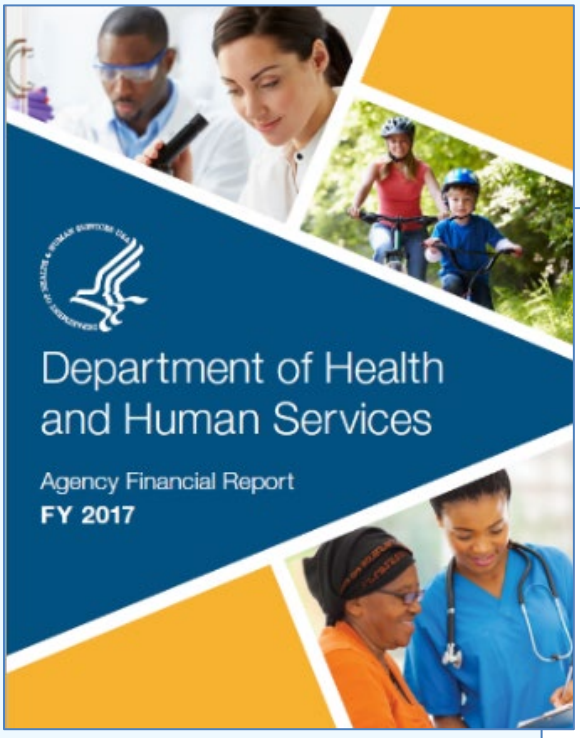
Department of Health and Human Services

FY 2018

Agency Financial Report

Certificate of Excellence in Accountability Reporting

In May 2018, the United States Department of Health and Human Services (HHS) received the Certificate of Excellence in Accountability Reporting (CEAR) from the Association of Government Accountants for its Fiscal Year (FY) 2017 Agency Financial Report. The CEAR Program was established by the Association of Government Accountants in collaboration with the Chief Financial Officers Council and the 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 2017 marked the fifth consecutive year the Department received this prestigious award.



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Message from the Secretary

Alex M. Azar II

I am pleased to present the Fiscal Year (FY) 2018 Agency Financial Report for the U.S. Department of Health and Human Services (HHS). This report contains our financial and performance highlights over the FY ended September 30, 2018.

Each year, HHS is proud to execute on our mission to enhance and protect the health and well-being of all Americans. We fulfill this mission through more than 300 programs across our Operating Divisions, facilitating effective health care and human services, and fostering advances in science and public health.

Our daily work is organized through five strategic goals, laid out in our 2018 – 2022 Strategic Plan: (1) reforming, strengthening, and modernizing the nation's health care system; (2) protecting the health of Americans where they live, learn, work, and play; (3) strengthening the economic and social well-being of Americans across the lifespan; (4) fostering sound, sustained advances in the sciences; and (5) promoting effective and efficient management and stewardship. In addition, I have identified four priorities for the Department that demand particular levels of focus and innovation: (1) combating the opioid crisis; (2) reforming the individual market for health insurance; (3) bringing down the high cost of prescription drugs; and (4) transforming our health care system into one that pays for value.

At HHS, we aim not just to perform the regular duties necessary to achieve these strategic goals and make progress on our priorities, but also to transform our work and systems to achieve the same aims. This year, the HHS team lived up to that ambitious calling.

Strategic Goal 1: Reform, Strengthen, and Modernize the Nation's Healthcare System

In 2018, HHS took significant steps to improve the affordability and quality of American health care, including through greater competition and transparency. The Food and Drug Administration approved a record number of generic drugs, improving affordability, while the Centers for Medicare & Medicaid Services worked to empower patients and providers through reduced burdens and expanded choices. The Department endeavored to strengthen our health care workforce to better meet the nation's behavioral health needs and supported ways for health professionals to perform broader arrays of services, providing more access to care at a lower cost, especially in rural areas. In addition, HHS worked to improve the integrity of our programs through reducing improper payment rates and health care fraud, protecting both program beneficiaries and the resources we use to serve them.

Strategic Goal 2: Protect the Health of Americans Where They Live, Learn, Work, and Play

In 2018, the Department continued its focus on combating America's unprecedented crisis of opioid addiction and overdose, implementing its 5-Point Opioid Strategy to empower communities on the frontlines. The Department expanded access to treatment and recovery services, with a special emphasis on medication-assisted treatment; increased the timeliness and accuracy of data on the crisis; and launched a new initiative at the National Institutes of Health to develop new treatments for pain and addiction and expand our understanding of our existing tools. Another important health challenge is serious mental illness, which afflicts more than 10 million Americans each year; increasing the number of Americans who receive effective treatment is a priority goal for the agency for this coming year. At home and abroad in 2018, HHS worked to support the implementation of the Global Health Security Agenda, which aims to protect the health of Americans by building capacity in every country to prevent, detect, and respond to infectious disease threats that can cross borders.

Strategic Goal 3: Strengthen the Economic and Social Well-Being of Americans Across the Lifespan

HHS strives to help all Americans live up to their full potential, including through engaging beneficiaries of our programs in work and other forms of community activities. In 2018, the Department worked with states to help them accomplish this goal in the HHS-funded programs they administer, while also providing flexibility in services delivery. The Department took a broad, transformational view of how health and human services interact, approving community engagement requirements to improve health outcomes in the Medicaid program and exploring how integration between health care and human services can support a value-based health care system.

Strategic Goal 4: Foster Sound, Sustained Advances in the Sciences

One of the unique assets HHS has to advance understanding of the medical and social sciences is its vast troves of data. In 2018, the Department took a number of important strides toward maximizing the use of this data: (1) hosting an Opioids Code-a-thon that brought together private-sector developers to work with an unprecedented assemblage of departmental data on the opioid epidemic; (2) initiating the development of a Department-wide data strategy; and (3) releasing, for the first time, Medicare Advantage claims data for researchers' use. HHS also collaborated with the private sector to advance research and development in a number of areas where more vigorous biomedical research is needed, including through the launch of the Anti-Microbial Resistance Challenge to spur investment to counter anti-microbial resistance, a fundamental threat to our health and our health systems.

Strategic Goal 5: Promote Effective and Efficient Management and Stewardship

In FY 2017, the Department launched an agency-wide effort, *ReImagine HHS*, to transform its operations and culture and become a more effective, efficient, and accountable organization. In FY 2018, *ReImagine HHS* launched a portfolio of 10 initiatives that advance our work in a number of areas: programmatic, like advancing human services and clinical innovation, and practical, like improving human resources management and coordination across the department. *ReImagine HHS* aligns and contributes to the goals of the 2018 President's Management Agenda and has already been recognized as leading the government in several reform areas, including acquisitions and grants management.

Fiscal Accountability

HHS is committed to sound stewardship and ensuring the transparency and accountability of the resources Congress and the taxpayers entrust to us. For the 20th consecutive year, we obtained an unmodified (clean) opinion on the Consolidated Balance Sheets, Statements of Net Cost, Statement of Changes in Net Position, and the Combined Statement of Budgetary Resources. The auditors disclaimed an opinion on the sustainability financial statements, which comprise the Statement of Social Insurance and the Statement of Changes in Social Insurance Amounts. This disclaimer is primarily due to the uncertainties surrounding provisions of the *Patient Protection and 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 *2018 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.

We also evaluated our internal control and financial management systems, as required by the *Federal Managers' Financial Integrity Act of 1982* and the Office of Management and Budget's Circular A-123, *Management's Responsibility for Enterprise Risk Management and Internal Control*. We identified two material noncompliances relating to: (1) improper payment error rate measurement, and (2) the Medicare appeals process. The "Management's Discussion and Analysis" section of this report includes further details. Based on our internal

assessments, I can provide reasonable assurance that the financial and performance information contained in this report is complete, reliable, and accurate.

Future Challenges and Priorities

Though we are pleased with our accomplishments, we also know there are opportunities for improvement. We 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 2018 Top Management and Performance Challenges Identified by the Office of Inspector General*. We are committed to addressing these challenges, including delivering quality services and benefits, exercising sound fiscal management, safeguarding public health and safety, and enhancing cybersecurity.

Conclusion

HHS employees are proud to serve our fellow Americans, both through accomplishing our goals and transforming our work to deliver on them even more effectively and efficiently in the future. In the years to come, we will continue to work closely with our stakeholders and colleagues in Congress to take bold steps to enhance and protect the health and well-being of the American people.

/Alex M. Azar II/

Alex M. Azar II
Secretary
November 14, 2018

About the Agency Financial Report

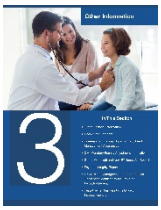
The HHS FY 2018 Agency Financial Report (AFR) provides fiscal and summary performance results that enable the President, Congress, and the American people to assess our accomplishments for the reporting period October 1, 2017, through September 30, 2018. This report provides an overview of our programs, accomplishments, challenges, and management's accountability for the resources entrusted to us. We prepared this report in accordance with the requirements of Office of Management and Budget Circular A-136*, Financial Reporting Requirements.* This document consists of three primary sections and supplemental appendices.

Section 1: Management's Discussion and Analysis

This section provides an overview of HHS's mission, activities, organizational structure, and program performance. It also includes an overview of the systems environment; a summary of the Department's financial results and compliance with laws and regulations; and provides management's assurances on HHS's internal control.

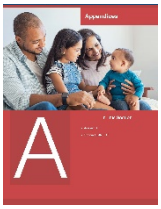
Section 2: Financial Section

This section begins with a message from the Acting Chief Financial Officer. It continues with the independent auditor's report, management's response to the audit report, financial statements with accompanying notes, and required supplementary information, including the Combining Statement of Budgetary Resources, Deferred Maintenance and Repairs, and Social Insurance information.



Section 3: Other Information

This section contains additional financial information and real property footprint data. It also includes a summary of the financial statement audit and management assurances, civil monetary penalties, grant closeout efficiencies, and a detailed payment integrity report. It concludes with the Inspector General's assessment of the Department's management and performance challenges.



Appendices

This section includes information that supports the main sections of the AFR. This includes a glossary of acronyms used throughout the report and resources for connecting with the Department.

The Department produces an AFR and *Annual Performance Plan and Report*. In conjunction with the release of the *President's Budget* in February 2019, additional reports that will be available on our website include:

1. FY 2020 *Annual Performance Plan and Report*
2. FY 2020 *Congressional Budget Justification*

Management's Discussion and Analysis

1

In This Section

- About the Department of Health and Human Services
- Performance Goals, Objectives, and Results
- Looking Ahead to 2019
- Systems, Legal Compliance, and Internal Control
- Management Assurances
- Financial Summary and Highlights

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About the Department of Health and Human Services

Our Mission

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

Our Vision

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

Who We Are

HHS is the U.S. government's principal agency for protecting the health of all Americans and providing essential human services, especially for those who are least able to help themselves. HHS accomplishes its mission through programs and initiatives that cover a wide spectrum of activities, serving and protecting Americans at every stage of life, from conception to natural death.

HHS is responsible for more than 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.

What We Do

HHS works closely with state, local, and tribal governments, and state or county agencies, private sector grantees, tribes, tribal organizations, or Urban Indian organizations provide many HHS-funded services at the local level. 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. While HHS is a domestic agency working to protect and promote the health and well-being of the American people, the interconnectedness of our world requires that HHS engage globally to fulfill its mission.

HHS, through its programs and partnerships:

- Provides health care coverage to more than 100 million people through Medicare, Medicaid, and the Children's Health Insurance Program (CHIP);
- 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, biologics, and medical devices;

Did you know?

On August 16, 2018, the Food and Drug Administration approved the first generic version of EpiPen and EpiPen Jr (epinephrine) auto-injector for the emergency treatment of allergic reactions, including those that are life-threatening (anaphylaxis), in adults and pediatric patients who weigh more than 33 pounds.

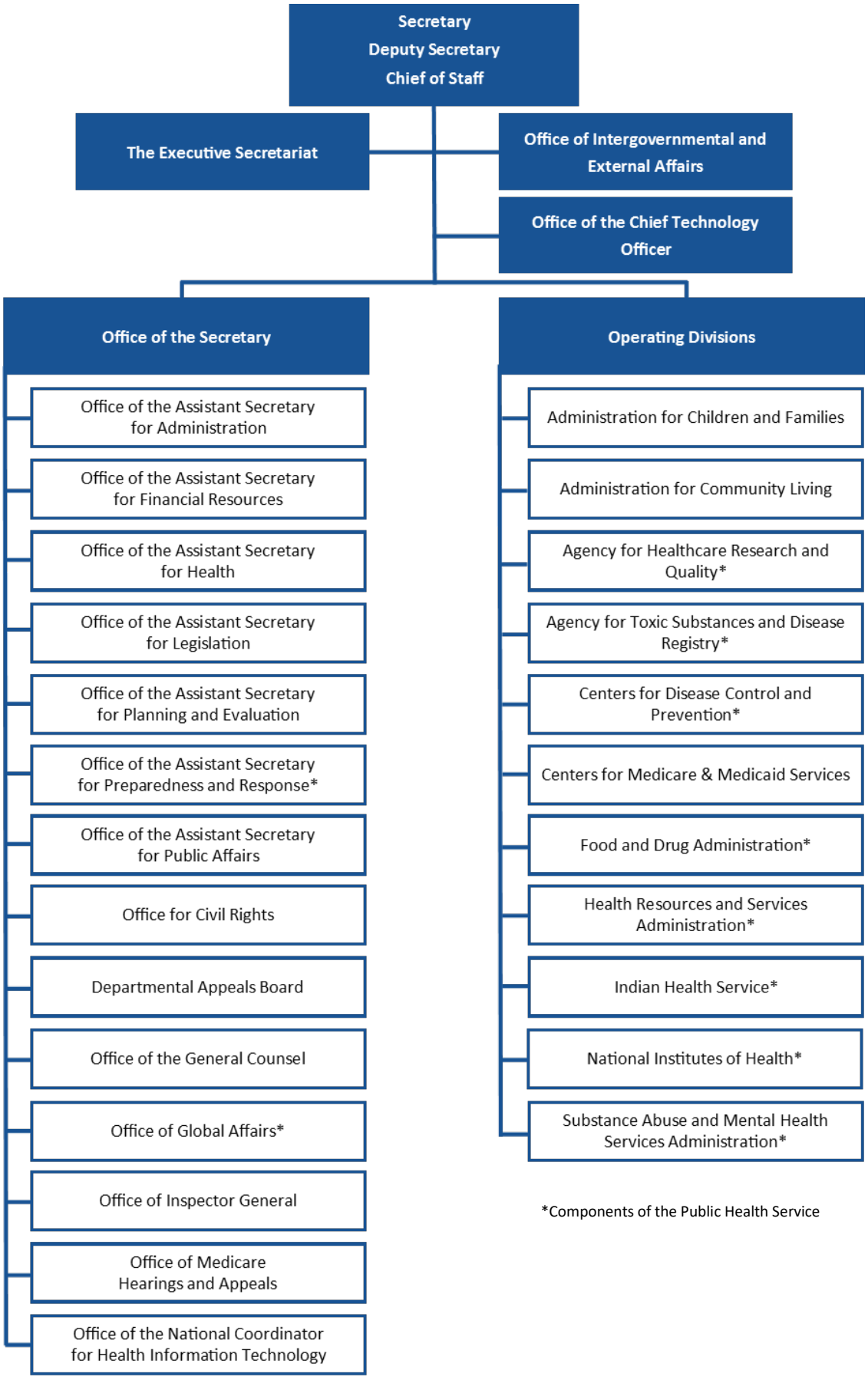
- Conducts health, social science, and medical research while creating hundreds of thousands of jobs for scientists in universities and research institutions in every state across America and around the globe;
- Leverages health information technology to improve the quality of care and to use HHS data to drive innovative solutions to health care, 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;
- 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;
- Serves as responsible stewards of the public's investments; and
- 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.

Did you know?

Several natural disasters impacted the U.S. and its territories in 2017-2018. The Substance Abuse and Mental Health Services Administration's Disaster Distress Helpline is a 24/7, 365-day-a-year, national hotline dedicated to providing immediate crisis counseling for people who are experiencing emotional distress related to any natural or human-caused disaster. Trained crisis counselors can be reached at 1-800-985-5990.

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. The HHS organizational chart is presented on the next page.



*Components of the Public Health Service

Each OpDiv contributes to our mission and vision as follows:

ADMINISTRATION FOR CHILDREN AND FAMILIES (ACF)

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. Visit ACF for more information.

ADMINISTRATION FOR COMMUNITY LIVING (ACL)

ACL was created around the fundamental principle that all people, regardless of age or disability, should be able to live independently, and fully participate in their communities. By advocating across the federal government for older adults, people with disabilities, and families and caregivers; funding services and supports primarily provided by networks of community-based organizations; and investing in training, education, research, and innovation, ACL helps make this principle a reality for millions of Americans. Visit ACL for more information.

AGENCY FOR HEALTHCARE RESEARCH AND QUALITY (AHRQ)

AHRQ produces evidence to make health care safer, higher quality, more accessible, equitable, and affordable, and works 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. Visit AHRQ for more information.

AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY (ATSDR)

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. Visit ATSDR for more information.

CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)

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 curable or preventable, due to human error or deliberate attack, CDC fights diseases and supports communities and citizens to do the same. Visit CDC for more information.

CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS)

CMS administers Medicare, Medicaid, CHIP, and the Health Insurance Exchanges, which together provide health care coverage for more than 100 million people. 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. Visit CMS for more information.

FOOD AND DRUG ADMINISTRATION (FDA)

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 is also responsible 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. Visit FDA for more information.

HEALTH RESOURCES AND SERVICES ADMINISTRATION (HRSA)

HRSA is responsible for improving access to quality health care and services, 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. Visit HRSA for more information.

INDIAN HEALTH SERVICE (IHS)

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 2.3 million American Indians and Alaska Natives who belong to 573 federally recognized tribes in 37 states. Visit IHS for more information.

NATIONAL INSTITUTES OF HEALTH (NIH)

NIH is the primary agency of the U.S. government responsible for biomedical and public health research. NIH provides leadership and direction to programs designed to improve the health of the nation by seeking 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. Visit NIH for more information.

SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION (SAMHSA)

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. Visit SAMHSA for more information.

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 guidance to the Department. The StaffDivs are:

IMMEDIATE OFFICE OF THE SECRETARY (IOS)

IOS oversees the Secretary's operations and coordinates the Secretary's work.

- **The Executive Secretariat (ES)**
  ES manages the Department's policy review and decision-making processes, coordinating the development, clearance, and submission of all policy documents for the Deputy Secretary and Secretary's review and approval.
- **Office of Intergovernmental and External Affairs (IEA)**
  IEA represents both the government and external perspective in federal policymaking and clarifies the federal perspective to government officials and external parties.
- **Office of the Chief Technology Officer (CTO)**
  CTO harnesses the power of data, technology, and innovation to create a more modern and effective government that works to improve the health of our nation.

OFFICE OF THE ASSISTANT SECRETARY FOR ADMINISTRATION (ASA)

ASA provides leadership for HHS departmental management, including human resource policy and departmental operations.

- **Program Support Center (PSC)**
  PSC is a shared services organization dedicated to providing support services to help its customers achieve mission-oriented results.

OFFICE OF THE ASSISTANT SECRETARY FOR FINANCIAL RESOURCES (ASFR)

ASFR provides advice and guidance to the Secretary on budget, financial management, acquisition policy and support, grants management, and small business programs. It also directs and coordinates these activities throughout the Department.

OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH (OASH)

OASH advises on the nation's public health and oversees HHS's U.S. Public Health Service for the Secretary.

OFFICE OF THE ASSISTANT SECRETARY FOR LEGISLATION (ASL)

ASL provides advice on legislation and facilitates communication between the Department and Congress.

OFFICE OF THE ASSISTANT SECRETARY FOR PLANNING AND EVALUATION (ASPE)

ASPE advises on policy development and contributes to policy coordination, legislation development, strategic planning, policy research, evaluation, and economic analysis.

OFFICE OF THE ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE (ASPR)

ASPR leads the federal public health and medical preparedness; response and recovery to disasters and public health emergencies; and coordinates the nation's medical and public health capabilities to save lives and protect Americans during emergencies and disasters, whatever their cause.

OFFICE OF THE ASSISTANT SECRETARY FOR PUBLIC AFFAIRS (ASPA)

ASPA provides centralized leadership and guidance on public affairs for HHS's StaffDivs, OpDivs, and regional offices. ASPA also administers the *Freedom of Information and Privacy Act*.

OFFICE FOR CIVIL RIGHTS (OCR)

OCR enforces federal laws that prohibit discrimination on the basis of race, color, national origin, disability, sex, age, religion, or conscience by health care and human services providers that receive funds from HHS as well as the federal laws and regulations governing the privacy and security of health information and the rights of individuals with respect to their health information.

DEPARTMENTAL APPEALS BOARD (DAB)

DAB provides impartial review of disputed legal decisions involving HHS.

OFFICE OF THE GENERAL COUNSEL (OGC)

OGC provides quality representation and legal advice on a wide range of highly visible national issues.

OFFICE OF GLOBAL AFFAIRS (OGA)

OGA provides leadership and expertise in global health diplomacy and policy to protect the health and well-being of Americans.

OFFICE OF INSPECTOR GENERAL (OIG)

OIG protects the integrity of HHS programs as well as the health and welfare of the program participants.

OFFICE OF MEDICARE HEARINGS AND APPEALS (OMHA)

OMHA administers nationwide hearings for the Medicare program.

OFFICE OF THE NATIONAL COORDINATOR FOR HEALTH INFORMATION TECHNOLOGY (ONC)

ONC provides counsel for the development and implementation of a national health information technology framework.

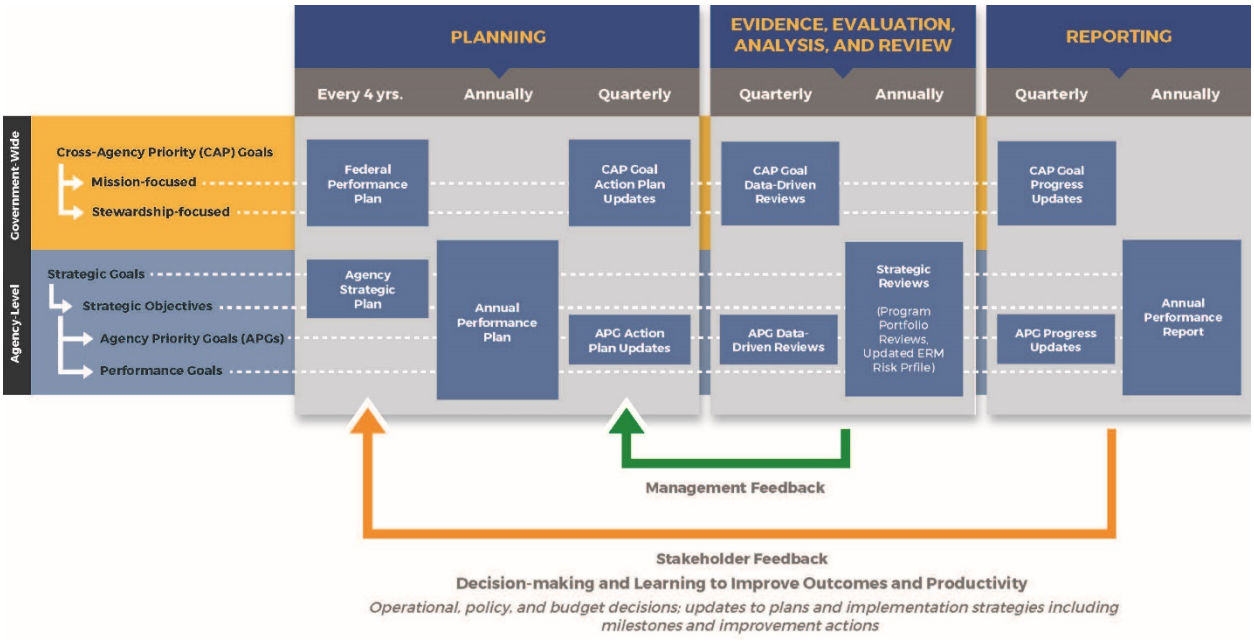
For more information regarding our organization, visit our website.

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, as required by the *Government Performance and Results Act of 1993* (GPRA) and the *GPRA Modernization Act of 2010*. The Department's Strategic Plan defines its mission, goals, and the means by which the Department will measure its progress in addressing specific national issues over a 4-year period. Each of the Department's OpDivs and StaffDivs contributes to the development of the Strategic Plan, as reflected in the strategic goals, and associated objectives, strategies, and performance goals. Performance goals require regular monitoring and measurement to track progress toward achieving the Strategic Plan's objectives. In addition, HHS engages in a variety of efforts to support the President's Management Agenda (PMA) and Cross-Agency Priority (CAP) Goals.

The following graphic illustrates how different operational levels of goals and objectives relate to and support efforts at individual agencies and government-wide. The graphic also illustrates the cyclical process of developing strategic plans, monitoring performance at achieving stated goals, and reporting performance to the Department's stakeholders through agency performance and financial reports. More information is provided on the following pages.



*Source: Office of Management and Budget (OMB) Circular A-11, *Preparation, Submission, and Execution of the Budget*

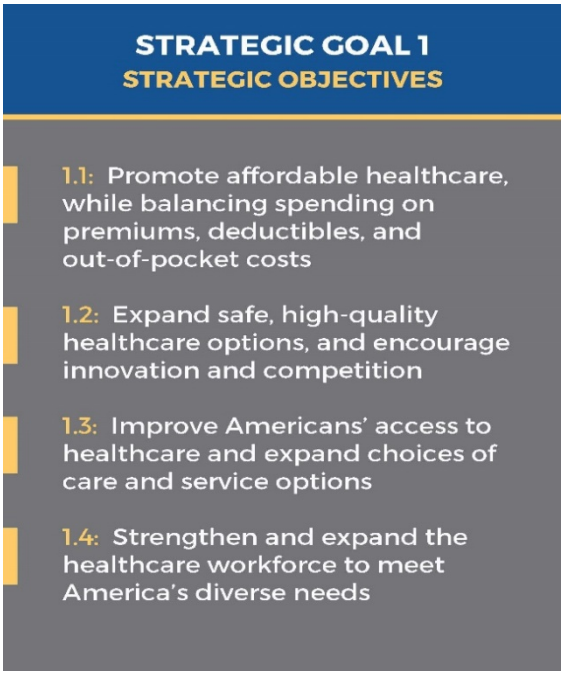
Strategic Goals

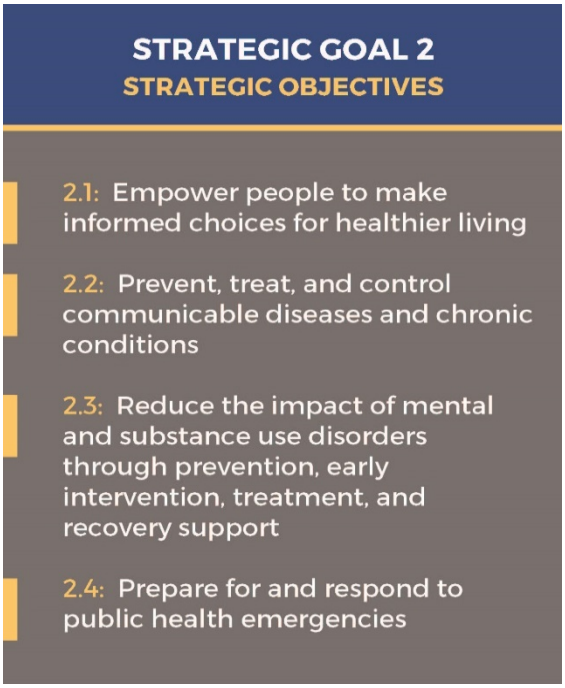
The HHS Strategic Plan Fiscal Year (FY) 2018 – 2022 is comprised of five strategic goals, representing input from all HHS OpDivs and StaffDivs as well as over 13,000 public comments. The Department's five strategic goals are:

1. Reform, Strengthen, and Modernize the Nation's Healthcare System
2. Protect the Health of Americans Where They Live, Learn, Work, and Play
3. Strengthen the Economic and Social Well-Being of Americans Across the Lifespan
4. Foster Sound, Sustained Advances in the Sciences
5. Promote Effective and Efficient Management and Stewardship

Strategic Goal 1: Reform, Strengthen, and Modernize the Nation's Healthcare System

For a nation to thrive, the population must be healthy both physically and mentally. To improve the nation's health, the Department is working with its public and private partners to make health care more affordable, higher quality, and more accessible. Improving access to health care goes beyond affordabilty. HHS is working to overcome access issues which exacerbate health problems, increase costs, and prevent better health outcomes. The Department is also making investments to strengthen and expand the health care workforce. This Strategic Goal seeks to improve health care outcomes for all people across the lifespan, including the unborn, children, youth, adults, and older adults across diverse health care settings.





Strategic Goal 2: Protect the Health of Americans Where They Live, Learn, Work, and Play

HHS aims to protect and improve the health of Americans by promoting health and wellness knowledge, preparing for fatal outbreaks or natural disasters, and improving accessibility to health care. HHS programs help Americans take control of their health. Healthy living involves more than avoiding risky behavior and disease; health and wellness improves with healthy eating, regular physical activity, preventive care, and positive relationships. Mental illness and substance abuse create health risks and place a heavy burden on affected individuals and their families. HHS invests in programs focused on prevention, screening, and early detection of these risks, including those related to opioid misuse. HHS also focuses on environmental health and reducing the burden caused by disease and other conditions.

STRATEGIC GOAL 3
STRATEGIC OBJECTIVES

- 3.1: Encourage self-sufficiency and personal responsibility, and eliminate barriers to economic opportunity
- 3.2: Safeguard the public against preventable injuries and violence or their results
- 3.3: Support strong families and healthy marriage, and prepare children and youth for healthy, productive lives
- 3.4: Maximize the independence, well-being, and health of older adults, people with disabilities, and their families and caregivers

Strategic Goal 3: Strengthen the Economic and Social Well-Being of Americans Across the Lifespan

A core component of the HHS mission commits to improving the well-being of Americans, from conception to natural death, including those individuals and populations who are at high risk of social and economic challenges. Overall wellness goes beyond physical health, it entails a positive social and economic development. HHS focuses on maximizing the opportunities to foster environments for individuals and families to be socially and economically independent. A strong family can lead to many positive outcomes for the health, social, and economic status of both adults and children. Financial and emotional support can encourage children and young adults to continue education and make healthier decisions as they mature. HHS is also working to expand partnerships and strategies to reduce injuries and violence against the population. Older Americans and those with disabilities also face a number of obstacles that may threaten their independence.

Strategic Goal 4: Foster Sound, Sustained Advances in the Sciences

HHS's success is contingent on scientific advances and discovery. Scientific investments through foundations, charities, private industry, and government entities strive to unlock mysteries that improve health and well-being; reduce the death tolls, disease, and disability; and extend and improve quality of life. These types of decisions rely on data acquired through surveillance, epidemiology, and laboratory services. Achievements in science tie to the other strategic goals, such as protecting Americans from disease outbreaks or reaching advances in public health care. Success in this domain starts with a high caliber workforce devoted to achieving award-winning breakthroughs. HHS aims to expand the capacity of the research workforce, equipping them with the tools to make discoveries of the future. To be effective, HHS must share, adopt, and implement scientific discoveries with fidelity. The Department is working to promote evidence-informed practices that improve health and human service fields. As a steward of public trust, HHS is responsible for promoting approaches that will improve health and well-being.

STRATEGIC GOAL 4
STRATEGIC OBJECTIVES

- 4.1: Improve surveillance, epidemiology, and laboratory services
- 4.2: Expand the capacity of the scientific workforce and infrastructure to support innovative research
- 4.3: Advance basic science knowledge and conduct applied prevention and treatment research to improve health and development
- 4.4: Leverage translational research, dissemination and implementation science, and evaluation investments to support adoption of evidence-informed practices

STRATEGIC GOAL 5
STRATEGIC OBJECTIVES

- 5.1: Ensure responsible financial management
- 5.2: Manage human capital to achieve the HHS mission
- 5.3: Optimize information technology investments to improve process efficiency and enable innovation to advance program mission goals
- 5.4: Protect the safety and integrity of our human, physical, and digital assets

Strategic Goal 5: Promote Effective and Efficient Management and Stewardship

HHS promotes sound stewardship and responsibility for the financial resources the American taxpayers and Congress entrust to the Department through support and cultivation of top talent, development of robust and responsive information management systems, and creating a safe and secure environment for human, digital, and physical assets. Efforts such as *ReImagine HHS* effectively improve efficiency and accountability of the Department. As the nation's largest grant-awarding agency, HHS is responsible for almost a quarter of federal outlays, and administers more grant dollars than all other federal agencies combined. HHS prioritizes the integrity of expenditures by maintaining effective risk and internal controls for payments, grants, contracts, and other financial transactions, and by developing a financial management workforce with the expertise to comply with legislative mandates and requirements.

HHS aligns its focus, strategies, and activities to achieve these strategic goals and objectives. Shorter-term Agency Priority Goals (APGs) and performance goals further focus efforts that direct activities for the next 24 months.

Agency Priority Goals

HHS uses APGs to improve performance and accountability. HHS develops APGs by collaborating across the Department to identify activities that reflect HHS priorities and strategic goals that 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. The Department has completed work on multiple rounds of APGs, and is currently in the process of fulfilling the APGs for FY 2018 – 2019. These new APGs use the knowledge gained through collaboration and data-driven reviews of past processes to deliver results to the public. The FY 2018 – 2019 APGs are:

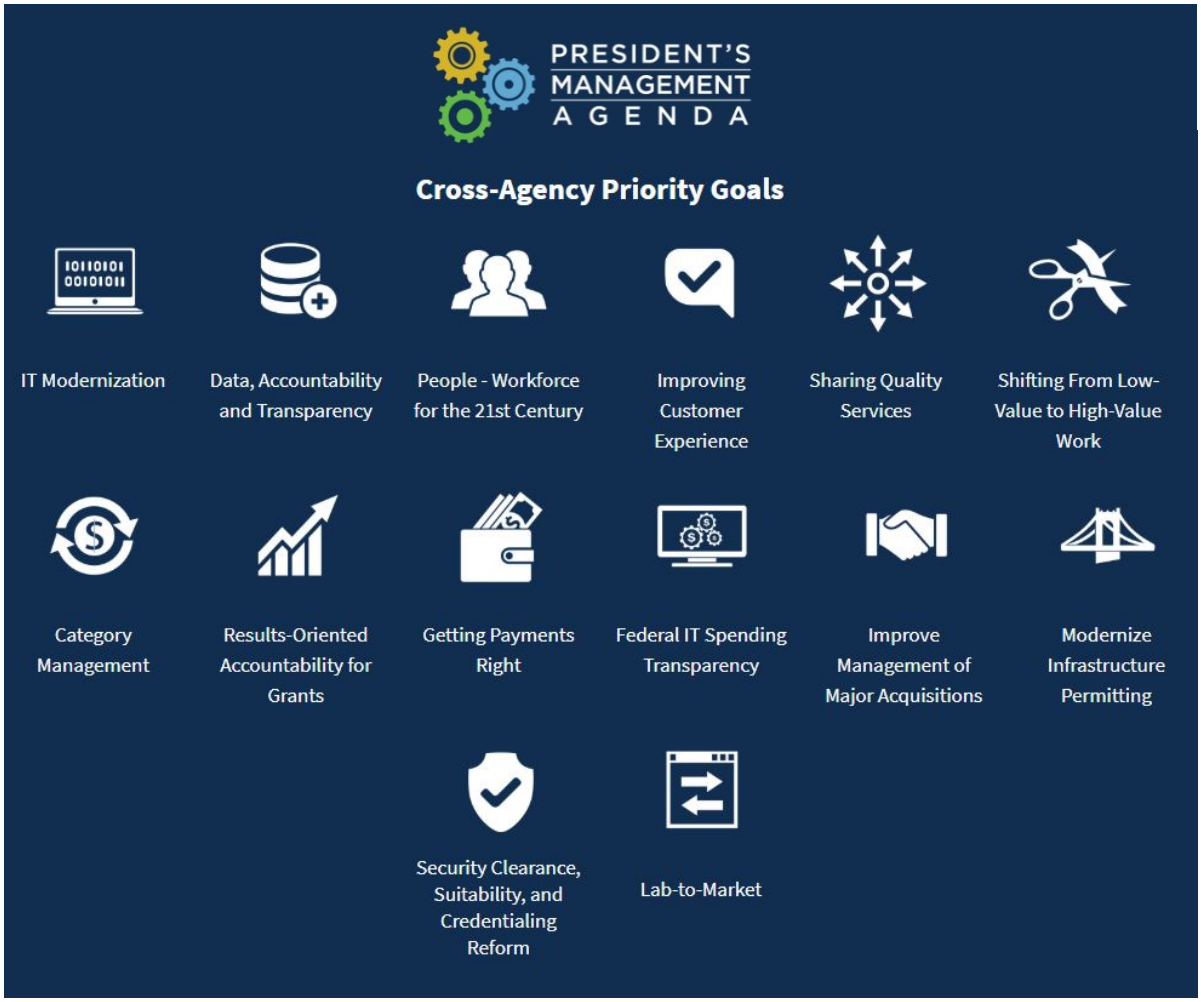
- Increase capacity to prevent health threats originating abroad from impacting the United States
- Reduce opioid-related morbidity and mortality
- Increase combined data analysis of disparate datasets in order to achieve better insights
- Improve treatment for individuals with Serious Mental Illness

For more information on HHS's APGs, visit Performance.gov. HHS performance initiatives continue to influence plans and policies as demonstrated in the Strategic Plan, which guides our efforts and investments into the future.

HHS also contributes to government-wide CAP Goals identified in the graphic below. CAP Goals drive the implementation of the PMA and align inter-agency efforts to tackle critical government-wide challenges through concrete goals and trackable metrics for accountability. The PMA provides a long-term vision for modernizing the federal government in key areas that will improve the ability of agencies to deliver mission outcomes, provide excellent service, and effectively steward taxpayer dollars on behalf of the American people.

HHS aligns its efforts to support the CAP Goals, and senior accountable officials within the Department facilitate oversight and ensure effective progress toward goal accomplishment. HHS shares a government-wide leadership role on several CAP Goals, including Results-Oriented Accountability for Grants, and Getting Payments Right.

For more information on HHS performance and contributions to the PMA and CAP Goals, visit Performance.gov.



*Source: President's Management Agenda on Performance.gov

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 2019" section for further details. HHS is working to achieve our APGs and is actively monitoring progress through quarterly data-driven reviews and other mechanisms.

Performance Results

The performance results in this section represent a small sample of key HHS measures across the Department. For more detailed performance information built around the FY 2018 – 2022 Plan, refer to the FY 2020 Annual Performance Plan and Report, to be released with the *FY 2020 President's Budget*.

Global Health Security. An infectious disease threat anywhere, particularly if it is novel or spreads rapidly through international travel, can threaten Americans' health, security, and prosperity. It may not be possible to completely prevent infectious disease or other threats from entering the U.S., and threats may not immediately and obviously reveal themselves, increasing risk to Americans. HHS is leveraging all of its expertise to evaluate current partner country capacity (i.e., skilled workforce to prevent, detect, and respond to biological threats, laboratory capacity, disease detection, and monitoring), jointly plan activities with these partner countries and other U.S. Government partners, provide technical assistance, and monitor progress towards achieving improved health security capabilities. HHS will maintain the capability to rapidly provide personnel and operational resources to support investigations of, and responses to, health threats in and with partner countries. For example, CDC's International Field Epidemiology Training Programs (FETP) are recognized worldwide as an effective means to strengthen countries' capacity in surveillance, epidemiology, and outbreak response. Graduates of these programs strengthen public health capacity so individual countries are able to transition from U.S.-led global health investments to more long-term host country ownership.

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

Unit of Measurement: New Residents

	FY 2014	FY 2015	FY 2016	FY 2017	FY 2018
Target	430	430	430	430	400
Result	402	483	470	403	June 2019
Status	Target Not Met but Improved	Target Exceeded	Target Exceeded	Target Not Met[1]	Pending

[1]This decline is due to CDC reducing the number of FETP fellows trained in order to accommodate a more targeted approach for priority countries. As such, the targets moving forward are smaller.

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 increasing precipitously in the twenty-first century, leading to the declaration of a nationwide public health emergency in October 2017. 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, while the surge of fentanyl use has been the main driver in increasing synthetic opioid deaths. OpDivs and StaffDivs across HHS recognize the urgency of halting the rise of opioid abuse and overdose, and are working to develop and implement the most effective interventions, from prevention through treatment, including making sure first responders are equipped with naloxone to use in emergencies. OpDivs made progress toward reducing the number of Americans initiating heroin usage and increased the number of people who received treatment for substance use disorder from 2016 to 2017.

Decrease the total morphine milligram equivalents (MMEs) dispensed[2]

Unit of Measurement: MMEs

	FY 2014	FY 2015	FY 2016	FY 2017	FY 2018
Target	N/A	N/A	179,242,504,449	169,808,688,426	142,179,191,774
Result	200,662,735,355	188,676,320,473	181,069,596,249	162,490,504,885	December 2018
Status	Historical Actual	Historical Actual	Target Not Met	Target Exceeded	Pending

Increase the number of prescriptions dispensed for naloxone[2]

Unit of Measurement: Prescriptions

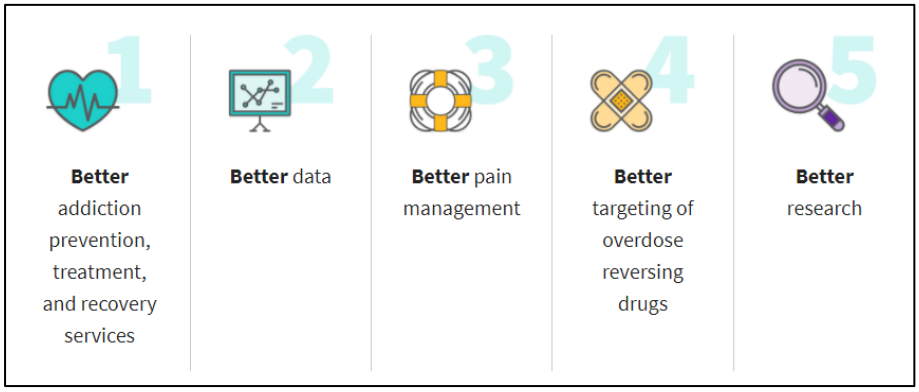
	FY 2014	FY 2015	FY 2016	FY 2017	FY 2018
Target	N/A	N/A	19,151	20,487	365,073
Result	4,455	17,815	100,769	280,825	December 2018
Status	Historical Actual	Historical Actual	Target Exceeded	Target Exceeded	Pending

Increase the number of unique patients receiving prescriptions for buprenorphine (average monthly) in a retail setting[2]

Unit of Measurement: Patients

	FY 2014	FY 2015	FY 2016	FY 2017	FY 2018
Target	N/A	N/A	491,796	515,215	637,475
Result	414,413	468,377	507,369	566,644	December 2018
Status	Historical Actual	Historical Actual	Target Exceeded	Target Exceeded	Pending

[2]HHS has recalculated the data retroactively to remove data collected on opioids and naloxone used in long-term care. These uses are for standard medical procedures and do not reflect opioid misuse and naloxone provision made to prevent overdose outside a hospital setting.



HHS enhanced the 5-Point Opioid Strategy to combat the opioid crisis by expanding the scope and improving the effectiveness of the strategy.

Serious Mental Illness. Individuals with serious mental illness are a high-need, high-cost population. They frequently use emergency departments and have high readmission rates 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; 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.

Number of evidence-based coordinated specialty care programs that have been implemented nationally

Unit of Measurement: Programs

	FY 2014	FY 2015	FY 2016	FY 2017	FY 2018
Target	N/A	N/A	N/A	N/A	N/A[3]
Result	37 Programs	53 Programs	140 Programs	214 Programs	December 2018
Status	Historical Actual	Historical Actual	Historical Actual	Historical Actual	Pending

[3]This measure is an APG with a 2-year FY 2019 target of 280 Programs.

Reduction in Head Start Grantees Receiving a Low Score on the Classroom Assessment Scoring System (CLASS: Pre- K). In support of the President's Cross-Agency Goal 8 and the HHS Strategic Goal 3, ACF focuses on the results of the Head Start Grantee program by striving to increase the percentage of Head Start children in high-quality classrooms. The Head Start Grantee program measures progress by reducing the proportion of 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 2017 indicates that 16 percent of grantees scored in the "low" range, exceeding the target of 24 percent. All low-range scores were in the Instructional Support domain and, overall, Head Start classrooms regularly score above a five in Emotional Support and Classroom Organization.

ACF continues to invest in building its CLASS-related resources and making those resources available to grantees. ACF provides more intentional targeted assistance to those grantees that score in the low range on CLASS. ACF continues to analyze the specific dimensions that are particularly challenging for grantees, such as concept development and language modeling, and tailors 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. For example, FACES data shows a statistically significant increase in the average score and the percentage of Head Start classrooms scoring three or higher on Instructional Support between 2006 and 2014. The FACES data also shows that over time fewer classrooms scored in the "mid" range and more classrooms scored in the "high" range on Emotional Support. The FACES data also includes another measure of classroom quality using the Early Childhood Environment Rating Scale where items are also rated on a seven-point scale, but this one ranges from inadequate to excellent. There was a statistically significant increase of classrooms moving into the good and excellent category on the *Teaching and Environments* and *Provisions to Learning* items from 2006 to 2014. For example, the percent of classrooms

The average Head Start program has 507 children enrolled, ranging from approximately 100 to 6,000 across programs.

in the good and excellent category in *Teaching and Environments* item moved from 13 percent in 2006 to 54 percent in 2014.

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 2014	FY 2015	FY 2016	FY 2017	FY 2018
Target	27%	26%	25%	24%	15%
Result	23%	22%	24%	16%	January 2019
Status	Target Exceeded	Target Exceeded	Target Exceeded	Target Exceeded	Pending

Medicare Fee-For-Service (FFS), Medicaid, and CHIP Improper Payment Rates. Aligning with the President's Cross-Agency Priority Goal 9, one of HHS'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 decrease in the reported Medicare FFS improper payment estimate of 9.51 percent in FY 2017 to 8.12 percent in FY 2018 was driven by a reduction in improper payments for home health and Skilled Nursing Facility (SNF) claims. Although the improper payment rate for these services and the national Medicare FFS improper payment rate decreased, improper payments for home health, Inpatient Rehabilitation Facility, SNF, and hospital outpatient claims were the major contributing factors to the FY 2018 Medicare FFS improper payment rate. While the factors contributing to improper payments are complex and vary by year, the primary causes of improper payments continue to be insufficient documentation and medical necessity errors. HHS uses data from the Comprehensive Error Rate Testing program and other sources of information to address improper payments in Medicare FFS through various corrective actions, such as policy clarifications and simplifications, when appropriate, as well as Targeted Probe and Educate reviews. These reviews include more individualized education through smaller probe reviews, followed by specific education based on the findings of these reviews. HHS is also continuing prior authorization initiatives, as appropriate, which help to ensure that applicable coverage, payment, and coding rules are met before services are rendered, while ensuring access to and quality of care.

Since one-third of the states are measured each year to calculate the Medicaid and CHIP improper payment rates, these measures are calculated as a rolling rate that includes the reporting year and the previous 2 years. Similar to recent years, state difficulties coming into compliance with provider screening, enrollment, and National Provider Identifier requirements was the driver of each rate. HHS is working with states to address all errors that contributed to the improper payment rates and improve compliance with the requirements to develop and submit corrective action plans. Refer to the "Other Information" section of this AFR, under "Payment Integrity Report" for further details.

Reduce the Percentage of Improper Payments Made Under the Medicare FFS Program

Unit of Measurement: Percent

	FY 2014	FY 2015	FY 2016	FY 2017	FY 2018
Target	9.9%	12.50%	11.50%	10.40%	9.40%
Result	12.7%	12.09%	11.00%	9.51%	8.12%
Status	Target Not Met	Target Exceeded	Target Exceeded	Target Exceeded	Target Exceeded

Reduce the Improper Payment Rate in the Medicaid Program

Unit of Measure: Percent

	FY 2014	FY 2015	FY 2016	FY 2017	FY 2018
Target	5.6%	6.70%	11.53%	9.57%	7.93%
Result	6.7%	9.78%	10.48%	10.10%	9.79%
Status	Target Not Met	Target Not Met	Target Exceeded	Target Not Met	Target Not Met

Reduce the Improper Payment Rate in CHIP

Unit of Measurement: Percent

	FY 2014	FY 2015	FY 2016	FY 2017	FY 2018
Target		6.50%	6.81%	7.38%	8.20%
Result		6.80%	7.99%	8.64%	8.57%
Status		Target Not Met	Target Not Met	Target Not Met	Target Not Met

Did you know?

Medicare is composed of different parts that cover specific services.

Medicare Part A (Hospital Insurance)

Part A covers inpatient care in hospitals, including critical access hospitals, and skilled nursing facilities (not custodial or long-term care). It also helps cover hospice care and some home health care. Beneficiaries must meet certain conditions to get these benefits. Most people do not pay a premium for Part A because they or a spouse already paid for it through their payroll taxes while working.

Medicare Part B (Medical Insurance)

Part B covers doctors' services and outpatient care. It also covers some other medical services that Part A does not cover, such as services of physical and occupational therapists, and some home health care. Part B helps pay for these covered services and supplies when they are medically necessary. Most people pay a premium for Part B.

Medicare FFS

Often referred to as the "Original Medicare," Medicare FFS is a federal health insurance program that provides Medicare Part A and Medicare Part B to eligible citizens.

Medicare Part C (Medicare Advantage)

Medicare pays a fixed amount to approved private companies to offer Part C Medicare Advantage Plans. Part C provides the same coverage benefits as Part A and Part B, and may offer Part D coverage or other extra coverage options (e.g., vision, hearing, dental and/or health and wellness programs). Private Medicare Advantage companies must follow requirements set by Medicare; however, Part C plans can have varying amounts of out-of-pocket costs or qualification rules based on the coverage provider.

Medicare Part D (Prescription Drug Coverage)

Medicare prescription drug coverage is available to everyone with Medicare. To get Medicare prescription drug coverage, people must join a plan approved by Medicare that offers Medicare drug coverage. Most people pay a monthly premium for Part D.

Visit Medicare.gov to find more information.

Looking Ahead to 2019

HHS is the U.S. Government's principal agency for protecting the health of all Americans and providing essential human services, especially for those who are least able to help themselves. While HHS is a domestic agency, the interconnectedness of our world requires that HHS engage globally to fulfill its mission. Our 11 OpDivs, including 8 agencies in the U.S. Public Health Service and 3 human services agencies, administer HHS's programs. In addition, StaffDivs provide leadership, direction, and policy guidance to achieve the Department's strategic goals and objectives.

Through the guidance of the HHS Strategic Plan, in 2019 HHS will address important health care, public health, and human services issues that impact all Americans.

HHS Strategic Goal 1: Reform, Strengthen, and Modernize the Nation's Healthcare System

Drug Pricing: HHS will continue its efforts to lower the list prices of prescription drugs through competition, negotiation, and pricing incentives to ensure that Americans have access to affordable prescription drugs. We will continue reforms to increase competition in areas such as approval of generic drugs and biosimilars, as well as pursue payment policies to help patients take advantage of this competition.

Insurance Reform: HHS will focus on the cost and availability of health insurance to ensure Americans have access to affordable insurance that meets their needs. In addition, we will continue our efforts to restore balance and enhance sustainability in the Medicaid program to eliminate barriers for people looking to move from dependence on Medicaid to independence.

Value Based Care: HHS is putting patients at the center of the health care system, making sure they have the information they need to determine value and make choices. We will address the value of health care services by moving from a system where payments are made based on the volume of services provided to a system where payments are based on outcomes and value.

Improving the Healthcare Workforce and Infrastructure: HHS will identify and address gaps in the health care workforce to enhance the capacity of the existing workforce, and identify opportunities to maximize health care productivity.

HHS Strategic Goal 2: Protect the Health of Americans Where They Live, Learn, Work, and Play

The Opioids Crisis: The Department will continue to empower local communities on the frontlines of the opioids crisis by implementing its 5-Point Opioid Strategy. The Department will advance efforts to increase access by addressing workforce shortages and treatment coverage including medication-assisted treatment; increasing the timeliness and accuracy of data to monitor opioid use, misuse, and overdose; and improving pain management with a focus on increasing the availability of effective non-opioid alternatives.

Rural Health: HHS will continue to improve access to, and the quality of, care in rural and underserved areas by identifying policies and models that deliver the right care at the right place, at the right time in rural America.

HHS Strategic Goal 3: Strengthen the Economic and Social Well-Being of Americans Across the Lifespan

Dependence to Independence: To build self-sufficiency and move families from dependence to independence, HHS will strive to fully engage all Americans and move them from the economic sidelines into work. We will continue promoting innovation in the Temporary Assistance for Needy Families (TANF) program to advance the objective of

helping families in need find stability and support through the employment and economic independence of adult participants and the healthy development of children whose families receive assistance.

Child Welfare and Adoption: HHS will work to increase child and family well-being by putting greater emphasis on preventing child maltreatment. We will also look to increase adoptions, an underutilized option in the U.S., for teens and women facing a crisis pregnancy, and to achieve permanency for children in the child welfare system, especially older children.

HHS Strategic Goal 4: Foster Sound, Sustained Advances in the Sciences

Data and Evidence: HHS strives to create, use, and analyze the best science and evidence possible for informed decision-making. Efforts across the Department are ongoing to ensure better access to HHS data for lower-cost analysis; to use evaluation and performance management data to drive learning, improvement, and analysis for better decision-making; and translate science into practice to ensure the best outcomes possible for the people served by HHS programs and policies.

HHS Strategic Goal 5: Promote Effective and Efficient Management and Stewardship

In 2017, HHS launched *ReImagine HHS*, an agency-wide effort to transform operations and culture across the Department to become more effective, efficient, and accountable. *ReImagine HHS* is a robust program led *by* HHS staff *for* HHS staff. HHS staff collaborated to identify six strategic shifts to drive the transformation. In FY 2018, *ReImagine HHS* launched a portfolio of 10 initiatives within the 6 strategic shifts, each with a focus on improving our programs and reimagining how HHS serves the American people. The initiatives drive accomplishment in innovation, cost and efficiency savings, operational and programmatic improvements, and a transition to new and enhanced infrastructure. The *ReImagine HHS* initiatives are leading innovation in acquisitions and grants across the government, and align and contribute to the goals of the 2018 President's Management Agenda. *ReImagine HHS* will enable the Department to advance technology, enhance internal and external collaborations, and institutionalize continuous improvement.

Systems, Legal Compliance, and Internal Control

Systems

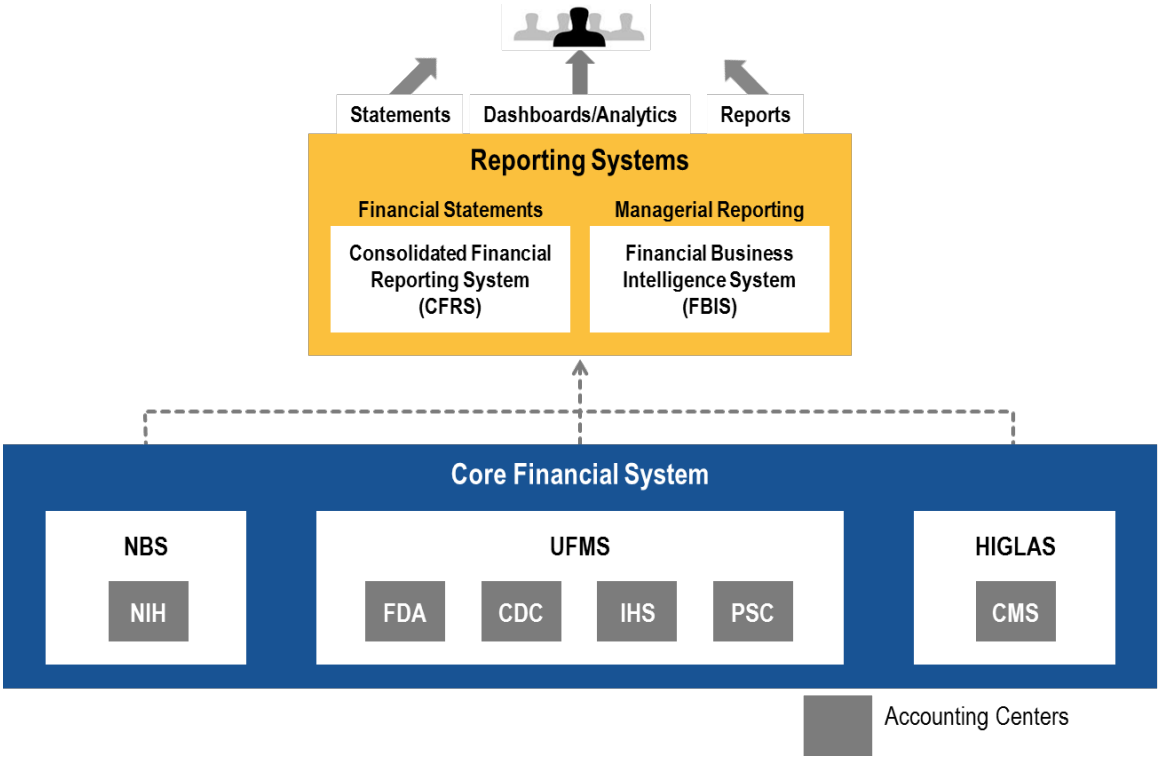
Financial Systems Environment

HHS's Chief Financial Officer (CFO) Community strives to enhance and sustain a financial management environment that supports the HHS mission by promoting accountability and managing risk. To support this vision, the HHS financial systems environment forms the financial and accounting foundation for managing the $1.8 trillion in budgetary resources entrusted to the Department in FY 2018. These resources represent more than a quarter of all federal outlays and encompass more grant dollars than all other federal agencies combined.

The robust financial systems environment sustains HHS's diverse portfolio of mission-oriented programs as well as business operations. Its purpose is to: (1) efficiently process financial transactions in support of program activities and HHS's mission; (2) provide complete and accurate financial information for decision-making; (3) improve data integrity; (4) strengthen internal control; and (5) 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 together support the Department's financial accounting and reporting needs.

The figure below graphically depicts the current financial systems environment.



Core Financial System

HHS's core financial system's three instances all operate on the same commercial off-the-shelf (COTS) platform to support data standardization and facilitate Department-wide reporting.

Three Instances of the Core Financial System

Instance	Description
Healthcare Integrated General Ledger Accounting System (HIGLAS)	HIGLAS supports CMS by serving 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.
NIH Business System (NBS)	NBS combines NIH administrative processes and financial information under one centralized component, supporting NIH's diverse biomedical research program; and business, financial, acquisition and logistics requirements for 27 NIH Institutes and Centers. NBS supports grant funding to more than 300,000 researchers at over 2,500 universities, medical schools, and other research institutions in every state and around the world.
Unified Financial Management System (UFMS)	UFMS serves 10 OpDivs (including the Office of the Secretary) and 14 StaffDivs across the Department. The following Accounting Centers utilize UFMS: CDC, FDA, IHS, and PSC. PSC provides shared service accounting support for all other OpDivs and StaffDivs utilizing UFMS.

Reporting Systems

Reporting components within the HHS financial systems environment consist of two Department-wide applications that facilitate data reconciliation, financial and managerial reporting, and data analysis.

HHS Reporting Systems

System	Description
Consolidated Financial Reporting System (CFRS)	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.
Financial Business Intelligence System (FBIS)	FBIS is the financial enterprise 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 provides 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 enables executives, managers, and operational end users to make informed business decisions to support their organization's mission.

Relevant Legislation and Guidance

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

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 continues to make significant progress in each of the following key strategic areas.

Financial Systems Modernization

- *Strategy*: HHS began FSIP by successfully completing foundational projects that included a major core financial system upgrade and transition of key financial systems to a cloud service provider for hosting and application management. With those major initiatives completed successfully, HHS is now directing resources towards incrementally improving the efficiency and effectiveness of the modern financial system. Taken together, the design of these projects will significantly mature the HHS financial systems environment, offering benefits that 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.

- *Progress*: While the Department focused FY 2017 efforts on strengthening the financial system security and control environment, FY 2018 modernization projects concentrated on improving system capabilities. Core financial system instances were successfully upgraded to the latest version of their COTS software (Oracle E-Business Suite 12.2.6/7) – reducing the cost and effort required to maintain systems by ensuring continued vendor support and also addressing multiple existing defects from the previous E-Business Suite

version, as well as improving business user productivity by eliminating workarounds and effort required for HHS to develop custom solutions. HHS also made significant progress implementing a long-term solution for *Digital Accountability and Transparency Act of 2014* (DATA Act) reporting, coordinating extensively across the financial, acquisition, and grants management and systems communities to develop a more sustainable, system-based approach for connecting data across systems. When complete, this solution will enable the Department to reliably and efficiently connect financial data to corresponding data in grants, financial assistance, and acquisition systems, including both future awards and historical records. CFRS capabilities were also enhanced with multiple pieces of functionality added to improve the efficiency of the financial statement development process. This included automating processes to load files and configure data, reducing the demand on resources during quarter and year-end; as well as developing solutions to eliminate the need for downstream manual processing and improve auditability of the system. Maturing the financial system infrastructure, applications, and security controls has provided HHS with a strong foundation. Current FSIP projects – such as planning for implementation of a Department-wide electronic invoicing solution – build on this foundation, improving business functionality, and enhancing the effectiveness and efficiency of the Department's financial management capabilities.

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 sustainably meet evolving information demands for fiscal accountability, performance improvement, and external compliance requirements.

- *Progress*: Since first deployed in FY 2012, FBIS has been providing operational and business intelligence to users across the HHS financial management community. FBIS offers accurate, consistent, near real-time data from UFMS and NBS (together comprising five of HHS's six Accounting Centers) and summary data from HIGLAS, supporting over 1,500 users across the Department. In FY 2018, key accomplishments included developing new, insight-driven FBIS reports and dashboards: (1) an Accounts Payable Dashboard provides users a central location to draw intuitive insights on payables performance and throughput, enabling prioritization and timely intervention; (2) a Central Accounting Reporting System Reconciliation and Reclassification Dashboard consolidates and aggregates reconciled/reclassified data from the financial system, enabling users to validate that transactions are reconciled by Schedule Numbers and Treasury Account Symbols (TAS), immediately see any discrepancies, and take action, as needed, to resolve issues; and (3) a Control Monitoring Dashboard extends the FY 2017 UFMS security redesign and strengthens segregation of duties controls implemented. FBIS is also playing a central role in the Department's DATA Act long-term solution, consolidating financial files from UFMS, NBS, and HIGLAS and integrating acquisition and financial assistance files (i.e., Files D1 and D2, respectively) to enable more efficient analysis and reporting. As FBIS continues to expand to include new users and business domains, HHS also focuses on optimizing the underlying solution architecture to improve performance and take full advantage of the cutting-edge capabilities of the FBIS commercial cloud hosting environment.

Systems Policy, Security, and Controls

- *Strategy*: The reliability, availability, and security of HHS's financial systems are of paramount importance. HHS places a high-priority on enhancing its financial systems security and controls environment,

strengthening policy, proactively monitoring emerging issues, and ensuring progress toward remediating identified weaknesses. HHS continues to implement a comprehensive, enterprise-wide financial systems policy, security, and controls program to mature and decrease risk across the environment.

- *Progress*: HHS strengthens its security and control environment by analyzing internal and external audit findings, identifying root causes, and implementing solutions collaboratively. Based on the significant progress made in recent years, in FY 2018 HHS refined its overall strategy to strengthen oversight, improve risk management, and enhance information and communication. Persistent weaknesses are being addressed with fewer than 5 percent of open Federal Information System Controls Audit Manual (FISCAM) findings aged 3 years or more. Targeted efforts are continuing to further reduce risk across the financial management systems portfolio as the annual closure rate of findings in high-risk control areas (access controls, configuration management, and segregation of duties) continues to increase year-over-year. Initiatives in FY 2018 significantly matured the Department-wide security and control environment, with system owners having completed corrective actions for 87 percent of FISCAM weaknesses identified in the prior year (FY 2017) audit. Beyond simply tracking closure of individual weaknesses to assess progress, HHS also developed a comprehensive management framework – including evaluation criteria and target measurements – to better inform HHS leadership and other stakeholders of overall progress made, the current maturity level of the security and control environment, and the associated level of risk. The FY 2018 assessment highlights HHS's demonstrated year-over-year progress since FY 2015 in remediating control deficiencies, institutionalizing governance and oversight, and strengthening the IT controls environment – providing management a holistic view of HHS's security and control posture, as well as aggregating data to substantiate assurances.

  To lead and sustain these efforts, in FY 2015 the Financial Management Governance Board (FGB) chartered the IT Material Weakness Working Group (MWWG), with members from OpDiv CFO, Chief Information Officer (CIO), and Chief Information Security Officer Communities. The IT MWWG meets monthly and is executing against its planned 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 is managing a portfolio of projects to address and minimize vulnerabilities and risks related to data and system security, access management, configuration management, and segregation of duties.

Governance

- *Strategy*: The Department established the FGB as an executive-level forum to address enterprise-wide issues, including those related to financial management policies and procedures, financial data, and technology. In addition, the board serves in an advisory capacity on Departmental-wide initiatives that may have a financial management impact. 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 and HHS mandates and priorities.

- *Progress*: The FGB convenes monthly to facilitate executive-level oversight of financial management-related areas. Its role and impact continues to grow since its inception 5 years ago. 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, acquisitions, grants, human resources, 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. Beyond improving collaboration and strengthening oversight across HHS's financial management and systems environment, the FGB serves as an advisory body, providing actionable recommendations to support project teams and guide future initiatives. Recent areas of focus have included key initiatives and federal mandates, such as the continued modernization of the Department's financial accounting systems, the implementation of the DATA Act interim and long-term solutions, and efforts to continuously enhance governance throughout the enterprise. Additionally, the Board anticipates focusing on key topics that will inform strategic planning and enable the HHS financial management community to effectively address evolving opportunities and challenges – this includes supporting the PMA CAP Goals, as well as the *ReImagine* HHS effort.

Program Management

- *Strategy*: To support FSIP and FBIP, HHS established a Department-wide financial systems 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 federal project managers, contractors, and federal contracting officers representing NBS, UFMS, and HIGLAS, that fosters communication and implementation of program and project management best practices.

- *Progress*: Department-wide program management and the Financial Systems Consortium continue to play critical roles in support of major system enhancements. In FY 2018, this included completing technical financial system upgrades, supporting planning and implementation of the DATA Act long-term solution, enhancing FBIS, and developing standards for project management and execution. Within this program management framework, project teams are able to share industry best practices, lessons learned, and risks identified, while minimizing overall costs. As the Department's business needs evolve, the Enterprise Program Management Office and the Financial Systems Consortium continue to mature and support ongoing 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 an established framework to continuously identify 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 implementation of a Department-wide Accounting Treatment Manual; 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 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.

Legal Compliance

Antideficiency Act

The *Antideficiency 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 on GAO - ADA.

HHS management is taking necessary steps to prevent 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, HHS is working through investigations and further assessment where necessary. HHS remains fully committed to resolving these matters appropriately and complying with all aspects of the law.

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, or the recipient uses the funds in an improper manner. In addition, when an agency's review is unable to discern whether a payment was proper as a result of insufficient or lack of documentation, this payment should also be considered an error. 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 for improper payments in high risk programs, and develop and implement corrective action plans for high risk programs. HHS works 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 has taken many corrective actions to prevent and reduce improper payments in our programs. In compliance with the IPIA as amended, HHS completed 22 improper payment risk assessments in FY 2018 (representing risk assessments of programs and charge cards) and determined that these programs were not susceptible to significant improper payments. In addition, HHS is publishing improper payment estimates and associated information for seven high risk programs in this year's AFR, of which six programs reported lower improper payment rates in FY 2018 compared to FY 2017. Lastly, HHS also utilizes the Do Not Pay portal to check payments and awardees to identify potential improper payments or ineligible recipients. In FY 2018, HHS screened more than $436.9 billion in Treasury-disbursed payments through the Do Not Pay portal; HHS identified only two improper payments. A detailed report of HHS's improper payment activities and performance is presented in the "Other Information" section of this AFR, under "Payment Integrity Report."

Patient Protection and Affordable Care Act

The *Patient Protection and Affordable Care Act* (PPACA) established Health Insurance Exchanges through which qualified individuals and qualified employers can purchase health insurance coverage. Many individuals who enroll in Qualified Health Plans through individual market Health Insurance Exchanges are eligible to receive a premium tax credit (PTC) to reduce their costs for health insurance premiums. PTCs can be paid in advance directly to the consumer's Qualified Health Plan insurer. Consumers then claim the PTC 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 on this process.

The PPACA also included provisions that address fraud and abuse in health care by toughening the sentences for perpetrators of fraud, employing enhanced screening procedures, and enhancing the monitoring of providers. These authorities have facilitated the government's efforts to reduce improper payments. For detailed information on improper payment efforts, see the "Other Information" section of this AFR, under "Payment Integrity Report."

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 government-wide data standards for developing and publishing reports, and to make more information, including award-related data, available on USAspending.gov. Among other goals, the DATA Act aims to improve the quality of the information on USAspending.gov, as verified through regular reviews of posted data, and to streamline and simplify reporting requirements through clear data standards.

Under the DATA Act, HHS is required to generate a group of files, each in accordance with the DATA Act Information Model Schema, set by Treasury as the reporting data standards. These files include those generated from HHS systems and those generated by Treasury's DATA Act Broker on our behalf for procurement and financial assistance activity. Financial and award files are subject to validations within the Treasury submission system to ensure alignment with the intent of the rules in place at the time of the submission. In addition, HHS conducts a series of reconciliations, validations, and reasonableness tests to ensure the completeness, accuracy, and timeliness of the files submitted for Treasury validations.

Since May 2017, HHS has successfully submitted financial and award-level data for quarterly certification to Treasury's DATA Act Broker. The submissions to date have largely been successful due to the highly efficient, but manual, interim solution as the system configurations to include award data in the financial system are not yet in production. Not only are the quarterly submissions consistently over $300 billion in award-level obligations, but using the interim solution, HHS has reconciled up to 99.9 percent of the financial records to the award records. The legislatively-required DATA Act audit over the second quarter (Q2) FY 2017 submission yielded a 0 percent error rate on sampled records. HHS's OIG conducted a voluntary follow-on audit over the Q2 FY 2018 submission to ensure consistency and promote continuous improvement. The Department looks to transition to the long-term solution by Q2 FY 2019. This integrated solution will leverage the Department's system capabilities – such as business intelligence and analytics in its FBIS – to streamline the reporting process and enable HHS's financial stewards to allocate more focus to analysis and management.

In addition to compliance with the original legislation and subsequent guidance from OMB over the DATA Act, a revised Appendix A to Circular A-123 was released in June 2018. The revised Appendix was accompanied with a cover letter that requires DATA Act reporting agencies to create Data Quality Plans. Consideration of this plan must be included in agencies' existing annual assurance statement for internal controls over reporting beginning in FY 2019 and continuing through the assurance statement covering FY 2021 at a minimum, or until agencies determine that they can provide reasonable assurance over the data quality controls that support achievement of the reporting objectives in accordance with the DATA Act. HHS's Data Quality Plan was finalized on October 1, 2018, and contains the framework and methodology for executing the plan in accordance with preliminarily specified milestones. HHS will update the plan in accordance with continuous monitoring activities and the results of quality assessments of HHS spending data.

Federal Information Technology Acquisition Reform Act

The *Federal Information Technology Acquisition Reform Act* (FITARA), enacted on December 19, 2014, established an enterprise-wide approach to federal IT investments and provides the 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.

In June 2017, HHS policy leadership set forth the vision for Department-wide collaboration to improve HHS's implementation of FITARA and its rating against the House Oversight and Government Reform Committee's FITARA scorecard. Recognizing HHS's May 2017 "D-" score was a foundation that provided ample opportunity for growth, HHS embraced a framework of data, dialogue and delivering real change to engage cross-community stakeholders inside and external to the Department, to strengthen understanding of FITARA requirements and ensure more robust implementation of the law. HHS's "A by May" Initiative delivered four "A's" and one "C" against the FITARA 5.0 scorecard metrics and changed the way IT, acquisition, financial, and programmatic communities viewed the value and importance of the law. The May 2018 FITARA 6.0 Scorecard gave HHS a numeric score of 3.33; its final grade was downgraded due to the CIO's reporting relationship to the Secretary and Deputy Secretary.

Fraud Reduction and Data Analytics Act of 2015

The Department continues to engage in various fraud reduction efforts, including activities to meet the requirements under the *Fraud Reduction and Data Analytics Act of 2015* (FRDAA). Since FRDAA's enactment in 2016, HHS has participated in the required OMB-led interagency working group. As part of this working group, HHS worked in FY 2018 to develop a fraud taxonomy that agencies can use to identify potential fraud vulnerabilities. Also in FY 2018, HHS participated in other interagency discussions around disaster recovery and fraud risk management. These meetings shared best practices and relevant, real-time information to assist agencies in identifying and preventing fraud among recent disaster recovery funding. In addition, HHS worked with the Government Accountability Office (GAO) on a government-wide review of FRDAA implementation (GAO's review is examining policies and procedures that agencies have implemented, and challenges that agencies face in implementing the law), and with the Department of the Treasury on the development of the Program Integrity Antifraud Playbook. HHS will continue working with OMB and other agencies to implement FRDAA and to further advance fraud risk management activities.

HHS continues to take steps, at both the Department and OpDiv/StaffDiv levels, to implement FRDAA, and to adopt leading practices in fraud risk management, as presented in GAO's *Fraud Risk Management Framework and Selected Leading Practices* published in July 2015. Select fraud risk management activities at the Department include:

- HHS is drafting a Fraud Risk Management Implementation Plan that outlines actions taken or planned in order to enhance financial and administrative controls relating to fraud. HHS expects to complete this implementation plan in FY 2019;
- In accordance with the law and OMB Circular A-123, *Management's Responsibility for Enterprise Risk Management and Internal Control*, HHS's internal control assessments include the consideration of fraud and financial management risks, as well as the control activities designed to mitigate these risks;
- Starting in FY 2018, HHS's improper payment risk assessments also include consideration of fraud risk in individual programs or payment activities, and HHS is working to analyze the data; and
- HHS continually reviews and updates its financial policies, and provides relevant and timely training sessions. For example, in FY 2018 HHS began a monthly Training and Enrichment Webcast Series on grants and acquisitions and included trainings specific to fraud (e.g., "Fraud and Civil Monetary Penalties" as it pertains to grant awards and "Suspension and Debarment" for all awards).

HHS OpDivs and StaffDivs generally manage fraud risk within other scopes of responsibility (e.g., yearly internal control reviews and audits; reviews of allegations involving misuse of grant or contractor funds, conflicts of interest, or other misconduct or misuse cases; continuous monitoring of grant recipients [audit resolution,

special conditions/drawdown restrictions, site visits, performance reports, etc.]; the use of SAM.gov [e.g., Do Not Pay/Suspension and Debarment]); and other activities. Some specific efforts at one Division are described below:

- Following the GAO's Fraud Risk Framework, CMS assessed the federally facilitated exchange's fraud risk in FY 2017, as recommended by GAO. In FY 2018, CMS initiated a fraud risk assessment for some programs in Medicare, including the Medicare Diabetes Prevention Program expanded model. CMS is also continuing to draft Fraud Risk Profiles for four other areas, including: (1) the Comprehensive End Stage Renal Disease Care model; (2) the Comprehensive Primary Care Plus model; (3) the permanent Medicare Shared Savings Program; and (4) the new Medicare Beneficiary Identifier. CMS is also assessing the Quality Payment Program, established by the *Medicare Access and CHIP Reauthorization Act of 2015* (MACRA), utilizing the GAO fraud risk assessment. The fraud risk assessments will help HHS identify vulnerabilities in CMS's programs and payment systems, and develop mitigation strategies to proactively help reduce the risk of fraud. Lastly, CMS is developing a training video, module, and curriculum to train staff agency-wide on fraud risks.

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 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 government-wide requirements. Section 2 of FMFIA outlines compliance with internal control requirements, while Section 4 dictates conformance with systems requirements. Additionally, agencies must report any identified material weaknesses and provide a plan and schedule for correcting the weaknesses.

In September 2014, GAO released an updated edition of its Standards for 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 revised 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 Enterprise Risk Management. The Department, with its OpDiv and StaffDiv stakeholders, are working together to implement these 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 Enterprise Risk Management. Based on thorough ongoing internal assessments and FY 2018 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 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 is also continuing to make progress toward adopting Enterprise Risk Management and integrating with 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 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 2018 OMB Circular A-123 assessment 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. Based on the results of this assessment, HHS provides reasonable assurance that its overall financial management systems substantially comply with the FFMIA.

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.

Management Assurances

Statement of Assurance

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 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 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, 2018, with the exception of 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 noncompliance related to the Medicare appeals process, as described in the "Corrective Action Plans" 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.

/Alex M. Azar II/

Alex M. Azar II
Secretary
November 14, 2018

Summary

1. Error Rate Measurement

HHS has identified one process limitation relating to the Temporary Assistance for Needy Families (TANF) program that results in a material noncompliance with IPIA. HHS identified this process limitation in a prior year and it continues to exist in FY 2018. The TANF program is unable to report an error rate for FY 2018 due to statutory limitations precluding HHS from requiring states to participate in a TANF improper payment measurement.

2. Medicare Appeals Process

Several factors, including the growth in Medicare claims – partially driven by the aging population – 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 contemplated time frames.

From FY 2010 through FY 2018, the HHS Office of Medicare Hearings and Appeals (OMHA) and the HHS Departmental Appeals Board (DAB) experienced a large increase in the number of Medicare related appeals received. As a result, at the end of FY 2018, 417,198 appeals were waiting to be adjudicated by OMHA and 17,863 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 continuing ongoing administrative actions (and without any additional appeals), it would take 4 years for OMHA and 8 years for the DAB Medicare Appeals Council to process their respective backlogs.

Corrective Action Plans

1. Error Rate Measurement

Since TANF is a state-administered program, corrective actions to reduce improper payments would be implemented at the state level. Since HHS cannot require states to participate in a TANF improper payment measurement, the Department is also unable to compel states to collect the required information to implement and report on corrective actions. Despite these limitations, HHS uses a multi-faceted approach to support states in improving TANF program integrity and preventing improper payments, including efforts such as: conducting and using results of a detailed risk assessment to mitigate payment risks at the federal level; promoting and supporting innovation using TANF data to better understand how states ensure program integrity; and monitoring compliance with the 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).

2. Medicare Appeals Process

HHS has a strategy to improve the Medicare appeals process through investing new resources at all levels of appeal to increase adjudication capacity and implement new strategies to alleviate the current backlog; taking administrative actions to reduce the number of pending appeals and encourage resolution of cases earlier in the process; and proposing legislative reforms that provide additional funding and new authorities to address the appeals volume.

HHS has undertaken, and continues to explore, new administrative actions expected to have a favorable impact on the Medicare appeals backlog. The *FY 2019 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. Based on projected impacts of current administrative actions, and the proposed funding increases and legislative actions outlined in the *FY 2019 President's Budget*, HHS projects that the backlog would be approximately 50,000 appeals by the end of FY 2021 and would be on a path to being resolved in subsequent years.

Financial Summary and Highlights

HHS received an unmodified audit opinion on the principal financial statements and notes[1] for the year ended September 30, 2018. This is the 20th year for an unmodified opinion. HHS takes pride in the preparation of the 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 principal financial statements, which include the Consolidated Balance Sheets, Consolidated Statements 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. HHS presents these in the "Financial Section" of this report. 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 readers in establishing the relevance of the financial statements to the operations of HHS.

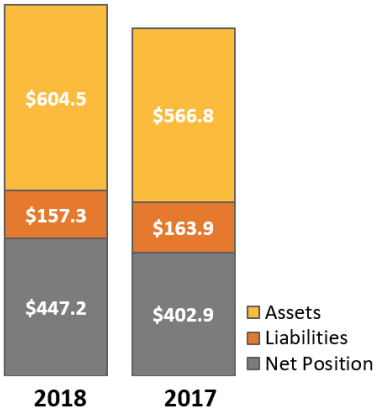
As a federal entity, HHS's financial position and activities are significant to the government-wide statements. Based on the *FY 2017 Financial Report of the United States Government*, HHS's net operating cost was larger than any single agency across the entire federal government[2]. A similar relationship exists within HHS, where the Department is significantly represented by one OpDiv, CMS. CMS alone consistently stewards the largest share of HHS's 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 HHS (Net Position). The table below summarizes the major components of the FY 2018 and FY 2017 year-end balances of HHS's assets available for use, the liabilities owed by HHS, and the equity retained by HHS.

Financial Condition Summary
(In Billions)

	2018	2017	$ Change (2018-2017)	% Change (2018-2017)
Fund Balance with Treasury	$ 250.2	$ 209.8	$ 40.4	19%
Investments, Net	307.1	275.5	31.6	11%
Accounts Receivable	27.9	34.0	(6.1)	(18)%
Advances	2.9	31.1	(28.2)	(91)%
Other Assets	16.4	16.4	-	-%
Total Assets	**$ 604.5**	**$ 566.8**	**$ 37.7**	**7%**
Accounts Payable	$ 2.0	$ 1.3	$ 0.7	54%
Entitlement Benefits Due and Payable	99.1	108.3	(9.2)	(8)%
Accrued Liabilities	14.5	11.9	2.6	22%
Federal Employee and Veterans' Benefits	14.4	13.5	0.9	7%
Other Liabilities	27.3	28.9	(1.6)	(6)%
Total Liabilities	**$ 157.3**	**$ 163.9**	**$ (6.6)**	**(4)%**
Net Position	**$ 447.2**	**$ 402.9**	**$ 44.3**	**11%**
Total Liabilities and Net Position	**$ 604.5**	**$ 566.8**	**$ 37.7**	**7%**



[1] Due to the uncertainty of the long-range assumptions used in the Statement of Social Insurance model, the auditors were not able to express an opinion on the Statement of Social Insurance, the Statement of Changes in Social Insurance Amounts, and associated footnotes.
[2] HHS's net cost is 24 percent of the federal government's total costs, Social Security Administration's net cost is 22 percent, Department of Defense's net cost is 15 percent, Department of Veterans Affairs's net cost is 11 percent, and Treasury's Interest on Treasury Security Held by the Public's net cost is 6 percent. All remaining agencies combined only represent 22 percent. Source: *FY 2017 Financial Report of the United States Government* fiscal.treasury.gov/fsreports/rpt/finrep/fr/fr_index.html

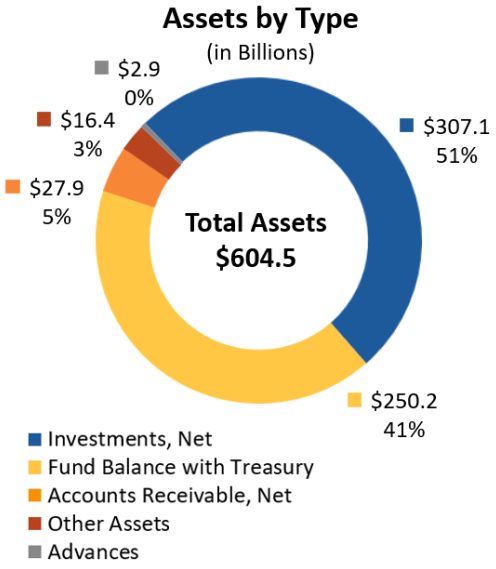
Assets

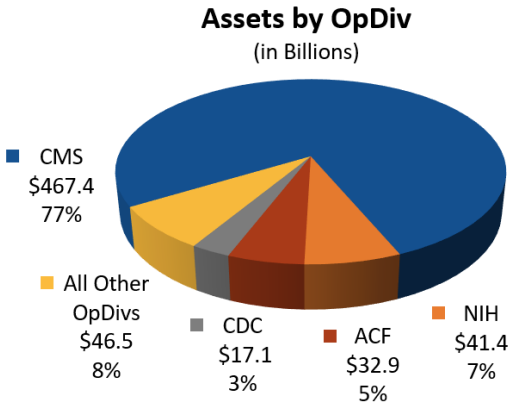
The total Assets for HHS were $604.5 billion at year-end, representing the value of what HHS owns and manages. This is an increase of approximately $37.7 billion or 7 percent over September 30, 2017. Fund Balance with Treasury (FBwT) and Investments, Net comprise $557.3 billion or 92 percent of HHS's total assets, which increased $72.0 billion or 15 percent.

The FBwT line contains the largest net change between FY 2018 and FY 2017 with a $40.4 billion or 19 percent increase. This primarily consists of a $20.6 billion increase in Medicaid due to the FY 2017 return on indefinite authority was higher, $6.0 billion in CHIP due to the Child Enrollment Contingency fund not yet invested, $3.7 billion for Child Care Program and Children and Family Services, $1.5 billion for Substance Abuse Treatment program, $1.2 billion for collections in risk adjustment program and the Market User Fees under the PPACA, and $0.9 billion for National Institute of Aging.

Investments had an increase of $31.6 billion mostly due to CMS increases in Supplementary Medical Insurance (SMI) of $27.7 billion and Medicare Hospital Insurance (HI) of $4.9 billion. These increases are offset by $1.1 billion in the *Children's Health Insurance Program Reauthorization Act* contingency, the available funds were not invested at the end of the FY 2018.

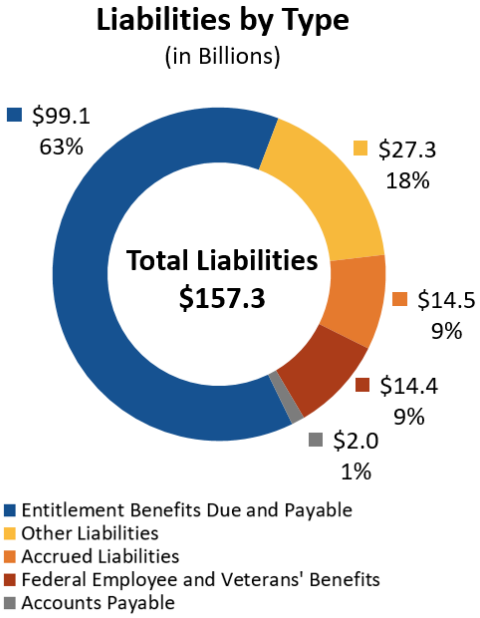
The HHS "Assets by OpDiv" chart demonstrates asset distribution within HHS, excluding eliminations. The OpDiv asset balances ranged from $344.6 million at AHRQ (shown in All Other OpDivs) to $467.4 billion at CMS. CMS had the largest percentage and dollar value asset increases at $23.2 billion or 5 percent over FY 2017 mostly due to the changes in FBwT and Investments, Net mentioned above.

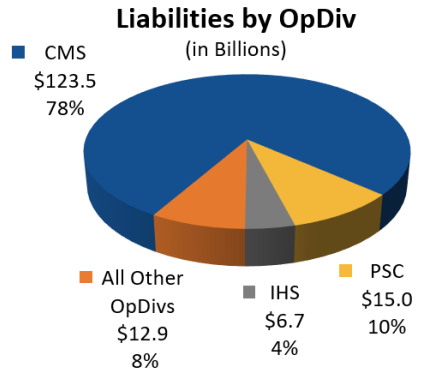




Liabilities

The total Liabilities for HHS were $157.3 billion at year-end, representing the amounts HHS owes from past transactions or events. This is a decrease of approximately $6.6 billion or 4 percent over September 30, 2017. The majority of the decrease is in the Entitlement Benefits Due and Payable line. This decrease of $9.2 billion or 8 percent from FY 2017, is based on the HHS's position that the agency's obligation for the Risk Corridors program was limited to the sum of payments that were made into the program of $12.3 billion. This position has been upheld by the courts in *Moda Health Plan, Inc. v. United States*, 892 F.3d 1311, 1323, 2018 U.S. App. LEXIS 16028, *23-24. This decrease is offset by increases in HI of $1.5 billion, and Medicaid of $1.5 billion.

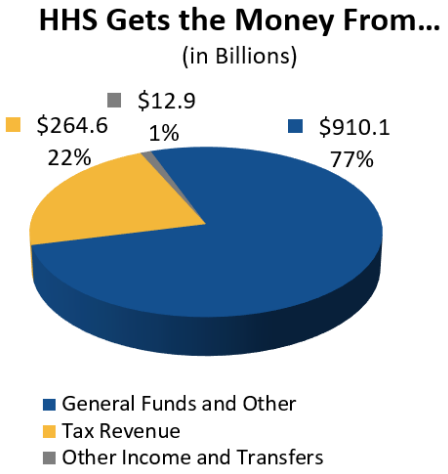




The HHS "Liabilities by OpDiv" chart shows liability distribution within HHS, excluding eliminations. The OpDivs with the largest and smallest asset balances are also the OpDivs with the largest and smallest liabilities. With the majority share, CMS reports $123.5 billion or 78 percent of the HHS liabilities, while AHRQ (shown in All Other OpDivs) has liabilities of $30.2 million. IHS had the largest OpDiv dollar value increase in liabilities over FY 2017 of $3.9 billion.

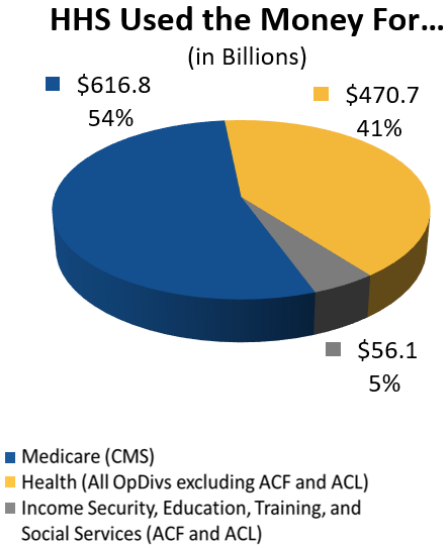
Statement of Changes in Net Position

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 the HHS Consolidated Balance Sheets. This is also represented as the difference between assets and liabilities.



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

HHS receives the majority of the funding through Congressional appropriations and reimbursement for the provision of goods or services to other federal agencies. The "HHS Gets the Money From…" chart shows the largest financing source, General Funds and Other, increased since FY 2017 by $94.8 billion or 12 percent. The fluctuations in tax revenue of $4.9 billion or 2 percent is related to the *Federal Insurance Contributions Act* (FICA) and *Self Employed Contributions Act* (SECA).



Statements of Net Cost

The Consolidated Statements of Net Cost represents how HHS spent the money. This can also be stated as the difference between the costs incurred by HHS's programs less associated revenues. The Net Cost of Operations for the year ended September 30, 2018, totaled approximately $1.1 trillion. The "HHS Used the Money For …" chart shows consolidating 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.

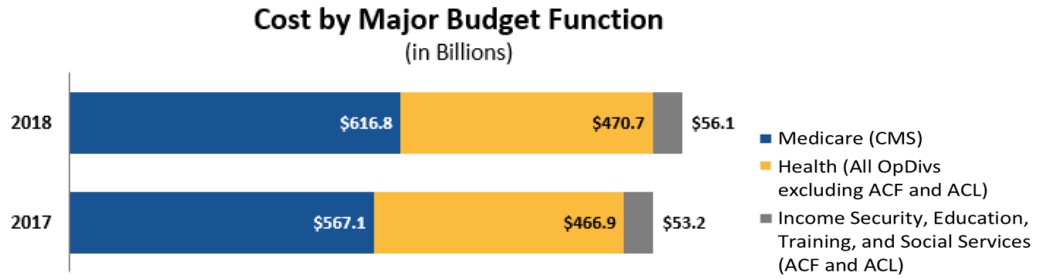
[3] Totals in the chart are exclusive of Intra-HHS eliminations from the Consolidating Statement of Net Cost by Budget Function. This statement can be found in Section III, Other Information.

The table below presents FY 2018 Consolidated Net Cost of Operations, which breaks costs into Responsibility Segments between CMS and the remaining OpDivs in Other Segments. Net cost for CMS increased by $45.4 billion or 5 percent over FY 2017. The majority of this increase relates to SMI expenses of $44.9 billion, which includes $29.3 billion in benefit expenses, $15.0 billion in Part D benefit expenses. HI and Medicaid expenses also increased by $15.3 billion and $10.7 billion, respectively. These expenses are offset by SMI premium of $10.7 billion. Additionally, as noted, the Risk Corridor program costs decreased by $12.3 billion. There was an increase in total Net Cost of Operations for the remaining HHS segments at $11.1 billion or 9 percent over FY 2017.

Net Cost of Operations
(in Billions)

	2018	2017	$ Change (2018-2017)	% Change (2018-2017)
Responsibility Segments:				
CMS Gross Cost	$ 1,115.2	$ 1,060.8	$ 54.4	5%
CMS Exchange Revenue	(106.3)	(97.3)	9.0	9%
CMS Net Cost of Operations	$ 1,008.9	$ 963.5	$ 45.4	5%
Other Segments:				
Other Segments Gross Cost	$ 140.2	$ 128.3	$ 11.9	9%
Other Segments Exchange Revenue	(5.8)	(5.0)	0.8	16%
Other Segments Net Cost of Operations	$ 134.4	$ 123.3	$ 11.1	9%
Net Cost of Operations	**$ 1,143.3**	**$ 1,086.8**	**$ 56.5**	**5%**

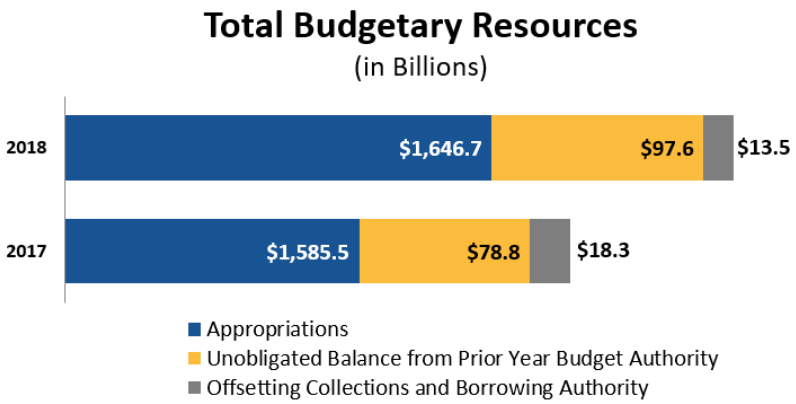
HHS classifies costs by major budget functions such as Medicare, Health, Income Security, and Education, Training, and Social Services. This is shown on the Consolidating Statement of Net Cost by Budget Function in the "Other Information" section of this report. The graph below shows the two-year cost trends for these major budget functions[4]. In FY 2018, total net costs for Medicare of $616.8 billion and Health of $470.7 billion account for 95 percent of HHS's annual net costs.



Statement of Budgetary Resources

The Combined Statement of Budgetary Resources displays the budgetary resources available to HHS throughout FY 2018 and FY 2017, and the status of those resources at the fiscal year-end. The primary components of HHS's resources, totaling approximately $1.8 trillion for FY 2018, are appropriations from Congress, resources not yet used from previous years (unobligated balances from prior year budget authority), and spending authority from offsetting collections and borrowing authority. This represents an increase of $75.2 billion or 4 percent, over FY 2017. The following graph highlights trends in these balances over the past two 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 is primarily related to increases in Medicaid of $20.7 billion, SMI of $16.3 billion, and Payments to the Trust Funds of $14.1 billion. For further details, see the Combining Statement of Budgetary Resources in the "Financial Section" of this report.

The increase of $18.8 billion in unobligated balance from prior year budget authority is primarily due to changes in unobligated balance of $41.2 billion reflecting an increase in Payment to the Trust Fund for repayment made in FY 2018 for the Federal Matching SMI Repayment Loan that was established in FY 2016 and an increase in Medicaid for the refund collections on PY Medicaid grant awards from the states. These increases are offset by the unobligated balance brought forward from prior year balance decrease of $22.9 billion.

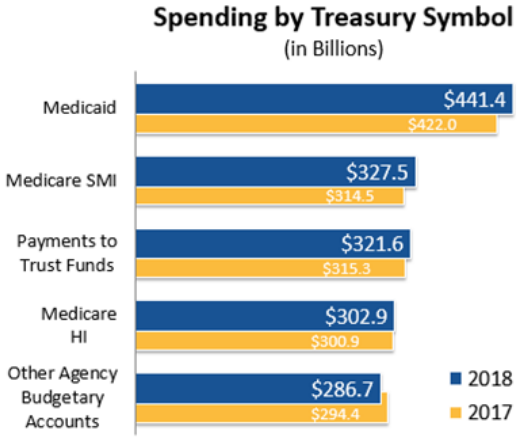
Schedule of Spending

HHS has elected to present the trends in spending in the audited notes to the principal financial statements titled, Combined Schedule of Spending. The chart below illustrates spending as of September 30, 2018, and 2017 for the top four 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 2018 were approximately $1.7 trillion or 2 percent increase over FY 2017.

The HHS'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 83 percent of HHS total obligations.

As the American public will soon be able to see more clearly on the USAspending.gov website, the majority of HHS spending was made through Grants, Subsidies, and Contributions at $840.7 billion or 50 percent. HHS is the largest grant-making agency in the federal government. Additionally, HHS has incurred obligations for Insurance Claims and Indemnities totaling $707.3 billion or 42 percent. HHS classifies obligations by items or services provided into categories known as object classes. For more information refer to Note 21, Combined Schedule of Spending in the "Financial Section" of this report.



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.

Did you know?

Health care is taking up an increasing share of the U.S. economy, and by 2026 the CMS Office of the Actuary projects that one in every five dollars spent in America will be spent on health care.

Actuarial present values are computed under the intermediate set of assumptions specified in the *2018 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds* (Trustees Report).

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) decreased from $(3.5) trillion, determined as of January 1, 2017, to $(4.7) trillion, determined as of January 1, 2018.

Including the combined HI and SMI Trust Fund assets increases the present value, as of January 1, 2018, the future cash flow for all current and future participants was $(4.4) trillion for the 75-year valuation period. The comparable closed group of participants, including the combined HI and SMI Trust Fund assets, is $(11.6) 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, 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 77 percent at the beginning of FY 2014 to 66 percent at the beginning of FY 2018.

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 2018 Trustees Report indicate that the HI Trust Fund is not adequately financed over the next 10 years. Under the intermediate assumptions of the 2018 Trustees Report, the HI Trust Fund ratio is estimated to decline steadily until the fund is depleted in calendar year 2026. Assets at the end of calendar year 2017 were $202 billion and are expected to decrease steadily until depleted in 2026.

Trust Fund Ratio Beginning Fiscal Year

FY	HI
2014	77%
2015	73%
2016	67%
2017	66%
2018	66%

Long-Term Financing

The short-range outlook for the HI Trust Fund has deteriorated compared to what was projected last year. The trust fund ratio declines until the fund is depleted in 2026, three years earlier than the date projected last year. HI financing is not projected to be sustainable over the long term with the projected tax rates and expenditure levels. 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 91 percent in 2026 to 78 percent in 2042 and then to increase to about 85 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 2017 to about 2.1 by 2092. In addition, health care costs continue to rise faster than the taxable wages used to support the program. In present value terms, the 75-year shortfall is $4.5 trillion, which is 0.8 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.

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 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. 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 $(33.0) 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 2017, SMI expenditures were 2.1 percent of GDP. By 2092, SMI expenditures are projected to grow to 3.9 percent of the GDP.

The following table presents key amounts from CMS's basic financial statements for fiscal year 2016 through 2018.

Table of Key Measures[5]

	2018	2017	2016
Net Position (end of fiscal year)			
Assets	$ 467.3	$ 444.2	$ 446.0
Less Total Liabilities	123.5	137.5	137.3
Net Position (assets net of liabilities)	$ **343.8**	$ **306.7**	$ **308.7**
Costs (end of fiscal year)			
Net Costs	$ 1,009.1	$ 963.3	$ 953.1
Total Financing Sources	1,017.7	984.6	960.1
Net Change in Cumulative Results of Operations	$ **8.6**	$ **21.3**	$ **7.0**
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 (as of 1/1/2018)	$ (4,708)	$ (3,532)	$ (3,822)
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 (as of 1/1/2017)	$ (3,532)	$ (3,822)	$ (3,187)
Change in Present Value	$ **(1,176)**	$ **290**	$ **(636)**

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, 2018, decreased by $168 billion due to advancing the valuation date by one year and including the additional year 2092, by $921 billion due to changes in projection base, and by $535 billion due to

[5] 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, CMS presents the closed group measure and open group measure.

change in legislation. However, the present value increased due to changes in demographic assumptions, and economic and health care assumptions, by $434 billion and $14 billion, respectively.

Required Supplementary Information

As required by Statement of Federal Financial Accounting Standards (SFFAS) 17, *Accounting for Social Insurance* (as amended by SFFAS 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 Trustees Report, 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 HHS's financial position and results of operations, pursuant to the requirements of 31 U.S.C. §3515(b). Although the statements have been prepared from HHS's 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.

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Financial Section

2

In This Section

- Message from the Acting 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 Acting Chief Financial Officer

I am proud to join the Secretary in issuing our Fiscal Year (FY) 2018 Agency Financial Report. For the 20th consecutive year, we received an unmodified (clean) audit opinion on our financial statements from our independent auditors. We provide stewardship and accountability of funds across HHS, by developing financial management policies and procedures, establishing and overseeing internal controls, and producing high-quality financial and managerial reports.

For the first time since 1996, the Department has no auditor-reported material weaknesses. The Department spearheaded an integrated multi-year strategy to mature our financial systems security and controls environment, resulting in the resolution of the long-standing material weakness related to Information System Controls and Security. While the auditors downgraded this material weakness to a significant deficiency, we will continue to strengthen our control environment by resolving deficiencies as quickly as possible through risk-based corrective action plans.

For the fifth consecutive year, HHS's financial report received the Association of Government Accountants' *Certificate of Excellence in Accountability Reporting*. Federal financial reports must pass a rigorous independent review against a comprehensive set of standards to earn this prestigious recognition, which is the highest award bestowed for federal financial reporting.

Our Chief Financial Officer (CFO) community is dedicated to collaboratively improving Department-wide operations. This year, our CFO Community developed the HHS CFO Community Strategic Plan for FY 2018-2022. This Strategic Plan has five core values: Accountability, Collaboration, Excellence, Integrity, and Transparency; and sets our HHS CFO priorities for the upcoming years. Furthermore, the Strategic Plan aligns with and supports the HHS Strategic Plan FY 2018-2022.

HHS's achievements illustrate the remarkable effort and dedication of our employees and partners. We will continue to serve as accountable and committed stewards supporting the Department's mission on behalf of the public.

/Jen Moughalian/

Jen Moughalian
Acting Assistant Secretary for Financial Resources and
Acting Chief Financial Officer
November 14, 2018

Report of the Independent Auditors

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201

November 14, 2018

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

FROM: /Gloria L. Jarmon/
Deputy Inspector General for Audit Services

SUBJECT: OIG Report on the Financial Statement Audit of the Department of Health and Human Services for Fiscal Year 2018 (A-17-18-00001)

This memorandum transmits the independent auditors' reports on the Department of Health and Human Services (HHS) fiscal year (FY) 2018 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, 2018 and 2017, 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 sustainability statements that comprise the statement of social insurance as of January 1, 2018, 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 19-01, *Audit Requirements for Federal Financial Statements.*

Results of the Independent Audit

Based on its audit, Ernst & Young found that the FY 2018 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. Ernst & Young was unable to obtain sufficient audit evidence for the amounts presented in the statements of social insurance as of January 1, 2018, 2017, 2016, 2015, and 2014, and the related statements of changes in social insurance amounts for the periods ended January 1, 2018 and 2017. As a result, 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 two 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 did not identify any deficiencies in internal control that it considered a material weakness. Ernst &Young noted improvements over internal controls but continued to identify two significant deficiencies related to HHS's Financial Information Systems and HHS's Financial Reporting Systems, Analyses, and Oversight, as described below.

Financial Information Systems—Ernst & Young noted that HHS had continued to make strides to improve information technology (IT) controls within its financial systems. HHS management continued to establish a governance model and was consistent in focusing on strengthening the maturity over HHS's IT controls. There has been a significant reduction in the number of high-risk internal control deficiencies noted in prior years that could affect financial reporting. Ernst & Young also noted that HHS continues to make improvements to its Managers' Internal Control Program, which has led to a focused and proactive remediation of higher risk issues related to IT controls. HHS management has also continued to make investments in key financial systems, which has led to the implementation of more robust automated controls that support material IT processes.

Even with these improvements and as in previous fiscal years, Ernst & Young identified control deficiencies related to segregation of duties, configuration management, and access to HHS systems that could affect HHS's financial statements. These deficiencies collectively constitute a significant deficiency in internal control.

- *Financial Reporting, Analysis and Reporting*—During the FY 2018 audit, Ernst & Young noted that HHS made significant progress in addressing certain issues that have impaired its ability to overcome significant deficiencies reported in prior years. HHS continued development of policies and procedures over financial processes, improved analyses to remediate data quality issues, and implemented processes to strengthen internal controls around manual journal entries at the National Institutes of Health.

  Although HHS made progress in these areas, the FY 2018 audit still identified a series of deficiencies in financial systems and processes for producing financial statements, including the lack of integrated financial management systems, antiquated processes that impacted journal entries to its financial and budgetary amounts, and insufficient analysis and oversight of certain significant accounts and programs. Ernst & Young specifically described concerns over the number and amount of nonstandard journal entries, Medicaid oversight, and the Statement of Social Insurance. Ernst & Young noted a significant number of non-standard journal vouchers are needed to record entries that cannot be recorded through routine processing in HHS Financial Systems. These entries are needed to ensure accurate account balances, but Ernst & Young noted that the volume and dollar value of them are a significant portion of HHS's overall financial activity.

For Medicaid Oversight, Ernst & Young noted the Centers for Medicare & Medicaid Services (CMS) had completed implementation of the Transformed-Medicaid Statistical Information System (T-MSIS), which modernizes the ways States submit operational data about beneficiaries, providers, health claims, and encounters. Since T-MSIS had just been completely implemented in June 2018, CMS still did not have reliable historical claims-level data, so data analysis using this information has been limited. CMS also still had not performed a claim-level detailed look-back analysis for the Medicaid Benefits Due and Payable to determine the reasonableness of various State calculations of unpaid claims that have not yet been reported as liabilities.

For the Statement of Social Insurance, Ernst & Young identified two formula errors in the spreadsheets used in the preparation of the statement. The two formula errors, one of which was significant, were not detected by CMS's monitoring and review function. Ernst & Young concluded that the control over the formula was not functioning as designed. These deficiencies collectively constitute a significant deficiency in internal control.

Ernst & Young identified several instances of noncompliance with laws and other matters. During FY 2018, 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 the Affordable Care Act[1] 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 three high priority programs, Medicaid, CHIP, and Foster Care, did not meet their FY 2018 target error rates. This 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 2018. HHS's management determined that it may have potential violations of the Anti-Deficiency Act (P.L. No. 101-508) related to an obligation of funds for conference spending at the Food and Drug Administration and certain contract obligations at HHS's Program Support Center occurring between FY 2006 and FY 2011. 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).

Evaluation and Monitoring of Audit Performance

In accordance with the requirements of OMB Bulletin 19-01, 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;

[1] 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.

- attending key meetings with auditors and HHS officials;
- monitoring the progress of the audit;
- examining audit documentation, including that related to the review of internal controls over financial reporting;
- reviewing the auditors' reports, and;
- reviewing the HHS *FY 2018 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 Carrie A. Hug, Assistant Inspector General for Audit Services, at (202) 619-3972 or through email at Carrie.Hug@oig.hhs.gov. Please refer to report number A-17-18-00001.

Attachment

Page 5—The Secretary

cc:
Jennifer Moughalian
Acting 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, 2018 and 2017, and the related consolidated statements of net cost and changes in net position, and the combined statements 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 sustainability financial statements, which comprise the statements of social insurance as of January 1, 2018, 2017, 2016, 2015, and 2014, the related statements of changes in social insurance amounts for the periods ended January 1, 2018 and 2017, and the related notes to the sustainability 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 statements of social insurance as of January 1, 2018, 2017, 2016, 2015, and 2014, the related statements of changes in social insurance amounts for the periods ended January 1, 2018 and 2017, 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 (OMB) Bulletin No. 19-01, *Audit Requirements for Federal Financial Statements*. Those standards and OMB Bulletin No. 19-01 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

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, 2018 and 2017, and the related consolidated statements of net cost and changes in net position, and the combined statements 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 22 to the 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. The sustainability financial statements are intended to aid users in assessing whether future resources will likely be sufficient to sustain public services and to meet obligations as they come due. The statements of social insurance and changes in social insurance amounts are based on income and benefit formulas in current law and assume that scheduled benefits will continue after any related trust funds are exhausted. The sustainability financial statements are not forecasts or predictions. The sustainability financial statements are not intended to imply that current policy or law is sustainable. 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 Children Health Insurance Program (CHIP) Reauthorization Act (MACRA).

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As further described in Note 23 to the financial statements, with respect to the estimates for the social insurance program presented as of January 1, 2018, 2017, 2016, 2015, and 2014, 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 23, the ability of health care providers to sustain these 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. Absent a change in the health care delivery system or level of update by subsequent legislation, beneficiaries' access to Medicare-participating providers and quality care may become significant issues in the long term under current law. Overriding the price updates in current law, 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. As a result of these limitations, we were unable to obtain sufficient audit evidence for the amounts presented in the statements of social insurance as of January 1, 2018, 2017, 2016, 2015, and 2014, and the related statements of changes in social insurance amounts for the periods ended January 1, 2018 and 2017.

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, 2018, 2017, 2016, 2015, and 2014, and the related changes in the social insurance program for the periods ended January 1, 2018 and 2017.

Opinion

In our opinion, the consolidated balance sheets, consolidated statements of net cost and changes in net position, and combined statements of budgetary resources referred to above present fairly, in all material respects, the consolidated financial position of HHS as of September 30, 2018 and 2017, and its net cost, changes in net position, and budgetary resources for the years then ended in conformity with U.S. generally accepted accounting principles.

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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 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.

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Other Reporting Required by Government Auditing Standards

In accordance with *Government Auditing Standards*, we also have issued our reports dated November 14, 2018, 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, contracts and grant agreements, and other matters. The purpose of those reports is solely 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 effectiveness of HHS' 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, 2018

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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 statement audits contained in *Government Auditing Standards* issued by the Comptroller General of the United States and Office of Management and Budget (OMB) Bulletin No. 19-01, *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, 2018, and the related consolidated statements of net cost and changes in net position, and the combined statement of budgetary resources for the fiscal year (FY) then ended, and the related notes to the principal financial statements, and we were also engaged to audit the sustainability financial statements, which comprise the statement of social insurance as of January 1, 2018, and the related statement of changes in social insurance amounts for the period ended January 1, 2018, and have issued our report thereon dated November 14, 2018. 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, 2018, and the related statement of changes in social insurance amounts for the period ended January 1, 2018.

Internal Control over Financial Reporting

In planning and performing our audit of the financial statements, we considered HHS' 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' internal control. We limited our internal control testing to those controls necessary to achieve the objectives described in OMB Bulletin No. 19-01. 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

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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 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 and, therefore, material weaknesses or significant deficiencies may exist that have not been identified. Given these limitations, during our audit we did not identify any deficiencies in internal control that we consider to be material weaknesses. However, material weaknesses may exist that have not been identified. We did identify certain deficiencies in internal control related to Financial Information Systems and Financial Systems, Analysis and Reporting, as described below, to be significant deficiencies.

Significant Deficiencies

Financial Information Systems

As a part of our procedures for the FY 2018 HHS financial statement audit, we noted that the Department continues to make strides to improve the controls within its supporting information technology (IT) financial systems. In particular, management has continued to establish a governance model and consistent tone at the top focused on strengthening the maturity of the Department's IT controls. Specifically, management has taken a leadership role in monitoring remediation activities across all IT systems in scope, with a focus on general ledger systems and high-risk control deficiencies of the consolidated FY 2018 financial statement audit. These efforts have led to a significant reduction of the number of high-risk internal control deficiencies noted in prior year audits. The following summarizes some additional improvements achieved that resulted from this increased attention:

- Management continues to make continuous improvement to their Managers' Internal Control Program (MICP) leading to the proactive remediation of issues, with a focus on higher risk issues identified during the audit, allowing for the residual risk of the issue to be minimized.

- Differential investments in key financial systems' leading to the implementation of more robust automated controls supporting material processes

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The following is a summary of the deficiencies that we considered most critical at the application layer. When assessed in aggregate, our conclusion of IT significant deficiency are based on the following:

- **Access controls** – We identified access controls exceptions across three of the eight applications in scope of our review, which spanned non-Centers for Medicare and Medicaid Services' (CMS) systems. Specifically, we noted: (1) the tool utilized for one application is not configured to automatically disable user accounts after a period of inactivity, (2) there was no method to pull a list of terminated users over the course of the FY since accounts are deleted from the system when an individual is terminated, (3) lack of user access monitoring procedures for generic ID's and retention of support for the review of audit logs, and (4) no monitoring procedures exist when an application team ceased service with a third-party tool. We identified similar exceptions at CMS: (1) CMS management did not perform or adequately perform periodic reviews of user access, including users with privileged access, (2) procedures for adding or removing users were not consistently followed, and (3) integration of user populations in the CMS enterprise identity management system and key financial systems and underlying infrastructure components was not complete.

- **Configuration management** – We identified configuration management exceptions in three of the eight applications in scope of our review, which spanned non-CMS systems. Specifically, we noted: (1) we were not able to validate the full population of changes made to various application in order to verify that only changes that went through the configuration management process were put into production, (2) no formal process in place to periodically monitor for unauthorized changes, (3) no formal process to monitor activity performed by individuals with access to both development and production environments, and (4) extended use of a previous version of the application exposing risk on an unsupported platform in which the enhancement patches addressing security issues are not implemented in a timely manner. CMS continues to experience deficiencies in the implementation and monitoring of compliance with its information systems control standards and processes at both the Medicare fee-for-service contractors and the Central Office. In addition, several vulnerabilities related to system configurations were identified with the Central Office information systems.

- **Segregation of duties (SOD)** – We identified segregation of duties exceptions across five of our eight applications in scope of our review, which spanned non-CMS systems. Specifically, we noted: (1) monitoring was not in place for the entire FY for a portion of the SOD controls and there are a number of high-risk SOD controls that do not have monitoring procedures implemented to date, (2) Cross-application SOD between two systems was not documented or monitored and there are a number of users who have conflicting roles between the two systems, (3) a number of SOD waivers were missing for a key financial system and the users with missing waivers were not identified within the

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periodic review/user recertification process, and (4) a user exists with access to a shared account which provides access to the production environment and in combination with the user's individual account, the user can both develop and migrate front-end application and configuration changes into production. CMS did not have adequate segregation of duties for those users conducting user access reviews and privileged application functions were not consistently implemented.

- **Risk management –** Findings identified by internal and external audits remain unresolved during the audit period. This includes the findings that sufficient security controls have not been implemented to ensure the resiliency of Medicare enrollment data. CMS' risk management strategy is decentralized and lacks an enterprise viewpoint, which has resulted in several control deficiencies in areas where business units share responsibility for oversight. Furthermore, risk management procedures have not been tailored to manage specific risks based on the role of IT systems within the CMS environment.

Recommendations

HHS should continue the focus achieved in FY 2018 to remediate the remaining deficiencies contributing to the significant deficiency and focus on continuous improvement. The following are some specific considerations:

- Management should continue to focus on high-priority remediation activities ultimately strengthening the IT controls maturity, with specific attention on the remaining high-risk control deficiencies identified as a part of the consolidated FY 2018 financial statement audit centered on access controls, configuration management and segregation of duties;

- Management should work to strengthen overarching governance / oversight to improve sustainability of remediation activities limiting the identification of new, high-risk observations during the audit;

- Execute on planned modernization of legacy systems with further investment, while ensuring that any major changes to the IT environment are performed with internal controls at the forefront, leading to strengthened overarching governance / oversight to improve sustainability of controls; and

- Continue to build on the maturity of the IT controls enterprise and strengthen all aspects of the HHS/CMS IT enterprise, to include operating system, data tier, and application layer, while being cognizant of the identification of new high-risk control deficiencies on material systems.

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We have performed a separate financial statement audit of CMS for FY 2018 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.

Financial Systems, Analysis and Reporting

During FY 2018, HHS made significant progress in addressing certain issues that have impaired its ability to overcome its significant deficiencies in the past. Improvements included:

- Continued development of policies and procedures over financial processes,
- Execution of analyses to remediate certain data quality issues allowing for data cleanup activities, and the
- Implementation of certain processes to automate and strengthen controls around the National Institutes of Health's (NIH) non-standard journal entries. We noted a reduction of total non-standard entries by over an approximate $276.0 billion during FY 2018 compared to FY 2017.

Although progress in certain areas has been identified, our review of internal control disclosed a series of deficiencies in financial systems and processes for producing financial statements, including lack of integrated financial management systems, antiquated processes that impacted journal entries to their financial and budgetary amounts, and/or insufficient analysis and oversight of certain significant accounts or programs. We identified the following items in the current year's audit that indicate additional improvements in the financial reporting systems and processes are required.

Non-Standard Journal Voucher Processes

HHS posts a significant number of non-standard journal vouchers to record entries that are unable to be recorded through routine systematic processing. The majority of these entries are generated by NIH; however in comparison to their budgetary resources, many of the other operating divisions also have a significant number of non-standard entries recorded to ensure consolidated financial statement amounts are accurate. During FY 2018, although HHS' annual total budgetary resources was $1.8 trillion, HHS was required to process approximately 9,914 manual entries totaling an absolute value of more than $471.0 billion to its NIH Business System (NBS) or Unified Financial Management Systems (UFMS). These entries consist of non-standard 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 post differences identified during the various reconciliations or analyses performed by HHS personnel. Although necessary to ensure

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balances are accurate, the volume and dollar value of manual entries is significant compared to the HHS's overall activity. We noted that HHS made significant improvements in FY 2018 with a reduction in the number and amount of non-standard entries as compared to the FY 2017.

CMS Oversight Processes

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 6, 2018. 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 to be a significant deficiency for the CMS internal control over financial reporting.

The most significant of those deficiencies fell within the oversight of the CMS Medicaid program and the Statements of Social Insurance.

Medicaid Oversight

The Medicaid program is the primary source of medical assistance for low-income Americans. Medicaid operates as a partnership between the states and the Federal government. The Federal government establishes the minimum requirements and provides oversight for the program and the states design, implement, administer and oversee their own Medicaid programs within the Federal parameters.

As of June 2018, CMS completed implementation of the Transformed-Medicaid Statistical Information System (T-MSIS). T-MSIS modernizes and enhances the way states submit operational data about beneficiaries, providers, health plans, claims and encounters. Although operational data is currently available, CMS must continue to work with states to assess and improve T-MSIS state data quality to support national and state level program analysis with timely, accurate, and complete data for policymaking and research. At this time the information contained within T-MSIS requires additional verification before it would be considered reliable. CMS should continue to enhance the usefulness of T-MSIS data so they will be able to perform robust analytical procedures and develop benchmarks to monitor and identify risks associated with the Medicaid program. Examples of risks to monitor could include outliers and unusual or unexpected results that demonstrate abnormalities in state-related Medicaid expenditures and/or allow CMS to assess the reliability of the T-MSIS data. Given that CMS does not currently maintain reliable historical claims level detail for Medicaid, data analyses have been limited. At this time, CMS is unable to perform a claims-level detailed look-back analysis for the Medicaid Entitlement Benefits Due and Payable (EBDP) to determine the reasonableness of the various state calculations of incurred (unpaid claims) but not reported liability. The Medicaid EBDP is a significant liability on the FY 2018 financial statements and is subject to volatility based on the complexity and judgement required in establishing this estimate. From time to time, claim processing cycle changes, such as

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a claims inventory buildup, may arise. As such, the lack of detailed claims data limits the ability to detect this type of situation on a timely basis or consider the potential volatility from this occurrence. With the implementation of T-MSIS, CMS now has access to data on which to base a claims-level detailed look-back analysis for Medicaid EBDP; however CMS must continue to evaluate and improve the quality and completeness of data reported by the states in T-MSIS. Until further analysis is developed and performed to verify the reliability of T-MSIS data, there remains a risk that potential updates to CMS' analysis will not be reflected in CMS' financial statements in a timely manner.

Statements of Social Insurance

The Statements of Social Insurance (SOSI) for CMS presents a long-term projection of the present value of the benefits to be paid for the closed and open groups of existing and future participants of the Medicare social insurance programs less the inflows to be received from, or on behalf of, those same individuals. The SOSI models are complex, 75-year projections that contain a high degree of estimation. The models and their results are heavily reviewed by actuaries and others within CMS. The veracity of the underlying data remains critical to the accuracy of the model, and as a result the reviews of the underlying data is robust, in line with CMS' policies and procedures. As part of this review, the input into the spreadsheet is checked against the original data sources to ensure that no input errors have been made. In addition, output data, including those that are generated from updating and running any macro in the spreadsheet, are checked by the reviewer. These checks include a comparison to the results from the year before, and testing of the formulas that are part of the spreadsheet or macro, to ensure that the projection output from the program is as expected and reasonable. During our procedures, two formula errors were identified, one of which was significant, that were not detected by the organization's monitoring and review function, and accordingly, the related control was not functioning as designed.

Recommendations

We recommend that HHS continue to develop and refine their financial management systems and processes to improve their accounting, analysis, and oversight of financial management activity. This will require focused efforts and continued prioritization of issues related to controls within and surrounding their financial information management systems. Specifically, we recommend the following:

- For non-standard journal processes, we recommend that HHS continue to focus on automating and reducing the number of non-standard journal vouchers 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.

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- We recommend that CMS continue to refine its financial management controls as a means to improve its accounting, analysis, and oversight of financial management activity, primarily relating to the oversight of the Medicaid program. Additionally, we recommend that CMS continue to adhere to established policies and procedures to ensure that the SOSI model methodology and related calculation and estimates are reviewed at a level of sufficient precision. More detailed recommendations related to our specific findings on these topics are included in our CMS Report on Internal Control.

Status of Prior Year Findings

In the reports on the results of the FY 2017 audit of the HHS consolidated 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 2018 Status**
Financial Information Systems	• Access Controls • Configuration Management • Segregation of Duties	Significant progress noted; certain issues need continued focus. Classified as a significant deficiency
Significant Deficiency		
NIH and CMS Financial Systems, Analysis, and Reporting	• National Institutes of Health • Centers for Medicare and Medicaid Services	Progress noted within operating divisions financial reporting processes. Modified Repeat Condition.

HHS's Response to Findings

HHS's response to the findings identified in our audit are included in the accompanying letter dated November 14, 2018. HHS's response was not subjected to the auditing procedures applied in the audit of the consolidated financial statements, and, accordingly, we express no opinion on it.

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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 effectiveness of 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, 2018

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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. 19-01, *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, 2018, and the related consolidated statements of net cost and changes in net position and the combined statement of budgetary resources for the fiscal year (FY) then ended, and the related notes to the principal financial statements, and we were also engaged to audit the sustainability financial statements, which comprise the statement of social insurance as of January 1, 2018, and the related statement of changes in social insurance amounts for the period ended January 1, 2018, and have issued our report thereon dated November 14, 2018. 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, 2018, and the related statement of changes in social insurance amounts for the period ended January 1, 2018.

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, contracts, and grant agreements, 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. 19-01, 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 those provisions 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. The results of our tests disclosed instances of noncompliance or other matters that are required to be reported under *Government Auditing Standards* and OMB Bulletin No. 19-01, as described below.

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During FY 2018, 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 an obligation of funds for conference spending at FDA and certain contract obligations serviced by the Program Support Center occurring between FY 2006 and FY 2011. 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 states 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 programs that did not meet their identified targets. 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.

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 no instances in which HHS's financial management systems did not substantially comply with requirements as discussed above.

* * * * *

HHS's Response to Findings

HHS' response to the findings identified in our audit are described in their letter dated November 14, 2018. HHS's response was not subjected to the auditing procedures applied in the audit of the financial statements, and, accordingly, we express no opinion on it. Additionally, HHS is updating its Department-wide corrective action plan to address the financial management issues discussed above.

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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, 2018

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Department's Response to the Report of the Independent Auditors

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary
Washington, DC 20201

To: Daniel R. Levinson, Inspector General

From: Jen Moughalian, Acting Assistant Secretary for Financial Resources and Acting Chief Financial Officer

Subject: FY 2018 Financial Statement Audit

Thank you for the opportunity to comment on the results of the Independent Auditors' Report. We appreciate the professionalism exhibited by the Office of Inspector General (OIG) and our independent auditors, Ernst & Young LLP (EY), throughout this process.

FY 2018 was a significant year for federal financial management at HHS. For the first time since 1996, the material weakness related to Information System Controls and Security is no longer reported by the auditors. As noted by EY, HHS made considerable progress in resolving audit findings, reducing risk across the operating environment, and maturing the security and controls posture of HHS's financial systems.

We acknowledge the two existing material noncompliances with laws and regulations and generally concur with the auditor's findings as presented in the Report on Internal Control. HHS will continue to implement corrective actions to address those deficiencies.

We are proud of our success in achieving an unmodified audit opinion and resolving the information systems material weakness. Overall, the Department made advances to enhance our internal control environment and is committed to a collaborative approach that will correct current deficiencies, further strengthen controls, and limit future deficiencies.

We would like to thank the OIG and EY for their efforts; and the OIG's continued partnership as we improve our stewardship and transparency.

/Jen Moughalian/

Jen Moughalian
Acting Assistant Secretary for Financial Resources and
Acting Chief Financial Officer
November 14, 2018

Principal Financial Statements

U.S. Department of Health and Human Services
Consolidated Balance Sheets
As of September 30, 2018 and 2017
(in Millions)

	2018	2017
Assets (Note 2)		
Intragovernmental Assets		
Fund Balance with Treasury (Note 3)	$ 250,163	$ 209,753
Investments, Net (Note 4)	307,115	275,524
Accounts Receivable, Net (Note 5)	1,129	962
Advances (Note 8)	255	233
Total Intragovernmental Assets	**558,662**	**486,472**
Accounts Receivable, Net (Note 5)	26,802	33,087
Inventory and Related Property, Net (Note 6)	9,815	9,698
General Property, Plant and Equipment, Net (Note 7)	6,350	6,248
Advances (Note 8)	2,694	30,859
Other Assets	204	459
Total Assets	**$ 604,527**	**$ 566,823**
Stewardship Land (Notes 19)		
Liabilities (Note 9)		
Intragovernmental Liabilities		
Accounts Payable	$ 1,029	$ 239
Other Liabilities (Note 13)	8,080	9,661
Total Intragovernmental Liabilities	**9,109**	**9,900**
Accounts Payable	957	1,099
Entitlement Benefits Due and Payable (Note 10)	99,148	108,347
Accrued Liabilities (Note 12)	14,521	11,872
Federal Employee and Veterans' Benefits (Note 11)	14,386	13,532
Contingencies and Commitments (Note 14)	13,475	14,797
Other Liabilities (Note 13)	5,736	4,358
Total Liabilities	**157,332**	**163,905**
Net Position		
Unexpended Appropriations - Funds from Dedicated Collections (Note 18)	22,934	17,284
Unexpended Appropriations - All Other funds	163,667	129,688
Cumulative Results of Operations - Funds from Dedicated Collections (Note 18)	262,972	257,676
Cumulative Results of Operations - All Other funds	(2,378)	(1,730)
Total Net Position - Funds from Dedicated Collections	**285,906**	**274,960**
Total Net Position - All Other Funds	**161,289**	**127,958**
Total Net Position	**447,195**	**402,918**
Total Liabilities and Net Position	**$ 604,527**	**$ 566,823**

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

U.S. Department of Health and Human Services
Consolidated Statements of Net Cost
For the Years Ended September 30, 2018 and 2017
(in Millions)

	2018	2017
Responsibility Segments		
Centers for Medicare & Medicaid Services (CMS)		
Gross Costs	$ 1,115,161	$ 1,060,793
Exchange Revenue	(106,304)	(97,294)
CMS Net Cost of Operations	1,008,857	963,499
Other Segments:		
Administration for Children and Families (ACF)	54,091	51,187
Administration for Community Living (ACL)	1,994	1,948
Agency for Healthcare Research and Quality (AHRQ)	344	340
Centers for Disease Control and Prevention (CDC)	12,382	11,945
Food and Drug Administration (FDA)	5,023	4,860
Health Resources and Services Administration (HRSA)	11,684	10,724
Indian Health Service (IHS)	10,766	6,456
National Institutes of Health (NIH)	33,587	31,376
Office of the Secretary (OS)	3,221	3,278
Program Support Center (PSC)	2,588	2,125
Substance Abuse and Mental Health Services Administration (SAMHSA)	4,124	3,625
Other Segments Gross Costs of Operations before Actuarial Gains and Losses	$ 139,804	$ 127,864
Actuarial (Gains) and Losses Commissioned Corp Retirement and Medical Plan Assumption Changes (Note 11)	416	449
Other Segments Gross Costs of Operations after Actuarial Gains and Losses	$ 140,220	$ 128,313
Exchange Revenue	(5,806)	(4,963)
Other Segments Net Cost of Operations	134,414	123,350
Net Cost of Operations (Note 20)	**$ 1,143,271**	**$ 1,086,849**

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, 2018
(in Millions)

	2018			
	Funds From Dedicated Collections	All Other Funds	Eliminations	Consolidated Total
Unexpended Appropriations:				
Beginning Balance	$ 17,284	$ 129,688	$ -	$ 146,972
Budgetary Financing Sources:				
Appropriations Received	376,964	653,567	-	1,030,531
Appropriations Transferred in/out (+/-)	-	1	-	1
Other Adjustments (+/-)	(34,637)	(85,787)	-	(120,424)
Appropriations Used	(336,677)	(533,802)	-	(870,479)
Total Budgetary Financing Sources	5,650	33,979	-	39,629
Total Unexpended Appropriations	**$ 22,934**	**$ 163,667**	**$ -**	**$ 186,601**
Cumulative Results of Operations:				
Beginning Balances	$ 257,676	$ (1,730)	$ -	$ 255,946
Budgetary Financing Sources:				
Other Adjustments (+/-)	(3)	(5)	-	(8)
Appropriations Used	336,677	533,802	-	870,479
Nonexchange Revenue				
Nonexchange Revenue - Tax Revenue	264,566	-	-	264,566
Nonexchange Revenue - Investment Revenue	9,746	27	-	9,773
Nonexchange Revenue - Other	4,946	-	-	4,946
Donations and Forfeitures of Cash and Cash Equivalents	75	-	-	75
Transfers-in/out without Reimbursement (+/-)	(5,203)	2,551	-	(2,652)
Other (+/-)	-	1	-	1
Other Financing Sources (Nonexchange):				
Donations and Forfeitures of Property	-	5	-	5
Transfers-in/out Without Reimbursement (+/-)	(2)	3	-	1
Imputed Financing	64	1,001	(323)	742
Other (+/-)	(8)	(1)	-	(9)
Total Financing Sources	610,858	537,384	(323)	1,147,919
Net Cost of Operations (+/-)	605,562	538,032	(323)	1,143,271
Net Change	5,296	(648)	-	4,648
Cumulative Results of Operations:	**$ 262,972**	**$ (2,378)**	**$ -**	**$ 260,594**
Net Position	**$ 285,906**	**$ 161,289**	**$ -**	**$ 447,195**

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, 2017
(in Millions)

	2017			
	Funds From Dedicated Collections	All Other Funds	Eliminations	Consolidated Total
Unexpended Appropriations:				
Beginning Balance	$ 35,912	$ 128,129	$ -	$ 164,041
Budgetary Financing Sources:				
Appropriations Received	348,468	605,538	-	954,006
Appropriations Transferred in/out (+/-)	-	(10)	-	(10)
Other Adjustments (+/-)	(41,644)	(97,081)	-	(138,725)
Appropriations Used	(325,452)	(506,888)	-	(832,340)
Total Budgetary Financing Sources	(18,628)	1,559	-	(17,069)
Total Unexpended Appropriations	**$ 17,284**	**$ 129,688**	**$ -**	**$ 146,972**
Cumulative Results of Operations:				
Beginning Balances	$ 233,470	$ 3,860	$ -	$ 237,330
Budgetary Financing Sources:				
Other Adjustments (+/-)	(3)	(4)	-	(7)
Appropriations Used	325,452	506,888	-	832,340
Nonexchange Revenue				
Nonexchange Revenue - Tax Revenue	259,740	-	-	259,740
Nonexchange Revenue - Investment Revenue	9,818	6	-	9,824
Nonexchange Revenue - Other	4,904	-	-	4,904
Donations and Forfeitures of Cash and Cash Equivalents	70	-	-	70
Transfers-in/out without Reimbursement (+/-)	(4,950)	3,145	-	(1,805)
Other Financing Sources (Nonexchange):				
Donations and Forfeitures of Property	-	(40)	-	(40)
Transfers-in/out Without Reimbursement (+/-)	(2)	2	-	-
Imputed Financing	37	682	(347)	372
Other (+/-)	4	63	-	67
Total Financing Sources	595,070	510,742	(347)	1,105,465
Net Cost of Operations (+/-)	570,864	516,332	(347)	1,086,849
Net Change	24,206	(5,590)	-	18,616
Cumulative Results of Operations:	**$ 257,676**	**$ (1,730)**	**$ -**	**$ 255,946**
Net Position	**$ 274,960**	**$ 127,958**	**$ -**	**$ 402,918**

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, 2018 and 2017
(in Millions)

Budgetary Resources		2018		2017
Unobligated Balance from Prior Year Budget Authority, Net (Discretionary and Mandatory)	$	97,593	$	78,846
Appropriations (Discretionary and Mandatory)		1,646,670		1,585,475
Borrowing Authority (Discretionary and Mandatory)		(127)		3,871
Spending Authority from Offsetting Collections (Discretionary and Mandatory)		13,644		14,360
Total Budgetary Resources (Note 21)	**$**	**1,757,780**	**$**	**1,682,552**
Status of Budgetary Resources				
New Obligations and Upward Adjustments (Notes 17 and 21)	$	1,680,053	$	1,647,162
Unobligated Balance, End of Year:				
Apportioned, Unexpired Accounts		43,508		15,376
Exempt from Apportionment, Unexpired Accounts		188		(12,103)
Unapportioned, Unexpired Accounts		9,970		7,997
Unexpired Unobligated Balance, End of Year		53,666		11,270
Expired Unobligated Balance, End of Year		24,061		24,120
Unobligated Balance, End of Year		77,727		35,390
Total Budgetary Resources (Note 21)	**$**	**1,757,780**	**$**	**1,682,552**
Outlays, Net:				
Outlays, Net (Discretionary and Mandatory) (Note 20)		1,589,140		1,562,696
Distributed Offsetting Receipts (Note 20)		(468,877)		(446,103)
Agency Outlays, Net (Discretionary and Mandatory) (Note 20)	**$**	**1,120,263**	**$**	**1,116,593**

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, 2018 and Prior Base Years

(in Billions)

	Estimates from Prior Years				
	2018	2017	2016	2015	2014
Actuarial present value for the 75-year projection period of estimated future income (excluding interest) received from or on behalf of: (Notes 22 and 23)					
Current participants who, in the starting year of the projection period:					
Have not yet attained eligibility age					
HI	$ 11,323	$ 10,679	$ 10,294	$ 9,134	$ 8,398
SMI Part B	24,143	21,641	19,386	17,027	17,127
SMI Part D	7,176	6,929	7,659	6,424	5,928
Have attained eligibility age (age 65 or over)					
HI	525	492	455	382	332
SMI Part B	4,725	4,122	3,660	3,300	2,873
SMI Part D	1,015	958	952	887	775
Those expected to become participants					
HI	10,959	10,567	9,952	8,386	7,812
SMI Part B	5,586	5,019	4,437	3,668	4,311
SMI Part D	2,932	2,869	3,602	2,845	2,609
All current and future participants					
HI	22,807	21,738	20,701	17,902	16,542
SMI Part B	34,453	30,783	27,484	23,995	24,311
SMI Part D	11,124	10,756	12,213	10,156	9,312
Actuarial present value for the 75-year projection period of estimated future expenditures for or on behalf of: (Notes 22 and 23)					
Current participants who, in the starting year of the projection period:					
Have not yet attained eligibility age					
HI	$ 18,604	$ 17,193	$ 16,800	$ 14,494	$ 14,117
SMI Part B	23,832	21,392	19,178	16,818	17,003
SMI Part D	7,176	6,929	7,659	6,424	5,928
Have attained eligibility age (age 65 and over)					
HI	5,027	4,539	4,285	3,803	3,484
SMI Part B	5,180	4,531	4,026	3,637	3,171
SMI Part D	1,015	958	952	887	775
Those expected to become participants					
HI	3,884	3,539	3,437	2,791	2,764
SMI Part B	5,442	4,860	4,281	3,540	4,137
SMI Part D	2,932	2,869	3,602	2,845	2,609
All current and future participants:					
HI	27,515	25,270	24,523	21,089	20,365
SMI Part B	34,453	30,783	27,484	23,995	24,311
SMI Part D	11,124	10,756	12,213	10,156	9,312
Actuarial present value for the 75-year projection period of estimated future excess of income (excluding interest) over expenditures (Notes 22 and 23)					
HI	$ (4,708)	$ (3,532)	$ (3,822)	$ (3,187)	$ (3,823)
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 22 and 23)					
HI	$ (4,708)	$ (3,532)	$ (3,822)	$ (3,187)	$ (3,823)
SMI Part B	-	-	-	-	-
SMI Part D	-	-	-	-	-
Trust Fund assets at start of period					
HI	202	199	194	197	205
SMI Part B	80	88	68	68	74
SMI Part D	8	8	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 22 and 23)					
HI	$ (4,506)	$ (3,333)	$ (3,628)	$ (2,990)	$ (3,618)
SMI Part B	80	88	68	68	74
SMI Part D	8	8	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, 2018 and Prior Base Years

(in Billions)

	Estimates from Prior Years				
	2018	2017	2016	2015	2014
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)	$ 6,266	$ 5,572	$ 5,067	$ 4,569	$ 3,980
Expenditures	11,222	10,027	9,263	8,328	7,430
Income less expenditures	(4,957)	(4,455)	(4,196)	(3,759)	(3,450)
Those who, in the starting year of the projection period, have not yet attained eligibility age:					
Income (excluding interest)	42,643	39,250	37,339	32,585	31,453
Expenditures	49,612	45,514	43,637	37,736	37,048
Income less expenditures	(6,970)	(6,264)	(6,298)	(5,151)	(5,595)
Actuarial present value of estimated future income (excluding interest) less expenditures (closed-group measure)	(11,926)	(10,719)	(10,493)	(8,909)	(9,045)
Combined Medicare Trust Fund assets at start of period	290	295	263	266	280
Actuarial present value of estimated future income (excluding interest) less expenditures plus trust fund assets at start of period	(11,637)	(10,425)	(10,230)	(8,643)	(8,764)
Future Participants:					
Actuarial present value for the 75-year projection period:					
Income (excluding interest)	19,477	18,456	17,992	14,898	14,732
Expenditures	12,258	11,268	11,320	9,176	9,510
Income less expenditures	7,219	7,187	6,672	5,722	5,222
Open-Group (all current and future participants):					
Actuarial present value of estimated future income (excluding interest) less expenditures	(4,708)	(3,532)	(3,822)	(3,187)	(3,823)
Combined Medicare Trust Fund assets at start of period	290	295	263	266	280
Actuarial present value of estimated future income (excluding interest) less expenditures plus trust fund assets at start of period	$ (4,418)	$ (3,237)	$ (3,559)	$ (2,921)	$ (3,542)

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, 2017 to January 1, 2018

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 24)					
As of January 1, 2017	$ 63,277	$ 66,809	$ (3,532)	$ 295	$ (3,237)
Reasons for change					
Change in the valuation period	2,355	2,523	(168)	-	(168)
Change in projection base	(502)	419	(921)	(5)	(926)
Changes in the demographic assumptions	(551)	(985)	434	-	434
Changes in economic and health care assumptions	3,176	3,162	14	-	14
Changes in law	629	1,165	(535)	-	(535)
Net changes	5,107	6,283	(1,176)	(5)	(1,181)
As of January 1, 2018	$ 68,385	$ 73,092	$ (4,708)	$ 290	$ (4,418)
HI - Part A (Note 24)					
As of January 1, 2017	$ 21,738	$ 25,270	$ (3,532)	$ 199	$ (3,333)
Reasons for change					
Change in the valuation period	747	915	(168)	11	(157)
Change in projection base	(612)	309	(921)	(8)	(929)
Changes in the demographic assumptions	(214)	(648)	434	-	434
Changes in economic and health care assumptions	1,223	1,208	14	-	14
Changes in law	(74)	461	(535)	-	(535)
Net changes	1,069	2,245	(1,176)	3	(1,173)
As of January 1, 2018	$ 22,807	$ 27,515	$ (4,708)	$ 202	$ (4,506)
SMI - Part B (Note 24)					
As of January 1, 2017	$ 30,783	$ 30,783	$ -	$ 88	$ 88
Reasons for change					
Change in the valuation period	1,154	1,154	-	(10)	(10)
Change in projection base	197	197	-	2	2
Changes in the demographic assumptions	(358)	(358)	-	-	-
Changes in economic and health care assumptions	2,087	2,087	-	-	-
Changes in law	591	591	-	-	-
Net changes	3,670	3,670	-	(8)	(8)
As of January 1, 2018	$ 34,453	$ 34,453	$ -	$ 80	$ 80
SMI - Part D (Note 24)					
As of January 1, 2017	$ 10,756	$ 10,756	$ -	$ 8	$ 8
Reasons for change					
Change in the valuation period	455	455	-	(1)	(1)
Change in projection base	(87)	(87)	-	1	1
Changes in the demographic assumptions	21	21	-	-	-
Changes in economic and health care assumptions	(133)	(133)	-	-	-
Changes in law	113	113	-	-	-
Net changes	368	368	-	-	-
As of January 1, 2018	$ 11,124	$ 11,124	$ -	$ 8	$ 8

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, 2016 to January 1, 2017

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 24)					
As of January 1, 2016	$ 60,398	$ 64,220	$ (3,822)	$ 263	$ (3,559)
Reasons for change					
Change in the valuation period	2,481	2,669	(187)	24	(163)
Change in projection base	(136)	(479)	342	8	350
Changes in the demographic assumptions	(122)	(20)	(102)	-	(102)
Changes in economic and health care assumptions	617	384	233	-	233
Changes in law	40	36	4	-	4
Net changes	2,880	2,590	290	31	321
As of January 1, 2017	$ 63,277	$ 66,809	$ (3,532)	$ 295	$ (3,237)
HI - Part A (Note 24)					
As of January 1, 2016	$ 20,701	$ 24,523	$ (3,822)	$ 194	$ (3,628)
Reasons for change					
Change in the valuation period	792	979	(187)	1	(186)
Change in projection base	133	(209)	342	4	346
Changes in the demographic assumptions	(152)	(50)	(102)	-	(102)
Changes in economic and health care assumptions	265	32	233	-	233
Changes in law	-	(4)	4	-	4
Net changes	1,037	748	290	5	295
As of January 1, 2017	$ 21,738	$ 25,270	$ (3,532)	$ 199	$ (3,333)
SMI - Part B (Note 24)					
As of January 1, 2016	$ 27,484	$ 27,484	$ -	$ 68	$ 68
Reasons for change					
Change in the valuation period	1,115	1,115	-	17	17
Change in projection base	281	281	-	3	3
Changes in the demographic assumptions	7	7	-	-	-
Changes in economic and health care assumptions	1,856	1,856	-	-	-
Changes in law	40	40	-	-	-
Net changes	3,299	3,299	-	20	20
As of January 1, 2017	$ 30,783	$ 30,783	$ -	$ 88	$ 88
SMI - Part D (Note 24)					
As of January 1, 2016	$ 12,213	$ 12,213	$ -	$ 1	$ 1
Reasons for change					
Change in the valuation period	575	575	-	5	5
Change in projection base	(550)	(550)	-	1	1
Changes in the demographic assumptions	22	22	-	-	-
Changes in economic and health care assumptions	(1,504)	(1,504)	-	-	-
Changes in law	-	-	-	-	-
Net changes	(1,457)	(1,457)	-	6	6
As of January 1, 2017	$ 10,756	$ 10,756	$ -	$ 8	$ 8

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 United States (U.S.) Department of Health and Human Services (HHS or the Department). In accordance with Statement of Federal Financial Accounting Standards (SFFAS) 47, *Reporting Entity*, HHS has included all consolidation entities for which it is accountable in this general purpose federal financial report. The Office of the Secretary (OS) and 11 Operating Divisions (OpDivs) listed below and all of their federal funding are consolidated into the HHS financial statements. HHS works with two Federally Funded Research and Development Centers (FFRDC). The FFRDCs are funded as contracts; all related HHS costs are consolidated in the financial statements.

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. The law established a new federal entity, 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

Each HHS OpDiv is 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)
- Centers for Medicare & 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)

CMS, the largest HHS OpDiv, administers Medicare, Medicaid, the Children's Health Insurance Program (CHIP), and other health related programs. CMS is also a separate reporting entity. The CMS annual financial report can be found at CMS.gov.

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 of 1990* (CFO Act), as amended by the *Government Management Reform Act of 1994*, 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 financial 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 219 appropriation 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, Statements of Net Cost, and Statement of Changes in Net Position. The Statement of Budgetary Resources is represented on a combined basis. Therefore, transactions and balances within HHS have not been eliminated from that statement. Supplemental information is accumulated from the OpDivs, 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.

C. Use of Estimates in Preparing Financial Statements

Financial statements prepared in accordance with GAAP 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. *Patient Protection and Affordable Care Act*

In FY 2010, President Barack Obama signed the *Patient Protection and Affordable Care Act* and the *Health Care and Education Reconciliation Act* collectively referred to as the PPACA. Further information is available at Healthcare.gov.

The PPACA contains the most significant changes to health care coverage since the *Social Security Act*. The PPACA 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 the Center for Consumer Information and Insurance Oversight (CCIIO). One of the main programs under CCIIO is the Health Insurance Exchanges (the "Exchanges"). A brief description of the remaining programs is presented below. There were two additional programs - Transitional Reinsurance and Risk Corridors – that are no longer in operation.

Health Insurance Exchanges

Grants have been provided to the States to establish Health Insurance Exchanges. The initial grants were made by 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 Exchanges were launched on October 1, 2013.

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 Exchanges. 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 that operate a State-based Exchange are eligible to establish a risk adjustment program. States operating a risk adjustment program may have an entity other than the Exchange perform this function. CMS operates a risk adjustment program for each state that does not operate its own risk adjustment program.

E. 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 has 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 Fiscal Year (FY) 2008 and beyond. Under this exception, HHS, as the child, assumed the financial statement reporting responsibilities of this fund.

Under the PPACA, 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 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).

F. Changes, Reclassifications and Adjustments

HHS revised the format of the Consolidated Statement of Changes in Net Position and Combined Statement of Budgetary Resources and reclassified certain FY 2017 balances to conform to FY 2018 financial statement presentations in accordance with the OMB Circular A-136. The effects are immaterial. The memorandum line within the new formats of the Statement of Budgetary Resources has been determined by OMB to be an illustrative disclosure and it is not required. Since this is not required, HHS's Statement of Budgetary Resources presentation does not include the memorandum line, which is the net adjustment to unobligated balance brought forward. Account balances for this line have been reflected in Budgetary Resource amounts.

HHS implemented SFFAS 53, *Budget and Accrual Reconciliation* this year. This standard is effective for reporting periods beginning after September 30, 2018, and allows early adoption. Comparison with the prior year is not required in the initial year of implementation. SFFAS 53 amends the requirement for a reconciliation between budgetary and financial accounting information. Last year's note, Reconciliation of Net Cost of Operations (Proprietary) to Budget (also known as the Statement of Financing) is replaced by the new Budget and Accrual

Reconciliation. The Budget and Accrual Reconciliation explains the relationship between the entity's net outlays on a budgetary basis and the net cost of operations during the reporting period.

G. 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. Benefit payments made by the Medicare contractors for Medicare Part A 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 of 1954* (SECA [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 net income. The *Social Security Act* requires the transfer of these contributions from the General Fund of the U.S. Government (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 established and maintained by SSA in accordance with wage information reports.

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

Section 1841 of the *Social Security Act* established the Medicare SMI Trust Fund. Benefit payments made by the Medicare contractors for Medicare Part B 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 Modernization Act of 2003* established the Medicare Prescription Drug Benefit – Part D. HHS reports the Prescription Drug Benefit within the financial statements as part of the SMI Trust Fund, in the Medicare column. Medicare also 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 and Medicaid Integrity Programs

The *Health Insurance Portability and Accountability Act of 1996* (HIPAA) established the Medicare Integrity Program at section 1893 of the *Social Security Act*. HIPAA section 201 also established the Health Care Fraud and Abuse Control Account, which provides a dedicated appropriation for carrying out the Medicare Integrity Program. The Medicare Integrity Program is funded by the HI trust fund.

Separately, the Medicaid Integrity Program was established by the *Deficit Reduction Act of 2005* (DRA), and codified at section 1936 of the *Social Security Act*. The Medicaid Integrity Program represents the Federal government's first national strategy to detect and prevent Medicaid fraud and abuse.

H. Revenue and Financing Sources

HHS receives the majority of funding needed to support its discretionary programs through Congressional appropriations 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.

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 services. 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 Reporting 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 Fund

or HHS designated Special Funds. 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 Bureau of Fiscal Service (Fiscal Service), 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 Statements of Net Cost and as an imputed financing source on the Consolidated Statement of Changes in Net Position.

I. 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 as well as beneficiary premiums and payments from states.

J. 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 related to delinquent child support payments withheld from federal tax refunds for the Child Support Enforcement program, interest accrued on over-payments, and cost settlements reported by the Medicare contractors.

K. Fund Balance with Treasury (FBwT)

The FBwT is the aggregate amount of funds in the Department's accounts with Treasury. FBwT is available to pay current liabilities and finance authorized purchases. Treasury processes cash receipts and disbursements for the Department's operations. HHS reconciles FBwT accounts with Treasury on a regular basis.

L. Custodial Activity

HHS reports custodial activities on its Consolidated Balance Sheets in accordance with OMB Circular A-136. 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 that are 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.

M. 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 needed 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 Fiscal Service to the HI and SMI Trust Funds as evidence of their receipt and are reported as an asset of 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 Fiscal Service 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 the Fiscal Service. Interest income is compounded semi-annually (i.e., June and December) by the Fiscal Service; 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 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 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 of 2009* established a Child Enrollment Contingency Fund to cover shortfalls in funding for the States. This fund is invested in interest-bearing Treasury securities.

N. 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 accounts on public receivables. Intragovernmental accounts receivable consist 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 are primarily composed of provider and beneficiary over-payments: Medicare Prescription Drug over-payments, Medicare premiums, civil monetary penalties, criminal restitution, state phased-down contributions, Medicaid/CHIP overpayments, audit disallowances, and Medicare Secondary Payer accounts receivable.

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

O. Advances and Accrued Grant Liability

HHS awards grants 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 is shown on the Consolidated Balance Sheets when the accrued grant expenses exceed the outstanding advances to grantees.

For most 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 amount accrued for unreported grant expenditures estimated for the fourth quarter based on the grantees' historical spending patterns.

Formula grants and block grants are funded differently. Grantees provide services or payments to individuals and local agencies from a fixed amount of money. These grants are funded based on allocations determined by budgets and agreements approved by the sponsoring OpDiv. The expenses are recorded as the grantees draw funds; no year-end accrual is required.

P. Inventory and Related Property, Net

Inventory and Related Property, Net primarily consists of Inventory Held for Sale and Use including 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.

Q. General Property, Plant and Equipment, Net

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 General 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 General 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 General 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, some GSA leases are cancelable with 120 days' notice. Under an operating lease, the cost of the lease is expensed as incurred.

General 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 SFFAS 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 $1.0 million and the threshold for revolving fund accounts is $500,000. 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.

R. 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 Alaska Natives in remote areas of the country where no other facilities exist. In accordance with SFFAS 29*, Heritage Assets and Stewardship Land,* HHS does not report a related amount on the Consolidated Balance Sheets.

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

S. 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, not covered by budgetary resources, or not requiring 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 *Federal Employee Compensation Act* (FECA) liability determined by the DOL but not yet billed is also included in this category.

Liabilities Not Requiring Budgetary Resources

Liabilities that have not in the past required and will not in the future require use of budgetary resources consisting of clearing accounts, non-fiduciary deposit funds, custodial collections, and unearned revenue.

T. Accounts Payable

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

U. Accrued Payroll and Benefits

Accrued Payroll and Benefits consist 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 consist primarily of HHS's current FECA liability to DOL.

V. 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/claims Incurred But Not Reported (IBNR) as of the end of the reporting period.

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;
- 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;
- Amounts owed to Medicare Advantage and Prescription Drug plans after completion of the Prescription Drug payment reconciliation and estimates relating to risk and other payment related adjustments including the estimate for the first 9 months of calendar year 2018; and
- An estimate of payments due to plan sponsors of retiree prescription drug coverage incurred but not yet paid as of September 30, 2018.

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 the CHIP estimates represent the net federal share of expenses incurred by the states but not yet reported to HHS.

W. 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 on the Consolidated Balance Sheets. Gains or losses from changes in assumptions in the PHS Commissioned Corps retirement benefits are recognized at year-end on the Statements of Net Cost.

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 Statements 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.

X. 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 5, *Accounting for Liabilities of the Federal Government*, as amended by SFFAS 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 may require future financial obligations.

Y. Statement of Social Insurance (unaudited)

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' reasonable 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, Statement of 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 *2018 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Fund* and *Social Security* (Medicare Trustees Report) and the *2018 Annual Report of the Board of Trustees of the Federal Old-Age and Survivors Insurance and Federal Disability Insurance Trust Funds* (OASDI Trustees Report). 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.

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

	2018	2017
Non-Entity Intragovernmental Assets	$ -	$ 2
Non-Entity With the Public Assets	45	47
Total Non-Entity Assets	45	49
Total Entity Assets	604,482	566,774
Total Assets	**$ 604,527**	**$ 566,823**

Note 3. Fund Balance with Treasury (in Millions)

	2018	2017
Status of Fund Balance with Treasury		
Unobligated Balance		
Available	$ 43,696	$ 3,273
Unavailable	34,031	32,117
Obligated Balance not yet Disbursed	237,535	234,869
Non-Budgetary Fund Balance with Treasury	(65,099)	(60,506)
Total Fund Balance with Treasury	**$ 250,163**	**$ 209,753**

The Unobligated Balance includes funds that are restricted for future use and not apportioned for current use of $14.7 billion as of September 30, 2018 ($11.2 billion in FY 2017). The restricted amount is primarily for the PPACA programs, CHIP, CMS Program Management, and State Grants and Demonstrations.

Note 4. Investments, Net (in Millions)

	2018				
	Cost	Amortized (Premium)	Interest Receivable	Investments, Net	Market Value Disclosure
Intragovernmental Securities					
Non-Marketable: Par Value	$ 301,003	$ -	$ 2,249	$ 303,252	$ 303,252
Non-Marketable: Market-Based	3,827	20	16	3,863	3,863
Total, Intragovernmental	**$ 304,830**	**$ 20**	**$ 2,265**	**$ 307,115**	**$ 307,115**

	2017				
	Cost	Amortized (Premium)	Interest Receivable	Investments, Net	Market Value Disclosure
Intragovernmental Securities					
Non-Marketable: Par Value	$ 268,423	$ -	$ 2,278	$ 270,701	$ 270,701
Non-Marketable: Market-Based	5,000	(210)	33	4,823	4,823
Total, Intragovernmental	**$ 273,423**	**$ (210)**	**$ 2,311**	**$ 275,524**	**$ 275,524**

HHS investments consist primarily of Medicare Trust Fund investments. Medicare Non-Marketable: Par Value Bonds are carried at face value and have maturity dates ranging from June 30, 2019, through June 30, 2033, with interest rates ranging from 1.88 percent to 5.13 percent. Medicare Non-Marketable: Par Value Certificates of Indebtedness mature on June 30, 2019, with interest rates ranging from 2.88 percent to 3.0 percent.

Securities held by the Vaccine Injury Compensation Trust Fund will mature in FY 2019 through FY 2023. The Market-Based Notes paid from 1.0 percent to 2.0 percent during October 1, 2017, to September 30, 2018, and 1.0 percent to 3.875 percent during October 1, 2016, to September 30, 2017. The Market-Based Bonds pay 6.875 percent through FY 2025.

The Market-Based Securities held in the NIH gift funds during 12 months of FY 2018, yielded from 1.0578 percent to 2.1379 percent depending on date purchased and length of time to maturity.

Note 5. Accounts Receivable, Net (in Millions)

	2018				
	Accounts Receivable, Principal	Interest Receivable	Accounts Receivable, Gross	Allowance	HHS Receivables, Net
Intragovernmental					
Entity	$ 1,129	$ -	$ 1,129	$ -	$ 1,129
Total, Intragovernmental	**$ 1,129**	**$ -**	**$ 1,129**	**$ -**	**$ 1,129**
With the Public					
Entity					
Medicare	$ 21,039	$ -	$ 21,039	$ (3,286)	$ 17,753
Medicaid	5,101	-	5,101	(957)	4,144
Other	5,379	305	5,684	(824)	4,860
Non-Entity	12	65	77	(32)	45
Total with the Public	**$ 31,531**	**$ 370**	**$ 31,901**	**$ (5,099)**	**$ 26,802**

	2017				
	Accounts Receivable, Principal	Interest Receivable	Accounts Receivable, Gross	Allowance	HHS Receivables, Net
Intragovernmental					
Entity	$ 962	$ -	$ 962	$ -	$ 962
Total, Intragovernmental	**$ 962**	**$ -**	**$ 962**	**$ -**	**$ 962**
With the Public					
Entity					
Medicare	$ 23,192	$ -	$ 23,192	$ (2,520)	$ 20,672
Medicaid	7,029	-	7,029	(993)	6,036
Other	6,806	288	7,094	(762)	6,332
Non-Entity	12	67	79	(32)	47
Total with the Public	**$ 37,039**	**$ 355**	**$ 37,394**	**$ (4,307)**	**$ 33,087**

As of September 30, 2018, the other accounts receivable with the public is primarily related to collections for Exchange activities and restitution. For FY 2018, restitution gross balances are approximately $2 billion with a net balance of $65 million.

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

	2018	2017
Inventory Held for Sale or Use	$ 48	$ 74
Stockpile Materials Held for Emergency or Contingency	9,767	9,624
Inventory and Related Property, Net	**$ 9,815**	**$ 9,698**

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

			2018		
	Depreciation Method	Estimated Useful Lives	Acquisition Cost	Accumulated Depreciation	Net Book Value
Land & Land Rights	-	-	$ 54	$ -	$ 54
Construction in Progress	-	-	771	-	771
Buildings, Facilities & Other Structures	Straight Line	5-50 Yrs	6,191	(3,247)	2,944
Equipment	Straight Line	3-20 Yrs	2,146	(1,258)	888
Internal Use Software	Straight Line	5-10 Yrs	3,439	(1,805)	1,634
Assets Under Capital Lease	Straight Line	1-30 Yrs	119	(71)	48
Leasehold Improvements	Straight Line	*Life of Lease	56	(45)	11
Totals			**$ 12,776**	**$ (6,426)**	**$ 6,350**

			2017		
	Depreciation Method	Estimated Useful Lives	Acquisition Cost	Accumulated Depreciation	Net Book Value
Land & Land Rights	-	-	$ 54	$ -	$ 54
Construction in Progress	-	-	682	-	682
Buildings, Facilities & Other Structures	Straight Line	5-50 Yrs	6,149	(3,072)	3,077
Equipment	Straight Line	3-20 Yrs	2,064	(1,235)	829
Internal Use Software	Straight Line	5-10 Yrs	2,918	(1,383)	1,535
Assets Under Capital Lease	Straight Line	1-30 Yrs	124	(67)	57
Leasehold Improvements	Straight Line	*Life of Lease	55	(41)	14
Totals			**$ 12,046**	**$ (5,798)**	**$ 6,248**

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

Note 8. Advances (in Millions)

	2018	2017
Intragovernmental		
Advances to Other Federal Entities	$ 255	$ 233
Total Intragovernmental	**$ 255**	**$ 233**
With the Public		
Prescription Drug and Medicare Advantage	-	29,233
Grant Advances	2,644	1,591
Other	50	35
Total with the Public	**$ 2,694**	**$ 30,859**

In FY 2017, advances with the public primarily represent payment of the Prescription Drug and Medicare Advantage benefit payments that occurred on September 29, 2017, instead of October 1, 2017. There were no prepayments made in 2018 for FY 2019 that would result in a similar advance in the Consolidated Balance Sheets as of September 30, 2018.

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

	2018	2017
Intragovernmental		
Accrued Payroll and Benefits	$ 55	$ 58
Other	1,533	1,510
Total Intragovernmental	**$ 1,588**	**$ 1,568**
Federal Employee and Veterans' Benefits (Note 11)	14,386	13,532
Accrued Payroll and Benefits	681	663
Contingencies and Commitments (Note 14)	13,475	14,797
Accrued Liabilities	6,933	5,984
Other	231	221
Total Liabilities Not Covered by Budgetary Resources	$ 37,294	$ 36,765
Total Liabilities Covered by Budgetary Resources	117,991	125,282
Total Liabilities Not Requiring Budgetary Resources	2,047	1,858
Total Liabilities	**$ 157,332**	**$ 163,905**

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

	2018	2017
Medicare Fee-For-Service	$ 51,031	$ 48,029
Medicare Advantage/Prescription Drug Program	11,165	12,596
Medicaid	35,570	34,070
CHIP	1,377	1,345
Other	5	12,307
Totals	**$ 99,148**	**$ 108,347**

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 fiscal year but paid in the subsequent fiscal year; and (e) an estimate of retroactive settlements of cost reports. The September 30, 2018 and 2017 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 2018. 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, 2018.

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 line item includes estimates of payments due to those participating in Exchange activities. The PPACA provided for a temporary Risk Corridors program that was administered by CMS. The Risk Corridors program is no longer in operation. As of September 30, 2018, due to changes in assumptions, no accruals have been recorded related to Risk Corridor activities.

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

	2018	2017
With the Public		
Liabilities Not Covered by Budgetary Resources		
PHS Commissioned Corp Pension Liability	$ 13,338	$ 12,603
PHS Commissioned Corp Post-Retirement Health Benefits	772	650
Workers' Compensation Benefits (Actuarial FECA Liability)	276	279
Total, Federal Employee and Veterans' Benefits	**$ 14,386**	**$ 13,532**

Public Health Service (PHS) Commissioned Corps

HHS administers the PHS Commissioned Corps Retirement System for 6,408 active duty officers and 7,065 retiree annuitants and survivors. As of September 30, 2018, the actuarial accrued liability for the retirement benefit plan was $13.3 billion and $0.8 billion for non-Medicare coverage of the Post-Retirement Medical Plan.

The Commissioned Corps Retirement System and the Post-Retirement Medical Plan are not funded. Therefore, in accordance with SFFAS 33, *Pensions, Other Retirement Benefits and Other Postemployment Benefits: Reporting the Gains and Losses from Changes in Assumptions and Selecting Discount Rates and Valuation Dates*, the 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 cash flow. A single discount rate may be used for all the projected cash flow, 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, 2018, and September 30, 2017, were:

	2018	2017
Discount rate	3.92 percent	4.05 percent
Annual basic pay scale increase	2.62 percent	2.56 percent
Annual inflation	2.12 percent	2.06 percent

	2018	2017
Beginning Liability Balance	$ 13,253	$ 12,620
Expense		
Normal Cost	380	339
Interest on the liability balance	526	527
Actuarial (Gain)/Loss		
From experience	57	(188)
From assumption changes		
Change in discount rate assumption	236	381
Change in inflation/salary increase assumption	109	85
Change in mortality rate/others	71	(17)
Total From assumption changes	$ 416	$ 449
Net Actuarial (Gain)/Loss	473	261
Total expense	$ 1,379	$ 1,127
Less amounts paid	(522)	(494)
Ending Liability Balance	**$ 14,110**	**$ 13,253**

The above shows key valuation results as of September 30, 2018, and 2017, in conformance with the actuarial reporting standards set forth in the SFFAS 5, *Accounting for Liabilities of the Federal Government* and SFFAS 33. The valuation is based upon the current plan provisions, membership data collected as of June 30, 2018, and actuarial assumptions. The September 30, 2018 valuation includes an increase in liabilities of $857 million resulting from a changes in the assumed annual inflation rate, the assumed salary scale, and in the assumed discount rate. These changes in combination with the actual plan experience over the past year (based upon new census data), resulted in an overall net increase in the actuarial accrued liability as compared to the prior valuation. The annual expense for the Retirement Benefit Plan for FY 2018 has also increased relative to the prior year expense.

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. For FYs 2018 and 2017, 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. Interest rate assumptions utilized for discounting as of September 30, 2018, and September 30, 2017, as follows.

	2018	2017
Wage Benefits	2.716% in Year 1 and years thereafter	2.683% in Year 1 and years thereafter
Medical Benefits	2.379% in Year 1 and years thereafter	2.218% 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. The actual rates for these factors are also used to adjust the methodology's historical payments to current year constant dollars. The compensation COLAs and CPIMs used in the projections are:

FY	COLA	CPIM
2018	N/A	N/A
2019	1.31%	3.21%
2020	1.51%	3.48%
2021	1.89%	3.68%
2022	2.16%	3.71%
2023	2.21%	4.09%

Note 12. Accrued Liabilities (in Millions)

	2018	2017
Grant Liability	$ 7,588	$ 5,888
Other Accrued Liabilities	6,933	5,984
Accrued Liabilities	**$ 14,521**	**$ 11,872**

Note 13. Other Liabilities (in Millions)

	2018		2017	
	Intra-governmental	With the Public	Intra-governmental	With the Public
Accrued Payroll & Benefits	$ 141	$ 1,108	$ 139	$ 988
Advances from Others	899	888	750	356
Deferred Revenue	-	1,066	-	1,421
Custodial Liabilities	342	8	362	7
Legal Liabilities	1,155	-	1,088	-
Other	5,543	2,666	7,322	1,586
Total Other Liabilities	**$ 8,080**	**$ 5,736**	**$ 9,661**	**$ 4,358**

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, for calendar years 2016 and 2017, which will be used to pay back the General Fund transfer without interest. These repayments are transferred quarterly. As of September 30, 2018, $5.0 billion ($6.4 billion in FY 2017) is still owed and is reported as Other. Legal Liabilities of $1.2 billion as of

September 30, 2018 ($1.1 billion as of September 30, 2017) consist of reimbursable claims due to the Judgment Fund, which is administered by the Fiscal Service.

Note 14. Contingencies and Commitments (in Millions)

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. The liabilities are primarily related to the Medicaid audit and program disallowances. 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 $6.3 billion ($12.2 billion in FY 2017) consists of Medicaid audit and program disallowances and 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, 2018, 9,370 cases (10,067 in FY 2017) remain on appeal. A total of 1,852 new cases (2,251 in FY 2017) were filed and 7 cases were reopened (11 in FY 2017). The PRRB rendered decisions on 96 cases (128 in FY 2017) and an additional 2,460 cases (2,072 in FY 2017) were dismissed, withdrawn, or settled prior to an appeal hearing. The PRRB receives no information on the value of the cases that are settled prior to a hearing, so nothing is recorded.

Other Accrued Contingent Liabilities

The U.S. Supreme Court decision in *Salazar v Ramah Navajo Chapter*, dated June 18, 2012, and subsequent cases related to contract support costs have resulted in increased claims against 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.

Other contingent liabilities against HRSA have been accrued in the financial statements for the Vaccine Injury Compensation program and other Health Center claims.

Note 15. 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 $230.9 billion, as of September 30, 2018, ($207.4 billion as of September 30, 2017), are included in Investments on the Consolidated Balance Sheets.

Exempt from Apportionment

This amount includes the FY 2018 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 *Antideficiency Act* has not been violated, as "[t]he prohibitions contained in the *Antideficiency Act* are directed at discretionary obligations entered into by administrative officers." B-219161 (Oct. 2, 1985).

Note 16. Explanation of Differences between the Combined Statement of Budgetary Resources and the Budget of the United States Government (in Millions)

	2017			
	Budgetary Resources	New Obligations and Upward Adjustments	Distributed Offsetting Receipts	Outlays, net (total) (discretionary and mandatory)
Combined Statement of Budgetary Resources	$ 1,682,552	$ 1,647,162	$ 446,103	$ 1,562,696
Expired Accounts	(26,356)	-	-	-
Other	(1,566)	(544)	(230)	(17)
Budget of the U.S. Government	**$ 1,654,630**	**$ 1,646,618**	**$ 445,873**	**$ 1,562,679**

The *Budget of the United States Government* (also known as the *President's Budget*), with the actual amounts for FY 2018, has not been published, therefore, no comparisons can be made between FY 2018 amounts presented in the Combined Statement of Budgetary Resources with amounts reported in the Actual column of the *President's Budget*. The *FY 2020 President's Budget* is expected to be released in February 2019 and may be obtained from OMB or from GPO.

HHS reconciled the amounts of the FY 2017 column on the Combined Statement of Budgetary Resources to the actual amounts for FY 2017 from the Appendix in the *FY 2019 President's Budget* for budgetary resources, new obligations and upward adjustments, distributed 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 new obligations and upward adjustments are due to Governmentwide Treasury Account Symbol Adjusted Trial Balance System revision window adjustments that 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 of prior year obligations.

Note 17. Apportionment Categories of New Obligations and Upward Adjustments: Direct vs. Reimbursable Obligations and Undelivered Orders (in Millions)

	2018		
	Direct	Reimbursable	Total
Category A (Distributed by Quarter)	$ 112,612	$ 9,253	$ 121,865
Category B (Restricted and Distributed by Activity)	817,052	5,022	822,074
Exempt from Apportionment	736,096	18	736,114
Total New Obligations and Upward Adjustments	**$ 1,665,760**	**$ 14,293**	**$ 1,680,053**

	2017		
	Direct	Reimbursable	Total
Category A (Distributed by Quarter)	$ 106,332	$ 8,587	$ 114,919
Category B (Restricted and Distributed by Activity)	795,136	4,750	799,886
Exempt from Apportionment	732,341	16	732,357
Total New Obligations and Upward Adjustments	**$ 1,633,809**	**$ 13,353**	**$ 1,647,162**

New Obligations and Upward Adjustments consist of expended authority and the change in undelivered orders. OMB has exempted CMS from the Circular 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*.

	2018			2017		
	Federal	Non-Federal	Total	Federal	Non-Federal	Total
Undelivered Orders, Paid	$ 6,474	$ 122,662	$ 129,136	$ 6,097	$ 114,199	$ 120,296
Undelivered Orders, Unpaid	249	2,873	3,122	233	31,034	31,267
Total Undelivered Orders	**$ 6,723**	**$ 125,535**	**$ 132,258**	**$ 6,330**	**$ 145,233**	**$ 151,563**

Undelivered Orders include obligations that have been issued but are not yet drawn down, as well as goods and services ordered that have not been received. HHS reported $132.3 billion of budgetary resources obligated for undelivered orders as of September 30, 2018 ($151.6 billion as of September 30, 2017). The change in unpaid is due to the timing of the Prescription Drug and Medicare Advantage benefit payments.

Note 18. 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 table below. The Medicare program includes the HI Trust Fund; the SMI Trust Fund which includes both Part B medical insurance, and the Medicare Prescription Drug Benefit – Part D; and the Medicare and Medicaid Integrity Programs. 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.

	2018			
Balance Sheet as of September 30	**Medicare**	**Other**	**Eliminations**	**Total**
Fund Balance with Treasury	$ 27,389	$ 11,152	$ -	$ 38,541
Investments	303,253	3,862	-	307,115
Other Assets	90,933	6,908	(74,037)	23,804
Total Assets	**$ 421,575**	**$ 21,922**	**$ (74,037)**	**$ 369,460**
Entitlement Benefits Due and Payable	$ 62,196	$ 3	$ -	$ 62,199
Other Liabilities	84,031	11,361	(74,037)	21,355
Total Liabilities	**$ 146,227**	**$ 11,364**	**$ (74,037)**	**$ 83,554**
Unexpended Appropriations	22,855	79	-	22,934
Cumulative Results of Operations	252,493	10,479	-	262,972
Total Liabilities and Net Position	**$ 421,575**	**$ 21,922**	**$ (74,037)**	**$ 369,460**
Statement of Net Cost for the Period Ended September 30				
Gross Program Costs	$ 717,153	$ (2,586)	$ (142)	$ 714,425
Less: Exchange Revenues	100,322	8,683	(131)	108,874
Net Cost of Operations	**$ 616,831**	**$ (11,269)**	**$ (11)**	**$ 605,551**
Statement of Changes in Net Position for the Period Ended September 30				
Net Position Beginning of Period	$ 276,993	$ (2,033)	$ -	$ 274,960
Nonexchange Revenue	278,884	374	-	279,258
Other Financing Sources	336,302	948	(11)	337,239
Net Cost of Operations	(616,831)	11,269	11	(605,551)
Change in Net Position	$ (1,645)	$ 12,591	$ -	$ 10,946
Net Position End of Period	**$ 275,348**	**$ 10,558**	**$ -**	**$ 285,906**

Balance Sheet as of September 30	2017 Medicare	Other	Eliminations	Total
Fund Balance with Treasury	$ 28,284	$ 7,881	$ -	$ 36,165
Investments	270,702	3,680	-	274,382
Other Assets	122,260	7,704	(72,739)	57,225
Total Assets	**$ 421,246**	**$ 19,265**	**$ (72,739)**	**$ 367,772**
Entitlement Benefits Due and Payable	$ 60,625	$ 12,303	$ -	$ 72,928
Other Liabilities	83,628	8,995	(72,739)	19,884
Total Liabilities	**$ 144,253**	**$ 21,298**	**$ (72,739)**	**$ 92,812**
Unexpended Appropriations	17,287	(3)	-	17,284
Cumulative Results of Operations	259,706	(2,030)	-	257,676
Total Liabilities and Net Position	**$ 421,246**	**$ 19,265**	**$ (72,739)**	**$ 367,772**
Statement of Net Cost for the Period Ended September 30				
Gross Program Costs	$ 656,922	$ 13,903	$ (418)	$ 670,407
Less: Exchange Revenues	89,793	10,168	(381)	99,580
Net Cost of Operations	**$ 567,129**	**$ 3,735**	**$ (37)**	**$ 570,827**
Statement of Changes in Net Position for the Period Ended September 30				
Net Position Beginning of Period	$ 268,602	$ 780	$ -	$ 269,382
Nonexchange Revenue	274,135	327	-	274,462
Other Financing Sources	301,385	595	(37)	301,943
Net Cost of Operations	(567,129)	(3,735)	37	(570,827)
Change in Net Position	$ 8,391	$ (2,813)	$ -	$ 5,578
Net Position End of Period	**$ 276,993**	**$ (2,033)**	**$ -**	**$ 274,960**

Note 19. 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 2.3 million American Indians and Alaska Natives who belong to 573 federally recognized tribes in 37 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.

The table below presents stewardship land held by HHS:

Indian Trust Land by Locations and Number of Sites

IHS Area	2018	2017
Albuquerque	4	4
Bemidji	2	2
Billings	7	7
Great Plains	9	9
Navajo	36	36
Oklahoma City	1	1
Phoenix	10	10
Portland	3	3
Tucson	5	5
Total	77	77

Note 20. Budget and Accrual Reconciliation (in Millions)

	2018		
	Intragovernmental	With the Public	Total
Net Cost of Operations	**$ 3,897**	**$ 1,139,374**	**$ 1,143,271**
Components of Net Cost Not Part of the Budget Outlays			
Property, Plant, and Equipment Depreciation	-	(751)	(751)
Property, Plant, and Equipment Disposal & Reevaluation	-	(2)	(2)
Other	-	(16)	(16)
	-	**(769)**	**(769)**
Increase/(Decrease) in Assets:			
Accounts Receivables	141	(6,282)	(6,141)
Investment	44	-	44
Other Asset – Regulatory Assets	24	(28,420)	(28,396)
	209	**(34,702)**	**(34,493)**
(Increase)/Decrease in Liabilities:			
Accounts Payable	(194)	8,805	8,611
Salaries and Benefits	(4)	(103)	(107)
Environmental and Disposal Liabilities	-	(11)	(11)
Other Liabilities (Unfunded leave, Unfunded FECA, Actuarial FECA)	(766)	(2,942)	(3,708)
	(964)	**5,749**	**4,785**
Other Financing Sources:			
Federal Employee Retirement Benefit Costs Paid by OPM and Imputed to the Agency	(742)	-	(742)
Transfers out (in) Without Reimbursement	3,289	-	3,289
	2,547	**-**	**2,547**
Components of Budget Outlays Not Part of Net Cost:			
Acquisition of Capital Assets	10	246	256
Acquisition of Inventory	1	740	741
Other	189	4,351	4,540
	200	**5,337**	**5,537**
Net Outlays	**$ 5,889**	**$ 1,114,989**	**$ 1,120,878**
Federal Share of Child Support Collections and Other[6]			(615)
Net Outlays, Net			**1,120,263**
Related Amounts on Combined Statement of Budgetary Resources			
Outlays, Net			1,589,140
Distributed Offsetting Receipts			(468,877)
Agency Outlays, Net			**$ 1,120,263**

[6] This amount is included in the HHS SBR, Distributed Offsetting Receipts but does not have an impact on Net Cost.

Note 21. Combined Schedule of Spending (in Millions)

The Combined Schedule of Spending presents an overview of how departments or agencies spend (i.e., obligating) money. 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.

Additional efforts to improve the transparency of spending activity in the federal government have recently come to fruition in the implementation of the *Digital Accountability and Transparency Act of 2014* (DATA Act). This legislation makes available to the public, at no cost, a searchable website that provides award and financial information on contracts and financial assistance awards (including grants). While the underlying obligation data used to generate both the Combined Schedule of Spending and the DATA Act submission are the same, there is a fundamentally different purpose behind each, which should be taken into account when comparing the two. The Combined Schedule of Spending presents total budgetary resources, total new obligations, and upward adjustments for the reporting entity. The website displaying the DATA Act submission, USAspending.gov[7], collects the same data as well as recoveries. Additional differences include the definition of key attributes in each. Programs for the Combined Schedule of Spending are defined by the Treasury Account Symbol, whereas the DATA Act uses the Program and Financing lines from the President's budget. Object Classes are the criteria by which both group spending activity by type. However, the DATA Act requires granular-level object class assignments while the Combined Schedule of Spending groups object classes at a higher level for presentation purposes. Additionally, the DATA Act submission at the award-level data does not include certain obligations, such as personnel compensation, travel, utilities, leases, intra-departmental and interagency spending, and various other categories of financial awards. The Combined Schedule of Spending has no such exclusions and is similar to the program activity reporting file for DATA Act. Lastly, the DATA Act reporting responsibility for award-level activity in allocation accounts is always assigned to the child entity. This is not entirely consistent with allocation account reporting for the financial statements for which either the parent or child will report.

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, purchase 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 and Object Class. Those Treasury Account Symbols with spending greater than $1.0 billion are presented separately. Object Classes that have a material impact on HHS reporting are present separately. These are Grants, Subsidies, & Contributions, Insurance Claims and Indemnities, Other Contractual Services and Personnel

[7] 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.

Compensation & Benefits. HHS Medicare payments are reported under Insurance Claims and Indemnities based on the OMB A-11 object class definition.

Combined Schedule of Spending
For the Years Ended September 30, 2018 and 2017
(in Millions)

What Money is Available to Spend		2018		2017
Total Resources	$	1,757,780	$	1,682,552
Less Amount Available but Not Agreed to be Spent		43,696		3,273
Less Amount Not Available to be Spent		34,031		32,117
Total Amounts Agreed to be Spent	**$**	**1,680,053**	**$**	**1,647,162**

Who Did the Money Go To		2018		2017
Federal	$	9,133	$	10,498
Non-Federal		1,670,920		1,636,664
Total Amounts Agreed to be Spent	**$**	**1,680,053**	**$**	**1,647,162**

Combined Schedule of Spending By Object Class

For the Year Ended September 30, 2018

(in Millions)

How was the Money Spent/Issued?	2018 Grants, Subsidies, & Contributions	Insurance Claims & Indemnities	Other Contractual Services	Personnel Compensation & Benefits	Other	Total
Medicaid	$ 437,108	$ -	$ 101	$ 19	$ 4,164	$ 441,392
Federal Supplementary Medical Insurance Trust Fund	-	322,244	88	1	5,146	327,479
Payments to Trust Funds	251,278	-	-	-	70,309	321,587
Federal Hospital Insurance Trust Fund	-	298,861	10	-	4,056	302,927
Medicare Prescription Drug Account	-	81,100	-	1	426	81,527
Taxation on OASDI Benefits, HI	24,192	-	-	-	-	24,192
State Children's Health Insurance Fund	17,484	-	5	-	-	17,489
Temporary Assistance for Needy Families	16,612	-	90	11	3	16,716
Children and Families Services Programs	11,244	-	384	149	13	11,790
Payments for Foster Care and Permanency	8,185	-	33	-	2	8,220
National Cancer Institute	3,678	-	1,683	555	132	6,048
Indian Health Services	2,571	10	888	1,455	821	5,745
Primary Health Care	5,118	-	240	74	12	5,444
National Institute of Allergy and Infectious Diseases	3,297	-	1,582	344	116	5,339
Payment to States for the Child Care and Development Block Grant	5,128	-	102	2	-	5,232
Payments to States for Child Support Enforcement and Family Support Programs	3,805	-	624	-	-	4,429
Risk Adjustment Program Payments	-	3,865	-	-	11	3,876
Substance Abuse Treatment	3,640	-	112	9	-	3,761
Low Income Home Energy Assistance	3,638	-	3	-	-	3,641
National Heart, Lung, and Blood Institute	2,715	-	508	160	33	3,416
Child Care Entitlement to States	2,955	-	18	-	2	2,975
National Institute of General Medical Sciences	2,653	-	113	30	1	2,797
National Institute on Aging	2,281	-	220	76	22	2,599
Refugee and Entrant Assistance	2,070	-	360	15	6	2,451
Ryan White HIV/AIDS Program	2,240	-	96	26	4	2,366
Public Health and Social Services Emergency Fund	338	-	1,291	157	453	2,239
Aging and Disability Services Programs	2,124	-	48	30	6	2,208
National Institute of Diabetes and Digestive and Kidney Diseases	1,673	-	239	121	28	2,061
Health Care Fraud and Abuse Control Account	1	-	1,371	59	588	2,019
National Institute of Neurological Disorders and Stroke	1,603	-	254	96	26	1,979
NIH Service and Supply Fund	-	-	1,310	287	350	1,947
PSC Service and Supply Fund	-	-	1,655	157	84	1,896
National Institute of Mental Health	1,421	-	232	105	18	1,776
Social Services Block Grant	1,661	-	10	1	-	1,672
Mental Health	1,445	-	89	5	1	1,540
National Institute of Child Health and Human Development	1,042	-	329	104	20	1,495
National Institute on Drug Abuse	955	-	238	66	12	1,271
Public Health Preparedness and Response	630	-	258	122	162	1,172
Chronic Disease Prevention and Health Promotion	758	-	275	129	8	1,170
HIV/AIDS, Viral Hepatitis, Sexually Transmitted Diseases and Tuberculosis Prevention	742	-	187	176	19	1,124
Other Agency Budgetary Accounts	14,418	1,185	14,368	7,573	3,502	41,046
Total Amounts Agreed to be Spent	**$ 840,703**	**$ 707,265**	**$ 29,414**	**$ 12,115**	**$ 90,556**	**$ 1,680,053**

Combined Schedule of Spending By Object Class

For the Year Ended September 30, 2017

(in Millions)

How was the Money Spent/Issued?	2017 Grants, Subsidies, & Contributions	Insurance Claims & Indemnities	Other Contractual Services	Personnel Compensation & Benefits	Other	Total
Medicaid	$ 417,710	$ -	$ 103	$ 19	$ 4,213	$ 422,045
Federal Supplementary Medical Insurance Trust Fund	4	308,851	141	1	5,546	314,543
Payments to Trust Funds	231,663	-	-	-	83,621	315,284
Federal Hospital Insurance Trust Fund	-	296,222	359	-	4,322	300,903
Medicare Prescription Drug Account	-	88,260	-	1	828	89,089
Taxation on OASDI Benefits, HI	24,206	-	-	-	-	24,206
State Children's Health Insurance Fund	15,964	-	2	-	-	15,966
Temporary Assistance for Needy Families	16,618	-	91	10	2	16,721
Children and Families Services Programs	10,871	1	317	157	16	11,362
Payments for Foster Care and Permanency	8,392	-	33	-	1	8,426
National Cancer Institute	3,337	-	1,702	542	108	5,689
Indian Health Services	2,441	1	841	1,413	744	5,440
Primary Health Care	4,751	-	222	75	9	5,057
National Institute of Allergy and Infectious Diseases	3,091	-	1,685	335	96	5,207
Payment to States for the Child Care and Development Block Grant	2,816	-	39	-	-	2,855
Payments to States for Child Support Enforcement and Family Support Programs	3,807	-	647	-	1	4,455
Risk Adjustment Program Payments	-	3,768	-	-	-	3,768
Substance Abuse Treatment	2,545	-	156	10	3	2,714
Low Income Home Energy Assistance	3,391	-	3	-	-	3,394
National Heart, Lung, and Blood Institute	2,554	-	502	164	32	3,252
Child Care Entitlement to States	2,925	-	19	-	-	2,944
National Institute of General Medical Sciences	2,517	-	112	32	1	2,662
National Institute on Aging	1,792	-	179	76	31	2,078
Refugee and Entrant Assistance	1,711	-	389	14	9	2,123
Ryan White HIV/AIDS Program	2,226	-	87	27	5	2,345
Public Health and Social Services Emergency Fund	471	1	1,298	140	487	2,397
Aging and Disability Services Programs	1,955	-	47	31	4	2,037
National Institute of Diabetes and Digestive and Kidney Diseases	1,733	-	219	120	25	2,097
Health Care Fraud and Abuse Control Account	1	-	1,429	74	471	1,975
National Institute of Neurological Disorders and Stroke	1,463	-	228	88	26	1,805
NIH Service and Supply Fund	-	-	1,252	285	360	1,897
PSC Service and Supply Fund	-	-	1,388	149	79	1,616
National Institute of Mental Health	1,278	-	215	101	20	1,614
Social Services Block Grant	1,647	-	12	1	-	1,660
Mental Health	1,066	-	124	5	2	1,197
National Institute of Child Health and Human Development	972	-	317	103	22	1,414
National Institute on Drug Abuse	876	-	248	68	11	1,203
Public Health Preparedness and Response	623	-	250	117	408	1,398
Chronic Disease Prevention and Health Promotion	726	-	256	127	8	1,117
HIV/AIDS, Viral Hepatitis, Sexually Transmitted Diseases and Tuberculosis Prevention	743	-	191	173	14	1,121
Other Agency Budgetary Accounts	13,954	10,865	14,391	7,405	3,471	50,086
Total Amounts Agreed to be Spent	**$ 792,840**	**$ 707,969**	**$ 29,494**	**$ 11,863**	**$ 104,996**	**$ 1,647,162**

Note 22. Statement of Social Insurance (Unaudited)

The Statement of Social Insurance (SOSI) 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 *2018 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 completed review occurred with the 2016-2017 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 5, 2018, with one exception, and do not reflect any actual or anticipated changes subsequent to that date. The one exception is that the projections disregard payment reductions that would result from the projected depletion of the Medicare HI trust fund. 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.

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 SOSI 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 SOSI 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 SOSI 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 SOSI. 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 5, 2018, except that the projections disregard payment reductions that would result from the projected depletion of the Medicare Hospital Insurance trust fund. 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 2018 SOSI actuarial projections are drawn from the Social Security and Medicare Trustees Reports for 2018. 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 http://www.cms.hhs.gov/CFOReport/.[8]

[8]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 2018

					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]
2018	1.81	1,678,000	776.4	1.59	3.82	2.23	2.7	1.4	5.3	0.5	0.1
2020	1.84	1,498,000	762.4	1.95	4.55	2.60	2.6	3.3	4.7	6.0	0.8
2030	2.00	1,321,000	697.7	1.28	3.88	2.60	2.1	4.4	5.3	5.3	2.7
2040	2.00	1,272,000	641.1	1.22	3.82	2.60	2.1	4.6	4.2	4.7	2.7
2050	2.00	1,247,000	591.5	1.23	3.83	2.60	2.1	3.8	3.8	4.7	2.7
2060	2.00	1,233,000	547.9	1.22	3.82	2.60	2.1	3.6	3.7	4.5	2.7
2070	2.00	1,225,000	509.4	1.15	3.75	2.60	2.1	3.8	3.6	4.4	2.7
2080	2.00	1,221,000	475.2	1.13	3.73	2.60	2.1	3.9	3.7	4.4	2.7
2090	2.00	1,218,000	444.7	1.15	3.75	2.60	2.1	3.4	3.5	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 pharmaceuticals 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 Statement of Social Insurance 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 below 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 2018-2014

					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]
2018	2.0	1,218,000	444.7	1.15	3.75	2.60	2.1	3.4	3.5	4.3	2.7
2017	2.0	1,227,000	438.7	1.15	3.75	2.60	2.0	3.4	3.4	4.3	2.7
2016	2.0	1,228,000	435.1	1.15	3.75	2.60	2.0	3.4	3.4	4.3	2.7
2015	2.0	1,060,000	458.4	1.13	3.83	2.70	2.1	3.8	4.1	4.4	2.9
2014	2.0	1,055,000	419.8	1.13	3.93	2.80	2.1	3.8	3.8	4.5	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. (Beginning with FY 2018 legal immigration is referred to as lawful permanent resident (LPR) immigration, and other, non-legal, immigration is referred to as other-than-LPR immigration.). The ultimate level of net legal immigration is 788,000 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 FY 2014 and FY 2015 and is the value assumed in the year 2090 for FYs 2016 - 2018.
[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 FY 2014 and FY 2015 and is the value assumed in the year 2090 for FYs 2016 - 2018.
[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 FY 2014 and FY 2015 and is the value assumed in the year 2090 for FYs 2016 - 2018.
[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 FY 2014 and FY 2015 and is the value assumed in the year 2090 for FYs 2016 - 2018.
[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 FY 2014 and FY 2015 and is the value assumed in the year 2090 for FYs 2016 - 2018.
[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 pharmaceuticals). 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 FY 2014 and FY 2015 and is the value assumed in the year 2090 for FYs 2016 - 2018.
[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 23. 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. In order for this outcome to be achievable, health care providers would have 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 estimated 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, access to Medicare-participating physicians may become a significant issue in the long term under current law. Overriding the price updates in current law, 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. This scenario illustrates the impact that would occur if the payment updates that are affected by the productivity adjustments transition from current law to the payment updates assumed for private health plans over the period 2028 to 2042. It also reflects physician payment updates that transition from current law to the increase in the Medicare Economic Index over the same period. Finally, the scenario assumes the continuation of the 5-percent bonuses for physicians in advanced alternative models (advanced APMs) and of the $500-million payments for physicians in the merit-based incentive payment system (MIPS), which are set to expire in 2025.[9] 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 on the next page 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.

[9]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 enactment of MACRA in 2015 replaced the SGR with specified physician updates.

Medicare Present Value

(in Billions)

	Current law (Unaudited)	Alternative scenario[1, 2] (Unaudited)
Income		
Part A	$22,807	$22,871
Part B	34,453	40,857
Part D	11,124	11,124
Expenditures		
Part A	27,515	32,581
Part B	34,453	40,857
Part D	11,124	11,124
Income less expenditures		
Part A	(4,708)	(9,710)
Part B	-	-
Part D	-	-

[1]These amounts are not presented in the 2018 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 year for these providers. If the payment updates that are affected by the productivity adjustments were to gradually transition from current law to the payment updates assumed for private health plans, the physician updates transitioned to the Medicare Economic Index, and the 5-percent bonuses paid to physicians in advanced APMs did not expire, 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 18 and 19 percent, respectively. 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 19 percent higher under the illustrative alternative scenario, since income is set each year to mirror expenditures.

The Part D values are the same under each projection because the services are not affected by the productivity adjustments or the physician updates.

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 24. 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 SCSIA shows the reconciliation from the period beginning on January 1, 2017 to the period beginning on January 1, 2018, and the reconciliation from the period beginning on January 1, 2016 to the period beginning on January 1, 2017. 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 23 summarizes these assumptions for the current year.

Period beginning on January 1, 2017 and ending January 1, 2018

Present values as of January 1, 2017 are calculated using interest rates from the intermediate assumptions of the 2017 Trustees Report. All other present values in this part of the Statement are calculated as a present value as of January 1, 2018. 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 2017 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 2018 Trustees Report.

Period beginning on January 1, 2016 and ending January 1, 2017

Present values as of January 1, 2016 are calculated using interest rates from the intermediate assumptions of the 2016 Trustees Report. All other present values in this part of the Statement are calculated as a present value as of January 1, 2017. 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 2016 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 2017 Trustees Report.

Change in the Valuation Period

From the period beginning on January 1, 2017 to the period beginning on January 1, 2018

The effect on the 75-year present values of changing the valuation period from the prior valuation period (2017-91) to the current valuation period (2018-92) 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 2017, replaces it with a much larger negative net cash flow for 2092, and measures the present values as of January 1, 2018, 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 (made more negative) when the 75-year valuation period changed from 2017-91 to 2018-92. 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 2017 are realized. The change in valuation period resulted in a very slight increase in the starting level of assets in the combined Medicare Trust Funds.

From the period beginning on January 1, 2016 to the period beginning on January 1, 2017

The effect on the 75-year present values of changing the valuation period from the prior valuation period (2016-90) to the current valuation period (2017-91) 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 2016, replaces it with a much larger negative net cash flow for 2091, and measures the present values as of January 1, 2017, 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 (made more negative) when the 75-year valuation period changed from 2016-90 to 2017-91. 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 2016 are realized. The change in valuation period increased the starting level of assets in the combined Medicare Trust Funds.

Change in Projection Base

From the period beginning on January 1, 2017 to the period beginning on January 1, 2018

Actual income and expenditures in 2017 were different than what was anticipated when the 2017 Trustees Report projections were prepared. Part A payroll tax income in 2017 was lower attributable to lowered wages and expenditures were higher than anticipated based on actual experience. Part B total income and expenditures were higher than estimated based on actual experience. For Part D, actual income and expenditures were both lower 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, 2017 and January 1, 2018 is incorporated in the current valuation and is less than projected in the prior valuation.

From the period beginning on January 1, 2016 to the period beginning on January 1, 2017

Actual income and expenditures in 2016 were different than what was anticipated when the 2016 Trustees Report projections were prepared. Part A payroll tax income in 2017 was lower attributable to lowered wages, and expenditures were higher than anticipated based on actual experience. Part B total income and expenditures were higher than estimated based on actual experience. For Part D, actual income and expenditures were both lower than prior estimates. The net impact of the Part A, B, and D projection base changes is an increase in the estimated

future net cash flow. Actual experience of the Medicare Trust Funds between January 1, 2016 and January 1, 2017 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, 2017 to the period beginning on January 1, 2018

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, 2018), with the exception of a small decrease of 10,000 lawful-permanent-resident (LPR) immigrants per annum in the future, 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 2016 indicated slightly lower birth rates than were assumed in the prior valuation.
- Recent fertility data suggests that the short-term increase in the total fertility rate used in the prior valuation to account for an assumed deferral in childbearing (resulting from the recent economic downturn) was no longer warranted. The observed persistent drop in the total fertility rate in recent years is now assumed to be a loss of potential births rather than just a deferral for this period.
- Incorporating 2015 mortality data obtained from the National Center for Health Statistics for ages under 65 and preliminary 2015 mortality data from Medicare experience for ages 65 and older resulted in higher death rates for all future years than were projected in the prior valuation.
- More recent LPR and other-than-LPR immigration data and historical population data were included.

There was one notable change in demographic methodology:

- Improved the method for projecting mortality rates by marital status by utilizing recent data from NCHS and the American Community Survey.

These changes 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 income and expenditures are both lower for Part A and Part B but higher for Part D.

From the period beginning on January 1, 2016 to the period beginning on January 1, 2017

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, 2017) 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 2015 indicated slightly lower birth rates than were assumed in the prior valuation.
- Incorporating 2014 mortality data obtained from the National Center for Health Statistics at ages under 65 and preliminary 2014 mortality data from Medicare experience at ages 65 and older resulted in higher death rates for all future years than were projected in the prior valuation.
- More recent legal and other-than-legal immigration data and historical population data were included.

There were no consequential changes in demographic methodology.

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

Changes in Economic and Health Care Assumptions

For the period beginning on January 1, 2017 to the period beginning on January 1, 2018

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.

The ultimate economic assumptions for the current valuation (beginning on January 1, 2018) 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 estimated level of potential GDP was reduced by about 1 percent in 2017 and throughout the projection period, primarily due to the slow growth in labor productivity for 2010 through 2017 and low unemployment rates in 2017. This lower estimated level of potential GDP means that cumulative growth in actual GDP is 1 percent less over the remainder of the projected recovery than was assumed in the prior valuation.
- Near-term interest rates were decreased, reflecting a more gradual path for the rise to the ultimate real interest rate than was assumed in the prior valuation.
- New data from the Bureau of Economic Analysis (BEA) indicated lower-than-expected ratios of labor compensation to GDP for 2016 and 2017, while new data from the Internal Revenue Service (IRS) indicated lower-than-expected ratios of taxable payroll to GDP for 2016 and 2017. This new data led to assumed extended recoveries in these ratios to the unchanged ultimate ratios.

There was one notable change in economic methodology:

- Improved the method for projecting educational attainment among women in age groups 45-49 and 50-54 in the labor force participation model.
- 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 were decreased.
- Utilization rate and case mix for skilled nursing facilities services were decreased.
- Payment rates to private health plans are higher than projected in last year's report primarily due to higher risk scores and increased coding by plans.
- Higher projected drug manufacturer rebates.

The net impact of these changes resulted in a small increase in the estimated future net cash flow for total Medicare. For Part A, these changes resulted in 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, these changes decreased the present value of estimated expenditures (and also income).

For the period beginning on January 1, 2016 to the period beginning on January 1, 2017

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, 2017), there was one change to the ultimate economic assumptions.

- The ultimate average real-wage differential is assumed to be 1.20 percent in the current valuation, which is close to a 0.01 percent decrease relative to the previous valuation (even though both ultimate average real-wage differentials are 1.20 when rounded to two decimal places).

In addition to this change in assumption, the assumed real-wage differential for the first ten years of the projection period averaged 0.05 percent lower than in the previous valuation. The lower long-term and near-term real-wage differential assumptions are based on new projections of faster growth in employer sponsored group health insurance premiums. Because these premiums are not subject to the payroll tax, faster growth in these premiums means that a smaller 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. Most significantly, an assumed weaker recovery from the recent recession than previously expected led to a reduction in the ultimate level of actual and potential GDP of about 1.0 percent for all years after the short-range period.

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 and skilled nursing facilities services were decreased.
- 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 2025, resulting in higher provider payment updates.
- Higher projected drug rebates.
- Change in projection methodology of drug spending for Part B patients with end-stage renal disease.

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, these changes increased the present value of estimated future expenditures (and also income). For Part D, these changes decreased the present value of estimated expenditures (and also income).

Changes in Law

For the period beginning on January 1, 2017 to the period beginning on January 1, 2018

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 *Disaster Tax Relief and Airport and Airway Extension Act of 2017* (Public Law 115-63, enacted on September 29, 2017) included one provision that affects the HI and SMI Part B programs.
    - The funding amount of $270 million previously provided to the Medicare Improvement Fund, for services provided during and after FY 2021, is decreased to $220 million. (This fund was intended to be available for improvements to the original fee-for-service program under Parts A and B.)

- An Act to Provide for Reconciliation Pursuant to Titles II and V of the Concurrent Resolution on the Budget for FY 2018 (Public Law 115-97, enacted on December 22, 2017, and also referred to as the *Tax Cuts and Jobs Act of 2017*) included three provisions that affect the HI program.
    - Federal income tax rates for individuals are reduced, effective for taxable years beginning after December 31, 2017 and ceasing to apply after December 31, 2025. In addition, the inflation index applied to the tax bracket thresholds and standard deductions is changed, effective for taxable years beginning after December 31, 2017, such that these amounts will permanently grow more slowly than under prior law.
    - The requirement that most individuals be covered by a health insurance plan or pay a financial penalty, commonly referred to as the individual mandate, is repealed, effective January 1, 2019. Accordingly, the percentage of people without health insurance is expected to increase. Because the change in this percentage is a factor used in determining payments to Medicare disproportionate share hospitals for uncompensated care, these payments are expected to increase as well. In addition, in light of this repeal, it is expected that some individuals will drop their employer-sponsored health insurance, thereby slightly increasing HI covered wages and taxable payroll.
    - Temporary tax changes for certain small businesses are made that will affect reported self-employment income and, in turn, HI covered wages and taxable payroll.
- An Act Making Further Continuing Appropriations for the FY Ending September 30, 2018, and for Other Purposes (Public Law 115-120, enacted on January 22, 2018) included one provision that affects the HI and SMI programs.
    - A moratorium for calendar year 2019 is placed on the annual fee to be paid by health insurance providers. This fee is imposed on certain large health insurance providers, including those furnishing coverage under Medicare Advantage (Part C) and Medicare Part D.
- The *Bipartisan Budget Act of 2018* (BBA 2018; Public Law 115-123, enacted on February 9, 2018) included provisions that affect the HI and SMI programs.
    - The sequestration process that is in place should Congress fail to address the budget deficit by certain deadlines, as described in previous annual reports, is extended by 2 years, through FYs 2026 and 2027.
    - The Independent Payment Advisory Board (IPAB) and all related provisions are repealed, effective upon enactment. (The IPAB was established by the *Affordable Care Act* to develop and submit proposals aimed at extending the solvency of Medicare, slowing Medicare cost growth, and improving the quality of care delivered to Medicare beneficiaries.)
    - For Medicare Advantage plans and stand-alone Part D plans that undergo a contract consolidation approved on or after January 1, 2019, the star rating (and any quality bonus payment) for the surviving contract is to reflect an enrollment-weighted average of the ratings for the continuing and closed contracts.
    - The authority for Medicare Advantage Special Needs Plans (SNPs), which was due to expire on December 31, 2018, is permanently extended. A number of reforms to dual-eligible SNPs and chronic-condition SNPs are also mandated.
    - For Medicare Advantage plans, certain provisions are enacted, effective January 1, 2020, which permit plans to offer to chronically ill enrollees (i) a broader range of supplemental benefits (which may include services that are not primarily health care services), as long as the benefit offers a reasonable expectation of improving or maintaining health or overall function, and (ii) expanded telehealth services as supplemental benefits, subject to certain specified requirements. In addition, the Value-Based Insurance Design (VBID) Model, which is a pilot program allowing certain plans to offer supplemental benefits or reduced cost sharing to enrollees with certain chronic

conditions, is expanded, effective no later than January 1, 2020, to allow plans in all States the opportunity to participate in it. The VBID program is also made exempt, through December 31, 2021, from certain spending and quality-of-care testing to which it would otherwise be subjected.

- For Medicare Accountable Care Organizations (ACOs), certain provisions are enacted to (i) provide more opportunities for beneficiaries to be assigned to, or voluntarily align with, ACOs; (ii) allow for the use of beneficiary incentive programs; and (iii) allow for expanded use of telehealth services. The specific types of ACOs to which each of these changes apply, as well as the effective dates, vary.
- Funding for the National Quality Forum is provided from the HI and SMI trust funds for the remainder of FY 2017 and for FYs 2018 and 2019.
- Funding for certain low-income outreach and assistance programs is extended 2 years, through September 30, 2019.
- Certain existing civil and criminal penalties are substantially increased for providers and suppliers who violate health care fraud and abuse laws, effective upon enactment.
- For home health agencies serving beneficiaries in rural areas, the 3-percent add-on payment is extended 1 year, through December 31, 2018. Then, for services furnished in rural areas from 2019 through 2022, three separate tiers of add-on adjustments are established, based on Medicare home health utilization and low-population density; these adjustments diminish over varying periods of time (and become 0 percent no later than 2020). Also, for services furnished on or after January 1, 2019, home health agencies are required to report the county in which the services are furnished.
- For the Medicare home health prospective payment system (PPS), the annual update for calendar year 2020 is set at 1.5 percent.
- Under the home health PPS, the unit of payment for home health services is changed from a 60-day to a 30-day episode of care, beginning in 2020. This change must be made in a budget-neutral manner, but adjustments to offset anticipated behavior changes that could result from the modified methodology are allowed. Also beginning in 2020, therapy thresholds are removed from the home health case mix adjustment.
- To demonstrate home-bound and medical-necessity status when determining if a patient is eligible for home health services, documentation in the medical records of home health agencies can be used as supporting material, in addition to documentation in the medical records of the certifying physician, effective January 1, 2019.
- For telehealth services furnished for purposes of diagnosis, evaluation, or treatment of symptoms of an acute stroke, the geographic restriction that limits originating sites to rural areas is eliminated, provided that all other Medicare telehealth coverage requirements are satisfied. In addition, no originating site facility fee is to be paid to sites that do not meet the current geographic and site type requirements. This provision is effective beginning on January 1, 2019.
- For the Medicare electronic health records incentive program, the provision requiring more stringent measures of meaningful use, over time, is eliminated, effective upon enactment.
- The funding amount of $220 million previously provided for the Medicare Improvement Fund (as noted above) is eliminated.
- The Medicare-Dependent Hospital (MDH) program is extended for 5 fiscal years, through September 30, 2022. In addition, the program is extended to certain rural hospitals that are located in all-urban States and that otherwise meet the MDH criteria.
- Medicare inpatient hospital add-on payments for low-volume hospitals are extended for 5 fiscal years, through September 30, 2022. In addition, for FYs 2019 through 2022, changes are made to the qualifying criteria (which are to be based on total discharges or Medicare discharges,

depending on the year, and on the distance from another inpatient hospital) and to the add-on adjustments (which are to be based on a sliding scale ranging from 25 percent to 0 percent).

- Two changes are made to the long-term care hospital (LTCH) site-neutral provision. First, the originally mandated 2-year transition period is extended for 2 additional years, covering FYs 2018 and 2019. Second, the inpatient hospital PPS comparable amount used in the site-neutral payment rate calculations for FYs 2018 through 2026 is to be reduced by 4.6 percent.
- For the inpatient hospital diagnosis-related groups (DRGs) subject to the post-acute care transfer policy, hospice is added as a setting of care, effective October 1, 2023.
- For the Medicare skilled nursing facility PPS, the annual update for FY 2019 is set at 2.4 percent.
- Physician assistants are added to the types of providers who may serve as attending physicians for the purposes of hospice care, effective January 1, 2019. (Previously, only physicians and nurse practitioners could serve.) Like nurse practitioners, physician assistants are not permitted to provide the written certification of terminal illness required for hospice services.
- A new income-related premium threshold is established. Specifically, beginning in calendar year 2019, individuals with incomes at or above $500,000 (and couples with incomes at or above $750,000) will pay premiums covering 85 percent (rather than 80 percent) of the average program cost for aged beneficiaries. These new threshold levels will not be inflation-adjusted until 2028 and later.
- The 1.00 floor on the geographic index for physician work is extended for 2 additional years, through December 31, 2019.
- The physician fee schedule update for 2019, which had been set at 0.5 percent, is decreased to 0.25 percent.
- A number of changes are made to the merit-based incentive payment system (MIPS) for physicians, including that it be applied only to covered professional services instead of to items and services (thereby excluding, most prominently, physician-administered Part B drugs) and that its transition period be extended by 3 years (such that the post-transition period now begins in 2022, not 2019). Certain additional changes to the system are mandated for the extended transition period, and others are mandated for the period thereafter. Effective dates vary.
- The annual payment limits on therapy services are permanently repealed, beginning on January 1, 2018. The threshold for the targeted manual medical review process is lowered, from $3,700 to $3,000, effective as of the same date and until 2028, after which the threshold is to be increased by a specified formula.
- Outpatient physical and occupational therapy services furnished by a therapy assistant are paid at 85 percent of the amount that otherwise would have been paid under the fee schedule, effective January 1, 2022.
- The freeze on coding and valuation of certain radiation therapy services reimbursed under the fee schedule, in place for 2017 and 2018, is extended through 2019.
- For qualified home infusion therapy suppliers, a temporary transitional payment for administering home infusion therapy is established, beginning on January 1, 2019. Payment rates in three categories will apply during the transition period, which will end on December 31, 2020, after which a new payment methodology will begin.
- Certain ground ambulance add-on payments are extended 5 additional years, through December 31, 2022. (These add-on payments include a 3-percent bonus for services originating in rural areas, a 2-percent bonus for services originating in other locations, and a 22.6-percent super rural bonus for rural areas with the lowest population densities.) The development of a system to collect certain data from providers and suppliers of ground ambulance services is also mandated.

- For non-emergency ground ambulance transports of beneficiaries with end-stage renal disease (ESRD) to and from renal dialysis services, the reduction in payments is increased from 10 percent to 23 percent for transports furnished on or after October 1, 2018.
- For beneficiaries with ESRD who receive home dialysis, all monthly physician visits can be provided via telehealth, beginning on January 1, 2019, as long as the beneficiary receives one in-person visit monthly for the initial 3 months and at least one every 3 months thereafter. (Previously, at least one in-person visit per month was required.) Also, the originating site requirements are modified in several ways, and no site facility fee is to be paid if the beneficiary's home is the originating site.
- Conditions are added to those that allow a beneficiary who qualifies for cardiac rehabilitation services to qualify for the more intensive set of services, effective upon enactment. Also, the supervision requirements for cardiac rehabilitation, intensive cardiac rehabilitation, and pulmonary rehabilitation are changed to allow physician assistants, nurse practitioners, and clinical nurse specialists (in addition to physicians) to supervise these programs, effective January 1, 2024.
- A provision of the *Steve Gleason Act of 2015*, requiring that Medicare payment for rental or lump-sum purchase of speech-generating devices and accessories be made without a cap on the amount, is made permanent.
- Enforcement is delayed an additional year, through December 31, 2017, for the instruction that, for outpatient therapeutic services provided in critical access and small rural hospitals, a physician or non-physician practitioner must provide direct supervision throughout the performance of a procedure. (In the 2018 outpatient hospital PPS rule, CMS extended these non-enforcement instructions for 2018 and 2019 and noted that, for 2017, while there was not a non-enforcement instruction in place, Medicare administrative contractors were directed not to prioritize enforcement of this requirement for these hospitals. This legislation provides the non-enforcement instruction that had been lacking for 2017.)
- Under the Part D standard benefit structure, the coverage gap closes 1 year earlier than previously scheduled for brand-name drugs only; that is, for brand-name drugs, beneficiaries in the coverage gap (excluding low-income enrollees eligible for cost-sharing subsidies) will pay 25 percent of drug costs beginning on January 1, 2019 (instead of 30 percent in 2019 and 25 percent thereafter). Also beginning on that date, these beneficiaries will receive a 70-percent manufacturer discount (instead of 50 percent) and a 5-percent benefit (instead of 20 percent in 2019 and 25 percent thereafter) from their Part D plans for applicable prescription drugs. (For purposes of drug discounts while beneficiaries are in the Part D coverage gap, applicable drugs are generally covered brand-name Part D drugs, while non-applicable drugs are generally covered generic Part D drugs.) For generic drugs, the law remains the same, with beneficiaries paying 37 percent of drug costs in 2019 and 25 percent thereafter.
- For purposes of drug discounts while beneficiaries are in the Part D coverage gap, the definition of applicable drugs is expanded to include biosimilars, effective January 1, 2019. (Applicable drugs previously included biologics but not biosimilars.)

Overall, these provisions 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 a slight decrease to the present value of estimated future income, with an overall net 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, 2016 to the period beginning on January 1, 2017

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 *21st Century Cures Act* included provisions that affect the HI and SMI Part B programs.
    - For inpatient hospital services, the adjustment to the payment rate increase of 0.5 percentage point for FY 2018, as established by the *Medicare Access and CHIP Reauthorization Act of 2015* (MACRA), is reduced to an adjustment of 0.4588 percentage point. (The adjustments to the rate increases of 0.5 percentage point for each of FYs 2019 through 2023, as also established by MACRA, are unchanged.)
    - For long-term care hospital (LTCH) discharges occurring during FY 2017, the LTCH 25-percent rule is suspended.
    - A change is made to the moratorium that prohibits the classification of new LTCHs and new LTCH satellite facilities and an increase in beds for existing LTCHs and existing LTCH satellite facilities. No exceptions to the moratorium had been provided to allow existing LTCHs and existing LTCH satellite facilities to increase their number of certified beds; however, under the Cures Act, these existing facilities are permitted to do so. This provision is effective as if the exception for these bed increases had always applied during the moratorium. A reduction to high-cost outlier payments to LTCH standard rate cases, through an increase to the qualifying threshold, is also provided for and is intended to offset costs of the moratorium exceptions provision.
    - Several changes are made that involve the LTCH site-neutral provision.
        - The first modification is to the calculation of the average length of stay for certain LTCHs. Under prior law, discharges paid at the site-neutral payment rate or by an MA plan were excluded from calculations determining the hospital's average length of stay, effective for cost-reporting periods starting on or after October 1, 2015. Under the Cures Act, this carve-out of site-neutral and MA discharges (which is generally advantageous to LTCHs) applies to the average length of stay calculation for newer LTCHs as well. Thus, the average length of stay calculation methodology is now the same for all LTCHs. This provision is effective retroactively, for cost-reporting periods starting on or after October 1, 2015.
        - Next, a temporary exception to the site-neutral criteria is provided for certain LTCHs that primarily treat patients with brain and spinal cord injuries, are non-profit, and have a significant number of admissions from out of state, for all discharges in cost-reporting periods beginning during FYs 2018 and 2019.
        - Finally, a temporary exception to the site-neutral criteria is created for certain discharges from certain LTCHs for beneficiaries receiving treatment for specified types of severe wounds. To qualify for the exception, the stay for one of the specified types of severe wounds must be classified under one of four specified Medicare severity LTCH diagnosis-related groups (MS-LTC-DRGs). Further, the facility must be a grandfathered LTCH. This provision is effective for these specified discharges occurring in cost-reporting periods that begin during FY 2018.
    - The Secretary of HHS is authorized to deny payment for services provided in temporary moratorium areas (which are geographic areas that have been established by CMS for specified types of providers, for the development and improvement of investigating and prosecuting fraud). Previously, denial was based on the location of the provider rather than on the location of the

patient; this provision eliminates the ability of a provider to locate a business office outside of a moratorium area but be paid for services furnished within it.

- Medicare beneficiaries with end-stage renal disease are allowed to enroll in MA plans, effective for plan years beginning in 2021 and later. Standard acquisition costs for kidneys are to be removed from the capitation rates and paid for by traditional Medicare.
- Additional requirements are established for assigning Medicare FFS beneficiaries to accountable care organizations (ACOs) under the Medicare shared savings program. Specifically, the basis for assignment is required to reflect beneficiaries' utilization of not only primary care services provided by ACO physicians but also services furnished in federally qualified health centers or rural health clinics, effective for performance years beginning on or after January 1, 2019.
- Under the competitive bidding program for certain durable medical equipment (DME) items, the transition period is extended, such that the implementation of payments based entirely on the competitively bid rates (rather than on a blend of these rates and rates under the prior fee schedule payment methodology) is delayed retroactively, from July 1, 2016 to January 1, 2017.
    - Also, for DME providers in non-competitively bid, new considerations are stipulated for determining adjustments to the competitively bid prices. Specifically, the Secretary of HHS is required to take into account stakeholder input and the highest winning bid in the competitively bid areas and to compare, with respect to non-competitively and competitively bid areas, the average travel distance and cost associated with furnishing the items and services, the average volume of the items and services furnished by suppliers, and the number of suppliers. This provision is effective for services furnished on or after January 1, 2019.
- For infusion drugs furnished by suppliers of DME, the reimbursement methodology is changed from 95 percent of the average wholesale price to the average sales price plus 6 percent (that is, to the methodology used for most physician-administered drugs), effective January 1, 2017. Also, these drugs are removed from the DME competitive acquisition areas, beginning on the date of enactment.
- Qualified home infusion therapy suppliers are to be reimbursed for administering home infusion therapy, effective January 1, 2021. Certain requirements and standards for suppliers, as well as payment methodology, are established.
- As described in last year's report, the *Bipartisan Budget Act of 2015* (BBA) directed that outpatient hospital services provided by new off-campus hospital-based outpatient entities (that is, those established on or after the BBA date of enactment of November 2, 2015 and located more than 250 yards from the hospital campus) are excluded from the outpatient hospital PPS, effective for services provided on or after January 1, 2017 (with certain exceptions, particularly for specific dedicated emergency departments). These services are instead to be reimbursed under the Medicare physician fee schedule or the ambulatory surgical center PPS (both of which provide lower reimbursement rates than the outpatient hospital PPS).
    - The Cures Act provides an exception for off-campus hospital provider-based outpatient entities that were "mid-build" on November 2, 2015. A mid-build entity is one that had a binding written agreement, before November 2, 2015, with an outside unrelated party for actual construction of the new off-campus department. To be eligible under this exception, the host hospital must (i) file a certification that the department meets the mid-build status requirement; (ii) file an attestation that the department is provider-based; and (iii) add the department to the host hospital's Medicare enrollment form. Entities that qualify will be eligible to bill under the outpatient PPS for services provided on or after January 1, 2018.

- Under the Cures Act, an off-campus outpatient department can also be eligible for payment under the outpatient hospital PPS for services furnished in 2017 if the host hospital submitted a voluntary attestation, prior to December 2, 2015, stating that the department is provider-based. (Under separate guidance from CMS that governs submission of provider-based attestations, for a hospital to have taken this step, the construction of the new off-campus outpatient department would have been completed and the hospital accepting, or poised to accept, patients. Thus, this exception benefits only a small number of departments that fell just outside of the deadline contained in the BBA.)
- To clarify, while the relief for 2017 applies only to off-campus outpatient departments with provider-based attestations filed before December 2, 2015, the relief for 2018 and beyond applies more broadly to off-campus outpatient departments with construction agreements in place as of November 2, 2015 (including hospitals eligible for the 2017 exception). Hence, most hospitals that qualify for the exception under this provision are not eligible for payment under the outpatient PPS during 2017 and are, instead, subject to lower payments for services furnished during that year, with return to the outpatient hospital PPS effective for services furnished on or after January 1, 2018.

- Off-campus outpatient departments of certain cancer hospitals are also granted exception from the BBA provision described above, thereby confirming that the BBA legislation intended these facilities to remain under their existing separate payment system. To qualify, these locations must file attestations stating that they are provider-based, within 60 days of the date of enactment or within 60 days of meeting the provider-based requirement. The attestations are subject to audit. A reduction to the additional payments that cancer hospitals receive (relative to payments under the inpatient hospital PPS) is also provided for and is intended to offset costs of the BBA exception for off-campus outpatient cancer hospital departments.
- Enforcement is delayed an additional year, through December 31, 2016, for the regulation requiring that, for outpatient therapeutic services provided in critical access and small rural hospitals, a physician or non-physician practitioner must provide direct supervision throughout the performance of a procedure.
- For wheelchair accessories and seat and back cushions furnished in connection with complex rehabilitative power wheelchairs, fee schedule adjustments do not apply until July 1, 2017 (which is a delay of 6 months relative to the previously stipulated date of January 1, 2017).

Overall these provisions resulted in a very small 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 and had no impact on the present value of estimated future income. For Part B, these changes increased the present value of estimated future expenditures (and also income). These changes had no impact on Part D.

Required Supplementary Stewardship Information

Investment in Human Capital (in Millions)

For the Year Ended September 30, 2018

Responsibility Segment Program	2018	2017	2016	2015	2014
National Institutes of Health					
Research Training and Career Development	$ 883	$ 1,807	$ 1,745	$ 1,631	$ 1,541
Health Resources and Services Administration					
HRSA Health Workforce Program	1,058	1,047	935	828	660
Other HRSA Training Investments	89	88	90	-	-
Other Investments in Human Capital					
Other	23	21	17	14	8
Totals	**$ 2,053**	**$ 2,963**	**$ 2,787**	**$ 2,473**	**$ 2,209**

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

NIH has long recognized that the most essential resource in the biomedical research enterprise are the scientists who make up our workforce. The NIH Research Training and Career Development Programs address the need for trained personnel to conduct biomedical 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. In addition, NIH launched the Next Generation Researchers Initiative which prioritizes funding opportunities for investigators who are in the early stages of their careers. 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 biomedical 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. In FY 2018, BHW made more than 8,440 awards worth a total of $1.3 billion to organizations and individuals. As of September 30, 2018, there were more than 12,500 National Health Service Corps (NHSC) and NURSE Corps members providing care to more than 13 million people in underserved areas nationwide. Another 1,725 primary care students are either in school or in residency preparing for future service with the Corps programs. More than 3,600 of these NHSC members are currently providing behavioral health care services, including medication-assisted treatment and other evidence-based substance use disorder care, in high-need areas. HRSA continues to invest in expanding access to substance use disorder treatment in rural and underserved areas. In Academic Year 2017-2018,

BHW also supported more than 840 residents in 57 Teaching Health Centers through the Teaching Health Center Graduate Medical Education program. Teaching Health Centers trained more than 500 future Family Medicine physicians, 200 future Internal Medicine physicians and 50 future Psychiatrists. For more information, visit HRSA Health Workforce.

Other HRSA human capital investments are primarily in the form of grants and cooperative agreements. HRSA Maternal and Child Health (MCH) Workforce Development awarded grants to educate and train the current and future generations of MCH professionals through interdisciplinary undergraduate, graduate, and post-graduate training programs, and through continuing education to practicing MCH professionals. HIV/AIDS Bureau investment supports the AIDS Education and Training Center Program provides training and technical assistance aimed at increasing the capacity of health care professionals to provide high quality HIV care and prevention services for people who are living with, or at risk for developing HIV/AIDS. From 2012 through 2017, AIDS Education and Training Center Programs conducted 60,986 training events with an average of 74,257 unique participants trained each year. The Rural Network Allied Health Training Program provide support for the recruitment, clinical training and retention of allied health professionals in rural areas. The PHS Act family planning service program provided clinical and programmatic training and technical assistance was provided to over 500 clinical providers annually and over 90 Title X family planning grantees; as well as, to help support the over 4,000 Title X clinical service sites.

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. As of September 30, 2018, 24 grants (totaling $9.2 million) and 7 contracts (totaling $2.3 million) were awarded in FY 2018. 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.

ACL's National Institute for Disability, Independent Living, and Rehabilitation Research (NIDILRR) administers the Advanced Rehabilitation Research and Training (ARRT) Program to increase capacity for high quality rehabilitation research by supporting grants to institutions to provide advanced research training to individuals with doctorates or similar advanced degrees who have clinical or other relevant experience. As of September 30, 2018, ACL has awarded 19 ARRT grants (totaling $2.8 million). These grants were made to institutions to recruit qualified persons, including individuals with disabilities, and to prepare them to conduct independent research related to disability and rehabilitation, with particular attention to research areas that support the implementation and objectives of the *Rehabilitation Act* and that improve the effectiveness of services authorized under the Act.

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, 2018

Responsibility Segments	Basic	Applied	Develop-mental	2018 Total	2017	2016	2015	2014	Grand Total
AHRQ	$ -	$ 187	$ -	$ 187	$ 217	$ 213	$ 167	$ 250	$ 1,034
CDC	69	320	35	424	509	502	490	394	2,319
FDA	180	-	8	188	142	170	129	103	732
NIH	18,320	17,001	147	35,468	29,465	28,258	28,093	27,719	149,003
Other	3	31	-	34	108	32	26	3	203
Totals	**$ 18,572**	**$ 17,539**	**$ 190**	**$ 36,301**	**$ 30,441**	**$ 29,175**	**$ 28,905**	**$ 28,469**	**$ 153,291**

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 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 FY 2018, Congress appropriated $168 million for CDC to continue to fight Antibiotic Resistance (AR), recognizing the gravity of the threat. With these investments, CDC fortified the AR Solutions Initiative, which has supported the national infrastructure to detect, respond, and prevent resistant infections across health care settings, food, and communities since 2016. CDC funding supports all 50 state health departments, the six local health departments, and Puerto Rico. Through these investments, CDC is transforming how the nation combats and slows antibiotic resistance at all levels. AR Solutions Initiative activities include putting state and local AR laboratory and epidemiological expertise in every state and making investments in public and private sector innovation to fight AR threats. For more information visit Antibiotic Resistance Solutions Initiative.

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 supports 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. In contrast, fewer than 10 such products supported by industry came to market between 1973 and 1983. The program has bought more than 60 products to marketing approval. Approximately 10 percent of the studies that received developmental support from the OPD Grants Program utilized to facilitate the marketing approval of those drugs, biologics, and medical devices. The Humanitarian Use Device Program has been the first step in approval of 70 Humanitarian Device Exemption approvals. For more information about the Orphan Products Clinical Trials Grants Program, including grants funded to date, visit Orphan Products Clinical Trials Grants Program.

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

NIH-supported research focuses on spurring advances in discovery along the biomedical research continuum, spanning basic, translational, and clinical research. NIH researchers undertake a wide array of research activities in pursuit of the NIH mission, including studying biology in health and disease states, undertaking observational and population-based research approaches, assessing new treatments or comparing different treatment approaches to provide new options for patients, and supporting a variety of health services research activities to inform medical practice. 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.

Congress passed the 21st *Century Cures Act* (Cures Act) in December 2016 authorizing several years of funding that is not subject to the discretionary caps. The Cures Act provides multiyear funding to four highly innovative scientific initiatives: 1) the *All of Us* Research Program 2) the Cancer Moonshot 3) the Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative, and 4) the Regenerative Medicine Innovation Project.

The *All of Us* Research Program aims to gather data from more than a million volunteer participants in the U.S. to advance precision medicine, which takes into account individual differences in lifestyle, environment, and biology to enable prevention and treatment strategies tailored to individuals. National enrollment for *All of Us* started in May 2018. The Cancer Moonshot aims to accelerate cancer research making more therapies available to more patients, improving the ability to prevent cancer, detecting it at the earliest stage possible. The BRAIN initiative seeks to understand how the brain encodes, stores, and retrieves information, which will transform the ability to diagnose and treat neurological/mental disorders. Furthermore, the Regenerative Medicine Innovation Project will support clinical research in coordination with the FDA using adult stem cells to further the field of regenerative medicine.

NIH is implementing provisions of the Cures Act relevant to the overall conduct of biomedical and behavioral research including reducing administrative burden, strengthening protections for participants involved with clinical research, bolstering the next generation of biomedical scientists, ensuring persons of all ages are included in clinical research, and requiring sharing of data resulting from NIH funded clinical trials. For more information visit the *21st Century Cures Act*.

Further, in April 2018, NIH launched an aggressive, trans-agency effort to speed scientific solutions to stem the national opioid public health crisis. The HEAL (Helping to End Addiction Long-term) Initiative builds on extensive, NIH-supported research to provide new strategies for the prevention and treatment of opioid misuse and addiction, as well as to enhance pain management by understanding how chronic pain develops and improving the pipeline of new pain treatments.

Additionally, Dr. Adriaan Bax, a scientist in the National Institute of Diabetes, Digestive, and Kidney Diseases, received the 2018 Robert A. Welch Award in Chemistry. Dr. Bax transformed nuclear magnetic resonance spectroscopy into a powerful tool to study biological macromolecules. Only one other NIH scientist has ever won this award—Dr. Earl Stadtman in 1991. For more information visit The 2018 Welch Award in Chemistry.

Other Investments in Research and Development

ACL, through the NIDILRR, conducts research to generate new knowledge and promote its effective use to improve the abilities of people with disabilities to perform activities of their choice in the community, and to expand society's capacity to provide full opportunities and accommodations for its citizens with disabilities.

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. MCH research is to support the MCH field, improving the health and well-being of women, children, and families. Healthcare Systems Bureau Division of Transplantation supports research to identify successful model interventions to increase deceased organ donation registration or family consent and to educate the public about the risks and benefits of living organ donation. Federal Office of Rural Health Policy increases the amount of research that is freely available to all who have an interest in rural health. HRSA's basic research supports the causes, diagnosis, transmission, prevention, and cure of Hansen's disease. For more information visit National Hansen's Disease Program.

Required Supplementary Information

Combining Statement of Budgetary Resources (in Millions)

For the Year Ended September 30, 2018

Budgetary Resources:	CMS				Other Agency Accounts	Agency Combined Totals
	Medicare HI	Medicare SMI	Payments to Trust Fund	Medicaid		
Unobligated Balance from Prior Year Budget Authority, Net (Discretionary and Mandatory)	$ 225	$ 345	$ 6,084	$ 45,360	$ 45,579	$ 97,593
Appropriations (Discretionary and Mandatory)	302,701	327,134	352,289	405,629	258,917	1,646,670
Borrowing Authority (Discretionary and Mandatory)	-	-	-	-	(127)	(127)
Spending Authority from Offsetting Collections (Discretionary and Mandatory)	-	-	-	1,417	12,227	13,644
Total Budgetary Resources	**$ 302,926**	**$ 327,479**	**$ 358,373**	**$ 452,406**	**$ 316,596**	**$ 1,757,780**
Status of Budgetary Resources:						
New Obligations and Upward Adjustments	$ 302,926	$ 327,479	$ 345,819	$ 437,004	$ 266,825	$ 1,680,053
Unobligated Balance, End of Year:						
Apportioned, Unexpired Accounts	-	-	6,470	15,093	21,945	43,508
Exempt from Apportionment, Unexpired Accounts	-	-	-	-	188	188
Unapportioned, Unexpired Accounts	-	-	-	309	9,661	9,970
Unexpired Unobligated Balance, End of Year	-	-	6,470	15,402	31,794	53,666
Expired Unobligated Balance, End of Year	-	-	6,084	-	17,977	24,061
Unobligated Balance, End of Year	-	-	12,554	15,402	49,771	77,727
Total Status of Budgetary Resources	**$ 302,926**	**$ 327,479**	**$ 358,373**	**$ 452,406**	**$ 316,596**	**$ 1,757,780**
Outlays, Net:						
Outlays, Net (Discretionary and Mandatory)	$ 301,412	$ 325,831	$ 343,981	$ 384,997	$ 232,919	$ 1,589,140
Distributed Offsetting Receipts	(35,893)	(430,777)	-	-	(2,207)	(468,877)
Agency Outlays, Net (Discretionary and Mandatory)	**$ 265,519**	**$ (104,946)**	**$ 343,981**	**$ 384,997**	**$ 230,712**	**$ 1,120,263**

Summary of Other Agency Accounts

	Budgetary Resources	Net Outlays
ACF	$ 60,877	$ 53,288
ACL	2,231	1,942
AHRQ	390	323
CDC	16,131	12,135
CMS	150,155	105,154
FDA	6,512	2,092
HRSA	12,443	11,057
IHS	9,142	4,982
NIH	43,268	32,637
OS	6,764	2,834
PSC	2,802	435
SAMHSA	5,881	3,833
Totals	**$ 316,596**	**$ 230,712**

Deferred Maintenance and Repairs

For the Years Ended September 30, 2018 and 2017

The FASAB issued SFFAS 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 repair 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 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. Equipment affixed to real property should be appropriately reflected in building and other structures. Prior year numbers reported for equipment have been adjusted to reflect this change.

Estimated Cost to Return to Acceptable Condition
(in Millions)

Category of Asset	2018	2017
General PP&E		
Buildings	$ 2,392	$ 2,240
Other Structures	21	26
Total	**$ 2,413**	**$ 2,266**

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 over 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 *2018 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, and the Trustees previously estimated 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, access to Medicare-participating physicians may 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); and the *Bipartisan Budget Act of 2018* (Public Law 115-123, enacted on February 9, 2018). The sequestration reduces benefit payments by 2 percent from April 1, 2013 through March 31, 2027 and by 4 percent from April 1, 2027 through September 30, 2027. Due to sequestration, non-salary administrative expenses are reduced by an estimated 5 to 7 percent from March 1, 2013 through September 30, 2027.

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 challenges 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 that (i) there would be a transition from current-law payment updates for providers affected by the economy-wide productivity adjustments to payment updates that reflect adjustments for health care productivity; (ii) the average physician payment updates would transition from current law to payment updates that reflect the Medicare Economic Index; and (iii) the 5-percent bonuses for physicians in advanced alternative payment models (advanced APMs) and the $500-million payments for physicians in the merit-based incentive payment system (MIPS) would continue indefinitely rather than expire in 2025. The timing of these assumed transitions in payment updates is later for this year's annual report than it was in prior reports. The difference between the illustrative alternative and the current-law projections continues to demonstrate that the long-range costs could be substantially higher than shown throughout much of the report if the MACRA[10] and *Affordable Care Act*[11] 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 23 in these financial statements, in section 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 https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds.

[10]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 for physicians in advanced APMs or MIPS, respectively. 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.

[11]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).

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.[12]

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.[13] 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.[14] 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 produce

[12]The Trustees' methodology is consistent with Finding III-2 and Recommendation III-3 of the 2010-2011 Medicare Technical Review Panel and with Finding 3-2 of the 2016-2017 Medicare Technical Review Panel. The Panel's final report is available at http://aspe.hhs.gov/health/reports/2013/MedicareTech/TechnicalPanelReport2010-2011.pdf and https://aspe.hhs.gov/system/files/pdf/257821/MedicareTechPanelFinalReport2017.pdf.

[13]See Recommendation III-1. 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.

[14]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.

the health care goods and services.[15] 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,[16] 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 2042, or GDP plus 0.0 percent, declining gradually to 3.5 percent in 2092, or GDP minus 0.3 percent.[17]

(ii) ***Physician services***

Payment rate updates are 0.75 percent per year for those physicians assumed to be participating in advanced APMs and 0.25 percent for those assumed to be participating in MIPS. The year-by-year per capita growth rates for physician payments are assumed to be 3.6 percent in 2042, or GDP minus 0.3 percent, declining to 2.8 percent in 2092, 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 that is not subject to competitive bidding,[18] 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 2042, or GDP minus 0.8 percent, declining to 2.7 percent in 2092, 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 17 percent of total Part B expenditures in 2026 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.[19] 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

[15]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.

[16]For convenience the term economy-wide private nonfarm business multifactor productivity will henceforth be referred to as economy-wide productivity.

[17]These growth rate assumptions are described relative to the per capita increase in GDP and characterized simply as GDP plus X percent.

[18]The portion of durable medical equipment that is subject to competitive bidding is included with all other Medicare services since the price is determined by a competitive bidding process.

[19]For example, physician-administered Part B drugs are reimbursed at the level of the average sales price in the market plus 6 percent.

corresponding year-by-year per capita growth rates for these services are 4.7 percent in 2042, or GDP plus 0.8 percent, declining to 4.3 percent by 2092, or GDP plus 0.5 percent.

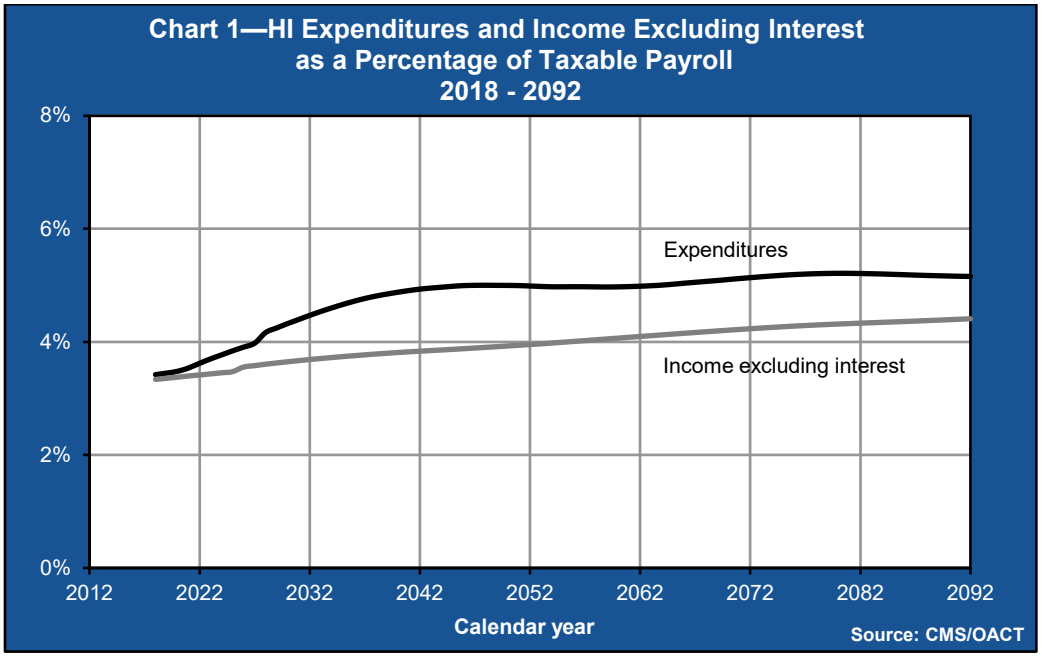
In addition, these long-range cost growth rates must be modified to reflect demographic impacts. For example, beneficiaries at ages 80 and above use Part A skilled nursing and home health services much more frequently than do younger beneficiaries. As the beneficiary population ages, Part A costs will 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 2092 is 3.7 percent or GDP minus 0.1 percent.

HI Cash Flow 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 cost rates shown in the 2018 report are higher than those from the 2017 report for all years largely due to higher spending and lower taxable payroll in all projected years.



Since the standard HI payroll tax rates are not scheduled to change in the future under current 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.

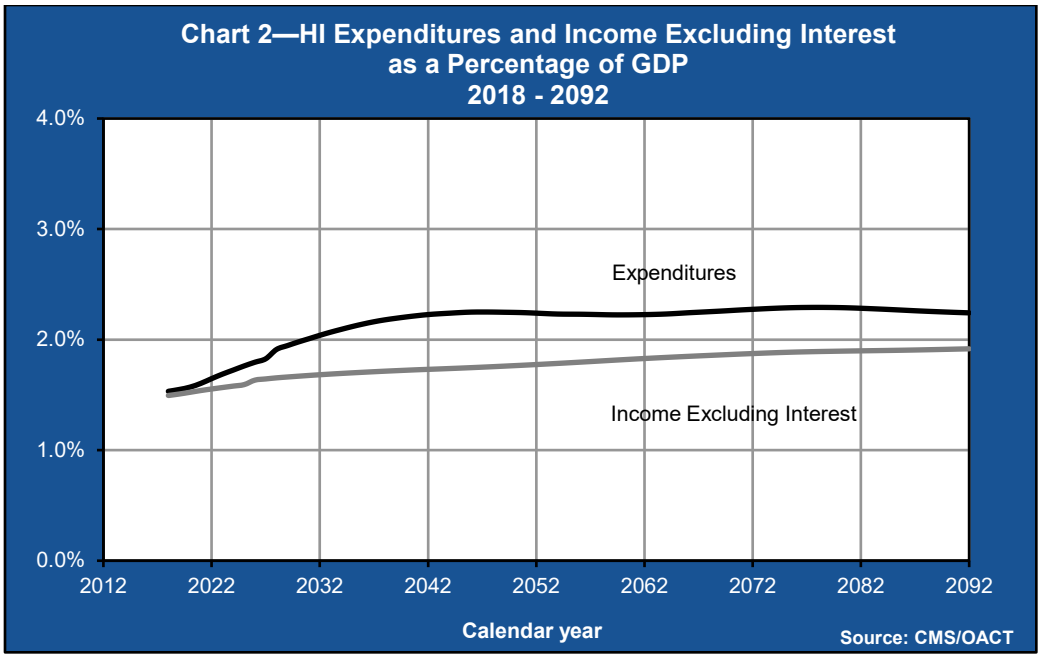
As indicated in Chart 1, the cost rate is projected to decline in 2018, largely due to (i) expenditure growth that was constrained in part by low utilization and low payment updates and (ii) a rebound of taxable payroll growth from 2007-2009 recession levels. After 2018 the cost rate is projected to rise primarily due to the continued 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 0.8 percent through 2027 and 1.1 percent thereafter. Under the illustrative alternative scenario, the HI cost rate would be 5.3 percent in 2043 and 8.1 percent in 2092.

HI and SMI Cash Flow 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 U.S. 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 2017, the expenditures were $296.5 billion, which was 1.5 percent of GDP. This percentage is projected to increase steadily until about 2046 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 3.5 percent in 2092.

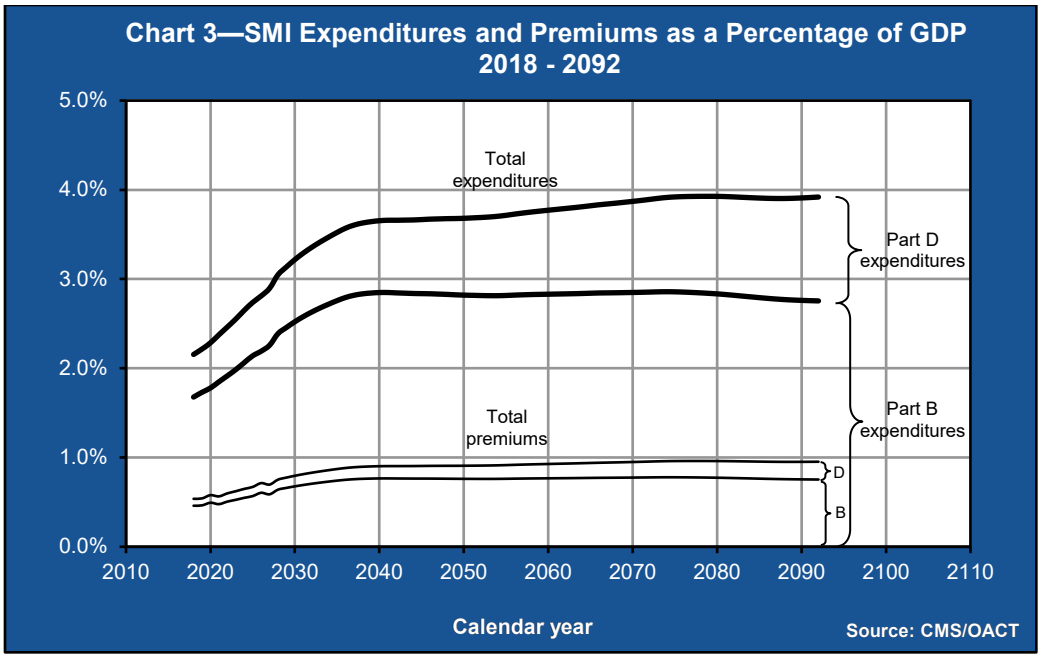


SMI

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 2017, SMI expenditures were $413.6 billion, or about 2.1 percent of GDP. Under current law, they would grow to about 3.7 percent of GDP within 25 years and to 3.9 percent by the end of the projection period. (Under the illustrative alternative, total SMI expenditures in 2092 would be 5.4 percent of GDP.)

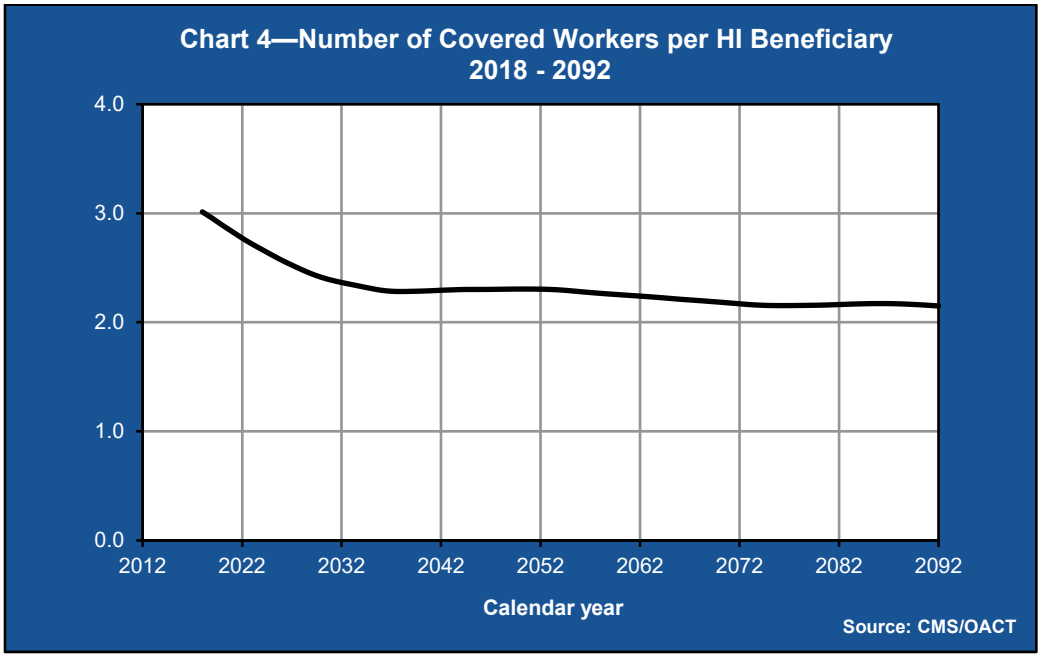


To match the faster growth rates for SMI expenditures, beneficiary premiums, along with general revenue contributions, would increase more rapidly than GDP over time but at a slower rate compared to the last 10 years. Average per beneficiary costs for Part B and Part D benefits are projected to increase after 2017 by about 4.3 percent annually. The associated beneficiary premiums—and general revenue financing—would increase by approximately the same rate. The special State payments to the Part D account are set by law at a declining portion of the States' forgone Medicaid expenditures attributable to the Medicare drug benefit. The percentage was 90 percent in 2006, phasing down to 75 percent in 2015 and later. Then, after 2015, the State payments are also expected to increase faster than GDP.

Worker-to-Beneficiary Ratio

HI

Another way to evaluate the long-range outlook of the HI trust fund is to examine the projected number of workers per HI beneficiary. Chart 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 2017, 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 2092.



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 current 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.[20] The assumptions varied are the health care cost factors, real-wage differential, CPI, real-interest rate, fertility rate, and net immigration.[21]

For this analysis, the intermediate economic and demographic assumptions in the *2018 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, 2018 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 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 projections.

Table 1—Present Value of Estimated HI Income Less Expenditures under Various Health Care Cost Growth Rate Assumptions

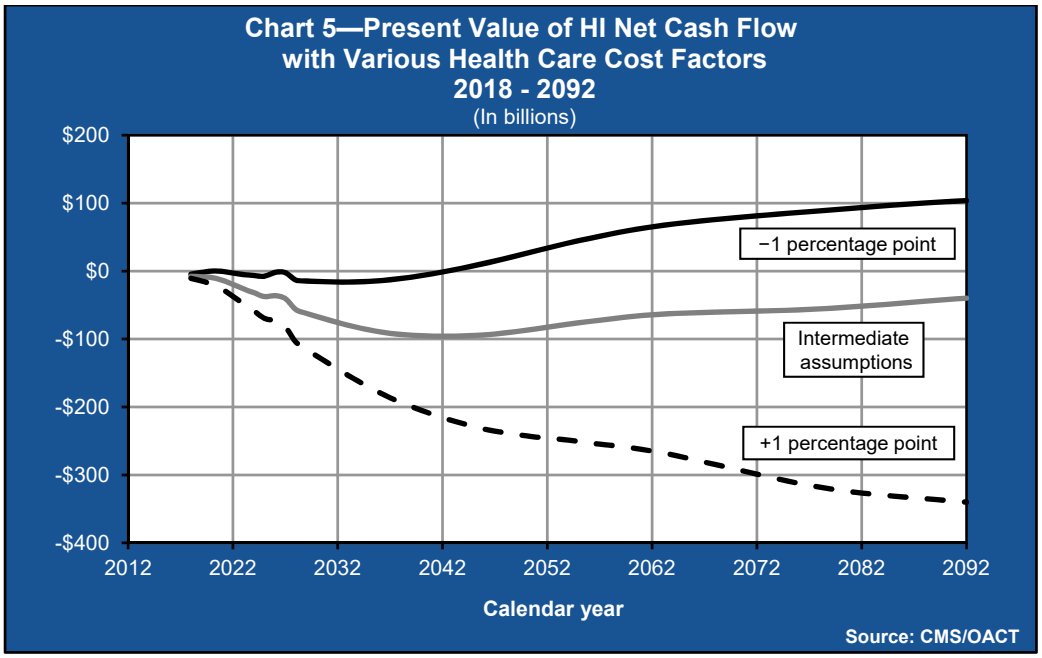
Annual cost/payroll relative growth rate	-1 percentage point	Intermediate assumptions	+1 percentage point
Income minus expenditures (in billions)	$3,104	-$4,708	-$17,180

Table 1 demonstrates that if the ultimate growth rate assumption is 1 percentage point lower than the intermediate assumptions, the deficit decreases by $7,812 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 $12,473 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.

[20]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.

[21]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.



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

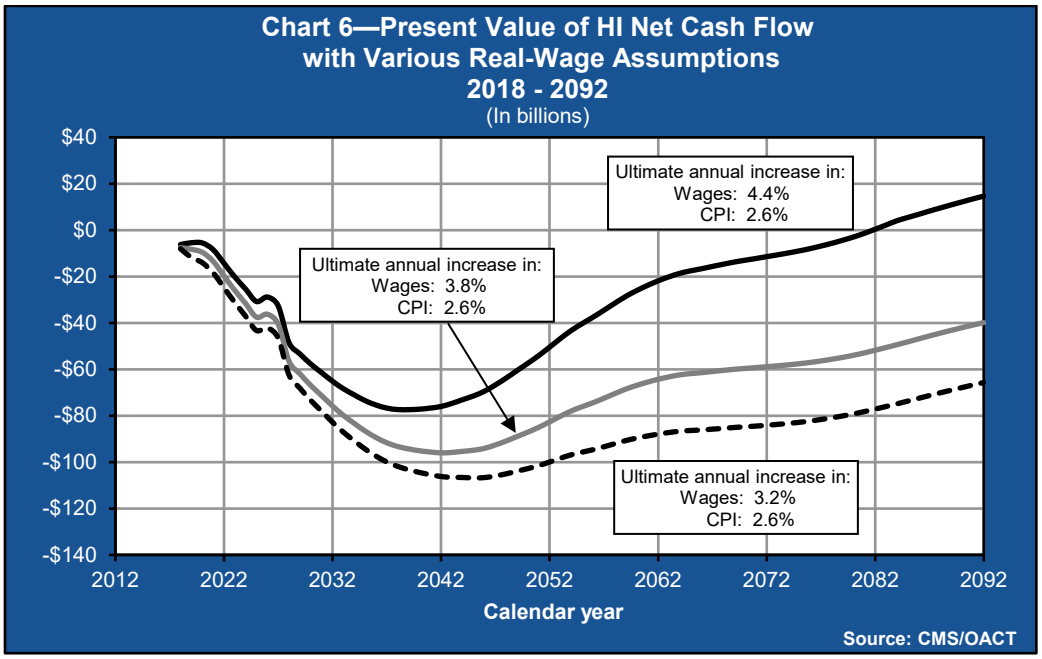
Table 2 shows the net present value of cash flow during the 75-year projection period under three alternative ultimate real-wage differential assumptions: 0.6, 1.2, and 1.8 percentage points.[22] In each case, the assumed ultimate annual increase in the CPI is 2.6 percent, yielding ultimate percentage 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)	−$5,979	−$4,708	−$2,314

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 $1,995 billion. Conversely, for a half-point decrease in the ultimate real-wage differential assumption, the deficit increases by about $1,060 billion.

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

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 sustainability 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.

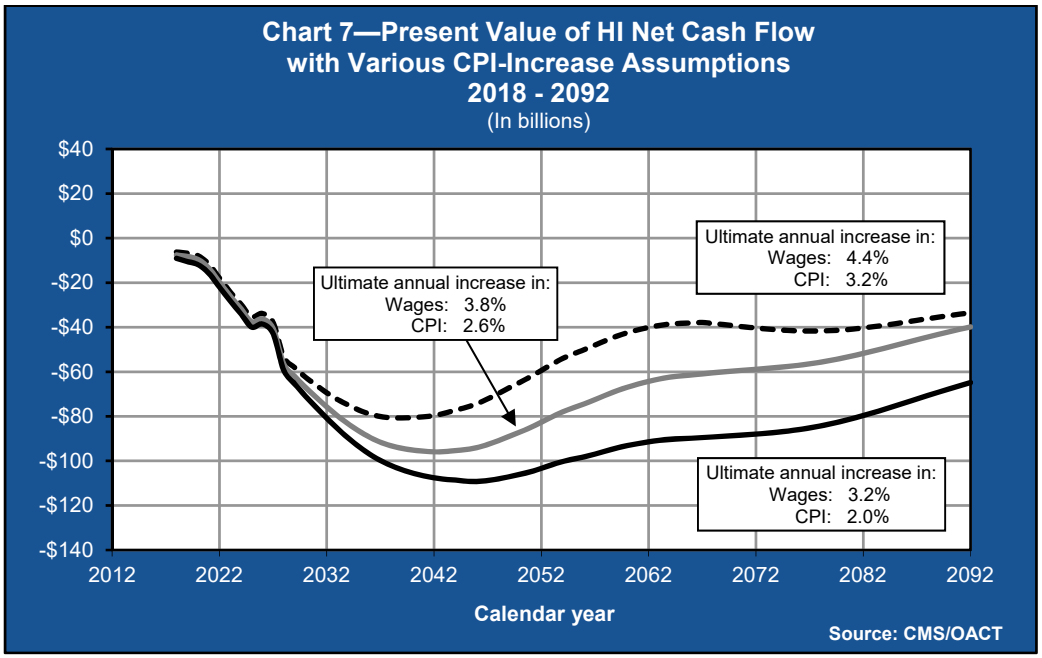
Consumer Price Index

Table 3 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—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)	−$3,648	−$4,708	−$6,083

Table 3 demonstrates that if the ultimate CPI-increase assumption is 3.2 percent, the deficit decreases by $1,060 billion. On the other hand, if the ultimate CPI-increase assumption is 2.0 percent, the deficit increases by $1,376 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 projected present values of HI cash flow are relatively insensitive to the assumed level of general price inflation because price inflation has about the same proportionate effect on income as it does on costs. 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

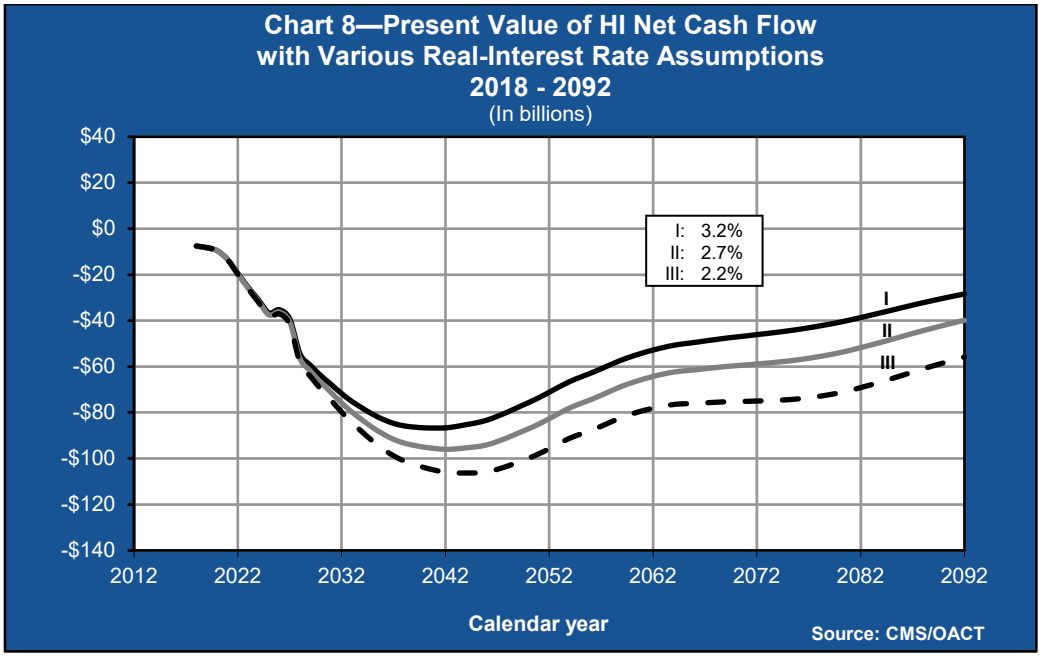
Table 4 shows the net present value of cash flow during the 75-year projection period under three alternative ultimate annual real-interest assumptions: 2.2, 2.7, and 3.2 percent. In each case, the assumed ultimate annual increase in the CPI is 2.6 percent, which results in ultimate annual yields of 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)	-$5,542	-$4,708	-$4,018

As illustrated in Table 4, for every increase of 0.1 percentage point in the ultimate real-interest rate, the deficit decreases by approximately $150 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 2026. 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.

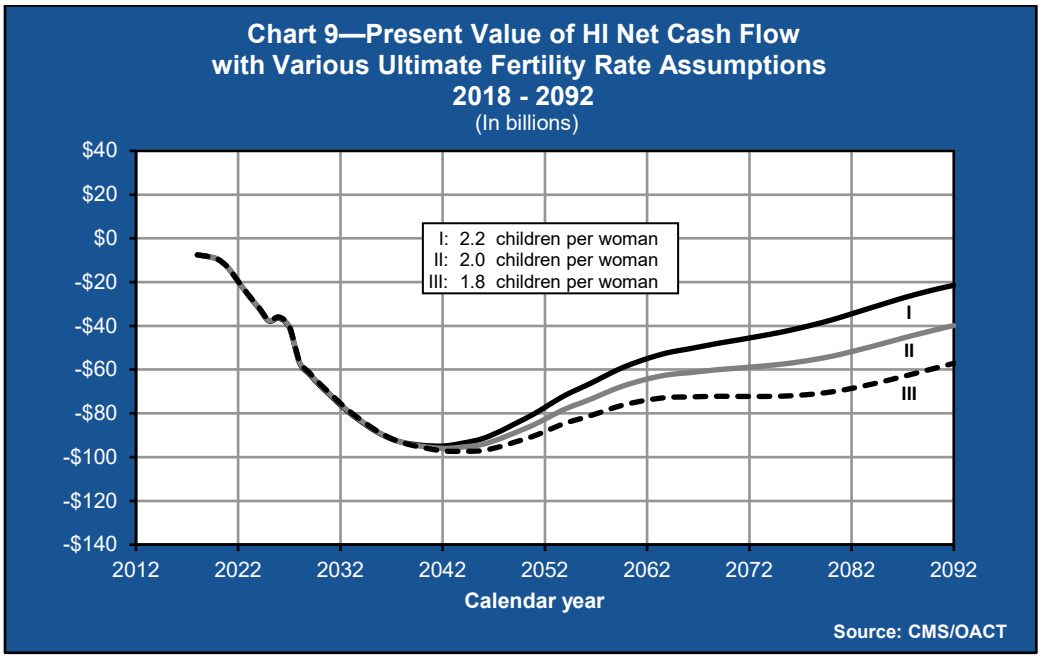
Table 5—Present Value of Estimated HI Income Less Expenditures under Various Fertility Rate Assumptions

Ultimate fertility rate[1]	1.8	2.0	2.2
Income minus expenditures (in billions)	−$5,265	−$4,708	−$4,146

[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 $560 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

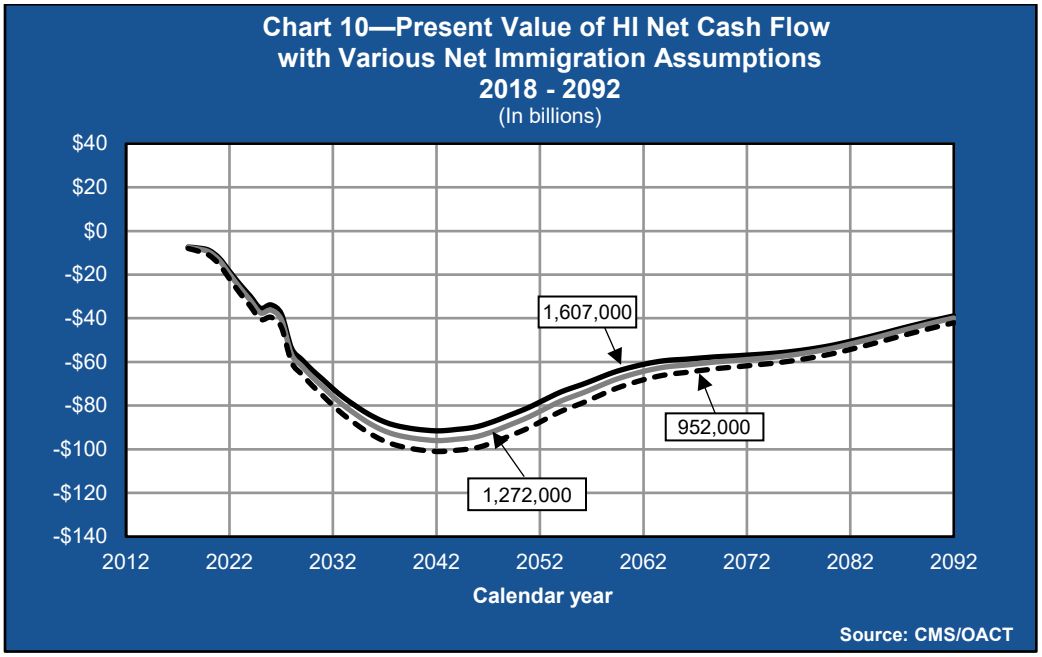
Table 6 shows the net present value of cash flow during the 75-year projection period under three alternative average annual net immigration assumptions: 952,000 persons, 1,272,000 persons, and 1,607,000 persons per year.

Table 6—Present Value of Estimated HI Income Less Expenditures under Various Net Immigration Assumptions

Average annual net immigration	952,000	1,272,000	1,607,000
Income minus expenditures (in billions)	−$4,973	−$4,708	−$4,503

As indicated in Table 6, if the average annual net immigration assumption is 952,000 persons, the deficit—expressed in present-value dollars—increases by $265 billion. Conversely, if the assumption is 1,607,000 persons, the deficit decreases by $205 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 deteriorated 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 2026, 3 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 income is projected to be lower than last year's estimates due to (i) lower payroll taxes attributable to lowered wages for 2017 and lower levels of projected GDP and (ii) lower income from the taxation of Social Security benefits as a result of legislation. HI expenditures are projected to be slightly higher than last year's estimates, mostly due to higher-than-expected spending in 2017, legislation that increased hospital spending, and higher Medicare Advantage payments.

HI expenditures exceeded income each year from 2008 through 2015. In 2016 and 2017, however, there were fund surpluses amounting to $5.4 billion and $2.8 billion, respectively. The Trustees project deficits in all future years until the trust fund becomes depleted in 2026. 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 2018 is adequate to cover 2018 expected expenditures.[23] 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 trust fund is the impact of the rapid growth of SMI costs, which places steadily increasing demands on beneficiaries and taxpayers.

[23] A hold-harmless provision limited the Part B premium increase in 2016 and 2017 for about 70 percent of enrollees. These Part B enrollees saw an increase in their Part B premium from about $109 in 2017, on average, to about $130, on average, in 2018.

Medicare Overall

Federal law requires the Board of Trustees to test whether the difference between Medicare outlays and dedicated financing sources[24] is projected to exceed 45 percent of total Medicare outlays under current law within the next 7 fiscal years (2018-2024). If this level is attained within the 7-year timeframe, the law requires a determination of projected excess general revenue Medicare funding. For the 2018 Medicare Trustees Report, this difference is expected to exceed 45 percent of total expenditures in FY 2022, and therefore the Trustees are issuing this determination. Since this is the second consecutive such finding, the law specifies that a Medicare funding warning is triggered and that the President must submit to Congress proposed legislation to respond to the warning within 15 days after the submission of the FY 2020 Budget. The law also requires Congress to consider the legislation on an expedited basis. Such funding warnings were previously made in each of the 2007 through 2013 reports. To date, elected officials have not enacted legislation responding to these funding warnings.

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 2018 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."

[24]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.

Other Information

3

In This Section

- Other Financial Information
- Reduce the Footprint
- Summary of Financial Statement Audit and Management Assurances
- Civil Monetary Penalty Adjustment for Inflation
- Grants Oversight and New Efficiency Act Report
- Payment Integrity Report
- FY 2018 Top Management and Performance Challenges Identified by the Office of Inspector General
- Department's Response to the Office of Inspector General

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Other Financial Information

Consolidating Balance Sheet by Budget Function

As of September 30, 2018

(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)	$ 12,799	$ 190,563	$ 27,389	$ 19,412	$ 250,163	$ -	$ 250,163
Investments, Net (Note 4)	-	3,862	303,253	-	307,115	-	307,115
Accounts Receivable, Net (Note 5)	201	5,354	72,273	-	77,828	(76,699)	1,129
Advances (Note 8)	33	319	25	50	427	(172)	255
Total Intragovernmental Assets	**13,033**	**200,098**	**402,940**	**19,462**	**635,533**	**(76,871)**	**558,662**
Accounts Receivable, Net (Note 5)	1	8,937	17,753	111	26,802	-	26,802
Inventory and Related Property, Net (Note 6)	-	9,815	-	-	9,815	-	9,815
General Property, Plant and Equipment, Net (Note 7)	-	5,534	816	-	6,350	-	6,350
Advances (Note 8)	238	772	66	1,618	2,694	-	2,694
Other Assets	-	204	-	-	204	-	204
Total Assets	**$ 13,272**	**$ 225,360**	**$ 421,575**	**$ 21,191**	**$ 681,398**	**$ (76,871)**	**$ 604,527**
Stewardship Land (Notes 19)							
Liabilities (Note 9)							
Intragovernmental Liabilities							
Accounts Payable	$ 21	$ 506	$ 77,195	$ 2	$ 77,724	$ (76,695)	$ 1,029
Other Liabilities (Note 13)	2	3,120	5,032	102	8,256	(176)	8,080
Total Intragovernmental Liabilities	**23**	**3,626**	**82,227**	**104**	**85,980**	**(76,871)**	**9,109**
Accounts Payable	24	849	81	3	957	-	957
Entitlement Benefits Due and Payable (Note 10)	-	36,952	62,196	-	99,148	-	99,148
Accrued Liabilities (Note 12)	1,103	11,249	-	2,169	14,521	-	14,521
Federal Employee and Veterans Benefits (Note 11)	4	14,372	10	-	14,386	-	14,386
Contingencies and Commitments (Note 14)	-	12,634	841	-	13,475	-	13,475
Other Liabilities (Note 13)	18	4,836	872	10	5,736	-	5,736
Total Liabilities	**1,172**	**84,518**	**146,227**	**2,286**	**234,203**	**(76,871)**	**157,332**
Net Position							
Unexpended Appropriations - Funds from Dedicated Collections (Note 18)	-	79	22,855	-	22,934	-	22,934
Unexpended Appropriations - Other funds	11,995	132,757	-	18,915	163,667	-	163,667
Cumulative Results of Operations - Funds from Dedicated Collections (Note 18)	-	10,479	252,493	-	262,972	-	262,972
Cumulative Results of Operations - Other funds	105	(2,473)	-	(10)	(2,378)	-	(2,378)
Total Net Position - Funds from Dedicated Collections	**-**	**10,558**	**275,348**	**-**	**285,906**	**-**	**285,906**
Total Net Position - Other Funds	**12,100**	**130,284**	**-**	**18,905**	**161,289**	**-**	**161,289**
Total Net Position	**12,100**	**140,842**	**275,348**	**18,905**	**447,195**	**-**	**447,195**
Total Liabilities and Net Position	**$ 13,272**	**$ 225,360**	**$ 421,575**	**$ 21,191**	**$ 681,398**	**$ (76,871)**	**$ 604,527**

Consolidating Statement of Net Cost by Budget Function

For the Year Ended September 30, 2018

(in Millions)

Responsibility Segments	Education, Training, & Social Services	Health	Medicare	Income Security	Agency Combined Totals	Intra-HHS Eliminations		Consolidated Totals
						Cost (-)	Revenue	
ACF	$ 13,262	$ -	$ -	$ 40,812	$ 54,074	$ (84)	$ 66	$ 54,056
ACL	2,000	-	-	-	2,000	(9)	3	1,994
AHRQ	-	329	-	-	329	(20)	28	337
CDC	-	12,280	-	-	12,280	(321)	178	12,137
CMS	-	392,244	616,831	-	1,009,075	(404)	186	1,008,857
FDA	-	2,873	-	-	2,873	(285)	21	2,609
HRSA	-	11,947	-	-	11,947	(320)	10	11,637
IHS	-	9,190	-	-	9,190	(207)	218	9,201
NIH	-	33,160	-	-	33,160	(243)	359	33,276
OS	-	3,181	-	-	3,181	(724)	565	3,022
PSC	-	1,485	-	-	1,485	(78)	627	2,034
SAMHSA	-	4,001	-	-	4,001	(30)	140	4,111
Totals	**$ 15,262**	**$ 470,690**	**$ 616,831**	**$ 40,812**	**$ 1,143,595**	**$ (2,725)**	**$ 2,401**	**$ 1,143,271**

Gross Cost and Exchange Revenue

For the Year Ended September 30, 2018

(in Millions)

Responsibility Segments	Intragovernmental						With the Public		
	Gross Cost			Less: Exchange Revenue					
	Combined	Eliminations	Consolidated	Combined	Eliminations	Consolidated	Gross Cost	Less: Exchange Revenue	Consolidated Net Cost of Operations
ACF	$ 207	$ (84)	$ 123	$ (74)	$ 66	$ (8)	$ 53,968	$ (27)	$ 54,056
ACL	21	(9)	12	(3)	3	-	1,982	-	1,994
AHRQ	44	(20)	24	(29)	28	(1)	320	(6)	337
CDC	1,036	(321)	715	(373)	178	(195)	11,667	(50)	12,137
CMS	1,096	(404)	692	(204)	186	(18)	1,114,469	(106,286)	1,008,857
FDA	1,431	(285)	1,146	(39)	21	(18)	3,877	(2,396)	2,609
HRSA	443	(320)	123	(11)	10	(1)	11,561	(46)	11,637
IHS	869	(207)	662	(272)	218	(54)	10,104	(1,511)	9,201
NIH	1,501	(243)	1,258	(512)	359	(153)	32,329	(158)	33,276
OS	1,162	(724)	438	(745)	565	(180)	2,783	(19)	3,022
PSC	341	(78)	263	(1,593)	627	(966)	2,741	(4)	2,034
SAMHSA	81	(30)	51	(156)	140	(16)	4,073	3	4,111
Totals	**$ 8,232**	**$ (2,725)**	**$ 5,507**	**$ (4,011)**	**$ 2,401**	**$ (1,610)**	**$ 1,249,874**	**$ (110,500)**	**$ 1,143,271**

Reduce the Footprint

Reduce the Footprint Baseline Comparison
(in Square Footage)

	2015 Baseline	2017 Year End	Change
Total Leased	13,014,210	12,016,941	(997,269)
Total Owned	6,273,290	7,262,998	989,708
Total	**19,287,500**	**19,279,939**	**7,561**

Reporting of O&M Costs - Owned and Direct Lease Buildings
(in Millions)

	2015 Baseline	2017 Year End	Change
Operation and Maintenance Costs	$ 92.2	$ 88.7	$ (3.5)

OMB Memorandum 12-12, *Promoting Efficient Spending to Support Agency Operations*, and OMB Management Procedures Memorandum 2015-01, *Implementation of OMB Memorandum M-12-12 Section 3: Reduce the Footprint*, require CFO Act Departments to set annual targets for reducing the total square footage (sq.) of their domestic office and warehouse space compared to the FY 2015 baseline.

In FY 2017, HHS office and warehouse space decreased by 7,561 sq.; as compared to the Reduce the Footprint baseline of 19,287,500 sq. established for FY 2015. HHS expects to continue to reduce the inventory of office and warehouse space through reconfiguration of office spaces, Regional Office consolidations, and warehouse consolidations, and will continue to review its warehouse inventory to identify future reduction opportunities.

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 any 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 Disclaimed Opinion 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 Information Systems	1	-	1	-	0
Total Material Weaknesses	***1***	***-***	***1***	***-***	***0***

Definition of Terms – Tables 1 and 2
(Reference: OMB Circular A-136, *Financial Reporting Requirements*, July 30, 2018, page 109)

Beginning Balance: The beginning balance must agree with the ending balance from the prior year.

New: The total number of material weaknesses / non-conformances identified during the current year.

Resolved: The total number of material weaknesses / non-conformances that 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).

Ending Balance: The year-end balance that will be the beginning balance next year.

Table 2: Summary of Management Assurances

Effectiveness of Internal Control over Reporting (FMFIA Section 2)

Statement of Assurance	Unmodified					
Material Weaknesses	**Beginning Balance**	**New**	**Resolved**	**Consolidated**	**Reassessed**	**Ending Balance**
No Material Weaknesses Noted	0	-	0	-	-	0
Total Material Weaknesses	***0***	***-***	***0***	***-***	***-***	***0***

Effectiveness of Internal Control over Operations (FMFIA Section 2)

Statement of Assurance	Modified					
Material Weaknesses	**Beginning Balance**	**New**	**Resolved**	**Consolidated**	**Reassessed**	**Ending Balance**
	0	-	0	-	-	0
Error Rate Measurement	1	-	-	-	-	1
Medicare Appeals Process	1	-	-	-	-	1
Total Material Weaknesses	***2***	***-***	***0***	***-***	***-***	***2***

Compliance with Federal Financial Management System Requirements (FMFIA Section 4)

Statement of Assurance	Federal Systems comply to financial management system requirements					
Noncompliance	**Beginning Balance**	**New**	**Resolved**	**Consolidated**	**Reassessed**	**Ending Balance**
No Noncompliances Noted	0	-	0	-		0
Total Noncompliance	***0***	***-***	***0***	***-***		***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	No 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

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. Refer to Federal Register for the Annual Civil Monetary Penalties Inflation Adjustment.

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)	2017	2018	$ 1,504

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)	2017	2018	$ 14,664

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)	2017	2018	$ 5,639

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)	2017	2018	$ 12,383
Penalty for each pre-February 18, 2009 violation of the HIPAA administrative simplification provisions.	42 U.S.C. 1320(d)-5(a)	2017	2018	155
Calendar Year Cap		2017	2018	38,954
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.				
Minimum		2017	2018	114
Maximum		2017	2018	57,051
Calendar Year Cap		2017	2018	1,711,533

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)			
Minimum		2017	2018	1,141
Maximum		2017	2018	57,051
Calendar Year Cap		2017	2018	1,711,533
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.				
Minimum		2017	2018	11,410
Maximum		2017	2018	57,051
Calendar Year Cap		2017	2018	1,711,533
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.				
Minimum		2017	2018	57,051
Maximum		2017	2018	1,711,533
Calendar Year Cap		2017	2018	1,711,533

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	2017	2018	$ 19,639
Penalty for second and subsequent offenses by individuals who make an expenditure prohibited by regulations regarding lobbying disclosure.	31 U.S.C. 1352			
Minimum		2017	2018	19,639
Maximum		2017	2018	196,387
Penalty for the first time an individual fails to file or amend a lobbying disclosure form, absent aggravating circumstances.		2017	2018	19,639
Penalty for second and subsequent offenses by individuals who fail to file or amend a lobbying disclosure form, absent aggravating circumstances.				
Minimum		2017	2018	19,639
Maximum		2017	2018	196,387
Penalty for failure to provide certification regarding lobbying in the award documents for all sub-awards of all tiers.				
Minimum		2017	2018	19,639
Maximum		2017	2018	196,387
Penalty for failure to provide statement regarding lobbying for loan guarantee and loan insurance transactions.				

Penalty	Statutory Authority	Date of Previous Adjustment	Date of Current Adjustment	Current Penalty Level ($ Amount)
Minimum	31 U.S.C. 1352	2017	2018	19,639
Maximum		2017	2018	196,387
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	2017	2018	10,261
Penalty against any individual who - with knowledge or reason to know - makes, presents or submits a false, fictitious or fraudulent claim to the Department		2017	2018	10,261

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)	2017	2018	$ 340,130
Penalty for any other person who violates safety and security procedures related to handling dangerous biological agents and toxins.		2017	2018	680,262
Penalty per violation for committing information blocking.	42 U.S.C. 300jj-51	2017	2018	1,037,104
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)	2017	2018	20,000
Penalty for knowingly presenting or causing to be presented a request for payment which violates the terms of an assignment, agreement, or PPS agreement.		2017	2018	20,000
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.		2017	2018	30,000
Penalty for an excluded party retaining ownership or control interest in a participating entity.		2017	2018	20,000
Penalty for remuneration offered to induce program beneficiaries to use particular providers, practitioners, or suppliers.		2017	2018	20,000
Penalty for employing or contracting with an excluded individual.		2017	2018	20,000
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.		2017	2018	100,000
Penalty for ordering or prescribing medical or other item or service during a period in which the person was excluded.		2017	2018	20,000
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.		2017	2018	100,000
Penalty for knowing of an overpayment and failing to report and return.		2017	2018	20,000
Penalty for making or using a false record or statement that is material to a false or fraudulent claim		2017	2018	100,000
Penalty for failure to grant timely access to HHS OIG for audits, investigations, evaluations, and other statutory functions of HHS OIG.		2017	2018	30,000

Penalty	Statutory Authority	Date of Previous Adjustment	Date of Current Adjustment	Current Penalty Level ($ Amount)
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)	2017	2018	5,000
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.		2017	2018	5,000
Penalty for a physician who executes a document that falsely certifies home health needs for Medicare beneficiaries.		2017	2018	10,000
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)	2017	2018	38,159
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)	2017	2018	10,260
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)	2017	2018	51,302
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)	2017	2018	2,140
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)	2017	2018	10,697
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)	2017	2018	4,280
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)	2017	2018	38,954
Penalty for a Medicare Advantage organization that charges excessive premiums.		2017	2018	38,159
Penalty for a Medicare Advantage organization that improperly expels or refuses to reenroll a beneficiary.		2017	2018	38,159
Penalty for a Medicare Advantage organization that engages in practice that would reasonably be expected to have the effect of denying or discouraging enrollment.		2017	2018	152,638
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.		2017	2018	22,896
Penalty for a Medicare Advantage organization misrepresenting or falsifying information to Secretary.		2017	2018	152,638
Penalty for a Medicare Advantage organization misrepresenting or falsifying information to individual or other entity.		2017	2018	38,159
Penalty for Medicare Advantage organization interfering with provider's advice to enrollee and non-MCO affiliated providers that balance bill enrollees.		2017	2018	38,159
Penalty for a Medicare Advantage organization that employs or contracts with excluded individual or entity.		2017	2018	38,159

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 enrolling an individual in without prior written consent.	42 U.S.C. 1395w-27(g)(2)(A)	2017	2018	38,159
Penalty for a Medicare Advantage organization transferring an enrollee to another plan without consent or solely for the purpose of earning a commission.		2017	2018	38,159
Penalty for a Medicare Advantage organization failing to comply with marketing restrictions or applicable implementing regulations or guidance.		2017	2018	38,159
Penalty for a Medicare Advantage organization employing or contracting with an individual or entity who violates 1395w-27(g)(1)(A)-(J).		2017	2018	38,159
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)	2017	2018	13,333
Penalty for improper billing by Hospitals, Critical Access Hospitals, or Skilled Nursing Facilities.	42 U.S.C. 1395cc(g)	2017	2018	5,186
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)	2017	2018	106,965
Penalty for a hospital or responsible physician dumping patients needing emergency care, if the hospital has less than 100 beds.		2017	2018	53,484
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)	2017	2018	53,484
Penalty for HMOs/competitive medical plans that charge premiums in excess of permitted amounts		2017	2018	53,484
Penalty for a HMO or competitive medical plan that expels or refuses to reenroll an individual per prescribed conditions		2017	2018	53,484
Penalty for a HMO or competitive medical plan that implements practices to discourage enrollment of individuals needing services in future.		2017	2018	213,932
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.		2017	2018	30,782
Penalty for a HMO or competitive medical plan that misrepresents or falsifies information to the Secretary.		2017	2018	213,932
Penalty for a HMO or competitive medical plan that misrepresents or falsifies information to an individual or any other entity.		2017	2018	53,484
Penalty for failure by HMO or competitive medical plan to assure prompt payment of Medicare risk sharing contracts or incentive plan provisions.		2017	2018	53,484
Penalty for HMO that employs or contracts with excluded individual or entity.	42 U.S.C. 1395mm(i)(6)(B)(i)	2017	2018	49,096
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)	2017	2018	24,748
Penalty for circumventing Stark Law's restrictions on physician self-referrals.	42 U.S.C. 1395nn(g)(4)	2017	2018	164,992
Penalty for a material misrepresentation regarding Medigap compliance policies.	42 U.S.C. 1395ss(d)(1)	2017	2018	10,260
Penalty for selling Medigap policy under false pretense.	42 U.S.C. 1395ss(d)(2)	2017	2018	10,260

Penalty	Statutory Authority	Date of Previous Adjustment	Date of Current Adjustment	Current Penalty Level ($ Amount)
Penalty for an issuer that sells health insurance policy that duplicates benefits.	42 U.S.C. 1395ss(d)(3)(A)(ii)	2017	2018	46,192
Penalty for someone other than issuer that sells health insurance that duplicates benefits.	42 U.S.C. 1395ss(d)(3)(A)(ii)	2017	2018	27,714
Penalty for using mail to sell a non-approved Medigap insurance policy.	42 U.S.C. 1395ss(d)(4)(A)	2017	2018	10,260
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)	2017	2018	51,302
Penalty for a Medicaid MCO that charges excessive premiums.		2017	2018	51,302
Penalty for a Medicaid MCO that improperly expels or refuses to reenroll a beneficiary.		2017	2018	205,211
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.		2017	2018	30,782
Penalty for a Medicaid MCO misrepresenting or falsifying information to the Secretary.		2017	2018	205,211
Penalty for a Medicaid MCO misrepresenting or falsifying information to an individual or another entity.		2017	2018	51,302
Penalty for a Medicaid MCO that fails to comply with contract requirements with respect to physician incentive plans.		2017	2018	46,192
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)	2017	2018	2,140
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)	2017	2018	10,697
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)	2017	2018	4,280
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)	2017	2018	184,767
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)	2017	2018	18,477
Penalty for knowing provision of false information by drug manufacturer with rebate agreement.	42 U.S.C. 1396r-8(b)(3)(C)(ii)	2017	2018	184,767
Penalty for notifying home and community-based providers or settings of survey.	42 U.S.C. 1396t(i)(3)(A)	2017	2018	3,695
Penalty for failing to report a medical malpractice claim to National Practitioner Data Bank.	42 U.S.C. 11131(c)	2017	2018	22,363
Penalty for breaching confidentiality of information reported to National Practitioner Data Bank.	42 U.S.C. 11137(b)(2)	2017	2018	22,363

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)	2017	2018	$ 102,606

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)	2017	2018	2,052,107
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)	2017	2018	205,211
Penalty for any person who violates a requirement related to devices for each such violation.	21 U.S.C. 333(f)(1)(A)	2017	2018	27,714
Penalty for aggregate of all violations related to devices in a single proceeding.		2017	2018	1,847,663
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)	2017	2018	77,910
Penalty in the case of any other person other than an individual) for such introduction or delivery of adulterated food.		2017	2018	389,550
Penalty for aggregate of all such violations related to adulterated food adjudicated in a single proceeding.		2017	2018	779,089
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)	2017	2018	11,805
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)	2017	2018	11,805
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)	2017	2018	295,142
Penalty for aggregate of all such above violations in a single proceeding.		2017	2018	1,180,566
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)	2017	2018	295,142
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.		2017	2018	1,180,566
Penalty for aggregate of all such above violations adjudicated in a single proceeding.		2017	2018	11,805,665
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)	2017	2018	17,115
Penalty for aggregate of all such violations of tobacco product requirement adjudicated in a single proceeding.		2017	2018	1,141,021
Penalty per violation related to violations of tobacco requirements.	21 U.S.C. 333(f)(9)(B)(i)(I)	2017	2018	285,256
Penalty for aggregate of all such violation of tobacco product requirements adjudicated in a single proceeding.		2017	2018	1,141,021

Penalty	Statutory Authority	Date of Previous Adjustment	Date of Current Adjustment	Current Penalty Level ($ Amount)
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)	2017	2018	285,256
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)	2017	2018	1,141,021
Penalty for aggregate of all such violations related to tobacco product requirements adjudicated in a single proceeding.		2017	2018	11,410,218
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)	2017	2018	285,256
Penalty for aggregate of for all such above violations adjudicated in a single proceeding.		2017	2018	1,141,021
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)	2017	2018	285,256
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.		2017	2018	1,141,021
Penalty for aggregate above tobacco product requirement violations adjudicated in a single proceeding.		2017	2018	11,410,218
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)	2017	2018	295,142
Penalty for each subsequent above violation in any 3–year period.		2017	2018	590,284
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	2017	2018	285
Penalty in the case of a third tobacco product regulation violation within a 24–month period.		2017	2018	570
Penalty in the case of a fourth tobacco product regulation violation within a 24–month period.		2017	2018	2,282
Penalty in the case of a fifth tobacco product regulation violation within a 36–month period.		2017	2018	5,705
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.		2017	2018	11,410
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.		2017	2018	285

Penalty	Statutory Authority	Date of Previous Adjustment	Date of Current Adjustment	Current Penalty Level ($ Amount)
Penalty in the case of a second tobacco product regulation violation within a 12-month period.	21 U.S.C. 333 note	2017	2018	570
Penalty in the case of a third tobacco product regulation violation within a 24–month period.		2017	2018	1,141
Penalty in the case of a fourth tobacco product regulation violation within a 24–month period.	21 U.S.C. 333 note	2017	2018	2,282
Penalty in the case of a fifth tobacco product regulation violation within a 36–month period.		2017	2017	5,705
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.		2017	2018	11,410
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)	2017	2018	434,878
Penalty in the case of any other person (other than an individual) per above violation.		2017	2018	1,739,513
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)	2017	2018	2,852
Penalty imposed for any related series of violations of requirements relating to electronic products.		2017	2018	972,285
Penalty per day for violation of order of recall of biological product presenting imminent or substantial hazard.	42 U.S.C. 262(d)	2017	2018	223,629
Penalty for failure to obtain a mammography certificate as required.	42 U.S.C. 263b(h)(3)	2017	2018	17,395
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)	2017	2018	223,629

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)			
Minimum		2017	2018	$ 6,259
Maximum		2017	2018	20,521
Penalty for a clinical laboratory's failure to meet participation and certification requirements and the failure does not pose immediate jeopardy.				
Minimum		2017	2018	103
Maximum		2017	2018	6,156
Failure to provide the Summary of Benefits and Coverage (SBC)	42 U.S.C. 300gg-15(f)	2017	2018	1,128
Penalty for violations of regulations related to the medical loss ratio reporting and rebating.	42 U.S.C. 300gg-18	2017	2018	113

Penalty	Statutory Authority	Date of Previous Adjustment	Date of Current Adjustment	Current Penalty Level ($ Amount)
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)			
Minimum		2017	2018	1,128
Maximum		2017	2018	11,278
Calendar Year Cap		2017	2018	169,170
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)			
Minimum		2017	2018	11,278
Maximum		2017	2018	112,780
Calendar Year Cap		2017	2018	1,127,799
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)	2017	2018	112,780
Minimum penalty for the first offense of an administrator who fails to provide notice of facility closure.		2017	2018	564
Minimum penalty for the second offense of an administrator who fails to provide notice of facility closure.		2017	2018	1,692
Minimum penalty for the third and subsequent offenses of an administrator who fails to provide notice of facility closure.		2017	2018	3,383
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)	2017	2018	8,249
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.		2017	2018	7,779
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)	2017	2018	6,460
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)	2017	2018	225,560
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)	2017	2018	338,339
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)	2017	2018	225,560
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)	2017	2018	152

Civil Monetary Penalty Adjustment for Inflation

Penalty	Statutory Authority	Date of Previous Adjustment	Date of Current Adjustment	Current Penalty Level ($ Amount)
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)			
Minimum		2017	2018	107
Maximum		2017	2018	6,417
Penalty per instance of Category 2 noncompliance by a Skilled Nursing Facility.				
Minimum		2017	2018	2,140
Maximum		2017	2018	21,393
Penalty per day for a Skilled Nursing Facility that has a Category 3 violation of certification requirements.				
Minimum		2017	2018	6,525
Maximum		2017	2018	21,393
Penalty per instance of Category 3 noncompliance by a Skilled Nursing Facility.				
Minimum		2017	2018	2,140
Maximum		2017	2018	21,393
Penalty per day and per instance for a Skilled Nursing Facility that has Category 3 noncompliance with Immediate Jeopardy.				
Per Day (Minimum)		2017	2018	6,525
Per Day (Maximum)		2017	2018	21,393
Per Instance (Minimum)		2017	2018	2,140
Per Instance (Maximum)		2017	2018	21,393
Penalty per day of a Skilled Nursing Facility that fails to meet certification requirements. These amounts represent the upper range per day.				
Minimum		2017	2018	6,524
Maximum		2017	2018	21,393
Penalty per day of a Skilled Nursing Facility that fails to meet certification requirements. These amounts represent the lower range per day.				
Minimum		2017	2018	107
Maximum		2017	2018	6,418
Penalty per instance of a Skilled Nursing Facility that fails to meet certification requirements.				
Minimum		2017	2018	2,140
Maximum		2017	2018	21,393
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)	2017	2018	30,000
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)	2017	2018	4,104
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)	2017	2018	3,928

Penalty	Statutory Authority	Date of Previous Adjustment	Date of Current Adjustment	Current Penalty Level ($ Amount)
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)	2017	2018	30,000
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)	2017	2018	30,000
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)	2017	2018	30,000
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)	2017	2018	30,000
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)	2017	2018	1,650
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)	2017	2018	30,000
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)	2017	2018	30,000
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)	2017	2018	30,000
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)	2017	2018	30,000
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)	2017	2018	30,000
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)	2017	2018	30,000

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 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)	2017	2018	30,000
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)	2017	2018	30,000
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)	2017	2018	30,000
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)	2017	2018	30,000
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)	2017	2018	4,104
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)	2017	2018	13,333
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)	2017	2018	30,000
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)	2017	2018	30,000
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)	2017	2018	38,159
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)	2017	2018	15,264
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)	2017	2018	141,760

Penalty	Statutory Authority	Date of Previous Adjustment	Date of Current Adjustment	Current Penalty Level ($ Amount)
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)	2017	2018	9,239
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)	2017	2018	1,504
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)	2017	2018	3,300
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)	2017	2018	1,181
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 U.S.C. 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)	2017	2018	30,000
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)	2017	2018	19,639
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 U.S.C. 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)	2017	2018	15,582
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)	2017	2018	53,483
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)	2017	2018	27,714
Penalty for an issuer that sells or issues a Medicare supplemental policy without disclosure statement.		2017	2018	46,192
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)	2017	2018	27,714
Penalty for issuer that sells or issues a Medicare supplemental policy without an acknowledgement form.		2017	2018	46,192
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)	2017	2018	27,714
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)	2017	2018	46,192
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)	2017	2018	27,714

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 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)	2017	2018	46,192
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)	2017	2018	46,192
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)	2017	2018	46,192
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)	2017	2018	19,609
Penalty for any issuer of a Medicare supplemental policy that fails to fulfill listed responsibilities.	42 U.S.C. 1395ss(t)(2)	2017	2018	46,192
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)	2017	2018	19,999
Penalty for an issuer who sells, issues, or renews a Medigap Rx policy who is a Part D enrollee.		2017	2018	33,333
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)	2017	2018	4,280
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)	2017	2018	20,521
Penalty per day for home health agency's noncompliance (Upper Range).				
Minimum		2017	2018	17,443
Maximum		2017	2018	20,521
Penalty for a home health agency's deficiency or deficiencies that cause immediate jeopardy and result in actual harm.	42 U.S.C. 1395bbb(f)(2)(A)(i)	2017	2018	20,521
Penalty for a home health agency's deficiency or deficiencies that cause immediate jeopardy and result in potential for harm.		2017	2018	18,468
Penalty for an isolated incident of noncompliance in violation of established HHA policy.		2017	2018	17,443
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).				
Minimum		2017	2018	3,079
Maximum		2017	2018	17,443
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).				
Minimum				1,026
Maximum				8,208

Penalty	Statutory Authority	Date of Previous Adjustment	Date of Current Adjustment	Current Penalty Level ($ Amount)
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.	42 U.S.C. 1395bbb(f)(2)(A)(i)			
Minimum		2017	2018	2,052
Maximum		2017	2018	20,521
Penalty for each day of noncompliance (Maximum).	42 U.S.C. 1395bbb(f)(2)(A)(i)	2017	2018	20,521
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)			
Minimum		2017	2018	22,896
Maximum		2017	2018	152,638
Penalty for a PACE organization that charges excessive premiums.		2017	2018	38,159
Penalty for a PACE organization misrepresenting or falsifying information to CMS, the State, or an individual or other entity.		2017	2018	152,638
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.		2017	2018	38,159
Penalty for involuntarily disenrolling a participant.		2017	2018	38,159
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.		2017	2018	38,159
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)			
Minimum		2017	2018	107
Maximum		2017	2018	6,417
Penalty per instance for a nursing facility's failure to meet Category 2 certification				
Minimum		2017	2018	2,140
Maximum		2017	2018	21,393
Penalty per day for a nursing facility's failure to meet Category 3 certification.				
Minimum		2017	2018	6,525
Maximum		2017	2018	21,393
Penalty per instance for a nursing facility's failure to meet Category 3 certification, which results in immediate jeopardy.				
Minimum		2017	2018	2,140
Maximum		2017	2018	21,393
Penalty per day for nursing facility's failure to meet certification (Upper Range).				
Minimum		2017	2018	6,525
Maximum		2017	2018	21,393
Penalty per day for nursing facility's failure to meet certification (Lower Range).				

Civil Monetary Penalty Adjustment for Inflation

Penalty	Statutory Authority	Date of Previous Adjustment	Date of Current Adjustment	Current Penalty Level ($ Amount)
Minimum	42 U.S.C. 1396r(h)(3)(C)(ii)(I)	2017	2018	107
Maximum		2017	2018	6,417
Penalty per instance for nursing facility's failure to meet certification.				
Minimum		2017	2018	2,140
Maximum		2017	2018	21,393
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)	2017	2018	10,697
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)	2017	2018	10,697
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)			
Minimum		2017	2018	2
Maximum		2017	2018	18,477
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)	2017	2018	38,159
Penalty for Medicaid managed care organization that imposes premiums or charges on enrollees in excess of the premiums or charges permitted.		2017	2018	38,159
Penalty for a Medicaid managed care organization that misrepresents or falsifies information to another individual or entity.		2017	2018	38,159
Penalty for a Medicaid managed care organization that fails to comply with the applicable statutory requirements for such organizations.		2017	2018	38,159
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)	2017	2018	152,638
Penalty for Medicaid managed care organization that acts to discriminate among enrollees on the basis of their health status.		2017	2018	152,638
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)	2017	2018	22,896
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)	2017	2018	21,393
Penalty for disclosing information related to eligibility determinations for medical assistance programs.	42 U.S.C. 1396w–2(c)(1)	2017	2018	11,410
Failure to comply with requirements of the *Public Health Services Act*; Penalty for violations of rules or standards of behavior associated with issuer participation in the Federally-facilitated Exchange. (42 U.S.C. 300gg–22(b)(2)(C))	42 U.S.C. 18041(c)(2)	2017	2018	155
Penalty for providing false information on Exchange application.	42 U.S.C. 18081(h)(1)(A)(i)(II)	2017	2018	28,195
Penalty for knowingly or willfully providing false information on Exchange application.	42 U.S.C. 18081(h)(1)(B)	2017	2018	281,949
Penalty for knowingly or willfully disclosing protected information from Exchange.	42 U.S.C. 18081(h)(2)	2017	2018	28,195

Grants Oversight and New Efficiency Act Report

The *Grants Oversight and New Efficiency Act* (GONE Act) was signed into law on January 28, 2016, to facilitate the closing of expired grants and cooperative agreements, and to improve government efficiency. For FY 2018, the GONE Act requires agencies to submit to Congress an updated report for all grants and cooperative agreements reported in the FY 2017 GONE Act submission. Agencies must provide a status update (open or closed) for grants and cooperative agreements, the amount of undistributed dollar balances, progress made over the past year, challenges leading to delays in grant closeout, and remaining actions to be taken. Agencies must also explain, for their 30 oldest federal grant awards reported in FY 2017, why each award has not been closed out.

The GONE Act covers grants and cooperative agreements expired for 2 or more years that have not been closed out. Agency Heads must report to Congress whether the agency has closed out the covered awards discussed in the previous report. FY 2018 marks HHS's update to the FY 2017 GONE Act report submission. For more information on the GONE Act, see GONE Act, or visit Grants.gov.

Did you know?

Most HHS grants are provided directly to states, territories, tribes, and educational and community organizations (including faith-based organizations), then given to people and organizations who are eligible to receive funding.

For more information on HHS grant programs, the grant application process, and grant management, visit HHS Grants.

Progress Made

HHS OpDivs and grant-making StaffDivs continue to close out the backlog of expired awards. Across the Department, OpDivs and StaffDivs closed 3,621 grants reported in the FY 2017 GONE Act submission. Table 1 reflects the number, as of September 30, 2018, of remaining grants and cooperative agreements from the FY 2017 report that remain open.

Table 1: GONE Act Report Summary Table of Open but Expired HHS Awards

Category	Age of Expiration[1]			Submission Totals	
	2-3 Years	3-5 Years	> 5 Years	2018	2017 Amended[2]
Number of Grants/ Cooperative Agreements with Zero Dollar Balances	2,192	1,666	2,162	6,020	6,511
Number of Grants/ Cooperative Agreements with Undisbursed Balances	6,244	2,365	4,786	13,395	16,525
Total Number of Grants/Cooperative Agreements	8,436	4,031	6,948	19,415	23,036
Total Amount of Undisbursed Balances (in millions)	$973	$201	$516	$1,690	$1,972

[1] Period of performance expired on or before September 30, 2015

[2] 2017 Amended column reflects the removal of grants that had been erroneously included in original 2017 report.

Challenges

The 19,415 grants and cooperative agreements reported as open but not expired in the FY 2018 GONE Act submission require significant resources due to the complexities preventing closure. HHS's most pressing challenge is the financial reconciliation of pooled accounts. Pooled accounts consist of multiple awards, from different federal entities, allowing grantees to draw from one pool of funding rather than by individual award. Current grant closeout policy requires closeout at the individual award level. To address these challenges, HHS convened a Grants Closeout Integrated Project Team comprised of subject matter experts across functional areas to develop recommendations to resolve complex closeout issues.

Remaining Actions

HHS leadership will prioritize alternative methods to close open but expired grants and cooperative agreements, and to improve policy and procedures to prevent the creation of another backlog. For non-pooled accounts, HHS will investigate alternative approaches such as unilateral closeout for unresponsive recipients, closeout of unreconciled awards under specified thresholds, and debt write-off.

Payment Integrity Report

OVERVIEW

HHS is committed to advancing a transparent, accountable, and collaborative financial management environment to fulfill its federal requirements, as well as to provide stakeholders with accessible and actionable financial information. An important part of this commitment is the continuous improvement of payment accuracy in all of HHS's programs. The Department has implemented various innovative solutions to prevent, detect, and reduce improper payments, while reducing unnecessary administrative burden on its stakeholders and protecting beneficiaries' access to important programs.

As required by the *Improper Payments Information Act* (IPIA) *of 2002*, as amended by the *Improper Payments Elimination and Recovery Act* (IPERA) *of 2010* and the *Improper Payments Elimination and Recovery Improvement Act* (IPERIA) *of 2012*; Office of Management and Budget (OMB) Circular A-136; and Appendix C of OMB Circular A-123, HHS's Fiscal Year (FY) 2018 Payment Integrity Report includes a discussion of the following topics:

Refer to PaymentAccuracy.gov for additional detailed information on HHS's improper payment efforts.

1.0 PROGRAM DESCRIPTIONS

HHS utilizes annual improper payment risk assessments to identify new risk-susceptible programs. Risk-susceptible programs are required to estimate improper payments and report other information, such as reduction targets and corrective actions. Figure 1 provides a brief description of the risk-susceptible programs that HHS or OMB identified as risk-susceptible, and that are discussed in this report.

Figure 1: Risk-Susceptible Programs

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 (ESRD).
Medicare Part C	A federal health insurance program that allows beneficiaries to receive their Medicare benefits through a private health plan.
Medicare Part D	A federal prescription drug benefit program for Medicare beneficiaries.
Medicaid	A joint federal/state program, administered by the states, that provides health insurance to qualifying low-income individuals.
CHIP	A joint federal/state program, administered by the states, that provides health insurance for qualifying children.
Advance Premium Tax Credit (APTC)	A federal insurance affordability program, administered by HHS and/or the states, to support enrollees in purchasing Qualified Health Plan (QHP) coverage from state and federal insurance exchanges.
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.
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.
CCDF	A joint federal/state program, administered by the states, that provides child care financial assistance to low-income working families.

Program-specific information on each risk-susceptible program is located throughout the Payment Integrity Report. However, since HHS is not reporting an APTC improper payment estimate for FY 2018, the program is not included in Section 11.0: *Program-Specific Reporting Information.* See Section 9.1*: Accompanying Notes for Table 1* for more detailed information on the Department's efforts to develop an APTC improper payment measurement program. In addition, Department programs that received funding under the *Superstorm Sandy Disaster Relief Appropriations Act of 2013* expended disaster funding by the end of FY 2017 and, therefore, are excluded from reporting improper payment information in this year's report.

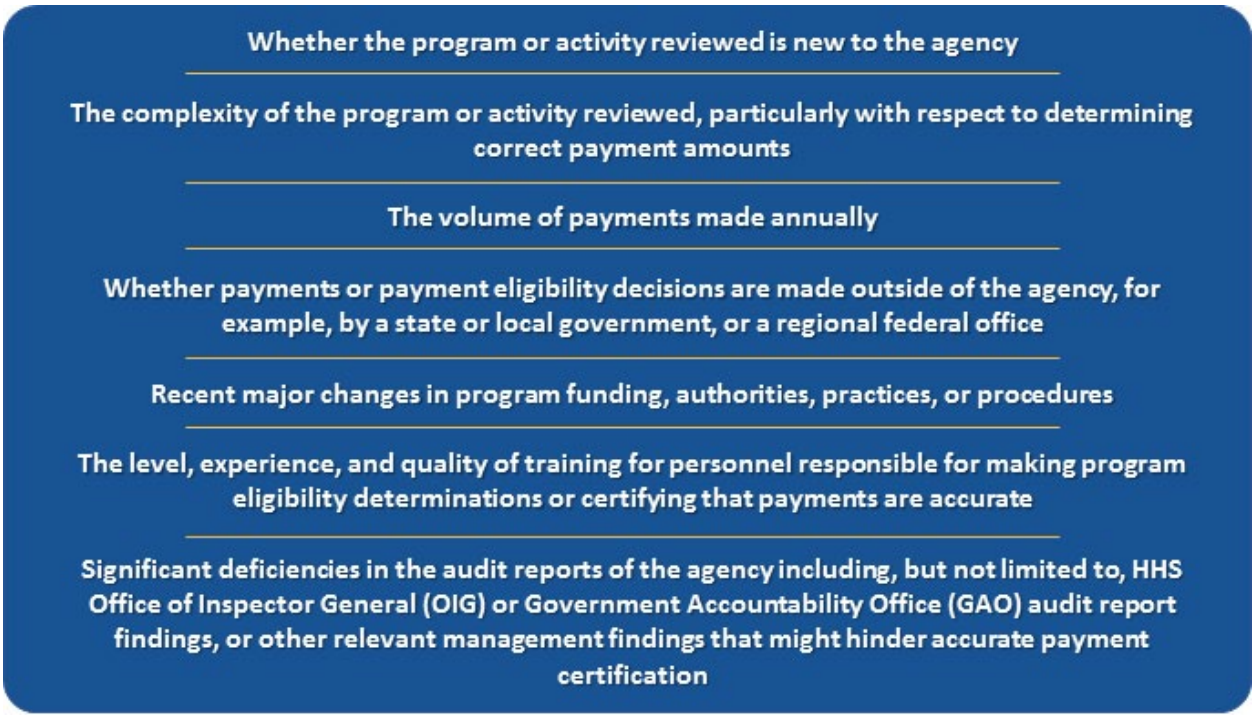
2.0 RISK ASSESSMENTS

As required by the amended IPIA and OMB implementing guidance, HHS reviews its non-risk-susceptible programs (including payment streams and activities) using the HHS IPERIA Risk Assessment Tool to determine susceptibility to significant improper payments. The HHS IPERIA Risk Assessment Tool contains:

- The seven risk factors required by OMB implementing guidance;
- Specific program-identified risks that may lead to improper payments; and
- Controls that may mitigate those risks.

Figure 2 lists the risk factors, as prescribed by Appendix C of OMB Circular A-123, Part I.C.Step2.b, that HHS included in the HHS IPERIA Risk Assessment Tool to determine susceptibility to significant improper payments.

Figure 2: Risk Factors Reviewed in the HHS IPERIA Risk Assessment Tool



By examining these areas, the HHS IPERIA Risk Assessment Tool provides for a comprehensive review and analysis of selected program operations to determine potential payment risks and risk severity. HHS follows guidance contained in OMB Circular A-123, Appendix C when determining how to group programs or activities for risk assessments, if applicable. In FY 2018, HHS made no changes to the grouping of programs for improper payment risk assessments. However, HHS strengthened its risk assessment and reporting activities in FY 2018 by enhancing policies and procedures, and improving the HHS risk assessment by applying lessons learned from the previous year. In FY 2018, HHS completed 22 risk assessments (representing risk assessments of programs and charge cards), and concluded that the 22 programs were not susceptible to the risk of significant improper payments.

HHS continues to defer a final risk assessment conclusion for the Basic Health Program, primarily in connection with continuing uncertainties (such as the establishment of a payment methodology) that may have a bearing on program size, structure, participation, and sustainability. HHS's decision to defer finalizing a risk assessment conclusion is intended to allow greater opportunity for the program to reach a steady state, minimizing the risk that HHS reaches an inaccurate risk assessment conclusion. HHS will monitor program developments and reassess whether it can finalize a risk assessment conclusion in FY 2019.

3.0 STATISTICAL SAMPLING PROCESS

All programs that reported improper payment estimates complied with OMB-approved statistical sampling plans and confidence intervals per OMB's previously issued guidance[25] on sampling and estimation plans. OMB updated its guidance in June 2018[26], and, effective for FY 2018 reporting, three programs (Medicare FFS, Medicare Part C, and Medicare Part D) complied with the new OMB requirements for statistical sampling plans and confidence intervals. Four other programs (Medicaid, CHIP, Foster Care, and CCDF) are considered non-statistical plans due to the rolling nature of the improper payment methodologies. Generally, these programs' improper payment estimates review each state every 3 years and, as a result, each year's improper payment estimates incorporates new review data for approximately one-third of the states. In FY 2018, all of the programs utilized the same statistical sampling process as in the previous year. HHS will continue to work with its risk-susceptible programs and OMB to modify, as needed and to the extent possible, its sampling and estimation plans to comply with OMB's prescribed statistical requirements.

The statistical sampling and estimation process is detailed in Section 11.0: *Program-Specific Reporting Information*.

3.1 IMPROPER PAYMENT MEASUREMENT ESTIMATES

As discussed in Section 1.0: *Program Descriptions* and throughout the Payment Integrity Report, HHS prioritizes protecting taxpayer resources, and the vast majority of the Department's payments are proper. Unfortunately, some payments are improper, and HHS strives to prevent and reduce future improper payments.

Most improper payments are either unintentional payment errors or instances where payment documentation is insufficient and the reviewer is unable to determine if a payment is proper. While fraud and abuse are also improper payments, it is important to note that not all improper payments constitute fraud, and improper payment estimates do not correlate to a rate of fraud. Although fraud may be one cause of improper payments that always results in a monetary loss to the federal government, a payment made to an ineligible recipient or a payment made in the wrong amount resulting in an overpayment is also considered monetary loss. However, an underpayment does not represent a monetary loss to the federal government.

Finally, HHS leverages improper payment methodologies to identify estimates of monetary loss (a subset of improper payments where the wrong recipient was paid, or the correct recipient was paid the wrong amount). All improper payments are not necessarily expenses that should not have occurred, and therefore, do not represent funding that the federal government would not have spent. For example, a significant amount of HHS's improper payments are due to documentation errors; that is, either lack of documentation or errors in the documentation that limited HHS's ability to verify information, and therefore could represent either a "known" monetary loss or "unknown" monetary loss. In the case of "unknown" monetary loss, there is insufficient or no documentation to support the payments as either proper or a "known" monetary loss. Some improper payment estimation methodologies are able to discern if the insufficient documentation payment error would have resulted in the government making the payment in the assigned amount, therefore representing a non-monetary loss to the federal government. Lastly, a smaller proportion of improper payments are payments that either should not have been made or should have been made in a different amount and represent monetary losses to the government.

[25] On October 20, 2014, OMB issued M-15-02, "Appendix C to Circular No. A-123, *Requirements for Effective Estimation and Remediation of Improper Payments*".
[26] On June 26, 2018, OMB issued M-18-20, "Transmittal of Appendix C to OMB Circular A-123, *Requirements for Payment Integrity Improvement*", which replaces M-15-02.

3.2 IMPROPER PAYMENT ROOT CAUSES AND DRIVERS

A key component of the improper payment sampling and reporting process is the identification of improper payment root causes. Once a program identifies improper payment root causes, the program staff can work with stakeholders to implement corrective actions to address those root causes. Table 2: Improper Payment Root Cause Category Matrix for HHS's Risk-Susceptible Programs and Section 11.0: *Program-Specific Reporting Information* include program-specific root cause information and corrective actions that align with OMB's root cause categories contained in OMB Circular A-123, Appendix C. In addition, some HHS risk-susceptible programs have also identified improper payment drivers that are more detailed or program-specific than OMB's root cause categories. Section 11.0 provides more information on these improper payment drivers and the related corrective actions.

4.0 CORRECTIVE ACTION PLANS

Generally, each program develops a multi-faceted corrective action plan with various remediation efforts taking place concurrently. Corrective actions vary by stage — from development, to piloting, to steady state implementation, to completion. Corrective action plans help set aggressive but realistic targets for reducing improper payments with a timetable to achieve scheduled targets. Under OMB's implementing guidance, OMB approves all corrective action plans and reduction targets published in the Agency Financial Report (AFR). The Department reviews corrective action plans annually to confirm remediation plans focus on the root causes of the improper payments, thus increasing the likelihood that targets are successfully met. If targets are not met, HHS develops new strategies, adjusts staffing and other resources, and/or revises targets.

See Section 11.0: *Program-Specific Reporting Information* for each program's corrective action plan for reducing the estimated rate of improper payments.

5.0 ACCOUNTABILITY IN REDUCING AND RECOVERING IMPROPER PAYMENTS

Strengthening program integrity throughout the organization is a top departmental priority, extending to all HHS senior executives and program officials. As evidence of this focus, beginning with senior leadership and cascading down, performance plans contain strategic goals related to enhancing program integrity, protecting taxpayer resources, and reducing improper payments. As part of the semi-annual and annual performance evaluations, senior executives and program officials are evaluated on progress toward achieving these goals.

6.0 INFORMATION SYSTEMS AND OTHER INFRASTRUCTURE

Section 11.0*:* *Program-Specific Reporting Information* details each program's information system(s) and other infrastructure. Unless otherwise stated in Section 11.0, HHS has the appropriate information systems and other necessary infrastructure to continue reducing improper payments to the targeted levels in applicable risk-susceptible programs.

7.0 MITIGATION EFFORTS RELATED TO STATUTORY OR REGULATORY BARRIERS

Section 11.0: *Program-Specific Reporting Information* details each program's statutory or regulatory barriers to reducing improper payments. Unless otherwise stated in Section 11.0, HHS has no current statutory or regulatory barriers to reducing improper payments.

8.0 FY 2018 ACHIEVEMENTS

In FY 2018, HHS implements strengthened efforts to reduce and recover improper payments in its programs. Results of the efforts are outlined here and in Section 11.0: *Program-Specific Reporting Information*. Six of the seven risk-

susceptible programs that report improper payment estimates reported lower improper payment rates in FY 2018 than in FY 2017. The more notable efforts are highlighted below and detailed information on program performance and corrective actions can be found in Section 11.0.

President's Management Agenda and Cross-Agency Priority Goal

In March 2018, the Administration announced the President's Management Agenda (PMA), which is designed to improve how the federal government operates, provides customer service, and oversees taxpayer resources. As part of the PMA, the Administration also announced a series of Cross-Agency Priority (CAP) Goals, where multiple agencies must collaborate to achieve success and meet the PMA's vision. CAP Goal 9, "Getting Payments Right," focuses on improving and streamlining improper payment regulations and reducing monetary loss.

In FY 2018, HHS assumed a key role in supporting the implementation of the "Getting Payments Right" CAP Goal – serving as an agency lead and contributor on multiple work groups created under the CAP Goal. HHS will continue to support this CAP Goal and other efforts to reduce improper payments in FY 2019.

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 FYs 2009 through 2012. In lieu of an annual error rate measurement, HHS monitors Head Start's existing internal controls and monitoring systems and annually reports to OMB on the status and results of the internal controls and monitoring systems. For FY 2018:

- HHS's onsite monitoring identified two of the 550 grantees with erroneous payments related to eligibility, providing reasonable assurance that the Department's control and monitoring systems are still working as intended; and
- An improper payment risk assessment of the program indicate that Head Start continues not to be susceptible to significant improper payments.

Centers for Medicare & Medicaid Services (CMS) Program Integrity (PI) Board

The PI Board, comprised of CMS executives:

- Identifies and prioritizes improper, wasteful, abusive, and potentially fraudulent payment vulnerabilities in its programs;
- Directs corrective actions; and
- Monitors issues to resolution.

To accomplish these objectives, the PI Board established an Improper Payment Action Plan workgroup to collect data from improper payment reports and formulate action plans for the Board's review. The PI Board also receives support from smaller workgroups—referred to as Integrated Project Teams (IPT)—that focus on specific projects to address vulnerabilities. Each IPT works independently under the PI Board's direction and provides regular updates to the PI Board. In FY 2018, the workgroups made significant strides, including:

- Documentation Requirements Simplification (DRS) IPT: The PI Board approved the DRS IPT goals of clarifying, simplifying, and/or eliminating documentation requirements that are unnecessary or where the burden outweighs the benefit. The PI Board also approved the operational structure of the initiative and informed topic selection and prioritization. This structure includes the Documentation Requirements Simplification Change Control Board, which facilitates stakeholder engagement and drives decision-making. The DRS IPT completed eight improvement projects in FY 2018 that reduced provider burden.
- Medicaid PI Strategy IPT: The PI Board approved the Medicaid PI Strategy IPT to develop and implement an approach to improve Medicaid program integrity through greater transparency and accountability,

strengthened data, and innovative and robust analytic tools. The Medicaid PI Strategy IPT regularly briefed the PI Board, which provided substantial input to help inform Medicaid PI initiatives to hold states accountable and assist them with protecting Medicaid resources. These initiatives include stronger audit functions, enhanced oversight of state-managed care programs, increased beneficiary eligibility oversight, expanded use of data for program integrity purposes, and stricter enforcement of state compliance with federal rules.

Provider Enrollment Moratorium

Section 1866(j)(7) of the *Social Security Act* authorizes HHS to impose a temporary moratorium on new provider and supplier enrollment as a tool to prevent or combat Medicare, Medicaid, or CHIP fraud, waste, or abuse in high-risk services and areas across the country. Establishing a moratorium in certain areas allows HHS to analyze and monitor the existing provider and supplier base in order to focus additional fraud prevention and detection tools in these areas, while continuing to monitor beneficiary access to care. HHS launched the first temporary (6-month) enrollment moratorium pursuant to this authority in 2013 for home health agencies (HHA) and ground ambulance suppliers (emergency and non-emergency) in limited areas for Medicare, Medicaid, and CHIP. Since then, HHS extended and modified the temporary enrollment moratoria in six-month increments. On July 29, 2016, HHS announced the following:

- The moratoria was expanded state-wide for HHAs in Florida, Illinois, Michigan, and Texas and for new Medicare Part B, Medicaid, and CHIP non-emergency ground ambulance suppliers in New Jersey, Pennsylvania, and Texas.
- The temporary moratorium was concurrently lifted on all Medicare Part B, Medicaid, and CHIP emergency ground ambulance suppliers.
- The Provider Enrollment Moratoria Access Waiver Demonstration was launched, granting waivers to the state-wide enrollment moratoria on a case-by-case basis in response to access to care issues in certain geographic areas, requiring heightened initial review and ongoing oversight of providers and suppliers enrolling via such waivers.

HHS expanded the moratoria to state-wide on July 29, 2016, to mitigate vulnerabilities that HHS observed in the previous county-based moratorium, such as providers or suppliers enrolling in counties outside a moratorium area while servicing beneficiaries within, which helped protect the integrity of the Medicare, Medicaid, and CHIP programs. HHS extended the moratorium an additional 6 months on January 26, 2018, and again on July 29, 2018.

As a result of the state-wide moratoria, HHS prohibited the new enrollment of HHAs and Part B non-emergency ambulance suppliers (e.g., denial of new enrollment applications) while still taking administrative actions (e.g., deactivations and revocations) on existing HHAs and ambulance suppliers. These efforts resulted in, to date:

- 776 deactivations, 138 revocations, and denial of 306 new enrollment applications for HHAs; and
- 189 deactivations, 34 revocations, and denial of 16 new enrollment applications for non-emergency ambulance suppliers.

Fraud Prevention System (FPS)

The FPS analyzes Medicare FFS claims using sophisticated algorithms to:

- Target investigative resources;
- Generate alerts for suspect claims or providers and suppliers; and
- Provide information to facilitate and support investigations of the most egregious, suspect, or aberrant activity.

HHS uses the FPS information to prevent and address improper payments using a variety of administrative tools and actions, including claim denials, payment suspensions, Medicare billing privilege revocations, and law enforcement referrals. In March 2017, HHS updated the FPS to modernize the system and user interface, improve model development time and performance measurement, and expand HHS's program integrity capabilities. In FY 2018, HHS continued to add and refine models in FPS.

During FY 2017, the FPS generated leads for 172 new investigations and augmented information for 244 ongoing investigations. Based on these leads, HHS took administrative action against 949 providers and suppliers. HHS will report FY 2018 FPS metrics in the FY 2019 AFR.

National Benefit Integrity (NBI) Medicare Drug Integrity Contractor (MEDIC)

The NBI MEDIC performs data analysis to fight fraud, waste, and abuse in Medicare Part C and Part D. It identifies improper payments and notifies plan sponsors to recover the corresponding overpayments. HHS also utilizes the NBI MEDIC's data analysis to select Part D plan sponsors and drugs for review through Part D plan sponsor self-audits. As a result of the NBI MEDIC's data analysis projects, including Part D plan sponsor self-audits, HHS recovered $3.12 million from Part D sponsors during the first three quarters of FY 2018. In addition, the NBI MEDIC refers certain information to law enforcement organizations. According to law enforcement notifications received during the first three quarters of FY 2018, NBI MEDIC referrals to law enforcement resulted in recoveries of $2.51 million for Part C and $9.97 million for Part D. The majority of savings were from court decisions ordering forfeiture for Part C and restitution for Part D.

Medicaid Integrity Program

Under Section 1936 of the *Social Security Act*, as amended by the *Deficit Reduction Act* (DRA) *of 2005*, HHS's Medicaid Integrity Program is responsible for:

- Hiring contractors to review Medicaid provider activities, audit claims, identify overpayments, and educate providers and others on Medicaid program integrity issues; and
- Supporting and assisting state efforts to combat Medicaid provider fraud, waste, and abuse.

Increased Medicaid recoveries demonstrate the increased focus on Medicaid program integrity. For example, the Medicaid Integrity Program provided federal staff specializing in program integrity and contractor support to states to bolster program integrity activities and collections. Since enactment of the DRA, total state Medicaid program integrity collections have grown from $265 million in FY 2006 to $442.54 million in FY 2018. The Medicaid Integrity Program works in coordination with the Medicaid program integrity activities funded by the Health Care Fraud and Abuse Control program. Such program integrity activities improve HHS's financial oversight of Medicaid and CHIP by supporting reviews of proposed Medicaid state plan amendments, financial management reviews, and other activities. The DRA also required HHS to establish a Comprehensive Medicaid Integrity Plan to guide the Medicaid Integrity Program's development and operations. In June 2018, HHS issued a Medicaid Program Integrity strategy with initiatives to improve state oversight and accountability. These initiatives – including conducting new audits of state beneficiary eligibility determinations and providing Medicaid provider education to reduce improper payments – will form the foundation for a revised Comprehensive Medicaid Integrity Plan.

Public Assistance Reporting Information System (PARIS)

PARIS provides state public assistance agencies in all 50 states, the District of Columbia, and Puerto Rico, with matching data to verify an individual's eligibility and to detect and deter improper payments in TANF, Medicaid, Workers' Compensation, child care related programs, and the Supplemental Nutrition Assistance Program. Provided to states at no cost, PARIS data helps states strengthen program administration. For example, New York used PARIS

to close or remove active clients from 8,923 public assistance cases for projected cost savings of $58.01 million during the most recent full state FY (April 2017 to March 2018). For more information, refer to PARIS.

Results of the Do Not Pay (DNP) Initiative in Preventing Improper Payments

In June 2010, the President issued a Memorandum on Enhancing Payment Accuracy Through a "Do Not Pay List" where agencies can access and analyze relevant information before determining eligibility for funding. Since 2010, HHS has worked diligently to implement the DNP initiative. Several of HHS's Divisions are using DNP to check for recipients' or potential recipients' eligibility for payment and to prevent improper payments. In FY 2017, HHS renewed a Computer Matching Agreement (CMA) with the U.S. Department of the Treasury (Treasury) under the DNP initiative, allowing HHS to match identifying information against restricted databases. This CMA is in effect for up to 3 years. In the meantime, HHS is pursuing CMAs for other users, as applicable, to improve DNP matches. Further, Treasury-disbursed payments are matched against the Social Security Administration's (SSA) Death Master File (DMF) and the General Services Administration's (GSA) excluded parties' elements of the System for Award Management in the DNP portal on a daily basis to identify improper payments. In FY 2018, the Department screened 1.2 million payments against IPERIA-listed databases, representing $436.9 billion. While the Department identified 12 potential improper payments over the past year through these daily matches, there were 2 confirmed matches in FY 2018. Lastly, CMS also checks certain payments against IPERIA-listed databases outside of the DNP portal. In FY 2018, CMS screened 1.2 billion payments against IPERIA-listed databases, representing $403.8 billion. Through these checks, CMS stopped 449,356 payments representing $1.7 billion.

9.0 IMPROPER PAYMENT REDUCTION OUTLOOK FY 2017 THROUGH FY 2019

Table 1 displays HHS's proper and improper payment estimates for, the prior year (PY) (FY 2017), the current year (CY) (FY 2018), and targets for FY 2019 (CY+1). The table includes the following information by year and program, as applicable:

- FY outlays;
- Estimated improper payment rate or future target rate (IP%); and
- Estimated amount and percent paid or projected to be paid properly (PP) and improperly (IP).

In addition, for the CY, Table 1 includes:

- Estimated amount of overpayments (CY Over Payments);
- Estimated amount of underpayments (CY Under Payments); and
- Estimated net improper payment rate (CY Net IP%) and amount (CY Net $), when available.

As mentioned earlier, HHS utilizes statistical sampling to calculate each program's estimated improper payment rate and a projected amount of improper payments, including gross improper payment rate and net improper payment rate (as shown below). The gross improper payment rate is the official program improper payment rate.

Table 1 presents each program's gross and net improper payment rates.

Table 1

Estimated Proper and Improper Payments for HHS's Risk-Susceptible Programs

FY 2017 – FY 2019 (in Millions) [1]

Program or Activity	PY Outlays $	PY IP %	PY IP $	CY Outlays $	CY PP %	CY PP $	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 $
Medicare FFS	$380,761.97 (a)	9.51	$36,208.00	$389,300.05 (b)	91.88	$357,682.11	8.12 [2]	$31,617.94	$30,568.03	$1,049.91	7.58	$29,518.12	$435,620.00 (c)	8.00	$34,849.60
Medicare Part C	$172,768.08 (d)	8.31	$14,351.71	$191,923.92 (e)	91.90	$176,369.61	8.10	$15,554.31	$9,094.97	$6,459.34	1.37	$2,635.63	254,298.00 [f]	7.90	$20,089.54
Medicare Part D	$77,450.28 (g)	1.67	$1,295.60	$79,559.54 (h)	98.34	$78,240.62	1.66	$1,318.92	$681.78	$637.14	0.06	$44.63	$88,252.00 [i]	1.65	$1,456.16
Medicaid	$363,839.35 (j)	10.10	$36,731.13	$370,391.00 (k)	90.21	$334,141.30	9.79 [3]	$36,249.70	$35,960.48	$289.22	9.63	$35,671.26	$394,920.55 (k)	N/A [5]	N/A [5]
CHIP	$14,305.14 [l]	8.64	$1,236.05	$16,223.92 (m)	91.43	$14,834.29	8.57 [4]	$1,389.63	$1,378.06	$11.57	8.42	$1,366.49	$17,112.48 (m)	N/A [5]	N/A [5]
APTC	$28,330.67 (n)	N/A	N/A	$33,755.55 (o)	N/A	N/A	N/A [6]	N/A	N/A	N/A	N/A	N/A	$48,190.37 [o]	N/A	N/A
TANF	$16,503.95 (p)	N/A	N/A	$16,330.95 (q)	N/A	N/A	N/A [7]	N/A	N/A	N/A	N/A	N/A	$16,511.11 [q]	N/A	N/A
Foster Care	$747.00 [r]	7.13	$53.28	$394.00 [s]	92.44	$364.21	7.56	$29.79	$29.32	$0.47	7.32	$28.85	$431.00 [s]	7.00	$30.17
CCDF	$5,746.27 [t]	4.13	$237.32	$7,549.78 [u]	96.00	$7,247.79	4.00	$301.99	$281.67	$20.32	3.46	$261.35	$8,023.97 [u]	N/A [8]	N/A

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

9.1 Accompanying Notes for Table 1: Estimated Proper and Improper Payments for HHS's Risk-Susceptible Programs

a) Medicare FFS PY outlays are from the FY 2017 Medicare FFS Improper Payments Report (based on claims from July 2015 – June 2016).
b) Medicare FFS CY outlays are from the FY 2018 Medicare FFS Improper Payments Report (based on claims from July 2016 – June 2017).
c) Medicare FFS CY+1 outlays are based on the FY 2019 Midsession Review (Medicare Benefit Outlays current law [CL]).
d) Medicare Part C PY outlays reflect 2015 Part C payments, as reported in the FY 2017 Medicare Part C Payment Error Final Report.
e) Medicare Part C CY outlays reflect 2016 Part C payments, as reported in the FY 2018 Medicare Part C Payment Error Final Report.
f) Medicare Part C CY+1 outlays are based on the FY 2019 Midsession Review (Medicare Benefit Outlays [CL]).
g) Medicare Part D PY outlays reflect 2015 Part D payments, as reported in the FY 2017 Medicare Part D Payment Error Final Report.
h) Medicare Part D CY outlays reflect 2016 Part D payments, as reported in the FY 2018 Medicare Part D Payment Error Final Report.
i) Medicare Part D CY+1 outlays are based on the FY 2019 Midsession Review (Medicare Benefit Outlays [CL]).
j) Medicaid PY outlays (based on FY 2016 expenditures) are based on the FY 2018 Midsession Review and exclude CDC Vaccine for Children program funding.
k) Medicaid CY (based on FY 2017 expenditures) and CY+1 outlays (Medicaid - Outlays [CL] exclude CDC Vaccine for Children program funding), are based on the FY 2019 Midsession Review.
l) CHIP PY outlays (based on FY 2016 expenditures) are based on the FY 2018 Midsession Review.
m) CHIP CY (based on FY 2017 expenditures) and CY+1 outlays (total outlays from the Children's Health Insurance Fund [CL]), are based on the FY 2019 Midsession Review.
n) APTC PY outlays are comprised of FY 2016 estimated expenditures; and are based on the FY 2018 Midsession Review.
o) APTC CY outlays are comprised of FY 2017 estimated expenditures, and are based on the FY 2019 Midsession Review. CY+1 outlays are based on the FY 2019 Midsession Review.
p) TANF PY outlays are based on the FY 2018 Midsession Review.
q) TANF CY and CY+1 outlays are based on the FY 2019 Midsession Review (TANF total outlays including the Healthy Marriage Promotion and Responsible Fatherhood Grants programs, and excluding the TANF Contingency Fund).
r) Foster Care PY outlays are based on the FY 2018 Midsession Review, and reflect the federal share of maintenance payments.
s) Foster Care CY and CY+1 outlays are based on the FY 2019 Midsession Review, and reflect the federal share of maintenance payments for those states or territories that are operating traditional title IV-E Foster Care programs.
t) CCDF PY outlays are based on the FY 2018 Midsession Review.
u) CCDF CY and CY+1 outlays are based on the FY 2019 Midsession Review.

1. HHS previously assessed the Cost-Sharing Reduction (CSR) program as susceptible to the risk of significant improper payments. In October 2017, federal payments related to the CSR program were discontinued pending a valid appropriation to fund program payments. Accordingly, the Department is not currently developing or piloting activities for the CSR improper payment measurement program.
2. 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 2018. 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 0.15 percentage points to 8.12 percent or $31.62 billion in projected improper payments. Additional information regarding the adjustment factor can be found on pages 166-167 of HHS's FY 2012 AFR.
3. HHS calculated and is reporting the national Medicaid improper payment rate based on measurements conducted in FYs 2016, 2017, and 2018. The national Medicaid component improper payment rates are: Medicaid FFS: 14.31 percent and Medicaid managed care: 0.22 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 11.4: *Medicaid*.
4. HHS calculated and is reporting the national CHIP improper payment rate based on measurements conducted in FYs 2016, 2017, and 2018. The national CHIP component improper payment rates are: CHIP FFS: 12.55 percent and CHIP managed care: 1.24 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 11.5: *CHIP*.
5. Medicaid and CHIP are not reporting CY+1 improper payment targets. As described in Sections 11.4: *Medicaid* and 11.5: *CHIP*, HHS will resume the Medicaid and CHIP eligibility component measurements and report updated national eligibility improper payment estimates in FY 2019. Since HHS uses a 17-state three-year rotation for measuring Medicaid and CHIP improper payments, reduction targets will be published once a full baseline, including eligibility, has been established and reported in FY 2021.
6. While a FY 2016 risk assessment concluded that the program is susceptible to significant improper payments, the APTC program is not yet reporting improper payment estimates for FY 2018. The Department is committed to implementing an improper payment measurement program as required by the IPIA, as amended. As with similar HHS programs, developing an effective and efficient improper payment measurement program requires multiple, time-intensive steps. The measurement program requires developing measurement policies, procedures, and tools, as well as extensive pilot testing to ensure an accurate improper payment estimate. Contractor procurement timelines are also a consideration for implementation timing. HHS will continue to monitor and assess the program for any changes and adapt accordingly. In FYs 2017 and 2018, HHS conducted development and piloting activities for the APTC improper payment measurement program and will continue these activities in FY 2019. The Department will continue to update its annual AFRs on the status of the measurement program development until the improper payment estimate is reported.
7. The TANF program is not reporting an error rate for FY 2018. As discussed in Section 11.6: *TANF*, statutory limitations preclude HHS from requiring states to participate in a TANF improper payment measurement.
8. The *Child Care and Development Block Grant Act* (CCDBG) *of 2014* reauthorized the CCDF program for the first time since 1996. Regulations for the CCDBG, released in September 2016, will significantly impact current state policies and procedures. Rolling implementation of the new requirements will likely affect the error rate beginning with the FY 2019 measurement, making it challenging to determine a target rate; therefore, a reduction target is not being set for this year's reporting as the baseline is reestablished for the CCDF program.

10.0 IMPROPER PAYMENT ROOT CAUSE CATEGORIES

OMB guidance requires agencies to report improper payment root causes for risk-susceptible programs with reported improper payment estimates. Table 2 displays HHS's FY 2018 improper payment root causes and the estimated amount of overpayments or underpayments for each risk-susceptible program. For reporting purposes, Administrative or Process Errors Made by Other Party may include health care providers, contractors, or any other organization administering federal dollars. Additional information on root causes and corrective actions can be found in each program-specific reporting section in Section 11: *Program-Specific Reporting Information*.

Table 2
Improper Payment Root Cause Category Matrix for HHS's Risk-Susceptible Programs
FY 2018 (in Millions)

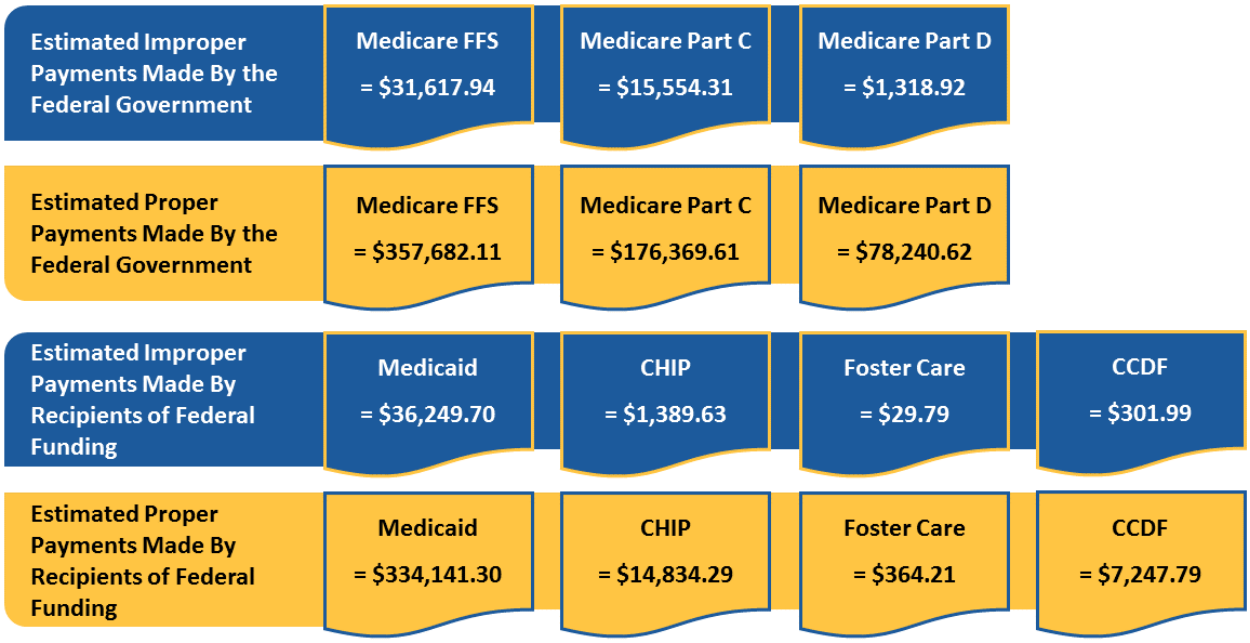
Reason for Improper Payment		Medicare FFS		Medicare Part C		Medicare Part D		Medicaid [1]		CHIP [1]		Foster Care		CCDF	
		Overpayments	Underpayments	Overpayments	Underpayments	Overpayments	Underpayments	Overpayments	Underpayments	Overpayments	Underpayments	Overpayments	Underpayments	Overpayments	Underpayments
Inability to Authenticate Eligibility:	Inability to access data							$11,596.65	$281.10	$655.28	$6.72				
Failure to Verify Death Data								$29.73							
Administrative or Process Error Made by:	State or Local Agency							$16,570.53	$8.12	$583.49	$4.75	$29.32	$0.47	$104.75	$20.32
	Other Party	$4,695.96	$1,048.94		$6,459.34		$637.14	$162.45		$8.45	$0.11				
Medical Necessity		$6,739.63	$0.97							$0.01					
Insufficient Documentation to Determine		$19,132.44		$9,094.97		$681.78		$7,601.12		$130.82				$176.92	
Total [2]		$30,568.03	$1,049.91	$9,094.97	$6,459.34	$681.78	$637.14	$35,960.48	$289.22	$1,378.06	$11.57	$29.32	$0.47	$281.67	$20.32

Notes:

1. As described in Sections 11.4: *Medicaid* and 11.5: *CHIP*, HHS did not conduct the Medicaid and CHIP eligibility measurement components for FYs 2015 – 2018 and FY 2014 eligibility improper payment rates were held constant in the overall national Medicaid and CHIP improper payment rates. Therefore, Medicaid and CHIP improper payments reported under Inability to Authenticate Eligibility: Inability to Access Data represent the historical eligibility improper payment rates held constant in the national rates, which include multiple types of historical eligibility improper payments and are not only reflective of situations in which the data needed existed but the Department did not have access to the data.
2. Totals do not necessarily equal the sum of the rounded components.

OMB Circular A-136 also requires agencies to report the estimated amount of improper payments made directly by the federal government or by recipients of federal money by program as reported in Figure 3. At HHS, all of the estimated improper payments for Medicare FFS, Medicare Part C, and Medicare Part D are made by the federal government or its representatives. For the remaining programs (i.e., Medicaid, CHIP, Foster Care, and CCDF), the estimated improper payments are made by recipients of federal money (e.g., state agencies or grantees).

Figure 3: FY 2018 Estimated Proper and Improper Payments Made by the Federal Government or Recipients of Federal Funding (in Millions)



11.0 PROGRAM-SPECIFIC REPORTING INFORMATION

11.1 MEDICARE FFS (PARTS A AND B)

Medicare FFS Statistical Sampling Process

HHS uses the Comprehensive Error Rate Testing (CERT) program to estimate the Medicare FFS improper payments. The CERT program reviews a stratified random sample of Medicare FFS claims to determine if HHS properly paid claims under Medicare coverage, coding, and billing rules. The CERT program considers any payment for a claim that should have been denied or that was made in the wrong amount (including both overpayments and underpayments) to be an improper payment. The claim can be counted as either a total or a partial improper payment, depending on the error. The Medicare FFS improper payment estimate includes improper payments due to insufficient or no documentation. Furthermore, the CERT program includes improper payments of all dollar amounts (i.e., there is no dollar threshold under which errors will not be cited) and improper payments caused by policy changes as of the new policy effective date (i.e., there is no grace period permitted). Figure 4 depicts the CERT process.

Figure 4: CERT Process

The CERT program ensures statistically valid random sampling across four claim types:

- Part A claims excluding hospital Inpatient Prospective Payment System (IPPS) (including but not limited to home health, Inpatient Rehabilitation Facility [IRF], Skilled Nursing Facility [SNF], and hospice);
- Part A hospital IPPS claims;
- Part B claims (e.g., physician, laboratory, and ambulance services); and
- Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS).

HHS sampled approximately 50,000 claims during the FY 2018 report period. The improper payment rate estimated from this sample reflects all claims processed by the Medicare FFS program during the report period. Additional information on Medicare FFS improper payment methodology can be found on pages 166-167 of HHS's FY 2012 AFR.

Service Areas Driving Improper Payments

The Medicare FFS gross improper payment estimate for FY 2018 is 8.12 percent of total outlays or $31.62 billion. The FY 2018 net improper payment estimate is 7.58 percent of total outlays or $29.52 billion. The decrease from the prior year's reported improper payment estimate of 9.51 percent was driven by a reduction in improper payments for home health and SNF claims. Although the improper payment rate for these services and the gross Medicare FFS improper payment rate decreased, improper payments for home health, IRF, SNF, and hospital outpatient claims were the major contributing factors to the FY 2018 Medicare FFS improper payment rate, comprising 33.24 percent of the overall estimated improper payment rate. While the factors contributing to improper payments are complex and vary by year, the primary causes of improper payments continue to be insufficient documentation and medical necessity errors as described in the following four driver service areas:

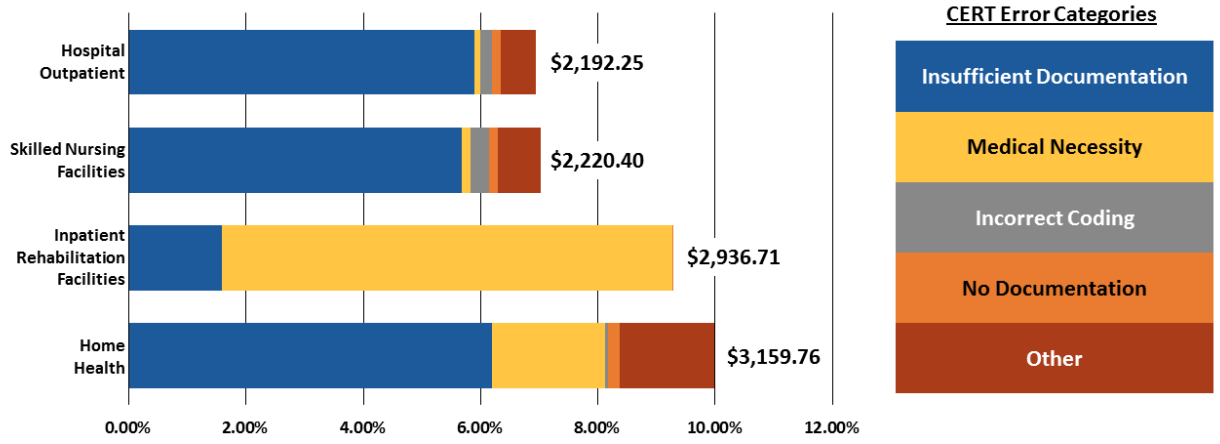
- Insufficient documentation for home health claims continues to be prevalent, despite the improper payment rate decrease from 32.28 percent in FY 2017 to 17.61 percent in FY 2018. The primary reason for these errors was that documentation to support the certification of home health eligibility requirements was missing or insufficient. Medicare coverage of home health services requires physician certification of the beneficiary's eligibility for the home health benefit (42 Code of Federal Regulations [CFR] 424.22).
- Medical necessity (i.e., the services billed were not medically necessary) continues to be the major error contributor for IRF claims. The improper payment rate for IRF claims increased from 39.74 percent in FY 2017 to 41.55 percent in FY 2018. The primary reason for these errors was that the IRF coverage criteria for medical necessity were not met. Medicare coverage of IRF services requires a reasonable expectation that the patient meets all of the coverage criteria at the time of IRF admission (42 CFR 412.622(a)(3)).
- Insufficient documentation continues to be the major error reason for SNF claims. The improper payment rate for SNF claims decreased from 9.33 percent in FY 2017 to 6.55 percent in FY 2018. The primary reason for these errors was that the certification/recertification statement was missing or insufficient. Medicare coverage of SNF services requires certification and recertification for these services (42 CFR 424.20).
- Insufficient documentation is the major error reason for hospital outpatient claims. The improper payment rate for hospital outpatient claims decreased from 4.38 percent in FY 2017 to 3.25 percent in FY 2018. The primary reason for these errors was that the order (or intent to order for certain services) or medical necessity documentation was missing or insufficient (42 U.S.C 1395y, 42 CFR 410.32).

Most CERT error categories are more detailed than OMB root cause categories to help generate useful information on the root causes of HHS improper payments. Figure 5 describes the CERT error categories, while Figure 6 shows the FY 2018 Medicare FFS drivers for home health, IRF, SNF, and hospital outpatient claims by CERT error category.

Figure 5: CERT Error Categories and Percentage of Improper Payments

CERT Error Category	Error Category Description	Share of Improper Payments
Insufficient Documentation	These errors occur when the medical records submitted are inadequate to determine whether the billed services were actually provided, were provided at the level billed, and/or were medically necessary; or when a specific documentation element, required as a condition of payment, is missing.	57.97%
Medical Necessity	These errors occur when the medical records submitted contain adequate documentation to make an informed decision that the services billed were not medically necessary based upon Medicare coverage and payment policies.	21.32%
Incorrect Coding	These errors occur when the medical records submitted support a different code than that which was billed, the service was performed by someone other than the billing provider or supplier, the billed service was unbundled, or the beneficiary was discharged to a site other than the one coded on the claim.	11.91%
No Documentation	These errors occur when the provider or supplier fails to respond to repeated requests for the medical records or when the provider or supplier responds that they do not have the requested documentation.	2.55%
Other	These errors include improper payments that do not fit into the previous categories (e.g., duplicate payment error, non-covered or unallowable service, ineligible Medicare beneficiary, etc.).	6.25%

Figure 6: FY 2018 Medicare FFS Percentage and Estimated Improper Payments (in Millions) of Overall Improper Payments for Service Areas Driving Improper Payments by CERT Error Category



Monetary Loss Findings

Improper payments do not necessarily represent expenses that should not have occurred. Instances where there is insufficient or no documentation to support the payment as proper are cited as improper payments. The majority of Medicare FFS improper payments are due to documentation errors where HHS could not determine whether the billed services were actually provided, were provided at the level billed, and/or were medically necessary. In Figure 7, "unknown" represents payments where there was insufficient or no documentation to support the payment as proper or a known monetary loss. In other words, when payments lack the appropriate supporting documentation,

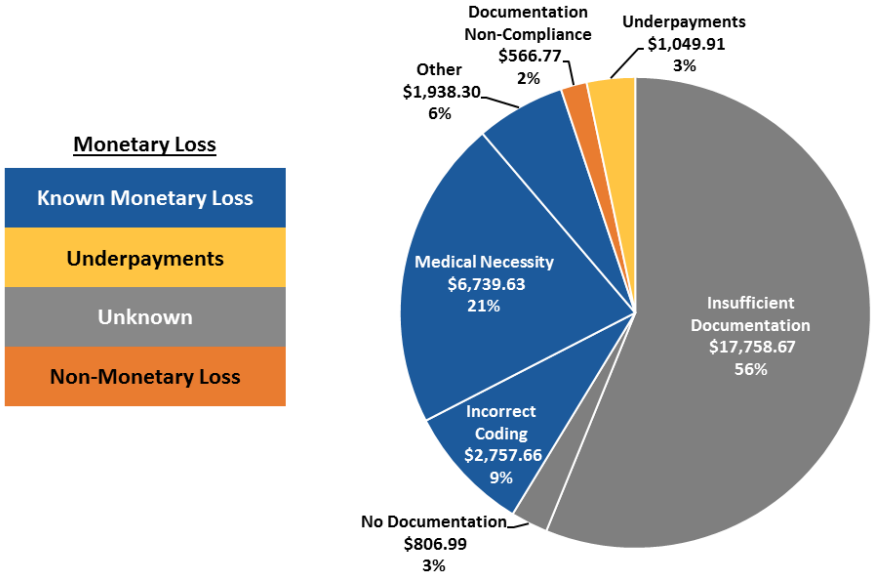
validity cannot be determined. These are payments where more documentation is needed to determine if the claims were payable or if they should be considered monetary losses to the program.

In an effort to provide additional information on the unknown, HHS reviewed insufficient documentation errors to determine if the errors were for services or items that were covered and necessary, were provided/delivered to an eligible beneficiary, and were paid in the correct amount, but the medical record documentation did not comply with rules and requirements per Medicare policy. These errors are called documentation non-compliance errors. HHS determined that 3.09 percent of the insufficient documentation errors were documentation non-compliance errors. Had the documentation non-compliance error been corrected, the government would have made the payment in the assigned amount, and therefore, it represents a "non-monetary loss" to the government. If the documentation non-compliance errors were counted as proper payments, the FY 2018 Medicare FFS improper payment rate would have been 7.98 percent, representing $31.05 billion in projected improper payments.

A smaller proportion of improper payments are claims where HHS determined that the Medicare FFS payment should not have been made or should have been made in a different amount. For this reason, medical necessity, incorrect coding, and other errors are, in fact, improper and known monetary losses to the program.

Figure 7 provides information on Medicare FFS improper payments that are known monetary losses, unknown, and non-monetary losses to the program.

Figure 7: FY 2018 Medicare FFS Percentage and Estimated Improper Payments (in Millions) by Monetary Loss and Type of CERT Error[1]



[1] Values in this figure may not add up precisely to other tables in this document due to rounding.

Medicare FFS Corrective Action Plan

HHS uses data from the CERT program and other sources of information to address improper payments in Medicare FFS through various corrective actions. The following sections discuss key corrective actions to address driver service area errors and OMB root cause categories.

Corrective Actions to Address Driver Service Areas

HHS developed a number of preventive and detective measures for specific service areas with high improper payment rates, such as home health, IRF, SNF, and hospital outpatient claims. HHS believes implementing targeted

corrective actions will prevent and reduce improper payments in these areas and reduce the overall improper payment rate.

Service Area: Home Health

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. Key Home Health corrective actions include:

Key Home Health Corrective Actions

Corrective Action	Description
Targeted Probe and Educate (TPE) for HHAs	During FY 2018, HHS transitioned home health agencies with high error rates after Round 2 of the Home Health Probe and Educate process into the TPE process. In October 2017, HHS implemented the TPE medical review strategy. Under the TPE strategy, MACs conduct up to three rounds of review of 20-40 claims per round, with one-on-one education provided at the conclusion of each round. HHAs with high error rates at the conclusion of round two of the previous Home Health Probe and Educate program, and those identified by MAC data analysis as statistical outliers, are included in the TPE process.
Review Choice Demonstration for Home Health Services	Following the pause of the Pre-Claim Review Demonstration for Home Health Services on April 1, 2017, HHS worked to revise the demonstration to offer more flexibility and choice for providers, as well as risk-based changes to reward providers who show compliance with Medicare home health policies. As noted in the September 27, 2018 Federal Register notice, the proposed Review Choice Demonstration for Home Health Services would give Jurisdiction M (Palmetto) providers operating in Illinois, Ohio, North Carolina, Florida, and Texas an initial choice of three options (i.e., pre-claim review, post-payment review, or minimal post-payment review with a 25 percent payment reduction for all home health services.) A provider's compliance with Medicare billing, coding, and coverage requirements would determine the provider's next steps under the demonstration. HHS proposes to begin this demonstration on December 10, 2018.
Home Health Recovery Audit Contractors (RAC)	In FY 2018, HHS approved the Medicare FFS Home Health and Hospice RAC to review home health claims for several factors, including lack of documentation to support medical necessity of provided home health services, insufficient documentation to support billed home health claims, and whether the home health services billed were rendered. HHS believes RACs help reduce improper payments by educating providers on Medicare policies. HHS also believes there is a sentinel effect in the provider community with more providers billing accurately because of the possibility of a future RAC audit.
Home Health Plan of Care/ Certification Template	In FY 2017, HHS released the first draft electronic and paper home health plan of care/certification templates. These voluntary templates will support HHAs and assist with improving physician documentation. In FY 2018, HHS hosted two special open-door forums to obtain industry feedback on improving the templates and released the second draft version of the template. HHS anticipates completing the *Paperwork Reduction Act* comment process in FY 2019.

Service Area: Inpatient Rehabilitation Facilities

HHS also continues to focus on addressing IRF payment errors, including errors resulting from medical necessity. Key IRF corrective actions include:

Key IRF Corrective Actions

Corrective Action	Description
IRF Prospective Payment System	In the FY 2015 IRF Prospective Payment System final rule (79 FR 45872, August 6, 2014), HHS required IRFs to record and report to HHS how much and what type of therapy (e.g., Individual, Concurrent, Group, and Co-Treatment) patients receive in each therapy discipline in the IRF setting. Data are still being collected as of September 30, 2018. HHS will utilize these data for potentially informing future IRF rulemaking (e.g., to clarify policies which could reduce improper payments).
Medicare Learning Network (MLN) Articles	In FY 2018, HHS published a MLN provider compliance tip, and a fact sheet with targeted education to IRFs, practitioners, and other practitioners with patients in IRFs receiving Part A inpatient services. The articles restate existing policy related to claims submission for services provided in IRFs, and clarifies how HHS conducts medical review on those claims.
RACs	In FY 2018, HHS approved the Medicare FFS RACs to review IRF claims for several factors, including medical necessity and insufficient documentation. HHS believes RACs help reduce improper payments by educating providers on Medicare policies. HHS also believes there is a sentinel effect in the provider community with more providers billing accurately because of the possibility of a future RAC audit.

Service Area: Skilled Nursing Facilities

HHS implemented corrective actions for payment errors related to SNF services resulting from missing or insufficient medical record documentation. Key SNF corrective actions include:

Key SNF Corrective Actions

Corrective Action	Description
RACs	During FY 2018, Medicare FFS RACs continued to identify and collect improper payments related to SNF claims for several factors, including medical necessity and insufficient documentation. HHS believes RACs help reduce improper payments by educating providers on Medicare policies. HHS also believes there is a sentinel effect in the provider community with more providers billing accurately because of the possibility of a future RAC audit.
MLN Provider Compliance Tip Fact Sheet	On February 14, 2018, HHS published an MLN provider compliance tip fact sheet with targeted education to physicians, non-physician practitioners, and providers who bill for SNF services. This fact sheet provides reasons for denials and restates existing policy related to claims submitted for services provided in SNFs.

Service Area: Hospital Outpatient

HHS implemented corrective actions for payment errors related to hospital outpatient services resulting from missing or insufficient medical record documentation. Key hospital outpatient corrective actions include:

Key Hospital Outpatient Corrective Actions

Corrective Action	Description
RACs	During FY 2018, Medicare FFS RACs continued to identify and collect improper payments related to outpatient claims for several factors, including insufficient documentation. HHS believes RACs help reduce improper payments by educating providers on Medicare policies.

Key Hospital Outpatient Corrective Actions

Corrective Action	Description
	HHS also believes there is a sentinel effect in the provider community with more providers billing accurately because of the possibility of a future RAC audit.
TPE Medical Review	During FY 2018, MACs implemented the TPE medical review strategy by conducting up to three rounds of hospital outpatient claims review of 20-40 claims per round, with one-on-one education being provided at the conclusion of each round. Providers with high error rates at the conclusion of round two of the TPE process and those who have been identified by MAC data analysis as statistical outliers are included in the TPE process.
Supplemental Medical Review Contractor (SMRC) Hospital Outpatient Review Projects	The SMRC performs medical reviews on a post-payment basis for hospital outpatient claims. After the SMRC completes its medical review, the results are shared with the MACs for claim adjustment. The providers receive detailed review result letters from the SMRC and demand letters for overpayment recovery from the MAC. These letters include educational information to providers regarding what was incorrect in the original billing of the claim.

Other Service Areas

HHS leverages prior corrective action successes in other service areas such as DMEPOS and other non-emergent services by working with providers to improve understanding of HHS policies and explore new opportunities for corrective actions. Key Other Service Area corrective actions include:

Key Other Service Area Corrective Actions

Corrective Action	Description
DME RAC	During FY 2018, the Medicare FFS DME RAC continued to work with HHS and the DME MACs to identify and collect improper payments for DMEPOS claims. HHS believes RACs help reduce improper payments by educating providers on Medicare policies. HHS also believes there is a sentinel effect in the provider community with more providers billing accurately because of the possibility of a future RAC audit. The DME RAC completed complex DME reviews for: • Medical necessity of DME items billed; • Insufficient documentation to support DME items billed; • Missing valid orders for DME items billed; and • Whether items/services billed were rendered. The DME RAC also completed automated DME reviews for inappropriate unbundling and whether the DME items billed were medically necessary.
DMEPOS Prior Authorization	In FY 2018, HHS continued prior authorization for DMEPOS items. In September 2018, HHS began prior authorization nationwide on an additional 31 Healthcare Common Procedure Coding System codes for Power Mobility Devices (PMDs). (As noted below, the PMD Healthcare Common Procedure Coding System codes had been included in the PMD Prior Authorization Demonstration.)
PMD Prior Authorization	In FY 2012, HHS instituted a Prior Authorization Demonstration in seven states (California, Illinois, Michigan, New York, North Carolina, Florida, and Texas) for PMDs. Based on early successes, in FY 2014, 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, increasing the number of states to 19. In FY 2015, HHS extended the demonstration to August 31, 2018, for all 19 states. The PMD demonstration ended on August 31, 2018 and transitioned to the DMEPOS prior authorization program. Based on claims processed from the inception of the pilot on

Key Other Service Area Corrective Actions

Corrective Action	Description
	September 1, 2012, through April 30, 2018, monthly expenditures for the power mobility device codes included in the PMD demonstration decreased from $11.5 million in September 2012 to $1.8 million in April 2018 in the original seven demonstration states, $10.4 million in September 2012 to $1.8 million in April 2018 in the 12 additional expansion states, and $9.7 million in September 2012 to $2.0 million in April 2018 in the non-demonstration states.
Ambulance Transport Prior Authorization	In FY 2018, HHS continued 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 the *Medicare Access and CHIP Reauthorization Act* (MACRA) *of 2015*, HHS added five additional states (North Carolina, Virginia, West Virginia, Maryland, and Delaware) and the District of Columbia to the model. The model is currently scheduled to end in all states on December 1, 2018. Based on expenditure data, spending decreased in the initial model states from an average of $18.9 million to an average of $6.1 million per month. Based on data from the additional MACRA states, spending decreased from an average of $5.7 million to an average of $3.1 million per month.
Hyperbaric Oxygen Therapy Prior Authorization	HHS instituted the Medicare Prior Authorization of Non-Emergent Hyperbaric Oxygen Therapy Model, which began on March 1, 2015, for treatments occurring on or after April 13, 2015, in Michigan and on July 15, 2015, for treatments occurring on or after August 1, 2015, in Illinois and New Jersey. On February 28, 2018, the Hyperbaric Oxygen Therapy model ended. Facilities and beneficiaries continued to submit prior authorization requests after February 28, 2018, for treatments occurring prior to March 1, 2018. Prior to the model, spending on outpatient Hyperbaric Oxygen Therapy in the model states averaged $1.7 million per month. Since implementation, spending decreased to an average of $0.9 million per month. The independent evaluation of the completed model is ongoing.

In addition to these initiatives, HHS has implemented further efforts to reduce improper payments in Medicare FFS, spanning multiple service areas, and addressing the OMB root causes of improper payments as outlined below.

Corrective Actions to Address OMB Root Causes:

Root Cause: Administrative or Process Errors Made by Other Party

Administrative or process errors made by other party (18.17 percent) mainly consists of coding errors. Key corrective actions include:

Corrective Actions for Administrative or Process Errors Made by Other Party

Corrective Action	Description
Automated Edits	Due to the high volume of Medicare claims processed by HHS daily and the significant cost associated with conducting medical review of an individual claim, HHS relies on automated edits to identify inappropriate claims. HHS designed its systems to detect anomalies on the face of the claims, and through these efforts, prevents payment for many erroneous claims. HHS uses the National Correct Coding Initiative (NCCI) to stop claims that should never be paid. For example, this program prevents payments for services, such as the repair of an organ by two different methods. NCCI edits saved the Medicare program $505.30 million in the first three quarters of FY 2018.
Provider and Supplier Screening	HHS is required by regulation (42 CFR §424.515) to revalidate all existing Medicare providers and suppliers on an ongoing basis to ensure that only qualified and legitimate providers and suppliers deliver health care items and services to Medicare beneficiaries. In FY 2018, revalidation efforts resulted in approximately 39,445 deactivations and approximately

Corrective Actions for Administrative or Process Errors Made by Other Party

Corrective Action	Description
	267 revocations of providers' and suppliers' billing privileges that did not meet Medicare requirements.
Healthcare Fraud Prevention Partnership (HFPP)	HHS continues to engage with the HFPP, a public-private partnership to improve detection and prevention of health care fraud, waste, and abuse by exchanging data, information, and anti-fraud practices. During FY 2018, HFPP membership grew from 85 to 112 partner organizations, including federal and state partners, private payers, associations, and law enforcement organizations.
Medical Review Strategies	HHS and its contractors develop medical review strategies using improper payment data to target the areas of highest risk and exposure. HHS requires its Medicare review contractors to identify and prevent improper payments due to documentation errors in certain error-prone claim types, such as home health, IRF, SNF, and hospital outpatient claims.
Overpayment Recoveries Related to Regulatory Provisions	In the final rule titled "Medicare Program: Reporting and Returning of Overpayments" (81 FR 7654, February 12, 2016), HHS codified a rule requiring providers and suppliers to identify, report, and return any Medicare Part A or Part B overpayments. This rule implements Section 1128J(d) of the *Social Security Act* and obligates providers and suppliers to report, and return any amounts they have self-identified as overpayments. This rule incentivizes providers and suppliers to maintain documentation and submit accurate claims, which reduced the potential improper payments.

Root Cause: Insufficient Documentation to Determine and Medical Necessity

The primary cause of improper payments in Medicare FFS is insufficient documentation (60.51 percent). For these claims, the submitted medical records are inadequate to conclude that the billed services were actually provided, were provided at the level billed, and/or were medically necessary or when a specific documentation element, required as a condition of payment, is missing. Claims are also included in this category when the provider or supplier fails to respond to the repeated requests for the medical records or when the provider or supplier responds that they do not have the documentation. If the documentation had been submitted or the provider had complete and sufficient documentation, then the claim may have been payable.

Another cause of improper payments is medical necessity errors (21.32 percent). For these claims, the submitted medical records contain adequate documentation to make an informed decision that the services billed were not medically necessary based upon Medicare coverage and payment policies. Key corrective actions include:

Corrective Actions for Insufficient Documentation and Medical Necessity

Corrective Action	Description
SMRC Strategy	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 entities. 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 2018, upon the prior expiration of the existing SMRC contract, HHS recompeted the contract and awarded it to a new contractor. Post payment reviews began in FY 2018, and HHS anticipates that for FY 2019, the SMRC will perform post-payment reviews on multiple areas, such as urine drug screen services, spinal fusion procedures, hospice, outpatient right heart catheterizations, and select DMEPOS services. HHS uses the reviewers' results to improve billing accuracy. Results are shared with providers through detailed review results letters and possible overpayment determinations.

Corrective Actions for Insufficient Documentation and Medical Necessity

Corrective Action	Description
	These letters include educational information to providers regarding what was incorrect in the original billing of the claim.
Medical Review Strategies	HHS implemented a TPE process, which is a targeted approach where MACs focus on specific providers and suppliers within a particular service type, rather than all providers and suppliers billing the service. This eliminates burden to providers and suppliers who, based on data analysis, are already submitting claims that are compliant with Medicare policy. After completing TPE pilots in 2016 and 2017, HHS expanded the TPE process to all MAC jurisdictions at the beginning of FY 2018.
Medical Review Accuracy Award Fee Metric	Beginning in FY 2014, HHS included the Medical Review Accuracy Award Fee Metric in the Award Fee Plan for MACs that process Part A, Part B, and DME claims. The Medical Review Accuracy Award Fee Metric measures the accuracy of the MAC's complex medical review decisions. This project assists with consistent medical review decisions across MACs, leading to uniform education to providers on all improper payments, including medical necessity and the impact of insufficient documentation errors. Additional goals of this project in FY 2019 include identifying unclear and/or burdensome policy requirements that can be clarified or simplified to prevent unnecessary denials. HHS will also work to implement an accuracy review initiative for the MAC redetermination appeal units to ensure consistent medical review decisions are made at that level.
Provider Billing Review Evaluation	In order to assist providers and suppliers analyze coding and billing practices, HHS issues Comparative Billing Reports (CBR) to compare providers' billing patterns to their state and national peers. By giving comparative information, HHS empowers providers to review their own billing practices to determine if they are potentially aberrant. CBRs are a non-intrusive corrective action, and if a provider analyzes and makes modifications based on a CBR, future corrective action may not be warranted. In FY 2018 HHS completed eight CBRs for emergency department services, opioid prescribers, spinal and knee orthoses, critical care services, independent diagnostic testing facilities, and licensed clinical social workers.

Medicare FFS Information Systems and Other Infrastructure

HHS's systems are able to identify developing and continuing aberrant billing patterns through comparison of local payment rates to national rates. The systems at both the Medicare contractor and HHS levels are linked by a secure high-speed network that rapidly transmits 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.

Medicare FFS Statutory or Regulatory Barriers that Could Limit Corrective Actions

HHS has not identified statutory or regulatory barriers that could limit corrective actions.

11.2 Medicare Advantage (Part C)

Medicare Advantage Statistical Sampling Process

The Part C methodology estimates improper payments due to errors in beneficiary risk scores. The primary component of most beneficiary risk scores is clinical diagnoses submitted by the plan. If the diagnoses submitted to HHS are not supported by medical records, the risk scores will be inaccurate, ultimately resulting in payment errors. The Part C estimate is based on medical record reviews conducted under HHS's annual National Risk Adjustment Data Validation (RADV) process, where HHS identifies unsupported diagnoses and calculates corrected risk scores. In FY 2018, HHS selected a stratified random sample of beneficiaries for whom a risk adjusted payment was made in calendar year 2016, where the strata are high, medium, and low risk scores, and reviewed medical records of the

diagnoses submitted by plans for the sample beneficiaries. The RADV process (see Figure 8) calculates the beneficiary-level payment error for the sample, and performs extrapolation of the sample payment error to the population subject to risk adjustment, resulting in a Part C gross payment error amount.

Figure 8: RADV Process

The Medicare Part C gross improper payment estimate for FY 2018 is 8.10 percent or $15.55 billion. The FY 2018 net improper payment estimate is 1.37 percent or $2.64 billion. The decrease from the prior year's estimate of 8.31 percent was driven primarily by submission of more accurate diagnoses by Medicare Advantage (MA) organizations for payment.

Medicare Advantage Corrective Action Plan

The root causes of FY 2018 Medicare Part C improper payments consist of errors due to missing or insufficient documentation (58 percent) and administrative or process errors made by another party (i.e., the MA organizations) (42 percent), as displayed in Figure 9 below.

Figure 9: Root Causes of FY 2018 Medicare Part C Improper Payments

Corrective Actions to Address Root Causes:

Root Causes: Insufficient Documentation to Determine and Administrative or Process Errors Made by Other Party

HHS implemented three key corrective actions to address the Part C improper payment estimate:

Corrective Actions for Insufficient Documentation and Administrative or Process Errors Made by Other Party

Corrective Action	Description
Contract-Level Audits	Contract-level RADV audits are HHS's primary corrective action to recoup overpayments. RADV verifies, through medical record review, the accuracy of enrollee diagnoses submitted by MA organizations for risk adjusted payment. HHS expects that payment recovery will have a sentinel effect on the quality of risk adjustment data submitted by plans for payment, as contract-level RADV audits increase the incentive for MA organizations to submit valid and accurate diagnosis information, as well as encourage MA organizations to self-identify, report,

Corrective Actions for Insufficient Documentation and Administrative or Process Errors Made by Other Party

Corrective Action	Description
	and return received overpayments. HHS completed payment recovery for the 2007 pilot audits, totaling $13.7 million recovered in FYs 2012 through 2014. The Department completed several stages of the contract-level RADV audits for payment years 2011 through 2013. HHS expects to initiate payment year 2014 and 2015 audits in FY 2019, incorporating updated methodology.
Overpayment Recoveries Related to Regulatory Provisions	As required by the *Social Security Act*, HHS regulations specify that MA organizations must report and return identified overpayments. In FY 2018, MA organizations reported and returned approximately $64.93 million in self-reported overpayments. HHS believes that this requirement will reduce improper payments by encouraging MA organizations to submit accurate payment information.
Training	Historically, HHS has conducted fraud, waste, and abuse in-person and webinar training sessions for MA plans on program integrity initiatives, investigations, data analyses, and potential fraud schemes. In the third quarter of FY 2017, HHS conducted a small, in-person mission for MA sponsors in place of the larger training sessions because procurement activities were underway and contractor support was terminated in mid-FY 2017. In late FY 2017, HHS procured a new contractor to support this initiative and, in FY 2018, HHS conducted three in-person missions (one in October 2017 and two in April 2018) and a large in-person fraud, waste, and abuse training conference in July 2018.

Medicare Advantage Information Systems and Other Infrastructure

HHS uses the following internal Medicare systems to make and validate Medicare Part C payments:

- Medicare Beneficiary Database;
- Risk Adjustment Processing System;
- Encounter Data Processing System;
- Health Plan Management System; and
- Medicare Advantage Prescription Drug (MARx) payment system.

Medicare Advantage Statutory or Regulatory Barriers that Could Limit Corrective Actions

HHS has not identified statutory or regulatory barriers that could limit corrective actions.

11.3 Medicare Prescription Drug Benefit (Part D)

Medicare Prescription Drug Benefit Statistical Sampling Process

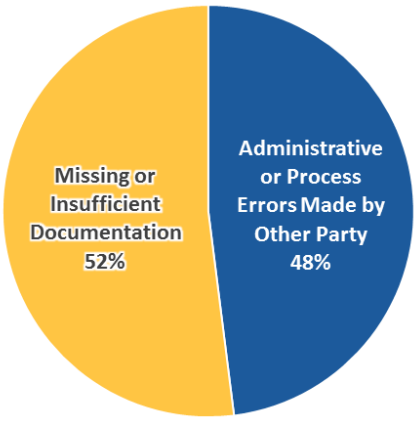
The Part D improper payment estimate measures the payment error related to prescription drug event (PDE) data, where the majority of errors for the program exist. HHS measures the inconsistencies between the information reported on PDEs and the supporting documentation submitted by Part D sponsors: prescription record hardcopies (or medication order, as appropriate) and detailed claims information. Based on these reviews, each PDE in the audit sample is assigned a gross drug cost error, which is simulated onto a representative sample of beneficiaries to determine the Part D improper payment estimate.

The Medicare Part D gross improper payment estimate for FY 2018 is 1.66 percent or $1.32 billion. The FY 2018 net improper payment estimate is 0.06 percent or $44.63 million. The decrease from the prior year's estimate of 1.67 percent was driven primarily by submission of more accurate data by Part D sponsors for payment.

Medicare Prescription Drug Benefit Corrective Action Plan

The root causes of the FY 2018 Part D improper payments are missing or insufficient documentation (52 percent) and administrative or process errors made by another party (48 percent), as displayed in Figure 10 below.

Figure 10: Root Causes of FY 2018 Medicare Part D Improper Payments



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 payment errors in Part D:

Corrective Actions for Insufficient Documentation and Administrative or Process Errors Made by Other Party

Corrective Action	Description
Outreach	HHS continued formal outreach to plan sponsors for invalid and incomplete documentation. The Department distributed Plan Sponsor Summary Reports to all plans participating in the national payment error estimate. The report provided feedback on submission and validation results against an aggregate of all participating plan sponsors.
Overpayment Recoveries Related to Regulatory Provisions	As required by the *Social Security Act*, HHS requires that Part D sponsors report and return all identified overpayments. HHS believes that the overpayment statute and regulation contribute to increased attention paid by Part D sponsors to data accuracy. In FY 2018, Part D sponsors reported and returned approximately $2.1 million in self-reported overpayments.
Training	HHS continued its national training sessions for Part D sponsors on payment and data submission by offering training sessions with detailed instructions as part of the improper payment estimation process. Historically, HHS also conducted fraud, waste, and abuse in-person and webinar training sessions for Part D sponsors on program integrity initiatives, investigations, data analysis, and potential fraud schemes. In FY 2017, HHS conducted a small in-person mission (May 2017). In late FY 2017, HHS procured a new contractor to support this initiative, and in FY 2018, HHS conducted three in-person missions (one in October 2017 and two in April 2018) and an in-person fraud, waste, and abuse training conference in July 2018.

Medicare Prescription Drug Benefit Information Systems and Other Infrastructure

HHS uses the following internal Medicare systems to make and validate the Medicare Part D payments:

- Medicare Beneficiary Database;
- Risk Adjustment Processing System;

- Health Plan Management System;
- MARx payment system; and
- Integrated Data Repository.

Medicare Prescription Drug Benefit Statutory or Regulatory Barriers that Could Limit Corrective Actions

HHS has not identified statutory or regulatory barriers that could limit corrective actions.

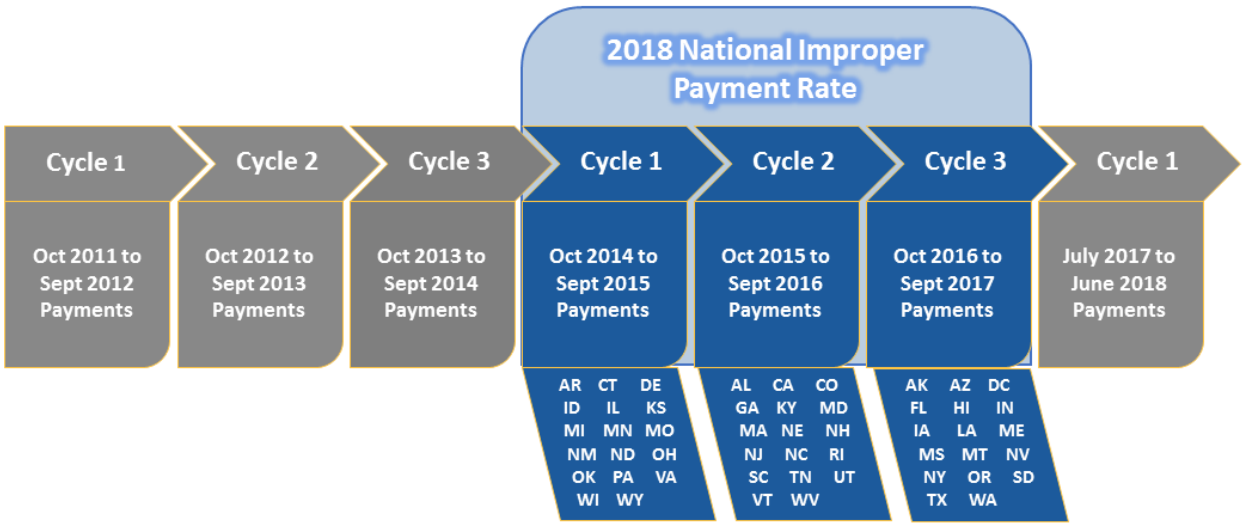
11.4 MEDICAID

Medicaid Statistical Sampling Process

Through the Payment Error Rate Measurement (PERM) program, HHS estimates Medicaid improper payments on a federal FY basis and measures three components: FFS, managed care, and eligibility. HHS, through its use of federal contractors, measures the FFS and managed care components. The eligibility component measurement has been paused, as described in the following Eligibility Component section.

HHS's PERM program uses a 17-state three-year rotation for measuring Medicaid improper payments. The national Medicaid improper payment rate includes findings from the most recent three cycle measurements so that all 50 states and the District of Columbia are reflected in one rate. Each time a group of 17 states is measured under the PERM program HHS removes the previous findings for that group of states from the calculation and includes the newest findings. The national FY 2018 Medicaid improper payment rate is based on measurements conducted in FYs 2016, 2017, and 2018 (see Figure 11 below).

Figure 11: FY 2018 Medicaid Cycle Measurements



To learn how HHS grouped states into three cycles, refer to pages 177 – 179 of HHS's FY 2012 AFR.

FFS and Managed Care Components

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 and managed care payments are only subjected to a data processing review. Based on each state's historical FFS and managed care improper payment data, the FFS sample size was between 303 and 1,063 claims per state and the managed care sample size was between 230 and 287 payments per state. When a state's FFS or managed care component accounted for less than two percent of the state's total Medicaid expenditures, HHS combined the state's FFS and managed care claims into one component for sampling and measurement purposes.

Eligibility Component

In light of changes to the way states adjudicate beneficiary eligibility for Medicaid under current law, in August 2013 and October 2015, HHS released guidance announcing temporary changes to PERM eligibility reviews. For FYs 2015 through 2018, HHS did not conduct the eligibility measurement component of PERM. During the pause of the PERM program's eligibility measurement component, HHS required states to implement pilots to ensure effective oversight and monitoring of Medicaid and CHIP eligibility determinations. In place of the PERM eligibility reviews, HHS required all states to conduct Eligibility Review Pilots that provided more targeted, detailed information on the accuracy of eligibility determinations 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. For the purpose of computing the overall national improper payment rate, the Medicaid eligibility component improper payment rate was held constant at the FY 2014 national rate of 3.11 percent.

HHS also used the Eligibility Review Pilots to test updated PERM eligibility processes and prepare states for the resumption of the PERM eligibility component measurement. Based on the pilots, HHS updated the eligibility component measurement methodology and published a final rule (82 FR 31158, July 5, 2017) to update the methodology for the PERM eligibility component. HHS resumed the eligibility component measurement under this final rule and will report an updated national eligibility improper payment estimate in FY 2019.

Calculations and Findings

The national Medicaid program improper payment estimate combines each state's Medicaid FFS, managed care, and eligibility improper payment estimate. In addition, HHS combines individual state component improper payment estimates to calculate the national component improper payment estimates. National component improper payment rates and the Medicaid program improper payment rate are weighted by state size, such that a state with a $10 billion program is appropriately weighted more in the national rate than a state with a $1 billion program. A correction factor in the methodology ensures that Medicaid eligibility improper payments are not "double counted." Additionally, HHS incorporates state-level improper payment rate recalculations for the states measured in prior FYs into the national Medicaid improper payment rate. For example, subsequent to FY 2017 reporting, HHS recalculated five state-level FFS improper payment rates to reflect appeal results and documentation HHS received after the reporting deadline, but within the allowable timeframes for claims paid between October 1, 2015, and September 30, 2016. HHS incorporated the recalculations into FY 2018 improper payment rate reporting.

The national Medicaid gross improper payment estimate for FY 2018 is 9.79 percent or $36.25 billion. The FY 2018 net improper payment estimate is 9.63 percent or $35.67 billion.

The FY 2018 national Medicaid improper payment rate for each component is:

- *Medicaid FFS*: 14.31 percent
- *Medicaid managed care*: 0.22 percent

Since FY 2014, the Medicaid improper payment estimate has been driven by errors due to state non-compliance with provider screening, enrollment, and National Provider Identifier (NPI) requirements. The majority of improper payments have been cited on claims where a newly enrolled provider had not been appropriately screened by the state, a provider did not have the required NPI on the claim, or a provider was not enrolled. Although these errors remain a driver of the Medicaid rate, state compliance has improved, as the Medicaid FFS improper payment rate for these errors decreased from 9.27 in FY 2017 to 7.21 in FY 2018.

While the screening errors described above are for newly enrolled providers, states are also required to screen providers upon revalidation of enrollment. States are required to revalidate the enrollment of all providers at least

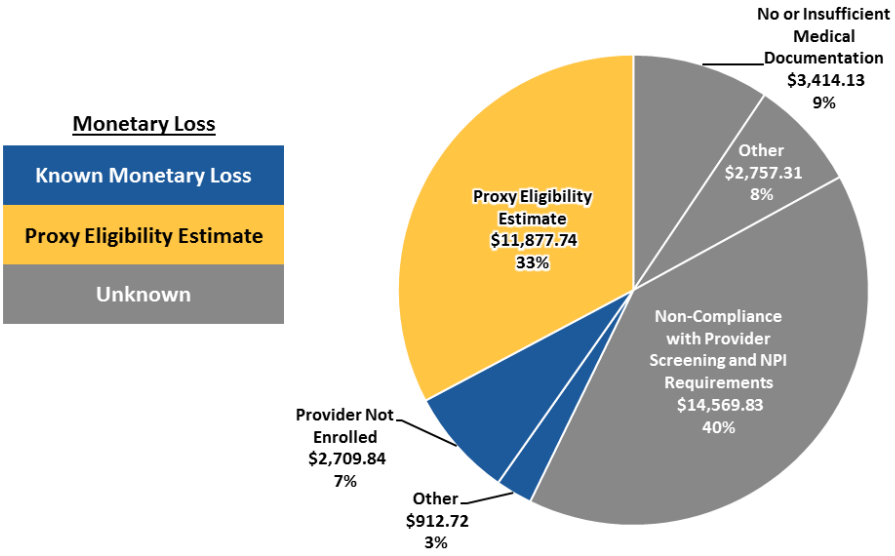
every 5 years and must have completed the revalidation process of all existing providers by September 25, 2016. In FY 2018, HHS measured the first cycle of states for compliance with requirements for provider screening at revalidation. Improper payments cited on claims where a provider had not been appropriately screened at revalidation is a new major source of error in the Medicaid improper payment rate. HHS will complete the measurement of all states for compliance with provider revalidation requirements in FY 2020.

Monetary Loss Findings

Improper payments do not necessarily represent expenses that should not have occurred. Instances where there is insufficient or no documentation to support the payment as proper are also cited as improper payments. A majority of Medicaid improper payments were due to instances where information required for payment was missing from the claim and/or states did not follow the appropriate process for enrolling providers. However, these improper payments do not necessarily represent payments to illegitimate providers and, if the missing information had been on the claim and/or had the state complied with the enrollment requirements, then the claims may have been payable. A smaller proportion of improper payments are considered a known monetary loss to the program, which are claims where HHS determines the Medicaid payment should not have been made or should have been made in a different amount.

Figure 12 provides information on Medicaid improper payments that are a known monetary loss to the program (i.e., provider not enrolled, incorrect coding, and other errors (like claims processing errors, duplicate claims, or pricing mistakes)). In the figure, "Unknown" represents payments where there was insufficient or no documentation to support the payment as proper or a known monetary loss (e.g., claims where information was missing from the claim or states did not follow appropriate processes). These are payments where more information is needed to determine if the claims were payable or should be considered monetary losses to the program.

Figure 12: FY 2018 Medicaid Percentage and Improper Payments (in Millions) by Monetary Loss and Type of PERM Error[1]



[1] As discussed in Section 11.4, HHS paused the PERM eligibility component between FY 2014 and FY 2018. The Proxy Eligibility Estimate is based on results from FY 2014. The Proxy Eligibility Estimate includes both overpayments and underpayments, whereas Known Monetary Loss and Unknown only include overpayments. The value of non-eligibility underpayments ($8.12 million) was too small to report in the figure. In addition, due to rounding, amounts in this chart may not add up precisely to other tables in this document.

Eligibility Review Pilot Findings

The Eligibility Review Pilots identified vulnerabilities in state processes and systems. States took actions based on these vulnerabilities to prevent future improper payments and improve verification processes. In the final round of pilots, a federal review contractor conducted reviews in 17 states, and the remaining 34 states conducted their own eligibility reviews. The pilots identified both caseworker and system vulnerabilities. The most prominent finding was cases where the state did not properly establish income. The reviews also identified delays in processing redeterminations and deficiencies in sending notices. Another common vulnerability was insufficient documentation, where information needed to support the eligibility determination was missing from the record. States are implementing corrective actions to address these vulnerabilities including targeted caseworker training, system fixes, and improved processes for maintaining documentation. More information can be found at Medicaid and CHIP Eligibility Review Pilots.

Medicaid Corrective Action Plan

HHS works closely with all states to develop state-specific corrective action plans to reduce improper payments. All states are responsible for implementing, monitoring, and evaluating the corrective action plan effectiveness, with assistance and oversight from HHS. When developing corrective action plans, states focus on the major causes of improper payments to help identify patterns.

HHS also establishes corrective actions to reduce improper payments. For example, HHS actively engages with states by:

- Conducting outreach during off-cycle PERM measurement years to address issues identified in corrective action plans;
- 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 is provided in the following sections.

Corrective Actions to Address OMB 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 errors mainly consist of errors resulting from non-compliance with provider enrollment, screening, and NPI requirements described above.

Because these errors primarily drive the Medicaid improper payment estimate, state corrective action plans focus on system or process changes to reduce these errors. Specific actions include implementing new claims processing edits, converting to a more sophisticated claims processing system, and continuing to implement provider enrollment process improvements to make it easier for ordering and 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 Medicaid provider is enrolled in both Medicare and Medicaid.

In addition to developing, executing, and evaluating state-specific corrective action plans, HHS has implemented corrective actions to specifically address compliance with Medicaid provider screening, enrollment, and revalidation efforts, as follows:

Key Corrective Actions to Comply with Medicaid Provider Screening, Enrollment, and Revalidation Efforts

Corrective Action	Description
State Medicaid Provider	HHS shares Medicare data to assist states with meeting Medicaid screening and enrollment requirements. Specifically, HHS shares the Medicare provider enrollment record via the

Key Corrective Actions to Comply with Medicaid Provider Screening, Enrollment, and Revalidation Efforts

Corrective Action	Description
Screening and Enrollment	Provider Enrollment, Chain, and Ownership System (PECOS) administrative interface and via data extracts from the PECOS system and OIG exclusion data. Since May 2016, HHS offered a data compare service that allows a state to rely on Medicare's screening in lieu of conducting state screening, particularly during revalidation. This allows states to remove dual-enrolled providers from the revalidation workload. Using the data compare service, a state provides a Medicaid provider enrollment data extract to HHS and then HHS returns information indicating which Medicaid providers the state can rely on Medicare's screening (thus reducing the state's work load). The following states have participated in the data compare service: Alabama, Arizona, California, Connecticut, the District of Columbia, Idaho, Iowa, Kansas, Louisiana, Maine, Michigan, Minnesota, New Mexico, New York, North Dakota, Ohio, Oregon, Pennsylvania, Tennessee, Texas,. Vermont, and Virginia. HHS is working to expand the data compare service to additional states. In addition to the data compare service, HHS will pilot a process to screen Medicaid-only providers on behalf of states. Two states will be selected to participate in this pilot in FY 2019. HHS will screen the state's Medicaid-only providers and produce a report of the providers found with licensure issues, criminal activity, and Do Not Pay activity.
Enhanced Assistance on State Medicaid Provider Screening and Enrollment	HHS provides ongoing guidance, education, and outreach to states on federal requirements for Medicaid enrollment and screening. In addition, HHS updated the Medicaid Provider Enrollment Compendium in July 2018 to provide additional sub-regulatory guidance to assist states in applying the regulatory requirements. • Technical Assistance for Provider Screening and Enrollment: In FY 2016, HHS procured a state assessment contractor to assist with ongoing state technical assistance and process improvements related to provider screening and enrollment. In FY 2018, the state assessment contractor visited the following states to assess compliance with provider screening and enrollment requirements, conduct a gap analysis, and develop strategic blueprints to help states improve processes: Alabama, California, Connecticut, Georgia, Indiana, Iowa, Minnesota, Nevada, New Hampshire, Ohio, Oregon, Tennessee, and Texas. For these states, the contractor assessed compliance with provider screening and enrollment requirements, conducted a gap analysis, and developed strategic blueprints to help states improve processes. • Site Visits: HHS continued state site visits during FY 2018 to assess provider screening and enrollment compliance, provide technical assistance, and offer states the opportunity to leverage Medicare screening and enrollment activities. In addition to the State Assessment contractor visits, HHS internally provided screening and enrollment assistance through visits to Delaware, the District of Columbia, Georgia, Kentucky, Louisiana, Maryland, Minnesota, Missouri, New Jersey, North Carolina, Pennsylvania, Rhode Island, South Carolina, Virginia, Washington, and Wisconsin in FY 2017 and FY 2018.
Death Master File	To help alleviate state concerns with the cost of completing the SSA DMF check as part of provider screening, HHS worked with the SSA to provide the DMF to states. In May 2017, HHS made DMF data available to pilot states via the same file server where states currently also access PECOS provider file extracts, Medicare revocations, Medicaid terminations, and OIG sanctions (i.e., suspensions, debarments, and exclusions). Florida, Minnesota, Nevada, Oklahoma, Ohio, Oregon, Tennessee, Texas, and Washington were able to secure access to the DMF through the file server. HHS expanded access to DMF data to additional states via the Data Exchange (DEX), which is a system for sharing data among HHS and the separate Medicaid programs of every state. As of September 2018, 46 states have access to DMF data through DEX. The remaining states have not yet requested access.

Key Corrective Actions to Comply with Medicaid Provider Screening, Enrollment, and Revalidation Efforts

Corrective Action	Description
Medicaid Integrity Institute (MII)	HHS offers training, technical assistance, and support to state Medicaid program integrity officials through the MII. The tentative FY 2019 course schedule includes a seminar in January 2019 that will focus exclusively on complying with the provider screening and enrollment requirements. The materials from previous MII provider enrollment courses remain available to states on the Regional Information Sharing System. More information can be found at Medicaid Integrity Institute.

Root Causes: Insufficient Documentation to Determine and Administrative or Process Errors Made by Other Party

Insufficient documentation to determine errors mainly consists of errors resulting from insufficient or no medical documentation submitted by providers. Administrative or process errors made by other party mainly consist of other provider errors identified through medical review. State corrective action plans also include conducting 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 developing, executing, and evaluating the state-specific corrective action plans, HHS implemented other efforts to lower the improper payment rate in these two root causes:

Corrective Actions for Insufficient Documentation and Administrative or Process Errors Made by Other Party

Corrective Action	Description
State Medicaid RAC Programs	From Medicaid RAC program inception in 2012 to the end of FY 2018, 47 states and the District of Columbia had cumulatively implemented Medicaid RAC programs to identify and recover overpayments and identify underpayments in their Medicaid programs. However, each state has flexibility to tailor the RAC program, where appropriate, with guidance from HHS. For example, several states with Medicaid RAC programs ended the RAC programs when HHS approved an exception due to the high proportion of beneficiaries enrolled in Medicaid managed care compared to FFS. As a result, 21 states and the District of Columbia currently have RAC programs. HHS believes RACs help reduce improper payments by educating providers on Medicaid policies. HHS also believes there is a sentinel effect in the provider community with more accurate billing because of the possibility of a future RAC audit.
Expanded Reviews/ Oversight	HHS aligned state program integrity reviews to reach "off-cycle" states in the PERM review schedule. Such alignment is intended to optimize HHS's review timing to most effectively engage with states working to correct PERM errors. During FY 2018, HHS completed its assessment of PERM corrective action plans submitted for the FY 2015 measurement and provided feedback to states on actions needed to complete corrective actions. In FY 2018, HHS also collected status information on PERM corrective action plans submitted for the FY 2016 measurement for Medicaid FFS and managed care. By December 2018, HHS will be working to complete status assessments of FY 2016 PERM corrective action plans and provide corresponding corrective action feedback to states. Additionally in FY 2019, HHS will collect, assess, and provide feedback to states on the status of PERM corrective action plan completion related to Medicaid FFS and managed care for the FY 2017 measurement. In addition, in FY 2018, HHS conducted reviews in selected states on the following topics: • Program integrity in managed care;

Corrective Actions for Insufficient Documentation and Administrative or Process Errors Made by Other Party

Corrective Action	Description
	• Safeguards in personal care services; • Terminated providers that should no longer be billing Medicaid; • States' fraud, waste, and abuse initiatives in response to the opioid crisis; and • States' completion of corrective actions from previous program integrity reviews.
Education	Historically, HHS has published 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 addition, a state technical assistance work group also helps educate states on working with providers to understand the causes of documentation errors, and provide recommendations for methods to can reduce errors.

Medicaid Information Systems and Other Infrastructure

Because Medicaid payments occur at the state level, information systems and other infrastructure needed to reduce Medicaid improper payments needs to be implemented at the state level. HHS encouraged and supported state efforts to modernize and improve state Medicaid Enterprise Systems, which will produce greater efficiencies in areas reflected in the PERM measurement and strengthen program integrity. In addition, HHS approved enhanced federal funding for nine states to implement predictive analytics technologies that are integrated with state Medicaid Enterprise Systems. 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 plan's primary goal 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 reduce state burden and provide 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 MSIS submittals in real-time. Through the use of T-MSIS, HHS will acquire higher quality data and reduce data requests to the states. As of August 20, 2018, 48 states, the District of Columbia, and Puerto Rico are submitting T-MSIS data. More information on states' overall data submission progress can be found at T-MSIS.

Medicaid Statutory or Regulatory Barriers that Could Limit Corrective Actions

HHS has not identified statutory or regulatory barriers that could limit corrective actions.

11.5 CHIP

CHIP Statistical Sampling Process

Through the PERM program, HHS estimates CHIP improper payments on a federal FY basis and measures three components: FFS, managed care, and eligibility. HHS, through its use of federal contractors, measures the FFS and managed care components. The eligibility component measurement has been paused, as described in the following Eligibility Component section.

CHIP utilizes the same state sampling process as Medicaid through the PERM program. 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. For information on how HHS grouped states into three cycles for CHIP, refer to page 183 of HHS's FY 2012 AFR.

FFS and Managed Care Components

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 and each managed care payment is only subject to a data processing review. Based on each state's historical FFS and managed care improper payment data, the FFS sample size was between 303 and 996 claims per state and the managed care sample size was between 101 and 241 payments per state. When a state's FFS or managed care component for a state accounted for less than 2 percent of the state's total CHIP expenditures, HHS combined the state's FFS and managed care claims into one component for sampling and measurement purposes.

Eligibility Component

In light of changes to the way states adjudicate beneficiary eligibility for CHIP under current law, HHS updated the eligibility component measurement methodology and published a final rule (82 FR 31158, July 5, 2017). For the purpose of computing the overall national improper payment rate, the CHIP eligibility component improper payment rate was held constant at the FY 2014 national rate of 4.22 percent. HHS resumed the eligibility component measurement under the new rule and will report an updated national eligibility improper payment estimate in FY 2019. See Section 11.4 for more information.

Calculations and Findings

The national CHIP improper payment estimate combines each state's FFS, managed care, and eligibility improper payment estimate. In addition, HHS combines individual state component improper payment estimates to calculate the national component improper payment estimates. National component improper payment rates and the CHIP improper payment rate are weighted by state size, such that a state with a $1 billion program is appropriately weighted more in the national rate than a state with a $200 million program. A correction factor in the methodology ensures that CHIP eligibility improper payments are not "double counted." Additionally, HHS incorporates state-level improper payment rate recalculations for the states measured in prior FYs into the national CHIP improper payment rate. For example, subsequent to FY 2017 reporting, HHS recalculated 10 state-level FFS improper payment rates to reflect appeal results and documentation that HHS received after the reporting deadline, but within the allowable timeframes for claims paid between October 1, 2015 and September 30, 2016. HHS incorporated these recalculations into FY 2018 improper payment rate reporting.

The national CHIP gross improper payment estimate for FY 2018 is 8.57 percent or $1.39 billion. The FY 2018 net improper payment estimate is 8.42 percent or $1.37 billion.

The FY 2018 national CHIP improper payment rate for each component is:

- *CHIP FFS:* 12.55 percent
- *CHIP managed care:* 1.24 percent

The majority of CHIP improper payments have been cited on claims where a newly enrolled provider or a provider due for revalidation had not been appropriately screened by the state or a provider did not have the required NPI on the claim (see Section 11.4 for further description of HHS's review of these errors). State compliance with screening requirements have not improved for CHIP. A higher percentage of CHIP providers are not enrolled in Medicare and, therefore, there are more CHIP providers where states cannot rely on Medicare's screening in lieu of conducting state screening.

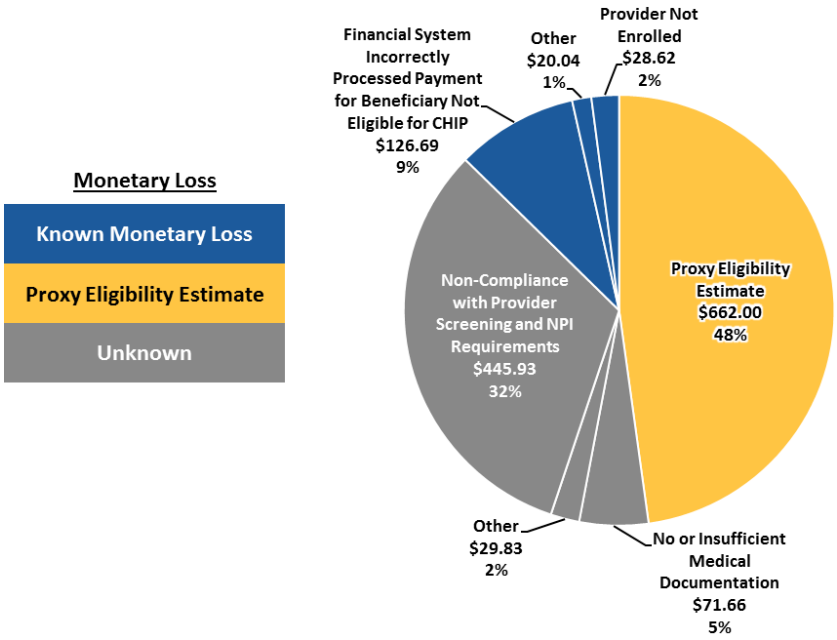
Monetary Loss Findings

Improper payments do not necessarily represent expenses that should not have occurred. Instances where there is insufficient or no documentation to support the payment as proper are cited as improper payments. A majority of CHIP improper payments were due to instances where information required for payment was missing from the claim

and/or states did not follow the appropriate process for enrolling providers. However, these improper payments do not necessarily represent payments to illegitimate providers and, if the missing information had been on the claim and/or had the state complied with the enrollment requirements, then the claims may have been payable in whole or in part. A smaller proportion of improper payments are claims where HHS determines that the CHIP payment should not have been made or should have been made in a different amount and are considered a known monetary loss to the program.

Figure 13 provides information on CHIP improper payments that are a known monetary loss to the program (i.e., provider not enrolled, incorrect coding, and other errors (like claims processing errors, duplicate claims, or pricing mistakes)). In the figure, "Unknown" represents payments where there was insufficient or no documentation to support the payment as proper or a known monetary loss (e.g., claims where information was missing from the claim or states did not follow appropriate processes). These are payments where more information is needed to determine if the claims were payable or should be considered monetary losses to the program.

Figure 13: FY 2018 CHIP Percentage and Improper Payments (in Millions) by Monetary Loss and Type of PERM Error[1]



[1] As discussed in Section 11.4, HHS paused the PERM eligibility component between FY 2014 and FY 2018. The Proxy Eligibility Estimate is based on results from FY 2014. The Proxy Eligibility Estimate includes both overpayments and underpayments, whereas Known Monetary Loss and Unknown only include overpayments. The value of non-eligibility underpayments ($4.86 million) was too small to report in Figure 13. In addition, due to rounding, amounts in this chart may not add up precisely to other tables in this document.

Eligibility Review Pilot Findings

Refer to Section 11.4 for information on the Medicaid and CHIP eligibility review pilots.

CHIP Corrective Action Plan

HHS works closely with all states to develop state-specific corrective action plans to reduce improper payments. All states are responsible for implementing, monitoring, and evaluating corrective action plan effectiveness, with assistance and oversight from HHS. When developing corrective action plans, states focus efforts on the major causes of improper payments to help identify patterns. HHS also establishes corrective actions to reduce improper payments. For example, HHS is actively engaging with states to address root causes by:

- Conducting outreach during off-cycle PERM measurement years to address issues identified in corrective action plans;
- 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 is provided in the following sections.

Corrective Actions to Address Root Causes:

Root Causes: Administrative or Process Errors Made by State or Local Agency

Administrative or process errors made by states or local agencies mainly consists of errors resulting from non-compliance with provider enrollment, screening, and NPI requirements described above. This root cause category also consists of instances where the state's financial system incorrectly processed payments for beneficiaries that were not eligible for CHIP, mostly payments made for beneficiaries that aged out of CHIP.

Because these errors primarily drive the CHIP improper payment estimate, state corrective action plans focus on system or process changes to reduce these errors. Specific actions include implementing new claims processing edits, converting to a more sophisticated claims processing system, and continuing to implement provider enrollment process improvements to make it easier for ordering and referring providers to enroll in the program.

In addition to developing, executing, and evaluating the state-specific corrective action plans, HHS implemented generalized 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 11.4.

Root Causes: Insufficient Documentation to Determine and Administrative or Process Errors Made by Other Party

Insufficient documentation to determine errors mainly consists of errors resulting from insufficient or no medical documentation submitted by providers. Administrative or process errors made by other parties mainly consist of other provider errors identified through medical review. State corrective action plans include conducting provider communication and education to reduce errors related to these categories. Communication and education methods include: holding provider training sessions and meeting 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 developing, executing, and evaluating the state-specific corrective action plans, HHS implemented other efforts to lower the improper payment rate in these root causes. More detailed information on these activities is provided in Section 11.4.

Root Cause: Medical Necessity

Although this has been identified as a minor issue in a few states, HHS works closely with those states to develop state-specific corrective actions to address such errors when they arise. In addition to state-specific corrective action plans, many of the corrective actions mentioned in Section 11.4 also address medical necessity errors.

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 need to be implemented at the state level. Refer to Section 11.4 for information on HHS and state-led efforts to modernize information and data systems at the national and state levels.

CHIP Statutory or Regulatory Barriers that Could Limit Corrective Actions

HHS has not identified statutory or regulatory barriers that could limit corrective actions.

11.6 TANF

TANF Statistical Sampling Process

Statutory limitations preclude HHS from requiring states to participate in a TANF improper payment measurement. As a result, the TANF program is not reporting an improper payment estimate for FY 2018.

TANF Corrective Action Plan

Since TANF is a state-administered program, corrective actions to reduce improper payments would be implemented at the state level. Since HHS cannot require states to participate in a TANF improper payment measurement, the Department is also unable to compel states to collect the required information to implement and report on corrective actions. Despite these limitations, HHS uses a multi-faceted approach to support states in improving TANF program integrity and preventing improper payments:

Corrective Actions for TANF Program Integrity

Corrective Action	Description
Risk Assessment	In FY 2016, HHS performed a detailed risk assessment of the TANF program to determine susceptibility to significant improper payments. HHS identified potential payment risks at the federal level and worked to mitigate these risks in FYs 2017 and 2018.
Promoting and Supporting Innovation in TANF Data	In FY 2017, HHS awarded a five-year contract for Promoting and Supporting Innovation in TANF Data. A component of the contract included engaging TANF stakeholders in FY 2018 to better understand how states assess improper payments and ensure program integrity in TANF. In FY 2019, an assessment of all TANF states, territories, and the District of Columbia will occur, including a detailed look at payment integrity efforts in a select group of states. This assessment will help HHS understand existing state approaches and alternative methods for measuring TANF improper payments, including the feasibility and cost-benefit analysis of different approaches.
Final Regulation on Reporting of Electronic Benefit Transfer 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). Thus far, HHS has not assessed any penalties for non-compliance with this regulation, and the Department continues to monitor compliance.

TANF Information Systems and Other Infrastructure

Information systems and other infrastructure needed to reduce TANF improper payments would have 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.

TANF Statutory or Regulatory Barriers that Could Limit Corrective Actions

Statutory limitations preclude HHS from requiring states to participate in a TANF improper payment measurement.

11.7 FOSTER CARE

Foster Care Statistical Sampling Process

There were no changes to the statistical sampling process for Title IV-E Foster Care in FY 2018. However, the program modified the formula used to calculate the state-level standard error as recommended by the OIG. This program uses the review cycle already in place (in compliance with 45 CFR 1356.71, *Foster Care Eligibility Reviews*) and, with OMB approval, leverages the existing review cycle to provide a rolling, three-year weighted average improper payment estimate. Since each state is reviewed every 3 years, each year's improper payments estimate incorporates new review data for approximately one-third of the states for the period under review. For a more detailed description of the Foster Care improper payment methodology, see pages 189 – 190 of HHS's FY 2012 AFR.

As stated in the FY 2015 AFR, an increasing number of time-limited child welfare waiver demonstration projects (which all must terminate no later than September 30, 2019 under current law) have temporarily reduced the number of jurisdictions subject to review and inclusion in the program improper payment estimate during the demonstration projects. More information on these demonstration projects and the impact on the Foster Care improper payment rate calculation can be found on pages 202-203 of the FY 2015 AFR.

The program's improper payment 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. This approach, approved by OMB, maintains continuity while also permitting consistent treatment of states with state-wide and non-state-wide waivers. Following this approach, the FY 2018 estimate is based on review data for 37 states or territories operating traditional Title IV-E programs. The FY 2018 estimate excludes data for 15 states operating statewide waiver demonstrations: two states that were due for a review this year (Maryland and Oregon) and 13 states that were due for a review in prior years (Arkansas, Colorado, the District of Columbia, Florida, Hawaii, Indiana, Kentucky, Nebraska, Oklahoma, Utah, Washington, West Virginia, and Wisconsin).

The Foster Care gross improper payment estimate for FY 2018 is 7.56 percent or $29.79 million. The FY 2018 net improper payment estimate is 7.32 percent or $28.85 million. There was no single factor that drove the program's slight increase from the prior year's improper payment estimate of 7.13 percent. Seven of the 10 states increased error rates from the previous review, while three states had error rates that decreased. As usual, the national error rate was affected by the interaction of the state error rate with its program size. One state with a large program (3rd nationally in terms of dollars) experienced a modest increase in its error rate, but was the most influential of the 10 newly-reviewed states in raising the national error rate due to the size of its program. Two other states' programs also experienced significant increases in error rates, which offset improvements in performance in other states. Despite declines in performance in a number of states, six of the 10 states reviewed in the most recent cycle had error rates below 4 percent.

Foster Care Corrective Action Plan

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 corrective action plans to help states address the payment errors that contribute most to Title IV-E improper payments.

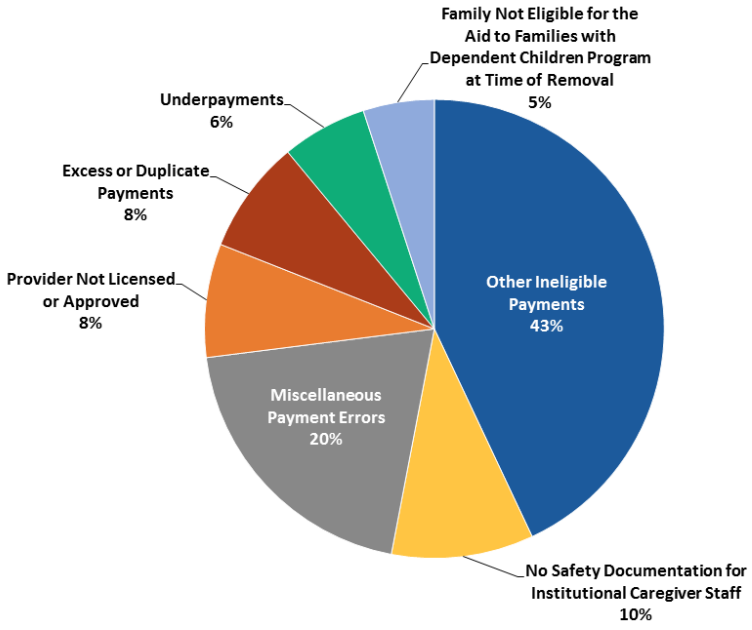
Corrective Actions to Address Root Cause:

Root Cause: Administrative or Process Error Made by State or Local Agency

Foster Care improper payments are caused by administrative or process errors made by state or local agencies. Corrective actions over the years helped reduce the frequency of some error types. For example, following years of work with State Court Improvement Programs and outreach to raise awareness, errors related to judicial determinations, 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. Figure 14 presents the most common administrative or process payment errors in FY 2018.

Figure 14: Root Causes for FY 2018 Title IV-E Foster Care Improper Payments across All States

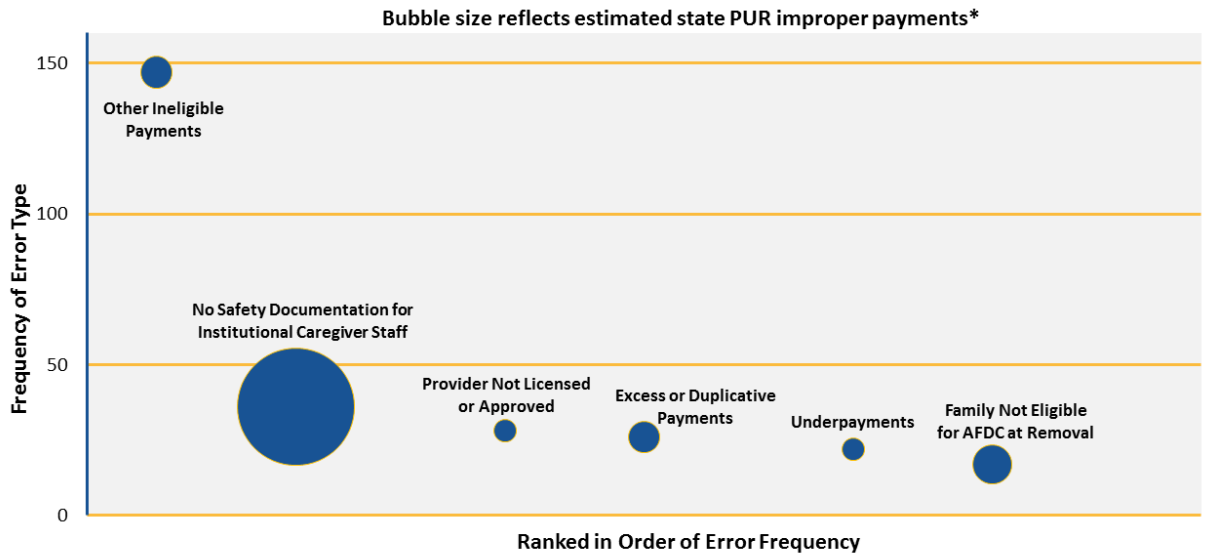


As shown in Figure 14, the six most frequent error types (with the exception of miscellaneous payment errors) account for 80 percent of Foster Care's payment errors.[27] Of the six most frequent error types, "Other ineligible payments" constitute 43 percent of errors. One newly reviewed state contributed about a third of "Other ineligible payments" errors due to a systemic pattern of incorrectly classifying foster parent training incentives as maintenance payments, rather than administrative costs.

While fewer in number of errors, the dollar amount of improper payments related to cases with "No safety documentation for institutional caregiver staff" is greater due to the high cost of institutional care relative to foster care placements. Cases with these payment errors account for over two-thirds of the gross improper payment estimate of 7.56 percent. While these types of errors were identified in states reviewed in the most recent cycle, the majority were identified in states reviewed in previous years. Figure 15 provides more information on the relative contribution of these top six payment error types.

[27] Because cases may have more than one type of overpayment error, the rate for any specific type of overpayment may involve some duplication and therefore slight overestimation.

Figure 15: Title IV-E Foster Care Program: Reasons for Improper Payments across All States – FY 2018 Frequency and Dollar Amount Across Error Types



* Improper payments for cases with more than one error type (N = 30) are counted under all applicable error types.

In FY 2018, HHS undertook the following key actions to reduce Foster Care Improper payments in the future:

Corrective Actions to Address Administrative or Process Errors Made by State or Local Agency

Corrective Action	Description
Emphasizing Quality Improvement	HHS engaged with title IV-E Foster Care agencies to enhance the understanding of program compliance requirements and to share successful strategies among states. 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. HHS emphasized viewing the quality assurance process as ongoing and developing sound program improvements that support systemic change and sustain the improvement effort.
Enhancing Targeted Outreach Strategies	Pre-Review Engagement of States: Since certain types of improper payments, such as those pertaining to foster care provider requirements, occur in a small number of states, HHS implemented pre-review outreach strategies (e.g., calls and site visits) tailored to particular state child welfare agencies to provide feedback about specific program performance areas needing improvement and to facilitate correction efforts. For example, HHS conducted state-specific calls with program leaders in each of the 10 states in the recent review cycle to discuss state policy and systemic factors supporting compliance with federal eligibility and payment requirements. HHS also visited five of the 10 states prior to the onsite review to examine and provide feedback on state documentation of safety checks for staff of child care institutions, given the comparatively high-dollar impact of errors pertaining to institutional care. The practice of pre-review site visits began in one region six years ago and was instituted more broadly beginning in early 2016. Additionally, for two states in this cycle, HHS reviewed safety documentation remotely prior to the onsite IV-E review. The state visits and remote pre-review of state documentation focused on the federal requirements to increase state agency staff and foster care providers' knowledge of the requirements, help the state identify missing or insufficient documentation, and help the state eliminate payment errors involving inadequate documentation of safety checks.
	Education to Address Specific Errors: Early in FY 2018, HHS conducted webinars for all states on federal safety check requirements of the staff of child care institutions. The webinars

Corrective Actions to Address Administrative or Process Errors Made by State or Local Agency

Corrective Action	Description
	discussed challenges and solutions in meeting the requirements and encouraged effective communication of the requirements between IV-E agency staff and licensing agencies to further promote adequate documentation of safety check compliance.
	Outreach Regarding Changes in Federal Requirements: *The Family First Prevention Services Act*, enacted in February 2018, as part of Public Law 115-123, changed the federal statutory requirements for staff safety checks at child care institutions. The new requirements become effective October 1, 2018, subject to any state-specific delays authorized by statute. In response to this legislation, HHS issued written guidance to federal and state staff and conducted a series of webinars in FY 2018 to instruct all staff on the new federal safety check requirements and other provisions of the new federal law. Additional guidance and instructional tools are planned for early FY 2019 to further federal and state staff knowledge on the federal requirements for state implementation and maintenance of required policies and practices. These will be applied prior to federal monitoring of state compliance with the requirements.
	Communications and Monitoring: HHS also has continued its work with states to encourage effective communication of the requirements between state child welfare agencies and licensing agencies to further promote adequate documentation of safety check compliance. Assisting states with developing and applying techniques to effectively engage Foster Care providers in a partnership to reduce or eliminate improper payments is integral to success. HHS also will encourage states to regularly and systematically monitor Foster Care providers to document and promote compliance with the safety requirements, and require non-compliant providers to undergo corrective action.

In addition, HHS continued the following ongoing corrective actions:

Corrective Actions to Address Administrative or Process Errors Made by State or Local Agency

Corrective Action	Description
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 bring about proper and efficient program administration and implementation. Furthermore, HHS issues a comprehensive final report that presents review findings to the state agency including whether the state exceeded the error threshold in a review and must develop a performance improvement plan (PIP).
Developing PIPs	HHS requires states that exceed the error threshold in a primary review to develop and execute state-specific PIPs that identify specific action steps to correct error root causes. A PIP is an effective tool with a successful track record at HHS with improper payments reporting; since FY 2004, only one state has not been found in compliance of an eligibility review conducted following PIP completion. States must complete each action strategy within one year from the date HHS approved the plan. In FY 2018, three of the 10 states reviewed did not comply and will be required to complete a PIP.
Providing Training and Technical Assistance	HHS provides states training and technical assistance to develop and implement program improvements, even when states are not required to develop a PIP. This assistance helps states expand organizational capacity and promote more effective program operations. In FY 2018, HHS trained all 10 states reviewed on the federal eligibility and payment requirements and provided technical assistance prior to, during, and after the Foster Care Eligibility Reviews.

Corrective Actions to Address Administrative or Process Errors Made by State or Local Agency

Corrective Action	Description
Conducting Secondary Reviews and Disallowances	HHS conducts secondary reviews for non-compliant states and establishes appropriate disallowances (e.g., to recover improper payments) consistent with the review findings (HHS establishes disallowances for error findings in both primary and secondary reviews). Three states reviewed in the FY 2018 cycle will undergo a secondary review. On a secondary review, if a state is found not in substantial compliance, HHS takes an extrapolated disallowance. Additional disallowances, in conjunction with PIP development and implementation, incentivize states to improve compliance.

Foster Care Information Systems and Other Infrastructure

HHS uses the Adoption and Foster Care Analysis and Reporting System (AFCARS) to draw samples for the regulatory reviews. This reduces the burden on states to draw their own samples, promotes uniformity in sample selection, and employs AFCARS 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 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 in accordance with federal regulations at 45 CFR §1355.50 through §1355.59. Comprehensive Child Welfare Information System project requirements include, but are not limited to, the performance of automated program eligibility determinations and bi-directional data exchanges with systems generating the financial payments and claims to ensure the availability of needed supporting documentation.

Foster Care Statutory or Regulatory Barriers that Could Limit Corrective Actions

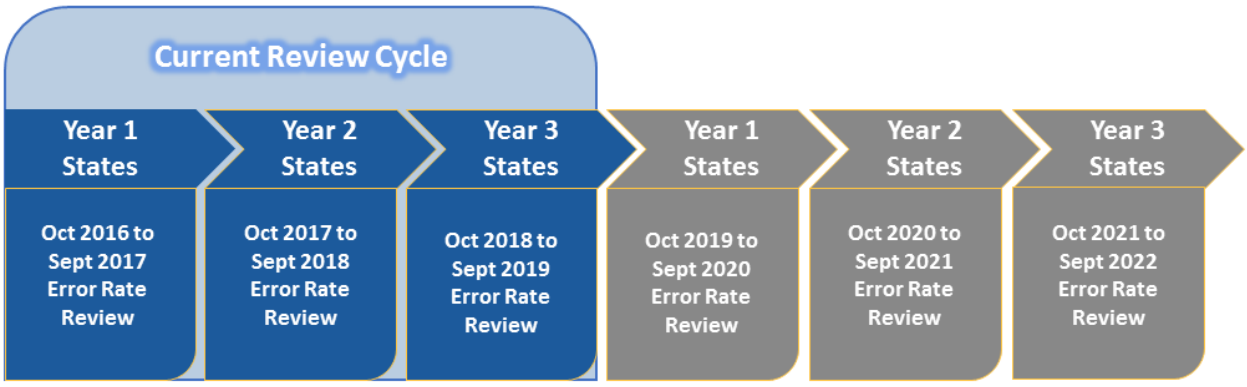
HHS has not identified statutory or regulatory barriers that could limit corrective actions.

11.8 CCDF

CCDF Statistical Sampling Process

The CCDF improper payments methodology uses a case-record review process to determine if child care subsidies were properly paid for services provided to eligible families. All states, the District of Columbia, and Puerto Rico are divided into three cohorts and conduct the error rate review once every 3 years (as shown in Figure 16).

Figure 16: CCDF Error Rate Review Cycle



In addition to federal rules, states have varying requirements for establishing and verifying eligibility. The methodology enables states to determine types of errors and their sources to reflect policies and procedures unique to each state. For CCDF improper payments methodology, see Improper Payments Error Rate Review Process.

The current methodology incorporates the following: (1) drawing a statistical sample from a universe of paid cases; (2) measuring improper payments; and (3) requiring states with improper payment estimates exceeding 10 percent to submit a corrective action plan. The improper payment methodology and reporting requirements focus on administrative errors associated with client eligibility. The CCDF gross improper payment estimate for FY 2018 is 4.00 percent or $301.99 million. The FY 2018 net improper payment estimate is 3.46 percent or $261.35 million.

There were several contributing factors to the slight decrease in the improper payment estimate from 4.13 percent in FY 2017 to 4.00 percent in FY 2018. While all states updated policies and procedures to ensure compliance with implementation of CCDBG, some states reporting in FY 2018 (referred to as Year Two states) had not put new policies in place, which potentially kept their improper payment estimates lower. HHS anticipates that as states establish new policies in accordance with new regulations to implement the CCDBG promulgated in September 2016, it will take time for states and child care providers to understand, implement, and follow the new requirements. While HHS is working with states to implement the new requirements, the CCDF program's errors may increase as states implement, and are evaluated against the new policies. The FY 2019 reporting states (Year Three states) will complete an initial baseline of reviews under the new law and regulations.

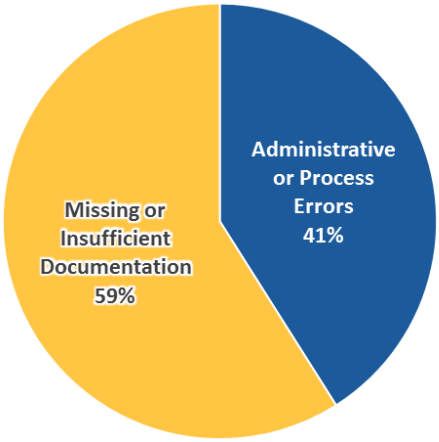
CCDF Corrective Action Plan

As reflected in Figure 17, CCDF program errors can be placed in two categories: (1) non-payment errors and (2) payment errors. These errors can further be defined as (1) administrative or process errors and (2) errors caused by missing or insufficient documentation. Root causes of errors relate to a misapplication of policy or procedure and can cause both a payment error and a non-payment error. The HHS Payment Integrity Report data only reflects payment errors. States have flexibility in the administration of Child Care programs and state-level policies and procedures reflect this variety.

Figure 17: CCDF Program Error Categories

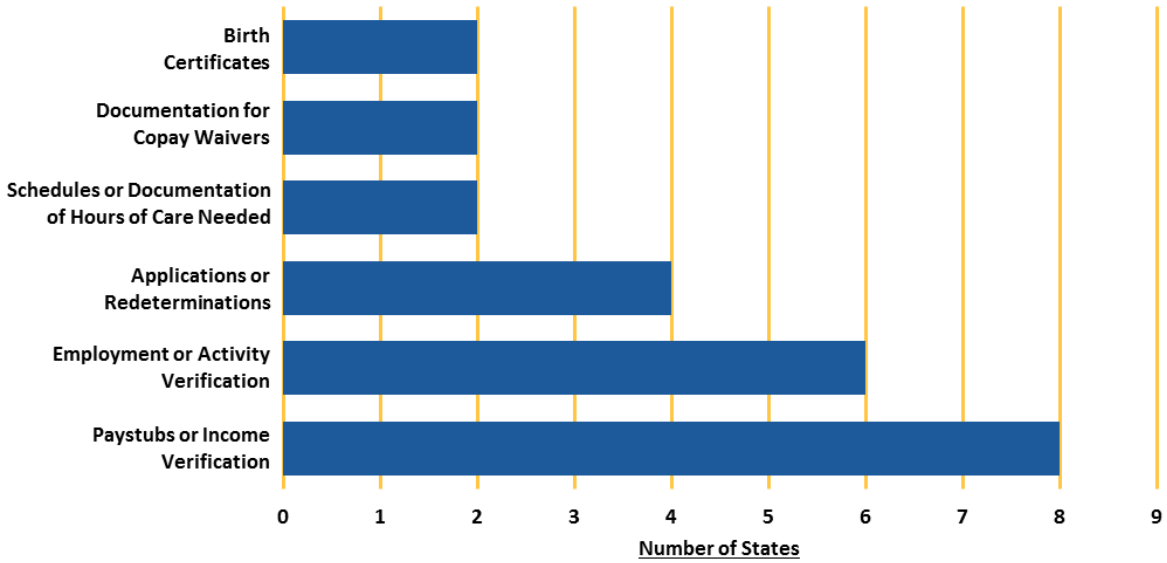
Historically, CCDF improper payments have been divided fairly evenly between administrative or process errors and missing or insufficient documentation. Figure 18 shows there were more errors from missing and insufficient documentation (about 59 percent) than administrative or process errors (41 percent) this year.

Figure 18: Root Causes of FY 2018 CCDF Improper Payments



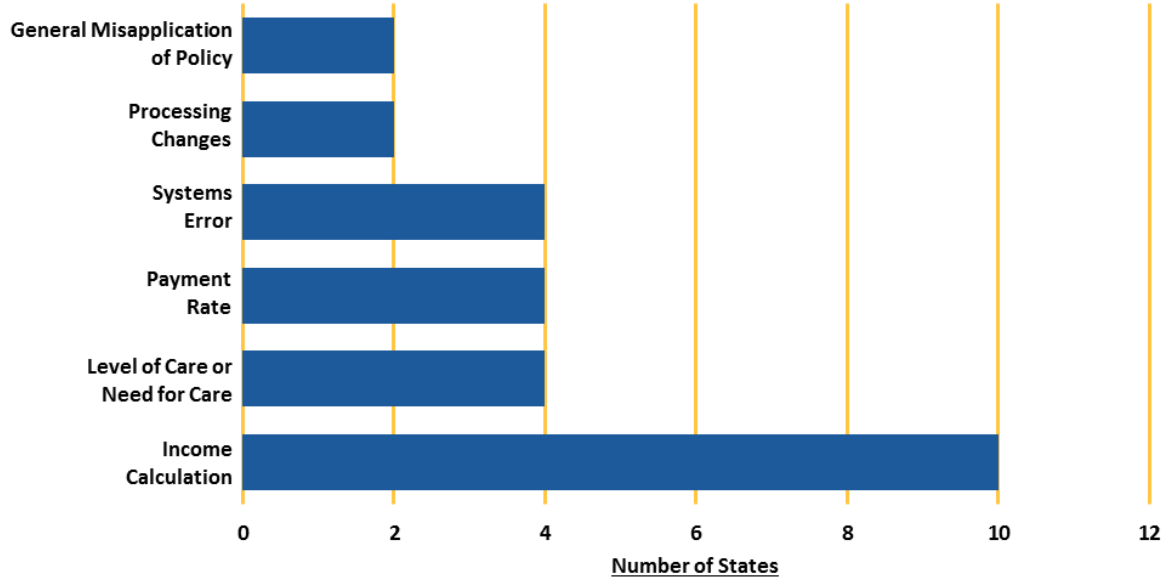
Missing or insufficient documentation errors account for an estimated 58.59 percent of errors identified in the CCDF improper payment review process. Errors were primarily due to missing or insufficient documentation in the case record. Figure 19 presents the most frequently cited errors.

Figure 19: Most Frequently Cited Errors Due to Missing or Insufficient Documentation for CCDF



Administrative or process errors represent approximately 41.41 percent of errors noted in the Year Two reviews. These errors consist of the failure to apply policy correctly, as shown in Figure 20.

Figure 20: Most Frequently Cited Errors Due to Administrative or Process Errors for CCDF



Corrective Actions to Address Root Causes:

Root Causes: Insufficient Documentation to Determine and Administrative or Process Errors Made by State or Local Agency

CCDF improper payments are driven by insufficient documentation to determine and administrative or process errors made by a state or local agency. HHS and states establish corrective actions targeting both error types. States are required to report on the root causes of errors once every 3 years. Each report also allows states to report on actions taken on errors from the prior review. States reporting in FY 2018 plan the following corrective actions:

State Corrective Actions for Missing or Insufficient Documentation and Administrative or Process Errors Made by State or Local Agency

Corrective Action	Description
Training	Fourteen states plan to conduct training with eligibility staff on CCDF policies and procedures.
Oversight	Reviews: Six states plan to conduct ongoing case reviews or audits.
	Meetings: Three states plan to conduct ongoing meetings at the Lead Agency level to continuously work toward the reduction of errors.
State Policies	Five states plan to make changes or updates to state eligibility policies and procedures.
Information Systems	Seven states plan to upgrade or enhance information technology (IT) systems.
Technical Assistance	Eligibility Agencies: Five states plan to provide technical assistance to eligibility agencies.
	Regulations: Three states plan to issue policy guidance, memos, or briefs based on error findings.

HHS has limited authority to require specific actions of state grantees given that states determine the specifics of their CCDF programs. As resources allow, HHS provides additional onsite and remote oversight of policy and procedure implementation to assist in lowering the improper payment rate. HHS will begin monitoring states for compliance with the CCDF regulations in FY 2019. In addition, HHS implemented other corrective actions to assist all states in the review process and error reduction, including:

HHS Corrective Actions for Insufficient Documentation and Administrative or Process Errors Made by State or Local Agency

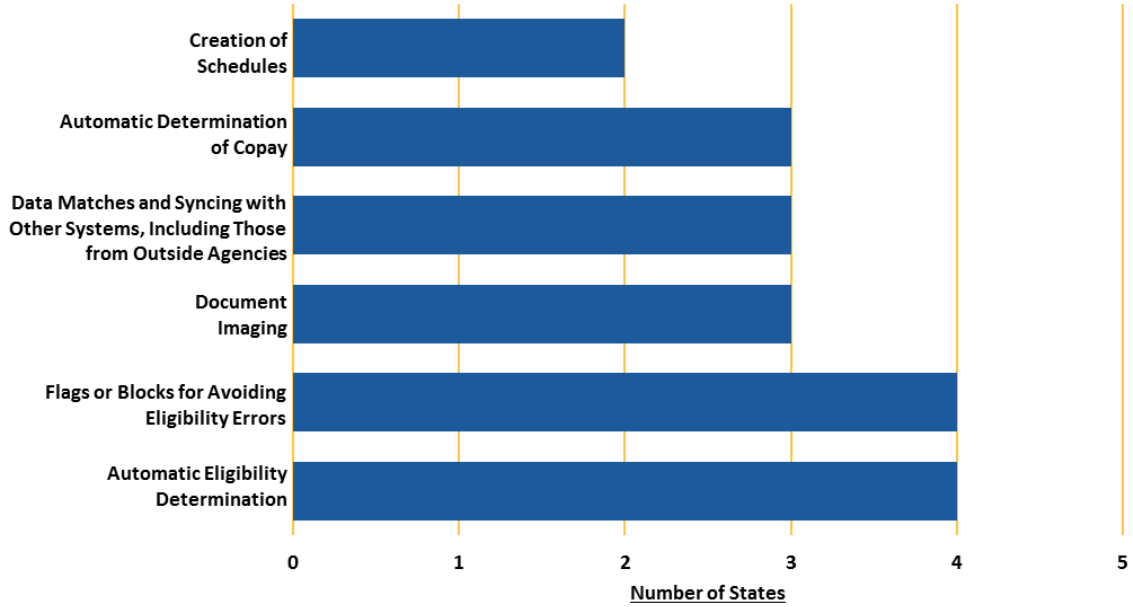
Corrective Action	Description
Oversight	All reporting states participate in a Joint Case Review process that HHS piloted in FY 2016 with Year Three states and then expanded to all reporting states in FY 2017. HHS gains insight into the error methodology implementation and provides additional technical assistance to states to ensure consistent reviews.
Technical Assistance	Site Visits: HHS visits states needing assistance to address root causes as resources allow.
	Regulations: HHS provides states with technical assistance on policy and procedure changes to meet new CCDBG requirements. HHS funds the Office of Child Care's National Center on Subsidy Innovation and Accountability to provide technical assistance to states and territories on program integrity and accountability, including targeting technical assistance to states to support reauthorization requirements.
	IT: HHS delivers technical assistance to states regarding updating or developing IT systems that will improve practices and reduce errors.
Methodology Training	HHS provides improper payments methodology training on how to conduct error rate reviews, which also allow states to share best practices on conducting the reviews with each other.

CCDF Information Systems and Other Infrastructure

Information systems and other infrastructure needed to reduce CCDF improper payments would need to be implemented at the state level where CCDF payments occur. In addition to the efforts outlined in prior HHS AFRs, states have taken many steps to improve IT systems and infrastructure including the following reported for FY 2018:

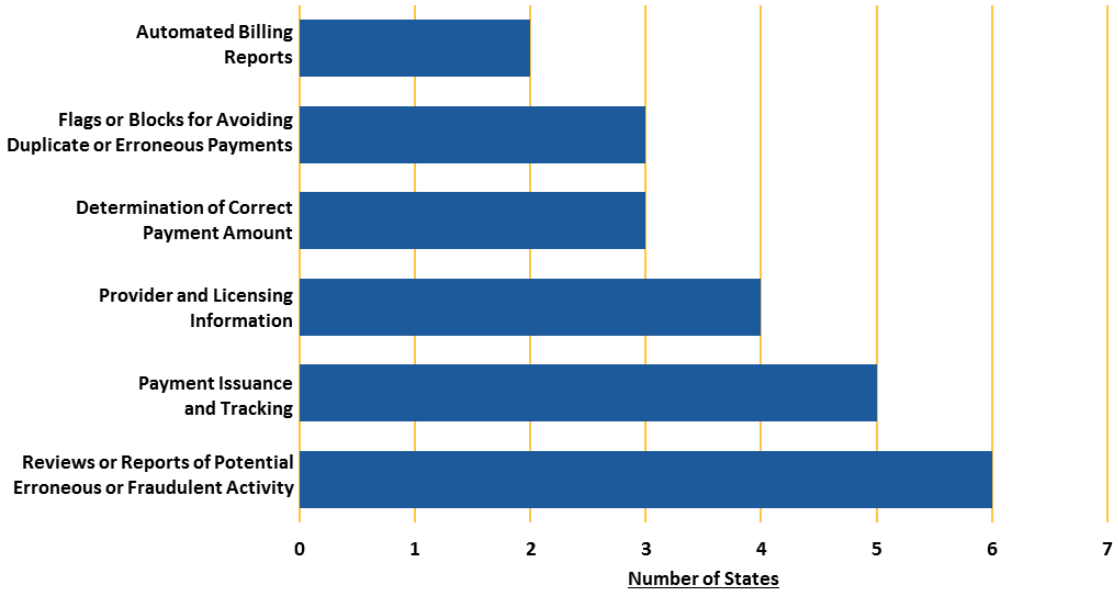
Thirteen Year Two states have IT systems that assist in eligibility determination and authorization. Figure 21 below shows the number of states with applicable capabilities (some states are listed in multiple categories).

Figure 21: Capabilities to Improve Eligibility Determination and Authorization



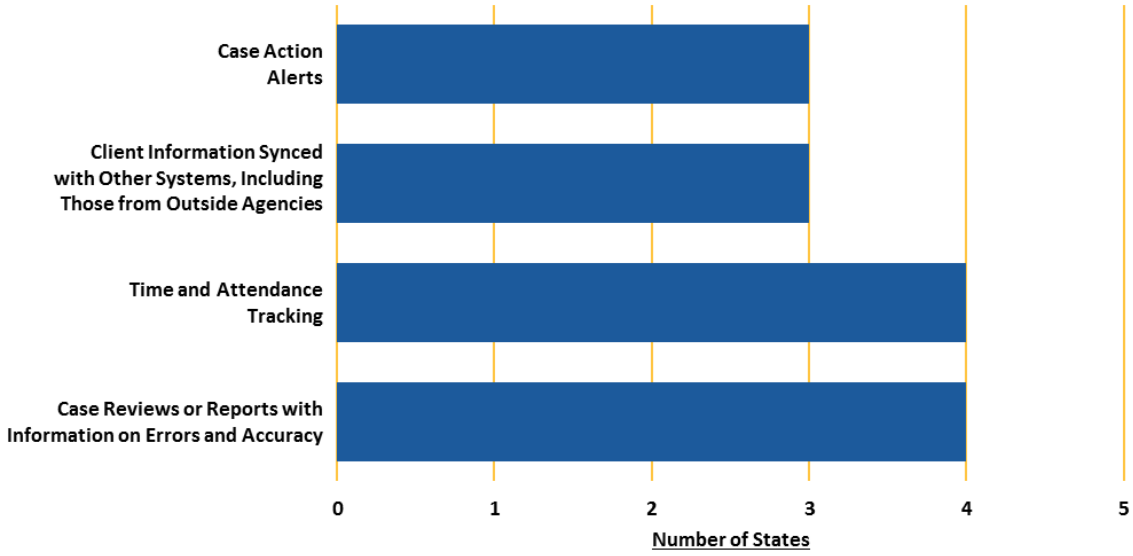
Twelve Year Two states have IT systems containing information on providers or provider payments. Figure 22 below shows the number of states with applicable capabilities (some states are listed in multiple categories).

Figure 22: Capabilities to Improve Information on Providers or Provider Payments



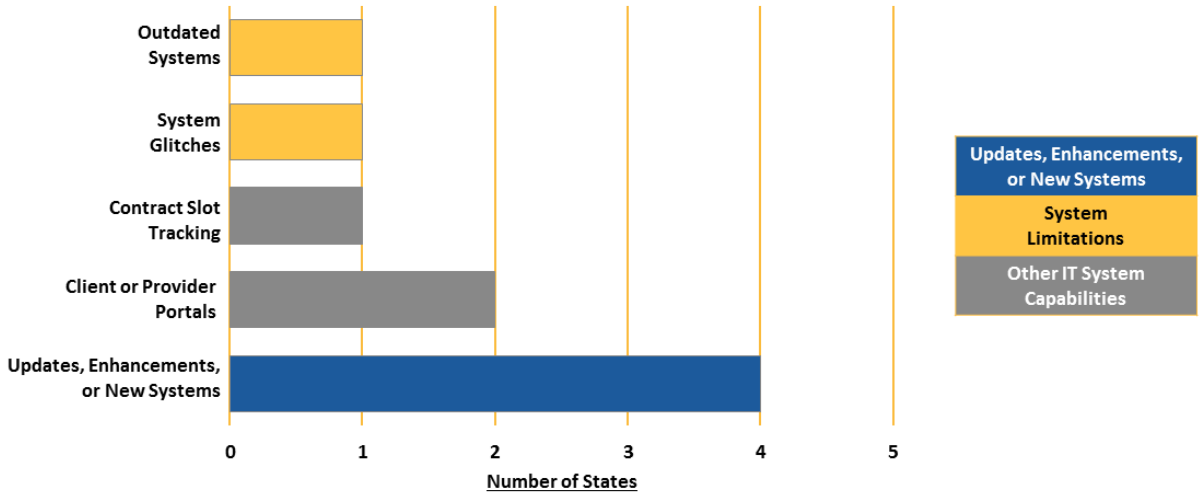
Ten Year Two states have IT systems containing information on active cases to assist in case management. Figure 23 below shows the number of states with applicable capabilities (some states are listed in multiple categories).

Figure 23: Capabilities to Improve Information on Active Cases to Assist in Case Management



Eight Year Two states described other IT system capabilities, including limitations with systems and plans for updates, enhancements, or new systems. Figure 24 below shows the number of states impacted by the other capabilities and improvements to IT systems and infrastructure.

Figure 24: Other Capabilities and Improvements to Information Systems and Infrastructure



CCDF Statutory or Regulatory Barriers that Could Limit Corrective Actions

The CCDBG Act, 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 were required to develop new policies and procedures to enact the law, which may increase errors as the changes continue to be implemented. CCDF regulations (issued in September 2016) will also require comprehensive changes for state programs. Many states need to pass legislative packages to enact the requirements under the regulations. Others are updating policy and procedure manuals, developing staff training and program oversight methods, and enhancing IT resources and infrastructure to monitor and oversee the new requirements.

12.0 RECOVERY AUDITING REPORTING

HHS developed a risk-based strategy to implement IPERA's recovery auditing provisions. Specifically, HHS focuses on implementing, or providing a framework for states to implement, recovery audit programs in Medicare and Medicaid, which accounted for 88 percent of HHS's outlays in FY 2018. HHS is progressing in recovering improper payments in Medicare and Medicaid and, most importantly, implementing corrective actions to prevent improper payments, as described In Section 11.0*: Program-Specific Reporting Information* and below. In addition, in FY 2018 HHS continued reviewing and cataloging potential opportunities to utilize RACs outside of Medicare and Medicaid. HHS will consider lessons learned from these experiences as it continues to implement this requirement.

Medicare FFS RACs

Section 1893(h)(3) of the *Social Security Act* requires HHS to implement the Medicare FFS RAC program in all 50 states by January 1, 2010. RACs are approved to review a variety of claim types, with restrictions on inpatient hospital patient status reviews, which are limited only to providers referred by the Quality Improvement Organizations for exhibiting persistent non-compliance with Medicare policies. On October 31, 2016, HHS awarded five new Medicare FFS RAC contracts that incorporated several program enhancements developed in response to industry feedback discussed on page 219 of HHS's FY 2017 AFR.

In FY 2018, the Medicare FFS RAC program identified approximately $89.44 million in overpayments and recovered $73.03 million. During FY 2018, the majority of Medicare FFS RAC collections were from Diagnosis Related Group validations and outpatient therapy reviews.

HHS also uses Medicare FFS RAC findings to prevent future improper payments. For example, in FY 2018, HHS released quarterly Provider Compliance Newsletters with detailed information on six findings identified by the Medicare FFS RACs. HHS used these findings to implement local and/or national system edits to prevent improper payments. More information can be found at Medicare FFS RAC program.

Medicare Secondary Payer (MSP) RACs

The MSP RAC, also known as the MSP Commercial Repayment Center (CRC), reviews HHS collected information regarding beneficiaries that had or have primary coverage through an employer-sponsored Group Health Plan (GHP) and situations where a Non-Group Health Plan (NGHP) (e.g., 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). At the end of 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, when the CRC initiates recovery of these conditional payments. In October 2017, HHS awarded the CRC contract to a new RAC. The contract transition completed in February 2018, and the previous contractor entered a one-year wind-down period.

In FY 2018, the CRC identified approximately $493.68 million and collected $126.57 million in mistaken payments. More information can be found at CRC.

Medicare Part C and Part D RACs

Section 1893(h) of the *Social Security Act* expanded the RAC program to Medicare Parts C and D.

The primary corrective action on Part C payment error has been the contract-level RADV audits. RADV verifies that diagnoses submitted by MA organizations for risk-adjusted payment are supported by medical record documentation. The RADV program is currently operational with the support of contractors. To effectively implement a successful Part C RAC program, in 2015, HHS issued a Request for Information on the proposal to place RADV under the purview of a Part C RAC. In response, the MA industry expressed concerns of burden related to the high overturn rate in the early experience of the FFS RAC program. Additionally, potential RAC vendors expressed concerns with the unlimited delay in the contingency payment due to timeframes not being established for appeal decisions in the MA appeal process (42 CFR. § 423.2600).

In light of these challenges, HHS believes Part C RAC functions are currently being performed by the contract-level RADV program. The proposed scope of the Part C RAC has been subsumed by an updated RADV methodology that also addresses recommendations GAO 16-76 Medicare Advantage: Fundamental Improvements Needed in CMS's Effort to Recover Substantial Amounts of Improper Payments. The new methodology targets payment error using historical payment error data. RADV audits for payment years 2014 and 2015 are expected to start in FY 2019.

In a circumstance similar to the Part C RAC, HHS believes that Part D RAC functions are currently being performed by the MEDIC. The MEDIC's primary focus is to conduct program integrity activities aimed to reduce fraud, waste, and abuse in Medicare Part C and Part D. The MEDIC's workload is substantially similar to that of the Part D RAC, and the MEDIC has a robust program to identify improper payments. After the MEDIC identifies improper payments, HHS requests that plan sponsors delete PDE records that are associated with potential overpayments. Subsequently, HHS validates whether plan sponsors actually delete the PDEs and do not resubmit such PDEs for payment. In FY 2019, the MEDIC will launch new self-audits and national audits that identify inappropriate payments. Additionally, continued education and outreach for Part D plan sponsors will be conducted.

The Part D RAC program became fully operational in FY 2012 and since its launch, has recouped overpayments resulting from prescriptions written by excluded or unauthorized providers and improper refills of Drug Enforcement Agency scheduled drugs. The Medicare Part D RAC contract ended in December 2015, but an administrative and appeals option period allows the RAC to complete work on outstanding audit issues through December 2018. Because the option period does not permit new audit work, no new improper payments were identified during FY 2018. In FY 2018, the Part D RAC recouped approximately $4.53 million in overpayments identified in previous years. See Medicare Part C and Part D RAC programs for more information.

State Medicaid RACs

Section 1902(a)(42)(B) of the *Social Security Act* required states to submit by December 31, 2010, assurances that programs meet statutory requirements to establish State Medicaid RAC programs. States were required to implement RAC programs by January 1, 2012. Thus, FY 2018 is the sixth full federal FY of reporting State Medicaid RAC recoveries. In FY 2018, State Medicaid RAC federal-share recoveries totaled $34.46 million and include overpayments collected, adjusted, or refunded to HHS, as reported by states on the CMS-64.

From inception of the Medicaid RAC program in FY 2012 through FY 2018, 47 States and the District of Columbia had cumulatively implemented Medicaid RAC programs to identify and recover overpayments and identify and correct underpayments in their Medicaid programs. However, each state has flexibility to tailor its RAC program where appropriate with guidance from HHS. For example, several states ended the Medicaid RAC programs when HHS approved an exception due to the high proportion of beneficiaries enrolled in Medicaid managed care compared to FFS. As a result, 21 states and the District of Columbia currently have RAC programs.

Recovery Auditing Reporting Tables

OMB Circular A-136 requires agencies to provide detailed information on agency recovery auditing programs, and other efforts to recapture improper payments. Some Department programs have results to report in this area (see Tables 3, 4A and 4B). If HHS excluded a program from a table, the program does not have results in that area.

Table 3
Overpayments Recaptured with and without Recapture Audit Programs
FY 2018 (in Millions)

Program or Activity	Overpayments Recaptured through Payment Recapture Audits			Overpayments Recaptured Outside of Payment Recapture Audits		
	Amount Identified	Amount Recaptured[1]	CY Recapture Rate	Amount Identified	Amount Recaptured[1]	CY Recapture Rate
CMS Error Rate Measurements[2]				$45.64	$17.97	39%
Medicare FFS Recovery Auditors	$89.44	$73.03	82%			
Medicare Secondary Payer Recovery Auditor	$493.68	$126.57	26%			
Medicare Contractors[3]				$13,227.82	$11,354.48	86%
Medicare Part C and Part D[4]				$66.99	$66.99	100%
Medicare Part D Recovery Auditors	N/A	$4.53	N/A			
Medicaid Integrity Contractors - Federal Share[5]				$19.78	$10.05	51%
State Medicaid Recovery Auditors - Federal Share[6]	N/A	$34.46	N/A			
ACF Error Rate Measurements and Eligibility Reviews[7]				$0.62	$0.53	86%
ACF OIG Reviews[8]				$10.47	$0.34	3%
ACF Single Audits[9]				$50.94	$5.75	11%
HRSA National Health Service Corps				$13.08	$4.46	34%
TOTAL	**$583.12**	**$238.59**	**41%**	**$13,435.34**	**$11,460.57**	**85%**

Notes:

1. The amount reported in the Amount Recaptured column is the amount recovered in FY 2018, regardless of the year HHS identified the overpayment.
2. The CMS Error Rate Measurements row includes recoveries from Medicare FFS (via the CERT program), as well as Medicaid and CHIP (via the PERM program). The actual overpayments identified by the CERT program during the FY 2018 report period were $20,302,062.01. The identified overpayments are recovered by the MACs via standard payment recovery methods. As of the report publication date, MACs reported collecting $17,178,901.72 or 84.62 percent of the actual overpayment dollars. For Medicaid and CHIP, 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 1903(d)(d) of the *Social Security Act* allows 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. The actual overpayments identified by the PERM program during the FY 2018 report period were $18,487,960.67 for Medicaid and $6,854,504.23 for CHIP. The amounts recovered were $334,411.00 for Medicaid and $460,145.00 for CHIP. The amounts recovered were for overpayments identified in prior report periods and, therefore, do not represent a proportion recovered from the identified overpayment amount for this report period.
3. Total reflects amounts reported by Medicare FFS Contractors excluding amounts reported for the Medicare FFS Recovery Auditors program and 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 row represent overpayments reported and returned by Medicare Advantage organizations and Part D sponsors. The actual overpayments identified and recovered during the FY 2018 report period were $64,933,411.00 for Medicare Part C and $2,060,495.00 for Medicare Part D.
5. 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.
6. For the State Medicaid Recovery Auditor row, states are only required to report the amount of recoveries, and not the amount of improper payments identified or recovery rates. The State Medicaid Recovery Auditors Amount Recaptured cell represents the federal share of the state recoveries as of the publication date of the AFR. The final amount recaptured for FY 2018 as a result of activities by State Medicaid Recovery Auditors will be reported in the FY 2018 Annual Report to Congress on the Medicare and Medicaid Integrity Programs.
7. The ACF Error Rate Measurements and Eligibility Reviews row contains Amount Identified information for the Foster Care and CCDF programs for which amounts were identified during the current reporting year. As a result of conducting Foster Care eligibility reviews in 10 states between July 2017 and June 2018, HHS recovered $0.50 million in Title IV-E improper payments (comprised of $0.34 million in disallowed maintenance payments and $0.16 million in disallowed administrative payments). For CCDF, 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 identified in the improper payments review. For the CCDF portion of the Amount Recaptured information, data reported in FY 2018 represent improper payments recovered by the Year Two states based on improper payments identified in FY 2015. States reported identifying $0.116 million and recovering $0.027 million.
8. The ACF OIG row includes Amount Identified information for all ACF programs for which amounts from an OIG Report were sustained in the FY 2018 reporting period.
9. The ACF Single Audits row includes Amount Identified information for all ACF programs subject to federal audit requirements for which audit report amounts were sustained in the FY 2018 reporting period.

Table 4A

Disposition of Funds Recaptured Through Payment Recapture Audit Programs

FY 2018 (in Millions) [1]

Program or Activity	Amount Recaptured	Agency Expenses to Administer the Program	Payment Recapture Auditor Fees	Original Purpose[2]	Returned to Treasury
Medicare FFS Recovery Auditors	$73.03	$38.22	$9.92	$10.00	N/A
Medicare Secondary Payer Recovery Auditor	$126.57	$5.68	$22.22	$98.68	N/A
Medicare Part D Recovery Auditors	$4.53	N/A	$0.91	$3.62	N/A
State Medicaid Recovery Auditors - Federal Share[3]	$34.46	N/A	N/A	$34.46	N/A
Total	**$238.59**	**$43.90**	**$33.05**	**$146.76**	**$0.00**

Notes:

1. HHS did not have any amounts that were used for financial management improvement activities or the OIG.
2. 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 ($7.67 million) and amounts collected in prior years but overturned on appeal in FY 2018 ($7.23 million).
3. 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 4B
Aging of Outstanding Overpayments Identified in the Payment Recapture Audit Programs
FY 2018 (in Millions) [1 and 2]

Program or Activity	CY Amount Outstanding (0 to 6 months)	CY % Outstanding (0 to 6 months)	CY Amount Outstanding (6 months to 1 year)	CY % Outstanding (6 months to 1 year)	CY Amount Outstanding (over 1 year)	CY % Outstanding (over 1 year)
Medicare FFS Recovery Auditors[3]	$14.66	72%	$4.71	23%	$1.05	5%
Medicare Secondary Payer Recovery Auditor[4 and 5]	$258.82	56%	$203.06	44%	$0.00	0%
Medicare Part D Recovery Auditor[6]	N/A	N/A	N/A	N/A	N/A	N/A
Total	**$273.48**	**56.7%**	**$207.77**	**43.1%**	**$1.05**	**0.2%**

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 currently outstanding.
2. HHS had no amount that was determined not to be collectable.
3. 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.
4. The MSP 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.
5. The amount of outstanding payments identified by MSP recovery auditor included in this table reflects the outstanding balances on debts identified in FY 2018.
6. The Medicare Part D RAC contract ended in December 2015, but an administrative and appeals option period allowed the RAC to complete work on outstanding audit issues until the end of December 2017. Because the option period does not permit new audit work, no new improper payments were identified by the Part D RAC during FY 2018.

FY 2018 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

DATE: NOV 05 2018

TO: Alex M. Azar II, Secretary

THROUGH: Ann C. Agnew, Executive Secretary

FROM: Daniel R. Levinson, Inspector General Daniel R. Levinson

SUBJECT: Top Management and Performance Challenges Facing the Department of Health and Human Services in Fiscal Year 2018

This memorandum transmits the Office of Inspector General's (OIG's) 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 2018 are:

1. Preventing and Treating Opioid Misuse
2. Ensuring Program Integrity in Medicare Fee-for-Service and Effective Administration of Medicare
3. Ensuring Program Integrity and Effective Administration of Medicaid
4. Ensuring Value and Integrity in Managed Care and Other Innovative Healthcare Payment and Service Delivery Models
5. Protecting the Health and Safety of Vulnerable Populations
6. Improving Financial and Administrative Management and Reducing Improper Payments
7. Protecting the Integrity of HHS Grants
8. Ensuring the Safety of Food, Drugs, and Medical Devices
9. Ensuring Quality and Integrity in Programs Serving American Indian/Alaska Native Populations
10. Protecting HHS Data, Systems, and Beneficiaries from Cybersecurity Threats
11. Ensuring that HHS Prescription Drug Programs Work as Intended
12. Ensuring Effective Preparation and Response to Public Health Emergencies

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.

U.S. Department of Health and Human Services

Office of Inspector General

2018 Top Management and Performance Challenges

Introduction

The *2018 Top Management and Performance Challenges Facing HHS* is an annual publication of the Department of Health and Human Services (HHS or the Department) Office of Inspector General (OIG). In this edition, OIG has identified 12 top management and performance challenges (TMCs) facing the Department as it strives to fulfill its mission "to enhance the health and well-being of all 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." These top challenges arise across HHS programs and cover critical HHS responsibilities that include delivering quality services and benefits, exercising sound fiscal management, safeguarding public health and safety, and enhancing cybersecurity. The Department should be mindful of these challenges and opportunities to address them as it undertakes its efforts to ReImagine HHS as part of the Federal Government's comprehensive plan to reform Government.

Top 12 Management and Performance Challenges Facing HHS

1. Preventing and Treating Opioid Misuse
2. Ensuring Program Integrity in Medicare Fee-for-Service and Effective Administration of Medicare
3. Ensuring Program Integrity and Effective Administration of Medicaid
4. Ensuring Value and Integrity in Managed Care and Other Innovative Healthcare Payment and Service Delivery Models
5. Protecting the Health and Safety of Vulnerable Populations
6. Improving Financial and Administrative Management and Reducing Improper Payments
7. Protecting the Integrity of HHS Grants
8. Ensuring the Safety of Food, Drugs, and Medical Devices
9. Ensuring Quality and Integrity in Programs Serving American Indian/Alaska Native Populations
10. Protecting HHS Data, Systems, and Beneficiaries from Cybersecurity Threats
11. Ensuring that HHS Prescription Drug Programs Work as Intended
12. Ensuring Effective Preparation and Response to Public Health Emergencies

HHS is responsible for a portfolio of more than $1 trillion, and its programs impact the lives of virtually all Americans. To identify the top 12 challenges, we synthesized our oversight, risk analysis, data analytics, and enforcement work. For each top challenge, we identify the key components, the Department's progress in addressing the challenge, and what needs to be done. There are many cross-cutting issues that transcend all the TMCs. Examples include improper payments, the quality of services provided and care received by beneficiaries, promoting effective use of health IT, and combatting fraud. Each challenge also lists key OIG resources related to that challenge.

Additionally, OIG maintains a list of significant unimplemented OIG recommendations, including legislative recommendations, to address vulnerabilities. These recommendations are drawn from OIG's audits and evaluations. OIG identifies the top unimplemented recommendations that, in OIG's view, would most positively affect HHS programs in terms of cost savings, program effectiveness and efficiency, and public health and safety.[28] More information on OIG's work, including the reports mentioned in this publication, is on our website at https://oig.hhs.gov.

[28] OIG, *Solutions to Reduce Fraud, Waste, and Abuse in HHS Programs: Top Unimplemented Recommendations*, July 2018. Available at https://oig.hhs.gov/reports-and-publications/compendium/files/compendium2018.pdf.

1. Preventing and Treating Opioid Misuse

Key Components of the Challenge
- Reducing inappropriate prescribing and misuse of opioids
- Combating fraud and diversion of prescription opioids and potentiator drugs
- Ensuring access to appropriate treatment for opioid use disorder
- Ensuring that funding for prevention and treatment is used appropriately

Why This Is a Challenge

In 2017, the President declared the opioid crisis a nationwide public health emergency. Some analysts estimate that up to 6 million Americans could have opioid use disorder.[29] In 2017, it is estimated that more than 49,000 opioid-related overdose deaths occurred in the United States (U.S.), an average of 134 deaths per day.

Across multiple agencies and programs, HHS has many opportunities to help curb the opioid epidemic. Medicare provides prescription drug coverage for 45 million Part D beneficiaries and Medicaid for 67 million beneficiaries. The Indian Health Service (IHS) provides care for 2.2 million beneficiaries. The U.S. Food and Drug Administration (FDA) oversees the approval and safe use of prescription drugs. HHS agencies also conduct research and award grants to support healthcare providers, researchers, and States in their efforts to combat the epidemic.

Reducing inappropriate prescribing and misuse of opioids

Key Components of the Challenge

OIG found that almost 460,000 Medicare Part D beneficiaries received high amounts of opioids in 2017. In addition, almost 300 prescribers engaged in questionable opioid prescribing. These prescribers ordered opioids for the highest number of beneficiaries at serious risk of opioid misuse or overdose. This does not include prescribing for beneficiaries who have cancer or were in hospice care. Beneficiaries at serious risk include those who received extreme amounts of opioids and those who appeared to be doctor shopping (i.e., receiving high amounts of opioids from multiple prescribers and multiple pharmacies).[30]

Medicaid beneficiaries may be especially vulnerable to opioid misuse because they are more likely than nonbeneficiaries to have chronic conditions and comorbidities that require pain relief, especially those who qualify because of a disability. In 2016, Medicaid covered nearly 4 in 10 nonelderly adults with opioid addiction, while only 15 percent of the nonelderly adult population is covered by Medicaid. OIG found that one in six Medicaid beneficiaries in Ohio received an opioid in a 1-year period, and nearly 5,000 Ohio beneficiaries received high amounts of opioids.

Health disparities and inadequate healthcare services for American Indians and Alaska Natives (AI/AN) have been a subject of concern for the Federal Government for almost a century. AI/AN had the second highest rate of opioid overdose deaths in 2015 and 2016.[31] IHS is responsible for implementing appropriate controls within its pharmacies to reduce and detect diversion of opioids. OIG has found

[29] Modern Healthcare, "Opioid Use Disorder Cases Triple Government's Early Estimates," September 14, 2018. Available at: http://www.modernhealthcare.com/article/20180914/NEWS/180919929.
[30] Extreme is defined as an average daily morphine equivalent dose greater than 240 mg for 12 months.
[31] Seth PS, et al., Overdose deaths involving opioids, cocaine, and psychostimulants—United States, 2015-2016, *MMWR*, Vol 67 (12) March 30, 2018, pp 349-358.)

vulnerabilities at some IHS pharmacies that could put patient safety at risk and allow inappropriate prescribing of opioids.

Progress in Addressing the Challenge

The Department has engaged several Operating Divisions in efforts to address inappropriate prescribing and misuse of opioids. Monitoring of prescription drug claims is one tool to prevent inappropriate prescribing and misuse of opioids. The Centers for Medicare & Medicaid Services (CMS) has taken steps to help reduce misuse of opioids, including strengthening drug utilization reviews, a tool that assists Medicare Part D sponsors in preventing misuse. In October 2017, States and CMS convened to discuss vulnerabilities, mitigation strategies, challenges, and barriers related to State Medicaid opioid efforts. In June 2018, CMS continued to provide guidance to help States combat the opioid crisis in Medicaid, including information on effective practices to identify substance use disorders covered under Medicaid. The Centers for Disease Control and Prevention (CDC) has awarded funding to States to improve prescription drug monitoring programs (PDMPs), which are statewide databases that track prescriptions. In 2016, IHS implemented a policy requiring prescribers to utilize PDMP data to identify at-risk patients. PDMPs assist in identifying prescribers at risk of inappropriate prescribing and allow authorized users to identify patients who are obtaining opioids from multiple providers.

Education of providers, the industry, and beneficiaries on appropriate prescribing and pain management also plays a role in the prevention of opioid abuse. For example, IHS changed its policy regarding opioid prescribing to align with CDC guidelines for prescribing opioids for chronic pain. Furthermore, FDA is encouraging appropriate prescribing of opioid analgesics through the Risk Evaluation and Mitigation Strategy (REMS) program for opioid analgesics. The Opioid Analgesic REMS, approved on September 18, 2018, includes as the primary component that training be made available to all healthcare providers (HCPs) who are involved in the management of patients with pain, including nurses and pharmacists. To meet this requirement, drug manufacturers with approved opioid analgesics will provide unrestricted grants to accredited continuing education providers for the development of education courses for HCPs based on the FDA Education Blueprint for Health Care Providers Involved in the Management or Support of Patients with Pain (Blueprint). It is expected that continuing education based upon the new Blueprint will be available to healthcare providers by March 2019.[32] To prevent misuse of opioids, HHS has educated providers and the public about alternative options for pain management. IHS established a National Committee on Heroin, Opioids, and Pain Efforts to promote appropriate and effective pain management, reduce overdose deaths, and improve access to treatment.

When opioid use becomes addiction, information on treatment is important. In 2017, HHS launched its 5-Point Opioid Strategy to improve access to treatment, improve data, promote better pain management, increase the availability of overdose-reversing drugs, and increase research on pain and addiction. In April 2018, NIH launched the Helping to End Addiction Long-term (HEAL) initiative to improve treatments for opioid misuse and addiction.

What Needs To Be Done

- HHS agencies should monitor and assess the effectiveness of their ongoing efforts.
- OIG recommends that CMS continue to develop prescriber educational tools outlining how to appropriately prescribe opioids when medically necessary. As part of this education, CMS should

[32] FDA, "Opioid Analgesic Risk Evaluation and Mitigation Strategy," September 27, 2018. Accessed at: https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm163647.htm.

engage with those providers who may be prescribing inappropriately, to make sure they have the tools to prescribe appropriately.

- States and IHS should continue efforts to implement and encourage the use of PDMPs.[33] Routinely checking States' PDMPs is an important step toward improving how opioids are prescribed and reducing opioid misuse, abuse, and overdose.
- Medicaid beneficiary data should be shared among States and with HHS so that potential patient harm is identified. Beneficiaries can cross State boundaries to obtain opioids and thereby miss being flagged by a State's PDMP for potentially excessive opioid use.

Combating fraud and diversion of prescription opioids and potentiator drugs

Key Components of the Challenge

Several years ago, OIG detected—and began taking action to address—a rise in fraud schemes involving opioids, as well as associated potentiator drugs. Opioid fraud encompasses a broad range of criminal activity from prescription drug diversion to addiction treatment schemes.

OIG investigations of opioid drug diversion, which is the redirection of legitimate drugs for illegitimate purposes, are on the rise. Diverted opioid drugs are at high risk to be used inappropriately and create significant harm, including increasing the risk of overdose. Also at risk for diversion are potentiator drugs, which are drugs that exaggerate euphoria when combined with opioids and escalate the potential for misuse. Prescription opioids indicated to treat pain and those indicated to treat opioid use disorder (particularly, buprenorphine) are also at high risk of diversion.

Progress in Addressing the Challenge

OIG, along with State and Federal law enforcement partners, participated in an unprecedented fraud takedown to combat healthcare fraud and the opioid epidemic in June 2018. More than 160 defendants were charged with participating in Medicare and Medicaid fraud schemes related to opioids or treatment for opioid use disorders. These defendants included 32 doctors who were charged for their roles in prescribing and distributing opioids and other dangerous narcotics.

To support public and private sector partners in combatting the opioid crisis, OIG released a toolkit providing detailed steps for using prescription drug claims data to analyze patients' opioid levels and identify certain patients who are at risk of opioid misuse or overdose. Partners such as Medicare Part D plan sponsors, private health plans, and State Medicaid Fraud Control Units (MFCUs) can now analyze their own prescription drug claims data using the methodology OIG developed on the basis of its work on opioids.

CMS finalized regulations to guide Medicare plans to implement "lock-in" authority. Lock-in allows Medicare plans to better manage at-risk beneficiaries' medication regimens by limiting their access to opioids to certain prescribers and pharmacies. CMS has issued Quarterly Reports of Part D outlier prescribers of opioids and other prescription drugs; these prescribers have a high potential for abuse. Additionally, IHS implemented system and physical controls at certain IHS hospitals to help ensure opioids are secure. These controls help to ensure prescription drugs and pharmacy information are protected, thus lessening the chance that drugs could be illegally diverted.

What Needs To Be Done

- HHS agencies should improve efforts to identify and investigate potential fraud and abuse. For instance, CMS should collect comprehensive data from Medicare Part D plan sponsors.
- CMS should ensure that national Medicaid data are sufficient to detect suspected fraud or abuse.
- CMS and States should follow up on prescribers with questionable prescribing patterns to ensure that Medicare Part D and Medicaid are not paying for unnecessary drugs that are being diverted for resale or recreational use.
- IHS should improve controls at entry points to sensitive areas of its hospitals to protect its pharmacy inventory from unauthorized access.
- IHS should continue to strengthen its systems controls to ensure unauthorized individuals cannot gain access to sensitive patient information.

Ensuring access to appropriate treatment for opioid use disorder

Key Components of the Challenge

Given the scope of the epidemic, access to high quality treatment of opioid use disorder is a priority and a challenge. Only 10 percent of people who need treatment for substance use disorder receive that treatment.[34] Rates of drug overdose deaths are rising in rural areas, surpassing rates in urban areas. At the same time, rural areas are often more limited in their access to treatment. The Government Accountability Office found that the regulatory restrictions placed on providers, such as patient limits, and the stigmas related to drug addiction and medication assisted treatment (MAT) are barriers that may limit providers' participation in treatment.

Increasing access to MAT and programs must be balanced with the increased risk for fraud involving addiction treatment schemes. Fraud committed by providers of treatment for opioid use disorder is a concern as it both diverts funds and puts beneficiaries at risk.

Progress in Addressing the Challenge

HHS has been implementing provisions of the *Comprehensive Addiction and Recovery Act of 2016*. This includes allowing a temporary expansion of prescribing authority for MAT to other healthcare providers beyond physicians, including nurse practitioners and physician assistants.

HHS agencies have taken steps to expand MAT treatment options and access. The Substance Abuse and Mental Health Services Administration (SAMHSA) reviewed the use of three medications (methadone, naltrexone, and buprenorphine) to treat opioid use disorders. In addition, in 2018, the Health Resources and Services Administration (HRSA) made $350 million available to expand access to treatment, including MAT, at community health centers. The number of health center clinicians providing MAT increased from 1,700 in 2016 to nearly 3,000 in 2017.[35] Further, FDA issued scientific recommendations

[34] SAMHSA, "Receipt of Services for Substance Use and Mental Health Issues among Adults: Results from the 2016 National Survey on Drug Use and Health," September 2017. Accessed at: https://www.samhsa.gov/data/sites/default/files/NSDUH-DR-FFR2-2016/NSDUH-DR-FFR2-2016.htm. The 2017 National Survey on Drug Use and Health data is estimated to be released in November 2018.

[35] HHS, "HHS Makes $350 Million Available to Fight the Opioid Crisis in Community Health Centers Nationwide," June 15, 2018. Accessed at: https://www.hhs.gov/about/news/2018/06/15/hhs-makes-350-million-available-to-fight-opioid-crisis-community-health-centers.html.

to encourage the development of MAT drugs.[36] FDA also approved the first generic versions of Suboxone, which may increase access to treatment of opioid dependence.[37]

Additionally, CMS has allowed States to design demonstration projects that increase access to a continuum of treatment services for opioid use disorders. It also allows State Medicaid agencies to reimburse for treatment at inpatient facilities with more than 16 beds which are otherwise prohibited by current exclusions.

What Needs To Be Done

- CMS and SAMHSA should monitor the success of their efforts to increase access to MAT.
- SAMHSA must adequately oversee the waiver process for physicians to prescribe or dispense specific narcotic medications in settings other than opioid treatment programs.
- CMS should continue to develop reimbursement policies that foster the development of services to ensure that treatment resources and the number of qualified providers are sufficient to provide beneficiaries ready access where and when needed.

Ensuring that funding for prevention and treatment is used appropriately

Key Components of the Challenge

To build upon the work started under the *21st Century Cures Act* (Cures Act), HHS was appropriated more than $1 billion in new funding to combat the opioid epidemic and address serious mental illness.

While Medicare and Medicaid pay the biggest share of Federal payments for treatment, SAMHSA is awarding approximately $930 million in fiscal year (FY) 2018 State Opioid Response grants and awarded approximately $484 million in Opioid State Targeted Response grants in FY 2017. Ensuring these funds are used appropriately is a top priority. As with any Federal program, significant increases in funding and subsequent disbursement raises the risk for waste, abuse, and inefficient use *(see TMC #7 for more information on challenges specific to HHS grants)*.

Progress in Addressing the Challenge

In the Agency Priority Goal Action Plan to Reduce Opioid Morbidity and Mortality, the Department publishes quarterly updates on its progress on HHS-funded projects to combat the opioid crisis. For example, HRSA reported that it collects quarterly progress-report data from grantees who received funding in 2017 to increase access to substance abuse and mental health services, the Rural Health Opioid Program, and the Substance Abuse Treatment Telehealth Network Grant Program.

NIH ensures its funded opioid research adheres to NIH Grants Compliance and Oversight policies. NIH uses proactive compliance site visits to assess institutional understanding of Federal policies and regulations, minimize or eliminate areas of noncompliance, and nurture partnerships between NIH and its recipient institutions. NIH also uses targeted site visits to focus on recipients' compliance with Financial Conflict of Interest regulations.

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[36] FDA, "FDA Takes New Steps to Encourage the Development of Novel Medicines for the Treatment of Opioid Use Disorder," August 6, 2018. Accessed at: https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm615892.htm.

[37] FDA, "FDA approves first generic versions of Suboxone sublingual film, which may increase access to treatment for opioid dependence," June 14, 2018. Accessed at: https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm610807.htm.

CMS conducts State Program Integrity desk reviews of State Medicaid activities to assist in combatting the opioid epidemic. In FY 2018, CMS began conducting opioid desk reviews to gather information related to certain States' current programs, delivery systems, policies and/or noteworthy practices in response to the opioid crisis.

What Needs To Be Done

- OIG will monitor and review grantees' use of Federal funds for opioid abuse prevention and treatment programs, and, as appropriate, use its criminal, civil, and administrative enforcement authorities to prevent fraud.
- SAMHSA and other HHS Operating Divisions should identify and refer cases to OIG involving grantee fraud or misuse of Federal funds for opioid abuse prevention and treatment programs.

Key OIG resources

- *Opioids in Medicare Part D: Concerns about Extreme Use and Questionable Prescribing* (OEI-02-17-00250), July 2017.
- *Two Indian Health Service Hospitals Had System Security and Physical Controls for Prescription Drug and Opioid Dispensing but Could Still Improve Controls* (A-18-16-30540), November 2017.
- *Toolkit: Using Data Analysis to Calculate Opioid Levels and Identify Patients at Risk of Misuse or Overdose* (OEI-02-17-00560), June 2018.
- *Opioid Use in Medicare Part D Remains Concerning* (OEI-02-18-00220), June 2018.
- *Opioids in Ohio Medicaid: Review of Extreme Use and Prescribing* (OEI-05-18-00010), July 2018.

2. Ensuring Program Integrity in Medicare Fee-for-Service and Effective Administration of Medicare

Key Components of the Challenge
- Reducing improper payments
- Combating fraud
- Fostering prudent payment policies
- Maximizing the promise of health information technology

Why This Is a Challenge

In FY 2017, Medicare spent $698.7 billion and provided health coverage to 58.4 million beneficiaries. Medicare spending represents more than 15 percent of all Federal spending. Future spending is expected to increase significantly because of growth in the number of beneficiaries and increases in per capita healthcare costs. The 2018 Annual Report of the Board of Trustees of the Federal Hospital Insurance and Federal Supplemental Medicare Insurance Trust Funds estimates that the Trust Fund for Medicare Part A (Hospital Insurance) will be depleted by 2026. It also projects that spending for Medicare Part B (Medical Insurance) will grow by almost 8.2 percent over the next 5 years, outpacing the U.S. economy, which is projected to grow by 4.7 percent during that time.

The Medicare Program continues to be susceptible to risks associated with volume-driven reimbursement, such as incentives for inappropriate utilization. The Department is working to transform Medicare into a more value-based system with shared accountability for quality, costs, and outcomes. However, given the millions of beneficiaries and hundreds of billions of dollars still associated with traditional Medicare, the Department must continue to ensure the integrity of the existing programs even as it develops new ones *(see TMC #4 for more information on ensuring value and integrity in managed care and other innovative payment and service healthcare delivery models).*

Reducing improper payments

Key Components of the Challenge

Reducing improper payments to providers is a critical element in protecting Medicare's financial integrity. The Medicare Fee-For-Service (FFS) improper payment rate decreased from 11.0 percent, or $41.1 billion, in FY 2016 to 9.51 percent, or $36.2 billion, in FY 2017. This represents positive momentum upon which the Department and CMS can build (*see TMC #6 for more information on measuring and reporting improper payment rates)*. Some types of providers and suppliers pose heightened risk to the financial integrity of Medicare. For instance, OIG and CMS have identified especially high rates of improper payments for home healthcare, hospice care, durable medical equipment (DME),

FOCUS ON HOSPICE

Hospice is an increasingly important benefit for the Medicare population. It can provide great comfort to beneficiaries, their families, and other caregivers at the end of a beneficiary's life. The number of hospice beneficiaries has grown every year for the past decade. In 2016, Medicare spent about $16.7 billion for hospice care for 1.4 million beneficiaries (compared to $9.2 billion for fewer than 1 million beneficiaries in 2006). With this growth, OIG has identified significant vulnerabilities and has raised concerns about hospice billing, Federal oversight, and quality of care provided to beneficiaries. OIG investigations have also uncovered hospices enrolling beneficiaries without their knowledge or under false pretenses, enrolling beneficiaries who are not terminally ill, billing for services not provided, paying kickbacks, and falsifying documentation.

chiropractic services, care in skilled nursing facilities (SNF), and certain hospital services.

Hospital billing for short inpatient stays also remains a concern. CMS's enforcement of its 2-midnight policy has been limited. OIG found that hospitals billed for many potentially inappropriate short inpatient stays; for these stays, Medicare paid a total of almost $2.9 billion. OIG also found that hospitals may have financial incentives to use short inpatient stays, and that some hospitals increased their use of these stays, which is inconsistent with the stated goals of the 2-midnight policy.

Progress in Addressing the Challenge

HHS and CMS have made several corrective actions for the Medicare FFS program that focus on specific service areas with high error rates, such as home health and inpatient rehabilitation facilities claims. These actions are designed to reduce fraud, waste, and abuse in the Medicare FFS program while ensuring patients receive necessary care.

CMS has put into place new requirements that make identification and recoupment of overpayments easier by using tax identification numbers and provider transaction access numbers in addition to national provider numbers. CMS has also improved identification of overpayments by sharing best practices across Unified Program Integrity Contractors and addressing challenges that hinder their identification of overpayments.

What Needs To Be Done

- CMS should take more effective actions to reduce improper payments among provider and supplier types and in geographic locations that present a high risk to the financial integrity of Medicare. This includes focusing on provider types that OIG and CMS have found to have extremely high rates of improper payments, such as chiropractors, home health providers, hospice, SNFs, and high-risk hospital services.
- HHS should continue to address and resolve program integrity weaknesses that OIG has identified. For example, CMS should implement the requirement for home health agencies to obtain surety bonds to ensure that Medicare can recoup at least some of its overpayments and to potentially deter ill-intended providers.
- CMS needs to strengthen oversight for hospice general inpatient billing and SNF billing.

Combating fraud

Key Components of the Challenge

Stopping fraud in Medicare is vital to safeguarding healthcare resources and protecting beneficiaries. OIG has identified common fraud schemes, such as billing for unnecessary services or services not provided; billing for more expensive services than needed or provided; paying kickbacks to recruiters, providers, and patients; and medical identity theft. Program areas susceptible to widespread fraud include home health, hospice services, DME, ambulance transportation, and clinical laboratory testing. Fraud schemes can become "viral"—spreading and replicating through communities—and can also evolve quickly. This creates challenges for CMS and law enforcement to detect and quickly respond to emerging schemes.

Since June 30, 2011, the Fraud Prevention System (FPS) has continuously run predictive algorithms and other sophisticated analytics nationwide against Medicare FFS claims prior to payment to identify, prevent, and stop fraudulent claims. When performing work to certify the actual and projected savings

and the return on investment related to HHS's use of FPS, OIG found that HHS might not have the capability to trace the savings from administrative actions back to the originating FPS model or formula. CMS could not track those savings because, according to CMS, that capability was not built into FPS. In addition, CMS did not make use of all pertinent performance results because it did not ensure that contractors' adjusted savings reported to CMS reflected the amounts certified by OIG, and CMS did not evaluate FPS model performance on the basis of the amounts expected to be prevented or recovered.

CMS needs accurate information to avoid doing business with—and exposing beneficiaries to—untrustworthy actors or ineligible providers. However, fraudulent providers sometimes provide false or incomplete information on ownership and business associations or misrepresent themselves to appear legitimate. Untrustworthy actors may also try to circumvent program safeguards in other ways. For example, an OIG review found that some patient lists supplied by home health agencies were missing Medicare beneficiaries, which excluded them from surveyor inspections. This illustrates a vulnerability that home health agencies could exploit to conceal fraudulent activity or health and safety violations.

Progress in Addressing the Challenge

In February 2016, CMS issued a technical direction letter (TDL) to the Zone Program Integrity Contractors (ZPICs or contractors) clarifying how to determine which administrative actions were attributable to the FPS. Additionally, in August 2018, CMS began providing the contractors with an annual report listing administrative actions and associated savings that CMS deemed FPS attributable and those CMS deemed not FPS attributable. This allowed CMS to go one step further and ensure that contractors' adjusted savings reflected the amounts certified by OIG.

In March 2017, CMS launched an updated FPS version ("FPS 2.0") that modernizes system and user interfaces, improves model development time and performance measurement, and aggressively expands CMS's program integrity capabilities. During FY 2016, the FPS models generated 688 leads that were included in the ZPICs' workload, resulting in 476 new investigations and augmented information for 212 existing investigations. CMS has also implemented a system to attribute savings from administrative actions back to specific models. CMS is also revising the FPS savings methodology.

HHS partners with OIG and the U.S. Department of Justice (DOJ) on Health Care Strike Force teams and other healthcare fraud enforcement activities through the Health Care Fraud and Abuse Control (HCFAC) program. Over its 22-year history, the HCFAC program has recovered billions of dollars and has further protected Federal healthcare programs by convicting criminals and excluding providers from participation in Medicare and other Federal healthcare programs.

Most recently, HHS, along with State and Federal law enforcement partners, participated in an unprecedented nationwide healthcare fraud takedown aimed at combating healthcare fraud and the opioid epidemic *(see TMC #1 for more information on the opioid epidemic)*. More than 600 defendants in 58 Federal districts were charged for their alleged participation in schemes involving approximately $2 billion in losses to vital healthcare programs, including Medicare.

CMS partners with OIG and DOJ in many ways to fight fraud. For example, Medicare and Medicaid policy experts, OIG and DOJ law enforcement officials, clinicians, and CMS fraud investigators coordinate before, during, and after the development of fraud leads to expedite referrals and investigation of providers suspected of endangering beneficiaries and/or defrauding Medicare. OIG, CMS, and DOJ also

coordinate with private sector health insurers through the Healthcare Fraud Prevention Partnership and the National Healthcare Anti-Fraud Association.

What Needs To Be Done

- CMS should fully employ available program integrity tools to prevent payment to fraudulent providers. For example, CMS must continue improving its oversight and the performance of contractors implementing Medicare provider enrollment safeguards.
- CMS should make better use of the performance results within its FPS to refine and enhance its predictive analytic models.

Fostering prudent payment policies

Key Components of the Challenge

Medicare should act as a prudent payer on behalf of taxpayers and beneficiaries by instituting economical payment policies. However, in certain contexts, Medicare payment policies, which are generally set by statute, result in Medicare and beneficiaries paying more for care provided in certain settings than for the same care provided in other settings. For example, Medicare could potentially save $4.1 billion over a 6-year period if swing-bed services at critical access hospitals were paid for at the same rates as at SNFs.

Medicare also pays hospitals different amounts for the same care depending on whether the hospital admits beneficiaries as inpatients or treats them as outpatients. Medicare and beneficiaries' coverage for SNF services and coinsurance costs following discharge also vary depending on their status as hospital inpatients or outpatients, even if they receive the same care during their stay.

Some payment policies create financial incentives that may actually drive up Medicare costs without improving care for beneficiaries. For example, OIG found that Medicare payments to SNFs for therapy greatly exceeded SNFs' costs for that therapy, creating incentives to bill for unnecessary therapy *(see TMCs #4 and #11 for more information on challenges of anticipating and addressing financial incentives in additional areas, including value-based payments and drug pricing and access).*

Progress in Addressing the Challenge

HHS has been instituting changes to promote more prudent payment policies in some healthcare settings. For example, recent statutory changes require Medicare to stop paying certain new hospital-owned, off-campus, "provider-based" departments that charge higher hospital rates than freestanding facilities that perform the same services for less. CMS projects that this will have saved Medicare approximately $50 million in 2017. CMS finalized the Patient Driven Payment Model, a new payment system for SNFs to be implemented in FY 2020, which bases Medicare payment on beneficiaries' conditions and care needed rather than on volume of services provided.

What Needs To Be Done

- CMS can take actions within existing authorities to mitigate financial risks and quality-of-care risks under the current systems. For example, CMS should reform the payment policy for hospices to align payments to costs and address the financial incentives for hospices to target beneficiaries likely to have long stays.
- CMS should evaluate the extent to which Medicare payment rates for therapy should be reduced, as well as adjust Medicare payments to SNFs to eliminate any increases in payments for therapy that

are unrelated to changes in beneficiary characteristics. CMS should also use data analytics to target oversight to SNFs that may be inappropriately billing for therapy.
- CMS can test and rigorously evaluate the effectiveness and efficiency of new payment and delivery models.

Maximizing the promise of health information technology

Key Components of the Challenge

Leveraging the benefits of Health Information Technology (Health IT) to ensure the appropriate flow of complete, accurate, timely, and secure information and to improve patient care is critical to promoting a value-driven healthcare system. HHS faces challenges in achieving a connected healthcare system in which data, including healthcare data and human services data about social determinants of health, flow freely, as appropriate. Challenges for HHS include ensuring that Health IT companies and providers do not inappropriately block the flow of information, preventing inappropriate payments to participants who do not meet program requirements, ensuring that electronic health records (EHR) are not used as tools for fraud, encouraging adoption and use of Health IT by those not eligible for existing incentive programs, ensuring that patient safety benefits are realized, and encouraging high-value uses of exchanged data. To avoid potential gaps in policy and oversight that could undermine the promise of Health IT, HHS must ensure coordination among internal agencies and other Federal partners that have overlapping responsibility for various aspects of Health IT *(see TMC #10 for more information on the intersection of HHS's data privacy and security)*.

Progress in Addressing the Challenge

HHS continues to develop programs and policies that foster the development, adoption, and effective use of Health IT to support the appropriate flow of complete, accurate, timely, and secure information within Medicare. As of July 2018, more than 642,500 eligible professionals and hospitals—including critical access hospitals—were actively registered in the EHR incentive programs. CMS and the Office of the National Coordinator for Health IT (ONC) have also undertaken efforts to educate providers about EHR fraud vulnerabilities, including conducting sessions with stakeholders on EHR coding and billing.

HHS also finalized a rule to implement the *Medicare Access and CHIP Reauthorization Act of 2015* (MACRA) provisions that replaced the Medicare EHR Incentive Program for eligible professionals with a performance category within Merit Based Incentive Payments System (MIPS). Additionally, HHS is in the process of implementing various provisions of the Cures Act that will facilitate the appropriate flow of complete, accurate, timely, and secure data. OIG will play a role moving forward by using its new civil monetary penalty (CMP) authority to enforce information-blocking violations.

What Needs To Be Done

- CMS must ensure that data collected and relied upon for Medicare program purposes are complete, accurate, timely, and secure, and that evolving technologies, such as telemedicine, achieve their intended results.
- HHS must address barriers to the appropriate flow of complete, accurate, timely, and secure data among providers, beneficiaries, and other stakeholders.
- ONC and CMS should strengthen their collaborative efforts to develop a comprehensive plan to address fraud vulnerabilities in EHRs.
- To the extent that resources, 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 of Medicare FFS while being mindful of minimizing the burdens placed on those implementing the practices.

Key OIG resources

- *Not All Recommended Safeguards Have Been Implemented in Hospital EHR Technology* (OEI-01-11-00570), December 2013.
- *Medicare Could Have Saved Billions at Critical Access Hospitals if Swing-Bed Services Were Reimbursed using the Skilled Nursing Facility Prospective Payment System Rates* (A-05-12-00046), March 2015.
- *The Centers for Medicare and Medicaid Services Could Improve Performance Measures Associated with the Fraud Prevention System* (A-01-15-00509), September 2017.
- *Medicare Paid Hundreds of Millions in Electronic Health Record Incentive Payments That Did Not Comply with Federal Requirements* (A-05-14-00047), June 2017.

3. Ensuring Program Integrity and Effective Administration of Medicaid

Key Components of the Challenge
- Improving the reliability of national Medicaid data
- Reducing improper payments
- Combating fraud
- Ensuring appropriate Medicaid eligibility determinations

Why This Is a Challenge

Medicaid is the largest Federal healthcare program, with 67 million individuals enrolled, and represents one-sixth of the national health economy. Medicaid is administered by States, according to Federal requirements. The program is funded jointly by the Federal Government and States. For FY 2017, CMS estimated Federal and State Medicaid expenditures of $592 billion. Expenditures are projected to increase at an average annual rate of 5.7 percent and reach over $1 trillion by 2026. Effectively administering the Medicaid program takes on heightened urgency as it continues to grow in spending and the number of beneficiaries served. The Department provides States with flexibility to administer their Medicaid programs, so they can design innovative waivers based on the unique needs of their Medicaid enrollees *(see TMC #4 for more information on challenges specific to managed care)*.

Improving the reliability of national Medicaid data

Key Components of the Challenge

Data is an essential tool for detecting fraud, waste, and abuse and administering the program effectively and efficiently. However, OIG's work has identified numerous issues with the completeness and reliability of Medicaid data. The lack of reliable national Medicaid data hampers States', CMS's, and other stakeholders' ability to quickly detect potential fraud, waste, or quality concerns at the State, multi-State, and national levels. While all 50 States, the District of Columbia, and Puerto Rico are now reporting Transformed Medicaid Statistical Information System (T-MSIS) data, data must be reliable, timely, and accurate to be of use to States, CMS, and other stakeholders in making comparisons across all States and identifying national trends and vulnerabilities.

Progress in Addressing the Challenge

CMS's efforts to work with States to report T-MSIS data has led to all 50 States, the District of Columbia, and Puerto Rico now reporting T-MSIS data. CMS also reported efforts underway to improve T-MSIS data through various data quality methods. On August 10, 2018, CMS issued a State Health Official letter that provided additional guidance to States on T-MSIS implementation. The letter stated that CMS expects States to resolve data quality for 12 top-priority items no later than 6 months after the date of the letter; for any State that cannot meet that timeframe, CMS would request a corrective action plan. CMS also anticipates making T-MSIS research-ready files available in 2019.

What Needs To Be Done

- CMS and States need to make complete, reliable, accurate, and timely T-MSIS data a management priority. In doing so, CMS should establish and adhere to a deadline for when national T-MSIS data will be available for program oversight and management.
- CMS must ensure that the same data elements are consistently reported and uniformly interpreted across States and use its enforcement authorities when States are not submitting timely and complete data.

Reducing improper payments

Key Components of the Challenge

Reducing improper payments to providers is a critical element in protecting the financial integrity of the Medicaid program. In FY 2017, HHS reported that it did meet the FY 2016 reduction target of 9.57 percent and reported an actual 10.10 percent improper payment rate in the Medicaid program. CMS must do more to ensure that Medicaid payments are made to the right providers, for the right amounts, for the right services, on behalf of the right beneficiaries. OIG audits have identified substantial improper payments to providers across a variety of Medicaid services, including school-based services, nonemergency medical transportation, targeted case management services, and personal care services.

Progress in Addressing the Challenge

CMS has engaged with State Medicaid agencies to develop corrective action plans that address State-specific reasons for improper payments as a part of CMS's Payment Error Rate Measurement (PERM) program, which measures Medicaid improper payments. In 2018, CMS also resumed the Medicaid Eligibility Quality Control program requiring States to engage in pilots studying certain eligibility determinations for accuracy, a program meant to complement State PERM reviews. CMS also engaged a contractor to design an Express Lane Eligibility error rate measurement methodology for States. CMS also has facilitated national best practices calls to share ideas across States, provided State education through the Medicaid Integrity Institute, offered ongoing technical assistance, and provided additional guidance as needed to address the root causes of improper payments. Time will tell whether CMS's efforts to measure and provide guidance yield reductions in improper payments.

What Needs To Be Done

- CMS should continue to engage with State Medicaid agencies to develop corrective action plans and provide specific guidance to States regarding services and benefits most vulnerable to improper payments.

Combating fraud

Key Components of the Challenge

A useful strategy to prevent Medicaid provider fraud is to keep bad actors intent on committing fraud from enrolling in the program. However, States are not screening high-risk providers with all the tools at their disposal, including site visits and required fingerprint-based criminal background checks during enrollment. In addition, sharing enrollment data across States and with Medicare enrollment data systems would streamline the Medicaid enrollment process and reduce the chance for error within any one database. Also, national Medicaid data can be used to identify fraud schemes and other vulnerabilities that cross State lines. Identifying such schemes in one State can alert other States to patterns of fraudulent or abusive practices that may be occurring in their jurisdiction. However, the lack of reliable national Medicaid data hampers enforcement efforts. For example, OIG published a data brief identifying concerns about extreme use and questionable prescribing of opioids in Medicare Part D. Unfortunately, OIG currently cannot replicate this type of analysis at a national level in Medicaid without national data such as what has been promised through T-MSIS.

Progress in Addressing the Challenge

CMS actively works with States on site visits and fingerprint-based criminal background checks to identify barriers related to State implementation and compliance with Federal requirements. This work includes issuing guidance, known as the *Medicaid Provider Enrollment Compendium*, to assist States in strengthening their provider screening and enrollment processes. To further streamline Medicaid provider enrollment, CMS has employed the use of a data compare tool, which allows States to compare their provider population against the data on those providers already screened and enrolled in Medicare. CMS also engages with States at least monthly via technical assistance calls when concerns, questions, and best practices are addressed and shared.

What Needs To Be Done

- CMS should continue to work directly with States to implement tools like site visits or fingerprint-based criminal background checks for high-risk providers.
- CMS should develop a central repository or "one-stop shop" with provider information that all States and Medicare can use. This could reduce data-collection duplication and burdens on States and providers and improve the completeness and accuracy of the data available to these programs.
- CMS should establish a deadline for when national T-MSIS data will be available for multistate program integrity efforts.

Ensuring appropriate Medicaid eligibility determinations

Key Components of the Challenge

CMS faces challenges in ensuring that States appropriately apply criteria for Medicaid eligibility. The Affordable Care Act allowed States to expand Medicaid eligibility for certain low-income adults and claim a higher Federal Medical Assistance Percentage for those who are newly eligible under the expansion. OIG reviews in three States estimated that more than $1.2 billion in Federal Medicaid payments has been made on behalf of potentially ineligible and ineligible beneficiaries. Lack of beneficiary eligibility systems functionality was a key contributor to these payments.

Progress in Addressing the Challenge

CMS indicated that it will initiate audits of State beneficiary eligibility determinations in States previously reviewed by OIG and will resume measuring eligibility under the PERM program in FY 2019. These audits will include an assessment of the impact of changes to State eligibility policies because of Medicaid expansion; for example, CMS will review whether beneficiaries were found eligible for the correct Medicaid eligibility category.

What Needs To Be Done

- CMS should closely monitor States to ensure they are correctly determining Medicaid eligibility for beneficiaries.
- CMS should continue to work with States to ensure that eligibility systems are able to verify eligibility, develop and implement written policies and procedures to address vulnerabilities, and undertake redeterminations as appropriate.

Key OIG resources

- *Status Update: T-MSIS Data Not Yet Available for Overseeing Medicaid* (OEI-05-15-00050), June 2017.
- *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 2017 (*A-17-18-52000*), May 2018.*
- *Medicaid Fraud and Overpayments: Problems and Solutions* (OIG Testimony), June 2018.
- *Improper Payments in State-Administered Programs: Medicaid* (OIG Testimony), April 2018.
- *Medicaid Enhanced Provider Enrollment Screenings Have Not Been Fully Implemented* (OEI-05-13-00520), May 2016.
- *New York Did Not Correctly Determine Medicaid Eligibility for Some Newly Enrolled Beneficiaries* (A-02-15-01015), January 2018.
- *California Made Medicaid Payments on Behalf of Newly Eligible Beneficiaries Who Did Not Meet Federal and State Requirements (*A-09-16-02023*), February 2018.*
- *New Jersey Claimed Hundreds of Millions in Unallowable or Unsupported Medicaid School-Based Reimbursement (*A-02-15-01010*), November 2017.*

4. Ensuring Value and Integrity in Managed Care and Other Innovative Healthcare Payment and Service Delivery Models

Key Components of the Challenge
- Ensuring effectiveness and integrity in new models
- Combatting provider fraud and abuse
- Fostering compliance by managed care organizations

Why This Is a Challenge

The HHS Secretary has made the transition to value-based care a top priority for the Department. HHS continues to enact reforms in Medicare and Medicaid that are designed to promote quality and value of care. Understanding what constitutes value and whether it is delivered is a challenge in complex healthcare programs and services. As managed care continues to play an increasingly important role in the Medicare and Medicaid programs, ensuring that beneficiaries get the services they need is essential. Finally, developing and implementing managed care and other innovative models in ways that promote innovation and effectiveness, while also protecting against fraud, waste, and abuse, is a significant challenge.

Ensuring effectiveness and integrity in new models

Key Components of the Challenge

HHS continues to seek innovative ways to move Medicare and Medicaid from volume-based payment to value-based payment. This shift involves the design of new systems, including through experimentation and development of new payment and coordinated care approaches. Developing effective incentives and policies can be difficult given complexities of the programs, the populations they serve, and the national healthcare system. HHS faces obstacles in correctly measuring the value of care. It can be a challenge to design measures that effectively incentivize high-quality care without being overly prescriptive or burdensome to providers. The Department is exploring—via a Deputy Secretary led Regulatory Sprint to Coordinated Care—whether better care coordination can be fostered through changes to existing laws that some view as barriers to coordination, including certain fraud and abuse laws administered by CMS and OIG, as well as certain SAMHSA and Office for Civil Rights (OCR) regulations.

CMS continues to manage a range of programs and test models through the Center for Medicare and Medicaid Innovation that address value-driven system reforms to improve quality of care in Medicare and Medicaid and reduce expenditures. New payment structures, business arrangements among providers, and incentives all give rise to risk-management challenges. In pursuing innovative models to improve the healthcare system, CMS must take steps to prevent programs and policies from having unintended consequences, such as misaligned incentives or abusive practices.

Progress in Addressing the Challenge

CMS continues to develop and administer new models and existing models and value-based programs, such as the Quality Payment Program and the Medicare Shared Savings Program. CMS has proposed changes to the Medicare Shared Savings Program to increase savings for the Trust Funds and mitigate losses, reduce gaming opportunity, and increase program integrity. CMS continues to coordinate with OIG on tailored waivers of fraud and abuse laws, where needed and authorized, to test and carry out

value-based models. HHS has published Requests for Information to seek stakeholder input on ways to revise certain fraud and abuse laws to promote care coordination without undermining their original fraud prevention purposes.

In 2017, CMS launched the Meaningful Measures Initiative. CMS has sought to enhance quality measurement by focusing on high-impact areas for quality improvement, identifying outcome-based measures that are most useful to patients and clinicians, minimizing the level of provider burden, and aligning the measures across programs.

What Needs To Be Done

- In testing value-based care models, CMS must continue to focus on program integrity risks, incorporate safeguards to reduce them, and promptly correct identified issues. This is especially important for models that introduce new payment incentives, which might lead to new fraud schemes, and for models for which waivers of payment, coverage, or fraud and abuse laws may have been issued.
- Where applicable, CMS must clearly define actionable and meaningful quality measures, ensuring their reliability and accuracy. CMS and other agencies currently using quality measurements should further align these efforts to reduce unnecessary provider burden.
- Moving forward, HHS will need to ensure that any metrics are effective, evidence-based measures for quality improvement.

Combatting provider fraud and abuse

Key Components of the Challenge

Managed care is the primary delivery system for Medicaid and covers approximately 80 percent of all enrollees. In Medicare, one-third of beneficiaries are enrolled in Medicare Advantage Organizations (MAOs). Fraud, waste, and abuse in Medicaid and Medicare cost taxpayers billions of dollars every year. MAOs and Medicaid Managed Care Organizations (MCOs) are essential to safeguarding the Medicare and Medicaid programs and taxpayer dollars. However, weaknesses exist in their efforts to identify and address fraud and abuse. Limitations in Medicare and Medicaid encounter data also hinder efficient and effective program oversight and program integrity *(see TMC #3 for more information on Medicaid data limitations)*. In addition, CMS does not require MAOs to include the identifiers for ordering and referring providers in their encounter data submissions, which makes it more difficult to detect potential fraud, waste, and abuse through data analytics.

Managed care plans often fail to effectively identify and address fraud and abuse by their providers. CMS requires MAOs and Medicaid MCOs to implement compliance plans that include measures to prevent, detect, and correct instances of fraud, waste, and abuse; however, these vary widely among the plans, as does the detection of suspected fraud. In Medicaid managed care, program integrity responsibilities are even more dispersed, as they are shared among CMS, States, and MCOs. This makes effective oversight by CMS more complex and challenging.

Progress in Addressing the Challenge

CMS is working to validate the completeness and accuracy of MAO and Medicaid MCO encounter data. CMS has increased its efforts to enhance data accuracy and recently released best practice guidance for MAOs to improve encounter data submission. CMS is also working with States to provide technical

assistance and education to identify and share best practices for improving Medicaid MCO identification and referral of cases of suspected fraud or abuse.

CMS conducts State Program Integrity Reviews, which include State oversight of Medicaid MCOs and compliance with applicable Federal regulations. For those States not compliant, CMS has provided technical assistance and requested corrective plans to address any identified concerns.

What Needs To Be Done

- CMS should take further actions to ensure the completeness, validity, and timeliness of MAO and Medicaid encounter data. This includes requiring MAOs to report identifiers for ordering and referring providers. Having comprehensive data is crucial to safeguard the programs' integrity and solvency and to ensure that beneficiaries are receiving quality care.
- CMS should work with its contractors and with States to make improvements in efforts to identify and address fraud and abuse.
- CMS should work to ensure that appropriate information and referrals are sent to law enforcement.

Fostering compliance by managed care organizations

Key Components of the Challenge

HHS must be vigilant about risks posed to HHS funds and beneficiaries by MAOs and Medicaid MCOs contracted to deliver healthcare services. These entities have incentives to maximize the capitated payments received while minimizing their costs in providing healthcare services. In Medicaid, OIG has found significant vulnerabilities in provider availability, which is a key indicator for access to care. Without adequate access, enrollees cannot receive the preventive care and treatment necessary to achieve positive health outcomes and improved quality of care. In Medicare, OIG found high rates of appealed denials are overturned, and CMS commonly cites MAOs for inappropriate denials in its audits. This raises concerns that some beneficiaries and providers may not be getting services and payments that MAOs are required to authorize under the Medicare program.

Progress in Addressing the Challenge

CMS has initiated audits to ensure that Medicaid MCOs are complying with the medical loss ratio standard that they spend at least 85 percent of their capitation rate on medical care and activities that improve beneficiary quality of care. CMS is also working to ensure that beneficiaries have adequate access to providers. For example, CMS requires State Medicaid agencies to develop and implement provisions that ensure beneficiaries have adequate access to Medicaid covered services. Furthermore, CMS published a toolkit and resource guide to assist States with ensuring adequate provider networks. In 2017, CMS issued guidance and best practices regarding increasing the accuracy of provider directories and stated that it plans to perform directory monitoring activities that could result in enforcement actions for MAOs.

What Needs To Be Done

- CMS should work with States and MAOs to see that plans' networks are substantial enough to ensure timely access to care for Medicaid and Medicare managed care beneficiaries.
- CMS should enhance its oversight of MAO contracts including those with extremely high overturn rates and/or low appeal rates and take corrective action as appropriate.

Key OIG resources

- *Medicare Shared Savings Program Accountable Care Organizations Have Shown Potential for Reducing Spending and Improving Quality* (OEI-02-15-00450), August 2017.
- *CMS Ensured That Medicare Shared Savings Beneficiaries Were Properly Assigned* (A-09-17-03010), October 2017.
- *Early Implementation Review: CMS's Management of the Quality Payment Program* (OEI-12-16-00400), December 2016.
- *Followup Review: CMS's Management of the Quality Payment Program* (OEI-12-17-00350), December 2017.
- *Weaknesses Exist in Medicaid Managed Care Organizations' Efforts to Identify and Address Fraud and Abuse* (OEI-02-15-00260), July 2018.
- *Medicare Advantage Organizations' Identification of Potential Fraud and Abuse* (OEI-03-10-00310), February 2012.
- *Medicare Advantage Encounter Data Show Promise for Program Oversight, But Improvements are Needed* (OEI-03-15-00060), January 2018.
- *The MEDIC Produced Some Positive Results but More Could be Done to Enhance its Effectiveness* (OEI-03-17-00310), July 2018.
- *Access to Care: Provider Availability in Medicaid Managed Care* (OEI-02-13-00670), December 2014.
- *Medicare Advantage Appeal Outcomes and Audit Findings Raise Concerns About Service and Payment Denials* (OEI-09-16-00410), September 2018.

5. Protecting the Health and Safety of Vulnerable Populations

Why This Is a Challenge

HHS programs provide critical health and human services to many vulnerable populations in many different settings. Therefore, HHS must ensure that the individuals in HHS programs have access to and receive high-quality care and services and are protected from abuse or neglect.

HHS, through the Administration for Children and Families' (ACF's) Office of Refugee Resettlement (ORR), is responsible for the ensuring the shelter and care of thousands of unaccompanied alien children (UAC) who enter the U.S. without legal status. ACF also administers the Child Care and Development Fund (CCDF) program and provides funding to State foster care programs. Ensuring that these children have access to safe, high-quality care remains a longstanding challenge for HHS.

Key Components of the Challenge

- Ensuring the safety and security of unaccompanied children in HHS care
- Addressing substandard nursing home care
- Reducing problems in hospice care
- Mitigating risks to individuals receiving home- and community-based services
- Ensuring access to safe and appropriate services for children
- Addressing serious mental illness

Additionally, healthcare providers such as nursing homes, group homes, and hospices have continued to experience issues with ensuring quality of care and safety for vulnerable individuals. HHS has not always acted to correct deficiencies in these facilities.

Ensuring the safety and security of unaccompanied children in HHS care

Key Components of the Challenge

Most UAC are initially taken into custody by the Department of Homeland Security (DHS) at the U.S. border and transferred into ORR's custody. ORR provides temporary shelter, care, and other related services to UAC, often in facilities operated by grantees that receive funding from ORR. HHS has encountered challenges caring for UAC in ORR grantee facilities, especially when the UAC program experiences a sudden surge in the number and/or needs of children. In FY 2017 alone, more than 40,000 UAC were referred to ORR custody, a dramatic increase from the 13,625 UAC referred in FY 2012.[38] Challenges also exist to ensuring the safety and well-being of UACs after being released to sponsors.

OIG reviews of ORR grantees determined that some grantees may not have complied with certain program requirements, including releasing children to sponsors without conducting all required background checks and documentating that public record checks were conducted on sponsors. As a result, ORR does not have assurance that all grantees properly released children to sponsors.

[38] ORR, "Facts and Data," June 25, 2018. Accessed at: https://www.acf.hhs.gov/orr/about/ucs/facts-and-data.

Progress in Addressing the Challenge

HHS has increased its efforts to promote the safety and well-being of UAC after their release from HHS care. ORR continues to provide case management services to the most vulnerable children; additionally, ORR now attempts to contact children and sponsors 30 days after release and operates helplines available to all children and sponsors.

HHS has also improved its coordination with DHS related to UAC. In February 2016, HHS and DHS signed a formal agreement to outline each Department's roles and responsibilities related to UAC. In 2017, OIG also reported that HHS had improved its coordination with DHS and increased its efforts to promote the safety and well-being of UAC after their release from HHS custody.

What Needs To Be Done

- ACF should continue to ensure the health and safety of children in ORR care, especially when the program experiences a sudden change in the number and/or needs of children.
- OIG will continue to provide oversight of the UAC program. For instance, OIG is conducting ongoing audits of ORR facilities' compliance with health and safety requirements as well as internal financial controls. OIG is also conducting a review focusing on the care and well-being of children residing in ORR-funded facilities.
- OIG will continue to examine instances of potential criminal misconduct to determine whether an investigation or referral is needed.

Addressing substandard nursing home care

Key Components of the Challenge

Many nursing home residents are at risk of abuse and neglect. OIG identified instances of nursing facilities' failing to identify and report abuse and neglect as required, as well as deficiencies in procedures for enforcing requirements. For example, OIG identified 134 Medicare beneficiaries whose injuries may have been the result of potential abuse or neglect that occurred from January 1, 2015, through December 31, 2016. OIG also identified instances where States fell short in conducting investigations of serious nursing home complaints within required timeframes.

Progress in Addressing the Challenge

HHS has taken steps to promote quality and prevent abuse and neglect. This includes making progress in developing the SNF Value-Based Purchasing Program, planned for launch in FY 2019. HHS has improved reporting of accurate nursing home quality information through the Nursing Home Compare Program and Five-Star Quality Rating System. HHS also works closely with law enforcement partners at DOJ and the Elder Justice Interagency Working Group to promote better care for older adults and to prosecute providers that subject them to abuse or neglect.

CMS has revised its requirements and guidelines for nursing home surveyors to focus on assessing adverse event identification and reductions. To help raise awareness of adverse events in post-acute care, CMS collaborated with the Agency for Healthcare Research and Quality to promote and create a final list of potential nursing home events. Additionally, OIG has entered quality-of-care corporate integrity agreements with more than 40 nursing home companies covering more than 1,000 facilities. These agreements require providers to retain an independent monitor to perform clinical and quality reviews and assessments of the delivery of quality healthcare.

What Needs To Be Done

- HHS should implement strategies to strengthen oversight of nursing homes and improve nursing care. For example, HHS should monitor how often nursing home residents are hospitalized and develop additional resources to help providers avoid adverse events.
- HHS must improve internal controls, as well as surveyor guidance and training, to ensure that nursing homes correct deficiencies and prevent recurrence of safety and quality issues.
- CMS should improve identification and reporting of nursing home resident abuse and neglect. For instance, CMS should take immediate action to ensure that incidents of potential abuse or neglect of Medicare beneficiaries residing in SNFs are identified and reported.
- To reduce incidence of adverse events, CMS should instruct nursing home surveyors to review facility practices for identifying and reducing adverse events, as well as assist States that are failing to meet timeframes for investigating nursing home complaints.

Reducing problems in hospice care

Key Components of the Challenge

OIG's body of work on the Medicare hospice benefit has identified numerous quality of care problems for Medicare beneficiaries in the hospice general inpatient care setting. For example, OIG found that most beneficiaries, including beneficiaries with complex needs, do not see a hospice physician, and key services to control pain and manage symptoms are sometimes lacking. OIG also raised concerns about hospice beneficiaries and their caregivers not receiving the information they need to make informed decisions.

Additionally, investigations have uncovered hospices enrolling patients without the beneficiary's knowledge or under false pretenses, enrolling beneficiaries who are not terminally ill, billing for services not provided, paying kickbacks, and falsifying documentation.

Progress in Addressing the Challenge

HHS launched the Hospice Compare web site to facilitate public access to hospice quality data. Medicare Administrative Contractors have targeted their monitoring toward hospices that rely heavily on nursing facility residents. By seeking out these residents, hospices may be looking to increase their profits by only serving beneficiaries associated with longer but less complex care. Additionally, HHS is also taking enforcement actions against hospices fraudulently enrolling beneficiaries.

What Needs To Be Done

- CMS should improve quality of care and consumer protections by strengthening the survey process. This will better ensure that hospices provide beneficiaries with needed services and quality care.
- CMS should promote physician involvement and accountability to guarantee that beneficiaries receive appropriate care, as well as take steps to tie payments to beneficiary care needs and quality of care to confirm that services rendered adequately serve beneficiaries' needs.
- CMS can take steps to make available consumer-friendly information that explains the hospice benefit to families and caregivers.

Mitigating risks to individuals receiving home- and community-based services

Key Components of the Challenge

In recent decades, healthcare has shifted from institutional care settings to more community-based services and support, such as group homes. These settings provide beneficiaries greater independence, increased flexibility for providers, and access to more opportunities than in an institutional setting. However, OIG has found that group home health and safety policies and procedures are not always followed, leaving beneficiaries at risk of serious harm. This is a systemic problem; in recent years, 49 States had media reports of health and safety problems in group homes.[39]

Payment and quality vulnerabilities also exist in home settings. Reported fraud and abuse incidents in personal care services (PCS) are a substantial and growing percentage of MFCU cases and outcomes. OIG work has demonstrated that existing program safeguards intended to ensure medical necessity, patient safety, and quality and prevent improper payments were often ineffective. In addition, OIG interviews with Medicaid beneficiaries revealed quality-of-care concerns including serious allegations including physical abuse or threats of abuse, property theft, and patient abandonment. Without proper control and oversight mechanisms, unscrupulous attendants could expose beneficiaries to substandard quality of care and injury.

Progress in Addressing the Challenge

In an HHS joint report, the Administration for Community Living (ACL), the HHS OCR, and OIG developed Model Practices that provide States with a roadmap for how to implement better health and safety practices. The report provides States with models for incident management and investigation, incident management audits, mortality reviews, and quality assurance.[15] In response to the Joint Report's suggestions, CMS issued an Informational Bulletin in June 2018 to encourage States to implement compliance oversight programs for group homes, such as the Model Practices.[40]

HHS is working with MFCUs to prevent, detect, and take enforcement action against PCS providers suspected of fraud or abuse. The Cures Act mandated that CMS implement the electronic visit verification (EVV) system for all Medicaid PCS and home health services that require an in-home visit by a provider.[41] CMS reported that it currently has reviewed 30 advance planning documents (APDs) from 31 States (including the Arizona and Hawaii joint APD), and 11 States have implemented EVV.

What Needs To Be Done

- CMS should continue to implement the Model Practices outlined in the HHS joint report. CMS needs to take immediate action in response to serious health and safety findings in home- and community-based services providers.
- CMS must also help ensure successful State implementation of EVV for all Medicaid PCS by January 1, 2020, and for home health services by January 1, 2023.
- CMS should issue policies and procedures to ensure effective reporting of critical incidents.

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[39] OIG, ACL, OCR, *Ensuring Beneficiary Health and Safety in Group Homes Through State Implementation of Comprehensive Compliance Oversight*, January 2018. Accessed at: https://www.hhs.gov/sites/default/files/report_joint_report_hcbs.pdf.
[40] CMS, CMCS Informational Bulletin, June 2018. Accessed at: https://www.medicaid.gov/federal-policy-guidance/downloads/cib062818.pdf.
[41] CMS, Electronic Site Visit Verification. Accessed at: https://www.medicaid.gov/medicaid/hcbs/guidance/electronic-visit-verification/index.html.

Ensuring access to safe and appropriate services for children

Key Components of the Challenge

OIG has identified vulnerabilities related to CCDF childcare providers who received neither a verified background check nor the necessary training, based on State requirements in place prior to changes in Federal requirements. In addition, OIG audits conducted in 10 States found that 96 percent of CCDF childcare providers visited had at least one health and safety violation. OIG also found that more ACF oversight of States' CCDF programs is needed. For instance, some States' monitoring requirements for CCDF childcare providers did not always meet recommendations issued by ACF prior to changes in Federal requirements. States also reported limitations in technology, resources, and coordination as challenges to program integrity. Taken together, these findings highlight the need for stronger ACF and State oversight to ensure that safe, high-quality care is provided to children.

In State foster care programs, OIG found that nearly one-third of children in foster care enrolled in Medicaid did not receive required health screenings. Additionally, some States' protocols for the use and monitoring of psychotropic medications for children in foster care were lacking treatment planning and medication monitoring. OIG has also identified instances in which States did not always ensure that documentation existed that Title IV-E eligible children received required healthcare and case management services.

Progress in Addressing the Challenge

HHS is working with States to implement expanded background checks for childcare providers mandated by the reauthorization of the *Child Care and Development Block Grant Act of 2014*. States are in the process of designing and implementing health and safety training for all providers before care begins and ongoing as professional development. HHS is also implementing a new on-site monitoring process to ensure that States are meeting Federal childcare requirements.

ACF continues to provide oversight of State compliance with Federal healthcare oversight requirements for children in foster care through ongoing program administration, and on-site monitoring through Child and Family Services Reviews, and technical assistance to State child welfare agencies to promote best practices. Additionally, ACF plans to engage State foster care managers to discuss how to improve oversight of psychotropic medications for children in foster care. CMS is also working with States to reduce inappropriate prescribing of antipsychotic drugs for children in foster care and to improve access to dental care for children in Medicaid.

What Needs To Be Done

- ACF needs to ensure that States are complying with required health and safety standards for childcare providers and examine the effectiveness of program integrity and fraud-fighting activities.
- ACF needs to improve its oversight of State foster care programs to ensure that children are receiving required health screenings in a timely manner, as well as treatment planning and medication monitoring. Specifically, ACF should improve compliance and strengthen State requirements to protect children at risk for inappropriate psychotropic medication treatment and prescribing.

Addressing serious mental illness

Key Components of the Challenge

In 2016, nearly one in five adults aged 18 or older in the U.S. (about 44.7 million) lived with a mental illness, and only 43 percent (about 19.2 million) of these adults received mental health treatment in the prior year. Additionally, in 2016, roughly 1 in 25 adults (about 9.8 million) in the U.S., age 18 and older, battled a serious mental illness, such as a psychotic or major depressive disorder.

Medicare and Medicaid both serve significant patient populations in need of mental health services. However, beneficiaries may experience barriers to accessing care, including being limited both geographically and by type of service. The Interdepartmental Serious Mental Illness Coordinating Committee has found that relatively few adults with serious mental illness receive effective treatments, effective treatment models that exist are not widely available, most counties in the U.S. face shortages of mental health professionals, and most States report insufficient psychiatric crisis response capacity as well as insufficient numbers of psychiatric hospital beds.[42] OIG has ongoing work examining reported access issues in certain State Medicaid managed care programs.

Progress in Addressing the Challenge

As required under the Cures Act, HHS released the Action Plan for Enhanced Enforcement of Mental Health and Substance Use Disorder Coverage in April 2018, which focuses on improvement of Federal and State coordination related to the enforcement of certain mental health and substance use disorder parity provisions. The Cures Act also authorized a new Assertive Community Treatment grant program for individuals with a serious mental illness, which helps communities improve behavioral health outcomes by reducing hospitalization rates of patients with serious mental illness.[43]

In addition, mental healthcare has been included in Essential Health Benefits since January 1, 2014. The Mental Health Parity and Addiction Equity Act (P.L. 110-343) requires Medicaid and CHIP programs to comply with mental health and substance use disorder parity requirements. On March 29, 2016, CMS published a final rule applying these requirements to certain Medicaid plans and all CHIP programs, resulting in the expansion of parity protections to about 23 million more individuals.[44] In 2016, HHS participated in the White House Mental Health and Substance Abuse Disorder Parity Task Force, which issued recommendations to Federal agencies on supporting consumers, improving parity implementation, and enhancing parity compliance and enforcement.[45] In response to the Parity Task Force's findings, HHS created a Mental Health and Substance Abuse Disorder Parity website, which provides parity-specific resources to consumers and providers, as well as updates on new ways Federal agencies enforce and clarify parity regulations.[46]

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[42] Interdepartmental Serious Mental Illness Coordinating Committee, *The Way Forward: Federal Action for a System That Works for All People Living With SMI and SED and Their Families and Caregivers*, December 2017. Accessible at https://www.samhsa.gov/sites/default/files/programs_campaigns/ismicc_2017_report_to_congress.pdf

[43] HHS, *FY2019 Budget in Brief*, February 19, 2018. Accessed at: https://www.hhs.gov/sites/default/files/fy-2019-budget-in-brief.pdf.

[44] Federal Register, March 29, 2016. Accessed at: https://www.federalregister.gov/documents/2016/03/30/2016-06876/medicaid-andchildrens-health-insurance-programs-mental-health-parity-and-addiction-equity-act-of

[45] White House Mental Health and Substance Use Disorder Parity Task Force, *Final Report*, October 2016. Accessed at: https://www.hhs.gov/sites/default/files/mental-health-substance-use-disorder-parity-task-force-final-report.PDF.

[46] HHS, Mental Health and Substance Use Disorder Parity. Accessed at: https://www.hhs.gov/programs/topic-sites/mental-health-parity/index.html.

HHS is increasing grant funding to develop strategies to expand access to mental health services and for mental health awareness training. New methods, including telemedicine, are also increasingly used to provide increased mental health access, particularly in rural areas. The *Bipartisan Budget Act of 2018* expanded telehealth services for Medicare Advantage plans and Accountable Care Organizations.

What Needs To Be Done

- While HHS agencies have taken steps to increase mental health parity and funding for mental health services, they can take additional steps to increase the access and quality of mental health services, particularly for serious mental illness.
- CMS should improve efforts to ensure beneficiaries have appropriate access to mental health services and to reduce barriers to care.
- HHS can take steps to implement the Mental Health and Substance Abuse Disorder Parity Task Force's recommendations.

Key OIG resources

- *Florence Crittenton Services of Orange County, Inc., Did Not Always Meet Applicable Safety Standards Related to Unaccompanied Alien Children* (A-09-16-01005), June 2018.
- *HHS's Office of Refugee Resettlement Improved Coordination and Outreach to Promote the Safety and Well-Being of Unaccompanied Alien Children* (OEI-09-16-00260), July 2017.
- *Early Alert: CMS Has Inadequate Procedures to Ensure That Incidents of Potential Abuse or Neglect at Skilled Nursing Facilities Are Identified and Reported in Accordance With Applicable Requirements* (A-01-17-00504), August 2017.
- *Vulnerabilities in the Medicare Hospice Program Affect Quality Care and Program integrity: An OIG Portfolio* (OEI-02-16-00570), July 2018.
- *Some WA State Group-Care Facilities for Children in Foster Care Did Not Always Comply with State Health and Safety Requirements* (A-09-16-01006), March 2018.
- Series of OIG reports on childcare providers' compliance with State health and safety requirements (http://oig.hhs.gov/oas/child-care/).
- *Child Care and Development Fund: Monitoring of Licensed Child Care Providers* (OEI-07-10-00230), November 2013.
- *More Effort Is Needed to Protect the Integrity of Child Care and Development Fund* (OEI-03-16-00150), July 2016.
- *Treatment Planning and Medication Monitoring Were Lacking for Children in Foster Care Receiving Psychotropic Medication* (OEI-07-15-00380), September 2018.
- *Ohio Did Not Always Comply with Requirements Related to the Case Management of Children in Foster Care* (A-05-16-00022), May 2018.
- *Oklahoma Did Not Always Comply with Requirements for Providing Health Care Services to Children in Foster Care* (A-06-16-07006), February 2018.

6. Improving Financial and Administrative Management and Reducing Improper Payments

Key Components of the Challenge
- Addressing weaknesses in financial management systems
- Addressing Medicare trust fund issues/social insurance
- Reducing improper payments
- Improving contract management
- Implementing the DATA Act

Why This Is a Challenge

HHS is the largest civilian agency in the Federal Government. In FY 2017, HHS reported total budgetary resources of approximately $1.1 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. Due to their size, HHS programs account for some of the largest estimated improper payment amounts. 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.

Addressing weaknesses in financial management systems

Key Components of the Challenge

OIG continues to report a material weakness in HHS's financial management systems related to inadequate internal controls over segregation of duties, configuration management for approved changes to HHS financial systems, and access to HHS financial systems. OIG continues to report that HHS does not substantially comply with requirements for financial system management because of these issues. Under the *Federal Financial Management Improvement Act of 1996*, Federal agencies must establish and maintain financial management systems and OIGs must report on compliance by their respective agency. These systems help agencies ensure operational effectiveness and efficiency, financial reporting reliability, and compliance with applicable laws and regulations.

Progress in Addressing the Challenge

HHS has continued to take corrective actions to resolve the IT-related deficiencies reported in the Agency Financial Report (AFR). In FY 2017, the Information Technology Material Weakness Working Group continued its HHS-wide focus on corrective actions. As a result, many prior-year control deficiencies related to user access, configuration management, and segregation of duties have improved. OIG noted investments and other actions that led to the remediation of these findings and which should improve internal controls over key financial management systems.

What Needs To Be Done

- HHS still needs to take additional actions to address and resolve the material weakness in its financial management systems.
- HHS should continue to work to control user access.
- HHS should ensure proper approval of system changes and maintain appropriate documentation that supports the approval of these changes.
- HHS should ensure appropriate segregation of duties so that no one employee can both enter and approve information entered into HHS financial management systems.

Addressing Medicare trust fund issues/social insurance

Key Components of the Challenge

The Statement of Social Insurance (SOSI) presents the actuarial present value of (1) contributions and tax income (excluding interest income); (2) scheduled expenditures; and (3) the difference between the two for all current and future participants (open group) of the Medicare program for the projection period, which covers 75 years. The Statement of Changes in Social Insurance Amounts (SCSIA) reconciles the beginning and ending open group measures and presents the components of the changes for 2 years. These statements cover the Medicare FFS, Medicare Advantage, and Medicare Prescription Drug Benefit programs, and the amounts they disclose are based on current law. According to the 2018 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, the Trustees assume that the various cost-reduction measures included in the Affordable Care Act will occur as current law requires. The Trustees stated that to achieve this outcome, healthcare providers would have to realize productivity adjustments at a faster rate than experienced historically. The Trustees also stated that should healthcare providers be unable to transition to more efficient models of care delivery and achieve productivity increases commensurate with economy-wide productivity and if the provider reimbursement rates paid by commercial insurers continue to be based on the same negotiated process in use, the availability and quality of healthcare received by Medicare beneficiaries under current law would fall short when compared to private health insurance. The Trustees also stated in the 2018 report that the Federal Hospital Insurance Trust Fund now is expected to be depleted by 2026 and that spending for Federal Supplementary Medical Insurance is expected to exceed inflation in the next 5 years.

The Medicare Board of Trustees included in the Annual Trustees Report an alternative scenario to illustrate, where possible, the potential understatement of Medicare costs and projection results. Since 2010, OIG has noted the inherent difficulties in projecting growth in healthcare costs over time and issued a disclaimer of opinion on the SOSI and SCSIA based on these uncertainties.

Progress in Addressing the Challenge

In FY 2017, HHS continued to present an illustrative alternative scenario to the current legal projections for Medicare to show the potential magnitude on Medicare outlays if certain components of current law are not sustainable. According to the CMS Chief Actuary, the techniques and methodology used to evaluate the financial status of the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund are based on sound principles of actuarial practice. With certain caveats, the principal assumptions used and the resulting actuarial estimates are individually, and in the aggregate, reasonable for evaluating the financial status of the trust funds. The Federal Accounting Standards Advisory Board (FASAB) does not have any active or planned projects that would revise existing guidance related to SOSI. OIG continues to expect to issue a disclaimer of opinion on the SOSI and SCSIA until the variances between income and expenditures between current law and the illustrative alternative scenario become much less significant.

What Needs To Be Done

- HHS should continue to work with the CMS Chief Actuary to analyze *the Patient Protection and Affordable Care Act* and its impact on providers' ability to sustain the productivity adjustments. The ability to sustain these productivity adjustments would greatly narrow the large variance between current law and the illustrative scenario.

- HHS should continue to support actions needed to ensure the long-term viability of the Federal Hospital Insurance Trust Fund.
- HHS should continue to work with FASAB to revise the accounting standards for SOSI and SCSIA.

Reducing improper payments

Key Components of the Challenge

Reducing improper payments is a critical element in protecting the financial integrity of HHS programs. Although not all improper payments constitute 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 estimates on improper payments and their efforts to reduce them for high risk programs. In the FY 2017 AFR, HHS reported improper payments of more than $90 billion for seven of the eight programs designated high risk and susceptible to improper payments. In the audit report of the HHS's FY 2017 AFR, published in May 2018, OIG found that while HHS met many requirements, HHS did not meet all IPIA requirements. Specifically, HHS did not report an improper payment estimate for the Temporary Assistance for Needy Families (TANF) program, as HHS does not believe it has the statutory authority to collect from States the data necessary for calculating such a rate.

In FY 2017, HHS reported that the improper payment rate exceeded 10 percent for the Medicaid program. In addition, two other programs that the Office of Management and Budget (OMB) has deemed susceptible to risk of improper payments (CHIP and Foster Care programs) did not meet their FY 2017 improper payment reduction target error rates *(see TMC #3 for more information on reducing Medicaid improper payments)*.

Progress in Addressing the Challenge

In FY 2017, HHS awarded a 5-year contract for promoting and supporting innovation in TANF data, and one component of this contract is to help HHS and stakeholders better understand how States assess improper payments and ensure program integrity. This assessment will help HHS understand existing State and alternative approaches to estimating improper payments for TANF. CMS's various corrective action efforts brought the Medicare FFS program into compliance with IPIA, resulting in reporting an improper payment estimate of less than 10 percent for the first time in several years. In the case of Medicaid, CMS continues working with the States to develop State-specific corrective action plans. CMS also shared Medicare data to assist States with meeting Medicaid screening and enrollment requirements and provided ongoing guidance, education, and outreach. CMS also offered training, technical assistance, and additional support to improve States' Medicaid program integrity *(see TMC #3 for more information on reducing Medicaid improper payments)*.

What Needs To Be Done

- HHS must continue to pursue needed legislative remedies to develop an appropriate methodology for measuring TANF payment accuracy and report an improper payment estimate for TANF.
- HHS should address and reduce improper payments in the Medicaid program.
- HHS must continue to establish and meet improper payments reduction targets, and report improper payments of less than 10 percent for all programs.

Improving contract management

Key Components of the Challenge

HHS is the fourth largest contracting agency in the Federal Government. In FY 2017, HHS awarded more than $24 billion in contracts across all program areas. These contracts can often have complex strategies involving multiple contractors, making them difficult to manage. Given the high dollar amounts and complexity of its contracts, it is paramount that HHS have strong monitoring and oversight.

However, challenges to the contract systems remain. OIG has identified vulnerabilities in acquisition planning and procurement and contract monitoring. For instance, key HHS contracts may not always undergo Contract Review Board oversight before being awarded, and when awarding contracts, CMS has not always performed thorough reviews of contractors' past performance.

OIG has also raised issues regarding payments to contractors and contract closeouts. In the past, CMS and other agencies have frequently chosen contract types that place the risk of cost increases solely on the Government. Large backlogs of unclosed contracts can pose a significant financial risk to HHS. Finally, HHS has faced obstacles in the oversight and performance measurement of its benefit integrity contractors, which sometimes have substantial differences in the number of investigations initiated and cases referred to law enforcement.

Progress in Addressing the Challenge

HHS has taken steps to enhance its acquisition systems and better monitor contract closeouts and contract payments. CMS's Office of Acquisition and Grants Management (OAGM) has increased productivity on its current backlog and implemented a quarterly closeout report that collects and monitors closeout data from each division. Additionally, CMS has improved the functionality of its Comprehensive Acquisition Management System to better track vendor invoicing.

CMS has also increased its efforts in examining workload statistics for benefit integrity contractors and improving performance outcomes. New investigations in program integrity priority areas (including home health, hospice, and laboratory services) increased from 18 to 25 percent from 2015 to 2016. The percentage of payment suspensions associated with the priority areas increased from 48 to 58 percent during that same time.

What Needs To Be Done

- To reduce vulnerabilities in acquisition planning and procurement, HHS should take steps to ensure that acquisition strategies are completed as required.
- Awarding agencies should assign systems integrators to complex contracts whenever appropriate, and CMS should ensure that its contracts undergo Contract Review Board oversight prior to being awarded.
- HHS must continue to strengthen its contracts oversight to assist in contract closeout and funds management.
- HHS can take further steps to improve coordination and collaboration across departmental staff with contract closeout responsibilities by, for example, establishing and maintaining guidelines for the division of work.

Implementing the DATA Act

Key Components of the Challenge

The Digital Accountability and Transparency Act of 2014 (DATA Act) required OMB and the Department of the Treasury to establish government-wide data standards for reporting financial and payment information by May 2015. Broadly, the DATA Act required that HHS begin using the government-wide data standards to enter information into USASpending.gov by May 2017 to ultimately increase transparency and accountability. The DATA Act also required the Inspector General of each agency to determine the accuracy, completeness, timeliness, and quality of this data. For FY 2017, OIG's audit of compliance with the DATA Act found that HHS complied with data standards established by OMB and the Department of the Treasury and entered the required information into USASpending.gov within the established timeframe. However, OIG found HHS relied on a manual and excessively labor-intensive process to comply with the government-wide data standards and continues to experience issues, as described above, with the information systems that support this data.

Progress in Addressing the Challenge

For FY 2017, HHS met the requirements for data accuracy, completeness, timeliness, and quality as well as complied with the reporting timeline established in the DATA Act.

What Needs To Be Done

- HHS must continue to address the weaknesses in its key financial management systems as described above and limit the need to rely on manual processes to submit the required data.

Key OIG resources

- *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 2017* (A-17-18-52000), May 2018.
- OIG Report on Financial Statement Audit of Health and Human Services for Fiscal Year 2017 (FY 2017 HHS Agency Financial Report), November 2017.
- *CMS Has Not Performed Required Closeouts of Contracts Worth Billions* (OEI-03-12-00680), December 2015.
- *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* (A-03-14-03002), September 2015.
- *U.S. Department of Health and Human Services Met the Requirements of the Digital Accountability and Transparency Act of 2014, but Key Areas Require Improvement* (A-17-17-02018), November 2017.

7. Protecting the Integrity of HHS Grants

Why This Is a Challenge

In FY 2017, HHS awarded $101 billion in grants (excluding CMS). HHS has increasingly used grant programs to address a variety of public health needs and crises, including the opioid epidemic, emergency preparedness, and natural disaster relief efforts *(see TMCs #1 and #12 for more information on these grants)*. This expansion comes with an increased need to effectively manage grant funding. The growth of Federal funding to State and local governments also requires additional verification of existing controls and reporting requirements.

Key Components of the Challenge

- Ensuring appropriate and effective use of grant funds
- Ensuring effective grant management at the department level
- Ensuring program integrity and financial capability at the grantee level
- Combating fraud, waste, and abuse

Ensuring appropriate and effective use of grant funds

Key Components of the Challenge

Administering grant programs requires implementing internal controls to help ensure that program goals are met and funds are used appropriately. This includes oversight of both recipients and sub-recipients. Otherwise, funds can be misspent, duplication of services can occur, and sub-recipients may not be adequately monitored. Grant files must also be kept in an organized, accessible manner, which allows auditors and third-party reviewers to assess program appropriateness and effectiveness in a comprehensive, streamlined manner. OIG consistently identifies fraud and improper payments in the CCDF program.

Progress in Addressing the Challenge

HHS has begun its ReInvent Grants Management initiative as part of ReImagine HHS, a department-wide effort to evaluate how to best perform its mission. This initiative's goal is to re-engineer the entire grant lifecycle to eliminate duplication and waste, and to reduce grantee burden. As part of this initiative, HHS has promoted enhancing performance measurements during application, award, and management processes. The Department is planning to develop analytical methods to allow better assessments of impact and value-based grant funding. HHS has also worked to provide quality assurance guidance to grantees. HRSA, for example, provided more specific guidance to grantees regarding the focus of their quality assurance programs and how they should conduct periodic assessments.

What Needs To Be Done

- HHS must maintain transparency and accountability for Federal funds. This includes ensuring that all HHS agencies maintain official files in accordance with HHS policy.
- Grant programs will need to effectively set baseline expectations and incentivize improvement.
- HHS should also issue an updated Grants Policy Statement that references the Part 75 grant rules and reflects the changes made by that rule.
- HHS must examine States' methods for ensuring that sub-recipients of CCDF funds are adequately performing program integrity activities.
- When necessary, HHS should expand the scope of its State reviews to ensure that compliance with States' CCDF plans are sufficiently assessed.

Ensuring effective grant management at the departmental level

Key Components of the Challenge

HHS is responsible for providing infrastructure for overseeing grants across the Department. Information must be effectively shared across grant programs to both correct for grant-awarding systems that do not interface and prevent the potential duplication of grant missions and funding. To fulfill this responsibility, HHS must collect and maintain timely, accurate, and complete data on grants programs. HHS should also implement OIG recommendations in a timely manner, which will ensure that Federal funds are effectively and efficiently used to carry out only the activities for which they are authorized.

Progress in Addressing the Challenge

In implementing its ReInvent Grants Management initiative, HHS has indicated a move towards outcome-based performance management in its grant process.

HHS is taking steps toward improving the interoperability of its IT systems. The HHS Office of the Assistant Secretary for Financial Resources (ASFR) has conducted an analysis to plan the implementation and usage of integrated databases that contain grantees' past performance data, which will help promote transparency and accountability. In its ReInvent Grants Management initiative, HHS has begun implementing plans to develop a single platform that would streamline data entry and management and align shared services grant systems.

ASFR has taken steps to increase department-wide coordination. For instance, it has taken steps to facilitate department-wide information-sharing regarding grantees with past performance issues, which could help identify and prevent duplicative payments in the future. Additionally, on October 1, 2018, the Department launched the HHS Audit Tracking and Analysis System (ATAS). The system was primarily designed to systematically automate the assignment of Single Audit findings. The implementation of ATAS supports the Department and operating divisions in the timely resolution of Single Audit findings, intra-Department visibility of these findings, and identification of potential grantee risks across Operating Divisions.

What Needs To Be Done

- In implementing its new initiative, the Department will need to set appropriate measurement standards, monitor outcomes, and oversee program integrity.
- HHS must use ASFR's ongoing analysis to guide the full implementation of interoperable grant management systems.
- HHS agencies should continue to use data and technology to improve grant system management.
- HRSA can develop additional data processes that work across the grant management lifecycle to reduce the elevated financial risks of health centers.

Ensuring program integrity and financial capability at the grantee level

Key Components of the Challenge

In managing its many grant programs, HHS is responsible for providing up-to-date policies to grantees, along with addressing States' and other grantees' inadequate financial management and internal controls. OIG has identified grantee-level concerns in many HHS programs, including some UAC program grantees reporting unallowable costs and lacking effective systems for administering program funds; States not sufficiently overseeing their CCDF program payments; and Head Start grantees not properly addressing audit findings. HHS also must hold States accountable to complying with the activities they outline in their specific State plans.

Progress in Addressing the Challenge

HHS has taken steps to improve its outreach and training on financial risk assessments for grant programs. The Department is providing information to HHS Operating Divisions on risk assessments, which they have used to update their policies. HRSA, for example, has updated its risk management process incorporating OIG input. Recently, NIH announced an increased effort to protect the integrity of U.S. biomedical research by partnering with NIH-funded academic institutions, relevant Government agencies, and other stakeholders. The initiative focuses on improving accurate reporting, mitigating risk to intellectual property security, and protecting the integrity of peer review. Furthermore, HHS also continues to conduct provider record reviews and onsite visits. For the CCDF program, States participating in site visits complete a self-assessment on fiscal responsibilities that identifies risks and issues related to program payments, as well as mitigation steps to improve practices. ACF has also implemented a new monitoring process for CCDF to help assess compliance with activities reported in State CCDF plans.

What Needs To Be Done

- HHS awarding agencies should work with States and other grantees to assess and strengthen their program integrity and program evaluation tools. For example, ACF should provide training for Head Start grantees on how to implement corrective action plans and take steps to resolve recurring Head Start Single Audit findings.
- HHS should help increase States and other grantees' fraud-fighting efforts. HRSA, for example, should continue to explore additional steps that it could take to help health centers reduce their elevated financial risk.

Combatting fraud, waste, and abuse

Key Components of the Challenge

HHS faces persistent and heightened challenges in preventing fraud in its grant programs. Without sufficient grantee oversight and internal controls, grants are vulnerable to fraud schemes, including embezzlement.

Progress in Addressing the Challenge

HHS has worked to increase its employees' knowledge of and effectiveness in combatting fraud. For instance, it has collaborated with OIG on training opportunities, including the OIG 2018 Grants Forum, that have focused on topics related to fraud, including suspension and disbarment and how to report potential fraud, waste, and abuse.

HHS has also worked to strengthen some program integrity efforts. For instance, it issued guidance to HHS awarding agencies about facilitating a review of prospective grantees prior to awarding grants. This information enhances awarding agencies' assessment of prospective grant recipients' integrity and potential performance. In addition, the Federal Awardee Performance and Integrity Information System database includes information—such as contractor criminal, civil, and administrative proceedings related to Federal awards, and suspensions and debarments—that will improve HHS's access to information pertaining to contractor misconduct and performance.

Further, HHS awarding agencies have begun reaching out to OIG regarding allegations of fraud. For example, HRSA officials referred allegations to OIG that resulted in significant criminal convictions and recoveries on behalf of HRSA's grant program and shut down a fraud scheme in which Federal funds were being stolen and diverted for personal use.

What Needs To Be Done

- HHS grant programs, grantees, and sub-recipients, in collaboration with OIG, must work to recognize the prevalent fraud schemes and regularly engage in antifraud activities, including reviewing provider records for potential fraud, identifying duplicate payments, performing verification checks, and conducting onsite visits.
- Once identified, HHS, grantees, and grant sub-recipients must continue to refer suspected fraud to OIG.
- All HHS agencies with grant programs should work to increase their number of referrals each year. This collaboration and referrals will allow for the full use of all available enforcement remedies—criminal, civil, and administrative—when fraud, waste, or abuse is identified.

Key OIG resources

- *Not All of Missouri's Child Care Subsidy Program Payments Complied with Federal and State Requirements* (A-07-1504226), November 2017.
- *Texas Did Not Appropriately Spend Some State Balancing Incentive Payments Program Funds* (A-06-15-00041), December 2017.
- *The National Institutes of Health Did Not Always Administer Superfund Appropriations During Fiscal Year 2015 In Accordance With Federal Requirements* (A-04-16-04046), February 2018.
- *The Administration for Children and Families Region II Did Not Always Resolve Head Start Grantees' Single Audit Findings in Accordance With Federal Requirements* (A-02-16-02009), February 2018.
- *HRSA Helped Health Centers with Elevated Risks and Can Continue to Take Additional Steps* (OEI-05-14-00470), May 2018.
- *The Administration for Children and Families Did Not Always Resolve Audit Recommendations In Accordance With Federal Requirements* (A-07-1703225), July 2018.
- *More Effort Is Needed to Protect the Integrity of the Child Care and Development Fund Block Grant Program* (OEI-03-16-00150), July 2016.

8. Ensuring the Safety of Food, Drugs, and Medical Devices

Why This Is a Challenge

FDA has the continuing challenge of ensuring the safety and security of the Nation's food and medical products (including drugs, biological products, and medical devices), which directly affect the health of every American. With an annual budget of more than $5 billion, FDA oversees products that represent about 20 percent of all U.S. consumer spending. FDA has a broad statutory mandate that has continued to expand through recent legislation. The Cures Act, for instance, provided new authorities to help spur medical innovation and modernize medical product regulation throughout a product's lifecycle.

Key Components of the Challenge
- Ensuring food safety
- Ensuring the safety, effectiveness, and quality of drugs and medical devices
- Ensuring the security of drug supply chains

Ensuring food safety

Key Components of the Challenge

Each year roughly 48 million people get sick from a foodborne illness, 128,000 are hospitalized, and 3,000 die.[47] FDA inspects food facilities to ensure food safety and compliance with regulations. Various administrative tools and enforcement authorities can be used to protect the public from unsafe food. However, FDA faces challenges in ensuring that inspections of domestic food facilities are conducted in a timely manner and that significant inspection violations are corrected. FDA has not always used its full enforcement authorities and faces obstacles in maintaining an efficient and effective food recall process.

Progress in Addressing the Challenge

FDA is currently on track to meet the domestic food facility inspection timeframes for the initial cycles mandated by the Food Safety Modernization Act. It has also initiated a new food recall quality system audit process and has developed a plan to provide early notice to the public. FDA also established the Strategic Coordinated Oversight of Recall Execution (SCORE) initiative, a team of FDA senior leaders that examines cases that present significant hazards to human health and makes decisions pertaining to challenging high-risk food-recall cases.

What Needs To Be Done

- FDA should work to keep the food supply safe by creating a process for timely, effective corrections of problems identified during domestic food facility inspections.
- FDA should take appropriate actions against all food facilities with significant inspection violations.
- Procedures should also be in place to guarantee that food recalls are initiated promptly. For example, FDA should use its SCORE initiative to establish set timeframes, expedite decision making and move recall cases forward, and improve electronic recall data.

[47] CDC, Food Safety, Foodborne Illnesses and Germs, February 16, 2018. Available at: https://www.cdc.gov/foodsafety/foodborne-germs.html.

Ensuring the safety, effectiveness, and quality of drugs and medical devices

Key Components of the Challenge

FDA's responsibility to ensure safe and effective medical devices begins before a device is brought to market and continues after FDA approval. This includes overseeing facilities; reviewing drugs, devices, and biologics for safety and efficacy; authorizing the use of investigational medical products; and conducting postmarket surveillance. FDA oversees more than 8,500 drug facilities and 21,000 medical device facilities, and in 2017, FDA approved 56 novel drugs and biologics, 80 first-time generic drugs, 5 biosimilars, and 95 novel medical devices. FDA, in partnership with State authorities, also oversees compounded drugs, which are not subject to FDA's premarket process. It continues to identify issues with the development of compounded drugs.

FDA must make sure that medical devices remain safe and retain an acceptable quality after they have entered the market. This involves adapting to changing technology and reviewing many factors both pre- and post-market release, including any potential cybersecurity threats to medical devices.

Cybersecurity of medical devices is increasingly important for patients' safety and health. With devices increasingly dependent on software and Internet access, procedures to address cybersecurity risks before and after a device is cleared or approved are essential.

Progress in Addressing the Challenge

FDA has worked to implement the tools provided by Congress in the Cures Act to help promote the development of safe and effective medical devices. For example, in December 2016 FDA established the Regenerative Medicine Advanced Therapy designation program as authorized in the Cures Act. Since the RMAT program inception, 24 RMAT Designations have been granted as of June 30, 2018. This program is intended to facilitate efficient development, and expedite review, of certain regenerative medicine therapies for serious conditions through, among other things, early and frequent interactions between FDA and product sponsors.

FDA has improved how it conducts its inspections and reviews. For example, it has increased capacity for inspecting generic drug manufacturers by finalizing its policies and procedures for requesting records in lieu of or in advance of an inspection. Additionally, FDA has increased its efforts to address cybersecurity as part of the pre-market review process. For example, FDA issued guidance on device submissions and cybersecurity in October 2014, which it uses to assist its cybersecurity review. On October 17, 2018, FDA updated its guidance to better help ensure device manufacturers are adequately addressing evolving cybersecurity threats.[48]

FDA has also taken steps to hold drug manufacturers accountable for satisfying regulatory requirements. For instance, it has improved its ability to hold drug manufacturers accountable for fulfilling REMS requirements by identifying and following up on incomplete assessments. For devices, FDA has prioritized development of active surveillance through continuing to build out the National Evaluation System for Health Technology (NEST) which uses real-world evidence to evaluate premarket and postmarket safety, reducing the time and cost of innovative device development, fostering reimbursement, and providing greater patient safeguards at a lower cost.

[48] FDA, FDA In Brief, October 17, 2018. Accessed at: https://www.fda.gov/NewsEvents/Newsroom/FDAInBrief/ucm623624.htm.

What Needs To Be Done

- FDA must continue to ensure timely implementation of the statutory authority granted in the Cures Act. FDA must also continue to take additional steps to improve both the premarket review process and its procedures for responding to postmarket cybersecurity incidents. This should include further integration of cybersecurity assessments into FDA's processes.
- FDA is encouraging device manufacturers to consider cybersecurity risks and implement controls as they create and develop each device to help mitigate potential cybersecurity threats. In addition, FDA should promote the use of early meetings between FDA and device manufacturers to discuss specific cybersecurity questions that manufacturers need to address prior to submitting a device application to FDA.
- FDA should include cybersecurity documentation (such as a threat modeling and cybersecurity risk assessment) as part of the hazard analysis describing a device's cybersecurity risks and controls that a manufacturer has considered, in information that manufacturers are required to submit to FDA for its premarket review.

Ensuring the security of the drug supply chain

Key Components of the Challenge

Drug supply chains continue to grow increasingly complex in both domestic and global markets. As a result, intricate supply chains present FDA with many challenges as drugs face risks of diversion, theft, counterfeiting, and adulteration. This makes open communication and exchange of necessary information even more important. To enhance drug supply chain security, the Drug Supply Chain Security Act (DSCSA) requires trading partners in the drug supply chain to exchange certain information in each drug product transaction and to identify and investigate suspect and illegitimate products.[49] It is therefore expected that the exchange of complete information among trading partners in the drug supply chain will facilitate FDA's investigations, identify harmful medical products, prevent further distribution of adulterated products, and facilitate efficient recalls.

Progress in Addressing the Challenge

Trading partners in the drug supply chain have been exchanging drug product tracing information in each transaction since the requirements to do so took effect in 2015. OIG has found that roughly one-half of wholesalers, including those representing the vast majority of transactions, exchange everything required by FDA. These companies have also developed a variety of methods for exchanging the necessary information. OIG has also found that dispensers are moving toward full implementation of the DSCSA requirements, but that some dispensers may still be unaware of the DSCSA or lack an understanding of their drug product tracing responsibilities.

What Needs To Be Done

- FDA needs to offer more educational and technical assistance to drug wholesale distributors and dispensers on how to best implement the drug product tracing provision of the DSCSA.

[49] Drug Quality and Security Act, P.L. No.113-54, Title II.

Key OIG resources

- *The Food and Drug Administration Food-Recall Process Did Not Always Ensure the Safety of the Nation's Food Supply* (A-01-11-601502), December 2017.
- *Drug Supply Chain Security: Wholesalers Exchange Most Tracing Information (*OEI-05-14-00640), September 2017.
- *Drug Supply Chain Security: Dispensers Received Most Tracing Information* (OEI-05-16-00550), March 2018.
- *The Food and Drug Administration Computed Prescription Drug User Fee Rates Accurately* (A-05-17-00040), June 2018.
- *FDA Should Further Integrate Its Review of Cybersecurity Into the Premarket Review Process for Medical Devices* (OEI-09-16-00220), September 2018.

9. Ensuring Quality and Integrity in Programs Serving American Indian/Alaska Native Populations

Why This Is a Challenge

Many HHS programs provide health and human services to AI/ANs throughout the U.S., with IHS directing the largest amount of targeted funding to AI/AN communities. With a budget of $5.5 billion in FY 2018, IHS is responsible for providing primary and preventive health services to 2.3 million AI/ANs in partnership with the 573 federally recognized Tribes. Other HHS agencies provide grants to Tribes for human services programs, including Head Start and the Low-Income Home Energy Assistance Program (LIHEAP).

Key Components of the Challenge

- Addressing deficiencies in IHS management, infrastructure, and quality of care
- Preventing fraud and misuse of HHS funds serving AI/AN populations

HHS faces significant challenges to ensuring effective delivery of crucial services to AI/AN communities and protecting funds from fraud, waste, and abuse. The AI/AN population historically has had disparate health outcomes compared to the rest of the U.S. population. There have been some important health improvements among the AI/AN population over the past two decades, such as reduced mortality rates from tuberculosis and heart disease, among others. Even with these improvements, AI/ANs continue to face numerous health disparities in comparison to the national population. For instance, the infant mortality rate for AI/ANs is about 25 percent higher than the national rate, and AI/ANs are almost twice as likely as the overall population to have diabetes. AI/AN populations also have disproportionately high rates of suicide, unintentional injuries resulting in death, and drug overdose deaths *(see TMC #1 for more information on IHS challenges and progress specific to opioid misuse)*. Many AI/AN communities are in geographically remote locations, adding to the operational and management challenges of the HHS programs that serve them.

Addressing deficiencies in IHS management, infrastructure, and quality of care

Key Components of the Challenge

During the past 3 years, Medicare compliance deficiencies affected patient care at 3 of the 25 IHS-operated hospitals. Two hospitals lost their Medicare certification and a third closed its emergency departments for 7 months in 2016. These deficiencies have a direct and detrimental effect on patient care and relate to several longstanding challenges. IHS faces difficulties in recruiting and retaining essential staff and in maintaining its staff's clinical competency in low-volume hospitals. Healthcare services are provided in remote locations, often in outdated buildings and using old equipment. Compounding these problems, the Purchased and Referred Care program, intended to supplement IHS services by purchasing select services from non-IHS providers, faces financial shortfalls in at least some Areas every year. When this happens, IHS prioritizes the most acutely urgent requests and some AI/ANs go without preventive services, primary and secondary care, and other services. Additionally, OIG found that some IHS hospitals have deficiencies in their continuity of operations programs and disaster recovery plans and were unable to retrieve patients' records in the event of physical damage. While most of OIG's work has focused on IHS-run facilities, OIG also found that one tribally run health center in Maine did not always have a physician who provided medical direction, clear lines of authority and

responsibility between medical and administrative decision making, and medical policies and procedures.

OIG found that IHS headquarters and Area offices do not provide sufficient oversight of the quality of care provided in IHS facilities. Area offices have a complaints and patient harm reports problem. Additionally, most area offices depend on infrequent Governing Board meetings to review quality metrics.

Progress in Addressing the Challenge

IHS is working to implement a broad quality framework with several initiatives to improve the care provided in its hospitals and clinics. These initiatives include developing a quality dashboard to track compliance and quality efforts, adopting new standards for hospital governing boards, and acquiring a new credentialing software system to ensure that providers have necessary qualifications. IHS is also pursuing expanded access for AI/AN services through new telehealth contracts and heightened standards for patient appointment-setting and wait times. IHS also awarded a contract to the Joint Commission for accreditation, training, and education to strengthen quality and patient safety. Supporting these efforts for IHS hospitals that participate in Medicare, CMS committed to conducting more frequent surveys of non-accredited IHS hospitals and is assisting with quality improvement efforts in IHS facilities through its Quality Improvement Network, Quality Improvement Organization (QIO), and Hospital Engagement Network programs.

What Needs To Be Done

- To improve quality of care and patient safety, HHS should reconvene a multi-agency council focused on overcoming the longstanding challenges to providing high quality care to AI/AN populations.
- IHS should develop and implement a comprehensive quality-focused compliance program for IHS hospitals.
- IHS should implement an agency-wide strategic plan with actionable initiatives and target dates.
- CMS should continue to communicate with IHS leadership about deficiencies in IHS facilities citations and continue to provide technical assistance and training to IHS hospitals in the QIO 11th Scope of Work.
- IHS should offer technical assistance to Tribes that operate their own clinics pursuant to the Indian Self-Determination and Education Assistance Act. This should include assistance to Tribes that operate health centers enrolled as Medicare Federally Qualified Health Centers to help Tribes ensure that their health centers are under the medical direction of a physician; establish clear lines of authority and responsibility between medical and administrative decision making; and develop and implement medical policies and procedures to comply with health and safety requirements.
- To better protect patient information and continuity of operations for IHS hospitals, IHS should test mechanisms at all IHS hospitals to ensure patient information is fully recoverable and implement an effective continuity of operations program and disaster recovery plan and procedures in accordance with Federal requirements.

Preventing fraud and misuse of HHS funds serving AI/AN populations

Key Components of the Challenge

OIG has found fraud and misuse of HHS funds in serving AI/AN populations and has performed audits and taken legal action. OIG has found that some Tribes and Tribal organizations have not adequately protected funds under the Indian Self-Determination and Education Assistance Act and other programs, resulting in embezzlement and theft of Federal funds. OIG has also enforced Civil Monetary Penalty (CMP) Law to reclaim funds from organizations in violation. OIG has also identified improper administration of funds by Tribes in the Indian Self-Determination and Education Assistance Act program and LIHEAP. Errors included, among others, failure to adequately track and support payments and failure to refund unobligated funds as required because the Tribes we audited did not have policies and procedures or internal controls to prevent these issues.

Progress in Addressing the Challenge

In May 2018, OIG led 2 days of compliance training for 250 IHS and Tribal employees and other stakeholders on internal controls, compliance programs, and ensuring quality care. OIG staff also made presentations to AI/AN audiences about compliance at four additional conferences led by HHS agencies and Tribal members.

OIG has taken multiple actions to prevent the misuse of Federal funding serving AI/AN populations. For example, OIG has enforced CMPs against Tribes and entered into settlement agreements for improperly billing Federal healthcare programs. OIG has identified improper payments at a tribal health clinic funded by IHS and in two Tribal LIHEAP programs. Additionally, OIG entered into a False Claims Act voluntary compliance agreement with a Tribe that improperly billed Medicaid, and has assisted DOJ in prosecuting Tribal employees who embezzled HHS funds.

What Needs To Be Done

- HHS agencies should continue to collaborate on strengthening program integrity and safeguarding HHS funds intended to serve AI/AN populations.
- OIG will continue to promote coordination and will expand oversight of HHS programs serving AI/ANs by conducting audits alongside OIGs from other departments serving these communities. Tribes and Tribal organizations can contribute to these goals by implementing strong internal control mechanisms and training staff on compliance and proper procedures, such as adherence to OMB cost principles when using Indian Self-Determination and Education Assistance Act funds.

Key OIG resources

- *Protecting Indian Health and Human Services Programs and Their Beneficiaries: The Basics of Health Care and Grants Management Compliance* (OIG 2018 Conference), May 2018.
- *The Indian Health Service Did Not Always Resolve Audit Recommendations in Accordance With Federal Requirements* (A-07-17-03227), September 2018.
- *The Passamaquoddy Tribe's Pleasant Point Health Center Did Not Always Meet Federal and Tribal Health and Safety Requirements* (A-01-11-701500), July 2018.
- *Two Indian Health Service Hospitals Had System Security and Physical Controls for Prescription Drug and Opioid Dispensing but Could Still Improve Controls* (A-18-16-30540), November 2017.
- *The Turtle Mountain Band of Chippewa Indians Improperly Administered Some Low-Income Home Energy Assistance Program Funds for Fiscal Years 2010 Through 2013* (A-07-16-04233), September 2017.
- *The Three Affiliated Tribes Improperly Administered Low-Income Home Energy Assistance Program Funds for Fiscal Years 2010 Through 2014* (A-07-16-04230), July 2017.
- *Expenses Incurred by the Rocky Boy Health Board Were Not Always Allowable or Adequately Supported* (A-07-15-04221), March 2016.
- *Indian Health Service Hospitals: More Monitoring Needed to Ensure Quality Care* (OEI-06-14-00010) and *Indian Health Service Hospitals: Longstanding Challenges Warrant Focused Attention to Support Quality Care* (OEI-06-14-00011), October 2016.

10. Protecting HHS Data, Systems, and Beneficiaries from Cybersecurity Threats

Why This Is a Challenge

Key Components of the Challenge
- Securing HHS's data and systems
- Advancing cybersecurity within the healthcare ecosystem

Data management, use, and security are essential to the effective and efficient operation across HHS's agencies and programs. Each agency has its own mission, budget, leadership, and IT systems. HHS spends more than $5 billion every year on IT (not including grants-related IT expenditures). The environment in which HHS must protect its systems is complex, with ever-increasing volumes of data residing in many places and with many entities and individuals, and with continued expansion of the Internet of Things, including networked medical devices. Those possessing health and human services data—including public stakeholders—have cybersecurity responsibilities, which include ensuring effective people, processes, and technologies are in place to protect HHS data. The Department's challenges are, thus, multifaceted and include protecting data on internal systems, overseeing the cybersecurity of data in cloud environments, and ensuring that providers, grantees, and contractors are adhering to sound cybersecurity principles.

Among HHS operating divisions, CMS is the single largest payer for healthcare in the U.S. The integrity of IT systems used to operate the $900+ billion in programs administered by CMS is thus critically important to the health and well-being of the American people. Oversight of the integrity of State Medicaid and MCO IT systems is also under HHS's jurisdiction. Moreover, the IT systems at FDA, IHS, and other HHS agencies present qualitatively different types of cybersecurity challenges. FDA, for example, is charged with regulating the safety, effectiveness, and security of food, cosmetics, drugs, biological products, and medical devices *(see TMC #8 for more information on challenges specific to safety of food, drugs, and medical products)*. By contrast, IHS is responsible for providing Federal health services to AI/ANs. FDA's IT systems process and maintain data that looks very different from that of IHS and other agencies. The cybersecurity of IHS systems will continue to remain a focus for OIG, as confidentiality, integrity, and availability of IHS healthcare systems is linked to improving care and patient safety.

The cybersecurity threats facing HHS are real and pressing. Healthcare data is a prime target for cybercriminals, and the value of a compromised EHR has been reported to be as much as 10 times that of a credit card number. In addition to identity threats, compromising the integrity and availability of HHS systems can adversely affect patient care. The WannaCry ransomware vulnerability, for example, affected an estimated 300,000 computers world-wide and resulted in thousands of operations and appointments being canceled unless ransoms of $300 to $600 were paid per malware instance. The Department has employed measures to notify hospitals about how to mitigate the impact of this vulnerability to the U.S. healthcare system.

Securing HHS's data and systems

Key Components of the Challenge

The infinite number of threats in cyberspace makes it nearly impossible to prevent every attack that looms on the horizon. As more healthcare functions come online (e.g., the healthcare Internet of Things, telemedicine, etc.), HHS will have to address new types of cybersecurity challenges. Any doubts

that the public may have about HHS's ability to protect confidential, personal health data may hinder the full potential of Federal initiatives (e.g., NIH's All of Us Research Program) that seek to leverage technology to create medical treatments of the future. HHS lacks robust resources to comprehensively prepare cybersecurity personnel (i.e., to test the different types of incident responses and recovery procedures that may reveal gaps) to respond efficiently and effectively when an actual attack occurs.

Progress in Addressing the Challenge

The 2017 HHS budget allocated $50 million to meet HHS's cybersecurity needs and to ensure that HHS could protect sensitive and critical information. HHS has implemented continuous monitoring tools to facilitate security compliance and has partnered with a commercial vendor to deploy threat hunting technologies at some HHS agencies. Security awareness and phishing prevention campaigns are instituted throughout the year. Continuous dialogue takes place across HHS agencies, focusing on cybersecurity and operational challenges. Select HHS agencies also coordinate with DHS to conduct cybersecurity testing. HHS is using a standardized log-analysis platform that will enable HHS and its operating divisions to better perform deep analysis of events and facilitate automation and integration with internal and external data sources and security tools. In addition, DHS conducts security scans of external-facing HHS systems. To help ensure the resilience of HHS systems, the Secretary signed a memorandum on April 5, 2018, informing all HHS agency leadership that entities within HHS would be responsible for planning and establishing necessary capabilities and being prepared to perform their respective Mission Essential Functions, with little or no warning and under any operating conditions. OIG continues to assess HHS cybersecurity vulnerabilities.

What Needs To Be Done

- A well-designed contingency program should be in place not only to respond to natural or man-made disasters but also as a key feature of cyber-defenses.
- Similarly, HHS must be proactive in identifying vulnerabilities and developing mitigation protocols in a timely manner to combat current and future cybersecurity threats. HHS should therefore focus on its capabilities to respond efficiently and effectively to a wide range of threats to healthcare and the resilience of its information systems, including its incident response coordination channels and contingency planning.
- To protect its data and systems, the Department must continue to take steps to address vulnerabilities previously identified by OIG and others.

Advancing cybersecurity within the healthcare ecosystem

Key Components of the Challenge

Information sharing is one of the most effective tools in the cybersecurity defense toolbox. The U.S. mitigated the effects of the WannaCry vulnerability largely because public and private sector entities shared information with stakeholders in real time. Within hours of the attack spreading through Europe, HHS notified its agencies and private sector entities about the attack. So, while cyber-attacks are nearly impossible to predict, once they occur, it is possible to obtain and share needed information with public and private partners, including how and where the exploit occurred, what types of systems are under attack, and, most important, what steps may be taken to mitigate the threat. HHS must continue to be at the forefront in encouraging cybersecurity information sharing and coordination among the healthcare public and private sectors. Because Government, academia, and private industry often employ similar technologies in providing healthcare and conducting medical research, there is great value in sharing cybersecurity vulnerabilities within commonly used systems.

Progress in Addressing the Challenge

The Department and its public and private partners and stakeholders have taken some steps to address coordination and information sharing concerning cybersecurity threats, but they must continue to work to enhance capabilities. Health-care-specific cybersecurity information sharing and analysis reports are available through numerous sources, including FireEye iSight reports, National Health Information Sharing and Analysis Center, Health Sector Cybersecurity Coordination Center, and the Computer Security Information Response Center. Some HHS agencies have created memoranda of understanding with outside information sharing organizations to better coordinate cybersecurity efforts. The FDA Commissioner announced a CyberMed Safety Analysis Board, a public-private entity composed of representatives from Government, academia, and industry to fully assess and validate high-risk medical device vulnerabilities and incidents.

What Needs To Be Done

- HHS agencies should continually seek opportunities to partner with other Government agencies, private industry, academia, and State Governments to share information on cybersecurity, emerging threats, risks, and best practices.
- HHS must continue to engage the healthcare and public health sectors to ensure that cybersecurity threats are properly communicated and that appropriate guidance on foundational cyber hygiene best practices is available. Both help protect the sector and, in turn, the HHS environment.

Key OIG resources

- *Maryland Did Not Adequately Secure Its Medicaid Data and Information Systems* (A-18-1630520), August 2018.
- *Summary Report for Fiscal Year 2016 OIG Penetration Testing of Four HHS Operating Division Networks* (A-18-1708500), December 2017.
- *Two Indian Health Service Hospitals Had System Security and Physical Controls for Prescription Drug and Opioid Dispensing but Could Still Improve Controls* (A-18-1630540), November 2017.
- *HealthCare.gov: Case Study of CMS Management of the Federal Marketplace* (OEI-06-14-00350), February 2016.
- *Hospitals Largely Reported Addressing Requirements for EHR Contingency Plans* (OEI-01-14-00570), July 2016.
- *Wireless Penetration Test of Centers for Medicare & Medicaid Services' Data Centers* (A-18-1530400), August 2016.
- *The Food and Drug Administration's Policies and Procedures Should Better Address Postmarket Cybersecurity Risk to Medical Devices* (A-18-16-30530), October 2018.
- *FDA Should Further Integrate Its Review of Cybersecurity Into the Premarket Review Process for Medical Devices* (OEI-09-16-00220), September 2018.

11. Ensuring that HHS Prescription Drug Programs Work as Intended

Why This Is a Challenge

HHS programs accounted for almost 40 percent ($130 billion) of the total U.S. prescription drug expenditures in 2016.[50] HHS oversees coverage of prescription drugs under various programs operated by the Department, such as Medicare, Medicaid, and IHS. In addition to providing drug coverage benefits through CMS and IHS, the Department also impacts prescription drug availability and pricing through agencies such as FDA and HRSA's 340B Drug Pricing Program.

Key Components of the Challenge
- Protecting the integrity of prescription drug programs
- Fostering prudent payments for prescription drugs
- Ensuring appropriate access to prescription drugs

Increases in drug prices have contributed to the growth in total prescription drug spending. Patients and Government programs may be overpaying for prescription drugs. Increases in drug prices may limit patients' access to needed prescription drugs if the out-of-pocket costs become unaffordable. The Administration recognized this with its release of "American Patients First," the President's blueprint to lowering drug prices and reducing out-of-pocket costs. HHS is committed to increasing transparency to improve oversight of prescription drug payments and reimbursements.

Protecting the integrity of prescription drug programs

Key Components of the Challenge

To limit Medicaid expenditures for prescription drugs, Congress created the Medicaid Drug Rebate Program in 1990; CMS and States implemented the Program in 1991. However, it is a longstanding challenge to ensure that drug manufacturers and State Medicaid agencies are complying with requirements. OIG recently found that potential misclassifications reported by drug manufacturers may have led to $1 billion in lost Medicaid rebates.

HHS faces challenges in ensuring the integrity of the Medicare prescription drug programs. For instance, OIG has continued to raise concern about payments for expired drugs. In addition, OIG found that Part D spending for compounded topical drugs was 24 times higher in 2016 than in 2010, raising concerns about fraud and abuse.

OIG has identified two longstanding fundamental vulnerabilities in the 340B program: (1) a lack of transparency that prevents ensuring that 340B providers are not overpaying pharmaceutical manufacturers and that State Medicaid programs are not overpaying 340B providers, and (2) a lack of clarity regarding program rules that creates inconsistencies in how contract pharmacies implement the program.

[50] CMS, National Health Expenditure Data. Accessed at: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/NHE2016.zip.

Progress in Addressing the Challenge

States are now appropriately reporting offset rebate amounts on their Medicaid expenditure reports. CMS is monitoring this as part of the certification review at the close of each reporting period. CMS reports that the amount of offset rebates collected increased by $400 million because of these efforts.

Additionally, in August 2018, the Administration released guidance clarifying how drug rebates are computed for a "line extension" of an existing pharmaceutical manufacturer's drug. The change intends to prevent manufacturers from treating new formulations of existing drugs as new medications to lower Medicaid rebate amounts owed to States. The Congressional Budget Office estimates that this change could save $6.5 billion over 10 years.[51]

CMS has taken a number of compliance and enforcement actions against Medicare Part D plan sponsors. CMS has also continued to expand use of its Overutilization Monitoring System and released guidance for Part D plan sponsors to implement lock-in programs to prevent abuse of Part D drugs.

HRSA has taken steps to improve oversight of the 340B program and was granted additional oversight authorities. HRSA received authority to share 340B ceiling prices with 340B providers and was given new enforcement tools, including authority to impose CMPs for manufacturers that knowingly and intentionally overcharge 340B providers.

What Needs To Be Done

- CMS should pursue a means to compel manufacturers to correct inaccurate classification data reported to the Medicaid Drug Rebate Program. The methods could include, for example, seeking legislative authority to compel manufacturers to submit accurate data and/or enhance its enforcement authority.
- Although States are now appropriately reporting rebates to CMS, CMS did not always provide accurate Medicaid quarterly unit rebate offset amounts to State Medicaid agencies. The State agencies would have used incorrect unit rebate offset amounts to calculate rebates that were reported to CMS, which would have resulted in incorrect rebate amounts being claimed. CMS should conduct periodic matches that would compare unit rebate offset amount information sent to State agencies with the Medicaid drug rebate system.
- For a covered outpatient drug to be eligible for Federal reimbursement under Medicaid's drug rebate requirements, manufacturers must participate in the Medicaid Drug Rebate program and pay rebates to the States for the drugs. State Agencies need to strengthen internal controls to ensure that all physician-administered drugs eligible for rebates are invoiced.
- OIG has recommended that Part D prescribers be required to enroll in Medicare for program integrity purposes. CMS recently established a preclusion list for problematic Part D prescribers that would prohibit Medicare payment for drugs prescribed by providers on this list. The list includes certain individuals and entities revoked from Medicare or those who have engaged in behavior for which CMS could have revoked the individual or entity if they had been enrolled in Medicare. OIG believes that requiring enrollment in Medicare would help ensure that only reputable and qualified individuals and entities are providing services to Medicare beneficiaries.
- CMS should require the use of claim-level methods to help States more accurately identify 340B drug claims, and thus reduce the risk of duplicate discounts and forgone rebates associated with

[51] CMS, "Medicaid Drug Rebate Program Notice No. 109 For Participating Drug Manufacturers," August 9, 2018. Available at: https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/mfr-releases/mfr-rel-109.pdf.

provider-level methods. CMS may need legislative authority to require States to use claim-level methods.

- HRSA should increase transparency by sharing 340B ceiling prices with 340B providers and States. HRSA may need new legislative authority to share 340B ceiling prices with States. HRSA should also clarify its guidance on preventing duplicate discounts for drugs paid through Medicaid MCOs.
- CMS should clarify Part D policies for coverage of compounded topical drugs and the use of utilization management tools. In addition, CMS should conduct training for Part D sponsors on fraud schemes and safety concerns related to compounded topical drugs.

Fostering prudent payments for prescription drugs

Key Components of the Challenge

How CMS sets the amount reimbursed for a drug can result in additional costs for programs and their beneficiaries. For example, Medicare Part B would have saved millions of dollars if dispensing fees for inhalation drugs administered through DME and supplying fees for immunosuppressive drugs associated with an organ transplant, oral anticancer chemotherapeutic drugs, and oral antiemetic drugs used as part of an anticancer chemotherapeutic regimen had been aligned with the rates that Part D and State Medicaid programs paid. Additionally, CMS includes noncovered versions of drugs when calculating payment amounts for two Part B drugs, Orencia and Cimizia. The inclusion of these drugs caused Medicare and its beneficiaries to pay an extra $366 million from 2014 through 2016.

Progress in Addressing the Challenge

The Bipartisan Budget Act of 2015 established a requirement that manufacturers pay an additional rebate when the average manufacturer price (AMP) for a generic-name drug increases by more than a specified inflation factor. The additional rebate for generic drugs applies to rebate periods beginning with the first quarter of 2017. Additionally, legislative change requiring DME infusion drugs to be paid using the average sales price (ASP) methodology will save $660 million over 10 years. Lastly, CMS altered its payment methodology for 340B drugs in the Hospital Outpatient Prospective Payment System (OPPS) to save beneficiaries an estimated $320 million on copayments in 2018. Starting in 2019, CMS will allow Medicare Advantage plans to use new cost-saving and negotiation tools for Part B drugs. These tools are already successfully used in the Part D program.

What Needs To Be Done

- CMS should seek a legislative change that would provide the agency flexibility to determine when noncovered versions of a drug should be included in Medicare Part B payment amount calculations.
- CMS should amend current regulations to decrease the Medicare Part B payment rates for dispensing and supplying Part B drugs to rates similar to those of other payers, such as Medicare Part D or Medicaid.

Ensuring appropriate access to prescription drugs

Key Components of the Challenge

High drug prices can limit access to needed prescription drugs. For instance, OIG found that increasing prices for brand-name drugs may result in increasing costs for Medicare and its beneficiaries, especially those beneficiaries who need access to expensive drugs. Increases in drug prices may limit patients' access to needed prescription drugs if the out-of-pocket costs become unaffordable.

Generic and biosimilar prescription drugs are important because they are often sold at lower prices and with lower patient payment obligations. Availability of generics and biosimilars can be an important mechanism for ensuring appropriate access to prescription drugs.

Progress in Addressing the Challenge

FDA announced a Drug Competition Action Plan to lower drug prices and increase access for patients by removing barriers to generic drug development and market entry.[52] The agency's actions include publishing a list of off-patent, off-exclusivity drugs without approved generics and implementing a revised prioritization policy to expedite the review of generic drug applications until there are three approved generics for a given drug product. In 2017, FDA approved 1,027 new generic drugs, the highest number of generic drug applications in its history.[53]

To complement the Drug Competition Action Plan, FDA subsequently released a Biosimilars Action Plan to facilitate the efficient development and approval of biosimilars to increase competition in the biologics marketplace and thereby reduce costs. As of October 2018, FDA has approved 13 biosimilars, including biosimilars for the treatment of cancer. Under the 2019 Part C and Part D regulation issued by CMS, Medicare beneficiaries receiving low-income subsidies can access biosimilars with lower out-of-pocket costs.

CMS has acknowledged that action is necessary to address rising drug costs and asked the industry to partner with the agency to find solutions that allow for both innovation and affordability. CMS has taken regulatory steps to increase access for Medicare beneficiaries, including allowing for certain low-cost generic drugs to be substituted onto plan formularies at any point during the year so beneficiaries immediately benefit by lower cost-sharing for these drugs.[54]

What Needs To Be Done

- When determining prudent payment policies and ensuring program integrity in HHS prescription drug programs, HHS should ensure appropriate access for beneficiaries. For instance, plans need to meet minimum access requirements when implementing their utilization management tools.

[52] FDA, "Statement from FDA Commissioner Scott Gottlieb, M.D., on the Trump Administration's plan to Lower Drug Prices," May 2018. Available at: https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm607495.htm
[53] FDA, "2017 Was Another Record-Setting Year for Generic Drugs," February 2018. Available at: https://blogs.fda.gov/fdavoice/index.php/2018/02/2017-was-another-record-setting-year-for-generic-drugs/
[54] CMS, "CMS Lowers the Cost of Prescription Drugs for Medicare Beneficiaries," April 2018. Available at: https://www.cms.gov/newsroom/press-releases/cms-lowers-cost-prescription-drugs-medicare-beneficiaries.

Key OIG resources

- *States' Collection of Medicaid Rebates from Drug Manufacturers* (OIG series of reports), February 2018.
- *Part D Plans Generally Include Drugs Commonly Used by Dual Eligibles: 2018* (OEI-05-18-00240), June 2018.
- *Potential Misclassifications Reported by Drug Manufacturers May Have Led to $1 Billion in Lost Medicaid Rebates* (OEI-03-17-00100), December 2017.
- *Questionable Billing for Compounded Topical Drugs in Medicare Part D* (OEI-02-16-00440), August 2018.
- *Examining Oversight Reports on the 340B Drug Pricing Program* (OIG Testimony), May 2018.
- *CMS Did Not Always Provide Accurate Medicaid Unit Rebate Offset Amounts to State Medicaid Agencies* (A-07-17-06074), May 2018.
- *Medicare Part B Prescription Drug Dispensing and Supplying Fee Payment Rates Are Considerably Higher Than the Rates Paid by Other Government Programs* (A-06-12-00038), September 2014.
- *Excluding Noncovered Versions When Setting Payment for Two Part B Drugs Would Have Resulted in Lower Drug Costs for Medicare and its Beneficiaries* (OEI-12-17-00260), November 2017.
- *Medicare Part B Prescription Drug Dispensing and Supplying Fee Payment Rates Are Considerably Higher Than the Rates Paid by Other Government Programs* (A-06-12-00038), September 2014.
- *Increases in Reimbursement for Brand-Name Drugs in Part D* (OEI-03-15-00080), June 2018.
- *The MEDIC Produced Some Positive Results but More Could be Done to Enhance its Effectiveness* (OEI-03-17-00310), July 2018.

12. Ensuring Effective Preparation and Response to Public Health Emergencies

Why This Is a Challenge

Public health emergencies, such as emerging infectious diseases and natural disasters, can severely strain public health and medical infrastructure and lead to serious illness and loss of life. As the lead agency for the Federal response to public health emergencies, HHS is responsible for ensuring both it and its State and local partners are prepared to respond to, and recover from, public health emergencies efficiently and effectively.

Key Components of the Challenge
- Ensuring access to health and human services during and after emergencies
- Ensuring effective use and oversight of funding
- Ensuring effective and timely responses to infectious disease threats

During a disaster response, Federal, State, and local entities must collaborate to provide response and recovery services. However, this often leads to challenges with coordination and information sharing within and across these entities.

Ensuring access to health and human services during and after emergencies

Key Components of the Challenge

During and after a public health emergency, State and local governments must ensure they have adequate plans (such as preparing for a medical surge) and mechanisms in place to efficiently and rapidly deploy assets and provide relief to those in need. For example, the destruction from the 2017 hurricane season left many individuals without medical care, including in facilities without electricity, and other needed health and human services resources in the immediate aftermath and for subsequent months. State and local governments must also coordinate with healthcare facilities and other entities to leverage resources during a response.

Prior OIG work has identified gaps in emergency preparedness and response planning and community preparedness for healthcare facilities during disasters and pandemics. For example, OIG found that many hospitals and other entities in disaster areas affected by Superstorm Sandy encountered problems with distributing shared resources, such as hospital beds and access to fuel and transportation, which decreased hospitals' capability to care for patients. OIG has also historically identified gaps in nursing home emergency planning, disaster response, and coordination with State and local entities. Nursing homes often struggle to execute emergency plans and protect residents after disasters hit, despite receiving enhanced guidance from CMS. For example, during the 2017 hurricane season, reports of nursing homes' performance found failures to evacuate residents or provide safe sheltering in place, which raises questions about the adequacy and execution of healthcare facilities' emergency plans.

Progress in Addressing the Challenge

CMS developed guidance to help healthcare facilities improve planning and preparing for disasters, improve access to medical care, and meet medical surge needs during disasters. In 2016, CMS finalized a rule to establish new national emergency preparedness requirements that apply to all facilities receiving Medicare or Medicaid reimbursement. In 2017, CMS issued guidelines for providers and surveyors when assessing compliance with Federal regulations for long-term-care facility emergency

planning and training. As of September 2018, CMS has reported surveying about 75 percent of facilities, and anticipates survey completion by February 2019.

The Office of the Assistant Secretary for Preparedness and Response (ASPR) continues to provide technical assistance and guidance to healthcare providers, emergency managers, and other public health emergency preparedness stakeholders on topics including medical surge and improving collaboration during and after disasters. Additionally, ASPR has developed data tools to assist entities with rapidly identifying resource availability (e.g., electricity and beds) and at-risk populations that need assistance during an emergency. ASPR is also integrating Federal, State, local public health, and medical assets on the ground and building regional capability to fight highly infectious and other disease threats through regular training, exercises, and ensuring that equipment and organization of medical components are updated.

What Needs To Be Done

- HHS should take steps to improve coordination within the public health and human services infrastructure. For example, CMS needs to ensure that all applicable providers are effectively implementing the emergency preparedness requirements.
- CMS needs to ensure that all surveyors are effectively assessing providers' compliance with these requirements. OIG will continue to monitor these requirements.
- ASPR should continue to improve the use and collection of data to access real-time information about emerging threats and to rapidly respond to emergencies to ensure they meet the health and human service needs of individuals.
- ASPR should continue to build regional surge capacity through formula-based cooperative agreements, Regional Disaster Health Response System pilots, and support programs related to healthcare preparedness, response, and recovery.

Ensuring effective use and oversight of funding

Key Components of the Challenge

HHS awards grant funds across Federal, State and local entities to strengthen emergency preparedness. HHS, States, and other grantees also receive supplemental appropriations to respond to emergencies. In 2017, HHS received almost $6 billion in supplemental funding for preparedness and response efforts for the hurricanes impacting Puerto Rico, the Virgin Islands, and the southern U.S. Funds awarded during emergencies are often susceptible to fraud and misuse by grantees.

HHS must also see that proper grant mechanisms are in place to ensure effective response coordination with domestic and international partners. For example, OIG found deficiencies in CDC's grant award process to award funds for international Ebola preparedness and response activities. States also reported wanting more direction from ACF on allowable activities and reporting requirements for Superstorm Sandy block grants. Uncertainty about allowable expenses may have hindered some States' use of funds for relief efforts. Additionally, OIG also found internal control weaknesses in audits of foreign grantees receiving President's Emergency Plan for AIDS Relief funds *(see TMC #7 for more information on challenges specific to HHS grants)*.

Progress in Addressing the Challenge

HHS has made efforts to assess grant program performance and improve grant oversight by identifying potential fraud, waste, and abuse. For instance, OIG found that HRSA complied with Federal and HHS

grant policies when awarding funding to health centers and other entities to expand access and delivery of healthcare services to respond to the spread of the Zika Virus in Puerto Rico and other U.S. territories from October 1, 2016, through March 15, 2017. Additionally, ACF is developing administrative guidance on lessons learned to use if additional supplemental disaster funds are appropriated to the agency under the Social Services Block Grant authority.

What Needs To Be Done

- HHS needs to improve its oversight of funds awarded to grantees for emergency response and recovery activities to ensure that grant funds are being used efficiently, effectively, and for their intended purposes.
- HHS agencies must provide appropriate guidance to its grantees about when the use and expiration of supplemental disaster relief funds and what documentation is needed to ensure program integrity.

Ensuring effective and timely responses to infectious disease threats

Key Components of the Challenge

The spread of infectious diseases, like Ebola and Zika, is an ongoing challenge and demonstrates the need for the Department to rapidly detect and diagnose infectious diseases and assess threats. HHS needs to ensure its ability to readily develop, distribute, and administer medical countermeasures (MCMs) (i.e., vaccines, therapeutics, and diagnostics) to effectively prevent and treat infectious diseases. OIG identified systemic issues that may prevent CDC from ensuring inventory in the Strategic National Stockpile (SNS)—a repository of MCMs.

Additionally, HHS needs to enhance State and local preparedness for influenza pandemics. OIG found that States and localities need to improve planning and preparedness in areas including medical surge and vaccine and antiviral drug distribution and dispensing. For example, during the Ebola crisis, many hospitals reported that they were unprepared to receive cases and experienced challenges, such as difficulty using Federal guidance, to sustain preparedness.

Progress in Addressing the Challenge

HHS continues to make significant investments to develop MCMs to protect against emerging infectious diseases and other threats. For example, ASPR is sustaining efforts to build domestic manufacturing infrastructure and a robust vaccine stockpile for pandemic influenza. As of September 2018, ASPR's Biomedical Advanced Research and Development Authority (BARDA) supported an MCM enterprise that included 42 FDA approvals of 38 medical products and technologies. BARDA's Division of Research, Innovation, and Ventures (DRIVe) program also supports transformational technologies to identify diseases earlier and address cross cutting health security threats.

HHS is also enhancing preparedness for future infectious disease threats. In April 2018, HHS executed its largest patient movement exercise, with more than 50 organizations (including Federal, State, and local agencies) participating, to test the nation-wide ability to move patients with highly infectious diseases safely and securely to regional treatment centers. OIG's ongoing work has also identified improvements in hospital preparedness for responding to emerging infectious diseases. For instance, following the Ebola crisis, hospitals reported taking actions such as revising infectious disease and emergency plans, conducting additional staff training and exercises, and participating in healthcare coalitions. In response to OIG's work, CMS is updating its *State Operations Manual* to include emerging

infectious diseases in hospital emergency planning. Additionally, ASPR is building on its successes using a regional response model during the Ebola response by developing a Regional Disaster Health Response System to surge medical response during disasters and emergencies.

What Needs To Be Done

- HHS agencies should take steps to improve collaboration and coordination of guidance to help healthcare facilities sustain preparedness for emerging infectious disease threats.
- CMS should monitor enforcement of its emergency preparedness requirements to ensure that emerging infectious diseases are included in hospital preparation.
- ASPR should continue efforts to expand the portfolio of emerging infectious disease MCMs under development.
- HHS should improve SNS coordination and readiness to ensure that inventory is readily deployable in a public health emergency. To that end, plans are underway for ASPR to assume operational control of the SNS to streamline MCM development and procurement and improve the speed and effectiveness of emergency response capabilities.

Key OIG resources

- *Examining Federal Efforts to Ensure Quality of Care and Resident Safety in Nursing Homes* (OIG Testimony), September 2018.
- *Hospital Emergency Preparedness and Response During Superstorm Sandy* (OEI-06-13-00260), September 2014.
- *Gaps Continue to Exist in Nursing Home Emergency Preparedness and Response During Disasters: 2007-2010* (OEI-06-09-00270), April 2012.
- *Superstorm Sandy Block Grants: Funds Benefited States' Reconstruction and Social Service Efforts, Though ACF's Guidance Could be Improved* (OEI-09-15-00200), September 2016.
- *CDC Awarded Selected Ebola Funds for International Response Activities in Accordance with Applicable Laws, Regulations, and Departmental Guidance* (A-04-16-03568), January 2017.
- *HRSA Complied with Federal and HHS Grant Policies When Awarding Zika Response and Preparedness Appropriations Act Funds During FY 2017* (A-04-17-02003), October 2017.
- *Readiness of CDC's SNS Could be at Risk in Case of a Public Health Emergency* (A-04-16-03554), June 2017.
- *Hospitals Reported Improved Preparedness for Emerging Infectious Diseases After the Ebola Crisis* (OEI-06-15-00230), October 2018.

U.S. Department of Health and Human Services

Office of Inspector General

2018 Top Management and Performace Challenges

Department's Response to the Office of Inspector General

THE DEPUTY SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

To: Daniel R. Levinson, Inspector General

From: Eric D. Hargan, Deputy Secretary

Subject: FY 2018 Department's Response to the OIG Top Management and Performance Challenges

On behalf of the Department, we want to thank you for the Office of Inspector General's (OIG) efforts to identify the top management and performance challenges confronting us now and in the near future. Your investigation, analysis, and straightforward explanations provide valuable insight into the threats and challenges regarding our enterprise objectives.

The HHS mission is dynamic and far-reaching, and the evolving challenges are increasingly varied and complex. Your office's recommendations to address these challenges are valued. We will ensure the insight is shared throughout the Department so leadership at every level can evaluate the risks and effectively prioritize resources and oversight efforts.

Though much improvement will come, the Department's transformational *ReImagine HHS* efforts are already demonstrating benefits that will allow us to better serve our stakeholders. This initiative, along with the OIG's recommendations, will enable the Department to advance innovation, institutionalize continuous improvement, and facilitate strategic collaboration with internal and external partners.

The nation is counting on us to overcome obstacles standing in the way of enhancing the well-being of all Americans, and we are committed to addressing these challenges and adjusting to a continuously evolving operating environment. We look forward to continued collaboration with the OIG in our endeavor to lower health care costs, increase outcomes, and improve lives.

/Eric D. Hargan/

Eric D. Hargan
Deputy Secretary
November 14, 2018

Appendices

A

In This Section

- Acronyms
- Connect with HHS

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Appendix A: Acronyms

A

ACF	Administration for Children and Families
ACO	Accountable Care Organization
ACL	Administration for Community Living
ADA	*Antideficiency Act*
AFCARS	Adoption and Foster Care Analysis and Reporting System
AFR	Agency Financial Report
AHRQ	Agency for Healthcare Research and Quality
AI/AN	American Indian and Alaska Native
AMP	Average Manufacture Price
APD	Advance Planning Documents
APG	Agency Priority Goal
APM	Alternative Payment Model
APTC	Advance Premium Tax Credit
AR	Antibiotic Resistance
ARRT	Advanced Rehabilitation Research and Training
ASA	Office of the Assistant Secretary for Administration
ASFR	Office of the Assistant Secretary for Financial Resources
ASL	Office of the Assistant Secretary for Legislation
ASP	Average Sales Price
ASPA	Office of the Assistant Secretary for Public Affairs
ASPE	Office of the Assistant Secretary for Planning and Evaluation
ASPR	Office of the Assistant Secretary for Preparedness and Response
ATAS	Audit Tracking and Analysis System
ATSDR	Agency for Toxic Substances and Disease Registry

B

BARDA	Biomedical Advanced Research and Development Authority
BBA	*Bipartisan Budget Act of 2015*
BEA	Bureau of Economic Analysis
BHW	Bureau of Health Workforce
BRAIN	Brain Research through Advancing Innovative Neurotechnologies

C

CAP	Cross-Agency Priority
CBR	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
CEAR	Certificate of Excellence in Accountability Reporting
CERT	Comprehensive Error Rate Testing
CFO	Chief Financial Officer
CFR	Code of Federal Regulations
CFRS	Consolidated Financial Reporting System
CHIP	Children's Health Insurance Program
CIO	Chief Information Officer
CL	Current Law
CLASS	Classroom Assessment Scoring System
CMA	Computer Matching Agreement
CMP	Civil Monetary Penalty
CMS	Centers for Medicare & Medicaid Services
COLA	Cost of Living Adjustment
COTS	Commercial Off-the-Shelf
CPI	Consumer Price Index
CPIM	Consumer Price Index-Medical
CRC	Commercial Repayment Center
CSR	Cost-sharing Reduction
CSRS	Civil Service Retirement System
CTO	Office of the Chief Technology Officer
Cures Act	*21st Century Cures Act*
CY	Current Year

D

DAB	Departmental Appeals Board
DATA Act	*Digital Accountability and Transparency Act of 2014*
DHS	Department of Homeland Security
DME	Durable Medical Equipment
DMF	Death Master File
DMEPOS	Durable Medical Equipment, Prosthetics, Orthotics, and Supplies
DNP	Do Not Pay
DOI	Department of the Interior
DOJ	U.S. Department of Justice
DOL	Department of Labor
DRA	*Deficit Reduction Act of 2005*
DRG	Diagnosis-related Groups
DRIVe	Division of Research, Innovation and Ventures
DRS	Documentation Requirements Simplification
DSCSA	*Drug Supply Chain Security Act*

E

EHR	Electronic Health Record
ES	The Executive Secretariat
ESRD	End-stage Renal Disease
EVV	Electric Visit Verification

F

FACES	Family and Child Experience Survey
FASAB	Federal Accounting Standards Advisory Board
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*
FERS	Federal Employees Retirement System
FETP	Field Epidemiology Training Programs
FFMIA	*Federal Financial Management Improvement Act of 1996*
FFRDC	Federally Funded Research and Development Centers
FFS	Fee-For-Service
FGB	Financial Management Governance Board
FICA	*Federal Insurance Contributions Act*
FIFO	First-In/First-Out
FISCAM	Federal Information System Controls Audit Manual
FITARA	*Federal Information Technology Acquisition Reform Act*
FMFIA	*Federal Managers' Financial Integrity Act of 1982*
FPS	Fraud Prevention System
FR	Federal Register
FRDAA	*Fraud Reduction and Data Analytics Act of 2015*
FSIP	Financial Systems Improvement Program
FY	Fiscal Year

Appendix A: Acronyms

G

GAAP	Generally Accepted Accounting Principles
GAO	U.S. Government Accountability Office
GDP	Gross Domestic Product
GHP	Group Health Plan
GONE Act	*Grants Oversight and New Efficiency Act*
GPRA	*Government Performance and Results Act of 1993*
GSA	General Services Administration

H

H5N1	Avian Influenza
HCFAC	Health Care Fraud and Abuse Control
HCP	Healthcare Providers
HEAL	Helping to End Addiction Long-Term
HEW	Department of Health, Education, and Welfare
HFPP	Healthcare Fraud Prevention Partnership
HHA	Home Health Agency
HHS	Department of Health and Human Services
HI	Hospital Insurance
HIGLAS	Healthcare Integrated General Ledger Accounting System
HIPAA	*Health Insurance Portability and Accountability Act of 1996*
HIV	Human Immunodeficiency Virus
HPMS	Health Plan Management System
HRSA	Health Resources and Services Administration

I

IBNR	Incurred But Not Reported
IEA	Office of Intergovernmental and External Affairs
IHS	Indian Health Service
IOS	Immediate Office of the Secretary
IP	Improper Payment
IPAB	Independent Payment Advisory Board
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*
IPPS	Inpatient Prospective Payment System
IPT	Integrated Project Team
IRF	Inpatient Rehabilitation Facility
IRS	Internal Revenue Service
IT	Information Technology

L

LIHEAP	Low Income Home Energy Assistance Program
LPR	Lawful Permanent Resident
LTCH	Long-Term Care Hospital

M

MA	Medicare Advantage
MAC	Medicare Administrative Contractor
MAO	Medicare Advantage Organizations
MACRA	*Medicare Access and CHIP Reauthorization Act of 2015*
MARx	Medicare Advantage Prescription Drug
MAT	Medication-assisted Treatment
MCH	Maternal and Child Health
MCM	Medical Countermeasures
MCO	Medicaid Managed Care Organization
MDH	Medicare-Dependent Hospital
MEDIC	Medicare Drug Integrity Contractor
MFCU	Medicaid Fraud Control Units
MIPS	Merit-based Incentive Payment System
MLN	Medicare Learning Network
MMEs	Morphine Milligram Equivalents
MSP	Medicare Secondary Payer
MSSP	Medicare Shared Savings Program
MWWG	Material Weakness Working Group

N

NBI	National Benefit Integrity
NBS	NIH Business System
NCCI	National Correct Coding Initiative
NEST	National Evaluation System for Health Technology
NGHP	Non-Group Health Plan
NHSC	National Health Service Corps
NIDILRR	National Institute for Disability, Independent Living, and Rehabilitation Research
NIH	National Institutes of Health
NPI	National Provider Identifier

O

OAGM	Office of Acquisition and Grants Management
OASDI	Old-Age, Survivors, and Disability Insurance
OASH	Office of the Assistant Secretary for Health
OCR	Office for Civil Rights
OGA	Office of Global Affairs
OGC	Office of the General Counsel
OHR	Office of Health Reform
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 Information Technology
OPD	Orphan Products Designation
OpDiv	Operating Division
OPM	Office of Personnel Management
OPPS	Outpatient Prospective Payment System
ORR	Office of Refugee Resettlements
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
PERM	Payment Error Rate Measurement
PHS	Public Health Service
PI	Program Integrity
PIP	Program Improvement Plan
PMA	President's Management Agenda
PMD	Power Mobility Device
PP	Paid Properly
PPACA	*Patient Protection and Affordable Care Act*
PPS	Prospective Payment System
PRRB	Provider Reimbursement Review Board
PSC	Program Support Center
PTC	Premium Tax Credit
PY	Prior Year

Q

QIO	Quality Improvement Organization

R

RAC	Recovery Auditor Contractor
RADV	Risk Adjustment Data Validation

REMS	Risk Evaluation and Mitigation Strategies
RSI	Required Supplementary Information

S

SAMHSA	Substance Abuse and Mental Health Services Administration
SCORE	Strategic Coordinated Oversight of Recall Execution
SCSIA	Statement of Changes in Social Insurance Amounts
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
SNP	Special Needs Plan
SSA	Social Security Administration
SSF	Service and Supply Funds
StaffDiv	Staff Division

T

TDL	Technical Direction Letter
T-MSIS	Transformed Medicaid Statistical Information System
TANF	Temporary Assistance for Needy Families
TAS	Treasury Account Symbol
TMC	Top Management and Performance Challenge
TPE	Targeted Probe and Educate
Treasury	U.S. Department of the Treasury

U

UAC	Unaccompanied Alien Children
UFMS	Unified Financial Management System
U.S.	United States
U.S.C.	United States Code
USSGL	United States Standard General Ledger

V

VFC	Vaccines for Children
VBID	Value-Based Insurance Design

Z

ZPIC	Zone Program Integrity Contractors

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 2018 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
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