107-300) (IPIA), as amended, and section 6411 of ACA related to the implementation of recovery activities for the Medicare Advantage program. HHS reported improper payment error rates for its high-risk programs, except for Temporary Assistance for Needy Families (TANF). HHS believes it does not have the authority under the Social Security Act to compel the States to report error rates for TANF. HHS reported an error rate of over 10 percent for the Medicare Fee-for-Service and Medicaid programs, which is a violation of the IPIA. Three other HHS high-priority programs reported error rates that did not meet their FY 2016 target error rates, which is another violation of the IPIA. We will report further on agency compliance with improper payment reporting, as required by the IPIA, later in FY 2017. HHS's management determined that it may have potential violations of certain provisions of the Anti-Deficiency Act (P.L. No. 101-508 and OMB Circular A-11) related to FY 2015 and FY 2016 obligation of funds for conference spending. HHS's management also determined that the agency's Medicare appeals process did not adjudicate appeals within the statutory timeframes required by the Social Security Act (P.L No. 74-271).

On the basis of the material weakness reported over Financial Information Systems and the significant deficiencies reported over Financial Reporting Systems, Analysis, and Oversight and NIH Financial Management System and Review processes, Ernst & Young concluded that HHS also did not comply with the Federal Financial Management Improvement Act of 1996 (P.L. No.104-208).

Evaluation and Monitoring of Audit Performance

In accordance with the requirements of OMB Bulletin 15-02, we reviewed Ernst & Young's audit of the HHS financial statements by:

- evaluating the independence, objectivity, and qualifications of the auditors and specialists;
- reviewing the approach and planning of the audit;
- attending key meetings with auditors and HHS officials;
- monitoring the progress of the audit;
- examining audit documentation, including those related to the review of internal controls over financial reporting;
- reviewing the auditors' reports, and;
- reviewing the HHS *FY 2016 Agency Financial Report*.

Ernst & Young is responsible for the attached reports and the conclusions expressed in those reports. Our review, as differentiated from an audit in accordance with U.S. generally accepted government auditing standards, was not intended to enable us to express, and accordingly we do not express, an opinion on HHS's financial statements, the effectiveness of internal controls, whether financial management systems substantially complied with the Federal Financial Management Improvement Act of 1996, or HHS's compliance with laws and regulations. However, our monitoring review, as limited to the procedures listed above, disclosed no instances in which Ernst & Young did not comply, in all material respects, with U.S. generally accepted government auditing standards.

If you have any questions or comments about this report, please do not hesitate to call me, or your staff may contact Gloria L. Jarmon, Deputy Inspector General for Audit Services, at (202) 619-3155 or through e-mail at Gloria.Jarmon@oig.hhs.gov. Please refer to report number A-17-16-00001.

Attachment

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

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

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Report of Independent Auditors

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

Report on the Financial Statements

We have audited the accompanying consolidated balance sheets of the U.S. Department of Health and Human Services (HHS) as of September 30, 2016 and 2015, and the related consolidated statement of net cost and changes in net position, and the combined statement of budgetary resources for the fiscal years then ended, and the related notes to the principal financial statements. We were also engaged to audit the statement of social insurance as of January 1, 2016, 2015, 2014, 2013, and 2012, the related statement of changes in social insurance amounts for the periods ended January 1, 2016 and 2015, and the related notes to these financial statements.

Management's Responsibility for the Financial Statements

Management is responsible for the preparation and fair presentation of these financial statements in conformity with U.S. generally accepted accounting principles; this includes the design, implementation, and maintenance of internal control relevant to the preparation and fair presentation of financial statements that are free of material misstatement, whether due to fraud or error.

Auditor's Responsibility

Our responsibility is to express opinions on these financial statements based on our audits. Except as discussed in the Basis for Disclaimer of Opinion paragraphs with respect to the accompanying statement of social insurance as of January 1, 2016, 2015, 2014, 2013, and 2012, the related statement of changes in social insurance amounts for the periods ended January 1, 2016 and 2015, and the related notes to these financial statements, we conducted our audits in accordance with auditing standards generally accepted in the United States, and the standards applicable to financial audits contained in *Government Auditing Standards*, issued by the Comptroller General of the United States, and Office of Management and Budget Bulletin No. 15-02, *Audit Requirements for Federal Financial Statements*. Those standards and bulletin require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the financial statements. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatement of the financial statements, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to HHS's preparation and fair presentation of the financial statements in order to design

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audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control. Accordingly, we express no such opinion. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of significant accounting estimates made by management, as well as evaluating the overall presentation of the financial statements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion on the consolidated balance sheets as of September 30, 2016 and 2015, and the related consolidated statement of net cost and changes in net position, and the combined statement of budgetary resources for the fiscal years then ended, and the related notes to the principal financial statements.

Basis for Disclaimer of Opinion on the Statement of Social Insurance and the Related Changes in the Social Insurance Program

As discussed in Note 24 to the principal financial statements, the statement of social insurance presents the actuarial present value of the Hospital Insurance (HI) and Supplementary Medical Insurance (SMI) trust funds' estimated future income to be received from or on behalf of the participants and estimated future expenditures to be paid to or on behalf of participants during a projection period sufficient to illustrate long-term sustainability of the social insurance program. In preparing the statement of social insurance, management considers and selects assumptions and data that it believes provide a reasonable basis for the assertions in the statement. Because of the large number of factors that affect the statement of social insurance and the fact that future events and circumstances cannot be known with certainty, there will be differences between the estimates in the statement of social insurance and the actual results, and those differences may be material. Projections of Medicare costs are sensitive to assumptions about future decisions by policymakers and about the behavioral responses of consumers, employers, and health care providers as policies, incentives, and the health care sector change over time. In addition to the inherent variability that underlies the expenditure projections prepared for all parts of Medicare, and as discussed below, significant additional variability and issues regarding the sustainability of the underlying assumptions under current law were introduced by the passage of the Patient Protection and Affordable Care Act (ACA) and the Medicare Access and CHIP Reauthorization Act (MACRA).

As further described in Note 25 to the principal financial statements, with respect to the estimates for the social insurance program presented as of January 1, 2016, 2015, 2014, 2013, and 2012, management has assumed in the projections of the program that the various cost-reduction measures will occur as the ACA and the specified physician updates established by MACRA require. Management has developed an illustrative alternative scenario and projections intended to quantify the potential understatement of projected Medicare costs to the extent that certain payment provisions were not fully implemented in all future years. The range of the social insurance liability estimates in the scenarios is significant. As described in Note 25, the ability of health care providers to sustain these price reductions will be challenging, as the best available

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evidence indicates that most providers cannot improve their productivity to this degree for a prolonged period given the labor-intensive nature of these services. As a result, actual Medicare expenditures are highly uncertain for reasons apart from the inherent difficulty in projecting health care cost growth over time. Absent an unprecedented change in health care delivery systems and payment mechanisms, the prices paid by Medicare for most health services will fall increasingly short of the costs of providing these services. For example, overriding the scheduled physician payment updates or the productivity adjustments for most providers, as was done repeatedly with the sustainable growth rate formula in the period leading up to passage of MACRA and may be necessary in the future if cost rates prove inadequate, would lead to substantially higher costs for Medicare in the long range than those projected in this report. As a result of these limitations, we were unable to obtain sufficient audit evidence for the amounts presented in the statement of social insurance as of January 1, 2016, 2015, 2014, 2013, and 2012, and the related statement of changes in social insurance amounts for the periods ended January 1, 2016 and 2015.

Disclaimer of Opinion on the Statement of Social Insurance and the Related Changes in the Social Insurance Program

Because of the significance of the matters described in the Basis for Disclaimer of Opinion paragraphs, the scope of our work was not sufficient to enable us to express, and we do not express, an opinion on the financial condition of the HHS social insurance program as of January 1, 2016, 2015, 2014, 2013, and 2012, and the related changes in the social insurance program for the periods ended January 1, 2016 and 2015.

Opinion

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of HHS as of September 30, 2016 and 2015, and its consolidated net cost, changes in net position, and budgetary resources for the years then ended in conformity with U.S. generally accepted accounting principles.

Other Matters

Required Supplementary Information

U.S. generally accepted accounting principles require that the Management's Discussion and Analysis, Required Supplementary Stewardship Information, and Required Supplementary Information as identified on HHS's Agency Financial Report Table of Contents, be presented to supplement the basic financial statements. Such information, although not a part of the basic financial statements, is required by the Federal Accounting Standards Advisory Board, which considers it to be an essential part of financial reporting for placing the basic financial statements in an appropriate operational, economic, or historical context. We have applied certain limited procedures to the required supplementary information in accordance with auditing standards

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generally accepted in the United States, which consisted of inquiries of management about the methods of preparing the information and comparing the information for consistency with management's responses to our inquiries, the basic financial statements, and other knowledge we obtained during our audits of the basic financial statements. We do not express an opinion or provide any assurance on the information because the limited procedures do not provide us with sufficient evidence to express an opinion or provide any assurance.

Other Financial Information and Other Information

Our audits were conducted for the purpose of forming opinions on the financial statements that collectively comprise HHS's basic financial statements. The Other Financial Information, as identified on HHS's Agency Financial Report Table of Contents, is presented for purposes of additional analysis and is not a required part of the basic financial statements.

The Other Financial Information is the responsibility of management and was derived from and relates directly to the underlying accounting and other records used to prepare the basic financial statements. Such information has been subjected to the auditing procedures applied in the audits of the basic financial statements and certain additional procedures, including comparing and reconciling such information directly to the underlying accounting and other records used to prepare the basic financial statements or to the basic financial statements themselves, and other additional procedures in accordance with auditing standards generally accepted in the United States. In our opinion, the Other Financial Information is fairly stated, in all material respects, in relation to the basic financial statements as a whole.

Except for the Other Financial Information described above, the Other Information has not been subjected to the auditing procedures applied in the audits of the basic financial statements, and, accordingly, we do not express an opinion or provide any assurance on it.

Other Reporting Required by Government Auditing Standards

In accordance with *Government Auditing Standards*, we also have issued our reports dated November 14, 2016, on our consideration of HHS's internal control over financial reporting and on our tests of its compliance with certain provisions of laws and regulations and other matters. The purpose of those reports is to describe the scope of our testing of internal control over financial reporting and compliance and the results of that testing, and not to provide an opinion on the internal control over financial reporting or on compliance. Those reports are an integral part of an audit performed in accordance with *Government Auditing Standards* in considering HHS's internal control over financial reporting and compliance.

Ernst & Young LLP

November 14, 2016

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Report of Independent Auditors on Internal Control over Financial Reporting Based on an Audit of Financial Statements Performed in Accordance With *Government Auditing Standards*

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

We have audited, in accordance with auditing standards generally accepted in the United States and the standards applicable to financial audits contained in *Government Auditing Standards* issued by the Comptroller General of the United States and Office of Management and Budget (OMB) Bulletin No. 15-02, *Audit Requirements for Federal Financial Statements*, the consolidated financial statements of the U.S. Department of Health and Human Services (HHS or the Department), which comprise the consolidated balance sheet as of September 30, 2016, and the related consolidated statement of net cost and changes in net position, and the combined statement of budgetary resources for the fiscal year then ended, and the related notes to the principal financial statements, and we were engaged to audit the statement of social insurance as of January 1, 2016, and the related statement of changes in social insurance amounts for the period ended January 1, 2016, and have issued our report thereon dated November 14, 2016. That report states that because of the matters described in the Basis for Disclaimer of Opinion paragraphs, the scope of our work was not sufficient to enable us to express, and we do not express, an opinion on the statement of social insurance as of January 1, 2016, and the related statement of changes in social insurance amounts for the period ended January 1, 2016.

Internal Control over Financial Reporting

In planning and performing our audit of the financial statements, we considered HHS's internal control over financial reporting (internal control) to determine the audit procedures that are appropriate in the circumstances for the purpose of expressing our opinion on the financial statements, but not for the purpose of expressing an opinion on the effectiveness of HHS's internal control. Accordingly, we do not express an opinion on the effectiveness of HHS's internal control. We limited our internal control testing to those controls necessary to achieve the objectives described in OMB Bulletin No. 15-02. We did not test all internal controls relevant to operating objectives as broadly defined by the *Federal Managers' Financial Integrity Act of 1982*, such as those controls relevant to ensuring efficient operations.

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

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deficiencies, in internal control that is less severe than a material weakness, yet important enough to merit attention by those charged with governance.

Our consideration of internal control was for the limited purpose described in the first paragraph of this section and was not designed to identify all deficiencies in internal control that might be material weaknesses or significant deficiencies; therefore, material weaknesses or significant deficiencies may exist that were not identified. Given these limitations, during our audit, we did identify certain deficiencies related to Financial Information Systems, described below, to be a material weakness. We also identified certain deficiencies related to Financial Reporting Systems, Analyses, and Oversight, and National Institutes of Health (NIH) Financial Management Systems and Review Processes, described below, to be significant deficiencies.

Material Weakness

Financial Information Systems

The Department continued to make strides during fiscal year (FY) 2016 to improve the controls within its supporting information technology (IT) infrastructure and financial systems. The Material Weakness Working Group (MWWG) has continued to take a leadership role in monitoring remediation activities across all IT systems in scope of the consolidated Financial Statement Audit and *Federal Information Security Modernization Act of 2014* (FISMA). The MWWG has effectively altered the culture and "tone at the top" by putting a heightened focus on addressing the root cause of issues identified during the audit, resulting in a more mature controls environment across the Department. The following summarizes some of the improvements achieved that resulted from this increased attention:

- Differential investments in key financial systems' underlying infrastructure (i.e., Oracle upgrades and movement to the cloud), providing a more modern and mature controls baseline that positions the Department well for future scalability in an efficient manner;

- Proactive remediation of issues identified during the audit, allowing for the residual risk of the issue to be minimized, while establishing the processes necessary to close the issue moving forward; and

- Strengthening of the Department-wide Plan of Actions and Milestone (POA&M) process, which has led to the remediation of a number of prior year objective attributes recap sheet (OARS) items.

Although the MWWG has implemented specific action plans to decrease the number and severity of the deficiencies remaining in the major financial systems, the remediation of deficiencies, which sometimes takes multiple years, is inherently an iterative process. A focused risk-driven effort is still necessary to completely remediate the remaining long-outstanding deficiencies in the areas of

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access controls, configuration management, and segregation of duties (SOD). The remaining deficiencies continue to constitute an IT material weakness in internal control. We grouped the deficiencies into the following topics and categories listed below:

- Access controls
  - Inconsistently performing user access reviews of generic IDs, some with administrative access, which impacts the ability to effectively identify and monitor access anomalies and other potentially suspicious activities
  - Users maintaining multiple user IDs to the application and/or users with excessive application access that is not commensurate with their job roles and responsibilities
- Configuration management
  - Understanding the full population of changes made to an application and verifying that no changes were made to a system that did not go through the change approval and management process
- Segregation of duties
  - Limited role-based security implementation and established policies and procedures supporting role-based security
  - Inconsistent implementation of least privileged access considerations for all users and limited documentation regarding business justifications for identified SOD conflicts

The following is a summary of the deficiencies that we considered most critical. When we assess the deficiencies in aggregate, we continue to conclude they could have a material effect on the financial statements, and as a result, this forms the basis for our conclusion of an IT material weakness:

- Access controls – We identified access controls exceptions across eight of the nine applications in scope of our review, which spanned HHS and NIH. Specifically, we noted (1) audit logs are used to monitor user access and activity, but the audit logs are not reviewed/monitored on a consistent basis, (2) user activity is not consistently reviewed for suspicious or malicious activity, (3) shared user IDs, some with privileged access, are used without monitoring user activity performed when using the shared IDs in question, (4) allowing the use of multiple user IDs creates the risk of individuals performing activities that may violate segregation of duties, and (5) several systems had issues identified within the new user provisioning process to include an incomplete set of roles identified for access provisioning forms, and access being provisioned prior to receipt of required approvals. Similarly, the Centers for Medicare & Medicaid Services (CMS) did not perform or adequately perform management reviews of user access and system parameters for key financially significant applications. In addition, procedures for adding or removing users were not consistently followed.

- Configuration management – We identified configuration management exceptions in seven of the nine applications in scope of our review, which spanned HHS and NIH. Specifically,

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we noted (1) configuration management and release management standard operating procedures were not developed or implemented across the span of the audit, (2) applications are not maintaining updated baseline configurations for certain aspects of the application, to include back-end database and operating system, and (3) we were not able to validate the full population of changes made to an application in order to verify that only changes that went through the change management and approval process were put into production. CMS continues to experience deficiencies in the implementation and monitoring of compliance with its defined computer security policies at both the Medicare fee-for-service contractors and the Central Office. Several vulnerabilities related to system configurations were identified with the Central Office and Medicare fee-for-service information systems. In several instances, the remediation, mitigation of risks, or monitoring of these vulnerabilities was not performed or not performed in a timely manner. In addition, evidence supporting the authorization and testing of claims processing software changes, application production support fixes, and infrastructure changes were not always retained and/or performed.

- Segregation of duties – We identified segregation of duties exceptions across four of our nine applications in scope of our review, which spanned HHS and NIH. Specifically, we noted (1) policies and procedures required to enforce segregation of duties among various roles have not been finalized and approved, (2) documented segregation of duties matrices have not been finalized by management and are still in draft form, (3) listing of all users with SOD conflicts and their respective business justifications is not proactively maintained, and (4) the use of multiple user IDs creates the risk of individuals performing functions that may violate SOD requirements. CMS continues to experience difficulties in implementing adequate segregation of duties. In addition, we identified users for two Central Office applications that were provided additional administrator rights.

Recommendations

HHS should continue the focus achieved in FY 2016 to remediate the remaining deficiencies contributing to material weakness. The following are some specific considerations:

- Continue to identify, assess, modify, and monitor access controls, configuration management, and segregation of duties to further enhance the security posture of all applications. Specific recommendations for the non-CMS Operating Division (OpDiv) applications are included within the respective OARS for each application in scope.

- A focused effort should be made to decommission systems that are being planned to retire based on the implementation of the new system in which the Department is no longer making a differential investment in remediating the issues identified within the system.

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- We have performed a separate financial statement audit of CMS for FY 2016 and, in conjunction with our reports on that audit, have provided recommendations specific to CMS on our IT internal control findings. Those findings and recommendations were considered in our overall HHS conclusions.

Significant Deficiencies

Financial Reporting Systems, Analysis, and Oversight

Although progress in certain areas has been identified, HHS and its OpDivs' internal reviews and the results of our testing of internal control have continued to identify internal control deficiencies in financial systems and processes for producing financial statements, including lack of integrated financial management systems and insufficient analysis of certain significant accounts. In many cases, processes continued to be developed throughout FY 2016 and will require additional refinements in FY 2017 and beyond. Within the context of the approximately $1 trillion in departmental net outlays, the ultimate resolution of our specific 2016 findings was not material to the consolidated financial statements taken as a whole. However, these matters are indicative of systemic issues that should continue to be resolved.

Lack of Integrated Financial Management System

Over the past 19 years, HHS has continued its efforts to overcome issues that have affected its ability to become compliant with the *Federal Financial Management Improvement Act of 1996* (FFMIA), including long-standing issues for which HHS and the audit have identified and reported in the past. For example:

- HHS records approximately $1.1 trillion in manual journal entries to ensure balances within financial systems are correct.

- As discussed above, departures from requirements specified in OMB A-123, *Management's Responsibility for Enterprise Risk Management and Internal Control*, and OMB A-130, *Management of Federal Information Resources*, related to access and change management controls within financial systems continue to be identified.

- The lack of sufficient integration within certain financial systems is not complemented with sufficient manual preventative and detective-type controls, including the NIH Business System (NBS), which continues to utilize two separate processes to report budgetary and financial statement activity and which requires significant manual periodic reconciliations to identify differences for research to ensure appropriate accounting in both processes.

- Although CMS utilizes the Healthcare Integrated General Ledger Accounting System (HIGLAS) in preparing its financial statements, the full functionality of HIGLAS has not

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yet been implemented. CMS's durable medical equipment (DME) Medicare Administrative Contractors (MACs) have not fully implemented CMS's HIGLAS. For these contractors, the accuracy of the financial reports remains heavily dependent on inefficient, labor-intensive, manual processes that are also subject to an increased risk of inconsistent, incomplete, or inaccurate information being submitted to CMS and, ultimately, HHS for consolidation.

Resource limitations and other priorities have consistently been identified as the causes for delays in upgrading certain system and financial internal control processes limiting HHS's ability to comply with requirements under FFMIA.

With the ongoing implementation of the *Digital Accountability and Transparency Act* (the DATA Act) and the completed upgrades of its financial systems, HHS has made progress in addressing its compliance with FFMIA. As it continues its pursuit in resolving these long-standing issues, HHS should continue in developing, maintaining, and implementing consistent policies and procedures, monitoring the implementation of its upgrades, providing extensive training throughout the Department to ensure consistent application, and enhancing its monitoring program to ensure continued compliance.

Financial Analysis and Oversight

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

Operating Division Periodic Analysis and Reconciliation

As deficiencies exist in financial systems, management compensates by implementing and strengthening other manual controls to ensure that errors and irregularities are prevented or detected in a timely manner. These manual and compensating controls may include monitoring of budgets, reconciliations of accounts, analyses of fluctuations, aging of accounts, and manual and supervisory reviews. During our audit, we found that certain controls still required further improvements. The following represent specific areas that need enhanced periodic reconciliation and analysis:

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- *Manual Journal Entries* – During FY 2016, although significant progress was made in certain OpDivs with the automation of certain transactions, more than 15,000 manual journal entries totaling approximately $1.1 trillion in absolute value were recorded in the Unified Financial Management System (UFMS) and NBS to post certain types of routine and non-routine transactions – including transactions to record proprietary and budgetary entries, record accruals, perform adjustments between governmental and nongovernmental accounts, perform adjustments to agree budgetary to proprietary accounts, perform other reconciliation adjustments at period-end, and correct errors identified as related to configuration issues within UFMS and NBS. These entries are posted to UFMS and NBS to record both the proprietary and budgetary effects of financial activities for which the financial system may not be configured properly to post automatically. Although these entries are required to be posted to the general ledger in order for the financial statements to be accurate, many of these entries should be configured as routine systematic entries within the systems. HHS's management indicated that it continues to develop and implement corrective actions to reduce the number of manual journal entries in future years.

- *Commissioned Corps* – During January 2014, HHS transferred the Commissioned Corps retiree payroll processes from a commercial financial shared service center to the U.S. Coast Guard. During FY 2015 and FY 2016, we determined that reviews of the respective Coast Guard internal control systems had not sufficiently taken place during the respective fiscal years nor had sufficient communications taken place to ensure timely access of Commissioned Corps data or documentation for audit purposes. HHS management has indicated that steps are being taken to ensure effective internal controls and appropriate access are available over its Commissioned Corps data.

- *Civilian Payroll Process* – HHS processes its civilian payroll through a series of computer systems and internal controls. During our FY 2016 audit, we noted certain internal control lapses, including the following: an incorrect pay calculation due to out-of-date personnel data entered on a new hire; information discrepancies between the two payroll systems which, resulted in inconsistencies in employee elections and deductions; and improper system updates, which resulted in untimely payroll reconciliations and untimely provisions of required personnel supporting documentation. We also observed deficiencies related to IT security, specifically relating to access and segregation of duties within certain payroll-related systems. HHS has indicated that it is working to resolve these control issues by strengthening IT security and manual controls.

- *Grant Accrual Process* – For more than 15 years, HHS's Payment Management Service has utilized a linear regression analysis of its grant advance and disbursement amounts to derive a quarterly grant accrual for each of its OpDivs. In the first quarter of FY 2016, the process was automated to allow for a more timely and less labor-intensive calculation to be produced. During our interim audit procedures, we were able to recalculate the grant

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accrual based on the linear methodology without exception. During our procedures at year-end, we noted differences totaling approximately $1 billion between our calculation using the linear regression analyses and the HHS-calculated accrual for 9 out of 10 OpDivs. The Payment Management Service indicated that they modified the fourth quarter accrual using the linear regression analysis based on calculating a growth estimate and net adjustment for new programs, followed up with look-back methodologies to confirm reasonableness of the modified accruals. As part of our audit procedures to substantiate the modified amounts, we were unable to obtain formalized policies documenting the new approach or monthly/periodic analysis to substantiate the adjustments.

Financial Management Controls at CMS

We performed a separate audit of the financial statements of CMS and reported on the results of our audit, including a report on its internal controls dated November 4, 2016. In that report, we outlined details of deficiencies noted and made recommendations for improvement in its financial management controls. Consistent with our findings in the previous year, we concluded that the aggregation of these deficiencies and those related to business partner risk management, noted elsewhere in this report, to be a significant deficiency for the CMS internal control over financial reporting.

Our observations related to financial management controls included a recommendation that as CMS continues to enhance its data analyses capability, further improvement can be made by developing robust analytical procedures or measures against benchmarks to monitor and mitigate risks associated with the decentralized nature of CMS operations. To the extent more robust analysis occurs within Centers and Offices, identifying, evaluating, and reviewing such analysis would assist in ensuring that a perspective that incorporates a financial reporting point of view is captured and considered. It may be beneficial for CMS to identify a cross-functional working group to perform such analysis.

Business Partner Risk Management at CMS

CMS relies heavily on third-party contractors as it outsources substantially all the day-to-day operations for its information technology systems, the payment of Medicare fee-for-service and Medicaid claims and certain services related to the Medicare Part C and Part D programs. We identified areas where improvements could be made in the control environment related to the oversight of third-party contractors.

The contracts between CMS and its Medicare fee-for-service contractors include provisions that require the MACs to develop policies and procedures that satisfy the objectives established by CMS. Through the established procedures, CMS monitors the MACs' compliance with its policies and procedures, established internal controls, and the completeness and accuracy of financial reporting. While this approach to financial integrity supports CMS's role in the monitoring of the

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MACs' financial controls, the oversight/monitoring process historically has not been fully effective in identifying and resolving financial recording and reporting issues or ensuring that the issues are remediated in a timely manner by the MACs.

As noted in the prior year, we identified deficiencies where actions are required but have not been taken or resolved in the following circumstances: (1) the Medicare Summary Notices, which are returned to the MACs but are not investigated as to why they are returned; (2) the claims outstanding greater than one year – periodically review, track, or monitor those aged claims other than those identified as bankruptcy, fraud, or abuse; and (3) the provider records – reconcile, review, or monitor provider records and provider eligibility status on a periodic basis to verify that all changes were processed in a timely, accurate, and complete.

Recommendations

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

- Continue to move forward to prioritize and centralize additional resources in addressing issues related to controls within and surrounding its financial information management systems.

- When all of the Federal Financial Reports (FFRs) for the quarter ended September 30, 2016 have been received, perform a look back analysis to the year-end grant accrual estimate. Using that analysis re-assess the grant accrual regression analysis and the need for the manual adjustments to that model made for the 2016 year-end close. Necessary revisions, if any, to the accrual process should be standardized to assure consistency of the process for each close. HHS should fully document any changes required to the model and processes. The adjusted policies should include providing monthly and/or quarterly documented analysis for each OpDiv to support the changes made to the automated linear regression analysis in determining the final grant accrual estimates so that OpDiv grants managers and financial management offices can complete their analysis and challenge of the fair presentation of the OpDiv financial statements.

- Continue to focus on automating and reducing the number of manual journal entries by determining the cause and the ability to upgrade systems to allow for automated posting of high-volume routine transactions and to ensure financial data is accurate. Additionally, we believe that HHS should strengthen controls surrounding review and approval functions around manual journal entries and reconciliations to provide for timely identification of errors and remediation of differences.

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- Continue to focus on enhancing systematic and manual internal controls surrounding civilian payroll and Commissioned Corps data.

Additionally, we recommend that CMS continue to develop and refine its financial management controls and business partner risk management as a means to improve its accounting, analysis, and oversight of financial management activity. More detailed recommendations related to our specific findings on these topics are included in our CMS Report on Internal Control.

NIH Financial Management Systems and Review Processes

Although NIH upgraded its core financial system (NBS), performed additional analysis of its balances, and invested both HHS and NIH resources in overcoming certain deficiencies in its internal controls supporting information technology (IT) infrastructure and financial application systems in FY 2015 and FY 2016, NIH and our audit continue to identify deficiencies that require additional focus in FY 2017 and beyond. For example:

- *Financial Reporting Processes* – Beginning in FY 2014, Treasury required that agencies utilize its governmentwide Treasury Account Symbol Adjusted Trial Balance System (GTAS) to submit not only its required budgetary reporting, but its financial activities for purposes of developing the governmentwide financial statements. Treasury guidance also indicated that the balances reported in the agencies financial statements should be consistent with that included within GTAS. For GTAS, NIH produces bulk files using a web-based SQL server tool, which pulls data from NBS and allows for adjustments related to timing and reclassification differences to be made within the tool prior to GTAS submission. Whereas, financial statement activity is reported directly from NBS to Consolidated Financial Reporting System (CFRS). These two separate processes of reporting budgetary and financial statement activity require significant periodic reconciliations and may create significant differences between GTAS and CFRS. Due to timing differences, certain transactions are not reported consistently between processes, resulting in differences that require research and manual posting of entries to ensure both systems are synchronized after the end of the period. NIH management has indicated that it plans to better align its budgetary and financial reporting processes in order to ensure consistency and appropriate accounting.

  Additionally, we noted that NBS does not electronically enforce some controls and sound accounting practices included in the HHS Accounting Treatment Manual. For example, we noted that NBS does not automatically close certain accounts and allows users to reopen previously closed periods. As a result additional analysis and manual adjustments are required to ensure the system will open in the next period with the proper beginning balances.

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- *Manual Journal Entries* – As discussed above, HHS posts a significant number of manual journal entries, with the majority of the entries being generated by NIH. During FY 2016, although NIH's annual total budgetary resources was only $38 billion, NIH was required to process approximately 13,000 manual journal entries totaling an absolute value of more than $897 billion to its NBS. These entries consist of nonstandard postings to record both the proprietary and budgetary effects of certain financial activities for which either the financial system is not configured properly to post automatically or to correct differences identified within the critical reconciliation processes of NBS to its subsidiary systems or GTAS balances to CFRS. Although necessary to ensure balances are accurate, the number of manual journal entries is significant compared to the NIH's overall activity.

  Additionally, we observed certain weaknesses in the manual journal entry process, including:

  – Improper or lack of approvals to both routine and non-routine manual journal entries

  – Allowing for the posting of certain entries that were inappropriate and required reversal

  – Limited descriptions as to the purpose of the manual journal entry

  – Insufficient controls and processes to determine what entries are routine and if all required entries were recorded in the proper period and for each period

  – Insufficient documentation to support the purpose of certain non-routine entries

  Our analysis of those entries did not cause us to change our opinion on the FY 2016 financial statements of HHS taken as a whole. However, we identified instances in which the research of the differences was inadequate, the supporting documentation underlying the manual journal entries was insufficient, and the HHS manual journal entries approval process was not followed. NIH management indicated that the reason for the large number of manual journal entries is due to system and resource limitations, the need to develop NIH-specific policies, and enhanced training of its personnel.

- *NIH's Grant Accrual* – Quarterly, NIH recorded an estimated grant accrual to its financial data to ensure that reported financial statement balances were correct. Although the grant accrual supports all 27 institutes for each of the current six years of appropriations, NIH records its estimate to only one institute's appropriation. At September 30, 2016, the estimated grant accrual totaled $5.3 billion. NIH management indicated that at quarter-end, there was insufficient time to post an estimate to each of its approximately 200 appropriations. Additionally, the process is recorded through a manually intensive entry process that would increase the chance for mistakes during the posting in the current month and the reversal during the future period.

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- *Policies and Procedures* – Although HHS has created a tracking system to develop and implement new policies, NIH has not taken the next step in developing NIH-specific desk procedures for its period-end closing to ensure all entries are recorded appropriately and complete.

- *IT System Infrastructure* – During our FY 2016 audit, we continue to identify deficiencies related to IT security, specifically relating to access and segregation of duties within NBS. NIH has indicated that it is working to resolve certain control issues by strengthening IT security and manual controls.

Recommendations

We recommend that NIH:

- Analyze its routine manual journal entries to determine if certain entries should be configured within the NBS to limit the number of higher-risk entries.

- Enhance its internal control processes related to manual journal entries, including the development of NIH-specific procedures and training to ensure its policy is consistently applied. The policies should suggest developing a log of routine entries to ensure all postings are complete and appropriate. Additionally, we recommend the level of authorization be documented, especially for non-routine high-risk entries, and that minimum documentation supporting the entry be maintained.

- Continue to focus efforts in remediating internal control issues related to IT infrastructure and systems controls for its NBS.

- Develop a process to reasonably allocate NIH's grant accruals to each of its 27 institutes to allow for accurate GTAS reporting.

- Evaluate NIH's budgetary and financial reporting processes to better enable for consistent reporting and more timely determination of differences between the two processes.

- Develop monthly analyses prepared for the audit which should be formalized and made a part of the accounting records of NIH. In addition, the analysis and adjustment processes related to balances at NIH should be revised to assure differences are thoroughly researched and adjustments are properly documented and approved.

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Status of Prior Year Findings

In the reports on the results of the FY 2015 audit of the HHS financial statements, a number of issues were raised relating to internal control over financial reporting. The chart below summarizes the current status of the prior year items:

Material Weakness		
Issue Area	**Summary Control Issue**	**FY 2016 Status**
Financial Management Information Systems	• Segregation of Duties • Configuration Management • Access Controls • FISMA Compliance	Certain progress noted; certain issues need continued focus Modified Repeat Condition
Significant Deficiencies		
Financial Reporting Systems, Analyses, and Oversight	• Lack of Integrated Financial Management System • Financial Analysis and Oversight	Progress noted; however, certain issues identified require continued focus; Modified Repeat Condition
NIH Financial Management Close and Review Processes	• Documentation to support NIH review and approval process is insufficient.	Progress noted; however, certain issues identified require continued focus; Modified Repeat Condition

HHS's Response to Findings

HHS's response to the findings identified in our audit and examination are included in the accompanying letter dated November 14, 2016. HHS's response was not subjected to either the auditing procedures applied in the audit of the financial statements or the attest procedures applied in the examination of internal control, and, accordingly, we express no opinion on it.

Purpose of This Report

The purpose of this report is solely to describe the scope of our testing of internal control and the results of that testing, and not to provide an opinion on the entity's internal control. This report is an integral part of an audit performed in accordance with *Government Auditing Standards* in considering the entity's internal control. Accordingly, this communication is not suitable for any other purpose.

Ernst & Young LLP

November 14, 2016

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

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

We have audited, in accordance with auditing standards generally accepted in the United States and the standards applicable to financial audits contained in *Government Auditing Standards* issued by the Comptroller General of the United States and the Office of Management and Budget (OMB) Bulletin No. 15-02, *Audit Requirements for Federal Financial Statements*, the consolidated financial statements of the Department of Health and Human Services (HHS or the Department), which comprise the consolidated balance sheet as of September 30, 2016, and the related consolidated statement of net cost and changes in net position and the combined statement of budgetary resources for the fiscal year then ended, and the related notes to the principal financial statements, and we were engaged to audit the statement of social insurance as of January 1, 2016, and the related statement of changes in social insurance amounts for the period ended January 1, 2016, and have issued our report thereon dated November 14, 2016. That report states that because of the matters described in the Basis for Disclaimer of Opinion paragraphs, the scope of our work was not sufficient to enable us to express, and we do not express, an opinion on the statement of social insurance as of January 1, 2016, and the related statement of changes in social insurance amounts for the period ended January 1, 2016.

Compliance and Other Matters

As part of obtaining reasonable assurance about whether HHS's consolidated financial statements are free of material misstatement, we performed tests of its compliance with certain provisions of laws and regulations, noncompliance with which could have a direct and material effect on the determination of financial statement amounts, and certain other laws and regulations specified in OMB Bulletin No. 15-02, including the requirements referred to in the *Federal Financial Management Improvement Act of 1996* (FFMIA) (P.L.104-208). However, providing an opinion on compliance with certain provisions of laws and regulations was not an objective of our audit, and, accordingly, we do not express such an opinion. We limited our tests of compliance to these provisions, and we did not test compliance with all laws and regulations applicable to HHS.

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The results of our tests of compliance with the laws and regulations described in the second paragraph of this report disclosed instances of noncompliance or other matters that are required to be reported under *Government Auditing Standards* and OMB Bulletin No. 15-02, as described below.

During fiscal year (FY) 2016, HHS's management determined that it may have potential violations of the Anti-Deficiency Act (P.L. 101-508 and OMB Circular A-11) related to FY 2015 and FY 2016 obligation of funds for conference spending. Additionally, HHS's management determined that its Medicare appeals process did not adjudicate appeals within the statutory decisional time frames required by the *Social Security Act*.

The *Improper Payments Information Act of 2002* (IPIA) (P.L. 107-300) as amended by the *Improper Payments Elimination and Recovery Act of 2010* (IPERA) (P.L. 111-204) and the *Improper Payments Elimination and Recovery Improvement Act of 2012* (P.L. 112-248) (hereinafter, the "Acts") require federal agencies to identify the program and activities that may be susceptible to significant improper payments and estimate the amount of the improper payments. While the Department continues to make progress, HHS currently is not in full compliance with the requirements of the Acts. For example, HHS has reported improper payment error rates for each of its high-risk programs, or components of such programs, except for the Temporary Assistance for Needy Families (TANF). HHS indicated that it is unable to compel states to collect the necessary information required to conduct an improper payment measurement for TANF due to Section 411 of the Social Security Act, which specifies the data elements that HHS may require states to report, and Section 417 of the same *Social Security Act*, which dictates that the federal government may only regulate the conduct of states where Congress has given them the express authority. Accordingly, HHS feels that it does not have the authority to collect data pertaining to case and payment accuracy for TANF since the information is not included under the *Social Security Act*. Additionally, we noted certain high-risk programs that did not meet their identified targets or exceeded the maximum 10% threshold stipulated by OMB. Also, HHS is not in full compliance with Section 6411 of the *Patient Protection and Affordable Care Act*, as HHS has not yet implemented recovery activities of the identified improper payments for the Medicare Advantage (Part C) program. HHS indicated it remains committed to implementing this provision of the Affordable Care Act, and anticipates awarding a Medicare Part C Recovery Audit Contractor contract in 2017.

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

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- During FY 2016, HHS recorded approximately $1.1 trillion in manual journal entries, as these transactions are not currently configured correctly within the financial systems and are for the purpose of ensuring that balances within financial systems are correct to enable the development of periodic financial statements and other required reporting.

- The lack of sufficient integration within certain financial systems are not complemented with sufficient manual preventative and detective-type controls, including the NIH Business System, which continues to utilize two separate processes to report budgetary and financial statement activity and which requires significant periodic manual reconciliations to identify differences for research to ensure appropriate accounting in both processes.

- Although the Centers for Medicare & Medicaid Services (CMS) utilizes the Healthcare Integrated General ledger Accounting System (HIGLAS) in preparing its financial statements, the full functionality of HIGLAS has not yet been implemented. CMS's durable medical equipment (DME) Medicare Administrative Contractors (MACs) have not fully implemented CMS's HIGLAS. For these contractors, the accuracy of the financial reports remains heavily dependent on inefficient, labor-intensive, manual processes that are also subject to an increased risk of inconsistent, incomplete, or inaccurate information being submitted to CMS and, ultimately, HHS for consolidation.

- Although progress was noted, reviews of general and application controls over financial management systems identified certain departures from requirements specified in OMB A-130, *Management of Federal Information Resources*, and OMB A-123, *Management's Responsibility for Enterprise Risk Management and Internal Control*. Additionally, the Office of Inspector General (OIG) identified certain issues, including access control deficiencies related to systems as part of its Federal Information Security Management Act and other OIG engagements. Finally, HHS management has identified certain weaknesses within its information technology general and application controls during its assessment of corrective action status and its OMB A-123 processes.

* * * * *

HHS's Response to Findings

Our Report on Internal Control dated November 14, 2016, includes additional information related to the financial management systems that were found not to comply with the requirements, relevant facts pertaining to the noncompliance to FFMIA, and our recommendations related to the specific issues presented. It is our understanding that management agrees with the facts as presented and that relevant comments from HHS's management responsible for addressing the noncompliance are provided in its letter dated November 14, 2016. HHS's response was not subjected to either the auditing procedures applied in the audit of the financial statements or the attest procedures applied in the examination of internal control, and, accordingly, we express no opinion on it.

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Additionally, HHS is updating its Department-wide corrective action plan to address FFMIA and other financial management issues.

Purpose of This Report

The purpose of this report is solely to describe the scope of our testing of compliance and the results of that testing, and not to provide an opinion on HHS's compliance. This report is an integral part of an audit performed in accordance with *Government Auditing Standards* in considering HHS's compliance. Accordingly, this communication is not suitable for any other purpose.

Ernst & Young LLP

November 14, 2016

DEPARTMENT'S RESPONSE TO THE REPORT OF THE INDEPENDENT AUDITORS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Washington, D.C. 20201

To: Daniel R. Levinson, Inspector General

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

Subject: FY 2016 Financial Statement Audit

We appreciate the opportunity to comment on the Independent Auditors' Report concerning the audit of our FY 2016 financial statements. We are pleased that the independent auditors found HHS's FY 2016 financial statements and notes were presented fairly, in all material respects, and in conformity with the U.S. generally accepted accounting principles. In response to their Report on Internal Control, we generally concur with their findings and are prepared to develop corrective action plans to address those findings. HHS leadership is dedicated to effectively resolving our challenges.

Central to HHS's information technology (IT) remediation effort is the establishment of a cross-Department, cross-functional IT Material Weakness Working Group (IT MWWG), which has met monthly since inception in June 2015. The IT MWWG is working on two fronts – coordinating responsive efforts to address current audit findings and vulnerabilities, as well as proactive efforts to mature the security and controls environment going forward. With regard to current findings, the IT MWWG has coordinated with system owners across the Department to resolve issues, identify target completion dates, and monitor progress. The size and complexity of our IT environment continues to pose substantial challenges as we address weaknesses across multiple systems, organizations, and business processes.

The Department's progress to address our significant deficiencies can be attributed to a robust and structured corrective action planning process sustained through effective communication and collaboration with the Operating Divisions. Corresponding policy, guidance, training, and on-site technical assistance to the Operating Divisions are key components of the process.

We take remediation of our deficiencies seriously and we will continue to focus our efforts and resources on addressing our longstanding and complex financial reporting audit findings. Under the strategic direction of the HHS Risk Management and Financial Oversight Board, the Department and its Operating Divisions are committed to sound financial management that delivers reliable and actionable information for both internal and external decision makers and stakeholders.

We would like to thank the Office of Inspector General (OIG) and our independent auditors, Ernst & Young LLP, for your efforts on our behalf. We appreciate the continued collaboration of the OIG to improve our stewardship and transparency of taxpayer funds.

/Ellen G. Murray/

Ellen G. Murray
Assistant Secretary for Financial Resources and
Chief Financial Officer
November 14, 2016

PRINCIPAL FINANCIAL STATEMENTS

U.S. Department of Health and Human Services

Consolidated Balance Sheets

As of September 30, 2016 and 2015

(in Millions)

	2016	2015
Assets (Note 2)		
Intragovernmental Assets		
Fund Balance with Treasury (Note 3)	$ 237,759	$ 219,459
Investments, Net (Note 4)	262,077	269,651
Accounts Receivable, Net (Note 5)	1,012	1,005
Advances (Note 8)	239	178
Total Intragovernmental Assets	501,087	490,293
Accounts Receivable, Net (Note 5)	24,203	21,915
Inventory and Related Property, Net (Note 6)	9,399	9,516
General Property, Plant and Equipment, Net (Note 7)	5,665	5,917
Advances (Note 8)	21,480	33
Other Assets	819	1,121
Total Assets	$ 562,653	$ 528,795
Stewardship Land (Notes 1 and 20)		
Liabilities (Note 9)		
Intragovernmental Liabilities		
Accounts Payable	$ 339	$ 309
Other Liabilities (Note 13)	7,063	3,609
Total Intragovernmental Liabilities	7,402	3,918
Accounts Payable	981	574
Entitlement Benefits Due and Payable (Note 10)	108,230	108,149
Accrued Liabilities (Note 12)	14,420	14,250
Federal Employee and Veterans' Benefits (Note 11)	12,892	12,072
Contingencies and Commitments (Note 14)	12,394	9,105
Other Liabilities (Note 13)	4,963	3,320
Total Liabilities	161,282	151,388
Net Position		
Unexpended Appropriations - Funds from Dedicated Collections (Note 19)	35,912	30,184
Unexpended Appropriations - All Other funds	128,129	116,089
Cumulative Results of Operations - Funds from Dedicated Collections (Note 19)	233,470	221,480
Cumulative Results of Operations - All Other funds	3,860	9,654
Total Net Position - Funds from Dedicated Collections	269,382	251,664
Total Net Position - All Other Funds	131,989	125,743
Total Net Position	401,371	377,407
Total Liabilities and Net Position	$ 562,653	$ 528,795

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

U.S. Department of Health and Human Services
Consolidated Statement of Net Cost
For the Years Ended September 30, 2016 and 2015
(in Millions)

	2016	2015
Responsibility Segments		
Centers for Medicare & Medicaid Services (CMS)		
Gross Costs	$ 1,044,615	$ 1,011,350
Exchange Revenue	(91,964)	(98,030)
CMS Net Cost of Operations	952,651	913,320
Other Segments:		
Administration for Children and Families (ACF)	51,515	50,300
Administration for Community Living (ACL)	2,058	1,755
Agency for Healthcare Research and Quality (AHRQ)	348	359
Centers for Disease Control and Prevention (CDC)	12,098	10,517
Food and Drug Administration (FDA)	4,617	4,225
Health Resources and Services Administration (HRSA)	10,223	9,158
Indian Health Service (IHS)	6,204	6,158
National Institutes of Health (NIH)	30,790	29,985
Office of the Secretary (OS)	3,176	3,174
Program Support Center (PSC)	2,033	1,942
Substance Abuse and Mental Health Services Administration (SAMHSA)	3,636	3,391
Other Segments Gross Costs of Operations before Actuarial Gains and Losses	$ 126,698	$ 120,964
Actuarial (Gains) and Losses Commissioned Corp Retirement and Medical Plan (Note 11)	483	(249)
Other Segments Gross Costs of Operations after Actuarial Gains and Losses	$ 127,181	$ 120,715
Exchange Revenue	(5,060)	(4,006)
Other Segments Net Cost of Operations	122,121	116,709
Net Cost of Operations (Note 15)	$ 1,074,772	$ 1,030,029

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

U.S. Department of Health and Human Services
Consolidated Statement of Changes in Net Position
For the Year Ended September 30, 2016
(in Millions)

	2016			
	Funds From Dedicated Collections	All Other Funds	Eliminations	Consolidated Total
Cumulative Results of Operations:				
Beginning Balances	$ 221,480	$ 9,654	$ -	$ 231,134
Budgetary Financing Sources:				
Other Adjustments (+/-)	-	(857)	-	(857)
Appropriations Used	323,452	495,197	-	818,649
Nonexchange Revenue				
Nonexchange Revenue - Tax Revenue	250,472	-	-	250,472
Nonexchange Revenue - Investment Revenue	9,938	17	-	9,955
Nonexchange Revenue – Other	3,980	-	-	3,980
Donations and Forfeitures of Cash and Cash Equivalents	80	-	-	80
Transfers-in/out without Reimbursement	(4,447)	2,768	-	(1,679)
Other (+/-)	-	1	-	1
Other Financing Sources (Nonexchange):				
Donations and Forfeitures of Property	-	7	-	7
Transfers-in/out Without Reimbursement (+/-)	(4)	7	-	3
Imputed Financing	38	736	(294)	480
Other (+/-)	134	(257)	-	(123)
Total Financing Sources	583,643	497,619	(294)	1,080,968
Net Cost of Operations (+/-)	571,653	503,413	(294)	1,074,772
Net Change	11,990	(5,794)	-	6,196
Cumulative Results of Operations:	$ 233,470	$ 3,860	$ -	$ 237,330
Unexpended Appropriations:				
Beginning Balance	$ 30,184	$ 116,089	$ -	$ 146,273
Budgetary Financing Sources:				
Appropriations Received	351,309	596,875	-	948,184
Appropriations Transferred in/out	-	(16)	-	(16)
Other Adjustments	(22,129)	(89,622)	-	(111,751)
Appropriations Used	(323,452)	(495,197)	-	(818,649)
Total Budgetary Financing Sources	5,728	12,040	-	17,768
Total Unexpended Appropriations	35,912	128,129	-	164,041
Net Position	$ 269,382	$ 131,989	$ -	$ 401,371

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

U.S. Department of Health and Human Services
Consolidated Statement of Changes in Net Position
For the Year Ended September 30, 2015
(in Millions)

	2015			
	Funds From Dedicated Collections	All Other Funds	Eliminations	Consolidated Total
Cumulative Results of Operations:				
Beginning Balances	$ 227,551	$ 6,981	$ -	$ 234,532
Budgetary Financing Sources:				
Other Adjustments (+/-)	-	(746)	-	(746)
Appropriations Used	295,986	478,803	-	774,789
Nonexchange Revenue				
Nonexchange Revenue - Tax Revenue	237,972	-	-	237,972
Nonexchange Revenue - Investment Revenue	10,854	5	-	10,859
Nonexchange Revenue – Other	3,557	-	-	3,557
Donations and Forfeitures of Cash and Cash Equivalents	75	-	-	75
Transfers-in/out without Reimbursement	(4,673)	3,467	-	(1,206)
Other (+/-)	-	(1)	-	(1)
Other Financing Sources (Nonexchange):				
Donations and Forfeitures of Property	-	10	-	10
Transfers-in/out Without Reimbursement (+/-)	(6)	(8)	-	(14)
Imputed Financing	30	668	(204)	494
Other (+/-)	1	841	-	842
Total Financing Sources	543,796	483,039	(204)	1,026,631
Net Cost of Operations (+/-)	549,867	480,366	(204)	1,030,029
Net Change	(6,071)	2,673	-	(3,398)
Cumulative Results of Operations:	$ 221,480	$ 9,654	$ -	$ 231,134
Unexpended Appropriations:				
Beginning Balance	$ 16,215	$ 107,427	$ -	$ 123,642
Budgetary Financing Sources:				
Appropriations Received	288,636	542,401	-	831,037
Appropriations Transferred in/out	-	387	-	387
Other Adjustments	21,319	(55,323)	-	(34,004)
Appropriations Used	(295,986)	(478,803)	-	(774,789)
Total Budgetary Financing Sources	13,969	8,662	-	22,631
Total Unexpended Appropriations	30,184	116,089	-	146,273
Net Position	$ 251,664	$ 125,743	$ -	$ 377,407

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

U.S. Department of Health and Human Services
Combined Statement of Budgetary Resources
For the Years Ended September 30, 2016 and 2015
(in Millions)

	2016		2015	
	Budgetary	Non-Budgetary Credit Reform Financing Account	Budgetary	Non-Budgetary Credit Reform Financing Account
Budgetary Resources				
Unobligated Balance, Brought Forward, Oct 1	$ 65,622	$ 2	$ 37,878	$ 3
Recoveries of Unpaid Prior Year Obligations	36,333	-	26,380	-
Other Changes in Unobligated Balance	(3,098)	-	20,176	-
Unobligated Balance from Prior Year Budget Authority, Net	98,857	2	84,434	3
Appropriations (Discretionary and Mandatory)	1,540,233	-	1,425,607	-
Borrowing Authority (Discretionary and Mandatory)	3,720	19	-	50
Spending Authority from Offsetting Collections (Discretionary and Mandatory)	24,844	638	32,931	80
Total Budgetary Resources (Note 23)	$ 1,667,654	$ 659	$ 1,542,972	$ 133
Status of Budgetary Resources				
New Obligations and Upward Adjustments (Notes 18, 22 and 23)	$ 1,607,771	$ 32	$ 1,477,350	$ 131
Unobligated Balance, End of Year:				
Apportioned, Unexpired Accounts	24,982	8	26,449	-
Exempt from Apportionment, Unexpired Accounts	(7,710)	-	(2,621)	-
Unapportioned, Unexpired Accounts	5,082	619	7,169	2
Unexpired Unobligated Balance, End of Year	22,354	627	30,997	2
Expired Unobligated Balance, End of Year	37,529	-	34,625	-
Unobligated Balance, End of Year	59,883	627	65,622	2
Total Budgetary Resources (Note 23)	$ 1,667,654	$ 659	$ 1,542,972	$ 133
Change in Obligated Balance				
Unpaid Obligations:				
Unpaid Obligations, Brought Forward, Oct 1	$ 236,348	$ 375	$ 216,166	$ 998
New Obligations and Upward Adjustments (Notes 18, 22 and 23)	1,607,771	32	1,477,350	131
Outlays (Gross)	(1,550,188)	(370)	(1,430,984)	(754)
Actual Transfers, Unpaid Obligations (Net)	-	-	196	-
Recoveries of Prior Year Unpaid Obligations	(36,333)	-	(26,380)	-
Unpaid Obligations, End of Year	$ 257,598	$ 37	$ 236,348	$ 375
Uncollected Payments:				
Uncollected Customer Payments from Federal Sources, Brought Forward, Oct 1	$ (22,124)	$ (160)	$ (11,838)	$ (430)
Change in Uncollected Customer Payments from Federal Sources	(4,342)	145	(10,286)	270
Uncollected Payments from Federal Sources, End of Year	$ (26,466)	$ (15)	$ (22,124)	$ (160)
Memorandum (non-add) Entries:				
Obligated Balance, Start of Year	$ 214,224	$ 215	$ 204,328	$ 568
Obligated Balance, End of Year	$ 231,132	$ 22	$ 214,224	$ 215
Budget Authority and Outlays, Net:				
Budget Authority, Gross (Discretionary and Mandatory)	$ 1,568,797	$ 657	$ 1,458,538	$ 130
Actual Offsetting Collections (Discretionary and Mandatory)	(22,019)	(782)	(23,260)	(350)
Change in Uncollected Customer Payments from Federal Sources (Discretionary and Mandatory)	(4,342)	145	(10,286)	270
Recoveries of Prior Year Paid Obligations (Discretionary and Mandatory)	513	-	-	-
Budget Authority, Net (Discretionary and Mandatory)	$ 1,542,949	$ 20	$ 1,424,992	$ 50
Outlays, Gross (Discretionary and Mandatory)	$ 1,550,188	$ 370	$ 1,430,984	$ 754
Actual Offsetting Collections (Discretionary and Mandatory)	(22,019)	(782)	(23,260)	(350)
Outlays, Net (Discretionary and Mandatory)	1,528,169	(412)	1,407,724	404
Distributed Offsetting Receipts	(428,128)	-	(380,187)	-
Agency Outlays, Net (Discretionary and Mandatory)	$ 1,100,041	$ (412)	$ 1,027,537	$ 404

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

U.S. Department of Health and Human Services

Statement of Social Insurance (Unaudited)

75-Year Projection as of January 1, 2016 and Prior Base Years

(in Billions)

	Estimates from Prior Years				
	2016	2015	2014	2013	2012
Actuarial present value for the 75-year projection period of estimated future income (excluding interest) received from or on behalf of: (Notes 24 and 25)					
Current participants who, in the starting year of the projection period:					
Have not yet attained eligibility age					
HI	$ 10,294	$ 9,134	$ 8,398	$ 8,147	$ 7,929
SMI Part B	19,386	17,027	17,127	15,227	14,431
SMI Part D	7,659	6,424	5,928	5,871	5,866
Have attained eligibility age (age 65 or over)					
HI	455	382	332	301	302
SMI Part B	3,660	3,300	2,873	2,620	2,395
SMI Part D	952	887	775	722	694
Those expected to become participants					
HI	9,952	8,386	7,812	7,744	7,367
SMI Part B	4,437	3,668	4,311	3,530	3,333
SMI Part D	3,602	2,845	2,609	2,617	2,568
All current and future participants					
HI	20,701	17,902	16,542	16,192	15,598
SMI Part B	27,484	23,995	24,311	21,377	20,159
SMI Part D	12,213	10,156	9,312	9,211	9,128
Actuarial present value for the 75-year projection period of estimated future expenditures for or on behalf of: (Notes 24 and 25)					
Current participants who, in the starting year of the projection period:					
Have not yet attained eligibility age					
HI	$ 16,800	$ 14,494	$ 14,117	$ 14,629	$ 14,919
SMI Part B	19,178	16,818	17,003	15,075	14,303
SMI Part D	7,659	6,424	5,928	5,871	5,866
Have attained eligibility age (age 65 and over)					
HI	4,285	3,803	3,484	3,422	3,369
SMI Part B	4,026	3,637	3,171	2,887	2,646
SMI Part D	952	887	775	722	694
Those expected to become participants					
HI	3,437	2,791	2,764	2,913	2,891
SMI Part B	4,281	3,540	4,137	3,415	3,211
SMI Part D	3,602	2,845	2,609	2,617	2,568
All current and future participants:					
HI	24,523	21,089	20,365	20,963	21,179
SMI Part B	27,484	23,995	24,311	21,377	20,159
SMI Part D	12,213	10,156	9,312	9,211	9,128
Actuarial present value for the 75-year projection period of estimated future excess of income (excluding interest) over expenditures (Notes 24 and 25)					
HI	$ (3,822)	$ (3,187)	$ (3,823)	$ (4,772)	$ (5,581)
SMI Part B	-	-	-	-	-
SMI Part D	-	-	-	-	-
Additional Information					
Actuarial present value for the 75-year projection period of estimated future excess of income (excluding interest) over expenditures (Notes 24 and 25)					
HI	$ (3,822)	$ (3,187)	$ (3,823)	$ (4,772)	$ (5,581)
SMI Part B	-	-	-	-	-
SMI Part D	-	-	-	-	-
Trust Fund assets at start of period					
HI	194	197	205	220	244
SMI Part B	68	68	74	66	80
SMI Part D	1	1	1	1	1
Actuarial present value for the 75-year projection period of estimated future excess of income (excluding interest) and Trust Fund assets at start of period over expenditures (Notes 24 and 25)					
HI	$ (3,628)	$ (2,990)	$ (3,618)	$ (4,551)	$ (5,337)
SMI Part B	68	68	74	66	80
SMI Part D	1	1	1	1	1

Please note for the entirety of the Statement of Social Insurance:
Totals do not necessarily equal the sum of the rounded components.
Current participants are assumed to be the "closed group" of individuals who are at least age 15 at the start of the projection period and are participating in the program as either taxpayers, beneficiaries or both.
The accompanying "Notes to the Principal Financial Statements" are an integral part of these statements.

U.S. Department of Health and Human Services

Statement of Social Insurance (Continued) (Unaudited)

75-Year Projection as of January 1, 2016 and Prior Base Years

(in Billions)

	Estimates from Prior Years				
	2016	2015	2014	2013	2012
Medicare Social Insurance Summary					
Current Participants:					
Actuarial present value for the 75-year projection period from or on behalf of:					
Those who, in the starting year of the projection period, have attained eligibility age:					
Income (excluding interest)	$ 5,067	$ 4,569	$ 3,980	$ 3,643	$ 3,391
Expenditures	9,263	8,328	7,430	7,031	6,709
Income less expenditures	(4,196)	(3,759)	(3,450)	(3,388)	(3,319)
Those who, in the starting year of the projection period, have not yet attained eligibility age:					
Income (excluding interest)	37,339	32,585	31,453	29,244	28,227
Expenditures	43,637	37,736	37,048	35,574	35,088
Income less expenditures	(6,298)	(5,151)	(5,595)	(6,330)	(6,861)
Actuarial present value of estimated future income (excluding interest) less expenditures (closed-group measure)	(10,493)	(8,909)	(9,045)	(9,718)	(10,180)
Combined Medicare Trust Fund assets at start of period	263	266	280	288	325
Actuarial present value of estimated future income (excluding interest) less expenditures plus trust fund assets at start of period	(10,230)	(8,643)	(8,764)	(9,430)	(9,855)
Future Participants:					
Actuarial present value for the 75-year projection period:					
Income (excluding interest)	17,992	14,898	14,732	13,891	13,268
Expenditures	11,320	9,176	9,510	8,945	8,669
Income less expenditures	6,672	5,722	5,222	4,946	4,599
Open-Group (all current and future participants):					
Actuarial present value of estimated future income (excluding interest) less expenditures	(3,822)	(3,187)	(3,823)	(4,772)	(5,581)
Combined Medicare Trust Fund assets at start of period	263	266	280	288	325
Actuarial present value of estimated future income (excluding interest) less expenditures plus trust fund assets at start of period	$ (3,559)	$ (2,921)	$ (3,542)	$ (4,484)	$ (5,256)

Please note for the entirety of the Statement of Social Insurance:
Totals do not necessarily equal the sum of the rounded components.
Current participants are assumed to be the "closed group" of individuals who are at least age 15 at the start of the projection period and are participating in the program as either taxpayers, beneficiaries or both.
The accompanying "Notes to the Principal Financial Statements" are an integral part of these statements.

U.S. Department of Health and Human Services

Statement of Changes in Social Insurance Amounts (Unaudited)

January 1, 2015 to January 1, 2016

Medicare Hospital and Supplementary Medical Insurance

(in Billions)

	Actuarial present value over the next 75 years (open group measure)				
	Estimated future income (excluding interest)	Estimated future expenditures	Estimated future income less expenditures	Combined HI and SMI trust fund account assets	Actuarial present value of estimated future income (excluding interest) less expenditures plus combined trust fund assets
Total Medicare (Note 26)					
As of January 1, 2015	$ 52,053	$ 55,240	$ (3,187)	$ 266	$ (2,921)
Reasons for change					
Change in the valuation period	2,162	2,330	(169)	2	(167)
Change in projection base	306	595	(289)	(5)	(294)
Changes in the demographic assumptions	(391)	(573)	182	-	182
Changes in economic and health care assumptions	6,501	6,867	(366)	-	(366)
Changes in law	(232)	(239)	6	-	6
Net changes	8,345	8,980	(635)	(3)	(638)
As of January 1, 2016	$ 60,398	$ 64,220	$ (3,822)	$ 263	$ (3,559)
HI - Part A (Note 26)					
As of January 1, 2015	$ 17,902	$ 21,089	$ (3,187)	$ 197	$ (2,990)
Reasons for change					
Change in the valuation period	687	855	(169)	2	(167)
Change in projection base	63	352	(289)	(6)	(294)
Changes in the demographic assumptions	63	(120)	182	-	182
Changes in economic and health care assumptions	1,987	2,353	(366)	-	(366)
Changes in law	-	(6)	6	-	6
Net changes	2,799	3,434	(635)	(4)	(638)
As of January 1, 2016	$ 20,701	$ 24,523	$ (3,822)	$ 194	$ (3,628)
SMI - Part B (Note 26)					
As of January 1, 2015	$ 23,995	$ 23,995	$ -	$ 68	$ 68
Reasons for change					
Change in the valuation period	990	990	-	-	-
Change in projection base	(113)	(113)	-	-	-
Changes in the demographic assumptions	(350)	(350)	-	-	-
Changes in economic and health care assumptions	3,183	3,183	-	-	-
Changes in law	(221)	(221)	-	-	-
Net changes	3,489	3,489	-	-	-
As of January 1, 2016	$ 27,484	$ 27,484	$ -	$ 68	$ 68
SMI - Part D (Note 26)					
As of January 1, 2015	$ 10,156	10,156	$ -	$ 1	$ 1
Reasons for change					
Change in the valuation period	485	485	-	-	-
Change in projection base	356	356	-	1	1
Changes in the demographic assumptions	(103)	(103)	-	-	-
Changes in economic and health care assumptions	1,330	1,330	-	-	-
Changes in law	(11)	(11)	-	-	-
Net changes	2,057	2,057	-	-	-
As of January 1, 2016	$ 12,213	$ 12,213	$ -	$ 1	$ 1

Totals do not necessarily equal the sum of the rounded components.
The accompanying "Notes to the Principal Financial Statements" are an integral part of these statements.

U.S. Department of Health and Human Services

Statement of Changes in Social Insurance Amounts (Continued) (Unaudited)

January 1, 2014 to January 1, 2015

Medicare Hospital and Supplementary Medical Insurance

(in Billions)

	Actuarial present value over the next 75 years (open group measure)				
	Estimated future income (excluding interest)	Estimated future expenditures	Estimated future income less expenditures	Combined HI and SMI trust fund account assets	Actuarial present value of estimated future income (excluding interest) less expenditures plus combined trust fund assets
Total Medicare (Note 26)					
As of January 1, 2014	$ 50,166	$ 53,988	$ (3,823)	$ 280	$ (3,542)
Reasons for change					
Change in the valuation period	2,106	2,308	(202)	(17)	(219)
Change in projection base	1,174	1,256	(82)	3	(79)
Changes in the demographic assumptions	149	184	(35)	-	(35)
Changes in economic and health care assumptions	(1,884)	(2,638)	755	-	755
Changes in law	342	142	201	-	201
Net changes	1,887	1,251	636	(14)	622
As of January 1, 2015	$ 52,053	$ 55,240	$ (3,187)	$ 266	$ (2,921)
HI - Part A (Note 26)					
As of January 1, 2014	$ 16,542	$ 20,365	$ (3,823)	$ 205	$ (3,618)
Reasons for change					
Change in the valuation period	610	812	(202)	(14)	(216)
Change in projection base	(38)	44	(82)	6	(77)
Changes in the demographic assumptions	3	38	(35)	-	(35)
Changes in economic and health care assumptions	784	30	755	-	755
Changes in law	-	(201)	201	-	201
Net changes	1,360	724	636	(8)	628
As of January 1, 2015	$ 17,902	$ 21,089	$ (3,187)	$ 197	$ (2,990)
SMI - Part B (Note 26)					
As of January 1, 2014	$ 24,311	$ 24,311	$ -	$ 74	$ 74
Reasons for change					
Change in the valuation period	1,054	1,054	-	(3)	(3)
Change in projection base	360	360	-	(3)	(3)
Changes in the demographic assumptions	82	82	-	-	-
Changes in economic and health care assumptions	(2,168)	(2,168)	-	-	-
Changes in law	356	356	-	-	-
Net changes	(316)	(316)	-	(6)	(6)
As of January 1, 2015	$ 23,995	$ 23,995	$ -	$ 68	$ 68
SMI - Part D (Note 26)					
As of January 1, 2014	$ 9,312	$ 9,312	$ -	$ 1	$ 1
Reasons for change					
Change in the valuation period	443	443	-	-	-
Change in projection base	852	852	-	-	-
Changes in the demographic assumptions	63	63	-	-	-
Changes in economic and health care assumptions	(500)	(500)	-	-	-
Changes in law	(13)	(13)	-	-	-
Net changes	844	844	-	-	-
As of January 1, 2015	$ 10,156	$ 10,156	$ -	$ 1	$ 1

Totals do not necessarily equal the sum of the rounded components.
The accompanying "Notes to the Principal Financial Statements" are an integral part of these statements.

NOTES TO THE PRINCIPAL FINANCIAL STATEMENTS

Note 1. Summary of Significant Accounting Policies

A. Reporting Entity

The accompanying financial statements include activities and operations of the U.S. Department of Health and Human Services (HHS or the Department).

HHS is a Cabinet-level agency within the executive branch of the federal government. Its predecessor, the Department of Health, Education and Welfare (HEW), was officially established on April 11, 1953. In 1979, the *Department of Education Organization Act* was signed into law, creating a separate Department of Education. The HEW officially became HHS on May 4, 1980. HHS is responsible for protecting the health of all Americans and providing essential human services, especially for those who are least able to help themselves.

Organization and Structure of HHS

HHS is composed of the Office of the Secretary (OS) and 11 Operating Divisions (OpDivs) with diverse missions and programs. OS and the OpDivs are each responsible for carrying out a mission, conducting a major line of activity, or producing one or a group of related products and/or services. Although organizationally located within OS, the Program Support Center (PSC) is a responsibility segment and reports separately due to the business activities conducted on behalf of other federal agencies and HHS OpDivs. The Agency for Toxic Substances and Disease Registry (ATSDR) is combined with the Centers for Disease Control and Prevention (CDC) for financial reporting purposes. Therefore, references to the CDC responsibility segment include ATSDR. Managers of the responsibility segments report directly to the Department's top management and the resources and results of operations can be clearly distinguished from those of other responsibility segments. The 12 responsibility segments are:

- Administration for Children and Families (ACF)
- Administration for Community Living (ACL)
- Agency for Healthcare Research and Quality (AHRQ)
- Centers for Disease Control and Prevention (CDC) and Agency for Toxic Substances and Disease Registry (ATSDR)
- Centers for Medicare and Medicaid Services (CMS)
- Food and Drug Administration (FDA)
- Health Resources and Services Administration (HRSA)
- Indian Health Service (IHS)
- National Institutes of Health (NIH)
- Office of the Secretary (OS) – excluding the Program Support Center
- Program Support Center (PSC)
- Substance Abuse and Mental Health Services Administration (SAMHSA)

Pursuant to Public Law 113-128, Section 491 of the *Workforce Innovation and Opportunity Act*, ACL received three groups of programs from the Department of Education, Office of Special Education and Rehabilitation Services. These programs include the National Institute on Disability, Independent Living and Rehabilitation Research programs; the Independent Living programs; and the Assistive Technology programs. The transfer was effective March 30, 2015.

B. Basis of Accounting and Presentation

HHS financial statements have been prepared to report the financial position and results of operations of the Department, pursuant to the requirements of 31 U.S. Code (U.S.C.) §3515(b), the *Chief Financial Officer Act*, as

amended by the *Government Management Reform Act*, and presented in accordance with the requirements in the Office of Management and Budget (OMB) Circular A-136, *Financial Reporting Requirements* (OMB Circular A-136). These statements have been prepared from HHS's financial records in conformity with accounting principles generally accepted in the U.S. The generally accepted accounting principles (GAAP) for federal entities are the standards prescribed by the Federal Accounting Standards Advisory Board (FASAB) and recognized by the American Institute of Certified Public Accountants as federal GAAP. Therefore, these statements are different from financial reports prepared pursuant to other OMB directives that are primarily used to monitor and control the use of budgetary resources.

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

The financial statements consolidate the balances of approximately 250 appropriations and fund accounts. The fund accounts include accounts used for suspense, collection of receipts, and general government functions. Transactions and balances within HHS have been eliminated in the presentation of the Consolidated Balance Sheets and Statements of Net Cost and Changes in Net Position. The Combined Statements of Budgetary Resources are presented on a combined basis. Therefore, transactions and balances within HHS have not been eliminated from these statements. Supplemental information is accumulated from the OpDivs' reports, regulatory reports and other sources within HHS. These statements should be read with the realization that they are for a component of the U.S. government, a sovereign entity. One implication of this is that liabilities cannot be liquidated without legislation providing resources and budget authority for HHS.

In FY 2016, changes have been made to the Statement of Budgetary Resources to reflect the new format prescribed by OMB Circular A-136.

C. Use of Estimates in Preparing Financial Statements

Financial statements prepared in accordance with accounting principles generally accepted in the U.S. are based on a selection of accounting policies and the application of significant accounting estimates. Some estimates require management to make significant assumptions. Further, the estimates are based on current conditions that may change in the future. Actual results could differ materially from the estimated amounts. The financial statements include information to assist the reader in understanding the effect of changes in assumptions on the related information.

D. Parent/Child Reporting

Allocation transfers are legal delegations by one agency of its authority to obligate budget authority and outlay funds to another agency. HHS is party to allocation transfers with other federal entities as both a transferring (parent) entity and a receiving (child) entity. All financial activity related to these allocation transfers is reported in the financial statements of the parent entity, from which the underlying legislative authority, appropriations, and budget apportionments are derived.

HHS received an exception to the parent/child reporting requirements of OMB Circular A-136, as it pertains to the allocation transfer from Department of Homeland Security to HHS for the Biodefense Countermeasures Fund for FY 2008 and beyond. Under this exception, HHS, as the child, assumed the financial statement reporting responsibilities of this fund.

Under the *Affordable Care Act*, HHS has established a child relationship with the Internal Revenue Service (IRS) of the Department of the Treasury (Treasury) for the payment of the advance premium tax credits and cost-sharing reductions to insurance providers. No financial activity is included in HHS's financial statements.

HHS also receives allocation transfers, as the child, from the Departments of Agriculture, Justice, and State. HHS allocates funds, as the parent, to the Bureau of Indian Affairs of the Department of the Interior (DOI), Treasury, and Social Security Administration (SSA).

E. Reclassifications and Adjustments

Certain FY 2015 balances have been reclassified to conform to FY 2016 financial statement presentations. The effects are immaterial.

F. Funds from Dedicated Collections

Generally, funds from dedicated collections are financed by specifically identified revenues, provided to the government by non-federal sources, often supplemented by other financing sources, which remain available over time. Dedicated collections must meet the following criteria:

1. A statute committing the federal government to use specifically identified revenues and/or other financing sources that are originally provided to the federal government from a non-federal source only for designated activities, benefits, or purposes;
2. Explicit authority for the fund to retain revenues and/or other financing sources not used in the current period for future use to finance the designated activities, benefits, or purposes; and
3. A requirement to account for and report on the receipt, use, and retention of the revenues and/or other financing sources that distinguishes the dedicated collections from the federal government's general revenues.

HHS's major funds from dedicated collections are described in the sections below.

Medicare Hospital Insurance (HI) Trust Fund – Part A

Section 1817 of the *Social Security Act* established the Medicare HI Trust Fund. Medicare contractors are paid by HHS to process Medicare claims for hospital in-patient services, hospice, and select skilled nursing and home health services. Benefit payments made by the Medicare contractors for these services as well as administrative costs, are charged to the HI Trust Fund. A portion of HHS payments to Medicare Advantage Plans is also charged to this fund. The financial statements include the HI Trust Fund activities administered by Treasury. The HI Trust Fund has permanent indefinite authority.

Employment tax revenue is the primary source of financing for the Medicare HI program. Medicare's portion of payroll and self-employment taxes is collected under the *Federal Insurance Contributions Act* (FICA) (26 U.S.C. Ch 21) and *Self Employment Contributions Act* (SECA) *of 1954* (Ch 2 of Subtitle A of the Internal Revenue Code, 26 U.S.C. §1401 through §1403). Employees and employers are both required to contribute 1.45 percent of earnings, with no limitation, to the HI Trust Fund. Self-employed individuals contribute the full 2.9 percent of their self-employment income. The *Social Security Act* requires the transfer of these contributions from the Treasury General Fund to the HI Trust Fund based on the amount of wages certified by the Commissioner of Social Security from the SSA records of wages. The SSA uses the wage totals reported by employers to the IRS via the Employer's Quarterly Federal Tax Return, as the basis for its quarterly certification of regular wages.

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

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

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

Medicare SMI Trust Fund – Part D

The *Medicare Prescription Drug, Improvement and Modernization Act* established the Medicare Prescription Drug Benefit – Part D. The program makes a prescription drug benefit available to all Medicare beneficiaries who opt into the program. Beneficiaries eligible for both Medicare and Medicaid are automatically enrolled unless they have other credible drug coverage. HHS reports the Prescription Drug Benefit within the financial statements as part of the SMI Trust Fund, in the Medicare column. Drug plans are offered by insurance companies and other private companies approved by Medicare and are of two types: Medicare Prescription Drug Plans, which add coverage to fee-for-service Medicare; and Medicare Advantage Prescription Drug Plans and other Medicare Health Plans in which drug coverage is offered as part of a benefit package that includes Part A and Part B services. Medicare helps employers and unions continue to provide retiree drug coverage that meets Medicare's standards through the Retiree Drug Subsidy. The Low Income Subsidy helps those with limited income and resources.

Medicare Integrity Program

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

G. Revenue and Financing Sources

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

Appropriations

HHS receives annual, multi-year, and no-year appropriations that may be used within statutory limits. For example, funds for general operations are normally made available for one fiscal year. Funds for long-term

projects such as major construction will be available for the expected life of the project, and funds used to establish revolving fund operations are generally available indefinitely (i.e., no-year funds).

Permanent Indefinite Appropriations

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

Borrowing Authority

HHS uses indefinite borrowing authority under the *Federal Credit Reform Act*, as amended, for its loan programs. Borrowing authority increases budgetary resources and enables costs to be financed by borrowing from Treasury. Any unobligated borrowing authority does not carry forward to the next fiscal year. HHS has two programs with borrowing authority: the CMS Consumer Operated and Oriented Plan (CO-OP) Loan Program and the Health Center Loan Program.

HHS reports loans in accordance with the *Federal Credit Reform Act*. Budgetary related activity is reported separately within the Combined Statement of Budgetary Resources.

Exchange Revenue

Exchange revenue results when HHS provides goods or services to another entity for a price and is recognized when earned (i.e., when goods have been delivered or services have been rendered). These revenues reduce the cost of operations.

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

With minor exceptions, all revenue receipts by federal agencies are processed through the Treasury Central Accounting System. Regardless of whether they are derived from exchange or non-exchange transactions, all receipts not earmarked by Congressional appropriation for immediate HHS use are deposited in the General or Special Funds of the Treasury. Amounts not retained for use by HHS are reported as Transfers-in/out Without Reimbursement to other government agencies on the HHS Consolidated Statement of Changes in Net Position.

Non-Exchange Revenue

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

Non-exchange revenue is not considered to reduce the cost of the Department's operations and is separately reported on the Consolidated Statement of Changes in Net Position. Employment tax revenue collected under FICA and SECA is considered non-exchange revenue.

Imputed Financing Sources

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

H. Intragovernmental Transactions and Relationships

Intragovernmental transactions are business activities conducted between two different federal entities. Transactions with the public are transactions in which either the buyer or seller of the goods or services is a non-federal entity.

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

In the course of operations, HHS has relationships and financial transactions with numerous federal agencies including SSA and Treasury. SSA determines eligibility for Medicare programs and also deducts Medicare Part - B premiums from Social Security benefit payments for Social Security beneficiaries who elect to enroll in the Medicare Part - B program and elect to deduct their premiums from their benefit checks. SSA then transfers those funds to the Medicare Part-B Trust Fund. Treasury receives the cumulative excess of Medicare receipts and other financing over outlays and issues interest-bearing securities in exchange for the use of those monies. Medicare Part - D is primarily financed by the General Fund of the Treasury, as well as beneficiary premiums and payments from states.

I. Entity and Non-Entity Assets

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

Non-entity assets are assets held by the reporting entity, but not available for use. HHS non-entity assets are composed of delinquent child support payments for the Child Support Enforcement Program, which are withheld from federal tax refunds, interest accrued on over-payments, and cost settlements reported by the Medicare contractors.

J. Fund Balance with Treasury (FBwT)

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

K. Custodial Activity

In accordance with guidance set forth in OMB Circular A-136, HHS reports custodial activities on its Consolidated Balance Sheets. However, HHS does not prepare a separate Statement of Custodial Activity since custodial activities are incidental to its operations and the amounts collected are immaterial.

ACF receives funding from the IRS for outlay to the states for child support. This funding represents delinquent child support payments withheld from federal tax refunds. FDA custodial activity involves collections of Civil Monetary Penalties assessed by the Department of Justice on behalf of the FDA. FDA is charged with assessing penalties for violations in areas such as illegally manufactured, marketed, and distributed animal food and drug products. CDC's custodial activity consists of the collection of interest on outstanding receivables and funds received from debts in collection status.

L. Investments, Net

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

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

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

The Vaccine Injury Compensation Trust Fund, a dedicated collections fund similar to the HI and SMI Trust Funds, invests in Non-Marketable, Market-Based securities issued by the Bureau of the Fiscal Service in the form of One Day Certificates and Market-Based Bills, Notes, and Bonds.

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

The *Children's Health Insurance Program Reauthorization Act* established a Child Enrollment Contingency Fund to provide additional funding to states that experience shortfalls in their Children's Health Insurance Programs (CHIP). The *Affordable Care Act* extended the availability of the fund through 2015, and MACRA extended the fund for an additional 2 years, through 2017. This fund is invested in Non-Marketable, Market-Based Bills issued by the Bureau of the Fiscal Service. These investments will be redeemed as funds are needed by the states to cover short-term shortfalls in the program.

M. Accounts Receivable, Net

Accounts Receivable, Net consists of the amounts owed to HHS by other federal agencies and the public for the provision of goods and services, less an allowance for uncollectible amounts on public receivables. Intragovernmental accounts receivable consists of the amounts owed to HHS by other federal agencies for reimbursable work. No allowance for uncollectible amounts is established for intragovernmental accounts receivable because they are considered fully collectible. Accounts Receivable, Net from the public is primarily composed of provider and beneficiary over-payments: Medicare Prescription Drug over-payments, Medicare premiums, civil monetary penalties and other restitutions, state phased-down contributions, Medicaid/CHIP overpayments, audit disallowances, and the recognition of Medicare Secondary Payer accounts receivable.

Accounts Receivable, Net from the public is presented net of an allowance for uncollectible amounts. The allowance is based on past collection experience and an analysis of outstanding balances. For Medicare accounts

receivable, HHS calculates the allowance for uncollectible amounts based on the collection activity and the age of the debt for the most current fiscal year, while taking into consideration the average uncollectible percentage for the preceding 5 years. The Medicaid accounts receivable have been recorded at a net realizable amount based on historical analyses of actual recoveries and the rate of disallowances found in favor of the states. Other accounts receivable have been recorded to account for amounts due from Marketplace activities.

N. Advances and Accrued Grant Liability

HHS awards grants to various grantees and provides advance payments to meet grantees' cash needs in carrying out HHS programs. Advance payments are liquidated upon grantees reporting expenditures on the quarterly *Federal Financial Report*. In some instances, grantees incur expenditures before drawing down funds that, when claimed, would reduce the Advances account to a negative balance. An Accrued Grant Liability occurs when the accrued grant expenses exceed outstanding advances to grantees.

HHS grants are classified into two categories: Grants Not Subject to Grant Expense Accrual and Grants Subject to Grant Expense Accrual. Grants Not Subject to Grant Expense Accrual represents formula grants, commonly referred to as block grants, under which grantees provide a variety of services or payments to individuals and local agencies. Expenses are recorded as the grantees draw funds. These grants are funded based on allocations determined by budgets and agreements approved by the sponsoring OpDiv.

For Grants Subject to Grant Expense Accrual, commonly referred to as non-block grants, grantees draw funds based on their estimated cash needs. As grantees report their actual disbursements quarterly, the amounts are recorded as expenses and their advance balances are reduced. At year-end, the OpDivs report both actual payments made through the fourth quarter and an unreported grant expenditure estimate for the fourth quarter based on historical spending patterns of the grantees.

O. Inventory and Related Property, Net

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

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

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

Stockpile Materials are held in reserve to respond to local and national emergencies. HHS maintains several stockpiles for emergency response purposes, which include the Strategic National Stockpile (SNS), Vaccines for Children (VFC) and Avian Influenza (H5N1). The H5N1 vaccine stockpile is held in reserve to respond to an avian flu pandemic declaration. The stockpile contains several million doses of vaccine in bulk which are stored and maintained for possible use.

Project BioShield has increased the preparedness of the nation by procuring medical countermeasures that include anthrax vaccine, anthrax antitoxins, botulin antitoxins, and blocking and decorporation agents for a radiological event. All stockpiles are valued at historical cost, using various cost flow assumptions, including the FIFO for SNS and specific identification for VFC and H5N1.

P. General Property, Plant and Equipment, Net

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

The cost of Property, Plant, and Equipment acquired under a capital lease is the amount recognized as a liability for the capital lease at its inception. When property is acquired through a donation, the cost recognized is the estimated fair market value on the date of acquisition. The cost of Property, Plant and Equipment transferred from other federal entities is the transferring entity's net book value. Except for internal use software, HHS capitalizes all Property, Plant, and Equipment with an initial acquisition cost of $25,000 or more and an estimated useful life of 2 years or more.

HHS has commitments under various operating leases with private entities as well as the General Services Administration (GSA) for offices, laboratory space, and land. Leases with private entities have initial or remaining non-cancelable lease terms from 1 to 50 years; however, GSA leases are cancelable with 120 days' notice. Under an operating lease, the cost of the lease is expensed as incurred.

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

In accordance with Statement of Federal Financial Accounting Standards (SFFAS) Number 10, *Accounting for Internal Use Software*, capitalization of internally developed, contractor-developed/commercial off-the-shelf software begins in the software development phase. HHS's capitalization threshold for internal use software costs for appropriated fund accounts is $1 million and the threshold for revolving fund accounts is $500 thousand. Costs below the threshold levels are expensed. Software is amortized using the straight line method over a period of 5 to 10 years consistent with the estimated life used for planning and acquisition purposes. Capitalized costs include all direct and indirect costs.

Q. Stewardship Land

HHS stewardship land (i.e., land not acquired for or in connection with general property, plant, and equipment) is Indian Trust land used to support the IHS day-to-day operations of providing health care to American Indians and Alaskan Natives in remote areas of the country where no other facilities exist. In accordance with SFFAS Number 29*, Heritage Assets and Stewardship Land,* HHS does not report a related amount on the Balance Sheet.

HHS asset accountability reports differentiate Indian Trust land parcels from General Property, Plant and Equipment situated thereon.

R. Liabilities

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

government. HHS's liabilities are classified as covered by budgetary resources or not covered by budgetary resources.

Liabilities Covered by Budgetary Resources

Available budgetary resources include new budget authority, spending authority from offsetting collections, recoveries of expired budget authority, unobligated balances of budgetary resources at the beginning of the year, permanent indefinite appropriation, and borrowing authority.

Liabilities Not Covered by Budgetary Resources

Sometimes funding has not yet been made available through Congressional appropriation or current earnings. The major liabilities in this category include contingencies, employee annual leave earned, but not taken, and amounts billed by the Department of Labor (DOL) for disability payments. The actuarial FECA liability determined by the DOL but not yet billed is also included in this category.

S. Accounts Payable

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

T. Accrued Payroll and Benefits

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

U. Entitlement Benefits Due and Payable

Entitlement Benefits Due and Payable represents a liability for Medicare, Medicaid and CHIP owed to the public for medical services Incurred But Not Reported (IBNR) as of the end of the reporting period. The Medicare and Medicaid programs are the largest entitlement programs in HHS.

Medicare

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

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

HHS develops estimates for medical costs IBNR using an actuarial process that is consistently applied, centrally controlled, and automated. The actuarial models consider factors such as time from date of service to claim receipt, claim backlogs, medical care professional contract rate changes, medical care consumption, and other

medical cost trends. HHS estimates liabilities for physician, hospital and other medical cost disputes based upon an analysis of potential outcomes, assuming a combination of litigation and settlement strategies.

Each period, HHS re-examines previously established medical cost payable estimates based on actual claim submissions and other changes in facts and circumstances. As the liability estimates recorded in prior periods become more exact, HHS adjusts the amount of the estimates and includes the changes in estimates in medical costs in the period in which the change is identified. In every reporting period, HHS operating results include the effects of more completely developed Medicare benefits payable estimates associated with previously reported periods.

Medicaid and CHIP

The Medicaid and CHIP estimates represent the net federal share of expenses incurred by the states but not yet reported to HHS. This estimate is developed based on historical relationships between prior net payables to the states and current activity.

V. Federal Employee and Veterans' Benefits

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

The liability for federal employee and veterans' benefits also includes an actuarial liability for estimated future payments for workers' compensation pursuant to the FECA. FECA provides income and medical cost protection to federal employees who are injured on the job or who sustained a work-related occupational disease. It also covers beneficiaries of employees whose deaths are attributable to job-related injury or occupational disease. The FECA program is administered by DOL, which pays valid claims and subsequently bills the employing federal agency. The FECA liability consists of two components: (1) actual claims billed by the DOL to agencies but not yet paid; and (2) an estimated liability for future benefit payments as a result of past events such as death, disability, and medical costs. The claims that have been billed by DOL are included in Accrued Payroll and Benefits.

Most HHS employees participate in the Civil Service Retirement System (CSRS), a defined benefit plan, or the Federal Employees Retirement System (FERS), a defined benefit and contribution plan. For employees covered under CSRS, the Department contributes a fixed percentage of pay. Most employees hired after December 31, 1983, are automatically covered by the FERS. The FERS plan has 3 parts: a defined benefit payment, Social Security benefits, and the Thrift Savings Plan. For employees covered under FERS, HHS contributes a fixed percentage of pay for the defined benefit portion and the employer's matching share for Social Security and Medicare Insurance. HHS automatically contributes 1 percent of each employee's pay to the Thrift Savings Plan and matches the first 3 percent of employee contributions dollar for dollar. Each additional dollar of the employee's next 2 percent of basic pay is matched at 50 cents on the dollar.

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

W. Contingencies

A loss contingency is an existing condition, situation, or set of circumstances involving uncertainty as to possible loss to HHS. The uncertainty ultimately should be resolved when one or more future events occur or fail to occur. The likelihood that the future event or events will confirm the loss or the incurrence of a liability can range from probable to remote. SFFAS Number 5, *Accounting for Liabilities of the Federal Government*, as amended by SFFAS Number 12, *Recognition of Contingent Liabilities from Litigation*, contains the criteria for recognition and disclosure of contingent liabilities.

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

HHS has no material obligations related to cancelled appropriations for which there is a contractual commitment for payment or for contractual arrangements which many require future financial obligations.

X. Statement of Social Insurance

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

In order to make projections regarding the future financial status of the HI and SMI Trust Funds, various assumptions have to be made. The projections in this report (with one exception related to depletion of the HI Trust Fund), are based on current law; that is, they assume that laws on the books will be implemented and adhered to with respect to scheduled taxes, premium revenues, and payments to providers and health plans. The estimates depend on many economic, demographic, and health care-specific assumptions. These include changes in per beneficiary health care cost, wages, the gross domestic product (GDP), the consumer price index (CPI), fertility rates, mortality rates, immigration rates, and interest rates. In most cases, these assumptions vary from year to year during the first 5 to 30 years before reaching their ultimate values for the remainder of the 75-year projection period. The assumed growth rates for per beneficiary health care costs vary throughout the projection period.

The assumptions underlying the Statement of Social Insurance actuarial projections are drawn from the *Social Security and Medicare Trustees Reports for 2016*. Specific assumptions are made for each of the different types of service provided by the Medicare program (for example, hospital care and physician services). These assumptions include changes in the payment rates, utilization, and intensity of each type of service.

Y. *Affordable Care Act*

In FY 2010, President Barack Obama signed health insurance reform legislation giving Americans more control over their health care. The *Patient Protection and Affordable Care Act* and the *Health Care and Education Reconciliation Act* collectively referred to as the *Affordable Care Act* ensures that all Americans have access to quality, affordable health care, while helping to reduce health care costs. Further information is available at www.healthcare.gov.

The *Affordable Care Act* contains the most significant changes to health care coverage since passage of the *Social Security Act*. The *Affordable Care Act* provided funding for the establishment by CMS of a Center for Medicare and Medicaid Innovation to test innovative payment and service delivery models to reduce program expenditures while preserving or enhancing the quality of care furnished to individuals. It also allowed for the establishment of a Center for Consumer Information and Insurance Oversight (CCIIO). The programs under CCIIO include: Health Insurance Marketplaces (the "Marketplace") and the CO-OP program. A brief description of these programs and their impact on the financial statement is presented below.

Health Insurance Marketplaces and the Basic Health Program

Grants have been provided to the States to establish Health Insurance Marketplaces. The initial grants were made by the HHS to the States "not later than one (1) year after the date of enactment." Thus, HHS made the initial grants by March 23, 2011. Subsequent grants were issued by CMS through December 31, 2014, after which time no further grants could be made. All Marketplaces were launched on October 1, 2013.

To help make health insurance more affordable to consumers, HHS makes payments of advance premium tax credits (APTC) and cost-sharing reductions (CSR) to health insurance issuers on behalf of consumers who are eligible for financial assistance. States may also opt to cover some Marketplace-eligible individuals through the Basic Health Program (BHP), and a state that operates a BHP receives federal funding equal to 95 percent of the amount of the premium tax credits and CSRs that would have otherwise been provided to (or on behalf of) eligible individuals if those individuals enrolled in Qualified Health Plans through the Marketplace. APTC, CSR, and BHP payments (which are included in the IRS financial statements; see Note 1-D) are a critical component of the Marketplace, and $42 billion has been allocated for these payments. In addition to these payments on behalf of consumers, HHS collects Marketplace user fees from issuers participating in the Federally-facilitated Marketplace.

Consumer Operated and Oriented Plan Program

The CO-OP Program fosters qualified non-profit health insurance issuers created to offer qualified health plans to the individual and small group markets. Under this program, HHS provides assistance to organizations applying to become qualified non-profit health insurance issuers through loans to assist in meeting start-up costs and to assist the applicant meet state solvency requirements. In accordance with regulations as well as legislative requirements, start-up loans shall be repaid within 5 years and the solvency loans within 15 years after disbursement, considering state reserve requirements and solvency regulations.

Transitional Reinsurance Program

The Transitional Reinsurance Program was established in each state to help stabilize premiums for coverage in the individual market from 2014 through 2016. All health insurance issuers and third party administrators, on behalf of self-insured group health plans, must make contributions to support reinsurance payments that cover high-cost individuals in non-grandfathered plans in the individual market, inside and outside the Marketplace. The Transitional Reinsurance Program is a critical element in helping to ensure a stabilized individual market in the initial years of the implementation of the *Affordable Care Act's* insurance market reforms.

Risk Adjustment Program

The Risk Adjustment Program is a permanent program. It applies to non-grandfathered individuals and small group plans inside and outside the Marketplaces. It provides payments to health insurance issuers that disproportionately attract higher-risk populations (such as individuals with chronic conditions) and transfers funds from plans with relatively lower risk enrollees to plans with relatively higher risk enrollees to protect against adverse selection. States may operate risk adjustment programs; CMS will operate a risk adjustment program for each state that does not operate its own. In 2015 and 2016, Massachusetts is the only state that operated its own risk adjustment program.

Risk Corridor Program

The temporary Risk Corridors Program will operate during the years 2014 through 2016. This program applies to qualified health plans in the individual and small group markets, inside and outside the Marketplaces and protects against inaccurate rate-setting by sharing risk (gains and losses) on allowable costs between CMS and qualified health plans to help ensure stable health insurance premiums.

Note 2. Entity and Non-Entity Assets (in Millions)

	2016	2015
Non-Entity Intragovernmental Assets		
Fund Balance with Treasury	$ -	$ 8
Accounts Receivable	5	3
Total Non-Entity Intragovernmental Assets	5	11
Accounts Receivable With the Public	37	27
Total Non-Entity Assets	42	38
Total Entity Assets	562,611	528,757
Total Assets	$ 562,653	$ 528,795

Note 3. Fund Balance with Treasury (in Millions)

Fund Balance with Treasury	2016	2015
Trust Funds	$ 54,050	$ 45,056
Revolving Funds	2,443	1,433
Appropriated Funds	172,984	170,155
Special Funds and Other Funds	8,282	2,815
Total	$ 237,759	$ 219,459

Status of Fund Balance with Treasury		
Unobligated Balance		
Available	$ 17,280	$ 23,828
Unavailable	43,230	41,796
Obligated Balance not yet Disbursed	231,154	214,439
Non-Budgetary Fund Balance with Treasury	(53,905)	(60,604)
Total	$ 237,759	$ 219,459

The FBwT are funds primarily available to pay current expenditures and liabilities. Special Funds includes the CHIP Child Enrollment Contingency of $5.4 billion and *Affordable Care Act* Risk Programs of $2.2 billion. Other Funds includes balances in deposit funds, management funds and related non-spending accounts. The Unobligated Balance includes funds that are restricted for future use and not apportioned for current use of $8.8 billion and $14.5 billion as of September 30, 2016 and September 30, 2015, respectively. The restricted amount is primarily for the *Affordable Care Act* programs, CHIP, CMS Program Management, and State Grants and Demonstrations.

Note 4. Investments, Net (in Millions)

2016	Cost	Amortized (Premium)	Interest Receivable	Investments, Net	Market Value Disclosure
Intragovernmental Securities					
Non-Marketable: Par Value	$ 255,545	$ -	$ 2,256	$ 257,801	$ 257,801
Non-Marketable: Market-Based	4,446	(195)	25	4,276	4,276
Total, Intragovernmental	$ 259,991	$ (195)	$ 2,281	$ 262,077	$ 262,077

2015	Cost	Amortized (Premium)	Interest Receivable	Investments, Net	Market Value Disclosure
Intragovernmental Securities					
Non-Marketable: Par Value	$ 261,585	$ -	$ 2,408	$ 263,993	$ 263,993
Non-Marketable: Market-Based	5,825	(194)	27	5,658	5,658
Total, Intragovernmental	$ 267,410	$ (194)	$ 2,435	$ 269,651	$ 269,651

HHS investments consist primarily of Medicare Trust Fund (i.e., funds from dedicated collections) investments. Medicare Non-Marketable: Par Value Bonds are carried at face value and have maturity dates ranging from June 30, 2017 through June 30, 2031 with interest rates ranging from 1.875 percent to 5.25 percent. Medicare Non-Marketable: Par Value Certificates of Indebtedness mature on June 30, 2017 with an interest rate from 1.625 percent to 1.875 percent.

Securities held by the Vaccine Injury Compensation Trust Fund (i.e., funds from dedicated collections) will mature in FY 2017 through FY 2021. The Market-Based Notes paid from 1.0 percent to 3.875 percent during October 1, 2015 to September 30, 2016 and 1.0 percent to 3.875 percent during October 1, 2014 to September 30, 2015. The Market-Based Bonds pay 9.125 percent through FY 2018.

The Market Based Bills held in the NIH gift funds held during 12 months of FY 2016, yielded from 0.0050 percent to 0.5163 percent depending on date purchased and length of time to maturity.

The investments held by the CHIP Child Enrollment Contingency Fund in the amount of $0.6 billion as of September 30, 2016, are short term Non-Marketable Market-Based Bills purchased at a discount which are fully amortized at the maturity date.

Note 5. Accounts Receivable, Net (in Millions)

2016	Accounts Receivable Principal	Interest Receivable	Accounts Receivable, Gross	Allowance	Net HHS Receivables
Intragovernmental					
Entity	$ 1,007	$ -	$ 1,007	$ -	$ 1,007
Non-Entity	5	-	5	-	5
Total, Intragovernmental	$ 1,012	$ -	$ 1,012	$ -	$ 1,012
With the Public					
Entity					
Medicare	$ 10,193	$ -	$ 10,193	$ (2,740)	$ 7,453
Medicaid	8,382	-	8,382	(1,186)	7,196
Other	9,722	278	10,000	(483)	9,517
Non-Entity	3	58	61	(24)	37
Total With the Public	$ 28,300	$ 336	$ 28,636	$ (4,433)	$ 24,203

2015	Accounts Receivable Principal	Interest Receivable	Accounts Receivable, Gross	Allowance	Net HHS Receivables
Intragovernmental					
Entity	$ 1,002	$ -	$ 1,002	$ -	$ 1,002
Non-Entity	3	-	3	-	3
Total, Intragovernmental	$ 1,005	$ -	$ 1,005	$ -	$ 1,005
With the Public					
Entity					
Medicare	$ 8,806	$ -	$ 8,806	$ (2,031)	$ 6,775
Other	16,713	269	16,982	(1,869)	15,113
Non-Entity	-	53	53	(26)	27
Total With the Public	$ 25,519	$ 322	$ 25,841	$ (3,926)	$ 21,915

As of September 30, 2016, the other accounts receivable with the public is primarily related to collections for Marketplace activities.

Note 6. Inventory and Related Property, Net (in Millions)

	2016	2015
Inventory Held for Current Sale, Net	$ 7	$ 7
Operating Materials and Supplies Held for Use	68	73
Stockpile Materials Held for Emergency or Contingency	9,324	9,436
Inventory and Related Property, Net	$ 9,399	$ 9,516

Note 7. General Property, Plant and Equipment, Net (in Millions)

			2016		
	Depreciation Method	Estimated Useful Lives	Acquisition Cost	Accumulated Depreciation	Net Book Value
Land & Land Rights	-	-	$ 54	$ -	$ 54
Construction in Progress	-	-	772	-	772
Buildings, Facilities & Other Structures	Straight Line	5-50 Yrs	5,980	(2,919)	3,061
Equipment	Straight Line	3-20 Yrs	2,029	(1,208)	821
Internal Use Software	Straight Line	5-10 Yrs	1,998	(1,132)	866
Assets Under Capital Lease	Straight Line	1-30 Yrs	139	(63)	76
Leasehold Improvements	Straight Line	*Life of Lease	52	(37)	15
Totals			$ 11,024	$ (5,359)	$ 5,665

			2015		
	Depreciation Method	Estimated Useful Lives	Acquisition Cost	Accumulated Depreciation	Net Book Value
Land & Land Rights	-	-	$ 53	$ -	$ 53
Construction in Progress	-	-	650	-	650
Buildings, Facilities & Other Structures	Straight Line	5-50 Yrs	6,140	(2,788)	3,352
Equipment	Straight Line	3-20 Yrs	1,922	(1,134)	788
Internal Use Software	Straight Line	5-10 Yrs	1,955	(965)	990
Assets Under Capital Lease	Straight Line	1-30 Yrs	126	(59)	67
Leasehold Improvements	Straight Line	*Life of Lease	51	(34)	17
Totals			$ 10,897	$ (4,980)	$ 5,917

*7 to 15 years or the life of the lease, whichever is shorter.

Note 8. Advances (in Millions)

	2016	2015
Intragovernmental		
Advances to Other Federal Entities	$ 239	$ 178
With the Public		
Travel Advances & Emergency Employee Salary Advances	2	5
Other Prepayments & Deferred Charges	18	28
Prescription Drug and Medicare Advantage	21,460	-
Total With the Public	$ 21,480	$ 33

As of September 30, 2016, advances with the public primarily represent payment of the Prescription Drug and Medicare Advantage benefit payments for October 2016 that occurred on September 30 instead of October 1.

Note 9. Liabilities Not Covered by Budgetary Resources (in Millions)

	2016	2015
Intragovernmental		
Accrued Payroll and Benefits	$ 59	$ 58
Other	4,867	1,699
Total Intragovernmental	$ 4,926	$ 1,757
Federal Employee and Veterans' Benefits (Note 11)	12,892	12,072
Accrued Payroll and Benefits	650	632
Contingencies and Commitments (Note 14)	12,394	9,105
Accrued Liabilities (Note 12)	14,420	14,250
Other	210	(1,512)
Total Liabilities Not Covered by Budgetary Resources	$ 45,492	$ 36,304
Total Liabilities Covered by Budgetary Resources	115,790	115,084
Total Liabilities	$ 161,282	$ 151,388

The *Bipartisan Budget Act of 2015* (Section 601) authorized a transfer from the General Fund to SMI, to temporarily replace the reduction in Medicare Part B premiums. Section 601 created an "additional premium" charged alongside the normal Medicare Part B monthly premiums, beginning in 2016, which will be used to pay back the General Fund transfer without interest. As of September 30, 2016, $3,289 million is still owed and reported under Other Liabilities.

Note 10. Entitlement Benefits Due and Payable (in Millions)

	2016	2015
Medicare Fee-For-Service	$ 44,866	$ 45,268
Medicare Advantage/Prescription Drug Program	19,045	20,953
Medicaid	35,419	36,758
CHIP	978	773
Other	7,922	4,397
Totals	$ 108,230	$ 108,149

Entitlement Benefits Due and Payable represents a liability for Medicare fee-for-service, Medicare Advantage and Prescription Drug Program, Medicaid, and CHIP owed to the public for medical services/claims IBNR as of the end of the reporting period.

The Medicare fee-for-service liability is primarily an actuarial liability which represents (a) an estimate of claims incurred that may or may not have been submitted to the Medicare contractors but were not yet approved for payment; (b) actual claims that have been approved for payment by the Medicare contractors for which checks have not yet been issued; (c) checks that have been issued by the Medicare contractors in payment of a claim and that have not yet been cashed by payees; (d) periodic interim payments for services rendered in the current FY but paid in the subsequent FY; and (e) an estimate of retroactive settlements of cost reports. The September 30, 2016 and 2015 estimate also includes amounts which may be due/owed to providers for previous years' disputed cost report adjustments for disproportionate share hospitals and teaching hospitals as well as amounts which may be due/owed to hospitals for adjusted prospective payments.

The Medicare Advantage and Prescription Drug program liability represents amounts owed to plans after the completion of the Prescription Drug payment reconciliation and estimates relating to risk and other payment related adjustments including the estimate for the first nine months of calendar year 2016. In addition, it includes an estimate of payments to plan sponsors of retiree prescription drug coverage incurred but not yet paid as of September 30, 2016.

The Medicaid and CHIP estimates represent the net federal share of expenses that have been incurred by the states but not yet reported to CMS.

The Other Liability line item includes estimates of payments due to those participating in Marketplace activities.

Note 11. Federal Employee and Veterans' Benefits (in Millions)

	2016	2015
With the Public		
Liabilities Not Covered by Budgetary Resources		
PHS Commissioned Corp Pension Liability	$ 11,995	$ 11,227
PHS Commissioned Corp Post-Retirement Health Benefits	625	574
Workers' Compensation Benefits (Actuarial FECA Liability)	272	271
Total, Federal Employee and Veterans' Benefits	$ 12,892	$ 12,072

Public Health Service (PHS) Commissioned Corps

HHS administers the PHS Commissioned Corps Retirement System for 6,583 active duty officers and 6,734 retiree annuitants and survivors. As of September 30, 2016, the actuarial accrued liability for the retirement benefit plan was $12.0 billion and $0.6 billion for non-Medicare coverage of the Post-Retirement Medical Plan.

The Commission Corp Retirement System and Post-Retirement Health Benefits are not funded. Therefore, in accordance with SFFAS Number 33*, Pensions, Other Retirement Benefits and Other Postemployment Benefits: Reporting the Gains and Losses from Changes in Assumptions and Selecting Discount Rates and Valuation Dates* (SFFAS Number 33), the discount rate should be based on long-term assumptions, for marketable securities (i.e., Treasury marketable securities) of similar maturity to the period over which the payments are to be made. The discount rates should be matched with the expected timing of the associated expected cashflow. A single discount

rate may be used for all the projected cashflow, as long as the resulting present value is not materially different than the resulting present value using multiple rates.

The significant assumptions used in the calculation of the pension and medical program liability, as of September 30, 2016 and September 30, 2015, were:

	2016	2015
Discount rate	4.26 percent	4.44 percent
Annual basic pay scale increase	2.51 percent	2.68 percent
Annual inflation	2.01 percent	2.18 percent

	2016	2015
Beginning Liability Balance	$ 11,801	$ 11,691
Expense		
Normal Cost	326	321
Interest on the liability balance	493	508
Actuarial (Gain)/Loss		
From experience	107	(98)
From assumption changes		
Change in discount rate assumption	303	326
Change in inflation/salary increase assumption	(259)	(508)
Change in mortality rate/others	332	31
Net Actuarial (Gain)/Loss	483	(249)
Total expense	$ 1,302	$ 580
Less amounts paid	(483)	(470)
Ending Liability Balance	$ 12,620	$ 11,801

The following shows key valuation results as of September 30, 2016 and 2015, in conformance with the actuarial reporting standards set forth in the SFFAS Number 5, *Accounting for Liabilities of the Federal Government* and SFFAS Number 33. The valuation is based upon the current plan provisions, membership data collected as of June 30, 2016, and actuarial assumptions. The September 30, 2016 valuation includes an increase in liabilities of $819 million resulting from an increase in normal cost and an actuarial loss from changes in assumptions and experience. Volatility of the discount rate significantly affects the liabilities for these benefits. Therefore, to mitigate the impact of this volatility, SFFAS Number 33 also provides for the use of historical average rates to prevent the undue influence of current or near term rates.

Workers' Compensation Benefits

The actuarial liability for future workers' compensation benefits includes the expected liability for death, disability, medical and miscellaneous costs for approved compensation cases, plus a component for incurred but not reported claims. The liability utilizes historical benefit payment patterns to predict the ultimate payment related to that period. In FY 2015, the fund effected a change in accounting estimate to refine the methodology used for selecting the interest rate assumptions and enhance matching between the timing of cash flows and interest rates. For FY 2016, discount rates were based on averaging the Treasury's Yield Curve for Treasury Nominal Coupon Issues (the TNC Yield Curve) for the current and prior 4 years for FY 2016 and FY 2015, respectively. Interest rate assumptions utilized for discounting as of September 30, 2016 and September 30, 2015 follow.

	2016	2015
Wage Benefits	2.781% in Year 1 and years thereafter	3.134% in Year 1 and years thereafter
Medical Benefits	2.261% in Year 1 and years thereafter	2.496% in Year 1 and years thereafter

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

FY	COLA	CPIM
2016	N/A	N/A
2017	1.31%	2.99%
2018	1.13%	3.09%
2019	1.23%	3.40%
2020	1.45%	3.68%
2021	1.85%	3.87%

Note 12. Accrued Liabilities (in Millions)

	2016	2015
Grant Liability	$ 4,915	$ 3,831
Other Accrued Liabilities	9,505	10,419
Accrued Liabilities	$ 14,420	$ 14,250

Note 13. Other Liabilities (in Millions)

	2016		2015	
	Intra-governmental	With the Public	Intra-governmental	With the Public
Accrued Payroll & Benefits	$ 136	$ 960	$ 118	$ 969
Advances from Others	609	744	446	720
Deferred Revenue	-	1,066	-	642
Custodial Liabilities	407	5	729	12
Contingent Liabilities (Note 14)	1,021	-	941	-
Other	4,890[8]	2,188	1,375	977
Total Other Liabilities	$ 7,063	$ 4,963	$ 3,609	$ 3,320

[8] Please refer to Note 9 - Liabilities Not Covered By Budgetary Resources for details.

Note 14. Contingencies and Commitments

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

Medicaid Audit and Program Disallowances

The Medicaid amount of $10.2 billion ($7.5 billion in FY 2015) consists of Medicaid audit and program disallowances of $2.8 billion ($2.4 billion in FY 2015) and of $7.4 billion ($5.1 billion in FY 2015) for reimbursement of State Plan amendments. Contingent liabilities have been established as a result of Medicaid audit and program disallowances that are currently being appealed by the states. The funds could have been returned or HHS can decrease the state's authority. HHS will be required to pay these amounts if the appeals are decided in favor of the states. In addition, certain amounts for payment have been deferred under the Medicaid program when there is a reasonable doubt as to the legitimacy of expenditures claimed by a state. There are also outstanding reviews of the state expenditures in which a final determination has not been made.

Appeals at the Provider Reimbursement Review Board

Other liabilities do not include all provider cost reports under appeal at the Provider Reimbursement Review Board (PRRB). The monetary effect of those appeals is generally not known until a decision is rendered. However, historical cases that have been appealed and settled by the PRRB are considered in the development of the actuarial Medicare IBNR liability. As of September 30, 2016, 10,005 cases (9,737 in FY 2015) remain on appeal. A total of 2,515 new cases (3,473 in FY 2015) were filed and 10 cases were reopened (9 in FY 2015). The PRRB rendered decisions on 66 cases (84 in FY 2015) and 2,191 additional cases (2,972 in FY 2015) were dismissed, withdrawn, or settled prior to an appeal hearing. The PRRB receives no information on the value of these cases that are settled prior to a hearing.

Other Accrued Contingent Liabilities

The U.S. Supreme Court decision in *Salazar v. Ramah Navajo Chapter*, dated June 18, 2012, is likely to result in increased claims against the IHS. As a result of this decision, many tribes have filed claims. Some claims have been paid and others have been asserted but not yet settled. It is expected that some tribes will file additional claims for prior years. An estimated loss related to this matter was accrued last year and the remaining unpaid accrued liability is included on the Consolidated Balance Sheet.

The Vaccine Injury Compensation Program is administered by HRSA and provides compensation for vaccine-related injury or death. A contingent liability has been accrued in the financial statements for the estimated future payment value of injury claims.

Note 15. Revenue (in Millions)

2016 Consolidated Gross Cost and Exchange Revenue by Budget Function Classification

	Education Training & Social Services	Health	Medicare	Income Security	OpDiv Combined Totals	Intra-HHS Eliminations	Consolidated Totals
Intragovernmental							
Gross Cost	$ 119	$ 6,275	$ 840	$ 73	$ 7,307	$ (2,338)	$ 4,969
Exchange Revenue	(17)	(2,973)	(12)	(7)	(3,009)	2,044	(965)
Net Cost, *Intragovernmental*	102	3,302	828	66	4,298	(294)	4,004
With the Public							
Gross Cost	14,823	467,160	646,201	38,643	1,166,827	-	1,166,827
Exchange Revenue	-	(15,113)	(80,915)	(31)	(96,059)	-	(96,059)
Net Cost, *With the Public*	14,823	452,047	565,286	38,612	1,070,768	-	1,070,768
Total Gross Cost	14,942	473,435	647,041	38,716	1,174,134	(2,338)	1,171,796
Total Exchange Revenue	(17)	(18,086)	(80,927)	(38)	(99,068)	2,044	(97,024)
Total Net Cost of Operations	$ 14,925	$ 455,349	$ 566,114	$ 38,678	$ 1,075,066	$ (294)	$ 1,074,772

2015 Consolidated Gross Cost and Exchange Revenue by Budget Function Classification

	Education Training & Social Services	Health	Medicare	Income Security	OpDiv Combined Totals	Intra-HHS Eliminations	Consolidated Totals
Intragovernmental							
Gross Cost	$ 122	$ 6,517	$ 1,026	$ 20	$ 7,685	$ (2,548)	$ 5,137
Exchange Revenue	(33)	(3,116)	(12)	(7)	(3,168)	2,344	(824)
Net Cost, *Intragovernmental*	89	3,401	1,014	13	4,517	(204)	4,313
With the Public							
Gross Cost	13,978	453,400	621,810	38,002	1,127,190	-	1,127,190
Exchange Revenue	-	(25,769)	(75,689)	(16)	(101,474)	-	(101,474)
Net Cost, *With the Public*	13,978	427,631	546,121	37,986	1,025,716	-	1,025,716
Total Gross Cost	14,100	459,917	622,836	38,022	1,134,875	(2,548)	1,132,327
Total Exchange Revenue	(33)	(28,885)	(75,701)	(23)	(104,642)	2,344	(102,298)
Total Net Cost of Operations	$ 14,067	$ 431,032	$ 547,135	$ 37,999	$ 1,030,233	$ (204)	$ 1,030,029

Exchange Revenue

HHS recognizes its revenue from exchange transactions when goods and services are provided. Total exchange revenue was $97.0 billion and $102.3 billion through September 30, 2016 and 2015, respectively. HHS's exchange revenue consists primarily of Medicare premiums collected from beneficiaries. HHS also charges user fees and collects revenues related to reimbursable agreements with other government entities.

Note 16. Legal Arrangements Affecting Use of Unobligated Balances

The unobligated balances on the Combined Statement of Budgetary Resources consist of Trust Funds, appropriated funds, revolving funds, management funds, gift funds, Cooperative Research and Development Agreement funds, and royalty funds. Annual appropriations are available for new obligations in the year of appropriation and for adjustments to valid obligations for 5 subsequent years. Other appropriations are available for obligation for multiple years or until expended based on Congressional authority.

All Trust Fund receipts collected in the fiscal year are reported as new budget authority in the Combined Statement of Budgetary Resources. The portion of Trust Fund receipts collected in the fiscal year that exceeds the amount needed to pay benefits and other valid obligations in that fiscal year is precluded by law from being available for obligation. This excess of receipts over obligations is Temporarily Not Available Pursuant to Public Law and is included in the calculation for appropriations on the Combined Statement of Budgetary Resources; therefore, it is not classified as budgetary resources in the fiscal year collected. However, all such excess receipts are assets of the Trust Funds and become available for obligation, as needed. The entire Trust Fund balances in the amount of $201.6 billion, as of September 30, 2016, ($201.1 billion as of September 30, 2015), are included in Investments on the Consolidated Balance Sheets.

Exempt from Apportionment

This amount includes the FY 2016 recording of obligations required by law, where such obligations are in excess of available funding. These obligations were incurred by operation of law; thus, they are reflected as exempt from apportionment. The *Anti-Deficiency Act* has not been violated, as "[t]he prohibitions contained in the *Anti-Deficiency Act* are directed at discretionary obligations entered into by administrative officers." B-219161 (Oct. 2, 1985).

Note 17. Explanation of Differences between the Combined Statement of Budgetary Resources and the Budget of the United States Government (in Millions)

2015	Budgetary Resources	Obligations Incurred	Distributed Offsetting Receipts	Outlays, net (total) (discretionary and mandatory)
Combined Statement of Budgetary Resources	$ 1,543,105	$ 1,477,481	$ 380,187	$ 1,408,128
Expired Accounts	(35,401)	2	-	-
Other	(334)	(545)	43	67
Budget of the U.S. Government	$ 1,507,370	$ 1,476,938	$ 380,230	$ 1,408,195

The *Budget of the United States Government* (also known as the *President's Budget*), with the actual amounts for FY 2016, has not been published, therefore, no comparisons can be made between FY 2016 amounts presented in the Combined Statement of Budgetary Resources with amounts reported in the Actual column of the *President's Budget*. The *FY 2018 President's Budget* is expected to be released in February 2017 and may be obtained from OMB's website, www.whitehouse.gov/omb/budget, or from Government Publishing Office's website, www.gpo.gov.

HHS reconciled the amounts of the FY 2015 column on the Combined Statement of Budgetary Resources to the actual amounts for FY 2015 from the Appendix in the *FY 2017 President's Budget* for budgetary resources, obligations incurred, offsetting receipts, and net outlays (i.e., gross outlays less offsetting collections), as presented above.

For the budgetary resources reconciliation, the amount used from the *President's Budget* was the total budgetary resources available for obligation. Therefore, a reconciling item that is contained in the Combined Statement of Budgetary Resources and not in the *President's Budget* is the budgetary resources that were not available. The Expired Accounts line in the above schedule includes expired authority, recoveries, and other amounts included in the Combined Statement of Budgetary Resources that are not included in the *President's Budget*.

The Other differences in the budgetary resources and obligations incurred are due to gift funds and trust funds reported on the HHS Combined Statement of Budgetary Resources but not in the *President's Budget*. Governmentwide Treasury Account Symbol revision window adjustments are not included in the HHS Combined Statement of Budgetary Resources but are included in the *President's Budget*. In addition, there are differences related to adjustments made to recoveries and spending authority.

Note 18. Apportionment Categories of Obligations Incurred and Undelivered Orders (in Millions)

	2016		
	Direct	Reimbursable	Total
Category A (Distributed by Quarter)	$ 102,101	$ 8,418	$ 110,519
Category B (Restricted and Distributed by Activity)	768,700	4,293	772,993
Exempt from Apportionment	724,276	15	724,291
Total Obligations Incurred	$ 1,595,077	$ 12,726	$ 1,607,803

	2015		
	Direct	Reimbursable	Total
Category A (Distributed by Quarter)	$ 95,359	$ 7,487	$ 102,846
Category B (Restricted and Distributed by Activity)	700,591	3,832	704,423
Exempt from Apportionment	670,199	13	670,212
Total Obligations Incurred	$ 1,466,149	$ 11,332	$ 1,477,481

Obligations incurred consist of expended authority and the change in undelivered orders. OMB has exempted CMS from the Circular Number A-11, *Preparation, Submission and Execution of the Budget*, requirement to report Medicare's refunds of prior year obligations separately from refunds of current year obligations on the SF-133, *Report on Budget Execution and Budgetary Resources*.

Undelivered Orders include obligations that have been issued but are not yet drawn down and goods and services ordered that have not been received. HHS reported $140.2 billion of budgetary resources obligated for undelivered orders as of September 30, 2016 and $105.8 billion as of September 30, 2015.

Note 19. Funds from Dedicated Collections (in Millions)

Medicare is the largest dedicated collections program managed by HHS and is presented in a separate column in the schedule below. The Medicare program includes the HI Trust Fund; the SMI Trust Fund which includes both Part B, medical insurance, and the Prescription Drug Benefit – Part D; and the Medicare Integrity Program. Portions of the Program Management appropriation have been allocated to the HI and SMI Trust Funds. See Note 1 for a description of each fund's purpose and how HHS accounts for and reports the funds.

	2016		
Balance Sheet as of September 30	Medicare	Other	Total
Fund Balance with Treasury	$ 53,806	$ 6,892	$ 60,698
Investments	257,801	3,706	261,507
Other Assets	28,385	10,470	38,855
Total Assets	$ 339,992	$ 21,068	$ 361,060
Entitlement Benefits Due and Payable	$ 63,911	$ 7,915	$ 71,826
Accrued Liabilities (Note 12)	-	9,505	9,505
Other Liabilities	7,479	2,868	10,347
Total Liabilities	$ 71,390	$ 20,288	$ 91,678
Unexpended Appropriations	36,012	(100)	35,912
Cumulative Results of Operations	232,590	880	233,470
Total Liabilities and Net Position	$ 339,992	$ 21,068	$ 361,060
Statement of Net Cost for the Period Ended September 30			
Gross Program Costs	$ 647,041	$ 18,653	$ 665,694
Less: Exchange Revenues	80,927	13,114	94,041
Net Cost of Operations	$ 566,114	$ 5,539	$ 571,653
Statement of Changes in Net Position for the Period Ended September 30			
Net Position Beginning of Period	$ 246,863	$ 4,801	$ 251,664
Nonexchange Revenue	264,044	346	264,390
Other Financing Sources	323,809	1,172	324,981
Net Cost of Operations	(566,114)	(5,539)	(571,653)
Change in Net Position	$ 21,739	$ (4,021)	$ 17,718
Net Position End of Period	$ 268,602	$ 780	$ 269,382

	2015		
Balance Sheet as of September 30	Medicare	Other	Total
Fund Balance with Treasury	$ 44,785	$ 6,598	$ 51,383
Investments	263,993	3,606	267,599
Other Assets	7,327	10,661	17,988
Total Assets	$ 316,105	$ 20,865	$ 336,970
Entitlement Benefits Due and Payable	$ 66,221	$ 4,195	$ 70,416
Accrued Liabilities (Note 12)	-	10,419	10,419
Other Liabilities	3,021	1,450	4,471
Total Liabilities	$ 69,242	$ 16,064	$ 85,306
Unexpended Appropriations	30,284	(100)	30,184
Cumulative Results of Operations	216,579	4,901	221,480
Total Liabilities and Net Position	$ 316,105	$ 20,865	$ 336,970
Statement of Net Cost for the Period Ended September 30			
Gross Program Costs	$ 622,836	$ 26,545	$ 649,381
Less: Exchange Revenues	75,701	23,813	99,514
Net Cost of Operations	$ 547,135	$ 2,732	$ 549,867
Statement of Changes in Net Position for the Period Ended September 30			
Net Position Beginning of Period	$ 237,110	$ 6,656	$ 243,766
Nonexchange Revenue	252,045	338	252,383
Other Financing Sources	304,843	539	305,382
Net Cost of Operations	(547,135)	(2,732)	(549,867)
Change in Net Position	$ 9,753	$ (1,855)	$ 7,898
Net Position End of Period	$ 246,863	$ 4,801	$ 251,664

Note 20. Stewardship Land

IHS provides federal health services to American Indians and Alaska Natives to help raise their health status to the highest possible level. IHS provides health care to approximately 2.2 million American Indians and Alaska Natives who belong to 567 federally recognized tribes in 36 states. Health services are provided on tribal/reservation trust land that was transferred to IHS by the DOI for this purpose. Although the structures on this land are operational in nature, the land on which these structures reside is managed in a stewardship manner. All trust land, when no longer needed by IHS, must be returned to the DOI's Bureau of Indian Affairs for continuing trust responsibilities and oversight. In FY 2016, the number of sites in Phoenix is reduced as a result of a reevaluation.

The table below presents stewardship land held by HHS:

Indian Trust Land by Locations and Number of Sites

	2016	2015
Albuquerque	4	4
Bemidji	2	2
Billings	7	7
Great Plains	9	9
Navajo	36	35
Oklahoma City	1	1
Phoenix	10	12
Portland	3	3
Tucson	5	5
Total	77	78

Note 21. Incidental Custodial Collections

HHS reports custodial activities on the Consolidated Balance Sheets; however, HHS does not prepare a separate Statement of Custodial Activity, since custodial activities are incidental to its operations and the amounts collected are immaterial.

The majority of the custodial collections is funding ACF receives from the IRS for outlays to the states for child support. This funding represents delinquent child support payments withheld from federal tax refunds. In addition, ACF transfers to the General Fund the federal share of state collections that were collected on behalf of children in the Temporary Assistance for Needy Families program and Foster Care Programs.

In FY 2016, the Department had custodial collections of $2.9 billion of which $2.6 billion was related to ACF. The Department made disbursements of $2.9 billion of which $2.6 billion was related to ACF.

In FY 2015, the Department had custodial collections of $2.1 billion of which $1.9 billion was related to ACF. The Department made disbursements of $2.1 billion of which $1.9 billion was related to ACF.

Note 22. Reconciliation of Net Cost of Operations (Proprietary) to Budget (in Millions)

	2016	2015
Resources Used to Finance Activities:		
Budgetary Resources Obligated		
New Obligations and Upward Adjustments	$ 1,607,803	$ 1,477,481
Spending Authority from Offsetting Collections and Recoveries	(63,331)	(60,006)
Obligations Net of Offsetting Collections and Recoveries	1,544,472	1,417,475
Distributed Offsetting Receipts	(428,128)	(380,187)
Net Obligations	$ 1,116,344	$ 1,037,288
Other Resources		
Net Non-Budgetary Resources Used to Finance Activities	367	1,332
Total Resources Used to Finance Activities	$ 1,116,711	$ 1,038,620
Resources Used to Finance Items Not Part of the Net Cost of Operations:		
Change in Budgetary Resources Obligated for Goods, Services and Benefits Ordered but Not Yet Provided	$ 33,922	$ (10,625)
Resources That Fund Expenses Recognized in Prior Periods	12	43
Budgetary Offsetting Collections and Receipts That Do Not Affect Net Cost of Operations	10,092	9,965
Resources That Finance the Acquisition of Assets or Liquidations of Liabilities	694	2,092
Other Resources or Adjustments to Net Obligated Resources That Do Not Affect Net Cost of Operations	(2,511)	3,405
Total Resources Used to Finance Items Not Part of the Net Cost of Operations	42,209	4,880
Total Resources Used to Finance the Net Cost of Operations	$ 1,074,502	$ 1,033,740
Components of Net Cost of Operations That Will Not Require or Generate Resources in the Current Period		
Components Requiring or Generating Resources in Future Periods	$ (1,024)	$ (2,884)
Components Not Requiring or Generating Resources	1,294	(827)
Total Components of Net Cost of Operations That Will Not Require or Generate Resources in the Current Period	270	(3,711)
Net Cost of Operations	$ 1,074,772	$ 1,030,029

Note 23. Combined Schedule of Spending (in Millions)

The Combined Schedule of Spending presents an overview of how departments or agencies are spending (i.e., obligating) money. The Combined Schedule of Spending presents total budgetary resources, total new obligations, and upward adjustments for the reporting entity. The data used to populate this schedule are the same underlying data used to populate the Combined Statement of Budgetary Resources. Simplified terms are used to improve the public's understanding of the budgetary accounting terminology used in the Combined Statement of Budgetary Resources.

OMB makes available a searchable website, www.USAspending.gov[9], that provides information on federal awards of contracts and financial assistance awards (including grants) and is accessible to the public at no cost. When comparing www.USAspending.gov data to the Combined Schedule of Spending one must take into account that

[9] The notes to the financial statements include URL references to certain websites. The information contained on those websites is not part of the financial statement presentation.

the website has a fundamentally different purpose. There are differences due to object classes not reported to www.USAspending.gov that include but are not limited to personnel compensation, travel, utilities, and leases, intra-departmental and interagency spending, and various other categories of financial awards. In addition, the reporting entity between the financial statements and www.USAspending.gov differs for awards resulting from funding allocations between agencies, and/or HHS OpDivs. Also, recovery of prior year obligations are reported as deobligations on www.USAspending.gov but are not reported on the Combined Schedule of Spending. As a result, www.USAspending.gov data will differ from the Combined Schedule of Spending.

What Money is Available to Spend? This section presents resources that were available to spend, as reported in the Combined Statement of Budgetary Resources. Total Resources refers to Total Budgetary Resources as described in the Combined Statement of Budgetary Resources and represents amounts approved for spending by law. Amount Available but Not Agreed to be Spent represents amounts that HHS was allowed to spend but did not take action to spend by the end of the FY. Amount Not Available to be Spent represents amounts that HHS was not approved to spend during the current FY. Total Amounts Agreed to be Spent represents spending actions taken by HHS – including contracts, orders, grants, or other legally binding agreements of the federal government – to pay for goods or services. This line total agrees to the New Obligations and Upward Adjustments line in the Combined Statement of Budgetary Resources.

Who did the Money Go To? This section identifies the recipient of the money by federal and non-federal entities. Amounts in this section reflect amount agreed to be spent and agree to the New Obligations and Upward Adjustments line on the Statement of Budgetary Resources.

How was the Money Spent/Issued? This section presents services or items that were purchased, categorized by Treasury Symbol. Those Treasury Account Symbols that have a material impact on the Statement of Budgetary Resources are presented separately. Other Treasury Account Symbols, such as National Institute of Allergy and Infectious Diseases, Payments to States for Child Support Enforcement and Family Support Programs, Low Income Home Energy Assistance, National Heart, Lung, and Blood Institute, and Child Care Entitlement to States, are summarized under Other Agency Budgetary Accounts.

Combined Schedule of Spending
As of September 30, 2016 and 2015
(in Millions)

What Money is Available to Spend	FY 2016	FY 2015
Total Resources	$ 1,668,313	$ 1,543,105
Less Amount Available but Not Agreed to be Spent	17,280	23,828
Less Amount Not Available to be Spent	43,230	41,796
Total Amounts Agreed to be Spent	$ 1,607,803	$ 1,477,481
Who did the Money Go To		
Federal	$ 9,105	$ 8,142
Non-Federal	1,598,698	1,469,339
Total Amounts Agreed to be Spent	$ 1,607,803	$ 1,477,481

Combined Schedule of Spending

As of September 30, 2016 and 2015
(in Millions)

How was the Money Spent/Issued?	FY 2016	FY 2015
Medicaid	$ 398,217	$ 378,897
Grants, Subsidies, and Contributions	393,919	375,142
Supplies and Materials	4,172	3,637
Other Contractual Services	108	101
Other	18	17
Payments to Trust Funds	310,112	262,902
Grants, Subsidies, and Contributions	215,830	195,385
Financial Transfers	94,282	67,445
Other	-	72
Federal Supplementary Medical Insurance Trust Fund	306,562	281,640
Financial Assistance Direct Payments	300,768	276,841
Financial Transfers	5,668	4,755
Other Contractual Services	126	44
Federal Hospital Insurance Trust Fund	296,848	285,074
Financial Assistance Direct Payments	291,252	277,004
Financial Transfers	5,594	8,068
Other	2	2
Medicare Prescription Drug Account	92,804	80,583
Financial Assistance Direct Payments	92,039	80,429
Financial Transfers	765	154
Taxation on OASDI Benefits, HI	23,022	20,208
Grants, Subsidies, and Contributions	23,022	20,208
Temporary Assistance for Needy Families	16,722	16,717
Grants, Subsidies, and Contributions	16,649	16,657
Other	73	60
State Children's Health Insurance Fund	14,070	11,496
Grants, Subsidies, and Contributions	14,002	11,486
Other	68	10
Children and Families Services Programs	10,975	10,545
Grants, Subsidies, and Contributions	10,509	10,121
Other Contractual Services	291	262
Personnel Compensation and Benefits	151	143
Other	24	19
Payments for Foster Care and Permanency	7,858	7,387
Grants, Subsidies, and Contributions	7,822	7,360
Other	36	27
Transitional Reinsurance Program	7,846	8,249
Financial Assistance Direct Payments	7,842	8,249
Other	4	-
National Cancer Institute	5,392	5,386
Grants, Subsidies, and Contributions	3,300	3,609
Other Contractual Services	1,457	1,178
Personnel Compensation and Benefits	511	504
Other	124	95
Indian Health Services	5,250	5,702
Grants, Subsidies, and Contributions	2,339	2,834
Personnel Compensation and Benefits	1,361	1,332
Other Contractual Services	847	803
Other	703	733
Primary Health Care	5,041	4,700
Grants, Subsidies, and Contributions	4,733	4,449
Other Contractual Services	232	200
Other	76	51
Other Agency Budgetary Accounts	107,084	97,995
Grants, Subsidies, and Contributions	57,034	51,862
Other Contractual Services	23,789	23,811
Other	14,117	12,664
Financial Assistance Direct Payments	12,144	9,658
Total Amounts Agreed to be Spent	$ 1,607,803	$ 1,477,481

Note 24. Statement of Social Insurance (Unaudited)

The Statement of Social Insurance presents, for the 75-year projection period, the present values of the income and expenditures of the Hospital Insurance (HI) and Supplementary Medical Insurance (SMI) trust funds for both the open group and closed group of participants. The open group consists of all current and future participants (including those born during the projection period) who are now participating or are expected to eventually participate in the Medicare program. The closed group comprises only current participants—those who attain age 15 or older in the first year of the projection period.

Actuarial present values are computed under the intermediate set of assumptions specified in the *2016 Annual Report of the Medicare Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds*. These assumptions represent the Trustees' reasonable estimate of likely future economic, demographic, and healthcare-specific conditions. As with all of the assumptions underlying the Trustees' financial projections, the Medicare-specific assumptions are reviewed annually and updated based on the latest available data and analysis of trends. In addition, the assumptions and projection methodology are subject to periodic review by independent panels of expert actuaries and economists. The most recent review occurred with the 2010-2011 Technical Review Panel.

Actuarial present values are computed as of the year shown and over the 75-year projection period, beginning January 1 of that year. The Trustees' projections are based on the current Medicare laws, regulations, and policies in effect on June 22, 2016 and do not reflect any actual or anticipated changes subsequent to that date. The present values are calculated by discounting the future annual amounts of non-interest income and expenditures (including benefit payments and administrative expenses) at the projected average rates of interest credited to the HI trust fund. HI income includes the portion of FICA and SECA payroll taxes allocated to the HI trust fund, the portion of Federal income taxes paid on Social Security benefits that is allocated to the HI trust fund, premiums paid by, or on behalf of, aged uninsured beneficiaries, and receipts from fraud and abuse control activities. SMI income includes premiums paid by, or on behalf of, beneficiaries and transfers from the general fund of the Treasury. Fees related to brand-name prescription drugs, required by the *Affordable Care Act,* are included as income for Part B of SMI, and transfers from State governments are included as income for Part D of SMI. Since all major sources of income to the trust funds are reflected, the actuarial projections can be used to assess the financial condition of each trust fund.

Beginning with this year's projections, the Part A present values in the Statement of Social Insurance include the income and expenditures for the roughly 1 percent of beneficiaries who are 65 or over but are uninsured because they do not meet the normal insured status or related requirements to qualify for entitlement to Part A benefits. The reason that these beneficiaries were previously excluded is that their costs were separately funded either through general revenue appropriations or through premium payments, and accordingly the exclusion of such amounts did not materially affect the financial balance of Part A.

Actuarial present values of estimated future income (excluding interest) and estimated future expenditures are presented for three different groups of participants: (1) current participants who have not yet attained eligibility age; (2) current participants who have attained eligibility age; and (3) new entrants, those who are expected to become participants in the future. Current participants are the closed group of individuals who are at least age 15 at the start of the projection period and are expected to participate in the program as either taxpayers, beneficiaries, or both.

The Statement of Social Insurance sets forth, for each of these three groups, the projected actuarial present values of all future expenditures and of all future non-interest income for the next 75 years. The Statement of Social Insurance also presents the net present values of future net cash flows, which are calculated by subtracting the actuarial present value of estimated future expenditures from the actuarial present value of estimated future

income. The HI trust fund is expected to have an actuarial deficit indicating that, under these assumptions as to economic, demographic, and health care cost trends for the future, HI income is expected to fall short of expenditures over the next 75 years. Neither Part B nor Part D of SMI has similar deficits because each account is automatically in financial balance every year due to its statutory financing mechanism.

In addition to the actuarial present value of the estimated future excess of income (excluding interest) over expenditures for the open group of participants, the Statement of Social Insurance also sets forth the same calculation for the closed group of participants. The closed group consists of those who, in the starting year of the projection period, have attained retirement eligibility age or have attained ages 15 through 64. In order to calculate the actuarial net present value of the excess of estimated future income over estimated future expenditures for the closed group, the actuarial present value of estimated future expenditures for or on behalf of current participants is subtracted from the actuarial present value of estimated future income (excluding interest) for current participants.

Since its enactment in 1965, the Medicare program has experienced substantial variability in expenditure growth rates. These different rates of growth have reflected new developments in medical care, demographic factors affecting the relative number and average age of beneficiaries and covered workers, and numerous economic factors. The future cost of Medicare will also be affected by further changes in these inherently uncertain factors and by the application of future payment updates. Consequently, Medicare's actual cost over time, especially for periods as long as 75 years, cannot be predicted with certainty and could differ materially from the projections shown in the Statement of Social Insurance. Moreover, these differences could affect the long-term sustainability of this social insurance program.

To develop projections regarding the future financial status of the HI and SMI trust funds, various assumptions have to be made. As stated previously, the estimates presented here are based on the assumption that the trust funds will continue to operate under the law in effect on June 22, 2016. In addition, the estimates depend on many economic, demographic, and healthcare-specific assumptions, including changes in per beneficiary health care costs, wages, and the consumer price index (CPI); fertility rates; mortality rates; immigration rates; and interest rates. In most cases, these assumptions vary from year to year during the first 5 to 30 years before reaching their ultimate values for the remainder of the 75-year projection period. The assumed growth rates for per beneficiary health care costs vary throughout the projection period.

The following table includes the most significant underlying assumptions used in the projections of Medicare spending displayed in this section. The assumptions underlying the 2016 Statement of Social Insurance actuarial projections are drawn from the Social Security and Medicare Trustees Reports for 2016. Specific assumptions are made for each of the different types of service provided by the Medicare program (for example, hospital care and physician services). These assumptions include changes in the payment rates, utilization, and intensity of each type of service. The projected beneficiary cost increases summarized below reflect the overall impact of these more detailed assumptions. Similar detailed information for the prior years is publicly available on the CMS website at www.cms.hhs.gov/CFOReport.[10]

[10] The notes to the financial statements include URL references to certain websites. The information contained on those websites is not part of the financial statement presentation.

Table 1: Significant Assumptions and Summary Measures Used for the Statement of Social Insurance 2016

					Annual percentage change in:						
								Per beneficiary cost[8]			
									SMI		
	Fertility rate[1]	Net immigration[2]	Mortality rate[3]	Real-wage differential[4]	Wages[5]	CPI[6]	Real GDP[7]	HI	B	D	Real-interest rate[9]
2016	1.90	1,579,000	773.0	2.08	2.94	0.86	2.8	0.9	2.1	0.9	1.2
2020	2.00	1,508,000	742.8	1.68	4.28	2.60	2.8	3.9	5.6	6.7	1.9
2030	2.00	1,332,000	679.1	1.30	3.90	2.60	2.1	3.9	4.5	4.7	2.7
2040	2.00	1,284,000	624.5	1.22	3.82	2.60	2.2	4.7	4.0	4.7	2.7
2050	2.00	1,259,000	576.8	1.25	3.85	2.60	2.2	3.8	3.7	4.6	2.7
2060	2.00	1,244,000	534.8	1.21	3.81	2.60	2.1	3.6	3.6	4.5	2.7
2070	2.00	1,235,000	497.6	1.15	3.75	2.60	2.1	3.8	3.6	4.4	2.7
2080	2.00	1,230,000	464.6	1.14	3.74	2.60	2.1	3.8	3.6	4.4	2.7
2090	2.00	1,228,000	435.1	1.15	3.75	2.60	2.0	3.4	3.4	4.3	2.7

[1]Average number of children per woman.
[2]Includes legal immigration, net of emigration, as well as other, non-legal, immigration.
[3]The age-sex-adjusted death rate per 100,000 that would occur in the enumerated population as of April 1, 2010, if that population were to experience the death rates by age and sex observed in, or assumed for, the selected year.
[4]Difference between percentage increases in wages and the CPI.
[5]Average annual wage in covered employment.
[6]Consumer price index represents a measure of the average change in prices over time in a fixed group of goods and services.
[7]The total dollar value of all goods and services produced in the United States, adjusted to remove the impact of assumed inflation growth.
[8]These increases reflect the overall impact of more detailed assumptions that are made for each of the different types of service provided by the Medicare program (for example, hospital care, physician services, and pharmaceutical costs). These assumptions include changes in the payment rates, utilization, and intensity of each type of service.
[9]Average rate of interest earned on new trust fund securities, above and beyond rate of inflation.

The projections presented in the SOSI are based on various economic and demographic assumptions. The values for each of these assumptions move from recently experienced levels or trends toward long-range ultimate values. Table 2 summarizes these ultimate values assumed for the current year and the prior 4 years, based on the intermediate assumptions of the respective Medicare Trustees Reports.

Table 2: Significant Ultimate Assumptions Used for the Statement of Social Insurance FY 2016-2012

					Annual percentage change in:						
								Per beneficiary cost[8]			
	Fertility rate[1]	Net immigration[2]	Mortality rate[3]	Real-wage differential[4]	Wages[5]	CPI[6]	Real GDP[7]	HI	SMI B	SMI D	Real-interest rate[9]
FY 2016	2.0	1,228,000	435.1	1.15	3.75	2.60	2.0	3.4	3.4	4.3	2.7
FY 2015	2.0	1,060,000	458.4	1.13	3.83	2.70	2.1	3.8	4.1	4.4	2.9
FY 2014	2.0	1,055,000	419.8	1.13	3.93	2.80	2.1	3.8	3.8	4.5	2.9
FY 2013	2.0	1,030,000	446.0	1.12	3.92	2.80	2.0	3.7	3.8	4.5	2.9
FY 2012	2.0	1,030,000	443.2	1.2	4.0	2.8	2.1	3.3	3.7	4.4	2.9

[1]Average number of children per woman. The ultimate fertility rate is assumed to be reached in the 12th year of the projection period.
[2]Includes legal immigration, net of emigration, as well as other, non-legal, immigration. The ultimate level of net legal immigration is 795,000 persons per year, and the assumption for annual net other immigration varies throughout the projection period. Therefore, the assumption presented is the value assumed in the year 2080 for FYs 2012-2015 and is the value assumed in the year 2090 for FY 2016.
[3]The age-sex-adjusted death rate per 100,000 that would occur in the enumerated population as of April 1, 2010, if that population were to experience the death rates by age and sex observed in, or assumed for, the selected year. Since the annual rate declines gradually during the entire period, no ultimate rate is achieved. The assumption presented is the value assumed in the year 2080 for FYs 2012-2015 and is the value assumed in the year 2090 for FY 2016.
[4]Difference between percentage increases in wages and the CPI. The value presented is the average of annual real-wage differentials for the last 65 years of the 75-year projection period, is consistent with the annual differentials shown in Table 1, and is displayed to two decimal places. The assumption varies slightly throughout the projection period. Therefore, the assumption presented is the value assumed in the year 2080 for FYs 2012-2015 and is the value assumed in the year 2090 for FY 2016.
[5]Average annual wage in covered employment. The value presented is the average annual percentage change from the 10th year of the 75-year projection period to the 75th year and is displayed to two decimal places. The assumption varies slightly throughout the projection period. Therefore, the assumption presented is the value assumed in the year 2080 for FYs 2012-2015 and is the value assumed in the year 2090 for FY 2016.
[6]Consumer price index represents a measure of the average change in prices over time in a fixed group of goods and services. The ultimate assumption is reached within the first 10 years of the projection period.
[7]The total dollar value of all goods and services produced in the United States, adjusted to remove the impact of assumed inflation growth. Since the annual rate declines gradually during the entire period, no ultimate rate is achieved. The assumption presented is the value assumed in the year 2080 for FYs 2012-2015 and is the value assumed in the year 2090 for FY 2016.
[8]These increases reflect the overall impact of more detailed assumptions that are made for each of the different types of service provided by the Medicare program (for example, hospital care, physician services, and pharmaceutical costs). These assumptions include changes in the payment rates, utilization, and intensity of each type of service. Since the annual rate of growth declines gradually during the entire period, no ultimate rate is achieved. The assumption presented is the value assumed in the year 2080 for FYs 2012-2015 and is the value assumed in the year 2090 for FY 2016.
[9]Average rate of interest earned on new trust fund securities, above and beyond rate of inflation. The ultimate assumption is reached soon after the 10th year of each projection period.

Note 25. Alternative Statement of Social Insurance Projections (Unaudited)

The Medicare Board of Trustees, in its annual report to Congress, references an alternative scenario to illustrate, when possible, the potential understatement of Medicare costs and projection results.

The Trustees assume that the various cost-reduction measures—the most important of which are the reductions in the annual payment rate updates for most categories of Medicare providers by the growth in economy-wide private nonfarm business multifactor productivity and the specified physician updates put in place by MACRA—will occur as current law requires. The Board of Trustees believes that this outcome is achievable if health care providers are able to realize productivity improvements at a faster rate than experienced historically. For those providers affected by the productivity adjustments and the specified updates to physician payments, sustaining the price reductions will be challenging, as the best available evidence indicates that most providers cannot improve their productivity to this degree for a prolonged period given the labor-intensive nature of these services and that physician costs will grow at a faster rate than the specified updates. As a result, actual Medicare expenditures are highly uncertain for reasons apart from the inherent difficulty in projecting health care cost growth over time.

The specified rate updates could be an issue in years when levels of inflation are high and would be problematic when the cumulative gap between the price updates and physician costs becomes large. The gap will continue to widen throughout the projection, and the Trustees anticipate that physician payment rates under current law will

be lower than they would have been under the sustainable growth rate (SGR) formula by 2048. Absent a change in the delivery system or level of update by subsequent legislation, the Trustees expect access to Medicare-participating physicians to become a significant issue in the long term under current law. Overriding the productivity adjustments and specified physician updates, as lawmakers repeatedly did in the case of physician payment rates, would lead to substantially higher costs for Medicare in the long range than those projected in this report.

To help illustrate and quantify the potential magnitude of the cost understatement, the Trustees asked the Office of the Actuary at CMS to prepare an illustrative Medicare trust fund projection under a hypothetical alternative that assumes that, starting in 2020, the economy-wide productivity adjustments gradually phase down to 0.4 percent and, starting in 2025, physician payments transition from a payment update of 0.0 percent to an increase of 2.2 percent. In addition, the illustrative alternative assumes that the 5 percent bonuses paid to physicians in alternative payment models (APMs) would continue and that the Independent Payment Advisory Board (IPAB) requirements would not be implemented.[11] This alternative was developed for illustrative purposes only; the calculations have not been audited; no endorsement of the policies underlying the illustrative alternative by the Trustees, CMS, or the Office of the Actuary should be inferred; and the examples do not attempt to portray likely or recommended future outcomes. Thus, the illustrations are useful only as general indicators of the substantial impacts that could result from future legislation affecting the productivity adjustments and physician updates under Medicare and of the broad range of uncertainty associated with such impacts.

The table below contains a comparison of the Medicare 75-year present values of estimated future income and estimated future expenditures under current law with those under the illustrative alternative scenario.

Medicare Present Values

(in Billions)

	Current law (Unaudited)	Alternative scenario[1, 2] (Unaudited)
Income		
Part A	$20,701	$20,874
Part B	27,484	34,465
Part D	12,213	12,411
Expenditures		
Part A	24,523	30,598
Part B	27,484	34,465
Part D	12,213	12,411
Income less expenditures		
Part A	(3,822)	(9,723)
Part B	-	-
Part D	-	-

[1]These amounts are not presented in the 2016 Trustees Report.
[2]At the request of the Trustees, the Office of the Actuary at CMS has prepared an illustrative set of Medicare trust fund projections that differs from current law. No endorsement of the illustrative alternative by the Trustees, CMS, or the Office of the Actuary should be inferred.

The difference between the current-law and illustrative alternative projections is substantial for Parts A and B. All Part A fee-for-service providers and roughly half of Part B fee-for-service providers are affected by the productivity adjustments, so the current-law projections reflect an estimated 1.1 percent reduction in annual cost growth each

[11]The illustrative alternative projections included changes to the productivity adjustments starting with the 2010 annual report, following enactment of the Affordable Care Act. The assumption regarding physician payments is being used because the SGR was replaced in 2015.

year for these providers. If the productivity adjustments were gradually phased out, the physician updates transitioned to the Medicare Economic Index update of 2.2 percent, the 5 percent bonuses paid to physicians in APMs did not expire, and the IPAB requirements were not implemented, as illustrated under the alternative scenario, the estimated present values of Part A and Part B expenditures would each be higher than the current-law projections by roughly 25 percent. As indicated above, the present value of Part A income is basically unaffected under the alternative scenario, and the present value of Part B income is also 25 percent higher under the illustrative alternative scenario, since income is set each year to mirror expenditures.

The Part D values are similar under each projection because the services are not affected by the productivity adjustments or the physician updates. The very minor effect is the result of the removal of the IPAB impact and a slight change in the discount rates that are used to calculate the present values.

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

Note 26. Statement of Changes in Social Insurance Amounts (Unaudited)

The Statement of Changes in Social Insurance Amounts reconciles the change (between the current valuation and the prior valuation) in the (1) present value of estimated future income (excluding interest) for current and future participants; (2) present value of estimated future expenditures for current and future participants; (3) present value of estimated future noninterest income less estimated future expenditures for current and future participants (the open-group measure) over the next 75 years; (4) assets of the combined Medicare Trust Funds; and (5) present value of estimated future non-interest income less estimated future expenditures for current and future participants over the next 75 years plus the assets of the combined Medicare Trust Funds. The Statement of Changes in Social Insurance Amounts shows the reconciliation from the period beginning on January 1, 2015 to the period beginning on January 1, 2016, and the reconciliation from the period beginning on January 1, 2014 to the period beginning on January 1, 2015. The reconciliation identifies several components of the change that are significant and provides reasons for the changes.

Because of the financing mechanism for Parts B and D of Medicare, any change to the estimated future expenditures has the same effect on estimated total future income, and vice versa. Therefore, any change has no impact on the estimated future net cash flow. In order to enhance the presentation, the changes in the present values of estimated future income and estimated future expenditures are presented separately.

The five changes considered in the Statement of Changes in Social Insurance Amounts are, in order:

- change in the valuation period,
- change in projection base,
- changes in the demographic assumptions,
- changes in economic and health care assumptions, and
- changes in law.

All estimates in the Statement of Changes in Social Insurance Amounts represent values that are incremental to the prior change. As an example, the present values shown for demographic assumptions represent the additional effect that these assumptions have, once the effects from the change in the valuation period and projection base have been considered. In general, an increase in the present value of net cash flows represents a positive change

(improving financing), while a decrease in the present value of net cash flows represents a negative change (worsening financing).

Assumptions Used for the Statement of Changes in Social Insurance Amounts

The present values included in the Statement of Changes in Social Insurance Amounts are for the current and prior year and are based on various economic and demographic assumptions used for the intermediate assumptions in the Trustees Reports for those years. Table 1 of Note 24 summarizes these assumptions for the current year.

Period beginning on January 1, 2015 and ending January 1, 2016
Present values as of January 1, 2015 are calculated using interest rates from the intermediate assumptions of the 2015 Trustees Report. All other present values in this part of the Statement are calculated as a present value as of January 1, 2016. Estimates of the present value of changes in social insurance amounts due to changing the valuation period, projection base, demographic assumptions, and law are presented using the interest rates under the intermediate assumptions of the 2015 Trustees Report. Since interest rates are an economic estimate and all estimates in the table are incremental to the prior change, the estimates of the present values of changes in economic and health care assumptions are calculated using the interest rates under the intermediate assumptions of the 2016 Trustees Report.

Period beginning on January 1, 2014 and ending January 1, 2015
Present values as of January 1, 2014 are calculated using interest rates from the intermediate assumptions of the 2014 Trustees Report. All other present values in this part of the Statement are calculated as a present value as of January 1, 2015. Estimates of the present value of changes in social insurance amounts due to changing the valuation period, projection base, demographic assumptions, and law are presented using the interest rates under the intermediate assumptions of the 2014 Trustees Report. Since interest rates are an economic estimate and all estimates in the table are incremental to the prior change, the estimates of the present values of changes in economic and health care assumptions are calculated using the interest rates under the intermediate assumptions of the 2015 Trustees Report.

Change in the Valuation Period

From the period beginning on January 1, 2015 to the period beginning on January 1, 2016
The effect on the 75-year present values of changing the valuation period from the prior valuation period (2015-89) to the current valuation period (2016-90) is measured by using the assumptions for the prior valuation period and extending them, in the absence of any other changes, to cover the current valuation period. Changing the valuation period removes a small negative net cash flow for 2015, replaces it with a much larger negative net cash flow for 2090, and measures the present values as of January 1, 2016, one year later. Thus, the present value of estimated future net cash flow (including or excluding the combined Medicare Trust Fund assets at the start of the period) decreased (became more negative) when the 75-year valuation period changed from 2015-89 to 2016-90. In addition, the effect on the level of assets in the combined Medicare Trust Funds of changing the valuation period is measured by assuming all values projected in the prior valuation for the year 2015 are realized. The change in valuation period slightly increased the starting level of assets in the combined Medicare Trust Funds.

From the period beginning on January 1, 2014 to the period beginning on January 1, 2015
The effect on the 75-year present values of changing the valuation period from the prior valuation period (2014-88) to the current valuation period (2015-89) is measured by using the assumptions for the prior valuation period and applying them, in the absence of any other changes, to the current valuation period. Changing the valuation period removes a small negative net cash flow for 2014 and replaces it with a much larger negative net cash flow for 2089. The present value of estimated future net cash flow (including or excluding the combined Medicare

Trust Fund assets at the start of the period) was therefore decreased (made more negative) when the 75-year valuation period changed from 2014-88 to 2015-89. In addition, the effect on the level of assets in the combined Medicare Trust Funds of changing the valuation period is measured by assuming all values projected in the prior valuation for the year 2014 are realized. The change in valuation period decreased the level of assets in the combined Medicare Trust Funds.

Change in Projection Base

From the period beginning on January 1, 2015 to the period beginning on January 1, 2016
Actual income and expenditures in 2015 were different than what was anticipated when the 2015 Trustees Report projections were prepared. Part A income and expenditures were higher than anticipated, based on actual experience. Part B total income and expenditures were lower than estimated based on actual experience. For Part D, actual income and expenditures were both higher than prior estimates. The net impact of the Part A, B, and D projection base changes is a decrease in the estimated future net cash flow. Actual experience of the Medicare Trust Funds between January 1, 2015 and January 1, 2016 is incorporated in the current valuation and is slightly less than projected in the prior valuation.

From the period beginning on January 1, 2014 to the period beginning on January 1, 2015
Actual income and expenditures in 2014 were different than what was anticipated when the 2014 Trustees Report projections were prepared. Part A income was very slightly lower and expenditures were very slightly higher than anticipated, based on actual experience. Part B total income and expenditures were also higher than estimated based on actual experience. For Part D, actual income and expenditures were both higher than prior estimates. The net impact of the Part A, B, and D projection base changes is a decrease in the estimated future net cash flow. Actual experience of the Medicare Trust Funds between January 1, 2014 and January 1, 2015 is incorporated in the current valuation and is slightly more than projected in the prior valuation.

Changes in the Demographic Assumptions

From the period beginning on January 1, 2015 to the period beginning on January 1, 2016
The demographic assumptions used in the Medicare projections are the same as those used for the Old-Age, Survivors and Disability Insurance (OASDI) and are prepared by the Office of the Chief Actuary at the Social Security Administration (SSA).

The ultimate demographic assumptions for the current valuation (beginning on January 1, 2016), with the exception of a small change in marriage rates, are the same as those for the prior valuation. However, the starting demographic values and the way these values transition to the ultimate assumptions were changed.

- Final birth rate data for 2013 and 2014 indicated lower birth rates than were expected in the prior valuation. The data also show an increase in birth rates starting in 2014, one year later than assumed in the prior valuation.
- Incorporating mortality data obtained from the National Center for Health Statistics at ages under 65 for 2012 and 2013 and from Medicare experience at ages 65 and older for 2013 resulted in slightly higher death rates than were projected in the prior valuation.
- Assumed ultimate marriage rates were decreased somewhat to reflect a continuation of recent trends.
- More recent legal and other-than-legal immigration data and historical population data were included.

There were two changes in demographic methodology:

- The transition from recent mortality rates to the ultimate rates starts sooner, immediately after the year of final data. The approach used for the prior valuation extended the trend of the last 10 years through the valuation year for the report and only thereafter started the transition to assumed ultimate rates of decline.
- Historical non-immigrant population counts were revised to match recent totals provided by the Department of Homeland Security. In addition, emigration rates for the never-authorized and visa-overstayer populations were recalibrated to reflect a longer historical period and to be less influenced by the high emigration rates experienced during the recent recession. Finally, the method for projecting emigration of the never-authorized population was altered to reflect lower rates of emigration for those who have resided here longer.

These changes slightly lowered overall Medicare enrollment for the current valuation period and resulted in an increase in the estimated future net cash flow. The present value of estimated expenditures is lower for all parts of Medicare; and the present value of estimated income is also lower for Parts B and D but very slightly higher for Part A.

From the period beginning on January 1, 2014 to the period beginning on January 1, 2015
The demographic assumptions used in the Medicare projections are the same as those used for the OASDI and are prepared by the Office of the Chief Actuary at the SSA.

The ultimate demographic assumptions for the current valuation (beginning on January 1, 2015), with the exception of changes made due to the execution on immigration, are the same as those for the prior valuation. However, the starting demographic values and the way these values transition to the ultimate assumptions were changed.

- Final birth rate data for 2012 and preliminary data for 2013 indicated lower birth rates than were expected in the prior valuation. In this year's report, the total fertility rate reaches the ultimate in 2027, which is eleven years earlier than in last year's projections.
- Incorporating mortality data obtained from Medicare experience at ages 65 and older for 2012 resulted in slightly higher death rates for 2012 and a slightly slower rate of decline in mortality over the next 25 years than were projected last year. Incorporating mortality data obtained from the National Centers for Health Statistics at ages under 65 for 2011 resulted in slightly lower death rates for 2011 and a slightly faster rate of decline in mortality over the next 25 years than were projected last year.
- Historical legal immigration was revised to include single age data (rather than 5-year age groups); including more recent marriage, legal immigration, and other-than-legal immigration data; historical data since 2001 was revised to be more consistent with the most recent estimates from the Census Bureau.

These changes slightly lowered overall Medicare enrollment for the current valuation period resulting in a decrease in the estimated future net cash flow, and had a very minor impact on the present value of estimated income and estimated expenditures for Part A, Part B, and Part D.

Changes in Economic and Health Care Assumptions

For the period beginning on January 1, 2015 to the period beginning on January 1, 2016
The economic assumptions used in the Medicare projections are the same as those used for the OASDI and are prepared by the Office of the Chief Actuary at SSA.

For the current valuation (beginning on January 1, 2016), there were three changes to the ultimate economic assumptions.

- The ultimate rate of price inflation (CPI-W) was lowered by 0.1 percentage point, to 2.6 percent from 2.7 percent for the previous valuation.
- The ultimate average real wage differential is assumed to be 1.20 percent in the current valuation period, compared to 1.17 percent in the previous valuation period.
- The ultimate real interest rate was lowered by 0.2 percentage point, to 2.7 percent from 2.9 percent for the previous valuation period.

While very low inflation in recent years is reflective of U.S. and international supply and demand factors that have been affected by the global recession, the average rate of change in the CPI-W over the last two complete business cycles (from 1989 to 2007) is 2.63 percent.

The higher real wage differential assumption is based on new projections by the CMS of slower growth in employer-sponsored group health insurance premiums. Because these premiums are not subject to the payroll tax, slower growth in these premiums means that a greater share of employee compensation will be in the form of wages that are subject to the payroll tax.

Real interest rates have been low since 2000, and particularly low since the start of the recent recession. An ongoing and much-debated question among experts is how much of this change is cyclic or a temporary response to extraordinary events, versus a fundamental permanent change. The Trustees believe that lowering the long-term ultimate real interest rate somewhat is appropriate at this time. The long-range present values are very sensitive to the ultimate interest rate assumption because they are used as the discount factor. The reduction in the ultimate interest rate assumption from 2.9 percent to 2.7 percent increases each of the present values by roughly 15-16 percent.

Otherwise, the ultimate economic assumptions for the current valuation are the same as those for the prior valuation. However, the starting economic values and the way these values transition to the ultimate assumptions were changed.

- A reduction in the ultimate level of actual and potential gross domestic product (GDP) of about 1.0 percent is assumed. Thus, by the end of the short-range period (2025) and for all years thereafter, projected GDP in 2009 dollars is about 1.8 percent below the level in last year's report.

The health care assumptions are specific to the Medicare projections. The following health care assumptions were changed in the current valuation.

- Utilization rate assumptions for inpatient hospital services were increased.
- The number of beneficiaries enrolled in Medicare Advantage plans and their relative costs are slightly different from last year’s assumptions.
- Lower productivity increases through 2021, resulting in higher provider payment updates.
- Greater reductions in expenditures attributable to the Independent Payment Advisory Board.
- Inclusion of the income and expenditures for aged non-insured beneficiaries in the Part A long-range analysis.
- Higher projected drug cost trend, particularly for certain high-cost specialty drugs.

The net impact of these changes resulted in a decrease in the estimated future net cash flow for total Medicare. For Part A, these changes resulted in an increase to the present value of estimated future expenditures and

income, with an overall decrease in the estimated future net cash flow. For Part B and Part D, these changes increased the present value of estimated future expenditures (and also income).

For the period beginning on January 1, 2014 to the period beginning on January 1, 2015
The economic assumptions used in the Medicare projections are the same as those used for the OASDI and are prepared by the Office of the Chief Actuary at the SSA.

For the current valuation (beginning on January 1, 2015), there was one change to the ultimate economic assumptions.

- The ultimate real-wage differential is assumed to be 1.17 percent in the current valuation period, compared to 1.13 percent in the previous valuation period.

The higher real wage differential assumption is more consistent with recent experience and expectations of slower growth in employer-sponsored group health insurance premiums from the Office of the Actuary at the CMS. Because these premiums are not subject to the payroll tax, slower growth in these premiums means that a greater share of employee compensation will be in the form of wages that are subject to the payroll tax.

Otherwise, the ultimate economic assumptions for the current valuation are the same as those for the prior valuation. However, the starting economic values and the way these values transition to the ultimate assumptions were changed.

- The ratio of average taxable earnings to the average wage averages about 0.6 percentage point higher during the long-range period, compared to the previous valuation period.
- The projected suspense file contains fewer wage items, which is consistent with having fewer workers (many of whom are undocumented immigrants) with wages on the suspense file and more of these workers with earnings in the underground economy, compared to the previous valuation.

The health care assumptions are specific to the Medicare projections. The following health care assumptions were changed in the current valuation.

- Lower long-range growth rate assumptions.
- Utilization rate assumptions for inpatient hospital services were decreased.
- Lower assumed hospice spending.
- Higher assumed enrollment in Medicare Advantage plans where benefits are more costly.
- Introduction of high-cost specialty drugs used to treat hepatitis C.

The net impact of these changes resulted in an increase in the estimated future net cash flow for total Medicare. For Part A, these changes resulted in an increase to the present value of estimated future expenditures and income, with an overall increase in the estimated future net cash flow. For Part B and Part D, these changes decreased the present value of estimated future expenditures (and also income).

Changes in Law

For the period beginning on January 1, 2015 to the period beginning on January 1, 2016

Most of the provisions enacted as part of Medicare legislation since the prior valuation date had little or no impact on the program. The following provisions did have a financial impact on the present value of the 75-year estimated future income, expenditures, and net cash flow.

- The *Trade Preference Extension Act of 2015* requires Medicare coverage for renal dialysis services provided by outpatient renal dialysis facilities to individuals with acute kidney injury, effective January 1, 2017.
- The *Bipartisan Budget Act of 2015* (BBA) included provisions that affect the HI and SMI programs.
  - The BBA required that the 2016 actuarial rate for enrollees aged 65 and older be determined as if the hold-harmless provision did not apply, thereby lowering the standard Part B premium rate from what it otherwise would have been. The premium revenue that was lost by using the resulting lower premium (excluding the forgone income-related premium revenue) was to be replaced by a transfer of general revenue from the Treasury, which will be repaid over time to the general fund. Starting in 2016, in order to repay the balance due (which is to include the transfer amount and the forgone income-related premium revenue), the monthly Part B premium otherwise determined is to be increased by $3.00. These repayment amounts are to be added to the Part B premium otherwise determined each year and paid back to the general fund of the Treasury. This $3.00 increase will not be matched by government contributions. These repayment amounts are to continue until the total amount collected is equal to the beginning balance due. (In the final year of the repayment, the additional amounts may be modified to avoid an overpayment). The repayment amounts (excluding those for high-income enrollees) are subject to the hold-harmless provision. The BBA also stipulated that if the Social Security cost-of-living adjustment (COLA) was 0 percent in 2017, then an additional transfer (and $3 repayment amount) would have again applied. However, the 2017 COLA of 0.3 percent was released on October 18, 2016.
  - Most outpatient hospital services provided on or after January 1, 2017 by new off-campus hospital provider-based outpatient departments (that is, those established on or after the BBA date of enactment of November 2, 2015 and located more than 250 yards from the campus) are excluded from the outpatient hospital prospective payment system, and are instead to be reimbursed under the applicable Part B payment system.
  - The sequestration process that is in place should Congress fail to address the budget deficit by certain deadlines is extended by one year, through FY 2025. In addition, Medicare benefit payments for services provided under periods of sequestration incur a payment reduction limited to 2 percent, so that the former differential payment reduction limits imposed for fiscal years 2023 and 2024 are replaced with 2 percent limits. Finally, the 2 percent limit is raised to 4.0 percent for the first six months of FY 2025 and reduced to 0.0 percent for the last six months of FY 2025.
- The *Consolidated Appropriations Act of 2016* included provisions that affect the HI and SMI programs.
  - The payment calculation associated with inpatient hospital operating costs for Puerto Rico hospital discharges on or after January 1, 2016 is to be based on 0 percent of the applicable Puerto Rico percentage and 100 percent of the applicable Federal percentage. (In addition, CMS announced that both the FY 2016 Inpatient Prospective Payment System Pricer and the Long-Term Care Hospital Pricer, which are used to determine all inpatient hospital payment rates and certain long-term care hospital payment rates, respectively, for providers nationwide, are to incorporate the Puerto Rico inpatient hospital payment modification. These conforming changes are applicable to inpatient hospital discharges and long-term care hospital discharges on or after January 1, 2016.)

- Puerto Rico hospitals are eligible to receive incentive payments under the Medicare Electronic Health Records Incentive Program, effective January 1, 2016.
- Effective January 1, 2017, separate Medicare payment is authorized to home health agencies when they use cost-effective disposable alternatives to negative pressure wound therapy equipment.
- To incentivize the transition from traditional x-ray imaging to digital radiography, Part B payment for the technical component of film x-rays, under the hospital outpatient prospective payment system and under the physician fee schedule, is reduced by 20 percent beginning in 2017. In addition, payment for the technical component of x-rays taken using computed radiography technology is reduced by 7 percent during 2018 through 2022 and by 10 percent beginning in 2023. Also, the discount in payment for the professional component of multiple imaging services furnished on or after January 1, 2017 is reduced from 25 percent to 5 percent, and the reduction is taken in a non-budget neutral manner.
- A one-year moratorium for calendar year 2017 is placed on the annual fee to be paid by health insurance providers. This fee, which was established by the *Affordable Care Act*, is imposed on certain large health insurance providers, including those furnishing coverage under Medicare Advantage (Part C) and Medicare Part D. (Since Medicare Advantage is paid for by the HI trust fund and the Part B account of the SMI trust fund, this provision affects all parts of Medicare.)

Overall these provisions resulted in a slight increase in the estimated future net cash flow for total Medicare. For Part A, these changes resulted in a slight decrease to the present value of estimated future expenditures, with an overall increase in the estimated future net cash flow. For Part B, these changes decreased the present value of estimated future expenditures (and also income). For Part D, the above-mentioned changes also resulted in a lower present value of estimated future expenditures (and also income) but only very slightly.

For the period beginning on January 1, 2014 to the period beginning on January 1, 2015

Although Medicare legislation was enacted since the prior valuation date, some of the provisions have a negligible impact on the present value of the 75-year estimated future income, expenditures, and net cash flow. The *Veteran's Access, Choice, and Accountability Act of 2014* established a temporary program that allows eligible veterans to receive hospital care and medical services from eligible providers outside of the Department of Veterans Affairs (VA) system, rather than waiting for a VA appointment or traveling to a VA facility. The *Improving Medicare Post-Acute Care Transformation Act of 2014* standardized the collection of data for post-acute providers and aligned the inflation of the hospice aggregate cap with that of hospice reimbursement. The *Tax Increase Prevention Act of 2014* accelerated the start date for the payment adjustment of misvalued codes under the physician fee schedule from 2017 to 2016, and delayed inclusion of oral-only end-stage renal disease (ESRD)-related drugs into the ESRD bundled payment system from 2024 to 2025. MACRA included many provisions affecting Medicare spending, including the repeal of the SGR formula for determining payments under the physician fee schedule, the continuation of extensions for several provisions from prior legislation, a reduction in payment updates for most post-acute providers in 2018, the replacement of a 3.2 percent reduction to inpatient hospitals in 2018 with a 0.5 percent reduction in 2018 through 2023, and a revision to the income thresholds for determining the income-related monthly adjustment amounts under Part B and Part D.

Overall these provisions resulted in an increase in the estimated future net cash flow for total Medicare. For Part A, these changes resulted in a decrease to the present value of estimated future expenditures, with an overall increase in the estimated future net cash flow. For Part B, these changes increased the present value of estimated future expenditures (and also income). For Part D, the above-mentioned changes decreased the present value of estimated future expenditures (and also income) only very slightly.

Potential Impact on the Social Insurance Statements of the June 23, 2016 Supreme Court Judgment on the 2014 DACA and DAPA Executive Actions

In November 2014, Presidential executive actions expanded the Deferred Action for Childhood Arrivals program (DACA) and established the Deferred Action for Parents of Americans program (DAPA). On June 23, 2016, the Supreme Court was divided (tied 4-4) on the ruling of the legality of the expanded DACA and DAPA programs, so the lower court's ruling, temporarily blocking these programs from being implemented, was upheld. As a result, the expanded DACA and DAPA programs will be either delayed or never implemented. The SSA Office of the Chief Actuary has concluded that the Supreme Court's judgment has an effect on the actuarial methods and assumptions used in developing the estimates presented in the Statement of Social Insurance and the Statement of Changes in Social Insurance Amounts. Whether the expanded DACA and DAPA programs are delayed or never implemented, we expect the judgment will not have a material impact on the present value of future noninterest income less future costs for current and future participants (open group measure) presented in the Statements of Social Insurance and Statement of Changes in Social Insurance Amounts.

REQUIRED SUPPLEMENTARY STEWARDSHIP INFORMATION

Investment in Human Capital (in Millions)

For the Year Ended September 30, 2016

Responsibility Segment Program	2016	2015	2014	2013	2012
National Institutes of Health					
Research Training and Career Development	$ 1,745	$ 1,631	$ 1,541	$ 1,621	$ 1,858
Health Resources and Services Administration					
Scholarships Loan Repayments and Loans	935	828	660	766	705
Other HRSA Training Investments	90	-	-	-	-
Other Investments in Human Capital					
Other	17	14	8	6	6
Totals	$ 2,787	$ 2,473	$ 2,209	$ 2,393	$ 2,569

Investments in Human Capital are expenses incurred by federal education and training programs for the public, intended to maintain or increase national productive capacity. The following OpDivs conduct education and training programs under this category:

National Institutes of Health

The NIH Research Training and Career Development Programs address the need for trained personnel to conduct medical research. The primary goal of the support that NIH provides for research training and career development is to produce new, highly trained investigators who are likely to perform research that will benefit the nation's health. NIH's major research training and career development programs include institutional research training grants for graduate students and post-doctoral scholars, individual pre- and post-doctoral fellowships, individual and institutional research career development awards for advanced post-doctorates and early-stage faculty, loan repayment programs, and research education awards that promote research experiences, curriculum development, and other related activities. These programs are administered by NIH institutes and centers with awarding authority, and are key to NIH's ability to maintain the momentum of recent scientific progress and international leadership in medical research.

Health Resources and Services Administration

HRSA's Bureau of Health Workforce (BHW) improves the health of the nation's underserved communities and vulnerable populations by developing, implementing, evaluating, and refining programs that strengthen the nation's health care workforce. BHW programs support a diverse, culturally competent workforce by addressing components including education, training, and financial support for students, faculty, practitioners, and supporting institutions. These efforts support development of a skilled health workforce serving in areas of the nation with the greatest need. In FY 2016 and FY 2015, BHW awarded more than $1.0 billion to organizations and individuals. These funds were distributed among BHW's scholarships, loans, loan repayment programs, health professions training programs, and programs supporting graduate medical education.

In FY 2016 HRSA gave Maternal and Child Health (MCH) Workforce Development grants to support lifelong learning, intended to encourage high school and college students to enter MCH professions and graduate training programs, to educate the next generation of MCH leaders, and to encourage continuing education for practicing MCH professionals. Additionally, HRSA gave human immunodeficiency virus (HIV) acquired immunodeficiency

syndrome grants to provide support to the Education and Training Center Program that conducts targeted, multidisciplinary education and training programs for health care providers treating people living with HIV.

Other Investments in Human Capital

Administered by ACL, Projects of National Significance grants and contracts are awarded to public and private non-profit institutions to enhance the independence, productivity, integration, and inclusion into the community of people with developmental disabilities. These monies also support the development of national and state policy to serve this community. ACL also presides over the Administration for Intellectual and Developmental Disabilities program. As of September 30, 2016, 24 grants (totaling $7.5 million) and 8 contracts (totaling $2.3 million) have been awarded for FY 2016. This program works to ensure that individuals with developmental disabilities and their families are able to fully participate in and contribute to all aspects of community life.

In addition, AHRQ provides an array of pre-doctoral and postdoctoral educational and career development grants and opportunities in health services research training. Research training and career development activities are administered by the Division of Research Education in the Office of Extramural Research, Education, and Priority Populations.

Investment in Research and Development (in Millions)

For the Year Ended September 30, 2016

Responsibility Segments	Basic	Applied	Develop-mental	2016 Total	2015	2014	2013	2012	Grand Total
AHRQ	$ -	$ 213	$ -	$ 213	$ 167	$ 250	$ 372	$ 401	$ 1,403
CDC	88	388	26	502	490	394	457	408	2,251
FDA	163	-	7	170	129	103	94	80	576
NIH	16,955	11,303	-	28,258	28,093	27,719	29,328	30,681	144,286
Other	2	30	-	32	26	3	1	2	64
Totals	$ 17,208	$ 11,934	$ 33	$ 29,175	$ 28,905	$ 28,469	$ 30,252	$ 31,572	$ 148,580

The research and development programs in HHS include the following:

Agency for Healthcare Research and Quality

AHRQ is the leading federal agency charged with improving the safety and quality of America's health care system. AHRQ develops knowledge, tools, and data needed to improve the health care system and help Americans, health care professionals, and policymakers make informed health decisions. AHRQ supports health services research that will improve the quality of health care and promote evidence based decision making.

Centers for Disease Control and Prevention

Diseases, Occupational Safety and Health, Health Promotion, and Environmental Health and Injury Prevention were the primary areas where CDC's research and development was invested. CDC works with partners around the country and world to protect Americans from infectious diseases; prevent the leading causes of disease, disability, and death; ensure global disease protection; keep Americans safe from environmental and work-related hazards; protect Americans from natural and bioterrorism threats; monitor health; and ensure laboratory excellence. CDC programs provide partners and Americans with the essential health information and tools they

need to protect and advance their health. In 2016, CDC developed and published the CDC Guideline for Prescribing Opioids for Chronic Pain to provide recommendations for prescribing opioid pain medication to patients 18 and older in primary care settings. Recommendations focus on the use of opioids in treating chronic pain (i.e., pain lasting longer than 3 months or past the time of normal tissue healing) outside of active cancer treatment, palliative care, and end-of-life care. For more information, visit www.cdc.gov/media/releases/2015/p1228-eoy.html

Food and Drug Administration

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

The OPD Program was established by the *Orphan Drug Act* with the purpose of identifying orphan products and facilitating their development. The *Orphan Drug Act* also created the Orphan Product Clinical Trials Grants Program to stimulate the development of promising products for rare diseases and conditions. Orphan product grants are a proven method of fostering and encouraging the development of new, safe, and effective medical products for rare diseases and conditions. Since Orphan Products Clinical Trials Grants Program's inception in 1983, FDA has received over 2,500 applications (generally, about 100 applications each year), reviewed over 2,200, and funded over 590 studies. The program has been used to bring more than 55 products to marketing approval. Approximately 10 percent of the studies that received developmental support from the OPD Grants Program have been utilized to facilitate the marketing approval of those drugs, biologics, and medical devices. In FY 2016, FDA funded 21 new grant awards – out of 68 grant applications – and provided funding or continued support for approximately 65 other ongoing clinical study projects. For more information about the Orphan Products Clinical Trials Grants Program, including grants funded to date, visit www.fda.gov/forIndustry/DevelopingProductsforRareDiseasesConditions/WhomtoContactaboutOrphanProductDevelopment/default.htm

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

National Institutes of Health

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

NIH issues yearly research highlights in December each year. The highlights cover Clinical Advances/Breakthroughs, Promising Medical Advances, and Insights from the Lab. In 2015, these honors included three NIH-supported Nobel Prize winners and two NIH-funded recipients of top awards from the Lasker Foundation. For more information on the yearly highlights, visit www.nih.gov/research-training/nih-research-highlights.

Other Investments in Research and Development

ACF oversees research and development programs that contribute to a better understanding of how to improve the economic and social well-being of families and children so that they may lead healthier and more productive lives. HRSA conducts health services research that will improve the quality of health care, increase capacity, and promote evidence-based decision making. Applied research includes MCH research programs to solve needs for current and emerging maternal and child health programs and help MCH professionals with planning and policymaking. Healthcare Systems conduct research for public outreach campaigns to promote organ, eye, and tissue donation. Rural Health programs produce policy-relevant research on health care and population health in rural areas. HRSA's basic research supports the causes, diagnosis, prevention, and cure of Hansen's disease.

REQUIRED SUPPLEMENTARY INFORMATION

Combining Statement of Budgetary Resources (in Millions)

For the Year Ended September 30, 2016

	CMS						
Budgetary Resources:	Medicare HI	Medicare SMI	Payments to Trust Fund	Medicaid	Other Agency Budgetary Accounts[1]	Agency Combined Budgetary Totals	Non-Budgetary Credit Reform Financing Account
Unobligated Balance, Brought Forward, Oct 1	$ -	$ -	$ 27,047	$ 334	$ 38,241	$ 65,622	$ 2
Recoveries of Unpaid Prior Year Obligations	2	1	484	30,726	5,120	36,333	-
Other Changes in Unobligated Balance	2	4	(3,659)	7	548	(3,098)	-
Unobligated Balance from Prior Year Budget Authority, Net	4	5	23,872	31,067	43,909	98,857	2
Appropriations (Discretionary and Mandatory)	296,844	314,009	333,197	362,295	233,888	1,540,233	-
Borrowing Authority (Discretionary and Mandatory)	-	3,720	-	-	-	3,720	19
Spending Authority from Offsetting Collections (Discretionary and Mandatory)	-	(11,172)	-	872	35,144	24,844	638
Total Budgetary Resources	$ 296,848	$ 306,562	$ 357,069	$ 394,234	$ 312,941	$ 1,667,654	$ 659
Status of Budgetary Resources:							
New Obligations and Upward Adjustments	$ 296,848	$ 306,562	$ 333,236	$ 393,821	$ 277,304	$ 1,607,771	$ 32
Unobligated Balance, End of Year:							
Apportioned, Unexpired Accounts	-	-	-	140	24,842	24,982	8
Exempt from Apportionment, Unexpired Accounts	-	-	-	-	(7,710)	(7,710)	-
Unapportioned, Unexpired Accounts	-	-	-	273	4,809	5,082	619
Unexpired Unobligated Balance, End of Year	-	-	-	413	21,941	22,354	627
Expired Unobligated Balance, End of Year	-	-	23,833	-	13,696	37,529	-
Unobligated Balance, End of Year	-	-	23,833	413	35,637	59,883	627
Total Status of Budgetary Resources	$ 296,848	$ 306,562	$ 357,069	$ 394,234	$ 312,941	$ 1,667,654	$ 659
Change in Obligated Balance:							
Unpaid Obligation:							
Unpaid Obligations, Brought Forward, Oct 1	$ 32,616	$ 23,481	$ 14,161	$ 41,572	$ 124,518	$ 236,348	$ 375
New Obligations and Upward Adjustments	296,848	306,562	333,236	393,821	277,304	1,607,771	32
Outlays (Gross)	(297,203)	(304,020)	(319,843)	(364,613)	(264,509)	(1,550,188)	(370)
Recoveries of Prior Year Unpaid Obligations	(2)	(1)	(484)	(30,726)	(5,120)	(36,333)	-
Unpaid Obligations, End of Year	$ 32,259	$ 26,022	$ 27,070	$ 40,054	$ 132,193	$ 257,598	$ 37
Uncollected Payments:							
Uncollected Customer Payments from Federal Sources, Brought Forward, Oct 1	$ -	$ (11,172)	$ -	$ -	$ (10,952)	$ (22,124)	$ (160)
Change in Uncollected Customer Payments from Federal Sources	-	11,172	-	(105)	(15,409)	(4,342)	145
Uncollected Payments from Federal Sources, End of Year	$ -	$ -	$ -	$ (105)	$ (26,361)	$ (26,466)	$ (15)
Memorandum (non-add) Entries:							
Obligated Balance, Start of Year	$ 32,616	$ 12,309	$ 14,161	$ 41,572	$ 113,566	$ 214,224	$ 215
Obligated Balance, End of Year	$ 32,259	$ 26,022	$ 27,070	$ 39,949	$ 105,832	$ 231,132	$ 22

[1] Other Agency Budgetary Accounts includes the budgetary accounts of the 11 HHS responsibility segments other than CMS, as well as the remaining budgetary accounts not reported by CMS under Medicare and Medicaid. This includes budgetary resources of $4.4 billion and net outlays of $4.4 billion for the Vaccine for Children Program which are appropriated to the Medicaid program and transferred to the CDC.

Combining Statement of Budgetary Resources (continued) (in Millions)

For the Year Ended September 30, 2016

	CMS						
	Medicare HI	Medicare SMI	Payments to Trust Funds	Medicaid	Other Agency Budgetary Accounts[1]	Agency Combined Budgetary Totals	Non-Budgetary Credit Reform Financing Account
Budget Authority and Outlays, Net:							
Budget Authority, Gross (Discretionary and Mandatory)	$ 296,844	$ 306,557	$ 333,197	$ 363,167	$ 269,032	$ 1,568,797	$ 657
Actual Offsetting Collections (Discretionary and Mandatory)	(2)	(4)	(111)	(774)	(21,128)	(22,019)	(782)
Change in Uncollected Customer Payments from Federal Sources (Discretionary and Mandatory)	-	11,172	-	(105)	(15,409)	(4,342)	145
Recoveries of Prior Year Paid Obligations (Discretionary and Mandatory)	2	4	111	7	389	513	-
Budget Authority, Net (Discretionary and Mandatory)	$ 296,844	$ 317,729	$ 333,197	$ 362,295	$ 232,884	$ 1,542,949	$ 20
Outlays, Gross (Discretionary and Mandatory)	$ 297,203	$ 304,020	$ 319,843	$ 364,613	$ 264,509	$ 1,550,188	$ 370
Actual Offsetting Collections (Discretionary and Mandatory)	(2)	(4)	(111)	(774)	(21,128)	(22,019)	(782)
Outlays, Net (Discretionary and Mandatory)	297,201	304,016	319,732	363,839	243,381	1,528,169	(412)
Distributed Offsetting Receipts	(35,450)	(391,627)	-	-	(1,051)	(428,128)	-
Agency Outlays, Net (Discretionary and Mandatory)	$ 261,751	$ (87,611)	$ 319,732	$ 363,839	$ 242,330	$ 1,100,041	$ (412)

Summary of Other Agency Budgetary Accounts

	Budgetary Resources	Status of Budgetary Resources	Net Outlays
ACF	$ 55,658	$ 55,658	$ 50,237
ACL	2,056	2,056	1,973
AHRQ	377	377	269
CDC	15,872	15,872	11,937
CMS	162,891	162,891	124,643
FDA	5,944	5,944	2,539
HRSA	11,577	11,577	10,263
IHS	7,649	7,649	4,704
NIH	38,472	38,472	29,229
OS	6,290	6,290	2,619
PSC	2,186	2,186	474
SAMHSA	3,969	3,969	3,443
Totals	$ 312,941	$ 312,941	$ 242,330

1] Other Agency Budgetary Accounts includes the budgetary accounts of the 11 HHS responsibility segments other than CMS, as well as the remaining budgetary accounts not reported by CMS under Medicare and Medicaid. This includes budgetary resources of $4.4 billion and net outlays of $4.4 billion for the Vaccine for Children Program which are appropriated to the Medicaid program and transferred to the CDC.

Deferred Maintenance and Repairs

For the Years Ended September 30, 2016 and 2015

The FASAB issued SFFAS No. 42, *Deferred Maintenance and Repairs*: Amending Statement of Federal Financial Accounting Standards 6, 14, 29, and 32 effective for periods after September 30, 2014. This standard clarifies that repair activities should be included to better reflect asset management practices, and improve reporting on deferred maintenance and repairs. Deferred maintenance and repairs are maintenance and repairs activities not performed when they should have been or were scheduled to be, and then put off or delayed for a future period. Maintenance and repairs are the activities directed toward keeping fixed capital assets in acceptable condition, including preventive maintenance, normal repairs, replacement of parts and structural components, and other activities needed to preserve the asset so that it continues to provide acceptable service. Other factors under consideration are whether the asset meets applicable building codes, and achieves its expected life. Maintenance and repairs do not include activities aimed at expanding the capacity of an asset or otherwise upgrading it to serve needs different from, or significantly greater than, those originally intended. Maintenance and repair expenses are recognized as incurred.

CDC, NIH, and FDA all use the condition assessment survey for all classes of property. IHS uses two methods to assess installations – annual general inspections and facility condition surveys. The landholding OpDivs prioritize their maintenance activities based on urgency and the best use of their limited resources, with life safety the top priority. Deferred maintenance and repairs have been reported for all active and inactive assets; excess buildings and structures that are slated for disposal or demolition are not included. For buildings, equipment, and other structures, acceptable condition is defined in accordance with standards comparable to those used in private industry. For example, factors can include Property, Plant and Equipment location, age, design etc. Prior year numbers have been adjusted to conform to SFFAS No. 42 and the current year presentation.

	Estimated Cost to Return to Acceptable Condition (in Millions)	
Category of Asset	2016	2015
General Property, Plant and Equipment		
Buildings	$ 2,068	$ 2,216
Equipment	13	13
Other Structures	25	21
Total	$ 2,106	$ 2,250

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

Social Insurance

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

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

RSI material is generally drawn from the 2016 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, which represents the official government evaluation of the financial and actuarial status of the Medicare trust funds. Unless otherwise noted, all data are for calendar years, and all projections are based on the Trustees' intermediate set of assumptions.

The projections in this year's report are based on current law and include the enactment of the *Medicare Access and CHIP Reauthorization Act of 2015* (MACRA; Public Law 114-10), which repealed the sustainable growth rate (SGR) formula that set physician fee schedule payments. While the physician payment updates and new incentives put in place by MACRA avoid the significant short-range physician payment issues that would have resulted from the SGR system approach, they nevertheless raise important long-range concerns. In particular, additional payments of $500 million per year for one group of physicians and 5 percent annual bonuses for another group are scheduled to expire in 2025, resulting in a significant one-time payment reduction for most physicians. In addition, the law specifies the physician payment update amounts for all years in the future, and these amounts do not vary based on underlying economic conditions, nor are they expected to keep pace with the average rate of physician cost increases. The specified rate updates could be an issue in years when levels of inflation are high and would be problematic when the cumulative gap between the price updates and physician costs becomes large. The gap will continue to widen throughout the projection period, and the Trustees anticipate that physician payment rates under current law will be lower than they would have been under the SGR formula by 2048. Absent a change in the delivery system or level of update by subsequent legislation, the Trustees expect access to Medicare-participating physicians to become a significant issue in the long term under current law.

Incorporated in these projections is the sequestration of non-salary Medicare expenditures as required by the following laws: the *Budget Control Act of 2011* (Public Law 112-25, enacted on August 2, 2011), as amended by the *American Taxpayer Relief Act of 2012* (Public Law 112-240, enacted on January 2, 2013); the *Continuing Appropriations Resolution, 2014* (Public Law 113-67, enacted on December 26, 2013); Sections 1 and 3 of Public Law 113-82, enacted on February 15, 2014; the *Protecting Access to Medicare Act of 2014* (Public Law 113-93, enacted on April 1, 2014); and the *Bipartisan Budget Act of 2015* (Public Law 114-74, enacted on November 2, 2015). The sequestration reduces benefit payments by 2 percent from April 1, 2013 through March 31, 2025 and by 4 percent from April 1, 2025 through September 30, 2025. Due to sequestration, non-salary administrative expenses are reduced by an estimated 5 percent from March 1, 2013 through September 30, 2025.

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

The financial projections for the Medicare program reflect substantial, but very uncertain, cost savings deriving from provisions of the *Affordable Care Act* and MACRA that lower increases in Medicare payment rates to most categories of health care providers. Without fundamental change in the current delivery system, these adjustments would probably not be viable indefinitely. It is conceivable that providers could improve their productivity, reduce wasteful expenditures, and take other steps to keep their cost growth within the bounds imposed by the Medicare price limitations. For such efforts to be successful in the long range, however, providers would have to generate and sustain unprecedented levels of productivity gains—a very challenging and uncertain prospect.

In view of the factors described above, it is important to note that Medicare's actual future costs are highly uncertain for reasons apart from the inherent difficulty in projecting health care cost growth over time. The current-law expenditure projections reflect the physicians' payment levels expected under the MACRA payment rules and the *Affordable Care Act* -mandated reductions in other Medicare payment rates. In addition, the Trustees reference in their report an illustrative alternative scenario, which assumes legislative changes that result in (i) physician payment updates that transition from the 0 percent update specified in current law for 2025 to the rate of growth in the Medicare Economic Index of 2.2 percent for 2040 and later; (ii) no expiration of the 5 percent bonuses for physicians in alternative payment models; (iii) a partial phase-out of the *Affordable Care Act* reductions in Medicare payment rates from 2020 through 2034; and (iv) an elimination of the cost-reducing actions of the Independent Payment Advisory Board (IPAB). The difference between the illustrative alternative and the current-law projections demonstrates that the long-range costs could be substantially higher than shown throughout much of the report if the MACRA[12] and *Affordable Care Act* [13] cost-reduction measures prove problematic and new legislation scales them back.

Additional information on the current-law and illustrative alternative projections is provided in Note 25 in these financial statements, in appendix V.C of this year's annual Medicare Trustees Report, and in an auxiliary memorandum prepared by the CMS Office of the Actuary at the request of the Board of Trustees.

Printed copies of the Trustees Report and auxiliary memorandum may be obtained from the CMS Office of the Actuary (410-786-6386) or can be downloaded from www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds.

[12] Under MACRA, a significant one-time payment reduction is scheduled for most physicians in 2025. In addition, the law specifies physician payment rate updates of 0.75 percent or 0.25 percent annually thereafter. These updates are notably lower than the projected physician cost increases, which are assumed to average 2.2 percent per year in the long range.

[13] Under the *Affordable Care Act*, Medicare's annual payment rate updates for most categories of provider services would be reduced below the increase in providers' input prices by the growth in economy-wide private nonfarm business multifactor productivity (1.1 percent over the long range). In addition, the IPAB would be charged with recommending cost savings as are necessary to hold overall per capita Medicare growth to the average of the Consumer Price Index for all Urban Consumers (CPI-U) and CPI-medical care increases in 2015-2019 and to the rate of per capita GDP growth plus 1 percentage point thereafter (subject to certain limits). Unless overridden by lawmakers, these recommendations would be implemented automatically.

Actuarial Projections

Long-Range Medicare Cost Growth Assumptions

The assumed long-range rate of growth in annual Medicare expenditures per beneficiary is based on statutory price updates and volume and intensity growth derived from the "factors contributing to growth" model, which decomposes the major drivers of historical and projected health spending growth into distinct factors. The Trustees assume that the productivity reductions to Medicare payment rate updates will reduce volume and intensity growth by 0.1 percent below the factors model projection. The Trustees' methodology is consistent with Finding III-2 and Recommendation III-2 of the 2010-2011 Medicare Technical Review Panel.[14]

In December 2011, the Technical Panel unanimously recommended a new approach that builds off of the longstanding Gross Domestic Product (GDP) plus 1 percent assumption while incorporating several key refinements (Recommendation III-1).[15] Specifically, the Panel recommended two separate means of establishing long-range growth rates:

- The first approach is a refinement to the traditional GDP plus 1 percent growth assumption that better accounts for the level of payment rate updates for Medicare (prior to the effects of the *Affordable Care Act*) compared to private health insurance and other payers of health care in the U.S. This refinement results in an increase in the long-range pre-*Affordable Care Act* baseline cost growth assumption for Medicare to GDP plus 1.4 percent.

- The "factors contributing to growth" model approach builds upon the key considerations underlying the earlier GDP plus 1 percent assumption. The model is based on economic research that decomposes health spending growth into its major drivers—income growth, relative medical price inflation, insurance coverage, and a residual factor that primarily reflects the impact of technological development.[16] It benefits from additional information that was not available when the 2000 Technical Panel recommended the GDP plus 1 percent assumption.

The Trustees used the statutory price updates and the volume and intensity assumptions from the factors model to derive the year-by-year Medicare cost growth assumptions for the last 50 years of the projection period.

For some time, the Trustees have assumed that it is reasonable to expect over the long range that the drivers of health spending will be similar for the overall health sector and for the Medicare program. This view was affirmed by the 2010-2011 Technical Panel, which recommended use of the same long-range assumptions for the increase in the volume and intensity of health care services for the total health sector and for Medicare. Therefore, the overall health sector long-range cost growth assumptions for volume and intensity are used as the starting point for developing the Medicare- specific assumptions.

Prior to the *Affordable Care Act*, Medicare payment rates for most non-physician provider categories were updated annually by the increase in providers' input prices for the market basket of employee wages and benefits, facility costs, medical supplies, energy and utility costs, professional liability insurance, and other inputs needed to

[14]The Panel's final report is available at www.aspe.hhs.gov/health/reports/2013/MedicareTech/TechnicalPanelReport2010-2011.pdf.

[15] For convenience, the increase in Medicare expenditures per beneficiary, before consideration of demographic impacts, is referred to as the Medicare cost growth rate. Similarly, these growth rate assumptions are described relative to the per capita increase in GDP and characterized simply as GDP plus X percent.

[16] Smith, Sheila, Newhouse, Joseph P., and Freeland, Mark S. "Income, Insurance, and Technology: Why Does Health Spending Outpace Economic Growth?" *Health Affairs*, 28, no. 5 (2009): 1276-1284.

produce the health care goods and services.[17] To the extent that health care providers can improve their productivity each year, their net costs of production (other things being equal) will increase more slowly than their input prices—but the Medicare payment rate updates prior to the *Affordable Care Act* were not adjusted for potential productivity gains. Accordingly, Medicare costs per beneficiary would have increased somewhat faster than for the health sector overall. The *Affordable Care Act* requires that many of these Medicare payment updates be reduced by the 10 year moving average increase in economy-wide private nonfarm business multifactor productivity,[18] which the Trustees assume will be 1.1 percent per year over the long range. The different statutory provisions for updating payment rates require the development of separate long-range Medicare cost growth assumptions for four categories of health care provider services:

(i) ***All HI, and some SMI Part B, services that are updated annually by provider input price increases less the increase in economy-wide productivity.***

HI services are inpatient hospital, skilled nursing facility, home health, and hospice. The primary Part B services affected are outpatient hospital, home health, and dialysis. Under the Trustees' intermediate economic assumptions, the year-by-year per capita increases for these provider services start at 3.9 percent in 2040, or GDP plus 0.0 percent, declining gradually to 3.5 percent in 2090, or GDP minus 0.3 percent.[19]

(ii) ***Physician services***

Payment rate updates are 0.75 percent per year for those physicians assumed to be participating in alternative payment models and 0.25 percent for those assumed to be participating in the merit-based incentive payment system. The year-by-year per capita growth rates for physician payments are assumed to be 3.6 percent in 2040, or GDP minus 0.3 percent, declining to 2.8 percent in 2090, or GDP minus 1.0 percent.

(iii) ***Certain SMI Part B services that are updated annually by the Consumer Price Index (CPI) increase less the increase in economy-wide productivity.***

Such services include durable medical equipment,[20] care at ambulatory surgical centers, ambulance services, and medical supplies. The Trustees assume the per beneficiary year-by-year rates to be 3.1 percent in 2040, or GDP minus 0.8 percent, declining to 2.7 percent in 2090, or GDP minus 1.1 percent.

(iv) ***All other Medicare services, for which payments are established based on market processes, such as prescription drugs provided through Part D and the remaining Part B services.***

These Part B outlays constitute an estimated 15 percent of total Part B expenditures in 2025 and consist mostly of payments for laboratory tests, physician-administered drugs, and small facility services. Medicare payments to Part D plans are based on a competitive-bidding process and are not affected by the productivity adjustments. Similarly, payments for the other Part B services are based on market factors.[21] The long-range per beneficiary cost growth rate for Part D and these Part B services is assumed to equal the increase in per capita national health expenditures as determined from the factors model. The corresponding year-by-year per capita growth rates for these services are 4.8 percent in 2040, or GDP plus 0.9 percent, declining to 4.3 percent by 2090, or GDP plus 0.5 percent.

[17] Historically, lawmakers frequently reduced the payment updates below the increase in providers' input prices in an effort to slow Medicare cost growth or to offset unwarranted changes in claims coding practices. The law did not specify any such adjustments after 2009.

[18] For convenience the term *economy-wide private nonfarm business multifactor productivity* will henceforth be referred to as *economy- wide productivity*.

[19] These growth rate assumptions are described relative to the per capita increase in GDP and characterized simply as GDP plus X percent

[20] Certain durable medical equipment (DME) is subject to competitive bidding, and the price is assumed to grow by the CPI increase less the increase in economy-wide productivity, the same update specified for DME not subject to bidding.

[21] For example, physician-administered Part B drugs are reimbursed at the level of the average sales price in the market plus 6 percent.

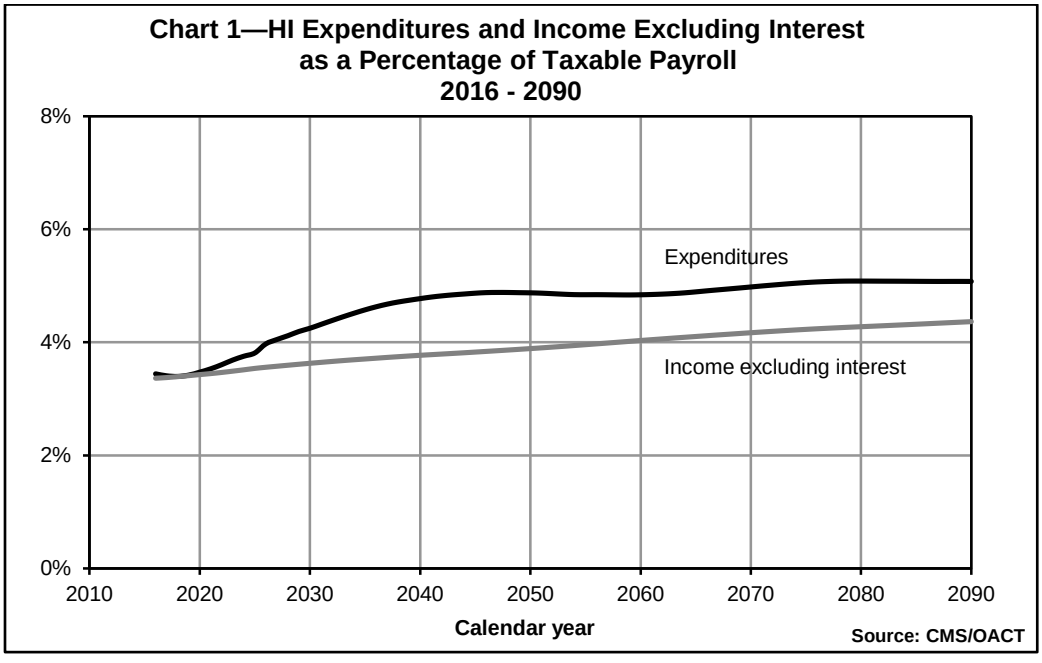
In addition, these long-range cost growth rates must be modified to reflect demographic impacts. For example, beneficiaries at ages 80 and above use Part A skilled nursing and home health services much more frequently than do younger beneficiaries. As the beneficiary population ages, Part A costs will grow at a faster rate due to increased use of these services. In contrast, the incidence of prescription drug use is more evenly distributed by age, and an increase in the average age of Part D enrollees has significantly less of an effect on Part D costs.

After combining the rates of growth from the four long-range assumptions, the weighted average growth rate for Part B is 3.6 percent per year for the last 50 years of the projection period, or GDP minus 0.3 percent, on average. When Parts A, B, and D are combined, the weighted average growth rate is 3.8 percent over this same time period or GDP minus 0.1 percent, while the growth rate in 2090 is 3.6 percent or GDP minus 0.2 percent.

HI Cashflow as a Percentage of Taxable Payroll

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

Chart 1 illustrates income (excluding interest) and expenditures as a percentage of taxable payroll over the next 75 years. The projected HI income and cost rates shown in the 2016 report are higher than those from the 2015 report for all years primarily due to the inclusion of the income and costs for the uninsured beneficiaries. Without the inclusion of these income and cost amounts, the income rate would have been slightly lower for the entire projection period, and the cost rate would have been slightly higher initially (due to the increased hospital utilization) but would have eventually become slightly lower by 2040.



Since the standard HI payroll tax rates are not scheduled to change in the future under present law, most payroll tax income as a percentage of taxable payroll is estimated to remain constant at 2.90 percent. In addition, starting in 2013, high-income workers pay an additional 0.9 percent of their earnings above $200,000 (for single workers) or $250,000 (for married couples filing joint income tax returns). Because these income thresholds are not indexed, over time an increasing proportion of workers will become subject to the additional HI tax rate, and

consequently total HI payroll tax revenues will increase steadily as a percentage of taxable payroll. Income from taxation of benefits will also increase as a greater proportion of Social Security beneficiaries become subject to such taxation, since the income thresholds determining taxable benefits are not indexed for price inflation. Thus, as Chart 1 shows, the income rate is expected to gradually increase over current levels.

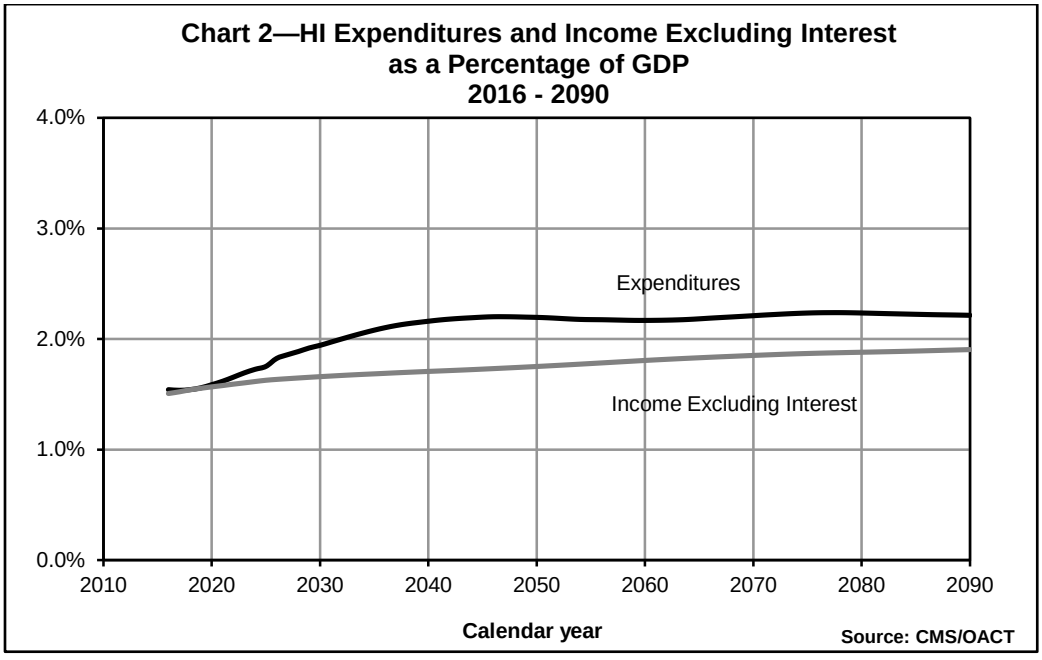
As indicated in Chart 1, the cost rate is projected to decline through 2018, largely due to (i) expenditure growth that was constrained in part by the sequester and low payment updates and (ii) a rebound of taxable payroll growth from 2007-2009 recession levels. After 2018 the cost rate is projected to rise primarily due to retirements of those in the baby boom generation and partly due to a projected return to modest health services cost growth. This cost rate increase is moderated by the accumulating effect of the productivity adjustments to provider price updates, which are estimated to reduce annual HI per capita cost growth by an average of 0.9 percent through 2025 and 1.1 percent thereafter. Under the illustrative alternative scenario, if the slower price updates were not feasible in the long range and were phased down during 2020-2034, then the HI cost rate would be 4.9 percent in 2035 and 8.4 percent in 2090. These levels are about 8 percent and 65 percent higher, respectively, than the current-law estimates under the intermediate assumptions.

HI and SMI Cashflow as a Percentage of GDP

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

HI

Chart 2 shows HI income (excluding interest) and expenditures over the next 75 years expressed as a percentage of GDP. In 2015, the expenditures were $278.9 billion, which was 1.6 percent of GDP. This percentage is projected to increase steadily until about 2045 and then remain fairly level throughout the rest of the 75-year period, as the accumulated effects of the price update reductions are realized. Based on the illustrative alternative scenario, HI costs as a percentage of GDP would increase steadily throughout the long-range projection period, reaching 3.6 percent in 2090.

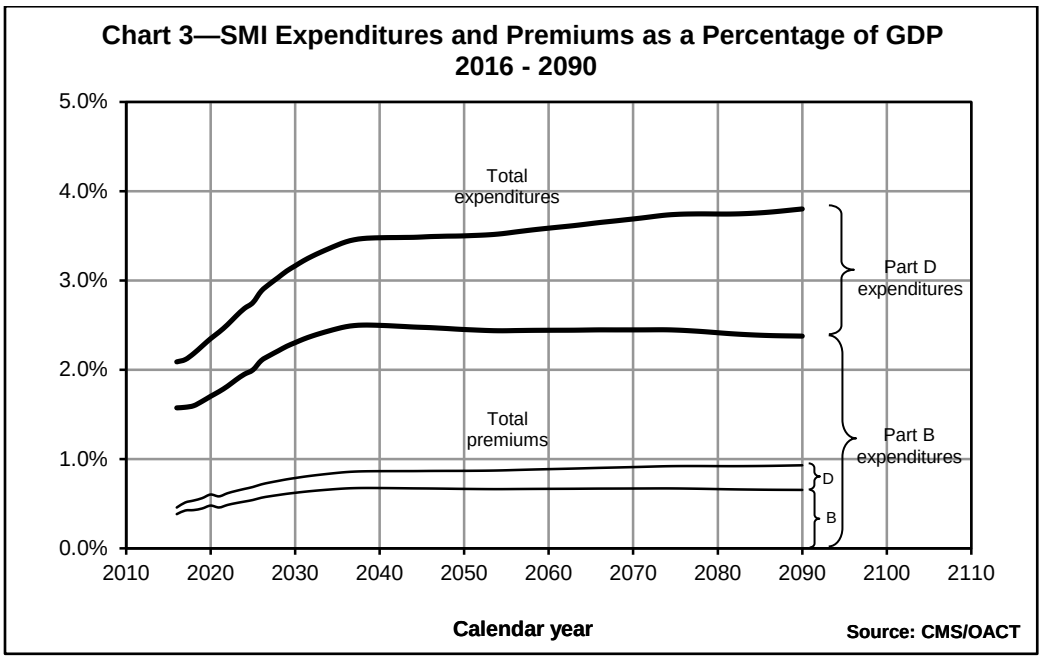


SMI

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

Chart 3 shows projected total SMI (Part B and Part D) expenditures and premium income as a percentage of GDP. The growth rates are estimated year by year for the next 10 years, reflecting the impact of specific statutory provisions. Expenditure growth for years 11 to 25 is assumed to grade smoothly into the long range assumption described previously.

In 2015, SMI expenditures were $368.8 billion, or about 2.1 percent of GDP. Under current law, they would grow to about 3.5 percent of GDP within 25 years and to 3.8 percent by the end of the projection period. (Under the illustrative alternative, total SMI expenditures in 2090 would be 5.4 percent of GDP.)

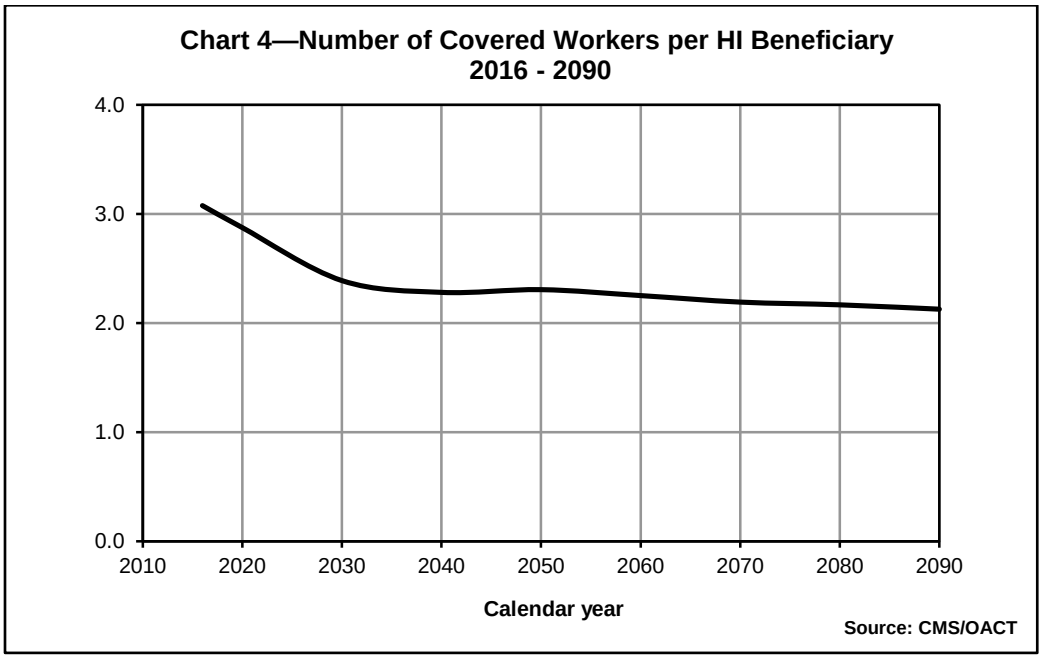


To match the faster growth rates for SMI expenditures, beneficiary premiums, along with general revenue contributions, would increase more rapidly than GDP over time but at a slower rate compared to the last 10 years. Average per beneficiary costs for Part B and Part D benefits are projected to increase after 2015 by about 4.2 percent annually. The associated beneficiary premiums—and general revenue financing—would increase by approximately the same rate. The special State payments to the Part D account are set by law at a declining portion of the States' forgone Medicaid expenditures attributable to the Medicare drug benefit. The percentage was 90 percent in 2006, phasing down to 75 percent in 2015 and later. Then, after 2015, the State payments are also expected to increase faster than GDP.

Worker-to-Beneficiary Ratio

HI

Another way to evaluate the long-range outlook of the HI trust fund is to examine the projected number of workers per HI beneficiary. Chart 4 illustrates this ratio over the next 75 years. For the most part, current workers pay for current benefits. The relatively smaller number of persons born after the baby boom will therefore finance the retirement of the baby boom generation. In 2015, every beneficiary had 3.1 workers to pay for his or her benefit. In 2030, however, after the last baby boomer turns 65, there will be only about 2.4 workers per beneficiary. The projected ratio continues to decline until there are just 2.1 workers per beneficiary by 2090.



Sensitivity Analysis

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

To illustrate the sensitivity of the long-range projections and determine the impact on the HI actuarial present values, six of the key assumptions were varied individually.[22] The assumptions varied are the health care cost factors, real-wage differential, CPI, real-interest rate, fertility rate, and net immigration.[23]

[22]Sensitivity analysis is not done for Parts B or D of the SMI trust fund due to the financing mechanism for each account. Any change in assumptions would have a negligible impact on the net cash flow, since the change would affect income and expenditures equally.

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

For this analysis, the intermediate economic and demographic assumptions in the *2016 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds* are used as the reference point. Each selected assumption is varied individually to produce three scenarios. All present values are calculated as of January 1, 2016 and are based on estimates of income and expenditures during the 75-year projection period.

Charts 5 through 10 show the present value of the estimated net cash flow for each assumption varied. Generally, under all three scenarios, the present values initially increase, as the effects of the *Affordable Care Act* result in trust fund surpluses, and then decrease through the first 25 to 30 years of the projection period, at which point they start to increase (or become less negative) once again. This pattern occurs in part because of the discounting process for computing present values, which is used to help interpret the net cash flow deficit in terms of today's dollar. In other words, the amount required to cover this deficit, if made available and invested today, begins to decrease at the end of the 75-year period, reflecting the long period of interest accumulation that would occur. The pattern is also affected by the accumulating impact of the lower Medicare price updates over time and the greater proportion of workers who will be subject to the higher HI payroll tax rate, as noted above.

Health Care Cost Factors

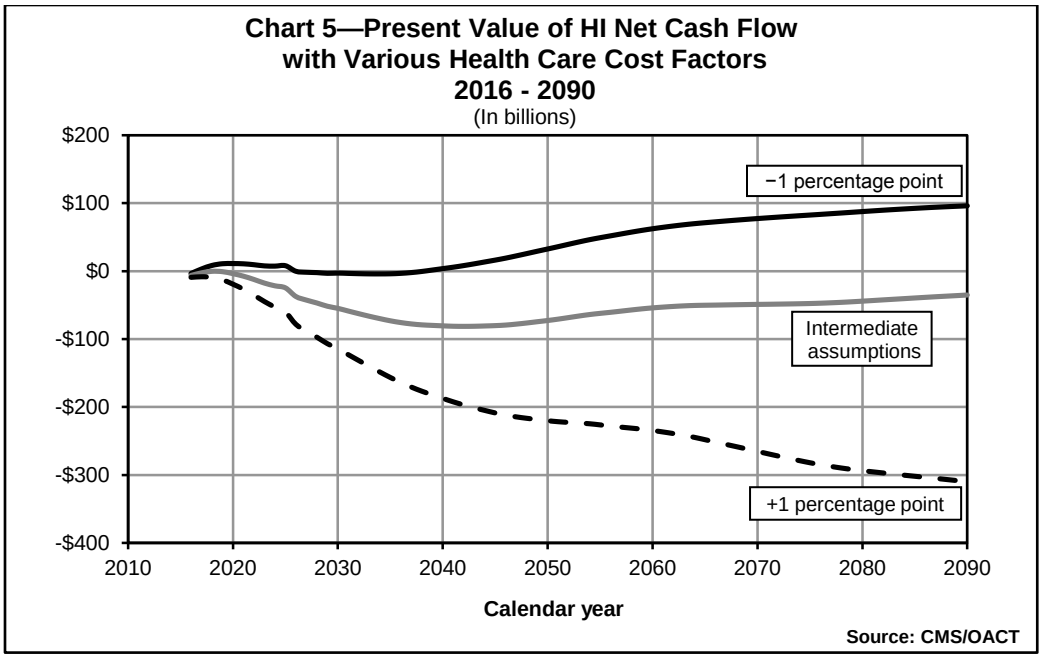
Table 1 shows the net present value of cash flow during the 75-year projection period under three alternative assumptions for the annual growth rate in the aggregate cost of providing covered health care services to beneficiaries. These assumptions are that the ultimate annual growth rate in such costs,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

Table 1—Present Value of Estimated HI Income Less Expenditures under Various Health Care Cost Growth Rate Assumptions

Annual cost/payroll relative growth rate	−1 percentage point	Intermediate assumptions	+1 percentage point
Income minus expenditures (in billions)	$3,198	−$3,822	−$15,054

Table 1 demonstrates that if the ultimate growth rate assumption is 1 percentage point lower than the intermediate assumptions, the deficit decreases by $7,020 billion. On the other hand, if the ultimate growth rate assumption is 1 percentage point higher than the intermediate assumptions, the deficit increases substantially, by $11,232 billion.

Chart 5 shows projections of the present value of the estimated net cash flow under the three alternative annual growth rate assumptions presented in Table 1.



This assumption has a dramatic impact on projected HI cash flow. The present value of the net cash flow under the ultimate growth rate assumption of 1 percentage point lower than the intermediate assumption actually becomes a surplus due to the improved financial outlook for the HI trust fund as a result of the *Affordable Care Act*. Several factors, such as the utilization of services by beneficiaries or the relative complexity of services provided, can affect costs without affecting tax income. As Chart 5 indicates, the financial status of the HI trust fund is extremely sensitive to the relative growth rates for health care service costs.

Real-Wage Differential

Table 2 shows the net present value of cash flow during the 75-year projection period under three alternative ultimate real-wage differential assumptions: 0.6, 1.2, and 1.8 percentage points.[24] In each case, the assumed ultimate annual increase in the CPI is 2.6 percent, yielding ultimate percentage increases in nominal average annual wages in covered employment of 3.2, 3.8, and 4.4 percent, respectively.

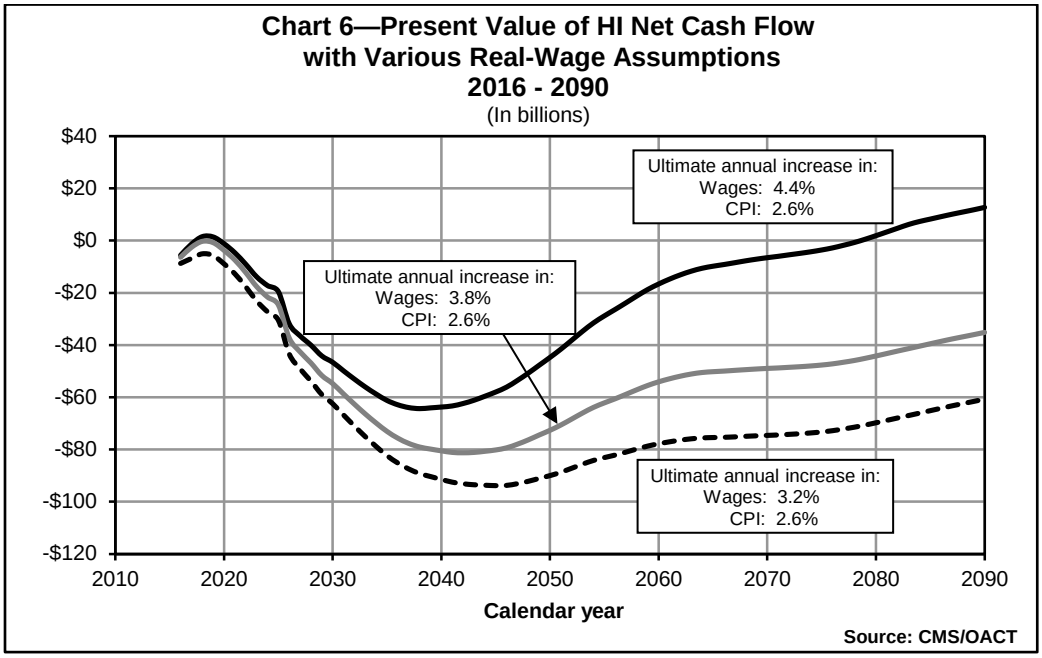
Table 2—Present Value of Estimated HI Income Less Expenditures under Various Real-Wage Assumptions

Ultimate percentage increase in wages – CPI	3.2 – 2.6	3.8 – 2.6	4.4 – 2.6
Ultimate percentage increase in real-wage differential	0.6	1.2	1.8
Income minus expenditures (in billions)	−$5,116	−$3,822	−$1,748

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

As indicated in Table 2, for a half-point increase in the ultimate real-wage differential assumption, the deficit—expressed in present-value dollars—decreases by approximately $1,730 billion. Conversely, for a half-point decrease in the ultimate real-wage differential assumption, the deficit increases by about $1,080 billion.

Chart 6 shows projections of the present value of the estimated net cash flow under the three alternative real-wage differential assumptions presented in Table 2.



As illustrated in Chart 6, faster real-wage growth results in smaller HI cash flow deficits, when expressed in present-value dollars. A higher real-wage differential immediately increases both HI expenditures for health care and wages for all workers. There is a full effect on wages and payroll taxes, but the effect on benefits is only partial, since not all health care costs are wage-related. In practice, faster real-wage growth always improves the financial status of the HI trust fund, regardless of whether there is a small or large imbalance between income and expenditures. Also, as noted previously, the closer financial balance for the HI trust fund under the *Affordable Care Act* and MACRA depends critically on the long-range feasibility of the lower Medicare price updates for hospitals and other HI providers. Sustaining these price reductions will be challenging for health care providers, as the best available evidence indicates that most providers cannot improve their productivity to this degree for a prolonged period given the labor-intensive nature of these services.

Consumer Price Index

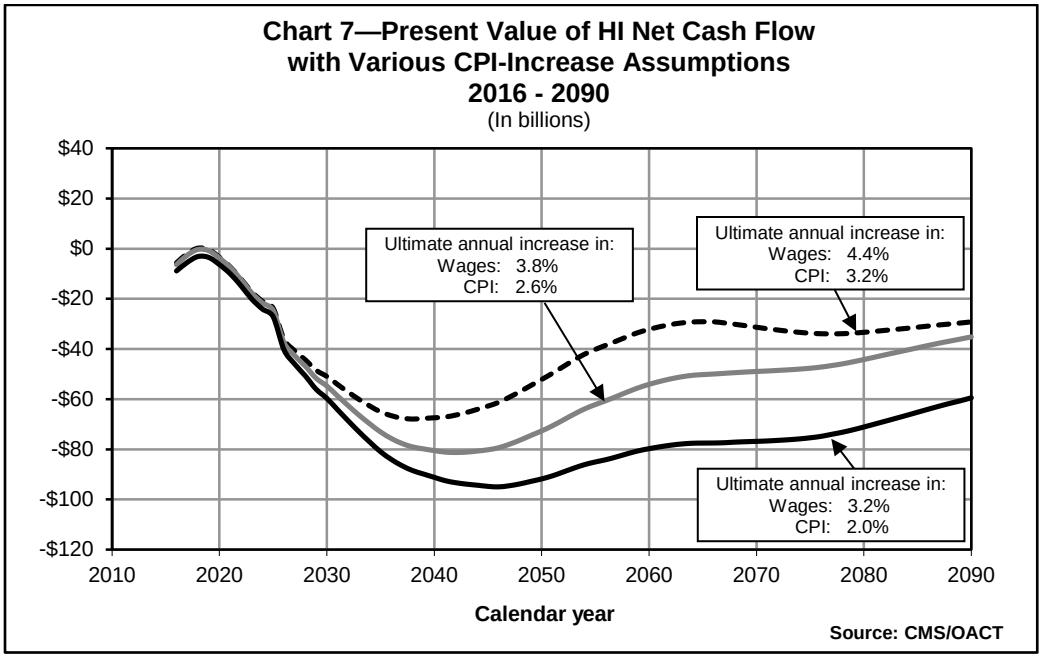
Table 3—Present Value of Estimated HI Income Less Expenditures under Various CPI-Increase Assumptions

Ultimate percentage increase in wages – CPI	4.4 – 3.2	3.8 – 2.6	3.2 – 2.0
Income minus expenditures (in billions)	–$2,902	–$3,822	–$5,133

Table 3 shows the net present value of cash flow during the 75-year projection period under three alternative ultimate CPI rate-of-increase assumptions: 3.2, 2.6, and 2.0 percent. In each case, the assumed ultimate real-wage differential is 1.2 percent, which yields ultimate percentage increases in average annual wages in covered employment of 4.4, 3.8, and 3.2 percent, respectively.

Table 3 demonstrates that if the ultimate CPI-increase assumption is 3.2 percent, the deficit decreases by $920 billion. On the other hand, if the ultimate CPI-increase assumption is 2.0 percent, the deficit increases by $1,311 billion.

Chart 7 shows projections of the present value of net cash flow under the three alternative CPI rate-of-increase assumptions presented in Table 3.



As Chart 7 indicates, this assumption has a small impact when the cash flow is expressed as present values. The relative insensitivity of the projected present values of HI cash flow to different levels of general inflation occurs because inflation tends to proportionately affect both income and costs in a similar manner. In present value terms, a smaller deficit results under high-inflation conditions because the present values of HI expenditures are not significantly different under the various CPI scenarios, but under high-inflation conditions the present value of HI income increases as more people become subject to the additional 0.9-percent HI tax rate required by the *Affordable Care Act* for workers with earnings above $200,000 or $250,000 (for single and joint income-tax filers, respectively). Since the thresholds are not indexed, additional workers become subject to the additional tax more quickly under conditions of faster inflation, and vice versa.

Real-Interest Rate

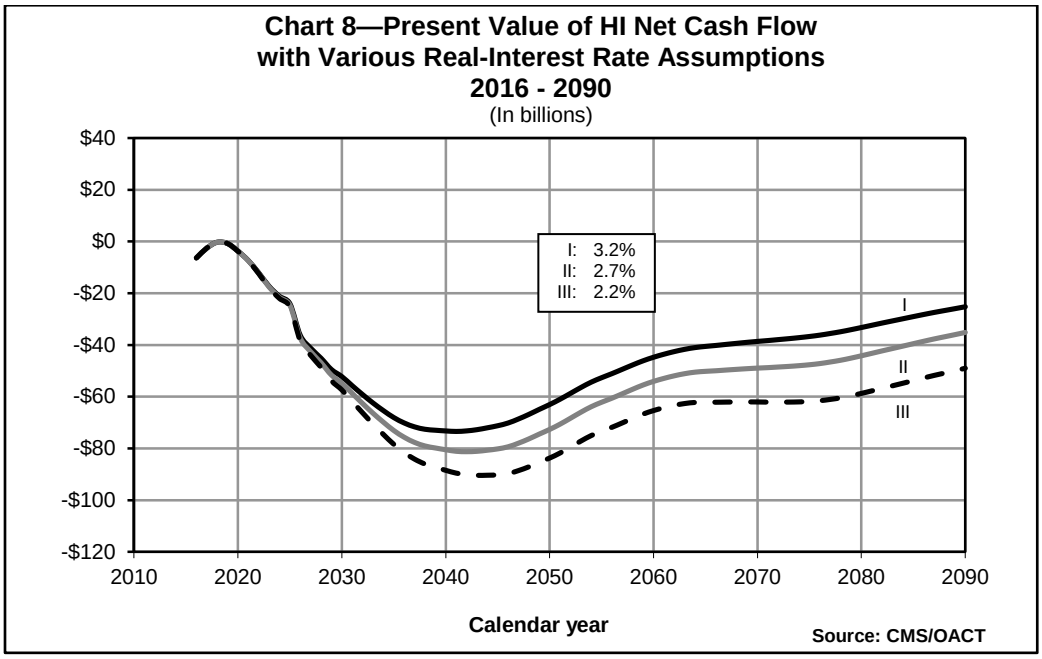
Table 4 shows the net present value of cash flow during the 75-year projection period under three alternative ultimate annual real-interest assumptions: 2.2, 2.7, and 3.2 percent. In each case, the assumed ultimate annual increase in the CPI is 2.6 percent, which results in ultimate annual yields of 4.8, 5.3, and 5.8 percent, respectively.

Table 4—Present Value of Estimated HI Income Less Expenditures under Various Real-Interest Assumptions

Ultimate real-interest rate	2.2 percent	2.7 percent	3.2 percent
Income minus expenditures (in billions)	−$4,505	−$3,822	−$2,266

As illustrated in Table 4, for every increase of 0.1 percentage point in the ultimate real-interest rate, the deficit decreases by approximately $125 billion.

Chart 8 shows projections of the present value of the estimated net cash flow under the three alternative real-interest assumptions presented in Table 4.



As shown in Chart 8, the projected HI cash flow when expressed in present values is fairly sensitive to the interest assumption. This is not an indication of the actual role that interest plays in HI financing. In actuality, interest finances very little of the cost of the HI trust fund because, under the intermediate assumptions, the fund is projected to be relatively low and exhausted by 2028. These results illustrate the substantial sensitivity of present value measures to different interest rate assumptions. With higher assumed interest, the very large deficits in the more distant future are discounted more heavily (that is, are given less weight), resulting in a smaller overall net present value.

Fertility Rate

Table 5 shows the net present value of cash flow during the 75-year projection period under three alternative ultimate fertility rate assumptions: 1.8, 2.0, and 2.2 children per woman.

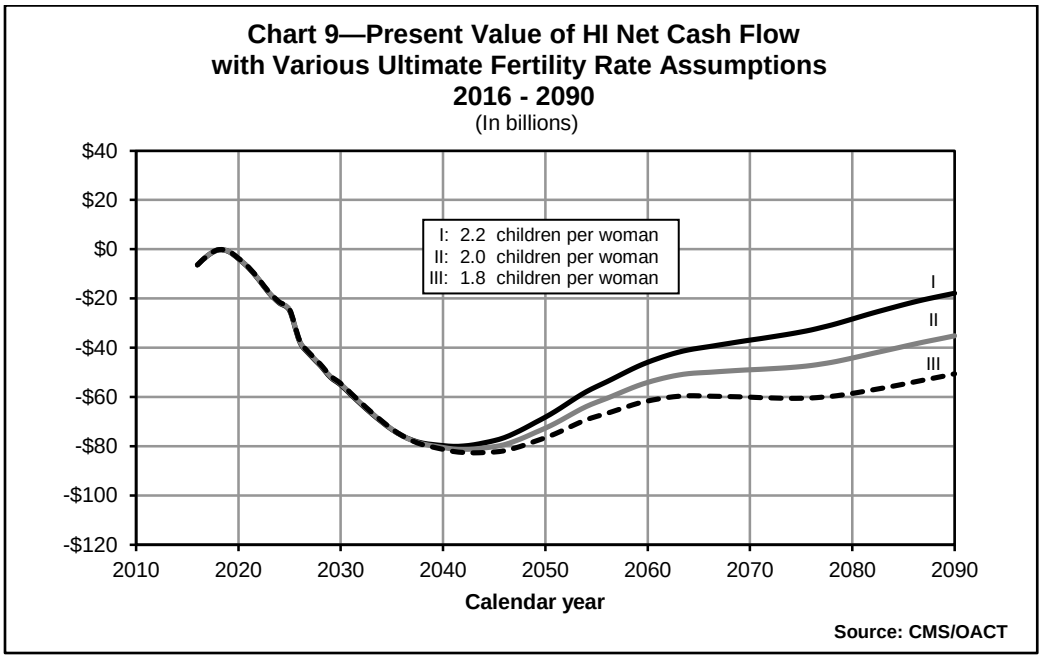
Table 5—Present Value of Estimated HI Income Less Expenditures under Various Fertility Rate Assumptions

Ultimate fertility rate[1]	1.8	2.0	2.2
Income minus expenditures (in billions)	−$4,280	−$3,822	−$3,318

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

As Table 5 demonstrates, for an increase of 0.2 in the assumed ultimate fertility rate, the projected present value of the HI deficit decreases by approximately $480 billion.

Chart 9 shows projections of the present value of the net cash flow under the three alternative fertility rate assumptions presented in Table 5.



As Chart 9 indicates, the fertility rate assumption has a substantial impact on projected HI cash flows. Under the higher fertility rate assumptions, there will be additional workers in the labor force after 20 years, and many will become subject to the additional HI tax, thereby lowering the deficit proportionately more on a present-value-dollar basis. On the other hand, under the lower fertility rate assumptions, there will be fewer workers in the workforce with a smaller number subject to the additional tax, in turn raising the HI deficit. It is important to point out that if a longer projection period were used, the impact of a fertility rate change would be more pronounced.

Net Immigration

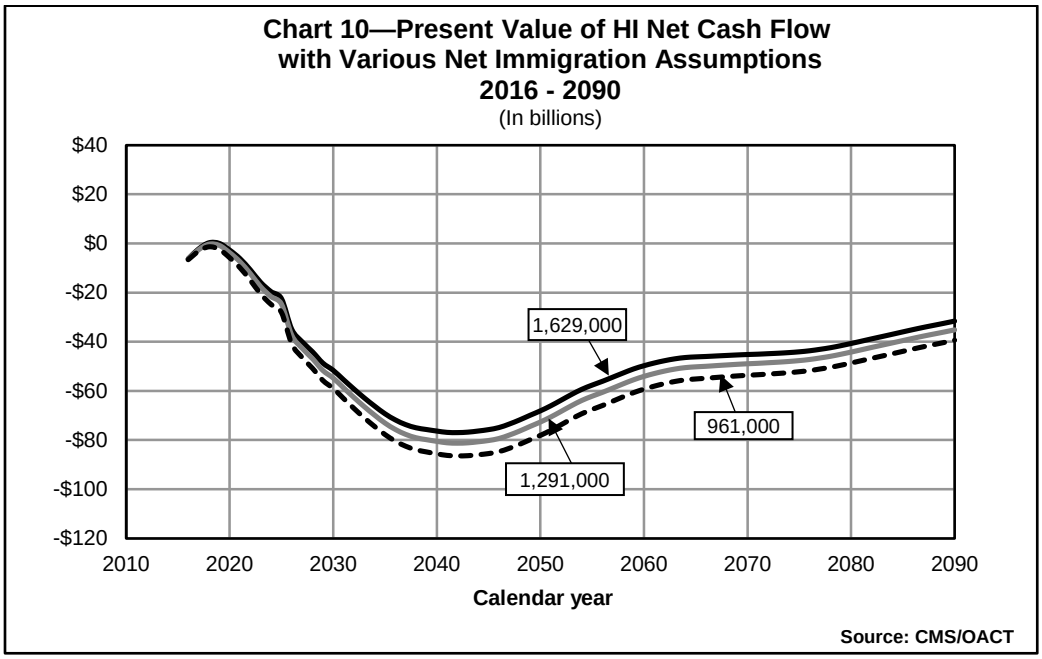
Table 6 shows the net present value of cash flow during the 75-year projection period under three alternative average annual net immigration assumptions: 961,000 persons, 1,291,000 persons, and 1,629,000 persons per year.

Table 6—Present Value of Estimated HI Income Less Expenditures under Various Net Immigration Assumptions

Average annual net immigration	961,000	1,291,000	1,629,000
Income minus expenditures (in billions)	−$4,153	−$3,822	−$3,558

As indicated in Table 6, if the average annual net immigration assumption is 961,000 persons, the deficit—expressed in present-value dollars—increases by $331 billion. Conversely, if the assumption is 1,629,000 persons, the deficit decreases by $264 billion.

Chart 10 shows projections of the present value of net cash flow under the three alternative average annual net immigration assumptions presented in Table 6.



Higher net immigration results in smaller HI cash flow deficits, as illustrated in Chart 10. Since immigration tends to occur most often among people at working ages, who work and pay taxes into the HI system, a change in the net immigration assumption affects revenues from payroll taxes almost immediately. However, the impact on expenditures occurs later as those individuals age and become beneficiaries.

Trust Fund Finances and Sustainability

HI

The short-range financial outlook for the HI trust fund has worsened as compared to the projections in last year's annual report. Under the Medicare Trustees' intermediate assumptions, the estimated depletion date for the HI trust fund is 2028, 2 years earlier than in last year's report. As in past years, the Trustees have determined that the fund is not adequately financed over the next 10 years. HI tax income and expenditures are projected to be lower than last year's estimates, mostly due to lower CPI assumptions. The impact on expenditures is mitigated by lower productivity increases.

HI expenditures have exceeded income annually since 2008. However, the Trustees project slight surpluses in 2016 through 2020, with a return to deficits thereafter until the trust fund becomes depleted in 2028. If assets were depleted, Medicare could pay health plans and providers of Part A services only to the extent allowed by ongoing tax revenues—and these revenues would be inadequate to fully cover costs. Beneficiary access to health care services would rapidly be curtailed. To date, Congress has never allowed the HI trust fund to become depleted.

The HI trust fund remains out of financial balance in the long range. Bringing the fund into actuarial balance over the next 75 years under the intermediate assumptions would require significant increases in revenues and/or reductions in benefits. Policy makers should determine effective solutions to ensure the financial integrity of HI in the long term and should also consider the likelihood that the price adjustments in current law may prove difficult to adhere to fully and may require even more changes to address this challenge.

SMI

The SMI trust fund will remain adequate, both in the near term and into the indefinite future, because of the automatic financing established for Parts B and D. There is no provision in the law for transferring assets between the Part D and Part B accounts; therefore, it is necessary to evaluate each account's financial adequacy separately.

The financing established for the Part B account for calendar year 2016 is adequate to cover 2016 expected expenditures.[25] Similarly, Part D income and outgo would remain in balance as a result of the annual adjustment of premium and general revenue income to cover costs. The appropriation for Part D general revenues has generally been set such that amounts can be transferred to the Part D account on an as-needed basis.

The Part B and Part D accounts in the SMI trust fund are adequately financed because premium and general revenue income are reset each year to cover expected costs. Such financing, however, would have to increase faster than the economy to cover expected expenditure growth. A critical issue for the SMI program is the impact of the rapid growth of SMI costs, which places steadily increasing demands on beneficiaries and taxpayers.

Medicare Overall

The law requires the Board of Trustees to determine whether the difference between Medicare outlays and dedicated financing sources[26] is projected to exceed 45 percent of total Medicare outlays under current law within

[25] A hold-harmless provision restricts Part B premium increases for most beneficiaries in 2016. The Bipartisan Budget Act of 2015 required that the 2016 monthly Part B premium be calculated as if the hold-harmless provision did not apply. However, it is required a transfer of funds from the general fund to cover the premium income that is lost as a result of the provision. In 2017 there may be a substantial increase in the Part B premium rate for some beneficiaries.

[26] Dedicated Medicare financing sources used in this year's determination include HI payroll taxes; income from taxation of Social Security benefits; State transfers for the prescription drug benefit; premiums paid under Parts A, B, and D; fees allocated to Part B related to brand-name prescription drugs; and any gifts received by the Medicare trust funds.

the next 7 fiscal years (2016-2022). If this level is attained within the 7-year timeframe, Federal law requires a determination of projected excess general revenue Medicare funding. For the 2016 Medicare Trustees Report, this difference is not expected to exceed 45 percent of total expenditures in fiscal years 2016-2022 (the first 7 years of the projection), and therefore the Trustees are not issuing this determination.

The projections shown continue to demonstrate the need for timely and effective action to address Medicare's remaining financial challenges—including the projected depletion of the HI trust fund, this fund's long-range financial imbalance, and the rapid growth in Medicare expenditures. Furthermore, if the growth in Medicare costs is comparable to growth under the illustrative alternative projections, then these further policy reforms will have to address much larger financial challenges than those assumed under current law. In their 2016 annual report to Congress, the Medicare Board of Trustees emphasized the seriousness of these concerns and urged the nation's policy makers to "work closely together with a sense of urgency to address these challenges." They also stated: "Consideration of such reforms should not be delayed."

Other Information

3

In This Section

- Other Financial Information
- Freeze the Footprint
- Civil Monetary Penalty Adjustment for Inflation
- Improper Payments Information Act Report
- Summary of Financial Statement Audit and Management Assurances
- FY 2016 Top Management and Performance Challenges Identified by the Office of Inspector General
- Department's Response to the Office of the Inspector General Top Management and Performance Challenges

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OTHER FINANCIAL INFORMATION

Consolidating Balance Sheet by Budget Function

As of September 30, 2016

(in Millions)

	Education, Training & Social Services	Health	Medicare	Income Security	Agency Combined Totals	Intra-HHS Eliminations	HHS Consolidated Totals
Assets (Note 2)							
Intragovernmental Assets							
Fund Balance with Treasury (Note 3)	$ 10,339	$ 158,539	$ 53,806	$ 15,075	$ 237,759	$ -	$ 237,759
Investments, Net (Note 4)	-	4,276	257,801	-	262,077	-	262,077
Accounts Receivable, Net (Note 5)	159	3,792	73,925	5	77,881	(76,869)	1,012
Advances (Note 8)	16	290	28	31	365	(126)	239
Total Intragovernmental Assets	10,514	166,897	385,560	15,111	578,082	(76,995)	501,087
Accounts Receivable, Net (Note 5)	-	16,679	7,453	71	24,203	-	24,203
Inventory and Related Property, Net (Note 6)	-	9,399	-	-	9,399	-	9,399
General Property, Plant and Equipment, Net (Note 7)	-	5,415	250	-	5,665	-	5,665
Advances (Note 8)	-	20	21,460	-	21,480	-	21,480
Other Assets	-	819	-	-	819	-	819
Total Assets	$ 10,514	$ 199,229	$ 414,723	$ 15,182	$ 639,648	$ (76,995)	$ 562,653
Stewardship Land (Notes 1 and 20)							
Liabilities (Note 9)							
Intragovernmental Liabilities							
Accounts Payable	$ 18	$ 321	$ 76,738	$ 1	$ 77,078	$ (76,739)	$ 339
Other Liabilities (Note 13)	2	3,948	3,299	70	7,319	(256)	7,063
Total Intragovernmental Liabilities	20	4,269	80,037	71	84,397	(76,995)	7,402
Accounts Payable	17	761	193	10	981	-	981
Entitlement Benefits Due and Payable (Note 10)	-	44,319	63,911	-	108,230	-	108,230
Accrued Liabilities (Note 12)	955	12,437	(55)	1,083	14,420	-	14,420
Federal Employee and Veterans Benefits (Note 11)	4	12,879	9	-	12,892	-	12,892
Contingencies and Commitments (Note 14)	-	11,734	660	-	12,394	-	12,394
Other Liabilities (Note 13)	19	3,570	1,366	8	4,963	-	4,963
Total Liabilities	1,015	89,969	146,121	1,172	238,277	(76,995)	161,282
Net Position							
Unexpended Appropriations - Funds from Dedicated Collections (Note 19)	-	(100)	36,012	-	35,912	-	35,912
Unexpended Appropriations - Other funds	9,414	104,726	-	13,989	128,129	-	128,129
Cumulative Results of Operations - Funds from Dedicated Collections (Note 19)	-	880	232,590	-	233,470	-	233,470
Cumulative Results of Operations - Other funds	85	3,754	-	21	3,860	-	3,860
Total Net Position - Funds from Dedicated Collections	-	780	268,602	-	269,382	-	269,382
Total Net Position - Other Funds	9,499	108,480	-	14,010	131,989	-	131,989
Total Net Position	9,499	109,260	268,602	14,010	401,371	-	401,371
Total Liabilities and Net Position	$ 10,514	$ 199,229	$ 414,723	$ 15,182	$ 639,648	$ (76,995)	$ 562,653

Consolidating Statement of Net Cost by Budget Function

For the Year Ended September 30, 2016

(in Millions)

Responsibility Segments	Education, Training, & Social Services	Health	Medicare	Income Security	Agency Combined Totals	Intra-HHS Eliminations: Cost (-)	Intra-HHS Eliminations: Revenue	Consolidated Totals
ACF	$ 12,866	$ -	$ -	$ 38,678	$ 51,544	$ (75)	$ 7	$ 51,476
ACL	2,059	-	-	-	2,059	(10)	8	2,057
AHRQ	-	282	-	-	282	(12)	78	348
CDC	-	11,922	-	-	11,922	(136)	118	11,904
CMS	-	386,946	566,114	-	953,060	(422)	13	952,651
FDA	-	2,818	-	-	2,818	(270)	14	2,562
HRSA	-	10,423	-	-	10,423	(277)	25	10,171
IHS	-	4,939	-	-	4,939	(192)	199	4,946
NIH	-	30,004	-	-	30,004	(327)	344	30,021
OS	-	3,122	-	-	3,122	(503)	485	3,104
PSC	-	1,354	-	-	1,354	(81)	630	1,903
SAMHSA	-	3,539	-	-	3,539	(33)	123	3,629
Net Cost of Operations	$ 14,925	$ 455,349	$ 566,114	$ 38,678	$ 1,075,066	$ (2,338)	$ 2,044	$ 1,074,772

Gross Cost and Exchange Revenue

For the Year Ended September 30, 2016

(in Millions)

Responsibility Segments	Intragovernmental: Gross Cost: Combined	Gross Cost: Eliminations	Gross Cost: Consolidated	Less: Exchange Revenue: Combined	Less: Exchange Revenue: Eliminations	Less: Exchange Revenue: Consolidated	With the Public: Gross Cost	With the Public: Less: Exchange Revenue	Consolidated Net Cost of Operations
ACF	$ 170	$ (75)	$ 95	$ (15)	$ 7	$ (8)	$ 51,420	$ (31)	$ 51,476
ACL	22	(10)	12	(9)	8	(1)	2,046	-	2,057
AHRQ	44	(12)	32	(78)	78	-	316	-	348
CDC	805	(136)	669	(272)	118	(154)	11,429	(40)	11,904
CMS	1,213	(422)	791	(33)	13	(20)	1,043,824	(91,944)	952,651
FDA	1,271	(270)	1,001	(33)	14	(19)	3,616	(2,036)	2,562
HRSA	370	(277)	93	(25)	25	-	10,130	(52)	10,171
IHS	712	(192)	520	(238)	199	(39)	5,684	(1,219)	4,946
NIH	1,366	(327)	1,039	(422)	344	(78)	29,751	(691)	30,021
OS	937	(503)	434	(517)	485	(32)	2,742	(40)	3,104
PSC	327	(81)	246	(1,237)	630	(607)	2,270	(6)	1,903
SAMHSA	70	(33)	37	(130)	123	(7)	3,599	-	3,629
Totals	$ 7,307	$ (2,338)	$ 4,969	$ (3,009)	$ 2,044	$ (965)	$ 1,166,827	$ (96,059)	$ 1,074,772

Combined Schedule of Spending By Object Class

As of September 30, 2016

(in Millions)

The Combined Schedule of Spending presented below includes the United States (U.S.) Department of Health and Human Services' (HHS) spending for all Treasury Account Symbols with spending greater than $1.0 billion to increase transparency.

How was the Money Spent/Issued?	Grants, Subsidies, & Contributions	Financial Assistance Direct Payments	Other Contractual Services	Personnel Compensation & Benefits	Other	FY 2016
Medicaid	$ 393,919	$ -	$ 108	$ 18	$ 4,172	$ 398,217
Payments to Trust Funds	215,830	-	-	-	94,282	310,112
Federal Supplementary Medical Insurance Trust Fund	-	300,768	126	-	5,668	306,562
Federal Hospital Insurance Trust Fund	-	291,252	2	-	5,594	296,848
Medicare Prescription Drug Account	-	92,039	-	-	765	92,804
Taxation on OASDI Benefits, HI	23,022	-	-	-	-	23,022
Temporary Assistance for Needy Families	16,649	-	71	2	-	16,722
State Children's Health Insurance Fund	14,002	-	4	-	64	14,070
Children and Families Services Programs	10,509	-	291	151	24	10,975
Payments for Foster Care and Permanency	7,822	-	35	-	1	7,858
Transitional Reinsurance Program	-	7,842	-	-	4	7,846
National Cancer Institute	3,300	-	1,457	511	124	5,392
Indian Health Services	2,339	-	847	1,361	703	5,250
Primary Health Care	4,733	-	232	64	12	5,041
National Institute of Allergy and Infectious Diseases	3,384	-	1,222	319	94	5,019
Payments to States for Child Support Enforcement and Family Support Programs	3,683	-	684	-	-	4,367
Risk Adjustment Program Payments	-	3,544	-	-	-	3,544
Low Income Home Energy Assistance	3,369	-	3	-	-	3,372
National Heart, Lung, and Blood Institute	2,465	-	525	158	35	3,183
Child Care Entitlement to States	2,928	-	23	-	-	2,951
Medicare Health Information Technology Incentive	-	2,794	-	-	-	2,794
Payment to States for the Child Care and Development Block Grant	2,719	-	42	-	-	2,761
National Institute of General Medical Sciences	2,442	-	83	31	1	2,557
Ryan White HIV/AIDS Program	2,149	-	92	24	4	2,269
Substance Abuse Treatment	2,045	-	144	9	2	2,200
Aging and Disability Services Programs	1,956	-	47	29	4	2,036
National Institute of Diabetes and Digestive and Kidney Diseases	1,662	-	218	116	22	2,018
Health Care Fraud and Abuse Control Account	-	-	1,267	74	533	1,874
Refugee and Entrant Assistance	1,502	-	346	13	4	1,865
Public Health and Social Services Emergency Fund	348	-	853	122	478	1,801
Service and Supply Fund	46	-	1,108	264	352	1,770
National Institute of Neurological Disorders and Stroke	1,416	-	215	89	31	1,751
Social Services Block Grant	1,657	-	10	1	-	1,668
National Institute on Aging	1,383	-	154	71	25	1,633
National Institute of Mental Health	1,261	-	206	95	16	1,578
State Grants and Demonstration	1,480	1	80	11	1	1,573
National Institute of Child Health and Human Development	982	-	311	99	18	1,410
Public Health Preparedness and Response	613	-	300	110	350	1,373
HHS Service and Supply Fund	-	-	1,108	149	96	1,353
Centers for Medicare and Medicaid Innovation	464	109	645	74	3	1,295
Mental Health	1,069	-	118	4	3	1,194
CDC-Wide Activities and Program Support	518	-	367	179	121	1,185
Chronic Disease Prevention and Health Promotion	762	-	283	127	7	1,179
National Institute on Drug Abuse	864	-	194	66	9	1,133
HIV/AIDS, Viral Hepatitis, Sexually Transmitted Diseases and Tuberculosis Prevention	738	-	200	171	14	1,123
Other Agency Budgetary Accounts	13,129	5,696	12,941	6,803	2,686	41,255
Total Amounts Agreed to be Spent	$ 749,159	$ 704,045	$ 26,962	$ 11,315	$ 116,322	$ 1,607,803

Combined Schedule of Spending By Object Class

As of September 30, 2015

(in Millions)

The Combined Schedule of Spending presented below includes HHS's spending for all Treasury Account Symbols with spending greater than $1.0 billion to increase transparency.

How was the Money Spent/Issued?	Grants, Subsidies, & Contributions	Financial Assistance Direct Payments	Other Contractual Services	Personnel Compensation & Benefits	Other	FY 2015
Medicaid	$ 375,142	$ -	$ 101	$ 17	$ 3,637	$ 378,897
Payments to Trust Funds	195,385	72	-	-	67,445	262,902
Federal Supplementary Medical Insurance Trust Fund	-	276,841	44	-	4,755	281,640
Federal Hospital Insurance Trust Fund	-	277,001	2	-	8,071	285,074
Medicare Prescription Drug Account	-	80,429	-	-	154	80,583
Taxation on OASDI Benefits, HI	20,208	-	-	-	-	20,208
Temporary Assistance for Needy Families	16,657	-	58	2	-	16,717
State Children's Health Insurance Fund	11,486	-	4	-	6	11,496
Children and Families Services Programs	10,121	-	262	143	19	10,545
Payments for Foster Care and Permanency	7,360	-	26	-	1	7,387
Transitional Reinsurance Program	-	8,249	-	-	-	8,249
National Cancer Institute	3,609	-	1,178	504	95	5,386
Indian Health Services	2,834	-	803	1,332	733	5,702
Primary Health Care	4,449	-	200	41	10	4,700
National Institute of Allergy and Infectious Diseases	3,043	-	1,492	310	83	4,928
Payments to States for Child Support Enforcement and Family Support Programs	3,637	-	710	-	-	4,347
Risk Adjustment Program Payments	-	2,141	-	-	-	2,141
Low Income Home Energy Assistance	3,392	-	3	-	-	3,395
National Heart, Lung, and Blood Institute	2,237	-	551	152	33	2,973
Child Care Entitlement to States	2,929	-	17	-	-	2,946
Medicare Health Information Technology Incentive	-	4,282	-	-	-	4,282
Payment to States for the Child Care and Development Block Grant	2,396	-	39	-	-	2,435
National Institute of General Medical Sciences	2,141	-	103	29	2	2,275
Ryan White HIV/AIDS Program	2,199	-	83	27	9	2,318
Substance Abuse Treatment	2,024	-	146	10	7	2,187
Aging and Disability Services Programs	1,850	-	35	27	4	1,916
National Institute of Diabetes and Digestive and Kidney Diseases	1,417	-	206	112	23	1,758
Health Care Fraud and Abuse Control Account	-	-	1,775	55	7	1,837
Refugee and Entrant Assistance	1,247	-	137	10	4	1,398
Public Health and Social Services Emergency Fund	455	-	1,085	119	304	1,963
Service and Supply Fund	-	-	980	261	372	1,613
National Institute of Neurological Disorders and Stroke	1,205	-	207	85	22	1,519
Social Services Block Grant	1,648	-	11	1	-	1,660
National Institute on Aging	1,094	-	151	68	16	1,329
National Institute of Mental Health	1,036	-	206	93	16	1,351
State Grants and Demonstration	524	37	65	11	50	687
National Institute of Child Health and Human Development	961	-	313	98	20	1,392
Public Health Preparedness and Response	633	-	273	104	343	1,353
HHS Service and Supply Fund	-	-	974	150	98	1,222
Centers for Medicare and Medicaid Innovation	595	63	649	61	3	1,371
Mental Health	946	-	142	4	4	1,096
CDC-Wide Activities and Program Support	605	-	332	151	115	1,203
Chronic Disease Prevention and Health Promotion	764	-	301	128	8	1,201
National Institute on Drug Abuse	723	-	222	66	13	1,024
HIV/AIDS, Viral Hepatitis, Sexually Transmitted Diseases and Tuberculosis Prevention	751	-	185	166	16	1,118
Other Agency Budgetary Accounts	11,410	3,135	12,418	6,467	2,327	35,757
Total Amounts Agreed to be Spent	$ 699,113	$ 652,250	$ 26,489	$ 10,804	$ 88,825	$ 1,477,481

FREEZE THE FOOTPRINT

For the Year Ended September 30, 2016

	Freeze the Footprint Baseline Comparison (in Square Footage)		
	2012 Baseline	2015 Year End	+/- Change
Total Leased	13,603,974	14,068,529	464,555
Total Owned	6,112,229	6,278,246	166,017
Total	19,716,203	20,346,775	630,572

	Reporting of O&M Costs - Owned and Direct Lease Buildings (in Millions)		
	2012 Baseline	2015 Year End	+/- Change
Operation and Maintenance Costs	$ 83.3	$ 92.2	$ 8.9

Per OMB Memorandum-12-12, *Promoting Efficient Spending to Support Agency Operations*, and OMB Management Procedures Memorandum 2013-02, the "Freeze the Footprint" implementing guidance, all *Chief Financial Officers Act of 1990* departments and agencies shall not increase the total square footage of their domestic office and warehouse inventory compared to the FY 2012 baseline.

Compared to the Fiscal Year (FY) 2012 Baseline, the FY 2015 HHS office and warehouse space inventory increased by 630,572 square feet or 3.0 percent; this happened because of known projects already underway and overlap between leases when relocating. This short term increase is consistent with the projections in the HHS Freeze the Footprint Plan. To reach this goal, HHS has aggressively pursued space and cost savings in office and warehouse space, implemented a 170 useable square feet per person policy, and targeted consolidation projects for both office and warehouse space.

CIVIL MONETARY PENALTY ADJUSTMENT FOR INFLATION

On November 2, 2015, the President signed into law the *Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015* (the 2015 Act) (Sec. 701 of Public Law 114-74), which further amended the *Federal Civil Penalties Inflation Adjustment Act of 1990* (Public Law 104-410), to improve the effectiveness of civil monetary penalties and to maintain their deterrent effect. Agencies must report the most recent inflationary adjustments to civil monetary penalties in order to ensure penalty adjustments are both timely and accurate.

The 2015 Act applies to eight Operating Divisions (OpDivs) and Staff Divisions (StaffDivs): ACF, AHRQ, HRSA, FDA, CMS, Office for Civil Rights, Office of the General Counsel, and Office of Inspector General. The table below illustrates HHS's civil monetary penalties by OpDivs and StaffDivs. For more information on HHS's Civil Monetary Penalties, visit www.federalregister.gov/documents/2016/09/06/2016-18680/adjustment-of-civil-monetary-penalties-for-inflation.

Administration for Children and Families				
Penalty	Statutory Authority	Date of Previous Adjustment	Date of Current Adjustment	Current Penalty Level ($ Amount)
Penalty for Misuse of Information in the National Directory of New Hires.	42 U.S.C. 653(l)(2)	1998	8/1/2016	$ 1,450

Agency for Healthcare Research and Quality				
Penalty	Statutory Authority	Date of Previous Adjustment	Date of Current Adjustment	Current Penalty Level ($ Amount)
Penalty for an establishment or person supplying information obtained in the course of activities for any purpose other than the purpose for which it was supplied.	42 U.S.C. 299c—(3)(d)	1999	8/1/2016	$ 14,140

Health Resources and Services Administration				
Penalty	Statutory Authority	Date of Previous Adjustment	Date of Current Adjustment	Current Penalty Level ($ Amount)
Penalty for each instance of overcharging a 340B covered entity.	42 U.S.C. 256b(d)(1)(B)(vi)	2010	8/1/2016	$ 5,437

Office for Civil Rights				
Penalty	Statutory Authority	Date of Previous Adjustment	Date of Current Adjustment	Current Penalty Level ($ Amount)
Penalty for violation of confidentiality provision of the *Patient Safety and Quality Improvement Act*.	42 U.S.C. 299b-22(f)(1)	2005	8/1/2016	$ 11,940
Penalty for each pre-February 18, 2009 violation of the HIPAA administrative simplification provisions.	42 U.S.C. 1320(d)-5(a)	1996	8/1/2016	150
Calendar Year Cap		1996	8/1/2016	37,561
Penalty for each February 18, 2009 or later violation of a HIPAA administrative simplification provision in which it is established that the covered entity or business associate did not know and by exercising reasonable diligence, would not have known that the covered entity or business associate violated such a provision.			8/1/2016	
Minimum		2009	8/1/2016	110
Maximum		2009	8/1/2016	55,010
Calendar Year Cap		2009	8/1/2016	1,650,300

Penalty	Statutory Authority	Date of Previous Adjustment	Date of Current Adjustment	Current Penalty Level ($ Amount)
Penalty for each February 18, 2009 or later violation of a HIPAA administrative simplification provision in which it is established that the violation was due to reasonable cause and not to willful neglect.	42 U.S.C. 1320(d)-5(a)		8/1/2016	
Minimum		2009	8/1/2016	1100
Maximum		2009	8/1/2016	55,010
Calendar Year Cap		2009	8/1/2016	1,650,300
Penalty for each February 18, 2009 or later violation of a HIPAA administrative simplification provision in which it is established that the violation was due to willful neglect and was corrected during the 30-day period beginning on the first date the covered entity or business associate knew, or, by exercising reasonable diligence, would have known that the violation occurred.			8/1/2016	
Minimum		2009	8/1/2016	11,002
Maximum		2009	8/1/2016	55,010
Calendar Year Cap		2009	8/1/2016	1,650,300
Penalty for each February 18, 2009 or later violation of a HIPAA administrative simplification provision in which it is established that the violation was due to willful neglect and was not corrected during the 30-day period beginning on the first date the covered entity or business associate knew, or by exercising reasonable diligence, would have known that the violation occurred.			8/1/2016	
Minimum		2009	8/1/2016	55,010
Maximum		2009	8/1/2016	1,650,300
Calendar Year Cap		2009	8/1/2016	1,650,300

Office of the General Counsel				
Penalty	Statutory Authority	Date of Previous Adjustment	Date of Current Adjustment	Current Penalty Level ($ Amount)
Penalty for the first time an individual makes an expenditure prohibited by regulations regarding lobbying disclosure, absent aggravating circumstances.	31 U.S.C. 1352	1989	8/1/2016	$ 18,936
Penalty for second and subsequent offenses by individuals who make an expenditure prohibited by regulations regarding lobbying disclosure.			8/1/2016	
Minimum		1989	8/1/2016	18,936
Maximum		1989	8/1/2016	189,361
Penalty for the first time an individual fails to file or amend a lobbying disclosure form, absent aggravating circumstances.		1989	8/1/2016	18,936
Penalty for second and subsequent offenses by individuals who fail to file or amend a lobbying disclosure form, absent aggravating circumstances.			8/1/2016	
Minimum		1989	8/1/2016	18,936
Maximum		1989	8/1/2016	189,361

CIVIL MONETARY PENALTY ADJUSTMENT FOR INFLATION

Penalty	Statutory Authority	Date of Previous Adjustment	Date of Current Adjustment	Current Penalty Level ($ Amount)
Penalty for failure to provide certification regarding lobbying in the award documents for all sub-awards of all tiers.	31 U.S.C. 1352		8/1/2016	
Minimum		1989	8/1/2016	18,936
Maximum		1989	8/1/2016	189,361
Penalty for failure to provide statement regarding lobbying for loan guarantee and loan insurance transactions.			8/1/2016	
Minimum		1989	8/1/2016	18,936
Maximum		1989	8/1/2016	189,361
Penalty against any individual who - with knowledge or reason to know - makes, presents or submits a false, fictitious or fraudulent claim to the Department	31 U.S.C. 3801-3812	1988	8/1/2016	9,894
Penalty against any individual who - with knowledge or reason to know - makes, presents or submits a false, fictitious or fraudulent claim to the Department		1988	8/1/2016	9,894

Office of Inspector General

Penalty	Statutory Authority	Date of Previous Adjustment	Date of Current Adjustment	Current Penalty Level ($ Amount)
Penalty for each individual who violates safety and security procedures related to handling dangerous biological agents and toxins.	42 U.S.C. 262a(i)(1)	2002	8/1/2016	$ 327,962
Penalty for any other person who violates safety and security procedures related to handling dangerous biological agents and toxins.		2002	8/1/2016	655,925
Penalty for knowingly presenting or causing to be presented to an officer, employee, or agent of the United States a false claim.	42 U.S.C. 1320a-7a(a)	1996	8/1/2016	15,024
Penalty for knowingly presenting or causing to be presented a request for payment which violates the terms of an assignment, agreement, or PPS agreement.		1996	8/1/2016	15,024
Penalty for knowingly giving or causing to be presented to a participating provider or supplier false or misleading information that could reasonably be expected to influence a discharge decision.		1996	8/1/2016	22,537
Penalty for an excluded party retaining ownership or control interest in a participating entity.		1996	8/1/2016	15,024
Penalty for remuneration offered to induce program beneficiaries to use particular providers, practitioners, or suppliers.		1996	8/1/2016	15,024
Penalty for employing or contracting with an excluded individual.		1997	8/1/2016	14,718
Penalty for knowing and willful solicitation, receipt, offer, or payment of remuneration for referring an individual for a service or for purchasing, leasing, or ordering an item to be paid for by a Federal health care program.		1997	8/1/2016	73,588

CIVIL MONETARY PENALTY ADJUSTMENT FOR INFLATION

Penalty	Statutory Authority	Date of Previous Adjustment	Date of Current Adjustment	Current Penalty Level ($ Amount)
Penalty for ordering or prescribing medical or other item or service during a period in which the person was excluded.	42 U.S.C. 1320a-7a(a)	2010	8/1/2016	10,874
Penalty for knowingly making or causing to be made a false statement, omission or misrepresentation of a material fact in any application, bid, or contract to participate or enroll as a provider or supplier.		2010	8/1/2016	54,372
Penalty for knowing of an overpayment and failing to report and return.		2010	8/1/2016	10,874
Penalty for making or using a false record or statement that is material to a false or fraudulent claim		2010	8/1/2016	54,372
Penalty for failure to grant timely access to HHS OIG for audits, investigations, evaluations, and other statutory functions of HHS OIG.		2010	8/1/2016	16,312
Penalty for payments by a hospital or critical access hospital to induce a physician to reduce or limit services to individuals under direct care of physician or who are entitled to certain medical assistance benefits.	42 U.S.C. 1320a-7a(b)	1986	8/1/2016	4,313
Penalty for physicians who knowingly receive payments from a hospital or critical access hospital to induce such physician to reduce or limit services to individuals under direct care of physician or who are entitled to certain medical assistance benefits.		1986	8/1/2016	4,313
Penalty for a physician who executes a document that falsely certifies home health needs for Medicare beneficiaries.		1996	8/1/2016	7,512
Penalty for failure to report any final adverse action taken against a health care provider, supplier, or practitioner.	42 U.S.C. 1320a-7e(b)(6)(A)	1997	8/1/2016	36,794
Penalty for the misuse of words, symbols, or emblems in communications in a manner in which a person could falsely construe that such item is approved, endorsed, or authorized by HHS.	42 U.S.C. 1320b-10(b)(1)	1988	8/1/2016	9,893
Penalty for the misuse of words, symbols, or emblems in a broadcast or telecast in a manner in which a person could falsely construe that such item is approved, endorsed, or authorized by HHS.	42 U.S.C. 1320b-10(b)(2)	1988	8/1/2016	49,467
Penalty for certification of a false statement in assessment of functional capacity of a Skilled Nursing Facility resident assessment.	42 U.S.C. 1395i-3(b)(3)(B)(ii)(1)	1987	8/1/2016	2,063
Penalty for causing another to certify or make a false statement in assessment of functional capacity of a Skilled Nursing Facility resident assessment.	42 U.S.C. 1395i-3(b)(3)(B)(ii)(2)	1987	8/1/2016	10,314
Penalty for any individual who notifies or causes to be notified a Skilled Nursing Facility of the time or date on which a survey is to be conducted.	42 U.S.C. 1395i-3(g)(2)(A)	1987	8/1/2016	4,126
Penalty for a Medicare Advantage organization that substantially fails to provide medically necessary, required items and services.	42 U.S.C. 1395w-27(g)(2)(A)	1996	8/1/2016	37,561

CIVIL MONETARY PENALTY ADJUSTMENT FOR INFLATION

Penalty	Statutory Authority	Date of Previous Adjustment	Date of Current Adjustment	Current Penalty Level ($ Amount)
Penalty for a Medicare Advantage organization that charges excessive premiums.	42 U.S.C. 1395w-27(g)(2)(A)	1997	8/1/2016	36,794
Penalty for a Medicare Advantage organization that improperly expels or refuses to reenroll a beneficiary.		1997	8/1/2016	36,794
Penalty for a Medicare Advantage organization that engages in practice that would reasonably be expected to have the effect of denying or discouraging enrollment.		1997	8/1/2016	147,177
Penalty per individual who does not enroll as a result of a Medicare Advantage organization's practice that would reasonably be expected to have the effect of denying or discouraging enrollment.		1997	8/1/2016	22,077
Penalty for a Medicare Advantage organization misrepresenting or falsifying information to Secretary.		1997	8/1/2016	147,177
Penalty for a Medicare Advantage organization misrepresenting or falsifying information to individual or other entity.		1997	8/1/2016	36,794
Penalty for Medicare Advantage organization interfering with provider's advice to enrollee and non-MCO affiliated providers that balance bill enrollees.		1997	8/1/2016	36,794
Penalty for a Medicare Advantage organization that employs or contracts with excluded individual or entity.		1997	8/1/2016	36,794
Penalty for a Medicare Advantage organization enrolling an individual in without prior written consent.		2010	8/1/2016	36,794
Penalty for a Medicare Advantage organization transferring an enrollee to another plan without consent or solely for the purpose of earning a commission.		2010	8/1/2016	36,794
Penalty for a Medicare Advantage organization failing to comply with marketing restrictions or applicable implementing regulations or guidance.		2010	8/1/2016	36,794
Penalty for a Medicare Advantage organization employing or contracting with an individual or entity who violates 1395w-27(g)(1)(A)-(J).		2010	8/1/2016	36,794
Penalty for a prescription drug card sponsor that falsifies or misrepresents marketing materials, overcharges program enrollees, or misuse transitional assistance funds.	42 U.S.C. 1395w-141(i)(3)	2003	8/1/2016	12,856
Penalty for improper billing by Hospitals, Critical Access Hospitals, or Skilled Nursing Facilities.	42 U.S.C. 1395cc(g)	1972	8/1/2016	5,000
Penalty for a hospital or responsible physician dumping patients needing emergency medical care, if the hospital has 100 beds or more.	42 U.S.C. 1395dd(d)(1)	1987	8/1/2016	103,139
Penalty for a hospital or responsible physician dumping patients needing emergency care, if the hospital has less than 100 beds.		1987	8/1/2016	51,570

CIVIL MONETARY PENALTY ADJUSTMENT FOR INFLATION

Penalty	Statutory Authority	Date of Previous Adjustment	Date of Current Adjustment	Current Penalty Level ($ Amount)
Penalty for a HMO or competitive plan is such plan substantially fails to provide medically necessary, required items or services	42 U.S.C. 1395mm(i)(6)(B)(i)	1987	8/1/2016	51,570
Penalty for HMOs/competitive medical plans that charge premiums in excess of permitted amounts		1987	8/1/2016	51,570
Penalty for a HMO or competitive medical plan that expels or refuses to reenroll an individual per prescribed conditions		1987	8/1/2016	51,570
Penalty for a HMO or competitive medical plan that implements practices to discourage enrollment of individuals needing services in future.		1987	8/1/2016	206,278
Penalty per individual not enrolled in a plan as a result of a HMO or competitive medical plan that implements practices to discourage enrollment of individuals needing services in the future.		1988	8/1/2016	29,680
Penalty for a HMO or competitive medical plan that misrepresents or falsifies information to the Secretary.		1987	8/1/2016	206,278
Penalty for a HMO or competitive medical plan that misrepresents or falsifies information to an individual or any other entity.		1987	8/1/2016	51,570
Penalty for failure by HMO or competitive medical plan to assure prompt payment of Medicare risk sharing contracts or incentive plan provisions.		1987	8/1/2016	51,570
Penalty for HMO that employs or contracts with excluded individual or entity.		1989	8/1/2016	47,340
Penalty for submitting or causing to be submitted claims in violation of the Stark Law's restrictions on physician self-referrals.	42 U.S.C. 1395nn(g)(3)	1994	8/1/2016	23,863
Penalty for circumventing Stark Law's restrictions on physician self-referrals.	42 U.S.C. 1395nn(g)(4)	1994	8/1/2016	159,089
Penalty for a material misrepresentation regarding Medigap compliance policies.	42 U.S.C. 1395ss(d)(1)	1988	8/1/2016	9,893
Penalty for selling Medigap policy under false pretense.	42 U.S.C. 1395ss(d)(2)	1988	8/1/2016	9,893
Penalty for an issuer that sells health insurance policy that duplicates benefits.	42 U.S.C. 1395ss(d)(3)(A)(ii)	1990	8/1/2016	44,539
Penalty for someone other than issuer that sells health insurance that duplicates benefits.		1990	8/1/2016	26,723
Penalty for using mail to sell a non-approved Medigap insurance policy.	42 U.S.C. 1395ss(d)(4)(A)	1988	8/1/2016	9,893
Penalty for a Medicaid MCO that substantially fails to provide medically necessary, required items or services.	42 U.S.C. 1396b(m)(5)(B)(i)	1988	8/1/2016	49,467

CIVIL MONETARY PENALTY ADJUSTMENT FOR INFLATION

Penalty	Statutory Authority	Date of Previous Adjustment	Date of Current Adjustment	Current Penalty Level ($ Amount)
Penalty for a Medicaid MCO that charges excessive premiums.	42 U.S.C. 1396b(m)(5)(B)(i)	1988	8/1/2016	49,467
Penalty for a Medicaid MCO that improperly expels or refuses to reenroll a beneficiary.		1988	8/1/2016	197,869
Penalty per individual who does not enroll as a result of a Medicaid MCO's practice that would reasonably be expected to have the effect of denying or discouraging enrollment.		1988	8/1/2016	29,680
Penalty for a Medicaid MCO misrepresenting or falsifying information to the Secretary.		1988	8/1/2016	197,869
Penalty for a Medicaid MCO misrepresenting or falsifying information to an individual or another entity.		1988	8/1/2016	49,467
Penalty for a Medicaid MCO that fails to comply with contract requirements with respect to physician incentive plans.		1990	8/1/2016	44,539
Penalty for willfully and knowingly certifying a material and false statement in a Skilled Nursing Facility resident assessment.	42 U.S.C. 1396r(b)(3)(B)(ii)(I)	1987	8/1/2016	2,063
Penalty for willfully and knowingly causing another individual to certify a material and false statement in a Skilled Nursing Facility resident assessment.	42 U.S.C. 1396r(b)(3)(B)(ii)(II)	1987	8/1/2016	10,314
Penalty for notifying or causing to be notified a Skilled Nursing Facility of the time or date on which a survey is to be conducted.	42 U.S.C. 1396r(g)(2)(A)(i)	1987	8/1/2016	4,126
Penalty for the knowing provision of false information or refusing to provide information about charges or prices of a covered outpatient drug.	42 U.S.C. 1396r-8(b)(3)(B)	1990	8/1/2016	178,156
Penalty per day for failure to timely provide information by drug manufacturer with rebate agreement.	42 U.S.C. 1396r-8(b)(3)(C)(i)	1990	8/1/2016	17,816
Penalty for knowing provision of false information by drug manufacturer with rebate agreement.	42 U.S.C. 1396r-8(b)(3)(C)(ii)	1990	8/1/2016	178,156
Penalty for notifying home and community-based providers or settings of survey.	42 U.S.C. 1396t(i)(3)(A)	1990	8/1/2016	3,563
Penalty for failing to report a medical malpractice claim to National Practitioner Data Bank.	42 U.S.C. 11131(c)	1986	8/1/2016	21,563
Penalty for breaching confidentiality of information reported to National Practitioner Data Bank.	42 U.S.C. 11137(b)(2)	1986	8/1/2016	21,563

Food and Drug Administration

Penalty	Statutory Authority	Date of Previous Adjustment	Date of Current Adjustment	Current Penalty Level ($ Amount)
Penalty for violations related to drug samples resulting in a conviction of any representative of manufacturer or distributor in any 10-year period.	21 U.S.C. 333(b)(2)(A)	1988	8/1/2016	$ 98,935

CIVIL MONETARY PENALTY ADJUSTMENT FOR INFLATION

Penalty	Statutory Authority	Date of Previous Adjustment	Date of Current Adjustment	Current Penalty Level ($ Amount)
Penalty for violation related to drug samples resulting in a conviction of any representative of manufacturer or distributor after the second conviction in any 10-yr period.	21 U.S.C. 333(b)(2)(B)	1988	8/1/2016	1,978,690
Penalty for failure to make a report required by 21 U.S.C. 353(d)(3)(E) relating to drug samples.	21 U.S.C 333(b)(3)	1988	8/1/2016	197,869
Penalty for any person who violates a requirement related to devices for each such violation.	21 U.S.C 333(f)(1)(A)	1990	8/1/2016	26,723
Penalty for aggregate of all violations related to devices in a single proceeding.		1990	8/1/2016	1,781,560
Penalty for any individual who introduces or delivers for introduction into interstate commerce food that is adulterated per 21 U.S.C. 342(a)(2)(B) or any individual who does not comply with a recall order under 21 U.S.C. 350l.	21 U.S.C 333(f)(2)(A)	1996	8/1/2016	75,123
Penalty in the case of any other person other than an individual) for such introduction or delivery of adulterated food.		1996	8/1/2016	375,613
Penalty for aggregate of all such violations related to adulterated food adjudicated in a single proceeding.		1996	8/1/2016	751,225
Penalty for all violations adjudicated in a single proceeding for any person who fails to submit certification required by 42 U.S.C. 282(j)(5)(B) or knowingly submitting a false certification.	21 U.S.C 333(f)(3)(A)	2007	8/1/2016	11,383
Penalty for all violations adjudicated in a single proceeding for any person who violates 21 U.S.C. 331(jj)(1) by failing to submit the certification required by 42 U.S.C. 282(j)(5)(B) or knowingly submitting a false certification; by failing to submit clinical trial information under 42 U.S.C 282(j); or by submitting clinical trial information under 42 U.S.C. 282(j) that is false or misleading in any particular under 42 U.S.C. 282(j)(5)(D).	21 U.S.C 333(f)(3)(B)	2007	8/1/2016	11,383
Penalty for any responsible person that violates a requirement of 21 U.S.C. 355(o) (post-marketing studies, clinical trials, labeling), 21 U.S.C. 355(p) (risk evaluation and mitigation (REMS)), or 21 U.S.C. 355-1 (REMS).	21 U.S.C 333(f)(4)(A)(i)	2007	8/1/2016	284,583
Penalty for aggregate of all such above violations in a single proceeding.		2007	8/1/2016	1,138,330
Penalty for REMS violation that continues after written notice to the responsible person for the first 30–day period (or any portion thereof) the responsible person continues to be in violation.	21 U.S.C 333(f)(4)(A)(ii)	2007	8/1/2016	284,583
Penalty for REMS violation that continues after written notice to responsible person doubles for every 30–day period thereafter the violation continues, but may not exceed penalty amount for any 30–day period.		2007	8/1/2016	1,138,330
Penalty for aggregate of all such above violations adjudicated in a single proceeding.		2007	8/1/2016	11,383,300
Penalty for any person who violates a requirement which relates to tobacco products for each such violation	21 U.S.C 333(f)(9)(A)	2009	8/1/2016	16,503
Penalty for aggregate of all such violations of tobacco product requirement adjudicated in a single proceeding.		2009	8/1/2016	1,100,200
Penalty per violation related to violations of tobacco requirements.	21 U.S.C 333(f)(9)(B)(i)(I)	2009	8/1/2016	275,050
Penalty for aggregate of all such violations of tobacco product requirements adjudicated in a single proceeding.		2009	8/1/2016	1,100,200
Penalty in the case of a violation of tobacco product requirements that continues after written notice to such person, for the first 30–day period (or any portion thereof) the person continues to be in violation.	21 U.S.C 333(f)(9)(B)(i)(II)	2009	8/1/2016	275,050

CIVIL MONETARY PENALTY ADJUSTMENT FOR INFLATION

Penalty	Statutory Authority	Date of Previous Adjustment	Date of Current Adjustment	Current Penalty Level ($ Amount)
Penalty for violation of tobacco product requirements that continues after written notice to such person shall double for every 30–day period thereafter the violation continues, but may not exceed penalty amount for any 30–day period.	21 U.S.C 333(f)(9)(B)(i)(II)	2009	8/1/2016	1,100,200
Penalty for aggregate of all such violations related to tobacco product requirements adjudicated in a single proceeding.		2009	8/1/2016	11,002,000
Penalty for any person who either does not conduct post-market surveillance and studies to determine impact of a modified risk tobacco product for which the HHS Secretary has provided them an order to sell, or who does not submit a protocol to the HHS Secretary after being notified of a requirement to conduct post-market surveillance of such tobacco products.	21 U.S.C 333(f)(9)(B)(ii)(I)	2009	8/1/2016	275,050
Penalty for aggregate of for all such above violations adjudicated in a single proceeding.		2009	8/1/2016	1,100,200
Penalty for violation of modified risk tobacco product post-market surveillance that continues after written notice to such person for the first 30–day period (or any portion thereof) that the person continues to be in violation.	21 U.S.C 333(f)(9)(B)(ii)(II)	2009	8/1/2016	275,050
Penalty for post-notice violation of modified risk tobacco product post-market surveillance shall double for every 30–day period thereafter that the tobacco product requirement violation continues for any 30–day period, but may not exceed penalty amount for any 30–day period.		2009	8/1/2016	1,100,200
Penalty for aggregate above tobacco product requirement violations adjudicated in a single proceeding.		2009	8/1/2016	11,002,000
Penalty for any person who disseminates or causes another party to disseminate a direct-to-consumer advertisement that is false or misleading for the first such violation in any 3–year period.	21 U.S.C 333(g)(1)	2007	8/1/2016	284,583
Penalty for each subsequent above violation in any 3–year period.		2007	8/1/2016	569,165
Penalty to be applied for violations of restrictions on the sale or distribution of tobacco products promulgated under 21 U.S.C. 387f(d) (e.g., violations of regulations in 21 CFR Part 1140) with respect to a retailer with an approved training program in the case of a second regulation violation within a 12–month period.	21 U.S.C 333 note	2009	8/1/2016	275
Penalty in the case of a third tobacco product regulation violation within a 24–month period.		2009	8/1/2016	550
Penalty in the case of a fourth tobacco product regulation violation within a 24–month period.		2009	8/1/2016	2,200
Penalty in the case of a fifth tobacco product regulation violation within a 36–month period.		2009	8/1/2016	5,501
Penalty in the case of a sixth or subsequent tobacco product regulation violation within a 48–month period as determined on a case-by-case basis.	21 U.S.C 333 note	2009	8/1/2016	11,002
Penalty to be applied for violations of restrictions on the sale or distribution of tobacco products promulgated under 21 U.S.C. 387f(d) (e.g., violations of regulations in 21 CFR Part 1140) with respect to a retailer that does not have an approved training program in the case of the first regulation violation.		2009	8/1/2016	275
Penalty in the case of a second tobacco product regulation violation within a 12-month period.		2009	8/1/2016	550

CIVIL MONETARY PENALTY ADJUSTMENT FOR INFLATION

Penalty	Statutory Authority	Date of Previous Adjustment	Date of Current Adjustment	Current Penalty Level ($ Amount)
Penalty in the case of a third tobacco product regulation violation within a 24–month period.	21 U.S.C 333 note	2009	8/1/2016	1,100
Penalty in the case of a fourth tobacco product regulation violation within a 24–month period.		2009	8/1/2016	2,200
Penalty in the case of a fifth tobacco product regulation violation within a 36–month period.		2009	8/1/2016	5,501
Penalty in the case of a sixth or subsequent tobacco product regulation violation within a 48–month period as determined on a case-by-case basis.		2009	8/1/2016	11,002
Penalty for each violation for any individual who made a false statement or misrepresentation of a material fact, bribed, destroyed, altered, removed, or secreted, or procured the destruction, alteration, removal, or secretion of, any material document, failed to disclose a material fact, obstructed an investigation, employed a consultant who was debarred, debarred individual provided consultant services.	21 U.S.C 335b(a)	1992	8/1/2016	419,320
Penalty in the case of any other person (other than an individual) per above violation.		1992	8/1/2016	1,677,280
Penalty for any person who violates any such requirements for electronic products, with each unlawful act or omission constituting a separate violation.	21 U.S.C 360pp(b)(1)	1968	8/1/2016	2,750
Penalty imposed for any related series of violations of requirements relating to electronic products.		1968	8/1/2016	937,500
Penalty per day for violation of order of recall of biological product presenting imminent or substantial hazard.	42 U.S.C. 262(d)	1986	8/1/2016	215,628
Penalty for failure to obtain a mammography certificate as required.	42 U.S.C.263b(h)(3)	1992	8/1/2016	16,773
Penalty per occurrence for any vaccine manufacturer that intentionally destroys, alters, falsifies, or conceals any record or report required.	42 U.S.C. 300aa-28(b)(1)	1986	8/1/2016	215,628

Centers for Medicare & Medicaid Services				
Penalty	Statutory Authority	Date of Previous Adjustment	Date of Current Adjustment	Current Penalty Level ($ Amount)
Penalty for a clinical laboratory's failure to meet participation and certification requirements and poses immediate jeopardy.	42 U.S.C. 263a(h)(2)(B) & 42 U.S.C. 1395w-2(b)(2)(A)(ii)		8/1/2016	
Minimum		1988	8/1/2016	$ 6,035
Maximum		1988	8/1/2016	19,787
Penalty for a clinical laboratory's failure to meet participation and certification requirements and the failure does not pose immediate jeopardy.			8/1/2016	
Minimum		1988	8/1/2016	99
Maximum		1988	8/1/2016	5,936
Failure to provide the Summary of Benefits and Coverage (SBC)	42 U.S.C. 300gg-15(f)	2010	8/1/2016	1,087
Penalty for violations of regulations related to the medical loss ratio reporting and rebating.	42 U.S.C. 300gg-18	2010	8/1/2016	109
Penalty for manufacturer or group purchasing organization failing to report information required under 42 USC 1320a-7h(a), relating to physician ownership or investment interests	42 U.S.C. 1320a-7h(b)(1)		8/1/2016	
Minimum		2010	8/1/2016	1,087
Maximum		2010	8/1/2016	10,874
Calendar Year Cap		2010	8/1/2016	163,117

CIVIL MONETARY PENALTY ADJUSTMENT FOR INFLATION

Penalty	Statutory Authority	Date of Previous Adjustment	Date of Current Adjustment	Current Penalty Level ($ Amount)
Penalty for manufacturer or group purchasing organization knowingly failing to report information required under 42 USC 1320a-7h(a) , relating to physician ownership or investment interests	42 U.S.C. 1320a-7h(b)(2)		8/1/2016	
Minimum		2010	8/1/2016	10,874
Maximum		2010	8/1/2016	108,745
Calendar Year Cap		2010	8/1/2016	1,087,450
Penalty for an administrator of a facility that fails to comply with notice requirements for the closure of a facility.	42 U.S.C. 1320a-7j(h)(3)(A)	2010	8/1/2016	108,745
Minimum penalty for the first offense of an administrator who fails to provide notice of facility closure.		2010	8/1/2016	544
Minimum penalty for the second offense of an administrator who fails to provide notice of facility closure.		2010	8/1/2016	1,631
Minimum penalty for the third and subsequent offenses of an administrator who fails to provide notice of facility closure.		2010	8/1/2016	3,262
Penalty for an entity knowingly making a false statement or representation of material fact in the determination of the amount of benefits or payments related to old-age, survivors, and disability insurance benefits, special benefits for certain World War II veterans, or supplemental security income for the aged, blind, and disabled.	42 U.S.C. 1320a-8(a)(1)	1994	8/1/2016	7,954
Penalty for the violation of 42 USC 1320a-8a(1) if the violator is a person who receives a fee or other income for services performed in connection with determination of the benefit amount or the person is a physician or other health care provider who submits evidence in connection with such a determination.		2015	8/1/2016	7,500
Penalty for a representative payee (under 42 USC 405(j), 1007, or 1383(a)(2)) converting any part of a received payment from the benefit programs described in the previous civil monetary penalty to a use other than for the benefit of the beneficiary.	42 U.S.C. 1320a-8(a)(3)	2004	8/1/2016	6,229
Penalty for failure of covered individuals to report to the Secretary and 1 or more law enforcement officials any reasonable suspicion of a crime against a resident, or individual receiving care, from a long-term care facility.	42 U.S.C. 1320b-25(c)(1)(A)	2010	8/1/2016	217,490
Penalty for failure of covered individuals to report to the Secretary and 1 or more law enforcement officials any reasonable suspicion of a crime against a resident, or individual receiving care, from a long-term care facility if such failure exacerbates the harm to the victim of the crime or results in the harm to another individual.	42 U.S.C. 1320b-25(c)(2)(A)	2010	8/1/2016	326,235
Penalty for a long-term care facility that retaliates against any employee because of lawful acts done by the employee, or files a complaint or report with the State professional disciplinary agency against an employee or nurse for lawful acts done by the employee or nurse.	42 U.S.C. 1320b-25(d)(2)	2010	8/1/2016	217,490
Penalty for any person who knowingly and willfully fails to furnish a beneficiary with an itemized statement of items or services within 30 days of the beneficiary's request.	42 U.S.C. 1395b-7(b)(2)(B)	1997	8/1/2016	147
Penalty per day for a Skilled Nursing Facility that has a Category 2 violation of certification requirements.	42 U.S.C. 1395i-3(h)(2)(B)(ii)(I)		8/1/2016	
Minimum		1987	8/1/2016	103
Maximum		1987	8/1/2016	6,188

CIVIL MONETARY PENALTY ADJUSTMENT FOR INFLATION

Penalty	Statutory Authority	Date of Previous Adjustment	Date of Current Adjustment	Current Penalty Level ($ Amount)
Penalty per instance of Category 2 noncompliance by a Skilled Nursing Facility.	42 U.S.C. 1395i-3(h)(2)(B)(ii)(I)		8/1/2016	
Minimum		1987	8/1/2016	2,063
Maximum		1987	8/1/2016	20,628
Penalty per day for a Skilled Nursing Facility that has a Category 3 violation of certification requirements.			8/1/2016	
Minimum		1987	8/1/2016	6,291
Maximum		1987	8/1/2016	20,628
Penalty per instance of Category 3 noncompliance by a Skilled Nursing Facility.			8/1/2016	
Minimum		1987	8/1/2016	2,063
Maximum		1987	8/1/2016	20,628
Penalty per day and per instance for a Skilled Nursing Facility that has Category 3 noncompliance with Immediate Jeopardy			8/1/2016	
Per Day (Minimum)		1987	8/1/2016	6,291
Per Day (Maximum)		1987	8/1/2016	20,628
Per Instance (Minimum)		1987	8/1/2016	2,063
Per Instance (Maximum)		1987	8/1/2016	20,628
Penalty per day of a Skilled Nursing Facility that fails to meet certification requirements. These amounts represent the upper range per day.			8/1/2016	
Minimum		1987	8/1/2016	6,291
Maximum		1987	8/1/2016	20,628
Penalty per day of a Skilled Nursing Facility that fails to meet certification requirements. These amounts represent the lower range per day.			8/1/2016	
Minimum		1987	8/1/2016	103
Maximum		1987	8/1/2016	6,188
Penalty per instance of a Skilled Nursing Facility that fails to meet certification requirements.			8/1/2016	
Minimum		1987	8/1/2016	2,063
Maximum		1987	8/1/2016	20,628
Penalty for knowingly, willfully, and repeatedly billing for a clinical diagnostic laboratory test other than on an assignment-related basis. (Penalties are assessed in the same manner as 42 USC 1395u(j)(2)(B), which is assessed according to 1320a-7a(a)).	42 U.S.C. 1395l(h)(5)(D)	1996	8/1/2016	15,024
Penalty for knowingly and willfully presenting or causing to be presented a bill or request for payment for an intraocular lens inserted during or after cataract surgery for which the Medicare payment rate includes the cost of acquiring the class of lens involved.	42 U.S.C. 1395l(i)(6)	1988	8/1/2016	3,957
Penalty for knowingly and willfully failing to provide information about a referring physician when seeking payment on an unassigned basis.	42 U.S.C. 1395l(q)(2)(B)(i)	1989	8/1/2016	3,787
Penalty for any durable medical equipment supplier that knowingly and willfully charges for a covered service that is furnished on a rental basis after the rental payments may no longer be made. (Penalties are assessed in the same manner as 42 USC 1395u(j)(2)(B), which is assessed according to 1320a-7a(a)).	42 U.S.C. 1395m(a)(11)(A)	1996	8/1/2016	15,024

CIVIL MONETARY PENALTY ADJUSTMENT FOR INFLATION

Penalty	Statutory Authority	Date of Previous Adjustment	Date of Current Adjustment	Current Penalty Level ($ Amount)
Penalty for any nonparticipating durable medical equipment supplier that knowingly and willfully fails to make a refund to Medicare beneficiaries for a covered service for which payment is precluded due to an unsolicited telephone contact from the supplier. (Penalties are assessed in the same manner as 42 USC 1395u(j)(2)(B), which is assessed according to 1320a-7a(a)).	42 U.S.C. 1395m(a)(18)(B)	1996	8/1/2016	15,024
Penalty for any nonparticipating physician or supplier that knowingly and willfully charges a Medicare beneficiary more than the limiting charge for radiologist services. (Penalties are assessed in the same manner as 42 USC 1395u(j)(2)(B), which is assessed according to 1320a-7a(a)).	42 U.S.C. 1395m(b)(5)(C)	1996	8/1/2016	15,024
Penalty for any supplier of prosthetic devices, orthotics, and prosthetics that knowing and willfully charges for a covered prosthetic device, orthotic, or prosthetic that is furnished on a rental basis after the rental payment may no longer be made. (Penalties are assessed in the same manner as 42 USC 1395m(a)(11)(A), that is in the same manner as 1395u(j)(2)(B), which is assessed according to 1320a-7a(a)).	42 U.S.C. 1395m(h)(3)	1996	8/1/2016	15,024
Penalty for any supplier of durable medical equipment including a supplier of prosthetic devices, prosthetics, orthotics, or supplies that knowingly and willfully distributes a certificate of medical necessity in violation of Section 1834(j)(2)(A)(i) of the Act or fails to provide the information required under Section 1834(j)(2)(A)(ii) of the Act.	42 U.S.C. 1395m(j)(2)(A)(iii)	1994	8/1/2016	1,591
Penalty for any supplier of durable medical equipment, including a supplier of prosthetic devices, prosthetics, orthotics, or supplies that knowingly and willfully fails to make refunds in a timely manner to Medicare beneficiaries for series billed other than on as assignment-related basis under certain conditions. (Penalties are assessed in the same manner as 42 USC 1395m(j)(4) and 1395u(j)(2)(B), which is assessed according to 1320a-7a(a)).	42 U.S.C. 1395m(j)(4)	1996	8/1/2016	15,024
Penalty for any person or entity who knowingly and willfully bills or collects for any outpatient therapy services or comprehensive outpatient rehabilitation services on other than an assignment-related basis. (Penalties are assessed in the same manner as 42 USC 1395m(k)(6) and 1395u(j)(2)(B), which is assessed according to 1320a-7a(a)).	42 U.S.C. 1395m(k)(6)	1996	8/1/2016	15,024
Penalty for any supplier of ambulance services who knowingly and willfully fills or collects for any services on other than an assignment-related basis. (Penalties are assessed in the same manner as 42 USC 1395u(b)(18)(B), which is assessed according to 1320a-7a(a)).	42 U.S.C. 1395m(l)(6)	1996	8/1/2016	15,024
Penalty for any practitioner specified in Section 1842(b)(18)(C) of the Act or other person that knowingly and willfully bills or collects for any services by the practitioners on other than an assignment-related basis. (Penalties are assessed in the same manner as 42 USC 1395u(j)(2)(B), which is assessed according to 1320a-7a(a)).	42 U.S.C. 1395u(b)(18)(B)	1996	8/1/2016	15,024
Penalty for any physician who charges more than 125% for a non-participating referral. (Penalties are assessed in the same manner as 42 USC 1320a-7a(a)).	42 U.S.C. 1395u(j)(2)(B)	1996	8/1/2016	15,024

CIVIL MONETARY PENALTY ADJUSTMENT FOR INFLATION

Penalty	Statutory Authority	Date of Previous Adjustment	Date of Current Adjustment	Current Penalty Level ($ Amount)
Penalty for any physician who knowingly and willfully presents or causes to be presented a claim for bill for an assistant at a cataract surgery performed on or after March 1, 1987, for which payment may not be made because of section 1862(a)(15). (Penalties are assessed in the same manner as 42 USC 1395u(j)(2)(B), which is assessed according to 1320a-7a(a)).	42 U.S.C. 1395u(k)	1996	8/1/2016	15,024
Penalty for any nonparticipating physician who does not accept payment on an assignment-related basis and who knowingly and willfully fails to refund on a timely basis any amounts collected for services that are not reasonable or medically necessary or are of poor quality under 1842(l)(1)(A). (Penalties are assessed in the same manner as 42 USC 1395u(j)(2)(B), which is assessed according to 1320a-7a(a)).	42 U.S.C. 1395u(l)(3)	1996	8/1/2016	15,024
Penalty for any nonparticipating physician charging more than $500 who does not accept payment for an elective surgical procedure on an assignment related basis and who knowingly and willfully fails to disclose the required information regarding charges and coinsurance amounts and fails to refund on a timely basis any amount collected for the procedure in excess of the charges recognized and approved by the Medicare program. (Penalties are assessed in the same manner as 42 USC 1395u(j)(2)(B), which is assessed according to 1320a-7a(a)).	42 U.S.C. 1395u(m)(3)	1996	8/1/2016	15,024
Penalty for any physician who knowingly, willfully, and repeatedly bills one or more beneficiaries for purchased diagnostic tests any amount other than the payment amount specified by the Act. (Penalties are assessed in the same manner as 42 USC 1395u(j)(2)(B), which is assessed according to 1320a-7a(a)).	42 U.S.C. 1395u(n)(3)	1996	8/1/2016	15,024
Penalty for any practitioner specified in Section 1842(b)(18)(C) of the Act or other person that knowingly and willfully bills or collects for any services pertaining to drugs or biologics by the practitioners on other than an assignment-related basis. (Penalties are assessed in the same manner as 42 USC 1395u(b)(18)(B) and 1395u(j)(2)(B), which is assessed according to 1320a-7a(a)).	42 U.S.C. 1395u(o)(3)(B)	1996	8/1/2016	15,024
Penalty for any physician or practitioner who knowingly and willfully fails promptly to provide the appropriate diagnosis codes upon CMS or Medicare administrative contractor request for payment or bill not submitted on an assignment-related basis.	42 U.S.C. 1395u(p)(3)(A)	1988	8/1/2016	3,957
Penalty for a pharmaceutical manufacturer's misrepresentation of average sales price of a drug, or biologic.	42 U.S.C. 1395w-3a(d)(4)(A)	2003	8/1/2016	12,856
Penalty for any nonparticipating physician, supplier, or other person that furnishes physician services not on an assignment-related basis who either knowingly and willfully bills or collects in excess of the statutorily-defined limiting charge or fails to make a timely refund or adjustment. (Penalties are assessed in the same manner as 42 USC 1395u(j)(2)(B), which is assessed according to 1320a-7a(a)).	42 U.S.C. 1395w-4(g)(1)(B)	1996	8/1/2016	15,024

CIVIL MONETARY PENALTY ADJUSTMENT FOR INFLATION

Penalty	Statutory Authority	Date of Previous Adjustment	Date of Current Adjustment	Current Penalty Level ($ Amount)
Penalty for any person that knowingly and willfully bills for statutorily defined State-plan approved physicians' services on any other basis than an assignment-related basis for a Medicare/Medicaid dual eligible beneficiary. (Penalties are assessed in the same manner as 42 USC 1395u(j)(2)(B), which is assessed according to 1320a-7a(a)).	42 U.S.C. 1395w-4(g)(3)(B)	1996	8/1/2016	15,024
Penalty for each termination determination the Secretary makes that is the result of actions by a Medicare Advantage organization or Part D sponsor that has adversely affected an individual covered under the organization's contract.	42 U.S.C. 1395w-27(g)(3)(A); 42 U.S.C. 1857(g)(3)	1997	8/1/2016	36,794
Penalty for each week beginning after the initiation of civil money penalty procedures by the Secretary because a Medicare Advantage organization or Part D sponsor has failed to carry out a contract, or has carried out a contract inconsistently with regulations.	42 U.S.C. 1395w-27(g)(3)(B);42 U.S.C. 1857(g)(3)	1997	8/1/2016	14,718
Penalty for a Medicare Advantage organization's or Part D sponsor's early termination of its contract.	42 U.S.C. 1395w-27(g)(3)(D); 42 U.S.C. 1857(g)(3)	2000	8/1/2016	136,689
Penalty for an employer or other entity to offer any financial or other incentive for an individual entitled to benefits not to enroll under a group health plan or large group health plan which would be a primary plan.	42 U.S.C. 1395y(b)(3)(C)	1990	8/1/2016	8,908
Penalty for any non-governmental employer that, before October 1, 1998, willfully or repeatedly failed to provide timely and accurate information requested relating to an employee's group health insurance coverage.	42 U.S.C. 1395y(b)(5)(C)(ii)	1998	8/1/2016	1,450
Penalty for any entity that knowingly, willfully, and repeatedly fails to complete a claim form relating to the availability of other health benefits in accordance with statute or provides inaccurate information relating to such on the claim form.	42 U.S.C. 1395y(b)(6)(B)	1994	8/1/2016	3,182
Penalty for any entity serving as insurer, third party administrator, or fiduciary for a group health plan that fails to provide information that identifies situations where the group health plan is or was a primary plan to Medicare to the HHS Secretary.	42 U.S.C. 1395y(b)(7)(B)(i)	2007	8/1/2016	1,138
Penalty for any non-group health plan that fails to identify claimants who are Medicare beneficiaries and provide information to the HHS Secretary to coordinate benefits and pursue any applicable recovery claim.	42 U.S.C. 1395y(b)(8)(E)	2007	8/1/2016	1,138
Penalty for any person that fails to report information required by HHS under Section 1877(f) concerning ownership, investment, and compensation arrangements.	42 U.S.C. 1395nn(g)(5)	1989	8/1/2016	18,936
Penalty for any durable medical equipment supplier, including a supplier of prosthetic devices, prosthetics, orthotics, or supplies, that knowingly and willfully fails to make refunds in a timely manner to Medicare beneficiaries under certain conditions. (42 USC 1395(m)(18) sanctions apply here in the same manner, which is under 1395u(j)(2) and 1320a-7a(a)).	42 U.S.C. 1395pp(h)	1996	8/1/2016	15,024
Penalty for any person that issues a Medicare supplemental policy that has not been approved by the State regulatory program or does not meet Federal standards after a statutorily defined effective date.	42 U.S.C. 1395ss(a)(2)	1987	8/1/2016	51,569
Penalty for someone other than issuer that sells or issues a Medicare supplemental policy to beneficiary without a disclosure statement.	42 U.S.C. 1395ss(d)(3)(A)(vi) (II)	1990	8/1/2016	26,723
Penalty for an issuer that sells or issues a Medicare supplemental policy without disclosure statement.		1990	8/1/2016	44,539

CIVIL MONETARY PENALTY ADJUSTMENT FOR INFLATION

Penalty	Statutory Authority	Date of Previous Adjustment	Date of Current Adjustment	Current Penalty Level ($ Amount)
Penalty for someone other than issuer that sells or issues a Medicare supplemental policy without acknowledgement form.	42 U.S.C. 1395ss(d)(3)(B)(iv)	1990	8/1/2016	26,723
Penalty for issuer that sells or issues a Medicare supplemental policy without an acknowledgement form		1990	8/1/2016	44,539
Penalty for any person that sells or issues Medicare supplemental polices after a given date that fail to conform to the NAIC or Federal standards established by statute.	42 U.S.C. 1395ss(p)(8)	1990	8/1/2016	26,723
Penalty for any person that sells or issues Medicare supplemental polices after a given date that fail to conform to the NAIC or Federal standards established by statute.		1990	8/1/2016	44,539
Penalty for any person that sells a Medicare supplemental policy and fails to make available for sale the core group of basic benefits when selling other Medicare supplemental policies with additional benefits or fails to provide the individual, before selling the policy, an outline of coverage describing benefits.	42 U.S.C. 1395ss(p)(9)(C)	1990	8/1/2016	26,723
Penalty for any person that sells a Medicare supplemental policy and fails to make available for sale the core group of basic benefits when selling other Medicare supplemental policies with additional benefits or fails to provide the individual, before selling the policy, an outline of coverage describing benefits.		1990	8/1/2016	44,539
Penalty for any person that fails to suspend the policy of a policyholder made eligible for medical assistance or automatically reinstates the policy of a policyholder who has lost eligibility for medical assistance, under certain circumstances.	42 U.S.C. 1395ss(q)(5)(C)	1990	8/1/2016	44,539
Penalty for any person that fails to provide refunds or credits as required by section 1882(r)(1)(B)	42 U.S.C. 1395ss(r)(6)(A)	1990	8/1/2016	44,539
Penalty for any issuer of a Medicare supplemental policy that does not waive listed time periods if they were already satisfied under a proceeding Medicare supplemental policy, or denies a policy, or conditions the issuances or effectiveness of the policy, or discriminates in the pricing of the policy base on health status or other specified criteria.	42 U.S.C. 1395ss(s)(4)	1990	8/1/2016	8,908
Penalty for any issuer of a Medicare supplemental policy that fails to fulfill listed responsibilities.	42 U.S.C. 1395ss(t)(2)	1990	8/1/2016	44,539
Penalty someone other than issuer who sells, issues, or renews a medigap Rx policy to an individual who is a Part D enrollee.	42 U.S.C. 1395ss(v)(4)(A)	2003	8/1/2016	19,284
Penalty for an issuer who sells, issues, or renews a Medigap Rx policy who is a Part D enrollee.		2003	8/1/2016	32,140
Penalty for any individual who notifies or causes to be notified a home health agency of the time or date on which a survey of such agency is to be conducted.	42 U.S.C. 1395bbb(c)(1)	1987	8/1/2016	4,126
Maximum daily penalty amount for each day a home health agency is not in compliance with statutory requirements.	42 U.S.C. 1395bbb(f)(2)(A)(i)	1988	8/1/2016	19,787
Penalty per day for home health agency's noncompliance (Upper Range).			8/1/2016	
Minimum		1988	8/1/2016	16,819
Maximum		1988	8/1/2016	19,787
Penalty for a home health agency's deficiency or deficiencies that cause immediate jeopardy and result in actual harm.		1988	8/1/2016	19,787
Penalty for a home health agency's deficiency or deficiencies that cause immediate jeopardy and result in potential for harm.		1988	8/1/2016	17,808
Penalty for an isolated incident of noncompliance in violation of established HHA policy.		1988	8/1/2016	16,819

CIVIL MONETARY PENALTY ADJUSTMENT FOR INFLATION

Penalty	Statutory Authority	Date of Previous Adjustment	Date of Current Adjustment	Current Penalty Level ($ Amount)
Penalty for a repeat and/or condition-level deficiency that does not constitute immediate jeopardy, but is directly related to poor quality patient care outcomes (Lower Range).	42 U.S.C. 1395bbb(f)(2)(A)(i)		8/1/2016	
Minimum		1988	8/1/2016	2,968
Maximum		1988	8/1/2016	16,819
Penalty for a repeat and/or condition-level deficiency that does not constitute immediate jeopardy and that is related predominately to structure or process-oriented conditions (Lower Range).			8/1/2016	
Minimum		1988	8/1/2016	989
Maximum		1988	8/1/2016	7,915
Penalty imposed for instance of noncompliance that may be assessed for one or more singular events of condition-level noncompliance that are identified and where the noncompliance was corrected during the onsite survey.			8/1/2016	
Minimum		1988	8/1/2016	1,979
Maximum		1988	8/1/2016	19,787
Penalty for each day of noncompliance (Maximum).		1988	8/1/2016	19,787
Penalty for each day of noncompliance (Maximum).		1988	8/1/2016	19,787
Penalty for PACE organization's practice that would reasonably be expected to have the effect of denying or discouraging enrollment.	42 U.S.C. 1396b(m)(5)(B)		8/1/2016	
Minimum		1997	8/1/2016	22,077
Maximum		1997	8/1/2016	147,177
Penalty for a PACE organization that charges excessive premiums.		1997	8/1/2016	36,794
Penalty for a PACE organization misrepresenting or falsifying information to CMS, the State, or an individual or other entity.		1997	8/1/2016	147,177
Penalty for each determination the CMS makes that the PACE organization has failed to provide medically necessary items and services of the failure has adversely affected (or has the substantial likelihood of adversely affecting) a PACE participant.	42 U.S.C. 1396b(m)(5)(B)	1997	8/1/2016	36,794
Penalty for involuntarily disenrolling a participant.		1997	8/1/2016	36,794
Penalty for discriminating or discouraging enrollment or disenrollment of participants on the basis of an individual's health status or need for health care services		1997	8/1/2016	36,794
Penalty per day for a nursing facility's failure to meet a Category 2 Certification.	42 U.S.C. 1396r(h)(3)(C)(ii)(I)		8/1/2016	
Minimum		1987	8/1/2016	103
Maximum		1987	8/1/2016	6,188
Penalty per instance for a nursing facility's failure to meet Category 2 certification.			8/1/2016	
Minimum		1987	8/1/2016	2,063
Maximum		1987	8/1/2016	20,628
Penalty per day for a nursing facility's failure to meet Category 3 certification.			8/1/2016	
Minimum		1987	8/1/2016	6,291
Maximum		1987	8/1/2016	20,628

CIVIL MONETARY PENALTY ADJUSTMENT FOR INFLATION

Penalty	Statutory Authority	Date of Previous Adjustment	Date of Current Adjustment	Current Penalty Level ($ Amount)
Penalty per instance for a nursing facility's failure to meet Category 3 certification.	42 U.S.C. 1396r(h)(3)(C)(ii)(I)		8/1/2016	
Minimum		1987	8/1/2016	2,063
Maximum		1987	8/1/2016	20,628
Penalty per instance for a nursing facility's failure to meet Category 3 certification, which results in immediate jeopardy.			8/1/2016	
Minimum		1987	8/1/2016	2,063
Maximum		1987	8/1/2016	20,628
Penalty per day for nursing facility's failure to meet certification (Upper Range).			8/1/2016	
Minimum		1987	8/1/2016	6,291
Maximum		1987	8/1/2016	20,628
Penalty per day for nursing facility's failure to meet certification (Lower Range).			8/1/2016	
Minimum		1987	8/1/2016	103
Maximum		1987	8/1/2016	6,188
Penalty per instance for nursing facility's failure to meet certification.			8/1/2016	
Minimum		1987	8/1/2016	2,063
Maximum		1987	8/1/2016	20,628
Grounds to prohibit approval of Nurse Aide Training Program - if assessed a penalty in 1819(h)(2)(B)(i) or 1919(h)(2)(A)(ii) of "not less than $5,000" [Not CMP authority, but a specific CMP amount (CMP at this level) that is the triggering condition for disapproval]	42 U.S.C. 1396r(f)(2)(B)(iii)(I)(c)	1987	8/1/2016	10,314
Grounds to waive disapproval of nurse aide training program - reference to disapproval based on imposition of CMP "not less than $5,000" [Not CMP authority but CMP imposition at this level determines eligibility to seek waiver of disapproval of nurse aide training program]	42 U.S.C. 1396r(h)(3)(C)(ii)(I)	1987	8/1/2016	10,314
Penalty for each day of noncompliance for a home or community care provider that no longer meets the minimum requirements for home and community care.	42 U.S.C. 1396t(j)(2)(C)		8/1/2016	
Minimum		1990	8/1/2016	2
Maximum		1990	8/1/2016	17,816
Penalty for a Medicaid managed care organization that fails substantially to provide medically necessary items and services	42 U.S.C. 1396u-2(e)(2)(A)(i)	1997	8/1/2016	36,794
Penalty for Medicaid managed care organization that imposes premiums or charges on enrollees in excess of the premiums or charges permitted.		1997	8/1/2016	36,794
Penalty for a Medicaid managed care organization that misrepresents or falsifies information to another individual or entity.		1997	8/1/2016	36,794
Penalty for a Medicaid managed care organization that fails to comply with the applicable statutory requirements for such organizations.		1997	8/1/2016	36,794
Penalty for a Medicaid managed care organization that misrepresents or falsifies information to the HHS Secretary.	42 U.S.C. 1396u-2(e)(2)(A)(ii)	1997	8/1/2016	147,177
Penalty for Medicaid managed care organization that acts to discriminate among enrollees on the basis of their health status.		1997	8/1/2016	147,177
Penalty for each individual that does not enroll as a result of a Medicaid managed care organization that acts to discriminate among enrollees on the basis of their health status.	42 U.S.C. 1396u-2(e)(2)(A)(iv)	1997	8/1/2016	22,077

CIVIL MONETARY PENALTY ADJUSTMENT FOR INFLATION

Penalty	Statutory Authority	Date of Previous Adjustment	Date of Current Adjustment	Current Penalty Level ($ Amount)
Penalty for a provider not meeting one of the requirements relating to the protection of the health, safety, and welfare of individuals receiving community supported living arrangements services	42 U.S.C. 1396u(h)(2)	1990	8/1/2016	20,628
Penalty for disclosing information related to eligibility determinations for medical assistance programs	42 U.S.C. 1396w-2(c)(1)	2009	8/1/2016	11,002
Penalty for PACE organization's practice that would reasonably be expected to have the effect of denying or discouraging enrollment.	42 U.S.C. 1903(m)(5)(B)		8/1/2016	
Minimum		1997	8/1/2016	22,077
Maximum		1997	8/1/2016	147,177
Penalty for a PACE organization that charges excessive premiums.		1997	8/1/2016	36,794
Penalty for a PACE organization misrepresenting or falsifying information to CMS, the State, or an individual or other entity.		1997	8/1/2016	147,177
Penalty for each determination the CMS makes that the PACE organization has failed to provide medically necessary items and services of the failure has adversely affected (or has the substantial likelihood of adversely affecting) a PACE participant.		1997	8/1/2016	36,794
Penalty for involuntarily disenrolling a participant.		1997	8/1/2016	36,794
Penalty for discriminating or discouraging enrollment or disenrollment of participants on the basis of an individual's health status or need for health care services		1997	8/1/2016	36,794
Failure to comply with requirements of *Public Health Services Act*; Penalty for violations of rules or standards of behavior associated with issuer participation in the Federally-facilitated Exchange. (42 USC 300gg-22(b)(C)).	42 U.S.C. 18041(c)(2)	1996	8/1/2016	150
Penalty for providing false information on Exchange application.	42 U.S.C. 18081(h)(1)(A)(i)(II)	2010	8/1/2016	27,186
Penalty for knowingly or willfully providing false information on Exchange application.	42 U.S.C. 18081(h)(1)(B)	2010	8/1/2016	271,862
Penalty for knowingly or willfully disclosing protected information from Exchange.	42 U.S.C. 18081(h)(2)	2010	8/1/2016	27,186

IMPROPER PAYMENTS INFORMATION ACT REPORT

1.0 Overview

HHS's FY 2016 Improper Payments Information Act Report includes a discussion of the following information, as required by *the Improper Payments Information Act of 2002* (IPIA), as amended by the *Improper Payments Elimination and Recovery Act of 2010* (IPERA) and the *Improper Payments Elimination and Recovery Improvement Act of 2012* (IPERIA)*;* Office of Management and Budget (OMB) Circular A-136; and Appendix C of OMB Circular A-123:

- Program Descriptions (Section 1.10)
- Risk Assessments (Section 2.0)
    - *Affordable Care Act* Risk Assessments (Section 2.10)
- Statistical Sampling Process (Section 3.0)
    - Error Rate Presentation (Section 3.10)
- Corrective Action Plans (CAPs) (Section 4.0)
    - Corrective Actions for High-Priority Programs (Section 4.10)
- Accountability in Reducing and Recovering Improper Payments (Section 5.0)
- Information Systems and Other Infrastructure (Section 6.0)
- Mitigation Efforts Related to Statutory or Regulatory Barriers (Section 7.0)
- FY 2016 Achievements (Section 8.0)
- Improper Payment Reduction Outlook FY 2015 through FY 2019 (Section 9.0)
    - Accompanying Improper Payment Reporting for OMB-Determined Risk-Susceptible Programs Notes (Section 9.10)
    - Accompanying Improper Payment Reporting for Superstorm Sandy Programs Notes (Section 9.20)
    - Accompanying Improper Payment Reporting for All Programs Notes (Section 9.30)
- Improper Payment Root Cause Categories (Section 10.0)
- Program-Specific Reporting Information (Section 11.0)
    - Medicare Fee-for-Service (FFS) (Parts A and B) (Section 11.10)
    - Medicare Advantage (Part C) (Section 11.20)
    - Medicare Prescription Drug Benefit (Part D) (Section 11.30)
    - Medicaid (Section 11.40)
    - Children's Health Insurance Program (CHIP) (Section 11.50)
    - Temporary Assistance for Needy Families (TANF) (Section 11.60)
    - Foster Care (Section 11.70)
    - Child Care and Development Fund (CCDF) (Section 11.80)
- Supplemental Measures and Targets for High-Priority Programs (Section 12.0)
- Superstorm Sandy Reporting Information (Section 13.0)
    - Head Start (Section 13.10)
    - Social Services Block Grant (SSBG) (Section 13.20)
    - Assistant Secretary for Preparedness and Response (ASPR) Research (Section 13.30)
    - Substance Abuse and Mental Health Services Administration (SAMHSA) (Section 13.40)
    - National Institutes of Health (NIH) Research (Section 13.50)
- Internal Control Over Payments (Section 14.0)
- Recovery Auditing Reporting (Section 15.0)
- Do Not Pay Initiative (Section 16.0)

1.10 Program Descriptions

The following is a brief description of the risk-susceptible programs discussed in this report. For the Superstorm Sandy risk-susceptible programs, the only programs included in the list below are those that are measuring and reporting improper payment estimates for FY 2016.

OMB-Determined Risk-Susceptible Programs:

1. **Medicare FFS** – A federal health insurance program for people age 65 or older, people younger than age 65 with certain disabilities, and people of all ages with End-Stage Renal Disease.
2. **Medicare Part C** – A federal health insurance program that allows beneficiaries to receive their Medicare benefits through a private health plan.
3. **Medicare Part D** – A federal prescription drug benefit program for Medicare beneficiaries.
4. **Medicaid** – A joint federal/state program, administered by the states, that provides health insurance to certain low-income individuals.
5. **CHIP** – A joint federal/state program, administered by the states, that provides health insurance for qualifying children.
6. **TANF** – A joint federal/state program, administered by the states, that provides time-limited cash assistance as well as job preparation, work support, and other services to needy families with children to promote work, responsibility, and self-sufficiency.
7. **Foster Care** – A joint federal/state program, administered by the states, for children who need placement outside their homes in a foster family home or a child care facility.
8. **CCDF** – A joint federal/state program, administered by the states, that provides child care financial assistance to low-income working families.

Superstorm Sandy Risk-Susceptible Programs:

9. **Head Start** – A federal program that provides comprehensive developmental services for America's low-income children from birth to five years of age and their families.
10. **SSBG** – A joint federal/state program, administered by the states, which supports programs designed to reduce dependency and promote self-sufficiency; to protect children, adults, and people with disabilities from neglect, abuse, and exploitation; and to help individuals who are unable to take care of themselves to stay in their homes or to find the best institutional arrangement.
11. **ASPR Research** – A federal initiative to build a strong scientific research dataset and to support research that will aid in the response to, and recovery from, Superstorm Sandy.
12. **SAMHSA** – A joint federal/state initiative to provide continued and enhanced mental health and substance abuse treatment to affected parties.
13. **NIH Research** – A federal initiative to restore investment in biomedical research and infrastructure that was severely damaged or destroyed by Superstorm Sandy.

2.0 Risk Assessments

In addition to the programs deemed by OMB to be susceptible to significant improper payments and those required to be measured under the Superstorm Sandy *Disaster Relief Appropriations Act of 2013* (*Disaster Relief Act*), HHS also reviews other programs and payment streams to determine if they are susceptible to significant improper payments. Per Appendix C of OMB Circular A-123, Part I.A.9.Step1.b, the HHS IPERIA Risk Assessment Template contains nine factors that are reviewed:

1. Whether the program is new to the agency;

2. The complexity of the program, particularly determining correct payment amounts;
3. The volume of payments made annually;
4. Whether payments or payment eligibility decisions are made outside of the agency;
5. Recent major changes in program funding, authorities, practices, or procedures;
6. The level, experience, and quality of training for personnel responsible for making program eligibility determinations or certifying that payments are accurate;
7. Inherent risks of improper payments due to the nature of agency programs or operations;
8. Significant deficiencies in agency audit reports including, but not limited to, HHS Inspector General or Government Accountability Office (GAO) findings, or other relevant management findings; and
9. Results from prior improper payment work.

In addition to these risk factors, the HHS IPERIA Risk Assessment Template includes information on specific risks identified by the program that may lead to improper payments, as well as controls that may help mitigate those risks. By continuing to examine both the required risk factors and additional internal control information, the risk assessment tool provides a comprehensive review and analysis of selected programs' operations to determine if a payment risk exists and the nature and extent of the risks identified.

In FY 2016, HHS strengthened its risk assessment process and reporting activities with added policies and procedures. For example, the Department made minor refinements to the HHS IPERIA Risk Assessment Template to incorporate lessons learned from the previous year's risk assessments and incorporated best practices from the revised version of GAO's *Standards for Internal Control in the Federal Government*. Furthermore, the Department increased the number of programs conducting improper payment risk assessments from 9 programs in FY 2015 to 22 programs in FY 2016. For a complete list of programs HHS reviewed under its risk assessment approach, see *Figure 2.0*.

Figure 2.0: FY 2016 Risk Assessments

Operating or Staff Division	Program Name
Administration for Children and Families (ACF)	Head Start
	Low Income Home Energy Assistance Program
	TANF
Administration for Community Living (ACL)	Home and Community Based Supportive Services
	State Councils on Developmental Disabilities
Agency for Healthcare Research and Quality (AHRQ)	Health Costs, Quality, and Outcomes Program
	Medical Expenditure Panel Survey
Assistant Secretary for Preparedness and Response	Ebola Supplemental Patient Care Reimbursement Program
Centers for Disease Control and Prevention	Vaccine for Children
	National Center for Chronic Disease Prevention and Health Promotion
Food and Drug Administration (FDA)	Vendor Payments
Health Resources and Services Administration (HRSA)	Health Service Corps Loan Repayment and Scholarship Programs
	Maternal and Child Health Block Grant
Indian Health Service (IHS)	Grants Management
	Health Information Technology
National Institutes of Health	Student Loan Repayment Program
	Extramural Loan Repayment Programs
Office of the Assistant Secretary for Health (OASH)	Title X Family Planning Grant Program
	Teen Pregnancy Prevention Program

Operating or Staff Division	Program Name
Office of the National Coordinator for Health IT (ONC)	Regional Extension Center Program
Substance Abuse and Mental Health Services Administration	Addiction Technology Transfer Center Grants
	Residential Treatment for Pregnant and Postpartum Women

HHS determined that none of the programs that were risk assessed in FY 2016 were at-risk for significant improper payments.

In FY 2016, HHS also met IPERIA's requirement to assess the risk of charge cards and employee pay by leveraging existing Departmental activities and implementing a new risk assessment approach. For charge card payments, which includes both purchase and travel cards, HHS developed a new, qualitative risk assessment tool—similar to the risk assessment tool used to assess programs' susceptibility to significant improper payments. The new risk assessment tool uses data generated through existing evaluations such as those mandated by legislative and administrative processes in addition to the findings of continuous monitoring activities and OMB's nine required risk factors that are listed earlier in this section. One Staff Division (Program Support Center) and three Operating Divisions (FDA, NIH, and CDC), historically representing the majority of charge card expenditures, completed the charge card risk assessment process and were determined not to be at-risk for significant improper payments. For employee pay, the Department primarily utilized control testing performed during the OMB Circular A-123, Appendix A process, and findings from internal reviews and external audits, to perform the improper payment risk assessment. Based on these processes, the Department concluded that employee payments were not at-risk for significant improper payments.

2.10 *Affordable Care Act* Risk Assessments

HHS and the Department of the Treasury (Treasury) each have responsibilities for ensuring payment accuracy in Marketplace programs created under the *Affordable Care Act*. Performing program-specific comprehensive risk assessments provides reasonable assurance of whether improper payments could exceed statutory thresholds, and remains critical to evaluating and improving payment accuracy. HHS has conducted risk assessments to determine areas that might affect Advance Premium Tax Credit (APTC), Cost-Sharing Reduction (CSR), and other programs' payment accuracy; and Treasury has conducted a risk assessment to determine areas that might affect Premium Tax Credit (PTC) payment accuracy. The Department leveraged the same Federally Funded Research and Development Center to facilitate interagency coordination, information exchange, and risk analysis during the APTC and PTC program risk assessments.

Qualitative risk assessments of the Marketplace programs, administered by the Department, were conducted using the HHS IPERIA Risk Assessment Template, which provides guidance and criteria in assessing the risk factors listed in Appendix C of OMB Circular A-123, Part I.A.9.Step1.b (See *Section 2.0* for a list of those factors). The risk assessments also identified and evaluated potential improper payment risks. A complete list of Marketplace and related programs that HHS risk assessed is included below in *Figure 2.1.*

Figure 2.1: FY 2016 *Affordable Care Act* Risk Assessments

Operating Division	Program Name
Centers for Medicare & Medicaid Services	APTC
Centers for Medicare & Medicaid Services	CSR
Centers for Medicare & Medicaid Services	Basic Health Program (BHP)
Centers for Medicare & Medicaid Services	Consumer Operated and Oriented Plan
Centers for Medicare & Medicaid Services	Navigator Grants

Operating Division	Program Name
Centers for Medicare & Medicaid Services	Risk Adjustment
Centers for Medicare & Medicaid Services	Risk Corridors
Centers for Medicare & Medicaid Services	Transitional Reinsurance
Centers for Medicare & Medicaid Services	Small Business Health Options
Centers for Medicare & Medicaid Services	State Marketplace Establishment Grants
Centers for Medicare & Medicaid Services	Women's Preventative Services Exception

HHS concluded that the APTC and CSR programs are susceptible to significant improper payments (See *Figure 2.1.1)*. HHS is deferring a final risk assessment conclusion for the BHP to allow the program to become more fully established. HHS determined that the remaining programs were not susceptible to significant improper payments. HHS will begin piloting improper payment measurement methodologies in FY 2017 for those programs deemed susceptible to significant improper payments, which will be used to develop annual estimates, report improper payments, and facilitate corrective actions. The BHP risk assessment conclusion and updates on the APTC and CSR improper payment measurement methodology development will be provided in the FY 2017 Agency Financial Report (AFR).

Figure 2.1.1: FY 2016 *Affordable Care Act* Programs Susceptible to Significant Improper Payments

	FY 2016 Risk Assessment Results		
	Below Statutory Thresholds	Susceptible to Significant Improper Payments (IPs)	Year Rate and Amount will be reported
APTC	No	Yes	To Be Determined*
CSR	No	Yes	To Be Determined*

*Note: Currently, HHS is unable to specify the year the rate and amount will be reported due to the complexity and timing of the error rate measurement methodology development process, which involves conducting pilot testing, using those pilots to refine the methodology, and then undergoing the rule making process before implementing the methodology.

Treasury has completed the risk assessment for the PTC program. Treasury's risk assessment determination and a detailed discussion are reported in the appropriate sections of the FY 2016 Treasury AFR. In addition to the work on the improper payment risk assessments, both Departments have established internal controls to provide for effective program operations, reliable financial reporting, and compliance with laws and regulations.

3.0 Statistical Sampling Process

Each program's statistical sampling process is discussed in *Section 11.0: Program-Specific Reporting Information* or *Section 13.0: Superstorm Sandy Reporting Information*. Unless otherwise stated in either section, all programs that reported an error rate estimate complied with the requirement that all estimates be based on the equivalent of a statistically valid random sample of sufficient size to yield an estimate with a 90 percent confidence interval of plus or minus 2.5 percentage points of the total amount of all program payments around the estimate of the dollars of erroneous payments. In addition, seven of the eight programs that OMB determined susceptible to significant improper payments are reporting error estimates calculated by a statistical contractor.

3.10 Error Rate Presentation

OMB Circular A-136 allows agencies to report net error rates in addition to the required gross error rates. Tables 1A and 1B in *Section 9.0: Improper Payment Reduction Outlook FY 2015 through FY 2019* present each high-risk or Superstorm Sandy program's gross and net error rates.

The *gross error rate* is the official program error rate; it is calculated by adding the sample's overpayments and underpayments and dividing by the total dollar value of the sample. The *net error rate* reflects the overall estimated monetary loss to the program; it is calculated by subtracting the sample's underpayments from overpayments and dividing by the total dollar value of the sample.

4.0 Corrective Action Plans (CAPs)

Each program's CAP for reducing the estimated rate of improper payments can be found in *Section 11.0: Program-Specific Reporting Information* or *Section 13.0: Superstorm Sandy Reporting Information*. CAPs are used to set aggressive, realistic targets and outline a timetable to achieve scheduled targets. OMB approves all CAPs and reduction targets published in the AFR. The Department reviews CAPs annually to ensure plans focus on the root causes of the errors, thus making it more likely that targets are met. If targets are not met, HHS will develop new strategies, adjust staffing and other resources, and possibly revise targets.

Many successful corrective actions were listed as best practices in previous AFRs. Beginning with the FY 2016 improper payments reporting section, HHS will no longer include these best practices in its AFR. However, information on these best practices can be found at www.hhs.gov/afr.

4.10 Corrective Actions for High-Priority Programs

Under Executive Order (EO) 13520 – "Reducing Improper Payments and Eliminating Waste in Federal Programs" - and its implementing guidance, OMB identifies programs that have more than $750 million in annual estimated improper payments and that contribute substantially to the governmentwide improper payment estimate. These programs, known as high-priority programs, are required to perform certain activities, including: appointing Accountable Officials to oversee the agency's improper payment efforts; posting improper payment information to www.PaymentAccuracy.gov; and developing and reporting supplemental measures in addition to reporting the annual error rates.

HHS has five programs that OMB deemed high-priority programs: Medicare FFS, Medicare Part C, Medicare Part D, Medicaid, and CHIP. Accordingly, additional information on HHS's efforts can be found on www.PaymentAccuracy.gov. In addition, while the root causes of errors in the Department's programs can fluctuate from year to year, HHS remains focused on reducing the annual error rates for its high-priority programs and is taking many actions to prevent and reduce improper payments (see *Section 11.0* for more information on HHS's corrective actions, and *Section 12.0* for information on HHS's supplemental measures).

5.0 Accountability in Reducing and Recovering Improper Payments

Strengthening program integrity throughout the organization is a top Departmental priority, extending to HHS senior executives and program officials at each of our agencies and programs. As evidence of this focus, beginning with senior leadership and cascading down, performance plans contain strategic goals that are related to strengthening program integrity, protecting taxpayer resources, and reducing improper payments. Senior executives and program officials are evaluated as part of their semi-annual and annual performance evaluations on their progress toward achieving these goals.

6.0 Information Systems and Other Infrastructure

Section 11.0: Program-Specific Reporting Information details each program's information systems and other infrastructure.

7.0 Mitigation Efforts Related to Statutory or Regulatory Barriers

Section 11.0: Program-Specific Reporting Information reports each program's statutory or regulatory barriers, if any, to reducing improper payments.

8.0 FY 2016 Achievements

In FY 2016, HHS strengthened its efforts to reduce and recover improper payments in its programs. While a few of these efforts are highlighted below, more detailed information on the programs' performance and corrective actions can be found in *Section 11.0: Program-Specific Reporting Information*.

Head Start

As of FY 2013, Head Start no longer reports annual improper payment estimates due to the strong internal controls, monitoring systems, and low reported error rates from FY 2009 through FY 2012. In lieu of an annual error rate measurement, HHS provides oversight through Head Start's existing internal controls and monitoring systems, and annually reports to OMB on its internal controls. Overall, FY 2016 monitoring results indicate the number of grantees with erroneous payments related to eligibility remained consistently low, indicating that the Department's control and monitoring systems are working as intended.

Centers for Medicare & Medicaid Services (CMS) Program Integrity Board

As part of HHS's efforts to reduce improper payments, CMS established an agency-wide Program Integrity (PI) Board to identify and prioritize improper, wasteful, abusive, and potentially fraudulent payment vulnerabilities in its programs. The PI Board is comprised of CMS executive leaders, all of whom share the mutual objective to identify and prevent improper and fraudulent payments. After identifying high-priority vulnerabilities, the PI Board directs corrective actions and tracks issues to resolution. Specifically, the PI Board established an Improper Payment Action Plan workgroup to periodically collect data from improper payment reports and formulate action plans for review by the PI Board. In FY 2016, the workgroup focused on vulnerabilities identified in the Medicare FFS, Medicare Parts C and D, and Medicaid and CHIP improper payment measurements. The PI Board also established smaller working groups—referred to as Integrated Project Teams (IPTs)—to focus on specific projects to address the identified vulnerabilities. For example, in FY 2015, the PI Board approved the Therapy Services IPT, Home Health IPT, and Medicare FFS Integrity Continuum IPT. In FY 2016, the PI Board approved the Marketplace IPT and Documentation Improvement IPT. Each IPT works independently under the directive of the PI Board and provides regular updates. Major initiatives include: launching the Pre-Claim Review Demonstration for Home Health Services in August 2016; releasing Skilled Nursing Facility (SNF) provider utilization and payment data in March 2016 that brought national attention to potential billing irregularities for therapy services; and launching the Provider Billing Review Evaluation in one Medicare Administrative Contractor (MAC) jurisdiction to help Medicare Part B providers analyze their coding and billing practices for specific procedures and services.

Affordable Care Act Provider Enrollment Moratorium

Section 6401 of the *Affordable Care Act* added Section 1866(j)(7) to the *Social Security Act* that provides HHS the authority to impose a temporary moratorium on the enrollment of new providers and suppliers as a tool to prevent or combat fraud, waste, or abuse in Medicare, Medicaid, or CHIP. Establishing a moratorium in certain geographic areas provides HHS the opportunity to analyze and monitor the existing provider and supplier base, and to focus on additional fraud prevention and detection tools in the areas. On July 30, 2013, HHS launched the first temporary (6-month) enrollment moratorium pursuant to this authority for Miami-area and Chicago-area home health agencies (HHAs) and ground ambulance suppliers (emergency and non-emergency) in the Houston-area for Medicare, Medicaid, and CHIP. On January 30, 2014, HHS extended the original moratoria for these locations by 6 months and expanded the temporary enrollment moratoria to include HHAs in the Fort Lauderdale,

Detroit, Dallas, and Houston areas. HHS also expanded the moratoria for ground ambulance suppliers into the Philadelphia area and surrounding New Jersey counties. Since the initial expansion, moratoria for all areas were continued until July 2016.

Most recently, on July 29, 2016, HHS announced:

- The moratoria were expanded state-wide for HHAs in Florida, Illinois, Michigan, and Texas and for new Medicare Part B, Medicaid, and CHIP non-emergency ambulance suppliers in New Jersey, Pennsylvania, and Texas;
- HHS concurrently lifted the temporary moratoria on all Medicare Part B, Medicaid, and CHIP emergency ground ambulance suppliers; and
- HHS launched the Provider Enrollment Moratoria Access Waiver Demonstration, which grants waivers to the state-wide enrollment moratoria on a case-by-case basis in response to access to care issues in certain geographic areas and requires heightened initial review and ongoing oversight of new providers and suppliers.

The focus of these efforts is to prevent and deter fraud, waste, and abuse in high-risk services and areas across the country through the use of heightened screening for new providers and suppliers in the moratoria areas while ensuring beneficiary access to care.

Fraud Prevention System

HHS launched the Fraud Prevention System (FPS) on June 30, 2011, as required by the *Small Business Jobs Act of 2010*. The FPS analyzes all Medicare FFS claims using risk-based algorithms developed by HHS and its contractors. HHS uses the FPS to target investigative resources, generating alerts for suspect claims or providers and suppliers in priority order, to investigate the most egregious, suspect, or aberrant activity. HHS and its program integrity contractors use the FPS information to prevent and identify improper payments using a variety of administrative tools and actions, including claim denials, payment suspensions, revocation of Medicare billing privileges, and referrals to law enforcement.

During FY 2015, HHS took administrative action against 943 providers and suppliers, resulting in an estimated $604.75 million in identified savings. These savings led to an $11 to $1 return on investment for FY 2015. Simultaneously, the FPS also generated leads for 492 new investigations and augmented information for 226 ongoing investigations. HHS is developing the next generation of predictive analytics with a new FPS system design that further improves its usability and efficiency. Through the award of the FPS 2.0 contract on April 1, 2016, HHS, in collaboration with its contractor, will modernize the FPS system to improve model performance measurement, optimize model development time to production, and aggressively expand program integrity capabilities.

National Benefit Integrity Medicare Drug Integrity Contractor

The National Benefit Integrity (NBI) Medicare Drug Integrity Contractor (MEDIC) performs data analysis to fight fraud, waste, and abuse in Medicare Part C and D. The NBI MEDIC identifies improper payments through data analysis and notifies plan sponsors to recover the corresponding overpayments. As a result of the NBI MEDIC's data analysis projects, HHS recovered $78.53 million in FY 2016 from Part D sponsors. In addition, HHS utilizes the NBI MEDIC's data analysis to select Part D plan sponsors and drugs for review through self-audits conducted by Part D plan sponsors. HHS recovered $6.25 million as a result of Part D plan sponsor self-audits in FY 2016. Lastly, the NBI MEDIC also refers some information to law enforcement organizations. According to notifications received from law enforcement for the first half of FY 2016, NBI MEDIC referrals to law enforcement resulted in recoveries of $3.12 million for Part C and $71.42 million for Part D. The majority of these savings were from sentences ordering restitution.

Medicaid Integrity Program

Under the authority of Section 1936 of the *Social Security Act*, as amended by the *Deficit Reduction Act of 2005* (DRA), HHS's Medicaid Integrity Program has two broad responsibilities:

- To hire contractors to review Medicaid provider activities, audit claims, identify overpayments, and educate providers and others on Medicaid program integrity issues.
- To provide effective support and assistance to states in their efforts to combat Medicaid provider fraud, waste, and abuse.

Increased Medicaid recoveries, since the enactment of the DRA, demonstrate the increased focus on Medicaid integrity. For example, the Medicaid Integrity Program has provided the assistance of federal staff specializing in program integrity and contractor support to bolster state activities. Based on states' quarterly reports to HHS, this assistance contributed to $784.50 million in total collections in FY 2016. The Medicaid Integrity Program works in coordination with the Medicaid program integrity activities funded by the Health Care Fraud and Abuse Control program. The DRA also required HHS to establish a Comprehensive Medicaid Integrity Plan to guide the Medicaid Integrity Program's development and operations. HHS's most recent Comprehensive Medicaid Integrity Plan for FYs 2014 to 2018 is available at www.cms.gov/Regulations-and-Guidance/Legislation/DeficitReductionAct/Downloads/cmip2014.pdf. During FY 2016, HHS significantly expanded its efforts to assist states with meeting Medicaid screening and enrollment requirements through enhanced sharing of Medicare enrollment and screening data with states, providing a new data compare service to help states identify providers for which the state is able to rely on Medicare's screening, and providing technical assistance to states through site visits and publishing guidance in the Medicaid Provider Enrollment Compendium.

Public Assistance Reporting Information System

The Public Assistance Reporting Information System (PARIS) is a federal/state partnership with all 50 states, the District of Columbia, and Puerto Rico that provides state public assistance agencies detailed information and data to detect and deter improper payments in TANF, Medicaid, Workers' Compensation, Child Care, and the Supplemental Nutrition Assistance Program.

HHS, the Department of Veterans Affairs (VA), and the Department of Defense (DOD) have partnered to advance the PARIS project at no cost to states. The DOD's Defense Manpower Data Center provides computer resources to produce a match file, using social security numbers submitted by the states, VA, and DOD as the key match indicator. States verify the matched individual's eligibility and take any necessary action. HHS contributes to this effort by executing Computer Matching Agreements and coordinating the quarterly matches. Since its establishment, PARIS has strengthened program administration among its programs and state public assistance agencies. For instance, New York State closed 10,337 cases for cost avoidance of $59.51 million during their most recent full state fiscal year (April 2015 to March 2016). More information on PARIS can be found at www.acf.hhs.gov/paris.

9.0 Improper Payment Reduction Outlook FY 2015 through FY 2019

The following tables (Table 1A, Table 1B, and Table 1C) display HHS's improper payment results for the current year (CY) FY 2016, the prior year (PY) FY 2015, and targets for FYs 2017 through 2019. The tables include the following information by year and program, as applicable: FY outlays, the error rate or future reduction target (IP%), and dollars paid or projected to be paid improperly (IP$). In addition, for the CY, HHS includes: the amount of overpayments (CY Overpayments), the amount of underpayments (CY Underpayments), and the net error rate (CY Net IP%) and the corresponding overpayments (CY net IP$), when available.

Table 1A includes improper payment information for HHS's OMB-determined risk-susceptible programs. Table 1B includes the FY 2016 improper payment results for the programs that received *Disaster Relief Act* funding and does

not include current year estimates or out-year reduction targets for programs where all of the funds have been expended. Table 1C presents the Department's aggregate improper payment information.

Table 1A

Improper Payment Reporting for OMB-Determined Risk-Susceptible Programs

FY 2015 – FY 2019 (in Millions)

Program or Activity	PY Outlays $	PY IP %	PY IP $	CY Outlays $	CY IP %	CY IP $	CY Over payment $	CY Under payment $	CY Net IP %	CY Net IP $	CY+1 Est. Outlays $	CY+1 IP %	CY+1 IP $	CY+2 Est. Outlays $	CY+2 IP %	CY+2 IP $	CY+3 Est. Outlays $	CY+3 IP %	CY+3 IP $
Medicare FFS	358,348.60 Note (a)	12.09	43,325.61	373,650.45 Note (b)	11.00 Note (1)	41,084.65	39,844.92	1,239.72	10.33	38,605.20	403,555.00 Note (c)	10.40	41,969.72	426,865.00 Note (c)	9.40	40,125.31	450,505.00 Note (c)	9.30	41,896.97
Medicare Part C	148,593.71 Note (d)	9.50	14,117.00	161,944.04 Note (e)	9.99	16,182.66	11,484.39	4,698.27	4.19	6,786.12	201,283.00 Note (f)	9.50	19,121.89	200,296.00 Note (f)	9.10 Note (2)	18,226.94	235,803.00 Note (f)	9.10 Note (2)	21,458.07
Medicare Part D	62,003.91 Note (g)	3.60	2,234.25	70,235.94 Note (h)	3.41	2,393.94	1,660.84	733.09	1.32	927.75	98,322.00 Note (i)	3.30 Note (3)	3,244.63	97,366.00 Note (i)	3.20 Note (2)	3,115.71	113,152.00 Note (i)	3.20 Note (2)	3,620.86
Medicaid	297,672.02 Note (j)	9.78	29,124.61	345,973.72 Note (k)	10.48 Note (4)	36,253.25	35,750.72	502.53	10.19	35,248.19	364,710.61 Note (k)	9.57	34,902.81	371,939.82 Note (k)	6.68	24,845.58	396,104.79 Note (k)	5.51	21,825.37
CHIP	9,293.91 Note (l)	6.80	632.11	9,233.06 Note (m)	7.99 Note (5)	737.59	732.07	5.52	7.87	726.55	15,007.44 Note (m)	7.38	1,107.55	16,015.86 Note (m)	7.06	1,130.72	12,414.94 Note (m)	6.24	774.69
TANF	16,215.32 Note (n)	N/A	N/A	15,496.33 Note (o)	N/A Note (6)	N/A	N/A	N/A	N/A	N/A	17,042.12 Note (o)	N/A	N/A	16,528.39 Note (o)	N/A	N/A	16,593.63 Note (o)	N/A	N/A
Foster Care	841.01 Note (p)	3.65	30.68	692.00 Note (q)	6.89	47.68	46.50	1.18	6.55	45.32	771.00 Note (q)	6.60	50.89	837.00 Note (q)	6.30	52.73	897.00 Note (q)	6.00	53.82
Child Care	5,420.32 Note (r)	5.74	311.13	5,547.09 Note (s)	4.34 Note (7)	240.74	225.21	15.53	3.78	209.68	5,919.10 Note (s)	8.00 Note (7)	473.53	5,691.71 Note (s)	8.00 Note (7)	455.34	5,687.48 Note (s)	7.50 Note (7)	426.56
SUB-TOTAL Note (t)	882,173.48	10.18	89,775.39	967,276.30	10.02	96,940.51	89,744.65	7,195.84	8.53	82,548.81	1,089,568.15	9.26	100,871.02	1,119,011.39	7.86	87,952.33	1,214,564.21	7.41	90,056.34

Note: The Current Year (CY) CY+1, CY+2 and CY+3 estimated dollars paid improperly (IP$) is calculated based on the target error rate and estimated outlays for each year, respectively. However, it is important to note that the measurement periods for each program vary. Therefore, the future outlay estimates presented may not be the actual amounts against which the error rates will be applied to compute the dollars paid improperly in future years.

9.10 Accompanying Improper Payment Reporting for OMB-Determined Risk-Susceptible Programs Notes

a) Medicare FFS PY outlays are from the FY 2015 Medicare FFS Improper Payments Report (based on claims from July 2013 – June 2014).
b) Medicare FFS CY outlays are from the FY 2016 Medicare FFS Improper Payments Report (based on claims from July 2014 – June 2015).
c) Medicare FFS CY+1, CY+2, CY+3 outlays are based on the FY 2017 Midsession Review (Medicare Benefit Outlays current law (CL)).
d) Medicare Part C PY outlays reflect 2013 Part C payments, as reported in the FY 2015 Medicare Part C Payment Error Final Report.
e) Medicare Part C CY outlays reflect 2014 Part C payments, as reported in the FY 2016 Medicare Part C Payment Error Final Report.
f) Medicare Part C CY+1, CY+2, CY+3 outlays are based on the FY 2017 Midsession Review (Medicare Benefit Outlays (CL)).
g) Medicare Part D PY outlays reflect 2013 Part D payments, as reported in the FY 2015 Medicare Part D Payment Error Final Report.
h) Medicare Part D CY outlays reflect 2014 Part D payments, as reported in the FY 2016 Medicare Part D Payment Error Final Report.
i) Medicare Part D CY+1, CY+2, CY+3 outlays are based on the FY 2017 Midsession Review (Medicare Benefit Outlays (CL)).
j) Medicaid PY outlays (based on FY 2014 expenditures) are based on the FY 2016 Midsession Review and exclude CDC Vaccine for Children program funding.
k) Medicaid CY (based on FY 2015 expenditures) and CY+1, CY+2, CY+3 outlays (Medicaid - Outlays (CL) exclude CDC Vaccine for Children program funding), are based on the FY 2017 Midsession Review.
l) CHIP PY outlays (based on FY 2014 expenditures) are based on the FY 2016 Midsession Review.
m) CHIP CY (based on FY 2015 expenditures) and CY+1, CY+2, CY+3 outlays (CHIP Total Benefit Outlays with *Children's Health Insurance Program Reauthorization Act* Bonus and Health Care Quality Provisions (CL)), are based on the FY 2017 Midsession Review.
n) TANF PY outlays are based on the FY 2016 Midsession Review.
o) TANF CY, and CY+1, CY+2, CY+3 outlays are based on the FY 2017 Midsession Review (TANF total outlays including the Healthy Marriage Promotion and Responsible Fatherhood Grants programs, and excluding the TANF Contingency Fund).
p) Foster Care PY outlays are based on the FY 2016 Midsession Review, and reflect the federal share of maintenance payments.
q) Foster Care CY, and CY+1, CY+2, CY+3 outlays are based on the FY 2017 Midsession Review, and reflect the federal share of maintenance payments.
r) Child Care PY outlays are based on the FY 2016 Midsession Review.
s) Child Care CY, and CY+1, CY +2, CY+3 outlays are based on the FY 2017 Midsession Review.
t) The "Total" does not represent a true statistical estimate for the agency, and does not include information for TANF.

1. Beginning in FY 2012, in consultation with OMB, HHS refined the improper payment methodology to account for the impact of rebilling denied Part A inpatient hospital claims for allowable Part B services when a Part A inpatient hospital claim is denied because the services (i.e., improper payments due to inpatient status reviews) should have been provided as outpatient services. HHS continued this methodology from FY 2013 through FY 2016. This approach is consistent with: (1) Administrative Law Judge and Departmental Appeals Board decisions that directed HHS to pay hospitals under Part B for all of the services provided if the Part A inpatient claim was denied, and (2) recent Medicare policy changes that allow rebilling of denied Part A claims under Part B.

HHS calculated an adjustment factor based on a statistical subset of inpatient claims that were in error because the services should have been provided as outpatient. This adjustment factor reflects the difference between what was paid for the inpatient hospital claims under Medicare Part A and what would have been paid had the hospital claim been properly submitted as an outpatient claim under Medicare Part B. Application of the adjustment factor decreased the overall improper payment rate by 0.19 percentage points to 11.00 percent or $41.08 billion in projected improper payments. Additional information regarding the adjustment factor can be found on pages 166 – 167 of HHS's FY 2012 AFR (available at: www.wayback.archive-it.org/3922/20131030171234/http:/www.hhs.gov/afr/hhs_agency_financial_report_fy_2012-oai.pdf).

2. The Medicare Part C and D targets for CY+2 and CY+3 are held constant based on the uncertainty of out-year trends. The targets for CY+3 will be re-evaluated after the FY 2017 reporting period.
3. The Medicare Part D targets for CY+1 and CY+2 were established and published in the FY 2015 AFR. In FY 2016, HHS revised the Medicare Part D methodology as described in *Section 11.31*, but HHS retained the program's previously established reduction targets.
4. HHS calculated and is reporting the national Medicaid improper payment rate based on measurements that were conducted in FYs 2014, 2015, and 2016. The national Medicaid component improper payment rates are: Medicaid FFS: 12.42 percent and Medicaid managed care: 0.25 percent. The Medicaid eligibility component improper payment rate is held constant at the FY 2014 reported rate of 3.11 percent as described in *Section 11.40*.
5. HHS calculated and is reporting the national CHIP improper payment rate based on measurements that were conducted in FYs 2014, 2015, and 2016. The national CHIP component improper payment rates are: CHIP FFS: 10.15 percent and CHIP managed care: 1.01 percent. The CHIP eligibility component improper payment rate is held constant at the FY 2014 reported rate of 4.22 percent as described in *Section 11.50*.
6. The TANF program is not reporting an error rate for FY 2016. Statutory limitations prohibit HHS from requiring states to participate in a TANF improper payment measurement. Please see *Section 11.60* for additional information on statutory limitations to establishing a TANF improper payment measurement.
7. The *Child Care and Development Block Grant Act of 2014* (CCDBG) reauthorized the Child Care and Development Fund program for the first time since 1996. HHS measures one-third of the Child Care grantees each year, which is called a reporting cohort. In FY 2016, HHS established a slight increase in the improper payment target rates to accommodate all reporting cohorts' implementation of the sweeping policy and procedure changes under the new CCDBG statute. While the FY 2016 improper payment rate declined from FY 2015, HHS anticipates increases in errors as states implement new policies. Fewer reporting states implemented new policy and procedure changes than anticipated for the FY 2016 report. Many states also requested and received waiver extensions for requirements under the CCDBG statute. HHS granted these requests for all but the health and safety requirements. New CCDF regulations released in September 2016 will have a great impact on states as they promulgate and implement new policies and procedures. Future targets have been reduced slightly from earlier projections, but still allow for an increase over the next three years as additional federal regulations are developed and implemented along with the CCDBG's requirements. Future targets may be adjusted as well, depending on future performance.

Table 1B

Improper Payment Reporting for Superstorm Sandy Programs

FY 2015 – FY 2019 (in Millions) Note (1)

Program or Operating Division	PY Outlays $	PY IP %	PY IP $	CY Outlays $	CY IP %	CY IP $	CY Over payment $	CY Under payment $	CY Net IP %	CY Net IP $	CY+1 Est. Outlays $	CY+1 IP %	CY+1 IP $	CY+2 Est. Outlays $	CY+2 IP %	CY+2 IP $	CY+3 Est. Outlays $	CY+3 IP %	CY+3 IP $
ACF Head Start	16.38	0.38	0.0616	71.78	0	0	0	0	0	0	2.91	0.38 Note (2)	0.011	N/A	N/A	N/A	N/A	N/A	N/A
ACF Social Services Block Grant	209.14	0.22	0.464	198.33	0.68	1.35	1.35	0.00001	0.68	1.35	60.56 Note (3)	0.67	0.41	N/A	N/A	N/A	N/A	N/A	N/A
ACF *Family Violence Prevention and Services Act*	0.893	0.89	0.00794	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
ASPR Research	1.55	0	0	3.055	0	0	0	0	0	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
CDC Research	4.6	0	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
SAMHSA	1.32	1.38	0.0182	1.279	0.047	0.0006	0.0006	0	0.05	0.0006	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
NIH Research	38.60	2.29	0.885	12.35	0	0	0	0	0	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
SUB-TOTAL Note (4)	272.483	0.53	1.437	286.79	0.47	1.35	1.35	0.00001	0.47	1.35	63.47	0.66	0.42	N/A	N/A	N/A	N/A	N/A	N/A

9.20 Accompanying Improper Payment Reporting for Superstorm Sandy Programs Notes

1. Table 1B does not include current or future information for programs where all of the funds were expended or will be expended, and are noted by a "N/A" in the relevant cells.
2. ACF Head Start improper payments during previous years resulted from unintentional human error in recipient record-keeping, some level of which may continue in the future. Therefore, HHS anticipates that it will not continue to report a 0 percent error rate in the future, and has set a reduction target of 0.38 percent, which is the highest previously reported rate for the program.
3. ACF Social Services Block Grant CY+1 outlays are based on the remaining grant award amounts (minus drawdowns) as of June 30, 2016, and grants will end on September 20, 2017.
4. The "Total" does not represent a true statistical estimate for the agency.

Table 1C
Improper Payment Reporting for All Programs
FY 2015 - FY 2019 (in Millions)

Name	PY Outlays $	PY IP %	PY IP $	CY Outlays $	CY IP %	CY IP $	CY Over payment $	CY Under payment $	CY Net IP %	CY Net IP $	CY+1 Est. Outlays $	CY+1 IP %	CY+1 IP $	CY+2 Est. Outlays $	CY+2 IP %	CY+2 IP $	CY+3 Est. Outlays $	CY+3 IP %	CY+3 IP $
Sub-Total of OMB-Determined Risk-Susceptible Programs from Table 1A	882,173.48	10.18	89,775.39	967,276.30	10.02	96,940.51	89,744.65	7,195.84	8.53	82,548.81	1,089,568.15	9.26	100,871.02	1,119,011.39	7.86	87,952.33	1,214,564.21	7.41	90,056.34
Sub-Total of Superstorm Sandy Programs from Table 1B	272.483	0.53	1.437	286.79	0.47	1.35	1.35	0.00001	0.47	1.35	63.47	0.66	0.42	N/A	N/A	N/A	N/A	N/A	N/A
TOTAL ALL PROGRAMS Note (1)	882,445.963	10.17	89,776.827	967,563.09	10.02	96,941.86	89,746.00	7,195.84	8.53	82,550.16	1,089,631.62	9.26	100,871.44	1,119,011.39	7.86	87,952.33	1,214,564.21	7.41	90,056.34

9.30 Accompanying Improper Payment Reporting for All Programs Notes

1. The “Total” does not represent a true statistical estimate for the agency.

10.0 Improper Payment Root Cause Categories

Appendix C to OMB Circular A-123 requires the reporting of improper payment root causes by agencies with high-risk programs. The following tables (2A and 2B) display HHS’s improper payment root causes for FY 2016 for each high-risk program. There is a separate column for each program. The tables include categories of improper payments and the amount of overpayment or underpayment associated with each improper payment category. Additional information on the root causes and corrective actions, for each high-risk program can be found in each program-specific reporting section.

Table 2A
Improper Payment Root Cause Category Matrix for OMB-Determined Risk-Susceptible Programs
FY 2016 (in Millions)

Reason for Improper Payment		Medicare FFS		Medicare Part C		Medicare Part D		Medicaid		CHIP		Foster Care		Child Care	
		Overpayments	Underpayments	Overpayments	Underpayments	Overpayments	Underpayments	Overpayments	Underpayments	Overpayments	Underpayments	Overpayments	Underpayments	Overpayments	Underpayments
Program Design or Structural Issue															
Inability to Authenticate Eligibility								$10,184.45	$286.99	$363.09	$4.03				
Failure to Verify:	Death Data							$109.68		$2.66					
	Financial Data														
	Excluded Party Data							$21.87		$0.37					
	Prisoner Data														
	Other Eligibility Data (explain)														
Administrative or Process Error Made by:	Federal Agency														
	State or Local Agency							$22,686.77	$244.47	$310.80	$1.64	$46.50	$1.18	$92.69	$15.53
	Other Party (e.g., participating lender, health care provider, or any other organization administering Federal dollars)	$4,405.18	$1,234.55		$4,698.27		$733.09	$338.48		$2.70	$0.07				
Medical Necessity		$8,131.99	$5.17					$0.23		$0.08					
Insufficient Documentation to Determine		$27,307.75		$11,484.39		$1,660.84		$2,409.24		$52.37				$132.52	
Other															
TOTAL		$39,844.92	$1,239.72	$11,484.39	$4,698.27	$1,660.84	$733.09	$35,750.72	$531.46 Note (1)	$732.07	$5.74 Note (1)	$46.50	$1.18	$225.21	$15.53

10.10 Accompanying Improper Payment Root Cause for OMB-Determined Risk-Susceptible Programs Notes

1. The total Medicaid and CHIP underpayments in Table 2A are greater than the underpayment totals displayed in Table 1A, which excludes underpayments that may have also been counted as overpayments.

Table 2B
Improper Payment Root Cause Category Matrix for Superstorm Sandy Programs
FY 2016 (in Millions)

Reason for Improper Payment		ACF Head Start		ACF Social Services Block Grant		ASPR Research		SAMHSA		NIH Research	
		Overpayments	Underpayments	Overpayments	Underpayments	Overpayments	Underpayments	Overpayments	Underpayments	Overpayments	Underpayments
Program Design or Structural Issue											
Inability to Authenticate Eligibility											
Failure to Verify:	Death Data										
	Financial Data										
	Excluded Party Data										
	Prisoner Data										
	Other Eligibility Data (explain)										
Administrative or Process Error Made by:	Federal Agency										
	State or Local Agency			$0.00001	$0.00001			$0.0006			
	Other Party (e.g., participating lender, health care provider, or any other organization administering Federal dollars)			$0.28							
Medical Necessity											
Insufficient Documentation to Determine				$1.07							
Other											
TOTAL		$0.00	$0.00	$1.35	$0.00001	$0.00	$0.00	$0.0006	$0.00	$0.00	$0.00

11.0 Program-Specific Reporting Information

11.10 Medicare FFS (Parts A and B)

11.11 Medicare FFS Statistical Sampling Process

Medicare FFS uses the Comprehensive Error Rate Testing (CERT) program to calculate the improper payment estimate. The CERT program considers any claim paid when it should have been denied or was paid in the wrong amount (including both overpayments and underpayments) to be an improper payment. To meet this objective, a stratified random sample of Medicare FFS claims is reviewed to determine if claims were paid properly under Medicare coverage, coding, and billing rules. If these criteria are not met, the claim is counted as either a total or a partial improper payment, depending on the error category. Approximately 50,000 claims were sampled during the FY 2016 report period. The CERT program ensures a statistically valid random sample; therefore, the improper payment rate calculated from this sample reflects all claims processed by the Medicare FFS program during the report period. Additional information on the Medicare FFS improper payment methodology can be found on pages 166 – 167 of HHS's FY 2012 AFR, available at: www.wayback.archive-it.org/3922/20131030171300/http:/www.hhs.gov/afr/hhs_agency_financial_report_fy_2012-oai.pdf.

The Medicare FFS gross improper payment estimate for FY 2016 is 11.0 percent or $41.08 billion. The FY 2016 net improper payment estimate is 10.33 percent or $38.61 billion. The decrease from the prior year's reported error estimate of 12.09 percent was driven by a reduction in improper payments for inpatient hospital claims. However, improper payments for home health and Inpatient Rehabilitation Facility (IRF) claims were the major contributing factors to the FY 2016 Medicare FFS improper payment rate. While the factors contributing to improper payments are complex and vary from year to year, the primary causes of improper payments continue to be insufficient documentation and medical necessity errors.

- Insufficient documentation to support medical necessity for home health claims continues to be prevalent, despite the decrease from 58.95 percent in FY 2015 to 42.01 percent in FY 2016.
- Medical necessity (i.e., the services billed were not medically necessary) was the major error reason for IRF claims. The improper payment rate for IRF claims increased from 45.50 percent in FY 2015 to 62.39 percent in FY 2016.

11.12 Medicare FFS CAP

The primary cause of improper payments is lack of documentation to support the services or supplies billed to Medicare, or missing or insufficient documentation errors (66.47 percent). The other causes of improper payments are medical necessity errors (19.81 percent), and administrative or process errors made by other party (13.73 percent).

HHS is committed to reducing improper payments in its programs. HHS uses data from the CERT program and other sources of information to address improper payments in the Medicare FFS program through various corrective actions. While some corrective actions have been implemented, others are in the early stages of implementation. These focused corrective actions will have a larger impact over time as they become integrated into business operations.

To reduce improper payments within Medicare FFS, HHS is implementing a number of measures that focus on prevention. HHS's corrective actions include policy clarifications and simplifications, when appropriate, and more individualized education through smaller probe reviews, followed by specific education based on the findings of these reviews (generally referred to as Probe and Educate reviews). HHS is also committed to exploring

opportunities to implement prior authorization and pre-claim review programs. In addition to helping educate providers and suppliers and decrease the number of appeals, prior authorization and pre-claim review programs also help reduce improper payments.

Of particular importance are corrective actions that focus on specific service areas with high error rates such as home health and IRF claims. HHS believes implementing targeted corrective actions in these areas will have a considerable effect in preventing and reducing improper payments.

- HHS continues to implement corrective actions to address program payment vulnerabilities related to home health services, including errors resulting from insufficient or missing documentation to support the beneficiary's eligibility for home health services and/or for skilled services. Home health corrective actions include: policy revisions; a pre-claim review demonstration; Probe and Educate reviews; and establishing a home health recovery auditor contractor.
  - HHS issued a final rule, CMS-1611-F (79 FR 66032, November 6, 2014) to update Medicare's Home Health Prospective Payment System payment rates and wage index for calendar year 2015. In this rule, HHS finalized changes to the face-to-face encounter requirements for home health episodes beginning on or after January 1, 2015. Specifically, HHS amended the HHA regulation to remove the requirement for documentation of a face-to-face visit to be provided in a prescribed encounter narrative. However, HHS maintained the requirement for a face-to-face visit to have occurred as part of the certification of patient eligibility for the benefit. Now reviewers should consider documentation in the certifying physician's medical records and/or the acute/post-acute care facility's medical records (if the patient was directly admitted to home health) to determine patient eligibility for the home health service.
  - To assist with documenting the home health face-to-face encounter, HHS completed, as part of the *Paperwork Reduction Act*, the required public comment periods in FY 2016 for a voluntary paper and electronic clinical template for ordering physicians (80 FR 80771, December 28, 2015). The template will help physicians capture the information needed to complete the face-to-face encounter documentation. This template is in the form of a progress note and will become part of the medical record.
  - In FY 2016, HHS began implementing a three-year Pre-Claim Review Demonstration for Home Health Services. Implementation began August 3, 2016, in Illinois. Based on early information from Illinois, HHS believes additional education efforts would be helpful before expanding the demonstration to other states. The start dates for Florida, Texas, Michigan, and Massachusetts have not been announced; however, HHS will provide at least 30 days' notice on its website prior to beginning this demonstration in any state. The demonstration tests whether: 1) pre-claim review improves methods for the identification and investigation of Medicare fraud occurring among HHAs, and 2) the demonstration helps reduce expenditures while maintaining or improving quality of care.
  - On October 1, 2015, HHS's MACs began pre-payment reviews of home health claims for episodes beginning on or after August 1, 2015 that are designed to help HHAs understand the new patient certification requirements. Specifically, HHS's MACs use a Probe and Educate strategy to review five home health claims for every HHA and provide education and/or training if needed.
  - During FY 2016, HHS continued the procurement for a new Medicare FFS Recovery Audit Contractor (RAC) to identify and correct improper payments for home health claims. HHS expects to award the new Home Health RAC contract in early FY 2017.
- Additionally, HHS focuses on addressing IRF payment errors resulting from missing or insufficient medical record documentation to support medical necessity for therapy programs, as well as addressing therapy services provided in other settings.

- HHS issued a final IRF Prospective Payment System (PPS) rule, CMS-1608-F (79 FR 4587, August 6, 2014), which required IRFs to record and report to HHS how much and what type of therapy (that is, Individual, Concurrent, Group, and Co-Treatment) patients receive in each therapy discipline in the IRF setting. HHS will utilize this data for potentially informing future IRF rulemaking.
- There are annual dollar limits to the outpatient therapy services (known as therapy caps) that a Medicare beneficiary can receive each year, though there are exceptions to the therapy cap for reasonable and necessary therapy services. *The Medicare Access and CHIP Reauthorization Act of 2015* (MACRA) extended the therapy cap exception process through December 31, 2017. MACRA also eliminated the requirement for manual medical review of all claims over the $3,700 thresholds and instead allows a targeted review process for services.
- In FY 2016, HHS tasked the Supplemental Medical Review Contractor (SMRC) with performing medical review on a post-payment basis for IRF services and other therapy services provided in various settings. The SMRC selects these other therapy claims for review based on:
  - Providers with a high percentage of patients receiving therapy beyond the threshold as compared to their peers during the first year of MACRA; and
  - Therapy provided in SNFs; therapists in private practice; and outpatient physical therapy, speech-language pathology providers, or other rehabilitation providers. Of particular interest in this medical review process will be the evaluation of the number of units or hours of therapy provided in a day.

In FY 2016, the Medicare FFS improper payment rate decreased due to the successes of the corrective actions to address improper payments for inpatient hospital services outlined below. As a result, the improper payment rate for inpatient hospital claims decreased from 6.18 percent in FY 2015 to 3.85 percent in FY 2016.

- HHS finalized updates to the Hospital Outpatient Prospective Payment System ("Two Midnight") rule (CMS-1633-FC, 80 FR 70298, November 13, 2015) regarding when hospital admissions are appropriate for payment under Medicare Part A. At the same time, HHS notified the public of two upcoming changes in education and enforcement strategies.
  - Beginning on October 1, 2015, the Quality Improvement Organizations (QIOs) assumed responsibility to conduct initial patient status reviews to determine the appropriateness of Part A payments for short stay hospital claims. From October 1, 2015 through December 31, 2015, short stay hospital reviews conducted by the QIOs were based on Medicare's payment policies in effect at the time.
  - Beginning on January 1, 2016, QIOs began conducting patient status reviews in accordance with policy changes finalized in the Hospital Outpatient Prospective Payment System rule (CMS-1633-FC, 80 FR 70298, November 13, 2015) that were effective for calendar year 2016.

HHS also leverages prior corrective action successes in other service areas such as inpatient hospital services; Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS); and certain non-emergent services by educating providers on policies and exploring opportunities to implement prior authorization models.

- During FY 2016, HHS continued the procurement for a new Medicare FFS RAC to identify and correct improper payments for claims for DMEPOS and Hospice Services. The RAC will review all applicable claims types through the appropriate review methods and work with HHS and the MACs to adjust claims to recoup overpayments and correct underpayments. HHS expects to award the new RAC contract in early FY 2017.
- Building on the success of the Power Mobility Device (PMD) prior authorization demonstration, HHS issued a DMEPOS prior authorization final rule in FY 2016 (CMS–6050–F, 80 FR 81674, December 30, 2015) that establishes a prior authorization program for certain DMEPOS items that are frequently subject

to unnecessary utilization. The rule defines unnecessary utilization and establishes a list of DMEPOS items that could be subject to prior authorization before payment is made. HHS expects to begin implementation in FY 2017.

- HHS continues to expand the use of prior authorization in the Medicare FFS program.
  - On September 1, 2012, HHS instituted a prior authorization demonstration program in seven states for PMDs. Prior authorization reviews were performed timely and feedback from the industry and beneficiaries has been largely positive. HHS expanded the demonstration to an additional 12 states (Arizona, Georgia, Indiana, Kentucky, Louisiana, Maryland, Missouri, New Jersey, Ohio, Pennsylvania, Tennessee, and Washington) effective October 1, 2014, bringing the total number of states participating in the demonstration to 19. In FY 2015, HHS also extended the demonstration to August 31, 2018. This demonstration project appears to have led to a decrease in the expenditures for PMDs in both the demonstration and non-demonstration states. Based on claims processed as of December 31, 2015, monthly expenditures for the PMD codes included in the demonstration project decreased from $12 million in September 2012 to $3 million in December 2015 in the original seven demonstration states, $10 million in September 2012 to $3 million in December 2015 in the 12 additional expansion states, and $10 million in September 2012 to $3 million in December 2015 in the non-demonstration states.
  - In December 2014, HHS implemented a prior authorization model for repetitive, scheduled non-emergent ambulance transport occurring on or after December 15, 2014 in New Jersey, Pennsylvania, and South Carolina. On January 1, 2016, in accordance with Section 515 of MACRA, HHS expanded the prior authorization model for repetitive scheduled non-emergent ambulance transports to five additional states (North Carolina, Virginia, West Virginia, Maryland, and Delaware) and the District of Columbia. Prior to implementing the model, spending on repetitive, scheduled non-emergent ambulance transports in the model states averaged $18.9 million per month. Based on data from the program's first year, spending decreased in the initial states to an average of $5.4 million per month.
  - In April 2015, HHS implemented a prior authorization model for non-emergent hyperbaric oxygen therapy in Michigan, Illinois, and New Jersey to test whether prior authorization reduces expenditures while maintaining or improving quality of care for certain non-emergent services. In FY 2016, HHS continued this prior authorization model for non-emergent hyperbaric oxygen therapy in these three states. This project will also help ensure services are provided in compliance with applicable Medicare coverage, coding, and payment rules before rendering services and paying claims.

In addition to these initiatives, HHS has implemented additional efforts to reduce improper payments in the Medicare FFS program that span multiple service areas and address the root causes of improper payments as outlined below.

Corrective Actions to Address Root Causes:

Root Cause: Administrative or Process Errors Made by Other Party

- Automated Edits: Due to the volume of claims processed by Medicare each day and the significant cost associated with conducting medical review of an individual claim, HHS relies on automated edits to identify many inappropriate claims. HHS designed its systems to detect anomalies on the face of the claims, and through these efforts, HHS prevents payment for many erroneous claims. HHS uses the National Correct Coding Initiative (NCCI) to stop claims that never should be paid. For example, this program prevents payments for services such as a hysterectomy for a man or a prostate exam for a woman. The use of the NCCI edits saved the Medicare program $700.66 million in FY 2015. HHS will report FY 2016 savings from the use of the NCCI edits in the FY 2017 AFR.

- Provider and Supplier Screening: The *Affordable Care Act* requires HHS to revalidate all existing Medicare providers and suppliers. All Medicare providers and suppliers enrolled prior to the new screening requirements becoming effective were sent revalidation notices by March 23, 2015. HHS is revalidating all 1.6 million existing Medicare providers and suppliers to ensure that only qualified and legitimate providers and suppliers deliver health care items and services to Medicare beneficiaries. These revalidation efforts alone resulted in approximately 378,500 deactivations as well as the revocation of approximately 24,400 providers and suppliers billing privileges as of September 30, 2016.
- Healthcare Fraud Prevention Partnership (HFPP): HHS continues to build the HFPP, a public-private partnership to improve detection and prevention of health care fraud, waste, and abuse. During FY 2016, HFPP membership grew from 43 to 69 partner organizations from the public and private sectors, including federal and state partners, private payers, associations, and law enforcement organizations. HFPP members exchange data, information and anti-fraud practices in an effort to prevent and detect fraud across all payers.
- Medical Review Strategies: HHS and its contractors develop medical review strategies using the improper payment data to ensure the areas of highest risk and exposure are targeted. HHS requires its Medicare review contractors to focus on identifying and preventing improper payments due to documentation errors in certain error prone claim types, such as home health, hospital outpatient, and SNF claims.
- Overpayment Recoveries Related to Regulatory Provisions: In CMS 6037-F, "Medicare Program: Reporting and Returning of Overpayments" (81 FR 7654, February 12, 2016), HHS codified rules that addressed the responsibilities of providers and suppliers to identify, report, and return any Medicare Part A or Part B overpayment.

Root Cause: Medical Necessity and Insufficient Documentation to Determine

- Medical Review Strategies: HHS contracted with the SMRC to perform medical reviews focused on vulnerabilities identified by HHS data analysis, the CERT program, professional organizations, and federal oversight agencies. The contractor evaluates medical records and related documents to determine whether claims were billed in compliance with Medicare coverage, coding, payment, and billing rules. In FY 2016, the SMRC performed post payment reviews on IRFs, SNF therapy services, chiropractic services, Medicare Part B drugs, and ophthalmology services. The results of these reviews are used to improve billing accuracy.
- Medical Review Strategies: HHS continues to allow review contractors to review more claim types than in previous years, while closely monitoring the decisions made by these contractors. As a result of stakeholder feedback, in February 2014 HHS announced a number of changes to the Medicare FFS RAC program that would take effect with the new contract awards. Due to the delay in the new contract awards, HHS included several of the changes in the current RACs' contracts. HHS believes that these improvements will result in a more effective and efficient program, including improved accuracy, less provider burden, and more program transparency. For further information on these changes, refer to www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Recovery-Audit-Program/Downloads/Recovery-Audit-Program-Enhancements11-6-15-Update-.pdf.
- Medical Review (MR) Accuracy Award Fee Metric: Beginning in FY 2014, HHS included the MR Accuracy Award Fee Metric in the Award Fee Plan for MACs that process Part A and Part B claims and DME claims for Medicare FFS beneficiaries. The MR Accuracy Award Fee Metric measures the accuracy of the MAC's complex medical review decisions. HHS believes this project assists with consistent medical review decisions across MACs, leading to uniform education to providers on medical necessity and insufficient documentation improper payments. HHS is considering expanding this project to the MAC

redetermination appeal units to ensure consistent medical review decisions are made at the MAC redetermination appeal level.

- Provider Billing Self-review: HHS issues Comparative Billing Reports (CBRs) to help Medicare Part B providers analyze their coding and billing practices for specific procedures or services. CBRs are proactive statements that enable these providers to examine their billing patterns compared to their peers in the state and across the nation.
- Provider Billing Self-review: HHS launched a Provider Billing Review Evaluation in one MAC jurisdiction in FY 2016 to help Part B providers analyze their coding and billing practices by expanding the self-service exchange of information beyond the transaction-based activities of claims, eligibility, medical review, prior authorization, and payment to now include utilization data and information designed to support Part B providers' awareness and compliance. In addition, the system prompts users to use self-service educational materials that will be tracked via web analytics.

11.13 Medicare FFS Information Systems and Other Infrastructure

HHS has the information systems and other infrastructure it needs to reduce improper Medicare FFS payments to the targeted levels. HHS's systems have the ability to identify developing and continuing aberrant billing patterns based upon a comparison of local payment rates with national rates. The systems at both the Medicare contractor level and the HHS level are tied together by a high-speed secure network that allows rapid transmission of large data sets between systems. In addition, HHS continuously reviews opportunities for centralizing the development and implementation of automated edits based on national coverage determinations, medically unlikely units billed, and other relevant parameters to prevent improper payments on a prepayment basis.

11.14 Medicare FFS Statutory or Regulatory Barriers That Could Limit Corrective Actions

HHS has limited authority to conduct prior authorization on services that account for a large portion of Medicare FFS improper payments. Currently, HHS can only conduct prior authorization for a limited set of DMEPOS items, advanced imaging, spinal subluxation, and non-emergency ambulance transport services, which generally account for a small portion of the Medicare FFS improper payments. For example, in December 2015, HHS promulgated a final rule that will implement prior authorization for a limited set of DMEPOS items. Specifically, Section 1834(a)(15) of the *Social Security Act* authorizes the Secretary to develop and periodically update a list of DMEPOS items determined to be subject to unnecessary utilization and to develop a prior authorization process for these items. Additionally, recent legislation, the *Protecting Access to Medicare Act of 2014* and MACRA, expanded prior authorization authorities to advanced imaging, spinal subluxation, and non-emergent ambulance transport. Because of these limited authorities, the *FY 2017 President's Budget* proposed amending the *Social Security Act* to authorize the Secretary to select any items or services for prior authorization without rulemaking where the items or services involve high cost, high utilization, patient risk, and/or high improper payment rates.

11.20 Medicare Advantage (Part C)

11.21 Medicare Advantage Statistical Sampling Process

The FY 2016 Medicare Part C gross improper payment estimate is 9.99 percent or $16.18 billion. The FY 2016 net improper payment estimate is 4.19 percent or $6.79 billion. The increase from the prior year's reported error estimate was due to volatility in underlying payment methodology and to lack of improvement in validity of plan-reported diagnoses.

The Part C methodology estimates errors resulting from incorrect beneficiary risk scores. The primary component of a beneficiary's risk score is based on clinical diagnoses submitted by plans. If the diagnoses submitted to HHS are not supported by medical records, the risk scores will be inaccurate and result in payment errors. The Part C estimate is based on medical record reviews conducted under HHS's annual Risk Adjustment Data Validation (RADV) process, where unsupported diagnoses are identified and corrected risk scores are calculated.

The FY 2016 methodology consisted of the following steps:

- Selection of a stratified random sample of beneficiaries for whom a risk adjusted payment was made in calendar year 2014, where the strata are high, medium, and low risk scores;
- Medical record review of the diagnoses submitted by plans for the sampled beneficiaries;
- Calculation of beneficiary-level payment error for the sample; and
- Extrapolation of the sample payment error to the population subject to risk adjustment, resulting in a Part C gross payment error amount.

11.22 Medicare Advantage CAP

The root causes of FY 2016 Medicare Part C improper payments resulted from errors due to missing or insufficient documentation (70.97 percent) and administrative or process errors made by other party (the Medicare Advantage [MA] organizations) (29.03 percent).

Corrective Actions to Address Root Causes:

Root Causes: Insufficient Documentation to Determine and Administrative or Process Errors Made by Other Party

HHS has implemented four key corrective actions to address the Part C improper payment rate:

- Contract-Level Audits: HHS is proceeding with the RADV contract-level audits to recover overpayments. RADV verifies, through medical record review, the accuracy of enrollee diagnoses submitted by MA organizations for risk adjusted payment. RADV audits are HHS's primary corrective action to recoup improper payments. HHS expects that payment recovery will have a sentinel effect on the quality of risk adjustment data submitted by plans for payment. Payment recovery for the pilot audits has been completed and totaled $13.7 million ($5.4 million was recovered in FY 2014, $5.0 million in FY 2013, and $3.4 million in FY 2012)[27]. RADV audits of payment year 2011, which began in FY 2014, will be the first HHS reviews to recoup funds based on extrapolated estimates. In addition, during FY 2016, payment year 2012 audits continued and payment year 2013 audits were initiated.
- Overpayment Recoveries Related to Regulatory Provisions: In CMS-4159-F, "Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs" (79 FR 29843, May 23, 2014), HHS codified the *Affordable Care Act* requirement that MA organizations report and return overpayments that they identify. In CMS-1613-F, "The Calendar Year 2015 Outpatient Prospective Payment System and Ambulatory Surgical Center Rule" (79 FR 66769, November 10, 2014), HHS also established a payment recovery and appeal mechanism to be applied when HHS identifies erroneous payment data submitted by an MA organization. In FY 2016, MA organizations reported and returned approximately $317 million in self-reported overpayments.
- Recovery Audit Contractor: As part of the procurement process to secure a Medicare Part C RAC, HHS posted a Request for Quote in June 2014; however, no responses were received from that solicitation. More recently, a Request for Information was posted in December 2015 to solicit additional feedback

[27] Values do not total due to rounding.

from industry regarding this program. HHS received several submissions in response to the announcement. HHS continues its implementation efforts and anticipates awarding a contract in 2017.

- Training: HHS continued its national fraud, waste, and abuse in-person and webinar training sessions for MA plans.

11.23 Medicare Advantage Information Systems and Other Infrastructure

HHS has the information systems and other infrastructure needed to reduce improper Medicare Part C payments. HHS uses the following internal Medicare systems to make and validate the Medicare Part C payments: the Medicare Beneficiary Database; the Risk Adjustment System, the Health Plan Management System; and the Medicare Advantage Prescription Drug (MARx) payment system.

11.24 Medicare Advantage Statutory or Regulatory Barriers that Could Limit Corrective Actions

No statutory or regulatory barriers that could limit corrective actions have been identified at this time.

11.30 Medicare Prescription Drug Benefit (Part D)

11.31 Medicare Prescription Drug Benefit Statistical Sampling Process

The Medicare Part D gross improper payment estimate for FY 2016 is 3.41 percent or $2.39 billion. The FY 2016 net improper payment estimate is 1.32 percent or $927.75 million. The FY 2016 Part D Payment Error Rate measures payment error related to prescription drug event data. The primary factor that drove the program's decrease from the prior year's reported error estimate was a change in the program's methodology.

The methodology for calculating the FY 2016 Part D error estimate has been revised from prior years, when HHS reported a Part D composite rate consisting of four components: Payment Error Related to Low Income Subsidy Status (PELS); Payment Error Related to Medicaid Status (PEMS); Payment Error Related to Prescription Drug Event Data Validation (PEPV); and Payment Error Related to Direct and Indirect Remuneration (PEDIR).

With OMB's approval, for FY 2016 and subsequent years, the Part D error estimate measures only one component, the PEPV, which is the area where the majority of error for the program exists. The three other previously measured components – PELS, PEMS, and PEDIR - pose very little risk of payment error to the government. Over the years of measurement, the error estimates for these components as demonstrated in previous measurement cycles significantly decreased, such that the effort and resources required to measure them were no longer cost effective. A description of the previous methodology is on pages 173 – 175 of HHS's FY 2012 AFR (www.wayback.archive-it.org/3922/20131030171300/http:/www.hhs.gov/afr/hhs_agency_financial_report_fy_2012-oai.pdf).

11.32 Medicare Prescription Drug Benefit CAP

The root causes of the FY 2016 Part D improper payments are missing or insufficient documentation (69.38 percent) and administrative or process error made by other party (30.62 percent).

Corrective Actions to Address Root Causes:

Root Causes: Insufficient Documentation to Determine and Administrative or Process Errors Made by Other Party

HHS conducted the following corrective actions to address errors:

- Training: HHS continued its national training sessions for Part D sponsors on payment and data submission. HHS also continued its national fraud, waste, and abuse in-person and webinar training sessions for Part D sponsors.
- Outreach: HHS continued formal outreach to plan sponsors for invalid/incomplete documentation. HHS distributed Plan Sponsor Summary Reports to all plans participating in the national payment error estimate. This report provided feedback on their submission and validation results against an aggregate of all participating plan sponsors.
- Overpayment Recoveries Related to Regulatory Provisions: HHS codified the *Affordable Care Act* requirement that Part D sponsors report and return overpayments that they identify. HHS also established a payment recovery and appeal mechanism to be applied when HHS identifies erroneous payment data submitted by a Part D sponsor (See *Section 11.22* for more information on the rules). In FY 2016, Part D sponsors reported and returned approximately $9.5 million in self-reported overpayments.

11.33 Medicare Prescription Drug Benefit Information Systems and Other Infrastructure

HHS has the information systems and other infrastructure needed to reduce improper Medicare Part D payments. HHS uses the following internal Medicare systems to make and validate the Medicare Part D payments: the Medicare Beneficiary Database, the Risk Adjustment System, the Health Plan Management System, the MARx payment system, and the Integrated Data Repository.

11.34 Medicare Prescription Drug Benefit Statutory or Regulatory Barriers that Could Limit Corrective Actions

HHS lacks specific statutory authority to require the submission of medical records from providers in connection with an investigation or audit of drugs paid under the Medicare Part D program, which could affect HHS's ability to reduce improper payments in the program.

11.40 Medicaid

11.41 Medicaid Statistical Sampling Process

The national FY 2016 Medicaid improper payment rate is based on measurements conducted in FYs 2014, 2015, and 2016. Medicaid improper payments are estimated on a federal FY basis and measure three component improper payment rates: FFS, managed care, and eligibility. HHS, through its use of federal contractors, measures the FFS and managed care components. The eligibility component measurement is currently "on hold" as described in the eligibility component section below.

The Payment Error Rate Measurement (PERM) program uses a 17-state three-year rotation for measuring Medicaid improper payments. To see how HHS grouped states into three cycles, refer to pages 177 – 179 of HHS's FY 2012 AFR (www.wayback.archive-it.org/3922/20131030171300/http:/www.hhs.gov/afr/hhs_agency_financial_report_fy_2012-oai.pdf).

FFS and Managed Care Component

States submit quarterly adjudicated claims data from which a randomly selected sample of FFS claims and managed care payments are drawn each quarter. Each selected FFS claim is subjected to a medical and data processing review. Managed care payments are subject only to a data processing review. The FFS sample size was between 292 and 966 claims per state and the managed care sample size was between 230 and 298 payments per state. The sample sizes were based on each state's historical FFS and managed care improper payment rate data. When a state's FFS component or managed care component accounted for less than 2 percent of the state's total Medicaid expenditures, the state's FFS and managed care claims were combined into one component for sampling and measurement purposes. This consolidation occurred in five states.

Eligibility Component

In light of changes to the way states adjudicate eligibility for Medicaid and CHIP under the *Affordable Care Act*, HHS is updating the eligibility component measurement methodology and related PERM program regulation to reflect these changes. HHS published a PERM Notice of Proposed Rule-Making (81 FR 40596, June 22, 2016) in FY 2016 to update the PERM eligibility component.

In August 2013 and October 2015, HHS released guidance announcing temporary changes to PERM eligibility reviews. For FYs 2015 through 2018, HHS will not conduct the eligibility measurement component of PERM, but will hold the eligibility component's error rate constant at the FY 2014 reported rate of 3.11 percent.

In place of the FYs 2015 through 2018 PERM eligibility reviews, all states are required to conduct eligibility review pilots that provide more targeted, detailed information on the accuracy of eligibility determinations. The pilots use targeted measurements to: provide state-by-state programmatic assessments of the performance of new processes and systems in adjudicating eligibility, identify strengths and weaknesses in operations and systems leading to errors, and test the effectiveness of corrections and improvements in reducing or eliminating those errors.

Calculations and Findings

The national Medicaid program improper payment rate represents the combination of each state's Medicaid FFS, managed care, and eligibility improper payment rates. In addition, individual state component improper payment rates are combined to calculate the national component improper payment rates. National component improper payment rates and the Medicaid program improper payment rate are weighted by state size, so that a state with a $10 billion program "counts" 10 times more toward the national rate than a state with a $1 billion program. A small correction factor ensures that Medicaid eligibility improper payments are not "double counted." Additionally, HHS incorporates state-level improper payment rate recalculations for the states measured in FY 2014 and FY 2015 into the national Medicaid improper payment rate. Subsequent to FY 2015 reporting, eight state-level FFS improper payment rates were recalculated to allow for appeal results and late documentation that was received prior to the cut-off date for claims submitted between July 1, 2013 and June 30, 2014 and are incorporated into FY 2016 improper payment rate reporting.

The national Medicaid gross improper payment estimate for FY 2016 is 10.48 percent or $36.25 billion. The FY 2016 net improper payment estimate is 10.19 percent or $35.25 billion. This rate increased from prior years due to an increase in the FFS component, as discussed in *Section 11.42.*

The FY 2016 national Medicaid improper payment rate for each component is:

- *Medicaid FFS*: 12.42 percent
- *Medicaid managed care*: 0.25 percent

As previously stated, the Medicaid eligibility component improper payment rate is held constant at the FY 2014 rate of 3.11 percent.

Eligibility Review Pilot Findings

The eligibility review pilots continue to identify vulnerabilities in processes and systems. States then take action to address these vulnerabilities, which is essential to preventing future improper payments and improving verification processes. In the most recent round of pilots, states continued to identify vulnerabilities related to caseworkers or systems not properly establishing income level, although these vulnerabilities did not necessarily always lead to eligibility determination errors. States also identified issues related to failures in sending appropriate notices, delays in processing eligibility determinations, and failing to follow verification plans that outline each state's verification policies and procedures. States are implementing corrective action strategies and focusing on targeted caseworker training, systems fixes and maintaining records as the pilots continue. More information on the pilots can be found at: www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicaid-and-CHIP-Compliance/PERM/FY2014_FY2016EligibilityReviewPilots-.html.

11.42 Medicaid CAP

States reviewed for the FY 2016 AFR measurement were the same states reviewed in FY 2013. The improper payment rate for these states increased from 5.73 percent in FY 2013 to 8.81 percent in FY 2016, causing an increase in the FY 2016 national Medicaid improper payment rate. The FFS component was the driver of the increase for these states, rising from 3.42 percent to 9.78 percent.

Similar to FY 2014 and FY 2015, the primary reason for the FY 2016 improper payments was errors related to state difficulties bringing systems into compliance with provisions put in place to strengthen program integrity. First, all referring or ordering providers are required to be enrolled in Medicaid or CHIP and claims must contain the referring or ordering National Provider Identifier (NPI) (42 CFR §455.410(b) and 455.440, respectively). Second, states are required to screen providers under a risk-based screening process prior to enrollment (42 CFR §455.450). Finally, the attending provider NPI is required to be submitted on all electronically filed institutional claims (45 CFR §162.1102). While these requirements will ultimately strengthen Medicaid program integrity, it is not unusual to see increases in improper payment rates following the implementation and initial measurement of new requirements because it takes time for states to make the changes required for compliance.

Although all states are included in the improper payment rates, HHS only reviews 17 states each year. In FY 2014, HHS reported a rate reflecting the first 17 states measured under new the requirements. The FY 2015 improper payment rates reflected the second group of 17 states subject to new requirements for a total of 34 states. The FY 2016 rate reflects the measurement of the final group of 17 states subject to new requirements. HHS expects to see a decrease in improper payment rates in following years as states that have implemented corrective actions are measured again.

HHS works closely with all states to develop state-specific CAPs. All states are responsible for implementing, monitoring, and evaluating the effectiveness of their CAPs, with assistance and oversight from HHS. The Department received CAPs from all states with Medicaid programs that were previously measured, and all states measured in FY 2016 are developing CAPs for submission to HHS. When developing the CAPs, states focus their efforts on the major causes of improper payments where the state can clearly identify patterns. In addition, states also take steps to reduce errors identified during the measurement. HHS also establishes corrective actions to reduce improper payments. For example, HHS is actively engaging with states to address these root causes by: conducting outreach during off-cycle PERM measurement years to address issues identified in CAPs; facilitating national best practice calls to share ideas across states; offering ongoing technical assistance; and providing additional guidance as needed. Additional information on states' and HHS's corrective actions are provided below.

Corrective Actions to Address Root Causes:

Root Causes: Administrative or Process Errors Made by State or Local Agency and Failure to Verify

Administrative or process errors made by a states or local agencies and failure to verify mainly consist of errors resulting from state difficulties bringing systems into compliance with new requirements as described above. Improper payments related to non-compliance with these new requirements do not necessarily represent payments to illegitimate providers. Typically, improper payments are cited when information required for payment was missing from the claim or states did not follow appropriate processes for enrolling providers. If the information had been on the claim and the state followed the correct enrollment process, then the claim may have been payable.

Because the Medicaid improper payment rate was primarily driven by these errors, state CAPs focus on systems or process changes to reduce these errors. Specific actions include implementing new claims processing edits, converting to a more sophisticated claims processing system, and implementing a new provider enrollment process to make it easier for referring providers to enroll in the program. For example, state Medicaid agencies may rely on Medicare's enrollment and screening of providers and on Medicare's site visits, where the provider is enrolled in Medicare and Medicaid.

In addition to the development, execution, and evaluation of the state-specific CAPs, HHS has implemented corrective actions to specifically address compliance with Medicaid provider screening, enrollment, and revalidation efforts to reduce errors related to this category:

- State Medicaid Provider Screening and Enrollment: HHS shares Medicare data to assist states with meeting Medicaid screening and enrollment requirements. Specifically, HHS shares the Medicare provider enrollment record via the Provider Enrollment, Chain and Ownership System (PECOS) administrative interface and via data extracts from the PECOS system. HHS also shares Office of the Inspector General (OIG) exclusion data with states. In May 2016, HHS began to offer a data compare service that allows a state to rely on Medicare's screening, in lieu of conducting state screening. Using the data compare service, a state provides an extract of Medicaid provider enrollment data to HHS and then HHS returns information to the state indicating for which providers the state is able to rely on Medicare's screening.
- Enhanced Assistance on State Medicaid Provider Screening and Enrollment: HHS provides ongoing guidance, education, and outreach (site visits and technical assistance) to states on federal requirements for Medicaid enrollment and screening. In addition, HHS published the Medicaid Provider Enrollment Compendium in March 2016, which is sub-regulatory guidance designed to assist states in applying the regulatory requirements.
    - Site Visits: HHS conducts state site visits to assess provider screening and enrollment compliance, provide technical assistance, and offer states the opportunity to leverage Medicare screening and enrollment activities.
    - Technical Assistance for Provider Screening and Enrollment: In FY 2016, HHS procured a contractor to assist with ongoing state technical assistance and process improvement related to provider screening and enrollment. The project will include assessing state compliance with requirements for provider screening and enrollment, conducting a gap analysis, and developing strategic blueprints to assist states with improving processes. In addition, in order to help alleviate state concerns with the cost of completing the Social Security Administration (SSA) Death Master File (DMF) check as part of the provider screening, HHS is working with the SSA to provide the DMF to states. HHS has obtained this data and is developing a secure method for housing and sharing the large volume of sensitive data with states. HHS plans to share this information with states by the end of 2016.

- Medicaid Integrity Institute: HHS offers training, technical assistance, and support to state Medicaid program integrity officials through the Medicaid Integrity Institute. The FY 2016 course schedule included seminars in May and September 2016 that focused exclusively on complying with the provider screening and enrollment requirements. More information on the Medicaid Integrity Institute can be found at: www.justice.gov/mii.

Root Causes: Insufficient Documentation to Determine and Administrative or Process Errors Made by Other Party

State CAPs also include provider communication and education to reduce errors related to these categories. These methods include holding provider training sessions and meetings with provider associations; issuing provider notices, bulletins, newsletters, alerts, and surveys; implementing improvements and clarifications to written state policies emphasizing documentation requirements; and performing more provider audits to identify areas of vulnerability and target solutions.

In addition to the development, execution, and evaluation of the state-specific CAPs, HHS has implemented additional efforts to lower improper payments rates in these two error categories:

- State Medicaid RAC Programs: By the end of FY 2016, 47 states and the District of Columbia had implemented Medicaid RAC programs to identify and recover overpayments and identify underpayments in their Medicaid programs. However, each state has the flexibility to tailor its RAC program where appropriate with guidance from HHS. For example, two of the states that have implemented Medicaid RAC programs ended their RAC programs when HHS approved an exception because of the high proportion of beneficiaries enrolled in Medicaid managed care compared to FFS. Five states currently have time-limited HHS-approved exceptions to Medicaid RAC implementation due to high managed care penetration or small beneficiary populations.
- Expanded Reviews/Oversight: HHS aligned state Program Integrity Reviews with off-cycle PERM reviews to maintain pressure on states that were previously reviewed to continuously correct errors. During FY 2016, HHS collected information on the status of the PERM CAP completion for states that submitted CAPs related to Medicaid FFS in FY 2015. In FY 2017, HHS will complete its assessment of states' PERM CAP status and provide feedback to states on actions needed to complete their PERM CAP.
- Education: HHS made available a variety of educational toolkits, which include presentations, fact sheets, and booklets that were made specifically for providers or beneficiaries. These educational resources are intended to educate providers, beneficiaries, and other stakeholders in promoting best practices and raising awareness of Medicaid fraud, waste, and abuse. In FY 2016, HHS posted the following new toolkits: Pharmacy Audit & Dispensing Toolkit, Behavioral Health Toolkit, and Medicaid Provider Enrollment Toolkit. HHS also posted a series of program integrity eBulletins, Infographics, Podcasts, and Key Messages and Tips on a variety of topics for providers and beneficiaries. More information on these educational toolkits can be found at: www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/edmic-landing.html.

Root Cause: Medical Necessity

Although this is a minor issue seen in a few states, HHS has worked closely with those states to develop corrective actions to address this root cause. State CAPs include:

- System Edits: Adding a system edit to require medical necessity documentation for certain procedures;
- Education: Providing additional provider education to improve clinical record documentation;
- Training: Encouraging facilities to develop and implement a quality assurance plan to bill revenue codes correctly prior to submitting claims; and

- Expanded Reviews: Performing independent post-payment reviews to identify any improper or erroneous billing activity.

In addition to the development, execution, and evaluation of the state-specific CAPs, HHS has also continued its education efforts, discussed in detail above, to increase state compliance with medical necessity requirements.

11.43 Medicaid Information Systems and Other Infrastructure

Since Medicaid payments occur at the state level, information systems and other infrastructure needed to reduce Medicaid improper payments would need to be implemented at the state level. HHS has encouraged and supported states in their efforts to modernize and improve state Medicaid Management Information Systems (MMIS), which will produce greater efficiencies in areas reflected in the PERM measurement and strengthen program integrity. In addition, HHS has approved enhanced federal funding for nine states to implement predictive analytics technologies that are integrated with state MMIS. Lastly, the state systems workgroup (composed of HHS and state staff representatives) meets regularly to identify and discuss system vulnerabilities and the impact on the measurement of improper payments.

HHS developed a comprehensive plan to modernize the federal Medicaid and CHIP data systems. The primary goal of this plan is to leverage technologies to create an authoritative and comprehensive Medicaid and CHIP data structure so that HHS can provide more effective oversight of its programs. The plan will also result in a reduction of state burden and the availability of more robust data for the PERM program.

HHS also developed the Transformed Medicaid Statistical Information System (T-MSIS) to facilitate state submission of timely claims data to HHS, expand the MSIS dataset, and allow HHS to review the completeness and quality of state Medicaid Statistical Information System submittals in real-time. HHS will use this data for the Medicaid improper payment measurement and to satisfy other HHS requirements. Through the use of T-MSIS, HHS will not only acquire higher quality data, but will also reduce data requests to the states.

As of September 30, 2016, 18 states are live in T-MSIS production, with the remaining states expected to submit data in the T-MSIS file format before the end of calendar year 2016.

11.44 Medicaid Statutory or Regulatory Barriers that could limit Corrective Actions

No statutory or regulatory barriers that could limit corrective actions have been identified at this time.

11.50 CHIP

11.51 CHIP Statistical Sampling Process

The national FY 2016 CHIP improper payment rate is based on measurements conducted in FYs 2014, 2015, and 2016. CHIP improper payments are estimated on a federal FY basis and measure three component improper payment error rates: FFS, managed care, and eligibility. HHS, through its use of federal contractors, measures the FFS and managed care components. The eligibility component measurement is currently “on hold” as described in the eligibility component section below.

CHIP utilizes the same state sampling process as Medicaid. HHS determined that CHIP can be measured in the same states selected for Medicaid review each FY with a high probability that the CHIP improper payment rate will meet the IPIA required confidence and precision levels. Since CHIP and Medicaid are measured in the same states each year, each state is measured once every three years. For information on how HHS grouped states into three

cycles, refer to page 183 of HHS's FY 2012 AFR (www.wayback.archive-it.org/3922/20131030171300/http:/www.hhs.gov/afr/hhs_agency_financial_report_fy_2012-oai.pdf).

FFS and Managed Care Component

States submit quarterly adjudicated claims data from which a randomly selected sample of FFS claims and managed care payments are drawn each quarter. Each selected FFS claim is subjected to a medical and data processing review. Managed care payments are subject only to a data processing review. The FFS sample size was between 299 and 968 claims per state and the managed care sample size was between 68 and 300 payments per state. When a FFS component or managed care component for a state accounted for less than 2 percent of the state's total CHIP expenditures, the state's FFS and managed care claims were combined into one component for sampling and measurement purposes. This consolidation occurred for claims in one state.

Eligibility Component

In light of changes to the way states adjudicate eligibility for Medicaid and CHIP under the *Affordable Care Act*, HHS is updating the eligibility component measurement methodology and related PERM program regulation to reflect these changes. HHS published a PERM Notice of Proposed Rule-Making (81 FR 40596, June 22, 2016) in FY 2016 to update the PERM eligibility component.

In August 2013 and October 2015, HHS released guidance announcing temporary changes to PERM eligibility reviews. For FYs 2015 through 2018, HHS will not conduct the eligibility measurement component of PERM, but will hold constant at the FY 2014 reported rate of 4.22 percent.

In place of FYs 2015 through 2018 PERM eligibility reviews, all states are required to conduct eligibility review pilots. The eligibility review pilots provide more targeted, detailed information on the accuracy of eligibility determinations. The pilots use targeted measurements to: provide state-by-state programmatic assessments of the performance of new processes and systems in adjudicating eligibility, identify strengths and weaknesses in operations and systems leading to errors, and test the effectiveness of corrections and improvements in reducing or eliminating those errors.

Calculations and Findings

The national CHIP improper payment rate represents the combination of each state's FFS, managed care, and eligibility improper payment rates. In addition, individual state component improper payment rates are combined to calculate the national component improper payment rates. National component improper payment rates and the CHIP improper payment rate are weighted by state size, so that a state with a $1 billion program "counts" 5 times more toward the national rate than a state with a $200 million program. A small correction factor ensures that CHIP eligibility improper payments are not "double counted." Additionally, HHS incorporates state-level improper payment rate recalculations for the states measured in FY 2014 and FY 2015 into the national CHIP improper payment rate. Subsequent to FY 2015 reporting, three state-level FFS improper payment rates were recalculated to allow for appeal results and late documentation that was received prior to the cut-off date for claims submitted between July 1, 2013 and June 30, 2014, and are incorporated into FY 2016 improper payment rate reporting.

The national CHIP gross improper payment estimate for FY 2016 is 7.99 percent or $737.59 million. The FY 2016 net improper payment estimate is 7.87 percent or $726.55 million. This rate increased from prior years due to an increase in the FFS component, as discussed in *Section 11.42.*

The FY 2015 national CHIP improper payment rate for each component is:

- *CHIP FFS:* 10.15 percent
- *CHIP managed care:* 1.01 percent

As previously stated, the CHIP eligibility component improper payment rate is held constant at the FY 2014 rate of 4.22 percent.

Eligibility Review Pilot Findings

Please refer to *Section 11.41* for information on the Medicaid and CHIP eligibility review pilots.

11.52 CHIP CAP

States reviewed for the FY 2016 AFR measurement were the same states reviewed in FY 2013. The improper payment rate for these states increased from 6.76 percent in FY 2013 to 12.42 percent in FY 2016, causing an increase in the FY 2016 national CHIP improper payment rate. The FFS component was the driver of the increase for these states, rising from 6.11 percent to 14.05 percent.

Overall, the largest reason for the FY 2016 errors was related to state difficulties bringing systems into compliance with provisions put in place to strengthen program integrity (as discussed in *Section 11.42*). While these requirements will ultimately strengthen CHIP program integrity, it is not unusual to see increases in improper payment rates following the implementation and initial measurement of new requirements because it takes time for states to make the changes required for compliance.

Although all states are included in the improper payment rates, HHS only reviews 17 states each year. In FY 2014, HHS reported a rate reflecting the first 17 states measured under new the requirements. The FY 2015 improper payment rate reflected the second group of 17 states subject to new requirements for a total of 34 states. The FY 2016 rate reflects the measurement of the final group of 17 states subject to new requirements. HHS expects to see a decrease in improper payment rates in following years as states that have implemented corrective actions are measured again.

HHS works closely with all states to develop state-specific CAPs. All states are responsible for implementing, monitoring, and evaluating the effectiveness of their CAPs, with assistance and oversight from HHS. The Department received CAPs from all states with CHIP programs that were previously measured, and all states measured in FY 2016 are developing CAPs for submission to HHS. When developing the CAPs, states focus their efforts on the major causes of improper payments where the state can clearly identify patterns. In addition, states also take steps to reduce errors identified during the measurement. HHS also establishes corrective actions to reduce improper payments. For example, HHS is actively engaging with states to address these root causes by: conducting outreach during off-cycle PERM measurement years to address issues identified in CAPs; facilitating national best practice calls to share ideas across states; offering ongoing technical assistance; and providing additional guidance as needed. Additional information on states' and HHS's corrective actions are provided below.

Corrective Actions to Address Root Causes:

Root Causes: Administrative or Process Errors Made by State or Local Agency and Failure to Verify

Administrative or process errors made by states or local agencies and failure to verify mainly consist of errors resulting from state difficulties bringing systems into compliance with new requirements as described above. Since the CHIP improper payment rate was primarily driven by these errors, state CAPs focus on systems or process changes to reduce these errors. Specific actions include implementing new claims processing edits,

converting to a more sophisticated claims processing system, and implementing a new provider enrollment process to make it easier for referring providers to enroll in the program.

In addition to the development, execution, and evaluation of the state-specific CAPs, HHS has implemented corrective actions to reduce errors related to this category. HHS's efforts include allowing states to rely on Medicare's enrollment screening of providers to help prevent PERM-related enrollment errors, sharing Medicare data to assist states with meeting screening and enrollment requirements, and providing ongoing education and outreach to states on federal requirements for enrollment and screening. More detailed information on these activities is provided in *Section 11.42: Medicaid CAP*.

Root Causes: Insufficient Documentation to Determine and Administrative or Process Errors Made by Other Party

State CAPs include provider communication and education to reduce errors related to these categories. These methods include holding provider training sessions and meetings with provider associations; issuing provider notices, bulletins, newsletters, alerts, and surveys; implementing improvements and clarifications to written state policies emphasizing documentation requirements; and performing more provider audits to identify areas of vulnerability and target solutions.

In addition to the development, execution, and evaluation of the state-specific CAPs, HHS has implemented additional efforts to lower improper payment rates in these two error categories. More detailed information on these activities is provided in *Section 11.42: Medicaid CAP*.

Root Cause: Medical Necessity

Although this is a minor issue seen in a few states, HHS has worked closely with those states to develop corrective actions to address this root cause. More detailed information on state and HHS activities can be found in *Section 11.42: Medicaid CAP*.

11.53 CHIP Information Systems and Other Infrastructure

Since CHIP payments occur at the state level, information systems and other infrastructure needed to reduce CHIP improper payments would need to be implemented at the state level. Please refer to *Section 11.43: Medicaid Information Systems and Other Infrastructure* for information on HHS and state-led efforts to modernize information and data systems at the national and state level.

11.54 CHIP Statutory or Regulatory Barriers that Could Limit Corrective Actions

No statutory or regulatory barriers that could limit corrective actions have been identified at this time.

11.60 TANF

11.61 TANF Statistical Sampling Process

Statutory limitations prohibit HHS from requiring states to participate in a TANF improper payment measurement. As a result, the TANF program is not reporting an error rate for FY 2016.

11.62 TANF CAP

Since TANF is a state-administered program, corrective actions that could help reduce improper payments would have to be implemented at the state level. Since HHS cannot require states to participate in a TANF improper payment measurement, HHS is also unable to compel states to collect the required information to implement and

report on corrective actions. Despite these limitations, HHS has taken the following actions to assist states in reducing improper payments:

- Single Audit Findings: HHS works with states to analyze Single Audit material non-compliance findings related to TANF and to implement corrective actions to address these findings.
- Risk Assessment: HHS performed a detailed risk assessment of the TANF program to determine susceptibility to significant improper payments. As part of this process, HHS identified potential payment risks at the federal level and is working to mitigate these payment risks.
- Program Integrity Innovation Pilot: HHS monitored a TANF Program Integrity Innovation Grant funded from OMB's Partnership Fund for Program Integrity Innovation. The state human service agency grantee in Connecticut conducted a pilot project designed to reduce improper payments and improve administrative efficiency in the state's TANF program. The final report, submitted to HHS in August 2016, includes lessons learned and valuable TANF program integrity information that will be shared with other states.
- Financial Reporting Improvement: HHS implemented revisions to the TANF financial reporting form to require states to provide more accurate information about how states are using TANF block grants and meeting their Maintenance-of-Effort obligations. The changes took effect in FY 2015, and include a revised and expanded list of spending categories as well as a change to the accounting method to track actual expenditures that occur in a FY. After adding six new categories, such as child welfare services and Pre-Kindergarten/Head Start and clarifying definitions, the amount initially reported as "other" decreased from 14.7 percent in FY 2014 to 4.0 percent in FY 2015.
- Final Regulation on Reporting of Electronic Benefit Transfer (EBT) Policies and Practices: In FY 2016, HHS issued final regulations regarding "State Reporting on Policies and Practices to Prevent the Use of TANF Funds in Electronic Benefit Transfer Transactions in Specified Locations" (81 FR 2092, January 15, 2016). The regulations require states, subject to penalty, to maintain policies and practices that prevent TANF funded assistance from being used in any EBT transaction in specified locations: liquor stores; any casino, gambling casino, or gaming establishment; and any retail establishment that provides adult-oriented entertainment in which performers disrobe or perform in an unclothed state for entertainment.

11.63 TANF Information Systems and Other Infrastructure

Information systems and other infrastructure needed to reduce TANF improper payments would need to be implemented at the state level. States utilize PARIS, the National Directory of New Hires, and the Income and Eligibility Verification System to minimize improper payments.

11.64 TANF Statutory or Regulatory Barriers

Statutory limitations prohibit HHS from requiring states to participate in a TANF improper payment measurement.

11.70 Foster Care

11.71 Foster Care Statistical Sampling Process

There were no changes to the statistical sampling process for Title IV-E Foster Care in FY 2016. Because current regulations require that programs be reviewed every three years for compliance, this program has taken the review cycle already in place (in compliance with 45 CFR 1356.71, Foster Care Eligibility Reviews) and, with OMB approval, leveraged the existing review cycle to provide a rolling three-year weighted average improper payment rate. Under this approved approach, the Foster Care improper payment estimate is calculated each year using

data collected in the most recent Foster Care Eligibility Review for each state, the District of Columbia, and Puerto Rico. A random sample is drawn from the state's universe of cases having at least one Title IV-E Foster Care maintenance payment during the 6-month period under review (PUR). A review of sampled individual case records identifies the number, nature, and amount of improper payments for each case in the sample. Since each state is reviewed every three years, each year's program improper payments estimate incorporates new review data for about one-third of the states. Examination of the confidence interval around the FY 2016 estimate confirms that the estimate conforms with precision requirements specified in OMB guidance for improper payments reporting. For a more detailed description of the Foster Care improper payments statistical sampling and estimation methodology, refer to pages 189 – 190 of HHS's FY 2012 AFR (www.wayback.archive-it.org/3922/20131030171300/http:/www.hhs.gov/afr/hhs_agency_financial_report_fy_2012-oai.pdf).

As stated in the FY 2015 AFR, an increasing number of time-limited child welfare waiver demonstration projects will temporarily reduce the number of jurisdictions subject to review and inclusion in the program error rate estimate for the duration of the demonstration projects. These child welfare waiver demonstration projects, authorized by Section 1130 of the *Social Security Act*, waive many program eligibility requirements and allow flexible use of Title IV-E funds to encourage innovative practices and improved child and family outcomes, while ensuring federal cost-neutrality. More information on these demonstration projects—and their impact on the Foster Care error rate calculation—can be found on pages 202-203 of the FY 2015 AFR, available at: www.hhs.gov/sites/default/files/afr/fy-2015-hhs-agency-financial-report.pdf.

As discussed in the FY 2015 AFR, the program error rate estimate includes data from the most recent review for states with non-statewide waivers, including subsequent reviews conducted on the non-waiver populations in those states following waiver implementation. The state error rate is based on review data for a sample of children receiving traditional Title IV-E services, and the sample rate is applied to overall state payments for those traditional Title IV-E services (i.e., excluding payments for the counties or other populations participating in demonstration projects).

This approach, approved by OMB, maintains continuity in the error rate while also permitting consistent treatment of states with statewide and non-statewide waivers. Following this approach, the FY 2016 estimate is based on review data for 43 states operating traditional Title IV-E programs.[28]

The Foster Care gross improper payment estimate for FY 2016 is 6.89 percent or $47.68 million. The FY 2016 net improper payment rate is 6.55 percent or $45.32 million. The primary factor that drove the program's significant increase from the prior year's estimate of 3.65 percent was the performance of two large states that were reviewed in this cycle. These states each previously had error rates below 3 percent, but were found to have error rates of over 20 percent in one instance and over 40 percent in the other instance. Had performance in the two large states remained at their previous levels, the FY 2016 Foster Care error rate would have fallen to 3.61 percent.

11.72 Foster Care CAP

All payment errors (100 percent) in the Title IV-E Foster Care Program are administrative or process errors due to incorrect case classification and payment processing by state agencies. The Foster Care program designs CAPs to help states address the payment errors that contribute most to Title IV-E improper payments.

[28] The FY 2016 estimate excludes data for nine states operating statewide waiver demonstrations: six states that were due for a review this year (Arkansas, Colorado, District of Columbia, Indiana, Nebraska, and Oklahoma) and three states that were due for a review in prior years (Florida, Utah, and Wisconsin).

Corrective Actions to Address Root Cause:

Root Cause: Administrative or Process Error Made by State or Local Agency

Corrective actions have decreased the overall number of payment errors and altered the composition of identified payment errors. For example, following years of work with State Court Improvement Programs and outreach to heighten judicial awareness, judiciary-related errors, once the most prevalent error type, are now among the least common.

Monitoring and Analysis: HHS continues to monitor, review results, and analyze the types of payment errors in the Foster Care program to target corrective action planning. In FY 2016, the most common payment errors included:

- Underpayments (14 percent of errors);
- No safety documentation for institutional caregiver staff (14 percent of errors);
- Provider not licensed or approved (13 percent of errors);
- Provider criminal records check not completed (10 percent of errors);
- Other ineligible payments (10 percent of errors); and
- Family not eligible for the Aid to Families with Dependent Children program at time of removal (8 percent of errors).

Together these 6 items account for 69 percent of Foster Care payment errors. Although underpayments represent 14 percent of all errors in terms of frequency, the dollar amount of the underpayments is quite small and, in fact, continued to decrease as the underpayment rate improved from 0.30 percent in FY 2015 to 0.17 percent in FY 2016. In contrast, because of the high cost of institutional care relative to other foster care placements, the dollar amount of improper payments related to cases lacking safety documentation for institutional caregiver staff is high.

In FY 2016, HHS undertook the following key actions to reduce improper payments:

- Emphasizing Continuous Quality Improvement: Based on discussions with individual states on review preparation and compliance results, HHS worked with states to emphasize and develop strategies for continuous program improvement with an emphasis on: viewing the quality assurance process as an ongoing process, and developing sound program improvements that support systemic change and sustain the improvement effort.
- Enhancing Outreach Strategies**:** Given that certain types of improper payments, such as those pertaining to foster care provider requirements, occur in a small number of states, HHS implemented outreach strategies tailored to particular state child welfare agencies to provide feedback about specific program performance areas needing improvement and facilitate efforts to correct them. The strategies consisted of enhanced communication and collaboration with these state child welfare agencies to increase their understanding of program compliance requirements and to share strategies that have proven successful in other states.

In addition, HHS continued the following ongoing corrective actions:

- Conducting Eligibility Reviews and Providing Feedback to State Agencies: HHS conducts onsite and post-site review activities to validate the accuracy of state claims for reimbursement of payments made on behalf of children and their Foster Care providers. Specific feedback is provided onsite to the state agency to affect proper and efficient program administration and implementation. Furthermore, HHS issues a comprehensive final report that presents findings of the review to the state agency. The final report serves as the basis for the development of a Program Improvement Plan (PIP) for states that exceed the error threshold in a review.

- Developing PIPs: HHS requires non-compliant states (those that exceed the error threshold in a review) to develop and execute state-specific PIPs that link corrective actions to the root cause of payment errors. In FY 2016, four of the 16 states reviewed in this cycle were found out of compliance and will complete the PIP. The PIP identifies the specific action steps necessary to target and correct root causes of the errors and each action strategy is required to have a projected completion within one year from the date HHS approved the plan. PIPs are an effective strategy, as reflected in the fact that, since FY 2004 improper payments reporting, only one state has been found not in compliance on an eligibility review conducted following PIP completion.
- Providing Training and Technical Assistance: HHS provides training and technical assistance to states to develop and implement program improvement strategies, even when states are not required to develop a PIP. This assistance helps states expand organizational capacity and promote more effective program operations.
- Conducting Secondary Reviews and Disallowances: HHS conducts secondary reviews for non-compliant states and takes appropriate disallowances consistent with the review findings (HHS takes disallowances for error findings in both primary and secondary reviews). Four states that were reviewed in the FY 2016 cycle will undergo a secondary review. On a secondary review, if a state is found not in substantial compliance, an extrapolated disallowance is taken. These additional disallowances, in conjunction with the development and implementation of the PIP, serve as a strong incentive to states to improve compliance.

11.73 Foster Care Information Systems and Other Infrastructure

HHS uses the Adoption and Foster Care Analysis and Reporting System to draw samples for the regulatory reviews. Utilization of this system reduces the burden on states to draw their own samples, promotes uniformity in sample selection, and employs the database in a practical and beneficial manner. Since Foster Care payments occur at the state level, information systems and other infrastructure needed to reduce Foster Care improper payments would need to be implemented at the state level. States have the option to receive federal financial participation to develop and implement a Comprehensive Child Welfare Information System (CCWIS) in accordance with federal regulations at 45 CFR § 1355.50 through §1355.59. CCWIS project requirements include, among others, the performance of automated program eligibility determinations and bi-directional data exchanges with systems generating the financial payments and claims to assure the availability of needed supporting documentation.

11.74 Foster Care Statutory or Regulatory Barriers

No statutory or regulatory barriers that could limit corrective actions have been identified at this time.

11.80 CCDF

11.81 CCDF Statistical Sampling Process

The methodology for measuring improper payments uses a case-record review process to determine if child care subsidies were properly paid for services provided to eligible families. The methodology focuses on improper payments made, and enables states to determine the types of errors and their sources. For the CCDF improper payments methodology, please see www.acf.hhs.gov/occ/resource/program-integrity-and-accountability-improper-payments-error-rate-review.

The current methodology incorporates the following: (a) drawing a statistical sample from a universe of paid cases; (b) measuring improper payments; and (c) requiring states with error rates exceeding 10 percent to submit a CAP.

The error rate methodology and reporting requirements focus on administrative errors associated with client eligibility. The CCDF gross improper payment estimate for FY 2016 is 4.34 percent or $240.74 million. The FY 2016 net improper payment estimate is 3.78 percent or $209.68 million.

There were several contributing factors to the decrease in the improper payment rate from 5.74 percent in FY 2015, most notably several states reported significant decreases in the number of cases with improper payments. While all states are updating their policies and procedures to ensure compliance with implementation of the *Child Care and Development Block Grant Act of 2014* (CCDBG), most of the states reporting in FY 2016 (referred to as Year Three states) had not put new policies in place, which potentially kept their error rates lower. HHS anticipates that as states establish new policies, it will likely take some time for states and providers to understand, implement, and follow the new requirements. Therefore, the CCDF's program errors may increase as states implement and are evaluated against the new policies.

11.82 CCDF CAP

Administrative or process errors represent approximately 44.95 percent of errors found in the reviews. These errors consist of the failure to apply policy correctly, including:

- Income calculation (16 states);
- Assessing the level of care (7 states); and
- Applying the incorrect payment rate (4 states).

Insufficient Documentation errors account for an estimated 55.05 percent of errors identified in the CCDF improper payment review process. Errors were primarily due to missing or insufficient documentation in the case record. The most frequently cited errors due to missing or insufficient documentation include:

- Verification of work activity (6 states);
- Work or activity schedules to demonstrate need for care (5 states);
- Application forms, redetermination forms, or family files (5 states); and
- Child support verification (3 states).

Corrective Actions to Address Root Causes:

Root Causes: Insufficient Documentation to Determine and Administrative or Process Errors Made by or Local Agency

HHS and states have established corrective actions targeting both error types. States reporting in FY 2016 (Year Three states) plan the following actions to correct both missing or insufficient documentation and administrative process improper payment error causes:

- Conducting training with eligibility staff on CCDF policies and procedures (16 states);
- Conducting ongoing case reviews or audits (10 states);
- Making changes or updates to state eligibility policies and procedures (9 states);
- Upgrading or enhancing information technology (IT) systems (7 states);
- Developing job aids or tools to assist eligibility staff (4 states);
- Reviewing findings with contractors and staff (4 states); and
- Issuing corrective action plans to the local offices (2 states).

In addition to implementing corrective actions for states reporting in FY 2016, HHS has implemented other corrective actions to assist all states in their review process and error reduction including the following activities:

- Oversight: Conduct joint case review oversight to ensure implementation of the HHS approved state review tools. This new review process was piloted in FY 2016 with a cohort of states that had previously been reviewed in FY 2014 (referred to as Year One states). HHS plans to implement this review process across all reporting states beginning in FY 2017;
- Site Visits: Conduct site visits with states needing assistance to address root causes of errors as resources allow;
- Technical Assistance: Provide technical assistance to states around policy and procedure changes to meet new requirements under the CCDBG. HHS continues to work with states through the Office of Child Care's National Center on Subsidy Innovation and Accountability which was funded to specifically provide technical assistance to states and territories on program integrity and accountability and has been targeting technical assistance to states as it relates to reauthorization;
- Technical Assistance: Deliver technical assistance to states regarding updating or developing IT systems that will improve practices and reduce errors; and
- Methodology Training: Provide individual reporting cohort training on the methodology that allows states to learn best practices from each other as they conduct the improper payment reviews.

11.83 CCDF Information Systems and Other Infrastructure

Since CCDF payments occur at the state level, information systems and other infrastructure needed to reduce CCDF improper payments would need to be implemented at the state level. In addition to the efforts outlined in prior HHS AFRs, states reported a range of other improvements to information systems including:

- Increase access to client information: Including data synced with other assistance programs, quality control case reviews or reports, and system flags and blocks to avoid duplication or errors.
- Increase access to provider information: Including automated billing reports, payment management tracking, provider licensing information, and automated payment rate determination.
- Assist with eligibility determinations: Including access to data in other assistance programs' systems to obtain or confirm eligibility information, increased automation of eligibility processes, system flags and blocks to avoid errors, automated copay calculation, and document storage.

Additionally, states also identified IT limitations with preventing or identifying caseworker error when erroneous data is entered.

11.84 CCDF Statutory or Regulatory Barriers

No statutory or regulatory barriers that would limit corrective actions have been identified at this time.

The CCDBG, signed into law in November 2014, reauthorized CCDF for the first time since 1996. The statute improves the quality and access to care for children across the country by requiring states to change eligibility to a minimum of 12 months, revise redetermination policies, update provider payment rates and payment practices, and increase health and safety standards for providers. States will be required to create new policies and procedures to enact the requirements of the law, which will likely increase errors as the changes are implemented. The improper payment reduction targets identified in Table 1A reflect the anticipated brief rise in the error rate as states adjust to the changes.

12.0 Supplemental Measures and Targets for High-Priority Programs

To comply with Executive Order 13520 and IPERIA, HHS developed supplemental measures for four high-priority programs: Medicare FFS, Medicare Part C, Medicare Part D, and Medicaid. Information on these programs' supplemental measures—including a description of the measure, the current performance, and future performance target—can be found below. In addition, more information on these programs and their supplemental measures can be found at www.PaymentAccuracy.gov.

Medicare FFS: A main driver of the Medicare FFS improper payment rate is insufficient documentation errors for home health claims. Some of HHS's corrective actions are discussed in *Section 11.0: Program-Specific Reporting Information*. This annual supplemental measure examines the percentage of improper Medicare FFS payments made for home health claims.

- Current performance: 42.01 percent
- Future performance target: 37.70 percent

Medicare Part C: Payments to Medicare Advantage organizations are partly based on enrollee health status. This annual supplemental measure analyzes the CMS Hierarchical Condition Categories (CMS-HCCs) that have the highest rates of error. CMS-HCCs are the disease groups that determine the disease component of risk-adjustment payment. The measure aggregates the CMS-HCCs that have the highest percentage of error as compared to the entire sample of CMS-HCCs, and divides that number of discrepancies by the overall number in the sample.

- Current performance: 4.0 percent
- Future performance target: 4.0 percent

Medicare Part D: The Prescription Drug Event (PDE) validation process validates the prescription against the PDE data submitted to HHS for payment and is the major driver of error in Part D. The root cause shown under this annual supplemental measure is missing or illegible supporting documentation.

- Current performance: 1.19 percent
- Future performance target: 1.19 percent

Medicaid: State non-compliance with new provider information, enrollment, and screening requirements has been a major driver of Medicaid improper payments in recent years. This annual supplemental measure shows the Medicaid FFS improper payment rate for these errors.

- Current performance: 9.97 percent
- Future performance target: 8.05 percent

13.0 Superstorm Sandy Reporting Information

Superstorm Sandy was a major hurricane that struck the United States' eastern seaboard on October 29, 2012 and caused extensive damage from Florida to Maine, with New Jersey and New York sustaining the most damage. In response to this disaster, Congress passed the *Disaster Relief Act*, which was signed into law on January 29, 2013 and provided $50.5 billion in aid for Superstorm Sandy disaster victims and their communities. HHS received $747 million, allocated among multiple programs across five Divisions: ACF, ASPR, CDC, SAMHSA, and NIH. Because funding of this type and magnitude often carries additional risk, the *Disaster Relief Act* and OMB guidance state that all federal programs or activities receiving funds are automatically considered susceptible to significant improper payments, regardless of any previous improper payment risk assessment results, and are required to calculate and report an improper payment estimate. Accordingly, HHS developed methodologies to estimate

improper payments in the programs that received *Disaster Relief Act* funding. Once a program's Superstorm Sandy funding has been spent, agencies are no longer required to report error rate information. In FY 2016, HHS halted reporting error rate information for two programs – CDC Research and ACF Family Violence and Prevention Services Act – because they expended their funding. Information on the remaining *Disaster Relief Act* programs' improper payment methodologies, results, and corrective actions can be found on subsequent pages.

13.10 Head Start

13.11 Head Start Statistical Sampling Process and Results

Head Start received approximately $95 million in *Disaster Relief Act* funding to provide services, training and oversight, and construction assistance to affected grantees. Every grantee who spends Superstorm Sandy funds receives an erroneous payments onsite monitoring visit in the quarter following the quarter when funds are spent, or as soon thereafter as possible. Superstorm Sandy transactions for each quarter are reviewed using a standard onsite monitoring tool to identify potential and actual erroneous payments. Additional information on Head Start's statistical sampling process can be found on pages 223 – 224 of HHS's FY 2015 AFR, available at: www.hhs.gov/afr.

Nearly all minor renovations and repairs to facilities, along with remaining enhanced mental health service activities, were completed in FY 2015. In FY 2016, grantees were primarily engaged in ongoing progress toward completion of major renovations and reconstruction of damaged facilities with HHS subject matter experts and regional staff working closely with grantees on a day-to-day basis. This resulted in fewer transactions in FY 2016, but larger total expenditures than in FY 2015.

The Head Start gross and net improper payment estimate for FY 2016 is 0 percent or $0.

13.12 Head Start Root Causes and CAP

Corrective Actions to Address Root Cause

No improper payments were identified for the review period. However, HHS continues to work with grantees to reduce the likelihood of the occurrence of improper payments by staying in regular communication with grantees to support ongoing compliance in areas such as procurement standards, source documentation, Davis-Bacon Act, cost allocation plan updates, and any other areas identified by subject matter experts as common areas of fiscal challenge in the general grantee community.

13.13 Head Start Improper Payment Recovery

No improper payments were identified during the period under review (PUR) and all prior year errors subject to recovery were recovered during the PUR in which they were identified.

13.20 SSBG

13.21 SSBG Statistical Sampling Process and Results

The SSBG program received $474.5 million in *Disaster Relief Act* funding to address necessary expenses resulting from Superstorm Sandy. These expenses include social, health, and mental health services for individuals; and repair, renovation and rebuilding of health care facilities (including mental health facilities), child care facilities, and other social services facilities. The SSBG *Disaster Relief Act* funds were allocated to five states affected by Superstorm Sandy: Connecticut, Maryland, New Jersey, New York, and Rhode Island. HHS selected 3 of the 5

states (Connecticut, New Jersey, and New York) to calculate improper payment error rates, since their allocations represent 99 percent of all SSBG *Disaster Relief Act* funds.

Because the states determine the types of services and eligibility for these services, as permitted by the SSBG law and regulations, there is considerable variation among states in their application of these funds. To account for this variation, HHS developed a two-fold (bifurcated) improper payment methodology to review the use of SSBG *Disaster Relief Act* funds in three states. The two methodologies are a case record review and a vendor payment review. The case record review examines payments or benefits provided to or on behalf of individuals, families or households (i.e., cases) based on specific eligibility criteria. The vendor payment review examines individual payments made to service vendors and assesses if the vendors provided adequate documentation (e.g., applications or authorizations) necessary to meet the eligibility requirements for these payments.

For the FY 2016 review period (July 1, 2015 to June 30, 2016), HHS completed case record and vendor payment reviews in Connecticut, New Jersey, and New York. HHS consolidated its review findings and calculated a national SSBG Superstorm Sandy *Disaster Relief Act* error rate from the aggregate findings across all three states.

HHS reviewed 612 records in FY 2016. For the case record review, HHS reviewed 312 case records across the 3 states – 47 cases in Connecticut, 181 cases in New Jersey, and 84 cases in New York. For the vendor payment review, HHS reviewed 300 vendor payments across the three states – 5 payments in Connecticut, 111 payments in New Jersey, and 184 payments in New York.

The SSBG gross and net improper payment estimate for FY 2016 is 0.68 percent or $1.35 million.

The error rate for the case record reviews was 1.84 percent, while the error rate for the vendor payment reviews was 0.55 percent.

13.22 SSBG Root Causes and CAP

Of the 612 records reviewed, 37 records had an improper payment.

Three errors (representing 0.002 percent of the estimated improper payments) were categorized as administrative or process errors due to state or local agency. These errors included: (1) miscalculation of payment amounts due to an incorrect formula; and (2) clerical errors in calculating payment amounts based on vendor claims.

Twenty-one errors (representing 20.74 percent of the estimated improper payments) were categorized as administrative or process errors due to other party (i.e., non-federal, non-state, and non-local agencies). These errors included: (1) clients receiving greater than necessary benefit amounts; (2) service provider mistakenly disposing of client eligibility documentation (though the provider was able to obtain new documentation after reviews were completed); (3) clients receiving benefits despite documentation indicating ineligibility for service; (4) clients receiving benefits despite not fully completing eligibility documentation; (5) clients receiving benefits before fully establishing their eligibility for service; (6) a service provider failing to obtain client's signature verifying receipt of benefits; and (7) a service provider issuing a benefit payment on a client's behalf before all internal payment approval processes were completed.

Thirteen errors (representing 79.26 percent of the estimated improper payments) were categorized as insufficient documentation to determine. These errors included: (1) case records missing necessary eligibility documentation (e.g., proof of insurance or proof of income); or (2) records missing necessary documentation of proper payment processing (e.g., proof of payment, payment approval forms, or copies of bills/invoices to be paid).

Corrective Actions to Address Root Causes:

In response to FY 2016 improper payment findings, HHS will provide each reviewed state a letter outlining the development of CAPs. These letters will be accompanied by itemized lists of unresolved errors from the FY 2016 review period (including descriptions of improper payment findings and amounts), and will establish a 30-day timeframe for states to respond with planned corrective actions. HHS will also hold calls with each state to answer any questions related to developing CAPs or establishing improper payment recovery amounts. In developing their responses, states may provide an explanation for recovery amounts to be sought for each error; however, HHS retains final discretion in determining total amounts of funds subject to recovery. Further information on specific root causes and corrective actions is located below.

Root Cause: Administrative or Process Errors Made by State or Local Agency

To address these errors, HHS will develop strategies with states to ensure that all documentation required for payment processing is present and complete before payments to vendors are approved. These activities will also emphasize examination of receipts and invoices to ensure that payments made by the states reflect established payment schedules and reimbursement protocols. HHS will continue to work with states to examine where in their payment approval processes the greatest intervention is warranted.

Root Cause: Administrative or Process Errors Made by Other Party

To address these errors, HHS will develop strategies with states to reinforce the importance of: (1) collecting all client eligibility documentation prior to the provision of service benefits; (2) ensuring that eligibility documentation is properly examined; (3) providing benefits to clients that match their documented needs; (4) preserving critical case record documentation for auditing needs; and (5) ensuring that payment processing procedures are followed, such that payments/benefits are not dispersed until all requisite signatures/approvals are obtained. HHS will continue to work with states to address how error-prone vendors can improve their client intake processes and improve processes for assessing and approving client benefits.

Root Cause: Insufficient Documentation to Determine

To address these errors, HHS will develop strategies with states to monitor and provide oversight to the most error-prone service agencies and providers. These strategies will reinforce the importance of record maintenance and organization. HHS will work with states to assess typical practices of record maintenance and organization.

13.23 SSBG Improper Payment Recovery

Of the total error findings, $1.35 million was associated with overpayments. As states receive and review all unresolved errors from the FY 2016 review period, HHS will work with states to identify items for which additional corrective action will be taken (including obtaining additional documentation, making process adjustments, and the current state of improper payment recovery). Where additional action around improper payment recovery is warranted, HHS will work with states to focus recovery efforts on improper payments resulting from core eligibility errors, where benefits or payments should not have been paid. HHS is also working with states to recover overpayments identified in previous measurement cycles, as appropriate.

13.30 ASPR Research

13.31 ASPR Research Statistical Sampling Process and Results

ASPR received approximately $11.9 million in *Disaster Relief Act* funding to evaluate preparedness and response activities in the affected states. ASPR's Superstorm Sandy improper payment methodology was conducted in two stages. Under the first stage, for FY 2014 reporting, HHS reviewed the eligibility of grantees that received funding in FY 2013. The second stage of the methodology was implemented in FY 2015 and continued in FY 2016. The

methodology calculates an unallowable spending error rate (e.g., unallowable expenses or lack of documentation) based on a review of each grantee's expenditures during the review period. The sample for the FY 2016 reporting period consisted of expenditures made during FY 2015 (October 1, 2014 to September 30, 2015).

Based on a review of over 900 transactions, the ASPR Research gross and net improper payment estimate for FY 2016 is 0 percent or $0.

13.32 ASPR Research Root Causes and CAP

Corrective Actions to Address Root Cause:

Although HHS has not identified any improper payments in the ASPR Research program in FY 2016, HHS established internal controls to prevent improper payments from occurring.

13.33 ASPR Research Improper Payment Recovery

No recoveries will be attempted as no improper payments were identified during this or previous reviews.

13.40 SAMHSA

13.41 SAMHSA Statistical Sampling Process and Results

SAMHSA received $10 million under the *Disaster Relief Act*. SAMHSA awarded approximately $6.2 million to four programs and returned approximately $3.8 million because fewer organizations applied for the funding and applications received were for amounts significantly less than expected. The four funded programs were: 1) Behavioral Health Treatment; 2) Disaster Distress Helpline; 3) Resiliency Training for Educators; and 4) Medication Assisted Treatment of Opioid Addiction Restoration.

For FY 2016, SAMHSA's program universe subject to sampling consisted of four grants awarded to New York State ($798,339), New York City ($2,947,786), New Jersey ($329,120), and Links2Health ($2,100,000) for the four funded programs listed above. Between July 1, 2015 and June 30, 2016, SAMHSA had outlays of $1.279 million across 13 transactions. Due to the small number of transactions, SAMHSA reviewed all outlays for payment accuracy and used the results to calculate the total improper payments for the program.

SAMHSA's gross improper payments for FY 2016 is 0.05 percent or $624.59; the net improper payments estimate is 0.05 percent or $624.59.

13.42 SAMHSA Root Causes and CAP

SAMHSA's improper payments identified during the review period were due to administrative or process errors made by the grantees (100 percent). The total gross improper payments of $624.59 were due to one transaction that improperly calculated direct and indirect expenses.

Corrective Actions to Address Root Cause:

Root Cause: Administrative or Process Errors Made by Other Party

SAMHSA's improper payment results were discussed with the grantee; to date, the grantee has not indicated concurrence with the findings. SAMHSA does not anticipate future improper payments, as the grants under the specified programs have ended.

13.43 SAMHSA Improper Payment Recovery

SAMHSA is correcting the entire $624.59 in improper payments by requesting a refund from the grantee.

13.50 NIH Research

13.51 NIH Research Statistical Sampling Process and Results

NIH received $148.7 million in funds under the *Disaster Relief Act* to support recovery efforts at eligible impacted universities and research institutions. These funds will restore NIH's investment in biomedical research and infrastructure that was severely damaged or destroyed by Superstorm Sandy.

Due to the variable grant expenditure amounts, NIH implemented a stratified random sampling process, with the sampling frame being divided into mutually exclusive groups or "strata" based on expenditure amount. Each sampling period consisted of six months. NIH selected a random sample of expenditures from the grantees quarterly reports for the respective two quarters. The sampling unit was the total quarterly expenditures for a single award, while the sampling frame was the collection of all reports filed containing expenditures during the sampling period. NIH used a random number generator to assign random numbers to each quarterly expenditure report. The list of expenditure reports was sorted by stratum and random number, and the appropriate number of items from each stratum was reviewed. NIH's methodology examined two areas for improper payments: (1) ensuring funds were used for an allowable program use and (2) grantee eligibility. For each grant in the sample, NIH requested detailed expenditure data and appropriate backup documentation from the grantee to determine allowability of expenditures. NIH also confirmed grantees' continued eligibility to receive *Disaster Relief Act* funding in accordance with HHS requirements.

Under its methodology, NIH completed two rounds of improper payment reviews from FY 2014 to FY 2016 covering 12-months of expenditures in two semi-annual sampling periods: July 1 to December 31 and January 1 to June 30. For FY 2015, NIH reviewed 357 expenditure reports representing 242 grant awards and 18 different grantee institutions. For FY 2016, NIH reviewed 71 expenditure reports representing 50 grant awards and 14 different grantee institutions. The sample was smaller in FY 2016 due to the end of the two-year funding period.

The NIH Research gross and net improper payment estimate for FY 2016 is 0 percent or $0.

13.52 NIH Research Root Causes and CAP

HHS did not identify any improper payments in the NIH Research program in FY 2016.

13.53 NIH Research Improper Payment Recovery

No recoveries will be attempted as no improper payments were identified.

14.0 Internal Control Over Payments

In FY 2016, the Department summarized HHS's status of internal control over payments for each program reporting an improper payment rate, as required by Appendix C to OMB Circular A-123. HHS's error rate measurements and root cause analyses have led to the implementation of a number of effective strategies to prevent, detect, and recover improper payments (many of which are discussed in *Section 11.0: Program-Specific Reporting Information*) and help create and maintain a robust internal control system. Generally, these strategies

are tailored to the nature of program improper payments resulting from administrative and documentation errors rather than from fraud and abuse. Examples of HHS's internal control over payment efforts include:

- Implementing key control activities to prevent and detect improper payments;
- Using, sharing, and communicating information that is timely, accurate, and reliable; and
- Performing monitoring and assessment activities.

Additional information on internal control over payment efforts can be found on pages 208 – 216 of the FY 2015 AFR, available at: www.hhs.gov/sites/default/files/afr/fy-2015-hhs-agency-financial-report.pdf. As shown in Table 3 below, HHS programs have implemented internal controls to prevent improper payments. HHS continues to improve and evaluate its internal control over payment efforts.

Table 3

FY 2016 Risk Susceptible Programs Status of Internal Controls

Internal Control Standards	Medicare FFS	Medicare Part C	Medicare Part D	Medicaid	CHIP	Foster Care	Child Care
Control Environment	4	4	4	3	3	3	3
Risk Assessment	4	4	4	4	4	4	3
Control Activities	3	3	3	3	3	4	3
Information and Communication	4	4	4	3	3	3	3
Monitoring	3	3	3	3	3	4	3

Legend:

4 = Sufficient controls are in place to prevent improper payments.
3= Controls are in place to prevent improper payments but there is room for improvement.
2 = Minimal controls are in place to prevent improper payments.
1= Controls are not in place to prevent improper payments.

15.0 Recovery Auditing Reporting

HHS developed a risk-based strategy to implement the recovery auditing provisions of IPERA. Specifically, HHS focuses on implementing recovery audit programs in Medicare and Medicaid, which accounted for 86 percent of HHS's outlays in FY 2016. HHS is progressing in recovering improper payments in Medicare and Medicaid and, most importantly, implementing corrective actions to prevent improper payments, as described below.

Medicare FFS RACs

Section 302 of the *Tax Relief and Health Care Act of 2006* required HHS to implement the Medicare FFS RAC program in all 50 states no later than January 1, 2010. HHS allows the RACs to review a variety of claim types, except for hospital patient status reviews, which are limited to only those providers referred by the QIOs for exhibiting persistent noncompliance with Medicare payment policies. HHS has been working to procure the next RAC contracts since 2013. However, multiple pre- and post-award protests have delayed the awards. As HHS continued the procurement process for the new contracts, the current contracts have been modified to allow the RACs to review claims through July 31, 2016, after which the RACs have continued to work to resolve all open claims and claims adjustments. As part of these contract modifications, HHS incorporated several program enhancements developed in response to industry feedback:

- Reducing the complex review timeframe from 60 to 30 days and withholding the contingency fee if the RAC does not meet its review deadline;

- Requiring the RAC to wait 30 days to allow for a discussion with the provider after identifying an improper payment before sending the claim to the MAC for adjustment;
- Confirming receipt of a discussion request and other written correspondence within three days;
- Broadening review topics to all provider types and requiring reviews of topics referred by HHS; and
- Enhancing the information available on the provider web portals.

In addition, HHS established requirements known as Additional Documentation Request (ADR) limits on the number of claims that RACs can review for each provider. In FY 2016, HHS revised its ADR limits for institutional providers to be diversified across the different claim types a facility submits (e.g., inpatient and outpatient claims). HHS will adjust the limits in accordance with a provider's denial rate. Providers with low denial rates will have lower ADR limits while providers with high denial rates will have higher ADR limits. RACs are also required to apply incrementally the ADR limits for providers new to RAC reviews. HHS expects to award the new RAC contracts in early FY 2017.

In FY 2016, the Medicare FFS RAC program identified approximately $440.53 million in overpayments and recovered $404.46 million. Policy changes regarding the payment and treatment of inpatient hospital claims and a delay in awarding new Medicare FFS RAC contracts resulted in fewer reviews in FY 2016 compared to previous years. Meanwhile, amounts that HHS identified in previous years continue to be collected. During FY 2016, the majority of Medicare FFS RAC collections were from Diagnosis Related Group validations and outpatient therapy reviews.

In addition to using the Medicare FFS RACs to identify overpayments, HHS also uses Medicare FFS RAC findings to prevent future improper payments. For example, in FY 2016, HHS released quarterly Provider Compliance Newsletters that offered detailed information on 12 findings identified by the Medicare FFS RACs. Also, HHS used these findings to implement local and/or national system edits to prevent improper payments. More information on the Medicare FFS RAC program can be found at: www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Recovery-Audit-Program.

Medicare Secondary Payer RACs

The Medicare Secondary Payer (MSP) RAC began full recovery operations at the end of FY 2013 and operates as the MSP Commercial Repayment Center (CRC). The CRC reviews information collected by HHS regarding beneficiaries that had or have primary coverage through an employer-sponsored Group Health Plan (GHP) and, as of FY 2016, situations where a Non-Group Health Plan (NGHP), such as a Workers' Compensation entity or No-Fault insurer, has or had primary payment responsibility. When GHP information is incomplete, Medicare FFS may mistakenly pay for services as the primary payer. The CRC recovers these mistaken payments from the entity that had primary payment responsibility (typically the employer or other plan sponsor, insurer, or claims processing administrator). The debtors for these GHP MSP debts do not have formal appeal rights, but do have the opportunity to dispute the debt through the established "defense" process. In FY 2016, the CRC workload expanded to include the recovery of certain conditional payments made by Medicare FFS until HHS identifies an NGHP with primary payment responsibility. Upon learning that the NGHP has primary payment responsibility, the CRC initiates recovery of these conditional payments.

In FY 2016, the CRC identified approximately $243.68 million and collected $106.29 million in mistaken payments. Collections decreased by about $43.31 million in FY 2016, compared to $149.60 in FY 2015. FY 2015 collections were higher due to a one-time surplus of available GHP recoveries during that year. More information on the CRC can be found at: www.cms.gov/Medicare/Coordination-of-Benefits-and-Recovery/Coordination-of-Benefits-and-Recovery-Overview/Group-Health-Plan-Recovery/Group-Health-Plan-Recovery.html.

Medicare Part C and Part D RACs

Section 6411(b) of the *Affordable Care Act* expanded the RAC program to Medicare Parts C and D. As part of the procurement process to secure a Medicare Part C RAC, HHS posted a Request for Quote in June 2014; however, HHS did not receive any responses to the solicitation. More recently, HHS posted a Request for Information in December 2015 to solicit additional feedback from industry regarding this program, and received several submissions in response to the announcement. HHS continues its implementation efforts and anticipates awarding a Part C RAC contract in 2017.

The Part D RAC program became fully operational in FY 2012. Since its launch, the Part D RAC recouped overpayments made as a result of prescriptions written by excluded or unauthorized providers and improper refills of Drug Enforcement Agency scheduled drugs. The Part D RAC recouped approximately $2.30 million in FY 2016. In addition, notifications of improper payments were sent to plan sponsors in FY 2016, totaling approximately $7.95 million and recoupments are expected to occur in FY 2017.

More information on the Medicare Part C and Part D RAC programs can be found at: www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/recovery-audit-program-parts-c-and-d/index.html.

State Medicaid RACs

Section 6411(a) of the *Affordable Care Act* required states to submit assurances by December 31, 2010 that their programs meet the statutory requirements to establish State Medicaid RAC programs. States were required to implement RAC programs by January 1, 2012. Thus, FY 2016 is the fourth full federal FY of reporting State Medicaid RAC recoveries. As states continue to implement their State Medicaid RAC programs, State Medicaid RAC federal-share recoveries totaled $44.31 million in FY 2016. State Medicaid RAC federal-share recoveries include overpayments collected, adjusted, or refunded to HHS, as reported by states on the CMS-64.

By the end of FY 2016, 47 States and the District of Columbia had implemented Medicaid RAC programs to identify and recover overpayments and identify underpayments in their Medicaid programs. However, each state has the flexibility to tailor its RAC program where appropriate with guidance from HHS. For example, two of the states that have implemented Medicaid RAC programs ended their RAC programs when HHS approved an exception due to the high proportion of beneficiaries enrolled in Medicaid managed care compared to FFS. Five states currently have time-limited HHS-approved exceptions to Medicaid RAC implementation due to high managed care penetration or small beneficiary populations.

Recovery Auditing Reporting Tables

OMB Circular A-136 requires agencies to provide detailed information on their recovery auditing programs, as well as other efforts related to the recapture of improper payments. Some of our programs have results to report in this area and those results are included in the following tables. If HHS excluded a program from a table, it is because it does not have results in that area.

Table 4
Overpayments Recaptured with and without Recapture Audit Programs
FY 2016 (in Millions)

	Payment Recapture Audits of Contracts					Payment Recapture Audits of Benefits					Total		Overpayments Recaptured Outside of Payment Recapture Audits	
Program or Activity	Amount Identified	Amount Recaptured Note (1)	CY Recapture Rate	CY + 1 Recapture Rate Target	CY + 2 Recapture Rate Target	Amount Identified	Amount Recaptured Note (1)	CY Recapture Rate	CY + 1 Recapture Rate Target	CY + 2 Recapture Rate Target	Amount Identified	Amount Recaptured	Amount Identified	Amount Recaptured
Medicare FFS Error Rate Measurement Note (2)													$25.55	$22.02
Medicare FFS Recovery Auditors	$440.53	$404.46	91.81%	85.00%	85.00%						$440.53	$404.46		
Medicare Secondary Payer Recovery Auditor	$243.68	$106.29	43.62%	85.00%	85.00%						$243.68	$106.29		
Medicare Contractors Note (3)													$14,534.26	$12,267.70
Medicare Part C Note (4)													$316.88	$316.88
Medicare Part C Recovery Auditors Note (5)														
Medicare Part D Note (4)													$9.53	$9.53
Medicare Part D Recovery Auditors	$7.95	$2.30	28.93%	85.00%	85.00%						$7.95	$2.30		
Medicare C RADV Audits Note (6)														
Medicaid Error Rate Measurement Note (7)													$4.08	$0.70
CHIP Error Rate Measurement Note (7)													$1.63	$0.26
Medicaid Integrity Contractors-Federal Share Note (8)													$33.64	$9.02
State Medicaid Recovery Auditors – Federal Share Note (9)						N/A	$44.31	N/A	N/A	N/A	N/A	$44.31		
Foster Care Eligibility Reviews-Post Payment Reviews													$1.43	$1.43 (Note 10)

Table 4
Overpayments Recaptured with and without Recapture Audit Programs
FY 2016 (in Millions)

	Payment Recapture Audits of Contracts					Payment Recapture Audits of Benefits					Total			Overpayments Recaptured Outside of Payment Recapture Audits	
Program or Activity	Amount Identified	Amount Recaptured Note (1)	CY Recapture Rate	CY + 1 Recapture Rate Target	CY + 2 Recapture Rate Target	Amount Identified	Amount Recaptured Note (1)	CY Recapture Rate	CY + 1 Recapture Rate Target	CY + 2 Recapture Rate Target	Amount Identified	Amount Recaptured		Amount Identified	Amount Recaptured
Foster Care OIG Reviews														$0.00	$65.52
Foster Care Single Audits														$2.27	$7.91
Child Care Single Audits														$25.43	$0.13
Child Care Error Rate Measurement Note (11)														$0.11	$0.02
Child Care OIG Reviews														$3.02	$7.38
Head Start OIG Reviews														$0.63	$0.15
Head Start Single Audits														$4.49	$2.22
ACF OIG Reviews – All Other Programs														$8.19	$25.53
ACF Single Audits – All Other Programs														$1.44	$2.12
Superstorm Sandy SSBG Error Rate Measurement Note (12)														$0.12	$0.00
Superstorm Sandy SAMHSA Error Rate Measurement														$0.0006	$0.00
TOTAL	$692.16	$513.05	74.12%	85.00%	85.00%		$44.31				$692.16	$557.36		$14,972.70	$12,738.52

Notes:

1. The amount reported in the Amount Recaptured column is the amount recovered in FY 2016, regardless of the year HHS identified the overpayment.
2. The actual overpayments identified by the CERT program during the FY 2016 report period were $25,552,562.45. The identified overpayments are recovered by the MACs via standard payment recovery methods. As of the report publication date, MACs reported collecting $22,015,289.85 or 86.16 percent of the actual overpayment dollars.
3. This total reflects amounts reported by the Medicare FFS Contractors excluding the amounts reported for the Medicare FFS Recovery Auditors program and the Medicare FFS Error Rate Measurement program, which HHS reports separately in this table.
4. The values in the Medicare Part C and Medicare Part D rows represent overpayments reported and returned by Medicare Advantage organizations and Part D sponsors, respectively.
5. HHS expects to award a contract for a Medicare Part C RAC program in 2017.
6. During FY 2016, HHS continued the contract-level RADV audits based on calendar years 2011 and 2012 and

launched the calendar year 2013 audits. As such, there were no RADV payment amounts identified or recovered in FY 2016.

7. For the Medicaid and CHIP Error Measurement rows, HHS works closely with states to recover overpayments identified from the FFS and managed care claims sampled and reviewed. Recoveries of Medicaid and CHIP improper payments are governed by the *Social Security Act* and related regulations under which states must return the federal share of overpayments. States reimburse HHS for the federal share of overpayments. Section 6506 of the *Affordable Care Act* amended the *Social Security Act* to allow states up to one year from the date of discovery of an overpayment for Medicaid and CHIP services to recover, or to attempt to recover, such overpayment before making an adjustment to refund the federal share of the overpayment.
8. For Medicaid, the Medicaid Integrity Contractors identified total overpayments that include both the federal and state shares. However, HHS reports only the actual federal share across audits.
9. For the State Medicaid Recovery Auditor row, states are only required to report the amount of recoveries on the CMS-64, and not the amount of improper payments identified or recovery rates or targets. The State Medicaid Recovery Auditors Amount Recaptured cell represents the federal share of the state recoveries as of the publication date of the AFR.
10. As a result of conducting Foster Care eligibility reviews in 16 states during the 12-month period between July 2015 and June 2016, HHS recovered over $1.4 million in Title IV-E improper payments. The recovered funds are comprised of $1,043,326 in disallowed maintenance payments and $382,688 in disallowed administrative payments.
11. The Child Care Error Rate Measurement information reflects overpayments that are identified through the statistical sampling process. The information reported represents the amount that is subject to disallowance. For the Child Care Error Rate Measurement Amount Recaptured information, states are required to recover child care payments that are the result of fraud and have discretion as to whether to recover misspent funds that were not the result of fraud, such as in cases of administrative error. Data reported in FY 2016 represent improper payments recovered by the Year Three states based on improper payments identified in FY 2013.
12. In FY 2016, HHS formally requested grantees to determine whether selected overpayments would be recaptured and allocated towards an allowable activity or repaid to the federal government. Grantees plan to complete actions for recapture or repayment in FY 2017.

Table 5

Disposition of Funds Recaptured Through Payment Recapture Audit Programs

FY 2016 (in Millions)

Program or Activity	Amount Recaptured	Type of Payment	Agency Expenses to Administer the Program	Payment Recapture Auditor Fees	Financial Management Improvement Activities	Original Purpose Note (1)	Office of Inspector General	Returned to Treasury
Medicare FFS Recovery Auditors	$404.46	Contract	$20.82	$39.12	N/A	$275.06	N/A	N/A
Medicare Secondary Payer Recovery Auditor	$106.29	Contract	$0.53	$17.41	N/A	$88.35	N/A	N/A
Medicare Part D Recovery Auditors	$2.30	Contract	N/A	$0.46	N/A	$1.84	N/A	N/A
State Medicaid Recovery Auditors – Federal Share Note (2)	$44.31	Benefits	N/A	N/A	N/A	N/A	N/A	$44.31
Total	$557.36		$21.35	$56.99	N/A	$365.25	N/A	$44.31

Notes:

1. Funds included under the Original Purpose column were returned to the Medicare Trust Funds after taking into consideration agency expenses to administer the program and recovery auditor contingency fees. In addition, the Medicare FFS Recovery Auditors Original Purpose cell also takes into consideration underpayments to providers that were identified and corrected ($69.46 million).
2. The state Medicaid recovery auditors' row only includes information on the federal share of recoveries, which are returned to Treasury. States do not report information to HHS on how the state portions of recoveries are used.

Table 6
Aging of Outstanding Overpayments Identified in the Payment Recapture Audit Programs
FY 2016 (in Millions)[Note (1)]

Program or Activity	Type of Payment	CY Amount Outstanding (0 – 6 months)	CY Amount Outstanding (6 months to 1 year)	CY Amount Outstanding (over 1 year)	Amount Determined to Not be Collectable
Medicare FFS Recovery Auditors	Contract	$45.51 Note (2)	$44.20	$1,598.15	N/A
Medicare Secondary Payer Recovery Auditor Notes (3) and (4)	Contract	$155.53	$24.36	$0.00	N/A
Medicare Part D Recovery Auditors	Contract	N/A Note (5)	N/A	N/A	N/A
Total		$201.04	$68.56	$1,598.15	N/A

Notes:

1. The state Medicaid recovery auditors are not included in this table since states do not report information to HHS that would allow the Department to calculate the aging of overpayment amounts that are currently outstanding.
2. Under the Medicare FFS recovery auditors program, recovery of identified overpayments cannot begin until the overpayment is at least 41 days old. Therefore, the CY Amount Outstanding (0-6 months) includes identified overpayments that HHS cannot begin collecting.
3. The Medicare Secondary Payer recovery auditor maintains debts established under prior MSP recovery programs; consequently, collections exclusively related to mistaken payments identified by the MSP recovery auditor does not directly correlate to the amount outstanding.
4. The amount of outstanding payments identified by the Medicare Secondary Provider recovery auditor included in this table reflect the outstanding balances on debts identified in FY 2016.
5. Recoupments of FY 2016 Part D overpayments will not begin until the appeals process is complete. The appeals process is ongoing, but is expected to be completed during FY 2017. However, as stated in *Section 15.0*, HHS recovered $2.30 million in overpayments that the Part D RAC identified in previous years.

16.0 Do Not Pay Initiative

In June 2010, the President issued a Memorandum on Enhancing Payment Accuracy Through a "Do Not Pay List" in a network of databases where agencies can access relevant information before determining eligibility for a benefit, grant or contract award, or other federal funding. Subsequently, the "Do Not Pay List" was codified by IPERIA. The Presidential memorandum and IPERIA identified six databases to include in the Do Not Pay (DNP) portal. Treasury's DNP website – www.donotpay.treas.gov/index.htm - includes information on currently available and pending data sources in the DNP portal.

Since 2010, HHS has worked diligently to implement the DNP initiative. HHS and CMS established a Computer Matching Agreement (CMA) with Treasury under the DNP initiative in FY 2014. HHS has continued to receive information through the CMA that was established in FY 2014 and worked to establish additional CMAs in FY 2016. In addition, several of our Divisions are continuing to use DNP to check for recipients' or potential recipients' eligibility and to prevent improper payments. Treasury-disbursed payments are matched against the SSA's DMF and the General Services Administrations' excluded parties' elements of the System for Award Management in the DNP portal to identify improper payments on a daily basis. While the Department identified four potential improper payments over the past year as part of these daily matches (as shown in Table 8), there were no confirmed matches in FY 2016. Lastly, CMS is also checking certain payments against IPERIA-listed databases outside of the DNP portal, and reporting results for the first time in FY 2016. The results of these matches can also be found in Table 7.

Table 7

Results of the Do Not Pay Initiative in Preventing Improper Payments

FY 2016

	Number (#) of payments reviewed for possible improper payments	Dollars ($) of payments reviewed for possible improper payments	Number (#) of payments stopped	Dollars ($) of payments stopped	Number (#) of potential improper payments reviewed and determined accurate	Dollars ($) of potential improper payments reviewed and determined accurate.
Reviews with the IPERIA specified databases disbursed by Treasury Note (1)	1,230,677 Note (2)	$385,481,524,698.27	0 Note (3)	0 Note (3)	4 Note (4)	$488.90 Note (4)
Reviews with the IPERIA specified database disbursed by CMS Note (5)	1,139,204,538	$395,065,205,838.23	656,399 Note (3)	$1,576,586,430.05 Note (3)	N/A Note (6)	N/A Note (6)
Reviews with databases not listed in IPERIA	N/A	N/A	N/A	N/A	N/A	N/A

Notes:

1. This row shows payments that are disbursed through Treasury and matched against IPERIA specified databases.
2. HHS data included 18,857 payment records that contained missing or invalid information.
3. "Payments Stopped" refers to payments for which the agency has implemented Stop Payment Rules or a similar method of disbursement prevention during the pre-payment stage. It does not include post-payment reclamations, collections, or offsets.
4. This cell includes information on payments that were flagged as potentially improper, but were determined proper after further review.
5. This row represents the Medicare FFS payments that were reviewed for improper payments. Medicare FFS payments are not disbursed by Treasury but are also matched against databases listed in IPERIA.
6. Data on payments that were flagged as potentially improper, but were determined proper after further review, is not included in the table. However, 134,073 payments totaling $67,724,395.65 for deceased beneficiary's claims were not stopped and subsequently determined improper after further review.

SUMMARY OF FINANCIAL STATEMENT AUDIT AND MANAGEMENT ASSURANCES

As described in the "Management's Discussion and Analysis" section, management annually presents an assurance statement on the effectiveness of internal control. The following two tables present summary information related to the material weakness identified during the audit, as well as conformance with FMFIA and compliance with FFMIA.

Table 1: Summary of Financial Statement Audit

Audit Opinion			Unmodified for Four Financial Statements. No Opinion Expressed on Statement of Social Insurance and Statement of Changes in Social Insurance Amounts		
Restatement			No		
Material Weaknesses	**Beginning Balance**	**New**	**Resolved**	**Consolidated**	**Ending Balance**
Financial Reporting, Systems, Analyses & Oversight	–	–	–	–	–
NIH Financial Management Systems and Review Processes	–	–	–	–	–
Financial Information Systems	1	–	–	–	1
Total Material Weaknesses	***1***	–	–	–	***1***

Definition of Terms – Tables 1 and 2
(Reference: OMB Circular A-136, *Financial Reporting Requirements*, October 7, 2016, page 143)

Beginning Balance: The beginning balance will agree with the ending balance of material weaknesses from the prior year.

New: The total number of material weaknesses that have been identified during the current year.

Resolved: The total number of material weaknesses that have dropped below the level of materiality in the current year.

Consolidated: The combining of two or more findings.

Reassessed: The removal of any finding not attributable to corrective actions (e.g., management has re-evaluated and determined a finding does not meet the criteria for materiality or is redefined as more correctly classified under another heading (e.g., Section 2 to a Section 4 and vice versa).

Ending Balance: The agency's year-end balance of material weaknesses.

Table 2: Summary of Management Assurances

Effectiveness of Internal Control over Financial Reporting (FMFIA #2)						
Statement of Assurance	Modified					
Material Weaknesses	**Beginning Balance**	**New**	**Resolved**	**Consolidated**	**Reassessed**	**Ending Balance**
Information System Controls and Security	1	-	-	-	1[29]	0
Total Material Weaknesses	***1***	**-**	**-**	**-**	***1***	***0***

Effectiveness of Internal Control over Operations (FMFIA #2)						
Statement of Assurance	Modified					
Material Weaknesses	**Beginning Balance**	**New**	**Resolved**	**Consolidated**	**Reassessed**	**Ending Balance**
Information System Controls and Security	1	-	-	-	-	1
Error Rate Measurement	1	-	-	-	-	1
Medicare Appeals Process	0	1	-	-	-	1
Total Material Weaknesses	***2***	***1***	**-**	**-**	**-**	***3***

Conformance with Federal Financial Management System Requirements (FMFIA #4)						
Statement of Assurance	Federal Systems conform to financial management system requirements					
Non-Conformances	**Beginning Balance**	**New**	**Resolved**	**Consolidated**	**Reassessed**	**Ending Balance**
Information System Controls and Security	1	-	-	-	1[29]	0
Total Non-Conformances	***1***	**-**	**-**	**-**	***1***	***0***

Compliance with Section 803(a) of the *Federal Financial Management Improvement Act* (FFMIA)		
	Agency	**Auditor**
1. Federal Financial Management System Requirements	No lack of compliance noted	Lack of compliance noted
2. Applicable Federal Accounting Standards	No lack of compliance noted	No lack of compliance noted
3. USSGL at Transaction Level	No lack of compliance noted	No lack of compliance noted

[29] With the revision of OMB Circular A-123, *Management's Responsibility for Enterprise Risk Management and Internal Control*, HHS reassessed the Information System Controls and Security material weakness and determined that the factors contributing to the material weakness are more correctly classified under the heading Effectiveness of Internal Control over Operations (FMFIA #2). The auditor categorized the same FMFIA material weakness as a lack of compliance with FFMIA (FMFIA #4).

FY 2016 TOP MANAGEMENT AND PERFORMANCE CHALLENGES IDENTIFIED BY THE OFFICE OF INSPECTOR GENERAL

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201

TO: The Secretary

FROM: Daniel R. Levinson, Inspector General

DATE: November 7, 2016

SUBJECT: Top Management and Performance Challenges Facing the Department of Health and Human Services in Fiscal Year 2016

This memorandum transmits the Office of Inspector General's (OIG) list of top management and performance challenges facing the Department of Health and Human Services (Department). The Reports Consolidation Act of 2000, Public Law 106-531, requires OIG to identify these management challenges, assess the Department's progress in addressing each challenge, and submit this statement to the Department annually.

OIG's top management and performance challenges for fiscal year 2016 are:

1. Ensuring Program Integrity in Medicare Parts A and B
2. Effectively Administering the Medicaid Program to Improve Oversight of Managed Care, Address High Improper Payments, and Strengthen Program Integrity
3. Health Information Technology and the Meaningful and Secure Exchange and Use of Electronic Information
4. Improving Financial and Administrative Management
5. Ensuring the Proper Administration of HHS Grants for Public Health and Human Services Programs
6. Curbing the Abuse and Misuse of Controlled and Non-controlled Drugs in Medicare Part D and Medicaid
7. Ensuring Quality of Care and Safety for Vulnerable Populations
8. Operating and Overseeing the Health Insurance Marketplaces
9. Managing Delivery System Reform and Strengthening Medicare Advantage
10. Ensuring the Safety of Food, Drugs, and Medical Devices

OIG looks forward to continuing to work with the Department to identify and implement strategies to protect the integrity of the Department's programs and the well-being of the beneficiaries of these programs. If you have any questions or comments, please contact me, or your staff may contact Christopher Seagle, Director of External Affairs, at (202) 260-7006 or Christopher.Seagle@oig.hhs.gov.

Top Management and Performance Challenges Facing the Department

The Office of Inspector General (OIG) has identified 10 top management and performance challenges facing the Department of Health and Human Services (HHS) as it strives to fulfill its mission "to enhance the health and well-being of Americans by providing effective health and human services and by fostering sound, sustained advances in the sciences underlying medicine, public health, and social services." These top challenges arise across HHS programs, including, Medicare, Medicaid, the Public Health Service, and the Indian Health Service. These challenges cover critical HHS responsibilities that include delivering quality services and benefits, exercising sound fiscal management, safeguarding public health and safety, and enhancing cybersecurity. OIG maintains a list of recommended solutions to address vulnerabilities detected in its audits and evaluations and identifies the top unimplemented recommendations that, if implemented, are likely to garner significant savings and improvements in efficiency and effectiveness. Unimplemented recommendations may be found on our website at https://oig.hhs.gov/reports-and-publications/compendium/index.asp.

2016 OIG Top Management and Performance Challenges Facing HHS

1. Ensuring Program Integrity in Medicare Parts A and B
2. Effectively Administering the Medicaid Program to Improve Oversight of Managed Care, Address High Improper Payments, and Strengthen Program Integrity
3. Health Information Technology and the Meaningful and Secure Exchange and Use of Electronic Information
4. Improving Financial and Administrative Management
5. Ensuring the Proper Administration of HHS Grants for Public Health and Human Services Programs
6. Curbing the Abuse and Misuse of Controlled and Non-controlled Drugs in Medicare Part D and Medicaid
7. Ensuring Quality of Care and Safety for Vulnerable Populations
8. Operating and Overseeing the Health Insurance Marketplaces
9. Managing Delivery System Reform and Strengthening Medicare Advantage
10. Ensuring the Safety of Food, Drugs, and Medical Devices

In this presidential transition year, HHS must address these challenges while undertaking the additional important responsibility of conducting a well-orchestrated transition to new leadership, consistent with the executive order on "Facilitation of a Presidential Transition" and other requirements. The transition will require heightened focus on effective coordination across HHS operating divisions, continuity of operations, and emergency preparedness. This transition must be accomplished while maintaining and strengthening HHS's many complex programs and protecting and serving its beneficiaries.

Top Management Challenge #1: Ensuring Program Integrity in Medicare Parts A and B

Key Components of the Challenge

- Reducing improper payments
- Preventing, detecting, and responding to fraud
- Fostering prudent payment policies

Why This Is a Challenge

Spending under Medicare Parts A and B is expected to increase significantly over time due to the growth in the number of beneficiaries and the increase in per capita health care costs. The 2016 Annual Report by Medicare's Board of Trustees estimates that the Trust Fund for Part A will be depleted by 2028. The report also projects Part B spending growth of almost 7 percent over the next 5 years, outpacing the projected 5 percent growth of the U.S. economy during that time. Further, the Part B payment system for providers is undergoing substantial changes through the Medicare Access and CHIP Reauthorization Act of 2015 and other reforms. (*For more information on Medicare payment and delivery reform, see TMC #9.)* HHS faces challenges—and opportunities—in each of the key areas addressed below.

Key Components of the Challenge

Reducing Improper Payments. In FY 2015, the Centers for Medicare & Medicaid Services (CMS) reported an improper payment rate of 12.1 percent, corresponding to $43.3 billion, for Medicare Fee-for-Service (Parts A and B). These measures include payments that were paid at an incorrect amount (including both overpayments and underpayments), as well as payments for unnecessary services, services not rendered, billing or coding errors, and claims that did not meet documentation or other Medicare coverage requirements. *(For more information on improper payment rate measurement and reporting, see TMC #4.)*

While OIG reviews all areas of improper payments, OIG efforts in recent years have focused on specific provider areas based on risk and program size. Our reviews of hospitals' compliance with and risk of not complying with Federal and State requirements have served an important role in highlighting vulnerabilities in hospital billings and returning improper payments to the Medicare Trust Fund. OIG has also focused attention on improper payments in home health and hospice care due to concerns about vulnerabilities in these areas. Through compliance audits of home health agencies, OIG has uncovered improper payments across a number of risk areas, such as insufficient documentation, medical necessity, and homebound determinations. With respect to hospice, OIG found that one-third of stays for hospice general inpatient care in 2012 did not meet Medicare requirements, costing $268 million. *(For more information on the quality of care in home health and hospice, see TMC #7.)*

In addition, OIG has focused efforts on improper payments to Part B providers, such as chiropractors, physical therapists, and certain durable medical equipment (DME) suppliers (e.g., power mobility device suppliers). Historically, these providers have had high improper payment rates, and OIG has identified error rates exceeding 50 percent in its reviews of them.

Preventing, Detecting, and Responding to Fraud. Curbing fraud is vital to protecting beneficiaries and conserving scarce health care resources. Fraud schemes can shift over time, but certain Medicare services have been consistent targets. Program areas susceptible to widespread fraud include home health and hospice services and DME. Common schemes include billing for unnecessary services or services not provided and kickbacks to recruiters and patients. Other concerns include aggressive and

illegal DME telemarketing and social targeting of Medicare beneficiaries, which can result in financial loss to Medicare and beneficiaries being put at risk of medical identity theft.

To help prevent fraud, Medicare must have accurate information about the individuals and entities with which it does business and must take appropriate steps to avoid doing business with, and exposing beneficiaries to, those who are untrustworthy. To this end, CMS must fully and effectively deploy all available program integrity tools, including those provided under the Patient Protection and Affordable Care Act, such as enhanced screening of provider enrollments. However, OIG found weaknesses in Medicare contractors' administration of provider enrollments that could leave Medicare vulnerable to billing by ineligible providers and beneficiaries vulnerable to seeking care from substandard providers. The weaknesses included gaps in the verification of key information, inconsistencies in site visit procedures, and failures to use site visit results for enrollment decisions. Further, CMS's Provider Enrollment, Chain and Ownership System (PECOS) is incomplete and, in some cases, inaccurate. The information in PECOS is intended to aid CMS in tracking enrollment and revalidation trends and to help determine whether CMS contractors are meeting requirements.

Fostering Prudent Payment Policies. In certain contexts, Medicare pays significantly different amounts for the same services provided to similar patients in different settings. For example, we estimated that during calendar year 2010 swing-bed services provided at 90 percent of the critical access hospitals (CAHs) we reviewed could have been provided at other nearby facilities that are paid under the Skilled Nursing Facility (SNF) Prospective Payment System. We believe that Medicare could have saved $4.1 billion over 6 years if payments for swing-bed services at CAHs were made to other facilities at SNF rates. Medicare and beneficiaries also typically pay more for a physician service provided in a "provider-based facility" (i.e., one owned by a hospital) than for the same service provided in an independent facility. OIG has highlighted weaknesses in CMS's management of these payment policies.

CMS is implementing a significant overhaul of the payment system for clinical laboratory tests pursuant to the Protecting Access to Medicare Act of 2014. The new system, which seeks to better align Medicare reimbursement for lab tests with market rates, takes effect on January 1, 2018. Before then, CMS must complete numerous tasks associated with collecting private payer data from labs and using it to establish the new reimbursement rates for lab tests. Timeframes for some of these tasks are tight, e.g., completing sub-regulatory guidance before the data-reporting period begins on January 1, 2017. Further, OIG has raised concerns about risks to payment accuracy on the basis of CMS's plans to rely on labs to self-identify whether they meet the criteria for reporting private payer data and CMS's plans to rely on reporting labs' self-attestations of the data's completeness and accuracy.

Some payment systems create financial incentives that may negatively affect patient care and drive up Medicare costs. For example, Medicare's payment policies for SNFs gives these facilities incentives to bill for higher levels of therapy than beneficiaries need. OIG work showed that SNFs have billed for the highest level of therapy at increasing rates that were not supported by patient needs. Additionally, hospices provided care much longer and received much higher Medicare payments for beneficiaries in inpatient assisted living facilities (ALFs) than for beneficiaries in other settings, creating incentives for hospices to target these patients. OIG found that Medicare payments for hospice care in ALFs more than doubled in 5 years, totaling $2.1 billion in 2012.

Progress in Addressing the Challenge

Through the Health Care Fraud and Abuse Control (HCFAC) Program, OIG, HHS, and the Department of Justice have made substantial strides in fighting fraud, waste, and abuse in Medicare (all parts) and

Medicaid and recovering stolen and misspent funds. From 2013 to 2015, the HCFAC Program has returned $6.10 for every $1 invested. In FY 2015, HCFAC-funded audits and investigations resulted in expected recoveries of $2.4 billion. To combat Medicare fraud, waste, and abuse, HHS has also taken steps to implement additional program integrity tools and many of OIG's recommendations. Specifically, in FY 2015, OIG reported potential savings of more than $18.4 billion from legislative, regulatory, and administrative actions taken by HHS and that were supported by OIG recommendations.

CMS is implementing prior authorization models and demonstrations in certain areas to help make sure items and services are provided in compliance with Medicare coverage, coding, and payment rules. CMS has established or is implementing prior authorization processes in certain locations that cover the following: power mobility devices, repetitive scheduled non-emergent ambulance transport, and certain durable medical equipment, prosthetics, orthotics, and supplies. CMS has also begun implementing a demonstration project in five States requiring home health agencies to submit required documentation for pre-claim review to help reduce and prevent improper payments. OIG has noted reductions in Medicare billing and payments for certain services and geographic areas known for fraud risks. For example, following law enforcement activities and CMS administrative actions, billing and payments for home health services and community mental health services declined significantly from 2009 to 2014 in fraud hot spots.

Furthermore, CMS has performed actions to improve provider enrollment safeguards to protect the integrity of the Medicare program. CMS has expanded its temporary provider enrollment moratoria for home health agencies to Statewide moratoria in certain geographic locations known for significant fraud. CMS has also proposed new regulations that would use its provider and supplier information more effectively to keep out or remove providers who pose risks to Medicare and its beneficiaries. In FY 2016, CMS reported that it has enhanced the address verification software in PECOS to better detect vacant or invalid addresses or commercial mailing reporting agencies. Further, CMS has reported improvements in its oversight and measurement of its contractors' performance and its corrective actions regarding improper payment vulnerabilities that contractors identify.

With respect to clinical laboratory services, CMS reports significant progress in several key areas, including promulgating regulations, establishing the Advisory Panel, publishing most of the sub-regulatory guidance, and building the data collection system. Finally, CMS is working to implement new legislation that would restrict the higher payment rates for provider-based facilities to “on-campus” facilities (those within 250 yards of the main provider) and to “off-campus” facilities that were designated as such before November 2, 2015.

What Needs To Be Done

Despite progress in some key areas, more must be done to protect Medicare from fraud, waste, and abuse and extend the solvency of the program. CMS could do more to ensure that fraudulent or abusive providers are not allowed to enroll or remain in Medicare in order to help prevent inappropriate payments, protect beneficiaries, and reduce the need for collection efforts against fraudulent providers who abscond with ill-gotten Medicare funds. CMS must continue improving its oversight and the performance of contractors in implementing Medicare provider enrollment safeguards, ensuring payment accuracy, and identifying and recovering overpayments in a timely manner. CMS should also improve the completeness, accuracy, and timeliness of its provider ownership data (maintained in PECOS) to support effective oversight.

HHS should continue to address and resolve program integrity weaknesses identified. OIG has recommended numerous actions, which remain unimplemented, to reduce improper payments for specific services. For example, OIG has recommended that CMS increase its oversight of hospice general inpatient claims, ensure that a physician is involved in the decision to use this level of care, and conduct prepayment reviews for lengthy stays. OIG has also recommended strengthened safeguards to ensure that Medicare pays for home health services only when the beneficiary meets the applicable homebound requirement and the home health agency has provided reasonable and necessary skilled services that are supported by and documented in the physician's certification plan.

OIG has also recommended changes to promote more prudent payment policies, including payments to hospital outpatient departments and ambulatory surgical centers, SNFs, and hospices. Many of these changes would require new statutory authority, and HHS's role is to develop legislative proposals for consideration by the Administration and Congress. Concurrently, OIG has recommended numerous actions that CMS can take within its existing authorities to mitigate the financial and quality of care risks under the current systems. For example, OIG recommended that CMS analyze billing data to identify SNFs that appear to be overbilling for therapy and expand its oversight reviews of those SNFs.

For laboratory tests, CMS must maintain focus on key remaining tasks, including completing the data collection system, ensuring completeness and accuracy of reported data, and establishing new Medicare payment rates after labs report data in 2017. CMS should monitor labs' reporting to ensure that all required labs' report data are accurate and complete. In the longer term, CMS should monitor the new system to ensure that it is meeting its cost savings goals.

Key OIG Resources

- OIG Testimony, "Medicare and Medicaid Program Integrity: Combatting Improper Payments and Ineligible Providers," May 2016. (https://oig.hhs.gov/testimony/docs/2016/maxwell-testimony05242016.pdf)
- OIG Report, "Medicare Hospices Have Financial Incentives to Provide Care in Assisted Living Facilities," January 2015. (https://oig.hhs.gov/oei/reports/oei-02-14-00070.pdf)
- OIG Report, "Medicare Compliance Review of Sea View Health Care Services, Inc.," May 2016. (https://oig.hhs.gov/oas/reports/region2/21401027.pdf)
- OIG Report, "The Medicare Payment System for Skilled Nursing Facilities Needs To Be Reevaluated," September 2015. (https://www.oig.hhs.gov/oei/reports/oei-02-13-00610.pdf)
- OIG Report, "Nationwide Analysis of Common Characteristics in OIG Home Health Fraud Cases," June 2016. (https://oig.hhs.gov/oei/reports/oei-05-16-00031.pdf)

Top Management Challenge #2: Effectively Administering the Medicaid Program to Improve Oversight of Managed Care, Address High Improper Payments, and Strengthen Program Integrity

Why This Is a Challenge

With over 72 million enrolled individuals, Medicaid serves more enrollees than any other Federal health care program and represents one-sixth of the national health economy. Effectively administering the Medicaid program takes on heightened urgency as the program expands under the Patient Protection and Affordable Care Act (Affordable Care Act) and undergoes other significant modernization reforms. The Centers for Medicare & Medicaid Services (CMS) reported that Federal and State Medicaid expenditures are projected to increase at an average annual rate of 6.4 percent and reach $921 billion by 2024.

Key Components of the Challenge

- Oversight of Medicaid managed care
- Reducing improper payment rates
- Strengthening program integrity to protect against fraud, waste, and abuse

Effectively administering Medicaid continues to be a top management challenge for HHS, given the needs of the beneficiaries served and longstanding vulnerabilities related to oversight of Medicaid managed care; high improper payment rates; and harnessing program integrity tools, including data, to protect the program from fraud, waste, and abuse.

Key Components of the Challenge

***Oversight of Medicaid Managed Care*.** The vast majority of Medicaid beneficiaries are enrolled in managed care. OIG has identified challenges to ensuring that these beneficiaries have access to high-quality care and that Medicaid funds are expended properly. For instance, OIG has found that varying State standards for access (e.g., States range from requiring one primary care provider for every 100 to 2,500 enrollees) and limited appointment availability may limit beneficiary access to services. OIG has also found that CMS does not have complete and timely managed care data from State Medicaid agencies. These data are necessary to identify and address possible fraud, waste, and abuse.

Improper Payment Rates Are High. Reducing improper payments to providers is a critical element in protecting the financial integrity of the Medicaid program. In FY 2015, HHS did not meet its established improper payment target for Medicaid. HHS set a FY 2015 target of 6.7 percent for Medicaid. However, the actual improper payment rate for FY 2015 was 9.8 percent. Although not all improper payments are fraud, all improper payments pose a risk to the financial security of the Medicaid program.

Program Integrity Needs Strengthening. CMS and State Medicaid agencies have a shared responsibility to ensure that Medicaid expenditures are spent appropriately and also to protect the program from fraud, waste, and abuse. However, OIG has found that the Affordable Care Act's screening tools designed to strengthen provider enrollment were not fully implemented by State Medicaid agencies. In addition, OIG has found that CMS's national Medicaid database—essential to effective program oversight—is incomplete and additional data are needed to enhance national program integrity activities. *(For more information on improving the flow of complete, accurate, and timely information, see TMC #3.)* Finally, OIG identified significant and persistent vulnerabilities related to personal care services (PCS), including ineffective program safeguards to ensure that beneficiaries are not exposed to unsafe or suboptimal care and Medicaid is not exposed to high improper payments. *(For more information on ensuring quality in PCS and other services, see TMC #7.)*

Progress in Addressing the Challenge

New Medicaid Managed Care Regulations. In May 2016, CMS issued a Medicaid Managed Care Final Rule. The rule addressed numerous OIG recommendations and will strengthen oversight of managed care entities by improving accountability and transparency. For example, the rule expanded requirements for managed care organizations to report data related to utilization and quality of services. The rule also requires State Medicaid agencies to develop and implement provisions ensuring that beneficiaries have adequate access to Medicaid covered services. Once provisions are implemented, State Medicaid agencies will be required to annually validate network adequacy.

Improper Payment Rate Corrective Action Plans. CMS determined that the primary reasons for the high FY 2015 improper payment rate errors were related to State Medicaid agencies' difficulties coming into compliance with new requirements. These include enrolling all referring or ordering providers, screening providers under the Affordable Care Act risk-based screening process, and including the attending provider National Provider Identifier on all electronically-filed institutional claims. CMS has engaged with State Medicaid agencies to develop State-specific corrective action plans that address these reasons for the high improper payment rate. CMS has also facilitated national best practice calls to share ideas across States, offered ongoing technical assistance, and provided additional guidance, as needed, to address the root causes of these improper payments.

CMS Working with States to Implement Program Integrity Measures. CMS indicated that it is taking actions to address provider enrollment vulnerabilities identified by OIG. CMS recently released guidance, "Medicaid Provider Enrollment Compendium," to assist State Medicaid agencies in implementing disclosure requirements and the Affordable Care Act's screening and enrollment requirements. Furthermore, CMS's final rule on managed care requires State Medicaid agencies to screen and enroll all network providers. This new requirement is a significant step in addressing a large number of providers previously exempt from State Medicaid agencies' screening and enrollment requirements. CMS continues to work with States to improve Medicaid data. Specifically, CMS works with all State Medicaid agencies to submit complete, accurate, and timely data. In addition, CMS conducted focused reviews of State Medicaid agencies' high-risk program integrity areas, including State Medicaid agencies' implementation of provider enrollment and screening provisions of the Affordable Care Act. Finally, CMS is assessing what actions it can implement to address the longstanding and persistent PCS vulnerabilities identified by OIG.

What Needs To Be Done

Full Implementation of the Medicaid Managed Care Regulation. CMS's issuance of the Medicaid Managed Care Final Rule is a positive step in addressing the managed care vulnerabilities identified by OIG. The final rule is the first major update to Medicaid managed care regulations in more than a decade. To facilitate full implementation of the final rule, CMS should continue to provide guidance to State Medicaid agencies in a timely manner and work closely with them to develop effective strategies to meet new requirements.

Reduce the Improper Payment Rate. CMS should continue its engagement with State Medicaid agencies to develop corrective action plans. Moreover, CMS should ensure that State Medicaid agencies are implementing and monitoring the effectiveness of their corrective action plans. Finally, CMS should continue innovative approaches, such as the creation of the Program Integrity Board, which leverages multiple CMS resources to identify payment vulnerabilities.

Ensure States Fully Implement Program Integrity Measures. CMS should continue to work with State Medicaid agencies to fully implement Affordable Care Act-required program integrity tools. Full implementation of these tools is critical to safeguarding the Medicaid program. CMS must ensure that State Medicaid agencies rigorously screen providers and make accurate beneficiary eligibility determinations. CMS should also continue to work with State Medicaid agencies to ensure that the submission of all required Medicaid data is complete, accurate, and timely. Finally, CMS must do more to address vulnerabilities in home- and community-based services, such as PCS. OIG recommends that CMS take a more active role to promote program integrity in PCS by promulgating regulations to, among other things, establish minimum qualifications and require attendants to undergo background checks and enroll in Medicaid or register with State Medicaid agencies.

Key OIG Resources

- OIG Testimony, "Medicare and Medicaid Program Integrity: Combatting Improper Payments and Ineligible Providers," May 2016. (https://oig.hhs.gov/testimony/docs/2016/maxwell-testimony05242016.pdf)
- OIG Report, "Personal Care Services: Trends, Vulnerabilities and Recommendations for Improvement – A Portfolio," November 2012. (http://oig.hhs.gov/reports-and-publications/portfolio/portfolio-12-12-01.pdf)
- OIG Report "Access to Care: Provider Availability in Medicaid Managed Care," December 2014. (https://oig.hhs.gov/oei/reports/oei-02-13-00670.pdf)
- OIG Report, "Early Outcomes Show Limited Progress for the Transformed Medicaid Statistical Information System," September 2013. (https://oig.hhs.gov/oei/reports/oei-05-12-00610.pdf)
- OIG Report, "Providers Terminated from One State Medicaid Program Continued Participating in Other States," August 2015. (https://oig.hhs.gov/oei/reports/oei-06-12-00030.pdf)

Top Management Challenge #3: Health Information Technology and the Meaningful and Secure Exchange and Use of Electronic Information

Why This Is a Challenge

In support of its mission and operations, HHS maintains and uses expanding amounts of sensitive information. Complete, accurate, and timely data can help ensure efficient operations of HHS and its programs, as well as support proactive program oversight. Similarly, the American health care system increasingly relies on health information technology (health IT) and the electronic exchange and use of health information. Health IT, including electronic health records (EHRs), offers opportunities for improved patient care, more efficient practice management, and improved overall public health. However, HHS continues to face a number of significant challenges in this information-rich environment.

Key Components of the Challenge

- Ensuring privacy and security of information
- Improving the flow of complete, accurate, and timely information
- Delivering on the promise of Health IT

Key Components of the Challenge

***Ensuring Privacy and Security of Information*.** Safeguarding privacy and ensuring data security—both physical and cyber security—are, and should remain, top priorities for HHS. HHS must ensure that the data it creates and maintains are protected. Equally important is the need to ensure appropriate protection of health information when considering and implementing policies related to the adoption of health IT and the exchange, storage, and use of electronic health information. The rapid pace at which technology evolves, the continuing expansion of the Internet of Things (including networked medical devices), and the rise of mobile health technology contribute to the complexity of the privacy and security challenges facing HHS.

The frequency of notable data breaches has increased significantly, and ransomware has emerged as a considerable threat in the health care space. Data breaches can have serious consequences for the health care industry, HHS, and those whom HHS serves. Threats to the confidentiality, integrity, and availability of data can result in a range of harms, including financial harm (to individuals and the public), identity theft, and physical patient harm. Frequently-identified weaknesses include inadequacies in access controls, patch management, encryption of data, and website security vulnerabilities at HHS, health care providers, States, and other entities that do business with HHS. Such weaknesses could impact the Department's ability to protect against unauthorized access to sensitive information. HHS is also responsible for implementing certain provisions of the Cybersecurity Act of 2015, as well as the Continuous Diagnostics and Mitigation program in conjunction with the Department of Homeland Security (DHS). When implementing technology, including complex, interoperable IT systems, HHS must utilize modern IT practices, such as those highlighted by the Digital Services Playbook.

***Improving the Flow of Complete, Accurate, and Timely Information*.** To capitalize on growing amounts of data in the health care context,[30] there must be meaningful access, subject to appropriate privacy and security safeguards, to complete, accurate, and timely data, where and when needed. However, enabling and encouraging the flow of information remains a challenge for HHS. Several factors may impede the flow of information. These include technical barriers (e.g., lack of interoperability), the

[30] Sources of relevant health care data, including patient-generated data, are ever increasing, particularly as the Internet of Things continues to expand.

complex nature of Federal and State privacy and security laws, financial considerations (e.g., the cost of health IT acquisition), and behavioral issues—such as information blocking[31] and consumer confidence—that relate to a willingness to share information.

Impediments to information sharing can present patient safety concerns. For example, a patient could be subjected to additional invasive testing that could have been avoided had information about prior results held by a different provider been shared. Improving the appropriate flow of health information among providers, patients, and those delivering related services is also critical to the success of many delivery reform and other initiatives, including the President's Precision Medicine Initiative (PMI) and the Cancer Moonshot. Without appropriate information sharing, those who participate in the initiatives may face challenges in achieving initiative goals. *(For more information on health care delivery reforms, see TMC #9.)*

The flow of information is also important between HHS and others, including providers. For example, data created, maintained, or transmitted using EHRs or other health IT are used to ensure correct Medicare and Medicaid payments, including value-based payments. Participants in certain initiatives also receive Departmental data for their use in improving the care they furnish. Additionally, HHS increasingly uses and shares data as part of its program operations and program integrity efforts. HHS must continue to find ways to leverage the vast amounts of data at its disposal to enhance decision-making, including streamlining and accelerating internal data exchange. Similarly, it is critical that HHS ensure that the systems on which it relies, including Medicare and Medicaid systems, are developed and operate in a way that ensures that the data are complete, accurate, timely, and appropriately protected. Prior OIG work has raised concerns about, for example, the completeness and accuracy of Transformed Medicaid Statistical Information System (T-MSIS) data.

***Delivering on the Promise of Health IT*.** HHS has made significant investments in health IT.[32] However, HHS faces challenges in ensuring that the goals associated with investing in the widespread adoption and use of EHRs and other health IT are fulfilled, and that the promise offered by health IT is realized. These challenges are in addition to the challenges of ensuring privacy and security and improving the flow of complete, accurate, and timely information. They include preventing inappropriate payments to participants who do not meet program requirements; ensuring that the beneficial characteristics of EHRs, including efficiency and ease of storage and access, are not used as tools for fraud; encouraging adoption and use of health IT by those who are not eligible for existing incentive programs; ensuring that patient safety benefits are realized; and encouraging the use of data that are exchanged.[33] Connecting the entire continuum of those involved in health care, as well as human services, is important to leveraging the benefits of health IT in a value-driven health care system. *(For more information on health delivery reforms, see TMC #9.)* Also important is ensuring that the underlying data

[31] For more information on the topic of information blocking, see The Office of the National Coordinator for Health Information Technology's (ONC) Report to Congress, "Report on Health Information Blocking," April 2015. (https://www.healthit.gov/sites/default/files/reports/info_blocking_040915.pdf).

[32] For example, in connection with the PMI, the National Institutes of Health (NIH) issued $55 million in grants, some of which will be used to establish a data and research support center and a participant technologies center. (https://www.nih.gov/news-events/news-releases/nih-awards-55-million-build-million-person-precision-medicine-study)

[33] ONC noted the need to improve the use of exchanged information by non-Federal acute care hospitals. ONC, Data Brief, No. 36, "Interoperability among U.S. Non-federal Acute Care Hospitals in 2015," May 2016. (https://www.healthit.gov/sites/default/files/briefs/onc_data_brief_36_interoperability.pdf)

are robust enough to be leveraged for important research and regulation.[34] When addressing these challenges, HHS must ensure coordination among internal agencies, as well as other Federal partners, with overlapping responsibility for various aspects of health IT to avoid potential gaps in policy and oversight that could undermine the promise of the health IT in which HHS has invested.

Progress in Addressing the Challenge

HHS has made progress with respect to privacy and security of its systems and information. Last year, HHS participated in the U.S. Chief Information Officer's 30-day Cybersecurity Sprint. More recently, HHS adopted DHS's Continuous Diagnostics and Mitigation program and is in the process of implementing EINSTEIN 3A.

Similarly, HHS has made progress regarding the privacy and security of external health information. For example, HHS participated in the development of the PMI: Data Security Policy Principles and Framework; the Food and Drug Administration (FDA) held a public workshop with DHS concerning medical device cybersecurity; HHS's coordination with the Federal Trade Commission led to the issuance of new resources for health IT developers, including some related to privacy and security; HHS, in conjunction with other Federal agencies, issued ransomware guidance discussing best practices; and the Office for Civil Rights (OCR) released a Fact Sheet on the Health Insurance Portability and Accountability Act (HIPAA) and ransomware. Further, HHS has taken steps to implement portions of the Cybersecurity Act of 2015, including convening a health care industry cybersecurity task force.

HHS has made great strides in developing a nationwide health IT infrastructure that supports the appropriate flow of complete, accurate, and timely information. As of September 2016, more than 599,000 eligible professionals, eligible hospitals, and critical access hospitals were actively registered in the EHR incentive programs.[35] Additionally, HHS has made a concerted effort to empower patients with respect to accessing their electronic health information.[36] HHS continues to focus on liberating health data in order to improve patient outcomes and health care delivery as well as social services. A sample of some of HHS's data initiatives include the Centers for Medicare & Medicaid Services' (CMS) release of new and updated public use files related to physician payment data and interactive online tools (such as the Medicare Part D Opioid Drug Mapping Tool and Mapping Medicare Disparities Tool); NIH's Genomic Data Commons platform to store, analyze, and distribute cancer genomics data; FDA's openFDA now allows direct downloads of data (openFDA offers access to medical device reports, enforcement reports, and drug adverse event reports); and Centers for Disease Control and Prevention's publically available data repository related to the ongoing Zika epidemic. The year 2016 also marked the 7th Annual Health Datapalooza, which brought together startups, academics, Government agencies, and individuals.[37]

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[34] FDA, for example, issued draft guidance concerning the use of real-world evidence to support regulatory decision-making for medical devices, which notes that "[real-world data] and associated [real world evidence] could constitute valid scientific evidence, depending on the characteristics of the data." (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM513027.pdf)

[35] CMS "State Breakdown of Registration by Medicaid and Medicare Providers through September 30, 2016," September 2016.

[36] OCR issued a Fact Sheet (http://www.hhs.gov/hipaa/for-professionals/privacy/guidance/access/index.html); ONC and OCR released educational videos (https://www.healthit.gov/access); and ONC issued a patient engagement playbook (https://www.healthit.gov/playbook/pe/).

[37] HHS also collaborated with Health Datapalooza to add a post-conference day devoted to health IT privacy and security. (https://www.healthit.gov/buzz-blog/privacy-and-security-of-ehrs/new-health-datapalooza-2016-day-devoted-privacy-security/)

With respect to information blocking, HHS established a hotline to receive complaints concerning potential information blocking practices and issued a final rule implementing related attestation requirements under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). Further, HHS obtained commitments from providers of hospital EHRs, large private health systems, and leading professional associations and stakeholder groups to make EHRs work better for patients and providers. One of the areas of commitment relates to avoiding information blocking.

HHS's participation and leadership in the Healthcare Fraud Prevention Partnership (HFPP) continues to improve the flow of information to address program integrity issues. The HFPP, a public-private partnership, brings interested parties—including private insurers, public payors, law enforcement agencies, and others—together to share and use data and analytic tools to proactively address health care fraud, waste, and abuse. Further, HHS continues to work with States to improve Medicaid data that are essential for protecting program integrity. Specifically, CMS issued a final rule in December 2015 authorizing the withholding of a subset of Federal funds for Medicaid administration from States until T-MSIS data are reported as required and information systems meet operability standards. In addition, CMS has established standards for the completeness, accuracy, and timeliness of T-MSIS data. According to CMS, it is in the process of implementing T-MSIS with all states, and there are 18 states in production as of September 2016. CMS also reports that it anticipates T-MSIS data to be available for the various stakeholders in early 2017 subject to state T-MSIS transition timelines.

HHS has continued to oversee the Medicare and Medicaid EHR incentive programs and has endeavored to advance the national conversation about important health IT issues to ensure that the potential benefits of health IT investments are realized.[38] HHS has also finalized a rule to implement the MACRA provisions that replace the Medicare EHR Incentive Program for eligible professionals with the Advancing Care Information Performance Category of the Merit-based Incentive Payment System (MIPS).

What Needs To Be Done

Threats to information privacy and security are evolving, as evidenced by the recent rise of ransomware, and HHS must remain vigilant. While HHS has made progress with respect to protecting its own information, as highlighted in OIG work and a congressional report from 2015, more remains to be done. OIG work will continue to focus on HHS systems' privacy and security to support HHS's efforts to mitigate the risk of unauthorized access to its sensitive information. HHS must also use available policy levers to address health IT privacy and security issues. OIG work released in 2016 examined HIPAA-required contingency planning for hospitals' EHRs and discussed the role contingency plans can play in preventing and mitigating disruptions caused by ransomware and other problems. Phase 2 of OCR's HIPAA Audit Program, which it launched in 2016, and OCR's efforts to increase investigations of smaller

[38] Last year, ONC issued a document entitled "Connecting Health and Care for the Nation: A 10-Year Vision to Achieve an Interoperable Health IT Infrastructure" (http://healthit.gov/sites/default/files/ONC10yearInteroperabilityConceptPaper.pdf) (10-Year Vision Paper), which describes plans to expand the sharing of information for health beyond EHRs and identifies privacy and security protections for health information as a building block for a nationwide interoperable health information infrastructure. More recently, ONC issued a document entitled "Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap Draft Version 1.0," (https://www.healthit.gov/sites/default/files/hie-interoperability/nationwide-interoperability-roadmap-final-version-1.0.pdf) which supports the vision laid out in the 10-Year Vision Paper. ONC has also issued an information-blocking report to Congress. (https://www.healthit.gov/sites/default/files/reports/info_blocking_040915.pdf), a Health IT Safety Center Roadmap (http://www.healthitsafety.org/uploads/4/3/6/4/43647387/roadmap.pdf), and an updated Federal Health IT Strategic Plan for 2015–2020 (http://www.healthit.gov/sites/default/files/9-5-federalhealthitstratplanfinal_0.pdf).

breaches (those involving fewer than 500 individuals)[39] are additional activities that will bring attention to health IT privacy and security. OIG work will continue to focus on privacy and security issues in the regulated community and on the related agencies to address concerns about similar risks for health information. Ongoing work is considering privacy and security issues related to networked medical devices, and future work may consider additional privacy and security issues that arise from the continuing expansion of the Internet of Things.

To reach HHS's goals, including goals related to achieving the learning health system identified in ONC's 10-Year Vision Paper and those associated with the PMI and Cancer Moonshot, HHS must do more to improve the flow of complete, accurate, and timely information, subject to appropriate privacy and security safeguards. This includes ensuring that HHS's data systems are developed and operated in a way that delivers complete, accurate, and timely data. HHS must also find ways to remove potential barriers to leveraging health IT and related data to advance public health initiatives and to facilitate sharing and use of information along the entire continuum of care (beyond just those who are eligible for EHR incentives).

Finally, to deliver on the promise of health IT, and given the magnitude of the investment in EHRs and other health IT programs, it will become increasingly important to measure the extent to which EHRs and health IT have achieved HHS's goals, which include improved health care and lower costs. As HHS develops policies, such as those related to the development and implementation of meaningful use stages and implementation of the Advancing Care Information Performance Category of MIPS created in MACRA, it should continue to consider feedback from stakeholders to ensure that adopted policies advance the Nation toward HHS's stated goals, while appropriately reflecting the rapidly changing health IT landscape and balancing privacy and security considerations. Additional guidance and technical assistance should be issued to address adoption, meaningful use, interoperability barriers, and program integrity safeguards. It is also essential that privacy, security, and fraud prevention remain at the forefront of health IT efforts of HHS, ONC, OCR, and CMS. Ongoing OIG work is examining the accuracy of Medicare and Medicaid EHR incentive payments for meaningful use and health IT interoperability across providers participating in accountable care organizations. Future work may also examine health IT interoperability across HHS and between providers and patients as well as outcomes from health IT investments.

Key OIG Resources

- OIG Summary Report, "Wireless Penetration Test of Centers for Medicare & Medicaid Services' Data Centers," August 2016. (https://oig.hhs.gov/oas/reports/region18/181530400.asp)
- OIG Report, "Hospitals Largely Reported Addressing Requirements for EHR Contingency Plans," July 2016. (https://oig.hhs.gov/oei/reports/oei-01-14-00570.asp)
- OIG Report, "Not All States Reported Medicaid Managed Care Encounter Data as Required," July 2015. (https://oig.hhs.gov/oei/reports/oei-07-13-00120.asp)
- OIG Report, "CMS and Its Contractors Have Adopted Few Program Integrity Practices To Address Vulnerabilities in EHRs," January 2014. (https://oig.hhs.gov/oei/reports/oei-01-11-00571.asp)
- OIG Report, "Not All Recommended Fraud Safeguards Have Been Implemented in Hospital EHR Technology," December 2013. (https://oig.hhs.gov/oei/reports/oei-01-11-00570.asp)

[39] OCR listserv email from August 19, 2016, entitled "OCR Announces Initiative to More Widely Investigate Breaches Affecting Fewer than 500 Individuals," available at https://list.nih.gov/cgi-bin/wa.exe?A2=OCR-PRIVACY-LIST;65d278ee.1608.

Top Management Challenge #4: Improving Financial and Administrative Management

Why This Is a Challenge

HHS is the largest civilian agency within the Federal Government. In FY 2015, HHS reported total costs of approximately $1 trillion. Responsible stewardship of HHS programs is vital, and operating a financial management and administrative infrastructure that employs appropriate safeguards to minimize risk and provide oversight for the protection of resources remains a challenge for HHS. HHS must also ensure the completeness, accuracy, and timeliness of any financial and program information provided to other entities, both internal and external to the Federal Government.

Key Components of the Challenge

- Addressing weaknesses in financial management systems
- Reducing improper payments
- Improving contracts management
- Implementing DATA Act standards.

Key Components of the Challenge

Financial Management Systems. We continue to report a material weakness in HHS's financial management systems related to inadequate internal controls over segregation of duties, configuration management, and access to HHS financial systems. HHS still does not substantially comply with financial management system requirements due to these issues. Under the Federal Financial Management Improvement Act of 1996, Federal agencies must establish and maintain financial management systems, and Inspectors General must determine compliance by their respective agency. These systems are intended to help agencies ensure the effectiveness and efficiency of operations, reliability of financial reporting, and compliance with applicable laws and regulations.

Improper Payments. Reducing improper payments is a critical element in protecting the financial integrity of HHS programs. Although not all improper payments are fraud, all improper payments pose a risk to the financial security of Federal programs. Pursuant to the Improper Payments Information Act of 2002 (IPIA), as amended, Federal agencies are required to provide uniform, annual reporting on improper payments and their efforts to reduce them. In its most recent Agency Financial Report (AFR), HHS reported improper payments totaling $89.7 billion overall for FY 2015 (excluding Superstorm Sandy programs). Our audit of HHS's FY 2015 AFR, published in May 2016, found that HHS did not meet all IPIA requirements. Specifically, we found that HHS did not report an improper payment rate for the Temporary Assistance for Needy Families (TANF) program, reported that the improper payment rate exceeded 10 percent for the Medicare Fee-for-Service program, reported four other risk-susceptible programs that did not meet their FY 2015 target error rates, and did not perform a risk assessment of payments to employees and charge card payments. HHS does not have the statutory authority to collect data from States that is necessary for calculating a TANF improper payment rate.

Contracts Management. HHS is one of the largest contracting agencies in the Federal Government. Given the high dollar amount and complexity of contracts, it is paramount that HHS have strong monitoring and oversight. OIG has raised issues about acquisition planning and procurement, contract monitoring, and payments to contractors related to the Federal Health Insurance Marketplaces operated by the Centers for Medicare & Medicaid Services (CMS). OIG has also identified issues regarding contract closeouts. OIG found that CMS had not closed out contracts totaling $25 billion, as required by the Federal Acquisition Regulation. Because the closeout process is typically the final

opportunity for improper payments to be detected and recovered, delays in the closeout process pose a substantial financial risk. Additionally, OIG has identified weaknesses in CMS's oversight and performance measurement for its benefit integrity contractors.

Digital Accountability and Transparency Act. The Digital Accountability and Transparency Act (DATA Act) required the Office of Management and Budget (OMB) and Department of the Treasury to establish Governmentwide data standards for reporting financial and payment information by May 2015. Broadly, the DATA Act requires HHS to begin using the Governmentwide data standards to enter information into USA Spending by May 2017 in an effort to ultimately increase transparency and accountability. Our readiness review of HHS's implementation of the DATA Act as of June 30, 2016, found that although HHS made progress, they have not fully met the requirements of the four initial steps of Treasury's *Agency 8-Step Plan*. Specifically, we found that HHS did not complete detailed project plans or determine how it will certify that the data is accurate and complete. Given the difficulty of defining and developing common data elements across multiple reporting areas and the volume of diverse programs administered by HHS, we determined that HHS will face challenges implementing these uniform data standards within the required timeframe.

Progress in Addressing the Challenge

HHS has taken corrective actions to resolve the information technology-related deficiencies reported in the AFR. In FY 2015, senior leadership placed additional focus on this area, which has remediated a number of deficiencies related to HHS financial management systems identified in past audits. HHS reviewed and updated critical entitywide governance documentation, such as authorities that allow systems to operate, plans to account for and improve system security, and configuration management. HHS also updated application-level contingency plans and backup policies and procedures and performed testing to improve redundancy and availability of the supporting information technology infrastructure and financial application system.

HHS has stated that when legislation is considered to reauthorize TANF, HHS plans to work with Congress to address a set of issues related to accountability and how funds are used, and to craft statutory changes that would allow for reliable error rate measurement, if appropriate. HHS also stated that it would perform risk assessments of payments to employees and charge card payments in FY 2016 and publish the results in the FY 2016 AFR.

In November 2015, HHS published a final rule that updated the HHS Acquisition Regulation (HHSAR) to supplement the Federal Acquisition Regulation. The HHSAR provides additional policy and procedural guidance to foster financial integrity and accountability across the acquisition lifecycle, from the concept of need through contract closeout. Additionally, CMS reported that it has prioritized closing out contracts. Since February 1, 2014, CMS reported that it has closed 4,909 contracts with an obligated value of $2.2 billion and de-obligated $82.49 million.

HHS has established a DATA Act Project Management Office within the Office of the Assistant Secretary for Financial Resources. This encompasses representatives from all of its operating divisions. HHS expects that these actions will enable it to meet the May 2017 due date for implementing the Governmentwide data standards. The HHS DATA Act Program Management Office has also been appointed by OMB's Office of Federal Financial Management (OFFM) as the executing agent of the financial assistance portion of the pilot required by Section V of the DATA Act. OFFM maintains strategic oversight for the pilot, while HHS is tasked with providing tactical leadership and establishing a pilot program to inform recommendations to Congress on methods to standardize reporting elements across

the Federal Government, eliminate unnecessary duplication in financial reporting, and reduce compliance costs for recipients of financial awards.

What Needs To Be Done

HHS should continue to address and resolve financial management system weaknesses identified by OIG, the Government Accountability Office, and other auditors contracted by OIG or HHS.

In addition, HHS must meet improper payment reduction targets and reduce improper payments to less than 10 percent for all programs. HHS must conduct thorough root cause analyses of significant improper payments and develop robust corrective action plans that target identified causes. HHS also must conduct a risk assessment of payments made to employees and use of charge cards.

CMS should improve coordination and collaboration across departmental staff with contract closeout responsibilities. CMS must also ensure that acquisition strategies are completed as required. Further, CMS must strengthen its contracts oversight, including proper accounting for contract costs related to the Federal Marketplace.

HHS must implement the Governmentwide data standards established by OMB and Department of the Treasury in accordance with the timeframes established by the DATA Act. HHS must also ensure that any information provided to comply with the Governmentwide data standards is complete, accurate, and timely.

Key OIG Resources

- OIG Report, "U.S. Department of Health and Human Services Met Many Requirements of the Improper Payments Information Act of 2002 But Did Not Fully Comply for Fiscal Year 2015," May 2016. (https://oig.hhs.gov/oas/reports/region1/171652000.asp)
- OIG Report on Financial Statement Audit of Health and Human Services for Fiscal Year 2015, November 2015. (http://www.hhs.gov/sites/default/files/afr/fy-2015-hhs-agency-financial-report.pdf)
- OIG Report, "CMS Has Not Performed Required Closeouts of Contracts Worth Billions," December 2015. (https://oig.hhs.gov/oei/reports/oei-03-12-00680.pdf)
- OIG Report, "CMS Did Not Identify All Federal Marketplace Contract Costs and Did Not Properly Validate the Amount to Withhold for Defect Resolution on the Principal Federal Marketplace Contract," September 2015. (https://oig.hhs.gov/oas/reports/region3/31403002.pdf)
- OIG Report, "Report on the DATA Act Readiness Review Audit of the Department of Health and Human Services," November 2016. (https://oig.hhs.gov/reports-and-publications/oas/dept.asp)

Top Management Challenge #5: Ensuring the Proper Administration of HHS Grants for Public Health and Human Services Programs

Why This Is a Challenge

HHS is the largest grant-making organization in the Federal Government, with more than $400 billion awarded in FY 2016. The Patient Protection and Affordable Care Act (Affordable Care Act) provided additional grants funding, adding to HHS's oversight responsibility. Responsible stewardship of these program dollars is vital to public health and well-being. Operating a financial management and administrative infrastructure that employs appropriate internal controls to minimize risk and protect resources remains a challenge for HHS.

Key Components of the Challenge

- Misuse of grant funds
- Inadequate oversight of programs for children
- Inadequate oversight of preparedness and response to emergencies and infectious diseases.

Vulnerabilities exist in grants management throughout HHS. For example, awarding agencies lack effective mechanisms to share information about problematic grantees. Intra-department communication is critical, especially because awarding agencies are now required to assess risks posed by grant applicants. Additionally, awarding agencies' monitoring of grantee progress over the life of the grant continues to need improvement. Once funds are awarded, effective oversight is key in ensuring that grantees expend Federal funds properly and efficiently. Lastly, many HHS grantees lack effective internal controls, including robust financial management systems required to provide effective accountability for Federal funds. To fulfill grant responsibilities and ensure accountability of Federal funds, grantees are required to maintain internal controls that provide reasonable assurance that operations are effective and efficient, ensure reliable reporting for internal and external use, and comply with laws and regulations. In addition to its usual grants administration and oversight activities, HHS faces the challenge of updating its internal and external grants policies and systems in accordance with 45 CFR part 75, its new regulation governing grants administration and the establishment of cost principles.

Examples of specific vulnerabilities in HHS grant programs include misuse of funds, inadequate oversight of programs for children, and inadequate oversight of preparedness and response to emergencies and infectious diseases.

Key Components of the Challenge

Misuse of Grant Funds. Misuse of Federal funds poses significant risks to the integrity of HHS programs. For example, in 2015 the University of Florida entered into a $19.875 million settlement agreement with OIG and HHS to resolve allegations that the University overcharged hundreds of HHS grants for the salary costs of its employees, charged some of these grants for administrative costs for equipment and supplies when those items should not have been directly charged to the grants under Federal regulations, and inflated costs charged to HHS grants. In another example, five individuals from Montana were convicted of fraud and sentenced in 2015 after improperly receiving Temporary Assistance for Needy Families (TANF) funds from the Blackfeet Tribe of the Blackfeet Nation in Montana and from the Federally funded State welfare program simultaneously. The Administration for Children and Families (ACF) worked with OIG to pursue a misuse of funds penalty against the Tribe for lack of oversight of HHS funds in its TANF program.

Oversight of Programs for Children. For HHS block grants, States are given broad flexibility to oversee and monitor funds and determine the fraud-prevention activities they will use to help ensure program integrity. OIG found that States differed in the scope and method of their program integrity and antifraud activities. For the Child Care and Development Fund (CCDF)—a $5.7 billion program that services nearly 1.4 million children every month—OIG identified weaknesses in the fiscal controls over CCDF funds in various States and, in total, reported more than $39.4 million in fund expenditures for FYs 2004–2010 that did not comply with Federal requirements. ACF has been working in the CCDF Block Grant structure to encourage States to adopt more uniform program integrity policies. The CCDF final rule, published on September 30, 2016, requires States to have effective procedures and practices to ensure integrity and accountability in the CCDF program. In addition, HHS oversees a variety of grantees providing for the care and services for unaccompanied children entering the United States from foreign countries and must maintain vigilance against fraud. For example, a grantee case manager in Florida defrauded more than 10 family members and/or potential sponsors of unaccompanied children who were in the custody of the Office of Refugee Resettlement by falsely representing that failing to send the case manager a requested amount of money might delay reunification with their children or result in the child's deportation. The case worker was sentenced to 18 months of imprisonment and ordered to pay $11,100 in restitution.

Oversight of Grants for Emergency Preparedness and Response and for Infectious Diseases. Effective protection against public health threats requires a well-coordinated public health infrastructure that can rapidly respond to emergencies at home and internationally. In dealing with infectious diseases such as Zika and Ebola, proper grant mechanisms need to be in place to foster effective response coordination with domestic and international partners. Once policies are in place, awarding agencies must also ensure that funds are effectively awarded and managed. OIG found that the Centers for Disease Control and Prevention (CDC) did not always adequately document its funding decisions to award $1.9 billion in President's Emergency Plan for AIDS Relief funds over a 5-year project period. OIG also found that CDC may have considered applications that it should not have or treated applicants inconsistently. HHS must also ensure that grant programs allow appropriate funding flexibility to best address response needs. For example, five States received almost $475 million in Social Services Block Grant (SSBG) funding to help cover social service and reconstruction expenses resulting directly from Superstorm Sandy. Although Sandy SSBG funds assisted States' recovery by supporting reconstruction and social service activities, ACF's guidance limited the effectiveness of State planning and use of the funds.

Progress in Addressing the Challenge

HHS has worked to strengthen its grants program integrity efforts. New grant regulations were codified at 45 CFR part 75, implementing Office of Management and Budget's Uniform Guidance requirements. Pursuant to those rules, the Assistant Secretary for Financial Resources (ASFR) is implementing a single audit resolution tracking system—scheduled for completion by September 30, 2017. These rules are intended to ensure that all grant closeout activities are completed within 270 days. *(For more information on the DATA Act, see TMC #4.)* Further, ASFR issued the Grants Policy Administration Manual in December 2015, which compiles all internal grants policies in a single location.

HHS has made efforts to assess grant program performance and improve grant oversight along with identifying and reporting potential fraud, waste, and abuse in its programs. For example, the Indian

Health Service partnered with OIG to provide training for employees of HHS and tribal facilities on identifying and reporting potential fraud, waste, and abuse. HHS has increased its use of suspension and debarment authorities, resulting in an increase from 32 debarments and 7 suspensions in FY 2014 to 26 debarments, 28 proposed debarments, and 37 suspensions in FY 2015—thus preventing prohibited businesses and individuals from receiving Federal funding. HHS is actively training awarding agencies on the suspension and debarment process. In addition, HHS has partnered with OIG in presenting suspension and debarment training.

What Needs To Be Done

HHS needs to take more aggressive action to identify poorly performing grantees and those at risk of misspending Federal dollars and either provide increased technical assistance and monitoring or prevent them from continuing to receive grant funds. Sustained focus and information sharing is needed to monitor and address vulnerabilities, and HHS must diligently continue efforts to ensure that recipients use funds consistent with legal requirements and Departmental policies and procedures.

As HHS moves forward to implement requirements related to the new grant regulations at 45 CFR part 75 and the DATA Act, it must ensure that the HHS awarding agencies have processes and appropriate internal controls in place to effectively award, monitor, and report on grants management activities. These include the development of:

- a framework to evaluate risks posed by grant applicants that is then included in funding opportunity announcements;
- a process to correlate grantee financial data to performance accomplishments to demonstrate effective practices and improve program outcomes; and
- a system to standardize grant data elements and publicly report financial spending data for grant awards.

In addition, HHS will need to successfully implement a system to track, monitor, and resolve single audit findings to effectively carry out new management responsibilities under 45 CFR part 75.

HHS should continue to provide training on identifying and pursuing misconduct in grants. Grant officers should more actively coordinate with and refer potential fraud to OIG for investigation. HHS should continue to pursue other avenues of training beyond the classroom setting, such as webinars or podcasts, to reach a broader range of HHS staff that are located domestically and internationally. HHS also needs to continue to refine its suspension and debarment procedures by streamlining the referral and decision process, to continue providing training and decrease the processing time of referrals. Moreover, HHS needs to implement a program to actively pursue fraud under the Program Fraud Civil Remedies Act.

Key OIG Resources

- OIG Report, “HHS Oversight of Grantees Could Be Improved Through Better Information Sharing,” September 2015. (https://oig.hhs.gov/oei/reports/oei-07-12-00110.asp)
- OIG Report, “Puerto Rico Improperly Claimed Some Child Care and Development Targeted Funds,” January 2016. (https://oig.hhs.gov/oas/reports/region2/21202016.asp)
- OIG Report, “More Effort is Needed to Protect the Integrity of the Child Care and Development Fund Block Grant Program,” July 2016. (https://oig.hhs.gov/oei/reports/oei-03-16-00150.asp)

- OIG Report, "CDC Did Not Award President's Emergency Plan for AIDS Relief Funds for 2013 in Compliance with Applicable HHS Policies," May 2016. (https://oig.hhs.gov/oas/reports/region4/41404021.pdf)
- OIG Report, "Link2Health Solutions, Inc., Budgeted Costs That Were Not Appropriate and Claimed Some Unallowable Hurricane Sandy Disaster Relief Act Funds," March 2016. (https://oig.hhs.gov/oas/reports/region2/21402013.asp)

Top Management Challenge #6: Curbing the Abuse and Misuse of Controlled and Non-controlled Drugs in Medicare Part D and Medicaid

Why This Is a Challenge

The Centers for Medicare & Medicaid Services (CMS) oversees prescription drug coverage for 41 million Medicare Part D and more than 72 million Medicaid beneficiaries.[40] Part D is the fastest growing component of the Medicare program. Since its inception in 2006, Part D spending has more than doubled to $137 billion in 2015. Medicaid expenditures for prescription drugs are also increasing, influenced by Medicaid expansion and increasing expenditures for expensive specialty drugs. In FY 2014, Medicaid spent approximately $22 billion, 5 percent of total Medicaid spending, on prescription drugs. HHS's oversight of its prescription drug programs faces numerous challenges, affecting beneficiary and community safety and the integrity of the benefit itself.

Key Components of the Challenge

- Questionable and inappropriate utilization of prescription drugs
- Abuse and misuse of controlled and noncontrolled substances

Key Components of the Challenge

Oversight. The Part D and Medicaid prescription drug programs are large and complex. In Part D, CMS contracts with plan sponsors, which are responsible for paying claims, monitoring billing patterns, and establishing compliance plans, among other things. CMS also contracts with the Medicare Drug Integrity Contractor to detect and prevent fraud, waste, and abuse in Part D. OIG has identified challenges concerning all of the players charged with safeguarding the program. These challenges relate to (1) the need to more effectively collect and analyze program data to proactively identify and resolve program vulnerabilities and prevent fraud, waste, and abuse before it occurs; and (2) the need to more fully implement robust oversight to ensure appropriate payments, prevent fraud, and protect beneficiaries. *(For information on Medicaid's oversight challenges related to other services, see TMC #2.)*

Drug Abuse and Diversion. Pharmaceutical fraud and drug diversion continue to rise. In FY 2015, OIG had 571 investigative cases and pending complaints involving Medicare and Medicaid prescription drug fraud. In FY 2016, the number of investigative cases and pending complaints rose to 692. Medicaid Fraud Control Units also investigate drug diversion, and they reported to OIG that they had 553 open drug diversion cases, 117 related convictions, and $4.3 million in recoveries related to drug diversion in FY 2015.

Abuse and Misuse of Controlled Substances. According to the Centers for Disease Control and Prevention, the use of opiates (drugs commonly used for pain relief) and other controlled substances has reached epidemic proportions, with more than 2 million people abusing or dependent upon prescription opioids. Nearly one in three Part D beneficiaries received commonly-abused opioids in 2015. Part D spending for these drugs reached $4.1 billion in 2015, a 165 percent increase since the program started in 2006. In addition to concerns this trend may raise around questionable and inappropriate utilization, novel abuse methods and refinement techniques present new challenges.

[40] The Medicaid beneficiary total includes full and partial dual eligible recipients as well as the Children's Health Insurance Program (CHIP) recipients. Dual eligible recipients receive prescription drug benefits through Part D plans and may also be reflected in the Medicare total numbers. CHIP recipients receive drug benefits through the individual State programs.

Several HHS operating divisions are responsible for programs related to the safety and efficacy of drugs and drug abuse prevention and treatment. Effectively coordinating all Departmental efforts and prioritizing initiatives are key to combating this complex epidemic. *(For more information on challenges for the Food and Drug Administration (FDA) and Medicaid, see TMCs #10 and #2.)*

Abuse and Misuse of Non-controlled Substances. It is often under-recognized that many non-controlled substances are abused along with opiates to enhance euphoria. These medically-inappropriate dosages and combinations contribute to adverse events, including respiratory depression (hypoventilation) and death. Additionally, Part D spending for compounded drugs (drugs that have been combined, mixed, or altered to create a medication tailored to the needs of an individual patient) increased significantly, particularly for topical medications that have risen by 3,400 percent since 2006. This rapid growth, along with a growing number of fraud cases involving medically-unnecessary compounded drugs, could indicate an emerging fraud trend. *(For more information on ensuring Medicaid quality of care, see TMC #2, and for more information on compounded drugs, see TMC #10.)*

Progress in Addressing the Challenge

Reducing Questionable and Inappropriate Utilization. CMS has taken steps to improve the oversight provided by the key players tasked with safeguarding Part D. For example, CMS updated its audit process to ensure that sponsors' compliance programs addressed all of the required compliance program elements. When implemented successfully, a compliance plan that includes a comprehensive fraud, waste, and abuse program helps plan sponsors protect the integrity of Medicare funds and may also improve the operating efficiency and effectiveness of plan sponsors. CMS is also taking steps to prevent pharmacy billing fraud and overutilization of prescription drugs. Specifically, CMS has implemented a system to reject payments for Part D prescriptions written by providers who have been excluded from Federal health care programs.

In April 2015, CMS launched Predictive Learning Analytics Tracking Outcome (PLATO), a web-based tool to allow CMS, law enforcement, and plan sponsors to share information and coordinate actions against high-risk pharmacies and prescribers.

Addressing the Rising Costs for Prescription Drugs

The effect of high and rising prices for drugs on beneficiary costs and access to medications is a significant challenge facing the Department and the entire health care system. Rising prescription drug prices also have a significant impact on the financial health of Federal and State programs that account for a significant portion of total prescription drug spending. In 2014, Medicaid paid $22 billion for outpatient drugs. In 2014, Medicare Part B and its beneficiaries paid more than $21 billion for prescription drugs, and Medicare Part D paid almost $78 billion. HHS is considering a number of policy options for both Medicare and Medicaid to address the rising cost of prescription drugs. To assist with this challenge, OIG is committed to providing information about the impact of prescription drug prices on Federal programs and enrollees.

Reducing Abuse and Misuse of Controlled Substances. CMS started publicly sharing data to raise community awareness among providers and local public health officials about regional opioid-prescribing habits. In November 2015, CMS released an interactive online mapping tool, which shows geographic comparisons at the State, county, and ZIP code levels of Medicare Part D opioid prescriptions (excluding private and personal information). HHS has also taken actions to restrict the manufacture, possession, or use of

potentially dangerous controlled substances. For example, FDA published abuse deterrent guidelines for manufacturers to make tamper-resistant products. FDA also requires that drug manufacturers develop and implement Risk Evaluation and Mitigation Strategies (REMS) for certain drugs, including many controlled substances. Also, many State Medicaid programs reported savings linked to implementing lock-in programs, which restrict certain beneficiaries to certain pharmacies or prescribers.

CMS supports States' efforts to improve care for individuals with substance use disorders, including individuals with opioid use disorder. Over the past several years, CMS has provided States with information and program support to enhance coverage for behavioral health conditions. For example, CMS has been providing technical support to States regarding improvements to their substance use disorder systems through the Medicaid Innovation Accelerator Program, which seeks to improve health care for Medicaid beneficiaries by supporting States' ongoing payment and delivery system reform efforts.

Reducing Abuse and Misuse of Non-controlled Substances. OIG has performed educational outreach to pharmacists in all 50 States on the dangers of mixing non-controlled medications with opiates as part of the substance abuse spectrum. CMS updated its Drug Diversion Toolkit, which provides education on the diversion of controlled and non-controlled medications.

What Needs To Be Done

To fully protect Part D from fraud, waste, and abuse, CMS should take further action and implement OIG's unimplemented recommendations to improve program oversight. For example, OIG recommended that CMS require plan sponsors to report the number of instances of fraud, waste, and abuse in their Part D plans and the corrective actions they subsequently took. This information will enable CMS to monitor the effectiveness of Part D plans' efforts to protect the program. Prescription Drug Monitoring Programs (PDMP) can help curb excessive and inappropriate prescribing. State continuity on requirements for checking the database, and State access to the data for utilization reviews, would assist in strengthening the program. HHS should support efforts to integrate PDMP data into the broader health care system.

HHS should continue to prioritize efforts to reduce opioid misuse and abuse. In Part D, implementing a lock-in program for certain Medicare beneficiaries, the authority for which was recently granted by Congress, would help the program more effectively protect beneficiaries from the harm of inappropriate utilization and also protect the program from drug diversion. With respect to the misuse and abuse of non-controlled substances, CMS and plan sponsors should monitor beneficiary use of a wider range of drugs that are frequently abused. In particular, CMS should expand drug utilization review programs to include additional drugs susceptible to fraud, waste, and abuse, focusing particularly on non-controlled drugs that are abused in conjunction with opioids. Additionally, FDA should continue to assess how best to use the REMS program and other strategies to improve medication safety.

Key OIG Resources

- OIG Portfolio, "Ensuring the Integrity of Medicare Part D," June 2015. (https://oig.hhs.gov/oei/reports/oei-03-15-00180.asp)
- OIG Data Brief, "High Part D Spending on Opioids and Substantial Growth in Compounded Drugs Raise Concerns," June 2016. (https://oig.hhs.gov/oei/reports/oei-02-16-00290.pdf)
- OIG Report, "Medicaid Fraud Control Units Fiscal Year 2014 Annual Report," April 2015. (https://oig.hhs.gov/oei/reports/oei-06-15-00010.pdf)

Top Management Challenge #7: Ensuring Quality of Care and Safety for Vulnerable Populations

Why This Is a Challenge

Programs operated and administered by HHS touch the lives of nearly all Americans. HHS faces special challenges in serving particularly vulnerable populations, including recipients of nursing home care, hospice care, and home- and community-based services (HCBS); Indian Health Service (IHS) beneficiaries; and children. People may also be especially vulnerable based on the type of conditions they have, such as mental health or substance abuse issues or multiple chronic conditions.

Key Components of the Challenge

- Nursing home and hospice care
- Home- and community-based services
- Indian Health Services
- Programs serving children

Key Components of the Challenge

Nursing Home Care. Problems continue with the quality of care and safety of people in nursing facilities, as well as concerns related to preventing abuse of nursing facility residents. For example, in a review of a nursing home's residents who were hospitalized with urinary tract infections, we found that providers did not always render services to residents in accordance with their care plans before the residents were hospitalized with urinary tract infections. Other problems OIG has identified include substandard care causing preventable adverse events, limited compliance with Federal regulations for reporting abuse and neglect, lack of monitoring of hospitalization rates, failure to correct deficiencies identified during the survey process, and employment of caregivers who do not meet relevant licensure requirements.

Hospice Care. Hospice care provides comfort for terminally ill beneficiaries and supports family and other caregivers. Problems include inadequate oversight of certification surveys and staff licensure requirements, care planning failures, inadequate medical and nursing care, fraudulent enrollments undertaken without beneficiary consent, and enrollment of beneficiaries who are not terminally ill.

Home- and Community-Based Services (HCBS). HCBS, including personal care services (PCS), help beneficiaries continue to live in their homes and avoid costly and disruptive facility-based care. PCS, a critical component of HCBS, serve several targeted populations, including people with mental illness or physical, cognitive, or developmental disabilities. PCS help promote beneficiary choice and preferences, but payment, compliance, and quality vulnerabilities persist and may serve to undermine HCBS goals of offering beneficiaries safe and high quality care outside of an institutional setting. *(For more information on vulnerabilities related to Medicaid PCS, see TMC #2.)* OIG and State Medicaid Fraud Control Units cite high amounts of PCS fraud, some of which involve the abuse or neglect of beneficiaries by PCS attendants that have resulted in deaths, hospitalizations, and less severe degrees of patient harm. Vulnerable beneficiaries may be unable to report the abuse and neglect because of limited communications skills or may be reluctant to report on PCS attendants whom they feel dependent.

Indian Health Service. IHS is the principal Federal health care provider for American Indians and Alaska Natives. HHS must ensure adequate access to care and quality of care for IHS beneficiaries. Recruiting and retaining competent clinical staff, aging facilities, hospitals unable to render competent emergency

or high-level care, and limited resources for referred care remain pressing challenges. *(HHS's challenge in combating diversion of opioids and other controlled substances as well as abuse and misuse of prescription drugs is addressed in TMC #6. HHS's challenge in ensuring appropriate use of grant funds is addressed in TMC #5.)*

Children. In partnership with the States, HHS operates Medicaid and the Children's Health Insurance Program to provide medical care for over 36 million children, including children from financially needy families, children in foster care, and children with disabilities. The Child Care and Development Fund (CCDF) supports childcare for about 1.4 million children from low-income families while their guardians work or attend school. Ensuring that these intended beneficiaries enjoy access to safely-delivered, high-quality services remains a longstanding challenge for HHS. OIG reviews revealed that many children covered by Medicaid do not receive required dental services, and many children in foster care do not receive required medical services. HHS also operates several programs that provide care for children arriving in the United States without legal status and who are unaccompanied by parents or guardians. (*HHS's challenge in adequately overseeing these programs is addressed in TMC #5.)*

Progress in Addressing the Challenge

Strengthening Processes to Promote Quality Improvement. HHS continues its efforts to improve the quality of nursing home, hospice, and HCBS programs; care for IHS beneficiaries; and services for especially vulnerable children. In July 2016, the Centers for Medicare & Medicaid Services (CMS) updated a booklet entitled "Preventing Medicaid Improper Payments for Personal Care Services." This guidance addresses problem areas identified by OIG and advises PCS agencies and attendants how to avoid improper payments in the following areas: (1) inadequate documentation for claims; (2) claims for ineligible services; (3) services without adequate supervision; (4) services rendered by unqualified providers or without adequate verification and documentation of qualifications; and (5) claims for home care services supposedly rendered to beneficiaries while the beneficiary was away from home and receiving institutional care.

In August 2016, CMS also issued an Informational Bulletin entitled "Suggested Approaches for Strengthening and Stabilizing the Medicaid Home Care Workforce" that discussed States' ability to implement basic training for home care workers in topics such as first aid and CPR certification.

HHS continues its efforts to incentivize improved quality of care by linking payment to value and promoting transparency. *(For more information on delivery system reform, see TMC #9.)* In September 2016, CMS published a final rule to improve the quality of nursing home care. The rule updates the requirements for long-term-care facilities that participate in Medicare and implements provisions of the Patient Protection and Affordable Care Act, including requirements for facilities to implement a quality assurance and performance improvement program to ensure that facilities continuously identify and correct quality deficiencies and promote and sustain performance improvement. CMS has also worked to improve the "Five Star Quality Rating System" to better inform beneficiaries and their families about nursing home options. In July 2016, CMS published a final rule on the Skilled Nursing Facility (SNF) Quality Reporting and Value Based Purchasing Programs. CMS continues to develop the SNF Quality Reporting Program (QRP) measures mandated by the Improving Medicare Post-Acute Care Transformation Act of 2014, including reviewing prescribed medication regimens and accounting for potentially preventable hospital readmissions. The rule also establishes penalties for SNFs that fail to submit required quality data to CMS.

HHS is also developing policies and procedures for public reporting of quality data. In July 2016, HHS updated the hospice Quality Reporting Program to include new quality measures and announced a plan to begin publicly reporting hospice quality measures via a Compare site in calendar year 2017. In August 2016, CMS directed State Survey Agency Directors to ensure that nursing homes do not misuse photography or recordings to compromise residents' right to privacy, confidentiality, and dignity. HHS continues to work closely with law enforcement partners at the Department of Justice and through the Federal Elder Justice Interagency Working Group to promote better care for elderly persons and to prosecute providers who subject them to abuse or neglect.

CMS has also been working to develop a new tool to improve person-centeredness of home- and community-based services. The Consumer Assessment of Healthcare Providers and Systems® HCBS Survey helps HCBS programs assess the experiences of beneficiaries. The Survey facilitates comparisons across the hundreds of State Medicaid HCBS programs throughout the country that target different adults with disabilities; including frail elderly, individuals with physical disabilities, people with developmental or intellectual disabilities, those with acquired brain injury, and persons with severe mental illness. The new tool is available for voluntary use in HCBS programs, including both fee-for-service programs as well as managed long-term services and support (LTSS) programs, as part of quality assurance and improvement activities. Aspects of LTSS covered by the survey are staff reliability, communication with staff, getting help from case managers, choice of services, personal safety, adequacy of medical transportation, and community inclusion and empowerment.

HHS has expressed its commitment to improving quality of care in IHS, especially in the Great Plains where recent reports of quality failures have been most pronounced. Recently, HHS created the Executive Council on Quality Care to improve patient safety at IHS hospitals and clinics. IHS' own quality improvement plans include development of a new Quality Framework and establishment of an Office of Quality in IHS Headquarters. IHS has also undertaken a survey initiative to assess IHS hospitals' compliance with conditions of participation and will track resulting performance data. IHS is also undertaking training initiatives for Area Office staff, service unit leaders, and hospitals, the latter with assistance from the Joint Commission. Additionally, IHS and CMS have committed to continue supporting IHS hospital improvement through the Quality Improvement Network – Quality Improvement Organization and Hospital Engagement Network programs.

In 2014, Congress reauthorized the Child Care and Development Block Grant Act. The Act sets basic health and safety standards for CCDF-funded childcare, requires staff background checks, and requires States to monitor childcare programs serving CCDF-funded children annually. HHS continues efforts to ensure that children enrolled in Medicaid can access Medicaid-covered services, including dental care. These efforts include assistance for States and requirements for States to establish access monitoring review plans.

Protecting Beneficiaries from Dishonest and Potentially Dangerous Providers. Successful enforcement activities continue to identify providers and grantees who violate program rules and prevent them from misappropriating additional funds or harming program beneficiaries. In June 2016, a national health care fraud takedown resulted in civil and criminal charges against 301 individuals, including numerous Medicaid HCBS providers. In July 2016, a national operation to combat CCDF fraud generated 18 prosecutions.

Sometimes, OIG determines that providers have rendered such inferior care that protecting the programs and beneficiaries going forward necessitates excluding those providers from serving program

beneficiaries. In other situations, OIG determines that the programs and beneficiaries are better served by allowing the offending provider to continue serving beneficiaries but under close supervision to ensure that future care meets safety and quality standards. To achieve this goal, OIG invests substantial efforts in helping providers improve. OIG has developed an innovative quality-oriented corporate integrity agreement (CIA) process to work with providers so they may better serve beneficiaries. OIG has placed nearly 40 nursing home companies (covering more than 900 facilities) under CIAs that include quality-monitoring provisions designed to ensure that beneficiaries receive the care they deserve. For example, one dental chain that targeted children enrolled in Medicaid was initially placed under a CIA to address substandard care. However, when the provider failed to meet the terms of the CIA and quality-of-care problems persisted, the CIA was terminated and the provider was excluded from further participation in the Federal health care programs.

What Needs To Be Done

HHS must strengthen procedures to ensure that providers and grant recipients comply with all relevant program rules and deliver safe and high-quality services to the programs' intended beneficiaries. Specifically, HHS should continue to prioritize quality of care in nursing homes and hospices as well as the care rendered as HCBS, with particular focus on PCS. HHS should monitor how often nursing home residents are hospitalized and develop additional resources to help providers avoid adverse events. In addition, HHS should improve internal controls and offer better guidance and training for surveyors to ensure that nursing homes with recorded quality and safety issues correct their deficiencies. CMS should improve coordination with State agencies to ensure that care providers meet relevant licensure requirements. HHS should also improve hospice oversight by (1) increasing physician involvement in decisions regarding general inpatient care, (2) establishing additional remedies for poor-performing hospices, (3) educating providers and beneficiaries about hospice enrollment requirements, and (4) developing and disseminating model text for hospice election statements. HHS should also continue developing policies that effectively link payment to quality.

Ensuring high-quality HCBS and enabling beneficiaries to avoid institutionalization relies heavily on appropriate PCS. CMS must do much more to address vulnerabilities in HCBS, such as PCS. As Medicaid expands, so too will beneficiaries' reliance on HCBS as they seek to avoid institutional care settings. As CMS continues its work to expand access to HCBS, it should also focus on strategies to prevent fraud, waste, and abuse and safeguard beneficiaries' safety. CMS should follow through on commitments to improve PCS program integrity by promulgating regulations and issuing clarifying guidance to States on the range of vulnerabilities that expose beneficiaries to risk of unsafe or suboptimal care.

HHS should ensure the integrity of Medicaid-funded PCS by establishing minimum Federal qualification standards for providers that are based on the needs of the individual being served; improving CMS's and States' ability to monitor billing and quality of care; and issuing operational guidance for claims documentation, beneficiary assessments, person-centered plans of care, and supervision of personal care attendants when hired by an agency. For self-directed programs in which a beneficiary directs his or her own PCS, CMS and the States should improve oversight of controls to ensure individual health and welfare and financial integrity. HHS should also issue guidance to States regarding adequate prepayment controls and help States access data necessary to identify overpayments.

HHS must better oversee IHS hospitals to identify and rectify quality issues and help hospitals implement data-driven quality improvement methods. Specifically, IHS should (1) implement a quality-focused compliance program, (2) establish standards for Area Office/Governing Board oversight activities, (3) set

hospital performance metrics, and (4) better train hospital administrators and staff. In addition, CMS should conduct more frequent surveys of non-accredited hospitals.

The Administration for Children and Families must fully implement its new authorities to ensure safer CCDF-funded childcare. HHS should develop a comprehensive plan to ensure children's access to Medicaid-covered dental services, such as by working with States to (1) develop and achieve service benchmarks, (2) identify areas of provider shortages and address barriers to Medicaid participation, and (3) analyze payment policies.

Key OIG Resources

- OIG Report, "Personal Care Services: Trends, Vulnerabilities and Recommendations for Improvement – A Portfolio," November 2012. (http://oig.hhs.gov/reports-and-publications/portfolio/portfolio-12-12-01.pdf).
- OIG Report, "Indian Health Service Hospitals: Longstanding Challenges Warrant Focused Attention to Support Quality Care," October 2016. (https://oig.hhs.gov/oei/reports/oei-06-14-00011.asp)
- OIG Report, "West Carrol Care Center Did Not Always Follow Care Plans for Residents Who Were Later Hospitalized with Potentially Avoidable Urinary Tract Infections," June 2016. (https://oig.hhs.gov/oas/reports/region6/61400073.asp)
- OIG Report, "Adverse Events in Skilled Nursing Facilities: National Incidence Among Medicare Beneficiaries," February 2014. (http://oig.hhs.gov/oei/reports/oei-06-11-00370.asp)
- OIG Report, "Puerto Rico Child Day Care Centers Did Not Always Comply With Commonwealth Health and Safety Requirements," September 2015. (https://oig.hhs.gov/oas/reports/region2/21402001.asp)

Top Management Challenge #8: Operating and Overseeing the Health Insurance Marketplaces

Why This Is a Challenge

The Health Insurance Marketplaces (Marketplaces), also known as health insurance Exchanges, are critical components of the health care reforms enacted through the Patient Protection and Affordable Care Act. Implementation, operation, and oversight of the Marketplaces were among the most significant challenges for HHS in previous years and continue to present a top management and performance challenge.

Key Components of the Challenge

- Payment accuracy
- Eligibility determinations
- Management and administration
- Security and privacy of information systems

The Marketplaces involve complex regulatory, operational, and technological challenges. Among these are effective communication and coordination between and among all internal and external parties with Marketplace responsibilities, including within HHS and with contractors, issuers, and partners in State and Federal Government. Effective coordination with the Internal Revenue Service (IRS) is particularly important for sound administration of the premium tax credit program—a refundable tax credit that helps eligible individuals and families with low or moderate income afford health insurance purchased through a Marketplace. In addition, the Centers for Medicare & Medicaid Services (CMS) is responsible for ensuring that State Marketplaces comply with Federal requirements and provide complete, accurate, and timely data used for Federal payments. Further, CMS must take appropriate steps to promote compliance by Qualified Health Plans (QHP) with Federal requirements, including network adequacy and non-discrimination requirements. CMS must also take appropriate steps to ensure that individuals are enrolled in the correct insurance program (e.g., Medicare, Medicaid, or private insurance) and to prevent the improper influence of individuals when choosing insurance.

Key Components of the Challenge

Payments. Ensuring sound expenditure of taxpayer funds for insurance affordability and other Marketplace purposes poses a substantial management challenge, and OIG found evidence of early deficiencies. For example, CMS's internal controls did not effectively ensure that payments for the advance premium tax credit program were made only for enrollees who paid their monthly premiums. Continued attention is warranted, especially given the introduction of an automated policy-based payment system at the Federal Marketplace and the continued use of interim solutions and manual systems at the State Marketplaces. Effective management of the premium stabilization programs is important because of these programs' impact on the private health insurance market. Attention also must be paid to expenditures of HHS funds used by State Marketplaces for grants and contracts.

Eligibility. Accurate eligibility determinations ensure that only eligible consumers are able to enroll in health plans and receive insurance affordability benefits during open and special enrollment periods. To appropriately determine eligibility, CMS must have effective internal controls and accurately and quickly resolve inconsistencies between applicant-reported information and Government databases. OIG and the Government Accountability Office have found vulnerabilities in CMS's eligibility verification and enrollment processes and resolution of inconsistencies.

Management and Administration. Management and administration of the Federal and State Marketplaces require, among other things, clear leadership, disciplined operations, and effective strategies and communication. An OIG review of the implementation of Healthcare.gov (the website consumers use to apply for insurance through the Federal Marketplace) identified management deficiencies that contributed to the initial breakdown of the website, as well as improved management afterwards. OIG identified lessons learned from this experience that HHS should continue to apply to the operation of the Federal Marketplace, including the automated policy-based payment system and other large-scale projects. OIG has also made recommendations to CMS to improve its acquisition planning and procurement, contract monitoring, and administration of payments for Marketplace contracts. *(For further information on contract administration, see TMC #4.)* In addition, some Consumer Oriented and Operated Plans (CO-OPs) have ceased operation, posing an additional challenge for HHS.

Security. Protecting the confidentiality and ensuring the integrity of consumers' personal information and Marketplace information systems is paramount. Effective operation of the Marketplaces requires rapid, accurate, and secure integration of data from numerous Federal and State sources, issuers, and consumers. HHS must vigilantly guard against intrusions and continuously assess and improve the security of Marketplace-related systems, including, among others, the Data Services Hub, a conduit through which a Marketplace sends and receives electronic data from multiple Federal agencies, and the Multidimensional Insurance Data Analytics System, a data warehouse and repository. *(For more discussion of information privacy and security, see TMC #3.)*

Progress in Addressing the Challenge

CMS implemented several core management principles identified in OIG's review that enabled the organization to improve the HealthCare.gov website as well as agency management and culture. In addition, CMS has reported progress in Marketplace operations, including implementing automated policy-based payments for the Federal Marketplace in May 2016; implementing parallel processing and multiple levels of review of financial assistance payments information; working to develop a strategic and unified view of Marketplace procurement and costs; and developing a strategy to improve Marketplace program integrity. As part of its strategy to improve program integrity, CMS has established standards for terminating or suspending agreements between agents and brokers and the Federal Marketplace in cases of fraud or conduct that may cause consumer harm. CMS is also developing outreach and education campaigns designed to inform consumers, agents, and brokers about the dangers of identity theft. CMS reports that it has taken steps to tighten eligibility standards and processes for special enrollment periods.

Additionally, CMS has coordinated with entities across and beyond HHS to improve the accuracy of eligibility and payment data. CMS reported that it updated its Standard Operating Procedures with additional directives to ensure that its Federal Marketplace eligibility support workers can resolve applicant inconsistencies of all types. Further, CMS has developed additional tools to help States report on their eligibility and enrollment processes and to oversee States' plans for addressing unresolved applicant inconsistencies. CMS also reported having regular communications with the IRS and the Department of the Treasury to validate payment information, conduct improper payment risk assessments to determine areas that might affect the accuracy of financial assistance payments, and provide technical and other support to the State Marketplaces. CMS also issued a request for information seeking public comment on concerns that some providers and organizations may be steering people eligible for Medicare and/or Medicaid into QHPs to obtain higher reimbursement rates.

What Needs To Be Done

HHS should continue to apply core management principles—including designating clear leadership, integrating policy and technology work, and continuously learning—to improve its operations and oversight of the Federal Marketplace, particularly the eligibility, administrative, and financial management functions. CMS should also address OIG recommendations to improve internal controls. Vulnerabilities in CMS's business processes must be addressed to ensure accurate and timely initial payments and reconciliations of payments. Additionally, CMS must focus on effective management and integrity of the premium stabilization programs. This includes validating information received from issuers to ensure that it is complete, accurate, and timely for payment purposes.

CMS must ensure that all pathways for enrollment operate with integrity, consumers are not improperly influenced in their selection of insurance, and consumers' personal information is secure. Vigilant monitoring and testing of systems and rapid mitigation of identified vulnerabilities are essential. CMS must also focus attention on the sound operation of financial assistance programs for beneficiaries. Consumers and issuers must receive accurate Marketplace information, including information relevant for tax purposes, such as Form 1095A tax forms. Furthermore, Marketplaces must continue to protect personally identifiable information and strengthen security controls.

CMS must also continue to work with States to improve State Marketplace operations, including payment systems, and to ensure compliance with Federal requirements for Marketplaces and health plans. HHS must continue to pay attention to the financial and operational challenges faced by CO-OPs. CMS must monitor for and address fraud, waste, and abuse risks in Marketplace programs. CMS must respond quickly and effectively to credible allegations of fraud, working with QHPs and with partners at the Federal and State level to hold those involved accountable.

Key OIG Resources

- For links to OIG's portfolio of reports on the Federal and State Marketplaces, as well as OIG's Health Reform Oversight Plan, please see the Patient Protection and Affordable Care Act Reviews section on OIG's website: https://oig.hhs.gov/reports-and-publications/aca/.

Top Management Challenge #9: Managing Delivery System Reform and Strengthening Medicare Advantage

Why This Is a Challenge

A paradigm shift is underway in the Nation's health care system—both public and private—to improve patient care and reduce wasteful spending through heightened focus on quality of care rather than quantity of care. The pace of change is rapid and the magnitude substantial. New models are being introduced that focus on rewarding the delivery of high-value health care and promoting innovative care redesigns that provide patients with better coordinated care. These models are intended to incorporate new understandings of medicine, social science, population health, technology, data analysis, and behavioral incentives. Medical, mental health, and social services are being integrated in new ways.

Key Components of the Challenge

- Implementing Medicare's Quality Payment Program
- Managing the CMS Innovation Portfolio
- Strengthening Medicare Advantage

For HHS, this shift—propelled by reforms under the Patient Protection and Affordable Care Act, Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), and other statutes—affects all parts of Medicare, as well as Medicaid and public health programs. Stakeholders include patients, providers, vendors, managed care organizations, private payers, administrative contractors, State agencies, and taxpayers. HHS is investing significant resources in developing evidence-based tools, realigning provider and beneficiary incentives, testing new coordinated and integrated care designs, promoting meaningful use of electronic health records (EHRs) and other technologies, and enhancing patient engagement and access to health information.

Delivery system reform in a highly complex environment requires concurrent, sustained, and multifaceted planning, execution, and oversight. To participate successfully in new models, providers and others must commit resources and reshape the delivery of care. Models often involve new types of caregivers as well as individuals and entities undertaking new roles and responsibilities in Federal health care programs. HHS must effectively educate and oversee both experienced participants and new entrants into these programs.

Key Components of the Challenge

Implementing Medicare's Quality Payment Program. MACRA revamped Medicare's physician reimbursement system, affecting physicians and other clinicians reimbursed under the Medicare Physician Fee Schedule. The new Quality Payment Program (QPP) introduces into physician reimbursement two new mechanisms linked to quality and efficiency: (1) a Merit-Based Incentive Payment System (MIPS) and (2) alternative payment models (APMs). To meet statutory deadlines, much must be accomplished quickly. This novel and complex program presents substantial policy, administrative, operational, logistical, and technological challenges. The Centers for Medicare & Medicaid Services (CMS) must consolidate three existing incentive programs into MIPS and craft advanced APMs suitable for physicians with various practice characteristics and levels of operational readiness. In so doing, CMS must be mindful of administrative burden. Notably, there is concern that small and rural providers may need assistance navigating the transition. Physicians must prepare for significant changes in reimbursement methodology, reporting, and, depending on circumstances, delivery of care and workflow. Quality measurement is a key component of the QPP. Challenges

highlighted in HHS's recent Quality Measure Development Plan[41] for the QPP include closing known measurement and performance gaps; harmonizing and aligning measures across programs, settings, and payers; and refining measure development. CMS has signaled plans to finalize measure sets in annual rulemaking.

Managing the CMS Innovation Portfolio. The diverse CMS innovation portfolio poses a significant management challenge for HHS. Comprising dozens of new models in various stages of development and implementation, the portfolio touches on virtually every aspect of health care delivery and experiments with a variety of payment structures, including shared savings, episode-based payments, population-based payments, capitation, and value-based purchasing. Many new payment structures are hybrids involving both traditional and new types of payments, giving rise to additional challenges in managing risk. Many models involve novel business arrangements among providers and new incentives to promote patient engagement in their own care. These arrangements and incentives also give rise to challenges for risk management. CMS operates both voluntary models and models that are mandatory in designated geographic areas; mandatory models pose unique challenges in ensuring provider readiness.

HHS must ensure that Medicare realizes benefit from the Government's substantial investment in designing, testing, and implementing new models, including the Center for Medicare & Medicaid Innovation's (CMMI) 10-year, $10 billion budget. Perhaps equally challenging is ensuring that models are viable in light of providers' substantial investments in infrastructure and care redesign. Responsibility for administering and overseeing new models is shared across several CMS components, including CMMI and the Center for Program Integrity. CMS leverages expertise across HHS through partnerships with other HHS operating divisions. These collaborations within and outside CMS require shared vision, clear communications, and continuous coordination.

Strengthening Medicare Advantage. Approximately 30 percent of Medicare beneficiaries are enrolled in Medicare Advantage (MA), a three-fold increase since 2004. Ensuring a sound MA program is essential to meeting intended coverage, access, quality, and cost goals. OIG work has identified challenges in the MA program with respect to the precision and use of data, payment accuracy, and program integrity, including vulnerabilities at both the plan and provider levels. CMS estimated for FY 2015 that 9.5 percent of payments to MA organizations were improper, mainly due to insufficient documentation to support diagnoses submitted by MA organizations.[42] Notwithstanding these vulnerabilities, MA organizations have the potential to increase efficiency and quality through better coordinated care, aligned incentives, and performance measurement. HHS is developing new models for MA, including a Value-Based Insurance Design model. *(For more information on improving the effectiveness of Medicaid managed care, see TMC #2.)*

Progress in Addressing the Challenge

Implementing the QPP. CMS is making steady early progress in implementing the QPP, including recently issued final program regulations. HHS has begun issuing other program policies and guidance, including the Office of the National Coordinator for Health Information Technology's guidance for measuring interoperability and heath information exchange. CMS is deploying an integrated policy and

[41] https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/Final-MDP.pdf

[42] GAO Report: http://www.gao.gov/assets/680/676441.pdf; Annual Financial Statement Audit http://www.hhs.gov/sites/default/files/afr/fy-2015-hhs-agency-financial-report.pdf

technology team to plan and execute the QPP. CMS is testing user-centered IT designs and planning education and technical assistance initiatives to promote clinician acceptance of, and readiness for, the QPP. In April 2016, CMS released a solicitation for direct technical assistance to support implementation of the QPP. CMS more recently announced a new, long-term initiative to increase clinician engagement, including an 18-month pilot program to reduce medical review for certain physicians practicing within specified alternate payment models with two-sided risk.

***Designing and Assessing Models*.** CMS is compiling a growing roster on its website of early results from, and evaluations of, new programs and models. For example, CMS reported that Medicare accountable care organization (ACO) programs, comprising over 400 ACOs, generated total gross program savings of more than $466 million for Medicare in 2015; CMS also reported improvements in quality performance.[43] Further, CMS reported second-year results for the Independence at Home (medical home) Demonstration of an average savings of $1,010 per beneficiary, with all participating practices improving quality from the first performance year in at least two of the six quality measures. Results vary across models, with some more promising than others.

CMS continues to test initiatives to speed adoption of best practices, accelerate development of new models, and reform Medicaid and the Children's Health Insurance Program, among others. Models include multiple types of ACOs, primary care medical homes, and bundled payment initiatives. More recently, CMS has been developing and refining models that will qualify as advanced APMs under the QPP. HHS is supporting the Health Care Payment Learning and Action Network to collaborate on aligning reforms across health care sectors. CMS issued regulations for an expanded Medicare Diabetes Prevention Model. CMS continues to provide guidance and education to model participants, as well as to state Medicaid agencies engaged in reforms through CMMI's Medicaid Innovation Accelerator Program, and has taken steps to include in new models program integrity safeguards, including transparency of data and monitoring for indicators of abuse or gaming.

In March 2016, HHS announced that it met, earlier than scheduled, its goal of tying 30 percent of traditional Medicare payments to APMs by the end of 2016. HHS aims to increase this amount to 50 percent by 2018.

Strengthening Medicare Advantage. CMS is using audits to oversee, among other things, MA organizations' implementation of programs to detect, correct, and prevent fraud, waste, and abuse, which are required by their compliance plans. CMS has issued guidance on sharing information between CMS contractors and with other program integrity stakeholders, such as State agencies, to more effectively coordinate efforts to identify and investigate fraud. HHS has stated a goal of having all MA contracts audited annually. CMS has taken steps to incorporate recovery audit contractors into MA, as required by statute.[44] CMS has enhanced the transparency of information about MA plans by publicly reporting on its website additional data, including information about grievances filed with plans and plans' oversight of sales agents and brokers. CMS announced changes to the Star Ratings system, developed through a public process, aimed at better accounting for costs of caring for enrollees. Further, CMS has developed a Network Management Module to help assess network adequacy.

[43] https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-08-25.html

[44] GAO Report: http://www.gao.gov/assets/680/676441.pdf

What Needs To Be Done

Continue Implementing the QPP. Physician payment reform under MACRA will require sustained focus. For a successful transition, CMS must address policy, infrastructure, data systems, oversight, and provider education needs. Physician representatives have identified challenges, including complexity of reporting and measurement, scope and availability of APMs, provider education, daunting timelines, infrastructure investments, new business requirements, and administrative burden. CMS should allocate sufficient resources to ensure issuance of timely and clear program regulations and guidance and to provide meaningful education and technical assistance. In addition to well-functioning, physician-oriented websites, CMS must ensure that it has fully operational back-end payment and data systems for the QPP. CMS must coordinate with the Office of the Assistant Secretary for Planning and Evaluation and the Physician-Focused Payment Model Technical Advisory Committee on the development of APM opportunities submitted by physicians. CMS needs to develop quality measures as outlined in the Quality Measure Development Plan and monitor for any unintended impacts the quality measures have on Medicare beneficiaries. CMS needs to ensure that its medical records review reduction pilot program operates in a manner that protects the Medicare program from fraud and abuse.

Effectively Manage and Oversee New Models. CMS must continue to manage its growing portfolio of complex models and innovations to ensure they achieve their intended quality of care and efficiency outcomes. CMS must issue clear guidance on program requirements; administer (or contract for) financial, beneficiary alignment, and other systems necessary for effective operations; and test, evaluate, and verify model progress and outcomes. Attention should be paid to the policy, evaluative, compliance, and practical day-to-day challenges for CMS and providers of concurrent participation in multiple models. Further, CMS must clearly define actionable and meaningful quality measures and ensure that they, in fact, measure what CMS intends them to measure to achieve desired quality goals. CMS should carefully monitor for successes and benefits that can be scaled and replicated, as well as for potential problems—including inefficiencies and misaligned incentives. As the testing of multiple models matures, CMS will need to effectively manage the transition from testing a model to its expansion, as appropriate.

New models rely significantly on data, EHRs, and technology. CMS must ensure that data collected and provided for new payment models are complete, accurate, timely, and secure and that new technologies, such as telemedicine, achieve their intended results. Data from providers and others must be integrated and shared across models within HHS and with stakeholders, as appropriate. (*For more information on the challenges associated with electronic information and health IT, see TMC #3.)* To the extent that resource, cost, and quality performance are measured on the basis of Medicare Parts A and B claims data, CMS must ensure the soundness and reliability of such data. CMS should adopt sound record retention and documentation practices for all models.

CMS must monitor for program integrity risks in new models, incorporate safeguards tailored to specific risks in particular models, and assess the effectiveness of the safeguards it employs. Detected program integrity problems should be remediated promptly and safeguards strengthened to prevent program and patient abuse or gaming. Sharp attention to program integrity is especially important for models that introduce new payment incentives, which might lead to new fraud schemes, or for which waivers of payment or fraud and abuse laws may have been issued under sections 1899(f) or 1115A of the Social Security Act. As a critical element of program integrity, CMS must maintain accurate historical and real-time information about new models, including, for example, information about providers and beneficiaries. *(For more information on fraud and abuse in Medicare Parts A and B, see TMC #1.)*

Strengthen Medicare Advantage. CMS should continue to focus on ensuring that MA plan enrollees have access to and receive the services to which they are entitled and that those services are of appropriate quality. CMS must strengthen the MA program to ensure that benefits are provided only to eligible beneficiaries. Further, CMS must ensure that data and other information related to payment from providers and plans are available for fraud detection and prevention. CMS must use data effectively to ensure payment accuracy and to review MA organizations' performance. Ensuring the accuracy and integrity of risk-adjustment and other data used to establish payment rates is also critical to protect against gaming or abuse and reducing the payment error rate. HHS should take steps to address the obstacles to accurate risk-adjustment payments and recovery of improper payments recently identified by the Government Accountability Office.[45] Finally, CMS will need to oversee new models within the MA program to ensure that they meet intended quality of care and cost-containment goals.

Key OIG Resources

- OIG Accountable Care Organization Resource Page: (https://oig.hhs.gov/compliance/accountable-care-organizations/index.asp)
- OIG Report, "Observations From our Review of CMS' Administration of the First Performance Year of the Pioneer Accountable Care Organization Payment Model," May 2016. (https://oig.hhs.gov/oas/reports/region1/11300509.pdf)
- OIG Report, "Medicare Improperly Paid Medicare Advantage Organizations Millions of Dollars for Unlawfully Present Beneficiaries for 2010 Through 2012," April 2014. (https://oig.hhs.gov/oas/reports/region7/71301125.pdf)
- OIG Report, "CMS Regularly Reviews Part C Reporting Requirements Data, but Its Followup and Use of the Data are Limited," March 2014. (https://oig.hhs.gov/oei/reports/oei-03-11-00720.pdf)
- OIG Report, "MEDIC Benefit Integrity Activities in Medicare Parts C and D," January 2013. (https://oig.hhs.gov/oei/reports/oei-03-11-00310.pdf)

[45] GAO Report: http://www.gao.gov/assets/680/676441.pdf

Top Management Challenge #10: Ensuring the Safety of Food, Drugs, and Medical Devices

Why This Is a Challenge

HHS, through the Food and Drug Administration (FDA), must ensure the safety, efficacy, and security of our Nation's food supply, drugs, biologics, and medical devices. FDA is also responsible for regulating tobacco products. Areas of particularly high risk include food safety, drug compounding, a complex drug supply chain, and improper marketing activities.

Key Components of the Challenge

- Food safety
- Drug compounding
- Complex drug supply chain
- Improper marketing

Key Components of the Challenge

Food Safety. Foodborne illnesses, such as those caused by *Salmonella*, *Listeria monocytogenes*, and *E. coli*, pose a continuing public health threat. Oversight is complicated by the immense diversity of the global food supply: 20 percent of our vegetables come from abroad, as does 50 percent of our fresh fruit, and more than 80 percent of our seafood.[46] When a problem with the U.S. food supply is identified, FDA must ensure that the problem is addressed using its various administrative tools and enforcement authorities. After reviewing 30 recalls selected on the basis of their risk factor, OIG recently alerted FDA that consumers remained at risk of illness or death for several weeks after FDA was aware of a potentially hazardous food in the supply chain.

Drug Compounding. The potential danger of improperly compounded drugs drew national attention in 2012 when drug injections meant to be sterile were contaminated during the compounding process and resulted in a deadly fungal meningitis outbreak. Compounded drugs are not subject to FDA's premarket approval process, in which FDA evaluates the safety and efficacy of conventionally-manufactured drugs. FDA continues to identify serious problems at facilities that compound drugs, the vast majority of which do not register with the FDA.[47] (*For information on rising costs and potential fraud involving compounded drugs, see TMC #6.)*

Complex Drug Supply Chain. The drug supply chain is growing increasingly complex, not only domestically but globally. This makes it difficult to track products to their sources in case of a recall and complicates FDA's task of ensuring the integrity of these products. Multiple manufacturers may be involved in the various stages of production. Currently, about 40 percent of prescription drugs sold in the United States and 80 percent of active ingredients used in drugs are made in other countries.[48] Once drugs are produced, multiple parties may distribute or repackage the finished product. Drugs from unapproved sources can also enter the U.S. drug supply chain. Disruptions in the supply chain can lead to problems with patient access to needed prescription drugs.[49]

Improper Marketing Activities. FDA approves the marketing of drugs, biologics, and medical devices for specific uses after determining that the products are safe and effective for those uses. Once approved,

[46] http://www.fda.gov/InternationalPrograms/FDABeyondOurBordersForeignOffices/ (accessed October 26, 2016).

[47] http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339771.htm

[48] http://www.fda.gov/NewsEvents/Testimony/ucm271073.htm

[49] https://aspe.hhs.gov/sites/default/files/pdf/108986/ib.pdf

qualified medical practitioners may prescribe them for any use, including uses not approved by the FDA. However, individuals and manufacturers are prohibited from marketing products for unapproved uses. In general, the Federal health care programs do not cover unapproved products. Improper marketing activities can put patients at risk of receiving inappropriate or harmful care and lead to fraudulent claims for payment from Federal health care programs. *(For more information on drug diversion and utilization of prescription drugs, see TMC #6.)*

Progress in Addressing the Challenge

Food Safety. FDA continues to implement its enhanced food-safety authorities statutorily granted in 2011 by the Food Safety Modernization Act. In 2015 and 2016, the Agency finalized rules on preventative controls for human food, current good manufacturing practices and preventative controls for animal food, produce safety, accredited third-party certification, sanitary transportation of human and animal food, protection against intentional adulteration, and the foreign supplier verification program. FDA's food scientists have also worked to further develop and broaden the use of whole genome sequencing technologies to better differentiate between organisms and strains to identify and prevent foodborne illnesses. FDA continues collaboration with State regulatory and public health partners to establish an integrated national food safety system and has initiated new efforts to incorporate produce safety. Additionally, as part of FDA's effort to leverage the comparable food safety oversight conducted by foreign partners, FDA entered into food safety systems recognition agreements with New Zealand in December 2012 and Canada in May 2016.

Drug Compounding. In 2013, the Compounding Quality Act clarified and amended FDA's authority to oversee compounding, including providing a new pathway for compounders to register with FDA as outsourcing facilities. Outsourcing facilities that compound drugs in accordance with the conditions set forth in the Compounding Quality Act are eligible for exemptions from certain FDA requirements, but are held to manufacturing quality standards similar to those applicable to conventional drug manufacturers. FDA continues to work to fully implement the Compounding Quality Act, and the Agency has issued numerous policy and guidance documents applicable to outsourcing facilities and other compounders. FDA also continues to inspect compounding facilities; oversee recalls of compounded drugs for contamination or lack of sterility assurance; and issue warning letters to compounders that violate the law.

Complex Drug Supply Chain. The Drug Supply Chain Security Act created the basis for building an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States, whether they originate in this country or not. FDA has issued guidance to establish initial standards for the interoperable exchange of product tracing information and also created a publicly available database of authorized wholesale distributors of traceable prescription drugs. OIG is reviewing wholesale distributors' and dispensers' early experiences in exchanging product tracing information.

Improper Marketing Activities. To protect patients and reduce the waste of Federal health care program money, OIG, FDA, and their law enforcement partners have pursued numerous enforcement actions against manufacturers for improperly marketing drugs, biologics, and devices. In addition, FDA has engaged in both outreach and enforcement actions on unapproved drugs and devices, including unapproved products from foreign sources. FDA has also undertaken efforts to warn consumers, medical practitioners, and others about the medical risks associated with importing unapproved drugs. FDA, OIG, and their law enforcement partners continue to investigate and prosecute physicians and

suppliers that distribute unapproved drugs and devices. FDA collaborates with international partners and has introduced improved border screening to enhance oversight of imported products.

What Needs To Be Done

Implementation. FDA must continue taking steps to fully implement its statutory authorities and develop robust policies and procedures to ensure that problems with the Nation's food supply are addressed in a timely manner. OIG has recommended that FDA remedy identified weaknesses in recall procedures and better ensure that recalls are promptly initiated, monitored, and closed out. FDA must continue to implement its new authorities to enhance oversight of drug compounders and better ensure the safety of compounded products, including by inspecting drug compounders and pursuing regulatory action when deficiencies are identified. FDA must also continue to implement its new authorities in tracking drugs through the supply chain.

Oversight. FDA must ensure that drug supply chain partners comply with product tracing requirements. FDA has twice delayed its enforcement of certain product tracing requirements for wholesale distributors and dispensers due to their requests for additional time to implement product tracing requirements. FDA must also continue combating improper marketing practices and importation of unapproved drugs for commercial distribution in the United States. OIG, in cooperation with the Department of Justice and other law enforcement partners, will continue to employ investigative and enforcement authorities to protect Federal health care programs and beneficiaries from these potentially-dangerous products.

OIG will continue monitoring the changing legal landscape, legislative developments, and FDA's oversight of food, drugs (both prescription and over-the-counter), biologics, dietary supplements, medical devices, and tobacco, and adjust priorities as needed.

Key OIG Resources

- OIG Report, "Early Alert: The Food and Drug Administration Does Not Have an Efficient and Effective Food Recall Initiation Process," June 2016. (http://oig.hhs.gov/oas/reports/region1/11501500.asp)
- OIG Report, "High Part D Spending on Opioids and Substantial Growth in Compounded Drugs Raise Concerns," July 2016. (https://oig.hhs.gov/oei/reports/oei-02-16-00290.asp)
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DEPARTMENT'S RESPONSE TO THE OFFICE OF INSPECTOR GENERAL TOP MANAGEMENT AND PERFORMANCE CHALLENGES

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Washington, D.C. 20201

To: Daniel R. Levinson, Inspector General

From: Mary K. Wakefield, Acting Deputy Secretary

Subject: FY 2016 Top Management and Performance Challenges Identified by the Office of Inspector General (OIG)

Thank you for the OIG's work in assessing the major management and performance challenges facing the Department of Health and Human Services (HHS). We appreciate the OIG's dedication to helping us improve operations through its audit and investigative work throughout the year.

HHS faces a number of long-term challenges. The suggestions you offer to address our challenges will help us inform and improve decisions related to budgeting, strategic planning, and other critical mission functions. It is critical we find innovative ways to work leaner. Looking ahead, we are committed to building on our progress. We recognize that there is more to be done that will require our organization's sustained attention, action, and improvement. The Department's Operating Divisions continue to focus on serving all Americans by protecting their health, providing essential human services, and promoting the well-being of individuals, families, and communities. The OIG's work will help us do this in the most effective and efficient way possible.

We look forward to cooperating with you and our stakeholders on the continuous improvement of our activities. We are committed to focusing our resources on the issues related to these challenges as we smoothly transition into a new Presidential administration and continue to execute our strategic plan.

/Mary K. Wakefield/

Mary K. Wakefield
Acting Deputy Secretary
November 14, 2016

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Appendices

A

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- Acronyms
- Connect with HHS

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APPENDIX A: ACRONYMS

A	
AA	Associate of Arts
ACF	Administration for Children and Families
ACO	Accountable Care Organization
ACL	Administration for Community Living
ADA	*Anti-Deficiency Act*
ADR	Additional Documentation Request
AFR	Agency Financial Report
AHRQ	Agency for Healthcare Research and Quality
AICPA	American Institutes of Certified Public Accountants
ALF	Assisted Living Facility
APG	Agency Priority Goal
APM	Alternative Payment Model
APTC	Advance Premium Tax Credit
ASFR	Assistant Secretary for Financial Resources
ASPR	Assistant Secretary for Preparedness and Response
ATM	Accounting Treatment Manual
ATSDR	Agency for Toxic Substances and Disease Registry
B	
BA	Bachelor of Arts
BBA	*Bipartisan Budget Act of 2015*
BHCC	Behavioral Health Coordinating Council
BHP	Basic Health Program
BUP	Buprenorphine
C	
CAH	Critical Access Hospital
CAPs	Corrective Action Plans
CBRs	Comparative Billing Reports
CCDBG	*Child Care and Development Block Grant Act of 2014*
CCDF	Child Care and Development Fund
CCIIO	Center for Consumer Information and Insurance Oversight
CDC	Centers for Disease Control and Prevention
CERT	Comprehensive Error Rate Testing
CFO	Chief Financial Officer
CFO Act	*Chief Financial Officers Act of 1990*
CFR	Code of Federal Regulations
CFRS	Consolidated Financial Reporting System
CHIP	Children's Health Insurance Program
CIA	Corporate Integrity Agreement
CIO	Chief Information Officer
CISO	Chief Information Security Officer
CMA	Computer Matching Agreement
CMMI	Center for Medicare and Medicaid Innovation
CMP	Civil Monetary Penalty
CMS	Centers for Medicare & Medicaid Services
CMS-HCCS	CMS Hierarchical Condition Categories
CO-OP	Consumer Oriented and Operated Plan
COTS	Commercial Off-the-Shelf
CPI	Consumer Price Index
CRC	Commercial Repayment Center
CSR	Cost-sharing Reduction
CSRS	Civil Service Retirement System
CY	Current Year
D	
DAP	DATA Act Program Management Office
DATA Act	*Digital Accountability and Transparency Act of 2014*
DCIA	*Debt Collection Improvement Act of 1996*
DHS	Department of Homeland Security
DME	Durable Medical Equipment
DMEPOS	Durable Medical Equipment, Prosthetics, Orthotics, and Supplies
DNP	Do Not Pay
DOD	Department of Defense
DOI	Department of the Interior
DOL	Department of Labor
DRA	*Deficit Reduction Act of 2005*
E	
EBT	Electronic Benefit Transfer
EHRs	Electronic Health Records
EHS-CCP	Early Head Start-Child Care Partnership
EO	Executive Order
ERM	Enterprise Risk Management
ESRD	End-stage Renal Disease
F	
FACES	Family and Child Experience Survey
FBIP	Financial Business Intelligence Program
FBIS	Financial Business Intelligence System
FBwT	Fund Balance with Treasury
FDA	Food and Drug Administration
FECA	*Federal Employees' Compensation Act*
FedRAMP	Federal Risk and Authorization Management Program

APPENDIX A: ACRONYMS

FERS	Federal Employees Retirement System
FETP	Field Epidemiology Training Programs
FFMIA	*Federal Financial Management Improvement Act of 1996*
FFS	Fee-For-Service
FGB	Financial Management Governance Board
FICA	*Federal Insurance Contributions Act*
FISCAM	Federal Information System Controls Audit Manual
FISMA	*Federal Information Security Management Act*
FITARA	*Federal Information Technology Acquisition Reform Act*
FMFIA	*Federal Managers' Financial Integrity Act of 1982*
FPS	Fraud Prevention System
FSIP	Financial Systems Improvement Program
FY	Fiscal Year
G	
GAAP	Generally Accepted Accounting Principles
GAO	U.S. Government Accountability Office
GDP	Gross Domestic Product
GHP	Group Health Plan
GMRA	*Government Management Reform Act of 1994*
GPRA	*Government Performance and Results Act of 1993*
GSA	General Services Administration
H	
H5N1	Avian Influenza
HCBS	Home and Community-based Services
HCFAC	Health Care Fraud and Abuse Control
HEW	Department of Health, Education, and Welfare
HFPP	Healthcare Fraud Prevention Partnership
HHA	Home Health Agency
HHS	Department of Health and Human Services
HHSAR	HHS Acquisition Regulation
HI	Hospital Insurance
HIGLAS	Healthcare Integrated General Ledger Accounting System
HIPAA	*Health Insurance Portability and Accountability Act of 1996*
HIV	Human Immunodeficiency Virus
HRSA	Health Resources and Services Administration

I	
IBNR	Incurred But Not Reported
IHS	Indian Health Service
IP	Improper Payment
IPERA	*Improper Payments Elimination and Recovery Act of 2010*
IPERIA	*Improper Payments Elimination and Recovery Improvement Act of 2012*
IPIA	*Improper Payments Information Act of 2002*
IPT	Integrated Project Team
IRF	Inpatient Rehabilitation Facility
IRS	Internal Revenue Service
IT	Information Technology
L	
L.m.	Listeria monocytogenes
LTSS	Long Term Services and Support
M	
MA	Medicare Advantage
MAC	Medicare Administrative Contractor
MACRA	*Medicare Access and CHIP Reauthorization Act of 2015*
MARx	Medicare Advantage Prescription Drug
MEDIC	Medicare Drug Integrity Contractor
MICs	Medicaid Integrity Contractors
MIPS	Merit-based Incentive Payment System
MMIS	Medicaid Management Information Systems
MMWR	Morbidity and Mortality Weekly Reports
MR	Medical Review
MRI	Magnetic Resonance Imaging
MSP	Medicare Secondary Payer
MWWG	Material Weakness Working Group
N	
NAL	Naltrexone
NBI	National Benefit Integrity
NBS	NIH Business System
NCCI	National Correct Coding Initiative
NFCSP	National Family Caregiver Support Program
NGHP	Non-Group Health Plan
NIH	National Institutes of Health
NIST	National Institute of Standards and Technology
NPI	National Provider Identifier
O	
OASDI	Old-Age, Survivors, and Disability Insurance

OCR	Office for Civil Rights
OHS	Office of Head Start
OIG	Office of Inspector General
OMB	Office of Management and Budget
OMHA	Office of Medicare Hearings and Appeals
ONC	Office of the National Coordinator for Health IT
OPD	Orphan Products Design
OpDiv	Operating Division
OS	Office of the Secretary
P	
PARIS	Public Assistance Reporting Information System
PCS	Personal Care Services
PDE	Prescription Drug Event
PDMP	Prescription Drug Monitoring Programs
PECOS	Provider Enrollment, Chain and Ownership System
PEDIR	Payment Error Related to Direct and Indirect Remuneration
PELS	Payment Error Related to Low Income Subsidy Status
PEMS	Payment Error Related to Medicaid Status
PEPV	Payment Error Related to Prescription Drug Event Data Validation
PERM	Payment Error Rate Measurement
PHS	Public Health Service
PIP	Program Improvement Plan
PMI	Precision Medicine Initiative
PMD	Power Mobility Device
PRRB	Provider Reimbursement Review Board
PSC	Program Support Center
PSNet	Patient Safety Network
PTC	Premium Tax Credit
PUR	Period Under Review
PY	Prior Year
Q	
QHP	Qualified Health Plans
QIOs	Quality Improvement Organizations
QPP	Quality Payment Program
QRIS	Quality Rating and Improvement Systems
QRP	Quality Reporting Program
R	
RAC	Recovery Auditor Contractor
RADV	Risk Adjustment Data Validation
REMS	Risk Evaluation and Mitigation Strategies
RMFOB	Risk Management and Financial Oversight Board
RSI	Required Supplementary Information
S	
SAMHSA	Substance Abuse and Mental Health Services Administration
SECA	*Self Employment Contributions Act of 1954*
Section 601	*Bipartisan Budget Act of 2015*
SFFAS	Statement of Federal Financial Accounting Standards
SGR	Sustainable Growth Rate
SMI	Supplementary Medical Insurance
SMRC	Supplemental Medical Review Contractor
SNF	Skilled Nursing Facility
SNS	Strategic National Stockpile
SOSI	Statement of Social Insurance
SSA	Social Security Administration
SSBG	Social Services Block Grant
StaffDiv	Staff Division
T	
T-MSIS	Transformed Medicaid Statistical Information System
TANF	Temporary Assistance for Needy Families
TAS	Treasury Account Symbol
TMC	Top Management Challenge
Treasury	U.S. Department of the Treasury
U	
UFMS	Unified Financial Management System
U.S.	United States
U.S.C.	United States Code
USSGL	United States Standard General Ledger
V	
VA	Department of Veterans Affairs
VFC	Vaccines for Children
W	
WIOA	*Workforce Innovation and Opportunity Act*

APPENDIX B: CONNECT WITH HHS

The Hubert H. Humphrey Building, headquarters of the U.S. Department of Health and Human Services, was the first federal building dedicated to a living person.

Thank you for your interest in HHS's FY 2016 AFR. We welcome your comments on how we can make this report more informative for our readers. Please send your comments to:

Mail: U.S. Department of Health and Human Services
Office of Finance/Office of Financial Reporting and Policy
Mail Stop 549D
200 Independence Avenue, S.W.
Washington, DC 20201

Email: HHSAFR@hhs.gov

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