



U.S. Department of Health & Human Services

HHS Presidential Transition Agency Landing Team Book

HHS Presidential Transition Team

HHS - 200 Independence Avenue SW - Washington, DC 20201



Message from the 2016 HHS Presidential Transition Team:

Welcome to the Department of Health and Human Services (HHS). We are pleased to provide you with the 2016 HHS Presidential Transition briefing book for the Landing Team. This document is being distributed in both hard and soft copy to each member of the President-elect's Transition Team assigned to HHS. To maintain its purpose as a briefing document, the volume is not and was not intended to be all inclusive. In developing these materials, we reviewed prior Presidential Transition documents, interviewed individuals who led or participated in past Transitions, partnered with the Partnership for Public Service, and exchanged ideas through the Agency Transition Director's Council. Based on the lessons learned from past HHS Transitions and best practices gleaned from our government-wide teaming, we designed this package as follows:

- The documents were prepared by senior career officials within HHS prior to the outcome of the election being known.
- The book provides a comprehensive overview of HHS, but is not intended to provide every fact and figure. Instead, we have crafted a concise summary of major Departmental functions, activities, and processes to provide an overview which will assist you in gathering additional material about programs and processes of particular interest.
- The briefing book includes key issues related to issues likely to come before the new Secretary within the first 30, 60, 90 days after the inauguration.
- We have included information which provides a sense of how specific HHS policy processes – both internal and external – can be marshaled to achieve Administration and Secretarial objectives.

We are pleased to welcome you to HHS and stand ready to meet with you, answer your questions, and provide additional information as requested. For further information, contact the HHS Transition Director, John Gentile, at 202-690-7512 (John.Gentile@hhs.gov, Room 510G.1 in the Humphrey Building).

You should also feel free to reach out to the other members of the HHS Presidential Transition Team:

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Table of Contents

Section I: Organizational Overview	1
Budget Resources	2
Select Highlights of Performance	3
Workforce and Organizational Culture	4
Secretarial Succession	6
Statutory Requirements and Enabling Legislation	7
Organizational History of HHS	9
Section II: Top Issues for New Leadership.....	14
Issues Immediately Facing a New Administration.....	15
Emergency Response Preparation	15
Budget Development and Appropriations	15
Top Policy Issues – First 100 Days	16
HHS Litigation Issues	20
Common Challenges or Roadblocks	20
Staffing the New Policy Team.....	21
Section III: Budget Overview	25
Context for Developing the HHS Budget	26
HHS Budget at a Glance.....	27
Budget Formulation Process	32
Funding Sources	34
Budget Execution Tools and Processes	36
Section IV: Oversight.....	39
Section V: Governance and Coordination	44
Governance Bodies.....	45
Additional Processes and Enterprise Wide Collaboration.....	45
HHS Strategic Management Processes	47
Commissions and the Federal Advisory Committee Act	48
Delegations of Authorities.....	49
Section VI: Regulations and Litigation.....	51
Overview of the Policy/Regulation Review Process	52
Overview of Regulatory Enforcement Process.....	54



Overview of Litigation	57
Section VII: Congressional Relations	60
Committees of Interest for HHS	61
Required Reports and Updates to Congress	65
Key Pending Legislation	66
Working with Other Legislative Offices to Clear Materials for Congress	69
Interaction with Congress	69
Section VIII: External Stakeholders	71
Section IX: Crisis Management and Emergency Response	73
Section X: Administrative Information	76
Contact Information for the HHS Presidential Transition Team	77
Computer Access, Technology Usage Information, Telephone Instructions	77
Transportation and Parking Information.....	77
Appendix A: Acronyms	78
Appendix B: Headshots and Biographies	82



SECTION I: ORGANIZATIONAL OVERVIEW



SECTION I: ORGANIZATIONAL OVERVIEW

HHS AT-A-GLANCE

The mission of the U.S. Department of Health & Human Services (HHS) is to enhance and protect the health and well-being of all Americans. HHS fulfills that mission by providing for effective health and human services and fostering advances in medicine, public health, and social services.

Not only is the HHS mission broad and far-reaching, it is supported by one of the largest budgets in the world at over \$1.1 trillion annually. In comparison, HHS's FY 2016 spending would rank it 15th in the world by nominal gross domestic product and HHS manages one of every four dollars spent by the Federal government. HHS is the largest Federal grant-maker and third largest Federal contracting agency.

This section includes information on HHS's:

- Summary of budget resources,
- Select highlights of performance since 2008,
- Workforce and survey data,
- Statutory authorities, and
- Organizational history.

BUDGET RESOURCES

HHS comprises about 28 percent of the Federal budget. HHS's budget authority has increased from \$720 billion in FY 2008 to \$1,100 billion in FY 2016 (+\$379 billion or 53 percent). The largest drivers of this increase can be attributed to growth in Medicare expenditures (from \$384.8 billion in FY 2008 to \$585.8 billion in FY 2016), Medicaid expansion under the Affordable Care Act (an increase of 13.5 million beneficiaries from FY 2013 to FY 2016), increased funding for the Children's Health Insurance Program, and the enactment of mandatory funding to supplement discretionary activities. [Section III](#) – Budget Overview – provides additional information on HHS's budgetary resources.

TABLE 1: HHS BUDGET TOTALS

(Dollars in millions)

	FY 2008	FY 2016 Enacted 1/	FY 2017 President's Budget 1/	FY 2016 +/- 2008
Discretionary Budget Authority	71,399	83,168	82,763	+11,769
Changes in Mandatory Programs	--	--	-4,294	--
Revised Discretionary Budget Authority	71,399	83,168	78,469	+11,769
Mandatory Budget Authority	649,240	1,016,728	1,062,439	+367,488
Total Budget Authority	720,639	1,099,896	1,140,908	+379,257
Total Outlays	698,847	1,108,597	1,139,930	+409,750

Note: The FY 2008 and FY 2016 columns reflect enacted levels and have not been adjusted for comparability with the FY 2017 President's Budget levels.

1/ Amounts are adjusted to reflect the most recent economic assumptions provided by OMB as part of the Mid-Session Review process.



SELECT HIGHLIGHTS OF PERFORMANCE

The Department tracks data on the investments and results. Planning programs and tracking performance of those program outcomes is supported by strategic performance measures in the budget. The Department reports on the results of over one hundred performance measures within its [Annual Performance Plan and Report](#). The measures in the annual report are a subset of the measures reported in the budget and are considered representative of the activities and performance of the Department as a whole. [Section V – Governance and Coordination](#) – provides additional information about how performance measures intersect with the Department’s Strategic Management process. Below are examples of selected performance outcomes from a variety of notable HHS activities.

HEALTH INSURANCE - AFFORDABLE CARE ACT

UNINSURED POPULATION REDUCTION

As of the end of 2015, the number of uninsured nonelderly Americans stood at 28.5 million, a decrease of nearly 13 million since 2013. In 2015, the nonelderly uninsured rate was 10.5 percent, the lowest rate in decades.

HEALTH INSURANCE MARKETPLACE ENROLLMENT

For the first half of 2016, an average of 10.4 million consumers had effectuated Health Insurance Marketplace coverage – which means those individuals paid their premiums and had an active policy through one of the Health Insurance Marketplaces nationwide as of that date.

MEDICARE PRESCRIPTION DRUG COST REDUCTIONS

Since the enactment of the Affordable Care Act (ACA) through July 2016, more than 11 million seniors and people with disabilities have received savings and discounts in the coverage gap of over \$23.5 billion on prescription drugs, an average of \$2,127 per beneficiary.

INFECTIOUS DISEASES - EBOLA OUTBREAK RESPONSE

In 2014, HHS collaborated to expedite research, development, manufacturing, and provision of Ebola vaccines and treatments. Utilizing existing and new partnerships with government, academia, and industry stakeholders, HHS leveraged assets across the U.S. Government to accelerate development and appropriate use of investigational Ebola vaccines and treatments. HHS also used novel contracting methods and moved funding quickly to support development and evaluation of candidate vaccines and treatments. HHS conducted vaccine trials in Liberia and Sierra Leone, and developed and implemented a novel clinical trial design in West Africa to test ZMapp (an experimental drug for Ebola treatment) and other medications that may have applicability in future outbreaks.

PREVENTION AND TREATMENT

CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC) SMOKING PREVENTION CAMPAIGN

In 2015, CDC launched a series of powerful new ads for its Tips from Former Smokers national education campaign. The ads highlighted health conditions such as colorectal cancer and macular degeneration, the benefits of quitting for smokers’ loved ones, and the importance of quitting smoking completely. The campaign has proven to be a “best buy” in public health by costing just \$393 to save a year of life (well under the widely accepted limit for the cost-effectiveness of a public health program of \$50,000 per year of life saved).



AIDS TREATMENT

Under the Health Resources and Services Administration (HRSA) Ryan White HIV/AIDS Program, the State AIDS Drug Assistance Program used a variety of strategies to maximize resources, which resulted in effective funds management, enabling HRSA to potentially serve more people. Cost-containment approaches used include: (1) using drug purchasing strategies such as cost recovery through drug rebates and third party billing; (2) directing the negotiation of pharmaceutical pricing; (3) reducing formularies; (4) capping enrollment; and (5) lowering financial eligibility levels. Cost savings resulting from these activities approach approximately \$900 million annually.

PATIENT SAFETY

An example of a well-regarded Priority Goal success is the coordinated effort to improve patient safety by reducing the national rate of healthcare-associated infections during FY 2014 - 2015. HHS Divisions worked together employing a number of initiatives to reduce hospital-acquired catheter-associated urinary tract infections. The end result was that, of the healthcare organizations tracked, overall, they achieved a 13.5 percent relative reduction in infection rates. Non-intensive care units achieved a 23.4 percent relative reduction in infection rates, whereas intensive care units achieved a 5.9 percent reduction in infection rates. The infection rate reduction in non-intensive care units is greater than in intensive care units in part because intensive care units have higher rates of catheter utilization than non-intensive care units. This effort is part of a broader HHS patient safety initiative that has resulted in 2.1 million fewer patients harmed, 87,000 lives saved, and nearly \$20 billion in cost-savings since 2011.

WORKFORCE AND ORGANIZATIONAL CULTURE

WORKFORCE DATA AND TRENDS

For FY 2016, HHS had approximately 76,342 employees on a full-time equivalent (FTE) basis, made up of close to 70,000 full-time and 26,600 part-time and intermittent employees. OpDiv staffing levels vary greatly: four OpDivs account for 78 percent of total HHS staff, while the four smallest OpDivs combined account for only two percent.

Nearly 60 percent of the workforce are women and over 45 percent of HHS's employees are minorities. The average age of an HHS employee is the same as the government-wide average – 47 years old, and 46 percent of HHS employees are 40 years old or older. Over 49 percent of the HHS workforce is at the GS-13 level or above (compared to 21.5 percent government-wide).

HHS manages, on a government-wide basis, the Commissioned Corps of the Public Health Service (PHS) which promotes public health and disease prevention and helps advance public health science. There are about 6,500 Corps members, and about 76 percent of them serve HHS components. The rest are billeted to help other Departments provide medical services (such as in the Bureau of Prisons and Department of Homeland Security immigration detention centers). The Corps comprises about eight percent of the HHS workforce.

Current staffing levels are about 20 percent higher than FY 2008. Most recently, FTE increases support emergency preparedness and disease prevention, food and drug safety, and healthcare fraud and abuse control efforts.

**TABLE 2: FTE COUNT BY OPDIV**

OpDiv	FY 2008 Actual FTE Levels	FY 2017 Estimated FTE Levels
Administration for Children and Families (ACF)	1,299	1,345
Administration for Community Living (ACL)	176	195
Agency for Healthcare Research and Quality (AHRQ)	297	325
Centers for Disease Control & Prevention (CDC)	8,951	11,151
Centers for Medicare and Medicaid Services (CMS)	4,483	6,360
Food and Drug Administration (FDA)	10,299	16,185
Health Resources and Services Administration (HRSA)	1,491	1,846
Indian Health Service (IHS)	14,989	15,227
National Institutes of Health (NIH)	17,240	18,000
Office of Medicare Hearings and Appeals (OMHA)	374	565
Office for Civil Rights (OCR)	228	179
Office of the National Coordinator for Health Information Technology (ONC)	30	177
Office of Inspector General (OIG)	1,518	1,616
Office of the Assistant Secretary for Preparedness and Response (ASPR)	306	612
Other Office of the Secretary (OS)	1,530	1,939
Substance Abuse & Mental Health Services Administration (SAMHSA)	544	620
Total, HHS	63,755	76,342

ORGANIZATIONAL SURVEYS OVERVIEW

The Federal Employee Viewpoint Survey (FEVS) is a key decision-making tool intended to provide employee insights in support of agency improvement. The survey supports improvements to the extent leadership widely shares survey results, supports action, and provides year round communication informing employees of steps taken to make improvement as a response to the survey.

In the 2016 survey, 39 items were identified for HHS as strengths (65 percent positive or higher).

TOP FIVE STRENGTHS

1. When needed I am willing to put in the extra effort to get a job done – 97 percent
2. I am constantly looking for ways to do my job better – 92 percent
3. The work I do is important – 91 percent
4. I know how my work relates to the agency’s goals and priorities – 87 percent
5. I am held accountable for achieving results – 86 percent

In the 2016 survey, two items identified as challenges (35 percent negative or higher).

TOP CHALLENGES

1. Pay raises depend on how well employees perform their jobs – 38 percent
2. In my work unit, steps are taken to deal with a poor performer who cannot or will not improve – 36 percent

KEY HIGHLIGHTS

- More HHS employees participated in 2016 than any prior year since the 2002 launch.



- HHS exceeded the 2016 government-wide response rate of 45.8 percent by 9.5 percentage points.
- Four of 12 OpDivs exceeded the HHS goal of 70 percent participation.
- HHS improved employee engagement scores by 3.8 percentage points in 2016 compared to 2014.

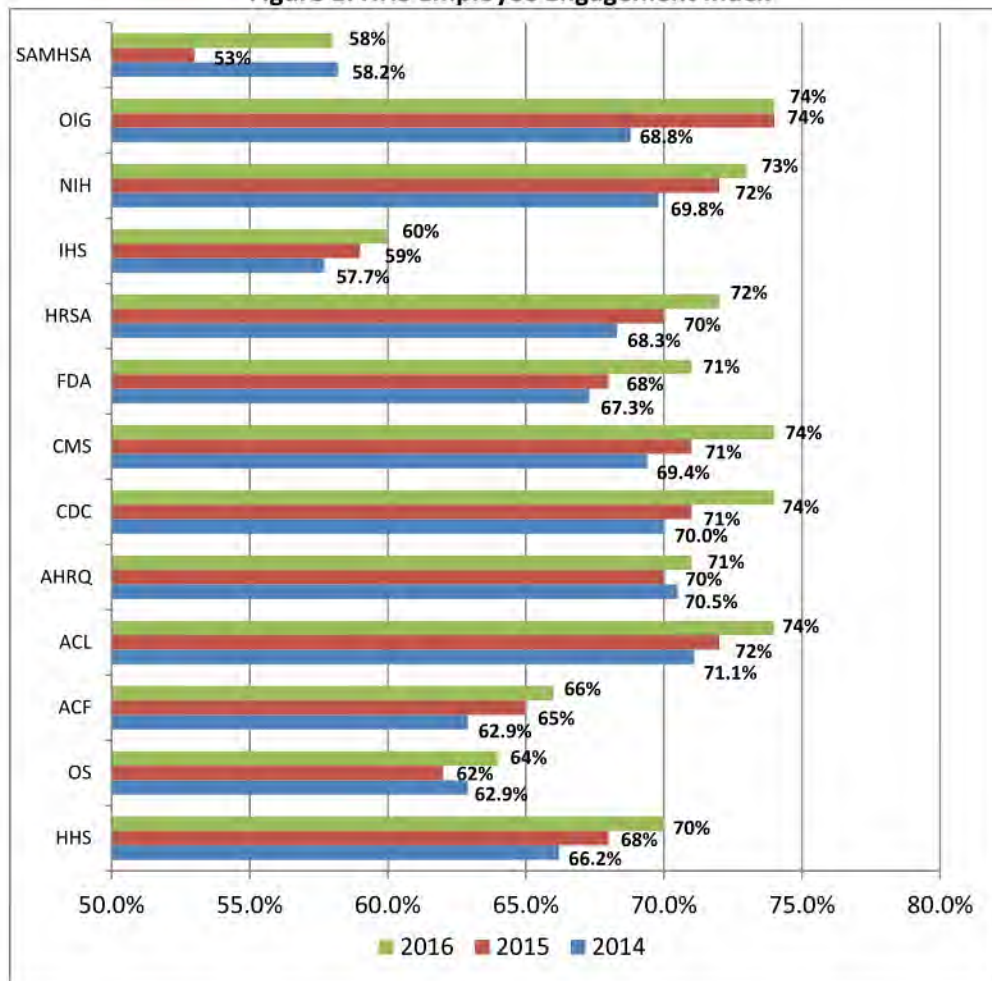
BEST PLACES TO WORK

HHS has gradually improved the Best Places to Work index scores from 2011 (62.7) to 2015 (63.9). The HHS index is above the large agency median and the government-wide average.

HHS EMPLOYEE ENGAGEMENT INDEX

The Employment Engagement Index is a tool developed by OPM that shows the average of several FEVS questions to provide a measure of an employee’s sense of purpose as it relates to their position within the organization. Since 2015, the overall Employee Engagement Index increased one percentage point government-wide for an overall score of 65 percent.

Figure 1: HHS Employee Engagement Index



SECRETARIAL SUCCESSION

In the absence of the Secretary the order of succession is listed below in Table 3. Executive Order 13461 (February 15, 2008) provides an order of succession within HHS. No individual who is serving in an acting



capacity shall act as Secretary pursuant to this order. The President retains discretion to depart from this order in designating an acting Secretary.

The officers named in the order listed shall act as and perform the functions and duties of the Secretary, if they are eligible to act as Secretary under the provisions of the Federal Vacancies Reform Act of 1998, during any period in which the Secretary has died, resigned, or become otherwise unable to perform the functions and duties of the OS.

TABLE 3: CURRENT SECRETARIAL SUCCESSION

Position	Current Confirmed Individual
Deputy Secretary	Vacant
General Counsel	Vacant
Assistant Secretary for Financial Resources	Ellen G. Murray
Assistant Secretary for Planning and Evaluation	Vacant
Centers for Medicare & Medicaid Services Administrator	Vacant
Food and Drug Administration Commissioner	Robert Califf
National Institutes of Health Director	Francis Collins
Assistant Secretary for Children and Families	Vacant
<i>Other Assistant Secretaries of the Department of Health and Human Services appointed by the President, in the order in which they shall have taken the oath office:</i>	
Assistant Secretary for Preparedness and Response	Nicole Lurie
Assistant Secretary for Legislation	Jim Esquea
Assistant Secretary for Public Affairs	Kevin Griffis
Assistant Secretary for Aging	Vacant
Assistant Secretary for Health	Vacant
<i>Other Listed Officers in Prescribed Order:</i>	
Centers for Disease Control and Prevention Director*	Tom Frieden
Region 4 (Atlanta) Director*	Pamela Roshell

* Non-career position not subject to Presidential appointment or Senate confirmation.

STATUTORY REQUIREMENTS AND ENABLING LEGISLATION

SECRETARIAL AUTHORITIES

In general, for a Federal agency to act, three criteria must be met:

- First, the agency must have a statutory authorization to take the action. Some of HHS's statutory authorizations are specific to HHS and its programs, and some are government-wide (procurement, travel, funds management, etc.). The authorizing statute may identify a specific component of HHS to carry it out; in other cases, the statute delegates authorities to the Secretary, and then the Secretary sub-delegates the authorities to a specific OpDiv or office.
- Second, if regulations have been issued to implement a law, the action must be consistent with those regulations. Agencies frequently have wide latitude in interpreting laws and issuing regulations to implement them – but once issued, agencies must abide by them. Specific public processes are required to issue new regulations or modify existing ones.
- Third, the agency must have received from Congress an appropriation of funds that can be used under that specific statutory authorization. Note that Congress sometimes enacts program authorizations that it never funds. The Congress provides funding to HHS in over 100 appropriation accounts, with each



account available for specific purposes and for specific periods of time (most often one year). In many cases, the appropriation act itself will specify how an appropriation must be divided among specific programs or how it must be used for particular purposes. Congressional reports indicate in further detail how appropriated funds are to be allocated. Together, the statutory provisions and the reports subdivide into 650 to 700 programmatic areas for the roughly 10 percent of the HHS budget that is funded through annual discretionary appropriations.

Authorizations for mandatory programs generally are more directive than those of discretionary programs. Some mandatory programs have appropriations included in the authorizing statute while others are guaranteed full funding through customary provisions in annual appropriations acts and Continuing Resolutions.

To enable agencies to address evolving issues and developing priorities, Congress has provided a range of funding flexibilities. Some laws include limited ability to waive requirements in order to conduct research on alternative ways to provide services, or to respond to emergencies. The Secretary can transfer limited amounts between some appropriations to address unexpected situations. Within a specific appropriation, there are formal procedures for notifying Congress if HHS wants to "reprogram" the funds – to allocate them in a way different from that indicated by the Congress.

HHS STATUTES AND REGULATIONS

HHS's statutory authorizations include two broad purpose acts (the Social Security Act and the Public Health Service Act) and statutes that are specific to particular OpDivs or particular programs. Most implementing regulations for HHS programs are codified in one of three volumes of the Code of Federal Regulations (C.F.R.): Food and Drugs (Title 21), Public Health (Title 42) and Public Welfare (Title 45).

SOCIAL SECURITY ACT

The Social Security Act authorizes the large HHS entitlement programs in CMS and the ACF, as well as smaller discretionary child welfare programs at ACF and maternal and child health grants in HRSA. Implementing regulations for CMS are included in Title 42 of the C.F.R.; other programs' regulations are in title 45. The Act directly appropriates funds for Temporary Assistance for Needy Families (TANF), the Children's Health Insurance Program (CHIP), some child care, and parts of Medicare. Annual appropriations from Congress fund Medicaid and the Foster Care entitlement programs. Some of these statutes are open to interpretation by HHS, while others (such as TANF) give HHS little flexibility. HHS often has some flexibility in modifying benefits and costs when issuing regulations and related guidance for most entitlement programs. Medicare's share of the health market means that it has a substantial effect on the practice of medicine through conditions for participation in Medicare, and the manner in which reimbursements are structured.

PUBLIC HEALTH SERVICE ACT

The Public Health Service Act authorizes most programs in HRSA, CDC, NIH, SAMHSA, ASPR, OASH, and AHRQ, as well as some activities in FDA, IHS, CMS, ACL, and ACF. The Act governs over 60 percent of HHS's discretionary funding. NIH and CDC have substantial flexibility in setting the requirements for receipt of grants and deciding funding levels. OpDivs that fund service programs (SAMHSA and HRSA) tend to have more prescriptive authorizations, with most grant funding allocated by statutory formula. Each affected component's annual appropriation is tied to specific titles or sections of the Act. The agency budget justifications and committee reports that accompany the appropriation provide added clarity on which specific authorities are funded. This approach provides OpDivs some flexibility to adapt to developing issues and priorities through formal reprogramming interactions with the Congress.



AGENCY-SPECIFIC AND PROGRAM-SPECIFIC AUTHORITIES

Other authorizing statutes are specific to particular HHS components or particular programs. Examples are the Federal Food, Drug, and Cosmetic Act; the Indian Healthcare Improvement Act; and the Older Americans Act, which provide most of the authorities for FDA, IHS, and ACL, respectively. Program-specific examples are the statutes authorizing the Head Start, Low-Income Home Energy Assistance, and Community Services Block Grant programs, all of which are administered by ACF. Appropriations for these programs are generally provided in annual appropriations acts. The larger service programs tend to have statutory funding allocation formulas. For smaller programs, HHS usually has more statutory flexibility, though historical relationships with outside partners often make modification a time-consuming and laborious process.

ORGANIZATIONAL HISTORY OF HHS

The organizational structure of HHS has evolved over time to reflect both the policy/management focus of successive administrations, and issues of concern in the Congress. Some aspects of HHS's organization are in statute; many others are not. For those that are in statute, the Secretary often has significant flexibility to structure the Department. For example, while the National Center for Health Statistics is established by law, its placement in CDC was an Executive Branch decision. Major organizational changes are summarized below.

ORGANIZATIONAL CHANGES IN PRIOR ADMINISTRATIONS

At the beginning of the Carter Administration, the Department of Health, Education, and Welfare included what is now HHS, the Department of Education, and the Social Security Administration. The Social Security Administration included what is now CMS and many parts of ACF. The OASH had line authority over the PHS agencies and those agencies did not report directly to the Secretary.

In 1980, the Department of Health, Education, and Welfare was split into the current two Departments to provide a greater focus on education, and CMS was made a separate agency (as the Healthcare Financing Administration). Early in the Reagan Administration, a number of programs were turned into block grants. Some were blocked in order to cap rapidly growing entitlement spending (Social Services Block Grant); others sought to devolve funding decisions from Federal agencies to States. Later in the Reagan Administration, the Secretary split the Social Security Administration into two organizations – the Social Security Administration focused on large entitlement programs for the elderly and disabled, while the Family Support Administration focused on moving families from welfare to work and increasing collections of child support. The residual of the Community Services Administration (post-block grants) also was merged into the new organization.

During the first Bush Administration, there were several changes in the structure of HHS agencies. The Alcohol, Drug Abuse, and Mental Health Administration was split into an agency focused on prevention and treatment (SAMHSA), with the research components becoming three NIH institutes (mental health, drug abuse, alcohol). What is now AHRQ was created as the Agency for Healthcare Policy and Research to focus on cost-effectiveness research. The current ACF and the Administration on Aging (AoA) were created from the former Family Support Administration and the Office of Human Development Services (which ran Head Start and child welfare programs).

There were two major changes in HHS during the Clinton Administration. The Social Security Administration was separated from HHS and became an independent agency. As part of an overall effort to reduce management levels, the public health agencies stopped reporting to the OASH, and started reporting directly to the Secretary. The OASH, which oversaw those agencies, was reduced in size. The Program Support Center was created in 1995 by combining service provision components from OS, HRSA, and FDA. This consolidation included



personnel, payroll, finance, procurement, and building management from OS, accounting and occupational health from HRSA, and data center services from FDA. These activities are funded by fees paid to the HHS Service and Supply Fund.

In the second Bush Administration the ASPR was established in 2002 and the Healthcare Financing Administration was renamed the Centers for Medicare & Medicaid Services (CMS) as part of an effort to shift the agency's focus from paying bills to improving the quality of healthcare the agency funded. CMS's health role was subsequently expanded by the enactment of prescription drug coverage in the Medicare Modernization Act of 2003. That Act also shifted the Medicare appeals process from the Social Security Administration to the OMHA within OS.

In addition, ONC and the position of the National Coordinator were established within OS in 2004 to coordinate Health IT activities across HHS and the Federal government. They were later written into law in the HITECH Act of 2009.

During the Obama Administration, the implementation of the Affordable Care Act (ACA) resulted in the creation of the Center for Consumer Information and Insurance Oversight within CMS.

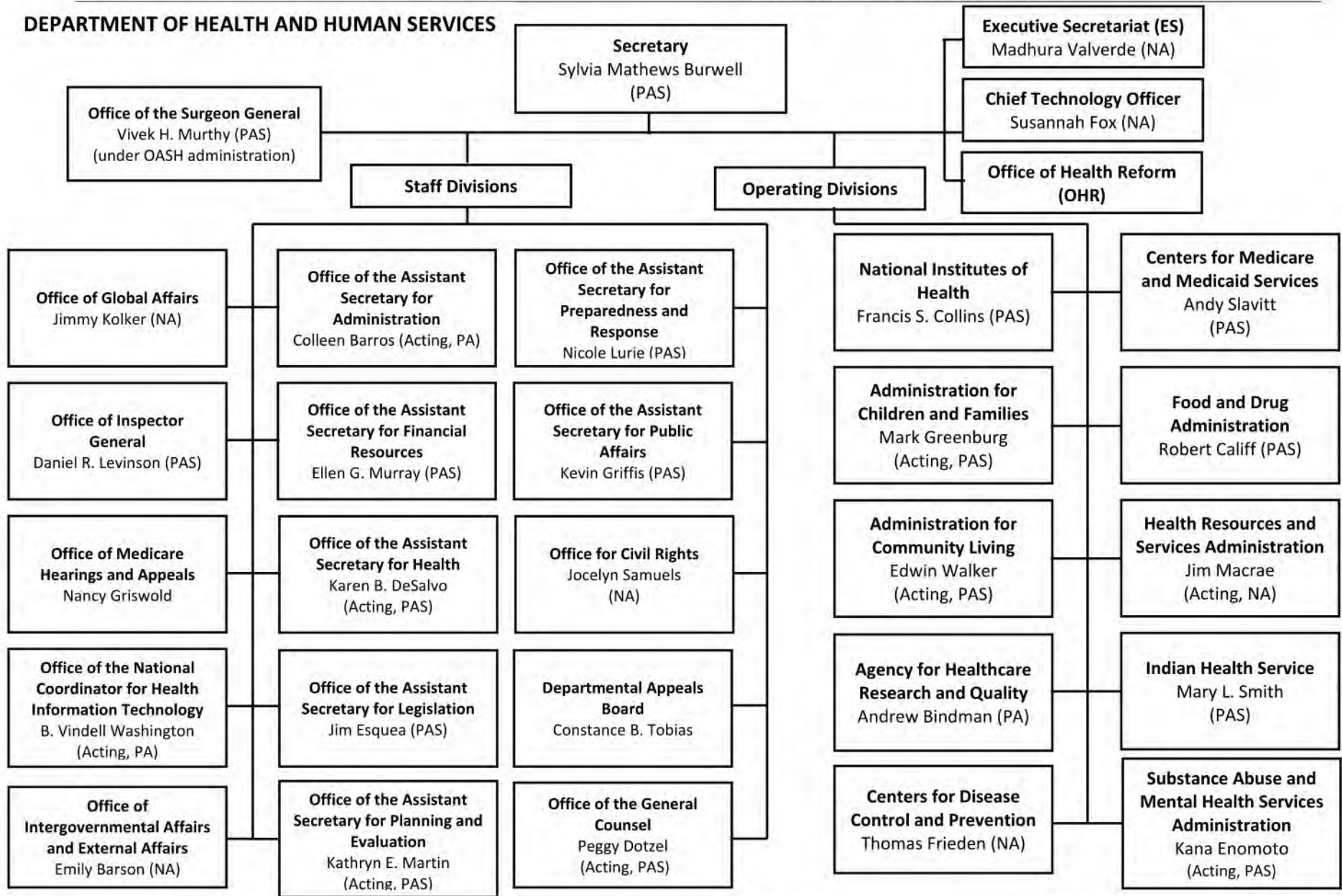
With the passage of the Family Smoking Prevention and Tobacco Control Act in 2009, the Center for Tobacco Products was established at FDA. The Center regulates the manufacture, marketing and distribution of tobacco products to protect public health and to reduce tobacco use by youth.

In addition, the National Center for Advancing Translational Sciences was established within NIH in 2012. The impetus for the Center came from a 2010 recommendation from NIH's Scientific Management Review Board. The purpose of the Center is to enhance the development, testing, and implementation of diagnostics and therapeutics across a wide range of human diseases and conditions.

In the second Obama Administration, ACL was initially established in 2012 by bringing together the Administration on Aging, the Office on Disability and the Administration on Intellectual and Developmental Disabilities. Through legislation in subsequent years, Congress moved several programs that serve older adults and people with disabilities from other agencies to ACL, including the State Health Insurance Assistance Program, the Paralysis Resource Center, and the Limb Loss Resource Center. The 2014 Workforce Innovation and Opportunities Act moved the National Institute on Disability, Independent Living, and Rehabilitation Research and the independent living and assistive technology programs from the Department of Education to ACL.



DEPARTMENT OF HEALTH AND HUMAN SERVICES





ORGANIZATIONAL CHART: TEXT VERSION

Department of Health and Human Services

- Secretary Sylvia Mathews Burwell (PAS)

The following offices report directly to the Secretary:

- The Executive Secretariat
 - Madhura Valverde (NA)
- Chief Technology Officer
 - Susannah Fox (NA)
- Office of Health Reform
- Office of Intergovernmental and External Affairs
 - Emily Barson (NA)
- Office of the Surgeon General
 - Vivek H. Murthy (PAS)

The following offices report to the Secretary, comprising 6,073 employees:

- Office of Global Affairs
 - Jimmy Kolker (NA)
- Office of the Inspector General
 - Daniel R. Levinson (PAS)
- Office of Medicare Hearings and Appeals
 - Nancy Griswold
- Office of the National Coordinator for Health Information Technology
 - B. Vindell Washington (Acting, PA)
- Office of the Assistant Secretary for Administration
 - Colleen Barros (Acting, PA)
- Office of the Assistant Secretary for Financial Resources
 - Ellen G. Murray (PAS)
- Office of the Assistant Secretary for Health
 - Karen B. DeSalvo (Acting, PAS)
- Office of the Assistant Secretary for Planning and Evaluation
 - Kathryn E. Martin (Acting, PAS)
- Office of the Assistant Secretary for Preparedness and Response
 - Nicole Lurie (PAS)
- Office of the Assistant Secretary for Public Affairs
 - Kevin Griffis (PAS)
- Office for Civil Rights
 - Joeelyn Samuels (NA)
- Departmental Appeals Board
 - Constance B. Tobias
- Office of the General Council (Acting, PAS)
 - Peggy Dotzel



The following Operating Divisions report to the Secretary:

- National Institutes of Health
 - Francis S. Collins (PAS)
- Administration for Children and Families
 - Mark Greenburg (Acting, PAS)
- Administration for Community Living
 - Edwin Walker (Acting, PAS)
- Agency for Healthcare Research and Quality
 - Andrew Bindman (PA)
- Centers for Disease Control
 - Thomas Frieden (NA)
- Centers for Medicare and Medicaid Services
 - Andy Slavitt (PAS)
- Food and Drug Administration
 - Robert Califf (PAS)
- Health Resources and Services Administration
 - Jim Macrae (Acting, NA)
- Indian Health Service
 - Mary L. Smith (PAS)
- Substance Abuse and Mental Health Services Administration
 - Kana Enomoto (Acting, PAS)



SECTION II: TOP ISSUES FOR NEW LEADERSHIP



SECTION II: TOP ISSUES FOR NEW LEADERSHIP

The information in this section provides a quick look at issues immediately facing the new Secretary after Inauguration, including emergency preparedness, contingency planning, onboarding political appointees, and top policy and budget issues facing the new Administration. This section is intended to be a guide to the issues that may arise during the first 100 days at HHS.

ISSUES IMMEDIATELY FACING A NEW ADMINISTRATION

Immediately after the Inauguration, the new HHS leadership team will face four large tasks: (1) developing a familiarity with HHS's emergency preparedness procedures; (2) preparing to issue a top-level budget for FY 2018; (3) responding to ongoing critical policy issues affecting HHS; and (4) beginning work on the President's priorities for his/her first term, including staffing up the new leadership team. More information on each of these crucial tasks is below.

EMERGENCY RESPONSE PREPARATION

Developing a familiarity with HHS's emergency preparedness procedures will include scheduling a high-level emergency preparedness briefing for new leadership and participating in preparedness exercises, ideally HHS and government-wide. Please see [Section IX](#) – Crisis Management and Emergency Response – for more information on HHS roles and responsibilities in response to emergencies, which can include natural disasters, public health emergencies such as the outbreak of a novel virus or food recall, or acts of bioterrorism.

WITHIN 30 DAYS OF INAUGURATION: SCHEDULE A PREPAREDNESS EXERCISE

To ensure that the new HHS leadership team is prepared as soon as possible for potential scenarios where either relocation is required or HHS's National Response Framework responsibilities have to be exercised, the new team should experience a Continuity of Operations tabletop exercise. This experience will help the new team become aware as quickly as possible not only about HHS's responsibilities regarding continuity of operations and the National Response Framework, but also about the capacities of the various components of the Department to assist in responding. This exercise should be scheduled within 30 days of the Inauguration.

BUDGET DEVELOPMENT AND APPROPRIATIONS

During the first 100 days of a new administration, the primary tool at the leadership team's disposal for advancing policy proposals will be development of the President's FY 2018 Budget.

FY 2017 BUDGET PROCESS

During summer 2016, the House and Senate Appropriations Committees considered spending bills for Labor-HHS, Agriculture (which funds FDA), and Interior (which funds IHS). None of these bills were considered by the full House or Senate. The Senate Labor-HHS appropriations bill would provide \$76.9 billion in discretionary program funding for components of HHS, an increase of \$1.2 billion above the FY 2016 Enacted level and \$2.2 billion above the FY 2017 Budget request. The House Labor-HHS bill provides funding for HHS at \$77.2 billion.

As of October 1, 2016, the Federal government is operating under a Continuing Resolution (CR) that is set to expire on December 9. The current CR ([P.L. 114-223](#)) continues government-wide spending at FY 2016 levels with a 0.496 percent reduction across the board and includes a \$1.1 billion spending package to combat Zika virus, \$933 million of which was provided to HHS. As of November 1, 2016,



negotiations over an FY 2017 omnibus appropriations bill are ongoing and a final bill is unlikely before early December. If Congress is unable to complete work before adjourning at the end of December, it is possible the FY 2017 appropriations process will extend into the new administration's tenure.

FY 2018 BUDGET DEVELOPMENT

Transition year budgets are developed very differently than subsequent President's Budgets given the truncated timeline. Development of the FY 2018 Budget will begin in earnest immediately after the Inauguration and will be complicated by expected negotiations on total spending levels as part of debt ceiling talks. As noted above, the FY 2018 Budget process could be made more complicated if the FY 2017 appropriations process is not yet complete. [Section III](#) – Budget Overview – contains information about both the normal process and anticipated timeline.

Point of contact:

ASFR – Norris Cochran, Deputy Assistant Secretary for Budget

TOP POLICY ISSUES – FIRST 100 DAYS

Below are some of the key policy issues that the new leadership team will face soon after the Inauguration. For each issue noted, we have included primary HHS Presidential Transition Council point of contact. Current appointees may also serve as valuable points of contact beyond the names provided below.

MARKETPLACE OPEN ENROLLMENT

Open enrollment for 2017 coverage in the Health Insurance Marketplaces extends from November 1, 2016, through January 31, 2017. Due to some issuers deciding not to participate in Marketplace coverage in 2017, this year will be the first since establishment of the Marketplaces where consumers may have fewer choices of plans than the year before. In an effort to increase Marketplace enrollment and plan stability in the Marketplaces, CMS is expanding the marketing and outreach efforts devoted to the 2017 open enrollment. In particular, the agency is focusing outreach to 26- to 34-year-olds including enhancing the ability to shop for Marketplace plans on mobile devices and working with the Department of the Treasury to send notices to individuals who paid the individual responsibility penalty, 45 percent of whom are under age 35.

Point of Contact:

CMS – Patrick Conway, Deputy Administrator for Innovation & Quality, CMS Chief Medical Officer

MEDICARE APPEALS BACKLOG

There currently exists a backlog in the adjudication of Medicare claims at HHS. Medicare beneficiaries appealing claims decisions move through a five-level appeals process: Levels 1 and 2 exist within CMS, Level 3 appeals are heard before the Office of Medicare Hearings and Appeals (OMHA), Level 4 appeals appear before the Council within the Departmental Appeals Board (DAB), and Level 5 appeals are heard outside of HHS by United States District Courts. As of November 1, 2016, CMS is not experiencing a backlog at Level 1 or 2, but OMHA and the Council are immediately impacted by the adjudication backlog. Between FY 2010 and FY 2015, OMHA experienced an increase of 442 percent in annual appeal receipts; and the Council experienced an increase of 267 percent in annual appeal receipts. At the end of the third quarter of FY 2016, the pending work at OMHA exceeded 700,000 appeals with annual adjudication capacity of approximately 84,500 appeals; the pending workload at Council exceeded 19,000 appeals with annual adjudication capacity of approximately 2,300 appeals. Due to the backlog, the Department is currently a defendant in several appeals-related lawsuits. Please refer to [Section VI](#) – Regulations and Litigation – for more information.



HHS's available appropriations to adjudicate claims have not kept pace with this increase in receipts. Additional background on the Medicare Appeals backlog is posted at [HHS Primer – The Medicare Appeals Process](#).

HHS has pursued a three-pronged strategy to improve the Medicare Appeals process and prevent the growth in the backlog by: (1) investing resources in adjudication capacity and implementing new strategies to alleviate the current backlog; (2) pursuing administrative action to reduce the number of pending appeals and encourage resolution of cases earlier in the process; and (3) proposing legislative reforms that provide additional funding and new authorities to address the appeals volume.

The Department has created an agency-wide working group to address the backlog and improve the Medicare Appeals process. Led by the Immediate Office of the Secretary and the Office of the Assistant Secretary for Financial Resources, the working group plays a central role coordinating the following organizational components to facilitate discussion and action across the various impacted offices.

Points of contact:

CMS – George Mills, Deputy Director of the Center for Program Integrity; Patrick Conway, Deputy Administrator for Innovation & Quality, CMS Chief Medical Officer

OMHA – Chief Administrative Law Judge Nancy Griswold

DAB – Council Chair Judge Constance Tobias

ASFR – Norris Cochran, Deputy Assistant Secretary for Budget

UNACCOMPANIED CHILDREN AND REFUGEE PROGRAMS

The Administration for Children and Families (ACF) is statutorily required to serve all unaccompanied children (minors under the age of 18 who enter the United States alone and do not have a parent or guardian to provide custody for them) and newly arrived refugees to the United States, regardless of the amount of discretionary funding provided by Congress through the annual appropriations process. Determining a budget request for unaccompanied children and refugees is complex, as referrals of unaccompanied children have grown from 6,560 in FY 2011 to nearly 60,000 in FY 2016; these numbers fluctuate from year to year, creating a challenge for estimating the need for shelter capacity and funding. Furthermore, while the Administration can set the total number of refugee arrivals for a given year, the number of other new arrivals eligible for refugee benefits is difficult to predict.

Financing for both programs has been challenging. Referrals of unaccompanied children and the number of arriving Cuban/Haitian entrants remain uncertain for FY 2017. The Administration recently increased the refugee ceiling to 110,000. In FY 2016, HHS sheltered the highest number of unaccompanied children in the history of the program, and monthly referrals have increased steadily since February 2016. At the same time, HHS served a record number of refugees, Cubans, and other entrants. HHS was able to support the full cost of both programs in FY 2016 by spending \$300 million in prior year funding and reallocating \$62 million from the Unaccompanied Children program to the program that serves refugees. Funding for FY 2017 is currently unclear. New Jersey, Kansas, and Texas have formally withdrawn from the Refugee program and ACF has been working to create an orderly transition of State-administered activities to non-profit organizations.

Congress also allows the Secretary to transfer up to 10 percent of funding across the Department into the Office of Refugee Resettlement. Authority for contingency funding triggered by growth in referrals of unaccompanied children was requested by the Administration but not provided by Congress. In



FY 2014, HHS requested a supplemental appropriation from Congress to deal with a surge in unaccompanied children arriving in the United States, but Congress did not provide additional funds.

If HHS does not receive a full-year appropriations bill prior to the Inauguration or if no additional funds are provided to care for unaccompanied children and refugees, securing funding for these programs will be an appropriations priority immediately facing the new HHS leadership team.

Points of contact:

ACF – Naomi Goldstein, Deputy Assistant Secretary for Planning, Research and Evaluation

ASFR – Norris Cochran, Deputy Assistant Secretary for Budget

ZIKA IMPLEMENTATION

Zika virus poses a serious public health threat both at home and abroad. There is active transmission of Zika virus in over 40 countries, including the United States. Zika infection during pregnancy can cause a birth defect of the brain called microcephaly and other severe fetal brain defects. Other problems have been detected among fetuses and infants infected with Zika virus before birth, such as defects of the eye, hearing deficits, and impaired growth. There also have been increased reports of Guillain-Barré syndrome, an uncommon sickness of the nervous system, in areas affected by Zika. Zika can be transmitted through mosquito bites of infected mosquitoes, from a pregnant woman to her fetus, and through sexual contact. Zika also likely can be spread through blood transfusion of infected samples. Currently, there is no specific medicine or vaccine for Zika virus. As of October 26, 2016, there were a total of 4,091 laboratory-confirmed cases of Zika in the United States, and an additional 28,723 cases in the U.S. territories.

The Zika Response and Preparedness Act ([P.L. 114-223](#)) was enacted as part of the Continuing Resolution on September 29, 2016. The Act provides \$933 million in supplemental funding to HHS for Zika preparedness and response activities, including \$394 million to CDC, \$152 million for NIH, and \$387 million to the Public Health and Social Services Emergency Fund. The Emergency Fund appropriation directly supports preparedness and response activities through the Office of the Assistant Secretary for Preparedness and Response (ASPR), the Health Resources and Services Administration (HRSA), and CMS. An additional \$1 million is provided for oversight of Zika activities.

The Act includes reporting and implementation requirements for the use of the funds, including the requirement that HHS provide a spend plan to Congress within 30 days of enactment; the spend plan was transmitted to the Congress on October 26, 2016. Updated spend plans must be submitted by HHS every 60 days until September 30, 2017. The updated spend plans are due to Congress by December 27, 2016; February 25, 2017; April 26, 2017; June 25, 2017; August 24, 2017. All funds appropriated in the Act must be obligated by September 30, 2017.

HHS is closely coordinating across the Department to ensure that activities funded through the Zika Response and Preparedness Act are complementary across programs, reflect investments to date, consider the evolving factors of Zika virus, and support the highest priority response activities to protect public health.

Points of contact:

ASFR – Norris Cochran, Deputy Assistant Secretary for Budget

ASPR – Melissa Harvey, Acting Chief of Staff

CDC – Sherri Berger, Chief Operating Officer



CMS – Patrick Conway, Deputy Administrator for Innovation & Quality, CMS Chief Medical Officer
HRSA – Elizabeth DeVoss, Budget Director; Diana Espinosa, Deputy Administrator
NIH – Larry Tabak, Principal Deputy Director

INDIAN HEALTH SERVICE CHALLENGES

Due to significant barriers such as healthcare access, geography, and resource levels, the Indian Health Service (IHS) faces long-standing challenges in delivering healthcare and critical public health services to American Indians and Alaskan Natives in the United States. Currently, IHS is focused on a series of short-, medium-, and long-term solutions to key funding and quality of care issues facing the agency. For example, the Administration worked with Congress provide a new appropriations mechanism for Contract Support Costs in the FY 2016 Omnibus Appropriations Act that allows IHS to fund contract support costs at the actual total funding need for the fiscal year, aligning the budget to the Supreme Court's decision in *Salazar v. Ramah Navajo Chapter*. The Supreme Court ruled that the Federal government is responsible for fully reimbursing Tribes contract support costs, regardless of the previous appropriations limit for this funding stream. This new funding mechanism allows IHS to carry out the program according to the Supreme Court's decision, while avoiding the need to redirect funding away from healthcare services IHS provides to Tribes. Further, IHS, with support from the Executive Council on Quality Care lead by the Acting Deputy Secretary, has worked over the last 18 months to resolve quality of care issues raised by Medicare surveys at three hospitals in the Great Plains area. IHS has taken action to divert patients from the emergency room at one facility while critical improvements were made, and has entered into long-term systems improvement agreements with CMS to identify and address the root causes of the quality issues identified in the area, among other actions. While IHS has made significant progress in addressing these issues, challenges remain and pressure from the Tribes and Congress continue to call for further improvement.

Points of contact:

IHS – Elizabeth Fowler, Deputy Director for Management Operations
ASFR – Norris Cochran, Deputy Assistant Secretary for Budget
CMS – Patrick Conway, Deputy Administrator for Innovation & Quality, CMS Chief Medical Officer

FDA USER FEES REAUTHORIZATION

FDA's authority to assess and spend fees under the Prescription Drug User Fee Act, Medical Device User Fee Amendments, Biosimilar User Fee Act, and the Generic Drug User Fee Amendments will expire at the end of FY 2017. Current authorities for these programs require HHS to submit legislative reauthorization packages to the Congress by January 15, 2017. Upon receipt, Congress will begin to schedule briefings and carry out committee markups of the proposed statutory language. It is likely that appropriations and authorizing committees will request significant HHS and FDA technical assistance during this process.

Points of contact:

ASFR – Norris Cochran, Deputy Assistant Secretary for Budget
ASL – Barbara Clark, Deputy Director, Human Services Legislation
FDA – Tom Kraus, Chief of Staff
OGC – Jeff Davis, Deputy General Counsel



HHS LITIGATION ISSUES

As of September 30, 2016, there are over 7,400 cases pending to which HHS is a party. This number represents all types of cases from routine matters (personnel, contract claims, and administrative actions), a range of enforcement actions, and high-profile policy issues currently in litigation. CMS has the largest share of the issues, with over 4,000 pending matters, but a significant part of these are provider enforcement appeals. [Section VI](#) – Regulations and Litigation – includes a summary of provider enforcement efforts and active HHS litigation. HHS’s Office of the General Counsel is available to provide additional information on cases and pending decisions, as appropriate.

Point of contact:

OGC – Jeff Davis, Deputy General Counsel

COMMON CHALLENGES OR ROADBLOCKS

HUMAN RESOURCES

Human resources is a high priority and a high-risk area because of ongoing difficulties to attract, hire, develop, and retain a diverse and inclusive workforce in the Federal government due to compensation constraints; hiring rules and regulations; an inability to attract and retain human resources professionals; and a fiercely competitive job market, especially in the Science, Technology, Engineering and Mathematics arena. Workforce demographic trends suggest that by September 2017, around 31 percent of all Federal employees will be eligible to retire, government-wide, which could result in a significant “knowledge drain” at HHS.

In addition to the above challenges, the Office of the Secretary, StaffDivs, and some smaller OpDivs currently receive human resources services from the Washington Human Resource Service Center. The Center has experienced multiple reorganizations and leadership changes in the past decade and the level of service provided by the organization is insufficient to meet customer demand in many areas. In 2015, the Acting Deputy Secretary directed a review of the organization, which identified the following deficiencies: inadequate funding for staff and systems; unclear picture of existing workload; lack of consistent operating protocols; variable expertise in existing staff; and lack of communication, transparency, and accountability.

A Steering Committee, comprised of senior level customers, has been established to provide direction and governance. While some resources have been added, allowing the Center to eliminate a significant backlog of recruitment actions and improve data integrity and workload tracking, more are needed just to obtain a minimal level of customer service. While the Center has made progress in implementing the recommendations identified by the review team, the transformation of this business area cannot be addressed with short-term fixes. A comprehensive plan has been established to address the systemic issues that have been in existence for the past 10 years. This plan will require significant changes on the part of the staff and their customer base. New and innovative business practices need to be adopted and resources must be dedicated to transform the organization, enabling HHS to hire the talent needed to enhance and protect the health and well-being of all Americans and drive discoveries and advancement in healthcare.

CYBERSECURITY

HHS information security efforts aim to protect information during the delivery of program operations and include cybersecurity and appropriate handling of protected health information and personally identifiable information. Information security is a high-risk and high priority area for HHS because of potential security incidents across HHS and cybersecurity breaches at other agencies and major healthcare providers. HHS has placed a high priority on maturing and enhancing its financial systems control environment, strengthening



policy, proactively monitoring emerging issues, and ensuring progress towards remediating the Department's IT Material Weakness, which were identified based on the Federal Information Systems Control Audit Manual and Federal Information Security Management Act assessments. HHS continues to invest resources to address weaknesses and will need continued investments in FY 2018 and beyond to keep up with emerging threats.

CLEARANCE OF HHS DOCUMENTS

Within the Executive Branch, there are several types of clearances processes that documents produced by HHS must go through. Who clears documents through which processes depends on the type of document and the intended audience for the document, and documents may go through internal (HHS) clearance as well as external clearance through OMB. Detailed descriptions of HHS's clearance requirements can be found in individual agency Transition Books and throughout this volume, including in [Section VI](#) – Regulations and Litigation – and [Section VII](#) – Congressional Relations.

Requirements for OMB clearance are outlined in OMB Circulars [A-11](#) and [A-19](#); ASFR and ASL will assist the new leadership team in navigating these processes and developing timelines for HHS products and policy proposals.

STAFFING THE NEW POLICY TEAM

The Federal hiring system is very complex, but it can accommodate many actions a new Secretary will want to take to staff the Department. The Deputy Assistant Secretary for Human Resources within the Assistant Secretary for Administration (ASA) is available to consult with the Secretary and key advisors on all issues relating to human resources and to facilitate the implementation of the Secretary's Department-wide staffing plans.

SELECTION OF A WHITE HOUSE LIAISON

Early identification of an advisor who will be the Secretary's point of contact for appointed personnel issues is essential. Historically, this position has been termed the "White House Liaison" due to their interaction with the White House on staffing and coordination issues. Naming a White House Liaison before the Secretary's arrival can help expedite all follow-on actions. The White House Liaison can discuss appropriate placement and compensation with principal players in the White House Presidential Personnel Office, top appointees in the Department, key assistants of the Secretary, and ASA.

The White House Liaison can assist with pre-screening, interviewing, and matching applicants with potential positions. Similarly, internal, security, ethics, and advance personnel paperwork can be coordinated out of the White House Liaison Office. After the White House and the Office of Personnel Management (OPM) approval of appointments is received, the White House Liaison Office can engage other offices that are involved in bringing appointees on-board.

The White House Presidential Personnel Office usually works closely with the Secretary in the selection of OpDiv and StaffDiv heads, Assistant Secretaries, and other high-level appointees. The White House Liaison Office can help prepare supporting documentation and work closely with ASA and other key players to ensure hiring decisions are quickly implemented and rules and ethics requirements are followed.

MAJOR TYPES OF APPOINTMENTS

There are four major types of non-career appointments available to the Secretary to facilitate staffing the HHS policy team: (1) Presidential; (2) non-career Senior Executive Service (SES); (3) Limited Term and Limited Emergency; and (4) Schedule C.



The requirements for each appointment category vary and are described below. During the initial stages of a new Administration, nominees may be brought on-board using special transitional hiring authorities, also described below. Even though these nominees would be temporary HHS employees, incoming individuals can opt-in for certain government-sponsored benefits, such as health and life insurance coverage. The new Secretary may also bring in individuals pending nomination as consultants to the Department. Consultants may not manage an organization with the Department, but can analyze issues.

The four major types of appointments include:

PRESIDENTIAL APPOINTMENTS

HHS has 21 positions that require presidential appointment, 19 of which require Senate confirmation.

When the President plans to nominate an individual for a position (i.e., an Assistant Secretary or agency head), the White House Liaison and ASL help shepherd the nominee through several clearance procedures that are critical to assuring a successful confirmation vote in the Senate. Background investigations for nominees are given expedited consideration, but can take time and may delay an individual's confirmation process. Detailed financial disclosures from each nominee are examined by HHS and the White House as well as the Office of Government Ethics. This process may also take considerable time.

Once the initial clearance processes for a nominee are complete, ASL helps steer nominees through the Senate confirmation process. Once the Senate confirms a nominee and the President signs the commission of appointment, a confirmed individual can be sworn in and assume his/her position at HHS. Such appointments can and usually do occur immediately following the President's signature, but formal swearing in ceremonies may occur at a later date.

The Senate confirmation process can be lengthy, but the Secretary has the authority to bring potential nominees on board using the temporary transitional procedures described in this section.

SENIOR EXECUTIVE SERVICE APPOINTMENTS

In general, the Secretary or his/her representatives may appointment an individual as a non-career SES into any SES general position within the Department without competing the appointment. However, per White House-imposed limits, HHS may not have more than 80 non-career SES at any given time. The Secretary or his/her representative may also set the pay level for non-career SES appointments (following general requirements established by OPM). Appointments to the non-career SES require advance clearance from the White House and approval from OPM.

LIMITED TERM AND LIMITED EMERGENCY SES APPOINTMENTS

Limited Term and Limited Emergency SES appointments can be made for time-limited periods: Limited Term appointments may not exceed three years; Limited Emergency appointments may not exceed 18 months. In addition, to help with transitions, OPM may authorize a Limited Term appointment authority for an individual who has been nominated by the President, but whose appointment is pending Senate confirmation. These limited appointments may not be made to the target position for which the individual has been nominated.



SCHEDULE C POSITIONS

Schedule C appointments are excepted from the competitive service because of the confidential or policy-determining nature of the position duties. Most Schedule C positions are at grade 15 of the General Schedule (GS-15) and below. Appointments require advance clearance from the White House and approval by OPM. There is no specific ceiling on the number of Schedule C positions the Department can fill. As of October 2016, HHS has 90 Schedule C positions.

In addition to the appointment categories described above, HHS is able to establish a limited number of Temporary Transitional Schedule C positions. Temporary Transitional Schedule C appointments are for 120 days and may be renewed once, for a total appointment not to exceed 240 days. Temporary Transitional Schedule C employees may be treated as non-temporary employees for benefits purposes and may be converted to a permanent Schedule C appointment. HHS may use this authority during the first year of a new Administration or during a one-year period immediately following the appointment of a new agency head or the designation of a new “acting” agency head.

PRESIDENTIAL APPOINTEES WITH SENATE CONFIRMATION

Nineteen positions in HHS require the advice and consent of the Senate and two are Presidential Appointments. These positions are captured in the tables below.

TABLE 1: HHS PRESIDENTIAL APPOINTEES WITH SENATE CONFIRMATION

Organizational Component	Position Title	Reports to
OS	Secretary	POTUS
OS/DS	Deputy Secretary	Secretary
OS/ASFR	Assistant Secretary for Financial Resources	Secretary
OS/ASPR	Assistant Secretary for Preparedness and Response	Secretary
OS/ASL	Assistant Secretary for Legislation	Secretary
OS/ASPE	Assistant Secretary for Planning and Evaluation	Secretary
OS/OPHS	Assistant Secretary for Health (ASH)	Secretary
OS/OPHS	Surgeon General	ASH
OS/OGC	General Counsel	Secretary
OS/ACL	Assistant Secretary on Aging and Administrator for Community Living	Secretary
OS/ACF	Assistant Secretary for Children and Families (ASCF)	Secretary
ACF/ACYF	Commissioner, Administration for Children, Youth and Families	ASCF
ACF/ANA	Commissioner, Administration for Native Americans	ASCF
CMS	Administrator, Centers for Medicare & Medicaid Services	Secretary
SAMHSA	Administrator, Substance Abuse and Mental Health Services Administration	Secretary
FDA	Commissioner of Food and Drugs	Secretary
IHS	Director, Indian Health Service	Secretary
NIH	Director, National Institutes of Health	Secretary
OS/OIG	Inspector General	Secretary

TABLE 2: HHS PRESIDENTIAL APPOINTEES

Organizational Component	Position Title	Reports to
OS/ASPA	Assistant Secretary for Public Affairs	Secretary
NIH	Director, National Cancer Institute	NIH Director



OPM LIMITS ON APPOINTMENTS AND HIRING RULES

SCHEDULE C POSITIONS

Schedule C positions are excepted from the competitive service because of their confidential or policy-determining character. Schedule C positions above the GS-15 level are either in the Senior Level personnel system or are specifically authorized in law.

OPM determines whether a position can be filled by a Schedule C appointment. Such determinations are made upon agency request and are considered on a case-by-case basis. Along with the justification submitted by the agency, OPM may conduct an independent review and analysis when making this determination. In addition to the Schedule C positions authorized by the OPM Director, a limited number of positions may be placed under Schedule C by Executive Order of the President or by legislation.

The immediate supervisor of a Schedule C position must be a Presidential appointee, a SES appointee (career or non-career) occupying a General position, or a Schedule C appointee. The immediate supervisor may not occupy a position in the competitive service or a SES Career Reserved position.

The only time OPM approval is not required for a Schedule C position is when a position is filled by a Temporary Transition Schedule C appointee. By law, the agency head must certify to OPM that both Schedule C and temporary Schedule C positions are not being requested for the sole purpose of detailing the incumbent to the White House.

HHS may fill Schedule C positions noncompetitively. Because of the confidential or policy-determining nature of Schedule C positions, the incumbents serve at the pleasure of the appointing authority (usually the agency head) and may be removed at any time. Schedule C appointees are not covered under conduct based or performance-removal procedures that apply to other excepted service positions. Schedule C positions authorized by OPM are automatically revoked when the incumbent leaves the position (i.e., there is no such thing as a “vacant” Schedule C position). As of October 2016, HHS has 90 Schedule C allocations.

APPOINTMENTS TO NON-CAREER SES POSITIONS

By law, no more than 10 percent of total SES positions government-wide may be filled by non-career appointees. The proportion of non-career appointees may vary from agency to agency, generally up to a limit of 25 percent of the agency’s total number of SES positions. OPM must approve each use of a non-career authority by an agency, and the authority reverts to OPM when the non-career appointee leaves the position.

Non-career SES appointees may be appointed to any SES general position with a Department. There is no requirement for competitive staffing, but the agency head must certify that the appointee meets the qualifications requirements for the position. Any non-career appointee may be removed by the appointing authority (e.g., for loss of confidence or change in policy) and appointees have no right to a termination appeal. All non-career appointees must be cleared through the White House Presidential Personnel Office. As of October 2016, HHS has 87 non-career SES allocations.



SECTION III: BUDGET OVERVIEW



SECTION III: BUDGET OVERVIEW

INTRODUCTION

The President is required by statute to submit an annual aggregate budget request, outlining funding recommendations for each Executive Branch agency, for the upcoming fiscal year to Congress by the first Monday in February. In a transition year, the President's first budget is submitted later, as described more fully below. The budget request is the primary mechanism for the President to set his/her policies and priorities for the coming fiscal year. Once appropriations are made by Congress, the Department is responsible for administering its budget through the execution process. The policies and processes described in this section are run by the HHS Office of Budget in the Office of the Assistant Secretary for Financial Resources (ASFR).

Specifically, this section:

- Provides a context for developing the Federal budget in this transition year;
- Summarizes the historical trends of the HHS Budget;
- Describes the formulation process for a typical budget year, including the roles of key players involved (internal and external), and the products produced during the process;
- Describes the different funding sources that comprise the HHS budget; and
- Describes the execution process and the mechanisms and flexibilities by which HHS can spend funds.

CONTEXT FOR DEVELOPING THE HHS BUDGET

STATUTORY LIMITS ON SPENDING

The Budget Control Act of 2011 established caps on discretionary appropriations allocated by the Appropriation Committees. This process limits what can be proposed and enacted for discretionary programs like NIH. The current law caps for FY 2018 are modestly lower than those for FY 2017, and the new President will have to decide almost immediately whether, and if so, by how much to propose to increase or decrease them.

Mandatory funding (Medicare, Medicaid, etc.) is subject to a different set of controls. If Congressional changes to spending and revenues, in the aggregate, increased the deficit, additional sequesters would be triggered to offset the increase. Over the last eight years, HHS has been asked to create a list of proposals that would create efficiencies and reduce mandatory spending over time to allow for new spending elsewhere in the mandatory budget. The proposals that would reduce mandatory spending are not necessarily related to the proposals for additional spending. These proposals are developed during the budget formulation process, and have mostly been related to Medicare.

TRANSITION YEAR FORMULATION PROCESS

Transition year budgets are developed very differently than subsequent President's Budgets. As noted in the Budget Formulation Section below, in a normal budget year, the contents of the President's Budget are negotiated between the departments and OMB from September to January, with a complete budget due the first Monday in February. In recent transition years, the President has issued a top-level budget in either mid-February (Clinton) or late February (Bush, Obama). The full array of detailed budget publications is most commonly released in early April. The Obama Administration delayed its budget submissions in 2009 and 2013 due to the work needed to enact the Recovery Act (budget was released February 17, 2009) and a full-year annual appropriation (the 2013 budget was released March 10).



OMB typically has all of its budget-related policy appointees in place quickly. OMB will generally develop the top-level February budget in a manner that reflects the most important campaign promises, with fewer opportunities for the domestic cabinet agencies (who may not have confirmed appointees) to negotiate top-line numbers. OMB will usually initiate the process within a week or two of the Inauguration. OMB will usually provide:

- A single number for each agency’s domestic discretionary appropriations (the programs that are controlled by the annual appropriations process);
- A multi-year savings target for mandatory/entitlement programs that are controlled by the authorizing committees in Congress; and
- A few selected policy issues to be highlighted in the February budget document.

After agency totals are settled, OMB will negotiate with agencies how to divide those totals, and propose funding levels for all HHS programs for the full budget submission package.

The Federal government will lose its legal ability to take on new public debt on March 15. While Treasury can use “extraordinary measures” to continue funding the government for a few months, a revised debt ceiling will be needed by roughly the end of FY 2017. The new President will also want to create budgetary space for campaign promises. As a result, one can expect intensive negotiation on budgetary totals during the new Administration’s first several months. Since HHS has about two-thirds of government-wide mandatory spending (excluding Social Security), there will likely be significant pressure to find ways to manage the cost of those programs.

ASFR has been working with the components of HHS to identify the costs of continuing operations, and what funding may be needed in FY 2018 for new challenges that are discussed elsewhere in this document. ASFR also works closely with CMS to maintain an array of alternatives for reducing the cost of healthcare programs, especially Medicare.

HHS BUDGET AT A GLANCE

TABLE 1: HHS BUDGET TOTALS
(Dollars in millions)

	FY 2008	FY 2016 Enacted 1/	FY 2017 President’s Budget 1/	FY 2016 +/- 2008
Discretionary Budget Authority	71,399	83,168	82,763	+11,769
Changes in Mandatory Programs	--	--	-4,294	--
Revised Discretionary Budget Authority	71,399	83,168	78,469	+11,769
Mandatory Budget Authority	649,240	1,016,728	1,062,439	+367,488
Total Budget Authority	720,639	1,099,896	1,140,908	+379,257
Total Outlays	698,847	1,108,597	1,139,930	+409,750

1/ Amounts are adjusted to reflect the most recent economic assumptions provided by OMB as part of the Mid-Session Review process.

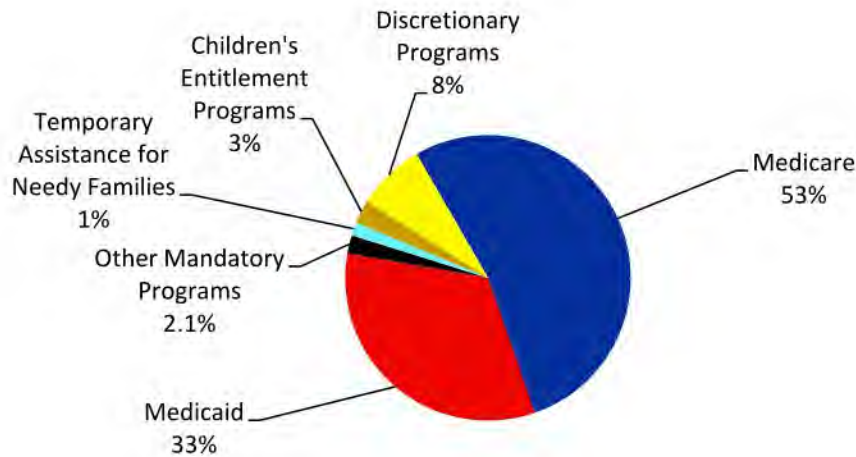
BUDGET HISTORY

HHS comprises about 28 percent of the Federal budget. HHS’s budget authority has increased from \$720 billion in FY 2008 to \$1,100 billion in FY 2016 (+\$379 billion or 53 percent). The largest drivers of this increase can be attributed to growth in Medicare expenditures (from \$384.8 billion in FY 2008 to \$585.8 billion in FY 2016), Medicaid expansion under the Affordable Care Act (an increase of 13.5 million beneficiaries from FY 2013 to



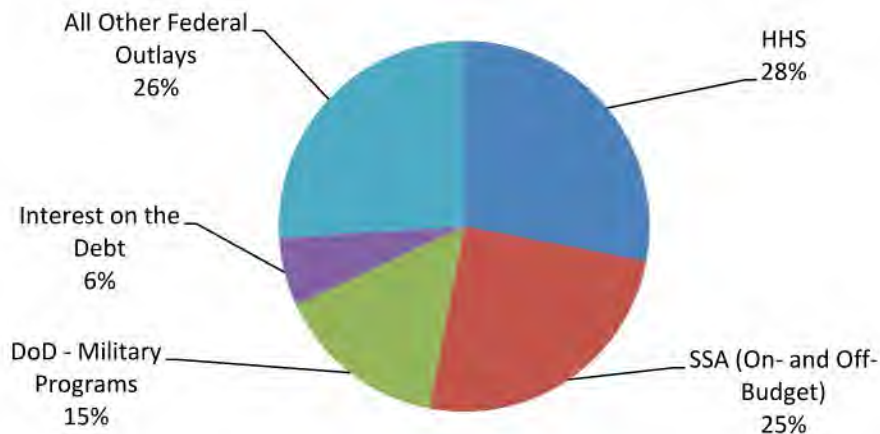
FY 2016), increased funding for the Children’s Health Insurance Program, and the enactment of mandatory funding to supplement discretionary activities. The Affordable Care Act spending for insurance subsidies, \$36 billion in FY 2016, is in addition to this amount, as it is appropriated to Treasury, but spent by CMS.

FIGURE 1: TOTAL FY 2016 ENACTED HHS OUTLAYS
\$1,109 Billion in Outlays



In FY 2016, HHS had the largest share of Federal outlays of any single agency, at approximately 28 percent of total outlays. This can be attributed to the large annual cost of Medicare and Medicaid. HHS is closely followed by the Social Security Administration, which also administers a large entitlement program. The below chart illustrates the distribution of outlays across the Federal government, including HHS, the Social Security Administration (SSA), and the Department of Defense (DoD).

FIGURE 2: TOTAL FY 2016 ENACTED ESTIMATED OUTLAYS FOR THE FEDERAL GOVERNMENT





As of FY 2016, mandatory funds are 92 percent of HHS's total funding, with Medicare and Medicaid accounting for the majority of those funds. The increase in outlays for Other Mandatory Programs reflects Congress's decision to provide mandatory funding to supplement activities in HRSA and ACF, and a Prevention and Public Health Fund that the appropriation bill allocates across HHS. The below table provides a detailed breakdown of mandatory programs funded within HHS.

TABLE 2: MANDATORY OUTLAYS BY PROGRAM
(Dollars in millions)

	FY 2008 Enacted	FY 2016 Enacted 1/	FY 2017 President's Budget 1/	FY 2016 +/- 2008
Medicare	385,782	585,809	598,191	+200,027
Medicaid	201,426	369,111	385,149	+167,685
Temporary Assistance for Needy Families	17,880	16,199	18,416	-1,681
Foster Care and Adoption Assistance	6,750	7,478	8,058	+728
Children's Health Insurance Program	6,900	15,181	16,199	+8,281
Child Support Enforcement	4,283	4,167	4,321	-116
Child Care Entitlement	2,909	2,850	6,006	-59
Social Services Block Grant	1,843	1,771	2,136	-72
Other Mandatory Programs	1,626	22,396	14,269	+20,770
Offsetting Collections	-1,199	-797	-795	+402
Subtotal, Mandatory Outlays	628,200	1,024,165	1,051,950	+395,965
Total, HHS Outlays	698,847	1,108,597	1,139,930	+409,750

1/ Amounts are adjusted to reflect the most recent economic assumptions provided by OMB as part of the Mid-Session Review process.

Since FY 2008, discretionary budget authority for HHS has increased from \$71.4 billion to \$83.2 billion in FY 2016. A significant portion of the increased discretionary funding has been targeted to ACF (Head Start +\$2.3 billion), IHS (Clinical Services and other +\$1.8 billion), and NIH (+\$1.9 billion).

Table 3 below displays the budget authority and total program level funding for each OpDiv and StaffDiv. The program level lines include major user fees, mandatory appropriations that supplement discretionary programs, insurance collections for IHS, and PHS Evaluation transfers (discussed below) that substitute for budget authority.



TABLE 3: HHS DISCRETIONARY SPENDING
(Dollars in millions)

	FY 2008 Enacted	FY 2016 Enacted	FY 2017 President's Budget	FY 2016 +/- FY 2008
Food and Drug Administration	1,870	2,728	2,743	+858
<i>Program Level</i>	2,420	4,745	4,975	+2,325
Health Resources and Services Administration	6,857	6,147	5,743	-710
<i>Program Level 1/</i>	6,194	10,543	10,677	+4,349
Indian Health Service	3,346	4,808	5,185	+1,462
<i>Program Level 1/</i>	4,297	6,160	6,562	+1,863
Centers for Disease Control and Prevention	6,214	6,345	6,042	+131
<i>Program Level</i>	9,163	12,056	12,005	+2,893
National Institutes of Health	29,457	31,381	30,314	+1,924
<i>Program Level 1/</i>	29,615	32,311	33,136	+2,696
Substance Abuse and Mental Health Services Admin	3,234	3,634	3,489	+400
<i>Program Level</i>	3,356	3,781	4,322	+425
Agency for Healthcare Research and Quality	–	334	280	+334
<i>Program Level</i>	335	428	470	+93
Centers for Medicare & Medicaid Services	3,157	3,975	4,110	+818
<i>Program Level</i>	3,858	6,228	7,356	+2,370
Administration for Children and Families	14,140	18,870	19,952	+4,730
<i>Program Level 1/</i>	14,140	18,870	19,952	+4,730
Administration for Community Living	1,901	1,966	1,994	+65
<i>Program Level</i>	1,913	2,050	2,078	+137
Office of the Secretary:				
General Departmental Management	355	456	479	+101
<i>Program Level</i>	407	528	552	+121
Office of Medicare Hearing and Appeals	64	107	120	+43
<i>Program Level</i>	64	107	250	+43
Office of the National Coordinator	42	60	0	+18
<i>Program Level</i>	61	60	82	-1
Office of Inspector General	43	77	85	+34
<i>Program Level</i>	248	342	419	+94
Office for Civil Rights	34	39	43	+5
Public Health and Social Services Emergency Fund	648	1,533	1,431	+885
<i>Program Level</i>	648	1,533	1,431	+885
Discretionary HCFAC	–	681	725	+681
Accrual for Commissioned Corps Medical Benefits	37	27	28	-10
Total, HHS Discretionary Budget Authority	71,399	83,168	82,763	+11,769

Note: The FY 2008 and FY 2016 columns reflect enacted levels and have not been adjusted for comparability with the FY 2017 President's Budget levels.

1/ Reflects mandatory funding which expires after FY 2017.

DISCRETIONARY CAP HISTORICAL TRENDS

Aggregate limits on discretionary appropriations (discretionary “caps”) were reinstated by the Budget Control Act of 2011 as part of an agreement to increase the debt limit. When the Congress did not subsequently enact the required \$1.2 billion in savings anticipated by that Act, FY 2013 appropriations were sequestered and the discretionary caps were automatically reduced for subsequent years. Two subsequent laws have provided some



relief from the reductions in two-year increments, but no relief has been enacted for FY 2018. Table 4 below displays the discretionary caps, post-sequester/reduction. These numbers for prior years differ from the most recent sequestration preview reports since those reports “reclassify” certain savings provisions as mandatory after enactment.

The caps are separated into non-defense discretionary spending and defense discretionary spending. The table below shows the annual caps on non-defense discretionary budget authority, HHS’s appropriations that are subject to those caps, and what percentage was allocated to HHS. Given the size of the agency’s budget, HHS receives a substantial portion of the non-defense discretionary funding available across the Federal government.

TABLE 4: DISCRETIONARY CAPS
(Dollars in millions)

	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Non-Defense, Total 1/	475,202	491,773	492,356	518,491	518,531
Non-Defense, HHS					
HHS Discretionary Budget Authority 2/	73,112	78,354	79,282	83,168	82,763
HHS Percentage of Non-Defense Discretionary Cap	15.4%	15.9%	16.1%	16.0%	16.0%

1/ Totals do not include adjustments for emergency funding, overseas contingency operations, or other statutory cap adjustments.

2/ Does not include emergency supplemental funding.

The discretionary caps place limits on the amount of new authority to obligate funds that the appropriations committees can provide, but does not restrict outlays from those funds. Since discretionary outlays are not capped, the appropriations committees provide some relief from the stringent caps with provisions affecting mandatory funding enacted in authorizing legislation that agencies cannot use in the near term. Depending on the nature of the account, the savings provision may either make the funds unavailable for obligation for a fiscal year, or rescind the money. These are called “Changes in Mandatory Programs” (CHIMPs), which are scored as negative budget authority. Most of these changes in HHS have been rescissions of appropriations that were in excess of need. The table below illustrates the dollar amount of CHIMPs in HHS programs since FY 2013. It is important to note that for FY 2018, the level of CHIMPs available from HHS will be down substantially, further straining the government-wide discretionary totals. The amount available in FY 2018 will not be known until after Congress completes the FY 2017 appropriation bills.

TABLE 5: CHANGES IN MANDATORY PROGRAMS (CHIMPS)
(Dollars in millions)

	FY 2013 Enacted	FY 2014 Enacted	FY 2015 Enacted	FY 2016 Enacted	FY 2017 President’s Budget
HHS CHIMPs (Rescissions & Obligation Limitations)	-6,578	-6,317	-6,304	-6,742	-6,525

As a result of these budget constraints, the FY 2017 President’s Budget proposed an increase in mandatory funding for programs in HHS that are normally funded with discretionary budget authority. For example, the

**STEP 1: OPDIVS AND STAFFDIVS FORMULATION (JANUARY-JUNE)**

Each OpDiv and StaffDiv develops their budget request for submission to the Department by the first week in June. The HHS Justification is an internal document that is drafted in accordance with the guidance provided by ASFR and OMB. This guidance outlines internal deadlines and the total funding level that OpDivs must meet in their request.

STEP 2: DEPARTMENTAL REVIEW (JUNE-JULY)

Throughout June, the Department staff analyze and summarize the OpDivs' and StaffDivs' requests in preparation for Secretary's Budget Council meetings in July. At these meetings, OpDivs and StaffDivs present their budget request to senior HHS leadership.

STEP 3: SECRETARIAL DECISIONS (JULY-AUGUST)

The Secretary issues final decisions on which proposals should be included in the budget request to OMB. The Secretary's decisions are passed back to OpDivs and StaffDivs at the end of July or the beginning of August.

STEP 4: HHS BUDGET REQUEST SUBMITTED TO OMB (SEPTEMBER)

After receiving final decisions from the Secretary, OpDivs and StaffDivs revise their documents where necessary to submit their Department-approved budget request to OMB in early September, which is called an OMB Justification.

STEP 5: OMB REVIEW OF HHS REQUEST (SEPTEMBER-NOVEMBER)

OMB begins an internal process similar to the Department's review of OpDiv and StaffDiv submissions. The Department defends its resource needs. OMB holds numerous meetings, sometimes at the staff level and often at the senior policy level to gather additional information on the Department's request and to determine the Secretary's priorities.

STEP 6: OMB PASSBACK AND APPEAL (USUALLY THE FIRST WEEK AFTER THANKSGIVING)

OMB informs HHS of the Administration's decision on the Department's request through a process called "Passback." OMB "passes back" specific policy and budget decisions to the Department, typically at top line funding levels below where OMB expect to end up for each department. The Department is given a short time frame (usually two to three days) to appeal OMB decisions. Senior management must prioritize needs and decide which items to negotiate with OMB among the many discretionary and mandatory funding items of interest to HHS leadership. Passback week, which usually starts the Monday after Thanksgiving, is one of the most hectic weeks of the budget formulation process.

STEP 7: NEGOTIATIONS AND PRESIDENTIAL DECISIONS (DECEMBER)

After appeals are submitted, the Department and OMB continue to engage in negotiations until final agreement is reached (usually in late December) as to the content of the President's Budget. If necessary, any outstanding issues may be appealed by the Secretary to whatever appeals process the White House establishes. This process may include an appeals board consisting of the Chief of Staff and Vice-President before appeals are presented to the President.

STEP 8: PRODUCTION OF THE PRESIDENT'S BUDGET (DECEMBER-FEBRUARY)

With final agreement reached between OMB and the Secretary on the appeal items, OpDivs and StaffDivs then revise their documents where necessary and submit the Administration-approved budget request to Congress in the form of a Congressional Justification.

HHS also produces a public document called the Budget in Brief that summarizes the HHS budget request across all OpDivs and StaffDivs for the upcoming fiscal year. The document is concise across the Department.



The release of the Budget in Brief is a high profile activity for the department, with the Secretary typically holding a press conference to discuss the Department’s request on the day the President’s Budget is released.

HHS provides information to OMB for inclusion in the government-wide President’s Budget documents, which include the Budget, the Appendix, Analytical Perspectives, and Historical Tables.

The budget formulation cycle starts over again soon after the submission of the President’s Budget with OpDivs and StaffDivs internally planning their budget recommendations for the next fiscal year.

FUNDING SOURCES

FIGURE 4: UNIVERSE OF FEDERAL SPENDING (FY 2016 OUTLAY ESTIMATES)

BUDGET ENFORCEMENT ACT (BEA) CATEGORY	Discretionary		Mandatory		
	Annual Appropriations Acts			Authorizing Legislation	
FUNDING PROVIDED BY...	Capped			Open-ended	
WHICH IS...	Discretionary Spending		Appropriated Entitlements		Entitlement Authority or Mandatory Spending or Mandatory Appropriations
REFERRED TO AS...	Discretionary Spending		Appropriated Entitlements		Entitlement Authority or Mandatory Spending or Mandatory Appropriations
HHS EXAMPLES...	National Institutes of Health research grants [\$30.2 billion]	Social Services Block Grant [\$1.8 billion] Promoting Safe & Stable Families [\$506 million]	Medicaid [\$369.1 billion] Child Support Enforcement [\$4.2 billion]	Children’s Health Insurance Program [\$15.1 billion]	Medicare [\$585.8 billion]

DISCRETIONARY APPROPRIATIONS – LABOR-HHS, INTERIOR, AND AGRICULTURE BILLS

HHS’s discretionary appropriations come from three annual appropriations bills: the Labor-HHS, Interior, and Agriculture bills, each of which originates from its own appropriations subcommittee. Most of HHS’s appropriations come from Labor-HHS. The Interior bill provides funding for the Indian Health Service, the Agency for Toxic Substances and Disease Registry, and parts of the National Institute for Environmental Health Sciences within NIH. The Agriculture bill funds the Food and Drug Administration. While only eight percent of the HHS budget is discretionary funding appropriated in these bills, they are a critical source of funding for all HHS OpDivs and StaffDivs. HHS also carries out a substantial portion of the President’s Emergency Plan for AIDS Relief, funded through the Department of State. The appropriations bills that fund HHS recently have been incorporated into final omnibus legislation rather than passed individually. For example, Labor-HHS has not been passed on its own since FY 2006.



MANDATORY FUNDS

Mandatory funds comprise 92 percent of HHS's budget. A few large mandatory programs receive appropriations in the bills outlined above (such as Medicaid, Child Support Enforcement, and Foster Care). Medicare, CHIP, and all new mandatory programs receive appropriations in authorizing legislation. Funds to subsidize health insurance purchased in the marketplaces are appropriated in authorizing legislation to the Department of the Treasury, and made available to HHS.

INVESTMENT FUNDING

HHS has two major cross-cutting funding sources that can be used to finance investments to improve facilities and systems in the Department: the Non-Recurring Expenses Fund and the Service and Supply Fund.

NON-RECURRING EXPENSE FUND

The Non-Recurring Expense Fund (NEF) was authorized in 2008 and grants HHS the authority to transfer unobligated balances from expired discretionary accounts to the NEF, which may be used for capital acquisitions necessary for the operations of the Department, such as facilities and information technology infrastructure. For FY 2017, HHS is still refining the estimates for the full year but will have funds to allocate for new acquisitions, and will be implementing \$500 million for projects initiated in prior years. This account supplements amounts appropriated to HHS for facilities and other activities.

SERVICE AND SUPPLY FUND

The Service and Supply Fund (SSF) is a self-supporting \$1.1 billion revolving fund used to finance activities needed by multiple OpDivs. The SSF is funded entirely through charges to its customers for their use of goods and services, such as financial management, information and systems management, and Federal occupational health services. The SSF maintains funding reserves that can be used to improve the services it provides. The SSF is governed by a Board of Directors, on which the customers have the majority of votes. It is chaired by the HHS Deputy Secretary, with the ASFR serving as Vice Chair.

OTHER FLEXIBLE FUNDING

Two other funding sources provide some flexibility, but almost all decisions have been made by Congress in recent years.

PUBLIC HEALTH SERVICE EVALUATION FUND

The Public Health Service (PHS) Evaluation Fund provides some flexibility in budget formulation, but only a modest portion can be spent at the discretion of the Secretary or OpDiv heads. Under Section 241 of the Public Health Service Act, the Secretary has discretionary authority to set-aside up to one percent of any funds appropriated for programs authorized in the Act, and to use the funds for the evaluation of the implementation and effectiveness of these programs. Congress instead modifies the set-aside to 2.5 percent, and specifies in either law or other communication how the funds are to be used in the annual Labor-HHS bill.

PREVENTION AND PUBLIC HEALTH FUND

The Affordable Care Act established the Prevention and Public Health Fund to provide expanded and sustained national investments in prevention and public health, to improve health outcomes, and to enhance healthcare quality. In the early years of the Prevention and Public Health Fund, HHS had flexibility in deciding its uses. Now, Congress decides the allocation of all new funds in the Labor-HHS bill.



BUDGET EXECUTION TOOLS AND PROCESSES

Once the President enacts an appropriation, HHS initiates budget execution activities. Budget execution refers to the various processes through which the Department is able to spend money. These steps typically move in sequential order and include controls at each level to ensure funds are spent consistently with the appropriated purpose, amount, and time limits. There are some limited flexibilities provided within annual appropriations acts which allow HHS to allocate resources differently than they were enacted or specified in the accompanying act's report language (see Section VIII – Congressional Relations – for more information).

Budgets are executed within a fiscal year, which begins on October 1 and ends on September 30 of the following calendar year. Below are some of the key elements in the timeline for spending and controlling funds to ensure funds are used consistent with the appropriation. Failure to follow some elements of funds control may constitute a violation of the Anti-Deficiency Act, which requires formal notice to the President and Congress, and can, in some instances, involve criminal penalties.

BUDGET EXECUTION

STEP 1 – BUDGET AUTHORITY: The first major event in the process is the establishment of resources. Most typically, this step occurs through enactment of an appropriation. HHS also receives a significant amount of spending authority from offsetting collections (often referred to as reimbursable authority). This authority includes user fees, agreements with other agencies, and Medicare premiums. Some Departments also receive substantial borrowing authority and contract authority.

STEP 2 – APPORTIONMENTS: It is illegal to spend money before it is apportioned by OMB (unless OMB has provided an express exemption from apportionment). Apportionments are done by account, each fiscal year. The apportionment identifies the financial boundaries for funds control (such as program levels or quarterly allocations), and establishes any other requirements OMB may have for the obligation of funds. HHS must often provide detailed financial plans to OMB, and negotiate changes to them, in the apportionment process.

STEP 3 - ACCOUNTING CONTROLS (ALLOTMENTS AND ALLOWANCES): Once funds have been apportioned for the fiscal year by OMB, the funds availability is recorded in the OpDiv accounting system. Funds are often further segmented within the apportioned amounts to align with the appropriated purpose(s) or programs identified in report language. Once this step is completed, funds are available to obligate (spend).

STEP 4 – OBLIGATIONS: An obligation is an action that legally binds the Federal government to a future outlay from the Treasury. An obligation could be an agreement to pay for a good or service, such as a contract award or when hiring personnel. Grants and cooperative agreements also constitute obligations, at the time the award is made.

STEP 5 – OUTLAYS: An outlay refers to the process in which obligations are liquidated or disbursed (paid out). Upon fulfillment of the terms of the obligation (such as a contract for goods or services), HHS will direct Treasury to liquidate the obligation through the outlay of funds.

STEP 6 – CANCELATION: Once obligated, there is typically a five-year period in which the funds may be outlaid. Amounts which have not outlaid during that period are canceled. During the five-year period before funds have canceled, but after the available period of obligation has passed (which is most commonly one year), unobligated funds are known as expired.



BUDGETARY FLEXIBILITIES

Once funds are appropriated, there are two primary mechanisms, transfers and reprogrammings, which the Department may use to execute funding in a manner different than the way Congress anticipated when appropriating the funds. These flexibilities apply to discretionary funds provided in the annual appropriations act. They do not allow the Department to undertake new activities for which HHS otherwise does not have authority. Additionally, the transfer and reprogramming limitations prevent the Department from making significant adjustments to enacted funds.

In annual appropriation acts, Congress provides direction in three ways. Congress often provides a lump sum appropriation to cover a broad array of programs in an OpDiv, and then provides detailed allocations in non-statutory report language. For other activities, Congress will specify in law the amount available for that program. Congress also enacts statutory limitations that preclude spending on certain purposes or activities.

REPROGRAMMINGS

A reprogramming is a shift of funds between two or more programs identified in the report language. Funds can be reprogrammed if all of the programs involved are part of a single lump sum amount that is in law. Reprogramming notifications to Congress are necessary when an agency wants to deviate from a funding level identified in a Conference Report, which typically subdivides the amounts specified in law. After the notice is provided to Congress, HHS must wait either 15 or 30 days before shifting funds, depending on the appropriation subcommittee.

TRANSFERS

HHS receives limited authority to shift funding between accounts or between programs whose funding levels are specified in law. HHS's recurring transfer authorities are:

SECRETARY'S ONE PERCENT TRANSFER AUTHORITY

This authority is provided annually in the Labor-HHS appropriations bill, and enables the Secretary to shift funds between discretionary appropriations provided in the final bill. The authority is limited to discretionary accounts of that subcommittee. No appropriation may be increased by over three percent, and no appropriation may be decreased by more than one percent. Congress must be notified 15 days in advance of using the transfer authority. Most recently, this authority was used to increase funding for Zika-related response activities.

OTHER TRANSFER AUTHORITIES

The Director of NIH has two transfer authorities which pertain only to funds appropriated to NIH. One authority is specific to AIDS research, and the other pertains to National Research Service Awards. FDA has transfer authority between statutory earmarks within their Salaries and Expenses account.

SEQUESTRATION

A sequester is the automatic across-the-board cancellation of a portion of previously enacted spending to get spending down to statutorily specified target levels. All spending can be sequestered unless explicitly exempt in law. Currently, the Federal government operates under three possible sequesters.

The Statutory Pay-As-You-Go Act of 2010 (PAYGO) reestablished sequestration of mandatory programs to prevent future legislation from increasing the deficit. The Budget Control Act (BCA) of 2011 reestablished discretionary cap sequesters to assure that appropriations bills do not exceed the target discretionary spending levels, and created a new sequester that would apply if Congress did not meet overall deficit reduction targets.



Prior to the BCA, the historical concept behind sequester statutes had been to ensure that future Congresses do not enact spending in excess of the specified levels. When used that way, sequester statutes have been very successful – Congress has consistently avoided taking actions that would trigger sequestration.

The BCA, on the other hand, sought to use the threat of a sequester to spur Congress to enact reductions in mandatory spending and/or increases in revenues. It established the Joint Select Committee on Deficit Reduction, and required Congress to pass a deficit reduction bill with at least \$1.2 trillion in savings by January 2, 2013, to avoid the sequester. Congress and the President could not agree on how to save that much, and sequesters were implemented in FY 2013. For discretionary programs, the discretionary caps were reduced for subsequent years in lieu of continued sequesters (since the funding levels for those programs are decided annually by the Congress). For mandatory programs, sequesters were to be executed October 1 of each fiscal year through FY 2021.

Two laws have subsequently been enacted to provide some relief from the reduced discretionary caps through FY 2017 (and as a result, the caps are lower in FY 2018 than in FY 2017). Congress has taken the opposite approach for mandatory programs, and has found extending the mandatory sequester to be a viable savings provision to enact.

DISCRETIONARY CAP SEQUESTERS

Permanent law sets separate limits on defense and non-defense discretionary spending through FY 2021. If countable appropriations enacted as of the end of a session of Congress (or in a subsequent supplemental) exceed those targets, the President must order a reduction in funding to eliminate the excess. The Committees on Appropriations work closely with the Congressional Budget Office and OMB to assure that the total amounts they appropriate for each fiscal year are within those limits. As a result, the likelihood of a discretionary cap sequester is low. Emergency response appropriations, such as HHS's recent Zika supplemental, can be enacted in a way that they do not count toward the discretionary caps.

PAYGO SEQUESTERS

For PAYGO, OMB maintains a multi-year scorecard that tracks the net budget impacts of newly enacted legislation. The scoring rules are such that a provision that has future savings can offset spending in the budget year. If, in January of any fiscal year, the scorecard is in deficit for that fiscal year, the President must order a sequester reducing spending by the amount of the scorecard's deficit. Most retirement and low-income mandatory programs are statutorily exempt from sequestration. As a result, Medicare comprises about 88 percent of the mandatory base subject to sequester. PAYGO sequesters of Medicare benefit payments are capped at a four percent reduction. Congress has assured that legislation either stayed within the PAYGO limits, or was statutorily excluded from the PAYGO scorecard – so no PAYGO sequester has been required.

BUDGET CONTROL ACT MANDATORY SEQUESTER

Each year, when the President's Budget is released, the President also issues a sequester order for mandatory appropriations that includes OMB's calculation of what accounts should be sequestered and a calculation of the percentage reductions. Different percentages are calculated for defense (9.1 percent in FY 2017), non-defense mandatory (6.9 percent in FY 2017), and Medicare benefits (capped at two percent). Once the percentages are determined, OMB applies the percentages to all government accounts that are eligible for sequester. In FY 2017, Medicare accounts for 70 percent of the non-defense mandatory sequester savings.



SECTION IV: OVERSIGHT



SECTION IV: OVERSIGHT

The Assistant Secretary for Legislation (ASL), working with the Office of General Counsel (OGC), the Assistant Secretary for Financial Resources (ASFR), and Assistant Secretary for Public Affairs (ASPA), leads the Department's intake and response to congressional oversight and oversight from the Government Accountability Office (GAO). The HHS Office of Inspector General (OIG) works directly with the OpDivs and StaffDivs. ASFR, in collaboration with the OpDivs and StaffDivs, tracks OIG engagements and provides regular reports to senior HHS management.

CONGRESSIONAL OVERSIGHT

In the 114th Congress, HHS received over 300 oversight letters and eight subpoenas from congressional oversight committees including the House of Representatives' Committee on Energy and Commerce, Committee on Ways and Means, and Committee on Oversight and Government Reform, and the Senate's Committee on Health, Education, Labor, and Pensions; Committee on Finance; and Committee on Homeland Security and Governmental Affairs (including its Permanent Subcommittee on Investigations). Notable areas of oversight in the 114th Congress include the following:

- The Affordable Care Act's (ACA) cost-sharing reduction, basic health, reinsurance, risk-corridors, and Consumer Operated and Oriented Plans (CO-OPs) programs;
- HHS's response to the Zika outbreak;
- HHS's Unaccompanied Children Program;
- Biosafety and biosecurity at high-containment laboratories;
- Fetal tissue research;
- HHS's response to the opioids epidemic;
- Drug pricing; and
- Issues at NIH's Clinical Center and Pharmaceutical Development Section.

GOVERNMENT ACCOUNTABILITY OFFICE

ASL serves as HHS's liaison to GAO, which has authority to audit and investigate Executive Branch agencies at the request of congressional committees, Members of Congress, or by mandate of public law or committee reports. GAO also undertakes studies under the authority of the Comptroller General.

GAO'S HIGH-RISK REPORT

At the start of each new Congress, GAO calls attention to agencies and program areas that are high-risk due to vulnerabilities to fraud, waste, abuse, and mismanagement, or are most in need of transformation. The 2015 GAO High-Risk Report identified [32 high risk areas](#). The following areas have a direct impact on HHS:

- Improving Federal Oversight of Food Safety;
- Protecting Public Health through Enhanced Oversight of Medical Products;
- The Medicare Program; and
- The Medicaid Program.

GAO'S FRAGMENTATION, OVERLAP, OR DUPLICATION REPORT

GAO is statutorily mandated to identify and report annually to the Congress on Federal programs, agencies, offices, and initiatives where they identify fragmentation, overlap, and duplication between Federal programs.



This report is intended to help Congress reduce, eliminate, or better manage fragmentation, overlap or duplication; achieve cost savings; or enhance revenue. In its 2016 Fragmentation, Overlap, or Duplication Report, GAO identified [37 areas](#). The following areas affect HHS:

- [Bridge Contracts](#) (include extensions to existing contracts and short-term noncompetitive contracts to avoid a gap in service – if utilized the government is at risk of paying more than it should for goods and services);
- Federal Supply Schedules;
- Distribution of Medicaid Supplemental Payments;
- Eligibility of Medicare Providers and Suppliers;
- Medicaid Demonstration Approved Spending;
- Medicaid Eligibility Determinations;
- Medicaid Payments to Institutional Providers;
- Medicare Payments by Place of Service;
- Medicaid and Exchange Coordination; and
- Federal Mobile Telecommunications.

NOTABLE GAO AUDITS

Since FY 2015, HHS has received nearly 270 new audits and over 200 recommendations from GAO. Below are a few high-profile reports that were released during this time period.

- Mental Health: HHS Leadership Needed to Coordinate Federal Efforts Related to Serious Mental Illness ([GAO-15-113](#));
- HEALTHCARE.GOV: CMS Has Taken Steps to Address Problems, but Needs to Further Implement Systems Development Best Practices ([GAO-15-238](#));
- Unaccompanied Children: HHS Can Take Further Actions to Monitor Their Care ([GAO-16-180](#));
- Patient Protection and Affordable Care Act: CMS Should Act to Strengthen Enrollment Controls and Management Fraud Risk ([GAO-16-29](#));
- High-Containment Laboratories: Improved Oversight of Dangerous Pathogens Needed to Mitigate Risk ([GAO-16-642](#)); and
- Patient Protection and Affordable Care Act: Final Results of Undercover Testing of the Federal Marketplace and Selected State Marketplaces for Coverage Year 2015 ([GAO-16-792](#)).

OFFICE OF INSPECTOR GENERAL

HHS's [OIG](#) is the largest inspector general's office in the Federal government, with approximately 1,600 employees dedicated to combating fraud, waste, and abuse and to improving the efficiency of HHS programs. The majority of OIG's resources go toward the oversight of Medicare and Medicaid, but OIG's oversight extends to all programs within HHS. HHS's OIG includes the following sections.

OIG OFFICES

THE OFFICE OF AUDIT SERVICES

The Office of Audit Services conducts independent audits of HHS programs and/or HHS grantees and contractors. These audits examine the performance of HHS programs and/or grantees in carrying out their responsibilities and provide independent assessments of HHS programs and operations.



THE OFFICE OF EVALUATION AND INSPECTIONS

The Office of Evaluation and Inspections conducts national evaluations of HHS programs from a broad, issue-based perspective. These evaluations offer practical recommendations to improve the efficiency and effectiveness of HHS programs with a focus on preventing fraud, waste, and abuse.

THE OFFICE OF INVESTIGATIONS

The Office of Investigations conducts criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs, operations, and beneficiaries.

RECURRING REPORTS

OIG WORK PLAN

Each year, OIG produces a Work Plan that sets forth the issues that will be addressed by OIG during that fiscal year. OIG updates the Work Plan mid-year. Both documents are published on the [OIG website](#).

OIG TOP MANAGEMENT CHALLENGES

Every year, as part of OIG's Annual Financial Report, OIG reports on its top management and performance challenges. This report identifies OIG's top challenges and assesses HHS's progress in addressing those challenges. The [FY 2015 report](#) includes the following challenges sections:

- Protecting an Expanding Medicaid Program from Fraud, Waste, and Abuse
- Fighting Fraud, Waste, and Abuse in Medicare Parts A and B;
- The Meaningful and Secure Exchange and Use of Electronic Information and Health Information Technology;
- Administration of Grants, Contracts, and Financial and Administrative Management Systems;
- Ensuring Appropriate Use of Prescription Drugs;
- Ensuring Quality in Nursing Home, Hospice, and Home- and Community-Based Care;
- Implementing, Operating, and Overseeing the Health Insurance Marketplaces;
- Reforming Delivery and Payment in Healthcare Programs;
- Effectively Operating Public Health and Human Services Programs; and
- Ensuring the Safety of Food, Drugs, and Medical Devices.

OIG COMPENDIUM OF UNIMPLEMENTED RECOMMENDATIONS

Each year, OIG submits to the Congress a report that includes a list of unimplemented recommendations for which implementation is a priority for OIG. This report is required by Congress and is coordinated within HHS by ASFR. The [2016 Compendium](#) contained recommendations related to:

- Medicare Parts A and B (8 recommendations);
- Medicare Parts C and D (3 recommendations);
- Human Service Programs (2 recommendations);
- Food and Drug Safety (1 recommendation);
- Medicaid (6 recommendations);
- Affordable Care Act: Marketplaces (3 recommendations);
- Improper Payments Information (1 recommendation); and
- Health Information Technology (1 recommendation).

**NOTABLE REPORTS**

In FY 2015, OIG published 201 audit reports and 52 evaluation and inspection reports. In FY 2016, OIG published 155 audit reports and 36 evaluation and inspection reports. Below are a few high profile reports released in this time period.

- “Quarterly Progress Report on U.S. Government International Ebola Response and Preparedness Activities” ([A-04-15-03560](#)), produced in coordination with the USAID OIG;
- “Review of the Accounting Structure Used for the Administration of Premium Tax Credits” ([OEI-06-14-00590](#)), produced in coordination with the Treasury OIG for Tax Administration;
- “Not All of the Federally Facilitated Marketplace’s Internal Controls were Effective in Ensuring that Individuals were Properly Determined Eligible for Qualified Health Plans and Insurance Affordability Programs” ([A-09-14-01011](#));
- “HealthCare.gov: Case Study of CMS Management of the Federal Marketplace” ([OEI-06-14-00350](#));
- “Indian Health Service Hospitals: Longstanding Challenges Warrant Focused Attention to Support Quality Care” ([OEI-06-14-00011](#)); and
- “Indian Health Service Hospitals: More Monitoring Needed to Ensure Quality Care” ([OEI-06-14-00010](#)).



SECTION V: GOVERNANCE AND COORDINATION



SECTION V: GOVERNANCE AND COORDINATION

In order to manage across an organization as large as HHS, the Office of the Secretary employs a number of governance and collaborative bodies and processes. This infrastructure works to surface issues to leadership and to implement or oversee actions directed by leadership.

This section includes information on:

- Governance through the HHS Management Council and various lines of business councils;
- Processes to surface emerging issues and recommendations for decisions;
- Strategic management activities;
- Clearance processes to ensure HHS-wide interests are considered in leadership decisions;
- Federal Advisory Committee Act bodies; and
- Delegations of authority.

GOVERNANCE BODIES

HHS MANAGEMENT COUNCIL

The HHS Management Council, established in April 2013, facilitates the dissemination of information and provides a forum for discussion and decision-making at the principal level on key administrative, management, and operational issues. This Council is chaired by the Deputy Secretary and includes senior leaders from each OpDiv as well as the Assistant Secretaries for Administration (ASA), Financial Resources (ASFR), and Preparedness and Response (ASPR).

LINES OF BUSINESS GOVERNANCE

The administrative lines of business (e.g., financial management, information technology, and human resources) have established governance processes to provide cross-HHS collaboration on high priority issues. For example, the Financial Management Governance Board was established to ensure the successful implementation of HHS-wide financial management initiatives. The Board is chaired by the ASFR and is made up of OpDiv Chief Financial Officers and leaders of financial management enterprise business areas.

HHS also has evolved our program integrity governance process into the Enterprise Risk Management Council, which is chaired by the ASFR and reports to the Management Council. The Enterprise Risk Management Council develops and manages HHS's risk profile and risk portfolio.

ADDITIONAL PROCESSES AND ENTERPRISE WIDE COLLABORATION

The Office of the Secretary also utilizes a number of formal and informal working groups and processes to ensure cross-department and cross-Executive Branch collaboration. As outlined in [Section III – Budget Overview](#) – ASFR manages the Department-wide process to develop the HHS portion of the President's annual budget, which includes managing the Secretary's Budget Council. In addition, the Assistant Secretary for Planning and Evaluation (ASPE), ASFR, the Assistant Secretary for Legislation (ASL), and the Office of the General Counsel (OGC) may collaborate to develop legislative proposals through an annual legislative development process pursuant to [OMB Circular A-19](#) on legislative proposals.

In general, it is often valuable to include representatives from OGC, ASFR, ASPE, and the Executive Secretary when considering policy options to identify legal, budgetary, and policy paths to achieve desired outcomes.



These entities frequently coordinate across HHS and are able to leverage existing processes or tailor new processes to ensure appropriate collaboration.

CLEARANCE PROCESSES

To ensure that all relevant parts of the Department have the ability to review and clear relevant Administration, HHS, and OpDiv policy decisions, regulations, congressional testimony and correspondence, press releases, and other similar materials, HHS has a series of clearance processes managed by the Office of the Executive Secretary, OGC, the Assistant Secretary for Public Affairs (ASPA), ASFR, and ASA. These include the following.

CORRESPONDENCE CLEARANCE

The Secretary receives thousands of letters and emails each year, including letters from constituents, Members of Congress, governors, associations, key stakeholders, and other interest groups. By responding to the letters, the Secretary is provided important opportunities to publicly state Administration policies and/or recommendations.

For incoming letters addressed to the Secretary, the Office of the Executive Secretary assigns the task of drafting a response letter to the Opdiv or StaffDiv with primary jurisdiction over the particular issues raised in the letter. Once a response letter is drafted, the Executive Secretary clears it and ultimately presents the letter to the Secretary for approval and signature. A subgroup of the response letters may be assigned to OpDivs or StaffDivs for direct response on behalf of the Secretary. In these instances, the OpDiv or StaffDiv manages their own clearance and signature process.

POLICY CLEARANCE

The Executive Secretary's Policy Coordination team manages the Department's development and review of regulations, correspondence, reports to Congress, and other policy documents, facilitating discussions to reconcile policy disagreements. Documents requiring the Secretary's approval or signature, as well as other significant policy documents of interest to HHS, are reviewed by the Department through the Executive Secretary's clearance process. The Executive Secretary's process brings policy issues and options to the Secretary's attention in an organized fashion. Through their process, the Executive Secretary works to ensure that the views of the Secretary's advisors are heard, therefore ensuring that key decision-making benefits from multiple viewpoints.

When an issue requires a decision by the Secretary, the Executive Secretary provides the Secretary with thoroughly developed options and supporting materials on the issue at hand. The Executive Secretary also manages the Department's regulatory review process described in further detail in [Section VI – Regulations and Litigation](#). ASA and ASFR work with the Executive Secretary to clear reorganizations that require the Secretary's approval. Reorganizations requiring the Secretary's approval are of such significance or public interest that they require notification of the congressional Committees on Appropriations.

CLEARANCE OF PUBLIC COMMUNICATIONS AND PRESS

To help successfully communicate the Administration's and Secretary's goals and priorities, ASPA provides advice, strategic counsel, and communications support to the Secretary and other HHS leaders to ensure that the public affairs impact is considered in the development and execution of departmental policies. ASPA is the principal contact with the White House regarding communications and press issues.

ASPA manages and responds to daily inquiries from the national and local media and develops and executes proactive communications strategies designed to advance and support the Secretary's priorities and departmental initiatives. These proactive communications activities, including blog posts and social media,



are developed in conjunction with the Secretary and other senior departmental leaders and serve as an important component of advancing key policy initiatives.

ASPA also works closely with OpDivs to ensure that press and communications activities across HHS are well-coordinated and provide the media and public with a consistent policy message. All media materials and interview requests are reviewed and cleared by ASPA before they are issued and/or conducted by individual OpDivs.

CLEARANCE OF OTHER EXECUTIVE BRANCH MATERIALS

OGC, through OMB's Legislative Referral Memorandum process, handles the review of non-HHS, Executive Branch matters that require HHS clearance. These instances include review and clearance of regulations, reports to Congress, testimonies, and statements of administration policy.

HHS STRATEGIC MANAGEMENT PROCESSES

The Department's strategic planning, performance measurement, Enterprise Risk Management, and evaluation functions are the foundations of HHS's approach to strategic management. Under the leadership of the Deputy Secretary/Chief Operating Officer, the strategic management approach provides tools and information to help HHS leadership answer four key questions:

- What are we trying to achieve?
- How do we know we are on track?
- What are the challenges and opportunities we must address to achieve success?
- How can we do things better?

By setting a strategic plan, measuring progress, making trade-offs required to pursue priorities while managing challenges and opportunities, and evaluating our progress and impact, Department leadership makes data-driven and evidence-based decisions to support and achieve the HHS mission.

STRATEGIC PLANNING

What are we trying to achieve? The Government Performance and Results Act (GPRA) of 1993, the [GPRA Modernization Act of 2010](#), and related [OMB Circular A-11 guidance](#) require all Federal agencies to develop a quadrennial strategic plan to be published one year following the start of a new administration. According to Circular A-11, the purpose of a strategic plan is to provide direction for programmatic and management functions, guide implementation and management, and engage external entities. ASPE leads the development of the HHS Strategic Plan, coordinating closely with the ASFR because of ASFR's role in budgeting, performance management, and risk management across HHS. A working group made up of liaisons from OpDivs and StaffDivs contributes to the development of the HHS Strategic Plan and ensures that HHS leadership's values and priorities are represented in the plan.

PERFORMANCE MANAGEMENT

How do we know we are on track? The ASFR Performance Improvement Officer supports the Secretary and the Deputy Secretary in leading performance management efforts to set goals, make results transparent, review progress, and make course corrections across HHS. ASFR, in collaboration with ASPE, conducts an annual, OMB-required strategic review process to assess progress on the Department's strategic objectives. In addition, ASFR leads the Agency Priority Goal process, which brings together leaders from across the Department to coordinate and enhance efforts toward a shared goal. This process has led to a number of successes in a short



timeframe and has provided visibility and support to Department priorities. ASFR also leads efforts to provide public reporting on Department performance measures and activities.

ENTERPRISE RISK MANAGEMENT

What are the challenges and opportunities we must address to achieve success? The Deputy Secretary oversees and chairs the HHS Management Council, which consists of senior leaders from the Office of the Secretary and OpDiv and StaffDiv senior officials. The HHS Management Council reviews and approves the Department Risk Profile at least once per year. The Council also provides leadership oversight to address the Department's most significant risks, including those that potentially affect achievement of the Department's mission.

The HHS Enterprise Risk Management Council, chaired by the ASFR, regularly advises the HHS Management Council on risk management, develops and manages the HHS Risk Profile, and shares risk-related information across HHS. Council representation includes senior executives from OpDivs and StaffDivs who lead their agency risk management efforts. This function is located in the ASFR Office of Finance. [OMB Circular A-123](#) requires that the Department's Risk Profile inform the development of the Department's Strategic Plan, Department contributions to future presidential budgets (starting with the President's FY 2019 Budget, and that Enterprise Risk Management be coordinated with each Department's Strategic Reviews and Internal Control.

EVALUATION

How can we do things better? HHS has a range of different types of evaluation offices that provide a variety of support and capacity to their respective agencies. These offices conduct evaluations, research, and analysis for decision-making purposes, and often work in collaboration with their performance and budget colleagues. Across the Department there are many models for ensuring we evaluate our programs and our performance to determine if we can do better. Some operating divisions focus more on ensuring performance metrics are incorporated into evaluation and analysis, whereas some agencies focus their efforts on conducting rigorous longer-term evaluations and studies of programs over time, and several offices may have examples of all of these activities. Currently, ASPE is working with operating and staff divisions to build a culture of learning, which is a shift from conducting single evaluation studies to one of engaging in continuous learning and improvement.

COLLABORATION

Many of the activities undertaken by ASFR and ASPE implement requirements of GPRA, the [Federal Managers' Financial Integrity Act of 1982](#), OMB Circular-A-123 *Management's Responsibility for Enterprise Risk Management and Internal Control*, and the Government Accountability Office's (GAO) [Standards for Internal Control in the Federal Government](#) ("The GAO Green Book"). GPRA laws charge the Deputy Secretary with advising and assisting the Secretary in these efforts. ASFR's Performance Improvement Officer and ASPE's strategic planning and evaluation team support these efforts. ASFR, ASPE, and the Office of the Secretary coordinate closely to ensure that the planning and execution of all strategic management-related activities across HHS are aligned to leadership needs and OMB requirements. Each OpDiv has staff designated to lead these activities and support related activities coordinated through the Office of the Secretary.

COMMISSIONS AND THE FEDERAL ADVISORY COMMITTEE ACT

Advisory committees play an important role in shaping programs and policies of the Federal government, and can be a tool the Secretary uses to seek policy advice, advance a policy agenda, or provide a public forum for discussion on a particular topic. Through enactment of the [Federal Advisory Committee Act of 1972](#), Congress formally recognized the merits of seeking the advice and assistance of the Nation's citizens. At the same time, the Congress also sought to assure that advisory committees:



- Provide advice that is relevant, objective, and open to the public;
- Act promptly to complete their work; and
- Comply with reasonable cost controls and recordkeeping requirements.

APPOINTING COMMITTEE MEMBERS

Agency officials, Members of Congress, the general public, professional societies, and current or former committee members may nominate potential candidates for membership on advisory committees. Selection of committee members is made based on requirements set forth in the Federal Advisory Committee Act and the potential member's background and qualifications. Final selection is made by the President or Department heads, depending on the committee.

HHS COMMITTEES

Currently, there are 252 active Federal advisory committees and 17 inactive committees. Under current law, the President makes appointments to eight of the active advisory committees and three inactive committees; the Secretary may appoint members to 79 of the active committees and 11 inactive committees. The balance of the advisory committee members are appointed by agency heads by Delegation of Authority.

For further information see the [Federal Advisory Committee Management Handbook](#) and [GSA.gov](#).

DELEGATIONS OF AUTHORITIES

A delegation of authority is the formal assignment or commitment of legal power from the Secretary or another senior official to a subordinate so that the subordinate can make decisions and take actions that have legal effect on behalf of the delegating office. Delegations of authority are important to the operation of the Department because without them, only the Secretary would be legally empowered to act. The Department's delegation policy prescribes how the Secretary may delegate his/her authorities, typically to an OpDiv or StaffDiv head, so that those officials may legally carry out the many programs and activities necessary to run the Department. The policy also prescribes how subordinate officials can in turn delegate their authorities to other officials. If a subordinate official were to implement a program or exercise authority without properly delegated authority, that action could be overturned by a court. Therefore, HHS policy states that each official of the Department should have written evidence of his/her legal authority before taking any action to expend or use government funds or resources. In some instances, statute assigns authority and responsibility for a program directly to a particular HHS official rather than assigning them to the Secretary. In these cases, additional delegation of authority from the Secretary is not required.

LEGAL BASIS FOR DELEGATING AUTHORITY

It is a basic principle of administrative law that if a statute or a delegation has conferred an authority on an agency official, that official may re-delegate the authority unless the law or initial delegation itself restricts the authority to re-delegate. Additional specific authority of the Secretary to delegate comes from several provisions of law. Section 6 of the Reorganization Plan No. 1 of 1953 and Section 2 of the Reorganization Plan No. 3 of 1966 authorize the Secretary to delegate any of his/her functions to any other officer, agency, or employee of the Department. Section Five U.S.C. § 301 authorizes agency heads to prescribe regulations for allocation of their agencies' business. Section Five U.S.C. § 302 authorizes agency heads to delegate personnel administration matters to subordinate officials. Any HHS officer or employee who delegates or re-delegates authority may continue to exercise the authority, because the act of delegating does not divest the authority from the delegating official.

**HHS POLICY ON DELEGATION**

It has been Department policy to delegate decision-making authority to the organization level that will provide the most timely, economical, and effective management of the program or activity. All OpDiv and StaffDiv heads are required to identify those legal authorities that they need to administer their programs and that are vested in the Secretary, and each HHS OpDiv and StaffDiv head is responsible for requesting that the Secretary grant him/her those authorities. This request takes the form of a delegation memorandum from the OpDiv or StaffDiv head to the Secretary.

In general, delegations and re-delegations should follow organizational lines and must be submitted and approved in writing. For example, once the Secretary delegates authority to an OpDiv or StaffDiv head, that OpDiv or StaffDiv head may re-delegate the authority to officials at a lower level within their chain of command, unless current law or the Secretary specifically restricts the authority to re-delegate. It is the responsibility of each OpDiv or StaffDiv head to make sure subordinate officials understand the substance and limits of their authorities. ASA coordinates each delegation request with OGC and maintains documentation of delegations of authority active within the Department.. Further information about delegations can be found in the HHS General Administration Manual, chapter 8-100.



SECTION VI: REGULATIONS AND LITIGATION



SECTION VI: REGULATIONS AND LITIGATION

This section provides an overview of regulation- and rule-making processes as well as an overview of litigation involving the Department. The regulations section details how HHS promulgates regulations that affect nearly every American. The authority to issue regulations is reserved for the Secretary (with the exception of certain FDA regulations), signifying the important policy-making and leadership role of this position. The litigation section below highlights the most high-profile of the approximately 7,400 cases currently pending that name HHS as a party.

OVERVIEW OF THE POLICY/REGULATION REVIEW PROCESS

A regulation is a rule or directive made and maintained by an authority, such as HHS, that is used to implement legislation. Through legislation, the Congress may direct Executive Branch agencies to issue regulations on a specific issue or give agencies authority to do so at the agency's discretion. Under the procedures of the Federal Administrative Procedure Act, agencies first draft regulatory proposals, which are reviewed by the Department through a process managed by the Office of the Executive Secretary. Once the Secretary approves a proposal, it is sent to OMB; OMB has 90 days to review proposed regulations. Proposed rules are next open to public comment. The proposed regulation is finalized after a second round of agency and OMB review. This process is often referred to as the promulgation of regulations.

Within HHS, agencies work with the Office of the Executive Secretary and the Secretary's senior advisors to determine the best way to accomplish particular policy goals through regulatory and sub-regulatory processes. Sub-regulatory guidance is non-binding, instructive material for regulated industry that describes agency positions or current thinking. Sub-regulatory guidance does not carry the force of law.

THE ROLE OF THE OFFICE OF THE EXECUTIVE SECRETARY

Decision-making at the Secretarial level requires a process under which the views of all of the Secretary's advisors are considered. The process also allows the Secretary ample opportunity for input and is designed to ensure the Secretary has all necessary information before making final decisions. The Executive Secretary manages the internal decision-making procedures central to the process, including impartially enforcing its rules, so that participants at decision meetings can bring important and often divergent viewpoints to the table.

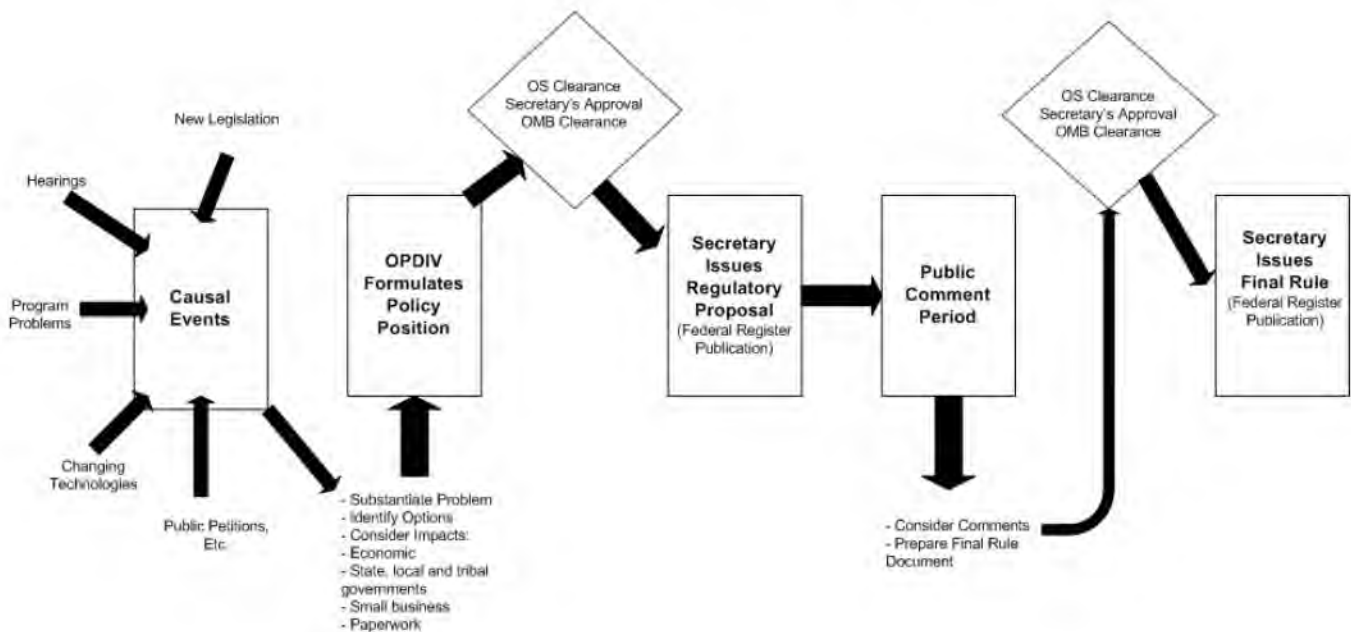
The Executive Secretary assigns the development of written materials for policy briefings to the OpDiv or StaffDiv most familiar with the issues at stake and clears this written material prior to briefings. Under current guidelines, briefing memoranda for the Secretary and/or senior Department officials are intended to delineate the issue(s) to be addressed, the major options open to the Secretary, and the pros and cons associated with each option. To be useful, these materials must be made available on a timely basis, with all players having a chance to read/digest and offer suggestions for revisions. Using the Secretary's Policy System document management system, the Executive Secretary assures that all the necessary advisors are rapidly informed and provided with necessary documents. The Executive Secretary may postpone meetings when documents are not available in a timely fashion. Policy Coordinators (career, professional staff) with the Office of the Executive Secretary attend policy meetings to record decisions, make assignments, and perform necessary follow-up actions. The Executive Secretary ensures that the Administration's message is carried throughout documents flowing from the Secretary.



PROMULGATION AND COMMUNICATION OF REGULATORY AND SUB-REGULATORY ACTIONS

All regulatory documents and correspondence that require the Secretary’s signature, as well as other policy documents that are of interest to HHS policy officials, are reviewed and cleared by policy officials within the Office of the Secretary and others (as appropriate) within the Department. Regulations and certain other significant policy documents are also cleared by OMB prior to publication. The Office of the Executive Secretary manages these clearance processes, which bring key policy issues and options to the Secretary’s attention in an organized fashion.

FIGURE 1: THE REGULATIONS PROCESS



ORIGINS OF A RULE

A regulation is a rule or directive made and maintained by an authority that is used to implement a primary piece of legislation or to account for emerging circumstances or factors. The Federal Administrative Procedure Act governs the way in which Federal agencies may propose and establish regulations.

REGULATION DEVELOPMENT

The authority to issue proposed and final regulations is reserved to the Secretary, with an exception for many of the regulations issued by the FDA, which may be promulgated by the FDA Administrator.

The promulgation process generally begins with an OpDiv or StaffDiv draft of a proposed rule for the Secretary’s signature. Before the drafting process begins, the originating OpDiv or StaffDiv may coordinate a “concept briefing” to allow senior officials from across the Department to provide feedback on the policy issues to be addressed in the rule.

DEPARTMENT REVIEW

Once a proposed regulation is drafted and cleared by the authoring OpDiv or StaffDiv, it is sent to the Office of the Executive Secretary for review. The Executive Secretary ensures all relevant policy officials have an



opportunity to review and comment on the document, and resolves any outstanding policy issues, convening meetings with Department staff and/or policy officials as necessary to discuss policy options. Once all issues are resolved, the Secretary signs the document and the regulation advances to the next stage of the regulatory process.

EXECUTIVE OFFICE OF THE PRESIDENT/OMB REVIEW

After the Secretary signs the proposed regulation, it is in most cases formally submitted to OMB for review. Under [Executive Order 12866](#), OMB has 90 days to either approve the document or return it to the Department with comments. Executive Secretary staff work with the authoring OpDiv or StaffDiv to respond to OMB questions and comments. For high-profile rules, a briefing for senior policy officials at the White House may be coordinated by the Executive Secretary.

PUBLIC COMMENT AND REVISION OF PROPOSED REGULATIONS

Once OMB clears a proposed regulation, the regulation is made available for public comment through the Office of the Federal Register. Anyone can submit comments on or view other public comments submitted for a proposed regulation through the Office of Federal Register's online process during the period of "notice and comment" for the regulation. Public comments are returned to HHS at the end of the comment period and the authoring agency revised the regulation based on feedback received from the public. The revised regulation is then cleared again through the Executive Secretary's process and OMB.

ROLL-OUT OF A FINAL RULE

After OMB signs off on a proposed regulation for the second time, the authoring agency's public roll-out strategy is confirmed with Department policy officials and the regulation is released to the Office of the Federal Register for publication. That Office of the Federal Register sends a notice to Department policy officials once the regulation is available for public display and publication dates are confirmed. The effective dates for regulations vary on a case-by-case basis.

MIDNIGHT RULEMAKING

The term "midnight rulemaking" refers to regulatory actions promulgated by an outgoing administration during its final weeks in office. These regulations are handled in the same manner as standard regulatory actions and, in general, an incoming administration has the opportunity to review regulations not yet finalized. Please refer to OGC for more specifics on midnight rulemaking. For more information on midnight rulemaking please see this [Congressional Research Service report](#).

OVERVIEW OF REGULATORY ENFORCEMENT PROCESS

HHS is authorized by statute and regulations to enforce its regulations. Below is a sampling of how HHS exercises regulatory enforcement options across the Department. Generally speaking, grants are subject to Department-wide rules available at [45 C.F.R. §§ 75](#) (exceptions are noted in Part 75).

ADMINISTRATION FOR CHILDREN AND FAMILIES

The Administration for Children and Families (ACF) engages in regulatory enforcement for grants provided to States, local governments, non-profit entities, and/or other grant recipients. Regulatory enforcement can take the form of a State plan non-approval, a termination, a disallowance of funds, a suspension of funds, or placing an awardee on some kind of special status, such as reimbursement status.

**OFFICE OF CIVIL RIGHTS**

The Office of Civil Rights (OCR) enforces non-discrimination regulations that apply to programs, services, and activities receiving Federal financial assistance through HHS. OCR also enforces non-discrimination provisions of other laws as they apply to programs and activities receiving Federal financial assistance through HHS. OCR implements the Privacy, Security, and Breach Notification Rules under the Health Insurance Portability and Accountability Act (commonly referred to as “HIPAA”). As HHS’s enforcement agency for HIPAA, OCR investigates complaints, conducts compliance reviews, develops policy, promulgates regulations, and provides technical assistance and public education to ensure understanding of and compliance with HIPAA’s health information privacy laws. Additionally, OCR has responsibility for interpreting and implementing the confidentiality protections and the enforcement provisions of the Patient Safety Rule, which implements select provisions of Patient Safety and Quality Improvement Act of 2005.

CENTERS FOR MEDICARE AND MEDICAID SERVICES

CMS is authorized to impose enforcement remedies on Medicare-certified providers. Depending on the provider type, enforcement remedies can include suspension of payments for new admissions, denial of payments for new admissions, civil money penalties, and termination from the Medicare program. CMS is primarily responsible for interpreting and enforcing the Federal Physician Self-Referral Law (commonly known as the “Stark Law”) and does so mainly through issuing guidance and advisory opinions. In addition, CMS has established a self-disclosure protocol to allow providers to self-disclose actual or potential violations of the Stark Law. In addition to CMS, the Office of Inspector General (OIG) is authorized to seek civil monetary penalties and exclusion of providers from participation in Federal healthcare programs for Stark Law violations. OIG also investigates suspected violations of the Stark Law and may refer the case to the U.S. Department of Justice for criminal or civil actions if such violations are in conjunction with violations of the Anti-Kickback Statute or the False Claims Act.

Additionally, CMS has enforcement authority with respect to the Open Payments program, a national transparency program that publishes annual data on the financial relationships between the healthcare industry and healthcare providers. CMS and OIG have primary responsibility for enforcing the Open Payments program through the issuance of guidance documents and the enforcement of established civil monetary penalties, but OIG also has delegated authority to pursue civil monetary penalties for suspected Open Payment program reporting violations.

CMS has the authority to issue sanctions to Medicare Part C and Part D plans and sponsors for violating various CMS regulations, including guidance such as the Marketing Guidelines. CMS may issue to Part D sponsors and Medicare Advantage plans warning letters, corrective action plan letters, intermediate sanctions, civil monetary penalty notices, and non-renewal or termination notices.

FOOD AND DRUG ADMINISTRATION

FDA is responsible for regulating the Nation’s food, drugs, biological products (including blood and vaccines), medical devices, electronic products that emit radiation, cosmetics, veterinary medicine, and tobacco products. FDA’s primary enforcement authorities are contained in the Federal Food, Drug and Cosmetic Act and the Public Health Service Act. These statutes provide FDA with a range of authorities to protect the public health through administrative and judicial actions, including product recalls, suspension or withdrawal of product approvals or clearances, refusal to admit products offered for import, civil seizures to remove products from distribution, injunctions, or criminal prosecutions.



OVERVIEW OF LITIGATION

As of September 30, 2016, there are over 7,400 cases pending to which HHS is a party. This number represents all types of litigation from routine matters (personnel, contract claims, and administrative actions), a range of enforcement actions, and high-profile policy issues currently in litigation. CMS has the largest share of the Department's pending litigation with over 4,000 pending matters, a significant portion of which are provider enforcement appeals. Below are some of the important policy issues currently under litigation.

CENTER FOR MEDICARE AND MEDICAID SERVICES

AFFORDABLE CARE ACT (ACA)

CONTRACEPTIVE COVERAGE (ZUBIK)

The Supreme Court granted certiorari in seven cases challenging the procedures put in place to accommodate the religious beliefs of certain non-profit organizations while still ensuring contraceptive coverage for their employees. The Supreme Court vacated the judgments and remanded to the respective appellate courts to afford the parties on remand "an opportunity to arrive at an approach going forward that accommodates petitioners' religious exercise while at the same time ensuring that women covered by petitioners' health plans 'receive full and equal health coverage including contraceptive coverage.'"

COST-SHARING REDUCTION PAYMENTS (HOUSE V. BURWELL)

The House of Representatives sued the Treasury and HHS Secretaries alleging that they spent monies that were not appropriated to fund cost-sharing reductions required by the ACA.

RISK CORRIDORS

Section 1342 of the ACA directs HHS to establish a temporary Risk Corridors program that protects against inaccurate rate-setting to help ensure stable health insurance premiums. Qualified health plans have sued to recover risk corridor payments because, due to funding restrictions, HHS has only paid risk corridor obligations to the extent it has collected payments under that program.

RISK ADJUSTMENT

The ACA established a risk adjustment program under which insurers whose plans have healthier-than-average enrollees must pay charges that fund payments to insurers whose plans have sicker-than-average enrollees. Plaintiffs in these cases challenge the Secretary's methodology for calculating risk adjustment payments.

TRANSITIONAL REINSURANCE FEE

These cases challenge application of the transitional reinsurance fee. The ACA requires health insurance issuers and group health plans to pay the Secretary a "transitional reinsurance fee," which is used to make payments to certain individual market issuers to offset the costs of insuring high-risk individuals during the first three years of the ACA.

EMPLOYER MANDATE

The ACA prescribes a tax for certain large employers that do not offer affordable, minimum-value coverage to their full-time employees and their dependents. This tax is known as the



employer mandate. In *Northern Arapaho Tribe v. Burwell*, a Federally-recognized Indian Tribe challenges the applicability of the large employer mandate to it.

MEDICARE

DISPROPORTIONATE SHARE FRACTION

A number of cases challenge CMS's methodology in calculating an add-on payment made to hospitals that treat a disproportionate share of low-income patients.

PROVIDER REIMBURSEMENT REVIEW BOARD JURISDICTION

The Provider Reimbursement Review Board is an administrative tribunal that hears provider reimbursement matters. These cases challenge the Board's determination that it lacks jurisdiction over a provider's appeal.

OUTLIER PAYMENTS

Outlier payments are made in special cases for which the cost of hospital treatment far exceeds the average cost. The outlier litigation generally challenges the Secretary's rulemaking in setting forth the methodology for calculating the cost threshold above which a hospital may receive an outlier payment. There is also litigation challenging the criteria for determining whether a hospital's outlier payments were so inaccurate that they should be recalculated, or reconciled.

OFFICE MEDICARE HEARINGS AND APPEALS BACKLOG

In *American Hospital Association v. Burwell*, plaintiffs seek a writ of mandamus to compel the Secretary to meet the 90-day statutorily provided period for review of Medicare appeals submitted for Administrative Law Judge review under the administrative appeals process administered by CMS's Office of Medicare Hearings and Appeals.

PLANNED PARENTHOOD CASES

In a number of States, Planned Parenthood affiliates and Jane Doe plaintiffs challenge the State's termination of its Medicaid Provider Agreement with the Planned Parenthood affiliate. The Federal government has filed a Statement of Interest or Amicus Curiae brief in some of these cases.

FOOD AND DRUG ADMINISTRATION

FDA faces significant litigation defending challenges to the agency's approval processes and product regulation. These challenges are primarily to FDA's drug approval programs, including for generic drugs; food regulation activities; and tobacco product regulation. Some notable issues in litigation are described below.

E-CIGARETTES, VAPING DEVICES, AND E-LIQUIDS

Litigation challenging FDA's authority to regulate e-cigarettes, vaping devices, and e-liquids as tobacco products under the Tobacco Control Act and FDA's Deeming Rule, which was published in May 2016.

BIOLOGIC PRODUCTS

A manufacturer of a wound-care product derived from human tissue is challenging FDA's authority to order the company to cease manufacturing and distribution and conduct a recall of their products that are in violation of FDA's regulations governing biologic products.

**FIRST AMENDMENT AND STRICT LIABILITY ENFORCEMENT CHALLENGE**

In *United States v. Facticeau et al*, Former Acclarent executives William Facticeau and Patrick Fabian are challenging their July 2016 misdemeanor device misbranding and adulteration convictions on First Amendment and due process grounds. A District Court jury convicted the defendants on charges relating to their distribution of an FDA-cleared sinus stent for the unapproved use of delivering steroids to the nasal cavity. Defendants also challenge the strict liability nature of the misdemeanor convictions, arguing that the lack of *mens rea* exacerbates the due process violation.

ADMINISTRATION FOR CHILDREN AND FAMILIES**UNACCOMPANIED CHILDREN**

Unaccompanied children are referred by the Department of Homeland Security to the Office of Refugee Resettlement with ACF. Unaccompanied children are minors under the age of 18 who cross the U.S. border alone and lack lawful immigration status to remain in the United States. These children do not have a parent or legal guardian available to provide them care and physical custody. Litigation regarding unaccompanied children includes *habeas* petitions; a motion to enforce a settlement agreement, known as the Flores settlement agreement, dating from 1996; and a case alleging an Establishment Clause violation for providing awards to organizations with religious objections to providing abortion and/or contraception.

REFUGEES

Texas and Alabama recently brought separate lawsuits against HHS, alleging that the Federal government failed to comply with law by not adequately consulting the States regarding certain aspects of refugee resettlement. To date, the Federal government has prevailed in these matters; as of November 1, 2016, both cases are under appeal.

INDIAN HEALTH SERVICE**CONTRACT SUPPORT COSTS LITIGATION AND SETTLEMENTS**

On June 18, 2012, the U.S. Supreme Court in *Salazar v. Ramah Navajo Chapter* held that the Indian Self-Determination and Education Assistance Act, mandates that the government pay the full amount of contract support costs incurred by each Tribe in performing its contracts under the law. As a result of this decision, the Indian Health Service (IHS) has received more than 1,500 claims for unpaid contract support costs, with claims totaling \$1.97 billion. As of September 2016, IHS has resolved more than 1,100 of those claims. Tribes sought \$1.77 billion over these 1,100 claims, but IHS settled the claims for a total of \$806 million, plus interest, resulting in a savings of \$967 million. Approximately \$320 million claims remain pending against the government by contracting Tribes. Additionally, the Department has estimated that Tribes could bring additional claims against the government for Fiscal Years 2010-2013 in the amount of approximately \$246 million. Taken together, HHS estimates \$566 million in both asserted and unasserted claims. The Office of the General Counsel can provide additional context on these claims.

NATIONAL INSTITUTES FOR HEALTH**FALSE CLAIMS ACT CASES**

NIH is involved in multiple cases filed under the False Claims Act, which makes the filing of false or fraudulent claims with the Federal government and other similar acts illegal. The Department of Justice



may intervene in a case filed by a private individual or bring actions on behalf of the United States under this law. NIH works closely with the Office of the General Counsel, the Office of Inspector General, and the Department of Justice in litigating matters brought under the False Claims Act.

OFFICE OF CIVIL RIGHTS

CHALLENGES TO HHS REGULATIONS IMPLEMENTING THE AFFORDABLE CARE ACT

A lawsuit filed by five States (Texas, Wisconsin, Nebraska, Kansas, and Kentucky) and a Christian Medical organization in Texas alleges that regulations promulgated under Section 1557 of the Affordable Care Act violate the Administrative Procedure Act, the Religious Freedom Restoration Act, and principles of State Sovereign Immunity, as well as the First and Tenth Amendments to and the Due Process, Equal Protection, and Spending Clauses of the U.S. Constitution. The lawsuit challenges the definition of “sex discrimination” to include gender identity and the prohibition on discrimination on the basis of gender identity in the provision of health services and health insurance. In particular, the lawsuit challenges the across-the-board prohibition on exclusions for coverage for all services and care related to gender transition and the prohibition on denials and limitations from coverage for health services related to gender transition when it results in discrimination. The American Civil Liberties Union of Texas and River City Gender Alliance have filed a joint motion to intervene in the lawsuit.

HEALTH RESOURCES SERVICES ADMINISTRATION

NATIONAL PRACTITIONER DATA BANK

Four cases are currently pending against HHS that involve defense of HRSA’s actions under the Privacy Act, Freedom of Information Act, and Administrative Procedure Act in reporting medical providers to the National Practitioner Data Bank. The Data Bank is an electronic information repository administered by HRSA that contains information on medical malpractice payments and certain adverse actions related to healthcare practitioners, entities, providers, and suppliers.

GRANT FRAUD CASES

HRSA has been involved in several grant fraud cases against individuals, including *United States v. Jonathan Wade Dunning*. In this case, the defendant was convicted of embezzling \$14 million from Federal grant funds intended to benefit the population served by Birmingham Healthcare. The case is currently in the sentencing phase.

VACCINE INJURY COMPENSATION PROGRAM

HHS is party to a legal challenge to a vaccine licensing case related to Merck’s Measles, Mumps, and Rubella vaccine license. In this case, the plaintiff seeks damages and an injunction prohibiting the sale or distribution of the vaccine for alleged “conspiracy to commit research fraud,” “evidence tampering” by concealing evidence of harm, and vaccine injuries stemming from vaccines produced by Merck.

OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH

DIETARY GUIDELINES

The Physicians Committee for Responsible Medicine filed a challenge to the 2015 Dietary Guidelines for Americans, a joint HHS-USDA publication that provides nutritional information to the general public. The Physicians Committee alleges that the egg industry improperly influenced the Dietary Guidelines Advisory Committee’s recommendation to remove the previously-recommended limit of no more than 300 milligrams of dietary cholesterol intake per day.



SECTION VII: CONGRESSIONAL RELATIONS



SECTION VII: CONGRESSIONAL RELATIONS

COMMITTEES OF INTEREST FOR HHS

APPROPRIATIONS COMMITTEES (ASFR)

The Appropriations Committees of the United States House of Representatives and Senate have jurisdiction over all of discretionary spending legislation for the Federal government. Each Appropriations Committee is divided into 12 subcommittees, each of which has jurisdiction over the funding available to a set number of Executive Branch departments. Three of these subcommittees have jurisdiction over HHS components: the Subcommittee on Labor, Health and Human Services, Education, and Related Agencies provides funding for most of HHS (referred to as “Labor-HHS” below); the Subcommittee on Agriculture, Rural Development, Food and Drug Administration (FDA), and Related Agencies provides funding for FDA; and the Subcommittee on Interior, Environment, and Related Agencies provides funding for IHS. References in this section to the Appropriations Committee refer to both the full Appropriations Committee and relevant subcommittees. Member and staff information for the 114th Congress as of October 1, 2016, is provided below.

ASFR staff engages with the House and Senate Appropriations Committees regularly, primarily through the three subcommittees listed above. ASFR’s primarily congressional relations functions include preparing principals for hearings before the Appropriations Committee; responding to Questions for the Record and other formal inquiries, including correspondence from Members of the Committee; and providing information to the Committee through reports, in-person and telephone briefings, and technical assistance.

Committee	Chairman	Majority Staff Contact	Ranking Member	Minority Staff Contact
<u>House Appropriations Committee</u>	Rep. Hal Rogers (R-KY)	Will Smith, Staff Director	Rep. Nita Lowey (D-NY)	David Pomerantz, Staff Director
<u>Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies – FDA</u>	Rep. Robert Aderholt (R-AL)	Tom O’Brien, Clerk	Rep. Sam Farr (D-CA) <i>Retiring</i>	Martha Foley, Clerk
<u>Subcommittee on Interior, Environment, and Related Agencies – IHS</u>	Rep. Ken Calvert (R-CA)	Darren Benjamin, Staff Assistant	Rep. Betty McCollum (D-MN)	Rita Culp, Clerk
<u>Subcommittee on Labor, Health and Human Services, Education, and Related Agencies – all other HHS</u>	Rep. Tom Cole (R-OK)	Susan Ross, Clerk	Rep. Rosa DeLauro (D-CT)	Stephen Steigleder, Clerk
<u>Senate Appropriations Committee</u>	Senator Thad Cochran (R-MS)	Bruce Evans, Staff Director	Senator Barbara Mikulski (D-MD) <i>Retiring</i>	Chuck Kieffer, Staff Director



<u>Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies</u> – FDA	Senator Moran (R-KS)	Patrick Carroll, Professional Staff Member	Senator Jeff Merkley (D-OR)	Jessica Schulken, Clerk
<u>Subcommittee on Interior, Environment, and Related Agencies</u> – IHS	Senator Lisa Murkowski (R-AK)	Leif Foncesbeck, Clerk	Senator Tom Udall (D-NM)	Rachael Taylor, Clerk
<u>Subcommittee on Labor, Health and Human Services, Education, and Related Agencies</u> – all other HHS	Senator Roy Blunt (R-MO)	Laura Friedel, Clerk	Senator Patty Murray (D-WA)	Alex Keenan, Clerk

BUDGET COMMITTEES (ASL)

The primary jurisdiction of the Budget Committees of the United States House of Representatives and Senate is to provide oversight of the Federal budget process. ASL and ASFR have limited interaction with the Budget Committees, but HHS officials may testify before the Budget Committees during roll-out of the President’s Budget. Member and staff information for the 114th Congress as of October 1, 2016, is provided below.

Committee	Chairman	Majority Staff Contact	Ranking Member	Minority Staff Contact
<u>House Budget Committee</u>	Rep. Tom Price (R-GA)	Caleb Graff, Brad Watson; Policy Advisors	Rep. Chris Van Hollen (D-MD) <i>Vacating seat</i>	Ellen Balis, Budget Review Director
<u>Senate Budget Committee</u>	Senator Mike Enzi (R-WY)	Greg D’Angelo, Professional Staff Member	Senator Bernie Sanders (I-VT)	Marissa Barrera, Director of Healthcare Policy

AUTHORIZING COMMITTEES (ASL)

Note that some authorizing committees also have oversight subcommittees or oversight functions. ASFR and ASL interact with congressional oversight staff.

Committee	Chairman	Majority Staff Contact	Ranking Member	Minority Staff Contact
<u>House Committee on Education and the Workforce</u>	Rep. John Kline (R-MN) <i>Retiring</i>	Kathlyn Ehl	Rep. Robert Scott (D-VA)	Alex Payne
<u>House Committee on Energy and Commerce</u>	Rep. Fred Upton (R-MI) <i>Term-limited</i>	Paul Edattel	Rep. Frank Pallone (D-NJ)	Tiffany Guarascio



SECTION VII: CONGRESSIONAL RELATIONS

<u>Subcommittee on Health</u>	Rep. Joseph Pitts (R-PA) <i>Retiring</i>	Heidi Stirrup	Rep. Gene Green (D-TX)	Kristin O'Neal
<u>Subcommittee on Oversight and Investigations</u>	Rep. Tim Murphy (R-PA)	Charles Ingebretson	Rep. Diana DeGette (D-CO)	Chris Knauer
<u>House Committee on the Judiciary</u>	Rep. Bob Goodlatte (R-VA)	Andrea Loving, Tracy Short	Rep. John Conyers (D-MI)	Gary Merson
<u>Subcommittee on Immigration and Border Security</u>	Rep. Trey Gowdy (R-SC)	Andrea Loving, Tracy Short	Rep. John Conyers (D-MI)	Maunica Sthanki
<u>House Committee on Ways and Means</u>	Rep. Kevin Brady (R-TX)	Matt Weidinger	Rep. Sander Levin (D-MI)	Nick Gwyn
<u>Subcommittee on Health</u>	Rep. Patrick Tiberi (R-OH)	Emily Murry	Rep. Jim McDermott (D-WA)	Amy Hall
<u>Subcommittee on Human Resources</u>	Rep. Vern Buchanan (R-FL)	Anne DeCesaro	Rep. Lloyd Doggett (D-TX)	Morna Miller
<u>Subcommittee on Oversight</u>	Rep. Peter Roskam (R-IL)	Machalagh Carr	Rep. John Lewis (D-GA)	Amy Hall
<u>Senate Committee on Finance</u>	Senator Orrin Hatch (R-UT)	Christopher Campbell, Becky Shipp, Kim Brandt	Senator Ron Wyden (D-OR)	Liz Jurinka, Laura Berntsen, David Berick
<u>Senate Committee on Health, Education, Labor, and Pensions</u>	Senator Lamar Alexander (R-TN)	David Cleary, Mary Sumpter Lapinski, Stacy Amin	Senator Patty Murray (D-WA)	Nick Bath, Sarah Bolton, Beth Stein
<u>Subcommittee on Children and Families</u>	Senator Rand Paul (R-KY)	Natalie Burkhalter	Senator Bob Casey (D-PA)	Larry Smar
<u>Subcommittee on Primary Health and Retirement Security</u>	Senator Mike Enzi (R-WY)	Elizabeth Schwartz	Senator Bernie Sanders (I-VT)	Sophie Kasimow
<u>Senate Committee on Indian Affairs</u>	Senator John Barrasso (R-WY)	Mike Andrews, Rhonda Harjo, Emily Newman	Senator Jon Tester (D-MT)	Anthony Walters, Kim Moxley



Senate Committee on the Judiciary	Senator Chuck Grassley (R-IA)	Kathy Nuebel Kavarik	Senator Patrick Leahy (D-VT)	Anya McMurray
Subcommittee on Immigration and the National Interest	Senator Jeff Sessions (R-AL)	Gene Hamilton	Senator Chuck Schumer (D-NY)	Lucy Panza
Senate Special Committee on Aging	Senator Susan Collins (R-ME)	Kevin Kelley	Senator Claire McCaskill (D-MO)	Derron Parks

OVERSIGHT COMMITTEES (ASFR AND ASL)

Note that some authorizing committees also have oversight subcommittees or oversight functions.

Committee	Chairman	Majority Staff Contact	Ranking Member	Minority Staff Contact
House Committee on Oversight and Government Reform	Rep. Jason Chaffetz (R-UT)	Jennifer Hemingway	Rep. Elijah Cummings (D-MD)	Dave Rapallo
Subcommittee on Healthcare, Benefits, and Administration Rules	Rep. Jim Jordan (R-OH)	Sean Hayes	Rep. Matt Cartwright (D-PA)	Ali Golden
Senate Committee on Homeland Security and Governmental Affairs	Senator Ron Johnson (R-WI)	David Brewer	Senator Tom Carper (D-DE)	Jim Secreto
Subcommittee on Investigations	Senator Rob Portman (R-OH)	Brian Callanan	Senator Claire McCaskill (D-MO)	Margaret Daum

OTHER MEMBERS WITH SPECIAL INTEREST

There are a number of Congressional Caucus Groups that focus on specific issues related to HHS. ASL has primary responsibility for interacting with these caucus groups.

CONGRESSIONAL TRI-CAUCUS

- Congressional Black Caucus (CBC)
 - Reps. G.K. Butterfield (D-NC), Yvette Clark (D-NY), Robin Kelly (D-IL; Health Braintrust Chair)
- Congressional Hispanic Caucus (CHC)
 - Reps. Linda Sanchez (D-CA), Michelle Lujan Grisham (D-NM), Joaquin Castro (D-TX), Ruben Gallego (D-AZ)
- Congressional Asian Pacific American Caucus (CAPAC)
 - Rep. Judy Chu (D-CA)

**ADDICTION AND DRUG ABUSE GROUPS**

- Congressional Addiction, Treatment and Recovery Caucus
 - Reps. Tim Ryan (D-OH), John Fleming (R-LA), Paul Tonko (D-NY)
- Caucus on Prescription Drug Abuse
 - Reps. Hal Rogers (R-KY), Stephen Lynch (D-MA)
- Bipartisan Task Force to Combat the Heroin Epidemic
 - Reps. Frank Guinta (R-NH), Anne Kuster (D-NH)

THE WOMEN'S CAUCUS

- Reps. Kristi Noem (R-SD), Doris Matsui (D-CA), Nita Lowey (D-NY)

LGBT EQUITY CAUCUS

- Reps. Jared Polis (D-CO), David Cicilline (D-RI), Sean Patrick Maloney (D-NY), Mark Pocan (D-WI), Kyrsten Sniema (D-AZ)

MEDICINE AND RESEARCH GROUPS

- Doctors Caucus
 - Reps. Phil Roe (R-TN), John Fleming (R-LA), Diane Black (R-TN)
- Biomedical Research Caucus
 - Reps. Steve Stivers (R-OH), Jackie Speier (D-CA), Joe Barton (R-TX), Steve Cohen (D-TN)
- Senate NIH Caucus
 - Sens. Lindsay Graham (R-SC), Dick Durbin (D-IL)
- Congressional Brain Injury Task Force
 - Rep. Bill Pascrell (D-NJ)
- Congressional Mental Health Caucus
 - Rep. Grace Napolitano (D-CA)
- Coalition for Autism Research and Education Information
 - Reps. Mike Doyle (R-PA), Chris Smith (R-NJ)
- Congressional Task Force on Alzheimer's Disease
 - Reps. Chis Smith (R-NJ), Maxine Waters (D-CA), Michael Burgess (R-TX)
 - Sens. Susan Collins (R-ME), Mark Warner (D-VA), Ed Markey (D-MA), Pat Toomey (R-PA)

CHILDREN'S GROUPS

- Congressional Baby Caucus
 - Reps. Duncan Hunter (R-CA), Rosa DeLauro (D-CT)
- Pre-K Caucus
 - Rep. Richard Hanna (R-NY), Rep. Tom Cole (R-OK), Rep. Joaquin Castro (D-TX), Rep. Katherine Clark (D-MA)

CONGRESSIONAL TASK FORCE ON SENIORS

- Rep. Jan Schakowsky (D-IL), Rep. Doris Matsui (D-CA)

REQUIRED REPORTS AND UPDATES TO CONGRESS**ASFR**

Appropriations legislation generally includes instructions to HHS to provide the relevant Appropriations subcommittees with information on various topics in the form of reports to Congress. These reporting



requirements generally appear in the report language that accompanies appropriations bill text. It is ASFR practice to adopt the reporting requirements laid forth in all underlying report language for an enacted appropriations bill, including the underlying House and Senate reports, even if the legislation accompanying the report was never passed. For example, prior to passing an omnibus appropriations law in FY 2016, the House and Senate Appropriations Committees considered – but never passed – appropriations legislation for HHS. Report language that included reporting requirements accompanied each of these bills. When the Omnibus Appropriations Act for FY 2016 was drafted, it carried its own report language containing a provision directing HHS to follow the guidance laid out in the underlying reports, meaning the House and Senate Labor-HHS reports.

ASFR holds primary responsibility for managing the reports required by appropriations language, including assigning individual reports to OpDivs or StaffDivs and tracking the progress of each report to completion. Once ASFR receives a finished report from an OpDivs or StaffDivs, ASFR clears the report through the Office of the Secretary and then to OMB for review. The final report and letters are transmitted under the ASFR's signature. Appropriations Reports to Congress are not generally cleared through the Executive Secretariat. In general, reports required by appropriations language are shared only with the relevant Subcommittee and are not public.

ASL

Most authorizing legislation includes statutory requirements for reports to Congress with specific due dates required by the Committees of jurisdiction. The agency responsible for administering a specific program prepares the report and forwards it to the Executive Secretariat for distribution to all relevant StaffDivs and other appropriate offices in the Department for clearance. The final report is delivered by ASL with a transmittal letter signed by the Assistant Secretary for Legislation to the appropriate Committees and/or the Speaker of the House and the President of the Senate, as required by the statute.

KEY PENDING LEGISLATION

ASFR

CONTINUING RESOLUTION THROUGH DECEMBER 9

On Wednesday, September 28, the House and Senate agreed to a Continuing Resolution (CR) to fund the government through December 9, 2016. This bill, which was signed by the President on September 29, also includes a \$1.1 billion spending package to combat Zika virus and the FY 2017 Military Construction-VA spending bill.

The CR continues spending at FY 2016 levels with a 0.496 percent reduction across the board. The following anomalies affecting HHS were included in the CR:

FDA

Section 120 extends the Rare Pediatric Disease Priority Review Voucher Program through December 9, 2016. The program would have otherwise ended on September 30, 2016.

OPIOIDS FUNDING FOR THE COMPREHENSIVE ADDICTION AND RECOVERY ACT

The CR includes an additional \$17 million above the FY 2016 level for HHS to begin implementation of the Comprehensive Addiction and Recovery Act (CARA). Only \$7 million of this amount is available during the period of the CR. The CR did not specify the HHS agencies which would carry out this provision, nor which portions of CARA were envisioned to be implemented with these funds.

**ACF MANDATORY**

The House and Senate bill language for the FY 2017 full-year appropriations act provides that none of the funds provided for the Promoting Safe and Stable Families appropriation may be used for Court Improvement Program (sections 438(c)(3)(A)(ii) and (iii) of the Social Security Act). As a result, funds authorized under the continuing resolution for the Court Improvement Program may not be obligated until the FY 2017 full-year appropriations are provided (to the extent the Court Improvement Program is funded in such full-year appropriations).

The CR also provides \$1.1 billion to HHS, the Department of State, and the United States Agency for International Development to combat Zika virus. Of this total, \$933 million is provided to HHS. The conference bill provides authority for the Secretary to transfer funding between appropriations included in the bill.

FY 2017 OMNIBUS APPROPRIATIONS BILL

During summer 2016, the House and Senate Appropriations Committees considered spending bills for Labor-HHS, Agriculture, and Interior. None of these bills were considered on the Floor. Accordingly, the expectation is that the Congress will work to pass an omnibus appropriations bill for the remainder of FY 2017 when the current CR expires in early December.

ASL

There are several pending bills of note that were not completed before the recess and will be under consideration during the lame duck session when Congress returns in mid-November.

21ST CENTURY CURES/INNOVATION BILL

House Energy and Commerce bipartisan staff and Senate Health, Education, Labor, and Pensions (HELP) Committee bipartisan staff are working together to determine the final details of a Cures/Innovation bill that we understand will be considered in the lame duck session of the 114 Congress. In early 2016, the House passed (344-77) the "21st Century Cures Act" (H.R. 6), and the Senate HELP Committee approved its smaller, more targeted version of the legislation. Once there is agreement and the final compromise is unveiled, the authors' goal is to pass a 21st Century Cures bill through both chambers and avoid a conference committee. The overall goal of the legislation – which largely targets NIH and FDA, but also touches on Office of the National Coordinator for Health IT and CDC – is to make changes or provide strategic direction to accelerate the process of getting "cures" and treatments to patients. The bill leads are Chairman Upton (R-MI) and Ranking Member Pallone (D-NJ) in the House and Chairman Alexander (R-TN) and Ranking Member Murray (D-WA) in the Senate.

H.R. 2646, HELPING FAMILIES IN MENTAL HEALTH CRISIS ACT

Speaker Ryan listed mental health legislation H.R. 2646 by Rep. Tim Murphy (R-PA) as a priority for the lame duck session of the 114 Congress. On July 6, 2016, the House passed H.R. 2646 and it has been referred to the Senate HELP Committee. The Senate HELP Committee held a markup of S. 2680, the Mental Health Reform Act, in March 2016. H.R. 2646 would create an Assistant Secretary for Mental Health and Substance Use to assume the responsibilities of the SAMHSA Administrator. It would expand coverage of mental illness treatment by the Centers for Medicare and Medicaid Services, make it easier for caregivers to access protected patient information and establish grants for screening, prevention and treatment of mental illness, and training for providers, especially in underserved areas. Passage during lame duck depends on whether the Senate flips. If Republicans maintain control of the Senate, there is a chance that the House bill will pass in the Senate and be merged with H.R. 2646.

**H.R. 5456, FAMILY FIRST PREVENTION SERVICES ACT OF 2016**

This bill was introduced by Rep. Buchanan (R-FL) on June 13, 2016, and passed the House under suspension on June 21. The Senate companion bill was introduced by Senator Hatch (R-UT) on June 16, 2016. H.R. 5456 would amend Parts B and E of title IV of the Social Security Act to invest in funding prevention and family services to help keep children safe and supported at home, to ensure that children in foster care are placed in the least restrictive, most family-like, and appropriate settings. The bill is currently pending consideration on the Senate floor, however, several Senators have holds on the bill and it was not cleared prior to recess.

IMPLICATIONS OF CHANGES IN NEW CONGRESS**ASFR**

The only major change to the Appropriations Committee currently known for the 115th Congress is the retirement of Senator Barbara Mikulski (D-MD), Ranking Member of the Senate Appropriations Committee. Which Senator will replace Mikulski as Ranking Member is currently unknown and will likely remain so until after the new Congress convenes.

Representative Hal Rogers, Chairman of the House Appropriations Committee, has served in that role for three terms. The House limits leadership roles on the Appropriations Committee to three terms and Mr. Rogers has said that he will give up the chairmanship rather than seek a waiver to continue in that role. Which congressman will replace Rogers is unknown and will likely remain so until after the new Congress convenes.

In general, ASFR enjoys collegial relationships with the House and Senate, majority and minority staff of the Appropriations Committee, especially on the Labor-HHS Subcommittee. Appropriations Committee staff interactions are focused on technical budget assistance and are generally less partisan than HHS's interactions with authorizing committees; accordingly, any changeover in leadership is not likely to substantially impact ASFR's staff contacts.

ASL

If the Senate Majority changes, there will a longer period of reorganization of all committees, including voting on Chairmen and Ranking Members and redistribution of committee staffs.

Senate HELP Committee may experience a leadership change. Currently, Ranking Member Patty Murray (D-WA), who also serves as Ranking Member on Senate Labor-HHS Appropriations Subcommittee, may seek to replace Barbara Mikulski as Ranking Member for the full Senate Appropriations Committee. If Senator Murray decides to leave HELP, Senators Casey (D-PA) or Sanders (I-VT) may seek the post.

In the House, there are a number of Chairmen and Ranking Members either retiring from Congress or turning over the gavel due to term limits. House Education and the Workforce Chairman Kline is retiring and Subcommittee Chair Virginia Foxx (R-VA) has expressed an interest in running for chairman and has the support of Rep. Joe Wilson (R-SC), second in seniority after Kline.

House Energy and Commerce Committee will experience a few key leadership changes, including the departure of Chairman Upton (R-MI) due to term limits and Health Subcommittee Chairman Pitts (R-PA), who is retiring from Congress. Representatives Shimkus (R-PA) and Walden (R-OR) are said to be vying for Chairman Upton's spot, while Representatives Burgess (R-TX) is said to be vying for the Subcommittee leadership post.



WORKING WITH OTHER LEGISLATIVE OFFICES TO CLEAR MATERIALS FOR CONGRESS

TESTIMONY AND QUESTIONS FOR THE RECORD

A Committee will initiate the hearing process by contacting ASL or ASFR to identify a witness for a hearing under development. This witness may be the Secretary, Deputy Secretary, or any appropriate staff from the relevant OpDiv or StaffDiv. This usually occurs through a formal letter of invitation from the Chairman, but ASL or ASFR may receive advance notice from committee staff. ASL manages appearances before authorizing committees on authorization-related topics; ASFR manages appearances before appropriations and budget committees and on appropriations- or budget-related topics. ASL and ASFR have joint responsibility for oversight testimony.

Once testimony is drafted by the appropriate program office (often an OpDiv or StaffDiv), ASL or ASFR circulate the draft testimony to relevant OpDiv, StaffDivs, and policy officials within HHS for review and clearance, and then to OMB for comment or clearance. OMB may disseminate the testimony to other agencies or offices for review under this process (this is very common for authorizing committee testimony, less so for budget- or appropriations-related testimony). Witnesses representing StaffDivs often rely on ASL or ASFR for Member biographies, briefing materials, and hearing preparation meetings, while OpDiv witnesses utilize their own legislative staff to work on these tasks.

Department witnesses are frequently asked to submit answers to questions submitted by Members of Congress following a hearing for the hearing record (Questions for the Record or “QFRs”). Responses to these QFRs are prepared and cleared through the same process as testimony before being sent back to the Committee and incorporated in the official hearing record.

Other documents and congressional inquiries, such as views letters on legislation and other correspondence to Congress are cleared by the Office of the General Counsel/Legislation. They are the official departmental liaison with OMB for these types of document clearance.

SPECIAL CONSIDERATIONS FOR BUDGET TESTIMONY

Traditionally, the Secretary testifies at seven hearings on the President’s Budget before the Department’s major Committees of jurisdiction: Senate Finance Committee, House Ways and Means Health Subcommittee, Senate Appropriations Labor-HHS Subcommittee, House Appropriations Labor-HHS Subcommittee, House Energy and Commerce Health Subcommittee, and House Education and Workforce Committee. The Senate Health, Education, Labor, and Pensions Committee may also invite the Secretary to testify on the Budget. ASFR handles development and clearance of testimony related to the Budget and prepares the Secretary for these appearances, including providing the Secretary and relevant Department staff with briefing materials in advance of the hearing.

INTERACTION WITH CONGRESS

The Secretary and members of HHS’s legislative leadership team have regular interactions with Authorizing, Oversight, and Appropriations Committee Chairs and Ranking Members, and with individual Members of Congress throughout the hearing, markup, and conference process. ASL and ASFR also work with congressional staff to address Member interests and constituent issues.

ASL is responsible for the Department’s interactions with all of the non-appropriations activities of the Congress, including preparing the Secretary for the numerous hearings at which his/her presence is requested. ASL also is



responsible for coordinating the Department's responses to Congressional requests, including subpoenas and interviews, on all matters related to oversight and investigations into Departmental programs and activities. ASL is charged with ensuring timely compliance to inquiries in an effective and appropriate manner.

ASL engages in negotiations with congressional staff to accommodate oversight activity while protecting Executive privilege. ASL's Office of Oversight and Investigations serves as the Department's liaison to the Government Accountability Office, which is an independent, non-partisan arm of Congress charged with investigating how the Federal government spends taxpayer dollars. ASL is responsible for coordinating responses to Government Accountability Office investigations, including audits, reports and testimony, and the office proactively monitors progress achieved by HHS in response to Government Accountability Office recommendations. More information on HHS oversight activities can be found in [Section IV – Oversight](#).

ASFR is responsible for engaging with the Senate and House Appropriations Committees, staffing the Secretary when s/he engages with Appropriators and when preparing for budget hearings before the Appropriations and Budget Committees, and for working with Subcommittee staff to achieve the Secretary's and the Administration's budget priorities.

ASFR also works informally with analysts at the Congressional Budget Office to share program and scorekeeping information, particularly around scoring assumptions of major legislation and the President's Budget proposals.



SECTION VIII: EXTERNAL STAKEHOLDERS



SECTION VIII: EXTERNAL STAKEHOLDERS

ENGAGING WITH ORGANIZATIONS OUTSIDE OF THE DEPARTMENT AND US GOVERNMENT

The relationships that HHS has developed with newly formed and long standing stakeholder organizations are important to disseminating important information on department policy and action as well as gathering input on public input throughout the process.

HHS manages formal and informal engagement with State and local governments; public, private and not-for-profit organizations through a variety of mechanisms structures and processes. Examples include, but are not limited to, advisory boards, committees and councils, individual and large format meeting with organizations such as consumer, industry, and labor organizations.

Management of engagement with these organizations is determined by the organizations subject matter interest or operating structure and is assigned to the relevant HHS office, staff, or operating division with programmatic responsibility. Detailed information about subject specific stakeholder engagement and mechanisms is included in Staff and Operating Division transition documents.

EXAMPLES OF STAKEHOLDER ENGAGEMENT

The following list is provided to illustrate selected examples of stakeholder engagement responsibilities within the Office of the Secretary.

ASSISTANT SECRETARY FOR PUBLIC AFFAIRS

Manages engagement with all levels (local, State, national and international) and forms (print, broadcast and digital) of media.

ASSISTANT SECRETARY FOR ADMINISTRATION

Manages engagement with Federal labor unions.

OFFICE OF EXTERNAL AND INTERGOVERNMENTAL AFFAIRS

Manages engagement with State, local, and tribal governments as well as territories.



SECTION IX: CRISIS MANAGEMENT AND EMERGENCY RESPONSE



SECTION IX: CRISIS MANAGEMENT AND EMERGENCY RESPONSE

HHS engagement in emergency response and recovery is initiated through authority which is activated when a disaster or public health emergency is declared. This section refers to both public health emergencies and disaster declarations, which are often closely related although each has important distinctions related to HHS roles, responsibilities, and requirements for use of appropriated funds and performing statutory duties.

The Secretary has responsibility for public health and medical emergency preparedness, response, and recovery activities. The Department also has additional responsibilities related to Federal disaster declarations through government-wide response coordination led by Federal Emergency Management Agency (FEMA) as well as managing the continuity of operations (COOP) for HHS in the event of a disaster which affects normal business operations. Incoming leadership should participate in a COOP exercise within the first 30 days of the Administration.

PUBLIC HEALTH EMERGENCIES

Public health response activities occur when the Secretary declares a public health emergency using authorities in the Public Health Service Act. Such a declaration may occur when it is determined that a disease or disorder presents a public health emergency or when there is a significant outbreak of infectious disease or potential for bioterrorist attacks. Additional emergency response activities could involve food safety recalls. The type of emergency event informs which HHS assets are mobilized for the response and the funding source used to support those activities.

The Assistant Secretary for Preparedness and Response (ASPR), the Assistant Secretary for Financial Resources (ASFR), and certain OpDivs are among the components available to the Secretary to identify assets and initiate and manage the response, regardless of the event type. The Secretary's Operations Center, operated by ASPR, serves as a central location to coordinate all HHS emergency response efforts and is the initial entry point for the Department on all emergency public health issues, and during potential and actual emergency or disaster situations. The Center is always operational.

ASPR is the lead office within HHS to coordinate and execute response activities involving deployment of assets. Additionally, in the case of a disaster response ASPR works closely with FEMA to coordinate Federal assistance to supplement State, territorial, tribal, and local resources in response to public health and medical care needs. Roles and responsibilities are delineated through the National Response Framework and its Emergency Support Functions as well as the FEMA led Response Support Functions, which involve support for social service-related efforts managed by ACF during disaster recovery. As the U.S. Government lead for Emergency Support Function #8, HHS coordinates the provision of Federal public health and medical assistance to fulfill the requirements identified by the affected State and local authorities. Information on the response support functions is available at on the [FEMA website](#).

ASFR supports Department efforts to manage and execute the financing of HHS response and recovery efforts, including supporting the Secretary in identifying legally available funds or managing supplemental appropriations to make funding available to OpDivs and StaffDivs to support response operations and related program support. Determination of funding source and availability of funds for response activities is required before assets can be deployed.



It is important to note that public health, emergency response, and natural disaster activities frequently involve multiple departmental components such as Public Health Service Commissioned Corps Officers and assets across the Department, including at ACF, ASPR, NIH, CDC, and FDA.

CONTINUITY OF OPERATIONS INFORMATION

HHS COOP plans document the specific roles and responsibilities for OpDivs and StaffDivs to ensure continued Department operations in the event of an emergency and include standard operation procedures for ensuring the safety of property and Department employees.

The ASPR Office of Emergency Management is responsible for ensuring that the Department meets the national continuity requirements for Federal Departments and agencies. These continuity requirements are managed by the Department of Homeland Security's FEMA National Continuity Programs. To address these requirements, ASPR coordinates with senior HHS officials as well as the continuity managers for each OpDiv and StaffDiv. ASPR manages the HHS COOP Program budget, operates the Office of the Secretary's continuity site, and maintains, and tests the Department's continuity communications capability.

COOP programs in individual StaffDivs and OpDivs may be structured and managed differently provided that they meet the minimum requirements in the HHS COOP Policy and Framework and support the achievement of the goals identified by ASFR in the HHS COOP Multi-Year Strategy.

In the event the Humphrey Building and Southwest complex are not available to continue normal business operations, a Mission Support Center located in Frederick, Maryland is activated for use by COOP managers.

The focus of the HHS Continuity Program is performance of three primary missions which support the Emergency Support Functions:

- Prepare for, mitigate, respond to, and recover from public health and medical emergencies;
- Ensure the safety of procedures and products intended for human and animal use or consumption; and
- Ensure continuous national leadership, resource support, and access to and provision of authorized medical care and public health services.

The continuity programs are led by OpDiv and StaffDiv Heads and managed by program points of contact. These programs may be structured and managed differently provided that they meet the minimum requirements in the HHS COOP Policy and National Response Framework and support the achievement of the goals identified by ASPR in the HHS COOP Multi-Year Strategy.

PRIMARY POINTS OF CONTACT

PUBLIC HEALTH EMERGENCIES:

George Korch, ASPR Career Official
Norris Cochran, ASFR Career Official
Jewel Mullen, OASH Career Official

FOOD SAFETY:

Stephen Ostroff, FDA Career Official

COOP:

George Korch, ASPR Career Official
Christine Major, ASA Career Official



SECTION X: ADMINISTRATIVE INFORMATION



SECTION X: ADMINISTRATIVE INFORMATION

CONTACT INFORMATION FOR HHS PRESIDENTIAL TRANSITION TEAM

NAME	PHONE NUMBER	EMAIL ADDRESS
John Gentile, HHS Transition Director	(202) 690-7512	John.Gentile@hhs.gov
Christine Major	(202) 690-7431	Christine.Major@hhs.gov
Janis Coughlin	(202) 690-5689	Janis.Coughlin@hhs.gov
Valerie Gill	(202) 690-7431	Valerie.Gill@hhs.gov
Justin Hentges	(202) 690-8661	Justin.Hentges@hhs.gov
Tim Barfield	(202) 260-9621	Timothy.Barfield@hhs.gov
Kimberly Cosby	(202) 205-9332	Kimberly.Cosby@hhs.gov
Jeff Davis	(202) 690-7721	Jeffrey.Davis@hhs.gov

SECURITY PROCEDURES

You will be able to access the Hubert H. Humphrey Building through the main entrance on Independence Avenue. Please bring government-issued photo identification (driver's license or passport). Upon arrival, please contact one of the individuals noted above who can escort you into the building. After your first day, you will meet with a member of our security personnel to receive appropriate identification so that you can access the turnstiles to enter the building and the secured access to your suite.

COMPUTER ACCESS, TECHNOLOGY USAGE INFORMATION, TELEPHONE INSTRUCTIONS

Guest access to the HHS WiFi network, as well as printing capabilities, will be provided to all landing team members. To access the guest WiFi network please select the "HHS-Visitor" option under the WiFi settings of your device. Each workspace in the landing team office will also be set-up with a desk telephone and phone number. The assigned phone numbers will be located at each work station with directions for voicemail set-up.

TRANSPORTATION AND PARKING INFORMATION

Parking passes can be assigned to landing team members upon arrival. Each landing team member who requests parking in the Hubert H. Humphrey Building will receive their parking passes either at the guards' booth upon arrival or in the landing team suite after initial entry into the building.

The HHS transition team will request the information below from those that wish to park in the building.

1. Name
2. Date of arrival
3. Make/model of vehicle
4. State tags



APPENDIX A - ACRONYMS



APPENDIX A - ACRONYMS

ACRONYMS AND ABBREVIATIONS

Acronym	Full Name
ACA	Affordable Care Act
ACF	Administration for Children and Families
ACL	Administration for Community Living
ACYF	Administration on Children, Youth and Families
AHA	American Hospital Association
AHRQ	Agency for Healthcare Research and Quality
AIDS	Acquired Immunodeficiency Syndrome
ARS	Acute Radiation Syndrome
ASA	Assistant Secretary for Administration
ASFR	Assistant Secretary for Financial Resources
ASH	Assistant Secretary for Health
ASL	Assistant Secretary for Legislation
ASPA	Assistant Secretary for Public Affairs
ASPE	Assistant Secretary for Planning and Evaluation
ASPR	Assistant Secretary for Preparedness and Response
ATSDR	Agency for Toxic Substances and Disease Registry
BARDA	Biomedical Advanced Research and Development Authority
BEA	Budget Enforcement Act
CCDF	Child Care and Development Fund
CDC	Centers for Disease Control and Prevention
CFO	Chief Financial Officer
CFR	Code of Federal Regulations
CHIP	Children's Health Insurance Program
CMMI	Center for Medicare and Medicaid Innovation
CMS	Centers for Medicare & Medicaid Services
COOP	Continuity of Operations Plan
CO-OPs	Consumer Operated and Oriented Plans
CR	Continuing Resolution (budget)
DAB	Departmental Appeals Board
DoD	Department of Defense
DOJ	Department of Justice
EEO	Equal Employment Opportunity
EHR	Electronic Health Record
ESF	Emergency Support Function
FDA	Food and Drug Administration
FEMA	Federal Emergency Management Agency
FEVS	Federal Employment Viewpoint Survey
FOIA	Freedom of Information Act
FTE	Full-Time Equivalent
FY	Fiscal Year
GAO	Government Accountability Office
GDM	General Departmental Management



GPRA	Government Performance and Results Act
GS	General Schedule
GSA	General Services Administration
HCFAC	Healthcare Fraud and Abuse Control
HEAT	Healthcare Fraud Prevention and Enforcement Action Team
HELP	Health, Education, Labor, and Pensions
HHS	Department of Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act
HITECH	Health Information Technology for Economic and Clinical Health Act
HIV	Human Immunodeficiency Virus
HRSA	Health Resources and Services Administration
IEA	Intergovernmental and External Affairs
IG	Inspector General
IHS	Indian Health Service
IOS	Immediate Office of the Secretary
IPAB	Independent Payment Advisory Board
IT	Information Technology
JFA	Joint-Funding Agreement
LIHEAP	Low Income Home Energy Assistance Program
MACRA	Medicare Access and CHIP Reauthorization Act of 2015
NCI	National Cancer Institute
NIH	National Institutes of Health
NIOSH	National Institute for Occupational Safety and Health
OCR	Office for Civil Rights
OGC	Office of the General Counsel
OGA	Office of Global Affairs
OIG	Office of Inspector General
OMHA	Office of Medicare Hearings and Appeals
ONC	Office of the National Coordinator for Health Information Technology
OPDIV	Operating Division
OPM	Office of Personnel Management
OS	Office of the Secretary
OSSI	Office of Security and Strategic Information
PB	President's Budget
PCORTF	Patient-Centered Outcomes Research Trust Fund
PEPFAR	President's Emergency Plan for AIDS Relief
PHS	Public Health Service
PHSA	Public Health Service Act
PHSSEF	Public Health and Social Services Emergency Fund
P.L.	Public Law
PPHF	Prevention and Public Health Fund
PPS	Prospective Payment Systems
PSC	Program Support Center
QFR	Question for the Record
QIO	Quality Improvement Organizations
RAC	Recovery Audit Contractor
RO	Regional Office
SAMHSA	Substance Abuse and Mental Health Services Administration



SES	Senior Executive Service
SG	Surgeon General
SSA	Social Security Administration
SSBG	Social Services Block Grant
SSF	Service and Supply Fund
STAFFDIV	Staff Division
STD	Sexually Transmitted Diseases
TANF	Temporary Assistance for Needy Families
TB	Tuberculosis
TPP	Teen Pregnancy Prevention
UC	Unaccompanied Children
USG	U.S. Government
WHO	World Health Organization



APPENDIX B – HEADSHOTS AND BIOGRAPHIES



APPENDIX B – HEADSHOTS AND BIOGRAPHIES

Food and Drug Administration



Agency Head: Commissioner Robert M. Califf, M.D.

Robert.Califf@fda.hhs.gov

Robert M. Califf, MD, MACC, is the Commissioner of Food and Drugs at the U.S. Department of Health and Human Services. As the top official of the FDA, Dr. Califf is committed to strengthening programs and policies that enable the agency to carry out its mission to protect and promote the public health.

Previously, Dr. Califf served as the FDA's Deputy Commissioner for Medical Products and Tobacco from February 2015 until his appointment as commissioner in February 2016. In that capacity, he provided executive leadership to the agency's three medical product centers. He also oversaw the Office of Special Medical Programs and provided direction for cross-cutting clinical, scientific, and regulatory initiatives, including precision medicine, combination products, orphan drugs, pediatric therapeutics, and the advisory committee system.

Prior to joining the FDA, Dr. Califf was a professor of medicine and vice chancellor for clinical and translational research at Duke University. He also served as director of the Duke Translational Medicine Institute and founding director of the Duke Clinical Research Institute. A nationally and internationally recognized expert in cardiovascular medicine, health outcomes research, healthcare quality, and clinical research, Dr. Califf has led many landmark clinical trials and is one of the most frequently cited authors in biomedical science, with more than 1,200 publications in the peer-reviewed literature.



Career Acting Official: Dr. Stephen Ostroff, M.D.

Stephen.Ostroff@fda.hhs.gov

Stephen Ostroff, M.D., is the Food and Drug Administration's Deputy Commissioner for Foods and Veterinary Medicine. As Deputy Commissioner, he provides leadership and direction to FDA's Food Safety, Nutrition, and Veterinary Medicine programs and the foods-related programs of FDA's inspection and compliance arm, the Office of Regulatory Affairs (ORA). His responsibilities include leading the implementation of the FDA Food Safety Modernization Act of 2011. Previously Dr. Ostroff was the acting FDA Commissioner, serving from April 2015 to late February 2016.

Before being named acting commissioner, Dr. Ostroff served as the FDA's Chief Scientist since February 2014. Dr. Ostroff joined FDA in 2013 as Chief Medical Officer in the Center for Food Safety and Applied Nutrition and Senior Public Health Advisor to FDA's Office of Foods and Veterinary Medicine.

Prior to that, he served as Deputy Director of the National Center for Infectious Diseases at the Centers for Disease Control and Prevention (CDC). Dr. Ostroff was also the Director of the Bureau of Epidemiology and Acting Physician General for the Commonwealth of Pennsylvania and has consulted internationally on public health projects in South Asia and Latin America.

**Presidential Transition Council Member: Tom Kraus**

Thomas.Kraus@fda.hhs.gov

Tom Kraus is the Chief of Staff at the U.S. Food and Drug Administration (FDA). He previously served as the Associate Commissioner for Legislation, where he led legislative efforts to advance the FDA's public health priorities.

Prior to joining the FDA, he served as health policy advisor to Senators Tom Harkin and Edward Kennedy and as Deputy Staff Director for Health on the Senate Committee on Health, Education, Labor and Pensions. In that role he oversaw the development of legislation to protect the safety of the food supply and medical products and to improve healthcare quality. He has also served as a strategic advisor to public and private health systems and to medical product manufacturers in the healthcare and life sciences practices at McKinsey & Company and Ernst and Young.

He received a B.S. in biology from the University of Michigan, a J.D. from the Georgetown University Law Center and a Master of Health Sciences from the Johns Hopkins University Bloomberg School of Public Health.

Health Resources and Services Administration**First Assistant, Agency Head, and Career Acting Official: James (Jim) Macrae, MA, MPP**

JMacrae@hrsa.gov

James Macrae became HRSA's Acting Administrator of the Health Resources and Services Administration in April 2015. Previously, as head of HRSA's Bureau of Primary Healthcare, he managed a \$5 billion budget that supported over 9,000 health center sites, which provide high-quality primary healthcare to more than 24 million people. Macrae also served as Associate Administrator for HRSA's Office of Performance Review from 2000 to 2006, where he oversaw the work of staff in regional divisions across the country, working to improve HRSA-supported programs in States and communities. Macrae has received numerous awards, including the Hubert H. Humphrey Award for Service to America (2015), the HRSA Administrator's Award for

Equal Opportunity Achievement (2014), the Presidential Meritorious Executive Rank Award (2010), and many others.

James earned a Bachelor of Arts degree in Sociology from Illinois Wesleyan University, an M.A. in Sociology from Duke University, and a Master of Public Policy degree from Harvard University. James has been named First Assistant to serve as the Agency lead during the transition.

**Presidential Transition Council Member: Diana Espinosa, MPP**

Diana.Espinosa@hhs.gov

Diana Espinosa was named HRSA's Deputy Administrator in March 2015. In this position, she plays a key role in defining the strategic direction of the agency and implementing program and policy changes aimed at providing the greatest benefit to the millions of people HRSA serves. Previously, Espinosa served as Senior Health Advisor to the HRSA Administrator, providing counsel to the Administrator on a wide range of policy, program, and management issues. From 2007 through 2012, she served as the Deputy Associate Administrator for HRSA's Bureau of Health Professions where she managed programs focused on developing and retaining a diverse, culturally competent health workforce. Prior to joining HRSA, Espinosa served as Deputy Assistant Director for Management at the U.S. Office and Management and Budget where she led government-wide efforts to improve program performance and accountability. She attended the University of Michigan where she received a Master of Public Policy degree and a Bachelor of Arts degree in Social Anthropology.

Indian Health Service**Agency Head: Mary L. Smith**

Mary.Smith@ihs.gov

Mary L. Smith, a member of the Cherokee Nation, is the Principal Deputy Director of the Indian Health Service. Ms. Smith administers a \$4.8 billion nationwide healthcare delivery program that is responsible for providing preventive, curative, and community healthcare to approximately 2.2 million American Indians and Alaska Natives in hospitals, clinics, and other settings throughout the United States. Her key priorities include behavioral health, native youth initiatives such as Generation Indigenous, contract support costs and making sustainable improvements for direct service Tribes to increase quality of care.

Ms. Smith previously served in the Clinton White House as the Associate Counsel to the President and also as Associate Director of Policy Planning in the Domestic Policy Council. In those roles, she provided leadership on a variety of policy priorities, including Native American issues, and coordinated with the Indian Health Service on preventive care and efforts to reduce health disparities. She was the highest-ranking Native American during the Clinton Administration. Ms. Smith graduated from the University Of Chicago School Of Law, cum laude, where she was a member of the Law Review. She received a Bachelor of Science degree in Mathematics and Computer Science, magna cum laude, from Loyola University of Chicago.

**Career Acting Official: CAPT Chris Buchanan**

Chris.Buchanan@ihs.gov

CAPT Chris Buchanan, an enrolled member of the Seminole Nation of Oklahoma, is the Career Acting Official for the Indian Health Service. His position of record is Director of the IHS Office of Direct Services and Contracting Tribes.

Most recently serving as the Acting Director of the IHS Great Plains Area, CAPT Buchanan exercised administrative responsibility for 19 service units consisting of seven hospitals and 10 health centers. He managed a varied health program for more than 126,000 American Indian people eligible for IHS services. CAPT Buchanan began his IHS career in 1993 serving in environmental health officer positions in the Phoenix, Albuquerque, and Oklahoma City Areas. He held management positions in the

Oklahoma City Area, including serving as the Administrative Officer for Lawton Indian Hospital and the Chief Executive Officer for Haskell Health Center. He was awarded a Bachelor of Science degree in environmental health and a Master of Public Health degree in health policy and administration from the University of North Carolina at Chapel Hill.

**Presidential Transition Council Member: Elizabeth A. Fowler**

Elizabeth.Fowler@ihs.gov

Elizabeth A. Fowler, a member of the Comanche Nation, is the Deputy Director for Management Operations for the Indian Health Service. Ms. Fowler serves as the principal advisor to the IHS Director for the management of IHS operations. She is responsible for providing management direction to the IHS program offices, including implementing IHS agency goals and mission; providing overall organization management to improve agency performance; developing strategic plans; and planning, directing, and evaluating the operations of the Headquarters functions, authorities, and responsibilities in support of the Director.

Centers for Disease Control and Prevention**Agency Head: Thomas R. Frieden, MD, MPH**

txf2@cdc.gov

Tom Frieden, MD, MPH, became Director of the Centers for Disease Control and Prevention (CDC) in June 2009. Dr. Frieden has worked to control health threats from infectious diseases, respond to emergencies, and battle the leading causes of suffering and death in our nation and around the world.

As the director of our nation's health protection agency, he is leading CDC to address these challenging health priorities: Improving health security at home and around the world, reducing the leading causes of death and illness, and strengthening public health & healthcare collaboration - by aligning, coordinating and integrating public health and healthcare to improve health outcomes.



A physician with training in internal medicine, infectious diseases, public health, and epidemiology, Dr. Frieden is especially known for his expertise in tuberculosis control. Dr. Frieden worked for CDC from 1990 until 2002. He began his career at CDC as an Epidemic Intelligence Service (EIS) Officer at the New York City Health Department.

Dr. Frieden speaks Spanish and graduated from Oberlin College. He received both his medical degree and master's of public health degree from Columbia University and completed infectious disease training at Yale University. He has received many awards and honors and has published more than 200 scientific articles.



Career Acting Official: Anne Schuchat, MD (RADM, USPHS)

acs1@cdc.gov

Anne Schuchat, M.D. has been Principal Deputy Director for CDC since September 2015. Dr. Schuchat began her public health career in 1988 when she came to CDC as an Epidemic Intelligence Service Officer. She was director of CDC's National Center for Immunization and Respiratory Diseases from 2006-2015. Other CDC leadership posts include: acting director of the National Center for Infectious Diseases (NCID) and the Center for Global Health; chief of the Respiratory Diseases Branch and Chief Health Officer for CDC's 2009 H1N1 pandemic influenza response. Schuchat was the initial medical director of ABCs - the Active Bacterial Core surveillance of the Emerging Infections Program Network and spearheaded prevention of newborn infection from group B streptococcal disease in the 1990s. She also served as CDC's interim deputy director for Science and Program in early 2009. She was promoted to Rear Admiral in the United States Public Health Service in 2006 and earned a second star in 2010. Schuchat was elected to the Institute of Medicine of the National Academy of Sciences in 2008.

Globally, Dr. Schuchat has worked in West Africa on meningitis, pneumonia, and Ebola vaccine trials, in South Africa on surveillance and prevention projects, and in China on Beijing's SARS emergency response. She has authored or co-authored more than 230 scientific articles, book chapters, and reviews. Her contributions have been recognized by receipt of the USPHS Meritorious Service Medal, the American Public Health Association's Maternal and Child Health Young Investigator Award, the USPHS Physician Research Officer of the Year, and an Honorary Doctorate in Science from Swarthmore College. Dr. Schuchat graduated with highest honors from Swarthmore College and with honors from Dartmouth Medical School and completed her residency and Chief residency in Internal Medicine at NYU's Manhattan VA Hospital.



Presidential Transition Council Member: Sherri A. Berger, MSPH

sob8@cdc.gov

Sherri Berger, MSPH, became Chief Operating Officer of the Centers for Disease Control and Prevention (CDC), one of 10 major operating divisions of the Department of Health and Human Services (HHS), in August 2011. As COO, she oversees management, facilities, and operations at the Atlanta-based public health agency. She provides substantial strategic direction for CDC's 10,000 employees, 5,000 contractors, and \$13 billion budget – while ensuring CDC has proper resources to fulfill its critical work to save lives and protect people from health threats.

Specifically, Berger manages CDC's budget; oversees facilities design, maintenance, security, management analysis, and safety and personnel security; leads acquisitions, contractual assistance and grants; manages



information technology and security; and directs human resources strategy, training, and workplace development.

Berger is a manager with extensive experience at both the program and senior leadership level. She began her Federal career in 1996 as one of four graduate students selected nationwide to participate in the CDC/Association of Schools of Public Health Experimental Learning Program. Berger worked as an epidemiologist at the community level until moving to CDC headquarters in Atlanta to serve as a principal epidemiologic investigator. As a result of her management at the program level, she was nominated to participate in the Senior Executive Service Candidate Development Program, where she expanded her career into business management. Berger has held several leadership positions at CDC, including associate director for formulation, evaluation, and analysis in CDC's Financial Management Office, deputy director of one of CDC's national centers, and director of the agency's Recovery Act Coordination Unit. Berger received her bachelor's in political science from the University of Florida and a master's of science in public health with a concentration in epidemiology from the University of South Florida.

National Institutes of Health



Agency Head: Francis Collins, MD, PhD
collinsf@od.nih.gov

Francis S. Collins, MD, PhD is the Director of the National Institutes of Health (NIH). In that role he oversees the work of the largest supporter of biomedical research in the world, spanning the spectrum from basic to clinical research.

Dr. Collins is a physician-geneticist noted for his landmark discoveries of disease genes and his leadership of the international Human Genome Project, which culminated in April 2003 with the completion of a finished sequence of the human DNA instruction book. He served as director of the National Human Genome Research Institute at NIH from 1993-2008.

Before coming to NIH, Dr. Collins was a Howard Hughes Medical Institute investigator at the University of Michigan. He is an elected member of the National Academy of Medicine (formerly, the IOM) and the National Academy of Sciences, was awarded the Presidential Medal of Freedom in November 2007, and received the National Medal of Science in 2009.



Career Acting Official and Presidential Transition Council Member: Lawrence A. Tabak, DDS, PhD
Lawrence.Tabak@nih.gov

Dr. Tabak is the Principal Deputy Director of the National Institutes of Health (NIH) and the Deputy Ethics Councilor of the Agency. He previously served as the Acting Principal Deputy Director of NIH (2009), and prior to that as Director of the National Institute of Dental and Craniofacial Research from 2000-10.

Dr. Tabak has provided leadership for numerous trans-NIH activities, including the NIH Roadmap effort to support team science, the NIH Director's initiative to enhance peer-review, the NIH's American Recovery and Reinvestment Act implementation, and the NIH-Wide Strategic Plan.



He co-chaired working groups of the Advisory Committee to the Director of NIH on the Diversity of the Biomedical Research Workforce and Information Technology and Informatics.

Prior to joining NIH, Dr. Tabak was the Senior Associate Dean for Research and Professor of Dentistry and Biochemistry & Biophysics in the School of Medicine and Dentistry at the University of Rochester in New York. Dr. Tabak is a former NIH MERIT recipient and an elected member the National Academy of Medicine (formerly, the IOM).



Acting Director, National Cancer Institute: Douglas R. Lowy, M.D.
LowyD@mail.nih.gov

Douglas R. Lowy, M.D., was officially named the National Cancer Institute's (NCI) Acting Director in April 2015. Prior to his appointment, Dr. Lowy served as NCI's deputy director from July 2010 helping lead NCI's key scientific initiatives.

Dr. Lowy received his medical degree from New York University School of Medicine and trained in internal medicine at Stanford University and dermatology at Yale University.

His research interests include the biology of papillomaviruses and the regulation of normal and neoplastic cell growth. The papillomavirus research is carried out in close collaboration with Dr. John Schiller, with whom he has co-authored more than 125 papers over the past 30 years.

In the 1980s, Drs. Lowy and Schiller studied the genetic organization of papillomaviruses and identified the oncogenes encoded by the virus. More recently, they have worked on papillomavirus vaccines and the papillomavirus life cycle. Their laboratory was involved in the initial development, characterization, and clinical testing of the preventive virus-like particle-based HPV vaccines that are now used in three FDA-approved HPV vaccines.

Substance Abuse and Mental Health Services Administration



Agency Head and Career Acting Official: Kana Enomoto
Kana.Enomoto@samhsa.hhs.gov

Ms. Enomoto has been delegated the functions, duties, and authorities of the Administrator by the Department of Health and Human Services Secretary. Ms. Enomoto oversees an agency with four centers and four offices, over 600 employees, and a budget of \$3.7 billion. Through data, policy, public education, and grants, Ms. Enomoto and the SAMHSA team advance the agency's mission to reduce the impact of substance abuse and mental illness on America's communities. Ms. Enomoto has served as Principal Deputy Administrator and principal advisor to the SAMHSA Administrator on operations, policies, and programmatic activities for the agency since August 2011. Prior to that, Ms. Enomoto served as the Director of the Office of Policy, Planning, and Innovation, where she developed, coordinated, and communicated SAMHSA policies across the full spectrum of mental health and substance abuse issues. From 2005-2009, Ms. Enomoto served as the Principal Senior Advisor to three SAMHSA Administrators, and as the Acting Deputy Administrator between 2008 and 2009. She began her tenure at SAMHSA in 1998 as a



Presidential Management Fellow. She began her career in research and clinical services with a focus on minority mental health and trauma.



Presidential Transition Council Member: Monica Feit

Monica.feit@hhs.gov

As the Director of the Office of Policy, Planning, and Innovation (OPPI), Dr. Monica Feit is responsible for providing leadership on cross-cutting policy issues at SAMHSA and with external stakeholders. She works with SAMHSA's Office of the Administrator and SAMHSA's Offices and Centers to foster a unified understanding of policy and budget directions and to operationalize them. Dr. Feit also coordinates and facilitates activities between SAMHSA and State, regional, tribal, national, and international partners. Dr. Feit joined the Department of Health and Human Services in 2013 as the director of the Division of Public Health Services in the Office of the Assistant Secretary for Planning and Evaluation (ASPE) where her work was largely focused on policy related to safety net programs and the Affordable Care Act. Prior to joining the Department she served as a senior program officer at the Institute of Medicine (IOM) where she directed multiple health policy studies. In 2009, she was named an American Public Health Association Government Fellow and worked as a staffer on the Senate Health, Education, Labor and Pension Committee in the office of Senator Dodd (D-CT) during the development of the Affordable Care Act.

Agency for Healthcare Research and Quality



Agency Head: Andrew Bindman, M.D.

Andrew.Bindman@ahrq.gov

Andrew (Andy) Bindman, MD, was appointed as Director of AHRQ on May 2, 2016. Prior to his appointment, Dr. Bindman served as Professor of Medicine and Epidemiology & Biostatistics at the University of California, San Francisco (UCSF). He is a primary care physician with Federal and State health policy experience who has practiced, taught, and conducted health services research at San Francisco General Hospital, an urban safety-net hospital, for almost 30 years. Dr. Bindman is a Senior Associate Editor of the journal Health Services Research and he was elected to the National Academy of Medicine in 2015.

From 2009 to 2010, Dr. Bindman was a Robert Wood Johnson Health Policy Fellow who worked as a staff member on the Energy and Commerce Committee in the U.S. House of Representatives. From September 2011 until June 30, 2014, Dr. Bindman served as a senior advisor within the Assistant Secretary for Planning and Evaluation's Office of Health Policy, where he worked to establish new Medicare payment codes for transitional care and chronic care management. From July 2014 until November 2015, Dr. Bindman was a senior advisor to the Centers for Medicare & Medicaid Services, where he helped launch the Innovation Accelerator Program to support care transformation in State Medicaid programs.



Career Acting Official and Presidential Transition Council Member: Sharon B. Arnold, Ph.D.

Sharon.Arnold@ahrq.gov

Sharon Arnold helps lead the Agency's efforts to develop the knowledge, tools, and data needed to improve the healthcare system and help Americans, healthcare professionals, and policymakers make informed health decisions. Prior to coming to AHRQ, Sharon directed the Payment Policy and Financial Management Group at the Centers for Medicare & Medicaid Services (CMS), where she led work related to program payments and developed the premium stabilization programs for private insurance under the Affordable Care Act.

Sharon has held a number of other positions in health policy, including Vice President at AcademyHealth, where she directed the Robert Wood Johnson Foundation grant program Changes in Healthcare Financing and Organization, which provided funding to academic researchers for policy-relevant research on healthcare financing topics; and Director of the Program Development and Information Group at CMS, where she directed Medicare payment demonstrations and the implementation of risk adjustment in Medicare.

Centers for Medicare and Medicaid Services



Agency Head: Andy Slavitt

Andy.Slavitt@cms.hhs.gov

Andy Slavitt is the Acting Administrator for the Centers for Medicare & Medicaid Services (CMS). A leader with decades of experience, Andy has shaped and delivered important healthcare services and programs for millions of consumers. As Acting Administrator, Slavitt oversees programs that provide access to quality healthcare for 140 million Americans, including Medicaid, Medicare, the Children's Health Insurance Program, and the Health Insurance Marketplace. Slavitt and the CMS team are focused on improving quality, health outcomes, access and affordability while addressing health equity and protecting program integrity, including combating healthcare fraud.

Since joining CMS on July 8, 2014 as Principal Deputy Administrator, Slavitt has been integral to strengthening the performance of the Health Insurance Marketplace and the success of the 2014 Open Enrollment season. Since taking the role in February, Slavitt's focus as Acting Administrator is on strengthening CMS's role in helping the healthcare delivery system meet the evolving needs of consumers by transforming the way care is paid for, providing the tools to make the system thrive and by fostering simplicity and transparency.

Most recently Slavitt served as Group Executive Vice President for Optum where he oversaw the delivery of clinical, technology and operational solutions to healthcare clients and consumers. Prior to his role at Optum, Slavitt was CEO of OptumInsight from 2006 through 2011.

He was founder and CEO of HealthAllies, a consumer healthcare service company focused on serving people who are uninsured or underinsured by contracting affordable care on their behalf nationwide. Prior to that, he was a strategy consultant with McKinsey & Company, and an investment banker with Goldman Sachs.



Slavitt graduated from the Wharton School and The College of Arts & Sciences at the University of Pennsylvania, and received his Master of Business Administration degree from the Harvard Business School.



Career Acting Official and Presidential Transition Council Member: Patrick H. Conway, MD, MSc

Patrick.Conway@cms.hhs.gov

Patrick Conway, MD, MSc, is the CMS Acting Principal Deputy Administrator and Deputy Administrator for Innovation and Quality & CMS Chief Medical Officer. As the CMS Acting Principal Deputy Administrator and CMS Chief Medical Officer, Dr. Conway is responsible for overseeing the programs that serve the over 130 million Americans that access healthcare services through Medicare, Medicaid, the Children's Health Insurance Program, and the Health Insurance Marketplace. He and the CMS team focus on health system transformation by improving quality, affordability, access to care and health outcomes.

Dr. Conway is also Director of the Center for Medicare and Medicaid Innovation (CMMI) at CMS. The CMS Innovation Center is responsible for testing numerous new payment and service delivery models across the nation that reward quality and value. Models include accountable care organizations, bundled payments, primary care medical homes, State innovation models, and many more. These models involve millions of people and hundreds of thousands of providers across the nation. Successful models can be scaled nationally. The CMS Innovation Center budget is \$10 billion over 10 years.

In 2014, he was elected to the National Academy of Medicine Institute of Medicine (IOM) recognizing individuals who have demonstrated outstanding professional achievement. Election to the IOM is considered one of the highest honors in the fields of health and medicine. He is a practicing pediatric hospitalist and was selected as a Master of Hospital Medicine from the Society of Hospital Medicine. He has received the President's Distinguished Senior Executive Rank and HHS Secretary's Distinguished Service awards. These are the President's and Secretary's highest distinction for executive excellence. He is a former White House Fellow, Robert Wood Johnson Clinical Scholar, and leader of quality improvement, research, and clinical operations at Cincinnati Children's Hospital. He completed pediatrics residency at Harvard Medical School's Children's Hospital Boston, graduated with High Honors from Baylor College of Medicine, and graduated summa cum laude from Texas A&M University.

Administration on Children, Youth and Families



Agency Head: Mark Greenberg

Mark.Greenberg@ACF.hhs.gov

Before joining HHS, Mark H. Greenberg directed the Georgetown University Center on Poverty, Inequality and Public Policy, a joint initiative of the Georgetown University Law Center and the Georgetown Public Policy Institute. In addition, he was a Senior Fellow at the Center for American Progress (CAP) and the Center for Law and Social Policy (CLASP). He previously served as the Executive Director of CAP's Task Force on Poverty and as CLASP's Director of Policy. During his career, Mr. Greenberg has written extensively on issues relating to Federal and State welfare reform efforts; workforce policy issues affecting low-income families; child care and early education



policy; tax policy; poverty measurement; and a range of other low-income issues. In addition, he frequently provided technical assistance to State and local governments regarding poverty reduction strategies. Prior to coming to D.C., Mr. Greenberg worked at Jacksonville Area Legal Aid in Florida and the Western Center on Law and Poverty in Los Angeles, California. Mr. Greenberg is a graduate of Harvard College and Harvard Law School.

Mr. Greenberg joined ACF in 2009 as the Deputy Assistant Secretary for Policy, and served in that position until 2013, when he became the Acting Assistant Secretary for the Administration for Children and Families. He also served as Acting Commissioner for the Administration on Children, Youth and Families from 2013-2015.



Career Acting Official and Presidential Transition Council Member: Naomi Goldstein
Naomi.Goldstein@acf.hhs.gov

Naomi Goldstein is Deputy Assistant Secretary for Planning, Research and Evaluation. She advises the Assistant Secretary for Children and Families on improving the effectiveness and efficiency of ACF programs. Goldstein joined ACF as Director of the OPRE Division of Child and Family Development in 2000. She became Director of OPRE in 2004 and Deputy Assistant Secretary in 2015.

Prior to her appointment as Director of OPRE in November 2004, Goldstein served as Director of the Division of Child and Family Development in OPRE. Previously, she directed the United States Postal Service Commission on a Safe and Secure Workplace, an independent commission that examined workplace violence affecting the postal service and the nation. She served as project manager for the Urban Institute's Assessing the New Federalism project and as Executive Officer in the Office of the Assistant Secretary for Planning and Evaluation at HHS. Earlier in her career, she worked in the Massachusetts State government and developed infant mortality prevention programs at Brigham and Women's Hospital in Boston.

Goldstein received a B.A. in philosophy from Yale University, a Masters in Public Policy from the Kennedy School of Government, and a Ph.D. in Public Policy from Harvard University. She was awarded the Presidential Rank of Distinguished Executive in 2012.



Lillian A. Sparks Robinson, Commissioner of the Administration of Native Americans

Lillian.Sparks@acf.hhs.gov

Lillian Sparks Robinson, a Lakota woman of the Rosebud and Oglala Sioux Tribes, is the Commissioner of the Administration of Native Americans. Miss Sparks was confirmed by the United States Senate as the Commissioner on March 3, 2010, and was sworn in on March 5, 2010. She has devoted her career to supporting the educational pursuits of Native American students, protecting the rights of indigenous people, and empowering tribal communities.

Prior to her appointment, Lillian served as the Executive Director of the National Indian Education Association (NIEA) where she worked extensively on k-12 and early childhood education policy and appropriations impacting American Indian, Alaska Native, and Native Hawaiian students. Before joining NIEA, she served as a staff attorney with the National Congress of American Indians where she worked on international indigenous rights, sacred sites and religious protection, and issues related to youth and healthcare.



Ms. Sparks Robinson also previously worked in the legal department at the National Indian Gaming Commission at the Department of the Interior.

Named one of seven young Native American Leaders by USA Today Magazine, Ms. Sparks Robinson received her B.A. in Political Science from Morgan State University, located in her hometown of Baltimore, MD, and her Juris Doctorate from Georgetown University Law Center in Washington, DC. Ms. Sparks Robinson is admitted to practice in Maryland.



Stacey Ecoffey, Acting Commissioner Administration for Native Americans and Principal Advisor for Tribal Affairs

stacey.ecoffey@hhs.gov

Stacey currently serves as the Acting Commissioner, Administration for Native Americans (ANA) and the Principal Advisor for Tribal Affairs in the Office of Intergovernmental and External Affairs (IEA) in the Immediate Office of the Secretary at the Department of Health and Human Services. In October of 2016 she took on the Acting Commissioner for ANA and splits her time in her permanent role at IEA. She provides policy support to the Secretary, Deputy Secretary and the Director of Intergovernmental and External Affairs on Tribal issues. Her portfolio focuses on

consultation, communication, and outreach with Tribal Governments. In her current role she was instrumental in the revision of the HHS Tribal Consultation Policy and led the development and implementation of the Secretary's Tribal Advisory Committee, which is the first tribal advisory committee ever established to a Cabinet Secretary. Since the implementation of the Affordable Care Act, she has been an active leader in the outreach and education to Tribes.

As an enrolled member of the Oglala Sioux Tribe she was born and raised on the Pine Ridge Reservation. In 2015 she received the HHS Secretary's Award for Distinguished Service, this is the highest honor given at HHS. In addition in 2014 she was awarded a National Impact Awards from the National Indian Health Board and in 2012 she was awarded the National Center for American Indian Enterprise Development "40 Under 40" award. Stacey has 15 years of experience working with Tribal governments, Policy development and implementation on Federal Tribal relations. Stacey received a Bachelor's degree from Colorado State University, and a Masters of Social Work from Boston College.



Rafael López, Commissioner of the Administration on Children, Youth and Families

Rafael.Lopez@acf.hhs.gov

Rafael López is the Commissioner of the Administration on Children, Youth and Families (ACYF) at the U.S. Department of Health and Human Services. From 2013-2015, López served as a Senior Policy Advisor at the White House Office of Science and Technology Policy within the Executive Office of the President and with the Domestic Policy Council.

Prior to his service at the White House, López was an Associate Director at the Annie E. Casey Foundation, a private, national philanthropy devoted to developing a brighter future for millions of children at risk of poor educational, economic, social and health outcomes. Previously, López served as the President and CEO of The Family League of Baltimore City, Inc. where he was a member of the Baltimore City



Mayor's Cabinet. From 2006-2009, López was appointed by Mayor Antonio Villaraigosa to serve on his Cabinet as the Executive Director of the City of Los Angeles Commission for Children, Youth and Their Families. López previously served as the Deputy Director of the City and County of San Francisco Department of Children, Youth, and Their Families and as Senior Deputy for Health and Human Services for Los Angeles County Supervisor Gloria Molina.

Born and raised in Watsonville, California, López is an alumnus of Vassar College and the University of California Santa Cruz where he graduated with honors in American Studies. He is a graduate of Harvard University's John F. Kennedy School of Government where he earned a Master in Public Administration and was named a Lucius N. Littauer Fellow.

Administration for Community Living



Agency Head and Career Acting Official: Edwin Walker

Edwin.walker@acl.hhs.gov

Edwin Walker currently serves as the Acting Assistant Secretary for Aging and Acting Administrator of ACL, assuming both roles in July 2016.

As the Acting Administrator of ACL, Edwin leads the effort to bring together the Federal government's work on behalf of older adults and people with disabilities. ACL focuses on one guiding principle – that people with disabilities and older adults should be able to live independently and participate fully in their communities.

In addition, Edwin continues to directly lead the Administration on Aging within ACL. He guides and promotes the development of home and community-based long-term care programs, policies and services designed to afford older people and their caregivers the ability to age with dignity and independence and to have a broad array of options available for an enhanced quality of life. This includes the promotion and implementation of evidence-based prevention interventions proven effective in avoiding or delaying the onset of chronic disease and illness.

Prior to Federal service, Mr. Walker served as the director of the Missouri Division of Aging, responsible for administering a comprehensive set of human service programs for older persons and adults with disabilities.



Presidential Transition Council Member: Dan Berger

Dan.Berger@acl.hhs.gov

As the Deputy Administrator of the Center for Management and Budget (CMB) within the Administration for Community Living (ACL), Dan Berger serves as the Executive Officer and Chief Financial Officer for ACL, and advises the Administrator for Community Living on all matters related to resource management and internal administration. He also serves as the ACL member on the HHS Transition Council. Mr. Berger oversees the administration of ACL's financial resources; discretionary and mandatory grants; information technology and telecommunications; procurement and facilities services; personnel and human capital development; and internal control activities. Under his leadership, the Center is responsible for improving the efficiency and effectiveness of ACL's operations and providing effective administrative services to support ACL's programs.



Prior to assuming his current position, Mr. Berger served in a variety of budget and management positions in the Department. Management positions at AoA included Director of the Center for Management and Budget, Director of the Office of Management Analysis and Resources, and Director of the Office of Information Resources Management. He entered Federal service as a Presidential Management Fellow in 1997 and spent 8 years as a budget analyst in the Office of the Secretary and AoA.

Immediate Office of the Secretary



Career Acting Official and Presidential Transition Council Member: Wilma M. Robinson, PhD, MPH

Wilma.Robinson@hhs.gov

Dr. Wilma Robinson has served as the Deputy Executive Secretary at the U.S. Department of Health and Human Services (HHS) since February, 2016, where she assists in ensuring an orderly and inclusive decision-making process at the Secretarial level; manage and track all documents that come to the Secretary for review/signature; manage the regulatory process for the Department; maintain all records for the Office of the Secretary; and manage and support all staff in the Office of the Executive Secretariat. Prior to coming to the Office of the Executive Secretary,

Dr. Robinson was the Deputy Director of the U.S. Department of Health and Human Services (HHS) Office of Adolescent Health, a position she held for four years. Dr. Robinson also served as the Acting Director and a Senior Health Policy Analyst for the Division of Public Health Services within the Office of the Assistant Secretary for Planning and Evaluation (ASPE) at HHS for 11 years. Prior to joining HHS, she worked as a Policy Associate for Health Systems Research Inc. (Altarum Institute) for three years. Dr. Robinson holds a Ph.D. in Organizational Leadership with a focus on Health and Human Services from the University of Maryland Eastern Shore, a M.P.H. in Maternal and Child Health from the University of Alabama Birmingham, and a B.A. in Biology from Emory University.

Assistant Secretary for Administration



Agency Head and Career Acting Official: Colleen Barros

Colleen.Barros@hhs.gov

Colleen Barros is the Acting Assistant Secretary for Administration (ASA) and is responsible for the leadership and management of the following services to the Department of Health and Human Services (HHS): Human Resources; Equal Employment Opportunity Compliance and Operations; Information Technology; Business Transformation; Security and Strategic Information, and the Program Support Center Ms. Barros comes to the Office of Administration from her role as the Deputy Director for Management and Chief Financial Officer at the National Institutes

of Health (NIH) where she reported directly to the NIH Director on management functions of the NIH, the world's premier medical research organization with a budget of over \$30 billion. Earlier in her career, Ms. Barros served as the Associate Director for Administration for the National Institute on Aging (NIA) and the Project Manager for the NIH Business System (NBS), a multi-million dollar project to replace the legacy electronic systems that supported NIH's fundamental business processes. Ms. Barros has received the 2008 Presidential



Rank of Distinguished Executive Award, the 2003 Presidential Rank of Meritorious Executive Award. She received her Master of Science in Management of Scientific and Technical Information Systems from American University and her Bachelor of Science from the University of Maryland.



Presidential Transition Council Member: Christine M. Major

Christine.Major@hhs.gov

Christine M. Major currently serves as the Principal Deputy Assistant Secretary (PDAS) for Administration. In this role, Ms. Major supports the Assistant Secretary for Administration portfolio which includes: human resources, equal employment opportunity compliance and operations, information technology, business transformation, security and strategic information, and the HHS Program Support Center (PSC). Ms. Major was designated as the Senior Accountable Official for the 2016 HHS implementation of the SES Reform Executive Order. Ms. Major has over 25 years of experience in the Human Resource field at the National Institutes of Health (NIH) and the Department of Health and Human Services (DHHS). Prior to her role as PDAS, she served as the Director of Human Resources for the National Institutes of Health. Ms. Major directed the activities of five separate divisions and over 300 staff members, comprising the full range of Human Resource functions including recruitment, HR Systems, employee/labor relations, benefits, policy and training and development. Ms. Major holds a Bachelor of Science Degree in Human Resource Management from the University of Maryland.

Assistant Secretary for Financial Resources



Agency Head: Ellen G. Murray

Ellen.Murray@hhs.gov

Ellen G. Murray has served as Staff Director for the United States Senate Appropriations Subcommittee on Labor, Health and Human Services, Education and related Agencies since 1999. In that capacity, she oversees the annual \$150 billion Labor-HHS Appropriations bill. Murray has extensive knowledge of the Department of Health and Human Services budget. Prior to her tenure with the Senate, she served in both the budget office and the Office of the General Counsel at HHS. Previously, Murray served as an economist at the Social Security Administration. She is a graduate of Trinity College in Washington, DC with a degree in Economics and the George

Mason University School of Law.



Career Acting Official: Norris Cochran

norris.cochran@hhs.gov

Norris W. Cochran is the Deputy Assistant Secretary for Budget of the U.S. Department of Health and Human Services. He joined Federal service in 1996 at the Centers for Disease Control and Prevention in Atlanta, Georgia. Mr. Cochran served on the House Committee on Appropriations as a CDC staff detailee in 2000 and 2001. Mr. Cochran worked from 2001 to 2006 in the Health Division of the Office of Management and Budget. He entered the Senior Executive Service when joining HHS on February 5, 2006. Mr. Cochran earned the Meritorious Presidential Rank Award in



2010. He received a bachelor's degree from the University of California, Santa Barbara, and master's degrees from the University of Texas, Austin. As Director of the Office of Budget, Mr. Cochran leads a staff of 95 Federal employees across 4 divisions led by Senior Executive Service level directors and an Associate Deputy Assistant Secretary. Mr. Cochran leads the Office of Budget on issues related to budget formulation, execution and policy, working with the operating and staff divisions of the Department. He also supports the Assistant Secretary for Financial Resources in his or her roles as the HHS Chief Performance Officer, the lead policy official for all budget matters in the Department, the lead policy official for budget formulation and execution within the Office of the Secretary, the lead policy point of contact for the Office of Management and Budget and the Committees on Appropriations, and the vice-chair of the Service and Supply Fund.



Presidential Transition Council Member: John Gentile

John.Gentile@hhs.gov

John Gentile is a financial management and financial systems executive with over 44 years combined experience in the public and private sectors. Throughout his career John has held positions of increasing responsibilities in the fields of accounting, budgeting and finance. He has over 35 years' experience in building, managing and leading high performing financial operations in large and small organizations. John has also directed the successful implementation of two major, enterprise-wide financial management system projects. In November 2009, Mr. Gentile joined the HHS

Office of the Secretary as the Director, Office of the Secretary Budget and the Deputy CFO for the Office of the Secretary within the Assistant Secretary for Financial Resources (ASFR) Office of Budget. In this role John was responsible for the budget formulation and execution for the 17 Staff Divisions that make up the Office of the Secretary. As Deputy CFO John was responsible for the A-123 Internal Control program for the Office of the Secretary and served as the Fund Manager for the HHS Service and Supply Fund, a working capital fund, totaling over \$1 billion.

In August 2014 John moved into the ASFR Immediate Office as a Senior Advisor to the Assistant Secretary for Financial Resources (HHS CFO). In this role John served as the Executive Sponsor for the HHS Oracle Release 12 Upgrade (R12) and the HHS implementation of the Digital Accountability and Transparency Act of 2014 (DATA Act). In March 2015 Mr. Gentile assumed the responsibilities of the Principal Deputy Assistant Secretary for ASFR. In addition to continuing his Executive Sponsorships John also became responsible for the administrative operations for ASFR. During this period the Department successfully completed its upgrade to Oracle Release 12 on time and on budget. The UFMS instance of the R12 upgrade was also successfully migrated to the Oracle Cloud and for the first time a Department-wide Accounting Treatment Manual was written, approved and implemented.



Assistant Secretary for Legislation



Agency Head: Jim Esquea

Jim.Esquea@hhs.gov

Jim Esquea serves as the Assistant Secretary for Legislation at the US Department of Health and Human Services. He was confirmed by the US Senate on June 22, 2010. He is responsible for the development and implementation of the Department's legislative agenda, provides advice to the Secretary on legislation and facilitates communication between the Department and Congress. His office informs the Congress of the Department's views, priorities, actions, grants and contracts. As the ASL, he is the Department liaison with Members of Congress, staff, Committees, and with the Government Accountability Office.

Assistant Secretary Jim Esquea was the analyst for Income Security and Medicaid for the Democratic staff of the U.S. Senate Budget Committee from 1999 to 2010. While on the committee he covered issues ranging from veterans affairs and justice programs to child welfare, Temporary Assistance for Needy Families, supplemental nutrition assistance, public housing, Medicaid, the Children's Health Insurance Program and other health programs.

Before working for the Budget Committee, Mr. Esquea worked in the health division focusing on the Food and Drug Administration for the White House Office of Management and Budget from 1994 to 1999 under the Clinton Administration. He has a Bachelor of Arts Degree from Wesleyan University and a Master in Public Administration from Columbia University.



Career Acting Official and Presidential Transition Council Member: Barbara Pisaro Clark

Barbara.Clark@hhs.gov

Barbara Pisaro Clark is the Deputy Director for Human Services Legislation in the HHS Office of the Assistant Secretary for Legislation (ASL); the office responsible for the development and implementation of the Department's legislative agenda and congressional liaison activities. She is responsible for the development, clearance and advocacy of formal and informal communications with the Congress, management of congressional hearings, and representing ASL in liaison activities between the Department and Congress to further the human services legislative objectives.

Ms. Clark began her career in government service at the Social Security Administration in 1988 in the Office of Legislation and Congressional Affairs, organizing the Commissioner's policy briefings for and visits to Members of Congress. She moved to ASL in 1990, first handling Social Security legislation, then shifting her portfolio to the Administration on Children and Families and the Administration on Aging. She became Deputy Director in 2004. In the last presidential transition she served as Acting Assistant Secretary for seven months. She is a graduate of the University of Cincinnati.



Assistant Secretary for Public Affairs



Agency Head: Kevin Griffis

Kevin.Griffis@hhs.gov

Kevin Griffis serves as the Assistant Secretary for Public Affairs. Kevin joined the department in May 2014 as a Senior Advisor in the Office of the Assistant Secretary for Public Affairs. He initially focused on matters related to oversight investigations and was involved in a number of projects, including open enrollment and the department's Ebola response.

Prior to joining HHS, Kevin worked as Communications Director for U.S. Sen. Cory Booker (D-NJ), and as Communications Director and Senior Advisor for Booker's successful 2013 special election. He also has experience in the private sector as a Principal on the Podesta Group's public relations team.

In March 2009, Kevin joined the U.S. Department of Commerce as Director of Public Affairs. Prior to his work in the Commerce Department, Kevin spent 2007-2008 working on the Obama campaign, first as the Communications Director for the South Carolina primary, going on to work in the primary elections in Virginia, Ohio, Mississippi, Indiana and South Dakota. In the general election, Kevin was Virginia Communications Director. Before joining President Obama's campaign, Kevin served as Communications Director for a 2006 U.S. Senate race in Arizona and for the State Coordinated Campaign during Tim Kaine's successful 2005 bid for governor in Virginia. He spent the first six years of his career covering government and politics as a reporter for newspapers in Maryland and Atlanta, Ga.



Career Acting Official: Mark Weber

Mark.Weber@hhs.gov

As Deputy Assistant Secretary (DAS) for Public Affairs (January 2012-Present), Mark Weber is responsible for communications oversight and management for ASPA's Human Services portfolio of agencies: Administration for Children and Families (ACF), Indian Health Service (IHS), Substance Abuse and Mental Health Services Administration (SAMHSA), Administration for Community Living (ACL), Office of Civil Rights (OCR), Office of Medicare Hearings and Appeals (OMHA), and Department Appeals Board (DAB). He has directed numerous controversial and crisis communication issues for HHS; in particular, the Department's communications work

on the humanitarian response to the dramatic increase in unaccompanied children referred to HHS care by immigration officials.

Mark has consistently challenged the status quo to create meaningful lasting change throughout his Federal career. Most recently, Mark led the effort to "re-imagine" HHS.gov; an initiative that already has dramatically improved customer satisfaction from 20 percent before the launch to 80 percent one year later. In addition, Mark eliminated a publication policy and procedure that failed to produce results for 25 years by implementing a strategic communications planning tool which has reduced by 75 percent the number of documents requiring ASPA review.

As the Director of the Office of Communications (OC) at SAMHSA (September 1995-January 2012), Mark planned and executed rollouts for a number of high-profile government initiatives including the National Action Alliance



to Prevent Suicide, the Surgeon General's Call to Action on Underage Drinking Prevention, the President's New Freedom Commission on Mental Health, and the Surgeon General Report on Mental Health: Culture, Race and Ethnicity. From October 1989 – September 1995, Mark was a speech writer and managed event scheduling and advance work in the Office of the Assistant Secretary for Health (OASH). Mark has received the Secretary's Distinguished Service Award and SAMHSA's Leading Change and Outstanding Service Awards.



Presidential Transition Council Member: Catherine Teti

Catherine.Teti@hhs.gov

Catherine serves as ASPA's senior management official, responsible for the Division's administrative operations and business management functions. In addition, she serves as the Assistant Secretary's surrogate on matters related to the Department's implementation of and compliance with the Federal Freedom of Information Act (FOIA) and Privacy Act. During her 2 ½ year tenure with ASPA (March 2014–Present), Catherine's teams have consolidated and realigned all of ASPA's business operations to provide budget transparency, accountability, and improved operational oversight both within ASPA and to all of ASPA's serviced organizations; reduced the initial request backlog for Office of the Secretary FOIA requests by 46 percent; the lowest number for which there is historical data; provided consultation services and hands-on assistance to support operational improvements in the FOIA program managed by one of the HHS Operating Divisions; developed and implemented an HHS-wide FOIA Strategic Plan; one of a few, if not the only, such plan in the Federal government; progress is tracked and reported monthly to the Deputy Secretary; developed and implemented a revised, usage based, methodology for funding ASPA's broadcast services operations.

Immediately prior to joining ASPA, Catherine served as the Director of the HHS National Capital Region Human Resources Center, where she completed the implementation of the newly organized center. From 2001 – 2014, Catherine served as the Managing Director for Knowledge Services at the U.S. Government Accountability Office (GAO). Prior to her tenure at GAO, Catherine directed information management and public disclosure programs at three Federal agencies and a government corporation. In addition, she managed major systems design and analysis projects for two private sector consulting firms and has served on Federal working groups charged with reviewing policies and practices for the effective capture and retention of electronic information assets.

Office of the General Counsel



Acting Agency Head: Peggy Dotzel

Peggy.Dotzel@hhs.gov

Peggy Dotzel is the Acting General Counsel of the Department of Health and Human Services. Prior to serving in this capacity, Ms. Dotzel served as Deputy General Counsel from 2011-2016. Before joining HHS, Peggy was a Special Counsel at Zuckerman Spaedar LLP.

From 2000-2003, Ms. Dotzel served as Associate Commissioner for Policy at the Food and Drug Administration, where she oversaw the development of major FDA policy initiatives and worked with HHS, the White House, and Congress on issues relating to FDA's regulatory policy. From 1999-2000, she was the Acting Associate Commissioner for Policy, and from 1995-1999 she was a Senior Policy Advisor at the Food and Drug Administration. Ms. Dotzel started her legal career as



a law clerk to Judge Jerry Buchmeyer in the Northern District of Texas. Following her clerkship she spent five years at the Washington, D.C. law firm of Wilmer, Cutler and Pickering.

Prior to attending law school, Ms. Dotzel practiced as a hospital pharmacist. Ms. Dotzel received her law degree (with honors) from the University of Texas School Of Law and her bachelor's degree (summa cum laude) from Temple University School of Pharmacy.



Career Acting Official and Presidential Transition Council Member: Jeffrey Davis
jeffrey.davis@hhs.gov

Jeff Davis is a graduate of Texas A&M University (1977) and the University of Texas School Of Law (1985). He was commissioned as a 2nd Lieutenant in the U.S. Army, Medical Service Corps, in 1977, was later selected to attend law school while on active duty, and spent most of his military career in the Judge Advocate General's Corps, from which he retired as a Lieutenant Colonel in 1998.

Jeff joined HHS OGC in 1998 in what was then the Business and Administrative Law Division as Chief of Administrative Law. He later became the first Deputy Associate General Counsel for Procurement, Fiscal, and Information Law in the General Law Division (GLD), and in 2005 became Associate General Counsel of GLD. In 2013, Jeff became Deputy General Counsel in the Immediate Office.

Departmental Appeals Board



Agency Head, Career Acting Official and Presidential Transition Council Member: Constance B. Tobias
Constance.Tobias@hhs.gov

Constance B. Tobias was appointed as the Chair of the Departmental Appeals Board (DAB) on April 29, 2007. As DAB Chair, Judge Tobias provides leadership to the larger staff organization, which includes three adjudicatory divisions – the Appellate Division, Civil Remedies Division, and Medicare Operations Division. Each Division has its own set of judges and staff as well its own areas of jurisdiction. In addition, Judge Tobias is a member of the Departmental Appeals Board (the Board), which is a Board of judges appointed by the Secretary to conduct appellate review of disputes arising in a wide range of HHS programs and certain types of Administrative Law Judge decisions. Judge Tobias sits on the Medicare Appeals Council, which reviews decisions concerning Medicare entitlement and requests for Medicare payments filed by healthcare providers and beneficiaries.

Under authority granted by the Administrative Dispute Resolution Act of 1996, Judge Tobias serves as the designated Dispute Resolution Specialist, and is responsible for implementing Alternative Dispute Resolution (ADR) across the Department. The DAB's ADR Division provides dispute resolution services in appeals filed with the DAB's three adjudicatory divisions as well as throughout the Department.

Judge Tobias previously served as the Chief Veterans Law Judge on the Board of Veterans' Appeals, Counsel to the Chairman, and as a staff attorney at the Department of Veterans Affairs. She received her J.D. from Cornell University and her Bachelor's Degree from Saint Augustine's College.

**Assistant Secretary for Global Affairs****Agency Head: Jimmy Kolker**

Jimmy.Kolker@hhs.gov

Ambassador Kolker is the Assistant Secretary for Global Affairs at the U.S. Department of Health and Human Services (HHS). In this role, Ambassador Kolker is the Department's chief health diplomat, representing the United States at World Health Organization meetings and as alternate Board Member of the Global Fund to Fight AIDS, Tuberculosis and Malaria.

Amb. Kolker had a 30 year diplomatic career with the U.S. Department of State where he served as the U.S. Ambassador to Uganda (2002-2005) and to Burkina Faso (1999-2002). From 2005-2007, he served as Deputy Global AIDS Coordinator in the Office of the U.S. Global AIDS Coordinator, leading implementation of the President's Emergency Plan for AIDS Relief (PEPFAR). Amb. Kolker was Deputy Chief of Mission at U.S. embassies in Denmark and Botswana and won awards for political reporting at earlier posts in the UK, Sweden, Zimbabwe, and Mozambique. From 2007-2011, prior to joining HHS, Amb. Kolker was Chief of the HIV and AIDS Section at UNICEF's New York headquarters.

Amb. Kolker holds a Master's in Public Administration from Harvard Kennedy School of Government and a B.A. magna cum laude from Carleton College in Minnesota. He was a Thomas J. Watson Foundation Fellow (1970-1971). He speaks French, Swedish, and Portuguese.

**Career Acting Official: Mitchell Wolfe, MD, MPH**

Mitchell.Wolfe@hhs.gov

Mitchell Wolfe, MD, MPH is the Deputy Assistant Secretary for Global Affairs at the U.S. Department of Health and Human Services. In this role he oversees the International Relationship Division of OGA, providing guidance and leadership for OGA's bilateral work, Operations, and supervision of US Health Attaches stationed in India, Brazil, South Africa, China, Mexico and Geneva. Dr. Wolfe manages HHS's governing relationship with the World Health Organization and its regional bodies, providing strategic direction on policy as well as supporting technical input and analysis.

As a member of the US Public Health Service since 1998, Dr. Wolfe has worked at the U.S. Centers for Disease Control and Prevention (CDC) in a number of capacities. From 2004-2014 he was Director of the CDC Thailand Office, Director of the CDC Global AIDS Program Thailand/Asia Regional Office, and Director of the CDC Vietnam Office. Before moving to Asia, Dr. Wolfe served as a medical epidemiologist, and then team leader, for the Clinical Outcomes Team, Behavioral and Clinical Surveillance Branch, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention. Dr. Wolfe joined CDC as an Epidemic Intelligence Service officer with the National Center for Environmental Health.

Dr. Wolfe attended earned a B.A. from the University of California, Santa Barbara; a Masters of Public Health degree from the University of California, Berkeley; and his M.D. from the University of Vermont College of Medicine. He has an American Board Certification in General Preventive Medicine and Public Health.

**Presidential Transition Council Member: Katie Kampf**

Katie.Kampf@hhs.gov

Katie Kampf is Chief of Staff in the Office of Global Affairs (OGA) at the U.S. Department of Health and Human Services. In her role, she serves as a key advisor to the Assistant Secretary for Global Affairs and other senior leadership in the Department, contributing to planning and decision-making on global health policy, program development and management. Katie contributes to management of daily and long-term activities within the Office and manages OGA's relationship with the Immediate Office of the Secretary.

Prior to joining HHS, she worked on the global health team at the Center for Global Development, a DC-based development think tank. There, she focused on antimicrobial drug resistance, family planning and how population policies can be used for poverty reduction at the household level and economic growth at the State level. Katie began her career in global health and development at The Earth Institute at Columbia University. In addition to her time at headquarters in New York, she spent two years working in Rwanda where she helped launch the country's Millennium Villages Project, supported a program focused on health systems management and developed a new project on poverty reduction and economic development at the village level.

Katie is a graduate of Barnard College, Columbia University.

Intergovernmental and External Affairs**Agency Head: Emily Barson**

Emily.Barson@hhs.gov

Emily Barson serves as the Director of Intergovernmental and External Affairs (IEA) at the U.S. Department of Health and Human Services. In this capacity, she provides advice to Secretary Sylvia Burwell on the Department's work with governmental and non-governmental stakeholders across the country. She manages a team of over 70 regional and Washington, DC-based HHS officials and oversees the Department's interactions with State, local, and tribal governments and external partners. She previously served as Principal Deputy Director of IEA, managing day-to-day operations and working closely with the HHS regional directors. Before joining the IEA team, Emily served as the Director of Scheduling and Advance for HHS Secretary Kathleen Sebelius.

Prior to her time at HHS, Emily worked in a variety of roles in the political and non-profit arenas, including at the Democratic National Committee and on congressional, Statewide, and presidential campaigns. Emily graduated from the George Washington University with a Bachelor of Arts in Political Communication. She lives in Washington, DC with her husband Matt Thornton and son Asher.



Career Acting Official and Presidential Transition Council Member: Nikki Bratcher-Bowman

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Mrs. Bowman serves as the Executive Officer of the Office of Intergovernmental and External Affairs (IEA) at the U.S. Department of Health and Human Services. She is responsible for managing and leading IEA's budget and financial resources, human resources, information technology, facilities management, travel programs, contracts and acquisitions, records management, emergency preparedness and safety, and information resources across a geographically dispersed organization. With broad experience in the Federal sector, her work has spanned in operations, human capital, performance optimization, organizational efficiency and effectiveness, and policy. Nikki has been at HHS for the last 25 years and held other positions, including Senior Dispute Resolution Specialist, Labor Relations, Employee Relations Officer, Policy Advisor and Budget Analyst. She is a seasoned collaborative relationship-builder, effective manager, and multi-audience communicator, with experience working in complex organizations and with Federal, State, local and tribal officials and public policy groups. Nikki is a graduate of the Federal Executive Institute and Liberty University.

Office of the Assistant Secretary for Health



Agency Head: Karen DeSalvo, MD, MPH, MSc

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Karen DeSalvo, MD, MPH, MSc, is Acting Assistant Secretary for Health at the U.S. Department of Health and Human Services. She leads development of HHS-wide health policy recommendations, oversees 12 core public health offices, including the Office of the Surgeon General, and 10 regional offices and advisory committees. Dr. DeSalvo also served as the National Coordinator for Health Information Technology, leading the nation's charge to develop an interoperable health IT system. Dr. DeSalvo is the former Health Commissioner in New Orleans and was previously vice dean for community affairs and health policy at Tulane University School of Medicine. She has focused her career on bringing better health and healthcare for everyone with attention to the social determinants of health. Dr. DeSalvo earned her medical degree and Master's in Public Health from Tulane University, and Master's in Clinical Epidemiology from Harvard School of Public Health.



Career Acting Official and Presidential Transition Council Member: Jewel Mullen

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Dr. Jewel Mullen is the Principal Deputy Assistant Secretary for Health at the U.S. Department of Health and Human Services. She fosters collaboration among offices within OASH with the goal of advancing public health. She is the lead liaison for the HHS Regions and advises the Acting Assistant Secretary for Health on a variety of priority public health issues, ranging from research integrity to women's health to health promotion and disease prevention. For the 5 years prior to joining OASH, Dr. Mullen was Commissioner of the Connecticut Department of Public Health. She has served on the medical faculty of New York University, the University of Virginia, Yale and Tufts. In 2014, she was elected President of the Association of State and Territorial Health Officials. Board-



certified in internal medicine, Dr. Mullen received her Bachelor and Master of Public Health degrees from Yale University. She graduated from the Mount Sinai School of Medicine, where she was elected to AOA, the National Medical Honor Society. She did her residency at the Hospital of the University of Pennsylvania. Dr. Mullen also holds a Master in Public Administration degree from Harvard University's John F. Kennedy School of Government.



Surgeon General: Vice Admiral (VADM) Vivek H. Murthy, M.D., M.B.A.
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Vice Admiral Vivek H. Murthy was confirmed on December 15, 2014, as the 19th United States Surgeon General. As "America's Doctor," Dr. Murthy is responsible for communicating the best available scientific information to the public regarding ways to improve personal and public health. He also oversees the operations of the U.S. Public Health Service Commissioned Corps, comprised of approximately 6,700 uniformed health officers who serve in nearly 800 locations around the world to promote, protect, and advance the health and safety of our nation and our world.

After attending Miami Palmetto Senior High School, he received his Bachelor's degree from Harvard and his M.D. and M.B.A. degrees from Yale. He completed his residency training at Brigham and Women's Hospital and Harvard Medical School where he later joined the faculty as an internal medicine physician and instructor. As a clinician-educator, Dr. Murthy has cared for thousands of patients and trained hundreds of residents and medical students. He regards caring for patients as the greatest privilege of his life.

In addition to clinical practice, Dr. Murthy has two decades of experience and perspective improving health in communities around the world. He co-founded VISIONS, an HIV/AIDS education program in India and the United States, which he led for eight years.



Deputy Surgeon General: Rear Admiral (RADM) Sylvia Trent-Adams, Ph.D., R.N., F.A.A.N.
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As Deputy Surgeon General, Rear Admiral (RADM) Sylvia Trent-Adams advises and supports the Surgeon General regarding operations of the U.S. Public Health Service (USPHS) Commissioned Corps and in communicating the best available scientific information to advance the health of the nation. She has served as the Chief Nurse Officer of the USPHS since November 2013. In this role, she advises the Office of the Surgeon General and the U.S. Department of Health and Human Services (HHS) on the recruitment, assignment, deployment, retention, and career development of Corps nurse professionals.

RADM Trent-Adams has held various positions in HHS, working to improve access to care for poor and underserved communities. As a clinician and administrator, she has had a direct impact on building systems of care to improve public health for marginalized populations domestically and internationally.

RADM Trent-Adams received her Bachelor of Science in Nursing from Hampton University, a Master of Science in Nursing and Health Policy from the University of Maryland, Baltimore, and a Doctor of Philosophy from the University of Maryland, Baltimore County. She became a Fellow in the American Academy of Nursing in 2014.

**Assistant Secretary for Planning and Evaluation****Acting Agency Head: Kathryn E. Martin**

Kathryn.Martin@hhs.gov

Katie Martin currently serves as Acting Assistant Secretary for Planning and Evaluation, advising the Secretary on policy development in health, disability, human services, data, and science; and providing advice and analysis on economic. In her previous role, Katie served as a Counselor for Health Policy at HHS, and worked closely with the Centers for Medicare and Medicaid Services, the Office of Medicare Hearings and Appeals, the Office of the National Coordinator for Health Information Technology, the Agency for Healthcare Research and Quality, and the Office for Civil Rights to drive progress across issues as diverse as reducing the Medicare appeals backlog, addressing the healthcare crisis in Puerto Rico, and advancing Delivery System Reform through the annual Medicare payment rules.

Prior to joining HHS, Katie served as Health Insurance Data and Analysis Branch Chief at the Office of Management and Budget during the enactment and implementation of the Affordable Care Act. In addition to ACA implementation, her work at OMB focused on other health reform issues, health-related tax policies, and matters related to both private insurance markets and the Federal Employee Health Benefits Program. Katie has a Master of Public Administration degree from Syracuse University.

**Career Acting Official: Laina Bush**

Laina.Bush@hhs.gov

Laina Bush is the Associate Deputy Assistant Secretary, Science and Data Policy. As such, she serves as a senior manager of the office and leads an expert team of analysts, economists, and strategic planners. She provides executive leadership in policy development, coordination, and leadership for policy research, analysis, evaluation, and planning related to public health, science, and data policy issues such as opioids, food safety and nutrition, drug and medical product safety, availability, and cost and improving data and evidence for decision-making. Laina serves as the HHS or ASPE lead for several interagency working groups.

Laina previously served as the Team Lead for Science Policy. She arrived in ASPE in 1998 as a Senior Food and Drug Policy Analyst. Previously, Laina was an Economist with the Food Drug Administration's Center for Food Safety and Applied Nutrition where she analyzed food safety and nutrition policies. Laina also served on a detail to the Office of Information and Regulatory Affairs, Office of Management and Budget where she reviewed regulations and information collection requests related to immigration, the National School Lunch Program, and the Food Stamp Program. While at OMB, Laina also assisted in preparing a report on the Costs and Benefits of Federal Regulation. Laina earned a BA in Economics and Business Administration from Vanderbilt University and an MBA from Marymount University

**Presidential Transition Council Member: Jennifer C. Burnszynski**

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Jennifer Burnszynski is the Associate Deputy Assistant Secretary for Human Services Policy in ASPE. She leads a team of highly skilled and committed analysts who apply research evidence, policy analysis, and critical thinking to increase the effectiveness of human services policies and programs and improve the well-being of the most vulnerable Americans. She provides executive leadership and coordination for HHS's human services policy development, analysis, research, and evaluation on issues including poverty and self-sufficiency, refugees, vulnerable populations, early childhood education, child welfare, family strengthening, and youth development.

Previously, Jennifer was the first Director of the Division of Program Innovation in the HHS Office of Child Support Enforcement and also served as the Senior Advisor to the Child Support Commissioner, where she helped to lead execution of evidence-based reforms to child support enforcement nationwide. Prior to that, Jennifer worked in ASPE developing child support policy and legislation and leading major child support, fatherhood, and family research. She has also worked at the State and local levels, and holds a M.A. from the Hubert H. Humphrey Institute of Public Affairs at the University of Minnesota.

Office of Medicare Hearings and Appeals**Agency Head and Career Acting Official: Judge Nancy J. Griswold**

Nancy.Griswold@hhs.gov

Judge Nancy J. Griswold was appointed as the OMHA Chief Administrative Law Judge on March 1, 2010. Judge Griswold began her Federal career as an Administrative Law Judge in the Shreveport, Louisiana, Social Security Administration Office of Hearings and Appeals (now the Office of Disability Adjudication and Review) hearing office in June of 1995, and held progressively more responsible positions within the Social Security Administration, as a Hearing Office Chief Administrative Law Judge, Regional Chief Administrative Law Judge, and as the Deputy Chief Administrative Law Judge.

**Presidential Transition Council Member: Judge C.F. (Spike) Moore**

C.F.Moore@hhs.gov

Judge C.F. (Spike) Moore was appointed as the OMHA Deputy Chief Administrative Law Judge on November 6, 2011. Judge Moore began his career as an Administrative Law Judge in the Dallas, TX, Social Security Administration Office of Hearings and Appeals hearing office in January of 1994, and gained extensive management experience with the Social Security Administration as a Hearing Office Chief Administrative Law Judge, an Associate Chief Administrative Law Judge, and as the Acting Deputy Chief Administrative Law Judge. Judge Moore has also served as the



Acting Associate Chief Administrative Law Judge in the OMHA Cleveland Field Office and the OMHA Arlington Field Office.

Office for Civil Rights



Agency Head: Jocelyn Samuels

Jocelyn.Samuels@hhs.gov

Jocelyn Samuels is the Director of the Office for Civil Rights at the United States Department of Health and Human Services. In that capacity, she oversees enforcement of Federal laws that help to ensure non-discrimination and equity in Federally funded health and human services. She also spearheads enforcement of Federal laws that protect the privacy and security of medical information and that ensure that individuals have access to their health records.

Prior to her tenure at the Office for Civil Rights, Ms. Samuels was the Acting Assistant Attorney General for Civil Rights at the United States Department of Justice.

Ms. Samuels also served as Principal Deputy Assistant Attorney General for Civil Rights from 2011 until 2013 and as Senior Counselor to the Assistant Attorney General from 2009 to 2011.

Prior to her service at the Department of Justice, Ms. Samuels was the Vice President for Education and Employment at the National Women's Law Center in Washington, D.C. Her prior experience also includes work as a Labor Counsel to Senator Edward M. Kennedy, then Ranking Member and subsequently Chair of the Senate Committee on Health, Education, Labor and Pensions, and as a senior policy attorney at the Equal Employment Opportunity Commission. Ms. Samuels has additional experience in the private sector and as a law clerk to a Federal judge on the U.S. Court of Appeals for the Ninth Circuit.

Ms. Samuels received her law degree from Columbia University, where she was a Notes Editor of the *Law Review*, and her bachelor's degree from Middlebury College, where she graduated *magna cum laude* and was elected to *Phi Beta Kappa*.



Career Acting Official: Robinsue Frohboese, J.D., Ph.D.

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Dr. Frohboese joined OCR in 2000 as the Principal Deputy Director and, during her tenure with OCR, has served in a variety of leadership positions, including Acting OCR Director during two Administration transitions. She has provided key leadership during OCR's significant expansion of responsibilities as the scope of OCR's traditional civil rights jurisdiction grew to include major new areas, beginning with health privacy and security and, most recently, Section 1557, the non-discrimination provision of the Affordable Care Act, and for a variety of White House special projects for which the Secretary charged OCR as the lead.

Prior to joining OCR, Dr. Frohboese worked for 17 years in the Civil Rights Division's Special Litigation Section at the U.S. Department of Justice, first as a Senior Trial Attorney and then as a Deputy Chief. She has combined her J.D. and Ph.D. in Psychology to address emerging issues throughout her more than 35 years' experience in health-related civil rights enforcement and policy at grassroots, State, and Federal levels.



She began her Federal career working as a Congressional Science Fellow and then staff attorney for the U.S. Senate's Health, Education, Labor, and Pensions Committee.



Presidential Transition Council Member: Steve Novy

Steve.Novy@hhs.gov

Steve Novy is the Deputy Director, Operations and Resources Division (ORD), Office for Civil Rights (OCR), Health and Human Services (HHS). Steve joined the HHS team on October 1, 2007, and served in a variety of leadership positions in the Assistant Secretary for Administration until March 2010, when he became the Affordable Care Act (ACA) Program Manager. In July 2011, he joined the OCR team.

Steve came to HHS from the private sector where he served 5 years as a program manager assisting in the stand-up of United States Northern Command. Prior to entering the private sector, Steve served 30 years in the United States Air Force as a flyer, commander, and staff officer. He retired as the Air Mobility Command Director of Staff in the grade of Colonel. Mr. Novy is a certified Project Management Professional (PMP), completed the Harvard University National Preparedness Leadership Institute, and has a Master of Science in Logistics and Acquisition and a Bachelor of Business Administration from the University of Texas.

Office of the National Coordinator for Health Information Technology



Agency Head: B. Vindell Washington, MD, MHCM, FACEP

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Dr. Vindell Washington is the National Coordinator for Health Information Technology (ONC) and provides high-level executive direction and leadership for ONC programs, operations, and policies and advances key Administration initiatives, such as delivery system reform, the Precision Medicine Initiative, and implementation of the Interoperability Roadmap.

Prior to joining ONC, Dr. Washington served as the President of the Franciscan Missionaries of Our Lady Health System (FMOLHS) Medical Group and as the health system's Chief Medical Information Officer. The FMOL Health System is headquartered in Baton Rouge and has five acute care hospitals and affiliated facilities located throughout Louisiana provide care to 40 percent of the State's population.

Before joining FMOLHS, Dr. Washington served as CEO of Piedmont Healthcare Management Group (PHMG) in Charlotte, North Carolina where he led the development efforts of coding and billing process technologies. PHMG was sold to Anodyne Health, which in turn was acquired by AthenaHealth. Before PHMG, he was president and CEO of Piedmont Emergency Medicine Associates, also located in Charlotte, NC, where he led a 70 provider hospitalist medicine and emergency medicine group.

Dr. Washington received a Bachelor of Science from Pennsylvania State University and a Doctor of Medicine from the University of Virginia. He earned his Master of Science in Healthcare Management from the Harvard University School of Public Health. He is board certified in Emergency Medicine and a Fellow of the American College of Emergency Physicians.

**Career Acting Official: Jon White, M.D.**

Jon.White@hhs.gov

Dr. Jon White, Deputy National Coordinator, is a family physician who has dedicated his career to improving health and healthcare quality through the use and sharing of electronic health information. Dr. White has been working in partnership with the Office of the National Coordinator for Health Information Technology (ONC) since 2004. ONC is at the forefront of the nation's efforts to adopt and meaningfully use health information technology, and achieve health information technology interoperability, as a foundational element of better health for everyone in America.

Before his service at ONC, Dr. White was Director of the Division of Health IT at the Agency for Healthcare Research and Quality (AHRQ), where he continues to provide consultation on select initiatives. In his role at AHRQ, Dr. White directed hundreds of projects in 48 States, including research, demonstration and implementation projects on a wide variety of health IT applications and issues. Dr. White has deep experience working with Federal government partners (including the Centers for Medicare and Medicaid Services and the Department of Veterans Affairs), as well as key healthcare professional, patient, policy, and health IT stakeholder groups to implement major healthcare initiatives.

Dr. White trained in family medicine at the University of Virginia and Lancaster General Hospital in Pennsylvania. He is a recipient of the national AAFP Award for Excellence in Graduate Education.

**Presidential Transition Council Member: Lisa A. Lewis**

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Lisa Lewis, Deputy National Coordinator for Operations and Chief Operating Officer at the Office of the National Coordinator for Health Information Technology (ONC), provides executive oversight for program integrity, budget, grants and contracts management, ethics, human capital, and operational services. Lisa also serves as ONC's Chief Information Officer and served as the Acting Principal Deputy National Coordinator in 2014.

Initially at ONC, Lisa served as the Chief Grants Management Officer, establishing and managing an office responsible for overseeing nearly \$2 billion in grants. Lisa championed innovative approaches to grants management and forged partnerships with program officials to provide a framework for program success and financial accountability. In 2012 and 2014, Lisa received the Secretary's Award for Meritorious Service for her extraordinary efforts in implementing the ONC grant programs.

Before coming to ONC, Lisa served as Director of Grants Management Division within the Federal Emergency Management Agency's (FEMA) Grant Programs Directorate, managing grants policy for FEMA's 56 grant programs, totaling over \$50 billion dollars. In addition, Lisa managed the awarding of 6,000 grants annually and managed close to 20,000 open grants.

Lisa holds a Bachelor of Science degree from the University of Maryland and attended the University of Maryland School of Law.

**Office of Inspector General****Agency Head: Inspector General Daniel R. Levinson**

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Mr. Levinson has headed HHS OIG for over a decade. A lawyer and a certified fraud examiner, Mr. Levinson leads an independent and objective organization of more than 1,500 auditors, evaluators, investigators, and lawyers who oversee the integrity and efficiency of the Nation's one trillion dollar annual investment in Federal health and human services programs. Oversight responsibilities include CMS, ACF, CDC, FDA, and NIH.

Mr. Levinson first entered Federal service in 1983 as Deputy General Counsel of the U.S. Office of Personnel Management. He thereafter served as General Counsel of the U.S. Consumer Product Safety Commission. In 1986, he was appointed by President Reagan to be chairman of the U.S. Merit Systems Protection Board, a bipartisan, quasi-judicial agency that adjudicates Federal civilian personnel appeals. He was appointed by President George W. Bush to be Inspector General of the U.S. General Services Administration beginning in 2001 and of HHS beginning in 2005.

**Career Acting Official: Joanne M. Chiedi, Principal Deputy Inspector General**

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Ms. Chiedi has served as the Principal Deputy Inspector General for HHS OIG since 2013. As the highest ranking career official, she leads an independent and objective organization of more than 1,600 investigators, auditors, evaluators, lawyers, and management professionals, who oversee the integrity and efficiency of the Nation's one trillion dollar investment in Federal health and human services programs. Ms. Chiedi works with stakeholders across the Federal government, private sector, and in Congress, particularly in areas of health care reform and delivery of quality of care, in order to elevate OIG's participation in external partnerships to

increase the effectiveness of government oversight.

From 2010 to 2013, Ms. Chiedi was the Deputy Inspector General for Management and Policy (OMP) at DHHS, and from 2005 to 2010, she was the Deputy Director for Management in the Office for Civil Rights, DHHS.

**Presidential Transition Council Member: Robert F. Owens**

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Mr. Owens is responsible for the administrative functions that support all of OIG, including budget, procurement, facilities, human resources, information technology, external affairs, and data analysis. Mr. Owens joined HHS OIG in February 2011 as an Assistant Inspector General for Management and Policy and the Chief Information Officer. In February 2015, he became the Deputy Inspector General for Management and Policy and the Chief Financial Officer. Mr. Owens brings more than 20 years of Federal management experience from his work at the Department of Justice.

**Assistant Secretary for Preparedness and Response****Agency Head: Nicole Lurie, MD, MSPH, RADM, US Public Health Service**

Nicole.Lurie@hhs.gov

Dr. Lurie is the Assistant Secretary for Preparedness and Response (ASPR) at the US Department of Health & Human Services (HHS). In that capacity, she has had leadership responsibility for multiple events, including H1N1, the Haiti earthquake, the Deepwater Horizon Oil Spill, the Joplin tornado, Superstorm Sandy, mental health responses to mass shootings, and the Boston Marathon bombing, Ebola, Zika, and Louisiana flooding. She is the Lead Federal Official for the Flint Water Crisis.

Previously, Dr. Lurie was Senior Natural Scientist and the Paul O'Neill Alcoa Professor of Health Policy at the RAND Corporation where she directed RAND's public health and preparedness work as well as its Center for Population Health and Health Disparities. She has previously served in leadership positions in both Federal and State government. She is an internationally renowned health services researcher and health policy expert.

Dr. Lurie attended college and medical school at the University of Pennsylvania, and completed her residency and MSPH at UCLA, where she was also a Robert Wood Johnson Foundation Clinical Scholar. She served as Senior Editor for Health Services Research and as President of the Society of General Internal Medicine, as well as on numerous other national committees. She is the recipient of many awards, and is a member of the National Academy of Medicine. Finally, Dr. Lurie continues to practice clinical medicine in the healthcare safety net in Washington, DC.

**Career Acting Official: George Korch**

George.Korch@hhs.gov

George W. Korch, Jr., PhD has served as the Senior Science Advisor to the Assistant Secretary for Preparedness and Response, Health and Human Services (HHS) since 2009. He has also served as the Acting Principal Deputy Assistant Secretary for Preparedness and Response. Dr. Korch currently coordinates and helps oversee the U.S. Government's Public Health Emergency Medical Countermeasures Enterprise at HHS. He has served on a variety of national and governmental committees under the auspices of the White House's National Security Council and the Office of Science and Technology Policy. He is the Co-chair of the Federal Expert Security Advisory Panel to the National Security Staff. Dr. Korch has authored a number of peer-reviewed

journal articles as well as co-authoring a book on medical countermeasures for biodefense. He retired with the rank of Colonel from the U.S. Army Medical Department in 2008, where he had served in a number of leadership roles, including the Commander of the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID). He also has an appointment as a Visiting Professor, Department of Molecular Microbiology and Immunology, The Johns Hopkins Bloomberg School of Public Health.

**Presidential Transition Council Member: Melissa Harvey, R.N., MSPH**

Melissa.Harvey@hhs.gov

Ms. Harvey is the Director of the Division of National Healthcare Preparedness Programs in the Office of the Assistant Secretary for Preparedness and Response (ASPR) at the U.S. Department of Health and Human Services. In this role, she is responsible for developing and advancing the implementation of policies and capabilities that aim to improve the nation's overall healthcare preparedness, including the Hospital Preparedness Program Cooperative Agreement. Recently, Melissa led ASPR's domestic healthcare system response to Ebola, including the development of a new regional and tiered strategy for the nation's healthcare facilities. She previously served as the Special Assistant to the ASPR, advising and supporting the Assistant Secretary on policy development, program

implementation, and disaster response operations to ensure that the Office met its public health emergency preparedness and response mission. Melissa has also served as a Global Health Analyst, preparing assessments of foreign governments' capabilities to detect and respond to emerging infectious diseases, terrorism, and natural disasters. Prior to her work in the United States Government, Melissa was the Program Manager of Emergency Management for the North Shore-LIJ Health System in New York, where she was responsible for all-hazards planning and response operations for the nation's second largest, non-profit, secular healthcare system. She was also an EMT for the Health System's New York City 911 and inter-facility EMS divisions.

Melissa attended Boston College, George Mason University, and Harvard University. She is a Registered Nurse in the Commonwealth of Virginia.



PRESIDENTIAL TRANSITION TEAM MEMBERS



HHS Transition Director: John Gentile
John.Gentile@hhs.gov

John Gentile is a financial management and financial systems executive with over 44 years combined experience in the public and private sectors. Throughout his career John has held positions of increasing responsibilities in the fields of accounting, budgeting and finance. He has over 35 years' experience in building, managing and leading high performing financial operations in large and small organizations. John has also directed the successful implementation of two major, enterprise-wide financial management system projects. In November 2009, Mr. Gentile joined the HHS Office of the Secretary as the Director, Office of the Secretary Budget and the Deputy CFO for the Office of the Secretary within the Assistant Secretary for Financial Resources (ASFR) Office of Budget. In this role John was responsible for the budget formulation and execution for the 17 Staff Divisions that make up the Office of the Secretary. As Deputy CFO John was responsible for the A-123 Internal Control program for the Office of the Secretary and served as the Fund Manager for the HHS Service and Supply Fund, a working capital fund, totaling over \$1 billion.

In August 2014 John moved into the ASFR Immediate Office as a Senior Advisor to the Assistant Secretary for Financial Resources (HHS CFO). In this role John served as the Executive Sponsor for the HHS Oracle Release 12 Upgrade (R12) and the HHS implementation of the Digital Accountability and Transparency Act of 2014 (DATA Act). In March 2015 Mr. Gentile assumed the responsibilities of the Principal Deputy Assistant Secretary for ASFR. In addition to continuing his Executive Sponsorships John also became responsible for the administrative operations for ASFR. During this period the Department successfully completed its upgrade to Oracle Release 12 on time and on budget. The UFMS instance of the R12 upgrade was also successfully migrated to the Oracle Cloud and for the first time a Department-wide Accounting Treatment Manual was written, approved and implemented.



Janis Coughlin-Piester
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Janis serves as the Director for Budget Policy, Execution, and Review in the HHS Office of Budget in ASFR. She is responsible for coordinating and integrating the work of HHS's 11 operating divisions and 16 staff divisions in the formulation and presentation of the HHS budget and performance targets and results; setting HHS-wide policy for budget formulation and execution, including providing technical assistance to Office of Management and Budget and Congressional Appropriations Committees; directing HHS-wide processes to conduct analysis of cross-cutting budget issues, including supplemental funding requests and reallocations of funds; and leading activities related to the implementation of improving program performance and managing Department-wide oversight of the systematic assessments of HHS programs, including the Agency Priority Goals process.

In March 2016, Janis graduated from the HHS SES Career Development Program while Chief, Congressional Liaison Branch in ASFR. Janis served as the HHS lead for conducting an orderly shutdown and reopening during



the September 2013 lapse in appropriations (government shutdown), directing the daily activities of the HHS team tasked with ensuring continued operations of exempt and excepted activities and communications with employees and external stakeholders. Prior to HHS, Janis was a Senior Appropriations Liaison at the U.S. Department of Homeland Security, a Senior Legislative Affairs Analyst at the U.S. Small Business Administration (SBA), the Budget Officer at the SBA Office of the Inspector General, and started her Federal career at the Office of Management and Budget.



Justin D. Hentges

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Justin currently serves as the Senior Advisor for Accountability and Oversight to the Assistant Secretary for Financial Resources (ASFR) at the Department of Health and Human Services. Justin began his Federal career at the National Institutes of Health (NIH) in the Administrative Fellows Program – a two-year administrative leadership training program. He served as a budget analyst for the National Institute of Dental and Craniofacial research and as a program analyst in ASFR Office of Budget. Prior to returning to ASFR, Justin served as a Special Assistant to the NIH Deputy Director.

Justin has a Bachelor of Arts in Political Science and Economics from the University of Wisconsin-Eau Claire and a Master of Public Policy from George Mason University.



Tim Barfield

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As a Management Analyst in the Immediate Office, Assistant Secretary for Financial Resources, Tim provides advice and assistance to all ASFR managers by developing and reviewing management and program-related initiatives to ensure adherence to the methods, principles, and practices of sound organizational management and efficient resource utilization. Tim also provides assistance with the development of formulation, justification, and execution materials, including the allocation of ASFR's funds across its sub-component offices, and monitors budget execution throughout the year, identifying policy decisions and bringing them to the ASFR as appropriate. By serving as the Information Technology Liaison for ASFR, he directs the interaction between ASFR and HHS Office of the Secretary IT operations and ensures that service provider meets their end of Service Level Agreements. Lastly, Tim coordinates support activities (i.e., travel, space, facilities, telecommunications, printing and reproduction, and records management, correspondence control, personal and real property management, timekeeping and payroll, etc.) within ASFR.

Before coming to the Department, Tim served 22 years in the United States Air Force directing, coordinating and monitoring administrative, logistical and IT functions providing Airmen the resources needed to protect the security of our country

**Christine M. Major**

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Christine M. Major currently serves as the Principal Deputy Assistant Secretary (PDAS) for Administration. In this role, Ms. Major supports the Assistant Secretary for Administration portfolio which includes: human resources, equal employment opportunity compliance and operations, information technology, business transformation, security and strategic information, and the HHS Program Support Center (PSC). Ms. Major was designated as the Senior Accountable Official for the 2016 HHS implementation of the SES Reform Executive Order. Ms. Major has over 25 years of experience in the Human Resource field at the National Institutes of Health (NIH) and the Department of Health and Human Services (DHHS). Prior to her role as PDAS, she served as the Director of Human Resources for the National Institutes of Health. Ms. Major directed the activities of five separate divisions and over 300 staff members, comprising the full range of Human Resource functions including recruitment, HR Systems, employee/labor relations, benefits, policy and training and development. Ms. Major holds a Bachelor of Science Degree in Human Resource Management from the University of Maryland.

**Kimberly Cosby**

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Kimberly Cosby serves as a program analyst in the Assistant Secretary for Administration (ASA) Immediate Office. In this role Kimberly is the primary point of contact for ASA communications and various special projects including Senior Executive Service Reform Activities, Executive Officer meetings, HHS Departmental Awards, Office of the Secretary events and interactions, and other high-level assignments. Prior to this position Kimberly served as an assistant to the Department of Health and Human Services Chief Human Capital Officer managing special projects like the HR Directors Strategy Council, HHS GovConnect initiatives, Office of Human Resources new employee onboarding, Office of Personnel Management HR Strategic Review, and other immediate office engagements.

**Valerie Gill**

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Valerie Gill serves as the Senior Advisor in the Office of the Assistant Secretary for Administration (ASA). Prior to joining ASA, she was the Director of Client Services for the National Institutes of Health (NIH) in the Office of Human Resources (HR) from 2008 to 2016. In this role, Valerie had leadership responsibility for a variety of HR functions, including Recruitment, Classification, Pay Setting, and Commissioned Corps programs. She transformed the HR function and provided leadership and direction to HR professionals that served as the first and primary point of contact for leadership, supervisors, and employees in the delivery of HR services. Prior to joining NIH, Valerie spent 17 years in the Intelligence Community supporting the National Geospatial-Intelligence Agency and the Central Intelligence Agency. She holds an undergraduate degree in Business from Towson University and a Master's degree from The George Washington University.

**Jeffrey Davis**

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Jeff Davis is a graduate of Texas A&M University (1977) and the University of Texas School Of Law (1985). He was commissioned as a 2nd Lieutenant in the U.S. Army, Medical Service Corps, in 1977, was later selected to attend law school while on active duty, and spent most of his military career in the Judge Advocate General's Corps, from which he retired as a Lieutenant Colonel in 1998.

Jeff joined HHS OGC in 1998 in what was then the Business and Administrative Law Division as Chief of Administrative Law. He later became the first Deputy Associate General Counsel for Procurement, Fiscal, and Information Law in the General Law Division (GLD), and in 2005 became Associate General Counsel of GLD. In 2013, Jeff became Deputy General Counsel in the Immediate Office.