Department of Health and Human Services

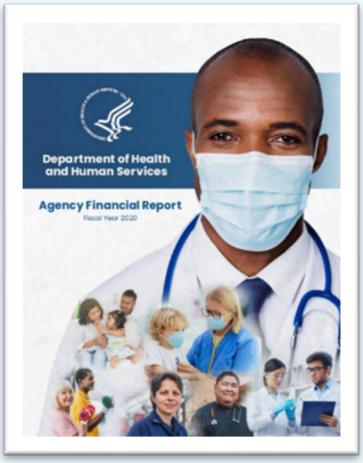
Agency Financial Report

Fiscal Year 2021

Certificate of Excellence in Accountability Reporting

The Department of Health and Human Services (HHS) promotes effective and responsible financial management by producing award-winning financial reports, aligning with its strategic plan. For 8 consecutive years, the Association of Government Accountants (AGA) has recognized HHS's Agency Financial Report through the Certificate of Excellence in Accountability Reporting (CEAR) Program. The CEAR Program was established in collaboration with the Chief Financial Officers Council and Office of Management and Budget to assist federal government agencies with performance and accountability reporting. Through this program, agencies improve accountability by streamlining reporting and enhancing the effectiveness of reports to clearly highlight what an agency accomplished during a fiscal year (FY) and to discuss any challenges that remain.

The FY 2020 AFR's success exemplifies our continuous dedication, perseverance, and commitment to the HHS mission and to the American people, despite the unprecedented circumstances in 2020.



Harold "Hal" Steinberg

Few people have contributed more to the advancement and professionalization of government financial management than Harold "Hal" Steinberg, who passed away in October 2021. The HHS CFO Community honors Hal's achievements and contributions in service to his country. He believed that every citizen deserves a clear accounting of taxpayer funds and government performance. He dedicated his 50-year career to making this belief a reality.

After twenty years in public accounting, Hal entered public service at the Office of Management and Budget implementing "good government" laws including the CFO Act. He was a driving force for creating the basic building blocks to achieve financial accountability across the U.S. Government such as establishing standards for Federal financial accounting, reporting, auditing, systems and personnel.

Hal was a key contributor for AGA's Certified Government Financial Management (CGFM) and CEAR programs, described above. Hal's legacy will endure in the Federal financial management foundation he forged and the legions of qualified professionals carrying out the financial accountability mission.

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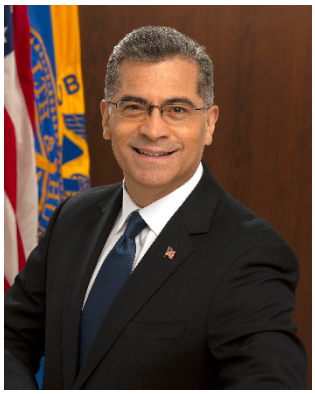
Message from the Secretary



Xavier Becerra

At the U.S. Department of Health and Human Services (HHS), we strive each day to enhance the health and well-being of all Americans. As the Department's Secretary, I am devoted to this critical mission and to ensuring our work supports the President's vision to Build Back Better. An essential component of HHS's success during fiscal year (FY) 2021, as highlighted throughout this Message, was largely made possible through the enactment of the *American Rescue Plan Act of 2021* (ARP). ARP provided over $160 billion in supplemental funding to help HHS change the course of the COVID-19 pandemic, expand access to health insurance coverage, lower health care costs, and ensure health care is a right for all Americans. This year's Agency Financial Report (AFR) provides insight into those efforts and other activities dedicated to executing our vital mission.

In FY 2021, HHS continued its heroic battle against the ongoing COVID-19 pandemic. From our Public Health Service officers who deployed coast to coast and beyond to assist local communities, to the scientists and specialists who continued to develop research and treatment protocols, to the social workers who treated the underserved populations at local community health centers, our selfless professionals continued to serve the health care needs of the American people. On April 22, HHS reached the goal of delivering 200 million COVID-19 vaccinations in the first 100 days of the President's Administration. By the end of FY 2021, we provided almost 400 million vaccinations. But our efforts to stop the pandemic are not limited to within our borders. HHS donated over 111 million doses of the COVID-19 vaccine to 65 countries around the world to stop the spread and prevent the emergence of new and potentially more dangerous variants of the virus. HHS is taking a truly global approach to beat COVID-19.

HHS is also advancing several initiatives with the goal of preventing the next pandemic. The Department is seeking the next effective antiviral treatment through a $3 billion ARP investment in the Antiviral Program for Pandemics, which seeks to accelerate the discovery, development, and manufacture of the next generation of COVID-19 treatments. HHS also invested $1.7 billion for the Centers for Disease Control and Prevention and state and local public health departments to monitor, track, and defeat emerging threats through genomic sequencing. This ARP investment is vital to our fight against new variants of COVID-19. On the diagnostics front, HHS's Biomedical Advanced Research and Development Authority (BARDA) partnered with industry to collaborate on rapid diagnostic testing for pooled samples to address COVID-19, detect novel and emerging coronaviruses, and increase pandemic preparedness. BARDA is also sponsoring a Mask Innovation Challenge promoting accelerated development and innovation to identify promising technologies to protect people from respiratory contagion.

The COVID-19 pandemic was not the only crisis HHS addressed in FY 2021. The climate crisis continues to plague the globe and we are taking clear action to mitigate its impact on our health. In the first week of this Administration, HHS established the Office of Climate Change and Health Equity (OCCHE) to address the impact of climate change on the health of the American people. Key OCCHE priorities include addressing health disparities made worse by climate impacts, assisting with regulatory efforts to reduce greenhouse gas emissions in the health care sector, and fostering innovation in climate adaptation and resilience for disadvantaged communities and vulnerable populations.

Ensuring equity for marginalized populations is a key tenet of this Administration's agenda and a principal objective of our work at HHS. The Office of Population Affairs in the Department's Office of the Assistant Secretary for Health took a significant step in 2021 to restore access to equitable, affordable, quality family planning services through a final rule revising regulations governing the Title X family planning program. Title X is the only federal grant program dedicated solely to providing comprehensive family planning and related preventive health services for millions of low-income or uninsured individuals. The rule reinforces the program's emphasis on quality, equity, and dignity for all individuals who seek Title X services. HHS is committed to ensuring quality equitable health care is a right, not a privilege. To support this commitment, we expanded access to continuous health care coverage and access to preventative care in rural areas to improve maternal health outcomes beyond the initial 60 days post-partum. The continued full Medicaid benefit coverage for mothers extends eligibility during the entire first year after delivery,

preventing loss of insurance, delayed care, and less preventive care. The Department also awarded nearly $1 billion of ARP funding through the Health Resources and Services Administration (HRSA) to modernize health centers in medically underserved communities across the nation and its territories. These awards will strengthen our primary health care infrastructure and advance health equity and outcomes.

The *Patient Protection and Affordable Care Act* (PPACA) continues to save lives of Americans across the country, especially those in vulnerable communities. More than 2.8 million people enrolled in health coverage on HealthCare.gov and State Marketplaces during the 2021 Special Enrollment Period, increasing the total number of enrollees to 12.2 million. Kentucky, Maine, and New Mexico also transitioned from HealthCare.gov to their own State-based Marketplaces, allowing these states to meet the specific needs of their residents. Additionally, over 82.3 million people now receive coverage through Medicaid and the Children's Health Insurance Program. Again, the ARP plays a key part in lowering health care costs for Americans through premium credits, with families saving on average $40 per person per month. Over a third of customers found coverage for $10 or less per month.

HHS's comprehensive Drug Pricing Plan will help Americans pay less for health care by also lowering prescription drug costs. Many Americans choose not to take medications as prescribed due to high drug prices. The tough decision between medications and other living expenses especially harms low-income families. A key factor in high drug costs is the lack of competition, but with the Department's recent Drug Pricing Plan, HHS is advancing the Administration's efforts to effect equitable drug pricing reform through competition, innovation, and transparency. Additionally, the Department's Centers for Medicare & Medicaid Services distributed $452 million to support efforts by 13 states to improve access to affordable, comprehensive health insurance coverage through state-based reinsurance waivers. These reinsurance programs improve health insurance affordability and market stability by reimbursing issuers for a portion of health care provider claims that would otherwise be paid by consumers through higher premiums.

HHS also continued its concerted efforts to reduce the impact of HIV through its Ending the HIV Epidemic in the U.S. initiative. This program made significant investments in community health centers through HRSA, with the aim to reduce the number of new HIV infections in the U.S. by 90 percent by 2030. These health centers provide critical services to 1.2 million Americans living with HIV and will ensure equitable access free from stigma and discrimination. Another HHS initiative to reduce stigma and increase prevention and treatment among racial and ethnic minorities is The HIV Challenge, a national competition to engage communities and seek innovative and effective approaches to increase the use of pre-exposure prophylaxis medication and antiretroviral therapy among people who have HIV or are at increased risk for HIV.

Since the founding of this country, people around the world seek freedom, opportunity, and a better life in America. Many people arriving at our borders today are unaccompanied children (UC) who made perilous trips from dangerous environments in their home countries. HHS, through its Office of Refugee Resettlement (ORR) under the Administration for Children and Families, responded to the challenges presented by the COVID-19 pandemic and high number of UC referrals from the Department of Homeland Security in the early part of 2021 by significantly expanding its bed capacity and standing up emergency shelters. ORR also played a significant role in welcoming tens of thousands of Afghans who evacuated Afghanistan through Operation Allies Welcome. HHS helps Afghans and refugees of other countries adjust to life in America and integrate into their new communities through ORR-funded support services, including the Ethnic Community Self-Help (ECSH) program. ECSH identifies and responds to the diverse needs of refugees by helping them learn English, find jobs, connect with their communities, and start the process toward citizenship.

The mission activities of HHS are diverse and complex, but the Department will fervently execute its duties for the best interest of every American through the sound, responsible, and equitable use of HHS resources.

Stewardship

As the single largest cabinet agency by spending, representing approximately one-fourth of the total federal budget, HHS maintained its reputation for excellence in budgetary and financial practices. For the 23rd 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 encompass 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 PPACA and the impact of potential legal changes affecting underlying assumptions of financial projections. These statements were developed based upon current law using information from the 2021 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 evaluate our internal controls and financial management systems annually, as required by the *Federal Managers' Financial Integrity Act* and the Office of Management and Budget's Circular A-123, *Management's Responsibility for Enterprise Risk Management and Internal Control*. These evaluations helped us identify material noncompliances with the *Payment Integrity Information Act of 2019* related to error rate measurement and with the *Social Security Act* related to 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 the financial and performance information contained in this report is complete, reliable, and accurate.

Moving Forward

I am so proud of the HHS team and our long-running culture of selfless service. During another challenging year in which the nation continued to battle the COVID-19 pandemic, our workforce stayed focused, engaged, and committed to excellence while fostering a positive, healthy, and innovative work environment. Once again, in "The Best Places to Work in the Federal Government" rankings, HHS placed in the top five among large government agencies. HHS is a great place to work and our public servants will continue to give their all for this country. I am proud to lead them as we carry out our crucial mission. The "Looking Ahead" section describes our mission priorities as we develop the new HHS Strategic Plan FY 2022 – 2026. I also recognize there is room for improvement in our mission areas, and we will work closely with the Office of Inspector General to understand our most significant management and performance challenges, as presented in the "Other Information" section.

Conclusion

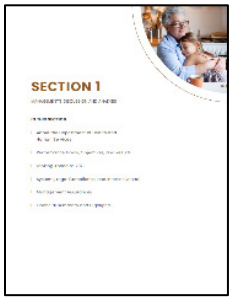
My father often reminded me it was a good day if I could get up and go to work. Indeed, I have already had many good days since assuming the role of HHS Secretary and beginning our work for the good of the nation. Despite the ongoing challenges HHS and the country face, I am pleased with the progress we have made in tackling COVID-19, expanding access to health care, and giving Americans hope that our best days are ahead when it comes to quality health care. I am eager to continue the stellar work of the Department and improve the lives and well-being of every American.

/Xavier Becerra/

Xavier Becerra
Secretary
November 12, 2021

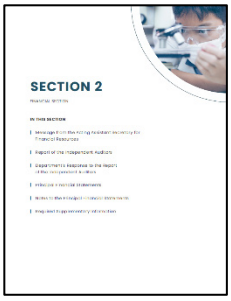
About the Agency Financial Report

The HHS FY 2021 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, 2020, through September 30, 2021. 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 a supplemental section for the appendices.



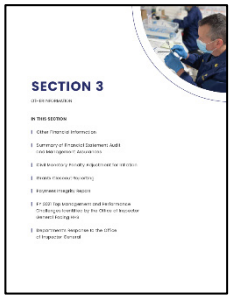
Section 1: Management's Discussion and Analysis

This section provides an overview of HHS's mission, activities, organizational structure, and program performance. Section 1 also includes an overview of the systems environment; a summary of HHS's financial results and compliance with laws and regulations; and management's assurances on HHS's internal controls.



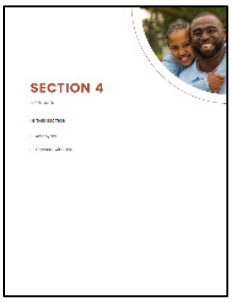
Section 2: Financial Section

This section begins with a message from the Acting Chief Financial Officer. Section 2 continues with the independent auditor's report, management's response to the audit report, financial statements with accompanying notes, and required supplementary information.



Section 3: Other Information

This section contains additional information, such as other financial information, the summary of the financial statement audit and management assurances, civil monetary penalties, grant closeout reporting, and a detailed payment integrity report. Section 3 concludes with the Office of Inspector General's assessment of the Top Management and Performance Challenges Facing HHS.



Section 4: Appendices

This section includes information that supports the sections of the AFR, such as the glossary of acronyms in the report and additional resources for connecting with HHS.

HHS produces an AFR and *Annual Performance Plan and Report*. Additional reports will be released on HHS's website in February 2022 including:

1. FY 2023 *Annual Performance Plan and Report*
2. FY 2023 *Congressional Budget Justification*

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SECTION 1

MANAGEMENT'S DISCUSSION AND ANALYSIS

IN THIS SECTION

- About the Department of Health and Human Services
- Performance Goals, Objectives, and Results
- Looking Ahead to 2022
- 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 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.

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 a wide spectrum of programs, initiatives, and activities; serving and protecting Americans at every stage of life.

HHS is responsible for approximately 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 healthcare insurance for 1 in 3 Americans.

What We Do

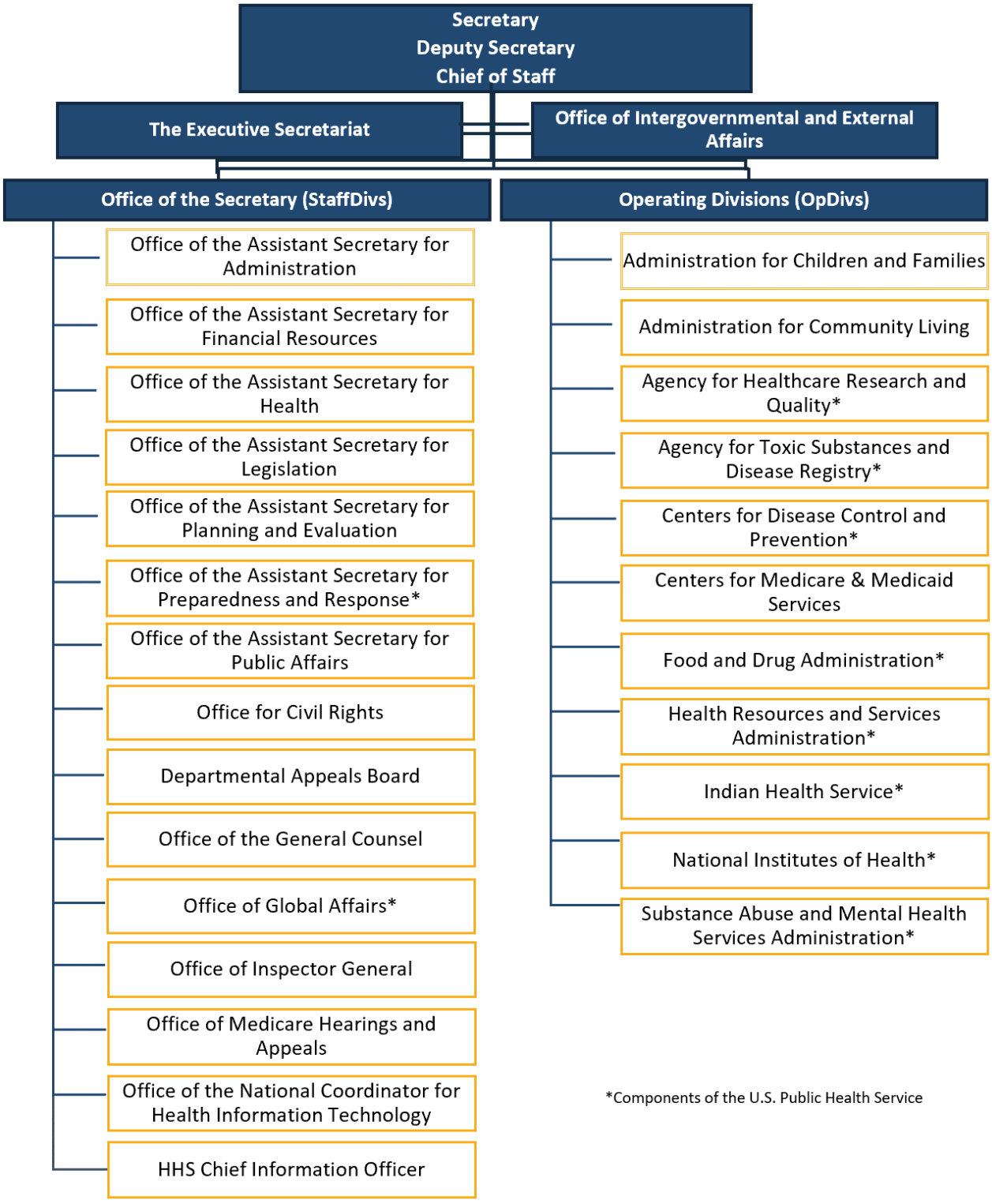
HHS works closely with U.S. state, local, territorial, and tribal governments; state or county agencies; private sector recipients; tribes; and tribal and Urban Indian organizations that provide many HHS-funded services at the local level. While HHS is a domestic agency working to protect and promote the health and well-being of the American people, the interconnectedness of our world requires that HHS engage globally to fulfill its mission. The HHS Office of the Secretary and the 11 Operating Divisions (OpDiv), including U.S. Public Health Service and human service agencies, administer HHS's programs. In addition, Staff Divisions (StaffDiv) provide leadership, direction, and policy guidance to the Department.

Through its programs and partnerships, HHS:

- Protects Americans by providing comprehensive responses to health, safety, and security threats, both foreign and domestic, natural or deliberate;
- Provides affordable healthcare coverage to more than 100 million people through Medicare, Medicaid, the Children's Health Insurance Program (CHIP), and the Health Insurance Marketplaces;
- Promotes patient safety and healthcare quality in healthcare settings and healthcare providers by assuring the safety, efficacy, and security of human and veterinary drugs, foods, biological products, and medical devices;
- 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 (IT) to improve the quality of care and to use data to drive innovative solutions to address the breadth of human services and healthcare challenges across HHS programs and its stakeholders;
- 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; and
- Prevents and manages the impacts of infectious diseases and chronic diseases and conditions, including the top causes of disease, disability, and death.

Organizational Structure

HHS's organizational structure is designed to accomplish its mission and provide a framework supporting sound business operations and management controls. Led by the HHS Secretary, the Office of the Secretary establishes the overarching vision and strategic direction for the Department and its OpDivs to provide a wide range of services and benefits to the American people. For more information, refer to HHS's website.



*Components of the U.S. Public Health Service

About the Department of Health and Human Services

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. ACF seeks to establish partnerships with front-line service providers, states, localities, and tribal communities to identify and implement solutions that transcend traditional program boundaries. ACF aims to improve access to services through planning, reform and integration, and address the needs, strengths, and abilities of vulnerable populations including refugees and migrants. Visit ACF for more information.

Did You Know? The Office of Refugee Resettlement has provided services for over 409,550 children, incorporating the principles and provisions established by the Flores Agreement in 1997, the *Trafficking Victims Protection Act of 2000* and its reauthorization acts, and the *William Wilberforce Trafficking Victims Protection Reauthorization Act of 2008*. For more ACF accomplishments, visit Office on Trafficking in Persons, an Office of the ACF.

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 healthcare safer, higher quality, more accessible, equitable, and affordable, and works within HHS and with other partners to make sure that evidence is understood and used. This mission is supported by focusing on three core competencies: (1) Health Systems Research; (2) Practice Improvement; and (3) Data & Analytics. Visit AHRQ for more information.

AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY (ATSDR)

ATSDR is responsible for 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.

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CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)

CDC works to protect America from health, safety, and security threats, both foreign and domestic. Whether diseases start at home or abroad, are chronic or acute, curable or preventable, due to human error or deliberate attack, CDC fights diseases and supports communities and citizens to do the same. CDC's cutting edge health security helps confront global disease threats through advanced computing and lab analysis of large amounts of data to quickly identify solutions, and puts science into action by tracking diseases to determine what makes people sick and identify effective prevention methods. Visit CDC for more information.

CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS)

CMS administers Medicare, Medicaid, CHIP, and the Clinical Laboratory Improvement Amendments of 1988 program. Over the last 50 years, CMS evolved into the largest purchaser of healthcare and now maintains the nation's largest collection of healthcare data. The Agency also has lead responsibility for the Federally-facilitated Health Insurance Marketplace, which provides access to private health insurance coverage to individuals and families in more than 30 states. In addition to these programs, CMS has the responsibility to ensure effective, up-to-date healthcare coverage, and to promote quality care for beneficiaries and consumers. Visit CMS for more information.

FOOD AND DRUG ADMINISTRATION (FDA)

FDA is responsible for protecting the public health by ensuring 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 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 regulates 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 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 programs provide equitable healthcare to people who are geographically isolated and economically or medically vulnerable. This includes programs that deliver health services to people with the human immunodeficiency virus (HIV), pregnant people, mothers and their families, those with low incomes, residents of rural areas, American Indians and Alaska Natives, and those otherwise unable to access high-quality healthcare. HRSA programs support health infrastructure, through the training of health professionals and dispersing them to areas where they are needed most, providing financial support to healthcare providers, and advancing telehealth. In addition, HRSA oversees programs for providing discounts on prescription drugs to safety net providers, facilitating organ, bone marrow, and cord blood transplantation, compensating individuals injured by vaccination, and maintaining data on healthcare malpractice payments. 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 healthcare provider and health advocate for the Indian people, with the mission of raising the physical, mental, social, and spiritual health of American Indians and Alaska Natives to the highest level. IHS provides a comprehensive health service delivery system for approximately 2.6 million American Indians and Alaska Natives who belong to 574 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. NIH fosters fundamental creative discoveries, innovative research strategies, and their applications as a basis for ultimately protecting and improving health. NIH expands the knowledge base in medical and associated sciences to enhance the economic well-being of the nation. 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. SAMHSA efforts are guided by five core principles: (1) Supporting the adoption of evidence-based practices; (2) Increasing access to the full continuum of services for mental and substance use disorders; (3) Engaging in outreach to clinicians, recipients, patients, and the American public; (4) Collecting, analyzing, and disseminating data to inform policies, programs, and practices; and (5) Recognizing that the availability of mental health and substance use disorder services are integral to everyone's health. Visit SAMHSA for more information.

Did You Know? The Children's Inn provides a free place to stay for children and young adult NIH patients while they participate in life changing clinical research studies at the NIH's Clinical Center. In FY 2021, NIH enabled children, teens, and young adults to participate in 522 clinical trials, advancing the treatment of cancer, bone and growth disorders, mental illness, genetic conditions, and other serious health issues. For more information, visit NIH's website.

The following 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.

IMMEDIATE OFFICE OF THE SECRETARY (IOS)

IOS is responsible for operations and coordination of the work of the Secretary through two offices: the Executive Secretariat and the Office of Intergovernmental and External Affairs (IEA). The Executive Secretariat 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. 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 ASSISTANT SECRETARY FOR ADMINISTRATION (ASA)

ASA provides leadership for HHS departmental management, including human resource policy and departmental operations. The Program Support Center (PSC), a component of ASA, 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. ASFR 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 the Department's key public health offices and programs, a number of Presidential and Secretarial advisory committees, 10 regional health offices across the nation, the Office of the Surgeon General, and the U.S. Public Health Service Commissioned Corps.

OFFICE OF THE ASSISTANT SECRETARY FOR LEGISLATION (ASL)

ASL is responsible for the development and implementation of the HHS's legislative agenda. ASL also 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)

The mission of ASPR is to save lives and protect Americans from 21st century health security threats. ASPR leads the nation's medical and public health preparedness for, response to, and recovery from disasters and public health emergencies. ASPR collaborates with hospitals, healthcare coalitions, biotech firms, community members, state, local, tribal, and territorial governments, and other partners across the country to improve readiness and response capabilities.

OFFICE OF THE ASSISTANT SECRETARY FOR PUBLIC AFFAIRS (ASPA)

ASPA serves as the principal counsel on public affairs and provides centralized leadership and guidance on public affairs for HHS's StaffDivs, OpDivs, and regional offices. ASPA also manages digital communication and administers the *Freedom of Information 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 healthcare 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, independent review of disputed legal decisions in a wide-range of Department programs for more than 60 statutory provisions. The DAB resolves disputes with outside parties such as state agencies, Head Start recipients, universities, nursing homes, doctors, and Medicare beneficiaries. The DAB conducts *de novo* reviews of administrative law judge action from the Office of Medicare Hearings and Appeals.

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 provides oversight to promote the economy, efficiency, effectiveness, and 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 for appeals arising from individual claims for Medicare coverage and payment for items and services furnished to beneficiaries under Medicare Parts A, B, C, and D. OMHA also hears appeals arising from claims for entitlement to Medicare benefits and disputes of Medicare Part B and Part D premium surcharges. OMHA operates separately from the other agencies involved in the Medicare claims appeal process.

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

ONC coordinates nationwide efforts to implement and uses the most advanced health IT and the electronic exchange of health information. ONC focuses on two objectives: advancing the development and use of health IT capabilities and establishing expectations for data sharing.

OFFICE OF THE CHIEF INFORMATION OFFICER (OCIO)

OCIO supports the HHS mission by leading the development and implementation of IT infrastructure across the agency.

For more information regarding our organization, visit HHS's website.

Performance Goals, Objectives, and Results

Overview of Strategic and Agency Priority Goals

The *Government Performance and Results Act of 1993* (GPRA) and the *GPRA Modernization Act of 2010* (GPRAMA) require federal agencies to update their Strategic Plan every 4 years at the beginning of an administration's new term. A strategic plan presents the long-term objectives an agency hopes to accomplish. It describes the agency's goals and objectives, what actions the agency will take to realize those goals, and how the agency will deal with potential challenges to achieving desired results.

The HHS Strategic Plan defines its goals and strategies, and how the Department will measure its progress to address complex, multifaceted, and evolving healthcare, public health, and human services issues. The Department's OpDivs and StaffDivs contribute to the development and success of the HHS Strategic Plan.

Strategic Goals

HHS is currently developing the HHS Strategic Plan FY 2022 – 2026 (Strategic Plan). In accordance with GPRAMA, the Strategic Plan will reflect input received from the public, Tribal consultation, and Congressional consultation. HHS will publish the final Strategic Plan in February 2022 with the release of the *FY 2023 President's Budget*.

The Strategic Plan will guide the Department's efforts as it carries out 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. HHS makes strategic investments to effectively and efficiently execute strategies to achieve our mission. For more information about the HHS Strategic Plan FY 2018 – 2022, visit the HHS Strategic Plan page. For more information about our investments, visit the HHS Budget & Performance page.

Agency Priority Goals

HHS is currently developing the FY 2022 – 2023 Agency Priority Goals (APGs), and will report them in the *FY 2023 Annual Performance Plan and Report.*

Performance Management

Performance goals and measures are powerful tools to advance an effective, efficient, and productive government. HHS regularly collects and analyzes performance data to inform decisions, gauge meaningful progress toward objectives, and identify cost-efficient ways to achieve results. Responding to opportunities afforded by GPRAMA, HHS continues to institute significant performance management improvements that include:

- Developing, analyzing, reporting, and managing APGs, and conducting performance reviews between OpDivs, StaffDivs, and HHS leadership to monitor progress toward achieving key performance objectives;
- Conducting the Strategic Reviews process to support decision-making and performance improvement across the Department;
- Coordinating performance measurement, budgeting, strategic planning, enterprise risk management (ERM), and evidence building activities within the Department;
- Fostering a network of OpDiv/StaffDiv Performance Officers who support, coordinate, and implement performance management efforts across HHS; and
- Sharing best practices in performance management at HHS through webinars and other media.

Data Quality

HHS follows GPRAMA guidelines for reporting data quality. For all measures that appear in APG reporting or in the HHS Strategic Plan, HHS publicly reports:

- Processes used to verify and validate measured values;
- Sources for the data;
- Confirmation that the data meets the level of accuracy required for its intended use;
- Any limitations to the data at the required level of accuracy; and
- How the agency will compensate for such limitations, if needed, to reach the required level of accuracy.

Each agency within HHS is responsible for certifying that this data undergoes a thorough quality assurance process and provides a signed letter of attestation to the Performance Improvement Officer. Data quality information for the APG-related measures mentioned below can be found online at Performance.gov. Data source and validation information on other data analyses, such as improper payment measures discussed in the "Other Information" section, can be found at HHS Budget and Performance.

Performance Results

In FY 2021, HHS monitored over 900 performance measures to improve the efficiency and effectiveness of departmental programs and activities. The HHS Schedule of Spending in the "Financial Section" highlights the total spending by each material program. Funding represents one of many factors that may influence performance results. More detailed information on HHS program performance and funding can be found at HHS Budget and Performance, expected to be updated in February 2022 concurrent with the *FY 2023 President's Budget*.

Ending the HIV Epidemic

The Department launched the *Ending the HIV Epidemic in the U.S.* (EHE) initiative in February 2019. The EHE aims to reduce the number of new HIV infections in the U.S. by 75 percent by 2025 and by 90 percent by 2030 through scaling up key HIV prevention and treatment strategies. Since 1981, more than 700,000 American lives have been lost to HIV/AIDS. While new HIV infections have declined since the early 2000s, CDC data indicates that progress has stalled and there are approximately 38,000 new infections per year. EHE's comprehensive approach focuses resources where needed most and strives to meet the needs with proper services. The initiative provides a targeted infusion of new resources and support to 50 local areas that account for more than half of new HIV diagnoses (48 counties; San Juan, Puerto Rico; and the District of Columbia), and seven states with a substantial burden of new rural cases. Through increased investments, infrastructure expansion, and local innovation, EHE aims to make history and end the domestic HIV epidemic once and for all.

EHE efforts focus on four key strategies that together can end the HIV epidemic in the U.S.: (1) Diagnose all people as early as possible; (2) Treat people with HIV rapidly and effectively to reach sustained viral suppression; (3) Prevent new HIV transmissions by using proven interventions, including pre-exposure prophylaxis and syringe services programs; and (4) Respond quickly to potential HIV outbreaks to get vital prevention and treatment services to people who need them.

Under HRSA, the Ryan White HIV/AIDS Program (RWHAP) works to improve health outcomes by preventing disease transmission or slowing disease progression for disproportionately impacted communities. One way RWHAP accomplishes its mission is through the provision of medications that help patients reach HIV viral suppression. People living with HIV who use medications designed to virally suppress the disease are less infectious, which reduces the risk of transmitting HIV to others. In March 2021, HRSA awarded approximately $99 million to 61 RWHAP recipients to link people with HIV to essential HIV care and treatment and support services, as well as to provide workforce training and technical assistance. In FY 2022, RWHAP will continue to play a central role in ending the HIV epidemic by ensuring that people living with HIV have access to regular care, receive antiretroviral medications, and adhere to a regular schedule for taking their medications. The percentage of RWHAP clients who are virally suppressed currently exceeds the national average as displayed in **Table 1** below.

July 2021 | In its second round of major EHE funding, CDC awards $117 million to advance innovation and health equity —and help HIV programs regain momentum in the wake of COVID-19.

Source: CDC Milestones, EHE in Action

Table 1: Increase in the Percentage of RWHAP Clients Receiving HIV Medical Care and At Least One Viral Load Test Who Are Virally Suppressed

	FY 2015	FY 2016	FY 2017	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Target	N/A	N/A	N/A	83%	83%	83%	83%	83%
Result	83%	85%	86%	87%	88%	10/31/22	10/31/23	10/31/24
Status	Actual	Actual	Actual	Target Exceeded	Target Exceeded	Pending	Pending	Pending

Did You Know? June 5, 2021 marked the 40th anniversary of the first official report about AIDS. HHS Secretary Becerra provided a statement recognizing the 40th anniversary and honoring the more than 32 million people who have died from AIDS-related illnesses globally, including 700,000 people in the U.S.

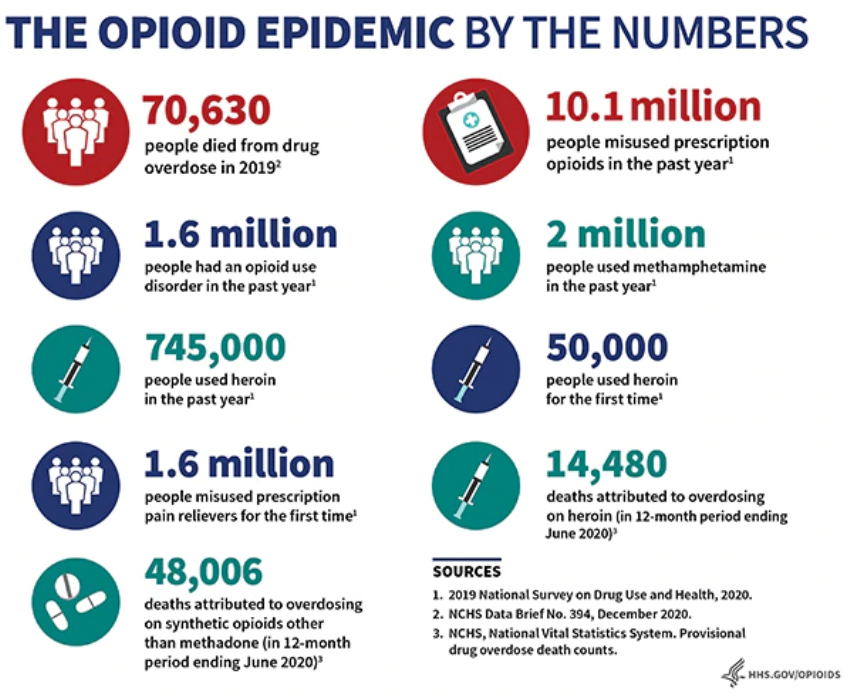
For more information on the Secretary's statement, visit HHS's website.

Reducing Opioid-related Morbidity and Mortality

Opioid misuse and overdose present a nationwide public health challenge. The crisis of opioid addiction and overdose in the U.S. continues to claim far too many lives, driven by highly potent illicit synthetic opioids in the drug supply. Over 450,000 people have died from overdoses involving opioids in the U.S. from 1999 through 2019. In response to this public health crisis, CDC's Overdose Data to Action (OD2A) cooperative agreement supports jurisdictions (i.e., recipients) in collecting high quality, comprehensive, and timely data on nonfatal and fatal overdoses, and in using the data to inform prevention and response efforts. OD2A funds 66 recipients comprising

of state, territorial, county, and city health departments. **Figure 1** demonstrates the devastating effects of the opioid epidemic by the numbers:

Figure 1: Opioid Epidemic by the Numbers



*Source: HHS's website, *What is the Opioid Epidemic*

In response to this public health emergency, HHS executes an Overdose Prevention Strategy for combatting opioid morbidity and mortality guided by four principles: (1) Equity, (2) Data and evidence, (3) Coordination, collaboration, and integration, and (4) Reducing stigma. This strategy focuses on four key strategic priorities:

1. Primary Prevention;
2. Harm Reduction;
3. Evidence-Based Treatment; and
4. Recovery Support.

HHS will continue to strengthen surveillance activities, identify interventions, and implement prevention programs that address the evolving nature of the epidemic. Surveillance components will continue to collect and disseminate timely morbidity and mortality data for all drug overdoses, including emerging threats such as polysubstance use and stimulants. HHS will also continue to fund innovative surveillance strategies to help drive action and inform more targeted prevention efforts. Prevention activities will strengthen prescription drug monitoring programs, improve consumer awareness around the risks of prescription opioids, establish linkages to care, and improve provider and health system support to increase safer prescribing, as projected in **Table 2**.

Table 2: Reduce Age-Adjusted Rate of Overdose Deaths Involving Natural and Semi-Synthetic Opioids or Methadone

	FY 2015	FY 2016	FY 2017	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Target	N/A	N/A	N/A	4.2 per 100,000 residents	4.1 per 100,000 residents	3.9 per 100,000 residents	3.7 per 100,000 residents	3.6 per 100,000 residents
Result	N/A	N/A	5.7 per 100,000 residents	4.9 per 100,000 residents	4.5 per 100,000 residents	1/30/22	1/30/23	1/30/24
Status	N/A	N/A	Baseline	Target Not Met	Target Not Met	Pending	Pending	Pending

The misuse of, and addiction to, opioids such as heroin and prescription pain medicines are serious national problems. This issue increased the number of opioid use disorders (OUD) and related fatalities from overdoses; rising incidence of newborns who experience neonatal abstinence syndrome because their mothers used these substances during pregnancy; and increased spread of infectious diseases, such as HIV and hepatitis C. One facet of NIH-funded research focuses in providing scientific evidence to inform the public health response to the opioid crisis. During FY 2021, NIH funded clinical trials to study an anti-opioid vaccine and a new medication to treat OUD. In FY 2022, NIH will fund clinical trials to study a medication for relapse prevention in OUD or overdoses.

For additional information on the opioid key indicators and other report updates, refer to *HHS FY 2022 Annual Performance Plan and Report*.

Health Equity

Behavioral health equity is the right to access quality healthcare for all populations regardless of the individual's race, ethnicity, gender, socioeconomic status, sexual orientation, or geographical location. This includes access to prevention, treatment, and recovery services for mental and substance use disorders. In conjunction with quality services, this involves addressing social determinants, such as employment and housing stability, insurance status, proximity to services, and culturally responsive care – all of which have an impact on behavioral health outcomes.

Mental illness creates health risks and substantial burden on affected individuals and their families. Mental disorders are health conditions that involve significant changes in thinking, emotion, and/or behavior and lead to distress and/or problems functioning in social, work, and/or family activities. Mental health disorders are illnesses that impact people's ability to go about their daily lives in family, social, and professional settings and place individuals at risk of additional health problems. HHS works closely with federal, state, tribal, local, territorial, and community partners, including faith-based and community organizations, to help identify and address mental health problems.

Performance Goals, Objectives, and Results

SAMHSA collaborated with states and the Interdepartmental Serious Mental Illness Coordinating Committee (ISMICC) to address the needs of children and youth with serious emotional disturbances. SAMHSA funded several programs to increase access to treatment, including Healthy Transitions continuation grants and contracts for technical assistance and evaluation. SAMHSA will work to improve these results by providing technical assistance to recipients and by continuing to monitor major depressive episodes in youth ages 12–17. The agency anticipates that these efforts will lead to reductions in the percentage of youth who report major depressive episodes, as projected in **Table 3**.

Table 3: Increase Percentage of Youth Ages (12–17) Who Experience Major Depressive Episodes with Severe Impairment in the Past Year Receiving Treatment for Depression

	CY 2015	CY 2016	CY 2017	CY 2018	CY 2019	CY 2020	CY 2021	CY 2022
Target	N/A	N/A	N/A	48%	48.5%	50%	55%	56%
Result	N/A	46.7%	47.5%	46.9%	49.7%	12/31/21	12/31/22	12/31/23
Status	N/A	Actual	Actual	Target Not Met	Exceeds Target	Pending	Pending	Pending

The National Survey on Drug Use and Health defines mental health services as inpatient treatment/counseling, outpatient treatment/counseling, or the use of prescription medication for mental health problems. In Calendar Year (CY) 2019, 65.5 percent of adults aged 18 or older received mental health services, which was less than targeted (68.0 percent). In CY 2021 and CY 2022, SAMHSA will continue to provide guidance to agencies on how to administer mental health services to individuals with serious mental illness. Federal efforts, including ISMICC, discretionary grant programs, and SAMHSA's Clinical Support Services for serious mental illness Technical Assistance Center will enable agencies to provide coordinated efforts and resources to individuals with serious mental illness, as projected in **Table 4**.

Table 4: Increase Percentage of Adults with Serious Mental Illness Receiving Mental Health Services

	CY 2015	CY 2016	CY 2017	CY 2018	CY 2019	CY 2020	CY 2021	CY 2022
Target	N/A	N/A	N/A	67%	68%	71%	75%	76%
Result	N/A	64.8%	66.7%	64.1%	65.5%	12/31/21	12/31/22	12/31/23

Climate Change

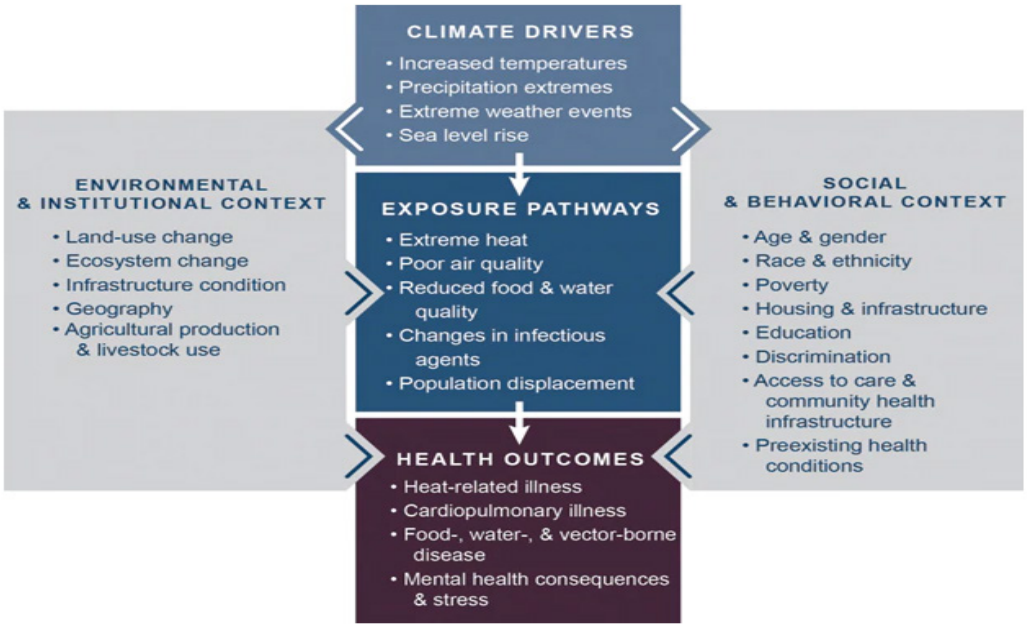
HHS invests in strategies to mitigate the impacts of environmental factors on health outcomes, including climate change. HHS established the Office of Climate Change and Health Equity (OCCHE) as the first national-level office established to address climate change and health equity in response to Executive Order 14008: Tackling the Climate Crisis at Home and Abroad. The Office's mission is to protect vulnerable communities who disproportionately bear the brunt of pollution and climate-driven disasters, such as drought and wildfires, at the expense of public health.

Source: OCCHE website

OCCHE will play a pivotal role in protecting our communities' health and climate health on a global scale. OCCHE will be tasked with: (1) Identifying communities with disproportionate exposures to climate hazards and vulnerable populations; (2) Addressing health disparities exacerbated by climate impacts to enhance community health resilience; (3) Promoting and translating research on public health benefits of multi-sectoral climate actions; (4) Assisting with regulatory efforts to reduce greenhouse gas emissions and criteria air pollution throughout the healthcare sector, including participating suppliers and providers; (5) Fostering innovation in climate adaption and resilience for disadvantaged communities and vulnerable populations; (6) Promoting training opportunities to build the climate and health workforce and empower communities; (7) Providing expertise and coordination to the White House, Secretary of Health and Human Services and federal agencies related to climate change and health equity deliverables and activities, including executive order implementation, and reporting on health adaption actions under the United Nations Framework Convention on Climate Change; and (8) Exploring opportunities to partner with the philanthropic and private sectors to support innovative programming to address disparities and health sector transformation.

Climate change may worsen existing differences in health, increasing the significance of health equity. The effects of climate change increase other longstanding differences among people that result in different health outcomes for communities in the U.S. Some of these impacts, as illustrated in **Figure 2**, may result in exposures to pollution, poor living conditions, and psychological stresses.

Figure 2: Impact of Climate Change on Human Health



Source: HHS OCCHE, Impact of Climate Change on Human Health

Grants Quality Service Management Office

The Office of Management and Budget (OMB) Memorandum M-19-16, *Centralized Mission Support Capabilities for the Federal Government*, created Quality Services Management Offices (QSMOs) to standardize services commonly used across federal agencies for select mission-support functions including grants management, cybersecurity, financial management, and human resources. QSMOs are tasked with offering and managing a marketplace of solutions (i.e., technology systems and non-technology services) that, over time, will improve customer satisfaction, automate processes, modernize technology, standardize data and related processes, and achieve efficiencies in time and money across the government.

On January 11, 2021, OMB formally designated HHS as the QSMO for Grants Management: Grant Program Administration and Oversight, Management of Grant Pre-Award, Award, Post-Award & Closeout, and Grant Recipient Oversight. With this designation, the Grants QSMO is working across all federal awarding agencies to assess business needs and viable solutions, modernize, automate, and standardize grants management processes and systems, and facilitate execution of key administration priorities as outlined in OMB Memorandums M-21-20, *Promoting Public Trust in the Federal Government through Effective Implementation of the American Rescue Plan Act of 2021* (ARP) *and Stewardship of the Taxpayer Resources* and further clarified M-22-02, *New Financial Assistance Transparency Reporting Requirements*. This work is guided by the Grants QSMO 2030 Vision to empower and enable applicants, recipients, and federal awarding agencies to efficiently and effectively deliver on the grants mission. This vision is further reinforced by three pillars:

1. To ease burden and drive efficiencies for grant applicants, recipients, and for federal workforce government-wide;
2. Respond to customer needs; and
3. Leverage data as a strategic asset.

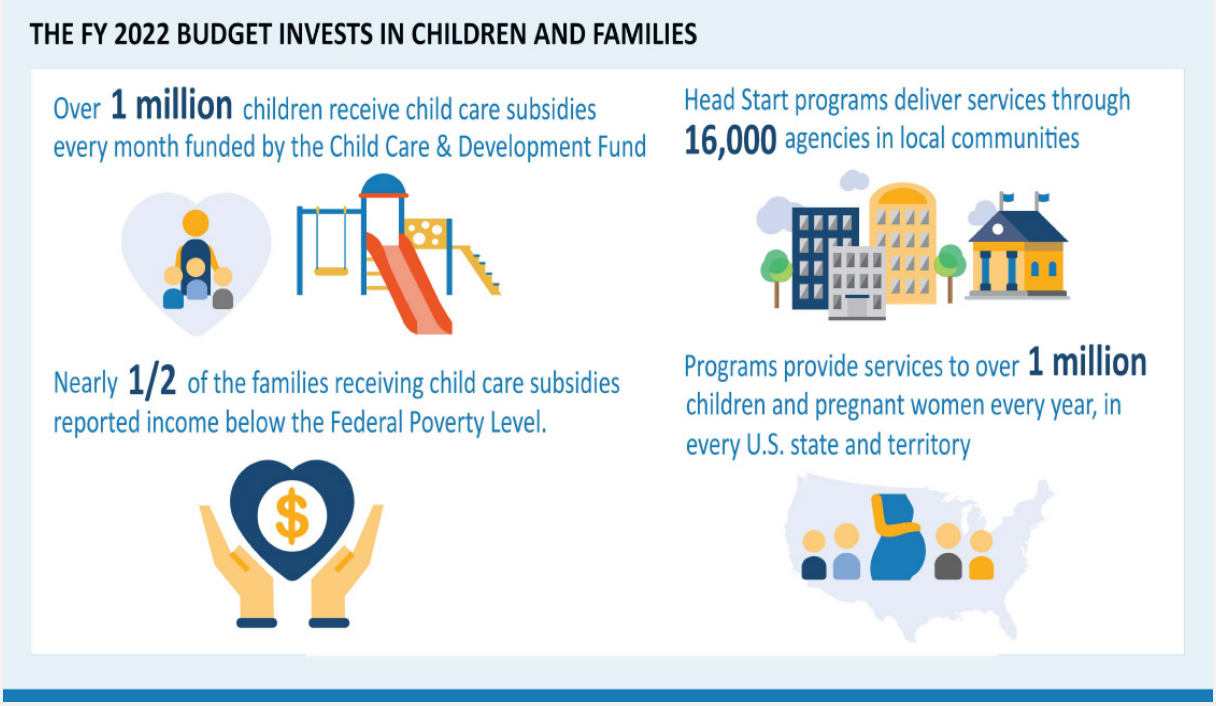
The designation of HHS as the Grants QSMO affirms the long-standing role of HHS as the largest grant-making agency and leader in improving grants management and recognizes HHS's ongoing commitment to improving Grants Management across the Federal government.

Looking Ahead to 2022

HHS accomplishes its mission through programs and initiatives that cover a wide spectrum of activities. Eleven OpDivs, including eight agencies in the U.S. Public Health Service and three human services agencies, administer HHS's programs. 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 HHS to engage globally to fulfill its mission. In addition, StaffDivs provide leadership, direction, and policy guidance to the Department.

As described in the Performance Goals, Objectives, and Results section, concurrent with the *FY 2023 President's Budget* submission, HHS will update its Strategic Plan to reflect the scope and breadth of the Department, aligned to the current Administration and Secretary priorities, including: Protect and expand Americans' access to quality, affordable healthcare; build on the *Patient Protection and Affordable Care Act* to meet the healthcare needs created by the pandemic; reduce healthcare costs and health disparities; make the healthcare system less complex to navigate; address the health impacts of climate change and other environmental factors; support maternal and child health; contain the COVID-19 crisis and prepare for future emergencies; and put equity at the center of the Department's approaches to achieving the HHS mission.

Did You Know? The FY 2022 budget will invest $250 billion over 10 years to make childcare affordable by providing high-quality early care and education, laying a strong foundation so children can take full advantage of education and training opportunities later in life. For more information on the *FY 2022 Budget in Brief*, visit HHS's website.



Systems, Legal Compliance, and Internal Control

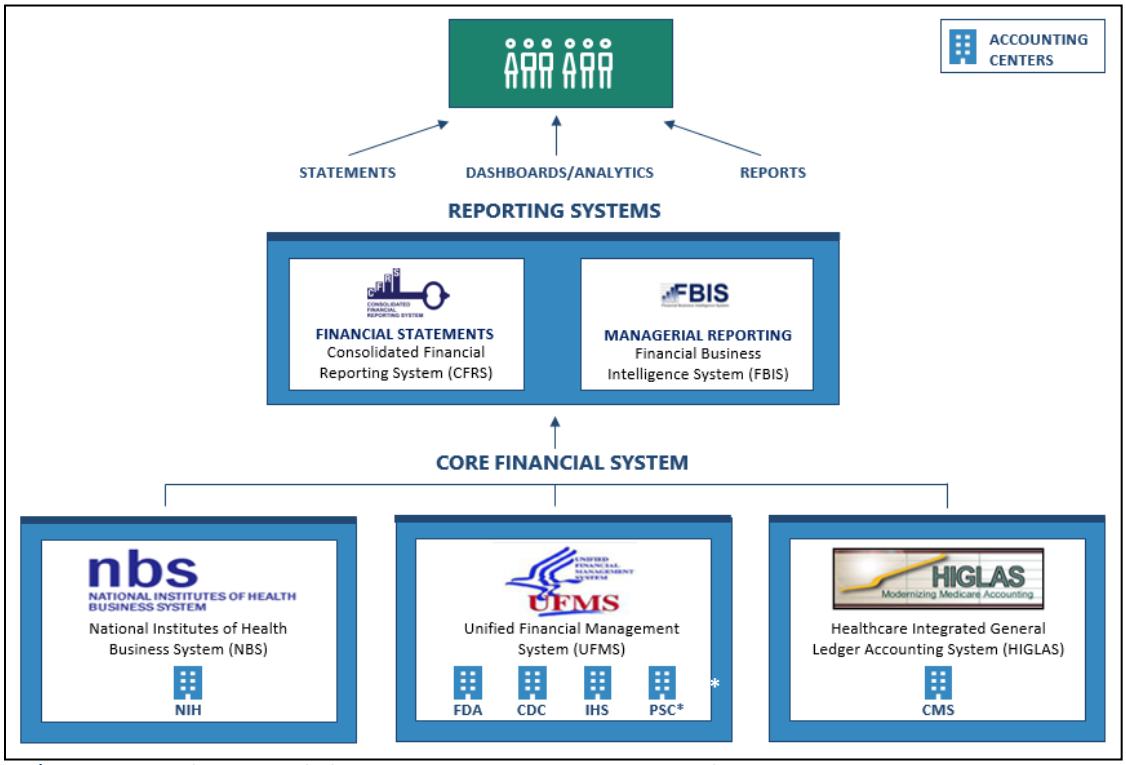
Systems

HHS's Chief Financial Officer (CFO) community continuously strives to enhance the financial management systems environment to sustain HHS's diverse portfolio of mission-oriented programs and business operations. The primary objectives of the financial management systems environment are 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 framework provides the foundation to manage approximately $2.7 trillion in budgetary resources entrusted to the Department in FY 2021. These resources include the *Coronavirus Aid, Relief, and Economic Security Act* (CARES Act), *American Rescue Plan Act of 2021* (ARP), and other supplemental funding vital to assisting citizens with the public health and economic impacts of COVID-19. HHS's financial management systems environment supports and ensures the efficient and timely disbursement of funds, which is a critical factor in advancing HHS's COVID-19 relief efforts. Additionally, HHS's robust financial management systems environment provides federal contract, grant, loan, and other financial assistance data to USASpending.gov, which presents clear, accurate, and timely awards information while providing transparency and accountability to the American public.

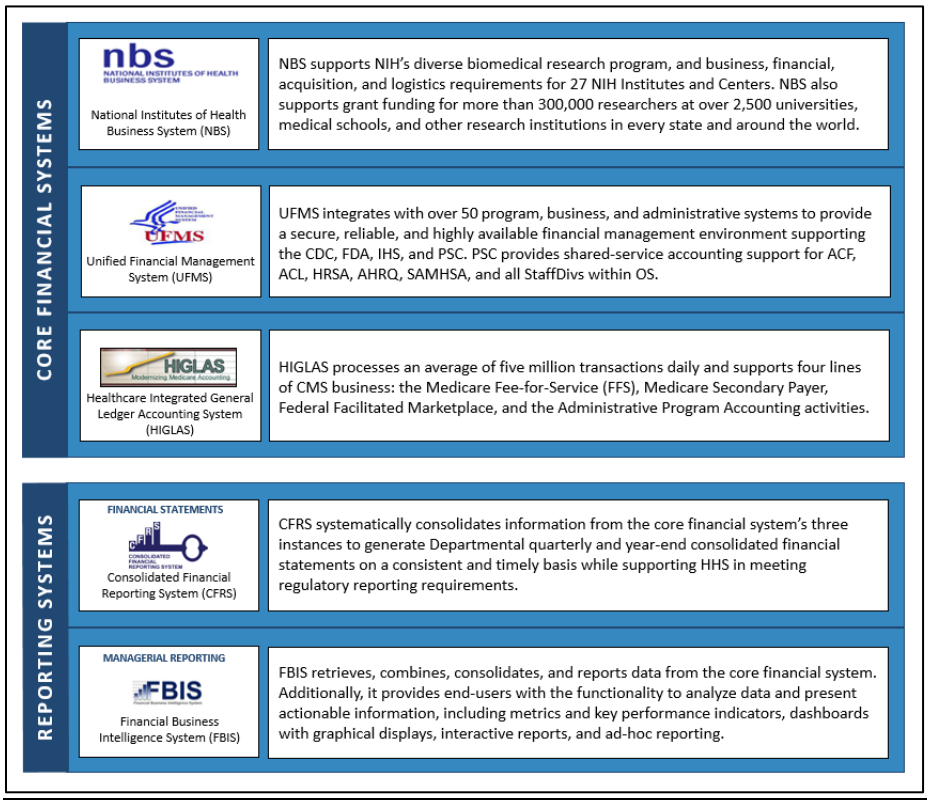
The HHS financial management systems environment, detailed in **Figure 3** and **Figure 4**, consists of a core financial system with three instances and two Department-wide systems. The core financial system's three instances operate on the same commercial off-the-shelf platform to promote Department-wide data standardization. The reporting systems within the HHS financial management systems environment facilitate financial statement compilation, data analysis, and financial and managerial reporting. Together, these systems fulfill HHS's financial accounting and reporting needs.

Figure 3: HHS Financial Management Systems Environment



* PSC-supported OpDivs include ACF, ACL, AHRQ, HRSA, SAMHSA, and OS.

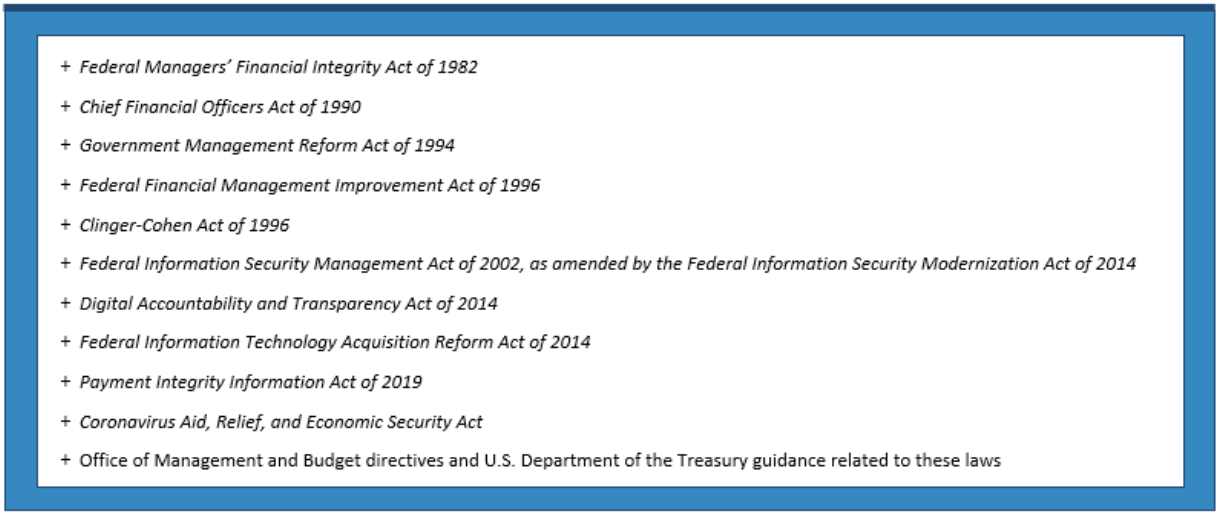
Figure 4: HHS Financial Management Systems



Relevant Legislation and Guidance

The HHS financial management systems environment must comply with all applicable federal laws, regulations, and authoritative guidance included in **Figure 5**.

Figure 5: Relevant Legislation and Guidance



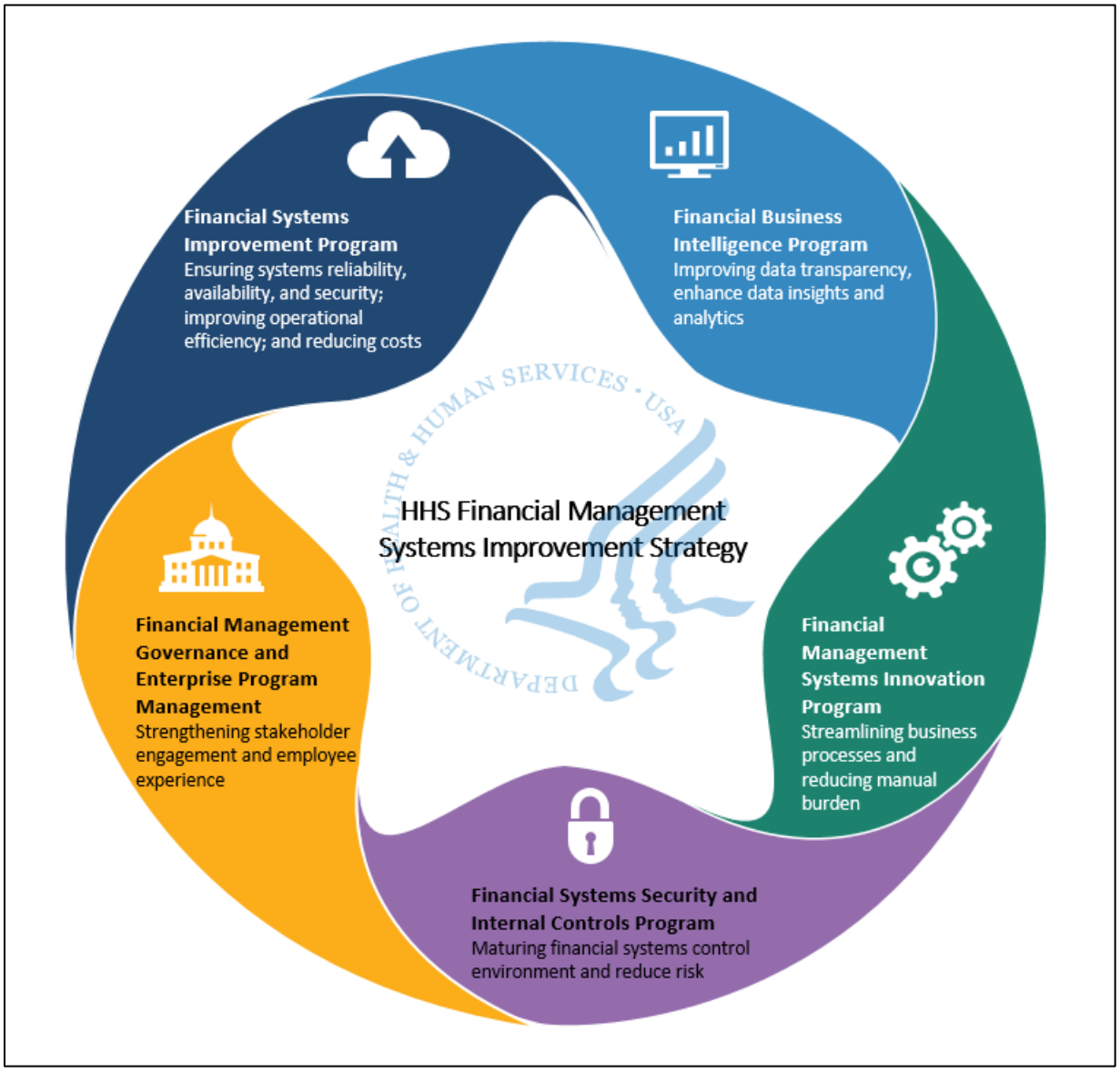
Systems, Legal Compliance, and Internal Control

Financial Management Systems Improvement Strategy

HHS made substantial progress in maturing the financial management systems environment over the years. Financial managers continue to face a rapidly changing financial management landscape with increasing demands for accountability and transparency, evolving federal mandates, increasing security threats, and the need to maximize the value of system investments.

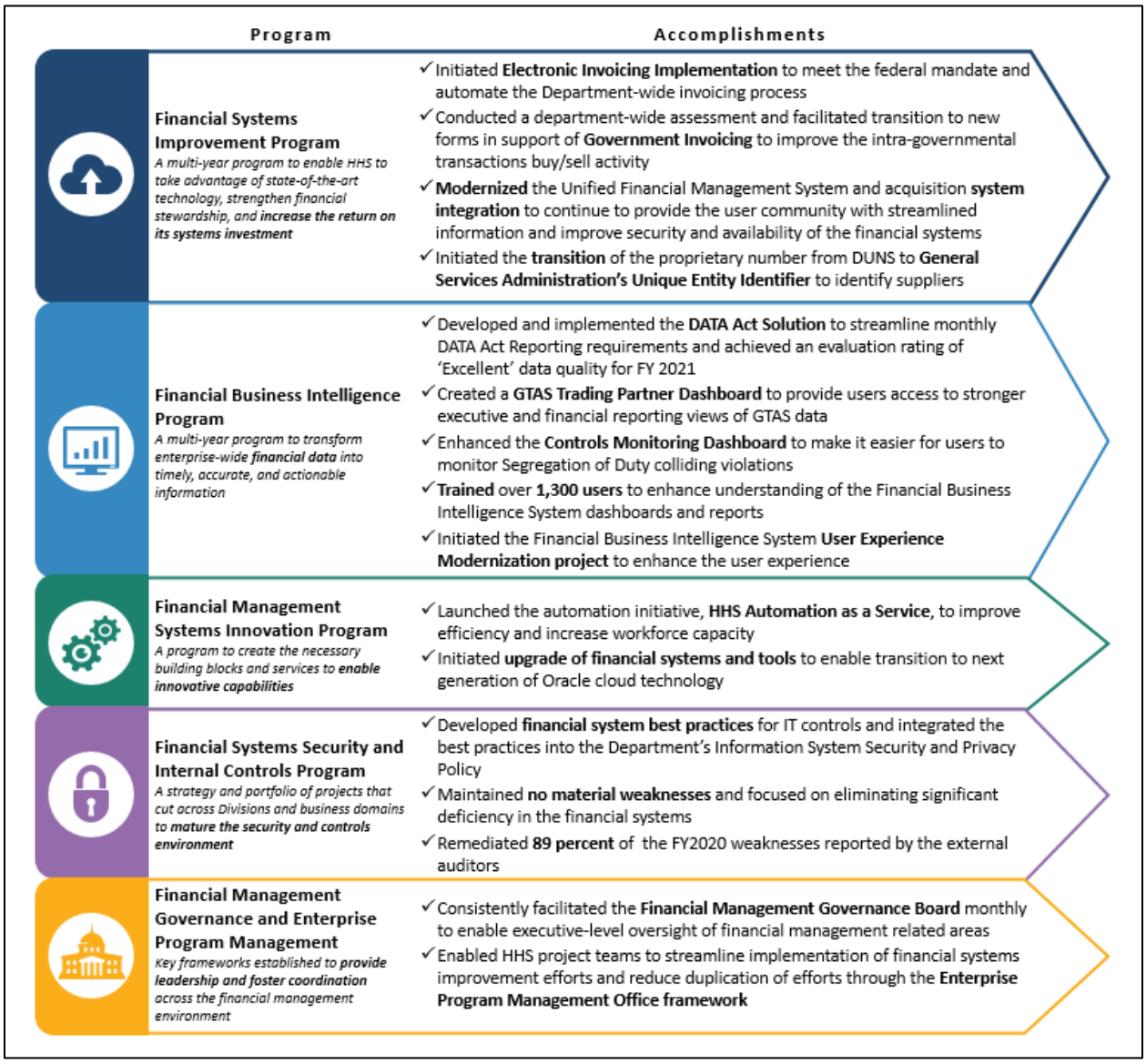
To combat these challenges, HHS developed a Department-wide financial systems improvement strategy with five programs and objectives, as illustrated in **Figure 6**.

Figure 6: Financial Management Systems Improvement Strategy



In addition, HHS remained focused on the customer experience, ensuring each mission critical project provides value to the end-user through improved capabilities of the enterprise-wide financial management systems. HHS continues to drive forward the five strategic programs summarized in **Figure 7**.

Figure 7: Financial Systems Improvement Strategy Programs and Accomplishments



1. Financial Systems Improvement Program

Through the Financial Systems Improvement Program (FSIP), HHS is actively pursuing multiple initiatives to generate efficiencies and improve the effectiveness of the financial management systems. HHS is modernizing the invoicing process by implementing an Electronic Invoicing (E-Invoicing) solution to automate the entry, approval, and processing of commercial invoices to reduce the time between invoice receipt and payment. HHS developed a comprehensive assessment and implementation strategy for E-Invoicing; CMS implemented the strategy in the Healthcare Integrated General Ledger Accounting System in August 2020. In FY 2021, NIH initiated implementation efforts for NBS and HHS initiated implementation efforts for UFMS to serve the remaining OpDivs and StaffDivs. Both initiatives are on schedule for Department-wide implementation by March 2022. Once implemented, the solution will automate the processing of over 300,000 invoices and provide a 295 percent return on investment with a payback period of less than 3 years.

HHS launched the Department-wide Government Invoicing (G-Invoicing) adoption to align with the U.S. Department of the Treasury's (Treasury) initiative to improve the intra-governmental transactions (IGT) buy/sell activity. In FY 2021, HHS completed a Department-wide assessment to understand the implications of G-Invoicing. To address the complexity and decentralized nature of HHS's IGT business processes, HHS strategically developed an incremental approach and provided Department-wide guidance and training materials to enable smooth adoption of new forms starting October 1, 2021. This early transition to the new forms will support a more seamless transition to G-Invoicing when it launches October 1, 2022.

In addition, HHS implemented the modernization of the UFMS and acquisition system integration. The modernization marks a pivotal milestone in HHS's continued commitment to provide the user community with reliable, accurate, and streamlined information; improve security and enhance financial system availability; and adopt modern technologies that serve as a foundation to increase efficiency and incrementally modernize UFMS interfaces with the remaining 50+ feeder systems. This integration also addressed E-Invoicing implementation gaps in UFMS and will improve data quality and make it easier to access payment information for suppliers at UFMS-serviced OpDivs.

Additionally, HHS is implementing the General Services Administration's (GSA) Unique Entity Identifier in HHS's financial systems to identify suppliers. Effective April 4, 2022 the federal government is transitioning from the proprietary Data Universal Numbering System to the Unique Entity Identifier. To align with the vendor patch release schedule, HHS developed an incremental approach, collaborated with the OpDivs, and implemented the changes that are independent of vendor patches on September 10, 2021, ahead of schedule. Now HHS is on schedule to implement the vendor solution and complete the project by the mandated date.

2. Financial Business Intelligence Program

The Financial Business Intelligence Program (FBIP) provides operational and business intelligence capabilities to 1,900 users within the HHS financial management community through its business intelligence system, FBIS. To facilitate improved stewardship and decision-making in FY 2021, HHS made a dedicated effort to bolster FBIS' capabilities and adoption.

HHS implemented commercial off-the-shelf based monthly *Digital Accountability and Transparency Act of 2014* (DATA Act) reporting in accordance with the CARES Act, OMB Memorandum M-20-21, *Implementation Guidance for Supplemental Funding Provided in Response to the Coronavirus Disease 2019 (COVID-19),* and Treasury implementation guidance. This solution allows HHS to meet COVID-19 reporting requirements in a manner that is easy to maintain and upgrade, significantly improves the quality of HHS's financial data, and provides additional analytic capabilities to HHS's users. HHS achieved an evaluation rating of 'Excellent' quality, the highest possible rating for HHS data, in the FY 2021 DATA Act Audit Report. The solution also positions HHS to meet additional Treasury requirements and deadlines.

HHS developed new, insight-driven FBIS reports and dashboards by enhancing HHS's managerial reporting capabilities and facilitating improved stewardship and decision-making. For example, the Governmentwide Treasury Account Symbol Adjusted Trial Balance System (GTAS) Trading Partner Dashboard provides users access to enhanced executive and financial reporting views of the GTAS data, used for performing analyses and reconciliations for DATA Act reporting. Additionally, HHS significantly improved the Segregation of Duties Control Monitoring Dashboard, now presenting users with only risk-based conflicting transactions for their review and certification. As a result, the financial management community has access to new insights, along with tools to execute financial management responsibilities effectively and efficiently.

In FY 2021, HHS enhanced customer understanding of FBIS dashboards and reports by providing training to over 1,300 users, tripling the Net Promoter Score indicating a significant increase in customers who are likely to

recommend the system to a colleague. Further, HHS initiated the FBIS User Experience Modernization Project to increase ease of access to FBIS, strengthen navigation capabilities, provide on-demand trainings, and create new dashboards – all to enhance the user experience.

3. Financial Management Systems Innovation Program

HHS undertook various initiatives to capitalize on technological advances and enable innovative capabilities to streamline business processes and reduce manual burden.

In FY 2021, HHS successfully launched the HHS Automation-as-a-Service (HAaaS) initiative to use robotic process automation to emulate human actions and automate repetitive manual processes, increase efficiency, improve quality, and increase capacity for the financial workforce. HAaaS was initiated with a simple mindset: think big, start small, and scale fast. HHS successfully implemented three automations to reduce invoice and receivable posting times, provide higher data quality, and streamline submission of financial information. In addition, HHS built the foundational framework including a vision, strategy, governance, security, and change/configuration management that positions the financial community to build additional automations at scale. These automations will enable improved productivity, lower costs, and enhanced business value while simultaneously maintaining compliance and security controls.

With a migration to the new generation of Oracle Cloud on the horizon, HHS initiated a program-wide approach to upgrade systems and tools from Oracle 12c onto the newest version of Oracle's Database Technology 19c. In FY 2021, HHS upgraded FBIS and three key tools to 19c and initiated the upgrade process for CFRS. As a result, HHS is well-positioned to maximize better performance, storage efficiencies, cost savings, and other features to streamline the migration of UFMS system infrastructure to a more modern cloud.

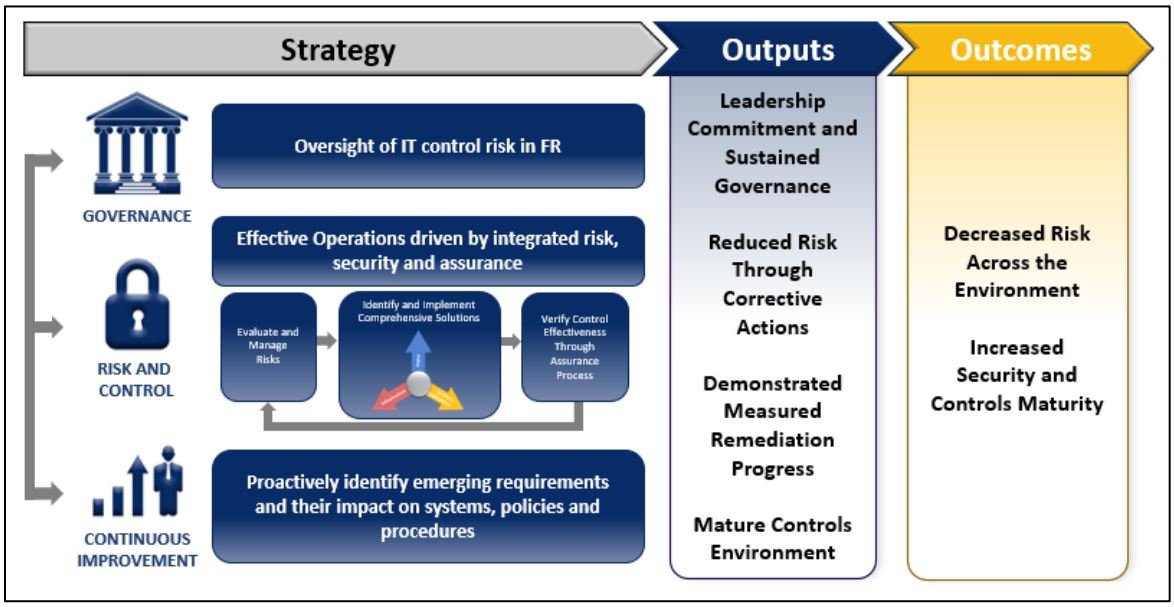
4. Financial Systems Security and Internal Controls Program

The reliability, availability, and security of HHS's financial systems are paramount. HHS prioritizes enhancing its financial systems security and controls environment, strengthening policy, proactively monitoring emerging issues, and remediating identified weaknesses to reduce risk.

HHS developed a comprehensive strategy to achieve its vision of a mature Financial Systems Control Environment (FSCE) that effectively mitigates risk. This Department-wide strategy, shown in **Figure 8**, provides the framework for governance and oversight; guides Department-wide actions to address systemic deficiencies and mitigate risk(s); and coordinates proactive efforts to continuously improve and mature the overall financial systems environment. These strategic initiatives chart the path to successful achievement of the desired strategic outputs and outcomes**.**

Systems, Legal Compliance, and Internal Control

Figure 8: Financial Systems Control Environment Maturity Strategy



In FY 2021, HHS made significant improvements toward its strategic vision and remediated 89 percent of the prior years' Federal Information System Controls Audit Manual (FISCAM) audit weaknesses. Most notably, HHS continues to operate its financial management systems with no material weakness and is focused on eliminating the significant deficiency identified by the external auditors.

HHS's internal control governance goals are to strengthen oversight, standardize policy and control implementation, and provide timely communications to HHS stakeholders at all levels. For example, HHS developed the financial system best practices for information technology (IT) controls and integrated the best practices into the Department's Information System Security and Privacy Policy (IS2P). In addition, HHS continued the standardization of IT control testing across the FSCE and enhanced communications with HHS stakeholders to promote risk understanding and awareness. The Department also hosted its fourth annual IT Audit, Internal Control, and Risk Management Summit. This Summit has earned recognition from the Department's CIO and CFO leadership as a vital platform for driving Department-wide IT security and control maturity.

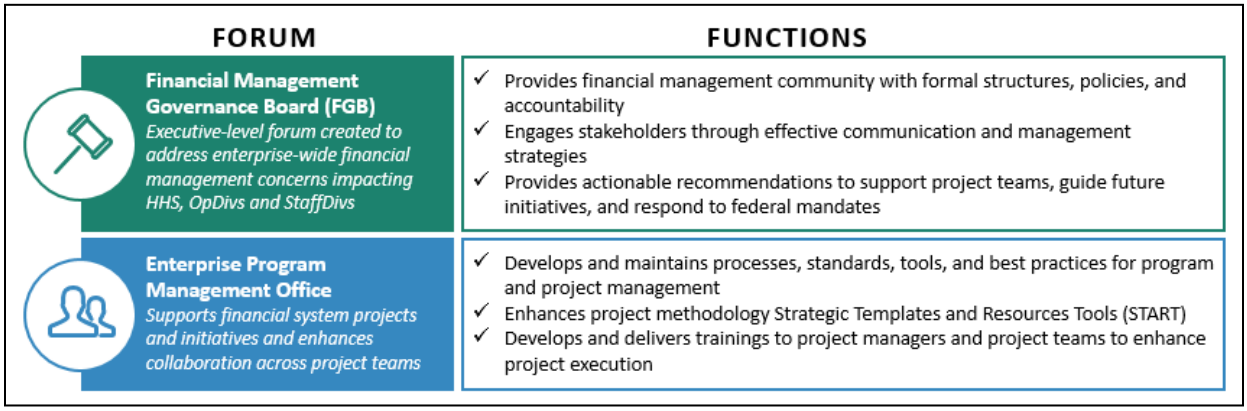
Risk management and control activities are the foundation of the Department-wide FSCE maturity strategy. These activities steward effective operations by integrating risk, security, and assurance processes. This integration is accomplished through tactical risk evaluations; comprehensive corrective action planning; and risk mitigation monitoring and verification processes. In addition, HHS continues to improve its security posture by modernizing financial systems, implementing innovative solutions, and monitoring emerging technology. For example, HHS established an annual Management Assessment Framework (MAF) process to evaluate IT control risks within the FSCE using objective and quantifiable risk measurement criteria. MAF enables management to assess the Department's progress toward achieving its vision of a mature FSCE that effectively mitigates risk. The FY 2021 MAF assessment determined that 92 percent of the 34 financial and mixed systems' tested controls were effective with no material weakness.

HHS also assembled a "Tiger Team" to immediately address cross-cutting issues identified internally and reported by external auditors. The "Tiger Team" is a collaboration of subject matter experts across the OpDivs and includes representatives from key financial and mixed systems, identity management systems, and OCIO. Together this team seeks to find comprehensive solutions to benefit the Department's efforts to optimize system access security controls.

5. Financial Management Governance and Enterprise Program Management

HHS institutionalized key frameworks to increase stakeholder engagement at all levels in the decision-making process to help establish a common direction and drive enterprise-wide priorities. To guide Department-wide initiatives that have a financial management impact, HHS established the Financial Management Governance Board (FGB), an executive-level forum to address enterprise-wide concerns related to financial management policies and procedures, financial data, financial systems, and technology impacting the Department, OpDivs, and StaffDivs. The FGB's goals complement the Department strategic goals, as illustrated in **Figure 9**.

Figure 9: Financial Management Governance and Enterprise Program Management Overview



In FY 2021, the FGB and its working groups continued to effectively transform the way financial management initiatives and activities are accomplished in HHS, moving from a Division-specific, vertical focus to a more enterprise-wide approach.

Enterprise Program Management provides a sustaining framework for the HHS financial management community stakeholders, while strengthening coordination, collaboration, and shared responsibilities related to programs and projects across the Department. In FY 2021, the Enterprise Program Management Office continued its efforts to transform project implementation and execution by enhancing its project methodology Strategic Templates and Resources Tools; including developing and delivering training to project managers and project teams to further enhance project execution, improve consistency, and standardize reporting. As the Department's business needs evolve, the Enterprise Program Management Office continues to mature and support ongoing collaboration and coordination across the financial systems environments and modernization initiatives.

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 unauthorized voluntary services. As required by the ADA, HHS notifies all appropriate authorities of any ADA violations. ADA reports can be found on U.S. Government Accountability Office (GAO) - ADA Resources.

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 for budget execution that specify basic fund control principles and concepts, including the administrative control of all funds for HHS and its OpDivs, StaffDivs, and Accounting Centers. HHS is currently reviewing four potential issues and remains fully committed to resolving these matters appropriately in compliance with all aspects of the law.

Coronavirus Aid, Relief, and Economic Security Act

The CARES Act, signed on March 27, 2020, provides emergency assistance and healthcare response for individuals, families, and businesses affected by the COVID-19 pandemic. The CARES Act was the first COVID-19 supplemental appropriation to both authorize emergency funds and mandate significant legal requirements. The CARES Act requirements and subsequent guidance, outlined in Section 15010(a)(6)(D), apply to all prior and future COVID-19 covered funds, including the *Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020*, the *Families First Coronavirus Response Act*, the *Paycheck Protection Program and Health Care Enhancement Act*, the *Coronavirus Response and Relief Supplemental Appropriations Act, 2021*, and the ARP. An additional set of significant legal requirements was included in ARP (detailed in the following section) and OMB-issued memorandums to help agencies meet the intent of the CARES Act and ARP's non-financial directives, as summarized in **Figure 10**.

Figure 10: Summary of CARES Act and ARP's Compliance Requirements

The HHS OIG released the *OIG Strategic Plan: Oversight of COVID-19 Response and Recovery* to demonstrate HHS's commitment to the requirements of CARES Act Section 15010. OIG collaborates with the CARES Act-formed Pandemic Response Accountability Committee (PRAC) and serves as the HHS-equivalent oversight function; HHS's Principal Deputy IG serves as the PRAC Healthcare Subgroup lead. By collaborating on the oversight of covered funds, OIG can share lessons learned and avoid duplication of effort. The PRAC has leveraged HHS OIG's mature data analytic operations to assist in building the Pandemic Analytics Center of Excellence providing analytic, audit, and investigation support to the oversight community.

To enhance program changes driven by requirements of CARES Act Sections 3201 and 3202, CMS released revised user guidance in February 2021 to help applicable group health plans and issuers comply with requirements to cover services related to COVID-19 diagnostic testing without imposing cost-sharing requirements or prior authorization.

OMB Memorandum M-20-21, *Implementation Guidance for Supplemental Funding Provided in Response to the Coronavirus Disease 2019 (COVID-19),* directed agencies to leverage existing financial reporting processes under the DATA Act described below, to help meet the CARES Act reporting requirements. HHS successfully transitioned to monthly reporting that includes additional COVID-19 related data to meet this requirement. Submissions to USASpending.gov provide greater transparency and oversight of spending related to covered funds.

American Rescue Plan Act of 2021

To further support the ongoing COVID-19 pandemic response, ARP was enacted on March 11, 2021, as a cornerstone of the Administration's response to the ongoing COVID-19 pandemic. ARP offers funds for economic relief to individuals, families, and businesses, for developing COVID-19 treatments and vaccines for mitigating the spread of the virus, and/or procuring supplies such as personal protective equipment (PPE). ARP strengthens our pandemic recovery by emphasizing oversight, transparency, equity-oriented results, and meeting the needs of under-served communities.

OMB released Memorandum M-21-20, *Promoting Public Trust in the Federal Government through Effective Implementation of the American Rescue Plan Act and Stewardship of the Taxpayer Resources,* 8 days after ARP was signed into law. OMB's existing policy directs agencies to report COVID-19 funds through the DATA Act and to assign a disaster emergency fund code to COVID-19 funds, enabling Treasury and the PRAC to identify COVID-19 spending data across the government. OMB Memorandum M-21-20 leverages this reporting model. HHS's mature DATA Act processes and cross-departmental communications enabled quick implementation of these requirements for ARP awards.

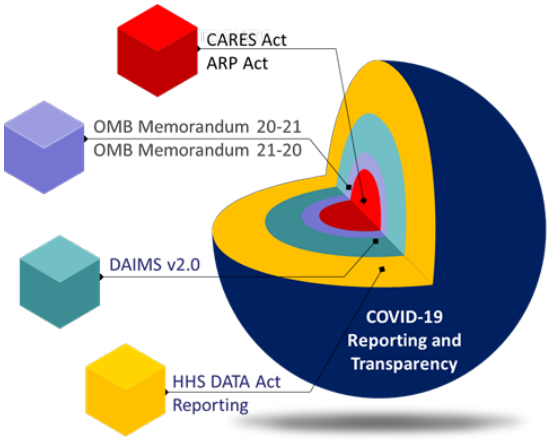
OMB emphasizes the critical role the financial assistance community plays in distributing relief funds. OMB added two new requirements to enhance transparency into covered funds. First, agencies must submit implementation plans for OMB's approval prior to issuing awards on programs newly authorized by ARP. Program managers meet with OIG, PRAC, and OMB to proactively review these ARP programs and share program implementation plans, internal controls, and highlight key risk areas. The second requirement mandates quarterly quality assessments of ARP award descriptions, enhancing prior requirements for improved quality of award descriptions.

To help agencies expedite ARP funds, OMB gave agencies 12 flexibilities authorizing administrative relief for financial assistance awards and recipients affected by the pandemic. HHS in turn gave HHS awarding agencies the authority to use these flexibilities. Examples of the flexibilities are registration waivers for the System for Award Management, waivers of certain prior approval requirements, and extensions on various report due dates.

Immediately after enactment of ARP, government-wide coordination teams were stood up to help agencies understand the guidance, implement the requirements, and leverage best practices across agencies. Agencies have used best practices from existing cross-governmental working groups and collaborated with PRAC and OIGs to carry out ARP requirements. In keeping with a government-wide effort to reduce recipient reporting burden, and consistent with OMB Memorandum M-19-16, *Centralized Mission Support Capabilities for the Federal Government*, OMB also directs agencies to consult with the relevant QSMO (e.g., the Grants Management Quality Services Management Office [Grants QSMO] at HHS), prior to developing new or modernized technology, or considering an existing provider, to support execution of ARP.

Digital Accountability and Transparency Act of 2014

The DATA Act expanded the *Federal Funding Accountability and Transparency Act of 2006* (FFATA) to increase accountability and transparency in federal spending, making federal expenditure information more accessible to the public. The Act directed 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 aimed 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.



The DATA Act requires agencies to generate data from their financial accounting systems using common fields, formats, and definitions for financial and award data in accordance with the DATA Act Information Model Schema (DAIMS). Treasury collects procurement, financial assistance, and recipient award data from government-wide databases reported under other FFATA requirements and merges it with the financial data produced from the HHS financial system. On a quarterly basis, agencies must certify the accuracy, completeness, and timeliness of the data considered reportable under these standards. HHS is responsible for meeting these requirements and has successfully ensured the alignment between the sets of internally maintained and externally managed data is valid and reliable in all submissions since May 2017.

Since May 2017, HHS has successfully submitted financial and award-level data for quarterly certification to Treasury's DATA Act Broker. In FY 2021, DATA Act award-level obligations increased to $1,676.7 billion compared to $1,670.7 billion in FY 2020. HHS completely reconciled to an average of 96 percent of award-level obligations for FY 2021. HHS has undergone both GAO and OIG audits of its DATA Act submissions since May 2017, yielding a 'high/excellent quality' data rating in FY 2019, 2020, and 2021.

The third quarter of FY 2021 was a benchmark for success in HHS DATA Act reporting as it marked the anniversary of the first successful transition to the monthly reporting requirement established by the CARES Act and OMB Memorandum M-20-21. The diagram above represents how multiple COVID-19 legislative publications each built on the prior one to create the holistic reporting and transparency approach, beginning with Section 15011 of the CARES Act at the core. OMB clarified that the DATA Act would be used as the reporting vehicle for COVID-19 spending data in OMB Memorandum M-20-21 and furthered the effort in OMB Memorandum M-21-20 to implement ARP. Treasury built on these requirements by issuing the revised DAIMS for version 2.0, which presented the methodology for agencies to provide public transparency of COVID-19 spending on a monthly basis.

Did You Know? The DATA Act was enacted on May 9, 2014, and requires federal agencies to undergo three biennial audits to determine compliance with DATA Act requirements, beginning FY 2017. FY 2021's audit constitutes HHS's third and final biennial DATA Act audit. During the FY 2021 DATA Act audit, HHS achieved a 99 point-level score – an 'excellent' quality rating according to the FY 2021 Council of the Inspector General on Integrity and Efficiency (CIGIE) Guide.

Range	Level
0-69.999	Lower
70-84.999	Moderate
85-94.999	Higher
95-100	Excellent

Source: CIGIE, Federal Audit Executive Council, Inspector General's Guide to Compliance under the DATA Act, December 4, 2020 (page 28)

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 provided the Chief Information Officer (CIO) of *Chief Financial Officers Act of 1990* (CFO Act) agencies with greater authority over IT investments, including authoritative oversight of IT budgets, budget execution, and IT-related personnel practices and decisions. Since last year, HHS has achieved the grade letter "A" on the recently added Enterprise Infrastructure Solutions metric. Additionally, HHS strengthened its FITARA scores by focusing on CIO authorities and responsibilities under the law. By working with regulators, HHS ensured that the CIO was engaging and reporting to the HHS Secretary and Deputy Secretary appropriately. HHS was able to highlight FITARA requirements while also fulfilling the associated congressional intent that all critical matters of IT have the appropriate time and attention from leadership.

On July 28, 2021, the House Committee on Oversight and Government Reform released its Scorecard version 12.0. HHS received a grade letter "B." This marks the first time that HHS has achieved a grade letter "B" twice in succession. This means that HHS performed better than 14 other federal agencies. With that strong foundation, HHS can focus on the larger FITARA related initiatives. Going forward, the House Committee has communicated a renewed focus on its Data Center Optimization Initiative, citing specifically a lack of faith in the current data center inventory process. The current Data Center guidance, OMB Memorandum M-19-19, *Update to Data Center Optimization Initiative*, has been extended once and is expected to sunset on September 30, 2022. Agencies should look forward to new guidance at that time.

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. Annually, agency heads must provide a statement of 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 the 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 on 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 implements requirements of the FMFIA with the intent to improve accountability in federal programs and increase federal agencies' consideration of ERM. The Department, with its OpDiv and StaffDiv stakeholders, are working together to implement 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 agencies to 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*.

HHS is fully focused on the requirements of FMFIA and FFMIA through its internal control program and a Department-wide approach to ERM. Based on internal assessments and FY 2021 audit findings, HHS provides reasonable assurance that controls are operating effectively. HHS is actively engaged with OpDivs to correct identified material weaknesses and non-compliances through a corrective action process focused on addressing the true root cause of deficiencies and supported by active management oversight. Refer to the "Internal Control" section and the "Management Assurance" section for more information.

Patient Protection and Affordable Care Act

The *Patient Protection and Affordable Care Act* (PPACA) established Health Insurance Marketplaces 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 Marketplaces are eligible to receive a premium tax credit to reduce their costs for health insurance premiums. Premium tax credits can be paid in advance directly to the consumer's Qualified Health Plan insurer. Consumers then claim the premium tax credit on their federal tax returns, reconciling the credit allowed with any advance payments made throughout the tax year. HHS coordinates closely with the Internal Revenue Service on this process.

PPACA also included provisions that address fraud and abuse in healthcare 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."

Payment Integrity Information Act of 2019

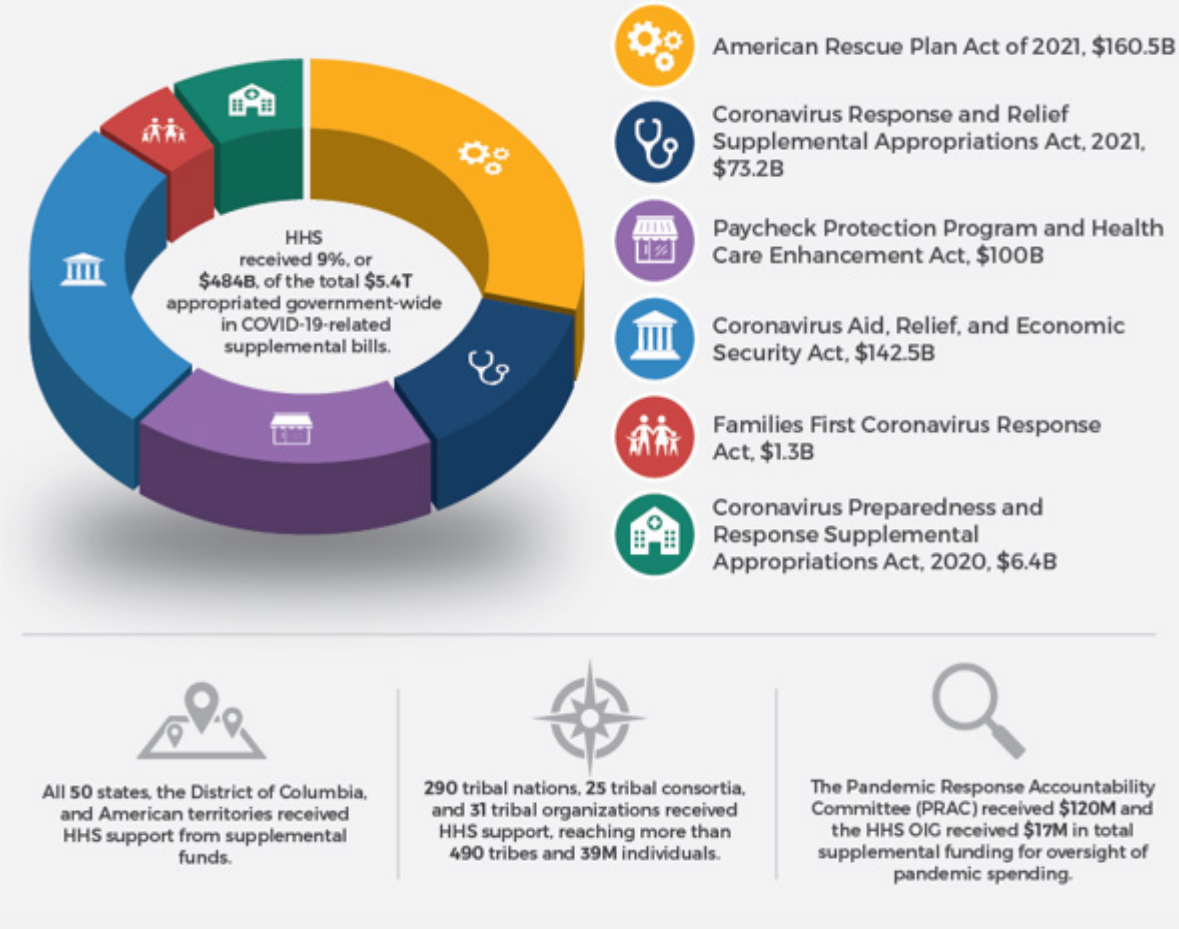
An improper payment occurs when a payment should not have been made, federal funds go to the wrong recipient, the recipient receives an incorrect amount of funds, or the recipient uses the funds in an improper manner. In addition, improper payments cited do not necessarily represent expenses that should not have occurred. On March 2, 2020, the *Payment Integrity Information Act of 2019* (PIIA) repealed and replaced the *Improper Payments Information Act of 2002* (IPIA), as amended by the *Improper Payments Elimination and Recovery Act of 2010* and the *Improper Payments Elimination and Recovery Improvement Act of 2012*. Similar to the IPIA, PIIA requires federal agencies to review their programs and activities to identify programs that may be susceptible to significant improper payments (also called high risk programs). High risk programs must estimate the amount of improper payments, establish reduction targets, and develop and implement corrective actions. HHS works to better prevent, detect, and reduce 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, detect, and reduce improper payments in our programs. In accordance with the PIIA, HHS completed 38 improper payment risk assessments in FY 2021 and determined that three new programs are susceptible to significant improper payments. HHS will work to establish and report estimates for these three programs in FY 2022. In addition, HHS is publishing improper payment estimates and associated information for eight high risk programs in this year's AFR. Lastly, HHS uses the Do Not Pay portal to check payments and awardees to identify potential improper payments or ineligible recipients. In FY 2021, HHS screened more than $653.9 billion in Treasury-disbursed payments through the Do Not Pay portal. A detailed report of HHS's improper payment and fraud reduction activities and performance is presented in the "Other Information" section of this AFR, under "Payment Integrity Report."

Did You Know? To support the response effort for the unprecedented public health and economic challenges caused by the COVID-19 pandemic, HHS received $484 billion in funding from six pandemic relief laws passed in 2020 and 2021.

For more information on the COVID-19 covered funds, visit HHS's website.



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 making progress in maturing ERM and integrating with Internal Controls.

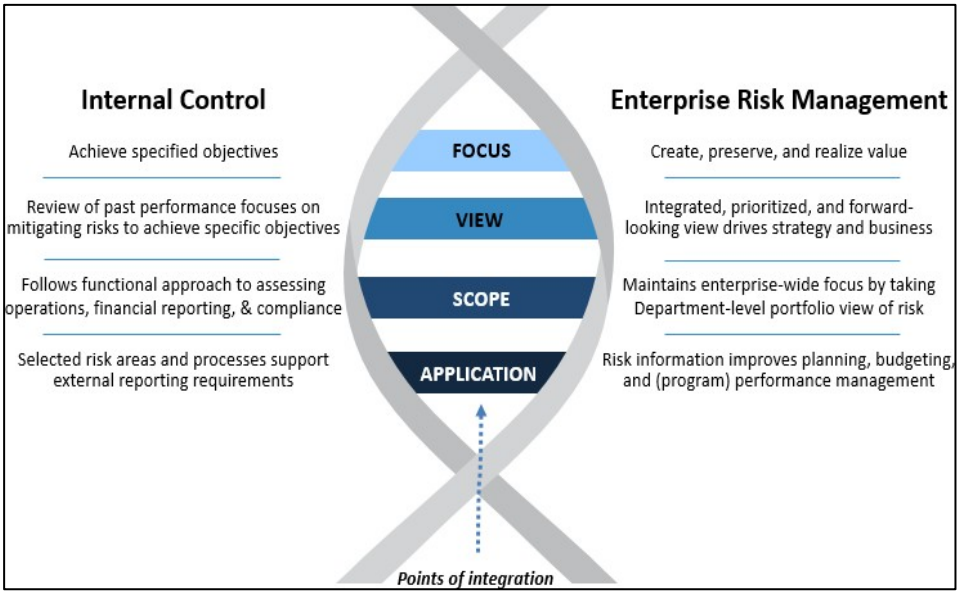
HHS aims to strengthen its internal control assessment and reporting process to more effectively identify key risks, develop effective risk responses, and implement timely corrective actions. HHS also follows OMB guidance to provide oversight of COVID-19 and ARP funds, as part of overall internal control efforts. OMB Memorandum M-20-21, Memorandum for agency CFOs on June 17, 2020, *Risk-Based Financial Audits and Reporting Activities in Response to COVID-19*; and OMB Memorandum M-21-20, *Promoting Public Trust in the Federal Government through Effective Implementation of the American Rescue Plan Act of 2021* (ARP) *and Stewardship of the Taxpayer Resources* direct agencies to "leverage existing transparency and accountability mechanisms whenever possible" and "apply a risk-based framework for balancing: (1) mission achievement, (2) expediency, and (3) transparency and accountability." To comply with this guidance, HHS's OpDivs and StaffDivs utilize existing internal control plans and updated disaster-related internal control plans, and enhanced current processes to provide reasonable assurance internal controls over COVID-19 and ARP funds achieve management's objectives.

HHS management is directly responsible for establishing and maintaining effective internal controls. As part of this responsibility, management regularly assesses internal controls and executive leadership provides annual assurance statements reporting on the effectiveness of those internal controls. The HHS FY 2021 OMB Circular A-123 assessment recognizes material noncompliances with the *Social Security Act* related to the Medicare appeals process and the PIIA related to error rate measurement. While HHS management recognized noncompliances with PIIA, our assessment also considers the internal controls around compliance. For FY 2021, HHS management identified an instance of noncompliance with PIIA for the Medicare Part C program due to a new estimation methodology that yielded an FY 2021 error rate slightly above (less than half of 1 percent) the rate stated in PIIA. The methodology was changed to remove potential bias and improve the accuracy of measuring and monitoring risk in this program. As a result, the program's internal controls over compliance were strengthened during FY 2021. Accordingly, this instance of noncompliance is not cited in the HHS Statement of Assurance. Refer to the Payment Integrity Report for additional discussion on the Medicare Part C error rate measurement process.

The HHS Risk Management and Financial Oversight Board evaluates OpDivs' management assurances and recommends a Department assurance for the Secretary's consideration and approval, resulting in the Secretary's annual Statement of Assurance.

Enterprise Risk Management

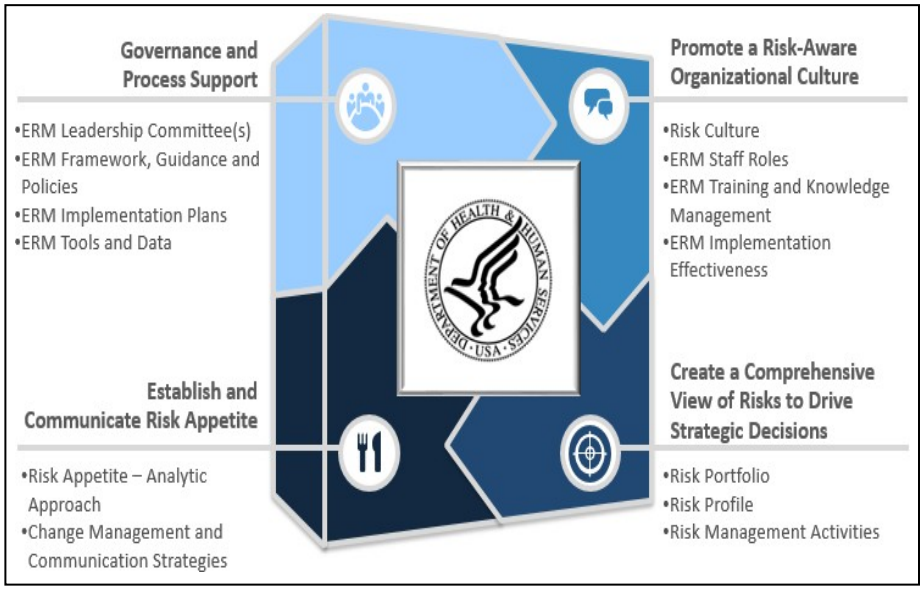
Figure 11: ERM and Internal Control are Integrated in HHS's Financial Management DNA



As required by the 2016 update to OMB Circular A-123, *Management's Responsibility for Enterprise Risk Management and Internal Control*, federal agencies must implement ERM to improve accountability and effectiveness of federal programs and mission support operations by identifying and managing risks to reduce or eliminate the potential for disruptive events. ERM is a strategic discipline that enables agencies to address the full spectrum of organizational risks. As illustrated in **Figure 11**, integrating ERM into Department, OpDiv, and StaffDiv operations improves HHS's ability to deliver on its mission of enhancing and protecting the health and well-being of all Americans. By incorporating ERM practices into daily operations, HHS enhanced its speed and agility in adapting to uncertainties that might otherwise impact its ability to execute on mission, achieve goals, and meet objectives.

HHS ASFR supports Department-wide ERM implementation through the HHS ERM Council, which consists of senior career executives from across HHS's OpDivs and StaffDivs. The ERM Council was originally established in 2010 as the HHS Program Integrity Coordinating Council, to focus on program integrity risk management concerns. The Council expanded its focus in 2014 by adopting ERM to improve risk management efforts throughout the Department and formally updated its charter and name in 2016 to the ERM Council. The ERM Council provides an internal forum for sharing and coordinating Department-wide risk management efforts. HHS facilitates ERM implementation by: translating the Department-level ERM Framework displayed in **Figure 12** into operational steps; serving as an ERM resource and liaison for OpDivs and StaffDivs; developing ERM guidance, tools, and techniques that can be tailored by OpDivs and StaffDivs; and advising on ERM tools, techniques, and approaches to support Division-

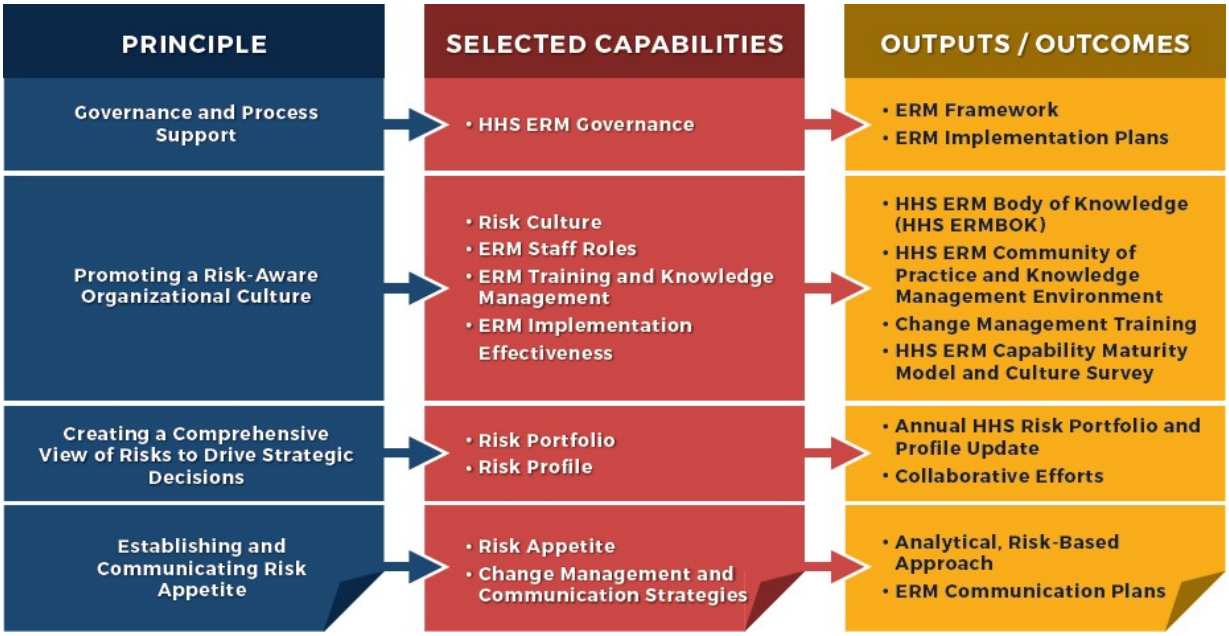
Figure 12: Principles-Based HHS ERM Framework and Capabilities



level ERM implementation. Working closely with OpDiv and StaffDiv ERM leads and subject matter experts, HHS supports implementation of a robust ERM culture and capabilities throughout the Department.

The HHS ERM Framework in **Figure 12** outlines the principles-based approach and capabilities that HHS uses to implement and mature ERM. By focusing on principles and capabilities rather than an annual risk profile, HHS's ERM Framework offers flexibility for OpDivs and StaffDivs to manage the pace of change. OpDivs and StaffDivs are encouraged to tailor the ERM Framework to align with their diverse operating cultures and missions. This includes tailoring the portfolio of risks considered and applicable governance to oversee risk management activities. HHS's Principles-Based ERM Framework translates selected capabilities into outputs and outcomes, as shown in **Figure 13.**

Figure 13: HHS ERM Principles-Based Framework Translates Capabilities into Outputs and Outcome



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, 2021, with the exception of material noncompliances with the *Payment Integrity Information Act of 2019* (PIIA) related to error rate measurements and with the *Social Security Act* related to the Medicare appeals process. HHS is taking steps to address the material noncompliance, as described in the "Corrective Action Plans" section.

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 at the transaction level. HHS conducted its evaluation of financial management systems compliance in accordance with OMB Circular A-123, Appendix D, Compliance with FFMIA. 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.

/Xavier Becerra/

Xavier Becerra
Secretary
November 12, 2021

Management Assurances

Summary

1. Error Rate Measurement

HHS identified material noncompliances with the PIIA related to (a) not reporting improper payment rates for Temporary Assistance for Needy Families (TANF), Foster Care, and Advance Premium Tax Credit (APTC); and (b) reporting improper payment rates for Medicaid and Children's Health Insurance Program (CHIP) via the Payment Error Rate Measurement (PERM) program that are above PIIA requirements.

HHS identified the TANF process limitation in prior years and it continues to exist in FY 2021. The TANF program is unable to report an error rate for FY 2021 due to statutory limitations precluding HHS from requiring states to participate in a TANF improper payment measurement.

HHS also identified that the Foster Care program did not report an improper payment estimate for FY 2021. In response to COVID-19, HHS postponed Title IV-E reviews to protect the health and safety of state and federal reviewers and to ensure that state child welfare officials remain focused on mission-critical activities serving children and families. Because IV-E reviews (which occur onsite) provide the data normally used to calculate improper payment estimates, the postponement of reviews resulted in HHS having no new data for FY 2021.

HHS identified that the APTC program did not report an improper payment estimate for FY 2021. Following an FY 2016 risk assessment, HHS concluded the APTC program is susceptible to significant improper payments and is required to establish and report an improper payment estimate; however, the APTC program has not yet reported an improper payment estimate.

HHS identified the Medicaid and CHIP noncompliance in FY 2019 and FY 2020, and it continues to exist in FY 2021. The improper payment rates for Medicaid and CHIP are based on reviews of the Fee-For-Service, managed care, and eligibility components. The PERM program uses a 17-state rotational approach to measure the 50 states and the District of Columbia over a 3-year period. As a result, HHS measures each state once every 3 years. National improper payment rates include findings from the most recent three-cycle measurements. Each time a cycle of states is measured, HHS removes the previous findings for that cycle and includes the newest findings. Factors that led to noncompliance in FY 2021 include:

- The reintegration of the PERM eligibility component for the third cycle of 17 states;
- Insufficient documentation to verify eligibility;
- Noncompliance with eligibility redeterminations; and
- Noncompliance with provider enrollment, screening, enrollment, revalidation, and National Provider Identifier requirements.

2. Medicare Appeals Process

Several factors, including the growth in Medicare claims and HHS's continued investment and focus on ensuring program integrity, have led to more appeals than Levels 3 and 4 of the Medicare appeals process can adjudicate within 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. During FY 2019 through FY 2021, appeal receipts steadily declined at OMHA but continued to increase at DAB. At the end

of Quarter 3 of FY 2021, 86,063 appeals were awaiting OMHA's adjudication and 18,374 appeals were awaiting DAB's review. This volume of pending appeals will prolong a near-term inability to meet statutory 90-day decisional timeframes at Levels 3 and 4 of the Medicare appeals process. Under current resources and continuing ongoing administrative actions, it would take approximately 1 year for OMHA and 4 years for the DAB to process their respective backlogs.

Corrective Action Plans

1. Error Rate Measurement

TANF is a state-administered program, so 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 Federal Register 2092, January 15, 2016).

To address the Foster Care program not reporting an improper payment estimate for FY 2021, HHS will need to resume the Title IV-E Reviews that are currently paused. Given the impact of COVID-19, HHS is uncertain when it will be safe to resume conducting onsite Title IV-E Reviews and how many states will be newly reviewed in the next improper payment reporting cycle. Despite pausing the Title IV-E Reviews, HHS continued other program integrity efforts through its review of claims and audit resolution for states to address financial reporting and claiming errors. These program integrity efforts are discussed in the "Payment Integrity Report" section within the FY 2021 AFR.

HHS is undertaking corrective actions to address the APTC program not reporting an improper payment estimate for FY 2021. As discussed in the "Payment Integrity Report" section within the FY 2021 AFR, developing an effective and efficient improper payment measurement program requires multiple time-intensive steps that can take several years to complete. In FY 2021, the Department commenced the improper payment measurement program for the Federally-facilitated Exchange and anticipates reporting an improper payment estimate in the FY 2022 AFR.

To address Medicaid and CHIP PERM-related errors, HHS continues to develop a multi-faceted approach to corrective actions, with multiple efforts underway to address the underlying causes. The Department will continue to emphasize to states the need to comply with HHS requirements and to work with providers and plans to reduce improper payments in Medicaid and CHIP. In addition, HHS will collect best practices to share with all states. Some of HHS's key efforts to prevent and reduce improper payments in the Medicaid and CHIP programs follow.

- HHS implemented a more robust state-specific CAP process that provides enhanced technical assistance and guidance to states. HHS works with the states to coordinate state development of CAPs to address each error and deficiency identified during the PERM cycle. After the CAP submissions, HHS monitors and follows up with all states on their progress in implementing effective corrective actions to address the errors and deficiencies. HHS uses lessons learned from this process to inform areas to evaluate for future guidance and education.
- Under the Medicaid Eligibility Quality Control (MEQC) program, states design and conduct projects to evaluate the processes that determine an individual's eligibility for Medicaid and CHIP benefits. States have great flexibility in designing pilots to focus on vulnerable or error-prone areas as identified by the

PERM program and state. The MEQC program also reviews eligibility determinations that are not reviewed under the PERM program, such as denials and terminations. MEQC pilots are conducted during the 2-year intervals that occur between states' triennial PERM review years ("off-years"), allowing states to implement prospective improvements in eligibility determination processes prior to their next PERM review;

- HHS shares Medicare data to assist states with meeting Medicaid screening and enrollment requirements, including (1) Medicare provider enrollment records via the Provider Enrollment, Chain, and Ownership System (PECOS) administrative interface and data extracts from the PECOS system; (2) access to the PECOS state's page, which includes provider enrollment information such as Medicare enrollment status, site visit information, fingerprint results, ownership information, reassignments, Medicare risk levels, and more; and (3) all state-submitted terminations as well as all Medicare revocations, and HHS-OIG exclusion data through the Data Exchange System.
- The Department offers a data compare service that allows a state agency to rely on Medicare's screening in lieu of conducting a state screening, particularly during revalidation. This allows states to remove dual-enrolled providers from the revalidation workload.
- HHS updated the Medicaid Provider Enrollment Compendium in March 2021 to provide further sub-regulatory guidance to assist states with applying the regulatory requirements for state Medicaid provider screening and enrollment.
- HHS offers training, technical assistance, and support to state Medicaid program integrity officials through the Medicaid Integrity Institute. Many sessions focused exclusively on national and state improper payment drivers, including beneficiary eligibility and compliance with the provider screening and enrollment requirements. HHS cancelled all residential courses after the start of COVID-19 and established virtual courses to continue educational offerings. Despite this change, state interest and participation were strong and consistent with previous years.

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 that are expected to have a favorable impact on the Medicare appeals backlog. The FY 2021 Budget provided flexibilities that allowed OMHA to continue processing a greater number of appeals and set DAB on a path where it can be successful in addressing appeals in future years. Based on projected impacts of current administrative actions and continued support in the FY 2022 President's Budget, HHS projects that the backlog at Level 3 will be resolved in FY 2022, while the backlog at Level 4 could start decreasing in future 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, 2021. This is the 23rd 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.

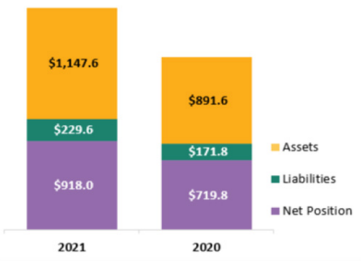
As a federal entity, HHS's financial position and activities are significant to the government-wide statements. Based on the *FY 2020 Financial Report of the United States Government*, HHS's net operating cost was larger than any single agency across the entire federal government[2]. A similar relationship 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 2021 and FY 2020 year-end balances of HHS's assets available for use, the liabilities owed by HHS, and the equity retained by HHS.

Financial Conditions Summary
(in Billions)

	2021	2020	$ Change (2021-2020)	% Change (2021-2020)
Fund Balance with Treasury	$ 710.5	$ 514.0	$ 196.5	38%
Investments, Net	312.3	226.2	86.1	38%
Accounts Receivable	29.4	22.4	7.0	31%
Advances and Prepayments	71.1	108.1	(37.0)	(34%)
Other Assets	24.3	20.9	3.4	16%
Total Assets	**$ 1,147.6**	**$ 891.6**	**$ 256.0**	**29%**
Accounts Payable	$ 6.0	$ 6.2	$ (0.2)	(3%)
Debt	36.8	1.4	35.4	2,529%
Entitlement Benefits Due and Payable	133.8	116.9	16.9	14%
Accrued Liabilities	18.5	15.8	2.7	17%
Federal Employee and Veterans Benefits Payable	17.2	16.2	1.0	6%
Contingencies & Commitments	12.1	11.3	0.8	7%
Other Liabilities	5.2	4.0	1.2	30%
Total Liabilities	**$ 229.6**	**$ 171.8**	**$ 57.8**	**34%**
Net Position	**$ 918.0**	**$ 719.8**	**$ 198.2**	**28%**
Total Liabilities and Net Position	**$ 1,147.6**	**$ 891.6**	**$ 256.0**	**29%**



[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 19 percent of the federal government's total costs, Social Security Administration's net cost is 16 percent, Department of Veterans Affairs' net cost is 13 percent, Department of Defense's net cost is 10 percent, and Department of the Treasury's net cost is 8 percent. All remaining agencies combined only represent 34 percent. Source: *FY 2020 Financial Report of the United States Government*

Financial Summary and Highlights

Assets

The total Assets for HHS were $1,147.6 billion at year-end, representing the value of what HHS owns and manages. This is an increase of approximately $256.0 billion or 29 percent over September 30, 2020. Fund Balance with Treasury (FBwT) and Investments comprise $1,022.8 billion or 89 percent of HHS's total assets, and collectively increased $282.6 billion or 38 percent.

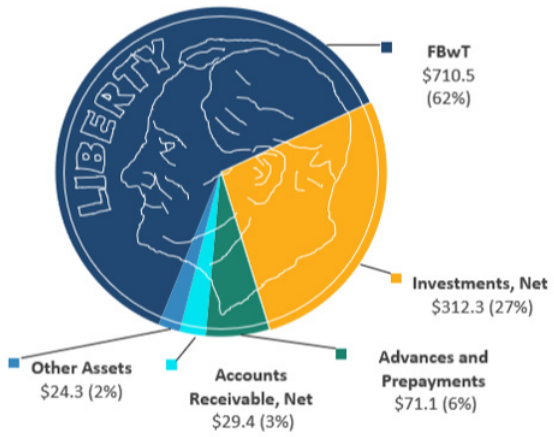
FBwT had an increase of $196.5 billion or 38 percent over FY 2020, which is primarily due to the Public Health and Social Services Emergency Fund (PHSSEF) for COVID-19 and additional COVID-19 relief funding received in FY 2021 from the *Coronavirus Response and Relief Supplemental Appropriations Act, 2021* and the ARP.

Investments had an increase of $86.1 billion or 38 percent over FY 2020, which is primarily due to the repayable advance and premium matching from Payments to the Trust Fund (PTF). This impacted SMI by $83.5 billion.

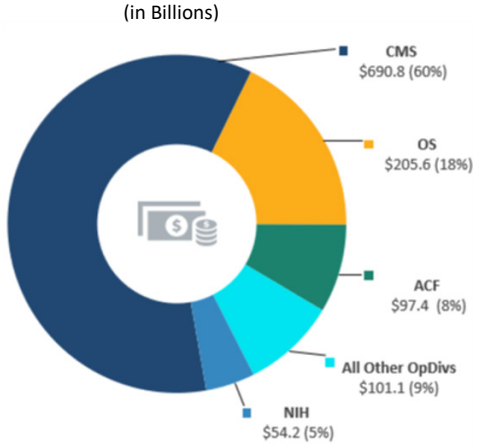
Advances and Prepayments had a decrease of $37.0 billion or 34 percent under FY 2020, which is primarily due to COVID-19 Accelerated and Advance Payment (AAP) refunds.

The HHS "Assets By OpDiv" chart demonstrates asset distribution within HHS, excluding eliminations. The OpDiv asset balances ranged from $349 million at AHRQ (shown in All Other OpDivs) to $690.8 billion at CMS. CMS had the largest dollar increase of $100.7 billion or 17 percent primarily due to FY 2021 SMI repayable advances and premium matching from PTF. ACF had the largest percentage increase of $52.7 billion or 118 percent primarily due to increase in funding for COVID-19 relief efforts.

Assets By Type
(in Billions)



Assets By OpDiv
(in Billions)

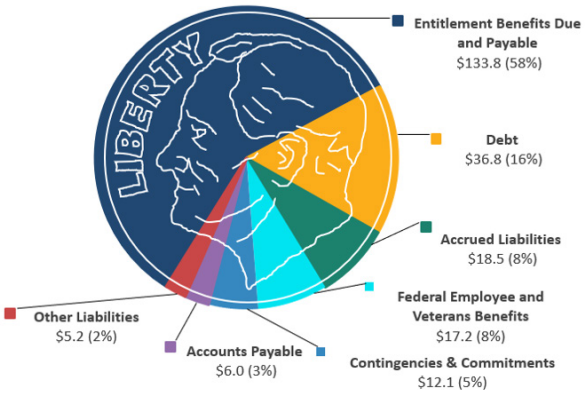


Liabilities

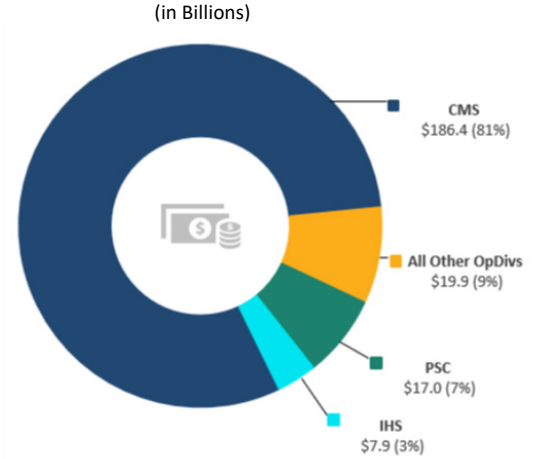
The total Liabilities for HHS were $229.6 billion at year-end, representing the amounts HHS owes from past transactions or events. This is an increase of approximately $57.8 billion or 34 percent over September 30, 2020.

This is attributed to increases in Debt and Entitlement Benefits Due and Payable. Debt had an increase of $35.4 billion or 2,529 percent over FY 2020, which is due to amounts borrowed to cover the accelerated and advance payments made for the COVID-19 AAP program. Entitlement Benefits Due and Payable had an increase of $16.9 billion or 14 percent over FY 2020, which is due to increase in medical services and claims incurred but not reported reflecting the impact of COVID-19.

Liabilities By Type
(in Billions)



Liabilities By OpDiv
(in Billions)

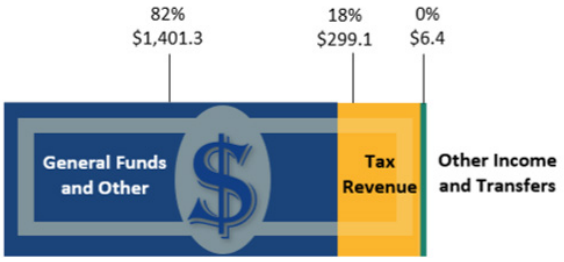


The HHS "Liabilities By OpDiv" chart shows liability distribution within HHS, excluding eliminations. The OpDivs with the largest and smallest asset balances are also the OpDivs with the largest and smallest liabilities. With the majority share, CMS reports $186.4 billion or 81 percent of the HHS liabilities, while AHRQ (shown in All Other OpDivs) had liabilities of $22 million. CMS had the largest OpDiv dollar value increase in liabilities over FY 2020 of $53.1 billion due to the increases in Debt and Entitlement Benefits Due and Payable mentioned above.

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.

HHS Gets the Money From…
(in Billions)

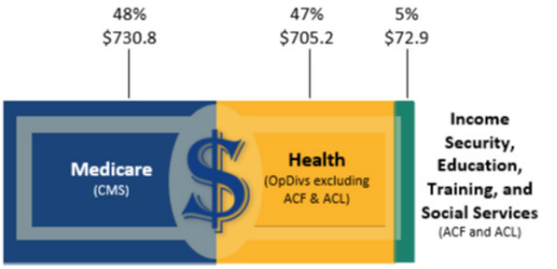


HHS receives the majority of the funding through Congressional appropriations and reimbursement for the provision of goods or services to other federal agencies. HHS's largest financing source, General Funds and Other, increased $72.6 billion or 5 percent over FY 2020. The fluctuations in tax revenue of $3.2 billion or 1 percent is related to the improvement in the economy.

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, 2021, totaled approximately $1,508.6 billion. The "HHS Used the Money For …" chart shows consolidating costs by major budget function[3], which are the categories displayed in the Federal Budget. 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. In FY 2021, total net costs for Medicare of $730.8 billion and Health of $705.2 billion account for 95 percent of HHS's annual net costs.

HHS Used the Money For…
(in Billions)



[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.

Financial Summary and Highlights

The table below presents FY 2021 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 $115.4 billion or 10 percent over FY 2020, which included increases in Medicaid and Medicare HI and SMI offset by a decrease in Risk Corridor. Medicaid had an increase in Net Cost of $63.2 billion primarily due to the benefit expense increase of $57.0 billion related to higher grant awards to the States to continue the COVID-19 relief efforts, increases in expenses related to State Plan Amendments and audit and program disallowances of $6.3 billion, offset by decreases in expenses of $1.6 billion related to the net change in receivables for disallowances and deferrals. Medicare SMI had an increase of $40.8 billion in Net Cost primarily due to increases in SMI benefit expenses of $46.0 billion offset by $5.2 billion increases in SMI revenues from collections of SMI and prescription drug premiums, Medicare Advantage, and ACA Medicare Shared Savings Program. Medicare HI had an increase in Net Cost of $27.5 billion primarily due to increases in benefit expenses of $42.3 billion offset by $16.2 billion in refunds. The Risk Corridor had a decrease in Net Cost of $12.3 billion due to decreases in expenses as a result of the judgment in FY 2020. The decrease in total Net Cost of Operations for the remaining HHS segments of $14.5 billion or 6 percent under FY 2020 is primarily due to the PHSSEF receiving less funding in FY 2021 for COVID-19 relief.

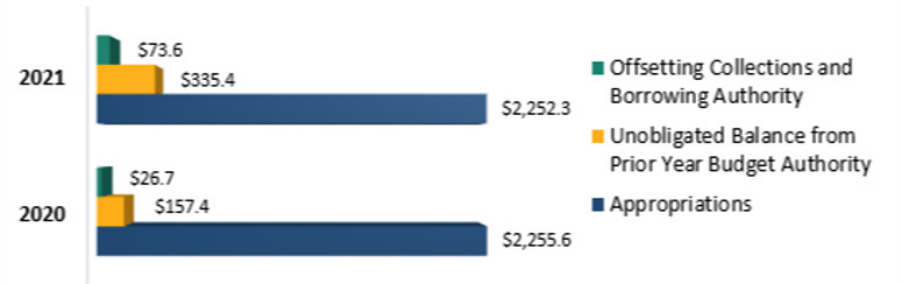
Net Cost of Operations
(in Billions)

	2021	2020	$ Change (2021-2020)	% Change (2021-2020)
Responsibility Segments				
CMS Gross Cost	$ 1,404.9	$ 1,281.9	$ 123.0	10%
CMS Exchange Revenue	(132.9)	(125.3)	(7.6)	6%
CMS Net Cost of Operations	$ 1,272.0	$ 1,156.6	$ 115.4	10%
Other Segments:				
Other Segments Gross Cost	$ 242.3	$ 256.7	$ (14.4)	(6%)
Other Segments Exchange Revenue	(5.7)	(5.6)	(0.1)	2%
Other Segments Net Cost of Operations	$ 236.6	$ 251.1	$ (14.5)	(6%)
Net Cost of Operations	**$ 1,508.6**	**$ 1,407.7**	**$ 100.9**	**7%**

Statement of Budgetary Resources

The Combined Statement of Budgetary Resources displays the budgetary resources available to HHS throughout FY 2021 and FY 2020, and the status of those resources at the fiscal year-end. The primary components of HHS's resources, totaling approximately $2.7 trillion for FY 2021, 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 $221.6 billion or 9 percent, over FY 2020. The following graph highlights trends in these balances over the past 2 fiscal years.

Total Budgetary Resources
(in Billions)



The decrease in appropriations of $3.3 billion is due to less COVID-19 appropriations received in FY 2021.

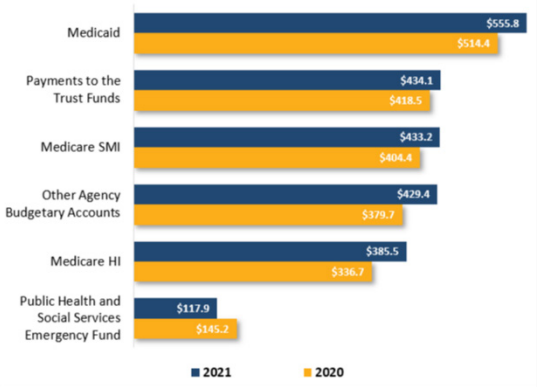
The increase of $178.0 billion or 113 percent in unobligated balance from prior year budget authority is primarily due to increases in apportioned authority for $85.7 billion in PHSSEF due to COVID-19 relief. The PTF had an increase of $47.7 billion due to the retention of prior year definite authority of $39.4 billion combined with $8.3 billion in recoveries of prior year unpaid obligations. HI and SMI had increases of $22.7 billion and $13.8 billion respectively, as the result of refund collections related to the COVID-19 AAP program. Definite authority is budget authority that is a specified sum at the time it is enacted and is expressed as "not to exceed" amount.

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 illustrates spending as of September 30, 2021 and 2020 for the top four Treasury Account Symbols (TAS). The remaining TAS are presented in Other Agency Budgetary Accounts.

The New Obligations and Upward Adjustments line on the Combined Statement of Budgetary Resources is the same as Total Amounts Agreed to be Spent line on the Combined Schedule of Spending. Total obligations for FY 2021 were approximately $2.4 trillion or 7 percent increase over FY 2020.

Spending by Treasury Symbol
(in Billions)



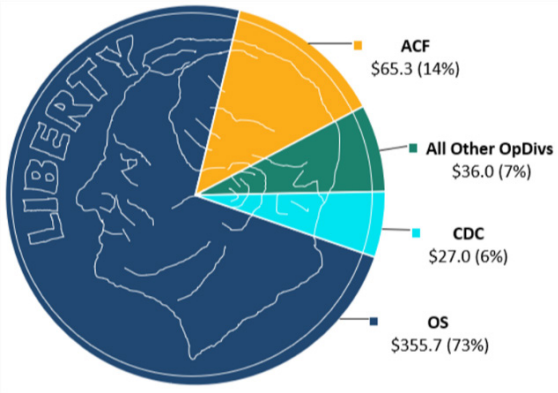
The HHS's total spending is once again significantly represented by four of CMS's TAS (Medicaid, Medicare SMI, PTF, and Medicare HI) at 77 percent of HHS total obligations.

As the American public will see more clearly on the USAspending.gov website, the majority of HHS spending was made through Grants, Subsidies, and Contributions at $1.2 trillion 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 $917.8 billion or 39 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.

COVID-19 Activities

In FY 2020, the CARES Act and three additional supplemental appropriations provided HHS with COVID-19 budgetary resources of $250.6 billion for response and recovery. Of this amount, $0.3 billion was transferred to the Department of Homeland Security. Additionally, *Coronavirus Response and Relief Supplemental Appropriations Act, 2021* and the ARP provided HHS $233.7 billion, resulting in net budgetary resources of $484.0 billion. The "COVID-19 Budgetary Resources by OpDiv" chart shows the amount of funding received by OpDiv. OS received $355.7 billion or 73 percent with the majority supporting the Provider Relief Fund, Strategic National Stockpile, and Biomedical Advanced Research and Development Authority.

COVID-19 Budgetary Resources by OpDiv
(in Billions)



As of September 30, 2021, HHS has obligated $364.1 billion to support efforts of which $203.2 billion has been outlayed and $119.9 billion remains available for future fiscal years in order to continue providing relief, testing, research, and other COVID-19 related activities. For more information refer to Note 24, COVID-19 Activities in the "Financial Section" of this report.

Statement of Social Insurance

The Statement of Social Insurance (SOSI) 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 important information in evaluating the potential future cost of the program. These projected potential future obligations are not included in the Consolidated Balance Sheets, Statements of Net Cost, Statements of Changes in Net Position, or Combined Statements of Budgetary Resources.

Actuarial present values are computed under the intermediate set of assumptions specified in the *2021 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds*. Beginning in 2020, the Medicare program was dramatically affected by the COVID-19 pandemic. The amount of payroll taxes expected to be collected by the HI trust fund was greatly reduced due to the economic effects of the pandemic on labor markets. Spending was directly affected by the coverage of testing and treatment of the disease. In addition, several regulatory policies and legislative provisions were enacted during the public health emergency that increased spending. More than offsetting these additional costs in 2020, spending for non-COVID care declined significantly (compared to both actual 2019 spending and expectations for 2020 spending in last year's Trustees Report). This decline was particularly true for elective services.

While the COVID-19 pandemic has significantly affected Medicare short-term financing and spending, it is not expected to have a large effect on the financial status of the trust funds after 2024. As discussed throughout the Trustees Report, the key measures of the financial adequacy for each trust fund are fairly comparable to those included in last year's report.

The Medicare Accelerated and Advance Payments (AAP) Program was significantly expanded during the COVID-19 public health emergency period. Total payments of approximately $107.1 billion were made: roughly $67.1 billion from the HI trust fund and $40.0 billion from the SMI Part B trust fund account. The Trustees assume that the accelerated and advance payments will be fully repaid by September of 2022, resulting in no net changes to trust fund expenditures, but the AAP program significantly affects the timing of expenditures from 2020 through 2022. It should be noted that there is an unusually large degree of uncertainty with these COVID-related impacts and that future projections could change significantly as more information becomes available. The pandemic is an example of the inherent uncertainty in projecting healthcare financing and spending over any duration.

The SOSI 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 $(4.8) trillion, determined as of January 1, 2020, to $(5.1) trillion, determined as of January 1, 2021.

When the combined HI and SMI trust fund assets are included, the present value increases. As of January 1, 2021, the future cash flow for all current and future participants was $(4.7) trillion for the 75-year valuation period. The comparable cash flow for the closed group of participants, including the combined HI and SMI trust fund assets, is $(13.1) trillion.

HI Trust Fund Solvency

Trust Fund Ratio Beginning of Fiscal Year[4]	
FY	HI
2021	39%
2020	50%
2019	63%
2018	66%
2017	66%

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; thus, the HI trust fund assets have been declining. The table shows the 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 steadily dropped from 66 percent at the beginning of FY 2017 to 39 percent at the beginning of FY 2021.

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 2021 Trustees Report indicate that the HI trust fund is not adequately financed over the next 10 years. Under the intermediate assumptions of the 2021 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 2020 were $134.1 billion and are expected to decrease steadily until depleted in 2026.

Long-Term Financing

The short-range outlook for the HI trust fund is similar to what was projected last year. The trust fund ratio declines until the fund is depleted in 2026, the same date as projected in the 2018 through 2020 Trustees Reports. 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 2045, and then to increase to about 91 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 individuals eligible for benefits drops from

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

2.9 in 2020 to about 2.2 by 2095. In addition, healthcare costs continue to rise faster than the taxable wages used to support the program. In present value terms, the 75-year shortfall is $4.9 trillion, which is 0.7 percent of taxable payroll and 0.3 percent of Gross Domestic Product (GDP) over the same period. Significant uncertainty surrounds the estimates for the SOSI. 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 5 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 this 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 $(43.2) 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 2020, SMI incurred expenditures were 2.3 percent of GDP. By 2095, SMI expenditures are projected to grow to 4.5 percent of the GDP.

The following table presents key amounts from CMS's basic financial statements for fiscal years 2019 through 2021.

Table of Key Measures[5]
(in Billions)

	2021	2020	2019
Net Position (end of fiscal year)			
Assets	$ 690.8	$ 590.1	$ 502.0
Less Total Liabilities	186.4	133.4	134.2
Net Position (assets net of liabilities)	**$ 504.4**	**$ 456.7**	**$ 367.8**
Costs (end of fiscal year)			
Net Costs	$ 1,272.4	$ 1,157.0	$ 1,087.3
Total Financing Sources	1,285.0	1,189.5	1,079.0
Net Change in Cumulative Results of Operations	**$ 12.7**	**$ 32.5**	**$ (8.3)**
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	$ (5,057)	$ (4,800)	$ (5,484)
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	$ (4,800)	$ (5,484)	$ (4,708)
Change in Present Value	**$ (257)**	**$ 683**	**$ (776)**

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, 2021, decreased by $166 billion due to advancing the valuation date by one year and including the additional year 2095, by $959 billion due to changes in economic and healthcare assumptions, and by $38 billion due to changes in the law. However, changes in the projection base and demographic assumptions increased the present value by $205 and $700 billion, respectively. The net overall impact of these changes is a decrease in the present value of $257 billion.

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 RSI presents required long-range cash-flow projections, the long-range projections of the ratio of contributors to individuals with Medicare (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

[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. Totals do not necessarily equal the sums of rounded components.

information is drawn from the *2021 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds*, which represents the official government evaluation of the financial and actuarial status of the Medicare trust funds.

Limitation of the Principal Financial Statements

The principal financial statements in the "Financial Section" have been prepared to report 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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SECTION 2

FINANCIAL SECTION

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Message from the Acting Assistant Secretary for Financial Resources

I am honored to join Secretary Becerra in presenting the Department of Health and Human Services (HHS) Fiscal Year (FY) 2021 Agency Financial Report (AFR). The financial statements and disclosures in the AFR reflect HHS's stewardship of the resources entrusted to us. While the Department continues its mission to enhance the health and well-being of all Americans through its many initiatives, HHS's Chief Financial Officer (CFO) Community continues to support that mission by promoting effective and efficient management and financial accountability. HHS's CFO Community works diligently to enhance and sustain a financial management environment that ensures the highest standard of financial excellence and transparency, while managing risks related to our significant budgetary resources.

FY 2021 brought many unique challenges that the CFO Community not only met but exceeded with the dedication and perseverance for which our community is known. Every day, the CFO Community rises to new challenges and demonstrates its commitment to the nation's health and well-being. We continue working together to improve Department-wide operations, financial reporting and systems, with the overall goal to consistently strengthen internal control, maintain data integrity, increase data transparency, and report reliable information on a timely basis.

The external annual audit performed by the Office of Inspector General (OIG) and its independent auditor (Ernst & Young, LLP) demonstrates our commitment to sound governance and effective internal control. For the 23rd consecutive year, HHS obtained an unmodified or "clean" opinion on our financial statements. The auditors disclaimed providing an opinion on the Statement of Social Insurance and the Statement of Changes in Social Insurance Amounts. The AFR's "Financial Section" provides detailed information about HHS's financial statements and activities.

In 2021, HHS received its eighth consecutive *Certificate of Excellence in Accountability Reporting* award from the Association of Government Accountants for its FY 2020 AFR in recognition of the exceptional quality of our report.

I want to thank our employees and partners for their remarkable efforts and dedication, especially in combatting the COVID-19 pandemic. In so many ways, great and small, their everyday commitment, resiliency, and hard work ensures the success of our stewardship efforts and helps advance our mission.

/Norris Cochran/

Norris Cochran
Acting Assistant Secretary for Financial Resources
November 12, 2021

Report of the Independent Auditors

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201

TO: The Secretary

FROM: Amy J. Frontz /s/ Amy J. Frontz
Deputy Inspector General for Audit Services

SUBJECT: *Financial Statement Audit of the Department of Health and Human Services for Fiscal Year 2021*, A-17-21-00001

This memorandum transmits the independent auditors' reports on the Department of Health and Human Services (HHS) fiscal year (FY) 2021 financial statements, internal control over financial reporting, 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, 2021 and 2020, 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, 2021, 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 19-03, *Audit Requirements for Federal Financial Statements.*

Results of the Independent Audit

Based on its audit, Ernst & Young found that the FY 2021 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, 2021, 2020, 2019, 2018, and 2017, and the related statements of changes in social insurance amounts for the periods ended January 1, 2021 and 2020. 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 execute a governance model and was consistent in focusing on strengthening the maturity over HHS's IT controls. In FY 2021, HHS management continued to take a leadership role in monitoring remediation activities across all IT systems within the scope of Ernst & Young's review, with a focus on general ledger systems and control deficiencies that contributed to the significant IT deficiency noted in the consolidated Financial Statement Audit. These efforts led to a reduction in the number of internal control deficiencies that contributed to the significant IT deficiency reported in FY 2020. Additional improvements made by HHS included the remediation of control deficiencies identified in non-General Ledger feeder systems that provide significant information to HHS Financial Systems.

  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 2021 audit, Ernst & Young noted that HHS made progress in addressing certain issues. However, the FY 2021 audit still identified a series of deficiencies in financial systems and processes for producing financial statements. These deficiencies included the need for a number of non-standard journal entries to significantly adjust financial and budgetary amounts and insufficient analysis and oversight of certain significant accounts and programs. Ernst & Young specifically described concerns about the number and dollar amount of non-standard journal entries, HHS acquisition processes, grant monitoring and closeout, Medicaid oversight, and the Statement of Social Insurance. Ernst & Young noted that a significant number of nonstandard 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 their volume and dollar values comprise a significant portion of HHS's overall financial activity. For example, Ernst & Young noted that the incorrect processing and correction of a National Institutes of Health (NIH) invoice in September 2021 for $1.025 million resulted in a series of non-standard entries recorded in October for approximately $1.015 billion. The corrections that were required impacted NIH, the HHS Office of the Secretary, and the consolidated financial statement balances, as well as the Governmentwide treasury Account Symbol (GTAS) submission that supports the development of the U.S. governmentwide financial statements. Although the error was

identified by the Department prior to the issuance of the HHS Agency Financial Report and the GTAS submission was corrected, certain controls at NIH were not working effectively, including analytical reviews, data analysis, and manual review controls, to identify the errors prior to impacting HHS' year-end reporting.

Ernst & Young noted that HHS management and HHS OIG, over the past several years, have identified a series of: (1) concerns related to internal control and (2) violations of laws and regulations related to acquisition processes at both the HHS Department and Operating Division levels. Consistent with FY 2020, Ernst & Young identified concerns related to accounting and reporting of procurement activity within financial systems, noting for example that the National Institutes of Health (NIH) maintains two separate acquisition systems. These two acquisition systems are: (1) the NIH Business System (NBS) Purchase Request Information System (PRISM), which supports 26 NIH Institutes and Centers, and (2) the Contract Award & Management System (CAMS), which is a standalone system within the National Heart, Lung, and Blood Institute (NHLBI). NBS PRISM is fully integrated with NBS and provides stringent controls across acquisition and financial management. CAMS is not integrated and requires alternative methods and tools to transfer acquisitions data into NBS PRISM to interface with the NBS financial system. Ernst & Young noted that the use of two systems poses significant financial management risks and additional costs that would not exist if NHLBI operated within the NBS PRISM system.

For grant closeout and monitoring, Ernst & Young noted that HHS should strengthen its processes related to grant activities by continuing to closely monitor outstanding grant balances, especially to ensure the timely closeout of grants. For grant reporting in FY 2021, Ernst & Young indicated there was slight improvement over FY 2020 reporting for open grants for expired project periods. There were 24,249 open grants with project expired project periods of FY 2019 or prior compared to 24,325 open grants with expired project periods of FY 2018 and prior. Recent legislation and guidance, including OMB Circular A-136 and the Code of Federal Regulations (2 CFR 200.344), has placed an emphasis on timely and efficient closing of grant awards, especially with a focus on older awards. HHS has made progress with project periods ending FY 2018 and prior – closing out approximately 9,300 grants in this category during FY 2021. Management indicated that efforts to close out grants timely were slowed due to competing priorities within grant offices.

For Medicaid oversight, Ernst & Young noted that the Centers for Medicare & Medicaid Services (CMS) continued its efforts to enhance internal controls as part of the financial reporting processes. Weaknesses in oversight of the Medicaid program included that although operational data is currently available, information contained within Transformed-Medicaid Statistical Information System (T-MSIS) requires additional verification before it would be considered reliable to utilize in the financial accounting and reporting for the Medicaid program. In addition, the process to perform a detailed claims-level look-back analysis related to the Entitlement Benefits Due and Payable accrual, which would determine the reasonableness of the various State calculations of the incurred but not reported liability, should be further developed. Also, there were

errors associated with the state plan amendment accrual, which includes accumulating the information from the states and applying a historical approval rate to determine the reported contingent liability at the end of the period. Specifically, amounts used in the calculation of the accrual did not agree to the underlying support and a portion of the amount accrued related to future periods beyond the balance sheet date.

For the Statement of Social Insurance, Ernst & Young identified formula errors in the spreadsheets used in the preparation of the statement, and these formula errors were not detected by the organization'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 2021, HHS was not in full compliance with the requirements of the Payment Integrity Information Act of 2019 (PIIA) (P.L. No. 116-117) 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) and Foster Care programs. HHS believes it does not have the authority under the Social Security Act to compel the States to report error rates for TANF. HHS did not report an improper payment estimate for the Foster Care program due to its pausing on-site Title IV-E eligibility reviews as a result of COVID-19. HHS reported three high priority programs (Medicare Advantage, Medicaid, and CHIP) with error rates in excess of 10 percent. Additionally, HHS has not calculated or reported an improper payment estimate for the Advance Premium Tax Credits program, which has been deemed susceptible to significant improper payments. These are also violations of the PIIA. CMS has specific initiatives underway to address the results for Medicaid, CHIP and Medicare Advantage Programs. We will report further on agency compliance with improper payment reporting, as required by the PIIA, later in FY 2022.

HHS's management also determined that it may have potential violations of the Anti-Deficiency Act (P.L. No. 101-508) related to: (1) an obligation of funds for conference spending at the Food and Drug Administration, (2) certain contract obligations at CMS that occurred in FYs 2014 and 2015 and at HHS's Program Support Center that occurred between FY 2006 and FY 2011, and (3) certain transfers and administrative costs within the Biomedical Advanced Research and Development Authority within the Office of the Secretary. 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). As discussed above, HHS identified potential violations with laws and regulations related to its acquisition processes. In FY 2019, CMS management was also notified that it may have potential violations of the Federal Acquisition Regulation related to contracting matters.

[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.

Evaluation and Monitoring of Audit Performance

We reviewed Ernst & Young's audit of the HHS financial statements by:

- evaluating the independence, objectivity, and qualifications of the auditors and specialists;
- reviewing the approach and planning of the audit;
- attending key meetings with auditors and HHS officials;
- monitoring the progress of the audit;
- examining audit documentation, including that related to the review of internal controls over financial reporting;
- reviewing the auditors' reports; and
- reviewing the HHS *FY 2021 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 Carla J. Lewis, Assistant Inspector General for Audit Services, at (202) 205-9125 or Carla.Lewis@oig.hhs.gov. Please refer to report number A-17-21-00001.

Attachment

cc:
Norris Cochran
Acting Assistant Secretary for Financial Resources
and Acting 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 financial statements of the U.S. Department of Health and Human Services (HHS), which comprise the consolidated balance sheets as of September 30, 2021 and 2020, and the related consolidated statements of net cost and changes in net position, and the combined statement of budgetary resources for the fiscal years then ended, and the 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, 2021, 2020, 2019, 2018, and 2017, and the related statements of changes in social insurance amounts for the periods ended January 1, 2021 and 2020, 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 an opinion 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, 2021, 2020, 2019, 2018, and 2017, and the related statements of changes in social insurance amounts for the periods ended January 1, 2021 and 2020, and the related notes to these financial statements, we conducted our audits 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 No. 21-04, *Audit Requirements for Federal Financial Statements*. Those standards and OMB Bulletin No. 21-04 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

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relevant to the entity'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, 2021 and 2020, and the related consolidated statements of net cost and changes in net position, and the combined statement of budgetary resources for the fiscal years then ended, and the 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 26 to the financial statements, the statement of social insurance presents the actuarial present value of the Hospital Insurance and Supplementary Medical Insurance 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 on 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* (PPACA) and the *Medicare Access and CHIP Reauthorization Act of 2015* (MACRA).

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As further described in Note 27 to the financial statements, with respect to the estimates for the social insurance program presented as of January 1, 2021, 2020, 2019, 2018, and 2017, the current-law expenditure projections reflect the physicians' payment levels expected under the MACRA payment rules and the PPACA-mandated reductions in other Medicare payment rates. 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 27, 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, access to Medicare-participating providers 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. As a result of these limitations, we were unable to obtain sufficient audit evidence for the amounts presented on the statements of social insurance as of January 1, 2021, 2020, 2019, 2018, and 2017, and the related statements of changes in social insurance amounts for the periods ended January 1, 2021 and 2020.

Disclaimer of Opinion on the Statements 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, 2021, 2020, 2019, 2018, and 2017, and the related changes in the social insurance program for the periods ended January 1, 2021 and 2020, and the related notes to these financial statements.

Opinion

In our opinion, the consolidated balance sheets, the consolidated statements of net cost and changes in net position, and the combined statement of budgetary resources referred to above present fairly, in all material respects, the consolidated financial position of HHS as of September 30, 2021 and 2020, and their consolidated net cost, consolidated changes in net position, and combined 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

Generally accepted accounting principles in the United States of America require that the Management's Discussion and Analysis and Required Supplementary Information, as identified on HHS's Agency Financial Report Table of Contents, be presented to supplement the financial statements. Such information is the responsibility of management and, although not a part of the 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 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 of America, 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 financial statements, and other knowledge we obtained during our audit of the 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 audit was conducted for the purpose of forming an opinion on the financial statements that collectively comprise HHS's 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 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 financial statements. Such information has been subjected to the auditing procedures applied in the audit of the financial statements and certain additional procedures, including comparing and reconciling such information directly to the underlying accounting and other records used to prepare the financial statements or to the financial statements themselves, and other additional procedures in accordance with auditing standards generally accepted in the United States of America. In our opinion, the Other Financial Information is fairly stated, in all material respects, in relation to the 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 audit of the 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 12, 2021 on our consideration of HHS's internal control over financial reporting and on our tests of its compliance with certain provisions of laws, 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's 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 12, 2021

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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 of America, 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. 21-04, *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, 2021, 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, 2021, and the related statement of changes in social insurance amounts for the period ended January 1, 2021, and the related notes to the sustainability financial statements and have issued our report thereon dated November 12, 2021. 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, 2021, and the related statement of changes in social insurance amounts for the period ended January 1, 2021.

Internal Control Over Financial Reporting

In planning and performing our audit of the financial statements, we considered HHS's internal control over financial reporting (internal control) as a basis for designing audit procedures that are appropriate in the circumstances for the purpose of expressing our opinion on the financial statements, but not for the purpose of expressing an opinion on the effectiveness of HHS's internal control. Accordingly, we do not express an opinion on the effectiveness of HHS's internal control. We did not consider 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 preparing performance information and ensuring efficient operations.

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

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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 as described below, to be significant deficiencies.

Significant Deficiencies

Financial Information Systems

As a part of our procedures for the FY 2021 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, HHS has continued to execute 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 IT systems in scope, with a focus on general ledger systems and control deficiencies that contributed to the IT significant deficiency of the consolidated financial statement audit. The following summarizes additional improvements achieved that resulted from this increased attention:

- Management has continued its enterprise-wide focus on corrective actions which has led to the remediation of a number of prior year control deficiencies.

- Management has made improvements in the remediation of prior year control deficiencies identified on feeder systems (non-GL) that are financially significant.

We have performed a separate financial statement audit of Centers for Medicare and Medicaid Services (CMS) for FY 2021 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 and are summarized below.

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 is based on the following:

- **Access controls** – We identified two access control exceptions across three of the applications in-scope of our review, which spanned non-CMS systems, in aggregate contributed to the IT significant deficiency. Specifically, the two exceptions are: (1) management has not consistently adhered to Department and system-level logging and monitoring requirements, and (2) the removal of user access across two different applications in-scope of our review was not performed in a timely manner. We identified

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similar exceptions at CMS: (1) procedures for the removal of users who no longer required access were not consistently followed, and (2) monitoring and/or recertification of privileged access for key applications and underlying IT infrastructure was not performed or evidence of such monitoring activity was not retained.

- **Configuration management** – We identified one type of configuration management exception across one application in-scope of our review which spanned non-CMS systems. Specifically, the exception is that there is a subset of users with access to source code as well as the ability to migrate source code to productions. In addition, CMS continues to experience deficiencies in the implementation and monitoring of compliance with its information systems control standards and processes. Specifically, one system configuration settings were not compliant with CMS requirements.

- **Segregation of duties** – We identified four types of segregation of duties (SOD) exceptions across three applications in scope of our review that spanned non-CMS systems. Specifically, the four types of exceptions are the following: (1) management is not consistently monitoring the activities performed by users with a combination of roles that cause SOD conflicts as defined by management, (2) management was unable to provide SOD waivers for all users that have access to roles that cause a SOD conflict, (3) management has not incorporated a complete or accurate listing of all roles and responsibilities into the SOD matrix for the application, and (4) sufficient justification was not provided for users with access to roles that cause SOD conflicts.

Recommendations

HHS should continue the progress achieved in FY 2021 to remediate the remaining deficiencies contributing to the significant deficiency and focus on continuous improvement. The following are some specific considerations:

- Continue to prioritize high-impact remediation activities ultimately strengthening the IT controls maturity, with specific attention on the remaining control deficiencies that contribute to the significant deficiency identified on financial information systems as a part of the FY2021 financial statement audit centered on access controls, configuration management, and segregation of duties,

- Work to strengthen overarching governance/oversight to improve sustainability of remediation activities limiting the identification of new internal control deficiencies that could contribute to the IT significant deficiency during the audit,

- Continue to build on the maturity of the IT controls enterprise and strengthen all layers of the IT enterprise, to include operating system, data tier, and application layer, while being cognizant of the identification of new internal control deficiencies on material systems that could contribute to the IT significant deficiency.

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Financial Systems, Analysis and Reporting

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 the need for a number of non-standard journal entries to significantly adjust financial and budgetary amounts, and/or insufficient analysis and oversight of certain significant accounts, balances, 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 National Institutes of Health (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 2021, although HHS's annual total budgetary resources were $2.661 trillion, HHS was required to process 7,284 manual entries totaling an absolute value of more than $367.3 billion to its NIH Business System (NBS) or Unified Financial Management Systems (UFMS). Although the number and absolute dollar value of manual entries decreased compared with FY 2020 where 7,943 manual entries totaling an absolute value of more than $480.6 billion were posted, the number and absolute dollar value of manual entries remain substantial. 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 balances are accurate, the volume and dollar value of manual entries is significant compared with HHS's overall activity.

Additionally, we noted that the incorrect processing and correction of an NIH invoice in September 2021 for $1.025 million resulted in a series of non-standard entries recorded in October for approximately $1.015 billion. The corrections that were required impacted NIH, the Office of the Secretary, and the consolidated financial statement balances, as well as the Governmentwide Treasury Account Symbol Adjusted Trial Balance System (GTAS) submission that supports the development of the U.S. government-wide financial statements. Although the error was identified by the Department prior to the issuance of the HHS Agency Financial Report and the GTAS submission was corrected, certain controls at NIH were not working as intended, including data analytics and reconciliations to identify substantial errors before submitting financial data which impacts HHS year-end reporting.

Grant Monitoring and Close out

During FY 2021, $1.2 trillion of HHS spending was made through grants. Although we found HHS's internal controls for grants were properly designed, we noted that HHS should strengthen

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its controls to ensure grants with expired project periods are closed out in a timely manner. Open grant awards represent obligations for goods and/or services that have not been delivered or are awards for which proper expenditure reporting from the grant recipient has not been received, recorded and/or reconciled. HHS grant managers are required to closely monitor outstanding grant balances and ensure grant recipients follow proper expenditure reporting guidance/timelines.

In FY 2021, Grant Reporting, formerly known as GONE Act reporting, indicated that there were 24,249 open grants with expired project periods of FY 2019 & prior. This was a slight improvement over FY 2020 Reporting which identified 24,325 open grants with expired project periods FY 2018 & prior. Recent legislation and guidance, including OMB Circular A-136 and the Code of Federal Regulations (2 CFR 200.344), has placed an emphasis on timely and efficient closing of grant awards, especially with a focus on older awards. HHS has made progress with project periods ending FY 2018 and prior – closing out approximately 9,300 grants in this category during FY 2021. However, HHS is still awarding far more grants than are being closed out with over 84,000 grants being issued in FY 2020 alone. Management indicated that efforts to close out grants timely were slowed due to competing priorities within grant offices.

HHS Procurement Processes

Over the past several years, HHS and our audit have identified several concerns related to internal control and potential violations of laws and regulations related to its procurement processes at both the HHS department and Operating Division Levels. We have reported that HHS identified a series of potential violations to the *Antideficiency Act* within our accompanying Report on Compliance and Other Matters.

Consistent with FY 2020, HHS and our audit identified certain concerns related to accounting and reporting of procurement activities within its financial systems. For example: the NIH leverages the Purchase Request Information System (PRISM) for their acquisition information management. NIH currently maintains two separate PRISM systems: (1) the NIH NBS PRISM system that supports 26 NIH Institutes and Centers (IC), and (2) the Contract Award & Management System (CAMS), which is a standalone PRISM system within the National Heart, Lung, and Blood Institute (NHLBI). NBS PRISM is fully integrated with the NBS financial system and provides stringent controls across acquisition and financial management. CAMS is not integrated and requires alternative methods and tools to transfer acquisitions data into NBS PRISM to interface with the NBS financial system. The dependency on non-integrated third-party applications to transfer acquisitions data poses significant financial management and information security risks and increases the level of effort required to reconcile data between the two acquisition systems. There are also significant costs associated with procuring and maintaining two PRISM systems. These increased risks and additional costs would be non-existent if NHLBI operated within the NBS PRISM system. Additionally, there appear to be no functional, operational, or cost benefits to maintaining a separate PRISM system that supports only one institute.

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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 5, 2021. 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, the Statements of Social Insurance, and improper payments.

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.

Medicaid Entitlement Benefits Due and Payable (EBDP)

CMS previously 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, information contained within T-MSIS requires additional verification before it would be considered reliable to utilize in the financial accounting and reporting for Medicaid. CMS should evaluate whether financial reporting risks can be addressed by using T-MSIS data to identify outliers and unusual or unexpected results that demonstrate abnormalities in state-related Medicaid expenditures, that may require consideration in determining the Medicaid EBDP as of year-end. Given the claims level detail is not yet considered reliable for financial accounting and reporting, CMS is unable to perform a claims-level detailed look-back analysis for the Medicaid EBDP to determine the reasonableness of the various state calculations of incurred (unpaid claims) but not reported liability calculated during prior periods which could serve to validate the appropriate use of a similar methodology. The Medicaid EBDP is a significant liability on the FY 2021 financial statements and is subject to volatility based on the complexity and judgment required in establishing this estimate. From time to time, claim processing cycle changes, such as 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, presenting a risk that potential updates to CMS' analysis will not be reflected in CMS' financial statements in a timely manner.

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Medicaid Contingencies

At the end of each quarter, an accrual is recognized for any pending state plan amendments (SPAs) which have not yet been approved but for which the approval would impact periods prior to the balance sheet date. The calculation of the SPA accrual includes accumulating the information from the states and applying a historical approval rate to determine the reported contingent liability at the end of the period. During our procedures, we identified errors in the SPA accrual calculation. Specifically, amounts used in the calculation of the accrual did not agree to the underlying support and a portion of the amount accrued improperly related to future periods beyond the balance sheet date.

Statements of Social Insurance

The Statements of Social Insurance (SOSI) for CMS present 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's 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. In the current year, CMS incorporated changes to the SOSI projection, resulting in changes to the inputs, formulas and macros, and outputs of certain spreadsheets. During our procedures, formula errors associated with certain of the changes were identified that were not detected by the organization's monitoring and review function, and accordingly, the related control was not functioning at the level of precision as designed.

Improper Payments

The nature and volume of its expenditures present a substantial challenge to CMS in the quantification, evaluation, and remediation of improper payments. Health insurance claims represent the vast majority of the CMS payments. These payments are complex and involve the evaluation of the program eligibility of both the recipient of the services and of the health provider, oversight of the medical necessity of each covered treatment and concurrence with the cost to be paid, some of which is based on complex financial formulas and/or coding decisions. CMS has developed sophisticated sampling processes for estimating improper payment rates in the high-risk CMS programs of Medicare Fee-for-Service, Medicare Advantage (Part C), Medicare Prescription Drug Program (Part D), Medicaid and CHIP.

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CMS builds time into its processes to allow all payments sampled for review sufficient time to allow for appeals of the errors and submission of additional documentation by the claimant. CMS believes that expediting the improper payment rate calculations would result in less time for sampled payments to complete the measurement process, allowing errors to be cited solely due to the fact that not enough time was given for things such as appeals or documentation submission. Allowing the maximum amount of time for this development causes the processes to be completed very near the required annual reporting deadline. CMS remains committed to achieving reductions in improper payment rates. For Medicaid and CHIP, CMS reintegrated the eligibility component of the measurement in FY 2019, resulting in a significant increase in the improper payment rates. Rates between years will not be comparable until after a baseline is established in FY 2021, when all states have been measured under the new eligibility requirements. For Part C, the FY 2021 measurement implemented refinements to the population of payments reviewed and at risk for diagnostic errors, as well as calculation changes, which led to the increase in the FY 2021 error estimate. This year's result is not comparable to the FY 2020 results due to the methodology and calculation changes. CMS has specific initiatives underway to address these new results for Medicaid, CHIP and Medicare Advantage (Part C).

Recommendations

We recommend that HHS continue to develop, refine, and adhere to its financial management systems and processes to improve its accounting, analysis, and oversight of financial management activity. This will require focused efforts and continued prioritization of issues related to controls within and surrounding its 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. Additionally, we recommend that HHS strengthen its controls around its manual journal entry process or reinforce its controls through training of personnel to ensure that control processes are operating effectively. Finally, we recommend that NIH revisit its controls, including data analytics, year-over-year comparisons and management review controls to ensure that errors in data are identified in a timely manner so that the number and amount of manual entries can be minimized.

- HHS should continue to strengthen its processes and accounting related to acquisition activities. As potential internal control and law and regulation concerns are identified, we recommend that policies and procedures are updated with training provided to the acquisition personnel to provide assurances that processes are executed properly. Further, we recommend that the ongoing monitoring process be enhanced to provide stronger internal controls so that anomalies can be prevented or identified in a timely manner. Finally, we recommend NIH consider transitioning to a single PRISM instance. Operating

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a standalone non-integrated PRISM system poses significant risks and does not provide cost benefit. In addition, maintaining a fully integrated acquisition system for 26 NIH ICs, and then procuring and maintaining a second acquisition system for only one component of NIH raises questions about responsible stewardship of resources to administer acquisition activities at NIH.

- HHS should continue to strengthen its processes related to grant activities by continuing to closely monitor outstanding grant balances, especially ensuring timely closeout of grants.

- We recommend that CMS continue to develop, refine, and adhere to its financial management systems and processes to improve its accounting, analysis, and oversight of financial management activity. This would include having CMS:

  – Continue to enhance the data analyses on Medicaid claims level data to develop robust analytical procedures and measures against benchmarks to monitor and identify risks associated with the financial accounting and reporting of the Medicaid program.

  – Establish a process to perform a claims-level detailed look-back analysis on the Medicaid EBDP to determine the reasonableness of the methodology utilized to record the approximately $52.8 billion liability.

  – Enhance the control attributes, including the precision of controls, around the completeness and accuracy of underlying data as it relates to the Medicaid SPA contingencies. Re-evaluate the responsible parties best suited to review the accrual at the balance sheet date particularly when the accrual changes between quarters exceed a specified amount.

  – 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. When changes are made, such as changes to the methodology or key assumptions, management should require an enhanced review specific to these changes.

  – Consider additional opportunities to further reduce improper payments which are consistent with the organization's objectives of improving payment accuracy levels.

More detailed recommendations related to our specific findings on these topics are included in our CMS Report on Internal Control.

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HHS's Response to Findings

HHS's response to the findings identified in our audit is included in the accompanying letter dated November 12, 2021. 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.

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 entity's internal control. Accordingly, this communication is not suitable for any other purpose.

Ernst & Young LLP

November 12, 2021

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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 of America, 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. 21-04, *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, 2021, 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 engaged to audit the sustainability financial statements, which comprise the statement of social insurance as of January 1, 2021, and the related statement of changes in social insurance amounts for the period ended January 1, 2021, and the related notes to the sustainability financial statements and have issued our report thereon dated November 12, 2021. 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, 2021, and the related statement of changes in social insurance amounts for the period ended January 1, 2021.

Compliance and Other Matters

As part of obtaining reasonable assurance about whether HHS's financial statements are free of material misstatement, we performed tests of its compliance with certain provisions of laws, regulations, contracts, and grant agreements, noncompliance with which could have a direct and material effect on the financial statements, as well as 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. 21-04, as described below.

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During FY 2021, HHS's management determined that it may have potential violations of the *Antideficiency Act* (P.L. 101-508 and OMB Circular A-11) related to (1) an obligation of funds for conference spending at the Food and Drug Administration, (2) certain contract obligations serviced by the Program Support Center between FY 2006 and FY 2011 and the Centers for Medicare & Medicaid Services (CMS) occurring between FY 2014 and FY 2015, and (3) certain transfers and administrative costs within the Biomedical Advanced Research and Development Authority within the Office of the Secretary. Additionally, during FY 2020, CMS management was notified that it may have potential violations of the Federal Acquisition Regulation related to contracting matters. Finally, HHS management determined that its Medicare appeals process did not adjudicate appeals within the statutory decisional time frames required by the *Social Security Act*.

The *Payment Integrity Information Act of 2019 (*P.L.116-117) (hereinafter, the "Act") (1) requires federal agencies to identify the program and activities that may be susceptible to significant improper payments and estimate the amount of the improper payments for risk-susceptible programs, and (2) establish certain reporting requirements surrounding such programs and their related estimates. While the Department continues to make progress, HHS currently is not in full compliance with the requirements of the Act. For example, HHS has not reported an improper payment error rate for the Temporary Assistance for Needy Families (TANF) program. 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, HHS has not calculated or reported an improper payment estimate for the Advance Premium Tax Credit program, which has been deemed susceptible to significant improper payments. Further, although HHS reported improper payment rates for Medicaid, CHIP, and Medicare Advantage (Part C), improper payment rates exceeded the statutorily required maximum of 10 percent. HHS also did not report an improper payment estimate for the Foster Care program due to pausing its on-site Title IV-E eligibility reviews as a result of the COVID-19 pandemic. Finally, 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.

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HHS's Response to Findings

HHS's response to the findings identified in our audit is described in the accompanying letter dated November 12, 2021. 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.

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 the entity's compliance. This report is an integral part of an audit performed in accordance with *Government Auditing Standards* in considering the entity's compliance. Accordingly, this communication is not suitable for any other purpose.

Ernst & Young LLP

November 12, 2021

Department's Response to the Report of the Independent Auditors

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Office of the Assistant Secretary for
Financial Resources
Washington, D.C. 20201

To: Christi A. Grimm, Principal Deputy Inspector General

From: Norris Cochran, Acting Assistant Secretary for Financial Resources

Subject: Fiscal Year (FY) 2021 Independent Auditors' Financial Statement Audit Report

Thank you for the opportunity to comment on the FY 2021 Independent Auditors' Report. We appreciate the commitment and diligent work of the Office of Inspector General (OIG) and its independent auditors, Ernst & Young LLP (EY), throughout the audit of the Department of Health and Human Services' financial statements.

We are pleased to see confirmation of the Department's financial health through the auditors' issuance of an unmodified opinion on our principal financial statements. We acknowledge that the auditors disclaimed providing an opinion on the Statement of Social Insurance and the Statement of Changes in Social Insurance Amounts. Additionally, the auditors identified material noncompliances with laws and regulations related to the *Payment Integrity Information Act of 2019* and the *Social Security Act*. We generally concur with the auditors' conclusions. The Department will consistently face new challenges given the scale and complexity of our mission and operations, especially when responding to unprecedented events like a global pandemic. We will continue to actively identify root causes, implement corrective actions, and monitor remediation efforts.

The Department diligently worked to improve the effectiveness of our internal control environment. Efforts to meet the requirements and cadence of the audit this year reflect the tremendous resilience and dedication by all parties. We are proud of our progress and remain committed to ensuring high standards of integrity and transparency in reporting our financial performance.

/Norris Cochran/

Norris Cochran
Acting Assistant Secretary for Financial Resources
November 12, 2021

Principal Financial Statements

U.S. Department of Health and Human Services
Consolidated Balance Sheets
As of September 30, 2021 and 2020
(in Millions)

	2021	2020
Assets (Note 2)		
Intragovernmental		
Fund Balance with Treasury (Note 3)	$ 710,558	$ 514,042
Investments, Net (Note 4)	312,291	226,215
Accounts Receivable, Net (Note 5)	705	715
Advances and Prepayments (Note 8)	1,000	1,993
Total Intragovernmental	**1,024,554**	**742,965**
With the Public		
Accounts Receivable, Net (Note 5)	28,676	21,712
Inventory and Related Property, Net (Note 6)	16,251	13,430
General Property, Plant and Equipment, Net (Note 7)	7,531	6,904
Advances and Prepayments (Note 8)	70,081	106,082
Other Assets:		
Loans Receivable	487	524
Other	10	9
Total With the Public	**123,036**	**148,661**
Total Assets	**$ 1,147,590**	**$ 891,626**
Stewardship Land (Note 21)		
Liabilities (Note 9)		
Intragovernmental		
Accounts Payable	$ 4,531	$ 3,625
Debt (Note 10)	36,781	1,361
Advances from Other and Deferred Revenue	332	282
Other Liabilities (Note 14)	391	774
Total Intragovernmental	**42,035**	**6,042**
With the Public		
Accounts Payable	1,452	2,583
Entitlement Benefits Due and Payable (Note 11)	133,777	116,935
Federal Employee and Veterans Benefits Payable (Note 12)	17,265	16,225
Environmental and Disposal Liabilities	326	213
Advances from Others and Deferred Revenue	2,449	2,007
Other Liabilities:		
Accrued Liabilities (Note 13)	18,472	15,798
Contingencies and Commitments (Note 15)	12,080	11,267
Other Liabilities (Note 14)	1,772	794
Total With the Public	**187,593**	**165,822**
Total Liabilities	**229,628**	**171,864**
Net Position		
Unexpended Appropriations – Funds from Dedicated Collections (Note 20)	134,943	98,117
Unexpended Appropriations – Funds from Other Than Dedicated Collections	480,253	333,140
Total Unexpended Appropriations	**615,196**	**431,257**
Cumulative Results of Operations – Funds from Dedicated Collections (Note 20)	296,328	285,692
Cumulative Results of Operations – Funds from Other Than Dedicated Collections	6,438	2,813
Total Cumulative Results of Operations	**302,766**	**288,505**
Total Net Position	**917,962**	**719,762**
Total Liabilities and Net Position	**$ 1,147,590**	**$ 891,626**

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, 2021 and 2020
(in Millions)

	2021	2020
Responsibility Segments		
Centers for Medicare & Medicaid Services (CMS)		
Gross Costs	$ 1,404,879	$ 1,281,918
Exchange Revenue	(132,908)	(125,288)
CMS Net Cost of Operations	1,271,971	1,156,630
Other Segments:		
Administration for Children and Families (ACF)	71,185	61,159
Administration for Community Living (ACL)	2,669	2,444
Agency for Healthcare Research and Quality (AHRQ)	337	334
Centers for Disease Control and Prevention (CDC)	16,160	11,980
Food and Drug Administration (FDA)	6,094	5,687
Health Resources and Services Administration (HRSA)	14,572	12,241
Indian Health Service (IHS)	12,029	8,429
National Institutes of Health (NIH)	40,569	36,819
Office of the Secretary (OS)	69,984	110,043
Program Support Center (PSC)	1,897	2,218
Substance Abuse and Mental Health Services Administration (SAMHSA)	6,110	5,339
Other Segments Gross Costs of Operations before Actuarial Gains and Losses	$ 241,606	$ 256,693
Actuarial (Gains) and Losses Commissioned Corp Retirement and Medical Plan Assumption Changes (Note 12)	665	71
Other Segments Gross Costs of Operations after Actuarial Gains and Losses	$ 242,271	$ 256,764
Exchange Revenue	(5,686)	(5,657)
Other Segments Net Cost of Operations	236,585	251,107
Net Cost of Operations (Note 22)	**$ 1,508,556**	**$ 1,407,737**

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, 2021
(in Millions)

	Funds from Dedicated Collections	All Other Funds	Eliminations	Consolidated Total
Unexpended Appropriations:				
Beginning Balance	$ 98,117	$ 333,140	$ -	$ 431,257
Appropriations Received	502,345	1,010,927	-	1,513,272
Appropriations Transferred in/out	-	26	-	26
Other Adjustments	(23,955)	(88,084)	-	(112,039)
Appropriations Used	(441,564)	(775,756)	-	(1,217,320)
Net Change in Unexpended Appropriations	36,826	147,113	-	183,939
Unexpended Appropriations: Ending Balance	**$ 134,943**	**$ 480,253**	**$ -**	**$ 615,196**
Cumulative Results of Operations:				
Beginning Balances	$ 285,692	$ 2,813	$ -	$ 288,505
Other Adjustments	(1)	(347)	-	(348)
Appropriations Used	441,564	775,756	-	1,217,320
Nonexchange Revenue:				
Nonexchange Revenue – Tax Revenue	299,147	-	-	299,147
Nonexchange Revenue – Investment Revenue	4,904	65	-	4,969
Nonexchange Revenue – Other	3,230	313	-	3,543
Donations and Forfeitures of Cash and Cash Equivalents	71	-	-	71
Transfers-in/out without Reimbursement	(4,802)	2,359	-	(2,443)
Donations and Forfeitures of Property	-	8	-	8
Imputed Financing	106	834	(327)	613
Other	22	(85)	-	(63)
Net Cost of Operations	733,605	775,278	(327)	1,508,556
Net Change in Cumulative Results of Operations	10,636	3,625	-	14,261
Cumulative Results of Operations: Ending Balance	**$ 296,328**	**$ 6,438**	**$ -**	**$ 302,766**
Net Position	**$ 431,271**	**$ 486,691**	**$ -**	**$ 917,962**

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, 2020
(in Millions)

	Funds from Dedicated Collections	All Other Funds	Eliminations	Consolidated Total
Unexpended Appropriations:				
Beginning Balance	$ 57,968	$ 170,438	$ -	$ 228,406
Appropriations Received	438,810	921,741	-	1,360,551
Appropriations Transferred in/out	-	(285)	-	(285)
Other Adjustments	(6,460)	(25,153)	-	(31,613)
Appropriations Used	(392,201)	(733,601)	-	(1,125,802)
Net Change in Unexpended Appropriations	40,149	162,702	-	202,851
Unexpended Appropriations: Ending Balance	**$ 98,117**	**$ 333,140**	**$ -**	**$ 431,257**
Cumulative Results of Operations:				
Beginning Balances	$ 258,392	$ (5,264)	$ -	$ 253,128
Other Adjustments	-	(9)	-	(9)
Appropriations Used	392,201	733,601	-	1,125,802
Nonexchange Revenue:				
Nonexchange Revenue – Tax Revenue	295,913	-	-	295,913
Nonexchange Revenue – Investment Revenue	6,406	242	-	6,648
Nonexchange Revenue – Other	3,971	310	-	4,281
Donations and Forfeitures of Cash and Cash Equivalents	61	-	-	61
Transfers-in/out without Reimbursement	(4,134)	1,895	-	(2,239)
Donations and Forfeitures of Property	-	127	-	127
Imputed Financing	12,358	825	(309)	12,874
Other	6	(350)	-	(344)
Net Cost of Operations	679,482	728,564	(309)	1,407,737
Net Change in Cumulative Results of Operations	27,300	8,077	-	35,377
Cumulative Results of Operations: Ending Balance	**$ 285,692**	**$ 2,813**	**$ -**	**$ 288,505**
Net Position	**$ 383,809**	**$ 335,953**	**$ -**	**$ 719,762**

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, 2021 and 2020
(in Millions)

	2021	2020
Budgetary Resources		
Unobligated Balance from Prior Year Budget Authority, Net (Discretionary and Mandatory)	$ 335,459	$ 157,422
Appropriations (Discretionary and Mandatory)	2,252,266	2,255,613
Borrowing Authority (Discretionary and Mandatory)	46,028	2
Spending Authority from Offsetting Collections (Discretionary and Mandatory)	27,592	26,710
Total Budgetary Resources (Note 23)	**$ 2,661,345**	**$ 2,439,747**
Status of Budgetary Resources		
New Obligations and Upward Adjustments (Note 23)	$ 2,355,877	$ 2,198,886
Unobligated Balance, End of Year:		
Apportioned, Unexpired Accounts	135,838	158,596
Exempt from Apportionment, Unexpired Accounts	204	188
Unapportioned, Unexpired Accounts	54,980	12,288
Unexpired Unobligated Balance, End of Year	191,022	171,072
Expired Unobligated Balance, End of Year	114,446	69,789
Unobligated Balance, End of Year	305,468	240,861
Total Budgetary Resources (Note 23)	**$ 2,661,345**	**$ 2,439,747**
Outlays, Net		
Outlays, Net (Discretionary and Mandatory)	$ 2,088,600	$ 2,037,911
Distributed Offsetting Receipts	(621,612)	(533,915)
Agency Outlays, Net (Discretionary and Mandatory) (Note 22)	**$ 1,466,988**	**$ 1,503,996**
Disbursements, Net	**$ 278**	**$ (7)**

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, 2021 and Prior Base Years
(in Billions)

	2021	Estimates from Prior Years 2020	2019	2018	2017
Actuarial present value for the 75-year projection period of estimated future income (excluding interest) received from or on behalf of: (Notes 26 and 27)					
Current participants who, in the starting year of the projection period:					
Have not yet attained eligibility age					
HI	$ 13,017	$ 12,454	$ 11,995	$ 11,323	$ 10,679
SMI Part B	34,467	32,165	27,556	24,143	21,641
SMI Part D	6,881	6,975	7,181	7,176	6,929
Have attained eligibility age (age 65 or over)					
HI	664	637	559	525	492
SMI Part B	6,536	5,864	5,232	4,725	4,122
SMI Part D	1,061	1,016	1,052	1,015	958
Those expected to become participants					
HI	13,029	12,464	11,805	10,959	10,567
SMI Part B	9,010	8,567	6,864	5,586	5,019
SMI Part D	2,921	3,043	3,000	2,932	2,869
All current and future participants					
HI	$ 26,710	$ 25,554	$ 24,359	$ 22,807	$ 21,738
SMI Part B	50,013	46,596	39,652	34,453	30,783
SMI Part D	10,863	11,035	11,232	11,124	10,756
Actuarial present value for the 75-year projection period of estimated future expenditures for or on behalf of: (Notes 26 and 27)					
Current participants who, in the starting year of the projection period:					
Have not yet attained eligibility age					
HI	$ 20,940	$ 20,103	$ 20,028	$ 18,604	$ 17,193
SMI Part B	34,075	31,819	27,270	23,832	21,392
SMI Part D	6,881	6,975	7,181	7,176	6,929
Have attained eligibility age (age 65 and over)					
HI	6,230	6,073	5,348	5,027	4,539
SMI Part B	6,892	6,194	5,741	5,180	4,531
SMI Part D	1,061	1,016	1,052	1,015	958
Those expected to become participants					
HI	4,597	4,179	4,467	3,884	3,539
SMI Part B	9,046	8,583	6,641	5,442	4,860
SMI Part D	2,921	3,043	3,000	2,932	2,869
All current and future participants:					
HI	$ 31,767	$ 30,355	$ 29,843	$ 27,515	$ 25,270
SMI Part B	50,013	46,596	39,652	34,453	30,783
SMI Part D	10,863	11,035	11,232	11,124	10,756
Actuarial present value for the 75-year projection period of estimated future excess of income (excluding interest) over expenditures (Notes 26 and 27)					
HI	$ (5,057)	$ (4,800)	$ (5,484)	$ (4,708)	$ (3,532)
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 26 and 27)					
HI	$ (5,057)	$ (4,800)	$ (5,484)	$ (4,708)	$ (3,532)
SMI Part B	-	-	-	-	-
SMI Part D	-	-	-	-	-
Trust Fund assets at start of period					
HI	198	195	200	202	199
SMI Part B	133	100	96	80	88
SMI Part D	10	9	8	8	8
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 26 and 27)					
HI	$ (4,859)	$ (4,606)	$ (5,283)	$ (4,506)	$ (3,333)
SMI Part B	133	100	96	80	88
SMI Part D	10	9	8	8	8

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, 2021 and Prior Base Years

(in Billions)

		Estimates from Prior Years			
	2021	2020	2019	2018	2017
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)	$ 8,261	$ 7,517	$ 6,843	$ 6,266	$ 5,572
Expenditures	14,184	13,284	12,140	11,222	10,027
Income less expenditures	(5,922)	(5,766)	(5,297)	(4,957)	(4,455)
Those who, in the starting year of the projection period, have not yet attained eligibility age:					
Income (excluding interest)	54,364	51,594	46,731	42,643	39,250
Expenditures	61,895	58,897	54,479	49,612	45,514
Income less expenditures	(7,531)	(7,303)	(7,748)	(6,970)	(6,264)
Actuarial present value of estimated future income (excluding interest) less expenditures (closed-group measure)	(13,453)	(13,069)	(13,045)	(11,926)	(10,719)
Combined Medicare Trust Fund assets at start of period	341	303	305	290	295
Actuarial present value of estimated future income (excluding interest) less expenditures plus trust fund assets at start of period	$ (13,112)	$ (12,766)	$ (12,740)	$ (11,637)	$ (10,425)
Future Participants:					
Actuarial present value for the 75-year projection period:					
Income (excluding interest)	$ 24,960	$ 24,074	$ 21,669	$ 19,477	$ 18,456
Expenditures	16,564	15,805	14,108	12,258	11,268
Income less expenditures	8,396	8,269	7,561	7,219	7,187
Open-Group (all current and future participants):					
Actuarial present value of estimated future income (excluding interest) less expenditures	(5,057)	(4,800)	(5,484)	(4,708)	(3,532)
Combined Medicare Trust Fund assets at start of period	341	303	305	290	295
Actuarial present value of estimated future income (excluding interest) less expenditures plus trust fund assets at start of period	$ (4,716)	$ (4,497)	$ (5,179)	$ (4,418)	$ (3,237)

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, 2020 to January 1, 2021

Medicare Hospital and Supplementary Medical Insurance

(in Billions)

	Actuarial present value over the next 75 years (open group measure)				Actuarial present value of estimated future income (excluding interest) less expenditures plus combined trust fund assets
	Estimated future income (excluding interest)	Estimated future expenditures	Estimated future income less expenditures	Combined HI and SMI trust fund account assets	
Total Medicare (Note 28)					
As of January 1, 2020	$ 83,185	$ 87,986	$ (4,800)	$ 303	$ (4,497)
Reasons for change					
Change in the valuation period	2,766	2,932	(166)	6	(160)
Change in projection base	(3,070)	(3,276)	205	32	237
Changes in the demographic assumptions	(947)	(1,648)	700	-	700
Changes in economic and health care assumptions	5,512	6,471	(959)	-	(959)
Changes in law	140	178	(38)	-	(38)
Net changes	4,401	4,658	(257)	38	(219)
As of January 1, 2021	$ 87,586	$ 92,643	$ (5,057)	$ 341	$ (4,716)
HI - Part A (Note 28)					
As of January 1, 2020	$ 25,554	$ 30,355	$ (4,800)	$ 195	$ (4,606)
Reasons for change					
Change in the valuation period	753	919	(166)	(9)	(175)
Change in projection base	(700)	(906)	205	13	218
Changes in the demographic assumptions	(110)	(810)	700	-	700
Changes in economic and health care assumptions	1,212	2,171	(959)	-	(959)
Changes in law	-	38	(38)	-	(38)
Net changes	1,156	1,412	(257)	4	(253)
As of January 1, 2021	$ 26,710	$ 31,767	$ (5,057)	$ 198	$ (4,859)
SMI - Part B (Note 28)					
As of January 1, 2020	$ 46,596	$ 46,596	$ -	$ 100	$ 100
Reasons for change					
Change in the valuation period	1,618	1,618	-	17	17
Change in projection base	(2,428)	(2,428)	-	16	16
Changes in the demographic assumptions	(665)	(665)	-	-	-
Changes in economic and health care assumptions	4,751	4,751	-	-	-
Changes in law	140	140	-	-	-
Net changes	3,416	3,416	-	34	34
As of January 1, 2021	$ 50,013	$ 50,013	$ -	$ 133	$ 133
SMI - Part D (Note 28)					
As of January 1, 2020	$ 11,035	$ 11,035	$ -	$ 9	$ 9
Reasons for change					
Change in the valuation period	395	395	-	(2)	(2)
Change in projection base	58	58	-	3	3
Changes in the demographic assumptions	(173)	(173)	-	-	-
Changes in economic and health care assumptions	(451)	(451)	-	-	-
Changes in law	-	-	-	-	-
Net changes	(171)	(171)	-	1	1
As of January 1, 2021	$ 10,863	$ 10,863	$ -	$ 10	$ 10

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, 2019 to January 1, 2020

Medicare Hospital and Supplementary Medical Insurance

(in Billions)

	Actuarial present value over the next 75 years (open group measure)				Actuarial present value of estimated future income (excluding interest) less expenditures plus combined trust fund assets
	Estimated future income (excluding interest)	Estimated future expenditures	Estimated future income less expenditures	Combined HI and SMI trust fund account assets	
Total Medicare (Note 28)					
As of January 1, 2019	$ 75,243	$ 80,727	$ (5,484)	$ 305	$ (5,179)
Reasons for change					
Change in the valuation period	2,691	2,926	(235)	(3)	(238)
Change in projection base	444	45	399	2	401
Changes in the demographic assumptions	(1,871)	(4,558)	2,687	-	2,687
Changes in economic and healthcare assumptions	7,455	9,170	(1,715)	-	(1,715)
Changes in law	(778)	(325)	(453)	-	(453)
Net changes	7,942	7,259	683	(1)	682
As of January 1, 2020	$ 83,185	$ 87,986	$ (4,800)	$ 303	$ (4,497)
HI - Part A (Note 28)					
As of January 1, 2019	$ 24,359	$ 29,843	$ (5,484)	$ 200	$ (5,283)
Reasons for change					
Change in the valuation period	799	1,034	(235)	(7)	(242)
Change in projection base	(17)	(415)	399	1	400
Changes in the demographic assumptions	(426)	(3,114)	2,687	-	2,687
Changes in economic and healthcare assumptions	1,386	3,101	(1,715)	-	(1,715)
Changes in law	(547)	(94)	(453)	-	(453)
Net changes	1,195	512	683	(6)	677
As of January 1, 2020	$ 25,554	$ 30,355	$ (4,800)	$ 195	$ (4,606)
SMI - Part B (Note 28)					
As of January 1, 2019	$ 39,652	$ 39,652	$ -	$ 96	$ 96
Reasons for change					
Change in the valuation period	1,449	1,449	-	3	3
Change in projection base	285	285	-	-	-
Changes in the demographic assumptions	(1,049)	(1,049)	-	-	-
Changes in economic and healthcare assumptions	6,414	6,414	-	-	-
Changes in law	(154)	(154)	-	-	-
Net changes	6,944	6,944	-	3	3
As of January 1, 2020	$ 46,596	$ 46,596	$ -	$ 100	$ 100
SMI - Part D (Note 28)					
As of January 1, 2019	$ 11,232	$ 11,232	$ -	$ 8	$ 8
Reasons for change					
Change in the valuation period	444	444	-	-	-
Change in projection base	176	176	-	1	1
Changes in the demographic assumptions	(395)	(395)	-	-	-
Changes in economic and healthcare assumptions	(345)	(345)	-	-	-
Changes in law	(77)	(77)	-	-	-
Net changes	(198)	(198)	-	1	1
As of January 1, 2020	$ 11,035	$ 11,035	$ -	$ 9	$ 9

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 United States (U.S.) Department of Health and Human Services (HHS or the Department) 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, the 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.

The accompanying financial statements include activities and operations of the HHS. 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 are consolidated in the HHS financial statements. HHS conducted a systematic and thorough review of all organizations and determined HHS does not have any disclosure entities.

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. Responsibility segment management 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 Officers 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 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 218 appropriation accounts. These accounts are used for general government functions, collection of receipts, and suspense. 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.

Accounting standards require all reporting entities to disclose that accounting standards allow certain presentations and disclosures to be modified, if needed, to prevent the disclosure of classified information.

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, the *Patient Protection and Affordable Care Act* and the *Health Care and Education Reconciliation Act* were signed and are collectively referred to as the PPACA. Further information is available at Healthcare.gov.

The PPACA contains the most significant changes to healthcare 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 a Center for Consumer Information and

Insurance Oversight (CCIIO). One of the main programs under CCIIO is the Health Insurance Marketplaces (the "Marketplaces"). 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 Marketplaces

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

Risk Adjustment Program

The Risk Adjustment program is a permanent program. It applies to non-grandfathered individual and small group plans inside and outside the Marketplaces. It provides payments to health insurance issuers that disproportionately attract higher-risk populations (such as individuals with chronic conditions) and transfers funds from plans with relatively lower-risk enrollees to plans with relatively higher-risk enrollees to protect against adverse selection. States that operate a State-based Marketplace are eligible to establish a Risk Adjustment program. States operating a Risk Adjustment program may have an entity other than the Marketplace perform this function. CMS operates a Risk Adjustment program for each state that does not operate its own Risk Adjustment program.

E. COVID-19 Activities

The *Coronavirus Aid, Relief, and Economic Security Act* (CARES Act), was signed on March 27, 2020 to provide emergency assistance and healthcare response for individuals, families, and businesses affected by the COVID-19 pandemic. In addition to the CARES Act, during FY 2020, HHS received additional supplemental appropriations through the *Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020*, the *Families First Coronavirus Response Act*, and the *Paycheck Protection Program and Health Care Enhancement Act*.

HHS received funding to support the new Provider Relief Fund which was created to prevent, prepare for, and respond to COVID-19, both domestically and internationally. The Provider Relief Fund provides necessary expense reimbursements to assist eligible healthcare providers for healthcare related expenses or lost revenues attributed to COVID-19. HHS also received funding to support Biomedical Advanced Research and Development Authority (BARDA) efforts to advance research, development, manufacturing, production, and purchase of COVID-19 vaccines, therapeutics, and testing and related supplies; rebuild the Strategic National Stockpile (SNS); and support other COVID-19 related activities.

The *Coronavirus Response and Relief Supplemental Appropriations Act, 2021* supplements existing initiatives under the Provider Relief Fund, as well as support for the expansion of COVID-19 vaccination activities across jurisdictions. In addition, the Child Care and Development Block Grants provided additional financial support to childcare providers during the COVID-19 public health crisis.

The *American Rescue Plan Act of 2021* provides relief funding to workers and families for nationwide testing sites and community vaccination sites as well as addressing disparities in obtaining quality healthcare. In addition, HHS received funding to support testing, contact tracing, and mitigation activities and the Child Care Stabilization and Development Block Grants received funding to help working parents by providing childcare subsidies and increasing childcare options.

F. 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 the Department of Homeland Security to HHS for the Biodefense Countermeasures Fund for FY 2008 and beyond. Under this exception, HHS, as the child, assumed the financial statement reporting responsibilities of this fund.

Under the PPACA, HHS has established a child relationship with the Internal Revenue Service (IRS) of the U.S. 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), Department of Labor (DOL), Treasury, and Social Security Administration (SSA).

G. Changes, Reclassifications and Adjustments

Effective FY 2021, the principal Balance Sheets, supplementary Balance Sheets and some footnotes have changed to be in compliance with the OMB Circular A-136. Thus, certain FY 2020 balances have been reclassified for comparability.

H. Funds from Dedicated Collections

Funds from dedicated collections are generally financed by specifically identified revenues and provided to the government by non-federal sources. The sources are 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 Trust Fund – Part A

Section 1817 of the *Social Security Act* established the Medicare Hospital Insurance (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 CMS payments to Medicare Advantage plans are also charged to this fund. The financial statements include 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 Medicare's HI program. Medicare's portion of payroll and self-employment taxes are collected under the *Federal Insurance Contribution Act* (FICA) and the *Self-Employment Contribution Act* (SECA). 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 U.S. Government (general fund) to the HI trust fund based on the amount of wages certified by the Commissioner of Social Security from SSA records of wages established and maintained by SSA in accordance with wage information reports.

Medicare Supplementary Medical Insurance Trust Fund – Part B

Section 1841 of the *Social Security Act* established the Supplementary Medical Insurance (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 CMS payments to Medicare Advantage plans are also charged to this fund. The financial statements include SMI trust fund activities administered by Treasury. The SMI trust fund has permanent indefinite authority.

SMI benefits and administrative expenses are financed primarily by monthly premiums paid by Medicare beneficiaries with matching 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 outlines the ratio for the match as the method to fully compensate the trust fund if insufficient funds are available in the appropriation to match all premiums received in the fiscal year.

Medicare Supplementary Medical Insurance Trust Fund – Part D

The *Medicare Modernization Act of 2003* (MMA), established the Medicare Prescription Drug Benefit – Part D. Medicare also helps employers or unions continue to provide retiree drug coverage that meets Medicare's standards through the Retiree Drug Subsidy. In addition, the Low Income Subsidy helps those with limited income and resources.

The PPACA provided that beneficiary cost sharing in the Part D coverage gap be reduced for brand-name and generic drugs to a 25 percent coinsurance. Part D is considered part of the SMI trust fund and is reported in the SMI column of the financial statements.

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.

I. 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 if 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.

J. 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 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.

K. 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.

L. 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.

M. 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.

N. 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.

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.

O. 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. Intragovernmental accounts receivable consists of the amounts owed to HHS by other federal agencies for reimbursable work. 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, the allowance for uncollectible accounts receivable derived this year has been calculated from data based on the agency's collection activity and the age of the debt for the most current fiscal year, while taking into consideration the average uncollectible percentage for the past 5 years. The Medicaid accounts receivable has been recorded at a net realizable value based on a historic analysis of actual recoveries and the rate of disallowances found in favor of the states. The other accounts receivable have been recorded to account for amounts due related to collections for Marketplace activities.

P. Advances and Prepayments and Accrued Liabilities

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.

Formula grants and block grants are funded when 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.

All other grants are funded when the 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.

The standard Accelerated and Advance Payment (AAP) program was established to help providers and suppliers who are experiencing disruptions in cash flow due to system issues or claims processing delays. Standard AAPs are most commonly used during local emergencies, such as hurricanes or wildfires, which impact a provider or supplier's ability to submit or receive claims payments.

On March 30, 2020, the COVID-19 AAP program was established, under the CARES Act, to address the significant disruption to the healthcare industry caused by delays in non-essential surgeries and procedures and disruptions to billing, among other challenges related to the pandemic. On October 1, 2020 under the terms of the *Continuing Appropriations Act, 2021 and Other Extensions Act*, CMS further delayed repayment for one year from the date each provider or supplier's COVID-19 AAP was issued. Then repayment occurs through an automatic recoupment by offset of 25 percent of Medicare claims payments for the next 11 months. After the 11-month period, recoupment increases to 50 percent of Medicare claims payments for an additional 6 months. If the provider or supplier is unable to repay the total amount of the COVID-19 AAP within 29 months, CMS will issue a demand letter requiring repayment of any outstanding balance, subject to an interest rates of 4 percent, consistent with the terms of the *Continuing Appropriations Act, 2021 and Other Extensions Act*.

Q. Inventory and Related Property, Net

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

Inventory Held for Sale and Use 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 and Use 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 SNS and Vaccines for Children (VFC). 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.

R. 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 noncancelable 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 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.

S. 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 healthcare 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.

T. 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 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. In addition, HHS has debt related to amounts borrowed to cover the accelerated and advance payments made for the COVID-19 AAP program.

Liabilities Not Requiring Budgetary Resources

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

U. 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.

V. 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.

W. Debt

The majority of HHS's debt to the Treasury is related to amounts borrowed to cover the accelerated and advance payments made for the COVID-19 AAP program. The *Continuing Appropriations Act, 2021 and Other Extensions Act* requires debt to Treasury for the AAP program to be repaid from collections (described in the Advances and Prepayments and Accrued Liabilities section of this note) on a periodic basis. The remaining is for amounts borrowed to cover premium shortfalls. 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 for calendar years 2016 and 2017. Section 601 created an additional premium charged alongside the normal Medicare Part B monthly premiums, which will be used to pay back the general fund transfer without interest. The *Continuing Appropriations Act, 2021 and Other Extensions Act* made similar changes for 2021. These repayments are transferred quarterly.

X. Entitlement Benefits Due and Payable

Entitlement Benefits Due and Payable represents a liability for Medicare fee-for-service, Medicare Advantage and the Prescription Drug Program, Medicaid, and CHIP owed to the public for medical services/claims incurred but not reported (IBNR) as of the end of the reporting period.

Y. Federal Employee and Veterans Benefits Payable

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 three 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 one percent of each employee's pay to the Thrift Savings Plan and matches the first three 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.

Z. 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.

Treaties and other international agreements are written agreements between the U.S. and other sovereign states, or between the U.S. and international organizations, governed by international law. The Department of State developed and continues to manage the Circular 175 procedure, which outlines the approval process for the negotiation and conclusion of international agreements which HHS will become a party. For reporting purposes HHS has no present or contingency obligation related to treaties and international agreements when entered into force.

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.

AA. 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 HI and 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 *2021 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.

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

	2021	2020
Non-Entity Intragovernmental Assets	$ 60	$ 8
Non-Entity With the Public Assets	80	41
Total Non-Entity Assets	140	49
Total Entity Assets	1,147,450	891,577
Total Assets	**$ 1,147,590**	**$ 891,626**

HHS reported an increase of $256.0 billion in Total Entity Assets primarily due to an increase of FBwT and Investments. FBwT had an increase of $196.5 billion primarily due to appropriations provided by the *American Rescue Plan Act of 2021*, the *Coronavirus Response and Relief Supplemental Appropriations Act of 2021* and the CARES Act. Investments increased $86.1 billion primarily due to an increase in SMI for repayable advances and premium matching from PTF. These increases were offset by a $36.0 billion decrease in Advances and Prepayments primarily due to the Accelerated & Advance Payment (AAP) refunds.

Note 3. Fund Balance with Treasury (in Millions)

	2021	2020
Status of Fund Balance with Treasury		
Unobligated Balance		
Available	$ 136,042	$ 158,784
Unavailable	169,426	82,077
Obligated Balance not yet Disbursed	470,977	338,106
Non-Budgetary Fund Balance with Treasury	(65,887)	(64,925)
Total Fund Balance with Treasury	**$ 710,558**	**$ 514,042**

The Unobligated Balance, Available decrease of $22.7 billion is mostly due to decreased apportionments in the Public Health and Social Services Emergency Fund (PHSSEF) for COVID-19.

The Unobligated Balance, Unavailable increase of $87.3 billion is primarily due to Payments to the Trust Funds with an increase in definite authority retained of $47.7 billion, and the increase in PHSSEF Unapportioned Authority of $38.7 billion from the *American Rescue Plan Act of 2021*.

The Unobligated Balance includes funds that are restricted for future use and not apportioned for current use of $28.6 billion as of September 30, 2021 ($29.8 billion as of September 30, 2020). The restricted amount is primarily for PPACA, CHIP, CMS Program Management, Center for Medicare and Medicaid Innovation, and State Grants and Demonstrations.

Note 4. Investments, Net (in Millions)

	2021				
	Cost	Amortized (Premium)	Interest Receivable	Investments, Net	Market Value Disclosure
Intragovernmental Securities					
Non-Marketable: Par Value	$ 306,845	$ -	$ 1,288	$ 308,133	$ 308,133
Non-Marketable: Market-Based	4,186	(38)	10	4,158	4,158
Total, Intragovernmental	**$ 311,031**	**$ (38)**	**$ 1,298**	**$ 312,291**	**$ 312,291**

	2020				
	Cost	Amortized (Premium)	Interest Receivable	Investments, Net	Market Value Disclosure
Intragovernmental Securities					
Non-Marketable: Par Value	$ 221,212	$ -	$ 922	$ 222,134	$ 222,134
Non-Marketable: Market-Based	4,095	(25)	11	4,081	4,081
Total, Intragovernmental	**$ 225,307**	**$ (25)**	**$ 933**	**$ 226,215**	**$ 226,215**

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, 2023, through June 30, 2036, with interest rates ranging from 0.750 percent to 2.875 percent. Medicare Non-Marketable: Par Value Certificates of Indebtedness mature on June 30, 2022, with interest rates ranging from 1.375 percent to 1.500 percent.

Securities held by the Vaccine Injury Compensation Trust Fund will mature in FY 2022 through FY 2025. The Market-Based Notes paid from 0.375 percent to 2.375 percent during October 1, 2020, to September 30, 2021 (0.375 percent to 2.375 percent during October 1, 2019, to September 30, 2020). 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 2021, yielded from 0.0150 percent to 0.1251 percent depending on date purchased and length of time to maturity.

Note 5. Accounts Receivable, Net (in Millions)

	2021				
	Accounts Receivable Principal	Interest Receivable	Accounts Receivable, Gross	Allowance	Accounts Receivable, Net
Intragovernmental					
Entity	$ 705	$ -	$ 705	$ -	$ 705
Total, Intragovernmental	**$ 705**	**$ -**	**$ 705**	**$ -**	**$ 705**
With the Public					
Entity					
Medicare	$ 19,356	$ -	$ 19,356	$ (3,709)	$ 15,647
Medicaid	7,349	-	7,349	(1,027)	6,322
Other	7,254	363	7,617	(990)	6,627
Non-Entity	57	71	128	(48)	80
Total, With the Public	**$ 34,016**	**$ 434**	**$ 34,450**	**$ (5,774)**	**$ 28,676**

	2020				
	Accounts Receivable Principal	Interest Receivable	Accounts Receivable, Gross	Allowance	Accounts Receivables, Net
Intragovernmental					
Entity	$ 715	$ -	$ 715	$ -	$ 715
Total, Intragovernmental	**$ 715**	**$ -**	**$ 715**	**$ -**	**$ 715**
With the Public					
Entity					
Medicare	$ 15,931	$ -	$ 15,931	$ (3,631)	$ 12,300
Medicaid	5,359	-	5,359	(1,038)	4,321
Other	5,700	344	6,044	(994)	5,050
Non-Entity	25	72	97	(56)	41
Total, With the Public	**$ 27,015**	**$ 416**	**$ 27,431**	**$ (5,719)**	**$ 21,712**

As of September 30, 2021, Accounts Receivable, Net increase of $7.0 billion is primarily due to an increase in Medicare receivables, of which $3.3 billion is due to program growth and larger prospective payments, and $2.0 billion increase in Medicaid grants receivables with States. In addition, there was an increase in the Risk Adjustment Program receivables of $1.6 billion.

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

	2021	2020
Inventory Held for Sale or Use	$ 422	$ 218
Stockpile Materials Held for Emergency or Contingency	15,829	13,212
Inventory and Related Property, Net	**$ 16,251**	**$ 13,430**

Inventory and Related Property, Net increase of $2.8 billion is mostly due to an increase in the PHSSEF for COVID-19 personal protective equipment and SNS inventory.

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

			2021		
	Depreciation Method	Estimated Useful Lives	Acquisition Cost	Accumulated Depreciation	Net Book Value
Land & Land Rights	N/A	N/A	$ 64	$ (2)	$ 62
Construction in Progress	N/A	N/A	1,284	-	1,284
Buildings, Facilities & Other Structures	Straight-Line	5-50 Yrs	6,619	(3,790)	2,829
Equipment	Straight-Line	3-20 Yrs	2,420	(1,427)	993
Internal Use Software	Straight-Line	5-10 Yrs	5,828	(3,519)	2,309
Assets Under Capital Lease	Straight-Line	1-30 Yrs	119	(84)	35
Leasehold Improvements	Straight-Line	*Life of Lease	74	(55)	19
Totals			**$ 16,408**	**$ (8,877)**	**$ 7,531**

			2020		
	Depreciation Method	Estimated Useful Lives	Acquisition Cost	Accumulated Depreciation	Net Book Value
Land & Land Rights	N/A	N/A	$ 61	$ (1)	$ 60
Construction in Progress	N/A	N/A	1,131	-	1,131
Buildings, Facilities & Other Structures	Straight-Line	5-50 Yrs	6,398	(3,591)	2,807
Equipment	Straight-Line	3-20 Yrs	2,356	(1,383)	973
Internal Use Software	Straight-Line	5-10 Yrs	4,761	(2,885)	1,876
Assets Under Capital Lease	Straight-Line	1-30 Yrs	119	(80)	39
Leasehold Improvements	Straight-Line	*Life of Lease	71	(53)	18
Totals			**$ 14,897**	**$ (7,993)**	**$ 6,904**

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

	2021			2020		
	Acquisition Cost	Accumulated Depreciation	PP&E, Net	Acquisition Cost	Accumulated Depreciation	PP&E, Net
Balance Beginning of Year	$ 14,897	$ (7,993)	$ 6,904	$ 13,658	$ (7,114)	$ 6,544
Capitalized Acquisitions from the Public	1,560	-	1,560	1,481	-	1,481
Capitalized Acquisitions from Government Agencies	83	(23)	60	2	-	2
Dispositions	(132)	130	(2)	(287)	65	(222)
Depreciation Expense	-	(991)	(991)	43	(944)	(901)
Balance End of Year	**$ 16,408**	**$ (8,877)**	**$ 7,531**	**$ 14,897**	**$ (7,993)**	**$ 6,904**

Note 8. Advances and Prepayments (in Millions)

	2021	2020
Intragovernmental		
Advances to Other Federal Entities	$ 1,000	$ 1,993
Total Intragovernmental	**$ 1,000**	**$ 1,993**
With the Public		
COVID-19 Accelerated and Advance Payment Program	$ 67,011	$ 103,638
Grant Advances	3,033	2,318
Other	37	126
Total with the Public	**$ 70,081**	**$ 106,082**

As of September 30, 2021, advances and prepayments with the public primarily represent payments made for the COVID-19 AAP program. On March 30, 2020, the AAP program was expanded based on the language included in the CARES Act. Collections of these items began in April 2021.

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

	2021	2020
Intragovernmental		
Accrued Payroll and Benefits	$ 49	$ 51
Debt (Note 10)	36,312	1,154
Other	1,419	1,809
Total Intragovernmental	**$ 37,780**	**$ 3,014**
Federal Employee and Veterans Benefits Payable (Note 12)	$ 17,260	$ 16,221
Contingencies and Commitments (Note 15)	12,080	11,267
Accrued Liabilities	6,221	4,547
Other	333	222
Total Liabilities Not Covered by Budgetary Resources	$ 73,674	$ 35,271
Total Liabilities Covered by Budgetary Resources	152,652	134,396
Total Liabilities Not Requiring Budgetary Resources	3,302	2,197
Total Liabilities	**$ 229,628**	**$ 171,864**

Liabilities Not Covered by Budgetary Resources had an increase of $38.4 billion, mostly due to Debt increase of $35.2 billion for the COVID-19 AAP program.

Note 10. Debt (in Millions)

	2020 Beginning Balance	2020 Net Borrowing	2020 Ending Balance	2021 Net Borrowing	2021 Ending Balance
Debt to the Treasury:					
Transitional SMI Contribution	$ 3,152	$ (1,998)	$ 1,154	$ 5,806	$ 6,960
COVID-19 Accelerated and Advance Payment Program	-	-	-	29,352	29,352
Other	207	-	207	262	469
Total Debt to the Treasury	**$ 3,359**	**$ (1,998)**	**$ 1,361**	**$ 35,420**	**$ 36,781**

HHS has $36.8 billion ($1.4 billion in FY 2020) in total debt due to Treasury. The majority of this debt is related to amounts borrowed to cover the accelerated and advance payments made for the COVID-19 AAP program. The remaining debt balance is for amounts borrowed to cover premium shortfalls.

Note 11. Entitlement Benefits Due and Payable (in Millions)

	2021	2020
Medicare Fee-For-Service	$ 57,765	$ 49,262
Medicare Advantage/Prescription Drug Program	22,013	20,890
Medicaid	52,757	45,850
CHIP	1,242	933
Totals	**$ 133,777**	**$ 116,935**

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: (1) an estimate of claims incurred that may or may not have been submitted to the Medicare contractors but were not yet approved for payment; (2) actual claims that have been approved for payment by the Medicare contractors for which checks have not yet been issued; (3) checks that have been issued by the Medicare contractors in payment of a claim and that have not yet been cashed by payees; (4) periodic interim payments for services rendered in the current fiscal year but paid in the subsequent fiscal year; and (5) an estimate of retroactive settlements of cost reports. The September 30, 2021 and 2020 estimates also include 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 the calendar year 2021. 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, 2021.

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 based on data from the states' latest audited Comprehensive Annual Financial Report. Each state's estimate is subject to variability due to the variety of programs offered by the respective states and the data required to formulate these estimates. Accordingly, the ultimate outcome of these estimates could vary from the amounts recorded at September 30, 2021 and 2020.

Note 12. Federal Employee and Veterans Benefits Payable (in Millions)

	2021	2020
With the Public		
Liabilities Not Covered by Budgetary Resources		
PHS Commissioned Corp Pension Liability	$ 15,272	$ 14,318
PHS Commissioned Corp Post-Retirement Health Benefits	752	718
Workers' Compensation Benefits (Actuarial FECA Liability)	269	283
Unfunded Leave	967	902
Liabilities Covered by Budgetary Resources		
Other	5	4
Total, Federal Employee and Veterans Benefits	**$ 17,265**	**$ 16,225**

Public Health Service Commissioned Corps

HHS administers the PHS Commissioned Corps Retirement System for 5,943 active duty officers and 7,587 retiree annuitants and survivors. As of September 30, 2021, the actuarial accrued liability for the retirement benefit plan was $15.3 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, 2021 and September 30, 2020, were:

	2021	2020
Discount Rate	3.37 percent	3.56 percent
Annual Basic Pay Scale Increase	2.28 percent	2.28 percent
Annual Inflation	1.98 percent	1.87 percent

The table below shows key valuation results as of September 30, 2021 and 2020, 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 September 30, 2021 and actuarial assumptions. The September 30, 2021 valuation includes an increase in liabilities of $988 million resulting from changes in the assumed annual inflation rate and in the assumed discount rate. These changes in combination with the actual plan experience over the past year (based upon new census data) and a law change (pursuant to the *National Defense Authorization Act of 2020*), 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 2021 has increased relative to the prior year expense.

	2021	2020
Beginning Liability Balance	$ 15,036	$ 14,550
Expense		
Normal Cost	417	400
Interest on the Liability Balance	524	535
Actuarial (Gain)/Loss		
From Experience	(27)	55
From Assumption Changes		
Change in Discount Rate Assumption	414	398
Change in Inflation/Salary Increase Assumption	259	(237)
Change in New Medical Trends Assumption	18	(105)
Change in Others	(26)	15
Total From Assumption Changes	$ 665	$ 71
Net Actuarial (Gain)/Loss	638	126
Total Expense	$ 1,579	$ 1,061
Less Amounts Paid	(591)	(575)
Ending Liability Balance	**$ 16,024**	**$ 15,036**

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 2021 and 2020, discount rates were based on averaging the Treasury's Yield Curve for Treasury Nominal Coupon Issues for the current and prior 4 years. Interest rate assumptions utilized for discounting as of September 30, 2021 and September 30, 2020, were:

	2021	2020
Wage Benefits	2.231% in Year 1 and years thereafter	2.414% in Year 1 and years thereafter
Medical Benefits	2.060% in Year 1 and years thereafter	2.303% 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
2021	N/A	N/A
2022	2.11%	3.14%
2023	2.48%	3.55%
2024	2.55%	3.96%
2025	2.62%	3.89%
2026	2.68%	4.19%

Note 13. Accrued Liabilities (in Millions)

	2021	2020
Grant Liability	$ 9,861	$ 7,972
Other Accrued Liabilities	8,611	7,826
Accrued Liabilities	**$ 18,472**	**$ 15,798**

Note 14. Other Liabilities (in Millions)

	2021	2020
Intragovernmental		
Benefit Program Contribution Payable	$ 210	$ 183
Custodial Liabilities	149	237
Other	32	354
Total Intragovernmental	**$ 391**	**$ 774**
With the Public		
Accrued Payroll and Benefits	$ 638	$ 582
Custodial Liabilities	99	20
Other	1,035	192
Total with the Public	**$ 1,772**	**$ 794**

Note 15. Contingencies and Commitments

HHS is a party in various administrative proceedings, legal actions, and tort claims which may ultimately result in settlements or decisions adverse to the federal government. HHS has accrued contingent liabilities where a loss is determined to be probable and the amount can be estimated. 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 $3.7 billion as of September 30, 2021 ($3.7 billion as of September 30, 2020) 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.

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. The estimated amount recorded for contract support costs is $5.8 billion as of September 30, 2021 ($5.5 billion as of September 30, 2020).

Other contingent liabilities against HHS have been accrued in the financial statements for the Vaccine Injury Compensation Program and the Health Center Program malpractice claims through the *Federal Tort Claims Act*.

Note 16. Net Adjustments to Unobligated Balance, Brought Forward, October 1 (in Millions)

	2021	2020
Unobligated Balance, End of Year (from Prior Year)	$ 240,861	$ 109,385
Adjustments to Unobligated Balance Brought Forward:		
Recoveries of Prior Year Unpaid Obligations	52,646	35,451
Recoveries of Prior Year Paid Obligations	55,610	20,470
Appropriations Temporarily Precluded from Obligation - Prior-Year	(4,922)	(488)
Cancelled Authority	(9,229)	(6,678)
Prior Year Adjustments	1,245	(634)
Other	(752)	(84)
Total Unobligated Balance Brought Forward, October 1	**$ 335,459**	**$ 157,422**

Net adjustments to the Unobligated Balance, Brought Forward, October 1 primarily includes activity related to recoveries of prior year unpaid and paid obligations, appropriations which were temporarily precluded from obligation in the prior year, cancelled authority, and prior year adjustments.

In FY 2021, HHS reported $1.2 billion in prior year adjustments. These adjustments were made to account for backdated authority issued by Treasury for Payments for Foster Care and Permanency and to adjust the carry forward amount for the Recovery Audit Contractor program. In FY 2020, HHS reported $0.6 billion in prior year adjustments. These adjustments were made to adjust for late de-obligations posted in October 2019 instead of September 2019 and overstated Recovery Audit Contractor payable.

Note 17. 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 $224.1 billion, as of September 30, 2021 ($146.5 billion as of September 30, 2020) are included in Investments on the Consolidated Balance Sheets.

Note 18. Explanation of Differences between the Combined Statement of Budgetary Resources and the Budget of the United States Government (in Millions)

	2020			
	Budgetary Resources	New Obligations and Upward Adjustments	Distributed Offsetting Receipts	Outlays, net (discretionary and mandatory)
Combined Statement of Budgetary Resources	$ 2,439,747	$ 2,198,886	$ 533,915	$ 2,037,911
Expired Accounts	(69,762)	-	-	-
Other	(968)	-	48	1
Budget of the U.S. Government	**$ 2,369,017**	**$ 2,198,886**	**$ 533,963**	**$ 2,037,912**

The *Budget of the United States Government* (also known as the *President's Budget*), with the actual amounts for FY 2021, has not been published; therefore, no comparisons can be made between FY 2021 amounts presented in the Combined Statement of Budgetary Resources with amounts reported in the Actual column of the *President's Budget*. The *FY 2023 President's Budget* is expected to be released in February 2022 and may be obtained from OMB or from the Government Publishing Office.

HHS reconciled the amounts of the FY 2020 column on the Combined Statement of Budgetary Resources to the actual amounts for FY 2020 from the Appendix in the *FY 2022 President's Budget* for budgetary resources, new obligations and upward adjustments, distributed offsetting receipts, and net outlays.

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*.

Note 19. Undelivered Orders (in Millions)

	2021			2020		
	Federal	Non-Federal	Total	Federal	Non-Federal	Total
Undelivered Orders, Paid	$ 1,565	$ 70,223	$ 71,788	$ 2,683	$ 106,250	$ 108,933
Undelivered Orders, Unpaid	34,844	288,841	323,685	20,640	187,189	207,829
Total Undelivered Orders	**$ 36,409**	**$ 359,064**	**$ 395,473**	**$ 23,323**	**$ 293,439**	**$ 316,762**

Undelivered Orders include obligations that have been issued but not yet drawn down, as well as goods and services ordered that have not been received. HHS reported $395.5 billion of budgetary resources obligated for undelivered orders as of September 30, 2021 ($316.8 billion as of September 30, 2020). The Undelivered Orders, Unpaid increase of $115.9 billion is primarily due to COVID-19 activity. The Undelivered Orders, Paid decrease of $37.1 billion is primarily due to the COVID-19 AAP program refunds.

Note 20. 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. See Note 1 for a description of each fund's purpose and how HHS accounts for and reports the funds.

Balance Sheet	2021 Medicare	Other	Combined Funds from Dedicated Collections	Eliminations	Consolidated Funds from Dedicated Collections
Fund Balance with Treasury	$ 145,714	$ 13,213	$ 158,927	$ -	$ 158,927
Investments	308,133	3,965	312,098	-	312,098
Accounts Receivable, Net	86,056	7,308	93,364	(92,821)	543
Advances and Prepayments	-	36	36	(30)	6
Other Assets	-	-	-	30	30
Total Intragovernmental Assets	**539,903**	**24,522**	**564,425**	**(92,821)**	**471,604**
Accounts Receivable, Net	15,647	6,148	21,795	-	21,795
General Property Plant and Equipment	286	1,496	1,782	-	1,782
Advances and Prepayments	67,012	80	67,092	-	67,092
Other Assets	-	7	7	-	7
Total Assets With the Public	**82,945**	**7,731**	**90,676**	**-**	**90,676**
Total Assets	**$ 622,848**	**$ 32,253**	**$ 655,101**	**$ (92,821)**	**$ 562,280**
Accounts Payable	$ 95,920	$ 45	$ 95,965	$ (92,875)	$ 3,090
Debt	36,312	-	36,312	-	36,312
Other Liabilities	1	29	30	54	84
Total Intragovernmental Liabilities	**132,233**	**74**	**132,307**	**(92,821)**	**39,486**
Accounts Payable	143	186	329	-	329
Entitlement Benefits Due and Payable	79,778	-	79,778	-	79,778
Federal Employee and Veterans Benefits Payable	5	90	95	-	95
Advances from Others and Deferred Revenue	815	1,513	2,328	-	2,328
Other Liabilities	9	8,984	8,993	-	8,993
Total Liabilities With the Public	**80,750**	**10,773**	**91,523**	**-**	**91,523**
Total Liabilities	**$ 212,983**	**$ 10,847**	**$ 223,830**	**$ (92,821)**	**$ 131,009**
Unexpended Appropriations	134,077	866	134,943	-	134,943
Cumulative Results of Operations	275,788	20,540	296,328	-	296,328
Total Liabilities and Net Position	**$ 622,848**	**$ 32,253**	**$ 655,101**	**$ (92,821)**	**$ 562,280**
Statement of Net Cost					
Gross Program Costs	$ 853,407	$ 17,332	$ 870,739	$ (1,244)	$ 869,495
Less: Exchange Revenues	(122,634)	(14,500)	(137,134)	1,227	(135,907)
Net Cost of Operations	**$ 730,773**	**$ 2,832**	**$ 733,605**	**$ (17)**	**$ 733,588**
Statement of Changes in Net Position					
Unexpended Appropriations:					
Beginning Balance	$ 97,863	$ 254	$ 98,117	$ -	$ 98,117
Appropriations Received	501,642	703	502,345	-	502,345
Other Adjustments	(23,947)	(8)	(23,955)	-	(23,955)
Appropriation Used	(441,481)	(83)	(441,564)	-	(441,564)
Unexpended Appropriations: Ending Balance	**134,077**	**866**	**134,943**	**-**	**134,943**
Cumulative Results of Operations:					
Beginning Balance	266,988	18,704	285,692	-	285,692
Other Adjustments	-	(1)	(1)	-	(1)
Appropriations Used	441,481	83	441,564	-	441,564
Nonexchange Revenue	307,277	4	307,281	-	307,281
Donations and Forfeitures of Cash and Cash Equivalents	-	71	71	-	71
Transfers-in/out without Reimbursement	(9,185)	4,383	(4,802)	-	(4,802)
Imputed Financing	-	106	106	(17)	89
Other	-	22	22	-	22
Net Cost of Operations	730,773	2,832	733,605	(17)	733,588
Net Change and Cumulative Results of Operations	8,800	1,836	10,636	-	10,636
Cumulative Results of Operations: Ending Balance	**275,788**	**20,540**	**296,328**	**-**	**296,328**
Net Position, End of Period	**$ 409,865**	**$ 21,406**	**$ 431,271**	**$ -**	**$ 431,271**

Balance Sheet	2020 Medicare	Other	Combined Funds from Dedicated Collections	Eliminations	Consolidated Funds from Dedicated Collections
Fund Balance with Treasury	$ 107,525	$ 11,975	$ 119,500	$ -	$ 119,500
Investments	222,134	3,967	226,101	-	226,101
Accounts Receivable, Net	75,070	6,822	81,892	(81,414)	478
Advances and Prepayments	-	21	21	(19)	2
Other Assets	-	-	-	19	19
Total Intragovernmental Assets	**404,729**	**22,785**	**427,514**	**(81,414)**	**346,100**
Accounts Receivable, Net	12,300	4,471	16,771	-	16,771
General Property Plant and Equipment	173	1,239	1,412	-	1,412
Advances and Prepayments	103,640	106	103,746	-	103,746
Other Assets	-	9	9	-	9
Total Assets With the Public	**116,113**	**5,825**	**121,938**	**-**	**121,938**
Total Assets	**$ 520,842**	**$ 28,610**	**$ 549,452**	**$ (81,414)**	**$ 468,038**
Accounts Payable	$ 84,008	$ 40	$ 84,048	$ (81,459)	$ 2,589
Debt	1,154	-	1,154	-	1,154
Other Liabilities	1	25	26	45	71
Total Intragovernmental Liabilities	**85,163**	**65**	**85,228**	**(81,414)**	**3,814**
Accounts Payable	144	203	347	-	347
Entitlement Benefits Due and Payable	70,152	-	70,152	-	70,152
Federal Employee and Veterans Benefits Payable	7	86	93	-	93
Advances from Others and Deferred Revenue	513	1,387	1,900	-	1,900
Other Liabilities	12	7,911	7,923	-	7,923
Total Liabilities With the Public	**70,828**	**9,587**	**80,415**	**-**	**80,415**
Total Liabilities	**$ 155,991**	**$ 9,652**	**$ 165,643**	**$ (81,414)**	**$ 84,229**
Unexpended Appropriations	97,863	254	98,117	-	98,117
Cumulative Results of Operations	266,988	18,704	285,692	-	285,692
Total Liabilities and Net Position	**$ 520,842**	**$ 28,610**	**$ 549,452**	**$ (81,414)**	**$ 468,038**
Statement of Net Cost					
Gross Program Costs	$ 779,800	$ 26,065	$ 805,865	$ 1,659	$ 807,524
Less: Exchange Revenues	(117,317)	(9,066)	(126,383)	(1,663)	(128,046)
Net Cost of Operations	**$ 662,483**	**$ 16,999**	**$ 679,482**	**$ (4)**	**$ 679,478**
Statement of Changes in Net Position					
Unexpended Appropriations:					
Beginning Balance	$ 57,895	$ 73	$ 57,968	$ -	$ 57,968
Appropriations Received	438,607	203	438,810	-	438,810
Other Adjustments	(6,458)	(2)	(6,460)	-	(6,460)
Appropriation Used	(392,181)	(20)	(392,201)	-	(392,201)
Unexpended Appropriations: Ending Balance	**97,863**	**254**	**98,117**	**-**	**98,117**
Cumulative Results of Operations:					
Beginning Balance	239,985	18,407	258,392	-	258,392
Appropriations Used	392,181	20	392,201	-	392,201
Nonexchange Revenue	306,288	2	306,290	-	306,290
Donations and Forfeitures of Cash and Cash Equivalents	-	61	61	-	61
Transfers-in/out without Reimbursement	(8,986)	4,852	(4,134)	-	(4,134)
Imputed Financing	3	12,355	12,358	(4)	12,354
Other	-	6	6	-	6
Net Cost of Operations	662,483	16,999	679,482	(4)	679,478
Net Change and Cumulative Results of Operations	27,003	297	27,300	-	27,300
Cumulative Results of Operations: Ending Balance	**266,988**	**18,704**	**285,692**	**-**	**285,692**
Net Position, End of Period	**$ 364,851**	**$ 18,958**	**$ 383,809**	**$ -**	**$ 383,809**

Note 21. 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 healthcare to approximately 2.6 million American Indians and Alaska Natives who belong to 574 federally recognized tribes in 37 states. Health services are provided on tribal/reservation trust land that DOI transferred to IHS 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	2021	2020
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 22. Reconciliation of Net Cost to Net Outlays (in Millions)

The Reconciliation of Net Cost of Operations to Net Outlays reconciles proprietary basis of accounting Net Cost of Operations to budgetary basis of accounting Outlays, Net. Reconciling items include activity impacting Net Cost of Operations but are not included in Outlays, Net and activity impacting Outlays, Net but are not included in Net Cost of Operations. The miscellaneous items account for activities to be added or removed based on HHS activities that are not reflected in the reconciliation crosswalk.

The FY 2021 Reconciliation of Net Cost of Operations to Net Outlays has been updated to conform to the FY 2021 presentation and FY 2020 is presented as previously published.

	2021		
	Intragovernmental	With the Public	Total
Net Cost of Operations	**$ 28,376**	**$ 1,480,180**	**$ 1,508,556**
Components of Net Cost Not Part of the Budget Outlays			
Property, Plant, and Equipment Depreciation Expense	-	(995)	(995)
Cost of Goods Sold	-	(28)	(28)
Applied Overhead/Cost Capitalization Offset	-	1,110	1,110
Gain/Losses on All Other Investments	-	(6)	(6)
	-	**81**	**81**
Increase/(Decrease) in Assets:			
Accounts Receivables	(10)	7,026	7,016
Securities and Investments	358	-	358
Advances and Prepayments	(993)	(36,001)	(36,994)
Other Assets	-	(36)	(36)
	(645)	**(29,011)**	**(29,656)**
(Increase)/Decrease in Liabilities:			
Accounts Payable	(906)	1,131	225
Debt	(35,420)	(1)	(35,421)
Benefits Due and Payable	-	(16,842)	(16,842)
Federal Employee and Veteran Benefits Payable	-	(1,040)	(1,040)
Accrued Liabilities	-	(2,934)	(2,934)
Contingencies and Commitments	-	(813)	(813)
Environmental and Disposal Liabilities	-	(113)	(113)
Other Liabilities	(62)	(1,035)	(1,097)
	(36,388)	**(21,647)**	**(58,035)**
Other Financing Sources:			
Imputed Cost	(613)	-	(613)
Total Components of Net Cost of Operating Costs Not Part of the Budgetary Outlays	**(37,646)**	**(50,577)**	**(88,223)**

	2021		
	Intragovernmental	With the Public	Total
Components of Budget Outlays Not Part of Net Cost:			
Acquisition of Capital Assets	4	494	498
Acquisition of Inventory	5	2,918	2,923
Acquisition of Other Assets	5	1	6
Other Financing Sources:			
Donated Revenue	-	(71)	(71)
Transfers out(in) without Reimbursement	2,442	-	2,442
Total Components of Budget Outlays Not Part of Net Cost	**2,456**	**3,342**	**5,798**
Miscellaneous Items:			
Custodial/Non-Exchange Revenue	(4,081)	(120)	(4,201)
Non-entity activity	717	-	717
Appropriated Receipts for Trust/Special Funds	-	6,888	6,888
Reconciling Items:			
Debt	35,420	1	35,421
Custodial/Non-Exchange Revenue	4,081	120	4,201
Federal Share of Child Support Collections	(887)	-	(887)
Total Miscellaneous Items	**35,250**	**6,889**	**42,139**
Net Outlays	**$ 28,436**	**$ 1,439,834**	**$ 1,468,270**
Other Reconciling Items			(1,282)
Agency Outlays, Net			**$ 1,466,988**

	2020		
	Intragovernmental	With the Public	Total
Net Cost of Operations	**$ 18,830**	**$ 1,388,907**	**$ 1,407,737**
Components of Net Cost Not Part of the Budget Outlays			
Property, Plant, and Equipment Depreciation	-	(942)	(942)
Property, Plant, and Equipment Disposal & Reevaluation	-	(3)	(3)
Other	-	804	804
	-	**(141)**	**(141)**
Increase/(Decrease) in Assets:			
Accounts Receivables	16	(2,436)	(2,420)
Investments	(5)	-	(5)
Advances and Other Assets	1,812	103,966	105,778
	1,823	**101,530**	**103,353**
(Increase)/Decrease in Liabilities:			
Accounts Payable	(892)	(7,461)	(8,353)
Other Liabilities (Unfunded leave, Unfunded FECA, Actuarial FECA)	(425)	4,128	3,703
	(1,317)	**(3,333)**	**(4,650)**
Other Financing Sources:			
Federal Employee Retirement Benefit Costs Paid by OPM and Imputed to the Agency	(12,874)	-	(12,874)
Transfers out (in) without Reimbursement	2,756	-	2,756
	(10,118)	**-**	**(10,118)**
Components of Budget Outlays Not Part of Net Cost:			
Acquisition of Capital Assets	7	488	495
Acquisition of Inventory	5	2,957	2,962
Acquisition of Other Assets	116	-	116
Other	793	5,016	5,809
	921	**8,461**	**9,382**
Net Outlays	**$ 10,139**	**$ 1,495,424**	**$ 1,505,563**
Federal Share of Child Support Collections and Other [6]			(1,567)
Net Outlays, Net			**$ 1,503,996**
Related Amounts on Combined Statement of Budgetary Resources			
Outlays, Net			2,037,911
Distributed Offsetting Receipts			(533,915)
Agency Outlays, Net			**$ 1,503,996**

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

Note 23. Combined Schedule of Spending (in Millions)

The Combined Schedule of Spending presents an overview of how departments or agencies spend (i.e., obligate) 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 considered 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*. The Combined Schedule of Spending and DATA Act both report spending activity by object class. 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 fiscal year. Amount Not Available to be Spent represents amounts that HHS was not approved to spend during the current fiscal year. 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 amounts agreed to be spent and agree to the New Obligations and Upward Adjustments line on the Statement of Budgetary Resources.

[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.

How was the Money Spent/Issued? This section presents services or items that were purchased and categorized by program with spending greater than $2.0 billion. Grants, Subsidies, & Contributions, Insurance Claims and Indemnities, Other Contractual Services and Personnel Compensation & Benefits are the object classes that have a material impact on HHS reporting. HHS Medicare payments are reported under Insurance Claims and Indemnities based on the OMB A-11, *Preparation, Submission, and Execution of the Budget*, object class definition.

Combined Schedule of Spending

For the Years Ended September 30, 2021 and 2020
(in Millions)

What Money is Available to Spend	2021	2020
Total Resources	$ 2,661,345	$ 2,439,747
Less Amount Available but Not Agreed to be Spent	136,042	158,784
Less Amount Not Available to be Spent	169,426	82,077
Total Amounts Agreed to be Spent	**$ 2,355,877**	**$ 2,198,886**

Who Did the Money Go To	2021	2020
Federal	$ 49,062	$ 27,009
Non-Federal	2,306,815	2,171,877
Total Amounts Agreed to be Spent	**$ 2,355,877**	**$ 2,198,886**

Total Amounts Agreed to be Spent increased by $157.0 billion, mostly due to increases related to Federal Medicare premiums, grant awards to the states for COVID-19 relief, and funding from the *Coronavirus Response and Relief Supplemental Appropriations Act, 2021* and the *American Rescue Plan Act of 2021*. This is offset by a decrease in PHSSEF, primarily related to COVID-19 relief.

Combined Schedule of Spending By Object Class

For the Year Ended September 30, 2021

(in Millions)

How was the Money Spent/Issued?	Grants, Subsidies, & Contributions	Insurance Claims & Indemnities	Other Contractual Services	Personnel Compensation & Benefits	Other	Total
Medicaid	$ 555,791	$ -	$ 2	$ -	$ -	$ 555,793
Payments to Trust Funds	336,728	-	-	-	97,404	434,132
Federal Supplementary Medical Insurance Trust Fund	-	428,315	118	1	4,737	433,171
Federal Hospital Insurance Trust Fund	-	381,772	2	-	3,703	385,477
Public Health and Social Services Emergency Fund	37,847	1	77,911	281	1,899	117,939
Medicare Prescription Drug Account	-	100,589	-	1	859	101,449
Payment to States for the Child Care and Development Block Grant	54,281	-	552	4	1	54,838
Taxation on OASDI Benefits, HI	24,975	-	-	-	-	24,975
State Children's Health Insurance Fund	18,144	-	7	-	-	18,151
Temporary Assistance for Needy Families	17,619	-	81	15	1	17,716
Children and Families Services Programs	16,047	-	374	173	11	16,605
CDC-Wide Activities and Program Support	9,043	-	6,348	207	75	15,673
Primary Health Care	12,378	-	462	100	11	12,951
Indian Health Services	6,215	1	1,403	1,715	1,147	10,481
Payments for Foster Care and Permanency	10,258	-	54	1	1	10,314
Low Income Home Energy Assistance	8,212	-	3	-	-	8,215
Refugee and Entrant Assistance	2,672	1	4,824	38	17	7,552
National Cancer Institute	4,046	-	1,967	653	109	6,775
National Institute of Allergy and Infectious Diseases	4,092	-	1,895	412	127	6,526
FDA Salaries and Expenses	321	1	2,409	3,083	665	6,479
Risk Adjustment Program Payments	-	6,341	-	-	-	6,341
CMS Program Management	98	-	5,351	763	102	6,314
Substance Abuse Treatment	5,172	-	99	5	1	5,277
Payments to States for Child Support Enforcement and Family Support Programs	3,715	-	910	-	-	4,625
Health Surveillance and Program Support	4,265	-	74	73	7	4,419
Aging and Disability Services Programs	4,040	-	58	32	4	4,134
National Institute on Aging	3,442	-	358	97	40	3,937
Vaccines for Children Program	133	-	87	24	3,562	3,806
National Heart, Lung, and Blood Institute	2,921	-	595	175	24	3,715
Child Care Entitlement to States	3,505	-	48	-	-	3,553
Mental Health	3,411	-	89	3	2	3,505
National Institute of General Medical Sciences	2,857	-	105	36	2	3,000
NIH Office of the Director	2,000	-	623	182	17	2,822
NIH Service and Supply Fund	-	-	1,941	337	362	2,640
National Institute of Neurological Disorders and Stroke	2,080	-	325	121	24	2,550
Ryan White HIV/AIDS Program	2,297	-	108	31	6	2,442
Health Care Fraud and Abuse Control Program	-	-	1,591	87	712	2,390
National Institute of Diabetes and Digestive and Kidney Diseases	1,841	-	264	140	22	2,267
National Institute of Mental Health	1,705	-	287	119	17	2,128
Other Agency Budgetary Accounts	21,366	780	10,332	5,525	2,797	40,800
Total Amounts Agreed to be Spent	**$ 1,183,517**	**$ 917,801**	**$ 121,657**	**$ 14,434**	**$ 118,468**	**$ 2,355,877**

Combined Schedule of Spending By Object Class

For the Year Ended September 30, 2020

(in Millions)

How was the Money Spent/Issued?	Grants, Subsidies, & Contributions	Insurance Claims & Indemnities	Other Contractual Services	Personnel Compensation & Benefits	Other	Total
Medicaid	$ 514,429	$ -	$ -	$ -	$ -	$ 514,429
Federal Supplementary Medical Insurance Trust Fund	-	416,066	125	1	2,287	418,479
Federal Hospital Insurance Trust Fund	-	403,401	13	-	979	404,393
Payments to Trust Funds	294,573	-	-	-	85,143	379,716
Public Health and Social Services Emergency Fund	12,434	-	125,518	226	7,046	145,224
Medicare Prescription Drug Account	-	91,901	-	1	1,506	93,408
Taxation on OASDI Benefits, HI	26,941	-	-	-	-	26,941
State Children's Health Insurance Fund	18,553	-	6	-	-	18,559
Temporary Assistance for Needy Families	16,622	-	83	13	1	16,719
Children and Families Services Programs	14,358	-	354	163	17	14,892
Payment to States for the Child Care and Development Block Grant	9,173	-	171	2	1	9,347
Payments for Foster Care and Permanency	9,206	-	39	-	1	9,246
Primary Healthcare	7,211	-	253	88	9	7,561
Indian Health Services	3,266	-	1,076	1,645	1,056	7,043
National Institute of Allergy and Infectious Diseases	4,042	-	2,113	385	133	6,673
National Cancer Institute	4,012	-	1,810	600	117	6,539
Risk Adjustment Program Payments	-	6,251	-	-	-	6,251
FDA Salaries and Expenses	318	1	2,314	2,826	707	6,166
CMS Program Management	32	-	5,045	732	156	5,965
Payments to States for Child Support Enforcement and Family Support Programs	4,009	-	983	-	-	4,992
Low Income Home Energy Assistance	4,639	-	3	-	-	4,642
CDC-Wide Activities and Program Support	2,834	-	1,401	144	206	4,585
Vaccines for Children Program	115	-	81	21	4,361	4,578
Substance Abuse Treatment	3,746	-	101	5	1	3,853
National Heart, Lung, and Blood Institute	2,954	-	559	165	31	3,709
National Institute on Aging	3,135	-	304	89	70	3,598
Aging and Disability Services Programs	3,399	-	57	30	4	3,490
Child Care Entitlement to States	2,933	-	33	-	-	2,966
National Institute of General Medical Sciences	2,805	-	110	33	-	2,948
NIH Office of the Director	1,933	-	609	149	10	2,701
Refugee and Entrant Assistance	2,350	1	319	23	3	2,696
Ryan White HIV/AIDS Program	2,377	-	94	30	3	2,504
NIH Service and Supply Fund	-	-	1,809	310	382	2,501
National Institute of Neurological Disorders and Stroke	1,989	-	346	105	34	2,474
National Institute of Diabetes and Digestive and Kidney Diseases	1,823	-	253	132	32	2,240
Healthcare Fraud and Abuse Control Program	-	-	1,477	89	661	2,227
National Institute of Mental Health	1,663	-	259	114	33	2,069
Other Agency Budgetary Accounts	23,245	691	10,378	5,352	2,896	42,562
Total Amounts Agreed to be Spent	**$ 1,001,119**	**$ 918,312**	**$ 158,096**	**$ 13,473**	**$ 107,886**	**$ 2,198,886**

Note 24. COVID-19 Activities (in Millions)

FY 2021	Budgetary Resources	Unobligated Balance	Obligations Incurred	Outlays
Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020				
CDC	$ 2,200	$ 293	$ 1,907	$ 1,374
FDA	61	3	58	28
HRSA	105	3	102	100
NIH	836	212	624	371
OS**	3,295	152	3,143	1,958
Total *Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020*	**$ 6,497**	**$ 663**	**$ 5,834**	**$ 3,831**
Families First Coronavirus Response Act				
ACL	$ 250	$ -	$ 250	$ 234
IHS	64	4	60	56
OS**	1,000	2	998	973
Total *Families First Coronavirus Response Act*	**$ 1,314**	**$ 6**	**$ 1,308**	**$ 1,263**
Coronavirus Aid, Relief, and Economic Security Act				
ACF	$ 6,274	$ 25	$ 6,249	$ 4,843
ACL	955	-	955	769
CDC	4,313	897	3,416	1,423
CMS	200	57	143	82
FDA	80	54	26	13
HRSA	1,595	4	1,591	1,477
IHS	1,032	9	1,023	866
NIH	945	353	592	260
OS**	126,725*	4,081	122,644	110,856
SAMHSA	425	6	419	209
Total *Coronavirus Aid, Relief, and Economic Security Act*	**$ 142,544**	**$ 5,486**	**$ 137,058**	**$ 120,798**
Paycheck Protection Program and Health Care Enhancement Act				
CDC	$ 456	$ 23	$ 433	$ 269
FDA	22	19	3	3
HRSA	600	2	598	527
NIH	1,033	9	1,024	671
OS**	97,889	35,363	62,526	50,166
Total *Paycheck Protection Program and Health Care Enhancement Act*	**$ 100,000**	**$ 35,416**	**$ 64,584**	**$ 51,636**

*The HHS budgetary resources amount is reduced by $289 million in *Coronavirus Aid, Relief, and Economic Security Act* funds transferred to the Department of Homeland Security.

**OS received COVID-19 funding through the PHSSEF.

FY 2021	Budgetary Resources	Unobligated Balance	Obligations Incurred	Outlays
Coronavirus Response and Relief Supplemental Appropriations Act, 2021				
ACF	$ 12,163	$ 349	$ 11,814	$ 4,832
ACL	275	-	275	47
CDC	8,540	2,485	6,055	1,076
FDA	55	30	25	4
IHS	1,000	434	566	491
NIH	187	60	127	11
OS**	46,705	10,125	36,580	7,358
SAMHSA	4,250	4	4,246	146
Total *Coronavirus Response and Relief Supplemental Appropriations Act, 2021*	**$ 73,175**	**$ 13,487**	**$ 59,688**	**$ 13,965**
American Rescue Plan Act of 2021				
ACF	$ 46,820	$ 308	$ 46,512	$ 2,106
ACL	1,720	205	1,515	10
CDC	11,520	4,361	7,159	485
CMS	735	700	35	-
FDA	500	361	139	19
HRSA	9,430	1,417	8,013	736
IHS	6,094	2,664	3,430	3,249
OS**	80,115	54,195	25,920	5,074
SAMHSA	3,560	617	2,943	3
Total *American Rescue Plan Act of 2021*	**$ 160,494**	**$ 64,828**	**$ 95,666**	**$ 11,682**
Total COVID-19	**$ 484,024**	**$ 119,886**	**$ 364,138**	**$ 203,175**

**OS received COVID-19 funding through the PHSSEF.

FY 2020	Budgetary Resources	Unobligated Balance	Obligations Incurred	Outlays
Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020				
CDC	$ 2,200	$ 392	$ 1,808	$ 604
FDA	61	28	33	7
HRSA	100	-	100	79
NIH	836	320	516	109
OS**	3,300*	513	2,787	593
Total *Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020*	**$ 6,497**	**$ 1,253**	**$ 5,244**	**$ 1,392**
Families First Coronavirus Response Act				
ACL	$ 250	$ -	$ 250	$ 172
IHS	64	11	53	48
OS**	1,000	500	500	499
Total *Families First Coronavirus Response Act*	**$ 1,314**	**$ 511**	**$ 803**	**$ 719**
Coronavirus Aid, Relief, and Economic Security Act				
ACF	$ 6,274	$ 76	$ 6,198	$ 2,068
ACL	955	-	955	277
CDC	4,313	2,403	1,910	222
CMS	200	116	84	12
FDA	80	71	9	3
HRSA	1,595	3	1,592	684
IHS	1,032	372	660	592
NIH	945	631	314	16
OS**	126,725*	76,947	49,778	29,921
SAMHSA	425	2	423	18
Total *Coronavirus Aid, Relief, and Economic Security Act*	**$ 142,544**	**$ 80,621**	**$ 61,923**	**$ 33,813**
Paycheck Protection Program and Health Care Enhancement Act				
CDC	$ 1,000	$ 751	$ 249	$ 157
FDA	22	22	-	-
HRSA	600	1	599	133
NIH	1,806	1,101	705	129
OS**	96,572	7,962	88,610	77,114
Total *Paycheck Protection Program and Health Care Enhancement Act*	**$ 100,000**	**$ 9,837**	**$ 90,163**	**$ 77,533**
Total COVID-19	**$ 250,355**	**$ 92,222**	**$ 158,133**	**$ 113,457**

*The HHS budgetary resources amounts include $300 million in *Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020* funds precluded from obligation and is reduced by $289 million in *Coronavirus Aid, Relief, and Economic Security Act* funds transferred to the Department of Homeland Security.

**OS received COVID-19 funding through the PHSSEF.

The *Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020* provides funding for HHS to reimburse costs incurred for COVID-19 preparedness and response activities. Funds could be used for contract support services to support the prevention of, preparation for, or response to COVID-19. HHS received $6.5 billion to support programs including: BARDA; SNS; grants for state, local, and tribal governments; Institute of Allergy and Infectious Diseases; and Institute of Environmental Health Sciences.

The *Families First Coronavirus Response Act* provides funding for paid leave, free COVID-19 testing, unemployment benefits, food assistance for vulnerable children and families, and states for economic consequences due to the pandemic. HHS received $1.3 billion primarily for the PHSSEF, with $1.0 billion for provider reimbursement.

The CARES Act provides emergency assistance and healthcare for individuals, families, and businesses impacted by COVID-19. HHS received $142.5 billion primarily for the PHSSEF, which received $126.7 billion. Through the PHSSEF, the Provider Relief Fund received $100.0 billion to prevent, prepare for, and respond to COVID-19 domestically and internationally. The Provider Relief Fund provides payments to assist eligible healthcare providers for healthcare related expenses or lost revenues attributed to the COVID-19 pandemic. Additionally, BARDA received funding to advance research, development, manufacturing, production, purchases, and other activities related to COVID-19 testing.

The *Paycheck Protection Program and Health Care Enhancement Act* provides additional funding to key programs under the CARES Act, including the Paycheck Protection Program, loans and grants to small businesses, health care providers and hospitals, and COVID-19 testing. HHS received $100.0 billion for the PHSSEF, including $75.0 billion for the Provider Relief Fund, and the remaining $25.0 billion to provide relief to state, local, and tribal governments and other COVID-19 response activities.

The *Coronavirus Response and Relief Supplemental Appropriations Act, 2021* provides funding to support a three-month extension of sequester relief from existing provider relief funds, reduce anticipated cuts to physician payments, and improve rural facility reimbursements. HHS received $73.2 billion which includes $63.2 billion ($46.7 billion for the PHSSEF) to carry out these activities and $10.0 billion for the Child Care and Development Block Grants to provide childcare providers additional financial support during the COVID-19 public health crisis.

The *American Rescue Plan Act of 2021* provides relief funding to workers and families for nationwide testing sites and community vaccination sites as well as addressing disparities in obtaining quality healthcare. HHS received $160.5 billion, of which $80.1 billion was for PHSSEF ($47.8 billion was for testing, contact tracing, and mitigation activities). In addition, the Child Care Stabilization and Development Block Grants received $38.9 billion to help working parents by providing childcare subsidies and increasing childcare options.

Refer to the following notes for additional information on COVID-19 activities: Summary of Significant Accounting Policies (Note 1), Entity and Non-Entity Assets (Note 2), Fund Balance with Treasury (Note 3), Inventory and Related Property, Net (Note 6), Advances (Note 8), Liabilities Not Covered by Budgetary Resources (Note 9), Debt (Note 10), Undelivered Orders (Note 19), and Combined Schedule of Spending (Note 23).

Note 25. Reclassification of Statement of Net Cost and Statement of Changes in Net Position for FR Compilation Process

Reclassification of Statement of Net Cost to Line Items Used for the Government-wide Statement of Net Cost For the Year Ending September 30, 2021 (in Millions)							
FY 2021 HHS Statement of Net Cost		Line Items Used to Prepare FY 2021 Government-wide Statement of Net Cost					
Financial Statement Line	Amounts	Dedicated Collections Combined	Dedicated Collections Eliminations	All Other Amounts (with Eliminations)	Eliminations Between Dedicated and All Other	Total	Reclassified Financial Statement Line
		$ 867,639	**$ -**	**$ 749,665**	**$ -**	**$ 1,617,304**	***Non-Federal Costs***
							Intragovernmental Costs
		384	-	1,811	-	2,195	*Benefit Program Costs*
		106	(18)	526	-	614	*Imputed Costs*
		2,489	(1,226)	24,425	-	25,688	*Buy/Sell Costs*
		-	-	14	-	14	*Purchase of Assets*
		-	-	11	-	11	*Borrowing and Other Interest Expense*
		121	-	552	-	673	*Other Expenses (w/o Reciprocals)*
		$ 3,100	**$ (1,244)**	**$ 27,339**	**$ -**	**$ 29,195**	**Total Intragovernmental Costs**
CMS: Gross Cost	$ 1,404,879						
Other Segments Gross Costs of Operations before Actuarial Gains and Losses	241,606						
Total Gross Costs	**$ 1,646,485**	**$ 870,739**	**$ (1,244)**	**$ 777,004**	**$ -**	**$ 1,646,499**	***Total Reclassified Gross Costs***
		$ (135,901)	**$ -**	**$ (1,847)**	**$ -**	**$ (137,748)**	**Non-Federal Earned Revenue**
							Intragovernmental Earned Revenue
		(1,233)	1,227	(799)	-	(805)	*Buy/Sell Revenue*
		-	-	(14)	-	(14)	*Purchase of Assets Offset*
		$ (1,233)	**$ 1,227**	**$ (813)**	**$ -**	**$ (819)**	**Total Intragovernmental Earned Revenue**
CMS: Exchange Revenue	$ (132,908)						
Other Segments: Exchange Revenue	(5,686)						
Total Exchange Revenue	**$ (138,594)**	**$ (137,134)**	**$ 1,227**	**$ (2,660)**	**$ -**	**$ (138,567)**	***Total Reclassified Earned Revenue***
Actuarial (Gains) and Losses Commissioned Corp Retirement and Medical Plan Assumption Changes	665	-	-	665	-	665	Gain/Loss on Changes in Actuarial Assumptions (Non-Federal)
Net Cost	**$ 1,508,556**	**$ 733,605**	**$ (17)**	**$ 775,009**	**$ -**	**$ 1,508,597**	**Net Cost**

*Subtotals and totals may not equal due to rounding.

Reclassification of Statement of Changes in Net Position to Line Items Used for Government-wide Statement of Operations and Changes in Net Position For the Year Ending September 30, 2021 (in Millions)						
FY 2021 HHS Statement of Change in Net Position		Line Items Used to Prepare FY 2021 Government-wide Statement of Changes in Net Position				
Financial Statement Line	Amounts	Dedicated Collections Combined	Dedicated Collections Eliminations	All Other Amounts (with Eliminations)	Total	Reclassified Financial Statement Line
UNEXPENDED APPROPRIATIONS						
Unexpended Appropriations, Beginning Balance	$ 431,257	$ 98,117	$ -	$ 333,139	$ 431,256	Net Position, Beginning of Period
Appropriations Received	1,513,272	502,345	-	1,010,928	1,513,273	Appropriations Received
		-	-	15	15	*Non-Expenditure Transfers-In of Unexpended Appropriations and Financing Sources (Federal)*
		-	-	6	6	*Non-Expenditure Transfers-Out of Unexpended*
Appropriations Transferred In/Out	26	-	-	21	21	Total Reclassified Appropriations Transferred In/Out
Appropriations Used	(1,217,320)	(441,564)	-	(775,756)	(1,217,320)	Appropriations Used
Other Adjustments	(112,039)	(23,955)	-	(88,084)	(112,039)	Appropriations Received as Adjusted
Total Unexpended Appropriations	**$ 615,196**	**$ 134,943**	**$ -**	**$ 480,248**	**$ 615,191**	**Total Unexpended Appropriations**
CUMULATIVE RESULTS OF OPERATIONS						
Cumulative Results, Beginning Balance	$ 288,505	$ 285,692	$ -	$ 2,814	$ 288,506	Net Position, Beginning of Period
		-	-	(342)	(342)	*Collections for Others Transferred to the General Fund of the U.S. Government*
		(1)	-	(4)	(5)	*Revenue and Other Financing Sources – Cancellations*
Other Adjustments	(348)	(1)	-	(347)	(348)	Total Other Adjustments
Appropriations Used	1,217,320	441,564	-	775,756	1,217,320	Appropriations Used
Nonexchange Revenue – Tax Revenue	299,147	301,937	-	313	302,250	Other Taxes and Receipts
Nonexchange Revenue – Investment Revenue	4,969	4,904	-	65	4,969	Federal Securities Interest Revenue, including Associated Gains/Losses (Non-Exchange)
		1,229	-	-	1,229	*Collections Transferred into a TAS Other Than the General Fund of the U.S. Government*
		(789)	-	-	(789)	*Other Taxes and Receipts*
Nonexchange Revenue – Other	3,543	440	-	-	440	Total Other Taxes and Receipts
Donations and Forfeitures of Cash and Cash Equivalents	71	71	-	-	71	Other Taxes and Receipts
		446,518	(445,883)	238	873	*Expenditure Transfers-In of Financing Sources*
		(451,302)	445,883	2,104	(3,315)	*Expenditure Transfers-Out of Financing Sources*
		875,744	(875,744)	-	-	*Nonexpenditure Transfers-In of Unexpended Appropriations and Financing Sources*
		(857,762)	875,744	18	-	*Nonexpenditure Transfers-Out of Unexpended Appropriations and Financing Sources*
		5	(5)	-	-	*Transfers-in without reimbursement*
		(5)	5	-	-	*Transfers-out without reimbursement*
Transfers-In/Out Without Reimbursement (+/-) – Budgetary	(2,443)	(4,802)	-	2,360	(2,442)	Total Reclassified Transfers-In/Out w/o Reimbursement – Budgetary

Note: Table continued on the next page.

*Subtotals and totals may not equal due to rounding.

Reclassification of Statement of Changes in Net Position to Line Items Used for Government-wide Statement of Operations and Changes in Net Position For the Year Ending September 30, 2021 (in Millions)						
FY 2021 HHS Statement of Change in Net Position		Line Items Used to Prepare FY 2021 Government-wide Statement of Changes in Net Position				
Financial Statement Line	Amounts	Dedicated Collections Combined	Dedicated Collections Eliminations	All Other Amounts (with Eliminations)	Total	Reclassified Financial Statement Line
Donations and Forfeitures of Property	$ 8	$ -	$ -	$ 8	$ 8	Other Taxes and Receipts
Imputed Financing	613	106	(17)	525	614	Imputed Financing Sources
		-	-	-	-	*Other Taxes and Receipts*
		-	-	(1,935)	(1,935)	Non-Entity Collections transferred to the General Fund
		1	-	396	397	*Accrual for Non-Entity Amounts to be Collected and Transferred to the General Fund*
		21	-	1,479	1,500	*Other*
Other (+/-)	(63)	22	-	(60)	(38)	*Total Other*
Total Financing Sources	**$ 1,522,817**	**$ 744,241**	**$ (17)**	**$ 778,620**	**$ 1,522,844**	**Total Financing Sources**
Net Cost of Operations	**$ 1,508,556**	**$ 733,605**	**$ (17)**	**$ 775,009**	**$ 1,508,597**	**Net Cost of Operations**
Ending Balance – Cumulative Results of Operations	**$ 302,766**	**$ 296,328**	**$ -**	**$ 6,425**	**$ 302,753**	**Total Cumulative Results of Operations**
Total Net Position	**$ 917,962**	**$ 431,271**	**$ -**	**$ 486,673**	**$ 917,944**	**Total Net Position**

*Subtotals and totals may not equal due to rounding.

To prepare the Financial Report of the U.S. Government (FR), Treasury requires agencies to submit an adjusted trial balance, which is a listing of amounts by U.S. Standard General Ledger account that appears in the financial statements. Treasury uses the trial balance information reported in Governmentwide Treasury Account Symbol Adjusted Trial Balance System (GTAS) to develop a Reclassified Balance Sheet, Reclassified Statement of Net Cost, and a Reclassified Statement of Changes in Net Position for each agency, which are accessed using GTAS. Treasury eliminates all intragovernmental balances from the reclassified statements and aggregates lines with the same title to develop the FR statements. This note shows the HHS financial statements and the HHS reclassified statements prior to elimination of intragovernmental balances and prior to aggregation of repeated FR line items. A copy of the 2020 FR can be found at Fiscal Service's website and the 2021 FR will be posted to the site as soon as it is released.

The Statement of Net Cost and Statement of Changes in Net Position have immaterial differences primarily due to the presentations between HHS's financial statements and the reclassified financial statements. There is a difference of $41 million for the Statements of Net Cost and $18 million for the Statement of Changes in Net Position due to custodial activities. The remainder of the differences are due to rounding.

Note 26. 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 *2021 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. Beginning in 2020, the Medicare program was dramatically affected by the COVID-19 pandemic, however, given the uncertainty of the impacts at the time the Trustees Report was released, the pandemic was not factored into the SOSI projections until 2021. The amount of payroll taxes expected to be collected by the HI trust fund was greatly reduced due to the economic effects of the pandemic on labor markets. Spending was directly affected by the coverage of testing and treatment of the disease. In addition, several regulatory policies and legislative provisions were enacted during the public health emergency that increased spending. More than offsetting these additional costs in 2020, spending for non-COVID care declined significantly (compared to both actual 2019 spending and expectations for 2020 spending in last year's Trustees Report). This decline was particularly true for elective services.

While the COVID-19 pandemic has significantly affected Medicare short-term financing and spending, it is not expected to have a large effect on the financial status of the trust funds after 2024. As discussed throughout the Trustees Report, the key measures of the financial adequacy for each trust fund are fairly comparable to those included in last year's report.

The Medicare Accelerated and Advance Payments (AAP) program was significantly expanded during the COVID-19 public health emergency period. Total payments of approximately $107.1 billion were made: roughly $67.1 billion from the HI trust fund and $40.0 billion from the SMI Part B trust fund account. The Trustees assume that the accelerated and advance payments will be fully repaid by September of 2022, resulting in no net changes to trust fund expenditures.

It should be noted that there is an unusually large degree of uncertainty with these COVID-related impacts and that future projections could change significantly as more information becomes available. The pandemic is an example of the inherent uncertainty in projecting healthcare financing and spending over any duration.

In addition, the projections and analysis do not reflect the potential effects of Medicare coverage of Aduhelm, the Alzheimer's disease drug that has been recently approved by the Food and Drug Administration. Given the uncertainty associated with these impacts, the Trustees believe that it is not possible to adjust the estimates accurately before a coverage determination is made.

Furthermore, 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 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 healthcare 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. The estimates presented here are based on the assumption that the trust funds will continue to operate under the law in effect on August 31, 2021, excluding the impact of Medicare coverage of Aduhelm and disregarding the payment reductions that would result from the projected depletion of the Medicare HI 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 healthcare 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 2021 SOSI actuarial projections are drawn from the Social Security and Medicare Trustees Reports for 2021. 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.[8]

Table 1: Significant Assumptions and Summary Measures Used for the Statement of Social Insurance 2021

					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[11]
2021	1.54	680,000	908.3	3.16	6.22	3.06	4.4	8.2[9]	13.1[9]	-0.2[10]	-2.0
2030	1.87	1,339,000	741.5	1.21	3.61	2.40	2.0	3.6	5.0	4.3	2.2
2040	1.98	1,288,000	683.0	1.19	3.59	2.40	1.9	4.2	4.5	4.1	2.3
2050	2.00	1,256,000	630.3	1.12	3.52	2.40	2.0	3.4	3.8	4.3	2.3
2060	2.00	1,240,000	583.7	1.16	3.56	2.40	2.0	3.3	3.8	4.2	2.3
2070	2.00	1,229,000	542.3	1.16	3.56	2.40	1.9	3.4	3.5	4.0	2.3
2080	2.00	1,222,000	505.5	1.13	3.53	2.40	2.0	3.5	3.7	4.1	2.3
2090	2.00	1,218,000	472.7	1.14	3.54	2.40	2.1	3.4	3.7	4.2	2.3

[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). These assumptions include changes in the payment rates, utilization, and intensity of each type of service.

[9] Reflects the assumed return of healthcare services that were reduced or deferred in 2020 due to the COVID-19 pandemic.

[10] Part D cost growth is projected to be negative in 2021 mainly due to higher assumed direct and indirect remuneration.

[11] Average rate of interest earned on new trust fund securities, above and beyond rate of inflation.

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

[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 2: Significant Ultimate Assumptions Used for the Statement of Social Insurance FY 2021-2017

					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]
2021	2.0	1,218,000	472.7	1.14	3.54	2.40	2.1	3.4	3.7	4.2	2.3
2020	1.95	1,218,000	460.5	1.13	3.53	2.40	2.0	3.3	3.6	4.1	2.3
2019	2.0	1,218,000	453.5	1.16	3.76	2.60	2.0	3.5	3.6	4.3	2.5
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

[1]Average number of children per woman. The ultimate fertility rate is assumed to be reached in 2056, later than last year due to using a cohort-based approach rather than the period-based used in the 2020 and prior Trustees Reports resulting in a much longer transition to ultimate birth rates from the current low birth rates.

[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 2090.

[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 2090.

[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 2090.

[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 2090.

[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 2090.

[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 2090.

[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 27. 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.

Certain features of current law may result in some challenges for the Medicare program. Physician payment update amounts are specified 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. Payment rate

updates for most non-physician categories of Medicare providers are reduced by the growth in economy-wide private nonfarm business multifactor productivity although these health providers have historically achieved lower levels of productivity growth. 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 healthcare 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 Trustees previously 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 and will be about 30 percent lower by the end of the projection period. Absent a change in the delivery system or level of update by subsequent legislation, the Trustees expect access to Medicare-participating physicians to become a significant issue in the long term. 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 2028–2042. 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 qualified physicians in advanced alternative payment 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.

Table 3 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.

Table 3: Medicare Present Values

(in Billions)

	Current law (Unaudited)	Alternative scenario[1, 2] (Unaudited)
Income		
Part A	$ 26,710	$ 26,779
Part B	50,013	56,228
Part D	10,863	10,863
Expenditures		
Part A	31,767	37,317
Part B	50,013	56,228
Part D	10,863	10,863
Income less expenditures		
Part A	(5,057)	(10,538)
Part B	-	-
Part D	-	-

[1]These amounts are not presented in the 2021 Trustees Report.

[2]A set of illustrative alternative Medicare projections has been prepared under a hypothetical modification to 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 1.0-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 qualified physicians in advanced APMs did not expire, as illustrated under the alternative scenario, the estimated present values of Part A would be higher than the current-law projections by roughly 17 percent and Part B expenditures would be higher than the current-law projections by roughly 12 percent. As indicated above, the present value of Part A income is basically unaffected under the alternative scenario, and the present value of Part B income is 12 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 28. Statement of Changes in Social Insurance Amounts (Unaudited)

The Statement of Changes in Social Insurance Amounts (SCSIA) 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, 2020 to the period beginning on January 1, 2021, and the reconciliation from the period beginning on January 1, 2019 to the period beginning on January 1, 2020. The reconciliation identifies several significant components of the change and provides reasons for the change.

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, 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 SCSIA are, in order, as follows:

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

All estimates in the SCSIA 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 SCSIA are for the current and prior years 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 26 summarizes these assumptions for the current year.

Period beginning on January 1, 2020 and ending January 1, 2021

Present values as of January 1, 2020 are calculated using interest rates from the intermediate assumptions of the 2020 Trustees Report. All other present values in this part of the Statement are calculated as present values as of January 1, 2021. 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 2020 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 healthcare assumptions are calculated using the interest rates under the intermediate assumptions of the 2021 Trustees Report.

Period beginning on January 1, 2019 and ending January 1, 2020

Present values as of January 1, 2019 are calculated using interest rates from the intermediate assumptions of the 2019 Trustees Report. All other present values in this part of the Statement are calculated as present values as of January 1, 2020. 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 2019 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 healthcare assumptions are calculated using the interest rates under the intermediate assumptions of the 2020 Trustees Report.

Change in the Valuation Period

From the period beginning on January 1, 2020 to the period beginning on January 1, 2021

The effect on the 75-year present values of changing the valuation period from the prior valuation period (2020-94) to the current valuation period (2021-95) 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 2020, replaces it with a much larger negative net cash flow for 2095, and measures the present values as of January 1, 2021, 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 (was made more negative) when the 75-year valuation period changed from 2020-94 to 2021-95. In addition, the effect on the level of assets in the combined Medicare Trust Funds of changing the valuation period is measured by assuming that all values projected in the prior valuation for the year 2020 are realized. The change in valuation period resulted in a slight increase in the starting level of assets in the combined Medicare Trust Funds. Accordingly, the present value of the estimated future net cash flow, including combined trust fund assets, decreased by $160 billion.

From the period beginning on January 1, 2019 to the period beginning on January 1, 2020

The effect on the 75-year present values of changing the valuation period from the prior valuation period (2019-93) to the current valuation period (2020-94) 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 2019, replaces it with a much larger negative net cash flow for 2094, and measures the present values as of January 1, 2020, 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 (was made more negative) when the 75-year valuation period changed from 2019-93 to 2020-94. In addition, the effect on the level of assets in the combined Medicare Trust Funds of changing the valuation period is measured by assuming that all values projected in the prior valuation for the year 2019 are realized. The change in valuation period resulted in a slight decrease in the starting level of assets in the combined Medicare Trust Funds. Accordingly, the present value of the estimated future net cash flow, including combined trust fund assets, decreased by $238 billion.

Change in Projection Base

From the period beginning on January 1, 2020 to the period beginning on January 1, 2021

Actual income and expenditures in 2020 were different from what was anticipated when the 2020 Trustees Report projections were prepared. For Part A and Part B income and expenditures in 2020 were lower than anticipated based on actual experience, mainly due to the impact of the COVID-19 pandemic. Part D was largely unaffected by the pandemic and total income and expenditures were only slightly higher than estimated based on actual experience. The net impact of the Part A, B, and D projection base changes is an increase of $237 billion in the present value of the estimated future net cash flow, including combined trust fund assets. Actual experience of the Medicare Trust Funds between January 1, 2020 and January 1, 2021 is incorporated in the current valuation and is more than projected in the prior valuation. In section III.B3 of the 2021 Trustees Report, the base change represented the impact of the change in the 2019 experience rather than the 2020 experience. This was done to

accurately quantify the full impact of the COVID-19 pandemic by attributing much of the reduction in 2020 income and expenditures to it. For purposes of the SCSIA, we have reflected the impact of the change in the 2020 experience to the projection base change in order to be consistent with prior reporting.

From the period beginning on January 1, 2019 to the period beginning on January 1, 2020

Actual income and expenditures in 2019 were different from what was anticipated when the 2019 Trustees Report projections were prepared. Part A income and expenditures in 2019 were lower than anticipated based on actual experience. For both Part B and Part D, total income and expenditures were higher than estimated based on actual experience. The net impact of the Part A, B, and D projection base changes is an increase of $401 billion in the present value of the estimated future net cash flow, including combined trust fund assets. Actual experience of the Medicare Trust Funds between January 1, 2019 and January 1, 2020 is incorporated in the current valuation and is more than projected in the prior valuation.

Changes in the Demographic Assumptions

From the period beginning on January 1, 2020 to the period beginning on January 1, 2021

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).

For the current valuation (beginning on January 1, 2021), there were two changes to the ultimate demographic assumptions and an associated change in methodology.

- The ultimate total fertility rate was increased from 1.95 to 2.00 children per woman. At the same time, the projection method was improved to project future birth rates using a cohort-based model, rather than a period-based model as used in the prior valuation.
- An additional cause of death category was added, by separating dementia out from the all-other-causes category, and ultimate mortality improvement rates were updated for cardiovascular disease for all age groups and for the all-other-causes category at ages 85 and over.

In addition to these changes in ultimate demographic assumptions and the associated methodology change, the starting demographic values and the way these values transition to the ultimate assumptions were changed. The most significant are identified below.

- Birth rate data through the third quarter of 2020 indicated somewhat lower birth rates than were assumed in the prior valuation.
- Death rates were increased significantly for 2020 and 2021, and to a lesser extent for 2022 and 2023, to account for the elevated deaths during the COVID-19 pandemic period.

These changes resulted in an increase in the estimated future net cash flow. The present values of estimated income and expenditures are lower for Parts A, Part B, and Part D. Overall, these changes increased the present value of the estimated future net cash flow by $700 billion.

From the period beginning on January 1, 2019 to the period beginning on January 1, 2020

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.

For the current valuation (beginning on January 1, 2020), there were two changes to the ultimate demographic assumptions.

- The ultimate total fertility rate was lowered from 2.00 to 1.95 children per woman, reflecting a continued decline in fertility rates since 2007.
- The ultimate disability incidence rate was lowered from 5.2 per thousand exposed in the prior valuation to 5.0 in the current valuation. In addition, near-term assumed disability incidence rates, in the period of transition from recent historical values to the ultimate rates, are somewhat lower in the current valuation than in the prior valuation.

In addition to these ultimate demographic assumption changes, the starting demographic values and the way these values transition to the ultimate assumptions were changed.

- Final birth rate data for 2018 and the first quarter of 2019 indicated somewhat lower birth rates than were assumed in the prior valuation.
- Incorporating 2017 mortality data obtained from the National Center for Health Statistics (NCHS) for ages under 65 in addition to final 2016, preliminary 2017, and preliminary 2018 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.
- The latest valuation included the impact of time to death on Medicare expenditures. Previously, the valuation included only the impact of age and sex on the expenditures.

These changes, especially the time to death assumption lowered Medicare expenditures for the current valuation period, particularly for Part A, and resulted in a large increase in the estimated future net cash flow. The present values of estimated income and expenditures are lower for Parts A, Part B, and Part D. Overall, these changes increased the present value of the estimated future net cash flow by $2,687 billion.

Changes in Economic and Healthcare Assumptions

For the period beginning on January 1, 2020 to the period beginning on January 1, 2021

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, 2021), there were two changes to the ultimate economic assumptions and an associated change in methodology.

- The ultimate average real wage differential was slightly increased from 1.14 percentage points in the prior valuation to 1.15 percentage points in the current valuation. Additionally, the real wage differential assumptions for the first ten years of the projection period were also increased.
- The ultimate age-sex-adjusted unemployment rate was reduced from 5.0 percent for the prior valuation to 4.5 percent in the current valuation. At the same time, the labor force participation model was updated to incorporate data from the latest complete economic cycle, thereby putting more weight on the recent relationships among the various factors affecting labor force participation.

In addition to these changes in ultimate economic assumptions and the associated change methodology change, the starting economic values and the way these values transition to the ultimate assumptions were changed. The most significant are identified below.

- Near-term real interest rates were adjusted downward significantly. Real interest rates are now assumed to be negative for calendar years 2021 through 2024, with a gradual rise to the ultimate real interest rate after the economy has fully recovered from the recession.
- There were several changes in starting values and near-term economic growth assumptions primarily related to the COVID-19 pandemic and ensuing recession. In particular, the level of potential GDP is assumed to be roughly 1 percent lower than the level in the prior valuation beginning with the second quarter of 2020.

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

- Slightly faster projected spending growth for outpatient hospital services and for physician-administered drugs.
- Higher direct and indirect remuneration (DIR) and the continuing enrollment shift from Prescription Drug Plans to Medicare Advantage Prescription Drug Plans, which more than offset the higher gross drug prices assumed in this year's report.

The net impact of these changes was a decrease in the estimated future net cash flow for total Medicare. For Part A and Part B, these changes increased the present value of estimated future income and expenditures. For Part D, these changes resulted in a decrease in the present value of estimated expenditures (and income). Overall, these changes decreased the present value of the estimated future net cash flow by $959 billion.

For the period beginning on January 1, 2019 to the period beginning on January 1, 2020

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, 2020), there were four changes to the ultimate economic assumptions.

- The ultimate rate of price inflation (CPI-W) was lowered by 0.2 percentage point, from 2.6 percent in the prior valuation to 2.4 percent in the current valuation.
- The ultimate average real-wage differential was decreased from 1.21 percentage points in the prior valuation to 1.14 percentage points in the current valuation. Most of this decrease is due to the repeal of the *Affordable Care Act* (ACA) excise tax, the effect of which is accounted for in the "Changes in Law or Policy" section. However, a small portion is due to faster assumed growth in employer-sponsored group health insurance premiums separate from this repeal.
- The ultimate age-sex-adjusted unemployment rate was reduced from 5.5 percent for the prior valuation to 5.0 percent in the current valuation. At the same time, long-term labor force participation rates were reduced by age and sex for the current valuation, such that projected employment rates remained essentially unchanged from the prior valuation to the current valuation.
- The ultimate real interest rate was lowered by 0.2 percentage point, from 2.5 percent in the prior valuation to 2.3 percent in the current valuation.

In addition to these changes in ultimate assumptions, the starting economic values and the way these values transition to the ultimate assumptions were changed. The most notable change was to include a 0.7 percent decrease in the estimated level of potential GDP for the fourth quarter of 2019 and thereafter. This and other smaller changes in starting values and near-term growth assumptions combined to decrease the present value of estimated future net cash flows.

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

- Higher projected spending growth for Medicare Advantage beneficiaries.
- Faster projected spending growth for Part B drugs.
- Slower overall drug price increases and higher direct and indirect remuneration.

The net impact of these changes was a decrease in the estimated future net cash flow for total Medicare. For Part A and Part B, these changes increased the present value of estimated future income and expenditures. For Part D, these changes resulted in a decrease in the present value of estimated expenditures (and income). Overall, these changes decreased the present value of the estimated future net cash flow by $1,715 billion.

Changes in Law

For the period beginning on January 1, 2020 to the period beginning on January 1, 2021

Several pieces of legislation were enacted since the prior valuation date, however, most of the provisions had little or no impact on the program. Further, the impact of certain provisions is unknown and still others that in practice had no actual impact because they would have occurred anyway. The following provisions reflect those that had a significant financial impact on the present value of the 75-year estimated future income, expenditures, and net cash flow. See section V.A of the 2021 Medicare Trustees Report for the complete list of enacted provisions.

- The CARES Act (Public Law 116-136, enacted on March 27, 2020) included provisions that affect the HI and SMI programs.
  - From May 1, 2020 through December 31, 2020, the Medicare program is exempted from the sequestration process that is in place should Congress fail to address the budget deficit by certain deadlines. In addition, the sequestration process is extended by 1 year, through fiscal year 2030. The benefit payment reductions of 4.0 percent for the first 6 months and 0.0 percent for the second 6 months that were ordered for fiscal year 2029 are now ordered instead for fiscal year 2030, while the reductions ordered for fiscal year 2029 are changed to a uniform 2.0 percent. (The sequestration order for a given fiscal year is applied to expenditures incurred from April 1 of that fiscal year through March 31 of the following fiscal year.)
  - The AAP Program is significantly expanded during the COVID-19 public health emergency period. First, critical access, pediatric, and certain cancer hospitals are added to the list of eligible providers and suppliers. (The usual eligibility criteria—to have billed Medicare during the last 180 days, to not be in bankruptcy, to not be under review or investigation, and to not have any outstanding delinquent Medicare overpayments—will still apply.) Next, the maximum amounts available under the AAP program are increased during the emergency period to (i) 100 percent of Medicare payments made during the past 6 months—for inpatient acute care, pediatric, and certain cancer hospitals; (ii) 125 percent of Medicare payments made during the past 6 months—for critical access hospitals; and (iii) 100 percent of Medicare payments made during the past 3 months—for all other eligible entities. (The maximum available AAP amounts had been 70 percent and 80 percent for providers and suppliers, respectively, of Medicare payments made during the past 90 days.) In addition, recoupments begin 120 days after the accelerated or advance payment is issued, and repayment is due in full within 1 year. (Normally, recoupments begin shortly after the payment is issued, and repayment is due in full within 90 days.)
- The *Continuing Appropriations Act, 2021 and Other Extensions Act* (Public Law 116-159, enacted on October 1, 2020) included provisions that affect the HI and SMI programs.

  - For providers and suppliers who receive accelerated or advance payments under the AAP program during the COVID-19 public health emergency, the repayment terms are amended from those provided by, and discussed previously under, the CARES Act. Specifically, recoupments are not to begin until 1 year has passed since the payment was issued, after which recoupments are to be 25 percent of the AAP amount over the first 11 months and 50 percent over the following 6 months. After that 29-month period has elapsed, the remaining balance will be due within 30 days. If not repaid, interest will accrue for each full 30-day period that the balance remains unpaid, but at an interest rate of 4 percent (instead of 10.25 percent). In addition, a $10 million limit on advance payments to Part B suppliers is established for the period from October 1, 2020 (the date of enactment) through December 31, 2020 and for each subsequent calendar year in which there is a COVID-19 public health emergency during all or part of the year.
- The *Consolidated Appropriations Act, 2021* (Public Law 116-260, enacted on December 27, 2020) included provisions that affect the HI and SMI programs.
  - The CARES Act provision described above that temporarily exempts the Medicare program from sequestration beginning May 1, 2020 is extended through March 31, 2021 (from December 31, 2020).
- *An Act to Prevent Across-the-Board Direct Spending Cuts, and for Other Purposes* (Public Law 117-7, enacted on April 14, 2021) included provisions that affect the HI and SMI programs.
  - The temporary exemption from sequestration for the Medicare program from May 1, 2020 to March 31, 2021 (as described previously under Public Laws 116-136 and 116-260) is extended through December 31, 2021. (This exemption extension applied retroactively as well, beginning April 1, 2021.) In addition, the sequestration amounts ordered for fiscal year 2030 are to be increased overall, with benefit payment reductions of 2.0 percent for the first 5.5 months, 4.0 percent for the next 6 months, and 0.0 percent for the final 0.5 months (instead of 4.0 percent for the first 6 months and 0.0 percent for the second 6 months). (The sequestration order for a given fiscal year is applied to expenditures incurred from April 1 of that fiscal year through March 31 of the following fiscal year.)

The net impact of all legislative changes was a decrease in the estimated future net cash flow for total Medicare. For Part A the present value of estimated expenditures is higher. The present values of estimated income and expenditures are higher for Part B. Overall, these changes decreased the present value of the estimated future net cash flow by $38 billion.

For the period beginning on January 1, 2019 to the period beginning on January 1, 2020

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 *Bipartisan Budget Act of 2019* (Public Law 116-37, enacted on August 2, 2019) included one provision that affects HI and SMI programs.
  - The sequestration process that is in place should Congress fail to address the budget deficit by certain deadlines is extended by two years, through fiscal years 2028 and 2029.
- The *Further Consolidated Appropriations Act, 2020* (Public Law 116-94, enacted on December 20, 2019) included provisions that affect HI and SMI programs.
  - The annual fee imposed on certain large health insurer providers, including those furnishing coverage under Medicare Advantage and Medicare Part D, is repealed for calendar years beginning after December 31, 2020.
  - The excise tax on employer-sponsored group health insurance premiums above a specified level (commonly referred to as the “Cadillac Tax” and provided for by legislation in 2010) is repealed. This

excise tax was expected to decrease the average cost of health insurance, thereby increasing the portion of employee compensation subject to the HI payroll tax, over both the short- and long-range projection periods. Although the implementation of this provision has been repeatedly delayed since inception, the 2010-2019 annual reports reflected the assumption that the excise tax would eventually be applied. Therefore, the repeal of this provision decreases the share of employee compensation that will be subject to the HI payroll tax.

- The 1.00 floor on the geographic index for physician work is extended through May 22, 2020 (from December 31, 2019).
- The clinical laboratory commercial payer data reporting requirement is delayed for 1 year (that is, until calendar year 2021).

The net impact of these changes was a decrease in the estimated future net cash flow for total Medicare. The present values of estimated income and expenditures are lower for Part A, Part B, and Part D. Overall, these changes decreased the present value of the estimated future net cash flow by $453 billion.

Required Supplementary Information

Combining Statement of Budgetary Resources

For the Year Ended September 30, 2021
(in Millions)

	CMS					
	Medicare HI	Medicare SMI	Payments to Trust Funds	Medicaid	Other Agency Accounts	Agency Combined Totals
Budgetary Resources						
Unobligated Balance from Prior Year Budget Authority, Net (Discretionary and Mandatory)	$ 22,764	$ 14,960	$ 103,901	$ 39,172	$ 154,662	$ 335,459
Appropriations (Discretionary and Mandatory)	362,713	372,514	481,368	515,679	519,992	2,252,266
Borrowing Authority (Discretionary and Mandatory)	-	45,697	-	-	331	46,028
Spending Authority from Offsetting Collections (Discretionary and Mandatory)	-	-	-	1,360	26,232	27,592
Total Budgetary Resources	**$ 385,477**	**$ 433,171**	**$ 585,269**	**$ 556,211**	**$ 701,217**	**$ 2,661,345**
Status of Budgetary Resources						
New Obligations and Upward Adjustments	$ 385,477	$ 433,171	$ 459,323	$ 555,793	$ 522,113	$ 2,355,877
Unobligated Balance, End of Year:						
Apportioned, Unexpired Accounts	-	-	15,510	-	120,328	135,838
Exempt from Apportionment, Unexpired Accounts	-	-	-	-	204	204
Unapportioned, Unexpired Accounts	-	-	6,535	418	48,027	54,980
Unexpired Unobligated Balance, End of Year	-	-	22,045	418	168,559	191,022
Expired Unobligated Balance, End of Year	-	-	103,901	-	10,545	114,446
Unobligated Balance, End of Year	-	-	125,946	418	179,104	305,468
Total Status of Budgetary Resources	**$ 385,477**	**$ 433,171**	**$ 585,269**	**$ 556,211**	**$ 701,217**	**$ 2,661,345**
Outlays, Net						
Outlays, Net (Discretionary and Mandatory)	$ 357,686	$ 416,938	$ 439,674	$ 515,814	$ 358,488	$ 2,088,600
Distributed Offsetting Receipts	(59,172)	(559,406)	-	-	(3,034)	(621,612)
Agency Outlays, Net (Discretionary and Mandatory)	**$ 298,514**	**$ (142,468)**	**$ 439,674**	**$ 515,814**	**$ 355,454**	**$ 1,466,988**
Disbursements, Net	**$ -**	**$ -**	**$ -**	**$ -**	**$ 278**	**$ 278**

Summary of Other Agency Accounts

	Budgetary Resources	Outlays, Net
ACF	$ 129,807	$ 69,153
ACL	4,365	2,662
AHRQ	386	329
CDC	38,773	16,035
CMS	180,017	123,975
FDA	8,954	3,218
HRSA	22,629	14,209
IHS	19,301	9,868
NIH	51,766	38,379
OS	228,911	71,678
PSC	2,059	39
SAMHSA	14,249	5,909
Totals	**$ 701,217**	**$ 355,454**

Deferred Maintenance and Repairs

For the Years Ended September 30, 2021 and 2020

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.

Estimated Cost to Return to Acceptable Condition

(in Millions)

Category of Asset	2021	2020
General PP&E		
Buildings	$ 3,692	$ 2,780
Other Structures	25	18
Total	**$ 3,717**	**$ 2,798**

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 *2021 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.

Beginning in 2020, the Medicare program was dramatically affected by the COVID-19 pandemic, however, given the uncertainty of the impacts at the time the Trustees Report was released, the pandemic was not factored into the SOSI projections until 2021. The amount of payroll taxes expected to be collected by the HI trust fund was greatly reduced due to the economic effects of the pandemic on labor markets. Spending was directly affected by the coverage of testing and treatment of the disease. In addition, several regulatory policies and legislative provisions were enacted during the public health emergency that increased spending; notably, the 3-day inpatient stay requirement to receive skilled nursing facility services was waived, payments for inpatient admission related to COVID-19 were increased by 20 percent, and the use of telehealth was greatly expanded. More than offsetting these additional costs in 2020, spending for non-COVID care declined significantly (compared to both actual 2019 spending and expectations for 2020 spending in last year's Trustees Report). This decline was particularly true for elective services.

Overall, the projections are based on actual experience through 2019. To account for the spending impacts of the pandemic, adjustment factors by type of service were developed through 2023. These factors are based on (i) projections of the pandemic; (ii) direct costs associated with the testing and treatment of COVID-19; (iii) projections for non-COVID costs; and (iv) costs for the vaccines. Certain services, such as prescription drugs, durable medical equipment, physician-administered drugs, and hospice, were not materially affected by the pandemic.

Because of the large wave of COVID-19 cases in early 2021, non-COVID-related spending is estimated to be lower than previously expected for the beginning of the year. As care that was reduced or deferred returns, the trend in the latter part of 2021 is slightly higher than anticipated previously. For 2022, the return of deferred care that is assumed to be more intensive results in spending that continues to be higher than previously estimated. The Trustees have not included any longer-term morbidity impacts, balancing (i) a potential increase in costs due to longer-lasting health needs from those who have had COVID-19 with (ii) a potential reduction in costs due to the higher mortality from COVID-19 among those with higher medical spending.

The estimates also incorporate the costs of the COVID-19 vaccines, which consist of both the payments for the vaccines themselves and the payments for their administration. The Trustees expect vaccine utilization to decrease somewhat over time, reflecting the likely reduction in the required number of doses and the possibility that the seriousness of COVID-19 will decrease.

It should be noted that there is an unusually large degree of uncertainty with these COVID-related impacts and that future projections could change significantly as more information becomes available.

The AAP Program was significantly expanded during the COVID-19 public health emergency period, by both legislative provisions and through administrative actions taken by CMS early on during the emergency. CMS first implemented an expedited process for eligible providers and suppliers to request and receive approval for these payments. Next, while the CARES Act added critical access, pediatric, and certain cancer hospitals to the list of eligible entities, CMS made several modifications to the AAP program that, in effect, expanded eligibility to all types of providers and suppliers.[10] The CARES Act increased the maximum amounts available under the AAP program during the emergency period to (i) 100 percent of Medicare payments made during the past 6 months—for inpatient acute care, pediatric, and certain cancer hospitals; (ii) 125 percent of Medicare payments made during the past 6 months—for critical access hospitals; and (iii) 100 percent of Medicare payments made during the past 3 months—for all other providers and suppliers.[11] In addition, under the *Continuing Appropriations Act, 2021 and Other Extensions Act*, recoupments are to begin 1 year after the accelerated or advance payment is issued, after which recoupments are to be 25 percent of the AAP amount over the first 11 months and 50 percent over the following 6 months; after that 29-month period has elapsed, the remaining balance will be due within 30 days. Total payments of approximately $107.1 billion were made: roughly $67.1 billion from the HI trust fund and $40.0 billion from the SMI Part B trust fund account. The Trustees assume that the accelerated and advance payments will be fully repaid by September of 2022, resulting in no net changes to trust fund expenditures.

The projections and analysis do not reflect the potential effects of Medicare coverage of Aduhelm, the Alzheimer's disease drug that has been recently approved by the Food and Drug Administration. Given the uncertainty associated with these impacts, the Trustees believe that it is not possible to adjust the estimates accurately before a coverage determination is made.

While the COVID-19 pandemic has significantly affected Medicare short-term financing and spending, it is not expected to have a large effect on the financial status of the trust funds after 2024. The key measures of the financial adequacy for each trust fund shown in this year's Trustees Report are fairly comparable to those included in last year's report. This consistency is partly due to the offsetting effects of lower income and expenditures in the HI trust fund and partly due to the expectation that the effects of the pandemic will last only several years. The pandemic is an example of the inherent uncertainty in projecting healthcare financing and spending over any duration.

The projections presented here are based on current law, certain features of which may result in some challenges for the Medicare program. Physician payment update amounts are specified 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. These 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. Payment rate updates for most non-physician categories of Medicare providers are reduced by the growth in economy-wide private nonfarm business multifactor productivity[12] although these health providers have historically achieved lower levels of productivity growth. If the health sector cannot transition to more efficient models of care delivery and if the provider reimbursement rates paid by commercial insurers continue to be based on the same

[10] The usual eligibility criteria—to have billed Medicare during the last 180 days, to not be in bankruptcy, to not be under review or investigation, and to not have any outstanding delinquent Medicare overpayments—still apply.
[11] The maximum available AAP amounts had been 70 percent and 80 percent for providers and suppliers, respectively, of Medicare payments made during the past 90 days.
[12] For convenience the term economy-wide private nonfarm business multifactor productivity will henceforth be referred to as economy-wide productivity.

negotiated process used to date, then the availability, particularly with respect to physician services, and quality of healthcare received by Medicare beneficiaries would, under current law, fall over time compared to that received by those with private health insurance.

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); the *Bipartisan Budget Act of 2015* (Public Law 114-74, enacted on November 2, 2015); the *Bipartisan Budget Act of 2018* (Public Law 115-123, enacted on February 9, 2018); the *Bipartisan Budget Act of 2019* (Public Law 116-37, enacted on August 2, 2019); the CARES Act (Public Law 116-136, enacted on March 27, 2020); the *Consolidated Appropriations Act, 2021* (Public Law 116-260, enacted on December 27, 2020); and *An Act to Prevent Across-the-Board Direct Spending Cuts, and for Other Purposes* (Public Law 117-7, enacted on April 14, 2021). The sequestration reduces benefit payments by 2 percent from April 1, 2013 through April 30, 2020, by 2 percent again from January 1, 2022 through September 15, 2030, and by 4 percent from September 16, 2030 through the first half of March 2031. Because of sequestration, non-salary administrative expenses are reduced by an estimated 5 to 7 percent from March 1, 2013 through September 30, 2030, excluding May 1, 2020 through December 31, 2021 when it was suspended.

The financial projections for the Medicare program reflect substantial, but very uncertain, cost savings deriving from current-law provisions that lower increases in Medicare payment rates to most categories of healthcare providers, but such adjustments would probably not be viable indefinitely without fundamental change in the current delivery system. 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 healthcare cost growth over time. The expenditure projections reflect the cost-reduction provisions required under current law. In addition, the Trustees reference in their report an illustrative alternative scenario, which assumes that (i) there would be a transition from current-law[13] payment updates for providers affected by the economy-wide productivity adjustments to payment updates that reflect adjustments for healthcare productivity; (ii) the average physician payment updates would transition from current law[14] to payment updates that reflect the Medicare Economic Index; and (iii) the 5-percent bonuses for qualified 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 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 cost-reduction measures prove problematic and new legislation scales them back.

[13] 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 of economy-wide productivity (1.0 percent over the long range).

[14] The law specifies physician payment rate updates of 0.75 percent or 0.25 percent annually thereafter for physicians in advanced alternative payment models (advanced APMs) or the merit-based incentive payment system (MIPS), respectively. These updates are notably lower than the projected physician cost increases, which are assumed to average 2.05 percent per year in the long range.

Additional information on the current-law and illustrative alternative projections is provided in Note 27 in these financial statements, in section V.C of this year's Medicare Trustees Report, and in a memorandum prepared by the CMS Office of the Actuary.

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 the CMS website.

Actuarial Projections

Long-Range Medicare Cost Growth Assumptions

Beginning with the 2013 report, the Trustees used the statutory price updates and the volume and intensity assumptions from the "factors contributing to growth" model to derive the year-by-year Medicare cost growth assumptions for the last 50 years of the projection period.[15] 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.[16]

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 healthcare 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.

Medicare payment rates for most non-physician provider categories are 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 the healthcare goods and services. These updates are then reduced by the 10-year moving average increase in economy-wide productivity, which the Trustees assume will be 1.0 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 healthcare 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 cost growth rates for these provider services start at 3.6 percent in 2045, or GDP plus 0 percent, declining gradually to 3.4 percent in 2095, or GDP minus 0.3 percent.

(ii) ***Physician services***

Payment updates are 0.75 percent per year for those qualified physicians assumed to be participating in advanced APMs and 0.25 percent for those assumed to be participating in MIPS. The year-by-year cost

[15] This assumed increase in the average expenditures per beneficiary excludes the impacts of the aging of the population, changes in the gender composition of the Medicare population, and changes in the distribution of the Medicare population on the basis of proximity to death, as the Trustees estimated these factors separately. For convenience, the increase in Medicare expenditures per beneficiary, before consideration of demographic impacts, is referred to as the Medicare cost growth rate.

[16] The Trustees' methodology is consistent with Finding III-2 and Recommendation III-3 of the 2010–2011 Medicare Technical Review Panel (final report available here) and with Finding 3-2 of the 2016–2017 Medicare Technical Review Panel (final report available here).

growth rates for physician payments are assumed to decline from 3.2 percent in 2045, or GDP minus 0.4 percent, to 2.8 percent in 2095, or GDP minus 0.9 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,[17] care at ambulatory surgical centers, ambulance services, and medical supplies. The Trustees assume the year-by-year cost growth rates for these services to decline from 2.8 percent in 2045, or GDP minus 0.8 percent, to 2.6 percent in 2095, or GDP minus 1.1 percent.

(iv) ***All other Medicare services, for which payments are established based on market processes, such as prescription drugs provided through Part D and the remaining Part B services.***

These Part B outlays constitute an estimated 15 percent of total Part B expenditures in 2030 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.[18] The long-range cost growth rates for Part D and these Part B services are assumed to equal the growth rates as determined from the factors model. The corresponding year-by-year cost growth rates for these services decline from 4.3 percent in 2045, or GDP plus 0.7 percent, to 4.2 percent by 2095, or GDP plus 0.5 percent.

In addition, these long-range cost growth rates must be modified to reflect demographic impacts. Beginning with the 2020 Trustees Report, these impacts reflect the changing distribution of Medicare enrollment by age, sex, and the beneficiary's proximity to death, which is referred to as a time-to-death (TTD) adjustment. The TTD adjustment reflects the fact that the closer an individual is to death, the higher his or her healthcare spending is. Thus, as mortality rates improve and a smaller portion of the Medicare population is likely to die at any given age, the effect of individuals getting older and spending more on healthcare is offset somewhat.[19] This is particularly the case for Part A services—such as inpatient hospital, skilled nursing, and home health services—for which the distribution of spending is more concentrated in the period right before death. For Part B services and Part D, the incorporation of the TTD adjustment has a smaller effect.

After combining the rates of growth from the four long-range assumptions, the weighted average cost growth rate for Part B is 3.8 percent in 2045, or GDP plus 0.2 percent, declining to 3.7 percent by 2095, or GDP plus 0 percent. When Parts A, B, and D are combined, the weighted average cost growth rate for Medicare is 3.8 percent, or GDP plus 0.2 percent in 2045, declining to 3.7 percent, or GDP plus 0 percent by 2095.

HI Cash Flow as a Percentage of Taxable Payroll

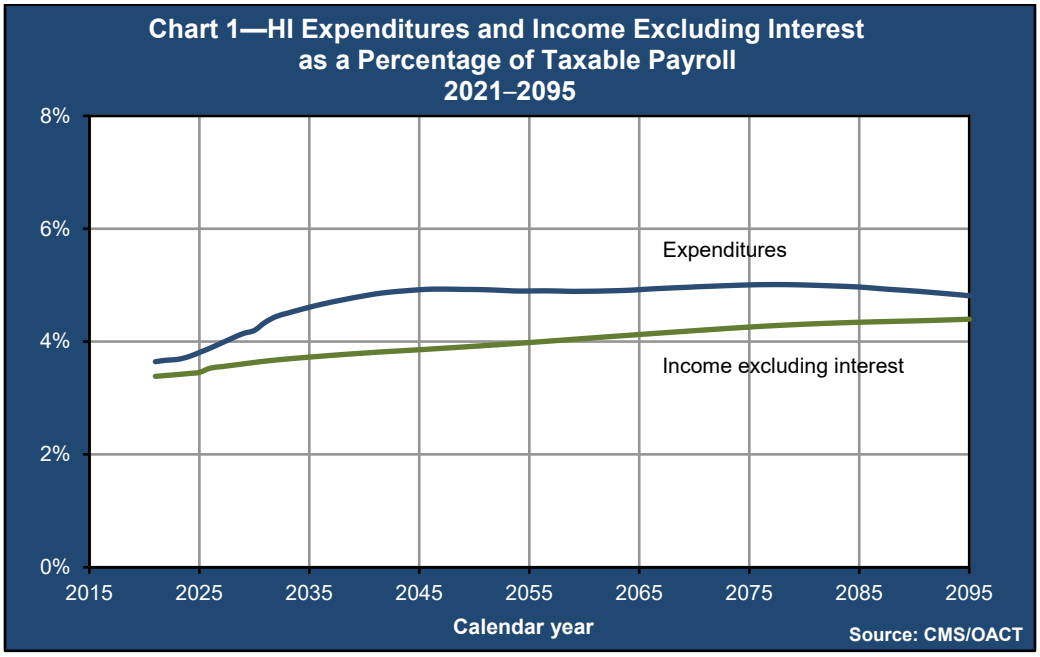
Each year, estimates of the financial and actuarial status of the HI trust fund are prepared for the next 75 years. It is difficult to meaningfully compare dollar values for different periods without some type of relative scale; therefore, income and expenditure amounts are shown relative to the earnings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

[17] 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. For more information on the bidding process, see section IV.B of the 2021 Medicare Trustees Report.

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

[19] More information on the TTD adjustment is available on the CMS website.

Chart 1 illustrates income (excluding interest) and expenditures as a percentage of taxable payroll over the next 75 years. The projected HI cost rates are very similar to those from last year for nearly all 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 income thresholds for determining eligibility for the additional HI tax are not indexed, over time an increasing proportion of workers will become subject to a higher 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; this result will occur because the income thresholds determining taxable benefits are not indexed for price inflation and because the income tax brackets are indexed to the chained CPI (CCPI-U), which increases at a slower rate than average wages.[20] Thus, as Chart 1 shows, the income rate is expected to gradually increase over current levels.

In 2021 and beyond, as indicated in Chart 1, the cost rate is projected to rise, primarily due to the continued retirements of those in the baby boom generation and partly due to an acceleration of 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 0.5 percent through 2030 and 1.0 percent thereafter. Under the illustrative alternative scenario, the HI cost rate would be 5.3 percent in 2046 and 7.2 percent in 2095.

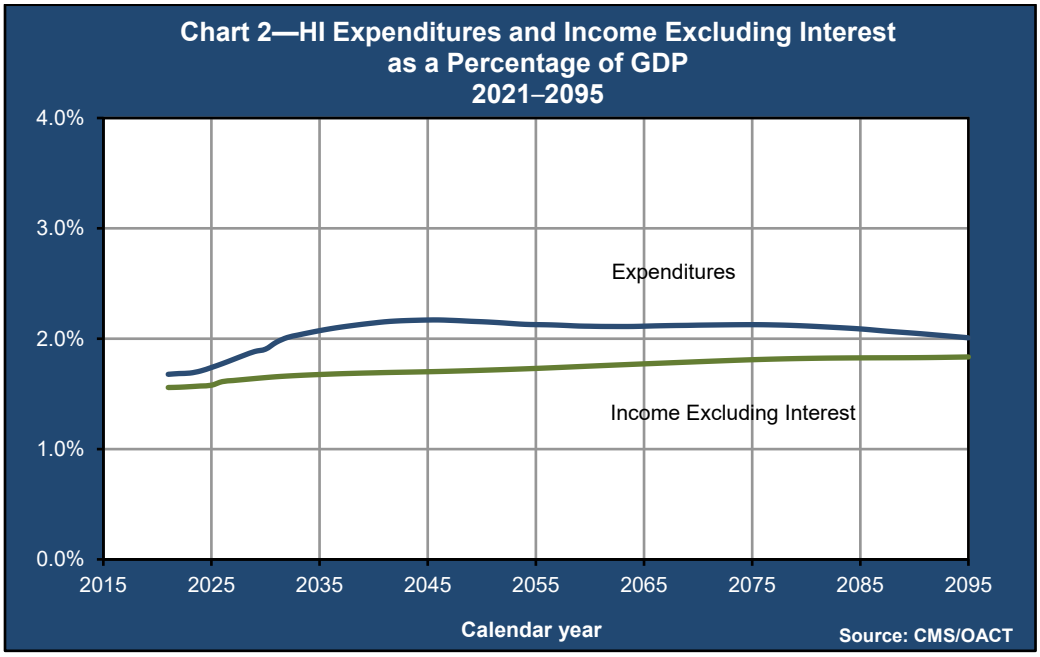
[20] After the 10th year of the projection period, income tax brackets are assumed to rise with average wages, rather than with the CCPI-U as specified in the Internal Revenue Code. As a result of this assumption, income from the taxation of Social Security benefits increases at a similar rate as, rather than significantly faster than, taxable payroll. See section V.C7 of the *2021 Annual Report of the Board of Trustees of the Federal Old-Age and Survivors Insurance and Federal Disability Insurance Trust Funds* for more detailed information on the projection of income from taxation of Social Security benefits.

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 United States. This measure provides an idea of the relative financial resources that will be necessary to pay for Medicare services.

HI

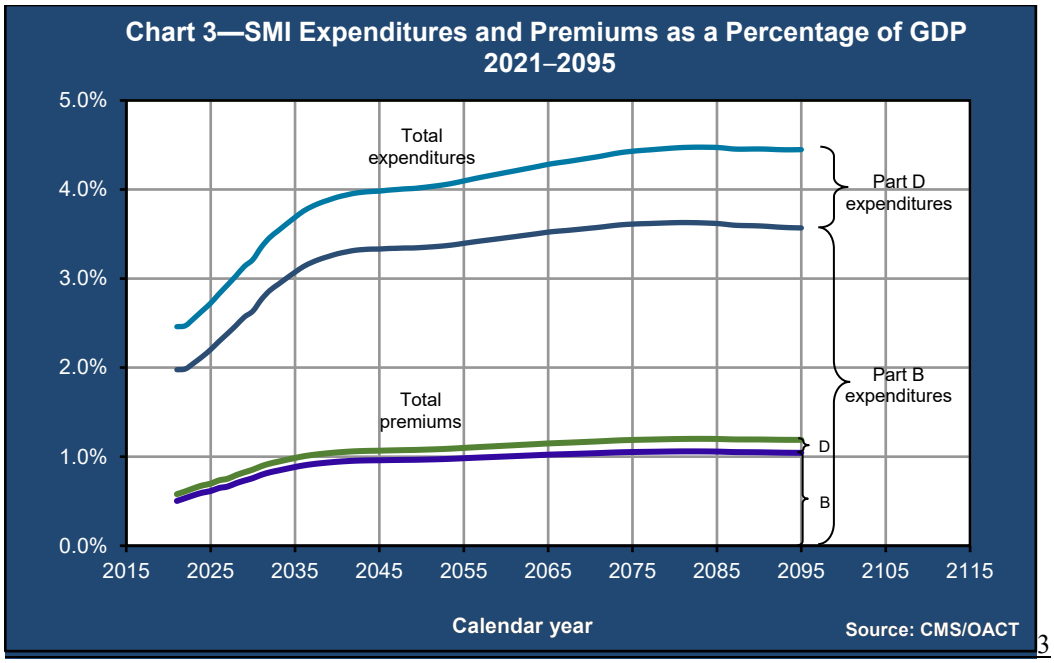
Chart 2 shows HI income (excluding interest) and expenditures over the next 75 years expressed as a percentage of GDP. In 2020, the expenditures were $402.2 billion, which was 1.9 percent of GDP. As Chart 2 illustrates, this percentage is projected to increase steadily until about 2042 and then remain 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 3.0 percent in 2095.



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.



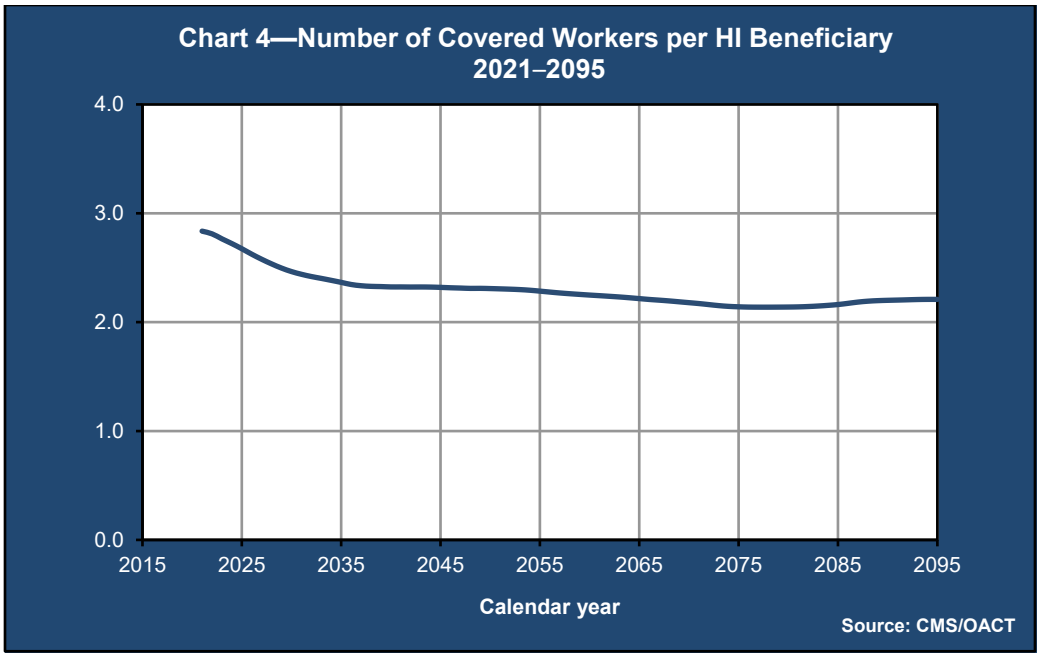
In 2020, SMI expenditures were $523.6 billion, or about 2.5 percent of GDP. Under current law, they would grow to about 4.0 percent of GDP within 25 years and to 4.4 percent by the end of the projection period, as demonstrated in Chart 3. Under the illustrative alternative, total SMI expenditures in 2095 would be 5.5 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 2020 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 2020, every beneficiary had about 2.9 workers to pay for his or her benefit. In 2030, however, after the last baby boomer turns 65, there will be only about 2.5 workers for each beneficiary, as indicated in Chart 4. The projected ratio continues to decline until there are only 2.2 workers per beneficiary by 2095.

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.[21] The assumptions varied are the healthcare cost factors, real-wage differential, CPI, real-interest rate, fertility rate, and net immigration.[22]

For this analysis, the intermediate economic and demographic assumptions in the 2021 Medicare Trustees Report 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, 2021 and are based on estimates of income and expenditures during the 75-year projection period.

[21] 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.
[22] 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.

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 20 to 25 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.

Healthcare Cost Factors

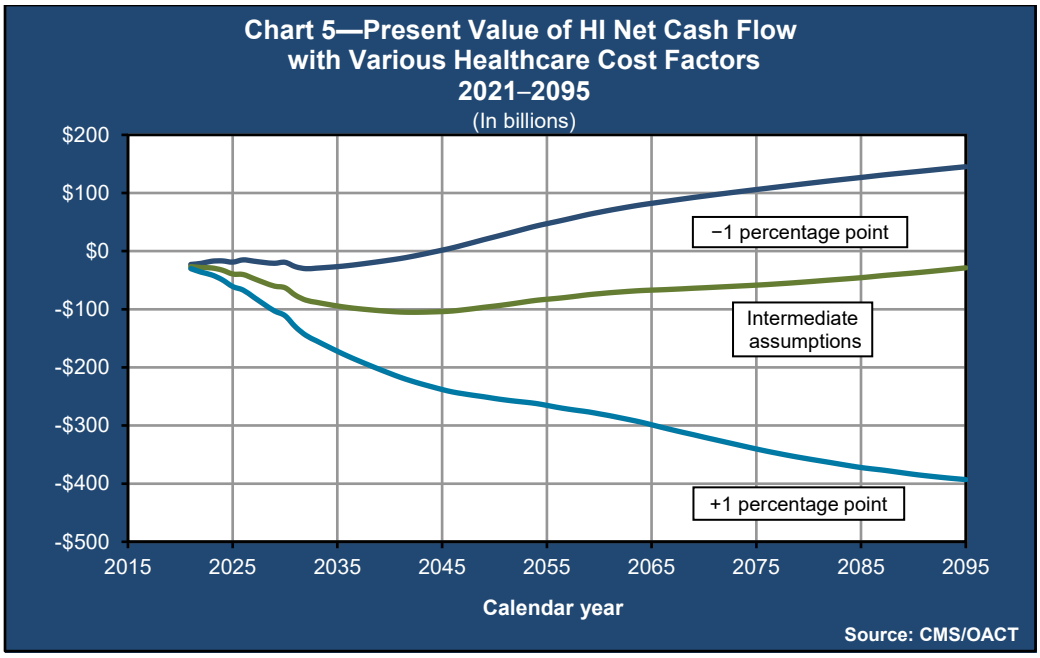
Table 1 shows the net present value of cash flow during the 75-year projection period under three alternative assumptions for the annual growth rate in the aggregate cost of providing covered healthcare services to beneficiaries. These assumptions are that the ultimate annual growth rate in such costs, 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 Healthcare Cost Growth Rate Assumptions

Annual cost/payroll relative growth rate	-1 percentage point	Intermediate assumptions	+1 percentage point
Income minus expenditures (in billions)	$3,990	-$5,057	-$19,568

Table 1 demonstrates that if the ultimate growth rate assumption is 1 percentage point lower than the intermediate assumptions, the deficit decreases by $9,047 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 $14,511 billion.

Chart 5 shows projections of the present value of the estimated net cash flow under the three alternative annual growth rate assumptions presented in Table 1.



This assumption has a dramatic impact on projected HI cash flow. The present value of the net cash flow under the ultimate growth rate assumption of 1 percentage point lower than the intermediate assumption actually becomes a surplus due to the improved financial outlook for the HI trust fund as a result of the cost-reduction provisions required under current law. 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 healthcare service costs.

Real-Wage Differential

Table 2 illustrates the net present value of cash flow during the 75-year projection period under three alternative ultimate real-wage differential assumptions: 0.53, 1.15, and 1.77 percentage points.[23] In each case, the assumed ultimate annual increase in the CPI is 2.4 percent, yielding ultimate percentage increases in nominal average annual wages in covered employment of 2.93, 3.55, and 4.17 percent, respectively.

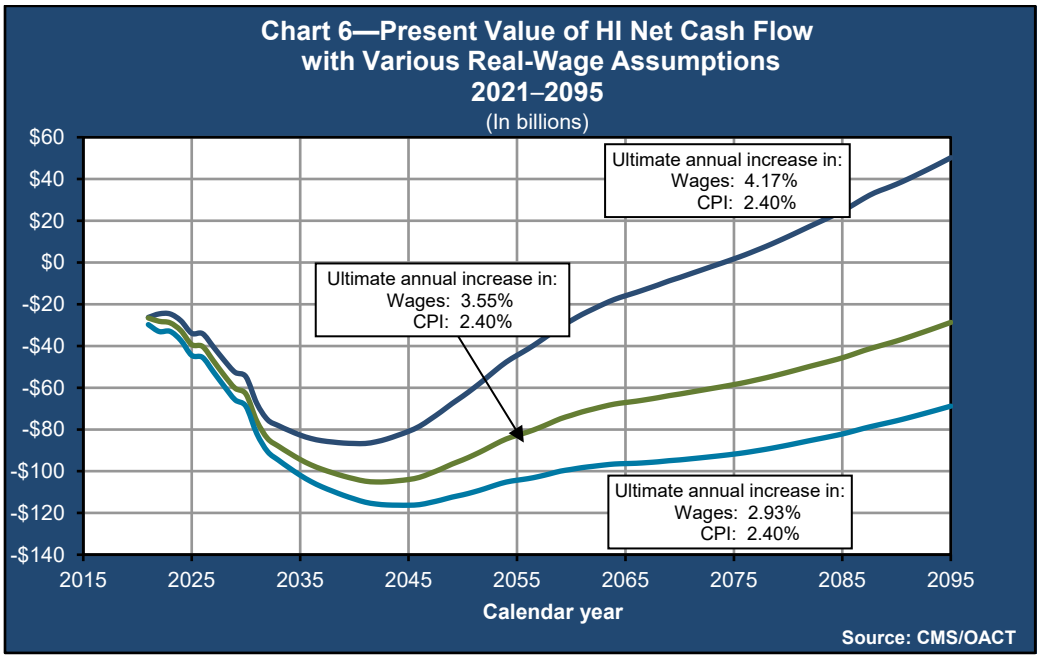
Table 2—Present Value of Estimated HI Income Less Expenditures under Various Real-Wage Assumptions

Ultimate percentage increase in wages - CPI	2.93 – 2.40	3.55 – 2.40	4.17 – 2.40
Ultimate percentage increase in real-wage differential	0.53	1.15	1.77
Income minus expenditures (in billions)	−$6,718	−$5,057	−$2,025

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 $2,445 billion. Conversely, for a half-point decrease in the ultimate real-wage differential assumption, the deficit increases by about $1,340 billion.

[23] 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.



Faster real-wage growth results in smaller HI cash flow deficits, when expressed in present-value dollars, as demonstrated in Chart 6. A higher real-wage differential immediately increases both HI expenditures for healthcare 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 healthcare 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 cost-reduction provisions 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 healthcare 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

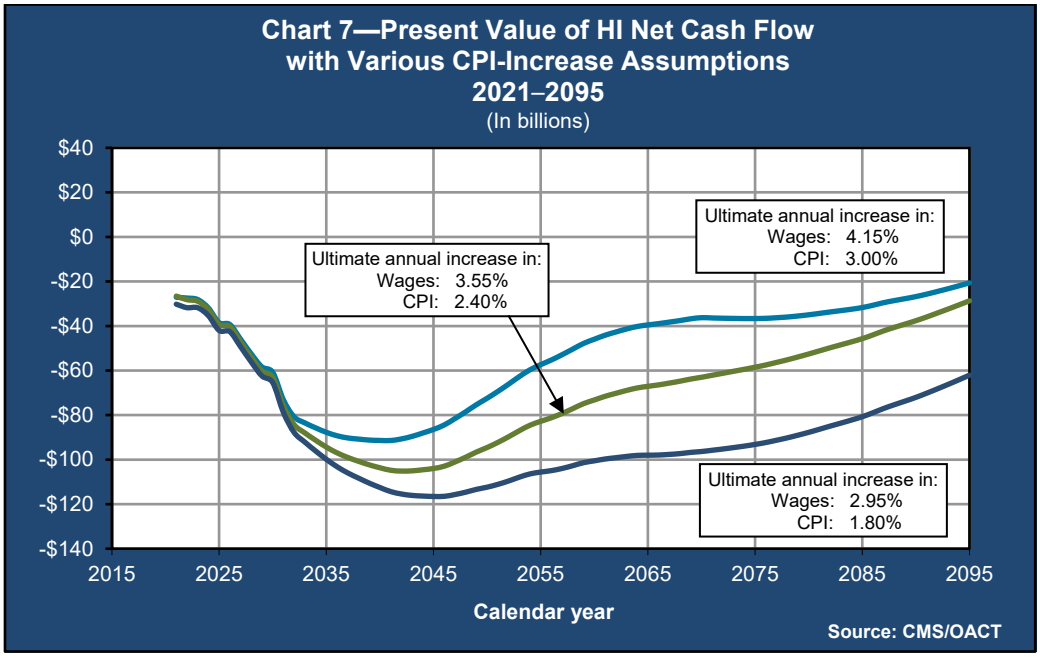
Table 3 illustrates the net present value of cash flow during the 75-year projection period under three alternative ultimate CPI rate-of-increase assumptions: 3.0, 2.4, and 1.8 percent. In each case, the assumed ultimate real-wage differential is 1.15 percent, which yields ultimate percentage increases in average annual wages in covered employment of 4.15, 3.55, and 2.95 percent, respectively.

Table 3—Present Value of Estimated HI Income Less Expenditures under Various CPI-Increase Assumptions

Ultimate percentage increase in wages - CPI	4.15 – 3.00	3.55 – 2.40	2.95 – 1.80
Income minus expenditures (in billions)	−$3,862	−$5,057	−$6,676

Table 3 demonstrates that if the ultimate CPI-increase assumption is 3.0 percent, the deficit decreases by $1,195 billion. On the other hand, if the ultimate CPI-increase assumption is 1.8 percent, the deficit increases by $1,619 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.



This assumption has a small impact when the cash flow is expressed as present values, as Chart 7 indicates. 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 is the result under high-inflation conditions because the present values of HI expenditures are not significantly different under the various CPI scenarios; under high-inflation conditions, however, the present value of HI income increases as more people become subject to the additional 0.9-percent HI tax rate required 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

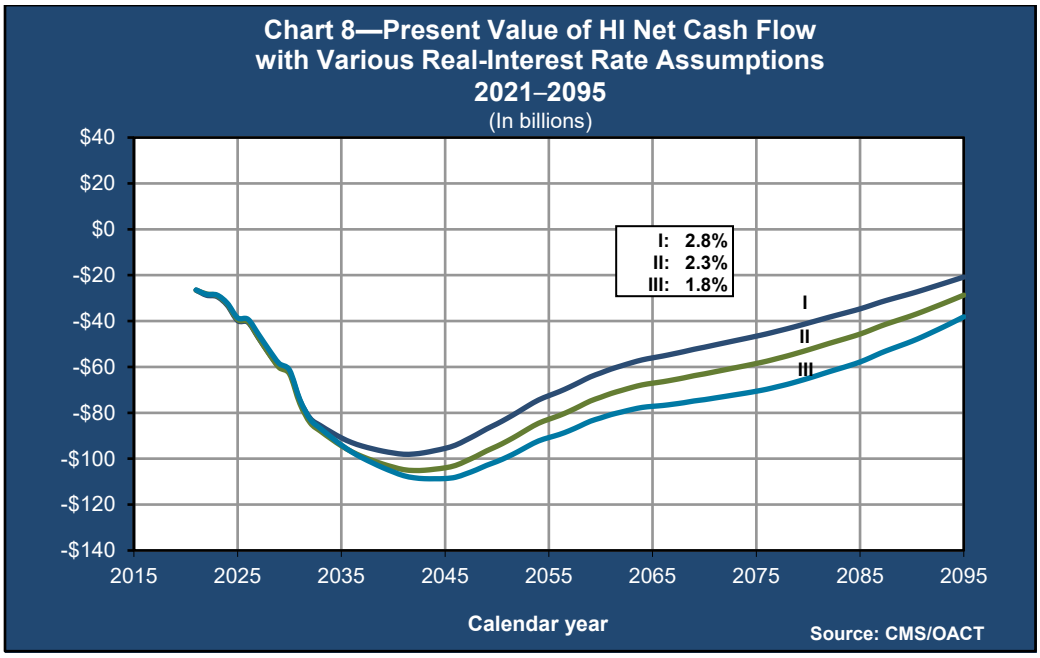
Table 4 shows the net present value of cash flow during the 75-year projection period under three alternative ultimate annual real-interest assumptions: 1.8, 2.3, and 2.8 percent. In each case, the assumed ultimate annual increase in the CPI is 2.4 percent, which results in ultimate annual yields of 4.2, 4.8, and 5.3 percent, respectively.

Table 4—Present Value of Estimated HI Income Less Expenditures under Various Real-Interest Assumptions

Ultimate real-interest rate	1.8 percent	2.3 percent	2.8 percent
Income minus expenditures (in billions)	-$5,563	-$5,057	-$4,446

As demonstrated in Table 4, for every increase of 0.1 percentage point in the ultimate real-interest rate, the deficit decreases by approximately $110 billion.

Chart 8 illustrates projections of the present value of the estimated net cash flow under the three alternative real-interest assumptions presented in Table 4.



The projected HI cash flow when expressed in present values is fairly sensitive to the interest assumption, as shown in Chart 8. 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: 1.69, 1.99, and 2.19 children per woman.

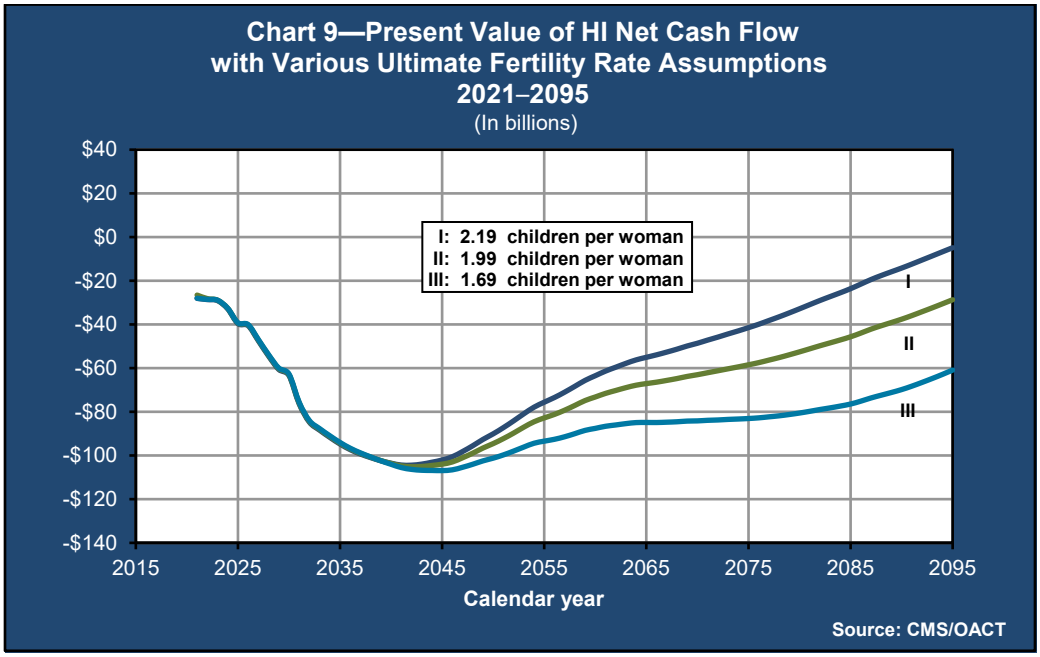
Table 5—Present Value of Estimated HI Income Less Expenditures under Various Fertility Rate Assumptions

Ultimate fertility rate[1]	1.69	1.99	2.19
Income minus expenditures (in billions)	−$6,093	−$5,057	−$4,326

[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 every increase of 0.1 percentage point in the assumed ultimate fertility rate, the projected present value of the HI deficit decreases by approximately $355 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.



The fertility rate assumption has a substantial impact on projected HI cash flows, as Chart 9 indicates. 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

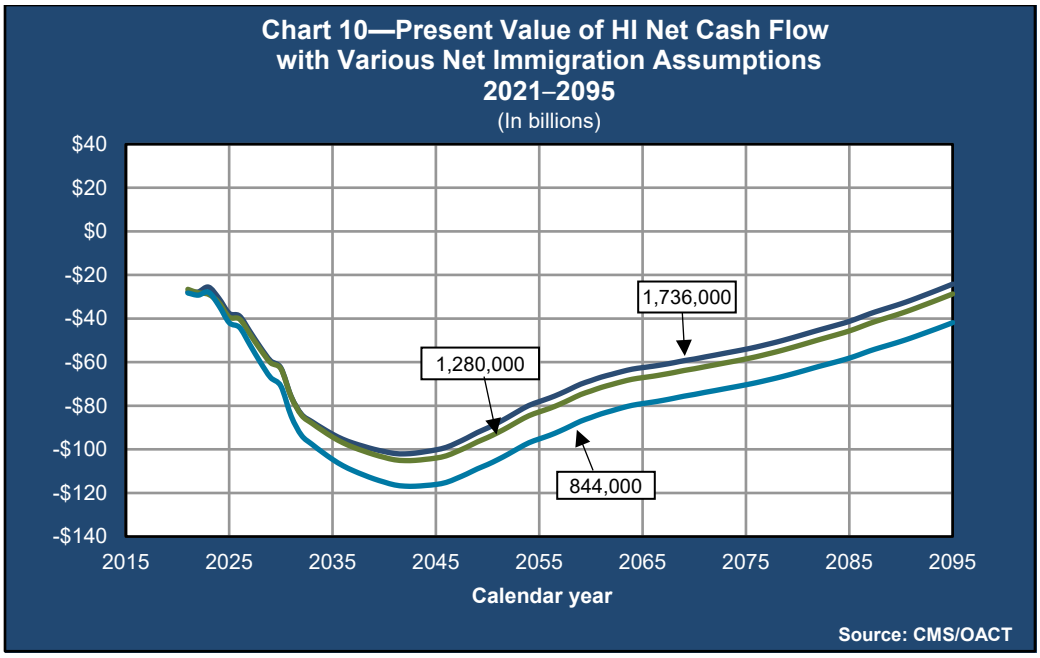
Table 6 illustrates the net present value of cash flow during the 75-year projection period under three alternative average annual net immigration assumptions: 844,000 persons, 1,280,000 persons, and 1,736,000 persons per year.

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

Average annual net immigration	844,000	1,280,000	1,736,000
Income minus expenditures (in billions)	−$5,861	−$5,057	−$4,783

As indicated in Table 6, if the average annual net immigration assumption is 844,000 persons, the deficit—expressed in present-value dollars—increases by $803 billion. Conversely, if the assumption is 1,736,000 persons, the deficit decreases by $274 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 demonstrated 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 is similar to the projections in last year's Medicare Trustees Report. The estimated depletion date for the HI trust fund is 2026, the same as in the 2018 through 2020 reports. 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 lower payroll taxes. HI expenditures are projected to be lower than last year's estimates because of lower projected provider payment updates and certain methodological improvements, including changes to the time-to-death factors used in the projection model.

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. In 2018, 2019, and 2020, expenditures again exceeded income, with trust fund deficits of $1.6 billion, $5.8 billion, and $60.4 billion, respectively. The large deficit in 2020 was mostly due to accelerated and advance payments to providers from the trust fund; these payments will be repaid to the trust fund over the next several years, which will lead to a much smaller deficit in 2021 and a surplus in 2022. After that, 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 healthcare 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 nature of the financing for both parts of SMI is similar in that the law establishes a mechanism by which income from the Part B premium and the Part D premium, and the corresponding general revenue transfers for each part, are sufficient to cover the following year's estimated expenditures. Accordingly, each account within SMI is automatically in financial balance under current law. 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.

Medicare Overall

Federal law requires that the Board of Trustees issue a determination of excess general revenue Medicare funding if they project that under current law the difference between program outlays and dedicated financing sources[24] will exceed 45 percent of total Medicare outlays within the next 7 fiscal years (2021–2027). For the 2021 Medicare Trustees Report, this difference is expected to exceed 45 percent of total expenditures in fiscal year 2021, and therefore the Trustees are issuing this determination. Since this determination was made last year as well, this year's determination triggers a Medicare funding warning, which (i) requires the President to submit to Congress proposed legislation to respond to the warning within 15 days after the submission of the Fiscal Year 2023 Budget and (ii) requires Congress to consider the legislation on an expedited basis. Such funding warnings were previously issued in each of the 2007 through 2013 reports and in the 2018 through 2020 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 policy reforms will have to address much larger financial challenges than those assumed under current law. In their 2021 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."

[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.

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SECTION 3

OTHER INFORMATION

IN THIS SECTION

- Other Financial Information
- Summary of Financial Statement Audit and Management Assurances
- Civil Monetary Penalty Adjustment for Inflation
- Grants Closeout Reporting
- Payment Integrity Report
- FY 2021 Top Management and Performance Challenges Identified by the Office of Inspector General Facing HHS
- 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, 2021

(in Millions)

	Education, Training & Social Services	Health	Medicare	Income Security	Agency Combined Totals	Intra-HHS Eliminations	HHS Consolidated Totals
Assets (Note 2)							
Intragovernmental							
Fund Balance with Treasury (Note 3)	$ 21,754	$ 466,031	$ 145,714	$ 77,059	$ 710,558	$ -	$ 710,558
Investments, Net (Note 4)	-	4,158	308,133	-	312,291	-	312,291
Accounts Receivable, Net (Note 5)	291	9,407	86,056	-	95,754	(95,049)	705
Advances and Prepayments (Note 8)	126	1,438	-	143	1,707	(707)	1,000
Total Intragovernmental	**22,171**	**481,034**	**539,903**	**77,202**	**1,120,310**	**(95,756)**	**1,024,554**
With the Public							
Accounts Receivable, Net (Note 5)	-	12,941	15,647	88	28,676	-	28,676
Inventory and Related Property, Net (Note 6)	-	16,251	-	-	16,251	-	16,251
General Property, Plant and Equipment, Net (Note 7)	-	7,245	286	-	7,531	-	7,531
Advances and Prepayments (Note 8)	400	820	67,012	1,849	70,081	-	70,081
Other Assets	-	497	-	-	497	-	497
Total With the Public	**400**	**37,754**	**82,945**	**1,937**	**123,036**	**-**	**123,036**
Total Assets	**$ 22,571**	**$ 518,788**	**$ 622,848**	**$ 79,139**	**$ 1,243,346**	**$ (95,756)**	**$ 1,147,590**
Stewardship Land (Note 21)							
Liabilities (Note 9)							
Intragovernmental							
Accounts Payable	$ 19	$ 3,637	$ 95,920	$ 4	$ 99,580	$ (95,049)	$ 4,531
Debt (Note 10)	-	469	36,312	-	36,781	-	36,781
Advances from Others and Deferred Revenue	24	1,015	-	-	1,039	(707)	332
Other Liabilities (Note 14)	3	341	1	46	391	-	391
Total Intragovernmental	**46**	**5,462**	**132,233**	**50**	**137,791**	**(95,756)**	**42,035**
With the Public							
Accounts Payable	19	1,205	143	85	1,452	-	1,452
Entitlement Benefits Due and Payable (Note 11)	-	53,999	79,778	-	133,777	-	133,777
Federal Employee and Veterans Benefits (Note 12)	20	17,236	6	3	17,265	-	17,265
Environmental and Disposal Liabilities	-	326	-	-	326	-	326
Advances from Others and Deferred Revenue	-	1,634	815	-	2,449	-	2,449
Other Liabilities:							
Accrued Liabilities (Note 13)	1,335	14,120	-	3,017	18,472	-	18,472
Contingencies and Commitments (Note 15)	-	12,075	5	-	12,080	-	12,080
Other Liabilities (Note 14)	9	1,657	3	103	1,772	-	1,772
Total With the Public	**1,383**	**102,252**	**80,750**	**3,208**	**187,593**	**-**	**187,593**
Total Liabilities	**1,429**	**107,714**	**212,983**	**3,258**	**325,384**	**(95,756)**	**229,628**
Net Position							
Unexpended Appropriations – Funds from Dedicated Collections (Note 20)	-	866	134,077	-	134,943	-	134,943
Unexpended Appropriations – Funds from Other Than Dedicated Collections	21,033	383,114	-	76,106	480,253	-	480,253
Total Unexpended Appropriations	**21,033**	**383,980**	**134,077**	**76,106**	**615,196**	**-**	**615,196**
Cumulative Results of Operations – Funds from Dedicated Collections (Note 20)	-	20,540	275,788	-	296,328	-	296,328
Cumulative Results of Operations – Funds from Other Than Dedicated Collections	109	6,554	-	(225)	6,438	-	6,438
Total Cumulative Results of Operations	**109**	**27,094**	**275,788**	**(225)**	**302,766**	**-**	**302,766**
Total Net Position	**21,142**	**411,074**	**409,865**	**75,881**	**917,962**	**-**	**917,962**
Total Liabilities and Net Position	**$ 22,571**	**$ 518,788**	**$ 622,848**	**$ 79,139**	**$ 1,243,346**	**$ (95,756)**	**$ 1,147,590**

Consolidating Statement of Net Cost by Budget Function

For the Year Ended September 30, 2021

(in Millions)

Responsibility Segments	Education, Training, & Social Services	Health	Medicare	Income Security	Agency Combined Totals	Intra HHS Eliminations		Consolidated Totals
						Cost (-)	Revenue	
ACF	$ 15,382	$ -	$ -	$ 54,839	$ 70,221	$ (194)	$ 1,084	$ 71,111
ACL	2,678	-	-	-	2,678	(10)	1	2,669
AHRQ	-	328	-	-	328	(16)	16	328
CDC	-	16,459	-	-	16,459	(723)	242	15,978
CMS	-	541,584	730,773	-	1,272,357	(405)	19	1,271,971
FDA	-	3,571	-	-	3,571	(332)	28	3,267
HRSA	-	14,846	-	-	14,846	(340)	12	14,518
IHS	-	10,261	-	-	10,261	(195)	244	10,310
NIH	-	39,137	-	-	39,137	(278)	1,312	40,171
OS	-	71,376	-	-	71,376	(2,448)	1,025	69,953
PSC	-	1,665	-	-	1,665	(104)	734	2,295
SAMHSA	-	5,984	-	-	5,984	(44)	45	5,985
Totals	**$ 18,060**	**$ 705,211**	**$ 730,773**	**$ 54,839**	**$ 1,508,883**	**$ (5,089)**	**$ 4,762**	**$ 1,508,556**

Gross Cost and Exchange Revenue

For the Year Ended September 30, 2021

(in Millions)

Responsibility Segments	Intragovernmental						With the Public		Consolidated Net Cost of Operations
	Gross Cost			Less: Exchange Revenue			Gross Cost	Less: Exchange Revenue	
	Combined	Eliminations	Consolidated	Combined	Eliminations	Consolidated			
ACF	$ 534	$ (194)	$ 340	$ (1,138)	$ 1,084	$ (54)	$ 70,845	$ (20)	$ 71,111
ACL	23	(10)	13	(1)	1	-	2,656	-	2,669
AHRQ	44	(16)	28	(17)	16	(1)	309	(8)	328
CDC	1,774	(723)	1,051	(363)	242	(121)	15,109	(61)	15,978
CMS	1,125	(405)	720	(27)	19	(8)	1,404,159	(132,900)	1,271,971
FDA	1,663	(332)	1,331	(44)	28	(16)	4,763	(2,811)	3,267
HRSA	477	(340)	137	(12)	12	-	14,435	(54)	14,518
IHS	805	(195)	610	(290)	244	(46)	11,419	(1,673)	10,310
NIH	1,742	(278)	1,464	(1,463)	1,312	(151)	39,105	(247)	40,171
OS	25,603	(2,448)	23,155	(1,040)	1,025	(15)	46,829	(16)	69,953
PSC	395	(104)	291	(999)	734	(265)	2,271	(2)	2,295
SAMHSA	85	(44)	41	(173)	45	(128)	6,069	3	5,985
Totals	**$ 34,270**	**$ (5,089)**	**$ 29,181**	**$ (5,567)**	**$ 4,762**	**$ (805)**	**$ 1,617,969**	**$ (137,789)**	**$ 1,508,556**

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 the *Federal Managers' Financial Integrity Act of 1982* (FMFIA) and compliance with the *Federal Financial Management Improvement Act of 1996* (FFMIA).

Table 1: Summary of Financial Statement Audit

Audit Opinion			Unmodified for Five 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**
No Material Weaknesses Noted	0	-	-	-	0
Total Material Weaknesses	***0***	***-***	***-***	***-***	***0***

Definition of Terms – Tables 1 And 2

(Reference: OMB Circular A-136, *Financial Reporting Requirements*, August 10, 2021, pages 109 – 110)

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
Total Material Weaknesses	***0***	***-***	***-***	***-***	***-***	***0***

Effectiveness of Internal Control over Operations and Compliance with Laws and Regulations (FMFIA Section 2)

Statement of Assurance	Modified					
Material Weaknesses/ Non-compliances	Beginning Balance	New	Resolved	Consolidated	Reassessed	Ending Balance
Error Rate Measurement	2	2	-	-	-	4
Medicare Appeals Process	1	-	-	-	-	1
Total Material Weaknesses/ Non-compliances	***3***	***2***	***-***	***-***	***-***	***5***

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

Statement of Assurance	Federal Systems conform to financial management system requirements					
Non-compliance	Beginning Balance	New	Resolved	Consolidated	Reassessed	Ending Balance
No Non-compliance Noted	0	-	-	-	-	0
Total Non-compliance	***0***	***-***	***-***	***-***	***-***	***0***

Compliance with Section 803(a) of the 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. U.S. Standard General Ledger at Transaction Level	No lack of compliance noted	No lack of compliance noted

Civil Monetary Penalty Adjustment for Inflation

The *Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015* (the 2015 Act), as amended, requires agencies to make regular and consistent inflationary adjustments of civil monetary penalties to maintain their deterrent effect. To improve compliance with the 2015 Act, agencies are required to publish annual inflation adjustments in the Federal Register and should report annually in their agency financial report.

The 2015 Act applies to eight Operating Divisions (OpDivs) and Staff Divisions (StaffDivs): Administration for Children and Families; Agency for Healthcare Research and Quality; Health Resources and Service Administration; FDA; Centers for Medicare & Medicaid Services; Office for Civil Rights; Office of the General Counsel; and Office of Inspector General. The tables below illustrate HHS's Civil Monetary Penalties by OpDivs and StaffDivs. Refer to the 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)	2020	2021	$ 1,588

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)	2020	2021	$ 15,480

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)	2020	2021	$ 5,953

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)	2020	2021	$ 13,072
Penalty for each pre-February 18, 2009, violation of the *Health Insurance Portability and Accountability Act* (HIPAA) administrative simplification provisions.	42 U.S.C. 299b-22(f)(1)	2020	2021	64
Calendar Year Cap	42 U.S.C. 299b-22(f)(1)	2020	2021	41,120
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:	42 U.S.C. 1320(d)-5(a)			
Minimum	42 U.S.C. 1320(d)-5(a)	2020	2021	120

Civil Monetary Penalty Adjustment for Inflation

Penalty	Statutory Authority	Date of Previous Adjustment	Date of Current Adjustment	Current Penalty Level ($ Amount)
Maximum	42 U.S.C. 1320(d)-5(a)	2020	2021	60,226
Calendar Year Cap	42 U.S.C. 1320(d)-5(a)	2020	2021	1,806,757
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	42 U.S.C. 1320(d)-5(a)	2020	2021	1,205
Maximum	42 U.S.C. 1320(d)-5(a)	2020	2021	60,226
Calendar Year Cap	42 U.S.C. 1320(d)-5(a)	2020	2021	1,806,757
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:	42 U.S.C. 1320(d)-5(a)	2020	2021	
Minimum	42 U.S.C. 1320(d)-5(a)	2020	2021	12,045
Maximum	42 U.S.C. 1320(d)-5(a)	2020	2021	60,226
Calendar Year Cap	42 U.S.C. 1320(d)-5(a)	2020	2021	1,806,757
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:	42 U.S.C. 1320(d)-5(a)	2020	2021	
Minimum	42 U.S.C. 1320(d)-5(a)	2020	2021	60,226
Maximum	42 U.S.C. 1320(d)-5(a)	2020	2021	1,806,757
Calendar Year Cap	42 U.S.C. 1320(d)-5(a)	2020	2021	1,806,757

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	2020	2021	$ 20,731
Penalty for second and subsequent offenses by individuals who make an expenditure prohibited by regulations regarding lobbying disclosure:	31 U.S.C. 1352			
Minimum	31 U.S.C. 1352	2020	2021	20,731
Maximum	31 U.S.C. 1352	2020	2021	207,314
Penalty for the first time an individual fails to file or amend a lobbying disclosure form, absent aggravating circumstances.	31 U.S.C. 1352	2020	2021	20,731
Penalty for second and subsequent offenses by individuals who fail to file or amend a lobbying disclosure form, absent aggravating circumstances:	31 U.S.C. 1352			
Minimum	31 U.S.C. 1352	2020	2021	20,731
Maximum	31 U.S.C. 1352	2020	2021	207,314
Penalty for failure to provide certification regarding lobbying in the award documents for all sub-awards of all tiers:	31 U.S.C. 1352			
Minimum	31 U.S.C. 1352	2020	2021	20,731
Maximum	31 U.S.C. 1352	2020	2021	207,314
Penalty for failure to provide statement regarding lobbying for loan guarantee and loan insurance transactions:	31 U.S.C. 1352			
Minimum	31 U.S.C. 1352	2020	2021	20,731
Maximum	31 U.S.C. 1352	2020	2021	207,314
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	2020	2021	10,833
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	2020	2021	10,833

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)	2020	2021	$ 359,053
Penalty for any other person who violates safety and security procedures related to handling dangerous biological agents and toxins.	42 U.S.C. 262a(i)(1)	2020	2021	718,109
Penalty per violation for committing information blocking.	42 U.S.C. 300jj-51	2020	2021	1,094,805
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)	2020	2021	21,113
Penalty for knowingly presenting or causing to be presented a request for payment which violates the terms of an assignment, agreement, or Prospective Payment System agreement.	42 U.S.C. 1320a-7a(a)	2020	2021	21,113
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.	42 U.S.C. 1320a-7a(a)	2020	2021	31,670

Civil Monetary Penalty Adjustment for Inflation

Penalty	Statutory Authority	Date of Previous Adjustment	Date of Current Adjustment	Current Penalty Level ($ Amount)
Penalty for an excluded party retaining ownership or control interest in a participating entity.	42 U.S.C. 1320a-7a(a)	2020	2021	21,113
Penalty for remuneration offered to induce program beneficiaries to use particular providers, practitioners, or suppliers.	42 U.S.C. 1320a-7a(a)	2020	2021	21,113
Penalty for employing or contracting with an excluded individual.	42 U.S.C. 1320a-7a(a)	2020	2021	21,113
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.	42 U.S.C. 1320a-7a(a)	2020	2021	105,563
Penalty for ordering or prescribing medical or other item or service during a period in which the person was excluded.	42 U.S.C. 1320a-7a(a)	2020	2021	21,113
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.	42 U.S.C. 1320a-7a(a)	2020	2021	105,563
Penalty for knowing of an overpayment and failing to report and return.	42 U.S.C. 1320a-7a(a)	2020	2021	21,113
Penalty for making or using a false record or statement that is material to a false or fraudulent claim	42 U.S.C. 1320a-7a(a)	2020	2021	59,527
Penalty for failure to grant timely access to HHS OIG for audits, investigations, evaluations, and other statutory functions of HHS OIG.	42 U.S.C. 1320a-7a(a)	2020	2021	31,670
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)	2020	2021	5,278
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.	42 U.S.C. 1320a-7a(b)	2020	2021	5,278
Penalty for a physician who executes a document that falsely certifies home health needs for Medicare beneficiaries.	42 U.S.C. 1320a-7a(b)	2020	2021	10,556
Penalty for knowingly presenting or causing to be presented a false or fraudulent specified claim under a grant, contract, or other agreement for which the Secretary provides funding.	42 U.S.C. 1320a-7a(o)	2020	2021	10,296
Penalty for knowingly making, using, or causing to be made or used any false statement, omission, or misrepresentation of a material fact in any application, proposal, bid, progress report, or other document required to directly or indirectly receive or retain funds provided pursuant to grant, contract, or other agreement.	42 U.S.C. 1320a-7a(o)	2020	2021	51,483
Penalty for knowingly making, using, or causing to be made or used, a false record or statement material to a false or fraudulent specified claim under grant, contract, or other agreement.	42 U.S.C. 1320a-7a(o)	2020	2021	51,483
Penalty for knowingly making, using, or causing to be made or used, a false record or statement material to an obligation to pay or transmit funds or property with respect to grant, contract, or other agreement, or knowingly conceals or improperly avoids or decreases any such obligation.	42 U.S.C. 1320a-7a(o)			
Maximum for each false record statement	42 U.S.C. 1320a-7a(o)	2020	2021	53,772
Maximum per day	42 U.S.C. 1320a-7a(o)	2020	2021	10,646
Penalty for failure to grant timely access, upon reasonable request, to the I.G. for purposes of audits, investigations, evaluations, or other statutory functions of I.G. in matters involving grants, contracts, or other agreements.	42 U.S.C. 1320a-7a(o)	2020	2021	15,445
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)	2020	2021	40,282

Civil Monetary Penalty Adjustment for Inflation

Penalty	Statutory Authority	Date of Previous Adjustment	Date of Current Adjustment	Current Penalty Level ($ Amount)
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)	2020	2021	10,832
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)	2020	2021	54,157
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)	2020	2021	2,259
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)	2020	2021	11,292
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)	2020	2021	4,518
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)	2020	2021	41,120
Penalty for a Medicare Advantage organization that charges excessive premiums.	42 U.S.C. 1395w-27(g)(2)(A)	2020	2021	40,282
Penalty for a Medicare Advantage organization that improperly expels or refuses to reenroll a beneficiary.	42 U.S.C. 1395w-27(g)(2)(A)	2020	2021	40,282
Penalty for a Medicare Advantage organization that engages in practice that would reasonably be expected to have the effect of denying or discouraging enrollment.	42 U.S.C. 1395w-27(g)(2)(A)	2020	2021	161,130
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.	42 U.S.C. 1395w-27(g)(2)(A)	2020	2021	24,169
Penalty for a Medicare Advantage organization misrepresenting or falsifying information to Secretary.	42 U.S.C. 1395w-27(g)(2)(A)	2020	2021	161,130
Penalty for a Medicare Advantage organization misrepresenting or falsifying information to individual or other entity.	42 U.S.C. 1395w-27(g)(2)(A)	2020	2021	40,282
Penalty for Medicare Advantage organization interfering with provider's advice to enrollee and non-MCO affiliated providers that balance bill enrollees.	42 U.S.C. 1395w-27(g)(2)(A)	2020	2021	40,282
Penalty for a Medicare Advantage organization that employs or contracts with excluded individual or entity.	42 U.S.C. 1395w-27(g)(2)(A)	2020	2021	40,282
Penalty for a Medicare Advantage organization enrolling an individual in without prior written consent.	42 U.S.C. 1395w-27(g)(2)(A)	2020	2021	40,282
Penalty for a Medicare Advantage organization transferring an enrollee to another plan without consent or solely for the purpose of earning a commission.	42 U.S.C. 1395w-27(g)(2)(A)	2020	2021	40,282
Penalty for a Medicare Advantage organization failing to comply with marketing restrictions or applicable implementing regulations or guidance.	42 U.S.C. 1395w-27(g)(2)(A)	2020	2021	40,282
Penalty for a Medicare Advantage organization employing or contracting with an individual or entity who violates 1395w-27(g)(1)(A)-(J).	42 U.S.C. 1395w-27(g)(2)(A)	2020	2021	40,282
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)	2020	2021	14,074
Penalty for improper billing by Hospitals, Critical Access Hospitals, or Skilled Nursing Facilities.	42 U.S.C. 1395cc(g)	2020	2021	5,475
Penalty for a hospital with 100 beds or more or responsible physician dumping patients needing emergency medical care.	42 U.S.C. 1395dd(d)(1)	2020	2021	112,916
Penalty for a hospital with less than 100 beds dumping patients needing emergency medical care.	42 U.S.C. 1395dd(d)(1)	2020	2021	56,460

Civil Monetary Penalty Adjustment for Inflation

Penalty	Statutory Authority	Date of Previous Adjustment	Date of Current Adjustment	Current Penalty Level ($ Amount)
Penalty for an HMO or competitive medical plan is such plan substantially fails to provide medically necessary, required items or services.	42 U.S.C. 1395mm(i)(6)(B)(i)	2020	2021	56,460
Penalty for HMOs/competitive medical plans that charge premiums in excess of permitted amounts.	42 U.S.C. 1395mm(i)(6)(B)(i)	2020	2021	56,460
Penalty for an HMO or competitive medical plan that expels or refuses to reenroll an individual per prescribed conditions.	42 U.S.C. 1395mm(i)(6)(B)(i)	2020	2021	56,460
Penalty for an HMO or competitive medical plan that implements practices to discourage enrollment of individuals needing services in future.	42 U.S.C. 1395mm(i)(6)(B)(i)	2020	2021	225,834
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.	42 U.S.C. 1395mm(i)(6)(B)(i)	2020	2021	32,495
Penalty for a HMO or competitive medical plan that misrepresents or falsifies information to the Secretary.	42 U.S.C. 1395mm(i)(6)(B)(i)	2020	2021	225,834
Penalty for a HMO or competitive medical plan that misrepresents or falsifies information to an individual or any other entity.	42 U.S.C. 1395mm(i)(6)(B)(i)	2020	2021	56,460
Penalty for failure by HMO or competitive medical plan to assure prompt payment of Medicare risk sharing contracts or incentive plan provisions.	42 U.S.C. 1395mm(i)(6)(B)(i)	2020	2021	56,460
Penalty for HMO that employs or contracts with excluded individual or entity.	42 U.S.C. 1395mm(i)(6)(B)(i)	2020	2021	51,827
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)	2020	2021	26,125
Penalty for circumventing Stark Law's restrictions on physician self-referrals.	42 U.S.C. 1395nn(g)(4)	2020	2021	174,172
Penalty for a material misrepresentation regarding Medigap compliance policies.	42 U.S.C. 1395ss(d)(1)	2020	2021	10,832
Penalty for selling Medigap policy under false pretense.	42 U.S.C. 1395ss(d)(2)	2020	2021	10,832
Penalty for an issuer that sells health insurance policy that duplicates benefits.	42 U.S.C. 1395ss(d)(3)(A)(ii)	2020	2021	48,762
Penalty for someone other than issuer that sells health insurance that duplicates benefits.	42 U.S.C. 1395ss(d)(3)(A)(ii)	2020	2021	29,256
Penalty for using mail to sell a non-approved Medigap insurance policy.	42 U.S.C. 1395ss(d)(4)(A)	2020	2021	10,832
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)	2020	2021	54,157
Penalty for a Medicaid MCO that charges excessive premiums.	42 U.S.C. 1396b(m)(5)(B)(i)	2020	2021	54,157
Penalty for a Medicaid MCO that improperly expels or refuses to reenroll a beneficiary.	42 U.S.C. 1396b(m)(5)(B)(i)	2020	2021	216,628
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.	42 U.S.C. 1396b(m)(5)(B)(i)	2020	2021	32,495
Penalty for a Medicaid MCO misrepresenting or falsifying information to the Secretary.	42 U.S.C. 1396b(m)(5)(B)(i)	2020	2021	216,628
Penalty for a Medicaid MCO misrepresenting or falsifying information to an individual or another entity.	42 U.S.C. 1396b(m)(5)(B)(i)	2020	2021	54,157
Penalty for a Medicaid MCO that fails to comply with contract requirements with respect to physician incentive plans.	42 U.S.C. 1396b(m)(5)(B)(i)	2020	2021	48,762
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)	2020	2021	2,259
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)	2020	2021	11,292
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)	2020	2021	4,518

Civil Monetary Penalty Adjustment for Inflation

Penalty	Statutory Authority	Date of Previous Adjustment	Date of Current Adjustment	Current Penalty Level ($ Amount)
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)	2020	2021	195,047
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)	2020	2021	19,505
Penalty for knowing provision of false information by drug manufacturer with rebate agreement.	42 U.S.C. 1396r-8(b)(3)(C)(ii)	2020	2021	195,047
Penalty for notifying home and community-based providers or settings of survey.	42 U.S.C. 1396t(i)(3)(A)	2020	2021	3,901
Penalty for failing to report a medical malpractice claim to National Practitioner Data Bank.	42 U.S.C. 11131(c)	2020	2021	23,607
Penalty for breaching confidentiality of information reported to National Practitioner Data Bank.	42 U.S.C. 11137(b)(2)	2020	2021	23,607

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)	2020	2021	$ 108,315
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-year period.	21 U.S.C. 333(b)(2)(B)	2020	2021	2,210,493
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)	2020	2021	216,628
Penalty for any person who violates a requirement related to devices for each such violation.	21 U.S.C. 333(f)(1)(A)	2020	2021	29,256
Penalty for aggregate of all violations related to devices in a single proceeding.	21 U.S.C. 333(f)(1)(A)	2020	2021	1,950,461
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)	2020	2021	82,245
Penalty in the case of any other person (other than an individual) for such introduction or delivery of adulterated food.	21 U.S.C. 333(f)(2)(A)	2020	2021	411,223
Penalty for aggregate of all such violations related to adulterated food adjudicated in a single proceeding.	21 U.S.C. 333(f)(2)(A)	2020	2021	822,445
Penalty for all violations adjudicated in a single proceeding for any person who violates 21 U.S.C. 331(jj) 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)(A)	2020	2021	12,462
Penalty for each day any above violation is not corrected after a 30-day period following notification until the violation is corrected.	21 U.S.C. 333(f)(3)(B)	2020	2021	12,462
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)	2020	2021	311,563
Penalty for aggregate of all such above violations in a single proceeding.	21 U.S.C. 333(f)(4)(A)(i)	2020	2021	1,246,249
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)	2020	2021	311,563
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.	21 U.S.C. 333(f)(4)(A)(ii)	2020	2021	1,246,249

Civil Monetary Penalty Adjustment for Inflation

Penalty	Statutory Authority	Date of Previous Adjustment	Date of Current Adjustment	Current Penalty Level ($ Amount)
Penalty for aggregate of all such above violations adjudicated in a single proceeding.	21 U.S.C. 333(f)(4)(A)(ii)	2020	2021	12,462,494
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)	2020	2021	18,068
Penalty for aggregate of all such violations of tobacco product requirement adjudicated in a single proceeding.	21 U.S.C. 333(f)(9)(A)	2020	2021	1,204,504
Penalty per violation related to violations of tobacco requirements.	21 U.S.C. 333(f)(9)(B)(i)(I)	2020	2021	301,127
Penalty for aggregate of all such violations of tobacco product requirements adjudicated in a single proceeding.	21 U.S.C. 333(f)(9)(B)(i)(I)	2020	2021	1,204,504
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)	2020	2021	301,127
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)	2020	2021	1,204,504
Penalty for aggregate of all such violations related to tobacco product requirements adjudicated in a single proceeding.	21 U.S.C. 333(f)(9)(B)(i)(II)	2020	2021	12,045,044
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)	2020	2021	301,127
Penalty for aggregate of for all such above violations adjudicated in a single proceeding.	21 U.S.C. 333(f)(9)(B)(ii)(I)	2020	2021	1,204,504
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)	2020	2021	301,127
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.	21 U.S.C. 333(f)(9)(B)(ii)(II)	2020	2021	1,204,504
Penalty for aggregate above tobacco product requirement violations adjudicated in a single proceeding.	21 U.S.C. 333(f)(9)(B)(ii)(II)	2020	2021	12,045,044
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)	2020	2021	311,563
Penalty for each subsequent above violation in any 3-year period.	21 U.S.C. 333(g)(1)	2020	2021	623,125
Penalty to be applied for violations of 21 U.S.C. 387f(d)(5) or of 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	2020	2021	301
Penalty in the case of a third violation of 21 U.S.C. 387f(d)(5) or of the tobacco product regulations within a 24-month period.	21 U.S.C. 333 note	2020	2021	601
Penalty in the case of a fourth violation of 21 U.S.C. 387f(d)(5) or of the tobacco product regulations within a 24-month period.	21 U.S.C. 333 note	2020	2021	2,409
Penalty in the case of a fifth violation of 21 U.S.C. 387f(d)(5) or of the tobacco product regulations within a 36-month period.	21 U.S.C. 333 note	2020	2021	6,022
Penalty in the case of a sixth or subsequent violation of 21 U.S.C. 387f(d)(5) or of the tobacco product regulations within a 48-month period as determined on a case-by-case basis.	21 U.S.C. 333 note	2020	2021	12,045

Civil Monetary Penalty Adjustment for Inflation

Penalty	Statutory Authority	Date of Previous Adjustment	Date of Current Adjustment	Current Penalty Level ($ Amount)
Penalty to be applied for violations of 21 U.S.C. 387f(d)(5) or of 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.	21 U.S.C. 333 note	2020	2021	301
Penalty in the case of a second violation of 21 U.S.C. 387f(d)(5) or of the tobacco product regulations within a 12-month period.	21 U.S.C. 333 note	2020	2021	601
Penalty in the case of a third violation of 21 U.S.C. 387f(d)(5) tobacco product regulations within a 24-month period.	21 U.S.C. 333 note	2020	2021	1,205
Penalty in the case of a fourth violation of 21 U.S.C. 387f(d)(5) or of the tobacco product regulations within a 24-month period.	21 U.S.C. 333 note	2020	2021	2,409
Penalty in the case of a fifth violation of 21 U.S.C. 387f(d)(5) or of the tobacco product regulations within a 36-month period.	21 U.S.C. 333 note	2020	2021	6,022
Penalty in the case of a sixth or subsequent violation of 21 U.S.C. 387f(d)(5) tobacco product regulations within a 48-month period as determined on a case-by-case basis.	21 U.S.C. 333 note	2020	2021	12,045
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)	2020	2021	459,074
Penalty in the case of any other person (other than an individual) per above violation.	21 U.S.C. 335b(a)	2020	2021	1,836,294
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)	2020	2021	3,011
Penalty imposed for any related series of violations of requirements relating to electronic products.	21 U.S.C. 360pp(b)(1)	2020	2021	1,026,380
Penalty per day for violation of order of recall of biological product presenting imminent or substantial hazard.	42 U.S.C. 262(d)	2020	2021	236,071
Penalty for failure to obtain a mammography certificate as required.	42 U.S.C. 263b(h)(3)	2020	2021	18,364
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)	2020	2021	236,071

Centers for Medicare & Medicaid Services

Penalty	Statutory Authority	Date of Previous Adjustment	Date of Current Adjustment	Current Penalty Level ($ Amount)
Penalty for a hospital's non-compliance with making public standard charges for hospital items and services.	42 U.S.C. 300gg-18, 1302			
Per Day (Maximum)	42 U.S.C. 300gg-18, 1302	2020	2021	304
Penalty for a provider's non-compliance with price transparency requirements regarding diagnostic tests for COVID–19	CARES Act, Pub. L. 116-136, Section 3202(b)(2)			
Per Day (Maximum)	CARES Act, Pub. L. 116-136, Section 3202(b)(2)	2020	2021	-
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) & 1395w-2(b)(2)(A)(ii)			
Minimum	42 U.S.C. 263a(h)(2)(B) & 1395w-2(b)(2)(A)(ii)	2020	2021	6,607

Civil Monetary Penalty Adjustment for Inflation

Penalty	Statutory Authority	Date of Previous Adjustment	Date of Current Adjustment	Current Penalty Level ($ Amount)
Maximum	42 U.S.C. 263a(h)(2)(B) & 1395w-2(b)(2)(A)(ii)	2020	2021	21,663
Penalty for a clinical laboratory's failure to meet participation and certification requirements and the failure does not pose immediate jeopardy:	42 U.S.C. 263a(h)(2)(B) & 1395w-2(b)(2)(A)(ii)			
Minimum	42 U.S.C. 263a(h)(2)(B) & 1395w-2(b)(2)(A)(ii)	2020	2021	109
Maximum	42 U.S.C. 263a(h)(2)(B) & 1395w-2(b)(2)(A)(ii)	2020	2021	6,498
Penalty for a clinical laboratory's failure to meet SARS-CoV-2 test reporting requirements:	42 U.S.C. 263a(h)(2)(B) & 1395w-2(b)(2)(A)(ii)			
First day of noncompliance	42 U.S.C. 263a(h)(2)(B) & 1395w-2(b)(2)(A)(ii)	2020	2021	-
Each additional day of noncompliance	42 U.S.C. 263a(h)(2)(B) & 1395w-2(b)(2)(A)(ii)	2020	2021	-
Failure to provide the Summary of Benefits and Coverage.	45 U.S.C. 300gg-15(f)	2020	2021	1,190
Penalty for violations of regulations related to the medical loss ratio reporting and rebating.	45 U.S.C. 300gg-18	2020	2021	119
Price against hospital identified by CMS as noncompliant according to 45 CFR 182.50 with respect to price transparency requirements regarding diagnostic tests for COVID-19.	45 U.S.C. 300gg-18			
Maximum penalty per day	45 U.S.C. 300gg-18	2020	2021	-
Penalty for manufacturer or group purchasing organization failing to report information required under 42 U.S.C. 1320a-7h(a), relating to physician ownership or investment interests:	42 U.S.C. 1320a-7h(b)(1)			
Minimum	42 U.S.C. 1320a-7h(b)(1)	2020	2021	1,190
Maximum	42 U.S.C. 1320a-7h(b)(1)	2020	2021	11,905
Calendar Year Cap	42 U.S.C. 1320a-7h(b)(1)	2020	2021	178,581
Penalty for manufacturer or group purchasing organization knowingly failing to report information required under 42 U.S.C. 1320a-7h(a), relating to physician ownership or investment interests:	42 U.S.C. 1320a-7h(b)(2)			
Minimum	42 U.S.C. 1320a-7h(b)(2)	2020	2021	11,905
Maximum	42 U.S.C. 1320a-7h(b)(2)	2020	2021	119,055
Calendar Year Cap	42 U.S.C. 1320a-7h(b)(2)	2020	2021	1,190,546
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-7h(b)(2)	2020	2021	119,055
Minimum penalty for the first offense of an administrator who fails to provide notice of facility closure.	42 U.S.C. 1320a-7j(h)(3)(A)	2020	2021	595
Minimum penalty for the second offense of an administrator who fails to provide notice of facility closure.	42 U.S.C. 1320a-7j(h)(3)(A)	2020	2021	1,787
Minimum penalty for the third and subsequent offenses of an administrator who fails to provide notice of facility closure.	42 U.S.C. 1320a-7j(h)(3)(A)	2020	2021	3,571

Civil Monetary Penalty Adjustment for Inflation

Penalty	Statutory Authority	Date of Previous Adjustment	Date of Current Adjustment	Current Penalty Level ($ Amount)
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)	2020	2021	8,708
Penalty for the violation of 42 U.S.C. 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.	42 U.S.C. 1320a-8(a)(1)	2020	2021	8,212
Penalty for a representative payee (under 42 U.S.C. 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)	2020	2021	6,820
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)	2020	2021	238,110
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)	2020	2021	357,163
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)	2020	2021	238,110
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)	2020	2021	161
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	42 U.S.C. 1395i-3(h)(2)(B)(ii)(I)	2020	2021	113
Maximum	42 U.S.C. 1395i-3(h)(2)(B)(ii)(I)	2020	2021	6,774
Penalty per instance of Category 2 noncompliance by a Skilled Nursing Facility:	42 U.S.C. 1395i-3(h)(2)(B)(ii)(I)			
Minimum	42 U.S.C. 1395i-3(h)(2)(B)(ii)(I)	2020	2021	2,259
Maximum	42 U.S.C. 1395i-3(h)(2)(B)(ii)(I)	2020	2021	22,584
Penalty per day for a Skilled Nursing Facility that has a Category 3 violation of certification requirements:	42 U.S.C. 1395i-3(h)(2)(B)(ii)(I)			
Minimum	42 U.S.C. 1395i-3(h)(2)(B)(ii)(I)	2020	2021	6,888
Maximum	42 U.S.C. 1395i-3(h)(2)(B)(ii)(I)	2020	2021	22,584

Civil Monetary Penalty Adjustment for Inflation

Penalty	Statutory Authority	Date of Previous Adjustment	Date of Current Adjustment	Current Penalty Level ($ Amount)
Penalty per instance of Category 3 noncompliance by a Skilled Nursing Facility:	42 U.S.C. 1395i-3(h)(2)(B)(ii)(I)			
Minimum	42 U.S.C. 1395i-3(h)(2)(B)(ii)(I)	2020	2021	2,259
Maximum	42 U.S.C. 1395i-3(h)(2)(B)(ii)(I)	2020	2021	22,584
Penalty per day and per instance for a Skilled Nursing Facility that has Category 3 noncompliance with Immediate Jeopardy:	42 U.S.C. 1395i-3(h)(2)(B)(ii)(I)			
Per Day (Minimum)	42 U.S.C. 1395i-3(h)(2)(B)(ii)(I)	2020	2021	6,888
Per Day (Maximum)	42 U.S.C. 1395i-3(h)(2)(B)(ii)(I)	2020	2021	22,584
Per Instance (Minimum)	42 U.S.C. 1395i-3(h)(2)(B)(ii)(I)	2020	2021	2,259
Per Instance (Maximum)	42 U.S.C. 1395i-3(h)(2)(B)(ii)(I)	2020	2021	22,584
Penalty per day of a Skilled Nursing Facility that fails to meet certification requirements. These amounts represent the upper range per day:	42 U.S.C. 1395i-3(h)(2)(B)(ii)(I)			
Minimum	42 U.S.C. 1395i-3(h)(2)(B)(ii)(I)	2020	2021	6,888
Maximum	42 U.S.C. 1395i-3(h)(2)(B)(ii)(I)	2020	2021	22,584
Penalty per day of a Skilled Nursing Facility that fails to meet certification requirements. These amounts represent the lower range per day:	42 U.S.C. 1395i-3(h)(2)(B)(ii)(I)			
Minimum	42 U.S.C. 1395i-3(h)(2)(B)(ii)(I)	2020	2021	113
Maximum	42 U.S.C. 1395i-3(h)(2)(B)(ii)(I)	2020	2021	6,774
Penalty per instance of a Skilled Nursing Facility that fails to meet certification requirements:	42 U.S.C. 1395i-3(h)(2)(B)(ii)(I)			
Minimum	42 U.S.C. 1395i-3(h)(2)(B)(ii)(I)	2020	2021	2,259
Maximum	42 U.S.C. 1395i-3(h)(2)(B)(ii)(I)	2020	2021	22,584
Penalty imposed for failure to comply with infection control weekly reporting requirements at 42 CFR 483.80(g)(1) and (2):	42 U.S.C. 1395i-3(h)(2)(B)(ii)(I)			
First Occurrence	42 U.S.C. 1395i-3(h)(2)(B)(ii)(I)	2020	2021	1,012
Incremental increases for each subsequent occurrence	42 U.S.C. 1395i-3(h)(2)(B)(ii)(I)	2020	2021	506

Civil Monetary Penalty Adjustment for Inflation

Penalty	Statutory Authority	Date of Previous Adjustment	Date of Current Adjustment	Current Penalty Level ($ Amount)
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 U.S.C. 1395u(j)(2)(B), which is assessed according to 320a-7a(a).)	42 U.S.C. 1395(h)(5)(D)	2020	2021	16,449
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. 1395(i)(6)	2020	2021	4,333
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)	2020	2021	4,146
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 U.S.C. 1395u(j)(2)(B), which is assessed according to 42U.S.C. 320a-7a(a)).	42 U.S.C. 1395m(a)(11)(A)	2020	2021	16,449
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 U.S.C. 1395u(j)(2)(B), which is assessed according to 320a-7a(a)).	42 U.S.C. 1395m(a)(18)(B)	2020	2021	16,449
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 U.S.C. 1395u(j)(2)(B), which is assessed according to 1320a-7a(a)).	42 U.S.C. 1395m(b)(5)(C)	2020	2021	16,449
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 U.S.C. 1395m(a)(11)(A), that is in the same manner as 42 U.S.C. 395u(j)(2)(B), which is assessed according to 42 U.S.C. 1320a-7a(a).)	42 U.S.C. 1395m(h)(3)	2020	2021	16,449
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)	2020	2021	1,742
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 U.S.C. 1395m(j)(4) and 1395u(j)(2)(B), which is assessed according to 42 U.S.C. 1320a-7a(a).)	42 U.S.C. 1395m(j)(4)	2020	2021	16,449
Penalty for an applicable entity that has failed to report or made a misrepresentation or omission in reporting applicable information with respect to a clinical diagnostic laboratory test.	42 U.S.C. 1395m-1(a)	2020	2021	10,967
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 U.S.C. 1395m(k)(6) and 1395u(j)(2)(B), which is assessed according to 42 U.S.C. 1320a-7a(a).)	42 U.S.C. 1395m-1(a)	2020	2021	16,449

Civil Monetary Penalty Adjustment for Inflation

Penalty	Statutory Authority	Date of Previous Adjustment	Date of Current Adjustment	Current Penalty Level ($ Amount)
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 U.S.C. 1395u(b)(18)(B), which is assessed according to 1320a-7a(a).)	42 U.S.C. 1395m(l)(6)	2020	2021	16,449
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 U.S.C. 1395u(j)(2)(B), which is assessed according to 42 U.S.C. 1320a-7a(a).)	42 U.S.C. 1395u(b)(18)(B)	2020	2021	16,449
Penalty for any physician who charges more than 125% for a non-participating referral. (Penalties are assessed in the same manner as 42 U.S.C. 1320a-7a(a).)	42 U.S.C. 1395u(j)(2)(B)	2020	2021	16,449
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) of the Act. (Penalties are assessed in the same manner as 42 U.S.C. 1395u(j)(2)(B), which is assessed according to 42 U.S.C. 1320a-7a(a).)	42 U.S.C. 1395u(k)	2020	2021	16,449
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 U.S.C. 1395u(j)(2)(B), which is assessed according to 42 U.S.C. 1320a-7a(a.)).	42 U.S.C. 1395u(l)(3)	2020	2021	16,449
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 U.S.C. 1395u(j)(2)(B), which is assessed according to 42 U.S.C. 1320a-7a(a).)	42 U.S.C. 1395u(m)(3)	2020	2021	16,449
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 U.S.C. 1395u(j)(2)(B), which is assessed according to 1320a-7a(a)).	42 U.S.C. 1395u(n)(3)	2020	2021	16,449
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 U.S.C. 1395u(b)(18)(B) and 1395u(j)(2)(B), which is assessed according to 42 U.S.C. 1320a-7a(a).)	42 U.S.C. 1395u(o)(3)(B)	2020	2021	16,449
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)	2020	2021	4,333
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)	2020	2021	14,074

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, 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 U.S.C. 1395u(j)(2)(B), which is assessed according to 42 U.S.C. 1320a-7a(a).)	42 U.S.C. 1395w-4(g)(1)(B)	2020	2021	16,449
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 U.S.C. 1395u(j)(2)(B), which is assessed according to 42 U.S.C. 1320a-7a(a).)	42 U.S.C. 1395w-4(g)(3)(B)	2020	2021	16,449
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 (or has the substantial likelihood of adversely affecting) an individual covered under the organization's contract.	42 U.S.C. 1395w-27(g)(3)(A); 1857(g)(3); 1860D-12(b)(3)(E)	2020	2021	40,282
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); 1857(g)(3); 1860D-12(b)(3)(E)	2020	2021	16,113
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); 1857(g)(3): 1860D-12(b)(3)(E)	2020	2021	149,637
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)	2020	2021	9,753
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)	2020	2021	1,588
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)	2020	2021	3,484
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)	2020	2021	1,247
Penalty for any non-group health plan that fails to identify claimants who are Medicare beneficiaries and provide information to the HHS Secretary to coordinate benefits and pursue any applicable recovery claim.	42 U.S.C. 1395y(b)(8)(E)	2020	2021	1,247
Penalty for any person that fails to report information required by HHS under section 1877(f) of the Act concerning ownership, investment, and compensation arrangements.	42 U.S.C. 1395nn(g)(5)	2020	2021	20,731
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)	2020	2021	16,449
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)	2020	2021	56,459

Civil Monetary Penalty Adjustment for Inflation

Penalty	Statutory Authority	Date of Previous Adjustment	Date of Current Adjustment	Current Penalty Level ($ Amount)
Penalty for someone other than issuer that sells or issues a Medicare supplemental policy to beneficiary without a disclosure statement.	42 U.S.C. 1395ss(d)(3)(A)(vi)(II)	2020	2021	29,256
Penalty for an issuer that sells or issues a Medicare supplemental policy without disclosure statement.	42 U.S.C. 1395ss(d)(3)(A)(vi)(II)	2020	2021	48,762
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)	2020	2021	29,256
Penalty for issuer that sells or issues a Medicare supplemental policy without an acknowledgement form.	42 U.S.C. 1395ss(d)(3)(B)(iv)	2020	2021	48,762
Penalty for someone other than issuer 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)	2020	2021	29,256
Penalty for an issuer 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)	2020	2021	48,762
Penalty for someone other than issuer 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)	2020	2021	29,256
Penalty for an issuer 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)	2020	2021	48,762
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)	2020	2021	48,762
Penalty for any person that fails to provide refunds or credits as required by section 1882(r)(1)(B) of the Act.	42 U.S.C. 1395ss(r)(6)(A)	2020	2021	48,762
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)	2020	2021	20,701
Penalty for any issuer of a Medicare supplemental policy that fails to fulfill listed responsibilities.	42 U.S.C. 1395ss(t)(2)	2020	2021	48,762
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)	2020	2021	21,112
Penalty for an issuer who sells, issues, or renews a Medigap Rx policy who is a Part D enrollee.	42 U.S.C. 1395ss(v)(4)(A)	2020	2021	35,188
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)	2020	2021	4,518
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)	2020	2021	21,663
Penalty per day for home health agency's noncompliance (Upper Range):	42 U.S.C. 1395bbb(f)(2)(A)(i)	2020	2021	-
Minimum	42 U.S.C. 1395bbb(f)(2)(A)(i)	2020	2021	18,413
Maximum	42 U.S.C. 1395bbb(f)(2)(A)(i)	2020	2021	21,663
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)	2020	2021	21,663
Penalty for a home health agency's deficiency or deficiencies that cause immediate jeopardy and result in potential for harm.	42 U.S.C. 1395bbb(f)(2)(A)(i)	2020	2021	19,496

Civil Monetary Penalty Adjustment for Inflation

Penalty	Statutory Authority	Date of Previous Adjustment	Date of Current Adjustment	Current Penalty Level ($ Amount)
Penalty for an isolated incident of noncompliance in violation of established HHA policy.	42 U.S.C. 1395bbb(f)(2)(A)(i)	2020	2021	18,413
Penalty for a repeat and/or condition-level deficiency that does not constitute immediate jeopardy, but is directly related to poor quality patient care outcomes (Lower Range):	42 U.S.C. 1395bbb(f)(2)(A)(i)			
Minimum	42 U.S.C. 1395bbb(f)(2)(A)(i)	2020	2021	3,251
Maximum	42 U.S.C. 1395bbb(f)(2)(A)(i)	2020	2021	18,413
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):	42 U.S.C. 1395bbb(f)(2)(A)(i)			
Minimum	42 U.S.C. 1395bbb(f)(2)(A)(i))	2020	2021	1,084
Maximum	42 U.S.C. 1395bbb(f)(2)(A)(i)	2020	2021	2,166
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	42 U.S.C. 1395bbb(f)(2)(A)(i)	2020	2021	2,166
Maximum	42 U.S.C. 1395bbb(f)(2)(A)(i)	2020	2021	21,663
Penalty for each day of noncompliance (Maximum)	42 U.S.C. 1395bbb(f)(2)(A)(i)	2020	2021	21,663
Penalty for each day of noncompliance (Maximum)	42 U.S.C. 1395bbb(f)(2)(A)(i))	2020	2021	21,663
Penalty for PACE organization that discriminates in enrollment or disenrollment, or engages in any practice that would reasonably be expected to have the effect of denying or discouraging enrollment, on the basis of health status or the need for services.	42 U.S.C. 1395eee(e)(6)(B); 1396u-4(e)(6)(B)	2020	2021	40,282
For each individual not enrolled as a result of the PACE organization's discrimination in enrollment or disenrollment or practice that would deny or discourage enrollment:	42 U.S.C. 1395eee(e)(6)(B); 1396u-4(e)(6)(B)			
Minimum	42 U.S.C. 1395eee(e)(6)(B); 1396u-4(e)(6)(B)	2020	2021	15,177
Maximum	42 U.S.C. 1395eee(e)(6)(B); 1396u-4(e)(6)(B)	2020	2021	101,182
Penalty for a PACE organization that charges excessive premiums.	42 U.S.C. 1395eee(e)(6)(B); 1396u-4(e)(6)(B)	2020	2021	40,282
Penalty for a PACE organization misrepresenting or falsifying information to CMS or the State.	42 U.S.C. 1395eee(e)(6)(B); 1396u-4(e)(6)(B)	2020	2021	161,130
Penalty for any other violation specified in 42 CFR 460.40.	42 U.S.C. 1395eee(e)(6)(B); 1396u-4(e)(6)(B)	2020	2021	40,282
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	42 U.S.C. 1396r(h)(3)(C)(ii)(I)	2020	2021	113
Maximum	42 U.S.C. 1396r(h)(3)(C)(ii)(I)	2020	2021	6,774
Penalty per instance for a nursing facility's failure to meet Category 2 certification:	42 U.S.C. 1396r(h)(3)(C)(ii)(I)			

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)	2020	2021	2,259
Maximum	42 U.S.C. 1396r(h)(3)(C)(ii)(I)	2020	2021	22,584
Penalty per day for a nursing facility's failure to meet Category 3 certification:	42 U.S.C. 1396r(h)(3)(C)(ii)(I)			
Minimum	42 U.S.C. 1396r(h)(3)(C)(ii)(I)	2020	2021	6,888
Maximum	42 U.S.C. 1396r(h)(3)(C)(ii)(I)	2020	2021	22,584
Penalty per instance for a nursing facility's failure to meet Category 3 certification:	42 U.S.C. 1396r(h)(3)(C)(ii)(I)			
Minimum	42 U.S.C. 1396r(h)(3)(C)(ii)(I)	2020	2021	2,259
Maximum	42 U.S.C. 1396r(h)(3)(C)(ii)(I)	2020	2021	22,584
Penalty per instance for a nursing facility's failure to meet Category 3 certification, which results in immediate jeopardy:	42 U.S.C. 1396r(h)(3)(C)(ii)(I)			
Minimum	42 U.S.C. 1396r(h)(3)(C)(ii)(I)	2020	2021	2,259
Maximum	42 U.S.C. 1396r(h)(3)(C)(ii)(I)	2020	2021	22,584
Penalty per day for nursing facility's failure to meet certification (Upper Range):	42 U.S.C. 1396r(h)(3)(C)(ii)(I)			
Minimum	42 U.S.C. 1396r(h)(3)(C)(ii)(I)	2020	2021	6,888
Maximum	42 U.S.C. 1396r(h)(3)(C)(ii)(I)	2020	2021	22,584
Penalty per day for nursing facility's failure to meet certification (Lower Range):	42 U.S.C. 1396r(h)(3)(C)(ii)(I)			
Minimum	42 U.S.C. 1396r(h)(3)(C)(ii)(I)	2020	2021	113
Maximum	42 U.S.C. 1396r(h)(3)(C)(ii)(I)	2020	2021	6,774
Penalty per instance for nursing facility's failure to meet certification:	42 U.S.C. 1396r(h)(3)(C)(ii)(I)			
Minimum	42 U.S.C. 1396r(h)(3)(C)(ii)(I)	2020	2021	2,259
Maximum	42 U.S.C. 1396r(h)(3)(C)(ii)(I)	2020	2021	22,584
Penalty imposed for failure to comply with infection control weekly reporting requirements at 42 CFR 483.80(g)(1) and (2):	42 U.S.C. 1396r(h)(3)(C)(ii)(I)			
First occurrence (Minimum)	42 U.S.C. 1396r(h)(3)(C)(ii)(I)	2020	2021	1,012
Incremental increases for each subsequent occurrence	42 U.S.C. 1396r(h)(3)(C)(ii)(I)	2020	2021	506
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)	2020	2021	11,292
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)	2020	2021	11,292

Civil Monetary Penalty Adjustment for Inflation

Penalty	Statutory Authority	Date of Previous Adjustment	Date of Current Adjustment	Current Penalty Level ($ Amount)
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	42 U.S.C. 1396t(j)(2)(C)	2020	2021	2
Maximum	42 U.S.C. 1396t(j)(2)(C)	2020	2021	19,505
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)	2020	2021	40,282
Penalty for Medicaid managed care organization that imposes premiums or charges on enrollees in excess of the premiums or charges permitted.	42 U.S.C. 1396u-2(e)(2)(A)(i)	2020	2021	40,282
Penalty for a Medicaid managed care organization that misrepresents or falsifies information to another individual or entity.	42 U.S.C. 1396u-2(e)(2)(A)(i)	2020	2021	40,282
Penalty for a Medicaid managed care organization that fails to comply with the applicable statutory requirements for such organizations.	42 U.S.C. 1396u-2(e)(2)(A)(i)	2020	2021	40,282
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)	2020	2021	161,130
Penalty for 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)(ii)	2020	2021	161,130
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)	2020	2021	24,169
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)	2020	2021	22,584
Penalty for disclosing information related to eligibility determinations for medical assistance programs.	42 U.S.C. 1396w-2(c)(1)	2020	2021	12,045
Failure to comply with ACA requirements related to risk adjustment, reinsurance, risk corridors, Exchanges (including QHP standards) and other ACA Subtitle D standards; Penalty for violations of rules or standards of behavior associated with issuer compliance with risk adjustment, reinsurance, risk corridors, Exchanges (including QHP standards) and other ACA Subtitle D standards.	42 U.S.C. 18041(c)(2)	2020	2021	164
Penalty for providing false information on Exchange application.	42 U.S.C. 18081(h)(1)(A)(i)(II)	2020	2021	29,764
Penalty for knowingly or willfully providing false information on Exchange application.	42 U.S.C. 18081(h)(1)(B)	2020	2021	297,636
Penalty for knowingly or willfully disclosing protected information from Exchange:	42 U.S.C. 18081(h)(2)			
Minimum	42 U.S.C. 18081(h)(2)	2020	2021	29,764
Maximum	42 U.S.C. 18081(h)(2)	2020	2021	304
Penalties for violation of applicable Exchange standards by consumer assistance entities in Federally-facilitated Exchanges:	42 U.S.C. 18041(c)(2)			
Maximum (Per Day)	42 U.S.C. 18041(c)(2)	2020	2021	101

Grants Closeout Reporting

The Grants Oversight and New Efficiency Act (GONE Act) (Public Law 114-117) reporting requirements have expired. Nevertheless, to promote the efficient administration of HHS grants programs, all reporting entities must submit a brief high-level summary of expired, but not closed, Federal grants and cooperative agreements (awards).

Table 1: HHS Expired-but-not-Closed Awards with a Period of Performance (POP) End Date Exceeding 2 Years

CATEGORY	2-3 Years FYs 2018 - 2019	3-5 Years FYs 2017 - 2018	More than 5 Years Before FY 2016
Number of Grants/Cooperative Agreements with Zero Dollar Balances	4,417	3,646	2,085
Number of Grants/Cooperative Agreements with Undisbursed Balances	5,031	6,056	3,968
Total Amount of Undisbursed Balances	$ 2,059,102,110	$ 835,417,641	$ 1,218,057,047

HHS continues to make grants closeout a priority by effecting business process improvements and grants system enhancements to prevent the future growth of the grant closeout backlogs. When the number of grants/cooperative agreements reported in Table 1 above are totaled, HHS has 25,203 grant awards with POP end dates of September 30, 2019, or earlier that are expired but not yet closed. Table 1 above is not comparable to previous HHS Agency Financial Report (AFR) GONE Act reporting as the OMB Circular A-136 reporting parameters were modified from before September 30, 2018, to the current requirement of September 30, 2019.

HHS remains committed to addressing and remediating the complexities that prevent the closeouts of open but expired accounts. During FY 2020, an HHS project team continued its focus on open grant documents with POP end dates prior to September 30, 2017. Much of this remaining backlog is due to expired amounts permitted under appropriations law and statutory authority. This project team will continue its work into FY 2022. Additionally, HHS continues to work on the challenges related to change management and operational priorities that delay the timely closeout of eligible grant awards by utilizing further business process improvements, policy enhancements, and training initiatives identified in the FY 2020 AFR.

Payment Integrity Report

OVERVIEW

HHS takes seriously its responsibility to safeguard the integrity of its programs to better serve recipients and protect taxpayer resources. An important part of HHS's financial management environment is the continuous improvement of payment accuracy in all HHS programs. To accomplish this goal, the Department implemented various innovative solutions to prevent, detect, and reduce improper payments, while protecting beneficiaries' access to important programs.

In accordance with the *Payment Integrity Information Act of 2019* (PIIA),[25] OMB Circular A-136, *Financial Reporting Requirements*; and Appendix C of OMB Circular A-123, *Requirements for Payment Integrity Improvement*,[26] HHS's Fiscal Year (FY) 2021 Payment Integrity Report includes a discussion of the following topics:

Payment Integrity Topics	
1.0	**Program Descriptions**
2.0	**OMB Payment Categories**
3.0	**Phases of Assessments:**
3.1	**• Phase 1: Risk Assessments**
3.2	**• Phase 2: Statistically Valid Sampling Plans**
4.0	**Identifying Root Causes**
5.0	**Mitigation Strategies:**
5.1	**• Payment Integrity Efforts**
5.2	**• Corrective Action Plans**
5.3	**• Fraud Reduction Report**
6.0	**Proper, Improper, and Unknown Payments for HHS's Risk Susceptible Programs:**
6.1	**• Improper and Unknown Payment Performance FY 2021 through FY 2022**
7.0	**Improper and Unknown Payment Error Categories and Types**
8.0	**Program-Specific Reporting Information:**
8.1	**• Medicare Fee-for-Service (FFS) (Parts A and B)**
8.2	**• Medicare Advantage (Part C)**
8.3	**• Medicare Prescription Drug Benefit (Part D)**
8.4	**• Medicaid**
8.5	**• Children's Health Insurance Program (CHIP)**
8.6	**• Temporary Assistance for Needy Families (TANF)**
8.7	**• Foster Care**
8.8	**• Child Care and Development Fund (CCDF)**
8.9	**• Head Start Disaster Relief**
8.10	**• Centers for Disease Control and Prevention (CDC) Disaster Relief**
9.0	**Recovery Auditing Reporting**

[25] The President signed PIIA (Public Law No. 116-117) into law on March 2, 2020, and PIIA contains substantially similar provisions as the *Improper Payments Information Act of 2002*, as amended by the *Improper Payments Elimination and Recovery Act of 2010* and the *Improper Payments Elimination and Recovery Improvement Act of 2012*.

[26] On March 5, 2021, OMB issued M-21-19, "Transmittal of Appendix C to OMB Circular A-123, *Requirements for Payment Integrity Improvement*," which replaces M-18-20, "Transmittal of Appendix C to OMB Circular A-123, *Requirements for Payment Integrity Improvement*."

1.0 PROGRAM DESCRIPTIONS

HHS uses annual improper payment risk assessments to identify new risk-susceptible programs, which 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 programs that HHS or OMB identified as risk-susceptible and 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 are deemed to need placement outside their homes in a foster family home or a childcare facility.
CCDF	A joint federal/state program, administered by the states, that provides childcare financial assistance to low-income working families.
Head Start Disaster Relief	Supplemental appropriation for a federal program that provides comprehensive developmental services for America's low-income, preschool children ages three to five and their families.
CDC Disaster Relief	Supplemental appropriation for the response, recovery, preparation, mitigation, and other expenses directly related to the consequences of Hurricanes Harvey, Irma, and Maria.

Program-specific information on each risk-susceptible program is located throughout the Payment Integrity Report. However, because HHS is not reporting an Advance Premium Tax Credit (APTC) improper payment estimate for FY 2021, the program is not included in Section 8.0: *Program-Specific Reporting Information*. For additional information on the Department's efforts to develop an APTC improper payment measurement program, see Note 6 of Section 6.1: *Improper and Unknown Payment Performance FY 2021 through FY 2022*, specifically the Accompanying Notes for Table 1. In addition, under the *Bipartisan Budget Act of 2018* (Public Law 115-123) and the

Additional Supplemental Appropriations for Disaster Relief Requirements Act of 2017 (Public Law 115-72) (for this report, these two laws are referred to as the Disaster Relief Act), HHS received approximately $1 billion to respond to and recover from hurricanes, wildfires, and other disasters. Because funding of this type and magnitude often carries additional risk, improper payment reporting and grant expenditure requirements have been applied to these funds. Department programs that received funding and expended more than $10 million during an annual reporting period are reporting improper payment estimates in the FY 2021 Payment Integrity Report, as appropriate. Two programs—CDC Disaster Relief and Head Start Disaster Relief—established methodologies and are reporting improper payment estimates for disaster funding in FY 2021. Section 8.0: *Program-Specific Reporting Information* provides detail on each disaster relief program.

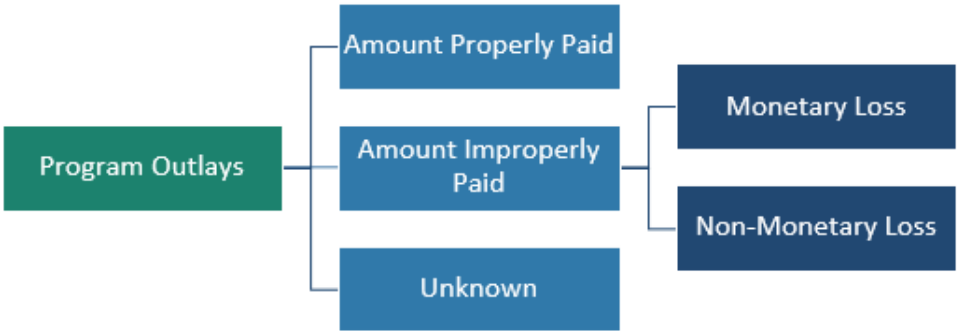
2.0 OMB PAYMENT CATEGORIES

While fraud and abuse are improper payments, not all improper payments constitute fraud, and improper payment estimates are not fraud rate estimates. HHS uses sampling and statistical methods to estimate proper payments, improper payments, and unknown payments among its programs (See **Figure 2** for an illustration of the payment categories and improper payment types). Under Appendix C to OMB Circular A-123, OMB identified two types of improper payments:

1) Monetary Loss**:** Payments to the wrong recipient, or to the correct recipient in a higher amount than what should have been disbursed, are monetary losses to the government.
2) Non-monetary Loss: There are two types of non-monetary loss improper payments: underpayments and technically improper payments. An underpayment is the difference between the amount paid and the amount due in a payment made to the right recipient for a lesser amount than they were due.

Unknown payments are instances where the reviewer cannot determine if a payment is proper or not because of insufficient payment documentation. Further, OMB guidance states that payments should be categorized as unknown if the agency is still conducting research or reviews to determine the appropriateness of the payment at the time the agency must finalize and report its estimates.

Figure 2: OMB Payment Categories



3.0 PHASES OF ASSESSMENT

Under Appendix C to OMB Circular A-123, all programs with annual outlays greater than $10 million fall into either phase 1 (subject to periodic risk assessments) or phase 2 (subject to estimation requirements), which require the varying degrees of oversight and effort described below.

3.1 PHASE 1: RISK ASSESSMENTS

As required by the PIIA and OMB guidance, HHS reviews its programs using the HHS PIIA Risk Assessment Tool to determine susceptibility to significant improper payments. The HHS PIIA Risk Assessment Tool provides for a comprehensive review and analysis of selected program operations, across a broad range of risk factors, to determine potential payment risks and risk severity. HHS follows OMB Circular A-123, Appendix C, when determining how to group programs or activities for risk assessments and when determining risk factors to examine. In FY 2021, HHS made minor updates to the risk assessment questionnaire and risk factor calculation as well as enhancements to the Risk Assessment Portal—an automated platform for collecting and processing risk assessments. HHS will continue to develop policies, procedures, and supporting tools throughout FY 2022.

For FY 2021, HHS conducted 38 improper payment risk assessments. Of these, HHS identified three programs as potentially susceptible to significant improper payments—(1) Head Start; (2) COVID-19 Claims Reimbursement to Health Care Providers and Facilities for Testing, Treatment and Vaccine Administration for the Uninsured Program (Uninsured Program); and (3) Provider Relief Fund General and Targeted Payments. HHS will work with the appropriate stakeholders to develop improper payment measurement methodologies and report improper payment estimates in the FY 2022 Payment Integrity Report (to the extent possible) for those newly identified risk-susceptible programs. For additional information on HHS programs assessed for risk of improper payments during the FY 2021 risk assessment cycle, refer to PaymentAccuracy.gov.

3.2 PHASE 2: STATISTICALLY VALID SAMPLING PLANS

All programs that reported improper payment estimates (Medicare FFS, Medicare Part C, Medicare Part D, Medicaid, CHIP, CCDF, Head Start Disaster Relief, and CDC Disaster Relief) complied with OMB guidance on sampling and estimation plans to produce a statistically valid methodology. Estimates for Medicaid, CHIP, and CCDF are based on a system of reviews wherein each state is reviewed triennially, and each year's improper payment estimate incorporates new review data for approximately one-third of states. As a result, the estimate is not based on the full population of payments for any one year, but rather on a combination of statistical samples drawn from several different years.

Medicare Part C and Medicare Part D updated their sampling and methodology plans for FY 2021. HHS endeavors to improve the improper payment estimation methodologies by reducing any potential sources of bias and enhancing sampling efficiency.

Due to COVID-19, in FY 2020, HHS exercised its enforcement discretion to temporarily suspend all improper payment related engagement, communications, and data requests from HHS to providers and state agencies as disclosed in HHS's FY 2020 AFR. HHS adjusted the sample size for the FY 2021 Medicare FFS, Medicaid, and CHIP measurement programs to account for the ongoing challenges incurred by providers, suppliers, and states during COVID-19 while continuing to maintain appropriate accountability measures and meet the statutory obligations.

In addition, HHS suspended Foster Care reviews in FY 2020 and has not resumed them since. Foster Care is assessing the impact of COVID-19 on the improper payment measurement and whether the sampling and estimation plan needs to be updated. Resuming the review process, when determined safe to do so, could result in the need to re-establish the baseline for Foster Care's improper payment measurement. Lastly, COVID-19 also affected the CCDF sampling process. Due to COVID-19, one state reviewed a smaller sample size and one state used previous sampling results in lieu of an updated measurement.

The statistical sampling and estimation processes are detailed in Section 8.0: *Program-Specific Reporting Information*.

4.0 IDENTIFYING ROOT CAUSES

A key component of the sampling, estimation, and reporting process is the identification of root causes. Once a risk-susceptible program identifies root causes, the program personnel work with stakeholders to implement corrective actions to address those root causes. Section 8.0*: Program-Specific Reporting Information* includes program-specific error category information and corrective actions that may not align with OMB Circular A-123, Appendix C's cause categories. Specifically, some HHS risk-susceptible programs have identified drivers and related corrective actions that are more detailed or program-specific than OMB's cause categories. Refer to the HHS risk-susceptible programs' submissions for FY 2021 on PaymentAccuracy.gov for information that aligns with OMB's cause categories.

5.0 MITIGATION STRATEGIES

HHS strives to improve payment integrity and prevent, reduce, and recover improper payments. HHS monitors existing corrective actions and explores innovative approaches to reducing improper and unknown payments.

5.1 PAYMENT INTEGRITY EFFORTS

In FY 2021, HHS strengthened its payment integrity efforts through prevention, enforcement, and collaboration with stakeholders. Results of the efforts are outlined in the following subsections. More detailed information on program performance and corrective actions can be found in Section 8.0: *Program-Specific Reporting Information*.

Vulnerability Collaboration Council (VCC)

To detect and combat fraud, waste, and abuse, HHS utilizes a centralized vulnerability-management process to identify, prioritize, track, and mitigate vulnerabilities that affect the integrity of federal health programs. The centralized component of this process, established in FY 2018 and known as the VCC, is comprised of Centers for Medicare & Medicaid Services (CMS) leadership and subject matter experts that work collaboratively to identify and mitigate vulnerabilities in payment and coverage policies. HHS aligned the VCC's risk-based approach with GAO's Fraud Risk Management Framework (GAO-15-593SP). In FY 2021, CMS focused on the potential vulnerabilities arising from the waivers and flexibilities that CMS issued as a result of COVID-19 as well as specific high-risk benefits and services such as durable medical equipment, prosthetics, orthotics, and supplies.

Major Case Coordination (MCC)

In FY 2018, HHS began the MCC initiative that includes representation from the HHS Office of Inspector General (OIG), United States Department of Justice (DOJ), and CMS. This initiative provides an opportunity for Medicare and Medicaid policy experts, law enforcement officials, clinicians, and fraud investigators to collaborate before, during, and after developing fraud leads. This level of collaboration contributed to several successful coordinated law enforcement actions and helped HHS to better identify national trends and program vulnerabilities that can lead to fraud and other improper payments. Since implementation of the MCC, there have been over 3,200 cases reviewed at MCC, and law enforcement partners have made over 2,000 requests for CMS to refer reviewed cases.

In FY 2020, HHS established the Medicaid MCC process, which brings together the HHS OIG, DOJ, State Medicaid Fraud Control Units (MFCU), state program integrity units, and representatives from CMS in a forum to discuss Medicaid-related law enforcement referrals. As of September 30, 2021, HHS has participated in 11 Medicaid MCCs, and law enforcement partners have made 22 requests for CMS to refer reviewed cases. The information gained from the Medicaid MCC process can also be used to identify Medicaid and CHIP vulnerabilities that can lead to

improper payments. The level of collaboration resulting from the Medicaid MCC has contributed to several successful coordinated law enforcement actions and helped HHS better identify national trends and program vulnerabilities that can lead to fraud and other improper payments.

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
- 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 FY 2021, HHS continued to add and refine models in FPS.

During FY 2021, the FPS generated alerts that resulted in 516 new leads for program integrity contractors (PICs) and augmented information for 521 existing PIC leads or investigations. The PICs reported initiating FPS-attributable actions against 778 providers in FY 2021.

Plan Program Integrity (PPI) Medicare Drug Integrity Contractor (MEDIC) and Investigations MEDIC (I-MEDIC)

As part of HHS's ongoing efforts to ensure effective oversight of the Medicare Part C and Part D programs, HHS contracts with two MEDICs: 1) the PPI MEDIC[27] and 2) the I-MEDIC. The PPI MEDIC primarily assists HHS with outreach and education support, audits of plan sponsors, and data analysis. The I-MEDIC conducts investigations of prescribers and pharmacies, recommends administrative actions, and submits case referrals to law enforcement. In FY 2021, the I-MEDIC initiated 764 investigations; submitted 20 recommendations for provider revocations; submitted 251 referrals to law enforcement, including 56 immediate advisements; and submitted 185 referrals to other entities, such as state pharmacy and medical boards, Medicare quality improvement organizations, and other Medicare contractors.

Based on the PPI MEDIC's data analysis projects and Part D plan sponsor self-audits, HHS recovered $8.68 million from Part D sponsors during the first three quarters of FY 2021.[28]

Medicaid Integrity Program

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

- Reviewing Medicaid provider activities, auditing claims, identifying overpayments, and educating providers and others on Medicaid program integrity issues; and
- Supporting and assisting state efforts to combat Medicaid provider fraud, waste, and abuse.

The Medicaid Integrity Program includes federal personnel specialized in program integrity and contractor support to states to bolster program integrity activities and collections. Increased Medicaid recoveries demonstrate HHS's continued commitment to Medicaid program integrity. Since enactment of the DRA, total state Medicaid program integrity collections (federal and state shares) have grown from $265 million in FY 2006 to $539.94 million in

[27] FY 2021 is the first full FY for the PPI MEDIC.

[28] HHS will report the full fiscal year recoveries from the PPI MEDIC's data analysis projects and Part D plan sponsor self-audits in the forthcoming Annual Report to Congress on the Medicare and Medicaid Integrity Programs.

FY 2021.[29] In addition, HHS uses DRA funding to support critical Medicaid financial management oversight activities, including reviewing quarterly state expenditure requests to ensure appropriate use of federal funds, conducting targeted state financial management reviews based on questionable claims identified through claims review processes, and working with states to recover the federal share of unallowable Medicaid expenditures.

The DRA also requires HHS to establish a 5-year Comprehensive Medicaid Integrity Plan (CMIP) that sets forth HHS's strategy to safeguard the integrity of the Medicaid program. HHS has released CMIPs since 2006. The current 5-year CMIP covers FYs 2019 through 2023 and focuses on protecting taxpayer dollars in the Medicaid program and CHIP by combatting fraud, waste, and abuse. Examples of initiatives in the current CMIP include conducting oversight of states' Payment Error Rate Measurement (PERM) corrective action plans and audits of Medicaid managed care plans' Medical Loss Ratio calculations.

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 public assistance eligibility and to detect and deter improper payments in TANF, Medicaid, Workers' Compensation, childcare related programs, and the Supplemental Nutrition Assistance Program. Provided to states at no cost, PARIS helps states strengthen program administration by allowing states to compare public assistance data between non-interoperable systems. Over the course of four quarterly matches (August 2020 to May 2021), states submitted over 285 million records for matching, and PARIS provided states with match records for an average of over 900,000 unique social security numbers each quarter.

State public assistance agencies realize cost savings in a variety of manners using PARIS data. For example:

- The Michigan Department of Health and Human Services reports its usage of the PARIS Interstate match resulted in $11.7 million in annualized cost avoidance in FY 2020.
- New York's Office of Temporary and Disability Assistance reports it used PARIS to close or remove active clients from 10,486 public assistance cases for projected cost savings of $75.1 million between April 2020 and March 2021.
- Washington State Health Care Authority's Veterans Program reports it had approximately $18.08 million in cost savings from fee-for-service claims and cessation of managed care premium payments between July 2020 and June 2021.

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 worked diligently to implement the DNP initiative. Several of HHS's OpDivs are using DNP to check for recipients' or potential recipients' eligibility for payment and to prevent improper payments. Further, U.S. Department of the Treasury (Treasury)-disbursed payments are matched against the Social Security Administration's (SSA) Death Master File (DMF); Department of Defense Death Records; Department of State Death Records; and American InfoSource Death Data (a commercial data source that sources information from funeral homes, newspapers, and county probate records) in the DNP portal daily to identify improper payments. In FY 2021, the Department screened 1 million payments against these death record databases, representing $653.9 billion. While the Department identified 32 potential improper payments over the past year through these daily matches, upon

[29] This amount may differ from that which is reported in the Annual Report to Congress on the Medicare and Medicaid Integrity Programs because the Agency Financial Report is prepared prior to the finalization of state reporting.

further investigation, HHS confirmed zero payments as improper in FY 2021. Lastly, CMS also checks certain payments against PIIA-listed databases outside of the DNP portal. In FY 2021, CMS screened 1.1 billion payments against PIIA-listed databases, representing $411 billion in payments. Through these checks, CMS stopped 396,285 payments, representing a savings of $2.5 billion.

HHS was one of the first agencies to establish a Computer Matching Agreement (CMA) with Treasury in FY 2014 and has been utilizing these data sources successfully since then to verify eligibility and stop improper payments.

5.2 Corrective Action Plans

Generally, each program develops a multi-faceted corrective action plan with various concurrent remediation efforts. Corrective actions vary by stage—from development, to piloting, to steady-state implementation, to refinement (if needed), to completion. For programs that established a baseline measurement, corrective action plans help HHS set aggressive but realistic targets for reducing improper payments with a timetable to achieve scheduled targets. The Department reviews corrective action plans annually to confirm remediation plans focus on the root causes of the improper payments and increase the likelihood that programs meet targets, reduce improper payment estimates, or perform other activities to strengthen program integrity. If targets are not met, HHS develops new strategies, adjusts staffing and other resources, and revises targets. Because corrective actions vary, are implemented on a concurrent basis, and may be implemented continuously, it can be difficult to establish key milestones and target completion dates for individual activities. Despite these challenges, HHS constantly evaluates the impact of corrective actions and refines program integrity activities as needed.

See Section 8.0: *Program-Specific Reporting Information* for each program's key corrective actions for reducing the estimated rate of improper payments. Additional information on these key and other corrective actions can also be found in the supplemental data call posted to PaymentAccuracy.gov.

5.3 Fraud Reduction Report

HHS continues to take steps, at the Department and OpDiv/StaffDiv levels, to implement fraud risk management requirements under PIIA and to adopt leading practices in fraud risk management, as presented in GAO's Fraud Risk Management Framework (GAO-15-593SP). HHS will also continue working with OMB and other agencies to implement PIIA and to further advance fraud risk management activities. Select fraud risk management activities at the Department in FY 2021 include:

- Finalizing a Fraud Risk Management Implementation Plan that outlines HHS's phased approach to establish a fraud risk management program;
- Initiating a department-level fraud risk assessment project to better understand where the Department has the most fraud risk and help target fraud prevention efforts;
- Conducting internal control assessments to include the consideration of fraud and financial management risks, in accordance with the law and OMB Circular A-123, *Management's Responsibility for Enterprise Risk Management and Internal Control*, as well as designing control activities to mitigate these risks; and
- Incorporating fraud risk in individual programs or payment activities into HHS's improper payment risk assessments.

HHS OpDivs and StaffDivs also generally manage fraud risk within other scopes of responsibility—such as yearly internal control reviews and audits; reviews of allegations involving misuse of grant or contractor funds, conflicts of interest, misconduct, or misuse; continuous monitoring of grant recipients via audit resolution, special

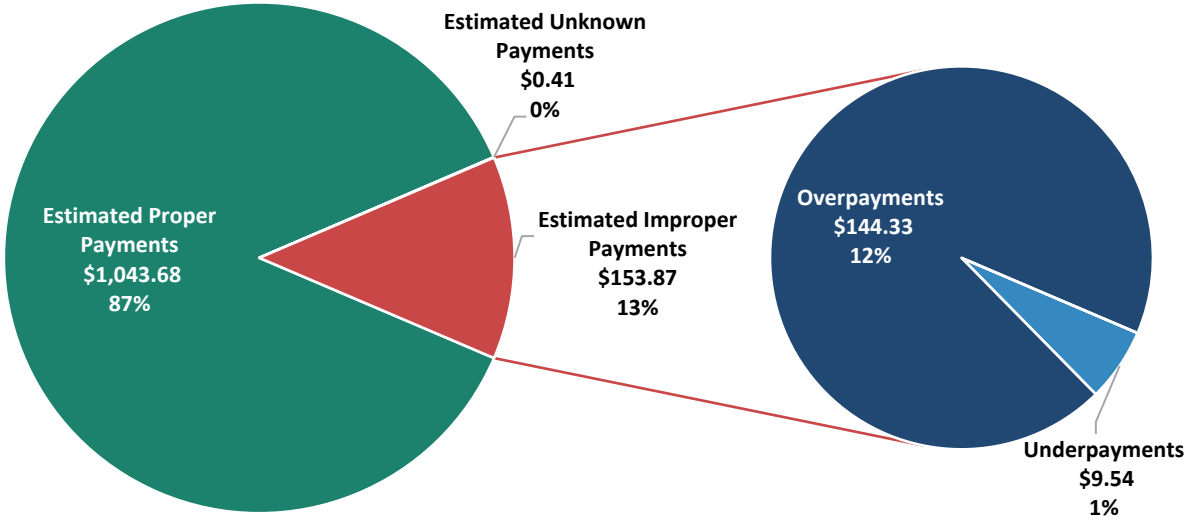
conditions/drawdown restrictions, site visits, performance reports, etc.; the use of SAM.gov (e.g., Suspension and Debarment); and other activities.

6.0 PROPER, IMPROPER, AND UNKNOWN PAYMENTS FOR HHS'S RISK SUSCEPTIBLE PROGRAMS

Overall, most of the Department's payments are proper and are made to the right recipient for the right amount. Some payments are improper and represent payments that either should not have been made or should have been made in a different amount. Some payments are unknown—as in neither demonstrably proper nor demonstrably improper. In past years, improper payment estimates included payments from three categories: overpayments, underpayments, and unknown payments. Under the latest OMB guidance (M-21-19), unknown payments are defined and reported as a category separate from improper payments (see Section 2.0 for a description of unknown payments). **Figure 3** illustrates the overpayment, underpayment, and unknown payment estimates for all of HHS's risk-susceptible programs.

Prior to FY 2021, HHS categorized all missing or insufficient documentation as unknown payments. Most of these errors are due to instances where information required for payment is missing. At the time of review, the agency did not have sufficient documentation to discern whether the payment was proper or improper. However, statute and regulation require CMS programs to document if claims are paid properly under coverage, coding, and payment rules. Therefore, HHS has always made recoveries on payments with missing or insufficient documentation for these programs even after review has ceased and multiple attempts to obtain documentation to support the payment have been made. Beginning in FY 2021, HHS now categorizes missing or insufficient documentation errors for CMS as improper payments (overpayments) due to updated guidance; and continues to pursue recovery. For ACF programs, HHS continues to categorize missing or insufficient documentation as unknown payments (that have not been recovered) since the programs still review the payment after the final estimate has been reported.

Figure 3: FY 2021 Estimated Proper, Improper, and Unknown Payments[1] (Dollar Amounts in Billions)



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

6.1 Improper and Unknown Payment Performance FY 2021 Through FY 2022

Each year, HHS reports updated payment estimates in the Payment Integrity Report. **Table 1** displays the following data, as applicable, for each risk-susceptible program:

- For FY 2021 reporting, i.e., the current year (CY):
  - Outlays (Total Payments Actually Made);
  - Estimated dollar amount ($) and rate (%) of:
    - Proper Payments (PP);
    - Improper Payments (IP);
    - Unknown Payments (UP); and
    - Improper Payments + Unknown Payments (IP + UP).
- For FY 2022 reporting, i.e., (CY+1):
  - Estimated outlays; and
  - Target amount ($) and rate (%) of Improper Payments + Unknown Payments (IP + UP).

HHS uses statistical sampling to calculate each program's estimated improper and unknown payment rates and a projected dollar amount of improper and unknown payments. **Figure 4** provides the equation for calculating the improper payment rate, and **Figure 5** provides the equation for calculating the unknown payment rate.

Figure 4: Improper Payment Rate Equation

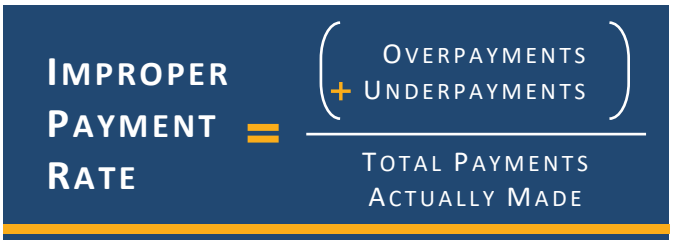
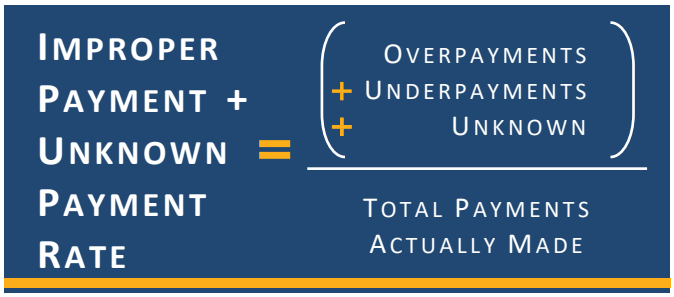


Figure 5: Unknown Payment Rate Equation

Figure 6 provides the equation for calculating the improper payment plus unknown payment rate. For programs reporting unknown payments, the term "improper payment plus unknown payment rate" used this year replaces (and is comparable to) the term "improper payment rate" used in previous years. The "improper payment rate" now only includes payments that are determined to be improper, whereas the historical "improper payment rate," reported in prior fiscal years, included what are now termed "unknown payments."

Figure 6: Improper Payment Plus Unknown Payment Rate Equation



The improper plus unknown payment rate is the official program rate and is included in **Table 1**. Lastly, **Figure 7** provides the equation for calculating the proper payment rate.

Figure 7: Proper Payment Rate Equation

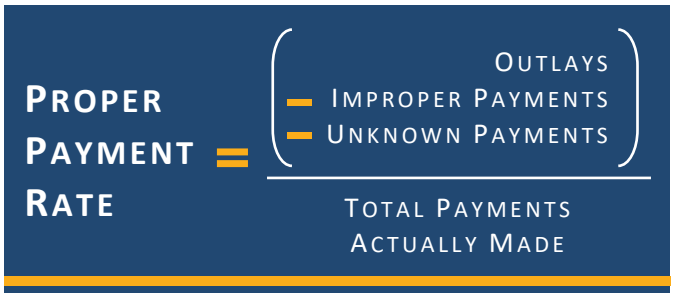


Table 1: Estimated Proper, Improper, and Unknown Payments for HHS's Risk-Susceptible Programs

FY 2021 – FY 2022 (in Millions)[1]

Program or Activity	CY Outlays $	CY PP %	CY PP $	CY IP + CY UP %	CY IP + CY UP $	CY IP %	CY IP $	CY UP %	CY UP $	CY+1 Est. Outlays $	CY+1 IP + UP %	CY+1 IP + UP $
Medicare FFS	$399,777.36 [a]	93.74	$374,743.18	6.26	$25,034.18	6.26 [2]	$25,034.18	0.00	$0.00	$382,175.81 [b]	6.16	$23,542.03
Medicare Part C	$225,603.67 [c]	89.72	$202,415.61	10.28	$23,188.06	10.28 [3]	$23,188.06	0.00	$0.00	$433,699.00 [d]	9.69	$42,025.43
Medicare Part D	$86,811.86 [e]	98.42	$85,442.62	1.58	$1,369.24	1.58	$1,369.24	0.00	$0.00	$115,818.00 [f]	1.20	$1,389.82
Medicaid	$455,175.62 [g]	78.31	$356,450.75	21.69	$98,724.88	21.69 [4]	$98,724.88	0.00	$0.00	$515,655.64 [g]	18.94	$97,665.18
CHIP	$16,879.46 [h]	68.16	$11,505.79	31.84	$5,373.68	31.84 [5]	$5,373.68	0.00	$0.00	$17,220.00 [h]	27.88	$4,800.94
APTC	$57,660.94 [i]	N/A	N/A	N/A	N/A	N/A [6]	N/A	N/A	N/A	$41,271.87 [i]	N/A	N/A
TANF	$17,150.00 [j]	N/A	N/A	N/A	N/A	N/A [7]	N/A	N/A	N/A	$17,800.00 [j]	N/A	N/A
Foster Care	$1,357.00 [k]	N/A	N/A	N/A	N/A	N/A [8]	N/A	N/A	N/A	$1,383.00 [k]	N/A [8]	N/A [8]
CCDF	$13,484.50 [l]	95.64	$12,896.14	4.36 [9]	$588.37	1.33	$179.42	3.03	$408.94	$28,385.09 [l]	N/A [10]	N/A [10]
Head Start Disaster Relief [o]	$43.31 [m]	99.91	$43.27	0.09	$0.04	0.09	$0.04	0.00	$0.00	$71.46 [m]	N/A [11]	N/A [11]
CDC Disaster Relief [o]	$182.89 [n]	99.93	$182.76	0.07	$0.13	0.07	$0.13	0.00	$0.00	$17.11 [n]	N/A [11]	N/A [11]

ACCOMPANYING NOTES FOR TABLE 1: ESTIMATED PROPER, IMPROPER, AND UNKNOWN PAYMENTS FOR HHS'S RISK-SUSCEPTIBLE PROGRAMS

a) Medicare FFS CY outlays are from the FY 2021 Medicare FFS Improper Payments Report (based on claims submitted from July 2019 – June 2020).
b) Medicare FFS CY+1 outlays are based on the *FY 2022 President's Budget*.
c) Medicare Part C CY outlays reflect 2019 Part C payments, as reported in the FY 2021 Medicare Part C Payment Error Final Report.
d) Medicare Part C CY+1 outlays are based on the *FY 2022 President's Budget*.
e) Medicare Part D CY outlays reflect 2019 Part D payments, as reported in the FY 2021 Medicare Part D Payment Error Final Report.
f) Medicare Part D CY+1 outlays are based on the *FY 2022 President's Budget*.
g) Medicaid CY outlays are based on FY 2020 expenditures, and CY+1 outlays (Medicaid - Outlays current law exclude CDC Vaccine for Children program funding) are based on the *FY 2022 President's Budget*.
h) CHIP CY outlays are based on FY 2020 expenditures, and CY+1 outlays are based on the *FY 2022 President's Budget*.
i) APTC CY and CY+1 outlays are based on the *FY 2022 President's Budget*.
j) TANF CY and CY+1 outlays are based on the *FY 2022 President's Budget* baseline (TANF total outlays including the Healthy Marriage Promotion and Responsible Fatherhood Grants programs and excluding the TANF Contingency Fund).
k) Foster Care CY and CY+1 outlays are based on the *FY 2022 President's Budget* baseline and reflect the federal share of maintenance payments.
l) CCDF CY and CY+1 outlays are based on the *FY 2022 President's Budget* baseline.
m) Head Start Disaster Relief CY outlays are from the *Bipartisan Budget Act of 2018* (Public Law 115-123), and are based on award recipient expenditures related to Hurricanes Harvey, Irma, and Maria during FY 2020, and CY+1 outlays are based on an estimated expenditure rate: (Total Appropriation, less reserve for Federal Administration, less grantee drawdowns through the period under review) divided by five expenditure years remaining through September 30, 2026.
n) CDC Disaster Relief CY outlays (based on FY 2019, FY 2020, and FY 2021 expenditures, advances, and adjustments) and CY+1 outlays are based on net difference of the total funding and accumulative outlays for FY 2021.
o) HRSA and ASPR Disaster Relief programs reported improper payment estimates in FY 2020. However, both estimates were below the OMB improper payment reporting threshold and are not included in this year's report.

1. Totals do not necessarily equal the sum of the rounded components.
2. Beginning in FY 2012, HHS consulted with OMB and 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 should have been provided as outpatient services (i.e., improper payments due to inpatient status reviews). HHS used this methodology from FY 2013 through FY 2021. 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 services provided if the Part A inpatient claim was denied and (2) 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 provided should have been outpatient services. This adjustment factor reflects the difference between the inpatient hospital claims paid under Medicare Part A and what the payment would have been had the hospital claim been properly submitted as a Medicare Part B outpatient claim. Application of the adjustment factor decreased the overall improper payment rate by 0.18 percentage points to 6.26 percent or $25.03 billion. Additional adjustment factor information is on pages 166-167 of HHS's FY 2012 AFR.
3. Beginning with FY 2021, the Part C measurement implemented refinements to the denominator methodology to only include for the calculation of the population of MA payments reviewed and at risk for diagnostic error, which led to the increase in the FY 2021 error estimate. Prior to FY 2021, the Part C denominator methodology reflected total MA payments and included some payments that were non-risk adjusted or were based on a different model resulting in a reported error biased downward, or potentially understated. More information is available in Section 8.2: *Medicare Advantage*.
4. HHS calculated and is reporting the national Medicaid estimates based on measurements conducted in FYs 2019, 2020, and 2021. The national Medicaid component improper payment estimates are: Medicaid FFS: 13.90 percent, Medicaid managed care: 0.04 percent, and Medicaid eligibility: 16.62 percent.

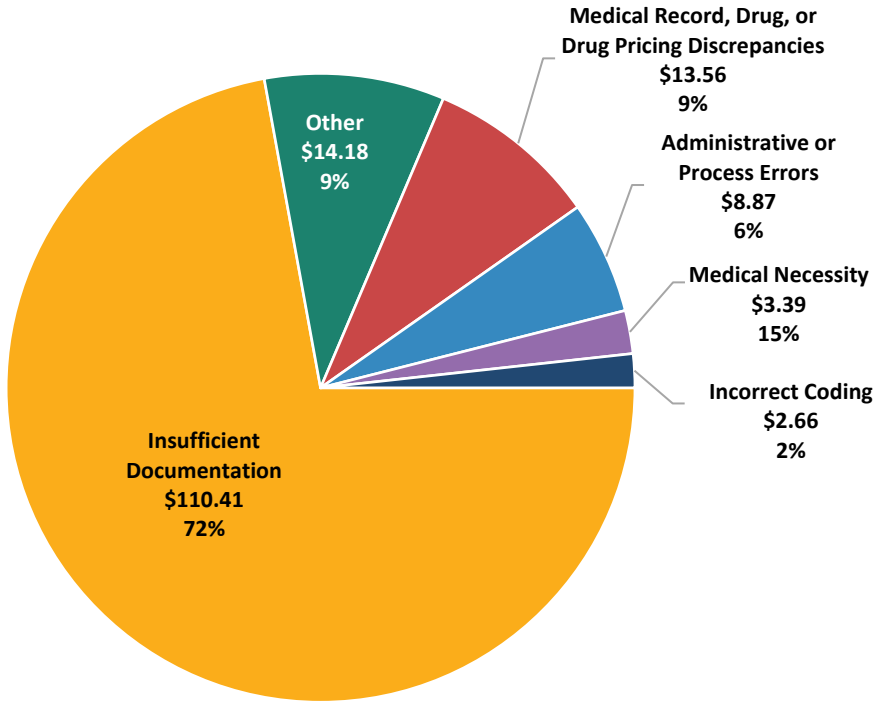
5. HHS calculated and is reporting the national CHIP estimates based on measurements conducted in FYs 2019, 2020, and 2021. The national CHIP component improper estimates are: CHIP FFS: 13.67 percent, CHIP managed care: 0.48 percent, and CHIP eligibility: 28.71 percent.
6. In FY 2021, the Department commenced the improper payment measurement program for the Federally-facilitated Exchange and anticipates reporting an improper payment estimate for the Federally-facilitated Exchange in the FY 2022 AFR. HHS continues to develop the improper payment measurement methodology for the State-based Exchanges and will continue to update the AFR with the measurement program development status. As with similar HHS programs, developing an effective and efficient improper payment measurement program requires multiple time-intensive steps, including contractor procurement; developing measurement policies, procedures, and tools; and extensive pilot testing to ensure an accurate improper payment estimate.
7. The TANF program is not reporting estimates for FY 2021. As discussed in Section 8.6: *TANF*, statutory limitations preclude HHS from requiring states to participate in a TANF improper payment measurement.
8. Foster Care is not reporting an error rate for FY 2021 or a CY+1 improper payment plus unknown payment target for FY 2022. Given the impact of COVID-19, HHS is uncertain when it will be safe to resume conducting onsite Title IV-E Reviews and how many states will be newly reviewed in time for the FY 2022 improper payment reporting cycle. Considering this uncertainty, as well as the unknown impact of the recent programmatic changes on the improper payment rate, HHS has chosen not to set an improper payment plus unknown payment reduction target for FY 2022.
9. The term "improper payment plus unknown payment rate" used this year replaces (and is comparable to) the term "improper payment rate" used in previous years. The "improper payment rate" now only includes payments that are determined to be improper, whereas the historical "improper payment rate," reported in prior fiscal years, included what are now termed "unknown payments."
10. CCDF is not reporting a CY+1 improper payment plus unknown payment reduction target for FY 2022. The *Child Care and Development Block Grant Act of 2014* (CCDBG) and CCDF regulations (2016) required states to create and adopt new policies and procedures. State grantees have been implementing large-scale changes to their childcare programs and HHS anticipated that the improper payment rate could be affected as states work to meet the new requirements. HHS anticipated reestablishing the baseline and setting a reduction target in FY 2022, however, limitations and restrictions due to COVID-19 impacted states' abilities to complete planned actions as states were granted needed flexibility. For these reasons, HHS delayed establishment of a baseline estimate in FY 2021. The effects of COVID-19 will continue to impact the improper payment rate in the FY 2022 measurement and beyond, making it challenging to determine a target rate.
11. Head Start and CDC Disaster Relief programs are not reporting CY+1 improper payment plus unknown payment reduction targets for FY 2022 since they are below the statutory threshold for reporting estimates.

7.0 IMPROPER AND UNKNOWN PAYMENT ERROR CATEGORIES AND TYPES

Figure 8 below displays HHS's FY 2021 main error categories for all of HHS's risk-susceptible programs. Refer to the HHS risk-susceptible programs' submissions for FY 2021 on PaymentAccuracy.gov for information that aligns with OMB's cause categories.

Section 8: *Program-Specific Reporting Information* provides additional information on the error categories and corrective actions for individual programs.

Figure 8: FY 2021 Improper and Unknown Payment Error Categories for HHS's Risk-Susceptible Programs[1] (Dollar Amounts in Billions)



[1] No Documentation and Unsupported and Excessive Fringe Benefit Costs each accounted for less than 1 percent of HHS's improper payments ($1.21 billion and $0.13 million, respectively) and, thus, were not included in Figure 8. In addition, due to rounding, amounts in this figure may not add up precisely to other tables in this document.

HHS's FY 2021 estimated improper payments are distributed between overpayments (monetary loss) and underpayments (non-monetary loss) for each program, as displayed in **Table 2** below. The total amount of overpayments also includes improper payments due to missing or insufficient documentation that do not necessarily represent monetary loss. See *Section 6.0: Proper, Improper, and Unknown Payments for HHS's Risk Susceptible Programs* for more detail on improper payments due to missing or insufficient documentation.

Table 2: Estimated Improper Payments by Program

FY 2021 (in Millions)

	Overpayments[1]		Underpayments	
Program or Activity	Amount	Percent of Total Payments	Amount	Percent of Total Payments
Medicare FFS	$24,584.87	**6.15%**	$449.31	**0.11%**
Medicare Part C	$15,182.20	**6.73%**	$8,005.86	**3.55%**
Medicare Part D	$686.49	**0.79%**	$682.75	**0.79%**
Medicaid	$98,357.37	**21.61%**	$367.51	**0.08%**
CHIP	$5,371.99	**31.83%**	$1.68	**0.01%**
CCDF	$142.25	**1.05%**	$37.17	**0.28%**
Head Start Disaster Relief	$0.04	**0.09%**	$0.00	**0.00%**
CDC Disaster Relief	$0.13	**0.07%**	$0.00	**0.00%**
Total [2]	**$144,325.34**	**12.05%**	**$9,544.28**	**0.80%**

[1] See *Section 8.0: Program-Specific Reporting Information* for more detail on each program's error categories.

[2] Totals do not necessarily equal the sum of the rounded components.

8.0 PROGRAM-SPECIFIC REPORTING INFORMATION

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

8.1 MEDICARE FFS (PARTS A AND B)

Medicare FFS Statistical Sampling Process

HHS uses the Comprehensive Error Rate Testing (CERT) program to estimate 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's policies on coverage, coding, and billing. **Figure 9** below depicts the CERT process.

Figure 9: 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).

In response to COVID-19, the CERT program stopped sending documentation request letters to or conducting phone calls with providers or suppliers to request medical documentation for claims in the FY 2021 report period (claims submitted July 1, 2019 through June 30, 2020). As a result, the FY 2021 rate reflects CERT program processes that had a four-month pause in contacting providers and suppliers for documentation and an adjusted sample size. Lastly, the waivers and flexibilities provided by HHS for providers and suppliers during COVID-19 apply to claims in the fourth quarter of FY 2021 report period.

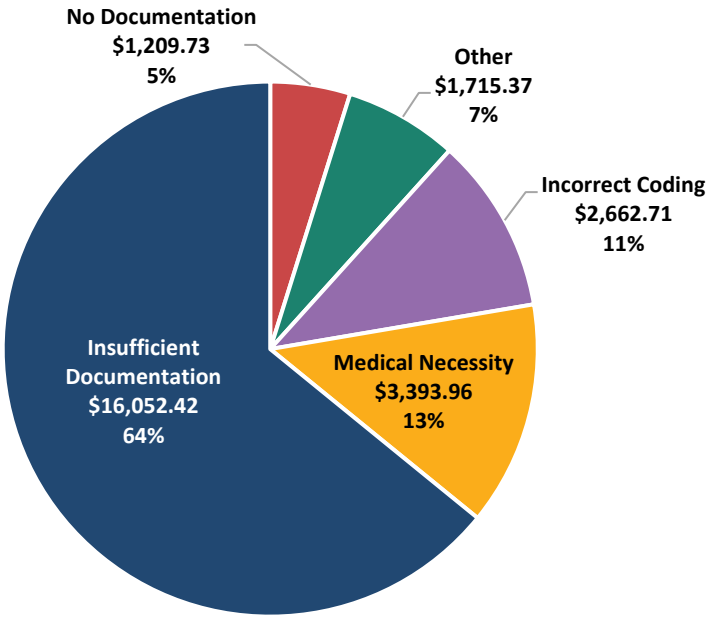
HHS sampled approximately 42,000 claims during the FY 2021 report period. The rate estimated from this sample reflects all claims processed by the Medicare FFS program during the report period. Additional information on the Medicare FFS improper payment methodology is on pages 166-167 of HHS's FY 2012 AFR.

Calculations and Findings

Medicare FFS properly paid an estimated 93.74 percent of total outlays or $374.74 billion in FY 2021. The improper payment estimate for FY 2021 is 6.26 percent of total outlays or $25.03 billion. The improper payment estimate due to lacking or insufficient documentation is 4.32 percent or $17.26 billion, representing 68.95 percent of total improper payments.

Most CERT error categories are more detailed than OMB cause categories to help generate useful information regarding HHS improper payments. **Figure 10** shows the percent of improper payments and improper payment dollars associated with each CERT error category.

Figure 10: FY 2021 Medicare FFS Estimated Improper Payments by Type of CERT Error[1]
(Dollar Amounts in Millions)



[1] Figure may not equal 100 percent or add up precisely to other tables in this document due to rounding.

Improper payments for hospital outpatient, SNF, home health, and hospice claims were major contributing factors to the FY 2021 Medicare FFS estimate, comprising 38.34 percent of the overall estimate. While the factors

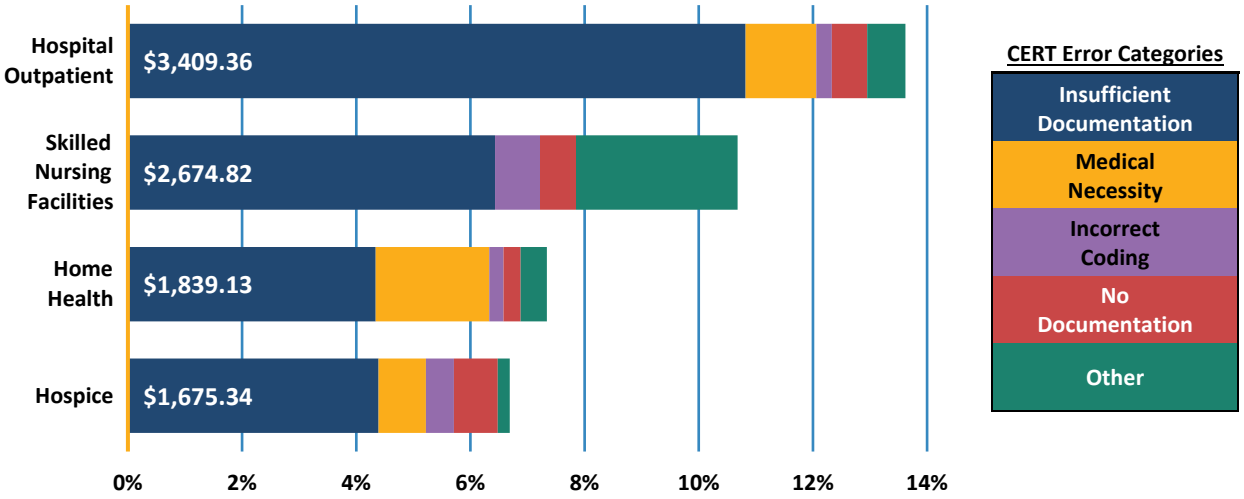
contributing to improper payments are complex and vary by year, the primary causes continue to be insufficient documentation and medical necessity errors as described in the following four driver service areas: [30]

- **Hospital Outpatient:** Insufficient documentation continues to be the major error reason for hospital outpatient claims. The improper payment estimate for hospital outpatient claims increased from 4.02 percent in FY 2020 to 4.57 percent in FY 2021; the change is not statistically significant. The primary reason for these errors is missing documentation to support the order, or the intent to order for certain services. (42 United States Code [U.S.C.] §1395y, 42 Code of Federal Regulations [CFR] §410.32).
- **SNF:** Insufficient documentation continues to be the major error reason for SNF claims. The improper payment estimate for SNF claims increased from 5.43 percent in FY 2020 to 7.79 percent in FY 2021. The primary reason for these errors is missing or insufficient documentation to support certification or recertification. Medicare coverage of SNF services requires certification and recertification for these services (42 CFR §424.20).
- **Home Health:** Insufficient documentation for home health claims continues to be prevalent. The improper payment estimate for home health claims increased from 9.30 percent in FY 2020 to 10.24 percent in FY 2021; the change is not statistically significant. The primary reason for these errors is missing or insufficient documentation to support the certification of home health eligibility requirements. Medicare coverage of home health services requires physician certification of the beneficiary's eligibility for the home health benefit (42 CFR §424.22).
- **Hospice:** Insufficient documentation is the major error reason for hospice claims. The improper payment estimate for hospice claims increased from 6.69 percent in FY 2020 to 7.77 percent in FY 2021; the change is not statistically significant. The primary reason for these errors is missing or insufficient documentation to support certification or recertification. Medicare coverage of hospice services requires physician certification that the individual is terminally ill (42 CFR §418.22) and must meet all coverage criteria (42 CFR §418.200).

Most CERT error categories are more detailed than OMB cause categories to help generate useful information regarding HHS improper payments. **Figure 11** shows the FY 2021 Medicare FFS drivers for hospital outpatient, SNF, home health, and hospice claims by CERT error category.

[30] Although increases and decreases are identified, some are not statistically significant. An increase or decrease estimated from a statistical sample is said to be "not statistically significant" if the estimate's margin of error is too wide to conclude that the improper payment rate is different from the previous year.

Figure 11: FY 2021 Medicare FFS Service Areas with the Largest Estimated Improper Payment Dollar Amounts: Percentage Share of Medicare FFS Improper Payments by CERT Error Category (Dollar Amounts in Millions)



Medicare FFS Corrective Action Plan

HHS addresses improper payments in Medicare FFS through various corrective actions. HHS's aggressive corrective actions have led to consistent reductions in the Medicare FFS rate since 2014. HHS achieved this reduction through commitment and steadfast efforts to identify the root causes, implement action plans to reduce and prevent improper and unknown payments, and extend our capacity to address emerging areas of risk through workgroups and interagency collaborations. The following sections discuss key HHS corrective actions to address drivers and other service area errors. Corrective actions with an asterisk (*) indicate that HHS temporarily paused, limited, and/or altered the corrective action in FY 2021 due to COVID-19.

Corrective Actions to Address Service Areas

HHS developed and refined multiple preventive and detective measures for specific service areas with high improper payment estimates, such as hospital outpatient, SNF, home health, hospice, and other areas. HHS believes implementing targeted corrective actions will prevent and reduce improper payments in these areas and reduce the overall improper payment estimate. Below is a description of three key corrective actions that address most of these areas with high improper payment estimates.

Key Corrective Actions Across Service Areas	
Corrective Action	**Description**
Medical Review/Targeted Probe and Educate (TPE)*	In FY 2021, Medicare Administrative Contractors (MACs) primarily conducted service-specific post-payment medical reviews, limited the number of requests for providers, and allowed extensions to providers who had difficulty submitting documentation due to COVID-19. As of September 1, 2021, HHS reinstated the TPE process[31] but continued to offer extensions, as needed. The TPE process consists of up to three rounds of review of 20-40 claims per round, with one-on-one education provided at the end of each round. HHS uses medical review/TPE in the hospital outpatient, IRF, SNF, home health, hospice, and DMEPOS service areas.

[31] See the CMS website for additional information on TPE.

Key Corrective Actions Across Service Areas	
Corrective Action	**Description**
Supplemental Medical Review Contractor (SMRC) Reviews*	In FY 2021, the SMRC conducted Medicare FFS reviews on a post-payment basis for hospital outpatient, IRF, SNF, hospice, and DMEPOS claims. The SMRC limited the number of requests for providers and allowed extensions to providers who had difficulty submitting the documentation due to COVID-19. The SMRC shares medical review results with the MACs for claim adjustments upon review completion. The providers receive detailed SMRC review result letters and MAC demand letters for overpayment recovery, which include educational information regarding what was incorrect in the original billing of the claim.
Recovery Audit Contractor (RAC) Reviews*	During FY 2021, Medicare FFS RACs identified and collected improper payments related to hospital outpatient, IRF, SNF, home health, and DMEPOS claims for several factors, including insufficient documentation and medical necessity, if appropriate. The RACs limited the number of requests for providers and allowed extensions to providers who had difficulty submitting the documentation due to COVID-19.

Service Area: Hospital Outpatient

HHS implemented corrective actions for payment errors related to hospital outpatient services resulting from missing or insufficient medical record documentation and medical necessity issues. In addition to the key corrective actions across service areas, key hospital outpatient corrective actions include:

Key Hospital Outpatient Corrective Actions	
Corrective Action	**Description**
Outpatient Prior Authorization	In FY 2021, HHS added Implanted Spinal Neurostimulators and Cervical Fusion with Disc Removal to the nationwide prior authorization process for hospital outpatient department (OPD) services, which was finalized as part of Calendar Year 2021 Outpatient Prospective Payment System/Ambulatory Surgical Center (OPPS/ASC) Final Rule (CMS-1736-FC). Effective July 1, 2021, HHS added these two services to the existing list of services requiring prior authorization, which include Blepharoplasty, Botulinum Toxin Injection, Rhinoplasty, Panniculectomy, and Vein Ablation, as finalized in the Calendar Year 2020 OPPS/ASC Final Rule (CMS-1717-FC). [32] This process serves as a method for controlling unnecessary increases in the volume of these seven groups of services. In FY 2021, HHS provisionally affirmed (approved) 104,194 services through this process.
Medical Review/TPE for Hospital Outpatient *	For TPE description, see related corrective action above in Key Corrective Actions Across Service Areas section. In FY 2021, MACs reviewed approximately 4,446 Hospital Outpatient providers on a service-specific post-payment basis.
SMRC Hospital Outpatient Reviews*	For SMRC description, see related corrective action above in Key Corrective Actions Across Service Areas section. In FY 2021, the SMRC performed medical reviews on a post-payment basis for hospital outpatient claims, such as Electrodiagnostic Testing, Spinal Cord Stimulator, Outpatient Hyperbaric Oxygen (HBO) services, Polysomnography services Intravenous Immunoglobulin (IVIG), Specimen Validity Urine Testing, Vitamin D Testing, Botulinum Toxins, Therapy (Physical, Occupational, and Speech-language), Carotid Artery Screening, Audio-Only Telehealth, and Transforaminal Epidural Injections (TEI).
RAC Outpatient Reviews*	During FY 2021, Medicare FFS RACs identified and collected improper payments related to outpatient claims for several factors, including insufficient documentation. 36.1 percent of all Medicare FFS RAC collections were from hospital outpatient overpayments.

[32] Refer to the CMS website for additional information on Prior Authorization for Certain Hospital Outpatient Department Services.

Service Area: Skilled Nursing Facilities

HHS implemented corrective actions for payment errors related to SNF services resulting from missing or insufficient medical record documentation. In addition to key corrective actions across service areas, key SNF corrective actions include:

Key SNF Corrective Actions	
Corrective Action	**Description**
SMRC SNF Reviews*	For SMRC description, see related corrective action above in Key Corrective Actions Across Service Areas section. In FY 2021, the SMRC continued performing medical review activities related to post-payment review of SNF claims.
RAC SNF Reviews*	In FY 2021, Medicare FFS RACs identified and collected improper payments related to SNF claims for several factors, including medical necessity and insufficient documentation. 8.3 percent of all Medicare FFS RAC collections were from SNF overpayments.

Service Area: Home Health

HHS implemented corrective actions for payment errors related to home health services, including errors resulting from missing or insufficient documentation. In addition to the key corrective actions across service areas, key home health corrective actions include:

Key Home Health Corrective Actions	
Corrective Action	**Description**
Review Choice Demonstration for Home Health Services*	The Review Choice Demonstration for Home Health Services gives 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. In FY 2021, the demonstration was ongoing for providers in Illinois, Ohio, and Texas. HHS phased in participation for providers in North Carolina and Florida to help ease the transition during COVID-19. Effective September 1, 2021, HHS discontinued the phased-in participation for North Carolina and Florida providers and moved to full implementation. In FY 2021, HHS provisionally affirmed (approved) 1,603,801 billing periods for home health services.
Medical Review/ TPE for Home Health Agencies (HHAs)	For TPE description, see related corrective action above in Key Corrective Actions Across Service Areas section. In FY 2021, MACs reviewed approximately 4,039 HHA providers on a service-specific post-payment basis.
Elimination of Home Health Requests for Anticipated Payment	As part of the Calendar Year 2021 Payment and Policy Changes for Home Health Agencies and Calendar Year 2021 Home Infusion Therapy Benefit (CMS-1711-FC), HHS issued a final rule to (1) decrease the upfront, split-percentage payment for 30-day home health periods of care beginning on January 1, 2020 to 20 percent for existing HHAs, and (2) lower the split-percentage payments to zero for all 30-day periods of care beginning on or after January 1, 2021. Newly enrolled HHAs already were not receiving split-percentage payments for periods of care beginning on or after January 1, 2020.

Service Area: Hospice

HHS implemented corrective actions for payment errors related to hospice services resulting from missing or insufficient medical record documentation. In addition to the key corrective actions across service areas, key hospice corrective actions include:

Key Hospice Corrective Actions	
Corrective Action	**Description**
Medical Review/TPE for Hospice*	For TPE description, see related corrective action above in Key Corrective Actions Across Service Areas section. In FY 2021, MACs reviewed 1,419 hospice providers on a service-specific post-payment basis.
SMRC Hospice Reviews*	For SMRC description, see related corrective action above in Key Corrective Actions Across Service Areas section. In FY 2021, the SMRC continued medical reviews on a post-payment basis for hospice claims such as general inpatient levels of care, services provided in a SNF, and services provided in an Assisted Living Facility. These reviews included hospice services associated with certain diagnoses and hospices that do not provide all levels of hospice care.
RAC Hospice Reviews*	In FY 2021, HHS authorized Medicare FFS RACs to identify and collect improper payments related to hospice claims for several factors, including physician services during hospice and continuous home care medical necessity and documentation requirements.

Service Area: 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 corrective actions. In addition to key corrective actions across service areas, key other service area corrective actions include:

Key Other Service Area Corrective Actions	
Corrective Action	**Description**
DMEPOS Prior Authorization*	HHS continued the prior authorization of 40 Power Mobility Devices and five Pressure Reducing Support Surface codes. On December 1, 2020, HHS expanded a prior authorization requirement for six Lower Limb Prosthetic codes nationwide. HHS initially required prior authorization of these codes beginning September 1, 2020 in California, Michigan, Pennsylvania, and Texas. Due to COVID-19, HHS delayed nationwide expansion of the prior authorization of these codes. In FY 2021 HHS provisionally affirmed (approved) 54,953 DMEPOS items through the prior authorization process. HHS expects to require prior authorization on additional items in FY 2022.
Ambulance Transport Prior Authorization*	In FY 2021, HHS continued a prior authorization model for repetitive scheduled non-emergent ambulance transport in New Jersey, Pennsylvania, South Carolina, North Carolina, Virginia, West Virginia, Maryland, the District of Columbia, and Delaware. On November 20, 2020, HHS published a Federal Register Notice announcing nationwide expansion of the model, as the model has met all expansion criteria under section 1834(l)(16) of the Act (as added by section 515(b) of the *Medicare Access and CHIP Reauthorization Act of 2015* [Public Law 114-10] [MACRA]). On August 27, 2021, HHS published an additional Federal Register Notice announcing the implementation dates for all remaining states and territories for the national expansion. HHS delayed implementation of the expansion to additional states due to COVID-19. Based on data from New Jersey, Pennsylvania, and South Carolina spending decreased from an average of $18.9 million to an average of $6.0 million per month. Based on data from North Carolina, Virginia, West Virginia, Maryland, the District of Columbia, and Delaware, spending decreased from an average of $5.7 million to an average of $2.6 million per month.

Key Other Service Area Corrective Actions	
Corrective Action	**Description**
Medical Review/TPE for IRF and Durable Medical Equipment (DME)*	For TPE description, see related corrective action above in Key Corrective Actions Across Service Areas section. In FY 2021, MACs reviewed 120 IRF providers and 23,666 DME suppliers on a service-specific post-payment basis.
SMRC DME Reviews*	For SMRC description, see related corrective action above in Key Corrective Actions Across Service Areas section. In FY 2021, the SMRC performed medical reviews on a post-payment basis for DME claims, such as Trans-Cutaneous Electrical Nerve Stimulation (TENS) units and Therapeutic Shoes for Diabetics.
RAC DME Reviews*	During FY 2021, the national Medicare FFS DME RAC conducted 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 if items/services billed were rendered. The DME RAC also conducted automated DME reviews for inappropriate unbundling, excessive units billed, and if the DME items billed were medically necessary.
DMEPOS Supplier Education	HHS educated providers and DMEPOS suppliers through Medicare Learning Network (MLN) articles called Provider Compliance Tips. HHS posted three articles, each on a different DMEPOS-related service area, to the MLN website in FY 2021. These Provider Compliance Tips are updated regularly because of improper payment findings, as well as regulatory and other policy changes, including the Calendar Year 2021 ESRD and DMEPOS Final Rule (CMS-1713-F).
Automated Edits	Due to the high volume of Medicare claims processed by HHS daily and the significant cost associated with conducting medical reviews 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 prevent payment for many erroneous claims through these efforts. HHS also uses the National Correct Coding Initiative (NCCI) to prevent inappropriate payments of Medicare Part B claims and Medicaid claims. For example, this program prevents payments for services such as the repair of an organ by two different methods. HHS will report FY 2021 savings from the NCCI edits in the forthcoming Annual Report to Congress on the Medicare and Medicaid Integrity Programs.
Provider and Supplier Screening*	Existing Medicare Providers and Suppliers: HHS revalidates all existing Medicare providers and suppliers on an ongoing basis to confirm that only qualified and legitimate providers and suppliers deliver health care items and services to Medicare beneficiaries. HHS's provider screening and enrollment initiatives have had a significant impact on removing ineligible providers and suppliers from the Medicare program. HHS manages close to 2.6 million distinct Medicare enrollments through the Provider Enrollment, Chain, and Ownership System (PECOS). In FY 2021, HHS performed 239,009 initial enrollment screenings, deactivated 123,388 enrollments, and revoked 2,291 enrollments. HHS paused revalidation efforts in FY 2021 due to COVID-19 and expects to resume revalidation in FY 2022.
	New Medicare Providers and Suppliers: HHS uses three levels of provider and supplier enrollment risk-based screening: limited, moderate, and high. Providers and suppliers in the "limited" risk category undergo verification of licensure and a wide range of database checks to confirm compliance with all provider- or supplier-specific requirements. Providers and suppliers in the "moderate" risk category are subject to unannounced site visits in addition to all the requirements in the "limited" screening level. Providers and suppliers in the "high" risk category are subject to fingerprint-based criminal background checks (FCBC) in addition to all requirements in the "limited" and "moderate" screening levels. In FY 2021, HHS conducted 29,618 site visits for non-DME Medicare FFS providers and suppliers, and 13,240 site visits for

Key Other Service Area Corrective Actions	
Corrective Action	**Description**
	Medicare DME suppliers. This work resulted in 225 revocations due to non-operational site visit determinations for all providers and suppliers. In FY 2021, HHS paused FCBCs due to COVID-19 and expects to resume these checks in FY 2022.
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 2021, HFPP membership grew from 172 to 222 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 SNF, hospital outpatient claims, IRF, and home health.
Overpayment Recoveries Related to Regulatory Provisions	In the Medicare Reporting and Returning of Self-Identified Overpayments (CMS-6037-F) final rule, HHS required providers and suppliers to identify, report, and return self-identified Medicare Part A or Part B overpayments. This rule incentivizes providers and suppliers to maintain documentation and submit accurate claims, reducing potential improper payments.
SMRC Reviews*	For SMRC description, see related corrective action above in Key Corrective Actions Across Service Areas section. In FY 2021, the SMRC performed post-payment reviews on multiple areas, such as Audio-Only Telehealth, Spinal Cord Stimulator, IRF services, Specimen Validity, Botulinum Toxin, IVIG, and TEI.
Medical Review Accuracy Award Fee Metric	HHS includes the Medical Review Accuracy Award Fee Metric in the Award Fee Plan for MACs that process Part A, Part B, and DME claims. This 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 FY 2021 project goals included identifying unclear and/or burdensome policy requirements that can be clarified or simplified to prevent unnecessary denials. HHS continues to work on implementing 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	HHS issued Comparative Billing Reports for these topics: Orthoses (Referring Providers); Intensity-Modulated Radiation Therapy; Initial Preventive Physical Examinations and Annual Wellness Visits; Comprehensive Eye Examinations; Chronic Care Management; Critical Care; Wound Debridement; COVID-19 Impact on Telehealth; and Drugs of Abuse Testing.

8.2 MEDICARE ADVANTAGE (PART C)

Medicare Advantage (MA) Statistical Sampling Process

The Part C Improper Payment Measurement (IPM) methodology estimates improper payments resulting from errors in beneficiary risk scores. The primary component of most beneficiary risk scores is clinical diagnoses (the CMS Hierarchical Condition Category [CMS-HCC]) submitted by the MA plan. If medical records do not support the diagnoses or CMS-HCC, submitted to HHS, the risk scores may be inaccurate and result in payment errors.

In FY 2021, HHS selected a stratified random sample of beneficiaries with a risk adjusted payment in Calendar Year 2019 and reviewed medical records of the diagnoses submitted by plans for the sample beneficiaries. The Part C

IPM (see **Figure 12** below) calculates the beneficiary risk score error and extrapolates that beneficiary-level error to the population subject to risk adjustment, resulting in a Part C gross payment error amount.

In FY 2021, HHS implemented refinements to the denominator methodology to only include the population of MA payments reviewed and at risk for diagnostic error, which led to the increase in the FY 2021 error estimate. For prior years, the Part C denominator methodology reflected total MA payments, and included some payments that were non-risk adjusted or based on a different model resulting in a reported error rate that was biased downward, or potentially understated. Therefore, the FY 2021 reporting year is a baseline and should not be compared with prior reporting years.

Figure 12: Part C Improper Payment Measurement Process

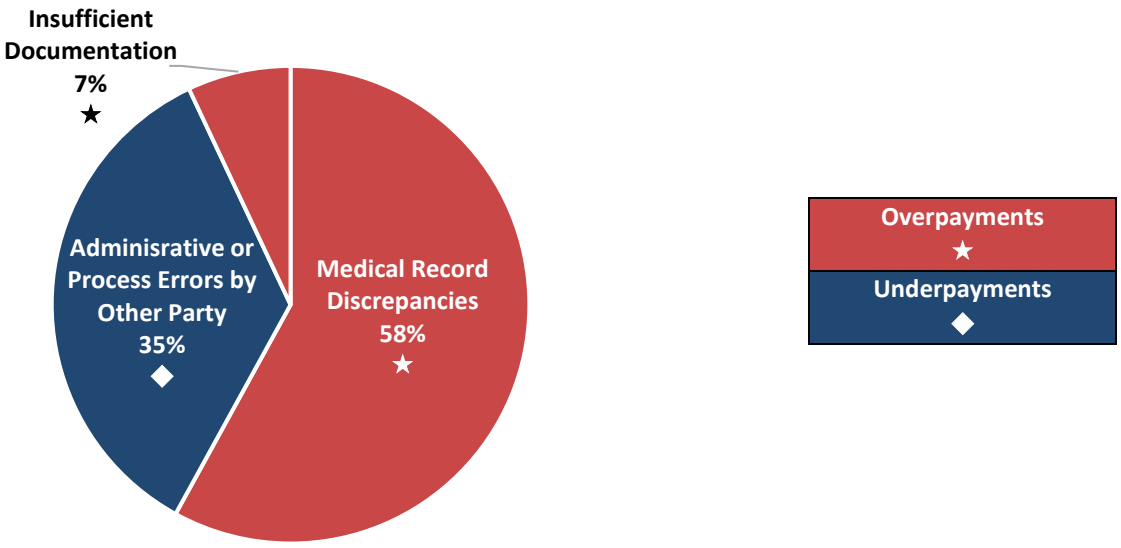
Calculations and Findings

Medicare Part C properly paid an estimated 89.72 percent of total outlays or $202.42 billion in FY 2021. The Medicare Part C improper payment estimate for FY 2021 is 10.28 percent[33] or $23.19 billion. The improper payment estimate due to lacking or insufficient documentation is 0.77 percent or $1.74 billion, representing 7.52 percent of total improper payments.

The primary error category of FY 2021 Medicare Part C improper payments consist of medical record discrepancies (5.96 percent in overpayments and 3.55 percent in underpayments), with a smaller portion of improper payments resulting from insufficient documentation to determine whether proper or improper, such as missing documentation (0.77 percent). Improper payments due medical record discrepancies occur when medical record documentation submitted by the MA organization does not substantiate the CMS-HCC for which it received payment. The underpayment component is comprised of risk scores identified during the medical review process that the MA organization did not submit for payment. The breakdown of Medicare Part C improper payments is displayed in **Figure 13** below.

[33] Using the FY 2020 and prior years' calculation method, the Part C FY 2021 improper payment rate would be 8.89 percent, comparable to the FY 2019 improper payment rate of 7.87 percent. HHS applied a COVID-19 bias adjustment and adjusted the sample size in the FY 2020 Medicare Part C improper payment rate; and therefore, FY 2019 provides a clearer comparison.

Figure 13: FY 2021 Medicare Part C Estimated Improper Payments by Error Categories[1]



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

Medicare Advantage Corrective Action Plan

HHS addresses improper payments in Medicare Part C through various corrective actions. The following sections discuss key HHS corrective actions to address error categories. Corrective actions with an asterisk (*) indicate that HHS temporarily paused and/or altered the corrective action due to COVID-19.

Corrective Actions to Address Error Categories:

Medicare Part C improper payments mainly consist of errors resulting from medical record discrepancies or insufficient documentation. HHS conducted the following three key corrective actions to address Part C payment errors:

Key Corrective Actions to Address Error Categories	
Corrective Action	**Description**
Contract-Level Risk Adjustment Data Validation (RADV) Audits*	Contract-level RADV audits are HHS's primary corrective action to recoup Part C overpayments. RADV uses medical record review to verify the accuracy of enrollee diagnoses submitted by MA organizations for risk adjusted payment. HHS expects payment recovery will have a sentinel effect on risk adjustment data quality submitted by plans for payment because contract-level RADV audits increase the incentive for MA organizations to initially submit valid and accurate diagnosis information. Contract-level RADV audits also encourage MA organizations to self-identify, report, and return overpayments. In FY 2021, HHS completed the payment year (PY) 2014 RADV audit medical record review phase and the PY 2015 RADV audit medical record submission phase. Due to COVID-19, HHS suspended the PY 2015 audit in March 2020 and resumed it in September 2020.
Part C Plan Sponsor Audits*	HHS conducts audits of Part C plan sponsors to reduce improper payments. The audits conducted during FY 2021 consisted of three program integrity audits,[34] with the goal of

[34] HHS conducts program integrity audits to ensure plans are performing effective monitoring to prevent, detect, and correct fraud, waste, and abuse in accordance with Section 1860D-4(c)(1)(D) of the *Social Security Act*, 42 CFR §§ 422.503(b)(4)(vi); 422.504(e)(2); 423.504(b)(4)(vi); and 423.505(e)(2), and Chapters 9 and 21 of the *Medicare Managed Care and Prescription Drug Benefit Manual*. The regulations cover Part C and Part D complaints, investigations, referrals, requests for information, past HHS audits, and past HHS Health Plan Management System memos (alerts and education).

Key Corrective Actions to Address Error Categories	
Corrective Action	**Description**
	educating Part C plan sponsors on issues of fraud, waste, and abuse. Due to COVID-19, onsite audits were made virtual, but HHS did not experience any delays as a result.
Training	HHS conducted training sessions for Medicare Part C and Part D sponsors on program integrity initiatives, investigations, data analyses, and potential fraud schemes. In FY 2021, HHS held Opioid Education Mission webinars in November 2020, December 2020, and May 2021; an updated COVID-19 fraud, waste, and abuse webinar in February 2021; and a MA Organization and Prescription Drug Plan fraud, waste, and abuse webinar in August 2021.

8.3 Medicare Prescription Drug Benefit (Part D)

Medicare Prescription Drug Benefit Statistical Sampling Process

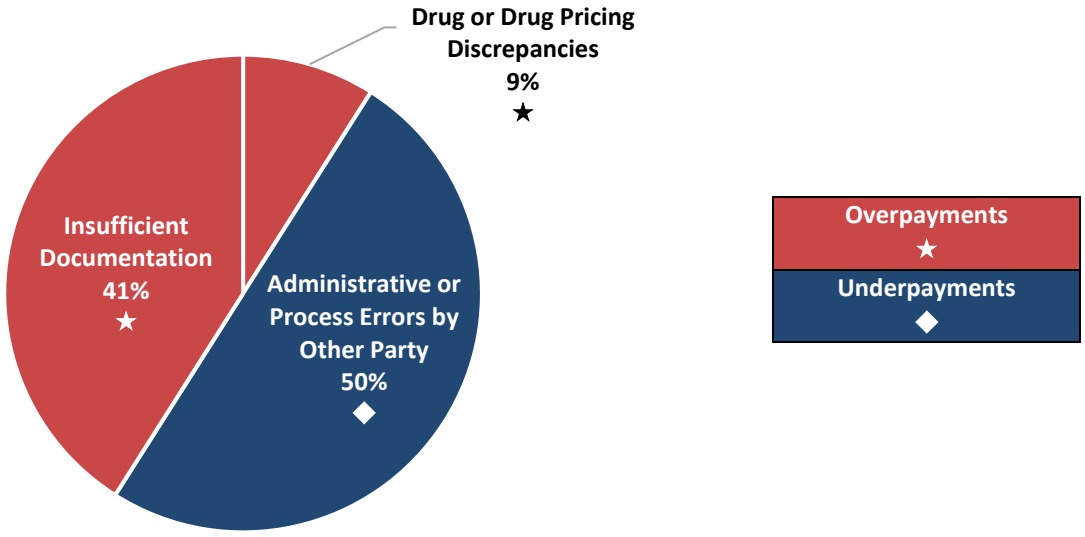
The Part D IPM measures the payment error related to prescription drug event (PDE) data. HHS measures inconsistencies between information reported on PDEs and supporting documentation submitted by Part D sponsors: prescription record hardcopies (or medication orders as appropriate) and detailed claims information. Based on these reviews, each PDE in the audit sample is assigned a gross drug cost error. A representative sample of beneficiaries undergoes a simulation to determine the Part D IPM estimate, HHS then extrapolates these improper payments to the entire Part D population to produce the final Part D estimate.

Calculations and Findings

Medicare Part D properly paid an estimated 98.42 percent of total outlays or $85.44 billion in FY 2021. The improper payment estimate is 1.58 percent or $1.37 billion. The improper payment estimate due to lacking or insufficient documentation is 0.65 percent or $0.56 billion, representing 41.19 percent of total improper payments. The increase from the prior year's estimate of 0.43 percent is due to year-over-year variability, and is not statistically different from the prior year. As the rate is already low, variation in sampled error values or error category breakouts can cause minor shifts in the total estimated error rate.

The FY 2021 Medicare Part D improper payment error categories are drug or drug pricing discrepancies (0.14 percent in Overpayments and 0.79 percent in Underpayments) and insufficient documentation to determine whether proper or improper, i.e., missing documentation (0.65 percent). Improper payments due to drug or drug pricing discrepancies occur when the prescription documentation submitted indicates that an overpayment occurred. Underpayments result when prescription record hard copies (or medication orders) indicates that CMS should have paid more. The breakdown of Medicare Part D improper payments is displayed in **Figure 14** below.

Figure 14: FY 2021 Medicare Part D Estimated Improper Payments by Error Categories[1]



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

Medicare Prescription Drug Benefit Corrective Action Plan

HHS addresses improper payments in Medicare Part D through various corrective actions. The following section discusses key HHS corrective actions to address error categories.

Corrective Actions to Address Error Categories:

Medicare Part D improper payments mainly consist of errors resulting from drug or drug pricing discrepancies or insufficient documentation. HHS conducted the following three key corrective actions to address Part D payment errors:

Key Corrective Actions to Address Error Categories	
Corrective Action	**Description**
Part D Plan Sponsor Audits	HHS conducts audits of Part D plan sponsors, with a focus on drugs that are at high risk of improper payments. Each type of audit is different in scope but with the same goal of educating Part D plan sponsors on issues of fraud, waste, and abuse, as well as identifying, reducing, and recovering inappropriate payments under Part D. In FY 2021, HHS conducted 13 Part D audits.
Outreach	In FY 2021, HHS continued formal outreach to plan sponsors for invalid or incomplete documentation. HHS distributed Final Findings Reports to all Part D sponsors participating in the PDE review process. This report provided feedback on the plan sponsor's submission and validation results against an aggregate of all participating plan sponsors.
Training	In FY 2021, HHS continued national training sessions on payment and data submission with detailed instructions as part of the improper payment estimation process for Part D sponsors. HHS also conducted in-person training sessions for Medicare Part C and Part D sponsors on program integrity initiatives, investigations, data analysis, and potential fraud schemes. In FY 2021, HHS held Opioid Education Mission webinars in November 2020, December 2020, and May 2021; an updated COVID-19 fraud, waste, and abuse webinar in February 2021; and a MA Organization and Prescription Drug Plan fraud, waste, and abuse webinar in August 2021.

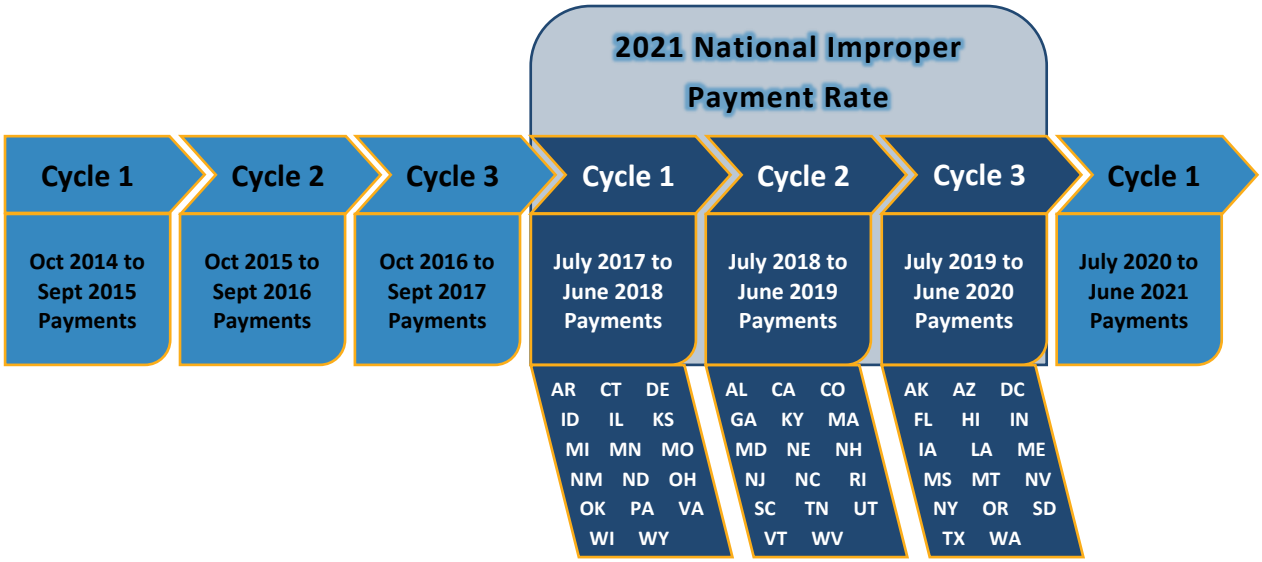
8.4 MEDICAID

Medicaid Statistical Sampling Process

Through the Payment Error Rate Measurement (PERM) program, HHS estimates Medicaid improper payments on an annual basis, using federal contractors to measure three components: FFS claims, managed care payments, and eligibility determinations.

HHS's PERM program uses a 17-states-per-year, 3-year rotation. All 50 states and the District of Columbia are reflected in the national Medicaid rate, as the rate includes findings from the most recent 3 years of measurements. Each time a group of 17 states is measured under the PERM program, HHS removes that group's previous findings from the calculation and includes its newest findings. The national FY 2021 Medicaid rate is based on FYs 2019, 2020, and 2021 measurements (see **Figure 15** below).

Figure 15: FY 2021 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

FFS includes the traditional method of paying for medical services under which a state pays providers for each service rendered to individual beneficiaries. Managed care is a delivery system where a state makes a monthly payment to a managed care plan, which is responsible for managing beneficiary care and rendering payments to providers. Quarterly, states submit adjudicated claims data and HHS randomly selects a sample of FFS claims and managed care capitated payments. Each FFS claim selected undergoes a medical and data processing review, while managed care payments are subjected to only a data processing review. Reviewing either the medical records associated with historical payments to providers or the medical records associated with payments to providers that occurred during the month sampled does not have a direct link to the established capitated payment sampled and, thus, is not included in the managed care component of the improper payment review.

Additionally, HHS selects a combination of FFS claims and managed care payments for eligibility review. Based on each state's expenditures, historical FFS, and managed care payment data, the FFS sample size was between 49 and 1,717 claims per state, the managed care sample size was between 38 and 200 payments per state, the eligibility FFS sample size was between 51 and 477 per state, and the eligibility managed care sample size was between 52 and 574 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

Through the eligibility component, a federal contractor assesses states' application of federal rules and the state's documented policies and procedures related to beneficiary eligibility. States must produce records and documentation to support the eligibility determination. Examples of noncompliance with eligibility requirements include a state: enrolling a beneficiary when ineligible for Medicaid; determining a beneficiary to be eligible for the incorrect eligibility category, resulting in an ineligible service or incorrect federal reimbursement amount being provided; not conducting beneficiary redeterminations timely or at all; or not performing, completing, or providing sufficient documentation to support a required element of the eligibility determination process, such as income verification. As described in the PERM final rule (82 Federal Register 31158, July 5, 2017), HHS resumed the eligibility component measurement for the 17 Cycle 3 states and reported an updated national eligibility improper payment estimate for FY 2021. Between FY 2015 and FY 2018, HHS did not conduct the eligibility measurement component of PERM; refer to pages 211-214 of HHS's 2018 AFR for more information.

Calculations and Findings

The national Medicaid program's improper payment estimate combines each state's Medicaid FFS, managed care, and eligibility estimates. In addition, HHS combines individual state component estimates to calculate the national component estimates. National component rates and the Medicaid program rate are weighted by state size, such that a state with a $10 billion program is weighted more in the national rate than a state with a $1 billion program. A correction factor in the methodology ensures that each Medicaid improper payment is counted only once in the combined national rate.

Medicaid properly paid an estimated 78.31 percent of total outlays or $356.45 billion in FY 2021. The national Medicaid improper payment estimate for FY 2021 is 21.69 percent or $98.72 billion. The improper payment estimate due to lacking or insufficient documentation is 19.13 percent or $87.08 billion, representing 88.21 percent of total improper payments.

The FY 2021 national Medicaid improper payment estimate for each component is:

- *Medicaid FFS*: 13.90 percent
- *Medicaid managed care*: 0.04 percent
- *Medicaid eligibility*: 16.62 percent

In response to COVID-19, the FY 2021 national Medicaid improper payment estimate reflects PERM reviews that accounted for certain flexibilities afforded to states during COVID-19, such as postponed eligibility determinations and reduced requirements around provider enrollment/validations. HHS will publish supplemental information related to the FY 2021 Medicaid results on the PERM page of the CMS website following AFR publication.

The area driving the FY 2021 Medicaid improper payment estimate is the continued reintegration of the PERM eligibility component, which was revamped to incorporate the *Patient Protection and Affordable Care Act* (PPACA) requirements in the PERM eligibility reviews. HHS began using the updated eligibility component in the FY 2019 measurement cycle; this was the first time Cycle 3 states were measured using the methodology. Under the updated eligibility component, a federal contractor conducts the eligibility measurement, allowing for consistent insight into the accuracy of Medicaid eligibility determinations and increased oversight of identified vulnerabilities. With the measurement of Cycle 3 states, HHS has completed the measurement of all states under the revamped eligibility component and established a national baseline in FY 2021.

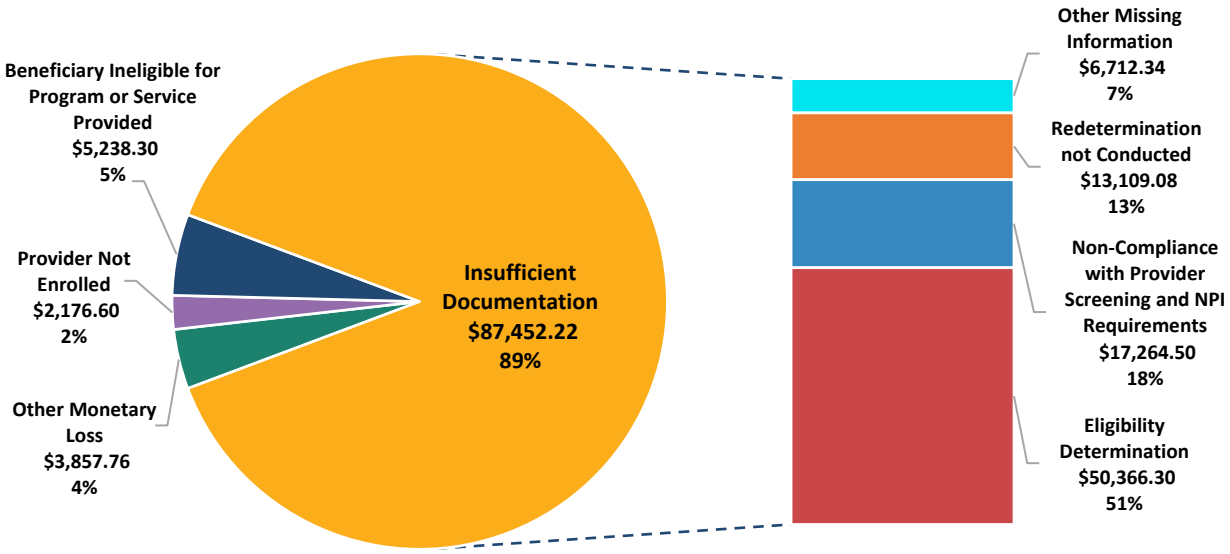
Eligibility errors are mostly due to insufficient documentation to affirmatively verify the eligibility determination or noncompliance with federal eligibility redetermination requirements. The majority of the insufficient documentation errors represent both situations where the required verification of eligibility data, such as income, was not done at all and where there is an indication that eligibility verification was initiated but the state provided no documentation to validate the verification process was completed.

The Medicaid improper payment estimate is also driven by errors due to state non-compliance with provider screening, revalidation, enrollment, and National Provider Identifier (NPI) requirements. Most improper payments cited on claims were related to enrolled providers not appropriately screened by the state; providers not appropriately rescreened at revalidation; providers not enrolled; and/or providers without the required NPI on the claim. Although these errors remain one of the drivers of the Medicaid rate, state compliance has improved as the Medicaid FFS component decreased from 16.84 percent in FY 2020 to 13.90 percent in FY 2021. COVID-19 review flexibilities afforded to states should also be considered in the identified decrease in the Medicaid FFS component between FY 2020 and FY 2021. Moving forward, HHS will track improvement in compliance with revalidation requirements as HHS measures each cycle of states a second time.

A majority of Medicaid improper payments were due to instances where information required for payment was missing, an eligibility determination was missing from the state system, states did not follow the appropriate process for enrolling providers, and/or states did not follow the appropriate process for determining beneficiary eligibility. However, these improper payments do not necessarily represent payments to illegitimate providers or on behalf of ineligible beneficiaries. If the missing information had been on the claim and/or the state had complied with the enrollment or redetermination requirements, then the claims may have been payable. Conversely, if the missing documentation had been available, it could have affirmatively indicated whether a provider or beneficiary was ineligible for Medicaid reimbursement and, therefore, improper.

Figure 16 below provides a breakdown of improper payments for Medicaid. The improper payments include those with provider not enrolled, beneficiary ineligible for program or service, incorrect coding, and other errors like claims processing errors, duplicate claims, or pricing mistakes. The insufficient documentation errors include claims where information was missing or states did not follow appropriate processes to discern whether a payment was proper or improper.

Figure 16: FY 2021 Medicaid Estimated Improper Payments by Type of PERM Error[1] (Dollar Amounts in Millions)



[1] Figure may not equal 100 percent or add up precisely to other tables in this document due to rounding.

Medicaid Corrective Action Plan

The Medicaid program is a federal-state partnership and HHS addresses improper payments in Medicaid through several corrective actions. HHS works closely with all states through enhanced technical assistance (including liaisons that are assigned to each state to assist with identifying and overcoming barriers to corrective action implementation) and guidance to develop state-specific corrective action plans to reduce improper payments. All states are responsible for implementing, monitoring, and evaluating the corrective action plan's effectiveness, with assistance and oversight from HHS. When developing corrective action plans, states focus on major causes of improper payments.

Several important ongoing activities inform the development of HHS's corrective actions by providing data and information directly from state experiences with implementing the Medicaid program:

- Reviewing improper payment rate data for each component of the PERM program;
- Conducting outreach during off-cycle PERM years to identify issues states are experiencing with the state-specific corrective action plans;
- Reviewing state data submitted through the Medicaid Eligibility Quality Control (MEQC) program;
- Facilitating Technical Assistance Group calls on various topics that help identify state promising practices;
- Offering ongoing technical assistance;
- Providing additional guidance, as needed; and
- Providing training to state partners through the Medicaid Integrity Institute (MII).

Corrective Actions to Address Error Categories:

Medicaid improper payments mainly consist of errors resulting from insufficient documentation to determine eligibility; noncompliance with eligibility redetermination requirements; cases where the beneficiary was ineligible for the program or service; insufficient or no medical documentation submitted by providers and other provider

errors identified through medical review; noncompliance with provider screening, revalidation, or NPI requirements; and other missing information from the state.

State corrective action plans focus on system or process changes to reduce these errors, including implementing new claims processing edits, converting to a more sophisticated claims processing system, implementing provider enrollment process improvements, implementing beneficiary enrollment and redetermination process improvements, and conducting provider communication and education to reduce errors related to documentation requirements. HHS's corrective actions include providing additional guidance, technical assistance, and oversight to states, including with the enrollment processes for providers and beneficiaries, described in the table below.

The following section discusses key HHS corrective actions to address multiple cause categories, including the categories described earlier in the Medicaid "Calculations and Findings" section. Corrective actions denoted with an asterisk (*) indicate that HHS temporarily paused, limited, and/or altered the corrective action due to COVID-19.

Key Corrective Actions to Address Error Categories	
Corrective Action	**Description**
Enhanced State PERM Corrective Action Plan Process*	In FY 2021, HHS continued working with states to implement a robust state-specific PERM Corrective Action Plan process that provides enhanced technical assistance and guidance to states. HHS works with states to coordinate state development of corrective action plans to address each error and deficiency identified during the PERM cycle. After each state submits the corrective action plan, monitors the state's progress in implementing effective corrective actions. On April 2, 2020, HHS suspended all improper payment-related engagement with providers and state agencies, including data requests related to existing PERM Corrective Action Plans through August 21, 2020. Even with this delay, HHS continued the development of its enhanced corrective action process and accepted Corrective Action Plans for all reporting year 2018 and 2019 states. Throughout the process, HHS also provided training opportunities to ensure compliance with federal policies. For example, in May 2021, HHS conducted a 3-day PERM Corrective Action Symposium with all states and offered quarterly training on various PERM-related topics. HHS continues to use lessons learned to develop future guidance and education for states.
MII*	HHS offers training, technical assistance, and support to state Medicaid program integrity officials through the MII. In FY 2021, HHS continued a robust training program, which included virtual training opportunities. FY 2021 offerings included trends in Medicaid COVID-19 Vulnerabilities, a PERM Corrective Action Symposium, and an Education and Outreach for the Territories workgroup. In response to COVID-19, HHS continued to offer virtual courses to provide educational offerings to states, territories, and other stakeholders. Despite this change, state interest and participation in FY 2021 was strong, consistent with previous years. More information is located at the Medicaid Integrity Institute website.
MEQC Program*	Under the MEQC program, states design and conduct pilots to evaluate the processes that determine an individual's eligibility for Medicaid and CHIP benefits. States have flexibility in designing pilots to focus on vulnerable or error-prone areas identified by the PERM program and state. The MEQC program also reviews eligibility determinations that are not reviewed under the PERM program, such as denials and terminations. MEQC pilots are conducted during the 2-year intervals that occur between states' triennial PERM review years ("off-years"), allowing states to implement prospective improvements in eligibility determination processes prior to their next PERM review. In FY 2021, HHS worked with the Cycle 1 states to submit their MEQC summary reports and corrective action plans in November 2020; with the Cycle 2 states to complete their MEQC reviews and prepare their summary-level reports and corrective action plans for submission in November 2021; and with the Cycle 3 states to design their MEQC pilots and start their case reviews in January 2021. Because of COVID-19's impact,

Key Corrective Actions to Address Error Categories	
Corrective Action	**Description**
	HHS issued revised supplemental MEQC guidance in May 2021 that reduced state burden by applying uniform summary reporting requirements and deadline extensions to all cycles, as well as a reduced workload requirement for Cycle 2 and Cycle 3 states.
Enhanced Assistance on State Medicaid Provider Screening and Enrollment*	HHS provides ongoing guidance, education, and outreach to states on federal requirements for Medicaid provider screening and enrollment. In addition, HHS updated the Medicaid Provider Enrollment Compendium in July 2018 and March 2021 to provide additional sub-regulatory guidance to assist states in applying the regulatory requirements, and is planning further updates in FY 2022. HHS also continued to assess provider screening and enrollment compliance, provide technical assistance, and offer states the opportunity to leverage Medicare screening and enrollment activities. Due to COVID-19, many states utilized Section 1135 waiver authority[35] to relax certain screening and enrollment requirements (e.g., revalidation, fingerprint-based criminal background checks, application fees, site visits). HHS is working with states to mitigate the impact of these waivers on compliance efforts by continuing to develop compliance plans with the states. Additionally, HHS provided the states training on how to mitigate risks associated with these waivers. Lastly, HHS continues to share Medicare provider and supplier enrollment data to assist states and territories with meeting Medicaid screening and enrollment requirements.
State Medicaid Provider Screening and Enrollment Data and Tools	HHS shares Medicare data to assist states and territories with meeting Medicaid screening and enrollment requirements. Specifically, HHS shares the Medicare provider enrollment record via the PECOS administrative interface and data extracts from the PECOS system and OIG exclusion data. Since May 2016, HHS has offered a data compare service allowing states and territories to rely on Medicare's screening in lieu of conducting a state screening, particularly during revalidation. This allows states and territories to remove dually-enrolled providers from the revalidation workload. HHS also returns information on providers with deactivated NPIs, are deceased, excluded by the HHS OIG, revoked by Medicare or terminated for cause by a State Medicaid Agency (thus allowing the state or territory to take deactivation or termination action against the provider when applicable). Using the data compare service, a state or territory provides a Medicaid provider enrollment data extract to HHS, and then HHS returns information indicating which providers have undergone a Medicare screening on which the state can rely (thus reducing the state's or territory's workload). The following states participated in the data compare service in FY 2021: North Dakota, Tennessee, Pennsylvania, South Dakota, New Jersey, Colorado, Rhode Island, New York, West Virginia, and New Hampshire. HHS is working to expand the data compare service to additional states. In addition to the data compare service, HHS piloted a process to screen Medicaid-only providers on behalf of states beginning in FY 2019. In FY 2020, HHS screened two states' Medicaid-only providers (Iowa and Missouri) and produced a report of providers with licensure issues, criminal activity, or Do Not Pay activity. HHS evaluated the pilot impact and results and expanded the service to additional states in FY 2021. Oklahoma, Nevada, North Dakota, Tennessee, Colorado, Rhode Island, Oregon, and West Virginia are also participating in the pilot and HHS continues to contact other states to gauge interest.
DMF	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 states the DMF. Since May 2017, HHS has made DMF data available to states via the same file server where states previously accessed PECOS provider file extracts, Medicare revocations, Medicaid terminations, and OIG exclusions. HHS expanded access to DMF data to additional states via the Data Exchange

[35] Section 1135 of the *Social Security Act* gives the Secretary the authority to waive requirements during natural emergencies to ensure that health care items and services are available to meet the needs of individuals in such areas enrolled in the programs and health care providers that furnish items and services in good faith, but that are unable to comply with one or more requirements, may be reimbursed.

Key Corrective Actions to Address Error Categories	
Corrective Action	**Description**
	(DEX), which is a system for sharing data among HHS and the separate Medicaid programs of every state. In FY 2021, all 50 states, the District of Columbia, and Puerto Rico have access to DMF data through DEX.

8.5 CHIP

CHIP Statistical Sampling Process

Through the PERM program, HHS estimates CHIP improper payments on an annual basis, utilizing federal contractors to measure three components: FFS claims, managed care payments, and eligibility determinations.

CMS uses the same state sampling process as Medicaid to measure CHIP improper payments through the PERM program. HHS determined that the states selected for Medicaid review each year can also be measured in CHIP. For information on how HHS grouped states into three cycles for CHIP, refer to pages 183-185 of HHS's FY 2012 AFR.

FFS and Managed Care Components

FFS includes the traditional method of paying for medical services under which a state pays providers for each service rendered to individual beneficiaries. Managed care is a delivery system where a state makes a monthly payment to a managed care organization, which is responsible for managing beneficiary care and rendering payments to providers. Quarterly, states submit adjudicated claims data, and HHS randomly selects a sample of FFS claims and managed care payments. Each FFS claim selected undergoes a medical and data processing review, while managed care payments are subjected to only a data processing review. Reviewing either the medical records associated with historical payments to providers or the medical records associated with payments to providers that occurred during the month sampled does not have a direct link to the established capitated payment sampled and, thus, is not included in the managed care component of the improper payment review.

Additionally, HHS selects a combination of FFS claims and managed care payments for eligibility review. Based on each state's expenditures and historical FFS and managed care improper payment data, the FFS sample size was between 32 and 968 claims per state, the managed care sample size was between 22 and 78 payments per state, the eligibility FFS sample size was between 42 and 324 per state, and the eligibility managed care sample size was between 36 and 396 per state. When a state's FFS or managed care component for a state accounted for less than two 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

Through the eligibility component, a federal contractor assesses states' application of federal rules and the state's documented policies and procedures related to beneficiary eligibility. States must produce records and documentation to support the eligibility determination. Examples of noncompliance with eligibility requirements include a state: inappropriately claiming a beneficiary under Title XXI (CHIP) rather than Title XIX (Medicaid); determining a beneficiary to be eligible for the incorrect eligibility category, resulting in an ineligible service or incorrect federal reimbursement amount being provided; not conducting beneficiary redeterminations timely or at all; or not performing, completing, or providing sufficient documentation to support a required element of the eligibility determination process, such as income verification. As described in the PERM final rule (82 Federal Register 31158, July 5, 2017), HHS resumed the eligibility component measurement for the 17 Cycle 3 states and reported an updated national eligibility improper payment estimate for FY 2021. Between FY 2015 and FY 2018,

HHS did not conduct the eligibility measurement component of PERM; refer to pages 211-214 of HHS's 2018 AFR for more information.

Calculations and Findings

The national CHIP improper payment estimate combines each state's FFS, managed care, and eligibility estimates. In addition, HHS combines individual state component improper payment estimates to calculate the national component estimate. National component rates and the CHIP 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 each CHIP improper payment is counted only once in the combined national rate.

CHIP properly paid an estimated 68.16 percent of total outlays or $11.51 billion in FY 2021. The national CHIP improper payment estimate for FY 2021 is 31.84 percent or $5.37 billion. The improper payment estimate due to lacking or insufficient documentation is 24.79 percent or $4.18 billion, representing 77.85 percent of total improper payments.

The FY 2021 national CHIP improper payment estimate for each component is:

- *CHIP FFS:* 13.67 percent
- *CHIP managed care:* 0.48 percent
- *CHIP eligibility*: 28.71 percent

In response to COVID-19, the FY 2021 national CHIP improper payment estimate reflects PERM reviews that accounted for certain flexibilities afforded to states during COVID-19, such as postponed eligibility determinations and reduced requirements around provider enrollment/validations. HHS will publish supplemental information related to the FY 2021 CHIP results on the PERM page of the CMS website following AFR publication.

The area driving the FY 2021 CHIP improper payment estimate is the continued reintegration of the PERM eligibility component, which was revamped to incorporate the PPACA requirements in the PERM eligibility reviews. HHS began using the updated eligibility component in the FY 2019 measurement cycle; this was the first time Cycle 3 states were measured using the methodology. Under the updated eligibility component, a federal contractor conducts the eligibility measurement, allowing for consistent insight into the accuracy of CHIP eligibility determinations and increased oversight of identified vulnerabilities. With the measurement of Cycle 3 states, HHS has completed the measurement of all states under the revamped eligibility component and established a national baseline in FY 2021.

Eligibility errors are mostly due to insufficient documentation to affirmatively verify the eligibility determination or noncompliance with eligibility redetermination requirements. The majority of the insufficient documentation errors represent both situations where the required verification of eligibility data, such as income, was not done at all and where there is indication that the eligibility verification was initiated but the state provided no documentation to validate the verification process was completed. The CHIP improper payment estimate was also driven by claims where the beneficiary was inappropriately claimed under Title XXI (CHIP) rather than Title XIX (Medicaid), mostly related to incorrect state calculations based on beneficiary income, the presence of third party insurance, or household composition/tax filer status.

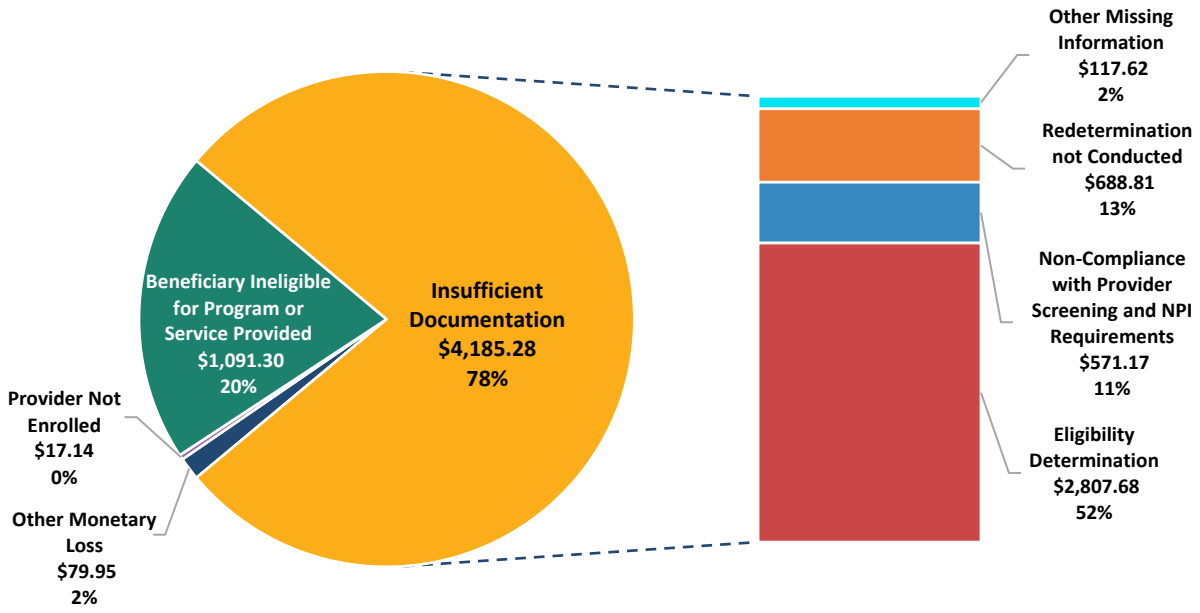
The CHIP improper payment estimate is also driven by errors due to state non-compliance with provider screening, revalidation, enrollment, and NPI requirements. Most improper payments cited on claims were related to enrolled providers not appropriately screened by the state; providers not appropriately rescreened at revalidation; providers not enrolled; and/or providers without the required NPI on the claim. Although these errors remain one of the drivers of the CHIP rate, state compliance has improved as the CHIP FFS improper payment estimate has decreased from 14.15 percent in FY 2020 to 13.67 percent in FY 2021. COVID-19 review flexibilities afforded to states should

also be considered in the identified decrease in the CHIP FFS component between FY 2020 and FY 2021. Moving forward, HHS will track improvement in compliance with revalidation requirements as HHS measures each cycle of states a second time.

A majority of CHIP improper payments were due to instances where information required for payment was missing, an eligibility determination was missing from the state system, states did not follow the appropriate process for enrolling providers, and/or states did not follow the appropriate process for determining beneficiary eligibility. However, these payments do not necessarily represent payments to illegitimate providers or on behalf of ineligible beneficiaries. If the missing information had been on the claim and/or the state had complied with the enrollment or redetermination requirements, then the claims may have been payable. Conversely, if the missing documentation had been available, it could have affirmatively indicated whether a provider or beneficiary was ineligible for CHIP reimbursement and, therefore, improper.

Figure 17 below provides a breakdown of improper payments for CHIP. The improper payments include those with provider not enrolled, beneficiary ineligible for program or service, incorrect coding, and other errors like claims processing errors, duplicate claims, or pricing mistakes. The insufficient documentation errors include claims where information was missing or states did not follow appropriate processes to determine whether a payment was proper or improper.

Figure 17: FY 2021 CHIP Estimated Improper Payments by Type of PERM Error[1] (Dollar Amounts in Millions)



[1] Figure may not equal 100 percent or add up precisely to other tables in this document due to rounding.

CHIP Corrective Action Plan

CHIP is a federal-state partnership and HHS addresses improper payments in CHIP through various corrective actions. HHS works closely with all states through enhanced technical assistance (including liaisons that are assigned to each state to assist states with identifying and overcoming barriers to corrective action implementation) and guidance to develop state-specific corrective action plans to reduce improper payments. All states are responsible for implementing, monitoring, and evaluating the corrective action plan's effectiveness, with assistance and oversight from HHS. When developing corrective action plans, states focus on major causes of improper payments.

Several important ongoing activities inform the development of HHS's corrective actions by providing data and information directly from state experiences with implementing CHIP; these activities are listed in the Medicaid section. The following sections discuss key HHS corrective actions to address error categories.

Corrective Actions to Address Error Categories:

CHIP improper payments mainly consist of errors resulting from insufficient documentation to determine eligibility; noncompliance with eligibility redetermination requirements; cases where the beneficiary was ineligible for the program or service; insufficient or no medical documentation submitted by providers and other provider errors identified through medical review; noncompliance with provider screening, revalidation, or NPI requirements; and other missing information from the state.

State corrective action plans focus on system or process changes to reduce these errors, including implementing new claims processing edits, converting to a more sophisticated claims processing system, implementing provider enrollment process improvements, implementing beneficiary enrollment and redetermination process improvements, and conducting provider communication and education to reduce errors related to documentation requirements. HHS's corrective actions include providing additional guidance, technical assistance, and oversight to states including with enrollment processes for providers and beneficiaries. Many of the same corrective actions that states are implementing to address Medicaid improper payments, as described in Section 8.4, also apply to CHIP.

8.6 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 estimate for FY 2021.

TANF Corrective Action Plan

Since TANF is a state-administered program, corrective actions would be implemented at the state level to reduce improper payments. Since HHS cannot require states to participate in a TANF 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:

Key Corrective Actions for TANF Program Integrity	
Corrective Action	**Description**
Risk Assessment	HHS performed a detailed risk assessment of the TANF program in FY 2019 to determine susceptibility to significant improper payments. HHS identified potential payment risks at the federal level and will continue to work to mitigate these risks.
Promoting and Supporting Innovation in TANF Data	HHS awarded a 5-year contract in FY 2017 for Promoting and Supporting Innovation in TANF Data. A component of the contract includes engaging TANF stakeholders to better understand how states assess improper payments and ensure program integrity in TANF. Through this contract, in FY 2019, HHS conducted a comprehensive needs assessment of all TANF states, territories, and the District of Columbia, including information about payment integrity efforts, and HHS will build off this assessment with a detailed look at payment integrity efforts in a select group of states. This assessment is helping HHS provide technical assistance to states around reducing improper payments and understand existing state approaches and alternative methods for measuring TANF improper payments, including the feasibility and cost-benefit analysis of different approaches.

Key Corrective Actions for TANF Program Integrity	
Corrective Action	**Description**
Final Regulation on Reporting of Electronic Benefit Transfer Policies and Practices	HHS issued final regulations in FY 2016 regarding State Reporting on Policies and Practices to Prevent the Use of TANF Funds in Electronic Benefit Transfer Transactions in Specified Locations (81 Federal Register 2092, January 15, 2016). The Department continues to monitor compliance with this regulation.

In addition to the federal corrective actions listed above, states also undertake efforts to reduce improper payments in TANF. States utilize PARIS, the National Directory of New Hires, and the Income and Eligibility Verification System to minimize improper payments.

8.7 Foster Care

Foster Care Statistical Sampling Process

In response to COVID-19, HHS postponed Title IV-E reviews to protect the health and safety of state and federal reviewers and to ensure that state child welfare officials remain focused on mission-critical activities serving children and families. Because IV-E reviews (which occur onsite) provide the data normally used to calculate improper payment estimates, the postponement of reviews resulted in HHS having no new data for FY 2021. Therefore, HHS is not reporting an improper payment plus unknown payment estimate.

Despite pausing the Title IV-E reviews, HHS continued other program integrity efforts through its review of claims and audit resolution to have states address financial reporting and claiming errors. HHS's Office of Grants Management (OGM) and the Children's Bureau reviewed Title IV-E quarterly claims submitted by states and addressed claiming errors and anomalies on an ongoing basis. States are required by federal law to have a periodic and independent audit conducted on their Title IV-E programs, and HHS continues to conduct audit resolution and require corrective actions. OGM also began enhanced financial monitoring reviews of certain grantees, including agencies operating the Title IV-E program. These reviews examine organizations' policies and procedures related to financial management with the goal of supporting compliance with federal requirements applicable to grant awards. Lastly, HHS also works with states to analyze Single Audit material non-compliance findings related to the Title IV-E program and to implement corrective actions to address these findings.

Foster Care Corrective Action Plan

HHS relied on previous data and experiences to update its corrective action plans. Traditionally, all improper payments (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 errors that contribute most to Title IV-E improper payments.

Over the years, these corrective actions, 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 error types. Information on the most recent root causes and leading payment error types can be found in the FY 2020 AFR.

In FY 2021, HHS undertook the following key actions to reduce Foster Care improper payments in the future:

Key Corrective Actions for Foster Care Program Integrity	
Corrective Action	**Description**
Emphasizing Quality Improvement	HHS engaged state Title IV-E Foster Care agencies to enhance understanding of program compliance requirements and to share successful strategies among states. Based on discussions with individual states on foster care program implementation and past performance on foster care IV-E Reviews, 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 improvement efforts. A continuous quality improvement effort helps maintain an awareness of the ongoing needs which reduces incidences of improper payments overall.
Enhancing Targeted Outreach Strategies	Outreach Regarding Changes in Federal Requirements: The *Family First Prevention Services Act*, enacted as Title VII of the *Bipartisan Budget Act of 2018*, changed the federal statutory requirements for staff safety checks at childcare institutions. All states become subject to all new restrictions effective October 1, 2021. In response to this legislation, HHS conducted a series of webinars in FY 2018 and issued written guidance to federal and state staff to instruct all staff on the updated federal safety check requirements and other provisions of the 2018 federal law. HHS expects to issue additional guidance and instructional tools in FY 2022 to deepen federal and state staff knowledge on the federal requirements for state implementation and maintenance of required policies and practices. HHS also reviewed state documentation and conferred on case findings throughout FY 2021. These exchanges with states helped resolve challenging eligibility questions. They also provided opportunities to explain Title IV-E requirements, clarify documentation requirements, and assist states' understanding of complex policy concepts and eligibility determination for foster care maintenance payments. HHS will continue using lessons learned from this process to inform future guidance and education.
	Communications and Monitoring: Given the high-dollar impact of improper payments that occurred pertaining to institutional care, HHS, through its interactions with states, encouraged effective communication between state child welfare agencies and licensing agencies to further promote adequate documentation of licensing and 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 will encourage states to regularly and systematically monitor foster care providers to document and promote compliance with the Title IV-E requirements and require non-compliant providers to undergo corrective action.
Providing Training and Technical Assistance	HHS trains and assists states in developing and implementing program improvements, even when states are not required to develop a program improvement plan. This assistance helps states expand organizational capacity and promote more effective program operations. Corrective actions have decreased the overall number of payment errors and altered the composition of identified payment errors. For example, following years of work with State Court Improvement Programs and outreach to heighten judicial awareness, judiciary-related errors, once the most prevalent error type, are now among the least common. HHS will continue to work closely with states and tribes to ensure they have a clear understanding of the federal requirements and are prepared to effectively manage their foster care programs. HHS staff and technical assistance providers have also offered technical assistance on Title IV-E eligibility issues to tribes operating or planning to operate the Title IV-E foster care program, many of whom have limited previous experience in matters relating to Title IV-E eligibility determinations. HHS partnered with the National Resource Center for Tribes to conduct a

Key Corrective Actions for Foster Care Program Integrity	
Corrective Action	**Description**
	2-day webinar in FY 2021 for tribal Title IV-E grantees to present key information on the Title IV-E requirements and federal regulations regarding the eligibility of the children on whose behalf foster care maintenance payments are made. HHS staff presented a detailed look at the program and documentation expectations necessary to comply with the requirements for judicial determinations. Two additional trainings on financial eligibility and staff safety checks at childcare institutions are planned for FY 2022.

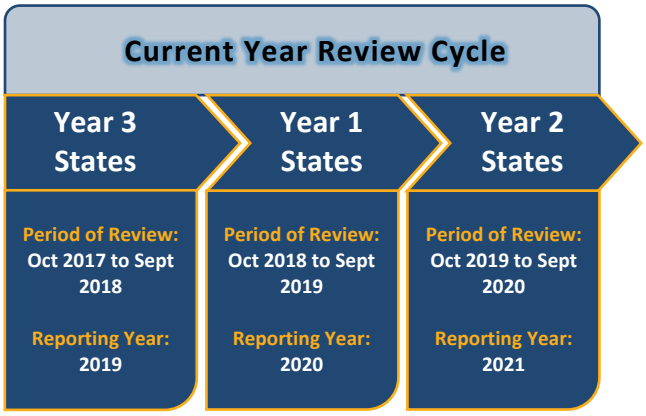
Since Foster Care payments occur at the state level, the state must implement the information systems and other infrastructure needed to reduce Foster Care improper payments. States have the option to receive federal financial participation to develop and implement a Comprehensive Child Welfare Information System (CCWIS) in accordance with federal regulations at 45 CFR §1355.50 through §1355.59. CCWIS project requirements include 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.

8.8 CCDF

CCDF Statistical Sampling Process

The CCDF improper payments methodology uses a case-record review process to determine if childcare subsidies were paid properly for services provided to eligible families. All states, the District of Columbia, and Puerto Rico (hereafter referred to as "states") are split into three cohorts and conduct the improper payment rate review once every 3 years (as shown in **Figure 18**).

Figure 18: CCDF Improper Payment Rate Review Cycle and Reporting Year



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's 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. Effective October 31, 2018, HHS revised the CCDF Data Collection Instructions (DCI) to states regarding implementation of the Error Rate Review. The DCI now instructs states to consider if making additional inquiries might mitigate what this report refers to as "unknown payments" and also requires states to

provide more information about error causes and action steps. Year Three states, Year One states, and Year Two states implemented the revised methodology in FYs 2019, 2020, and 2021, respectively.

COVID-19 impacted state improper payment reviews in FY 2021. Many Year Two states experienced challenges such as staffing shortages, limited access to files, and a need to conduct reviews remotely. As the State Improper Payments Report (ACF-404) submission deadline neared, HHS determined that some Year Two states would not be able to complete all 276 case reviews. A few states submitted their reviews after the deadline and one state submitted data based on only 209 out of 276 planned case reviews. HHS determined that a state's data would still be statistically representative, and thus could be included in the national improper payment measure calculations, as long as the state completed and reported on at least 203 case reviews. Additionally, one state received a waiver for Extraordinary Circumstances under 45 CFR 98.19 (b)(2) due to COVID-19. For that state, previous cycle data is used in the national error rate calculations.

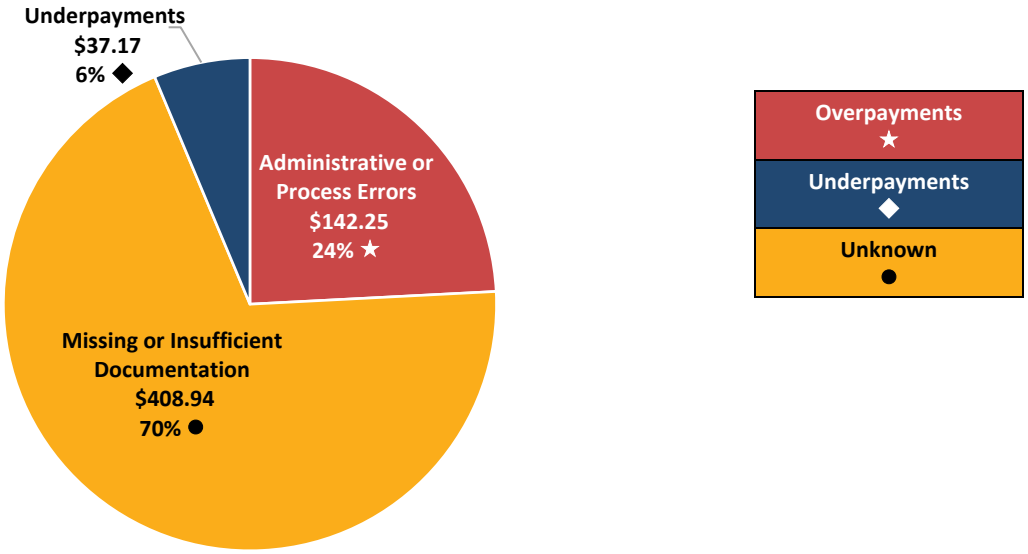
Calculations and Findings

The CCDF improper payment plus unknown payment estimate for FY 2021 is 4.36 percent or $588.37 million. HHS attributes the decrease, from 5.16 percent in FY 2020 to 4.36 percent in FY 2021, to HHS's successful multi-pronged approach to supporting states as they continue to comply with the CCDF reauthorization and related regulations. For example, HHS provided technical assistance while also allowing needed flexibility due to the unprecedented circumstances of COVID-19.

The HHS Payment Integrity Report data reflects only what CCDF refers to as payment errors—that is, errors that create a monetary discrepancy between the subsidy amount as determined by the reviewer and the sample month payment amount. A payment error example may include a missing paystub, if non-receipt of a paystub results in a monetary discrepancy. CCDF further classifies its payment errors as (1) administrative or process errors, corresponding to what this report terms "improper payments," and (2) errors caused by missing or insufficient documentation, corresponding to what this report terms "unknown payments."

Historically, there have not been large differences between CCDF improper payments (administrative or process errors) and unknown payments (missing or insufficient documentation errors). However, **Figure 19** shows that in FY 2021, unknown payments were considerably larger (at about 69.51 percent of total IPs plus UPs or $408.94 million) than improper payments (the sum of overpayments, at about 24.18 percent or $142.25 million, and underpayments, at about 6.32 percent or $37.17 million).

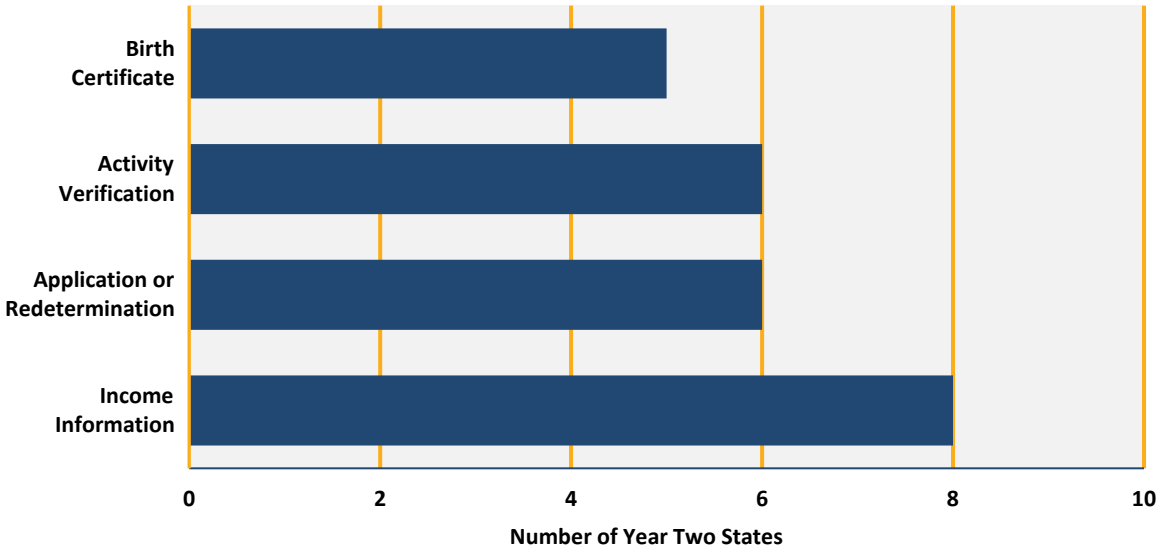
Figure 19: FY 2021 CCDF Improper Plus Unknown Payments by Error Category[1] (Dollar Amounts in Millions)



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

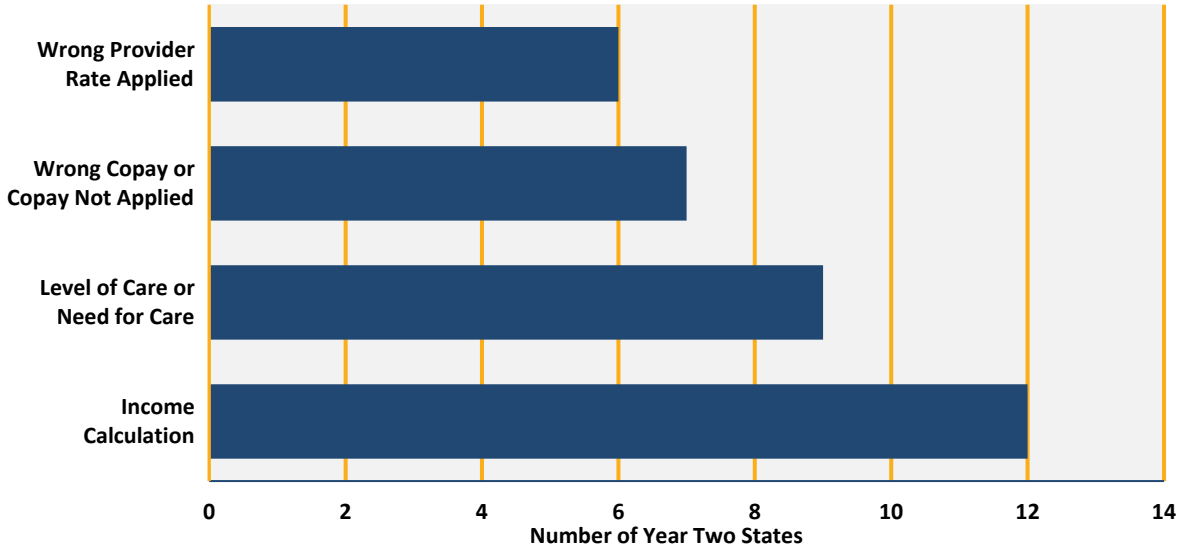
Missing or insufficient documentation errors accounted for an estimated 60.03 percent of payment errors identified in the CCDF review process. Errors were primarily due to missing or insufficient documentation in the case record. **Figure 20** presents the most frequently cited errors.

Figure 20: Most Frequently Cited Errors Due to Missing or Insufficient Documentation for CCDF



Administrative or process errors represent approximately 39.97 percent of number of errors noted in the Year Two reviews. These errors consist of the failure to apply policy correctly, as shown in **Figure 21**.

Figure 21: Most Frequently Cited Errors Due to Administrative or Process Errors for CCDF



CCDF Corrective Action Plan

Corrective Actions to Address Error Categories:

Missing or insufficient documentation (70 percent or $408.94 million) and administrative or process errors made by a state or local agency (28 percent or $162.75 million; $131.79 million Overpayments and $30.95 million Underpayments) drive CCDF improper plus unknown payments. HHS and states establish corrective actions targeting both error types. States must report on the categories of errors once every 3 years. Each report also allows states to report on actions taken on errors from the prior review. HHS offers targeted technical assistance to support each state's efforts to reduce errors. States reporting in FY 2021 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	Twelve states plan to conduct training with eligibility staff on CCDF policies and procedures.
Oversight	Three states plan to implement more internal monitoring of local eligibility agencies.
State Policies and Procedures	Seven states plan to review and, where appropriate, update state eligibility policies.
Information Systems	Ten states plan to upgrade or implement new IT systems.

HHS has limited authority to require specific actions of state grantees since states determine the specifics of their CCDF programs. As resources allow, HHS provides additional onsite and remote oversight of policy and procedure implementation to lower the improper plus unknown payment rate. HHS began monitoring states for compliance with the CCDF regulations in FY 2019. Beginning in Spring 2020, COVID-19 impacted some monitoring and onsite visit processes and procedures, however, HHS conducted these visits virtually in FY 2021 with some adjustments. In

addition, HHS implemented key corrective actions to assist all states in the review process and error reduction efforts, including:

HHS Key Corrective Actions for Missing or Insufficient Documentation and Administrative or Process Errors Made by State or Local Agency	
Corrective Action	**Description**
Oversight	All reporting states participate in Joint Case Reviews that include state and federal staff. Through these efforts, HHS gains insight into the error measurement methodology implementation and provides technical assistance to states to ensure consistent reviews.
Technical Assistance	Site Visits: HHS visits states needing assistance to address root causes as resources allow. Due to COVID-19, HHS conducted these visits virtually.
	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.

Information systems and other infrastructure needed to reduce CCDF improper payments need implementation 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. The following categories include the information systems and infrastructure capabilities that help minimize improper payments that some states chose to report for FY 2021:

- Eligibility determination and authorization;
- Information on providers or provider payments;
- Information on active cases to assist in case management; and
- Other information systems and infrastructure.

8.9 Head Start Disaster Relief

Head Start Disaster Relief Statistical Sampling Process

HHS received $650 million in Disaster Relief Act funds to assist Head Start and Early Head Start grantees to support program response, recovery, and other activities directly related to Hurricanes Harvey, Irma, and Maria. Of the $650 million provided to Head Start, $12.5 million was available for federal administrative expenses. Head Start and EHS grantees can use the remaining $637.5 million in the following six categories: 1) Facilities (repairs, renovations, purchase, and construction); 2) Materials, Supplies, and Equipment; 3) Program Operations; 4) Additional Health, Mental Health, Dental, and Nutrition Services; 5) Training and Technical Assistance; and 6) Disaster Recovery Expenses Incurred Prior to Availability of Funds under the Disaster Relief Act.

HHS required all grantees that received Disaster Relief Act funds to submit reconciliations of payments made by grantees. HHS then used these reconciliations for statistical sampling and estimation of improper payments. HHS designed a stratified sampling plan; the stratification reflects HHS disaster recovery funds recent oversight experience (e.g., from Superstorm Sandy) and breaks the population into subgroups to allow higher likelihood of

sampling high-dollar transactions where larger improper payments may reside and therefore have a higher priority for detection:

- The High Stratum (Stratum 3) consists of the largest dollar transactions, accounting for approximately one-third of all outlays for the FY being monitored. Because this stratum contains the largest payments and represents approximately the same level of aggregate outlays as the other strata, it consists of the fewest number of transactions.
- The Low Stratum (Stratum 1) consists of the lowest dollar transactions, also accounting for approximately one-third of all outlays for the FY being monitored. Because this stratum contains the smallest payments yet represents the same level of outlays as the other strata, it has the highest number of transactions.
- The Middle Stratum (Stratum 2) consists of the mid-tier transactions, between those in the High and Low Strata: these payments also represent approximately one-third of outlays.

HHS reviewed the sampled payments from strata 1, 2, and 3 to determine whether the items were supported by adequate documentation, and then HHS used a statistically valid formula to calculate an error rate of improper payments made against total disaster relief funding.

Calculations and Findings

The Head Start Disaster Relief improper payment plus unknown payment estimate for FY 2021 is 0.09 percent or $0.04 million.

Head Start Disaster Relief Corrective Action Plan

The five payment errors in the Head Start Disaster Relief program sample were due to administrative or process errors made by a third party (grant recipient). HHS designs corrective action plans to prevent similar errors from occurring in the future.

Corrective Actions to Address Error Categories:

The improper payment errors were caused by administrative errors made by third party recipients. The Office of Head Start will continue to work closely with recipients to reduce the likelihood of improper payments in the future by supporting ongoing compliance and providing training and technical assistance needed in areas such as procurement, source documentation, cost allocation plan updates, and any other areas identified by subject matter experts.

8.10 CDC Disaster Relief

CDC Disaster Relief Statistical Sampling Process

The Disaster Relief Act allocated $200 million to CDC for response, recovery, preparation, mitigation, and other expenses directly related to the consequences of Hurricanes Harvey, Irma, and Maria. To determine an improper payment rate, CDC developed a standardized procedure with a risk-based approach. HHS conducted risk assessments of administrative functions and program activity, reviewed sampled invoices for payment accuracy, and stratified the funding activities into subgroups to show a more accurate depiction of the funding activities sampled from a larger, more generalized population. Once HHS determined the sample population, the agency used a statistically valid formula to calculate an error rate of improper payments made against total disaster relief funding.

Calculations and Findings

The CDC improper payment plus unknown payment estimate for FY 2021 is 0.07 percent or $0.13 million.

The errors in the CDC Disaster Relief program are due to charges affiliated with unsupported and excessive fringe benefit costs. CDC identified fringe benefits in excess of the federal guidance and standards established by the U.S.

Bureau of Labor Statistics (BLS). The BLS is a federal agency that collects and disseminates various data about the U.S. economy and labor market, including the Consumer Price Index and the Producer Price Index, both of which are considered to be important measures of inflation. Overall, the provision provides a 31 percent fringe benefit rate which set the standards for the labor market as of June 2021. However, the rates claimed of 60 percent were higher than what was approved and identified as the standard fringe benefit rates. This error resulted in $117,987 in excessive charges.

CDC Disaster Relief Corrective Action Plan

HHS officials will continue to work closely with recipients to reduce the likelihood of improper payments. HHS efforts will include: increasing the post-award monitoring through training, communication, and technical assistance needed in areas such as cost allocation plan, source documentation, and closeout requirements, and any other areas identified by subject matter experts as common areas of fiscal challenge in the grant community.

Corrective Actions to Address Error Category:

The improper payment error was caused by administrative error when the recipient inadvertently used a higher established rate not officially approved in the budget.

9.0 RECOVERY AUDITING REPORTING

HHS developed a risk-based strategy to implement PIIA's recovery auditing provisions that expanded payment recovery audits. Specifically, HHS focuses on implementing recovery audit programs in Medicare and providing a framework for states to implement recovery audit programs in Medicaid, which together accounted for approximately 80 percent of HHS's outlays in FY 2021. 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 8.0*: Program-Specific Reporting Information* and the following subsections. HHS will consider lessons learned from these experiences as it implements 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 can review a variety of claim types, with restrictions on inpatient hospital patient status reviews (limited only to providers referred by the Quality Improvement Organizations for exhibiting persistent noncompliance 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. More recently, on March 26, 2021, HHS awarded a new Medicare FFS Region 1 RAC. HHS anticipates awarding another RAC region each subsequent year.

In FY 2021, the Medicare FFS RAC program identified approximately $390.28 million in overpayments and recovered $327.31 million. During FY 2021, outpatient claims represented the majority of Medicare FFS RAC collections. In FY 2021, the Medicare FFS RACs made recommendations to HHS to improve program operations and prevent improper payments. These recommendations resulted in proposed RAC topics for review.

HHS also uses Medicare FFS RAC findings to prevent future improper payments. For example, in FY 2021, HHS released quarterly Provider Compliance Newsletters with detailed information on nine 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 the Medicare FFS RAC program website.

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 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 began recovering certain conditional payments made by Medicare FFS until HHS identifies an NGHP with primary payment responsibility. The CRC is a single contractor with national jurisdiction.

In FY 2021, the CRC identified approximately $500.25 million and collected $286.83 million in mistaken payments. The MSP RAC recommended HHS improve program operations by:

- Changing systems to automatically send Proof of Debt to Treasury at the time of referral, thereby reducing efforts associated with Treasury inquiries and disputes for delinquent MSP debts.
- Improving the MSP recovery portals by implementing the "Go Paperless" option for debtors to receive letters digitally, which allowed for more timely resolution of outstanding debts as well as the savings on printing and mailing.

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.

In 2015, HHS issued a Request for Information on the proposal to implement RADV audits under the purview of a Part C RAC. In response, the MA industry expressed concerns of burden related to the high overturn appeal rate in the early experience of the Medicare FFS RAC program. Additionally, potential RAC vendors expressed concerns with the unlimited delay in the contingency payment due to timeframes for appeal decisions in the MA appeal process remaining unestablished (42 CFR 423.2600). Despite their success in Medicare FFS, RACs have found Medicare Part C to not be viable because of differing payment structures, a narrow scope of payment error, and unlimited appeal timeframes. Because HHS did not procure a Part C RAC, HHS's primary corrective action on Part C payment error is the contract-level RADV audits. RADV audits verify that diagnoses submitted by MA organizations for risk adjusted payment corroborate medical record documentation and recover overpayments. The RADV program is operational with the support of contractors. Given the purpose of RADV audits, HHS believes that the RADV audit program performs Part C RAC functions.

Similar to the Part C RAC, HHS believes that the PPI-MEDIC performs the Part D RAC functions. The PPI-MEDIC's workload is substantially like that of a Part D RAC, and the PPI-MEDIC has a robust program to identify improper payments. After the PPI-MEDIC identifies improper payments, HHS requests that plan sponsors delete PDE records that are associated with potential overpayments. Subsequently, HHS validates whether plan sponsors delete the PDEs and do not resubmit such PDEs for payment. In FY 2021, the PPI-MEDIC continued audits that identified potentially improper payments and conducted education and outreach for Part D plan sponsors. As stated in Section 5.1, based on the PPI MEDIC's data analysis projects and Part D plan sponsor self-audits, HHS recovered $8.68 million from Part D sponsors during the first three quarters of FY 2021.

State Medicaid RACs

Section 1902(a)(42)(B) of the *Social Security Act* required states to implement state Medicaid RAC programs by January 1, 2012. However, federal law allows states to request an exemption from the Medicaid RAC requirements, and in FY 2021, many states operated under an approved exemption (for example, because of the high proportion of beneficiaries enrolled in Medicaid managed care compared to FFS). In FY 2021, State Medicaid RAC federal-share

recoveries totaled $118.88 million and reflect overpayments collected, adjusted, or refunded to HHS, as reported by states on the Form CMS-64, Medicaid Statement of Expenditures.[36]

Recovery Auditing Reporting Tables

PIIA and OMB guidance requires agencies to provide detailed information where available on agency recovery auditing programs, and other efforts to recover improper payments.

[36] This amount may differ from the Annual Report to Congress on the Medicare and Medicaid Integrity Programs because the AFR is prepared prior to the finalization of state reporting.

Table 3: Overpayments Recovered through and Outside of Recovery Audits

FY 2021 (in Millions)

Program or Activity	Overpayments Recovered through Recovery Audits			Overpayments Recovered Outside of Recovery Audits	
	Amount Identified	Amount Recovered [1]	CY Recovery Rate	Amount Identified	Amount Recovered [1]
CMS Error Rate Measurements [2]				$19.26	$8.88
Medicare FFS Recovery Auditors	$390.28	$327.31	84%		
Medicare Secondary Payer Recovery Auditor	$500.25	$286.83	57%		
Medicare Contractors [3]				$12,769.94	$10,582.13
Medicaid Integrity Contractors - Federal Share [4]				$26.58	$3.21
State Medicaid Recovery Auditors - Federal Share [5]	N/A	$118.88	N/A		
ACF IP Rate Measurements and Eligibility Reviews [6]				$0.14	$0.004
ACF OIG Reviews [7]				$37.00	$24.09
Single Audits [8]				$13.31	$27.76
HRSA National Health Service Corps				$3.49	$5.99
TOTAL [9]	**$890.53**	**$733.02**	**82%**	**$12,869.72**	**$10,652.06**

Notes:

1. The amount reported in the Amount Recovered column is the amount recovered in FY 2021, 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 2021 report period were $15,811,242.88. The MACs recovered the identified overpayments via standard payment recovery methods. As of the report publication date, MACs reported collecting $8,077,217.63 or 51.09 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. The *Social Security Act* and related regulations govern the recoveries of Medicaid and CHIP improper payments. States reimburse HHS for the federal share of overpayments. Section 1903(d) of the *Social Security Act* allows states up to 1 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 2021 report period were $1,659,900.69 for Medicaid and $1,793,672.13 for CHIP. The amounts recovered were $627,278 for Medicaid and $178,584 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. Medicaid Integrity Contractors identified total overpayments that include both federal and state shares. However, HHS reports only the federal share across audits. The amount recovered may differ from that which is reported in the Annual Report to Congress on the Medicare and Medicaid Integrity Programs because the Agency Financial Report is prepared prior to the finalization of state reporting.
5. For the State Medicaid Recovery Auditors - Federal Share row, only the amount recovered is available. The amount recovered may differ from that which is reported in the Annual Report to Congress on the Medicare and Medicaid Integrity Programs because the Agency Financial Report is prepared prior to the finalization of state reporting.
6. The ACF Improper Payment Rate Measurements and Eligibility Reviews row contains Amount Identified information for the Foster Care, CCDF, and Head Start Disaster Relief programs for which the amounts were identified during the current reporting year. Since HHS postponed Foster Care reviews in FY 2021, no new reviews have taken place and consequently no overpayments have been recovered. For CCDF, states must recover childcare payments resulting from 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 Recovered information, data reported in FY 2021 represent improper payments recovered in FYs 2018 through 2020 by the Year Two states based on improper payments identified in FY 2018. States reported identifying $106,667 and recovering $4,094. For the Head Start Disaster Relief portion, HHS identified $34,493 during the FY 2021 report period. Although HHS did not recover any of these funds in the FY 2021 report period, HHS anticipates recovery during FY 2022.
7. The ACF OIG Reviews row, column Amount Identified includes information for all ACF programs for which the amounts from an HHS OIG Report were sustained from August 2020 to July 2021.
8. The Single Audits row includes information for all Divisions (in previous AFRs, HHS only reported results for ACF Single Audits in this table). All Divisions except ACF reported information for the full federal fiscal year (October 1, 2020 to September 30, 2021). ACF's information represents results from August 1, 2020 to July 31, 2021.
9. Totals do not necessarily equal the sum of the rounded components.

FY 2021 Top Management and Performance Challenges Identified By the Office of Inspector General Facing HHS

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201

DATE: November 1, 2021

TO: Xavier Becerra
Secretary

THROUGH: Karuna Seshasai
Executive Secretary

FROM: Christi A. Grimm
Principal Deputy
Performing Duties of the Inspector General

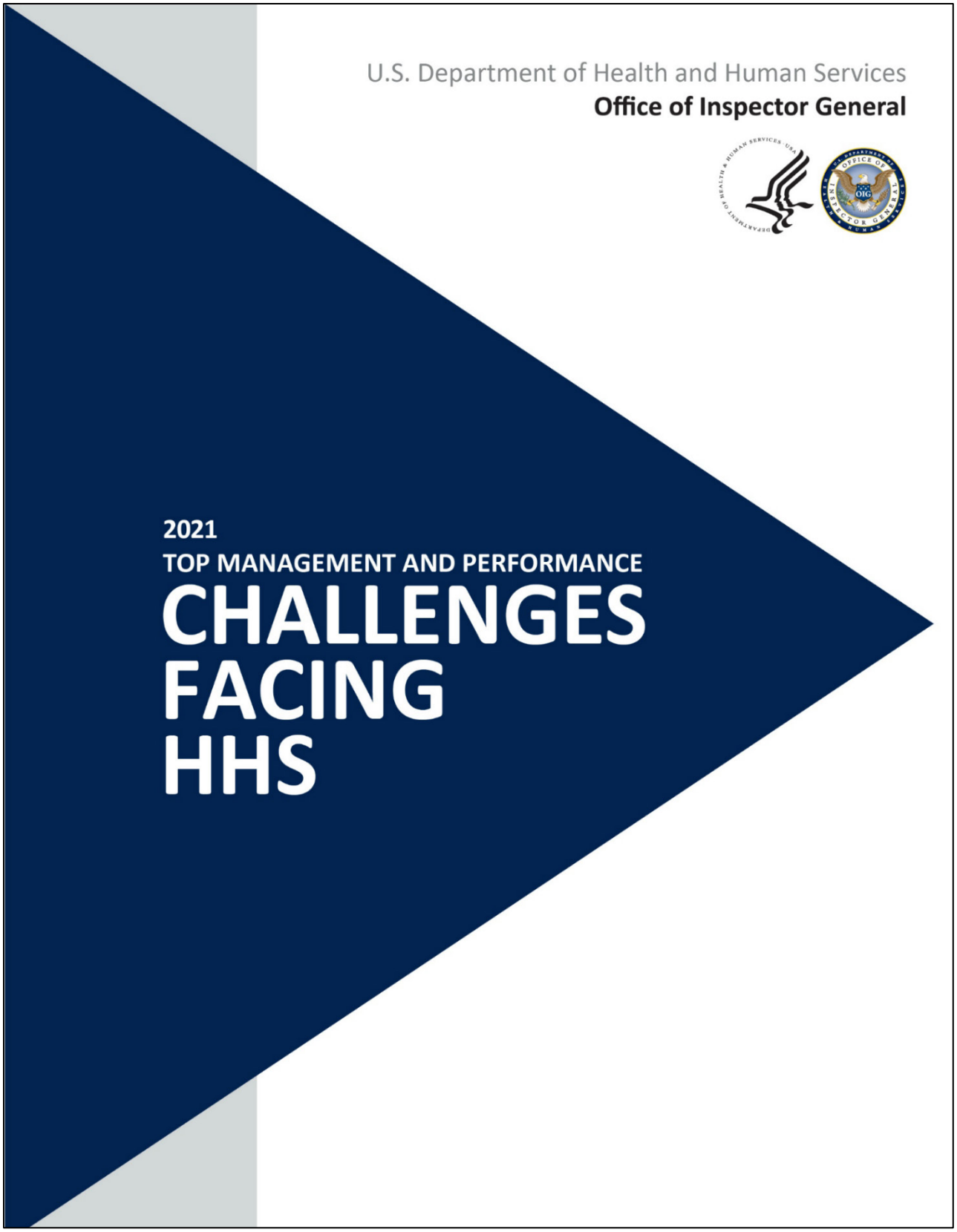
SUBJECT: Top Management and Performance Challenges Facing the Department of Health and Human Services in Fiscal Year 2021

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 (HHS or the Department). The Reports Consolidation Act of 2000, P.L. No. 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.

HHS's top management and performance challenges for fiscal year 2021 are:

1. Safeguarding Public Health
2. Ensuring the Financial Integrity of HHS Programs
3. Delivering Value, Quality, and Improved Outcomes in Medicare and Medicaid
4. Protecting the Health and Safety of HHS Beneficiaries
5. Harnessing and Protecting Data to Improve the Health and Well-Being of Individuals
6. Improving Collaboration to Better Serve Our Nation

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 Juliet Hodgkins, Acting Chief of Staff, at (202) 708-9797 or Juliet.Hodgkins@oig.hhs.gov.


U.S. Department of Health and Human Services
Office of Inspector General
2021
TOP MANAGEMENT AND PERFORMANCE
CHALLENGES
FACING
HHS

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TOP MANAGEMENT AND PERFORMANCE
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Introduction

The *2021 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 six top management and performance challenges (TMCs) that the Department faces 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 reflect overarching issues that affect multiple HHS programs and responsibilities. These are not the only challenges that confront HHS. OIG reports are a key resource that highlight specific opportunities to improve HHS programs and operations.

HHS is responsible for $2.8 trillion in budgetary resources and its programs impact the lives of virtually all Americans. To identify the six TMCs, we integrated OIG's oversight, enforcement, data analytics, and risk analysis work. For each TMC, we describe the dimensions of the challenge, highlight the progress the Department has made in addressing the challenge, and identify what remains to be done.

Throughout this document, we highlight the unprecedented challenges the Department faces because of coronavirus disease 2019 (COVID-19). As the lead Federal agency for medical support and coordination during public health emergencies, HHS has numerous and significant responsibilities in providing assistance as the United States confronts the COVID-19 pandemic. HHS's responsibilities include working with Federal, State, Tribal, local, and international governments to respond effectively to the pandemic; supporting the development and distribution of vaccines, treatments, and research on COVID-19; assisting the health care system by providing flexibility, resources, and funding; ensuring the safety of the health care workforce; and protecting the health and well-being of the public. Challenges related to the Department's COVID-19 response are primarily addressed in TMC 1 on public health. However, the COVID-19 response affects nearly every aspect of Department operations, and challenges related to it are also addressed in other TMCs.

Management and performance challenges are inherently crosscutting. The TMCs reflect how multiple HHS staff divisions (StaffDivs) and operating divisions (OpDivs) are addressing these pressing issues. For example, the challenge of financial integrity highlighted in TMC 2 has natural intersections with the challenge of delivering value, quality, and improved outcomes in Medicare and Medicaid, which is the subject of TMC 3. Given that challenges cross internal HHS boundaries and externally with Federal and State agencies, coordination among HHS agencies and across the government sector is integral to addressing these challenges.

In addition to this annual TMC publication, OIG maintains a list of significant and unimplemented OIG recommendations, including legislative recommendations, that address vulnerabilities. These recommendations are drawn from OIG's audits and evaluations. OIG identifies the top unimplemented recommendations which if implemented would, in OIG's view, most positively affect HHS programs in terms of cost savings, program effectiveness and efficiency, and public health and safety.

More information on OIG's work, including the reports mentioned in this publication, appears on our website at https://oig.hhs.gov.

FY 2021 Top Management and Performance Challenges Identified By the Office of Inspector General Facing HHS

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Acronyms

ACF	Administration for Children and Families
ACO	Accountable Care Organization
ADHD	Attention Deficit Hyperactivity Disorder
AHRQ	Agency for Healthcare Research and Quality
AMP	Average Manufacturer Price
API	Application Programming Interface
APTC	Advance Premium Tax Credit
ASPR	Office of the Assistant Secretary for Preparedness and Response
CARES	Coronavirus Aid, Relief, and Economic Security Act
CCDF	Child Care and Development Fund
CDC	Centers for Disease Control and Prevention
CHIP	Children's Health Insurance Program
CIO	Chief Information Officer
CMS	Centers for Medicare & Medicaid Services
DHS	Department of Homeland Security
DME	Durable Medical Equipment
DMI	Data Modernization Initiative
DOJ	Department of Justice
EHR	Electronic Health Record
EID	Emerging Infectious Diseases
EUA	Emergency Use Authorization
FDA	Food and Drug Administration
FFS	Fee-For-Service
FPS	Fraud Prevention System
FSIS	Food Safety Inspection Service
FY	Fiscal Year
GAO	Government Accountability Office
HC3	Health Sector Cybersecurity Coordination Center
HHS	Department of Health and Human Services
HIPAA	*Health Insurance Portability and Accountability Act of 1996*
HRSA	Health Resources and Services Administration
HHS	US Department of Health and Human Services
IHS	Indian Health Service
IT	Information Technology
LCA	Least Costly Alternative
MA	Medicare Advantage
MAO	Medicare Advantage Organization
MCO	Medicaid Managed Care Organization
NIH	National Institutes of Health
OCR	Office for Civil Rights
OGA	Office of Global Affairs
OIG	Office of Inspector General
OMB	Office of Management and Budget
ONC	Office of the National Coordinator for Health Information Technology
ORR	Office of Refugee Resettlement
OTP	Opioid Treatment Program
OUD	Opioid Use Disorder
PCS	Personal Care Services
PDMP	Prescription Drug Monitoring Program
PERM	Payment Error Rate Measurement
PPE	Personal Protective Equipment
PRF	Provider Relief Fund
REMS	Risk Evaluation and Mitigation Strategies
SAMHSA	Substance Abuse and Mental Health Services Administration
SNF	Skilled Nursing Facility
TANF	Temporary Assistance for Needy Families
T-MSIS	Transformed Medicaid Statistical Information System
UC	Unaccompanied Children

CHALLENGE
1

1: Safeguarding Public Health

HHS's core mission is to enhance the health and well-being of all Americans. Pandemic response and recovery efforts have exacerbated the Department's challenge to safeguard public health. With more than 730,000 deaths attributable to COVID-19 and more than 45 million cases of the disease in the United States as of October 28, 2021,[1] HHS must act vigilantly to mitigate the loss of life and negative short- and long-term health consequences associated with COVID-19 while effectively operating a range of programs and services that are essential to protecting individuals and communities. This work includes effectively preparing for future emergencies while advancing response capabilities, ensuring that products regulated by the Food and Drug Administration (FDA) are safe and effective, and combating the opioid epidemic while helping ensure access to treatment. To operate effective public health programs, the Department must ensure that its OpDivs and StaffDivs coordinate efforts internally as well as with partners at all levels of government and other stakeholders. (See TMC 6 for more information on the Department's challenge of coordinating with internal and external partners.)

KEY TAKEAWAYS

I. Relevant Agencies: All HHS
II. Elements of the Challenge:
- Strengthening emergency preparedness and response capabilities
- Providing adequate oversight of FDA-regulated products
- Tackling the opioid epidemic while ensuring access to treatment

Strengthening emergency preparedness and response capabilities

Public health emergencies can severely strain public health and medical infrastructure and lead to serious illness and loss of life, often with greater impacts on the most vulnerable populations, such as nursing home residents. In 2020, two in five Medicare beneficiaries in nursing homes were diagnosed either with COVID-19 or likely COVID-19 and almost 1,000 more beneficiaries died per day in April 2020 than in April 2019.[2] The negative health impacts of emergencies can also exacerbate racial and ethnic health disparities. Black, Hispanic, and Asian Medicare beneficiaries in nursing homes were more likely to have had COVID-19 or likely COVID-19 compared to White beneficiaries,[3] and HHS has identified pronounced racial and ethnic disparities in COVID-19 infections, hospitalizations, death rates, and vaccination rates that extend to the broader population.[4] Provisional estimates from the Centers for Disease Control and Prevention (CDC) show a decline in U.S. life expectancy in 2020, with COVID-19 having had the greatest effect on the decline. CDC data also show an increase in racial and ethnic disparities pertaining to life expectancy in 2020.[5] HHS programs must address racial, socioeconomic, geographic, and other types of disparities, and the effects that such disparities have on public health.

HHS has a leading role in preparing for, responding to, and recovering from the adverse health effects of public health emergencies including infectious disease outbreaks, natural disasters, and chemical, biological, radiological, and nuclear events. HHS is uniquely positioned to provide guidance, funding, and support to assist States and communities throughout the United States so that they can effectively and equitably plan for and respond to emergencies, as well as support sustained recovery efforts. The experience of the past year underscores that HHS must be prepared to address multiple public health emergencies occurring simultaneously with different response

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needs and challenges, such as hurricanes and wildfires that have occurred during the COVID-19 public health emergency. A key challenge is to have adequate planning and mechanisms in place prior to a public health emergency to efficiently and rapidly deploy assets and provide relief to those in need of HHS resources and assistance during the emergency. This includes planning agency controls and strategies to mitigate disaster preparedness and response risk.[6] In addition, an effective emergency response requires a prepared public health workforce. The *American Rescue Plan Act of 2021* provided HHS with additional funds, including $7.6 billion to establish, expand, and sustain the public health workforce.[7] HHS must ensure that the public health workforce is ready to address current and future emergencies.

For infectious disease emergencies, HHS plays a critical role in identifying, acquiring, developing, distributing, and administering medical countermeasures (e.g., vaccines, therapeutics, and diagnostics). Among HHS's operating divisions, the CDC is responsible for responding to health threats and providing critical scientific information to protect Americans. The Biomedical Advanced Research and Development Authority within the Office of the Assistant Secretary for Preparedness and Response (ASPR) promotes the development and acquisition of medical countermeasures, including supporting the transition of medical countermeasures from research through advanced development toward consideration for approval by FDA and inclusion in the Strategic National Stockpile. The National Institutes of Health (NIH) is responsible for research related to the development of medical countermeasures including vaccines. FDA is responsible for regulating the safety and effectiveness of such medical countermeasures and ensuring the safety and availability of the U.S. blood supply and tissue donations. FDA may use its Emergency Use Authorization (EUA) authority to facilitate the availability of medical countermeasures in public heath emergencies, as it did for COVID-19 diagnostics, vaccines, and therapeutics. The Office of Global Affairs (OGA) is responsible for leading international engagements to support both preparedness for and responses to public health emergencies.

Existing OIG work on prior outbreaks of communicable disease illustrates the importance of ongoing HHS readiness to detect, assess, and respond to new disease outbreaks and other emergencies. For instance, a 2019 OIG report about HHS's response to the 2014 Ebola outbreak recommended that HHS develop department-wide objectives and a strategic framework for responding to international public health emergencies.[8] HHS concurred with the recommendations in the report and indicated that it is continuing to coordinate these efforts and will provide additional updates.

In addition to coordinating emergency planning and response efforts effectively with its program offices, HHS works with States and localities to facilitate planning and preparedness to address a wide range of health and human service needs including the management and distribution of medical supplies, establishment of alternative care sites, and distribution of vaccines and antiviral drugs. (See TMC 6.) In an OIG survey of hospitals conducted in March 2021, hospitals reported that operating in "survival mode" for an extended period had created challenges with health care delivery, staffing, vaccinations, supplies, and finances. Hospitals found that the emergency exacerbated longstanding challenges in health care delivery, access, and health outcomes.[9] Prior OIG work identified opportunities for health care facilities to improve emergency preparedness and response planning during infectious disease outbreaks and disasters.[10] HHS should continue to support the development and maturation of health care coalitions and other entities in their efforts to plan for and coordinate emergency response among diverse entities such as hospitals, public health agencies,[11] emergency medical services, and emergency management.[12]

As the COVID-19 emergency continues to evolve and new data provide a deeper understanding of topics such as transmission, testing, therapeutics, vaccines, vaccination programs, public health communication, and short- and long-term health effects, HHS faces the challenge of ensuring that it is a continuously learning organization. HHS

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must rely on up-to-date information to sustain and strengthen its emergency response and provide effective public health guidance to the American public.

Ensuring FDA-regulated products are safe and effective

FDA is charged with ensuring the safety, effectiveness, and security of human and animal drugs, biological products, and medical devices; ensuring the safety of the nation's food supply, cosmetics, and products that emit radiation; and regulating tobacco products. These functions are critical to ensuring that Americans can trust the expansive array of products in FDA's purview.[13] FDA has the added challenge of facilitating emergency response efforts related to the current COVID-19 emergency, including reviewing scientific evidence and issuing emergency use authorizations, and approvals, for COVID-19 vaccines and other medical products, providing surveillance of medical product safety and effectiveness, and updating guidance based on emerging science.[14] The American public relies on FDA to expeditiously assess new medical products or new uses of legally marketed medical products (such as drugs or vaccines) that treat or offer protection from negative health effects associated with COVID-19 without sacrificing assurances of safety and efficacy.

Drug, biologic, and medical device safety

FDA's responsibility to help ensure the safety and effectiveness of medical products begins before approval and continues after the product is marketed. This includes inspections of manufacturing facilities; reviewing drugs, devices, and biologics for safety, effectiveness and quality; authorizing the use of investigational medical products; and conducting post-market surveillance. The public relies on FDA to be expeditious in evaluating products and thoughtful in its decisions and processes regarding approval for marketing in the United States. OIG is currently assessing how FDA implements its accelerated approval pathway.[15]

FDA's task of assessing products has become more difficult as manufacturing processes and products have evolved. The drug, biologic, and medical device supply chain is becoming increasingly complex, and many of the products used in the United States are manufactured overseas or are dependent on raw materials that are produced overseas. For all FDA-regulated drugs, 74 percent of the manufacturing facilities producing active pharmaceutical ingredients and 54 percent of the manufacturing facilities producing finished dosage forms of human drugs were located outside of the United States in 2020[16] In response to challenges with its foreign drug inspection process, FDA in May 2017 began implementing major programmatic changes to enhance its ability to protect public health. An OIG audit will assess whether programmatic changes improved FDA's foreign drug inspection process.[17]

Accurate drug tracing information is critical to identifying an illegitimate drug and removing it from the supply chain. If potentially harmful drugs enter the drug supply chain, investigators from FDA, State(s), and elsewhere need complete information about the trading partners that bought and sold the drug and about the drug's physical movement through the supply chain. An OIG evaluation found that tracing information could not be used to identify the physical movement through the supply chain for about half of selected drugs. FDA agreed with OIG's recommendations to take action to help protect patients from the effects of dangerous, ineffective, and illegitimate drugs by, for example, ensuring that trading partners in the drug supply chain are aware of Federal requirements and guidance and by seeking legislative authority to require information about a drug's complete physical path through the supply chain.[18]

The rapid evolution of science and technology presents new concerns for FDA to address via its oversight role. Managing cybersecurity risks associated with networked devices is increasingly difficult as more

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medical devices use internet connectivity. Networked medical devices approved by FDA can be susceptible to cybersecurity threats such as ransomware and unauthorized remote access if the devices lack adequate security controls.[19] These networked devices include infusion pumps, diagnostic imaging, and pacemakers that are commonly used in hospital settings and at home.

In 2021, OIG released a report highlighting the lack of oversight of medical devices by State surveyors and accrediting organizations in Medicare-participating hospitals, creating vulnerabilities to cyberattacks for patients requiring medical devices.[20] Additionally, in 2018 OIG released two reports assessing FDA's oversight of premarket and post-market cybersecurity risks to medical devices.[21] An underlying issue identified in both reports was the opportunity for FDA to take further action in addressing cybersecurity threats to reduce risks to patients and the health care industry. FDA has made administrative changes to improve its premarket and post-market processes, but FDA should continue to take steps to enhance its ability to receive relevant information as well as securely share it with key stakeholders. (See TMC 5 on data for additional actions FDA has taken related to cybersecurity.)

Food safety

Foodborne illnesses are a largely preventable threat to public health. An estimated 1 in 6 Americans gets sick, 128,000 are hospitalized, and 3,000 die from contaminated foods each year.[22] FDA has the complex responsibility of overseeing facilities that are responsible for producing foods that are safe. The American public relies on FDA, which works in collaboration with other Federal agencies and State, local, and territorial partners to help ensure the safety of both human and animal food.[23]

FDA's current approach to food safety includes goals to "enhance traceability, improve predictive analytics, respond more rapidly to outbreaks, address new business models, reduce the contamination of food, and foster the development of stronger food safety cultures."[24] FDA must continue to modernize the food safety system and respond effectively and efficiently when issues are identified. FDA should conduct risk-based inspections of domestic and foreign food facilities within the timeframes required by the *Food Safety Modernization Act*, identify instances of failure to comply with good manufacturing practices, and take necessary steps when health risks are identified, including administrative and enforcement actions when warranted.[25] FDA has made organizational changes with the goal of improving incident response through, for example, its Coordinated Outbreak Response and Evaluation Network and should continue to improve the timeliness and effectiveness of its processes, such as food recalls, to optimize its ability to protect the public from outbreaks of foodborne illnesses.

Tobacco

Tobacco use is the leading cause of preventable death and disease in the United States.[26] FDA regulates the manufacturing, marketing, and distribution of tobacco products to protect public health and has made a commitment to reduce harm from tobacco products, particularly among youth. Although FDA and the CDC's 2020 National Youth Tobacco Survey showed fewer middle and high school-aged tobacco product users in 2020 compared to the previous year, roughly 16 percent of students used a tobacco product, including almost 24 percent of high school and 7 percent of middle school students. In 2020, e-cigarettes were the most used tobacco product among both middle and high school students.[27] FDA must continue efforts to reduce harm amid increasing concerns surrounding the use and detrimental health effects of electronic nicotine delivery systems such as e-cigarettes and vape pens.

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Working with the CDC, FDA faces the challenge of better understanding the science of tobacco products and the most effective use of its authorities to regulate their manufacturing, marketing, and sale, including premarket reviews and health warnings on packaging and advertisements. OIG is assessing FDA's Tobacco Retailer Compliance Check Inspection program under which FDA contractors (generally States) carry out undercover-buy inspections of tobacco retailers to ensure they are complying with restrictions on sales to minors.[28]

Combating the opioid epidemic and helping to ensure access to treatment

From 2018 to 2019, the number of drug overdose deaths increased by nearly 5 percent, and since 1999 the number has quadrupled. In 2019, opioids were involved in more than 70 percent of the more than 70,500 drug overdose deaths.[29] The pandemic and related stressors are thought to put people at risk for substance use disorder,[30] and substance use disorder puts adults at high risk for severe illness from COVID-19.[31] Provisional data from the CDC show an approximately 30 percent increase in overdose deaths from February 2020 to February 2021, with more than 95,000 overdose deaths reported in that period.[32] In early FY 2022, HHS released an overdose prevention strategy.[33]

Current Federal priorities for drug policy include expanding access to evidence-based treatment, advancing racial equity in the approach to drug policy, and reducing the supply of illicit substances.[34] The Department should continue to use the tools available across its operating divisions to address the ongoing opioid epidemic while being mindful of patients' needs to access appropriate pain management, which may include the use of opioid analgesics.

FDA has key roles in ensuring the safe use of opioids. The agency approves new drugs before they are marketed in the United States, assesses the benefits and risks of each new drug,[35] and monitors the safety of marketed drugs as new information becomes available. FDA supports the treatment of opioid use disorders (OUDs) with FDA-approved drugs—i.e., buprenorphine, methadone, and naltrexone—as well as the development of additional therapies to treat OUDs, and employs tools to mitigate risks associated with approved drugs, including updating product labelling and developing Risk Evaluation and Mitigation Strategies (REMS) as needed.[36] An OIG evaluation found that data quality issues made it challenging for FDA to determine whether two REMS for opioid analgesics had been effective and that REMS may not be well-suited to quickly address the opioid crisis.[37] FDA must work to ensure that strategies it uses to mitigate the misuse and abuse of opioids achieve their intended impact.

The opioid crisis is partially fueled by opioids prescribed by licensed medical professionals, dispensed by licensed pharmacies, and paid for by Federal funds. Prescription opioids were involved in more than a quarter of all opioid overdose deaths in 2019.[38] The COVID-19 pandemic has heightened concern about opioid use and access to treatment. The pandemic has put people with OUD at particular risk, as they are at higher risk of developing COVID-19 and are more likely to experience hospitalizations or death from the illness.[39] More than 43,000 Medicare Part D beneficiaries had an opioid overdose—from prescription opioids, illicit opioids, or both—during 2020. Overall, nearly 1 in 4 Medicare Part D beneficiaries received opioids during 2020.[40] The number of beneficiaries who received drugs through Part D to treat OUD increased, but at a slower rate in 2020 than in prior years. Unlike in other recent years, there was no growth in the number of beneficiaries receiving prescriptions through Part D for the opioid overdose-reversal drug naloxone. These slower growth rates add to ongoing concerns about access to medications to treat OUD and naloxone. Ensuring this access is particularly important as we do not yet know the full extent to which the stressors of the COVID-19 pandemic may have increased the need for these drugs.

The Indian Health Service (IHS) also has an important role to play in preventing and detecting opioid misuse and abuse. Data from an OIG evaluation show that some patients received high amounts of opioids from IHS-run

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pharmacies, and IHS has taken steps to ensure appropriate opioid use among its patients. [41] At the same time, the agency could improve the efficiency of its opioid monitoring systems by further automating its system for electronic health records (EHRs). Additionally, IHS officials reported challenges in tracking patient care received outside IHS and in using State-run prescription drug monitoring programs (PDMPs), which are electronic databases that collect and disseminate controlled substance prescription information. Both factors can limit the abilities of IHS staff to monitor opioid use. IHS should assess the costs and benefits of updating the IHS EHR system with tools to support more automated monitoring, and request support from States and Federal partners to address challenges with State-run PDMPs. [42]

Ensuring access to effective OUD treatment, especially in regions with greater risk for opioid misuse and overdose, remains crucial to combating the opioid epidemic. [43] People suffering from an OUD are at risk for withdrawal and relapse, and without effective treatment may seek out illicit opioids such as heroin. However, fewer than 20 percent of the 2.1 million people with OUDs received treatment in 2018.[44] Measures to address COVID-19 have further challenged access to treatment. In a survey of 143 opioid treatment programs (OTPs), OIG identified various challenges OTPs encountered during the COVID-19 pandemic including maintaining pre-pandemic service levels, managing impacts on facility operations, and maintaining patient participation in opioid treatment program activities, among others.[45]

The *Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act* requires Medicare to cover certain treatment services provided by opioid treatment programs including methadone. As part of the effort to ensure access to effective treatment, HHS needs data to monitor access and unmet needs. An OIG evaluation identified opportunities to enhance information about access and the need for medication to treat OUD through the Buprenorphine Waiver Program, one of the Substance Abuse and Mental Health Services Administration's (SAMHSA's) key initiatives for combating the opioid crisis by expanding treatment services.[46] In spring 2021, HHS released new buprenorphine practice guidelines designed to expand access to evidence-based treatment for OUD.[47]

In addition, HHS must ensure that funding to address the opioid epidemic is efficiently and effectively spent for its intended purpose. An OIG audit found that 67 of 100 Health Resources and Services Administration (HRSA) health centers did not use grant funds that were intended to expand access to mental health and SUD services focusing on the treatment, prevention, and awareness of OUD consistent with Federal requirements and grant terms. [48] HHS's OpDivs must work with awardees and sub-awardees to ensure behavioral health grant dollars are used in accordance with Federal requirements and consistent with the funding opportunity.

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2: Ensuring the Financial Integrity of HHS Programs

HHS is the largest civilian agency in the Federal government, with $2.8 trillion in budgetary resources.[49] HHS's Medicare program is the Nation's largest health insurer by expenditures and handles more than 1 billion claims per year. Medicaid is the largest health insurer in terms of lives covered, with 81 million Medicaid beneficiaries and Children's Health Insurance Program (CHIP) enrolled individuals.[50] Medicare and Medicaid are the Department's largest programs; funding for these programs (including State funding) represents 41 cents of every dollar spent on health care annually in the United States.[51] CMS's Office of the Actuary estimates that Medicare expenditures totaled $915.4 billion and Medicaid expenditures totaled $682.7 billion in 2020.[52,53] Almost 140 million beneficiaries, or more than 40 percent of Americans, rely on these programs for their health insurance including senior citizens, individuals with disabilities, low-income families and individuals, and patients with end-stage renal disease.[54] CMS bears the responsibility at HHS for administering these programs. As many providers faced fiscal uncertainty due to COVID-19, CMS took steps to provide increased flexibility and advance payments to mitigate the financial effects of the pandemic.

KEY TAKEAWAYS

I. Relevant Agency: All HHS
II. Elements of the Challenge:
- Controlling costs by ensuring prudent payments for goods and services
- Reducing improper payments
- Combating fraud, waste, and abuse
- Monitoring and reporting on the integrity of HHS programs

HHS is also the largest grantmaking and second largest contracting agency in the Federal government. In fiscal year (FY) 2020, HHS awarded $244.7 billion in grants (excluding CMS grants) and $160.7 billion in contracts.[55,56] Responsible stewardship that ensures the transparency and accountability of HHS funds is paramount to making sure that HHS beneficiaries and the American public get the full benefit of this substantial financial investment.

The Department must protect the fiscal integrity of HHS funds and ensure that beneficiaries have access to the services they need. This is a growing challenge due to looming financial shortfalls in the Medicare program,[57, 58] the expansion of eligibility for Medicaid services, and the COVID-19 funds that HHS is responsible for distributing and overseeing via grants and other mechanisms. HHS must manage the efficient and effective use of funds internally and oversee the use of Federal funds by thousands of external funding recipients.

Controlling costs by ensuring prudent payments for goods and services

Whether HHS is paying for medical services, prescription drugs, or human service programs, managing what the Department pays and recognizing and remedying problematic payment policies are critical to controlling costs.

Medicare

Medicare should consider whether payment policies, which are generally set by statute by Congress, are continuing to deliver the intended value. For example, some current policies result in Medicare and beneficiaries paying more for care provided in certain settings than for the same care provided in other settings. An OIG report found that Medicare could have potentially saved $4.1 billion over a 6-year period if swing-bed services at critical-access hospitals had been paid for at the same rates as at skilled nursing

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facilities (SNFs).[59] Likewise, in some situations Medicare pays hospitals different amounts for the same care depending on whether the hospital admits beneficiaries as inpatients or treats them as outpatients.

Additionally, Medicare must take steps to mitigate program integrity risks related to payment and coverage policies. For example, OIG found that hospitals increasingly billed for inpatient stays under Medicare severity diagnosis related groups at the highest severity level—the most expensive level—from FY 2014 through FY 2019. These are indications that hospitals may be engaging in inappropriate billing practices such as upcoding.[60]

Prescription drug programs

In July 2021, President Biden issued an Executive Order aimed at combatting high prescription drug prices.[61] Increased drug costs may limit patients' ability to afford needed prescription drugs, in some cases causing patients to skip or split medication doses or forgo purchasing medications altogether. HHS programs accounted for 38 percent ($140 billion) of total U.S. prescription drug expenditures in 2019.[62] The Medicare Prescription Drug program had net costs of $83.8 billion for FY 2020.[63] Vulnerabilities exist in HHS's payment strategies for prescription drugs (including biologics).

The way that Medicare and Medicaid pay and reimburse for drugs can impact prescription drug prices and costs for programs and their beneficiaries. In the Part B program, OIG found that Medicare would have saved millions of dollars if dispensing fees for several drugs had been aligned with the rates that Part D and State Medicaid programs paid.[64] OIG found that CMS included prices for higher cost versions of drugs that are not covered under Medicare Part B when setting Part B payment amounts. Section 405 of the *Coronavirus Aid, Relief, and Economic Security Act* (CARES) required CMS to make the changes to Part B payment policy recommended by OIG. This lowered payment amounts for some Part B drugs as of July 1, 2021. OIG also found increases in costs for certain prostate cancer drugs reimbursed under Part B that had been subject to the least costly alternative (LCA) policy after that policy was rescinded. LCA bases the payment amount for a group of clinically comparable products on that of the least costly product. OIG found that Medicare expenditures for certain prostate cancer drugs would have been reduced by $33.3 million over 1 year (from $264.6 million to $231.3 million) under the LCA policy.[65] Furthermore, OIG found that although there was a 17-percent decrease in Medicare Part D prescriptions for brand-name drugs from 2011 to 2015, there was a 77-percent increase in total reimbursements for these drugs, leading to greater overall Part D spending and higher beneficiary out-of-pocket costs.[66]

OIG also found that Medicaid could save hundreds of millions of dollars by excluding authorized generic drug transactions to secondary manufacturers from brand-name drugs' average manufacturer price (AMP) calculations. Estimated to save $3.2 billion over 10 years, Section 1603 of the *Continuing Appropriations Act, 2020*, and *Health Extenders Act of 2019* amended section 1927(k)(1)(C) of the Act to exclude generic drug transactions to secondary manufacturers in the brand-name drug's AMP calculations.[67] Additionally, manufacturers' use of reasonable assumptions when calculating AMPs and best prices—a practice OIG's work has established as common—represents a vulnerability in drug pricing for thousands of drugs used in the Medicaid program.[68] HHS must endeavor to limit the impact of high prices on programs and beneficiaries while protecting access to medically necessary drugs. Additionally, the Department should be prepared to address coverage and reimbursement challenges of emerging technologies.

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Preventing and reducing improper payments

An improper payment is any payment that does not meet statutory, contractual, administrative, or other legally applicable requirements, and that may be an overpayment or an underpayment.[69] Reducing improper payments—such as payments to ineligible recipients or duplicate payments—is critical to safeguarding Federal funds. Due to their size, HHS programs account for some of the largest estimated improper payments in the Federal government. Medicare, Medicaid, and CHIP accounted for 65 percent, or $134.2 billion, of all governmentwide estimated improper payments reported in FY 2020.[70] Furthermore, insufficient HHS oversight of grant programs and contracts poses risks of significant improper payments.

Medicare

Original Medicare fee-for-service (FFS), Medicare Part C (also known as Medicare Advantage (MA)), and Medicare Part D (also known as Medicare Prescription Drug) accounted for $42.9 billion, or 32 percent, of the estimated improper payments that HHS reported in FY 2020.[71] Notably, the Medicare FFS improper payment rate estimate during the past 3 years has decreased from 8.1 percent ($31.6 billion) in FY 2018 to 7.3 percent ($28.9 billion) in FY 2019, and to 6.3 percent ($25.7 billion) in FY 2020.[72] This represents positive momentum upon which the Department and CMS can build. However, some types of providers and suppliers pose heightened risks to the financial security of Medicare. For instance, OIG and CMS have identified especially high rates of improper payments for home health, hospice, and SNF care; durable medical equipment, Prosthetics, Orthotics, & Supplies (DMEPOS); chiropractic services; and certain hospital services.[73] CMS has taken corrective actions for Medicare FFS by focusing on specific service areas with high improper payment rates. The reduction in the improper payment rate was driven primarily by reductions in improper payments for home health, Part B, and DME claims. However, CMS should take further action to reduce improper payments among certain provider and supplier types and in geographic locations that present a high risk to the financial security of Medicare. Furthermore, CMS should ensure that it is prepared to detect and prevent improper payments in burgeoning areas, such as telemedicine and genetic testing.

Moreover, improper payments to Medicare Advantage Organizations (MAOs) pose a significant vulnerability for CMS and cost taxpayers billions of dollars. In FY 2020, the improper payment rate for the MA program (Part C) was 6.8 percent, for a total of $16.3 billion in improper payments.[74] Unlike in FFS, through which CMS pays providers directly for each covered service received by a beneficiary, CMS under managed care makes a capitated payment to a MAO for each person enrolled in the organization. In turn, the MAO pays providers for services a beneficiary may require that are included in the organization's contract with CMS. CMS adjusts payments to pay MAOs different amounts for beneficiaries with different expected health care costs. This helps improve access to care for beneficiaries with greater health care needs and reduces incentives for selecting particular beneficiaries. However, OIG has found improper payments in MA that were driven by diagnoses not supported in the medical records.[75, 76]

Medicaid

Medicaid is a Federal-State financing partnership with the 50 States, 5 territories, and the District of Columbia each offering its own program variation reflecting State and local needs and preferences. CMS's Payment Error Rate Measurement (PERM) program measures improper payments in Medicaid and CHIP in all 50 States and the District of Columbia, and produces a national improper payment rate for each program. The estimated Medicaid improper payment rate increased significantly, from 14.9 percent in FY 2019 to

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21.4 percent in FY 2020, while CHIP increased from 15.8 percent to 27.0 percent. These increases were largely due to the continued re-introduction of beneficiary eligibility errors which had previously been paused while CMS updated the PERM eligibility component.[77] Medicaid accounted for approximately $86.5 billion in estimated improper payments in FY 2020. CMS attributes these increases to high levels of observed eligibility errors, such as those occurring when States maintain insufficient documentation to substantiate that income and other information were appropriately verified, failures in conducting timely and appropriate annual redeterminations, as well as errors when beneficiaries are claimed under incorrect eligibility categories that provide a Federal matching rate that was higher than appropriate.[78]

OIG work has found that States are not always correctly determining the eligibility of individuals for receiving Medicaid benefits, resulting in potential improper payments. OIG audits have also identified substantial improper payments to providers across a variety of Medicaid services including school-based, nonemergency medical transportation, targeted case management, and personal care services (PCS).[79] In addition to other corrective actions, CMS has engaged with State Medicaid and CHIP agencies to develop corrective action plans that address State-specific reasons for improper payments identified through the PERM program and as part of other Medicaid fiscal oversight efforts. Given that CMS will apply the updated Medicaid eligibility measurements to the last set of States for the first time in FY 2021, the improper payment rate is likely to see similar, significant increases in this fiscal year. As such, it will be imperative that CMS focus its efforts to examine the reasons for and implement strategies to reduce Medicaid and CHIP improper payment rates.

Grants and contracts

Administering grant programs and contracts requires that HHS implement internal controls to ensure that program goals are met and funds are used appropriately. For grant programs, this includes oversight and guidance to award recipients. HHS is responsible for providing up-to-date policies to grant recipients and helping States and other grantees address their own financial management and internal control issues. Without proper internal controls, funds may be misspent, duplication of services may occur, and sub-recipients may not be adequately monitored. OIG has identified grantee-level concerns in several HHS programs, including some Office of Refugee Resettlement's (ORR's) Unaccompanied Children (UC) Program grantees reporting unallowable costs and lacking effective systems for administering program funds.[80] OIG also found that ORR did not award or effectively manage a sole source contract in accordance with Federal regulations and HHS policies and procedures.[81] Additionally, OIG found that HHS has taken minimal action to improve policies and procedures for ensuring Small Business Innovation Research Program awardee eligibility and has taken no action to improve policies and procedures for preventing duplicative funding.[82]

To ensure that grant funds are used appropriately, HHS must track and report improper payment rates for its risk-susceptible grant programs and thus adhere to the *Payment Integrity Information Act of 2019*.[83] However, since the inception of these reporting requirements HHS has not reported an improper payment estimate for the Temporary Assistance for Needy Families (TANF) program.[84] States receive block grants ($16.2 billion in FY 2020) to design and operate TANF programs.[85] HHS has stated that it does not believe that it has the statutory authority to collect from States the data necessary for calculating an improper payment rate for the TANF program. The Office of Management and Budget (OMB) has identified TANF as a risk-susceptible program that must report estimated rates and amounts of improper payments. HHS must continue to pursue legislative remedies to develop an appropriate methodology for measuring TANF payment accuracy and report an improper payment estimate for TANF.

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In terms of the Department's oversight of contracts, HHS has taken steps to enhance its acquisition systems and better monitor contract closeouts and contract payments. Moreover, CMS has increased its efforts in examining workload statistics for benefit integrity contractors and improving performance outcomes. Although CMS has taken steps to improve its contract management and closeout processes, the Department needs to take additional actions to ensure that it is meeting other Federal requirements. For example, OIG found that CMS did not identify and report potential *Antideficiency Act* violations for 12 contracts used to establish the Federal Health Insurance Marketplace under the *Affordable Care Act*.[86] Additionally, OIG found that CMS did not administer and manage strategic communications services contracts in accordance with Federal requirements and made recommendations to both HHS and CMS to address the significant deficiencies we identified.[87] HHS is developing a permanent Procurement Management Oversight Review structure to provide further oversight of the HHS acquisition portfolio.

COVID-19 funding

Congress appropriated $484 billion to HHS for the COVID-19 response.[88] This includes $178 billion for the Provider Relief Fund (PRF) to support health care providers affected by the COVID-19 pandemic. PRF dollars are provided to hospitals and other health care providers on the front lines of the COVID-19 response and allocated to providers as part of general distributions and through targeted allocations to high impact areas, safety net hospitals, children's hospitals, rural providers, Tribal facilities, clinics and urban health centers, SNFs, and nursing homes.[89] In addition to PRF funds, Congress also appropriated additional funds for providers who serve rural Medicaid, CHIP, or Medicare patients. Furthermore, funds were dedicated to reimburse eligible providers and facilities for COVID-19 testing, treatment, and vaccine administration for individuals who do not have health coverage, as well as to patients whose health insurance does not cover vaccine administration fees or does cover but typically has patient cost-sharing.[90,91] HHS has developed financial assistance policy guidance and tracking mechanisms to support the COVID-19 supplemental funding appropriations.[92] Efficient and effective management and administration will be essential to ensuring that COVID-19 response programs achieve their intended purposes and provide relief to intended individuals and entities. OIG is conducting a series of audits of PRF distributions.[93]

Combating fraud, waste, and abuse in HHS programs

Fraud, waste, and abuse divert needed program resources to inappropriate, unauthorized, or illegal purposes. Effectively fighting fraud, waste, and abuse requires vigilance and sustained focus on preventing problems from occurring in the first place, detecting problems promptly when they occur, and rapidly remediating detected problems through investigations, enforcement, and corrective actions. To accomplish this, HHS must have controls to ensure the proper use of resources to detect and prevent fraud. The Department should also apply a robust variety of program integrity strategies to protect HHS programs. These strategies must include systems and processes to detect and prevent fraud, as well as plans for addressing fraud when it occurs.

COVID-19 funds

As noted above, HHS received $484 billion in COVID-19 funding.[94] Moreover, as of May 2021, CMS had made advanced and accelerated payments to Medicare providers totaling more than $107.3 billion and paid providers for certain services at enhanced rates applicable during the public health emergency.[95] In addition, as of September 2020, CMS reported more than $104.3 billion in Other Assets, which are mainly

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composed of these advanced and accelerated payments.[96] CMS also suspended or reduced the scope of many program integrity safeguards, such as provider enrollment screening. While these steps may be appropriate to ensure access to care, they also raise the risk that fraud will be committed by those seeking to exploit the emergency. Regardless of the source of funds, HHS must effectively and efficiently manage the use of funds internally, award and manage contracts related to COVID-19 funding in accordance with contracting requirements, and appropriately oversee the external use and accounting of Federal funds by thousands of recipients. HHS should ensure that funds are paid only to eligible recipients—in correct amounts—and used in accordance with program requirements.

Furthermore, HHS must apply effective internal controls and efficiently manage the collection, maintenance, and analysis of relevant data that are key to ensuring that COVID-19 funds are used for their intended purposes. OIG has identified serious concerns related to fraud schemes that would divert funds intended for COVID-19 response and recovery. For example, OIG settled a case for civil monetary penalties, involving a provider that received PRF funds despite having its Medicare billing privileges revoked and attesting in the PRF portal that it was not revoked.[97] OIG is currently investigating several other entities that allegedly received PRF funds despite being ineligible and providers that falsely attested that they were eligible to receive PRF funds. In May 2021, the Department of Justice (DOJ) and OIG announced criminal charges for the misuse of COVID-19 funds.[98] Among other charges, funds were allegedly misappropriated from PRF based on false applications.

HHS must also take action to protect individuals from being defrauded under the guise of the public health emergency. In August 2021, OIG alerted the public about COVID-19-related fraud schemes and potential harm to beneficiaries.[99] OIG noted that fraudsters were offering unapproved and illegitimate COVID-19 tests, HHS grants, and Medicare prescription cards in exchange for personal details, including Medicare information. Any personal information collected can be used to fraudulently bill Federal health care programs and commit medical identity theft.

Furthermore, as with all HHS grant programs, it will be critical that the Department provide up-to-date policies to COVID-19-related grant recipients and help States and other grantees address their own financial management and internal control issues. Without proper internal controls, funds may be misspent, duplication of services may occur, and sub-recipients may lack adequate monitoring.

Medicare and Medicaid

CMS must be vigilant in identifying and addressing fraud in its programs. Schemes to steal money from Medicare and Medicaid take many forms and vary depending on setting and services provided. These fraud schemes can be as simple as billing for services not provided and identity theft, or as complex as kickbacks, improper prescribing, deceptive marketing, and money laundering. The perpetrators of fraud schemes range from highly respected providers to organized criminal enterprises with no legitimate role in health care. OIG has encountered scams in which fraudsters use technology to impersonate official government personnel from HHS or OIG. Scammers target individuals through various methods including phone, email, or social media to obtain money or personal, medical, or financial information. OIG routinely alerts the public about emerging fraud scams. In recent years, OIG has issued fraud alerts involving durable medical equipment, genetic testing, and telephone fraud.[100] To combat fraud, CMS should continue its important coordination with, and support for, law enforcement, including taking parallel administrative actions as

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appropriate.

Managed care

HHS faces a significant challenge in conducting oversight of managed care programs and protecting against fraud, waste, and abuse. Managed care is the primary delivery system for Medicaid, covering at least some services for more than 80 percent of all enrollees.[101] In Medicare, more than one-third of beneficiaries are currently enrolled in MAOs. OIG has found weaknesses in MAOs' and Medicaid Managed Care Organizations' (MCOs') efforts to identify and address fraud and abuse by their providers.[102] For example, OIG has found Medicaid MCO capitation payments were made in one State on behalf of beneficiaries who were concurrently eligible and residing in another State.[103] To ensure program integrity requirements are met, CMS requires MAOs and Medicaid MCOs, prepaid inpatient health plans, and prepaid ambulatory health plans (referred to as managed care plans) to implement compliance programs that are designed to prevent, detect, and correct instances of fraud, waste, and abuse. However, these programs vary widely among the MAOs and Medicaid MCOs, 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 managed care plans. This makes effective program integrity oversight by CMS more complex and challenging.

Furthermore, the MA program is vulnerable to fraud, waste, and abuse perpetrated by MAOs to inappropriately inflate the payments that they receive from Medicare or to inappropriately deny care that they are obligated to provide. In multiple audits of MAOs, OIG sought to determine whether the MAOs submitted diagnosis codes to CMS for use in the risk adjustment program in accordance with Federal requirements. OIG found that risk-adjustment data that MAOs submit to CMS for use in the risk-adjustment program was not always supported by medical records. OIG has recommended that certain MAOs refund overpayments and enhance their policies and procedures to prevent, detect, and correct noncompliance with Federal requirements.[104] OIG also found that billions of dollars in estimated MA risk-adjusted payments supported solely through chart reviews or diagnoses reported only on health risk assessments raise concerns about the completeness of payment data submitted to CMS, the validity of diagnoses on chart reviews and health risk assessments, and the quality of care provided to beneficiaries.[105, 106] OIG has made recommendations to CMS to improve its oversight of MAOs so that MAOs will ensure practices drive better care—not just higher profits—as well as enact policies and procedures to improve the integrity and usefulness of payment data.

Additionally, significant concerns have been raised that the capitated payment model used in MA may provide a potential incentive for MAOs to inappropriately deny access to services and payments to increase their profits. An MAO that inappropriately denies authorization of services for beneficiaries or payments to health care providers may contribute to physically or financially harming beneficiaries and misuse Medicare program dollars that CMS paid for beneficiaries' health care. OIG found that high numbers of overturned denials upon appeal and persistent performance problems identified by CMS audits raise concerns that some beneficiaries and providers may not be getting services and payment that MAOs are required to provide.[107]

To strengthen CMS's oversight of the MA program, OIG has recommended that CMS make improvements to MA encounter data.[108] CMS has taken action to address potential errors in the data and ensure that billing provider identifiers are active and valid on all records. However, CMS must also provide targeted oversight of MAOs that have submitted a higher percentage of records with potential errors, track how

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MAOs respond to edits that reject data, and establish and monitor performance thresholds related to MAOs' submissions of records with complete and valid data.[109] Additionally, CMS continues to validate the completeness and accuracy of Medicare and Medicaid managed care plan encounter data and periodically updates guidance for MAOs in order to improve encounter data submission. OIG has found that identifiers for ordering providers are an essential tool for safeguarding program integrity but are largely missing from the encounter data, despite evidence that many MAOs can and do already collect this information.[110]

CMS should take further actions to ensure the completeness, validity, and timeliness of Medicaid encounter data. OIG found that most States did not provide complete and/or accurate data on Medicaid managed care payments to providers in the national data system— the Transformed Medicaid Statistical Information System (T-MSIS). CMS and States need complete and accurate payment data to effectively monitor and administer Medicaid managed care, the primary delivery system of the Medicaid program. The need for complete and accurate payment data is more important than ever, given the unprecedented stress that the COVID-19 pandemic has placed on the Medicaid program.[111]

Furthermore, CMS should work with its contractors and with States to improve efforts to identify and address fraud and abuse.[112] Additionally, the agency should work to ensure that appropriate information and referrals are sent to law enforcement. To improve Medicaid managed care plans' identification and referrals of cases of suspected fraud or abuse, CMS is working with States to provide technical assistance and education on best practices. (See TMC 5 for more information on expanding HHS's capacity to use and share data to support evidence-based policymaking, program management, and program involvement.)

Marketplace insurance

The Department must be attuned to ensuring that payments for advance premium tax credits (APTCs) for enrollees in marketplace insurance are accurate. There was an estimated 20 percent increase in people eligible for subsidized marketplace coverage after passage of the *American Rescue Plan Act of 2021* and an estimated $35.5 billion increase in premium tax credits.[113] OIG work has found weaknesses in State and Federal marketplace systems for ensuring correct eligibility determinations and accurate APTC payments. For example, a recent OIG audit determined that APTCs payments were paid on behalf of enrollees who did not make required premium payments and recommended improvements to processes and data collection and sharing with the Internal Revenue Service.[114]

Grants

Without adequate oversight and internal controls, HHS grants and contracts are vulnerable to fraud schemes including embezzlement.[115] HHS has worked to strengthen some of its program integrity efforts that are focused on grant programs. For instance, it issued guidance and developed tools to help HHS's awarding OpDivs examine prospective grantee risk prior to awarding grants.[116] This information enhances awarding OpDivs' assessment of prospective grant recipients' integrity and potential performance.

Prescription drugs

OIG has found that opioid-related fraud encompasses a broad range of criminal activity, from prescription drug diversion to addiction treatment schemes. OIG investigations show that opioid drug diversion (the redirection of legitimate drugs for illegitimate purposes) is on the rise. Diverted opioid drugs are at high

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risk of inappropriate use and causing significant harm such as overdose. Also, potentiator drugs (drugs that exaggerate euphoria and escalate the potential for misuse when combined with opioids) and drugs indicated to treat OUDs (particularly buprenorphine) are at high risk for diversion. 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 being diverted for resale or recreational use. OIG has also recommended that IHS improve its internal controls against opioid-related fraud, including controls at entry points to sensitive areas of its hospitals to protect its pharmacy inventory from unauthorized access.[117] In addition, the Department must guard against fraud in OUD treatment programs, including the submission of fraudulent insurance claims for purported OUD treatment and testing services.[118]

Furthermore, opioid treatment services were not being claimed by selected providers in accordance with applicable Federal and State regulations. Treatment deficiencies included individual counseling sessions not supported with adequate documentation, take-home medications not provided in accordance with Federal or State regulations, methadone dosing services administered without proper authorization, and individual counseling and methadone services provided without a treatment plan in effect.[119]

OpDivs should improve efforts to identify and investigate potential fraud and abuse in prescription drug programs. For instance, CMS should collect comprehensive data from Medicare Part D plan sponsors. CMS should also require pharmacies that bill Medicare Part D to enroll in the Medicare program. Currently, CMS's three key tools for safeguarding against fraud—enrollment, revocation, and preclusion—apply to pharmacies only when they bill Medicare Parts B or C, not when they bill Medicare Part D.[120] Furthermore, CMS should ensure that national Medicaid data are adequate to detect suspected fraud or abuse. The lack of reliable national Medicaid data hampers enforcement efforts. (See TMC 5.)

Systems and processes for detecting and preventing fraud

For detecting and preventing fraud and improper payments, CMS's Fraud Prevention System (FPS) serves as an important tool that should be improved to increase its effectiveness. Since 2011, FPS has continuously run predictive algorithms and provided other sophisticated analytics nationwide on Medicare FFS claims prior to payments to identify, prevent, and stop fraudulent claims. However, OIG found that FPS is not as effective in preventing fraud, waste, and abuse in Medicare as it could be and recommended that CMS make better use of the performance results within its FPS to refine and enhance its predictive analytic models.[121]

An effective provider enrollment screening process is an important tool for preventing Medicaid and Medicare fraud. It plays a vital role in identifying unscrupulous providers and preventing them from enrolling in Medicaid and Medicare. OIG work has found that Medicaid is vulnerable to being defrauded by high-risk providers that were not properly screened. Specifically, OIG found 13 States had not implemented fingerprint-based criminal background checks for their high-risk Medicaid providers as of January 2019. We also found that unscrupulous providers could exploit loopholes in the provider enrollment process to enroll in Medicaid without undergoing these checks.[122] In addition, OIG found 23 States had not enrolled all providers serving Medicaid beneficiaries in their respective Medicaid programs, exposing them to potentially harmful providers that had not been screened for fraud, waste, and abuse.[123] Furthermore, OIG work found that nearly 1,000 terminated providers—or 11 percent of all terminated providers—were inappropriately enrolled in State Medicaid programs.[124] Despite legislative requirements

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in the *21st Century Cures Act* designed to strengthen Medicaid program integrity, terminated providers continue to serve Medicaid beneficiaries. CMS should: (1) ensure that all States fully implement fingerprint-based criminal background checks for high-risk Medicaid providers; (2) work with States to ensure that they have the controls required to prevent unenrolled providers from participating in Medicaid; and (3) follow up with States to remove terminated providers that OIG identified as inappropriately enrolled in Medicaid.

Monitoring and reporting on the integrity of HHS programs

HHS must ensure the completeness, accuracy, and timeliness of financial and program information provided to other entities both internal and external to the Federal government. Responsible stewardship of HHS programs is vital to operating a financial management and administrative infrastructure that employs appropriate safeguards to minimize risk and provide oversight to protect resources. Although HHS continues to maintain a clean opinion on its basic financial statements, addressing weaknesses in financial management systems and resolving issues related to reporting requirements of the *Digital Accountability and Transparency Act of 2014* remain challenges for HHS. [125] For FY 2020, OIG recommended that HHS continue to focus efforts on resolving issues related to its information technology (IT) system controls and completing data cleanup activities.

In addition, financial management systems help OpDivs and StaffDivs ensure operational effectiveness and efficiency, financial reporting reliability, and compliance with applicable laws and regulations. OIG continues to find deficiencies in internal controls over segregation of duties, configuration management for approved changes to HHS financial systems, and access to HHS financial systems.[126] These deficiencies collectively constitute a significant deficiency in internal controls. HHS must take additional actions to address and resolve these issues, including continuing to work to control user access, ensuring proper approval of and documentation supporting system changes, and ensuring appropriate segregation of duties [127]

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3: Delivering Value, Quality, and Improved Outcomes in Medicare and Medicaid

HHS continues to reform Medicare and Medicaid to promote quality, efficiency, and value of care. Reforms underway touch virtually every type of health care service and offer opportunities for better care and health outcomes, improved access and health equity, lower costs, more transparency and choices for consumers, and reduced administrative burden.[128] Reforms also come with an array of operational and program integrity challenges.

KEY TAKEAWAYS

I. Relevant Agency: CMS
II. Elements of the Challenge:
- Aligning program incentives with quality, equity, and health outcomes
- Strengthening program integrity
- Delivering on the promise of innovative technology to improve health outcomes

Medicare and Medicaid are the two largest and most complex health care programs at HHS. They use multiple delivery models (FFS, managed care, and new models such as accountable care organizations (ACOs)); cover a broad array of health conditions, providers, services, and settings; and operate pursuant to intricate statutory directives and regulatory schemes. People of all ages and backgrounds—from seniors to children, and from the healthy to the seriously ill—depend on these programs. In fall 2021, the CMS Innovation Center set a strategic goal for its next 10 years "to transform the health system into one that achieves equitable outcomes through high quality, affordable, person-centered care." CMS further committed to designing models that include a variety of providers who care for underserved populations.[129] [130]

Medicare and Medicaid beneficiaries are increasingly choosing managed care options, and more providers are participating in value-based models. Continued growth in value-based care and payment is expected in public and private health care programs. CMS's Innovation Center continues to test new models across the health care spectrum. In a recent report to Congress, CMS estimated that more than 27.8 million Medicare and Medicaid beneficiaries and individuals with private insurance in multi-payer model tests had been included in Innovation Center models and initiatives as of September 30, 2020.[131] Estimated payments for model tests and initiatives (excluding reimbursement for covered services) totaled about $13 billion for FYs 2010-20. Among its permanent value-based programs, CMS administers the Quality Payment Program for physician reimbursement and the Medicare Shared Savings Program for ACOs. CMS recently announced plans to expand value-based care in home health. CMS paused timelines and modified some model and program requirements because of the COVID-19 public health emergency.

Both Medicare (FFS, Part C, and Part D) and Medicaid have proven susceptible to fraud, waste, and abuse. FY 2020 estimates of improper payments ranged from 6.3 percent (for Medicare FFS) to 21.4 percent (for Medicaid) of total expenditures. Improper payments for Medicare, Medicaid, and CHIP totaled approximately $134.2 billion.[132] These programs are on the Government Accountability Office's (GAO's) list of high-risk government programs. OIG's enforcement work shows that wrongdoers defraud Medicare and Medicaid through schemes ranging from false

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billings to kickbacks. OIG's oversight work demonstrates a range of vulnerabilities including:

- flawed program design and administration (e.g., improper payments) (see TMC 2);
- misaligned program incentives and confusing or insufficient program guidance;
- deficient delivery of care to beneficiaries such as poor quality and unsafe care (see TMC 4) or inappropriate utilization;
- gaps in provider enrollment systems and available data needed for proper oversight (see TMCs 2 and 5); and
- challenges with adequate access for beneficiaries to covered services in both FFS and managed care.

To reduce disease spread and expedite the delivery of medically needed care during the COVID-19 public health emergency, CMS implemented flexibilities addressing coverage and payment for items and services, and OIG implemented targeted flexibilities with respect to application of fraud and abuse authorities to specified types of business arrangements.[133] These flexibilities introduce additional regulatory risks and compliance challenges for stakeholders implementing them and the Department overseeing their effectiveness. Moreover, the pandemic amplified the effects of longstanding, systemic health care disparities among communities of color and in underserved areas.

To ensure the effectiveness of Medicare and Medicaid in delivering value, the Department should focus on three facets of the challenge: (1) aligning program incentives with quality, equity, and health outcomes; (2) strengthening program integrity; and (3) delivering on the promise of innovative technology.

Aligning program incentives with quality, equity, and health outcomes

Developing effective incentives and policies to drive better health outcomes is difficult given the complexities of medicine, the evolving science of quality measurement, and the varying needs of the populations served by these programs. The Department is undertaking initiatives to streamline, improve, and target quality measures more precisely and to move from process measures to outcome measures. In March 2021, CMS launched Meaningful Measures 2.0: Moving from Reduction to Modernization to "reduce the number of measures in its programs" and "further shape the entire ecosystem of quality measures that drive value-based care."[134] CMS reported that since the inception of the original initiative in 2017 it has reduced the number of Medicare quality measures by 18 percent, saving more than 3 million hours and a projected $128 million.[135] With the new iteration, CMS aims to better address health care priorities and gaps, emphasize digital quality measurement, and promote patient perspectives.

Moving forward, HHS should ensure that its programs use effective, evidence-based measures to improve quality of care and beneficiary outcomes. CMS must clearly define actionable and meaningful quality and outcomes measures for its programs and ensure their reliability, accuracy, and utility. CMS should continue, where appropriate, to align its efforts with other OpDivs using quality measurements to enhance efficiency and strengthen quality measurement. Accuracy and completeness of reported quality and performance information is critical for payment purposes. A recent OIG report found that CMS's monitoring was generally effective at ensuring that Medicare Shared Savings Program ACOs report complete and accurate data through claims, administrative data, and the CMS web portal. The report identified weaknesses in contractor oversight that could result in incomplete or inaccurate data reported through a patient survey.[136]

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Value-based models typically pay, in full or in part, based on health outcomes achieved for patients and reductions in health care costs. Providers are reimbursed for a set or bundle of services, often provided across a continuum of care settings, with accountability for outcomes and costs over an established period. To meet care and cost goals, providers are furnishing a range of services not typically reimbursed under volume-based, traditional fee-for-service. These might include social services, care coordination, or health information technology. Especially when nontraditional services affect the amount of payment, HHS should be attentive to ensuring that such services contribute to achieving quality, equity, and efficiency outcomes. Because these interventions are not reflected in normal claims data, CMS should ensure it has the available data necessary to understand the services provided and evaluate their effectiveness. This may require that CMS partner with other OpDivs and Federal agencies that support social services. Operation and oversight of models that integrate traditional health and other services may be hampered by data silos both within HHS and across the Federal Government. (See TMC 5 on data sharing.) There is a heightened program integrity risk if add-on, nontraditional services are offered to patients for marketing purposes, rather than to foster improvements in patient health outcomes, efficiencies, or equity.

In November 2020, CMS and OIG issued regulations intended to promote value and quality through better coordinated care for patients and broader sharing of patient information for patient care.[137] HHS should monitor results to ensure that the regulations operate as intended to promote beneficial arrangements and practices, and are not subject to abuse.

Access to care and health equity are longstanding challenges that have been exacerbated by the COVID-19 pandemic. OIG work has long identified access issues in Medicare and Medicaid. For example, a report examining provider shortages and limited availability of behavioral health services in New Mexico's Medicaid managed care provides insights into challenges likely shared by other States. Identified challenges included an uneven distribution of licensed providers across the state, staff retention, poor care coordination, and a lack of transportation and broadband services. Promising initiatives to increase availability of behavioral health services included open-access scheduling, a "treat first" clinical model, care integration, and telehealth.[138] Ensuring that programs have accurate demographic and other data is a requisite step in identifying, understanding causes of, and addressing health disparities. A recent OIG analysis of Medicare claims data showed that in nursing homes in 2020 about half of the Black, Hispanic, and Asian beneficiaries—and 41 percent of the White beneficiaries—had or likely had COVID-19.[139]

New payment structures, care delivery methods, business arrangements among providers, and incentives all give rise to risk-management challenges in Medicare and Medicaid. Notwithstanding identified successes, CMS must maintain a steady focus on quality of care and health outcomes. This is particularly true during the COVID-19 public health emergency when normal guardrails and conditions have been adjusted to address exigent public health circumstances and when providers may temporarily be unable to meet optimal care guidelines. (See TMC 4 for further discussion of quality-of-care challenges.)

Strengthening program integrity

HHS must be attentive across FFS and managed care programs to assess, identify, and mitigate program integrity risks. The nature of fraud and abuse risk differs depending on how Medicare and Medicaid pay for services. Traditional FFS risks, arising from volume-sensitive payments, include inappropriate increased utilization, increased program costs, and improper patient steering. In managed care, a capitated payment system leads to risks such as: stinting on care to reduce costs, discriminating against expensive patients, or manipulating or falsifying data used to measure performance, outcomes, acuity, or diagnoses for risk adjustment. In nontraditional health care models that

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marry FFS payments with value-based payments, such as shared savings or partial capitation payments, elements of both FFS and managed care risks may be present. In evaluating and managing risks for a specific model, CMS must consider the range of incentives in the model. Managed care is not immune from risks created by mixed incentives. OIG's oversight and enforcement work has revealed opportunities for "downstream" fraud and abuse in managed care by providers paid by plans on an FFS basis. (See TMC 2 for further discussion of program integrity in managed care.)

In testing and implementing value-based models, CMS must continue to focus on program integrity risks, incorporating safeguards to reduce them and strategies to correct them. Focusing on program integrity risk is especially important for models that introduce new payment incentives, which could lead to new fraud schemes, and for models for which customary payment, coverage, or fraud and abuse laws do not apply due to waivers, exceptions, or safe harbors. Additional risks may arise from novel flexibilities granted because of the COVID-19 public health emergency. HHS should incorporate guardrails to mitigate risks when designing flexibilities, monitor implementation of flexibilities for any abuse, and take prompt action to correct problems and hold wrongdoers accountable.

Many value-based models promote care in home and community settings through in-person home visits, remote monitoring, and other technologies. These services can be less costly and are often preferred by patients. OIG work in areas such as hospice care, home health, and PCS consistently demonstrates that patients and the programs may be vulnerable to fraud and abuse in home- and community-based settings. Moreover, home-based services may not meet quality of care requirements. For example, OIG work showed that hospices lacked oversight of their registered nurses, resulting in nurses failing to meet requirements for visiting beneficiaries' homes to assess the quality of care provided by hospice aides.[140]

Additional risks to program integrity across Medicare and Medicaid including improper payments, compliance with program requirements, provider eligibility and qualifications, data integrity and availability, transparency and accuracy of information available to consumers, patient safety, substandard care, and access to care are covered in more detail in TMCs 2, 4, and 5.

Delivering on the promise of innovative technology to improve health outcomes

Leveraging digital and health technology to foster efficient, high-quality, safe care is critical to a value-driven health care system, as is ensuring the appropriate flow of complete, accurate, timely, and secure information. For example, OIG's work examining how ACOs use health IT showed that, although ACOs have used health IT to aid in care coordination, the full potential of health IT has not been realized.[141]

HHS faces challenges in achieving a connected health care system to support better coordinated and value-based care in which patients' data—including conventional health care data and newer types of data related to social determinants, demographics, and personal trackers—flow freely across provider settings, with appropriate privacy and security protections. HHS should also be attentive to the challenges beneficiaries face in choosing reliable apps and technologies and assuring themselves that providers with whom they engage via an app or technology are trustworthy. (See TMC 5 for further discussion.) HHS will need to ensure that rural beneficiaries and underserved populations can participate fully in a technology-enriched, value-driven health system.

The Department also faces challenges in ensuring that evolving technologies are effective, enhance patient access to quality care, and support providers' ability to furnish such care. Law enforcement actions have illustrated how telephone-based remote physician consultations can turn a familiar fraud scheme—charging Medicare for DME or

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other services patients do not need—into a larger scale scheme with less effort. HHS must provide appropriate oversight of rapidly evolving technologies such as telehealth, networked medical devices, robotics, genomic testing, and remote monitoring.[142] New technologies and apps are being developed by entities and individuals (e.g., engineers or scientists) who may be unfamiliar with the complex regulations governing health care and unaware of the range of program integrity risks their inventions may face. These new participants in the health care system will need education, guidance, and appropriate oversight.

During the COVID-19 public health emergency, HHS determined that virtual services could be safer for patients and issued broad flexibilities for providers to furnish telehealth and other virtual care in settings and under conditions not typically allowed. HHS should monitor and assess services furnished and billed under these flexibilities for compliance with requirements, payment accuracy, and quality of care to ensure the flexibilities work as intended. As policymakers consider how and whether to incorporate such services into regular programs after the public health emergency abates, it will be important to consider program integrity risks. These risks could include unknown or unqualified providers furnishing virtual services, providers offering and billing for services not suitable for virtual care, substandard services, unsecured technology or data transmission, and improper incentives to beneficiaries, who receive virtual care or provide Medicare billing numbers to those purporting to furnish virtual services.

HHS faces a growing challenge in understanding and, as appropriate, overseeing providers' use of AI and machine learning in the delivery of health care such as in diagnostics, as well as for administrative functions such as coding and claims submission. AI and machine learning are introducing new paradigms that require fresh thinking about quality of care, compliance, and fraud prevention. Relatedly, HHS will need to assess how it can use AI, machine learning, and other technologies to foster program integrity, value, and quality of care in Medicare, Medicaid, and other HHS programs. (See TMC 1 for further information about FDA's role in emerging technology.)

In summary: Realizing the promise of value-based care and payment structures

To achieve better care at lower cost, HHS must maintain a steady focus on developing and refining effective, innovative, and evidence-driven models while being proactive in preventing and detecting fraud, waste, and abuse. HHS must pay special attention to effectiveness and program integrity in nascent areas such as the intersection of health care and social determinants of health as well as new uses of digital technology. This is vitally important given the current and anticipated growth in the costs of and number of beneficiaries in Medicare and Medicaid. Meeting this challenge will enable the Department to expand the reach of dollars devoted to these programs, thereby abating some of the anticipated rise in program costs in the coming decades and improving the lives and health outcomes of the beneficiaries they serve.

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4: Protecting the Health and Safety of HHS Beneficiaries

HHS programs provide critical services to diverse populations across a broad range of settings including hospitals, clinics, child care facilities, shelters, and beneficiaries' own homes. Some services are directly provided by HHS personnel, some delivered via HHS grant programs, some delivered by contractors working for HHS, and others rendered by professionals of a beneficiary's choosing who then claim reimbursements from Federal programs. Services include health care, education, child care, and, in limited circumstances, taking legal custody for select populations. Ensuring that intended beneficiaries receive appropriate services that meet standards for quality, are free from abuse or neglect, and are not exposed to infectious agents represents a major challenge for the Department. As the Department supports the Nation's efforts to respond to and recover from the COVID-19 pandemic, there will be challenges to ensuring safety and quality for beneficiaries receiving all varieties of care and services.

KEY TAKEAWAYS

I. Relevant Agencies: ACF, CMS, IHS, HRSA, SAMHSA
II. Elements of the Challenge:
- Ensuring safety and quality of care for beneficiaries of Federal health care programs
- Protecting the health and safety of children served by HHS programs
- Preventing abuse and neglect

Ensuring safety and quality of care for beneficiaries of Federal health care programs

HHS operates the Medicare program to serve about 63.3 million elderly or disabled Americans. In partnership with the States, the Medicaid program serves almost 76.5 million beneficiaries, and the CHIP program serves 7.4 million beneficiaries.[143] IHS provides direct services for about 2.6 million members of 574 Federally recognized Tribes.[144] These programs cover specific health care services that may include hospital care, physician services, prescription drugs, immunizations, hospice care, home and community-based care, DME, and skilled nursing care.

Delivering covered services

Ensuring access to and use of care that meets quality and safety standards remains a challenge. Even when Federal health care programs cover care, many beneficiaries do not actually receive the care they need. For example, OIG found that more than 500,000 children with attention-deficit/hyperactivity disorder (ADHD) who were Medicaid-enrolled did not receive timely followup care, and that more than 50,000 such children did not receive behavioral therapy as recommended by professional guidelines.[145] At the other end of the life cycle, OIG found that more than 80 percent of hospice providers—a growing health care sector serving beneficiaries and their families at extremely vulnerable times near end-of-life—had quality-of-care deficiencies.[146] Additionally, fixed daily payment structures may incentivize hospices to enroll beneficiaries for longer time periods but scrimp on care. At times, the greatest barrier to care derives from the beneficiary's own behaviors and beliefs. The Department is currently working to overcome substantial vaccine hesitancy that has hampered COVID-19 vaccination efforts, despite ample supplies of and an adequate ability to distribute and administer three highly safe and effective vaccines.[147]

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Improving quality of care

Although the Department has made progress, more work remains to improve access to and quality of all types of care. Oversight work revealed that patients experience significant rates of adverse events (patient harm as a result of medical care) in health care facilities. Specifically, OIG found that 27 percent of Medicare beneficiaries were harmed during their stays in acute-care hospitals, 29 percent in rehabilitation hospitals, 33 percent in SNFs, and 46 percent in long-term care hospitals.[148] OIG also found that hospitals did not identify when harm occurred in their facilities, in part due to confusion over HHS and other government guidance regarding how to define and report adverse events.[149] OIG is currently conducting a study to update the harm rate for Medicare beneficiaries in hospitals. The review will assess progress made in reducing harm in the decade since the prior study was released in 2010.[150] Additionally, OIG identified a 13 percent rate of adverse events for patients at IHS hospitals with higher rates for older patients, labor and delivery patients, and patients treated in smaller hospitals.[151] OIG also found that care in labor and delivery services at IHS Hospitals frequently deviated from national clinical guidelines or best practices, including for crucial services such as inducing labor and treating postpartum hemorrhage.[152] (See TMC 6 for more information on cross-government efforts to keep patients safe.)

Nursing Homes. The Department continues efforts to improve the quality of covered services as well the information available to beneficiaries and their families when selecting a care provider. One example is CMS's efforts to improve nursing home care. CMS's Five-Star Quality Rating System is intended to facilitate informed comparisons of nursing homes. As the COVID-19 pandemic continues, beneficiaries and their families are struggling to find accurate and timely information about infection rates in nursing homes or the vaccination status of staff. Nursing home residents were prioritized for COVID-19 vaccinations, but this vulnerable population sustained an outsized toll from the disease, especially early in the pandemic. In 2020, 42 percent of Medicare beneficiaries in nursing homes were diagnosed with or likely had COVID-19, with rates of disease even higher in Black, Latino, and Asian populations.[153] Especially given limited visitation and other access to nursing homes during the COVID-19 pandemic, accurate information about nursing home quality is critically important to inform patients' and families' choices. Given the important role friends and families usually play in identifying and reporting quality issues—an information source that may be diminished during the pandemic—OIG conducted an education and outreach campaign to promote nursing homes' attention to quality and inform patients, staff, and others on how to report quality-of-care concerns. The Quality Improvement Organizations (QIOs) have also conducted education and outreach to nursing homes, including assistance with COVID infection control and promoting vaccination for residents and staff.

As the COVID-19 pandemic has taken a heavy toll on beneficiaries in nursing homes, longstanding staffing and quality-of-care concerns remain pressing. Additionally, nursing homes were charged with implementing new infection control imperatives needed to maintain operations during natural disasters, utility service disruptions, and other occurrences that complicate continual delivery of care. OIG continues its series of audits to assess nursing homes' compliance with health and safety regulations. Such oversight is especially important as the pandemic brought a decrease in onsite nursing home surveys conducted on behalf of CMS.[154] OIG has recommended that CMS safeguard the health and safety of nursing home residents by ensuring facility correction of deficiencies.[155] Government enforcement actions have stopped some poorly performing nursing homes from rendering deficient services. One nursing home chain charged with rendering grossly

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substandard care to Medicare and Medicaid beneficiaries agreed to repay $18 million and abide by the terms of a Corporate Integrity Agreement to ensure that it delivers appropriate care going forward.[156]

Hospice care. OIG has identified as a top priority for HHS improving hospice care, including strengthening the survey process and better educating beneficiaries and their families and caregivers.[157] Furthermore, beneficiaries and families need better information about hospice providers.[158] CMS has announced plans to revamp its Hospice Quality Star Rating System to enable better informed decision making for beneficiaries seeking hospice care.

Indian Health Service. After a series of OIG reports about quality-of-care problems in IHS-operated hospitals,[159] IHS created a Quality Framework and Office of Quality to provide better guidance and oversight to its facilities and clinical staff.[160] IHS is also working to establish a nationwide compliance program to address several OIG recommendations and improve care for beneficiaries. However, some longstanding challenges, such as recruiting and retaining qualified staff, persist. As discussed below, there is also a pressing need to protect patients—especially children—from predators within the ranks of health care and service providers. To continue improvements at IHS, OIG has recommended that IHS prioritize developing and implementing a staffing program to ensure sufficient qualified staff at facilities; enhance training for staff and hospital leaders; intervene quickly and effectively when quality problems are identified; and establish better procedures, including improved external communication.[161]

Protecting the health and safety of children served by HHS programs

HHS operates or funds many programs that provide child care, education, and residential care in addition to health care for children, including some especially vulnerable children such as children living in foster care and children in the UC Program. The Head Start program promotes school readiness for nearly 900,000 children from low-income families,[162] and the Child Care and Development Fund (CCDF) provides child care assistance for about 1.4 million children from low-income families.[163] The importance of properly vetting program staff to ensure children's safety is discussed below.

Operating the UC Program

Through the UC Program, ORR assumes custody of children who enter the United States without immigration status and have no parent or guardian in the United States able to provide for their physical and mental well-being. An unaccompanied child may have arrived in the United States alone or may have been separated from parents or legal guardians at the border. The UC Program merits specific discussion as it uniquely tasks the Department with assuming custody for children and the ensuing responsibility for their welfare. Through the UC Program, ORR places unaccompanied children in State-licensed shelters and other facilities operated by grantees or contractors. These facilities provide food and shelter as well as medical and mental health care and other services. Children remain in these placements until a sponsor (usually a parent or family member) is found to whom the child may be safely released, the child's immigration status is resolved, or the child turns 18 years old and ages out of the program. Since ORR began operating the UC Program in 2002, it has served more than 400,000 children. As of August 31, 2021, more than 16,000 UCs were in HHS custody with a length of stay averaging 28 days.[164] The number of children entering the United States fluctuates and the Department must be prepared to serve additional children at

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times of increased need. In response to the increasing number of referrals of unaccompanied children in 2021, ORR opened Influx Care Facilities and Emergency Intake Sites to provide additional space when the capacity of permanent shelters was exceeded.

In recent years, ORR has been called upon to care for more children, including children who did not come to the United States alone but were separated from parents or guardians at or after arrival. HHS reported to a court as part of a lawsuit that 2,737 children who had been separated by the Department of Homeland Security (DHS) had remained in ORR care as of June 2018. Following OIG's January 2019 report finding that significantly more children had been separated from their parents than previously reported, the government identified an additional 1,556 children who had been separated. Neither ORR nor DHS had kept adequate records about separated families, impeding efforts to identify and reunite them. As of June 30, 2021, a court-appointed steering committee reported that it had been unable to locate the parents of 368 children; efforts to locate them were continuing. OIG also reported, and subsequent court filings confirmed, that children for various reasons continued to be separated by DHS from their parents, perhaps because of a parent's criminal history. However, ORR did not always receive adequate information about the parents of separated children.[165] The lack of complete and accurate data about separated children complicates HHS's ability to ensure appropriate placement. These factors may cause children to spend more time in HHS custody. Issues related to identifying and vetting appropriate sponsors may also prolong children's time in HHS care facilities. OIG also found failures in conducting required staff background checks and insufficient clinical staff to serve children's mental health needs,[166] lack of oversight over facilities' use of inspection checklists to ensure security measures,[167] and shortcomings in incident reporting systems to protect children's safety.[168]

The Department must work to ensure that UC Program-funded facilities meet all safety requirements, including new infection control priorities related to COVID-19, and provide adequate medical and mental health care. As discussed further below, HHS must also enhance efforts to ensure that all staff with access to children have passed required background checks.

Preventing abuse and neglect

HHS funds and oversees many types of services for a broad range of beneficiaries. Thousands of HHS-funded providers hold positions of trust that bring them into close contact with beneficiaries, often behind closed doors and at especially vulnerable times in the beneficiaries' lives. The vast majority of providers seek to serve beneficiaries' best interests. However, some providers may cause beneficiaries harm, and HHS must protect its beneficiaries from abuse and neglect. For example, a former IHS pediatrician is currently serving a prison sentence for sexually assaulting boys he treated as patients. This disturbing case commanded extensive attention, and the Department committed to collaborating with a Presidential Task Force on Protecting Native American Children in the IHS system established in March 2019.[169] The task force released a report in July 2020 detailing its investigation of institutional and systemic breakdowns that failed to protect children from abuse.[170] (See TMC 6 regarding protecting IHS patients.) Better attention to protecting vulnerable beneficiaries of all ages in all HHS care settings is also needed.

Vetting providers and staff

Although even the most thorough vetting cannot completely prevent all potential predators from abusing Federal programs to gain access to victims, background checks are a useful tool. OIG identified failure to conduct required background checks for UC facility staff whose jobs entail access to children.[171] OIG is currently reviewing whether the UC Program's Influx Care Facilities and Emergency Intake Sites, which are

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not State-licensed, conduct required background checks before employees are hired and implement mitigation strategies to ensure the safety and well-being of children if ORR permitted employees to have direct access to children before background checks were completed.[172] Failure to conduct adequate background checks has been a problem in other HHS-funded child care programs as well. In several audits, OIG found that some States have not fully implemented CCDF requirements to conduct comprehensive criminal background checks on current and prospective staff.[173] Additionally, some IHS-funded, Tribe-run health centers failed to conduct required background checks on employees working with American Indian children.[174] Implementation of background checks for long-term care providers remains a challenge as well.[175] Along with demonstrating job-specific competency and qualifications, ensuring that staff pass all required background checks is an important safety measure.

The Department should improve efforts to ensure staff pass required background checks before they have access to patients in various health care settings and to children in the UC Program, Head Start, and CCDF-funded programs. The Department is also working to support States' implementation of the CCDF background check requirements. The Department should continue to work with States to ensure that implementation of the *Child Care and Development Block Grant Act of 2014* background check requirements align with the statutorily required effective dates and the allowable timelines described in the CCDF Final Rule.

Identifying and reporting abuse and neglect

Beneficiaries in all care settings are at risk of abuse and neglect. Home and community-based services allow many Medicaid beneficiaries the opportunity to avoid undesired facility care. However, some beneficiaries have been abused or neglected by individuals such as family members who were paid by Federal health care programs to care for the beneficiary at home. Group homes provide care to many especially vulnerable people, including adults with developmental disabilities. OIG's work found extensive failures in the proper handling of critical incidents, including the suspected abuse and neglect of group home residents.[176] About 1.8 million Medicare beneficiaries receive care in SNFs each year.[177] OIG has identified substantial failures to report incidents of potential abuse or neglect of Medicare beneficiaries living in SNFs who require treatment in hospital emergency departments.[178] In addition, OIG work identified cases of potential abuse of Medicare beneficiaries in hospice care and that hospices failed to act in some instances.[179] These cases reveal vulnerabilities in beneficiary protections that CMS must address to better ensure that beneficiary harm is identified, reported, addressed, and ultimately prevented. All States have enacted mandatory reporting laws that require certain individuals such as school teachers or nursing home staff to report suspected abuse or neglect targeting vulnerable individuals. However, many instances of abuse and neglect go unreported, making it harder to help victims and hold wrongdoers accountable.[180] During the ongoing COVID-19 pandemic, as many students did not attend school in person and many patients were unable to receive visitors, ensuring well-functioning processes that identify and report abuse is particularly important. Continued oversight and contact with family and friends can be particularly important to ensure quality care in nursing homes. OIG is reviewing continuity of on-site oversight by CMS and State Survey Agencies during the pandemic. Also, CMS has issued guidance to help nursing homes resume in-person visitation while minimizing the risk of COVID-19 transmission.

The Department has created several resources to better address the abuse and neglect of residents in group homes. These resources include model practices for: (1) State incident management and investigation; (2)

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State incident management audits; (3) State mortality reviews; and (4) State quality assurance.[181] OIG is committed to promoting the continued adoption of model practices to improve critical incident reporting systems.

It is important to prevent harm by identifying providers and facilities that are subjecting beneficiaries to abuse or neglect. States and other partners should use claims data to better identify unreported abuse and neglect. OIG created a resource guide to help accomplish this goal.[182] OIG has also explored Medicaid claims data as an additional way to identity potential child abuse and neglect.[183] Additional efforts would help to improve reporting. For example, CMS should compile a list of diagnosis codes that indicate potential abuse or neglect, conduct periodic data extracts, and encourage States to better use data to facilitate compliance with mandatory reporting laws.

CMS should also work to ensure that Federal mandatory reporting laws sufficiently protect beneficiaries in all care settings and are adequately enforced. Protecting beneficiaries from abuse and neglect is a critical responsibility requiring attention and cooperation from all stakeholders.

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5: Harnessing and Protecting Data to Improve the Health and Well-Being of Individuals

The Department continues to improve how it collects, manages, shares, and secures its data. Yet, HHS faces significant challenges to both protect data from persistent cybersecurity threats and improve how the Department and related entities share an increasingly large amount of critical data, including public health data. The demands of these dual challenges have been made readily apparent during the pandemic. Responding to COVID-19 has required HHS to collect and report a wide range of data on an unprecedented scale. At the same time, large-scale cybersecurity attacks such as the SolarWinds hack demonstrated the need to improve cybersecurity governmentwide. HHS will need to apply lessons learned during its pandemic response in order to sustain and accelerate its efforts to get the right information to the right people at the right time.

KEY TAKEAWAYS

I. Relevant Agency: All HHS
II. Elements of the Challenge:
- Expanding HHS's capacity to use and share data to support evidence-based policymaking, program management and program improvement
- Providing data to HHS partners and promoting public data access and sharing
- Protecting data from misuse or unlawful disclosure

HHS's capabilities to operationalize and change how it uses, shares, and protects data for the COVID-19 response was in part aligned with the focus HHS had placed on modernizing its data practices across the Department.[184] The pandemic accelerated that need, and the Department built new systems intended to improve and centralize some data functions to support the COVID-19 response including HHS Protect—a platform for the authentication, amalgamation, and sharing of health care information.[185] Standing up and collecting data via HHS Protect presented initial difficulties related to the scalability, veracity, and security of the data critical for COVID-19 response and recovery. According to hospitals, changing reporting requirements and systems added to the frustration and burden of health care providers in the midst of the pandemic.[186] Continued modernization of HHS data practices is needed for HHS and its OpDivs to fulfill their missions, especially to prepare for future public health threats. All of this must happen as the Department continues to respond to COVID-19 and while the quantity, frequency, and sophistication of cybersecurity risks to HHS increases rapidly.

HHS's authorities shape how an individual's data are used and protected by other private and public entities. These authorities are increasingly important in a technology-enriched health and human services delivery system. HHS made progress, but COVID-19 has presented a new challenge by amplifying demand for easier access to data. While many health care providers, State and local governments, and others switched to remote and virtual interactions to slow the spread of COVID-19, the need to continue to improve data interoperability and security was evident. At the same time, the health care industry and related private sector entities have faced persistent and systemic cybersecurity challenges, particularly ransomware attacks.

The response to COVID-19 also highlighted HHS's need to focus on racial and geographical disparities within programs. These disparities warrant further scrutiny of how data is collected and used in health care settings under

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HHS's jurisdiction to ensure equitable access and care for beneficiaries. Improved and appropriate data collection and access can provide key support for efforts addressing systemic disparities. HHS will need to sustain efforts to ensure that early progress turns into lasting structural improvement across the health and human service systems. (See TMC 6 for more information on reducing health disparities.)

Expanding HHS's capacity to use and share data to support evidence-based policy making, management, and program improvement

Data are central role to every HHS program.[187] HHS operations depend on the effective collection, use, and exchange of a large amount of sensitive and important data about individuals, health care providers, key public health assets, regulated industry, and other entities and actors. The Department and its programs are increasingly able to collect, store, and analyze data from disparate sources and provide new pathways within HHS to improve access to data. However, having large amounts of data does not mean that the data can be used efficiently and effectively. HHS faces challenges in how it manages and leverages data across its programs. Although most OpDivs primarily collect data to administer their own programs, the use of data across programs and OpDivs remains a challenge. Data are often housed within a single OpDiv's "data silo" and not easily shared with other parts of HHS, even though OpDiv missions often overlap.[188] Data silos also impede data sharing within OpDivs.

The effect of these data silos was seen during the response to the pandemic, limiting how HHS and its partners gained insight about COVID-19.[189] In January 2021, President Biden issued an Executive Order on Ensuring a Data-Driven Response to COVID-19 and Future High-Consequence Public Health Threats.[190] The Executive Order highlighted the need to advance innovation in public health data and analytics, enhance data collection and collaboration capabilities for high-consequence, public health threats, and build a better public health infrastructure. Achieving a mature public health reporting system that can respond to future public health threats requires extensive collaboration among Federal, State, local, and Tribal entities. It requires interoperability and security across a range of systems to allow for the exchange of data in a timely fashion and data collection that is accurate, timely, and efficient in order to track and thwart emerging health threats. Similarly, through OGA the Department must continue to engage with international stakeholders to ensure that the public health reporting system can support international response and coordination.

Data silos may also impede deployment of emerging technologies, such as machine learning, that have enormous potential to improve the efficiency and effectiveness of the Department. These technologies often depend on large, standardized data sets and will require collaboration across the Department. Eliminating or reducing data silos within the Department and increasing appropriate access across programs will be an essential step for improving program management and evidence-based decisionmaking, as well as laying the groundwork for HHS to benefit from emerging technologies. For example, the CDC Data Modernization Initiative (DMI) includes plans to deploy next-generation tools to improve public health surveillance.[191] To effectively develop, deploy, and use those tools, HHS will have to rely on representative data from across its programs, which will require complex technical coordination among diverse types of data, some of which have technical limitations.

Improving data governance to enhance program management

One critical step for improving HHS's capacity to utilize its data is the adoption of a better data governance approach. Effective data governance can improve communication and transparency by making data more available and useable. However, data governance practices are not consistent across HHS. The need to improve data governance is not unique to the Department and is a priority and a requirement for all Federal

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agencies.[192] Although progress has been promising, the Department's challenge will be to operationalize its plans notwithstanding the continued effect of data silos, restrictions related to the privacy and use of certain data, and legacy technology and data systems that do not easily support data sharing. HHS must ensure any progress it makes on improving governance of its internally generated data must also apply to data that are generated by external entities but that are received and managed by the Department. This challenge will play a significant role as CDC moves forward with its DMI and especially its newly launched initiative—the Pandemic Ready Interoperability Modernization Effort.[193] This new, multiyear collaboration with the U.S. Digital Service is designed to automate data, improve public health reporting, and develop a flexible, cloud-based infrastructure that will improve public health data quality and IT systems. As this and other efforts move forward, HHS should learn from previous projects that encountered complex data collection and reporting issues in other HHS programs.

For example, OIG has raised concerns about the completeness and quality of data submissions by States for the national Medicaid data set, T-MSIS.[194] CMS's recent progress related to T-MSIS may be helpful in providing lessons learned. Nearly all State Medicaid programs now report data directly to T-MSIS, and CMS has worked with States to improve the quality of data submissions and release T-MSIS data to researchers. Based on this progress, CMS is able to use T-MSIS to provide programmatic insights, including insight about COVID-19 treatment and testing and how the public health emergency affected Medicaid service utilization.[195] CMS also publishes data quality information related to several data categories in T-MSIS through its DQ Atlas web application.[196] The DQ Atlas and other reviews indicate that there are still issues with the completeness and reliability of some T-MSIS data. CMS has issued guidance to States to improve T-MSIS reporting of certain variables including the collection of race, ethnicity, and social determinants of health data. But additional guidance and testing is needed.[197] (See also TMC 3 regarding data for new care models.) And OIG's recent analysis of Medicaid managed care payments illustrates that most States did not provide complete or accurate data in T-MSIS about managed care plan payments to providers.[198] It will be important for HHS to proactively address similar data quality and governance challenges as HHS modernizes how it collects and uses external data from grantees or other organizations.[199]

Although much of HHS's data are publicly available, some may not be easy to use. Or there may be other barriers such as a lack of standardization that limit stakeholders' and the public's access or use of the data.[200] Those barriers present a challenge to providing increased access to HHS data that are vital for public health and welfare and that could lead to innovation and improvement in health and human service systems. Many HHS external stakeholders rely on effective dissemination of data collected by departmental programs. Much of HHS's data are publicly available but may not be well understood or in easily accessed formats. For example, currently, most public access to HHS data does not use contemporary approaches, such as the use of application programming interfaces (APIs). OpDivs are planning and have made some progress to expand access to these important assets. In May 2020, NIH made beta access available to its *All of Us* Researcher Workbench.[201] In its first year of allowing beta access to its workbench for more than 800 researchers and more than 570 research projects, NIH has added new types of data including wearables and results from the COVID-19 Participant Experience Survey. NIH has also brought together 16 types of EHRs from more than 50 data providers and has continued to improve the research tools that can be used by researchers in the *All of Us* workbench.[202] In September 2019, FDA released a Technology Modernization Action Plan.[203] Among other goals, FDA aims to improve how it uses data and technology to carry out its mission and improve communication and collaboration with other government and external stakeholders.

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FDA has also made progress related to its New Era for Smarter Food Safety by, for example, prioritizing technology-enabled traceability.[204] These approaches and plans must be replicated across HHS to remove barriers to other HHS program data and allow HHS partners to more effectively use that data.

Making data sharing between health care providers, patients, and payers commonplace

Several OpDivs have authority or influence to shape how data are shared within the industries they regulate, among HHS partners, and with individuals and patients. Most notable is HHS's potential to improve the availability and interoperability of electronic health information. Yet the health care system and patients in general have not fully realized and benefited from modern approaches to improve the appropriate flow of electronic health information. As part of HHS's Information Technology Strategic Plan, two key goals are aimed at improving health information exchange: enhance data and interoperability, and improve IT management and governance.[205] Although work continues to improve upon the capabilities that enable this effort and there are signs of recent progress, routine and robust health information exchange between providers remains a challenge.[206] In 2019, 55 percent of acute-care hospitals electronically performed all four interoperability functions, which are to find patient health information and send, receive, and integrate patient summary-of-care records from sources outside health systems.[207] This is up from 23 percent of hospitals in 2014. Among the interoperability functions, the largest increase was in hospitals that can integrate data, rising from 40 percent to 71 percent over the same timeframe.[208]

Interoperability of EHRs also plays a crucial role in providing data for the response to COVID-19 and could be key to public health modernization efforts. HHS and other entities are exploring how best to use electronic case reporting (eCR), which is the automated generation and transmission of case reports from health care providers' EHRs to public health agencies. CDC is leading the project called eCR Now, which is designed to rapidly deploy eCR operations through the use Fast Healthcare Interoperability Resources APIs to meet the demands of public health reporting. As of July 2021, more than 9,200 facilities were actively sending COVID-19 case reports at multiple jurisdictions at the same time.[209]

Improvement in the way patients and providers can access, use, and exchange electronic health information continues largely in response to HHS regulatory action taken in 2020. Office of the National Coordinator for Health Information Technology (ONC) and CMS regulations related to interoperability, data standards, and data exchange mechanisms continue to shape industry progress as health care providers, health IT developers, and others operationalize the requirements, such as use of standard, open APIs.[210] Still, the health care industry faces some fundamental issues that hinder widespread interoperability. For example, ONC continues its efforts to improve the ability to match patient data across health IT, and in late 2020 began a new initiative to standardize how patient addresses are included in their electronic health records.[211] The challenge for HHS will be translating these authorities and other initiatives into more widespread improvements across the health care industry. This will require further engagement to ensure progress is not limited to those health care entities with resources to implement modern technologies and data practices.

Combating persistent, emerging cyberthreats and protecting data

The risk of cybersecurity attacks that threaten the confidentiality, integrity, and availability of government-held data are persistent and growing. For example, the recent rise in ransomware attacks is a major challenge. Overall ransomware is up more than 150 percent in North America as a result of a confluence of factors including an increase

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in the use of hard-to-trace cryptocurrencies, ransomware-as-a-service, and successful ransomware operations through which cybercriminals are paid.[212] Although ransomware risks are not unique to HHS, overall the Department and the Federal Government have been targeted by increasingly complex cybersecurity attacks that seek to exploit a range of vulnerabilities that exist across Government agencies.

In response to growing cybersecurity threats to Government operations, the Administration has made improving the cybersecurity of the Federal Government a top priority. In the May 2021 Executive Order "Improving the Nation's Cybersecurity," the President directed Federal agencies to fundamentally and systemically change the approach to cybersecurity that crosses Departments and industries and that will require significant investments of resources and cultural and organizational change.[213] The Executive Order will likely require HHS to reorient how its OpDivs and StaffDivs carry out the increasingly complex task of managing and implementing cybersecurity safeguards across a range of entities. In response, the Department will likely need to undertake a multiyear effort in coordination with other Federal agencies to assess and change its approach to cybersecurity, such as continuing efforts to reduce the several aspects of cybersecurity that remain siloed within OpDivs and StaffDivs. This effort will need to begin even as cyberthreats to HHS remain elevated, as adversaries attempt to take advantage of the public health emergency to infiltrate HHS systems or impede their performance.

Many HHS partners and grantees—and the health care system at large—are similarly subject to increases in cyberattacks. Consistent with cybersecurity advisory warnings, the potential for an increased and imminent threat of cybercrime in the form of ransomware to hospitals and other health care providers was realized as an increasing number of hospitals and other providers were victims of ransomware, with nearly 34 percent of health care organizations reported being hit by ransomware.[214] Public confidence in the health care sectors' and HHS's ability to protect crucial public health data or sensitive, personal health data is important for the success of Federal initiatives that seek to leverage technology to create future medical treatments. OIG is continuing to conduct work addressing cybersecurity in HHS programs.

Cybersecurity challenges in a federated environment

Although the Department continues to improve its overall cybersecurity posture, OIG and GAO audits have identified challenges and systemic weaknesses.[215] One persistent challenge that underpins a number of cybersecurity issues is the federated nature of IT and cybersecurity environments across HHS. For example, 24 of NIH's 28 entities receive individual funding from Congress and administer their own budgets. Each NIH entity designates its own chief information officer (CIO) who coordinates with the NIH CIO. This type of environment poses challenges in managing and responding to cybersecurity threats across distinct entities. Most OpDivs are stewards of sensitive personal information and are required to protect such information from improper disclosure, including by external entities. Given the size, complexity, and constant use of this data, OpDivs face challenges in ensuring that third parties access this information for legitimate purposes. For example, OIG investigations of health care fraud often involve criminals that use valid credentials to access systems with program beneficiary information for illicit purposes, such as identify theft.

To ensure cybersecurity governance is effective across HHS, the Department has instituted policies and procedures; however, it has limited capabilities to assess compliance with, implementation of, and effectiveness of its policies and procedures within OpDivs and StaffDivs. Progress is being made to improve HHS-wide insights into cybersecurity. For example, the HHS Computer Security Incident Response Center and the Health Sector Cybersecurity Coordination Center (HC3) serve as central points of contact for incident reporting, information sharing, and cyber-data repositories.[216] As HHS implements

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the cybersecurity Executive Order and enhances the governance, capabilities, and awareness of both of these entities, HHS's overall cyber hygiene should continue to improve.

In addition to cybersecurity, other threats to HHS programs and grantees put the integrity of information and data at risk. HHS is responsible for scientific development, integrity, and security at NIH. Foreign entities seek to gain medical research and intellectual property developed by the Federal government to further their economic and research goals or disrupt the normal functioning of the Department. Taxpayer-funded medical research is being targeted by foreign adversaries. While these risks are complex and affect many aspects of U.S. national interests, HHS- and NIH-funded research and grantees continue to be targeted. OIG work has identified several issues that NIH can address to improve its safeguards, and NIH is making progress by, for example, working with the HHS Office of National Security.[217] However, NIH must continue to strengthen its safeguards against foreign influence by updating its policies and procedures while advancing its technological capabilities to assess, identify, and respond to foreign threats.

Promoting the security and privacy of the health care system

HHS's responsibilities for ensuring cybersecurity also extend to the health care system. The strength of the health care system's cybersecurity defenses continues to be tested as cyberthreats increase during the COVID-19 pandemic. Additionally, many health care providers rapidly shifted care to telehealth and other remote technology and thus provided additional openings for possible attacks. Sustained utilization of telehealth may pose new cybersecurity challenges because health care entities remain primary targets, and health care data are reportedly among the most valuable data for cybercriminals. In addition to data and identity theft, cyberthreats can also pose safety risks by causing outages of systems needed for patient care or exploiting vulnerabilities in the growing number of connected medical devices and other medical equipment involved in direct patient care. To ensure these areas of focus are not vulnerable and remain effective, HHS will need to work with the health care industry to improve cybersecurity by, for example, ensuring contingency plans are updated and tested to cover telehealth.

The Department has made some progress to bolster cybersecurity in the health care industry. Since 2019, HC3 has issued many products aimed at educating the health care industry on specific threats, mitigation efforts, and other educational materials. The products describe trends and new cybersecurity threats designed to take advantage of the COVID-19 pandemic.[218] The Department also plays a significant role in ensuring the privacy of sensitive individual data, such as personal health information, genetic information, and more. Most notably, OCR established and enforces the *Health Insurance Portability and Accountability Act of 1996* (HIPAA) Privacy Rule's requirements. However, the bulk of the Privacy Rule's requirements were established nearly 20 years ago and may not adequately address modern issues related to privacy concerns about the use and disclosure of protected health information. Some of the limitations associated with HIPAA were highlighted as the health care industry responded to COVID-19. In response, OCR took several actions including exercising its enforcement discretion to support greater flexibilities for the types of technology used for telehealth and issuing guidance about sharing patient health information on COVID-19 to emergency first responders.[219] OCR's response to COVID-19 foreshadows the need for potential future actions to address privacy issues as the health care industry continues to modernize. As health care providers and patients shift to using more telehealth, remote-based care, and emerging technologies, new challenges related to the privacy and security of patient health information will arise. The Department's challenge is to keep up with changes in the health care industry and with nontraditional health care entities that may impact patient privacy.

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6: Improving Collaboration to Better Serve Our Nation

HHS faces some of the largest and most complex issues confronting our Government and the Nation. These problems commonly transcend a single HHS program. Often HHS's mission is only one piece in a larger puzzle of overlapping and coordinating responsibilities. To achieve its mission, HHS needs to collaborate effectively across HHS programs and with other Federal agencies as well as outside the Federal government including with Tribal, State and local governments, international entities, industry, and other stakeholders.

KEY TAKEAWAYS

I. Relevant Agency: All HHS
II. Elements of the Challenge:
- Combating COVID-19
- Reducing health disparities
- Turning the tide on the opioid crisis
- Protecting children
- Keeping patients safe

Improving HHS's collaboration can help Americans receive more efficient, higher-quality health and human services and benefit from greater advances in the sciences underlying them. Cross-agency efforts led by the Department such as the Secretary's Intradepartmental Council on Native American Affairs and the Behavioral Health Coordinating Council, along with those related to Department management and data, provide opportunities for HHS programs to work more efficiently and in greater alignment. Effective partnerships with other Federal agencies help ensure that critical initiatives and resources, such as those for emergency preparedness and response and law enforcement investigations, are working in concert. Established networks of information exchange, such as through the Secretary's Tribal Advisory Committee, can better allow HHS programs to reflect community needs. Effective collaboration with HHS's vast array of nongovernmental stakeholders—from health care practitioners to food and drug manufacturers, health systems, nursing homes, hospices, professional associations, scientists, consumers, and community nonprofits, just to name a few—is essential to delivering the best services and care to the American people and supporting HHS programs in achieving their intended outcomes.

The need for collaboration crosses many of the programs and challenges discussed in other TMCs, highlighting the broad and complex nature of HHS's work. To run effective and efficient programs, HHS must consider issues and impacts outside a single program or mission for any one of its agencies. For example, the importance of data access and sharing across stakeholders is discussed in TMC 5.

Barriers to HHS collaboration include navigating a wide breadth of stakeholders with different goals and authorities, the scope and complexity of the problems for which HHS needs partnerships to resolve, and the ever-changing landscape of the health and human services sectors. Overcoming these barriers requires HHS to engage in intentional and sustained efforts toward building effective partnerships both domestically and internationally, communicating effectively, managing collaborative work, and maintaining accountability. Recent OIG work reveals the importance of effective and collaborative management within HHS and with HHS's partners, and areas for improvement.

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Combating COVID-19

The unprecedented nature of the COVID-19 pandemic underscores the critical importance of effective coordination in emergency preparedness and response. From the onset of the pandemic, various stakeholders were quickly called upon to collaborate on a myriad of efforts including those related to temporary emergency expansions, distributing Federal funds, managing health care programs, nursing home safety, vaccine development and distribution, testing, personal protective equipment (PPE) and respirator availability from the national stockpile, and public health guidance.

An OIG survey of hospitals responding to COVID-19 that was conducted in late March 2020 found that changing and sometimes inconsistent guidance from Federal, State, and local authorities on issues such as testing, use of PPE, and obtaining supplies from the national stockpile posed challenges for hospitals and the public.[220] In a follow-up survey conducted in March 2021, hospitals reported receiving varying information from different levels of government about who was eligible to receive the COVID-19 vaccine and when they were eligible.[221] Federal, State, and local governments had prioritized different population groups to receive vaccines and hospitals reported that these differences in priorities complicated eligibility determinations, which meant the process could be time-consuming and resource-intensive. Reports from OIG related to coordination in past emergencies found Federal agencies can reduce burdens on States and other stakeholders by consolidating outgoing communication and requests for data or information, and that clearly defined roles can ensure that staff are not working at cross-purposes.[222,223]

The Department has taken steps to address challenges to emergency coordination efforts. Related to cross-agency coordination, ASPR, CDC, and CMS implemented a joint OIG recommendation in 2020 to continue to help hospitals sustain preparedness for emerging infectious diseases (EID) by coordinating guidance and providing practical advice for all hospitals.[224] These agencies have taken actions to update EID preparedness guidance to ensure that it is clear and concise, develop strategies for updating information about EID threats, and provide practical advice that hospitals can easily employ. These efforts continued during the COVID-19 response.

Reducing health disparities

The disparate impacts of the COVID-19 pandemic on various racial and ethnic groups have brought health equity concerns to the forefront. Health disparities are differences in health that adversely affect certain groups. People of color have been found to experience disparities in areas such as access to care and quality of care.[225] Such disparities have profound implications for the health and well-being of these individuals.

The COVID-19 Health Equity Task Force was established by Executive Order 13995, *Ensuring an Equitable Pandemic Response and Recovery*, which was issued on January 21, 2021.[226] The task force is part of a government-wide effort to identify and eliminate health and social disparities that result in disproportionately higher rates of exposure, illness, hospitalization and death related to COVID-19. In addition to HHS, five additional Federal agencies are represented on the task force including the Departments of Agriculture, Education, Housing and Urban Development, Justice, and Labor. The task force's mission is to provide specific recommendations to the President for mitigating inequities caused or exacerbated by the COVID-19 pandemic and for preventing such inequities in the future.

One of the COVID-19 Health Equity Task Force's interim recommendations is to create data transparency related to the demographics of those receiving therapeutics and providing public health intervention funding to address barriers to care. OIG has work assessing HHS efforts to collect and analyze data on disparities to address the COVID-19 pandemic as well as, more broadly, to identify and mitigate health disparities. In an evaluation of Medicare claims

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data that analyzed differences by beneficiary characteristics including race and ethnicity, OIG found that Black, Hispanic, and Asian Medicare residents of nursing facilities had higher rates of COVID-19 diagnoses than White Medicare residents.[227] Ensuring that Medicare is able to assess disparities is key to improving overall health, advancing health equity, and reducing overall health care costs. The ability to assess disparities hinges on the quality of the underlying race and ethnicity data. (See TMC 5 for more information on improving data related to health disparities.)

Addressing the opioid crisis

The COVID-19 pandemic has further challenged HHS efforts to achieve its goal of reducing opioid morbidity and mortality. The pandemic may be exacerbating the Nation's opioid epidemic and individuals with an OUD may be at greater risk for COVID-19.[228] (See TMC 1). A number of OpDivs within HHS and other Federal agencies play a role in addressing opioid abuse and misuse, and coordination among them and other partners is vital to turn the tide on this crisis. State sharing of PDMP data, for example, may help to improve safe prescribing practices and prevent prescription drug abuse and misuse.[229] Better collaboration is a key step in helping reduce geographic disparities in access to medication to treat OUD. Improved stakeholder communication may also help make medication to treat OUD more available through better data collection and expand the use of data to measure performance.[230]

Protecting children

HHS faces substantial continued challenges in coordinating with respect to the Unaccompanied Children Program. (See TMC 4 for program background.) In a review of challenges that HHS faced in responding to the zero-tolerance policy and reunifying separated children with their parents,[231] OIG identified shortfalls in internal HHS communication, collaboration across Federal agencies, and outreach to critical stakeholders. These challenges impeded HHS in protecting children in its custody. In the Department, key senior HHS officials did not act on the OpDiv staff's repeated warnings that family separations were occurring and might increase, which impeded the Department's ability to provide prompt and appropriate care for separated children when the zero-tolerance policy was implemented. For example, HHS could not always place separated children in HHS-funded care provider facilities in a timely manner due to the lack of sufficient bed capacity.

Problems with interagency coordination also limited the Department's ability to plan for the care of children in its custody. For instance, information was not effectively shared in advance of the zero-tolerance policy, despite existing channels to facilitate high-level interagency coordination and engagement on important immigration issues.[232] Furthermore, HHS and DHS did not collaborate on systems for tracking separated families across agencies for later reunification, leaving HHS to struggle to identify separated children and reunite them with their parents. Additionally, poorly communicated guidance from HHS complicated care provider facilities' ability to care for children separated from their parents.

HHS oversees numerous other programs that provide direct services to children. Program funding may pass from the Federal government to States and then to local implementing entities that provide services such as foster care and child care. OIG audits of State compliance with employee background checks and other health and safety requirements in HHS programs found lapses that can put children at risk,[233, 234] supporting the need for better coordination between HHS and States to keep children safe. (See TMC 4 for more information on keeping children safe.)

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Keeping patients safe

Health care and mental health care providers, as well as providers furnishing OUD treatment, hospice, and nursing home services are among those on the frontline of ensuring safety for beneficiaries receiving care through HHS programs and at HHS facilities. OIG reports have identified issues with HHS oversight of, coordination with, and outreach to external partners that may leave patients at risk of harm. These include a series of reports finding deficiencies in State agency oversight of nursing homes' compliance with life safety and emergency preparedness requirements.[235] (See TMC 4 regarding patient safety.)

Recent cases of patient abuse by IHS employees have raised concerns about protecting the American Indian/Alaska Native population. The convictions of a former IHS pediatrician in September 2018 and 2019 brought attention to the issue and shed light on areas requiring improvement within IHS.[236, 237] An OIG memorandum to IHS on past and ongoing OIG audits reported that Tribal health programs that received *Indian Self-Determination and Education Assistance Act* funds from the IHS were not conducting required Federal Bureau of Investigation fingerprint background checks for all employees, contractors, and volunteers who have regular contact with Indian children.[238] This increases the risk that an individual in one State with a disqualifying criminal history in a different State could be hired into a position that involves regular contact with Indian children.

In response to OIG's memorandum, IHS issued a letter to Tribal leaders identifying the need for immediate action and steps toward a collaborative response to address this vulnerability, which may compromise the safety and well-being of Indian children who receive treatment at IHS-funded Tribal health programs.[239] It is imperative that HHS ensure that both IHS and Tribe-operated health facilities meet Federal requirements for background verifications of employees, contractors, and volunteers in contact with children served by the facilities, and that health care providers treating these children are appropriately licensed.

By building and sustaining effective partnerships, HHS can better safeguard and improve the programs so crucial to the health and well-being of the Nation.

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Department's Response to the Office of Inspector General

THE DEPUTY SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

To: Christi A. Grimm, Principal Deputy Inspector General

From: Andrea Palm, Deputy Secretary

Subject: FY 2021 Top Management and Performance Challenges Facing HHS

We appreciate the Office of the Inspector General's (OIG) dedication to helping us improve operations through its audit and investigative work over the years. In FY 2021, the OIG identified six top management and performance challenges that reflect overarching issues affecting multiple HHS mission programs and responsibilities. HHS recognizes the importance of acknowledging and mitigating risks threatening our mission execution and proper stewardship of taxpayer dollars.

The OIG highlighted the unparalleled challenges the Department continues to face from the evolution of COVID-19. As the lead federal agency, HHS has numerous significant responsibilities to assist communities in response to the pandemic. We are committed to building on our progress and recognize our organization must sustain its attention, action, and improvement. Our management is devoted to resolving these many challenges so we can achieve our mission of improving the health and well-being of the American people.

The Department acknowledges the management and performance challenges identified by the OIG, and we look forward to partnering with you and our stakeholders on the continuous improvement of our operations.

/Andrea Palm/

Andrea Palm
Deputy Secretary
November 12, 2021

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SECTION 4

APPENDICES

IN THIS SECTION

- Acronyms
- Connect with HHS

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Appendix A: Acronyms

AAP	Accelerated and Advance Payment
ACA	Affordable Care Act
ACF	Administration for Children and Families
ACL	Administration for Community Living
ADA	*Antideficiency Act*
ADHD	Attention Deficit Hyperactivity Disorder
AFR	Agency Financial Report
AHRQ	Agency for Healthcare Research and Quality
AI	Artificial Intelligence
APG	Agency Priority Goal
APM	Alternative Payment Model
APTC	Advance Premium Tax Credit
ARP	American Rescue Plan
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
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
ATSDR	Agency for Toxic Substances and Disease Registry
BARDA	Biomedical Advanced Research and Development Authority
CAP	Cross-Agency Priority
CARES Act	*Coronavirus Aid, Relief, and Economic Security Act*
CCDBG	*Child Care and Development Block Grant Act of 2014*
CCDF	Child Care and Development Fund
CDC	Centers for Disease Control and Prevention
CEAR	Certificate of Excellence in Accountability Reporting
CERT	Comprehensive Error Rate Testing
CFO	Chief Financial Officer
CFRS	Consolidated Financial Reporting System
CHIP	Children's Health Insurance Program
CIO	Chief Information Officer
CMCS	Center for Medicaid and CHIP Services
CMIP	Comprehensive Medicaid Integrity Plan
CMS	Centers for Medicare & Medicaid Services
COLA	Cost of Living Adjustment
CPI	Consumer Price Index
CPIM	Consumer Price Index-Medical
CRC	Commercial Repayment Center
CSRS	Civil Service Retirement System
CTO	Office of Chief Technology Officer
CY	Current Year
DAB	Departmental Appeals Board
DATA Act	*Digital Accountability and Transparency Act of 2014*
DHS	Department of Homeland Security
DME	Durable Medical Equipment
DMEPOS	Durable Medical Equipment, Prosthetics, Orthotics, and Supplies
DMF	Death Master File
DNP	Do Not Pay
DOI	Department of the Interior
DOJ	Department of Justice
DOL	Department of Labor
E-Invoicing	Electronic Invoicing
EHE	Ending the HIV Epidemic
EHR	Electronic Health Record
EID	Emerging Infectious Diseases
ERM	Enterprise Risk Management
ESRD	End-stage Renal Disease
FASAB	Federal Accounting Standards Advisory Board
FCBC	Fingerprint-based Criminal Background Checks
FBIS	Financial Business Intelligence System
FBwT	Fund Balance with Treasury

FCBC	Fingerprint-based Criminal Background Checks
FDA	Food and Drug Administration
FECA	*Federal Employees' Compensation Act*
FERS	Federal Employees Retirement System
FFATA	*Federal Funding Accountability and Transparency Act of 2006*
FFMIA	*Federal Financial Management Improvement Act of 1996*
FFS	Fee-For-Service
FGB	Financial Management Governance Board
FICA	*Federal Insurance Contributions Act*
FITARA	*Federal Information Technology Acquisition Reform Act*
FMFIA	*Federal Managers' Financial Integrity Act of 1982*
FPS	Fraud Prevention System
FR	Financial Report of the United States Government
FSCE	Financial Systems Control Environment
FY	Fiscal Year
GAAP	Generally Accepted Accounting Principles
GAO	U.S. Government Accountability Office
GDP	Gross Domestic Product
GONE Act	*Grants Oversight and New Efficiency Act*
GPRAMA	*Government Performance and Results Act Modernization Act of 2010*
GSA	General Services Administration
GTAS	Governmentwide Treasury Account Symbol Adjusted Trial Balance System
HC3	Health Sector Cyber Security Coordination Center
HFPP	Healthcare Fraud Prevention Partnership
HHA	Home Health Agency
HHS	Department of Health and Human Services
HI	Hospital Insurance
HIPAA	*Health Insurance Portability and Accountability Act of 1996*
HIV/AIDS	Human Immunodeficiency Virus/ Acquired Immunodeficiency Syndrome
HRSA	Health Resources and Services Administration
I-MEDIC	Investigations Medicare Drug Integrity Contractor
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
IPM	Improper Payment Measurement
IPPS	Inpatient Prospective Payment System
IT	Information Technology
MA	Medicare Advantage
MACRA	*Medicare Access and CHIP Reauthorization Act of 2015*
MAF	Management Assessment Framework
MAO	Medicare Advantage Organization
MCC	Major Case Coordination
MCO	Medicaid Managed Care Organization
MEDIC	Medicare Drug Integrity Contractor
MEQC	Medicaid Eligibility Quality Control
MII	Medicaid Integrity Institute
MIPS	Merit-based Incentive Payment System
MSP	Medicare Secondary Payer
NBS	NIH Business System
NCHS	National Center for Health Statistics
NIH	National Institutes of Health
NPI	National Provider Identifier
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
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
OpDivs	Operating Divisions
ORR	Office of Refugee Resettlement

Acronyms

OS	Office of the Secretary
PARIS	Public Assistance Reporting Information System
Part A	Hospital Insurance
Part B	Medical Insurance
Part C	Medicare Advantage
Part D	Medicare Prescription Drug Benefit
PCS	Personal Care Services
PDE	Prescription Drug Event
PECOS	Provider Enrollment, Chain and Ownership System
PERM	Payment Error Rate Measurement
PHS	Public Health Service
PHSSEF	Public Health and Social Services Emergency Fund
PIIA	*Payment Integrity Information Act of 2019*
PPACA	*Patient Protection and Affordable Care Act*
PPI	Plan Program Integrity
PRAC	Pandemic Response Accountability Committee
PRF	Provider Relief Fund
PSC	Program Support Center
PY	Payment Year
RAC	Recovery Auditor Contractor
RADV	Risk Adjustment Data Validation
REMS	Risk Evaluation and Mitigation
RSI	Required Supplementary Information
SAMHSA	Substance Abuse and Mental Health Services Administration
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
SHO	State Health Official
SMI	Supplementary Medical Insurance
SMRC	Supplemental Medical Review Contractor
SNF	Skilled Nursing Facility
SNS	Strategic National Stockpile
SOSI	Statement of Social Insurance
SSA	Social Security Administration
SSF	Service and Supply Funds
StaffDiv	Staff Division
T-MSIS	Transformed Medicaid Statistical Information System
TANF	Temporary Assistance for Needy Families
TAS	Treasury Account Symbol
TPE	Targeted Probe and Educate
Treasury	U.S. Department of the Treasury
TTD	Time-to-death
UC	Unaccompanied Children
UFMS	Unified Financial Management System
U.S.	United States
U.S.C.	United States Code
VCC	Vulnerability Collaboration Council

Appendix B: Connect with HHS

On behalf of the Department, we would like to sincerely thank and acknowledge all the individuals that provided support, either through content contribution or review feedback, to produce the FY 2021 AFR. We could not have prepared the FY 2021 AFR without the talent, time, and dedication of the employees across the Department of Health and Human Services.

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 2021 AFR. We welcome your comments on how we can make this report more informative for our readers. Please send your comments to:

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