DEPARTMENT of HEALTH and HUMAN SERVICES

Fiscal Year **2021**

General Departmental Management
Medicare Hearings and Appeals
Office for Civil Rights
National Coordinator for Health Information Technology
Health Insurance Reform Implementation Fund
Nonrecurring Expenses Fund
Service and Supply Fund
Retirement Pay & Medical Benefits for Commissioned Officers
HHS General Provisions

Justification of Estimates for Appropriations Committees

DEPARTMENT OF HEALTH AND HUMAN SERVICES
DEPARTMENTAL MANAGEMENT

	FY 2021	
	FTE	**Budget Authority**
General Departmental Management	857	$347,105,000
PHS Evaluation Set-Aside – Public Health Service Act	138	$73,840,000
GDM Program Level[1]	***995***	***$420,945,000***
Medicare Hearings and Appeals (MHA)[2]		
Office of Medicare Hearings and Appeals (OMHA)	1,245	$172,381,000
Departmental Appeals Board (DAB)	94	$24,000,000
Proposed User Fee Collections – OMHA	0	$1,527,000
Proposed User Fee Collections - DAB	0	$900,000
MHA Program Level	***1,339***	***$198,808,000***
Office for Civil Rights	141	$30,286,000
Office of the National Coordinator for Health IT	164	$50,717,000
Service and Supply Fund	1,262	$0
TOTAL, Departmental Management	**3,901**	**$700,756,000**

[1] The FY 2021 GDM Program level does not include estimated reimbursable budget authority and associated FTE, HCFAC associated FTE, or MACRA PTAC associated FTE unless otherwise indicated.
[2] 2020 and 2021 funding levels for OMHA and DAB represent HHS allocations from the overall MHA appropriation, which are subject to change based on actual incoming appeal receipt levels and statuses of appeal backlogs at each organization

INTRODUCTION

The FY 2021 Congressional Justification is one of several documents that fulfill the Department of Health and Human Services' (HHS) performance planning and reporting requirements. HHS achieves full compliance with the Government Performance and Results Act of 1993 (GPRA) and Office of Management and Budget (OMB) Circulars A-11 and A-136 through the HHS agencies' FY 2020 Congressional Justifications and Online Performance Appendices, the Agency Financial Report, and the HHS Citizens' Report. These documents are available at http://www.hhs.gov/budget.

The FY 2021 Congressional Justifications and accompanying Online Performance Appendices contain the updated FY 2021 Annual Performance Report and FY 2021 Annual Performance Plan. The Agency Financial Report provides fiscal and high-level performance results. The Summary of Performance and Financial Information summarizes key past and planned performance and financial information.

Message from the Principal Deputy Assistant Secretary for Financial Resources

Enclosed, please find the Congressional Justification for Departmental Management activities within the Office of the Secretary. This Budget request represents the Administration's priorities for guiding the Department of Health and Human Services (HHS) to enhance the health and well-being of all Americans by fostering sound, sustained advances in the sciences underlying medicine, public health, and social services.

The Budget request supports the Secretary in his role as chief policy officer and general manager of HHS. The FY 2021 request totals $701 million to support:

- The Office of the Assistant Secretary for Health (OASH) coordinates *Ending the HIV Epidemic: A Plan for America* initiative, leads Department-wide efforts to combat the opioids crisis, the rise in tick-borne illness, and oversees the Office of the Surgeon General and the U.S. Public Health Service Commissioned Corps modernization;
- The Office of Women's Health (OWH) in OASH leads the Coordinating Committee on Women's Health, which works to reduce maternal mortality and morbidity through the *Improving Maternal Health Initiative*;
- The Kidney Innovation Accelerator (KidneyX) advances innovation in the prevention, diagnosis, and treatment of kidney disease by establishing partnerships and administering a series of prize competitions aimed at attracting entrepreneurs and innovators to develop breakthrough therapies and diagnostics, including the development of a truly artificial kidney;
- HHS supports the President's Management Agenda through ReImagine HHS, the Department's robust reform and transformation effort, organized around core goals to streamline processes, reduce burden, and realize cost savings. OMB pre-designated HHS as the Grants Quality Services Management Office (QSMO) to create and manage a marketplace of solutions for grants management; govern its long-term sustainability; institute a customer engagement model; and drive the implementation of standards and solutions to modernize grants management processes and systems;
- The Artificial Intelligence (AI) oversight committee will address AI investments and identify best opportunities for the use of Department-wide funding to pursue five pillars: Research and Development, Standards and Resources, Workforce, Governance and International Engagement;
- The Office of Medicare Hearings and Appeals (OMHA) and Departmental Appeals Board (DAB) expands support with congressionally merging funds for the two offices to maximize progress to reduce the Medicare appeals backlog;

- The Office for Civil Rights (OCR), the Department's chief law enforcer and regulator of civil rights, conscience, and religious freedom, and health information privacy and security; and
- The Office of the National Coordinator for Health IT (ONC) leadership of the government's efforts to ensure that electronic health information is available to improve the health and care of all Americans and their communities.

The Secretary looks forward to working with the Congress toward the enactment and implementation of the FY 2021 Budget.

Jen Moughalian
Principal Deputy Assistant Secretary for Financial Resources

Departmental Management Overview

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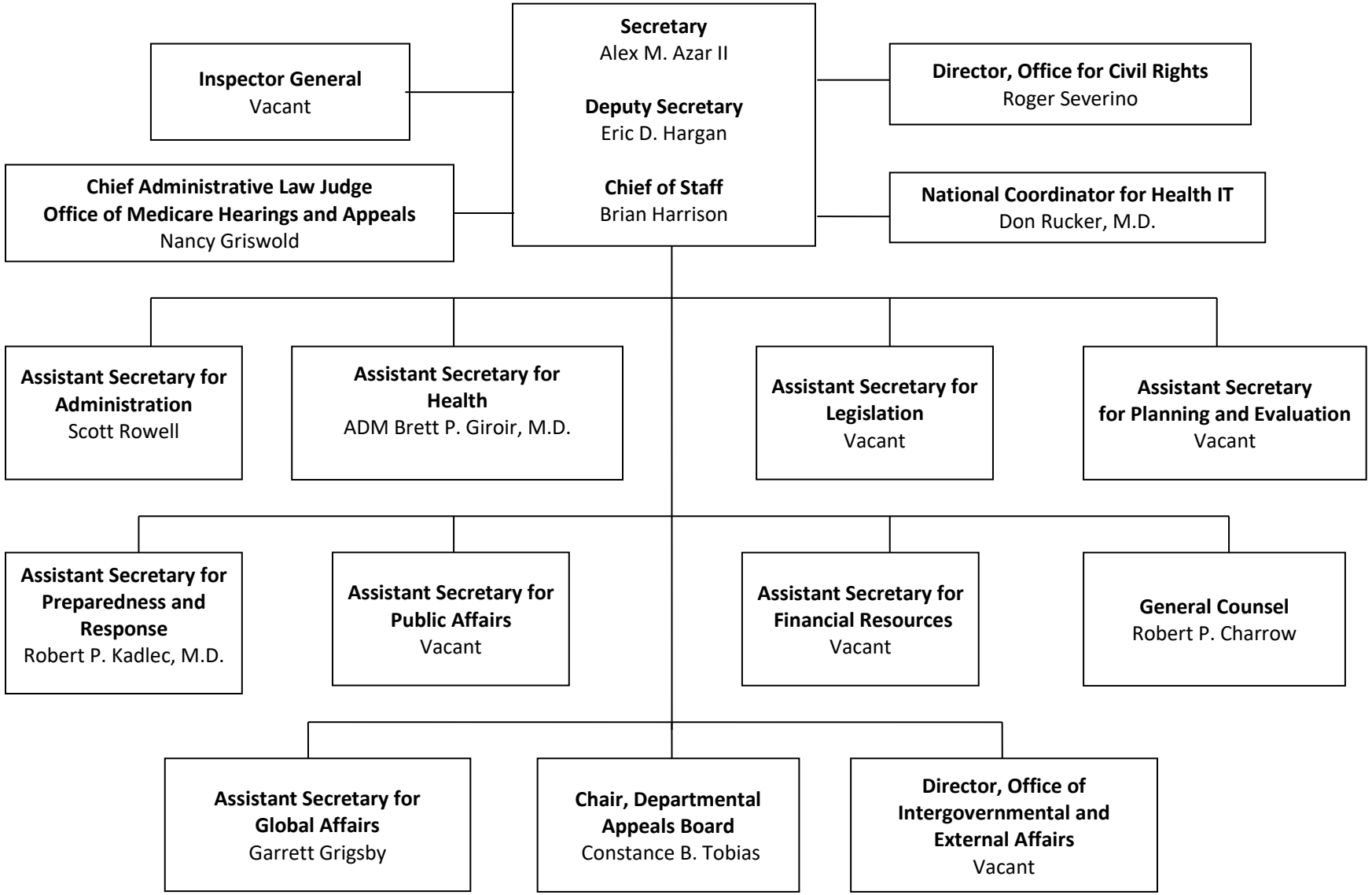
DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF THE SECRETARY



ORGANIZATIONAL CHART: TEXT VERSION

Department of Health and Human Services

- Secretary Alex M. Azar II
  - Deputy Secretary Eric D. Hargan
  - Chief of Staff Brian Harrison

The following offices report directly to the Secretary:

- Inspector General
  - Vacant
- Chief Administrative Law Judge of the Office of Medicare Hearings and Appeals
  - Nancy Griswold
- Director of the Office for Civil Rights
  - Roger Severino
- National Coordinator for Health Information Technology
  - Don Rucker, M.D.
- Assistant Secretary for Administration
  - Scott Rowell
- Assistant Secretary for Health
  - ADM Brett P. Giroir. M.D.
- Assistant Secretary for Legislation
  - Vacant
- Assistant Secretary for Planning and Evaluation
  - Vacant
- Assistant Secretary for Preparedness and Response
  - Robert Kadlec, M.D.
- Assistant Secretary for Public Affairs
  - Vacant
- Assistant Secretary for Financial Resources
  - Vacant
- General Counsel
  - Robert P. Charrow
- Assistant Secretary for Global Affairs
  - Garrett Grigsby
- Chief of the Departmental Appeals Board
  - Constance B. Tobias
- Director of the Office of Intergovernmental and External Affairs
  - Vacant

DEPARTMENTAL MANAGEMENT OVERVIEW

Departmental Management (DM) is a consolidated display that includes the Office of the Secretary (OS) activities funded under the following accounts:

- General Departmental Management (appropriation);
- Medicare Hearings and Appeals (appropriation);
- Office for Civil Rights (appropriation);
- Office of the National Coordinator for Health Information Technology (appropriation);
- Service and Supply Fund (revolving fund); and

The mission of the OS is to provide support and assistance to the Secretary in administering and overseeing the organization, programs, and activities of the Department of Health and Human Services.

The overall FY 2021 President's Budget request for DM totals $700,756,000 in program level funding, including 3,901 full-time equivalent (FTE) positions, a decrease of $134,747,000 below the FY 2020 Enacted Level.

The **General Departmental Management (GDM)** appropriation supports the activities associated with the Secretary's responsibilities as chief policy officer and general manager of the Department in administering and overseeing the organization, programs, and activities of HHS. These activities are carried out through eleven Staff Divisions (STAFFDIVs), including the Immediate Office of the Secretary, the Departmental Appeals Board, and the offices of public affairs, legislation, planning and evaluation, financial resources, administration, intergovernmental and external affairs, general counsel, global affairs, and the assistant Secretary for Health. The FY 2021 President's Budget program level request for GDM includes a total of $420,945,000 and 995 FTE.

Medicare Hearings and Appeals (MHA) The FY 2021 President's Budget adopts the new FY 2020 appropriations language and requests $196,381,000 in discretionary budget authority for the "Medicare Hearings and Appeals" appropriation from which the Office of Medicare Hearings and Appeals (OMHA) is allocated $172,381,000 and Departmental Appeals Board (DAB) is allocated $24,000,000. These allocations are subject to change based on actual incoming appeal receipt levels and statuses of appeal backlogs at each level. An additional $1,527,000 and $900,000 is proposed for user fees to address OMHA and DAB administrative costs, respectively. Overall, this funding enables OMHA and DAB to increase adjudication capacity and reduce the backlog of appeals.

The **Office for Civil Rights (OCR)** is the Department's chief enforcer and regulator of civil rights, conscience, and religious freedom, and health information privacy and security. The FY 2021 President's Budget request for OCR is $30,286,000 in budget authority and 141 FTE. The Budget supports OCR's essential programmatic focus as the primary defender of the public's right to nondiscriminatory access to, and receipt of, HHS-funded and conducted health and human services, conscience and religious freedom protections, and access, privacy, and security protections for individually identifiable health information. To carry out these functions, OCR investigates complaints, enforces rights, develops policy, promulgates regulations, and provides technical assistance and public education to ensure understanding of, and compliance with, non-discrimination and health information privacy laws.

The **Office of the National Coordinator for Health Information Technology (ONC)** was established by Executive Order 13335 on April 27, 2004, and subsequently authorized by the Health Information Technology for Economic and Clinical Health Act on February 17, 2009. The FY 2021 President's Budget request for ONC is $50,717,000 and 164 FTE, to coordinate national efforts related to the implementation and use of interoperable electronic health information exchange. ONC leads the government's efforts to ensure that electronic health information is available and can be shared safely and securely to improve the health and care of all Americans and their communities. ONC's work is pivotal to achieving interoperability, encouraging market competition, advancing patient access to their electronic records, combating information blocking, and bringing innovative easy-to-use products into the hands of users.

The **Service and Supply Fund** (SSF), the HHS revolving fund, is composed of two components: the Program Support Center (PSC) and the Non-PSC activities. For the FY 2021 President's Budget request, the SSF is projecting total revenue of $1,385,164 and usage of 1,262 FTE.

DEPARTMENTAL MANAGEMENT
BUDGET BY APPROPRIATION
(Dollars in thousands)

Details	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget
General Departmental Management [1]	484,226	479,629	347,105
PHS Evaluation Funds	64,828	64,828	73,840
Pregnancy Assistance Fund	25,000	-	-
Subtotal, GDM Program Level	**574,054**	**544,457**	**420,945**
Medicare Hearings and Appeals			
Office of Medicare Hearings and Appeals	182,381	172,381	172,381
Departmental Appeals Board	-	19,500	24,000
Proposed User Fee (OMHA) [2]	-		1,527
Proposed User Fee (DAB) [3]	-		900
Subtotal, MHA Program Level	**182,381**	**191,881**	**198,808**
Office for Civil Rights	**38,667**	**38,798**	**30,286**
Office of the National Coordinator for Health Information Technology	**60,163**	**60,367**	**50,717**
Total, Departmental Management	**855,396**	**835,503**	**700,756**

[1] The FY 2021 GDM Program level does not include estimated reimbursable budget authority and associated FTE, HCFAC associated FTE, or MACRA PTAC associated FTE unless otherwise indicated.

[2]The proposed user fee collections for the Office of Medicare Hearings and Appeals represent a proposal that creates a post-adjudication user fee applied to all unfavorable appeals (other than beneficiary appeals) at the third and fourth levels of appeal.

[3]The proposed user fee collections for Departmental Appeals Board represent a proposal that creates a post-adjudication user fee applied to all unfavorable appeals (other than beneficiary appeals) at the third and fourth levels of appeal.

General Departmental Management

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APPROPRIATION HISTORY TABLE

Fiscal Year	Details	Budget Estimates to Congress	House Allowance	Senate Allowance	Appropriations
2012	Appropriation	$363,644,000	$343,280,000	$476,221,000	$475,221,000
	Rescission	-	-	-	($898,000)
	Transfers	-	-	-	($70,000)
	Subtotal	***$363,644,000***	***$343,280,000***	***$476,221,000***	***$474,253,000***
2013	Appropriation	$306,320,000	-	$466,428,000	$474,323,000
	Rescission	-	-	-	($949,000)
	Sequestration	-	-	-	($23,861,000)
	Transfers	-	-	-	($2,112,000)
	Subtotal	***$306,320,000***	***-***	***$466,428,000***	***$447,401,000***
2014	Appropriation	$301,435,000	-	$477,208,000	$458,056,000
	Transfers	-	-	-	($1,344,000)
	Subtotal	***$301,435,000***	***-***	***$477,208,000***	***$456,712,000***
2015	Appropriation	$278,800,000	-	$442,698,000	$448,034,000
	Subtotal	***$278,800,000***	***-***	***$442,698,000***	***$448,034,000***
2016	Appropriation	$286,204,000	$361,394,000	$301,500,000	$456,009,000
	Transfers	-	-	-	($516,000)
	Subtotal	***$286,204,000***	***$361,394,000***	***$301,500,000***	***$455,493,000***
2017	Appropriation	$478,812,000	$365,009,000	$444,919,000	$460,629,000
	Transfers	-	-	-	($1,050,000)
	Subtotal	***$478,812,000***	***$365,009,000***	***$444,919,000***	***$459,579,000***
2018	Appropriation	$304,501,000	$292,881,000	$470,629,000	$470,629,000
	Rescission	-	-	-	($3,128,000)
	Transfers	-	-	-	($1,141,000)
	Subtotal	***$304,501,000***	***$292,881,000***	***$470,629,000***	***$466,360,000***
2019	Appropriation	$289,545,000	$379,845,000	$480,629,000	$480,629,000
	Transfers	-	-	-	$3,597,121
	Subtotal	***$289,545,000***	***$379,845,000***	***$480,629,000***	***$484,226,121***
2020	Appropriation	$339,909,000	$485,169,000	$490,879,000	$479,629,000
	Subtotal	***$339,909,000***	***$485,169,000***	***$490,879,000***	***$479,629,000***
2021	Appropriation	$347,105,000	-	-	-
	Subtotal	***$347,105,000***	***-***	***-***	***-***

APPROPRIATIONS LANGUAGE
GENERAL DEPARTMENTAL MANAGEMENT

For necessary expenses, not otherwise provided, for general departmental management, including hire of six passenger motor vehicles, and for carrying out titles III, XVII, XXI, and section 229 of the PHS Act, the United States-Mexico Border Health Commission Act, and *to carry out health or human services research and evaluation activities, including such activities that are similar to activities carried out by other components of HHS[*research studies under section 1110 of the Social Security Act**]**, **[**$479,629,000**]***$347,105,000*, together with **[**$64,828,000**]***$73,840,000* from the amounts available under section 241 of the PHS Act [to carry out national health or human services research and evaluation activities:**]** Provided, That of this amount, $53,900,000 shall be for minority AIDS prevention and treatment activities:**[**Provided further, That of the funds made available under this heading, $101,000,000 shall be for making competitive contracts and grants to public and private entities to fund medically accurate and age appropriate programs that reduce teen pregnancy and for the Federal costs associated with administering and evaluating such contracts and grants, of which not more than 10 percent of the available funds shall be for training and technical assistance, evaluation, outreach, and additional program support activities, and of the remaining amount 75 percent shall be for replicating programs that have been proven effective through rigorous evaluation to reduce teenage pregnancy, behavioral risk factors underlying teenage pregnancy, or other associated risk factors, and 25 percent shall be available for research and demonstration grants to develop, replicate, refine, and test additional models and innovative strategies for preventing teenage pregnancy**][**: Provided further, That of the amounts provided under this heading from amounts available under section 241 of the PHS Act, $6,800,000 shall be available to carry out evaluations (including longitudinal evaluations) of teenage pregnancy prevention approaches:**][** Provided further, That of the funds made available under this heading, $35,000,000 shall be for making competitive grants which exclusively implement education in sexual risk avoidance (defined as voluntarily refraining from non-marital sexual activity): Provided further, That funding for such competitive grants for sexual risk avoidance shall use medically accurate information referenced to peer-reviewed publications by educational, scientific, governmental, or health organizations; implement an evidence-based approach integrating research findings with practical implementation that aligns with the needs and desired outcomes for the intended audience; and teach the benefits associated with self-regulation, success sequencing for poverty prevention, healthy relationships, goal setting, and resisting sexual coercion, dating violence, and other youth risk behaviors such as underage drinking or illicit drug use without normalizing teen sexual activity: Provided further, That no more than 10 percent of the funding for such competitive grants for sexual risk avoidance shall be available for technical assistance and administrative costs of such programs**][**: Provided further, That funds provided in this Act for embryo adoption activities may be used to provide to individuals adopting embryos, through grants and other mechanisms, medical and administrative services deemed necessary for such adoptions**][**: Provided further, That such services shall be provided consistent with 42 CFR 59.5(a)(4)**]**: Provided further, That of the funds made available under this heading, **[**$5,000,000**]***$2,000,000* shall be for carrying out prize competitions sponsored by the Office of the Secretary to accelerate innovation in the prevention, diagnosis, and treatment of kidney diseases (as authorized by section 24 of the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3719)).

LANGUAGE ANALYSIS

Language Provisions	Explanation
[$479,629,000**]***$347,105,000*, together with **[**$64,828,000**]** *$73,840,000*	Update to amounts to be appropriated for GDM and PHS evaluation.
[*Provided further*, That of the funds made available under this heading, $101,000,000 shall be for making competitive contracts and grants to public and private entities to fund medically accurate and age appropriate programs that reduce teen pregnancy and for the Federal costs associated with administering and evaluating such contracts and grants, of which not more than 10 percent of the available funds shall be for training and technical assistance, evaluation, outreach, and additional program support activities, and of the remaining amount 75 percent shall be for replicating programs that have been proven effective through rigorous evaluation to reduce teenage pregnancy, behavioral risk factors underlying teenage pregnancy, or other associated risk factors, and 25 percent shall be available for research and demonstration grants to develop, replicate, refine, and test additional models and innovative strategies for preventing teenage pregnancy:**]**	The FY 2021 President's Budget does not make amounts available for Teen Pregnancy Prevention.
[*Provided further*, That of the amounts provided under this heading from amounts available under section 241 of the PHS Act, $6,800,000 shall be available to carry out evaluations (including longitudinal evaluations) of teenage pregnancy prevention approaches:**]**	The FY 2021 President's Budget does not make amounts available for PHS Act Teen Pregnancy Prevention evaluations.
[*Provided further*, That of the funds made available under this heading, $35,000,000 shall be for making competitive grants which exclusively implement education in sexual risk avoidance (defined as voluntarily refraining from non-marital sexual activity): *Provided further*, That funding for such competitive grants for sexual risk avoidance shall use medically accurate information referenced to peer-reviewed publications by educational, scientific,	The FY 2021 President's Budget does not make amounts available for Sexual Risk Avoidance.

governmental, or health organizations; implement an evidence-based approach integrating research findings with practical implementation that aligns with the needs and desired outcomes for the intended audience; and teach the benefits associated with self-regulation, success sequencing for poverty prevention, healthy relationships, goal setting, and resisting sexual coercion, dating violence, and other youth risk behaviors such as underage drinking or illicit drug use without normalizing teen sexual activity: *Provided further*, That no more than 10 percent of the funding for such competitive grants for sexual risk avoidance shall be available for technical assistance and administrative costs of such programs:**]**	
[*Provided further*, That funds provided in this Act for embryo adoption activities may be used to provide to individuals adopting embryos, through grants and other mechanisms, medical and administrative services deemed necessary for such adoptions:**]**	The FY 2021 President's Budget does not make amounts available for Embryo adoption activities.
Provided further, That of the funds made available under this heading, **[**$5,000,000**]***$2,000,000* shall be for carrying out prize competitions sponsored by the Office of the Secretary to accelerate innovation in the prevention, diagnosis, and treatment of kidney diseases (as authorized by section 24 of the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3719)).	Update to amount to be appropriated for Kidney Innovation Accelerator.

AUTHORIZING LEGISLATION

(Dollars in thousands)

Details	FY 2020 Authorized	FY 2020 Enacted	FY 2021 Authorized	FY 2021 President's Budget
General Departmental Management (GDM)				
Reorganization Plan No. 1 of 1953 (Federal Funds – OASH-Kidney)	Permanent	$155,643	Permanent	$161,393
P.L. 116-94, Further Consolidated Appropriations Act, 2020 (Embryo, MAIF, TPP, Kidney, SRA)	Indefinite	$195,900	Indefinite	$55,900
Subtotal, GDM Appropriation		***$351,543***		***$217,293***
Office of the Assistant Secretary for Health (OASH)				
Public Health Service Act, Title III, Section 301 (OASH) (Above Federal Funds –DHPA-AOH)	Permanent	$27,440	Permanent	$29,608
Public Health Service Act, Title, II, Section 229 (OWH)	Expired 2014	$33,640	Expired 2014	$33,640
Public Health Service Act, Title XVII, Section 1701 (DPHP)	Expired 2002	$7,894	Expired 2002	$7,894
Public Health Service Act, Title XVII, Section 1707 (OMH)	Expired 2016	$58,670	Expired 2016	$58,670
Public Health Service Act, Title XVII, Section 1708 (OAH)	Expired 2000	$442	Expired 2000	$0
Subtotal, OASH		***$128,086***		***$129,812***
Total GDM Appropriation		**$479,629**		**$347,105**

APPROPRIATIONS NOT AUTHORIZED BY LAW

Program	Last Year of Authorization	Authorization Level	Appropriations in Last Year of Authorization	Appropriations in FY 2021
GDM	-	-	-	-
Acquisition Reform	2019	-	$ 1,750,000	-
Embryo Adoption Awareness Campaign	2020	-	$ 1,000,000	-
Teen Pregnancy Prevention Initiative	2020	-	$ 101,000,000	-
Sexual Risk Avoidance	2020	-	$ 35,000,000	-
Teen Pregnancy Prevention (Evaluation)	2020	-	$ 6,800,000	-
Related Funding	-	-	-	-
Pregnancy Assistance Fund	2019	-	$ 25,000,000	-

AMOUNTS AVAILABLE FOR OBLIGATION

Detail	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget
Annual appropriation	$480,629,000	$479,629,000	$347,105,000
-	-	-	-
Transfer of funds to UAC	-1,402,879	-	-
Transfer of funds from the Centers for Medicare and Medicaid Services	$5,000,000	-	-

SUMMARY OF CHANGES

(Dollars in Thousands)

Budget Year and Type of Authority	Dollars	FTE
FY 2020 Enacted Level	479,629	890
Total Adjusted Budget Authority	479,629	890
FY 2021 Current Request	347,105	857
Total Estimated Budget Authority	347,105	857
Net Changes	-132,524	-33

Increases	FY 2020 Enacted Level	FY 2021 Request Change from Base
Departmental Appeals Board	4,500	1,500
Rent, Operations, Maintenance, and Related Services	15,464	3,125
Shared Operating Expenses – Overhead	10,628	1,125
Non-OASH GDM*	125,051	-
OASH PPAs	146,210	-
OASH **	35,776	1,726
Total	**337,629**	**7,476**

*Non-OASH GDM does not include DAB, Rent, and Shared Operating Expenses

**OASH includes increases in the Immediate Office only

Decreases	FY 2020 Enacted Level	FY 2021 Request Change from Base
Kidney X	5,000	-3,000
Teen Pregnancy Prevention	101,000	-101,000
Embryo Adoption Awareness Campaign	1,000	-1,000
Sexual Risk Avoidance	35,000	-35,000
Total	**142,000**	**-140,000**

Total Changes	FY 2020 Enacted Level	FY 2020 Enacted FTE	FY 2021 Request Change from Base	FY 2021 FTE Change from Base
Total Increase Changes	337,629	-	+7,476	-33
Total Decrease Changes	142,000	-	-140000	-
Total	**479,629**	**890**	**-132,524**	**857**

BUDGET AUTHORITY BY ACTIVITY - DIRECT

(Dollars in Thousands)

General Departmental Management	FY 2019 FTE	FY 2019 Final	FY 2020 FTE	FY 2020 Enacted	FY 2021 FTE	FY 2021 President's Budget
Immediate Office of the Secretary	73	14,200	86	14,200	86	14,200
Assistant Secretary for Legislation	25	4,100	27	4,100	27	4,100
Assistant Secretary for Public Affairs	39	8,408	52	8,408	52	8,408
Departmental Appeals Board	60	17,250	17	4,500	24	6,000
Office of the General Counsel	143	31,100	143	31,100	143	31,100
Assistant Secretary for Financial Resources	143	32,485	153	30,735	149	30,735
Acquisition Reform	3	1,750	-	-	-	-
Rent, Operations, Maintenance, and Related Services	-	14,589	-	15,464	-	18,589
Center for Faith Opportunities and Initiatives	5	1,299	5	1,299	5	1,299
Office of Intergovernmental and External Affairs	53	10,625	61	10,625	59	10,625
Assistant Secretary for Administration	68	16,558	74	16,558	63	16,558
Office of Global Affairs	20	6,026	20	6,026	20	6,026
Shared Operating Expenses	-	9,330	-	10,628	-	11,753
Secretarial Initiatives and Innovations	-	2,000	-	2,000	-	2,000
Kidney X	-	-	1	5,000	1	2,000
Office of the Assistant Secretary for Health	136	35,776	134	35,776	128	37,502
Total, GDM Federal Funds	***768***	***205,496***	***773***	***196,419***	***757***	***200,895***
-	-	-	-	-	-	-
GDM PPAs:	-	-	-	-	-	-
Teen Pregnancy Prevention	16	100,562	17	101,000	-	-
Embryo Adoption Awareness Campaign	-	996	-	1,000	-	-
Minority HIV/AIDS Fund	1	53,900	1	53,900	1	53,900
Office of Minority Health	40	56,424	57	58,670	57	58,670
Office on Women's Health	36	32,001	43	33,640	43	33,640
Sexual Risk Avoidance	-	34,848	-	35,000	-	-
Total, PPAs	***93***	***278,731***	***118***	***283,210***	***101***	***146,210***
-	-	-	-	-	-	-
Total, GDM Discretionary Budget Authority	**861**	**484,226**	**890**	**479,629**	**857**	**347,105**

BUDGET AUTHORITY BY OBJECT CLASS – DIRECT

(Dollars in Thousands)

Object Class Code	Description	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget
11.1	Full-time permanent	83,267	90,289	87,254
11.3	Other than full-time permanent	4,090	3,390	3,351
11.5	Other personnel compensation	2,183	1,619	1,603
11.7	Military personnel	2,357	2,094	2,360
Subtotal	***Personnel Compensation***	***91,897***	***97,392***	***94,568***
12.1	Civilian personnel benefits	25,839	30,411	29,513
12.2	Military benefits	863	797	862
13.0	Benefits for former personnel	-	-	
Total	***Pay Costs***	***118,599***	***128,600***	***124,944***
21.0	Travel and transportation of persons	4,294	4,322	4,295
22.0	Transportation of things	134	134	133
23.1	Rental payments to GSA	20,704	21,965	22,269
23.3	Communications, utilities, and misc. charges	1,448	1,478	1,481
24.0	Printing and reproduction	700	696	691
25.1	Advisory and assistance services	22,462	20,089	17,312
25.2	Other services from non-Federal sources	37,073	27,260	29,610
25.3	Other goods and services from Federal sources	126,385	123,555	87,673
25.4	Operation and maintenance of facilities	5,006	4,997	5,693
25.5	Research and development contracts	-	-	
25.6	Medical care	-	-	
25.7	Operation and maintenance of equipment	2,371	2,372	2,397
25.8	Subsistence and support of persons	125	125	126
26.0	Supplies and materials	985	965	965
31.0	Equipment	1,394	1,390	1,373
32.0	Land and Structures	-	-	
41.0	Grants, subsidies, and contributions	142,538	141,675	48,137
42.0	Insurance claims and indemnities	2	2	2
44.0	Refunds	5	5	5
Total	***Non-Pay Costs***	***365,627***	***351,029***	***222,161***
Total	**Budget Authority by Object Class**	**484,226**	**479,629**	**347,105**

BUDGET AUTHORITY BY OBJECT CLASS – REIMBURSABLE

(Dollars in Thousands)

Object Class Code	Description	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget
11.1	Full-time permanent	48,000	48,400	48,600
11.3	Other than full-time permanent	-	-	-
11.5	Other personnel compensation	-	-	-
11.7	Military personnel	1,500	1,540	1,340
Subtotal	***Personnel Compensation***	***49,500***	***49,940***	***49,940***
12.1	Civilian personnel benefits	13,000	13,400	13,480
12.2	Military benefits	550	560	480
13.0	Benefits for former personnel			-
Total	***Pay Costs***	***63,050***	***63,900***	***63,900***
21.0	Travel and transportation of persons	1,000	1,000	1,000
22.0	Transportation of things	-	-	-
23.1	Rental payments to GSA	6,000	6,000	6,000
23.3	Communications, utilities, and misc. charges	-	-	-
24.0	Printing and reproduction	-	-	-
25.1	Advisory and assistance services	29,000	29,000	29,000
25.2	Other services from non-Federal sources	18,000	18,000	18,000
25.3	Other goods and services from Federal sources	116,800	115,950	115,950
25.4	Operation and maintenance of facilities	3,000	3,000	3,000
25.5	Research and development contracts	-	-	-
25.6	Medical care	-	-	-
25.7	Operation and maintenance of equipment	5,000	5,000	5,000
25.8	Subsistence and support of persons			-
26.0	Supplies and materials			-
31.0	Equipment	1,000	1,000	1,000
32.0	Land and Structures			-
41.0	Grants, subsidies, and contributions	3,000	3,000	3,000
42.0	Insurance claims and indemnities			-
44.0	Refunds			-
Total	***Non-Pay Costs***	***182,800***	***181,950***	***181,950***
Total	**Budget Authority by Object Class**	**245,850**	**245,850**	**245,850**

SALARIES AND EXPENSES

(Dollars in Thousands)

Object Class Code	Description	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget
11.1	Full-time permanent	83,267	90,289	87,254
11.3	Other than full-time permanent	4,090	3,390	3,351
11.5	Other personnel compensation	2,183	1,619	1,603
11.7	Commissioned Corps personnel	2,357	2,094	2,360
Subtotal	***Personnel Compensation***	***91,897***	***97,392***	***94,568***
12.1	Civilian personnel benefits	25,839	30,411	29,513
12.2	Commissioned Corps benefits	863	797	862
13.0	Benefits for former personnel	-	-	-
Total	***Pay Costs***	***118,599***	***128,600***	***124,944***
21.0	Travel and transportation of persons	4,294	4,322	4,295
22.0	Transportation of things	134	134	133
23.3	Communications, utilities, and misc. charges	1,448	1,478	1,481
24.0	Printing and reproduction	700	696	691
25.1	Advisory and assistance services	22,462	20,089	17,312
25.2	Other services from non-Federal sources	37,073	27,260	29,610
25.3	Other goods and services from Federal sources	126,385	123,555	87,673
25.4	Operation and maintenance of facilities	5,006	4,997	5,693
25.5	Research and development contracts	-	-	-
25.6	Medical care	-	-	-
25.7	Operation and maintenance of equipment	2,371	2,372	2,397
25.8	Subsistence and support of persons	125	125	126
Subtotal	***Other Contractual Services***	***199,998***	***185,027***	***149,410***
26.0	Supplies and materials	985	965	965
Subtotal	***Non-Pay Costs***	***200,984***	***185,992***	***150,375***
Total	***Salary and Expenses***	***319,583***	***314,592***	***275,319***
23.1	Rental payments to GSA	20,704	21,965	22,269
Total	**Salaries, Expenses, and Rent**	**340,287**	**336,557**	**297,588**
Total	**Direct FTE**	**861**	**890**	**857**

GENERAL DEPARTMENTAL MANAGEMENT

ALL PURPOSE TABLE

(Dollars in Thousands)

GDM	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget	FY 2021 +/- FY 2020
Budget Authority	**484,226**	**479,629**	**347,105**	**-132,524**
Related Funding				
PHS Evaluation Set-Aside – Public Health Service Act	64,828	64,828	73,840	+9,012
Program Level	**549,054**	**544,457**	**420,945**	**-123,512**
FTE	**987**	**1,019**	**995**	**-24**

GENERAL DEPARTMENTAL MANAGEMENT

Overview of Performance

The General Departmental Management (GDM) supports the Secretary in his role as chief policy officer and general manager of HHS in administering and overseeing the organizations, programs and activities of the Department.

The Office of the Assistant Secretary for Health (OASH) is the largest single STAFFDIV within GDM, managing thirteen cross-cutting program offices, coordinating public health policy and programs across HHS operating and staff divisions (OPDIVs/STAFFDIVs), and ensuring the health and well-being of Americans.

The FY 2021 President's Budget reflects decisions to streamline performance reporting and improve HHS performance-based management. In accordance with this process GDM STAFFDIVs have focused on revising measures that depict the main impact or benefit of the program and support the rationale articulated in the budget request. This approach is reflected in the Department's Online Performance Appendix (OPA). The OPA focuses on key HHS activities, and includes performance measures that link to the HHS Strategic Plan for three GDM offices. They are Immediate Office of the Secretary (IOS), Offices of the Assistant Secretary for Administration (ASA), and Office of the Assistant Secretary for Health (OASH).

The FY 2021 President's Budget includes individual program narratives that describe accomplishments for most of the GDM components. The justification also includes performance tables that provide performance data for specific GDM components: ASA, IOS, OASH, and the Departmental Appeals Board (DAB).

OVERVIEW OF BUDGET REQUEST

The FY 2021 President's Budget for General Departmental Management (GDM) includes $347,105,000 in appropriated funds and 857 full-time equivalent (FTE) positions. This request is -$132,524,000 below FY 2020 Enacted.

The GDM appropriation supports activities associated with the Secretary's roles as chief policy officer and general manager of the Department. This justification includes narrative sections describing the activities of each Staff Division funded under the GDM account, including the Rent and Common Expenses accounts. This justification also includes selected performance information.

Departmental Appeals Board (+$1,500,000) – The FY 2021 President's Budget request is $6,000,000 which is $1,500,000 above the FY 2020 Enacted Level for non Medicare appeals related DAB activities. The FY 2021 request will allow the DAB to hire additional staff, as well as account for inflationary pay and non-pay costs. DAB's Medicare appeals related activities and corresponding Budget request is included within the Medicare Hearings and Appeals (MHA) section of the Congressional Justification.

Rent, Operation, and Maintenance and Related Services (+$3,125,000) – The FY 2021 President's Budget request is $18,589,000 which is $3,125,000 above the FY 2020 Enacted Level. The request includes funding to support increasing costs associated with rental charges from GSA and maintaining aging buildings.

Shared Operating Expenses (+1,125,000) – The FY 2021 President's Budget request for Shared Operating Expenses is $11,753,000, which is $1,125,000 above the FY 2020 Enacted Level. The request includes funding for inflationary increases for Service and Supply Fund charges and other shared expenses.

KidneyX (-$3,000,000) – The FY 2021 President's Budget request is $2,000,000 which is $3,000,000 below the FY 2020 Enacted Level. Funding will be directed to individuals, teams, and companies as part of a planned Artificial Kidney Prize, to advance artificial kidney development closer to human trials.

Office of the Assistant Secretary for Health (+$1,726,000) – The FY 2021 President's Budget request is $37,502,000 which is $1,726,000 above the FY 2020 Enacted Level. The request provides a $2,000,000 increase within the Immediate Office of the ASH to continue implementation of the Ready Reserve.

Teen Pregnancy Prevention (-$101,000,000) – The FY 2021 President's Budget does not request funds for this program.

Embryo Adoption Awareness Campaign (-$1,000,000) – The FY 2021 President's Budget does not request funds for this program.

Sexual Risk Avoidance (-$35,000,000) – The FY 2021 President's Budget does not request funds for this program.

IMMEDIATE OFFICE OF THE SECRETARY

Budget Summary

(Dollars in Thousands)

Immediate Office of the Secretary	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget	FY 2021 +/- FY 2020
Budget Authority	14,200	14,200	14,200	-
FTE	86	86	86	-

Authorizing Legislation……Reorginization Plan No. 1 of 1953
FY 2021 Authorization……Permanent
Allocation Method……Direct Federal

Program Description and Accomplishments

The Immediate Office of the Secretary (IOS) is a Staff Division in the Office of the Secretary in the U.S. Department of Health and Human Services (HHS). The IOS provides leadership, direction, policy, and management guidance to HHS and supports the Secretary and Deputy Secretary in their roles as representatives of both the Administration and HHS. IOS serves as the central point of coordination and oversight for all HHS activities and the Department's mission of enhancing the health and well-being of Americans.

The IOS supports Department leadership and the Department mission by managing review and approval of all HHS documents requiring Secretarial action, mediating issues among Departmental components, communicating Secretarial decisions, and ensuring the implementation of those decisions. IOS achieves these actions by bringing key issues to leadership's attention in a timely manner and facilitating discussions on policy issues and reviewing documents requiring Secretarial for policy consistency with that of the Secretary and the Administration. IOS works with other Departments to coordinate analysis of, and input on, healthcare policy decisions affecting all HHS activities. IOS supports efforts to reform health care across HHS by improving the quality of the health care system and lowering its costs, prompting electronic health records, and protecting the privacy of patients.

IOS sets the HHS regulatory agenda and reviews all new regulations and regulatory changes issued by the Secretary or the various components of the Department. The IOS reviews current regulations to reduce regulatory burden, and provides guidance, direction, and coordination to the White House and other Cabinet agencies regarding HHS issues.

IOS organization components include the Office of the Chief Technology Officer (CTO), Executive Secretariat, the Office of National Security (ONS), formerly known as the Office of Security and Strategic Information. IOS also leads the *ReImagine HHS* effort transforming operations and business practices across the Department to better serve the American people. This effort is aligned with nine of the 2018 Presidential Management Agenda (PMA) Cross-Agency Priority goals and is actively driving progress on PMA goals and objectives.

The Office of the Chief Technology Officer (CTO) harnesses the power of data, emerging technologies, and innovation to create a more modern and effective government that works to improve the health of the nation. CTO advises HHS agencies on key technology policies and programs, open government practices, and applications of data to improve health and health care. To ensure a unified and cohesive health information technology strategy for external stakeholders, CTO collaborates across the Department to develop health information technology policy and ensure a cohesive health Information Technology strategy on behalf of the Department.

Five Year Funding Table

Fiscal Year	Amount
FY 2017	$13,300,000
FY 2018	$14,200,000
FY 2019	$14,200,000
FY 2020	$14,200,000
FY 2021 Request	$14,200,000

Budget Request

The FY 2021 President's Budget request for IOS is $14,200,000, which is flat with the FY 2020 Enacted Level. The FY 2021 President's Budget request will allow IOS to sustain its staffing levels, ensuring continued leadership, direction, policy, and management guidance delivery to HHS. Any inflationary pay and non- pay cost increases will be absorbed.

Immediate Office of the Secretary, Chief Technology Officer- Outputs and Outcomes Table

Program/Measure	Year and Most Recent Result/Target for Recent Result / (Summary of Result)	FY 2020 Target	FY 2021 Target	FY 2021 Target +/- FY 2020 Target
1.1 Increase the number of strategically relevant data sets published across the Department as part of the Health Data Initiative	FY2019: 3,822Target: 3,400 (Target Exceeded)	4,000	4,000	-
1.2 Increase the number of opportunities for the public to co-create solutions through open innovation	FY2019: 16 Target: 25 (Target Not Met)	25	25	-
1.3 Increase the number of innovation solutions identified across the Department in collaboration with the HHS Chief Technology Officer	FY2019: 225 Target: 200 (Target Exceeded)	200	200	-
1.4 Expand Access to the Results of Scientific Research funded by HHS	FY2019: 5 million Target: 4.5 million (Target Exceeded)	5.5 million	5.5 million	-
1.5 Increase the number of innovative solutions supported across the Department in collaboration with the HHS Office of the Chief Technology Officer	FY2019: 50 Target: N/A	100	100	-

Performance Analysis

1.1 Increase number of strategically relevant data sets published across the Department as part of the Health Data Initiative

Pursuant to OMB Memorandum M-13-13, HHS is working to increase the availability of machine-readable data sources as well as enabling use of linked datasets through the uses of Application Programming (APIs) interfaces. The APIs support machine-to-machine interactions that automate the supply of data to analytic tools and consumer platforms.

CTO manages HealthData.gov, the Department's open data portal that fuels new research, applications, and products to improve health outcomes. Data inputs to HealthData.gov have increased during this fiscal year. There have also been expanded efforts to engage the public in creating solutions using data made publicly available by HHS. As of September 2018, there are 3,332 data sets from HHS and federated sources. This year, there was enhanced access to ONC, FDA, and CMS datasets through HealthData.gov.

In December 2017, HHS hosted the HHS Opioid Code-a-Thon and brought together 70+ federal, HHS, and state datasets for coders to use to develop solutions to the opioid epidemic. Fifty teams from industry, startups, and academia worked on producing solutions, resulting in new companies and business models being developed. In April 2018, HHS hosted the ninth Health Datapalooza highlighting new products and services developed with HHS data. HHS continues to expand its health data outreach efforts, particularly with its international partners.

1.2 Increase the number of opportunities for the public to co-create solutions through open innovation

HHS has used innovation in a wide array of business areas and research fields to spur new ideas and concepts to be tested. HHS sees positive benefits to its education, training, and mentoring programs to help build a cadre of challenge managers across the operating divisions. HHS's $20 million prize challenge to develop point-of-care diagnostics for antimicrobial resistance will conclude its second phase of prototype delivery in September. Thirty-one letters of intent have been received to date. Additionally, HRSA's maternal and child health bureau (MCHB) recently launched a grand challenge program with a first round of four three-phase challenges addressing remote monitoring of pregnancy, care coordination, childhood obesity, and opioid addiction. The goal is to appeal to a broad array of innovators to bring fresh thinking and technology-driven approaches to this space.

1.3 Increase the number of innovative solutions identified across the Department in collaboration with the Chief Technology Officer

CTO continued to identify innovative solutions across the Department during FY18 through outreach capabilities and knowledge of programs across the Department. In FY18, CTO launched two rounds of the Ignite Accelerator program. In FY18, we received 225 submissions through this program, of which 50 were selected for piloting and participation in the training "boot camp." Two HHS operating divisions, (HRSA and CDC) started their own incubator programs this year, aimed at expanding the scope of the early stage solution development innovation phase.

1.4 Expand Access to the Results of Scientific Research funded by HHS

In February 2015, HHS released the HHS Public Access Plans, which provide an outline of the Department's efforts to increase access to the results of its scientific research, as appropriate. These plans now apply to research funded by six of its key scientific agencies: NIH, CDC, FDA, AHRQ, ACL, and ASPR. The HHS public access plans build on an existing infrastructure, Pub Med Central, for the storing and sharing of publications with the public.

Thus far, the National Library of Medicine's PubMed Central (PMC) Database includes over 5 million journal articles. As the contents of PMC grow and diversify with HHS-funded journal articles, HHS anticipates that it will create yet more opportunities for new connections to be made among disparate fields of scientific inquiry, and new types of knowledge and insights that can benefit health and

healthcare. HHS expects it will allow for faster dissemination of research results into products, services, and clinical practices that can improve healthcare.

1.5 Increase the number of innovative solutions supported across the Department in collaboration with the HHS Office of the Chief Technology Officer

CTO supported numerous innovation solutions developed across HHS Operating Divisions and Staff Divisions. These include HHS Startup Day, which connects the public and private sector with the vision and priorities of a regulated landscape of our nation's healthcare system. One solution developed through the HHS Ignite Accelerator Program was the "Patient over Paperwork" Initiative launched at CMS.

This measure represents the number of projects developed at HHS that CTO supports through dedicated staff time. This can include projects where CTO support was provided over multiple fiscal years. This does not include projects that are captured in Measure 1.2 "opportunities for the public to co-create solutions through open innovation."

SECRETARIAL INITIATIVES AND INNOVATIONS

Budget Summary

(Dollars in Thousands)

Secretarial Initiatives and Innovations	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget	FY 2021 +/- FY 2020
Budget Authority	2,000	2,000	2,000	-
FTE	-	-	-	-

Authorizing Legislation: .....Reorganization Plan No. 1 of 1953
FY 2021 Authorization.....Permanent
Allocation Method.....Direct Federal

Program Description and Accomplishments

The Secretarial Initiatives and Innovation request will aid the Secretary in most effectively responding to emerging Administration priorities while supporting the missions of HHS Operating Divisions and Staff Divisions. The funding allows the Secretary the necessary flexibility to respond to evolving business needs and legislative requirements. Additionally, the request will allow the Secretary to promote and foster innovative, high-impact, collaborative, and sustainable initiatives that target HHS priorities and address intradepartmental gaps.

This funding allows the Secretary to proactively respond to the needs of the Office of the Secretary as they continue to implement programs intended to improve and ensure the health and welfare of Americans. These funds will be directed to the Secretary's highest priorities and are implemented and monitored judiciously. The impact of these resources will be monitored based on the Secretary's stated goals and objectives for their use.

Five Year Funding Table

Fiscal Year	Amount
FY 2017	$2,000,000
FY 2018	$2,000,000
FY 2019	$2,000,000
FY 2020	$2,000,000
FY 2021 Request	$2,000,000

Budget Request

The FY 2021 President's Budget request for Secretarial Initiatives and Innovations is $2,000,000, which is flat with FY 2020 Enacted Level. The funding will allow the Secretary to support HHS component offices as they respond to new and ongoing legislative requirements and seek to implement innovative programs to address new and existing critical health issues.

KIDNEY INNOVATION ACCELERATOR

Budget Summary

(Dollars in Thousands)

Kidney Innovation Accelerator	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget	FY 2021 +/- FY 2020
Budget Authority	-	5,000	2,000	-3,000
FTE	-	1	1	--

Authorizing Legislation……Reorganization Plan No. 1 of 1953
FY 2021 Authorization……Permanent
Allocation Method……Direct Federal

Program Description and Accomplishments

The Kidney Innovation Accelerator (KidneyX), is a public-private partnership between HHS and the American Society for Nephrology to catalyze innovation in the prevention, diagnosis, and treatment of kidney diseases. KidneyX is utilizing the authority of the COMPETES Act to establish partnerships and administer a series of prize competitions aimed at attracting entrepreneurs and innovators from a broad array of domains to develop breakthrough therapies and diagnostics, including the development of a truly artificial kidney. The partnership includes intra-Departmental collaboration among FDA, NIH, CDC, CMS, and the Office of the CTO. President Trump's Advancing American Kidney Health Initiative Executive Order signed July 10, 2019 specifically directs HHS in Section 6 to advance the development of an artificial kidney using KidneyX.

To date, KidneyX has completed Phase I of its $2.6M Redesign Dialysis Prize, aimed at solving specific engineering and technology problems towards the development of technologies that can displace dialysis.

KidneyX is also operating a Patient Innovator Prize aimed at recognizing the innovative capacity of patients and caregivers to inspire and inform medical product development. Most importantly, KidneyX has already helped catalyze both HHS's Advancing American Kidney Health Initiative and interest among startups, investors, and industry to solve important problems for the benefit of kidney disease patients.

Five Year Funding Table

Fiscal Year	Amount
FY 2017	$0
FY 2018	$0
FY 2019	$0
FY 2020	$5,000,000
FY 2021 Request	$2,000,000

Budget Request

The FY 2021 President's Budget request for KidneyX is $2,000,000, which is $3,000,000 below the FY 2020 Enacted Level. Funding will be directed to individuals, teams, and companies as part of a planned Artificial Kidney Prize, to advance artificial kidney development closer to human trials. As part of the public-private partnership, HHS will seek additional partner funds from the private sector to contribute to the artificial kidney prize.

ASSISTANT SECRETARY FOR ADMINISTRATION

Budget Summary

(Dollars in Thousands)

Assistant Secretary for Administration	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget	FY 2021 +/- FY 2020
Budget Authority	16,658	16,558	16,558	-
FTE	68	74	63	-11

Authorizing Legislation……Reorganization Plan No.1 of 1953
FY 2021 Authorization……Permanent
Allocation Method……Direct federal

Program Description and Accomplishments

The Office of the Assistant Secretary for Administration (ASA) advises the Secretary on all aspects of administration, and provides oversight and leadership across the Department in the areas of human resources, equal employment opportunity, diversity, facilities management, information technology, and departmental operations.

ASA provides critical Departmental policy and oversight through the following components: Immediate Office of the Assistant Secretary, Office of Human Resources, Office of Equal Employment Opportunity, Diversity and Inclusion, Office of the Chief Information Officer, Office of Business Management and Transformation, and Program Support Center[1] (PSC).

Office of Human Resources (OHR)

OHR is responsible for creating a dynamic workplace that assists with all aspects of employee development from recruitment and training to mentoring and leadership development. OHR strives to make HHS a dynamic place to work for current and prospective employees and managers. OHR recruits talented individuals from diverse backgrounds who care about achieving the mission of protecting the health of Americans.

Success is achieved when the right people with the required skills, experience, and competencies are placed in the appropriate positions. OHR helps new employees make the transition into their positions, supports hiring managers who are building collaborative teams, and works to preserve the knowledge of retiring employees. Programs are offered for professional development while also ensuring that HHS staff members maintain a healthy work/life balance.

Office of Equal Employment Opportunity, Diversity, and Inclusion (EEODI)

EEODI is a newly formed office within ASA. EEODI combined ASA's Equal Employment Opportunity and Compliance Division with the ASA/OHR's Diversity and Inclusion Division. EEODI is responsible for the overall leadership and management of the Equal Employment Opportunity (EEO), Reasonable Accommodation, and Diversity and Inclusion (D&I) programs at the Department by providing policy, oversight, and technical guidance to all organizational elements. EEODI leads and coordinates enterprise level activities, such as the development and implementation of the EEO and D&I strategic plan, with the OpDiv EEO and D&I Offices.

EEODI manages the EEO complaint-processing program, which provides for the consideration and disposition of complaints from employees and applicants for employment involving issues of

[1] PSC is funded solely through the HHS Service and Supply Fund; it is not included in this request.

discrimination based on race, color, religion, sex, sexual orientation, status as a parent, national origin, age, disability, genetic information, and retaliation. EEODI develops policies and strategies to provide for the timely resolution and equitable remedies to discrimination complaints. EEODI ensures that all HHS employees and applicants have equal access to services and are able to perform the critical elements of their position by ensuring timely and appropriate reasonable accommodations are provided.

EEODI also manages the Diversity and Inclusion program, which focuses on Special Emphasis programs and provides external reporting functions, to include such activities as periodic cultural climate assessments, diversity and inclusion benchmarking and best practice analyses, increased partnering with the Office of Human Resources to enhance targeted outreach planning and recruitment efforts, implementation of structured diversity and inclusion awareness and engagement activities, diversity and inclusion education/training, workforce analysis (statistical trend monitoring), and development of a diversity and inclusion toolkit for supervisors and managers.

Office of the Chief Information Officer (OCIO)
OCIO advises the Department on matters pertaining to the use of information and related technologies to accomplish Departmental goals and program objectives. OCIO establishes and provides assistance and guidance on the use of technology-supported business process reengineering, investment analysis and performance measurements while managing strategic development and application of information systems and infrastructure in compliance with the Clinger-Cohen Act. OCIO promulgates HHS IT policies supporting enterprise architecture, capital planning and project management, and security.

OCIO coordinates the implementation of IT policy from the Office of Management and Budget and guidance from the Government Accountability Office throughout HHS OPDIVs and ensures the IT investments remain aligned with HHS' strategic goals and objectives and the Enterprise Architecture. OCIO coordinates the HHS response to federal IT priorities including data center consolidation; cloud computing; information management, sharing, and dissemination; and shared services.

OCIO is responsible for compliance, service level agreement management, delivery of services, service and access optimization, technology refreshment, interoperability and migration of new services. OCIO works to develop a coordinated view to ensure optimal value from IT investments by addressing key agency-wide policy and architecture standards, maximizing smart sharing of knowledge, sharing best practices and capabilities to reduce duplication and working with OPDIVs and STAFFDIVs on the implementation and execution of an expedited investment management process.

Office of Business Management and Transformation (OBMT)
OBMT provides results-oriented strategic and analytical support for key management and various HHS components' improvement initiatives and coordinates the business functions necessary to enable the supported initiatives and organizations to achieve desired objectives. OBMT also oversees Department-wide multi-sector workforce management activities. OBMT provides business process reengineering services, including the coordination of the review and approval process for reorganization and delegation of authority proposals that require the Secretary's or designees' signature. OBMT leads Departmental and cross-government initiatives that promote innovation or implement effective management practices within the Department.

Five Year Funding Table

Fiscal Year	Amount
FY 2017	$17,458,000
FY 2018	$17,458,000
FY 2019	$17,458,000
FY 2020	$16,558,000
FY 2021 Request	$16,558,000

Budget Request

The FY 2021 President's Budget request for ASA is $16,558,000, which is flat with the FY 2020 Enacted Level. The requested resources will be used by ASA to continue its administrative and oversight responsibilities that support the HHS mission. At the requested level, ASA will absorb any inflationary pay and non-pay cost increases through efficient use of resources.

Outputs and Outcomes Table

Measure	Year and Most Recent Result Target for Recent Result (Summary of Result)	FY 2020 Target	FY 2021 Target	FY 2021 Target +/- FY 2020 Target
2.6 Increase HHS employee engagement through Employee Viewpoint Survey.	FY 2018: 72.5% employee engagement Target: 72.5% employee engagement (Target Met)	75% employee engagement index	75% employee engagement index	-
2.8 Decrease the cycle time to hire new employees.	FY 2018: 94 days Target: 80 days (Target Not Met but Improved)	80 days	80 days	-
3.3 Increase the percentage of systems with an Authority to Operate (ATO).	FY 2018: 96 % Target: 96 % (Baseline)	97 %	97.5 %	+ 0.5 %
3.4 Improve the score to an "A" in each of the FITARA-related Scorecard Metrics, per GAO and House Oversight and Government Reform Committee.	FY 2018: 89 % Target: 90 % (Target Not Met but Improved)	90 %	90 %	-
3.5 Decrease the Percentage of Susceptibility among Personnel to Phishing.	FY 2018: 7 % Target: 7 % (Baseline)	6.5 %	6.2 %	- 0.3 %
3.6 Maintain the number of days since last major incident of PII breach.	FY 2018: 365 days Target: 365 days (Baseline)	366 days	365 days	- 1 day

Performance Analysis

ASA's six corporate measures reflect performance across HHS.

2.6 Increase HHS employee engagement through Employee Viewpoint Survey

Improving employee engagement within HHS is a vital method for promoting new and dynamic solutions to challenges facing the organization. This metric is tracked using the employee engagement index, calculated from OPM Annual Employee Viewpoint survey. A successful agency fosters an engaged working environment to ensure each employee can reach their full potential and contribute to the success of their agency and the entire Federal Government.

2.8 Decrease the cycle time to hire new employees

HHS has engaged its Human Resources Center Subject Matter Experts as well as our program area customers to try to identify ways to streamline the hiring process via the HHS ReImagine Maximize Talent initiative. The Department determined that it can reduce some duplicative effort through standardization and sharing of efforts across staffing organizations. ReImagine projects are building the capacity to share certificates, build and share standard recruitment packages, and eventually share recruitments. These enhanced business practices are still emerging and so their impact will not be fully felt until next year. In FY 2021, ASA will continue using this process to identify and implement ways to streamline the time-to-hire cycle.

3.3 Increase the percentage of systems with an Authorization to Operate (ATO)

Federal Information Security Modernization Act (FISMA) of 2014 requires federal agencies to develop, document, and implement an agency-wide program to provide information security for the information and systems that support the operations and assets of the agency, including those provided or managed by another agency, contractor, or other sources.

In support of this requirement, all systems and applications supporting Federal government agencies must follow National Institute of Standards and Technology (NIST) Risk Management Framework (RMF) Special Publication (SP) 800-37 as the standard for Assessment and Authorization (A&A) process before an Authorization to Operate (ATO), and assessed every five years thereafter. The purpose of the measure is to mitigate risk and strength compliance with federal regulations and standards.

3.4 Improve the score to an "A" in each of the Federal IT Acquisition Reform Act (FITARA) related Scorecard Metrics, per GAO and House Oversight and Government Reform Committee

In December 2014, Congress enacted FITARA to promote federal IT modernization and strengthen the federal IT workforce. HHS made considerable progress in this area by improving its score from a D to a B+. HHS has developed plan to capture cost savings through portfolio review, data center optimization, and software licensing. In FY 2021, HHS will establish a software inventory to drive decision-making.

3.5 Decrease the percentage of susceptibility among personnel to phishing

Through the combination or training, education, and tools (e.g., email add-in), the purpose of the measure is to reduce the likelihood of staff falling for fake email attempts over time.
According to Forbes, phishing scams costs American businesses a half a billion dollars a year.[1]

3.6 Maintain the number of days since last major incident of personally identifiable information (PII) breach

This measure serves as an enterprise-wide countdown measure since the last day of a major PII incident in the Department as well as a gauge for the number of major PII incidents.

[1] Matthews, L. (2017). Phishing Scams Cost American Businesses Half A Billion Dollars A Year. *Forbes.* Retrieved on December 23, 2019, from https://www.forbes.com/sites/leemathews/2017/05/05/phishing-scams-cost-american-businesses-half-a-billion-dollars-a-year/#65dc9a3e3fa1.

ASSISTANT SECRETARY FOR FINANCIAL RESOURCES

Budget Summary

(Dollars in Thousands)

Assistant Secretary for Financial Resources	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget	FY 2021 +/- FY 2020
Budget Authority	32,485	30,735	30,735	-
FTE	143	153	149	-4

Authorizing Legislation:..... Reorganization Plan No. 1 of 1953
FY 2021 Authorization.....Permanent
Allocation Method.....Direct Federal

Program Description and Accomplishments

Office of Budget (OB)

The Office of Budget provides advice and support to the Secretary and the Assistant Secretary for Financial Resources on matters pertaining to: formulation of the HHS and President's budgets, management of program assessment and performance reporting, presentation of budgets and reconciliation legislation to OMB and the Congress, and resolution of issues arising from the execution of final appropriations.

OB manages the performance budget and prepares the Secretary to present the budget to the Office of Management and Budget, the public, the media, and Congressional committees; and manages HHS apportionment activities, which provide funding to the HHS Operating Divisions and Staff Divisions. OB coordinates, oversees, and convenes resource managers and financial accountability officials within the Office of the Secretary (OS) to update, share, and implement related HHS-wide policies, procedures, operations, rules, regulations, recommendations, and priorities. OB coordinates the preparation of guidelines governing reprogrammings, transfers between accounts, and other crosscutting funding methods and provides recommendations in managing and processing crosscutting funding proposals.

Additionally, OB leads the Service and Supply Fund by providing budget process, formulation, and execution support, including budget analysis and presentation, account reconciliations, reporting, status of funds tracking, and certification of funds availability. OB also manages all phases of HHS performance budget improvement activities required under the Government Performance and Results Modernization Act (GPRAMA).

Office of Finance (OF)

The Office of Finance provides financial management leadership to the Secretary through the Chief Financial Officer (CFO) and the Departmental CFO Community. The OF leads the HHS-wide financial management efforts and prepares the Secretary to present the HHS Agency Financial Report to OMB, Treasury, Government Accountability Office, Congressional committees, and the public, in coordination with HHS Operating Divisions and Staff Divisions. OF manages and directs the development and implementation of financial policies, standards, and internal control practices; and prepares the HHS annual consolidated financial and grant statements and audits, in accordance with the Chief Financial Officers Act, OMB Circulars, Federal Managers Financial Integrity Act, and the Federal Accounting Standards Advisory Board. OF provides Department-wide leadership to implement new financial management requirements and other mandated reporting, oversees the HHS financial management systems portfolio, and is the business and systems owner of such systems. OF also leads the

Department's Enterprise Risk Management initiative (ERM). This work includes supporting the HHS ERM Council, to collaboratively identify, assess, and manage HHS risks; collaboratively engaging the Operating Divisions and Staff Divisions to establish, communicate, and implement HHS ERM vision, strategy, culture, and framework; and leading the development of the annual HHS Risk Profile.

OF prepares the Agency Financial Report which includes the Department's consolidated financial statements, the auditor's opinion and other statutorily required annual financial reporting. For many years, HHS has earned an unmodified or clean opinion on the HHS audited Consolidated Balance Sheet, and Statements of Net Cost and Changes in Net Position, and Combined Statement of Budgetary Resources. OF successfully produced the Agency Financial Report on time in compliance with Federal requirements, and for the sixth year in a row, earned the prestigious Certificate of Excellence in Accountability Reporting for the FY 2018 HHS Agency Financial Report.

OF manages HHS's entire financial management systems environment, including projects to standardize financial accounting across the Department, implement government-wide financial management requirements, address security and control weaknesses, and develop Financial Business Intelligence System to enhance Department-wide analytic capabilities and support decision making. OF continues to progress on its strategic roadmap, manage programs to enhance system security, reliability, and availability; increase effectiveness and efficiency; and improve access to accurate, reliable, and timely information.

Office of Acquisitions (OA)

The Office of Acquisitions provides HHS-wide leadership, management, and strategy in acquisitions, small business policy development, performance measurement, and oversight and workforce training. OA nurtures collaboration, inspires innovative thinking, and focuses on accountability in the administration and management of HHS acquisitions portfolio, as well as supporting small business functions throughout the Department.

HHS has committed to and established a new HHS-wide Initiative – BuySmarter to bring its 26 federated, geographically dispersed, and mission-independent agencies together to drive best pricing and best value contracts for all parties leveraging the HHS ACCELERATE system. HHS has a unique opportunity to reshape the way acquisitions are purchased by the entire acquisition workforce. The ReImagine Acquisitions-BuySmarter Initiative maximizes HHS' group purchasing power by establishing a cohesive acquisition structure across HHS. Buying together to achieve scale in pricing, quality, value, and distribution is one of the most fundamental business practices across any industry. BuySmarter has developed essential processes utilizing technology and engaged acquisition staff HHS-wide. BuySmarter is now moving into the implementation phase, including utilizing the HHS ACCELERATE platform to deploy an Artificial Intelligence capability that will enable combined departmental negotiation and collaboration.

Office of Small Business Development Unit (OSBDU) continues to ensure that small businesses are given a fair opportunity to compete for HHS contracts. This year OSBDU created an enterprise-wide software solution that streamlined access to the stakeholder community by focusing on outreach and providing guidance to small businesses on conducting business with HHS.

Office of Grants (OG)

The Office of Grants provides department-wide leadership on grants strategy, policy, regulations, and systems management. OG also fosters collaboration, innovation, and accountability in the administration and management of grants. In its government-wide roles, OG is the managing partner of

Grants.gov, co-chairs the Financial Assistance Committee on e-Gov, and plays an integral advisory role in the revision to the 2 CFR 200 Uniform Administrative Requirements and Grants Data Standardization.

OG formulates department-wide grants policies including uniform administrative rules and provides oversight and review on the implementation of HHS grant policies. OG provides coordinated leadership in cost policy management and department-wide cost policies and procedures affecting assistance awards. OG leads the preparation of HHS and government-wide positions on proposed legislation or government-wide policies affecting grants and represents the Department's interest regarding internal and external grants management activities.

The OG, as the managing partner for Grants.gov, manages its operating budget and provides the Grants.gov platform for the posting of funding opportunities and processing of grants applications in the pre-award process for the entire federal government. Grants.gov provides the federal government with a single portal to provide funding opportunities to the public and for applicants to apply to over 5,000 grants programs.

The OG provides key leadership and oversight on HHS and government-wide electronic grant activities. OG represents the Department on matters of electronic assistance administration policy in dealing with recipients, OMB, other federal agencies, and the public. It fosters streamlined grants business, improved transparency, and leveraging data. OG supports the financial accountability and transparency initiatives such as those associated with the Federal Funding Accountability and Transparency Act (FFATA), the DATA Act, and Open Government Directive, by maintaining and operating HHS Tracking Accountability in Government Grants System (TAGGS).

HHS has a unique opportunity to reshape the way grants are administered across the entire grants community. The *ReImagine-ReInvent* Grants (RGM) Initiative took careful consideration in learning about the needs of the grant recipient community and their experiences in managing HHS-issued financial assistance awards. The OG will utilize this foundation to improve the HHS financial assistance workforce by providing a curriculum for grants staff and other stakeholders who are part of the overall process of delivering grants to optimize resources. Additionally, OG will transition the initial user-centered design prototypes into an operational tool that will increase transparency and enhance the day-to-day work of grant administrators, including a standard Notice of Award form and single Federal Financial Report portal to reduce recipient burden, especially for those with multiple HHS financial assistance awards.

Grants Quality Service Management Office (QSMO)

As the pre-designated Grants QSMO by OMB in Memorandum M-19-16, HHS continues to create and manage the development of a marketplace of solutions for grants management; govern its long-term sustainability; institute a customer engagement model; and drive the implementation of standards and solutions to modernize grants management processes and systems.

. In FY 2018, the government awarded over $750 billion in grants, issued over more than 300,000 awards across more than 1,500 programs. To meet the diverse needs of programs and recipients, agencies have historically turned to customized solutions, leading to over 200 identified grant systems with limited interoperability and an estimated annual spend of $300-400 million in these systems. Modernization and standardization of these systems requires significant engagement with stakeholders to ensure the Grants QSMO can meet the future needs for grants systems government-wide.

Five Year Funding Table

Fiscal Year	Amount
FY 2017	$30,444,000
FY 2018	$30,444,000
FY 2019	$30,735,000
FY 2020	$30,735,000
FY 2021 Request	$30,735,000

Budget Request

The FY 2021 President's Budget request for Assistant Secretary for Financial Resources is $30,735,000, which is flat with the FY 2020 Enacted Level.

The Office of Budget will continue to meet its responsibilities for providing financial management leadership including preparation of HHS annual performance budget; production of budget and related policy analyses, options, and recommendations; management and support of program performance reviews, annual strategic plans, and agency priority goals; and development and implementation related to accountability and transparency priorities.

The Office of Finance will continue to meet its responsibilities for providing financial management leadership including management, development, and implementation of HHS financial policies, standards and internal control practices; and preparing financial statements, financial audits, and other financial reports. OF will continue to modernize Department-wide financial systems by enabling new functionality, standardizing and simplifying financial systems environment, strengthening internal controls, and improving financial reporting. This multi-year modernization initiative will standardize financial management across HHS, modernize financial reporting to provide timely, reliable, and accurate information about HHS finances and enhance, standardize and simplify financial systems.

The Office of Grants and the Office of Acquisitions will continue to lead HHS to ensure that appropriate grant and acquisition related internal controls and policies are followed, provide technical assistance, policy advice, and training to HHS OPDIVs and STAFFDIVs to ensure stewardship of HHS grants, financial assistance, acquisition, and small business programs.

ACQUISITION REFORM

Budget Summary
(Dollars in Thousands)

Acquisition Reform	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget	FY 2021 +/- FY2020
Budget Authority	1,750	-	-	-
FTE	3	-	-	-

Authorizing Legislation:..... Reorganization Plan No. 1 of 1953
FY 2021 Authorization.....Permanent Allocation
Method.....Direct Federal

Program Description and Accomplishments
In March 2009, the President mandated that all federal agencies improve acquisition practices and performance by maximizing competition and value, minimizing risk, and review of the acquisition workforce to develop, manage, and oversee acquisitions appropriately. Guidance from the Office of Management and Budget, *Improving Government Acquisition*, and *Guidance for Specialized information Technology Acquisition Cadres*, directed agencies to strengthen acquisition workforce and increase civilian agency workforce, to more effectively manage acquisition performance.

Successful acquisition outcomes are the direct result of having the appropriate personnel with the requisite skills managing various aspects of the acquisition process. The federal acquisition workforce includes contract specialists, procurement analysts, program and project managers, and contracting officer representatives. This funding will be used to mitigate the risks associated with gaps in the capacity and capability of the acquisition workforce Department-wide, implement the suspension and debarment, increase contracting activities oversight, increase contract funding compliance, and improve the effectiveness of that workforce, in order to maximize value in HHS contracting.

In FY 2018 and FY 2019, the suspension and debarment program's oversight activities resulted in department-wide trainings to ensure personnel at any point in the acquisition and federal assistance life cycles are knowledgeable about the use of suspension and debarment as an administrative remedy. Oversight activities have resulted in over 102 administrative actions to protect HHS's procurement and federal assistance discretionary program dollars from non-responsible entities. Additionally, the program has worked to impose compliance agreements, which ensure that effective monitoring of entities business processes are conducted.

Five Year Funding Table

Fiscal Year	Amount
FY 2017	$1,750,000
FY 2018	$1,750,000
FY 2019	$1,750,000
FY 2020	-
FY 2021 Request	-

Budget Request
FY 2021 President's Budget does not request discretionary funding for acquisition practices, performance, and oversight. Acquisition Reform activities will be supported by the HHS Service and Supply Fund.

ASSISTANT SECRETARY FOR LEGISLATION

Budget Summary
(Dollars in Thousands)

Assistant Secretary for Legislation	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget	FY 2021 +/- FY 2020
Budget Authority	4,100	4,100	4,100	-
FTE	25	27	27	-

Authorizing Legislation:..... Reorganization Plan No. 1 of 1953
FY 2021 Authorization.....Permanent
Allocation Method.....Direct Federal

Program Description and Accomplishments
The Office of the Assistant Secretary for Legislation (ASL), headed by the Assistant Secretary for Legislation, is a Staff Division of the Office of the Secretary in the U.S. Department of Health and Human Services (HHS). ASL serves as the principal advocate before Congress for the Administration's health and human services initiatives; serves as chief HHS legislative liaison and principal advisor to the Secretary and the Department on Congressional activities; and maintains communications with executive officials of the White House, OMB, and other Executive Branch Departments on legislative matters, as well as with Members of Congress and their staffs, and the Government Accountability Office (GAO).

ASL informs the Congress of the Department's views, priorities, actions, grants, contracts, and provides information and briefings that support the Administration's priorities and the substantive informational needs of the Congress.

Immediate Office of the Assistant Secretary for Legislation
Serves as principal advisor to the Secretary with respect to all aspects of the Department's legislative agenda and Congressional liaison activities. Examples of ASL activities include: working closely with the White House to advance Presidential initiatives such as lowering the price of prescription drugs; managing the Senate confirmation process for the Secretary and the 19 other Presidential appointees requiring Senate confirmation; transmitting the Administration's proposed legislation to the Congress; and working with Members of Congress and staff on legislation for consideration by appropriate Committees and by the full House and Senate.

Office of Health Legislation
Assists in the legislative agenda and liaison for mandatory and discretionary health programs. This portfolio includes: health-science-oriented operating divisions, including SAMHSA, FDA, NIH, AHRQ, and CDC; medical literacy, quality, patient safety, privacy; bio-defense and public health preparedness and response; health services and health care financing operating divisions, including CMS; Medicare, Medicaid, and the Children's Health Insurance Program (CHIP); private sector insurance; Continuity of Operations (COOP) activities.

Office of Human Services Legislation
Assists in the legislative agenda and liaison for human services policy. This portfolio includes: ACF, ACL, IHS, HRSA, and ONC; health IT; cyber security.

These three offices develop and work to enact the Department's legislative and administrative agenda, coordinating meetings and communications of the Secretary and other Department officials with

Members of Congress, and preparing witnesses and testimony for Congressional hearings.

Congressional Liaison Office (CLO)
Assists in the legislative agenda and special projects. The office is the primary liaison to Members of Congress and serves as a clearing house for Member and Congressional staff questions and requests. This office maintains the Department's program grant and contract notification system to inform Members of Congress and is responsible for notifying and coordinating with Congress regarding the Secretary's travel and event schedule. Nearly 100,000 grant notifications are sent to Members of Congress annually. CLO is also responsible for processing correspondence from Members of Congress to the Assistant Secretary for Legislation and the Secretary. CLO provides staff support for the Assistant Secretary for Legislation, coordinating responsibilities to the HHS regional offices, and works with ASFR to coordinate budget distribution, briefings and hearings.

Office of Oversight and Investigations (O&I)
Responsible for all matters related to Congressional audit and investigations of Departmental programs, including those performed by the Government Accountability Office (GAO). O&I serves as the central point of contact for the Department in handling congressional requests for oversight interviews, briefings, and documents; developing responses with agencies within the Department; consulting with other Executive Branch entities; and negotiating with congressional and GAO staff regarding investigations. HHS receives hundreds of oversight letters from Congressional Oversight Committees. HHS has received hundreds of new audit inquiries and over 400 recommendations that require corrective actions.

Five Year Funding Table

Fiscal Year	Amount
FY 2017	$4,100,000
FY 2018	$4,100,000
FY 2019	$4,100,000
FY 2020	$4,100,000
FY 2021 Request	$4,100,000

Budget Request
The FY 2021 President's Budget request for ASL is $4,100,000, which is flat with FY 2020 Enacted. At this level, ASL will continue to provide mission critical support to the legislative healthcare and human services agenda and continue to meet Congressional inquiries related to the broad range of HHS programs.

The request for ASL continues to facilitate communication between the Department and Congress. This requires continued work on several mission critical areas with Members of Congress, Congressional Committees and staff, including: managing the Senate confirmation process for Department nominees; preparing witnesses and testimony for Congressional hearings; coordinating Department response to Congressional oversight and investigations as well as coordinating responses to GAO inquiries; improving Congressional awareness of issues relating to the programs and priorities of the Administration and advising Congress on the status of key HHS priority areas.

ASSISTANT SECRETARY FOR PUBLIC AFFAIRS

Budget Summary

(Dollars in Thousands)

Assistant Secretary for Public Affairs	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Request	FY 2021 +/- FY 2020
Budget Authority	8,408	8,408	8,408	-
FTE	39	52	52	-

Authorizing Legislation:.....Reorganization Plan No. 1 of 1953
FY 2021 Authorization.....Permanent
Allocation Method.....Direct Federal

Program Description and Accomplishments

The Office of the Assistant Secretary for Public Affairs (ASPA) is a Staff Division of the Office of the Secretary in the U.S. Department of Health and Human Services (HHS). ASPA serves as the principal HHS Public Affairs office and works to build relationships that empower Americans with information needed to lead healthy, productive lives. ASPA works to support the HHS mission, Secretarial initiatives and other priorities by building and maintaining relationships with the public through multiple communications channels including the news media, websites, broadcast, social media, speeches, articles, events, and Freedom of Information Act (FOIA) requests.

In FY 2020, ASPA will pilot a new Customer Relations Management system to modernize how it manages the more than 15,000 media interview requests, 400 press releases, 1,200 packages of press materials and 135 communications events from across HHS. While this Customer Relations Management system will support Agency and Office communications goals, the tool will improve ASPA's ability to coordinate messaging for all major announcements and encourage their amplification by the Office of the Secretary and other HHS components.

ASPA's communications functions include:

- Foster intra-departmental visibility and coordination of messaging for all major announcements and encourage their amplification by the Office of the Secretary and other HHS components.
- Create a forum for strategic, long-term planning for communication on public health, healthcare, and human services initiatives.
- Coordinate digital and specialty media staff across the Department to boost impact for high priority announcements, and deliver the right message to the right audience through the right channel(s).
- Advise the Secretary and senior staff on communication tactics and timing in accordance with the Department's strategic priorities.
- Work across the Department to develop a long-term outreach strategy, coordinate in-house communications efforts, and ensure consistency in messaging.
- Advise Agencies and Offices on using the Strategic Communication Planning (SCP) tool to develop plans for communication products targeting external audiences – digital and print – such as brochures, new websites, social media, reports, videos, toolkits, and public education public service campaigns.
- Support television, web, and radio appearances for the Secretary and senior HHS officials; managing the HHS studio and providing photographic services; producing and distributing internet, radio, and television outreach materials.

- Write speeches, statements, articles, and related material for the Secretary, Deputy Secretary, and Chief of Staff and other senior HHS officials.
- Oversee HHS-wide FOIA and Privacy Act program policy, implementation, compliance, and operations.

Five Year Funding Table

Fiscal Year	Amount
FY 2017	$8,408,000
FY 2018	$8,408,000
FY 2019	$8,408,000
FY 2020	$8,408,000
FY 2021 Request	$8,408,000

Budget Request

The FY 2021 President's Budget request for ASPA is $8,408,000, which is flat with the FY 2020 Enacted Level. At this level, ASPA will continue to support the HHS mission and empower Americans with information needed to lead healthy and productive lives. ASPA will balance resources including staff, operating, and contract costs, to support Secretarial and Department-wide communications to the American people.

In FY 2021 ASPA will use funds to provide citizens, in the most transparent and accessible manner possible, with the critical information they need about health and human services programs, designed to help them lead healthy and productive lives.

OFFICE OF THE GENERAL COUNSEL

Budget Summary
(Dollars in Thousands)

Office of the General Counsel	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget	FY 2021 +/- FY 2020
Budget Authority	31,100	31,100	31,100	-
FTE	143	143	143	-

Authorizing Legislation:……………………………………………………………………Reorganization Plan No. 1 of 1953
FY 2021 Authorization……………………………………………………………………………………………Permanent
Allocation Method………………………………………………………………………………… …………………..Direct Federal

Program Description and Accomplishments

The Office of the General Counsel (OGC) is a Staff Division of the Office of the Secretary in the U.S. Department of Health and Human Services (HHS). OGC, with a team of over 400 attorneys and a comprehensive support staff, is one of the largest, most diverse, and talented law offices in the United States. It provides client agencies throughout the Department of Health and Human Services (HHS) with representation and legal advice on a wide range of highly visible national issues. OGC's goal is to support the strategic goals and initiatives of the HHS Secretary and the Department, by providing high quality legal services, including sound and timely legal advice and counsel. OGC is comprised of the divisions of Children, Families and Aging; Centers for Medicare and Medicaid Services; General Law; Public Health; Ethics; Civil Rights; National Complex Litigation; and Legislation.

The Children, Families and Aging Division (CFAD) provided intensive litigation support and legal review to the Office of Refugee Resettlement, providing litigation support on more than a dozen litigations, including numerous class actions. CFAD played a significant role in drafting and finalizing the rule for the apprehension and care of unaccompanied alien children. CFAD worked closely with the Children's Bureau in issuing guidance and responding to inquiries on the Family First law. The new law requires major adjustments in the administration of foster care and adoption assistance under Titles IV-B and IV-E of the Social Security Act. CFAD continued to provide advice and assistance on access to the National Directory of New Hires, a database managed by the Office of Child Support Enforcement. Head Start attorneys have worked closely on a proposed rulemaking, and now the final rule and have continued to remain engaged on Head Start agency designation renewals. CFAD assisted in reviewing a rulemaking with the Temporary Assistance for Needy Families (TANF) program that would help to implement the President's initiative on fostering greater work participation.

The Centers for Medicare and Medicaid Services Division (CMSD) provided advice on numerous initiatives that the Centers for Medicare and Medicaid Services (CMS) and the Department are undertaking to reduce drug prices for Medicare, Medicaid, and program beneficiaries, including actions to implement the President's drug pricing blueprint. That work will continue in fiscal year 2021. In FY 2019, OGC coordinated with HHS leadership to draft and issue a final rule requiring drug pricing transparency. The rule is expected to improve the efficiency of the Medicare and Medicaid programs by putting downward pressure on drug prices and improving beneficiaries' ability to make informed decisions. OGC defended the rule in a challenge brought by pharmaceutical manufacturers. Although we did not prevail in the district court, we expect to defend the rule on appeal in the next fiscal year, and if we prevail, we will assist CMS in implementing the rule. OGC continues to work closely with CMS on the development of a proposed rule to implement a mandatory payment model that would set payment for the top fifty Medicare Part B drugs at amounts comparable to the lower prices other countries pay. OGC also assisted the Department of Justice and the Office of the Inspector General in pursuing fraud cases

against Medicare and Medicaid suppliers and providers resulting in over $1.2 billion in recoveries during FY 2019 thus far.

OGC's General Law Division (GLD) has been instrumental in advising CMS regarding the administration of its core programs, including advising policy makers regarding relevant fiscal and procurement laws. Additionally, GLD has had a lead role in providing advice regarding the Federal Advisory Committee Act, as well as providing advice on the disclosure, retention, and withholding of information requested through various mechanisms. Finally, GLD has provided employment and labor law advice to senior policy makers, and has represented the Department in related litigation matters.

OGC's National Complex Litigation Division (NCLD) serves as the in-house counsel for the Department on large, complex cases from across the HHS litigation portfolio, including class action litigation against HHS programs operated by the Centers for Medicare & Medicaid Services (CMS), the U.S. Food and Drug Administration (FDA), and the Administration for Children and Families (ACF), to administrative litigation challenging health care privacy or other enforcement actions by HHS components such as the Office of Civil Rights (OCR), to disputes involving tens of millions of dollars in grant funding administered by the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), and ACF. In addition, the NCLD serves as the in-house counsel for HHS on matters that involve consent decrees or court-ordered external monitors.

Five Year Funding Table

Fiscal Year	Amount
FY 2017	$31,100,000
FY 2018	$31,100,000
FY 2019	$31,100,000
FY 2020	$31,100,000
FY 2021 Request	$31,100,000

Budget Request

The FY 2021 President's Budget request for OGC is $31,100,000, which is flat with the FY 2020 Enacted Level. At this level OGC will support pay increases and non-pay inflationary costs incurred as a result of providing HHS with legal representation on key social, economic, and healthcare issues. OGC will absorb inflationary increases by reducing contract costs.

In FY 2021, OGC will continue to provide legal advice pertaining to fiscal law, grants, and procurements. OGC attorneys will be highly involved in rulemaking and will continue to assist and support CMS in its mission of making health insurance available, transforming the health care delivery system and the Medicaid program, and reducing fraud, waste and abuse in the federal health care systems.

OGC will provide legal advice to clients on high priority Administration initiatives, such as defending the revised family planning service grant rules, implementing the President's Kidney Health Initiative, and developing drug pricing control policies. OGC will also advise and assist the National Institutes of Health (NIH) on many important and complex matters, including the agency's large research grants portfolio, intellectual property, technology transfer, third-party reimbursement at NIH's Clinical Center, genomic data sharing, biodefense research, and diversity initiatives. OGC will continue to advise on multiagency preparedness efforts related to the opioid epidemic, including public health emergency declarations, grants for treatment and prevention activities, and enhanced distribution processes for Naloxone.

OGC will continue to advise clients seeking to revise and update program guidance, such as those for the Health Resources and Services Administration's (HRSA) health professional shortage designation, the Office of Human Research Protection's Common Rule, and the 340B Drug Pricing Program. OGC remains a source of expertise and consultation regarding questions on faith- and community-based organizations, including for the cases *Marouf v. Azar, Maddonna v. Department of Health and Human Services*, and *J.D. v. Azar*; and with respect to an exception granted to South Carolina regarding child placing agencies and certain provisions of 45 C.F.R. 75.300(c). OGC will continue to assist on the "477 program," and continue apace providing Indian tribes with more flexibility for social welfare programs that support employment.

OGC will continue to provide support to all department clients in our primary practice areas that include: legal support for all agency acquisitions of goods and services; fiscal law support for questions related to proper use of federal funds, the starting point for all government programs and activities; federal real property law support for questions relating to the lease and acquisition of real property; information law and other general administrative law support that is part of all federal programs; claims processing and adjudication for medical malpractice claims under the Federal Tort Claims Act and other claims against the agency; and labor and employment law advice and litigation support.

OGC anticipates assisting the Assistant Secretary for Preparedness and Response with the continuing process of reorientation to an operations focused organization, which has included diversifying procurement operations and assuming additional responsibilities and innovation initiatives and includes the Biomedical Advanced Research and Development Authority and its host of acquisition and fiscal matters. Such matters will include procurements for countermeasures to emerging threats, the award and administration of contracts or other transactions in furtherance of new authority to coordinate the acceleration of countermeasures, and product advanced research and development using strategic venture capital practices and other transaction authority.

DEPARTMENTAL APPEALS BOARD

Budget Summary
(Dollars in Thousands)

Departmental Appeals Board	FY 2019 Final[1]	FY 2020 Enacted	FY 2021 President's Budget	FY 2021 +/- FY 2020
Budget Authority	17,250	4,500	6,000	+1,500
FTE	68	17	24	+7

Funding levels displayed represent non-Medicare appeals related activities at the DAB for FY 2020 and FY 2021. Medicare-appeals related DAB activities are discussed in the Medicare Hearings and Appeals (MHA) section of the Congressional Justification.

Authorizing Legislation……Reorganization Plan No. 1 of 1953
FY 2021 Authorization……Permanent
Allocation Method……Direct Federal

Program Description and Accomplishments

The Departmental Appeals Board (DAB), a staff division within the Office of the Secretary, provides impartial, independent hearings and appellate reviews, and issues federal agency decisions pursuant to more than 60 statutory provisions governing HHS programs. Medicare Hearings and Appeals is an account created by Congress in FY 2020 to consolidate the costs of the adjudicative expenses associated with appeals of Medicare claims brought by beneficiaries and health care providers. DAB's Medicare claims adjudication costs are funded out of the same appropriation as the Office of Medicare Hearings and Appeals (OMHA). This section includes resources for non-Medicare appeals related DAB activities.

The DAB's mission is to provide high-quality adjudication and other conflict resolution services in administrative disputes involving HHS, and to maintain efficient and responsive business practices. Cases are initiated by outside parties who disagree with a determination made by an HHS agency or its contractor. Outside parties include States, universities, Head Start grantees, nursing homes, clinical laboratories, doctors, medical equipment suppliers, and Medicare beneficiaries. Disputes heard by the DAB may involve over $1 billion in federal funds in a single year. DAB decisions on certain cost allocation issues in grant programs have government-wide impact because HHS decisions in this area legally bind other Federal agencies. All of the judges (Board Members, Administrative Law Judges (ALJs), and Administrative Appeals Judges (AAJs)) are appointed by the Secretary. The DAB is organized into the following four Divisions, in addition to having an Immediate Office of the Chair and an Operations Division:

Board Members – Appellate Division

Board Members, including the DAB Chair who serves as the executive for the DAB, issue decisions in panels of three, with the support of Appellate Division staff. Board Members provide appellate review of decisions by DAB ALJs and Department of Interior ALJs (in certain Indian Health Service cases). In addition, Board Members provide *de novo* review of certain types of final decisions by HHS components, including ACF, CMS, HRSA, SAMHSA, ONC, and PSC, involving discretionary and mandatory grants and cooperative agreements.

In FY 2019, the Board/Appellate Division received 137 cases and closed 131 cases, 87 by decision.

[1] The FY 2020 LHHS Bill moved the $9,500,000 from General Departmental Management appropriation to the Medicare Hearings and Appeals appropriation.

Administrative Law Judges – Civil Remedies Division (CRD)
DAB Administrative Law Judges (ALJs), supported by CRD staff, conduct adversarial hearings and issue decisions on the record in a wide variety of proceedings that are critical to HHS programs. Hearings may last a week or more and may raise complex medical or clinical issues. Some cases require presentation of evidence to prove allegations of complicated fraudulent schemes. Cases may also raise legal issues of first impression, such as appeals of enforcement cases.

Approximately 90% of CRD's workload is made up of CMS cases. CRD ALJs hear cases appealed from CMS or OIG determinations which exclude providers, suppliers, or other healthcare practitioners from participating in Medicare, Medicaid, and other federal healthcare programs, or impose civil monetary penalties (CMPs) for fraud and abuse in such programs. CRD jurisdiction also includes appeals from Medicare providers or suppliers, including cases under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). ALJs provide expedited hearings when requested in certain types of proceedings, such as provider terminations and certain nursing home CMP cases. These cases typically involve important quality of care issues. ALJs also hear cases that require testimony from independent medical/scientific experts (e.g., in appeals of Medicare Local Coverage Determinations (LCDs) or issues of research misconduct for the purposes of fraudulently obtaining federal grants in cases brought by the Office of Research Integrity (ORI)). Additionally, CRD ALJs hear appeals of CMPs for privacy, security or breach notification violations brought by the Office for Civil Rights (OCR) and transactions violations brought by CMS under HIPAA and/or the Health Information Technology for Economic and Clinical Health (HITECH) Act brought by OCR or CMS.

CRD ALJs also hear appeals of other federal agency enforcement actions through reimbursable interagency agreements. The largest of these workloads are appeals of tobacco enforcement actions brought by the Food and Drug Administration (FDA), which include CMP determinations and No Tobacco Sale Orders (NTSOs). In addition, with reimbursable funding, ALJs conduct hearings on CMPs imposed by the Inspector General of the Social Security Administration (SSA), certain debt collection cases brought by SSA and HHS, and corporate integrity agreement enforcement actions brought by the HHS Office of the Inspector General. The ALJs, through an agreement with the Administration for Children and Families (ACF) also serve as independent hearing officers for appeals made by unaccompanied alien children.

In FY 2019, CRD received a total of 5,958 new cases and closed 5,845 (98%), 1,348 by decision. Of these cases, CRD received 4,816 FDA cases and closed 4,672 FDA cases (97%), 1,101 by decision.

Alternative Dispute Resolution (ADR) - Alternative Dispute Resolution Division
Under the Administrative Dispute Resolution Act, each federal agency must appoint a dispute resolution specialist and must engage in certain activities to resolve disputes by informal methods, such as mediation, that are alternatives to adjudication or litigation. The DAB Chair is the Dispute Resolution Specialist for HHS and oversees ADR activities pursuant to the HHS policy issued under the Act. Using ADR techniques decreases costs and improves program management by reducing conflict and preserving relationships that serve program goals (e.g., between program offices and grantees, or among program staff).

The ADR Division provides services in DAB cases and supports the Chair as the HHS Dispute Resolution Specialist. The ADR Division provides mediation in DAB cases, provides or arranges for mediation services in other HHS cases (including workplace disputes and claims of employment discrimination filed under the HHS Equal Employment Opportunity program), and provides policy guidance, training, and

information on ADR techniques (including negotiated rulemaking, a collaborative process for developing regulations with interested stakeholders).

In FY 2019, the ADR Division received 80 requests for ADR services and conducted 10 conflict resolution seminars.

Medicare Appeals Council - Medicare Operations Division (MOD)

MOD provides staff support to the Administrative Appeals Judges (AAJs) on the Medicare Appeals Council (Council). The Council provides the final administrative review within HHS of claims for entitlement to Medicare and individual claims for Medicare coverage and payments filed by beneficiaries or health care providers and suppliers. The costs of Medicare claims adjudication are funded out of the Medicare Trust Funds and the corresponding budget request appears in the "Medicare Hearings and Appeals" section of the Departmental Management budget justification.

Workload Statistics

Board Members – Appellate Division

Chart A shows total historical and projected caseload data for the Appellate Division. All data are based on (1) case receipt and closure data for FY 2019, as well as year-to-date data for FY 2020, (2) the retirement of a Board Member at the beginning of FY 2020; (3) the addition of one new staff member in FY 2020, and (4) the addition of one more staff member in FY 2021.

APPELLATE DIVISION CASES – Chart A

Cases	FY 2019 (actual)	FY 2020	FY 2021
Open/start of FY	97	103	127
Received	137	124	124
Cases Closed by Decisions	87	54	69
Total Closed	131	100	128
Open/end of FY	103	127	123

Administrative Law Judges – Civil Remedies Division, FDA Tobacco Program

Chart B shows caseload data for CRD. All FDA Tobacco Program data are projected based on historical trends and certain assumptions, including the extension of the interagency agreements in FY 2020 and FY 2021 to hear FDA cases, an increase in the number of NTSO enforcement actions, and no major regulatory changes.

CIVIL REMEDIES DIVISION, TOBACCO CASES – Chart B

Cases	FY 2019 (actual)	FY 2020	FY 2021
Open/start of FY	471	615	865
Received	4,816	5,200	5,200
Decisions	1,101	1,200	1,175
Total Closed	4,672	4,950	4,950
Open/end of FY	615	865	1,115

Five Year Funding Table

Fiscal Year	Amount
FY 2017	$14,000,000
FY 2018	$14,000,000
FY 2019	$14,000,000
FY 2020	$4,500,000
FY 2021 Request	$6,000,000

*Prior to FY 2020, DAB's budget was entirely funded out of the General Departmental Management appropriation. The FY 2020 LHHS Bill allowed Medicare claims adjudication costs to be charged to the Medicare Hearings and Appeals appropriation. For FYs 2017-2019, the amount attributable to Medicare claims adjudication is $9,500,000 of the overall $14,000,000 allocation.

Budget Request

The FY 2021 President's Budget request for non-Medicare appeals related DAB activities is $6,000,000 in discretionary budget authority from the General Departmental Management appropriation, which is an increase of $1,500,000 above FY 2020 Enacted. In FY 2021, DAB's Medicare claims adjudication costs are funded out of the same appropriation as the Medicare Hearings and Appeals (MHA) appropriation. Please see the MHS Congressional Justification section for more details on DAB's Medicare appeals related activities.

The FY 2021 request will allow the DAB to hire 7 additional staff members, as well as account for inflationary pay and non-pay costs. The DAB will use the additional staff to support operational and adjudicatory functions where most needed in order to enhance overall agency efficiency. Specifically, this increase in staffing will allow the DAB to continue to meet necessary adjudication levels and improve its ability to meet statutory and regulatory deadlines. It will also help reduce the burden on existing employees resulting from several years of growing caseloads and stagnant funding levels.

In addition to this increase in FTE, the DAB will continue seeking other ways to enhance adjudicative efficiency. These efforts involve continuing to improve newly implemented IT-based solutions, including e-filing, digitization of paper claim files, and cloud-based data storage. The DAB's goal is to build upon the DAB's existing e-filing and electronic record systems and transform case processing in all of its adjudicatory divisions into a completely paperless process. In FY 2020 and FY 2021, the DAB will also focus on cutting-edge IT enhancements, such as artificial intelligence and data analytics, as tools to collect, manage, and analyze case data.

DAB - Outputs and Outcomes Table

Measure	Year and Most Recent Result/Target for Recent Result (Summary of Result)	FY 2020 Target	FY 2021 Target	FY 2021 +/- FY 2020
1.1.1 Percentage of Board Decisions with net case age of six months or less	FY 2019: 59% Target: 50% (Target Exceeded)	50%	50%	Maintain
1.2.1 Percentage of Board decisions meeting applicable statutory and regulatory deadlines for issuance of decisions.	FY 2019: 100% Target: 90% (Target Exceeded)	90%	100%	+10%
1.5.1 Number of conflict resolution seminars conducted for HHS employees.	FY 2019: 10 Target: 10 Sessions (Target Met)	10	10	Maintain
1.5.2 Cases closed in a fiscal year as a percentage of cases open in the same fiscal year.	FY 2019: N/A (New for FY 2020 and FY 2021)	90%	90%	Maintain

Performance Analysis
DAB has made measurable progress in the strategic management of human capital by reengineering its operations and improving its case management techniques. The DAB shifts resources across its Divisions as needed to meet changing caseloads, and targets mediation services to reduce pending workloads.

Appellate Division
In FY 2019, 59 percent of Appellate Division decisions had a net case age of six months or less, exceeding the Measure 1.1.1 target of 50 percent. In FY 2020 and FY 2021, the target for Measure 1.1.1 remains 50 percent, due to the loss of productivity caused by the retirement of a long-serving Board Member, the need to train a new Board Member, and the appointment to the Medicare Appeals Council of a long-serving Appellate Division Staff Attorney. The Appellate Division expects to meet the target for Measure 1.1.1 in both fiscal years.

In FY 2019, the Appellate Division exceeded the target of 90 percent for Measure 1.2.1 by issuing decisions in 100 percent of appeals having a statutory or regulatory deadline. In FY 2020, the target for Measure 1.2.1 will remain at 90 percent for the same reason stated above. The target will return to 100 percent for FY 2021 as productivity increases after the addition of a new Board Member in FY2020 and a new Staff Attorney in FY2021. The Appellate Division expects to meet the target level for Measure 1.2.1 in both FY 2020 and FY 2021.

Alternative Dispute Resolution (ADR) Division
In FY 2019, ADR met Measure 1.5.1 (number of conflict resolution seminars offered to HHS employees), but was unable to meet Measure 1.5.2, which measured the number of "DAB cases (those logged into ADR Division database) requesting facilitative ADR interventions prior to more directive adjudicative processes." Not meeting this target in FY 2019 (100 logged cases) can be attributed to the unexpected loss of an experienced mediator in FY 2019.

For FY 2019 and FY 2020, ADR decreased its target for Measure 1.5.2 from 110 to 100. This decrease reflected an ADR initiative that required staff to give considerable effort to recruiting and training a group of collateral duty mediators from HHS. These efforts were undertaken because ADR lost one experienced ADR attorney FTE in FY 2018 and another in FY 2019. To make up for that loss, ADR created a collateral duty mediator pool to increase internal capacity for handling conflicts arising at HHS. However, ADR learned from experience that the collateral duty mediator pool, while helpful, could not replace the full capacity of the two staff lost in FY 2018 and FY 2019. This was due in in large part to the demands of the regular duties of the collateral duty volunteers.

To better measure actual ADR staff effort, the DAB proposes changing 1.5.2 in FY 2020 to measure "cases closed in a fiscal year as a percentage of cases open in the same fiscal year." With the proposed revision, ADR anticipates meeting its targets for Measures 1.5.1 and 1.5.2 in FY 2020 and FY 2021, which will be made possible by filling one of the vacant ADR positions and by continuing to leverage resources through technology, including developing e-filing and adding IT enhancements for scheduling mediations.

OFFICE OF GLOBAL AFFAIRS

Budget Summary

(Dollars in Thousands)

Office of Global Affairs	FY 2019 Final	FY 2020 Enacted	FY 2020 President's Budget	FY 2021 +/- FY 2020
Budget Authority	6,026	6,026	6,026	-
FTE	20	20	20	-

Authorizing Legislation.....Reorganization Plan No. 1 of 1953
FY2021 Authorization.....Permanent Allocation
Method.....Direct Federal

Program Description and Accomplishments

The Office of Global Affairs (OGA) promotes and protects the health of US citizens, and works to improve global health and safety. It does so by advancing HHS's global strategies and partnerships, and by working with HHS divisions and other US Government (USG) agencies in the coordination of global health policy and international engagement. OGA develops policy recommendations and provides significant staff support to the Secretary and other HHS senior leaders on global health and social services issues, a role that has expanded in recent years. OGA coordinates these matters within HHS, across the government, and at multilateral institutions working on major crosscutting global health initiatives.

OGA provides global health expertise on a range of policy issues, and identifies and uses capacities present in HHS to address needs and opportunities overseas, while providing knowledge and analysis of international developments for the benefit of the Secretary and HHS as a whole. Priority areas include global health security, health aspects of trade interests, antimicrobial resistance (AMR), infectious disease preparedness and response, multilateral and bilateral diplomacy and negotiations, international HIV/AIDS control through the President's Emergency Plan for AIDS Relief (PEPFAR), polio eradication, increasing access to safe and effective medicines, and reducing barriers to care.

HHS has a range of relationships with other USG departments as well as more than 200 Ministries of Health. Multilateral partners include the World Health Organization (WHO); the Pan American Health Organization (PAHO) and other regional offices of the WHO; the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund); the UN Joint Program on HIV/AIDS (UNAIDS); the Organization for Economic Cooperation and Development (OECD); and the GAVI Alliance.

Significant accomplishments include:

- Led the U.S. Government delegation to the annual World Health Assembly (WHA), where important commitments were made on a variety of issues including:
  - Agreement on a landmark resolution on improving the transparency of markets for medicines, vaccines, and other health products, notably urging WHO Member States to publish the net prices of these products in their markets;
  - Successful defense of the USG policy position related to the WHO-authorized CDC's retention of the smallpox virus, to include coordinating and conducting significant outreach to global partners to allow continued research on the virus to develop diagnostics, vaccines, and therapeutics should smallpox re-emerge;

    - Secretary Azar and co-sponsors from five nations hosted an official WHA side event "Promoting Vaccine Confidence: Enhancing Global Immunization Efforts to Protect the Health of All Generations" to launch a yearlong effort to enhance immunization against vaccine preventable diseases; and
    - OGA chaired negotiations related to antimicrobial resistance, which in 2019 resulted in the WHA adopting a Resolution to strengthen national AMR plans, and increase visibility and coordination on AMR.
- Continued strong and effective collaboration with WHO to strengthen global capacities to prevent, detect, and respond to infectious disease threats, a key priority for the Administration. OGA provided regular support to the WHO Secretariat implementing the International Health Regulations Global Strategic Plan, which includes a variety of tools and support for countries to increase their domestic capacity to prevent the spread of disease.
- Organized a Ministerial meeting, led by Secretary Azar, to discuss the Venezuelan migrant health crisis and plan steps to protect regional public health.
- Led an international working group to further the President's and the Secretary's priorities for the Global Health Security Agenda (GHSA), resulting in development and successful international launch of the next five-year phase of GHSA – GHSA 2024 – and its guiding framework.
- Jointly with the World Bank, led the development of a GHSA effort to address the need for a sustainable approach to financing for health security, including through country mobilization of domestic resources.
- OGA serves as the HHS focal point for communication and coordination with the WHO, the Government of the Democratic Republic of the Congo (DRC), and neighboring countries' Ministries of Health in response to the 2018 and ongoing 2018-2019 Ebola epidemic in the DRC.
- During United Nations General Assembly week, Secretary Azar cohosted with the Director General of the WHO and the President of the DRC the Ministers of Health from DRC's neighboring country who agreed to enhance both national and regional preparedness for Ebola virus disease
- Realigned the activities of the US-Mexico Border Health Commission to advance the GHSA and AMR objectives through projects on the Border.

Five Year Funding Table

Fiscal Year	Amount
FY 2017	$6,026,000
FY 2018	$6,026,000
FY 2019	$6,026,000
FY 2020	$6,026,000
FY 2021 Request	$6,026,000

Budget Request

The FY 2021 President's Budget request for OGA is $6,026,000, which is flat with the FY 2020 Enacted level. At this level, OGA will continue efforts to ensure the health and well-being of Americans and to improve health and safety across the globe, through bilateral engagement and U.S. leadership in and collaboration with multilateral organizations. OGA will work with organizations such as the World Health Organization and its regional offices (such as the Pan American Health Organization), the Group of Seven (G7) and the Group of Twenty (G20), the Food and Agriculture Organization, the

Organization for Animal Health, and others to advance U.S. and HHS priorities. OGA will continue its efforts to coordinate government policy and programs through political and diplomatic channels both with Embassies in Washington and Health Ministries in foreign capitals. OGA will continue to coordinate and facilitate the involvement of OPDIVs and STAFFDIVs with these entities. OGA will also continue to lead the Department's negotiations on issues where trade and health intersect, ensuring that the Secretary's directives are carried out, and representing HHS equities in health and trade settings where these issues arise. OGA will maintain a leadership role on GHSA coordination for the USG, and focus efforts on political, diplomatic, and coordination issues to advance USG policy positions on global health security. In addition, OGA will champion efforts to prevent, detect, and control illness and death related to infections caused by antibiotic-resistant bacteria and will lead the policy development of the international coordination pillar of the National Action Plan for Combating Antibiotic-Resistant Bacteria 2021-2025. It will coordinate with government and international partners to implement measures to mitigate the emergence and spread of antibiotic resistance and ensure the continued availability of therapeutics for the treatment of bacterial infections.

In South Africa, Brazil, China, India, Kenya, Switzerland, and Mexico, OGA health attachés will continue to represent HHS as they work with other government agencies, NGOs, and industry on research, regulation, information sharing, and multilateral issues important to pandemic preparedness, safety of products, intellectual property and clinical trials, among many other objectives.

OGA will also continue to provide Secretarial and senior HHS officials with support for global engagements, including planning and coordinating international travel, providing on-the-ground logistic support in collaboration with U.S. Embassies, and supporting bilateral and multilateral engagements with Secretarial counterparts.

OGA will continue its oversight of the Border Health Commission's work, in partnership with Mexican counterparts, to identify critical health problems affecting states along the United States' southern border with Mexico, and identify opportunities for collaboration to address these problems.

OFFICE OF INTERGOVERNMENTAL AND EXTERNAL AFFAIRS

Budget Summary

(Dollars in Thousands)

Office of Intergovernmental and External Affairs	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget	FY 2021 +/- FY 2020
Budget Authority	10,625	10,625	10,625	-
FTE	53	61	59	-2

Authorizing Legislation:..... Reorganization Plan No. 1 of 1953
FY 2021 Authorization.....Permanent
Allocation Method.....Direct Federal

Program Description and Accomplishments

The Office of Intergovernmental and External Affairs (IEA) serves the Secretary as the primary link between the HHS, state, local, territorial, and tribal governments and non-governmental organizations and its mission is to facilitate communication related to HHS initiatives with these stakeholders. IEA serves as a conduit to report stakeholder interest and positions to the Secretary for use in the HHS policymaking process.

The IEA is composed of a headquarters team that works on policy matters within HHS Operating and Staff Divisions; ten regional offices responsible for public affairs, business outreach and media activities; The Office of Tribal Affairs responsible for tribal and native policy issues, assists tribes in navigating through HHS programs and services, and coordinates the Secretary's policy development for Tribes and national Native organizations.

IEA is actively involved in leading the educational outreach and stakeholder engagement on the Secretary's priorities related to the Opioid Crisis, Value-Based healthcare, Health Insurance Reform and Drug Pricing. IEA's efforts significantly increase the awareness and understanding of states, local, tribal and territorial governments; organizations, groups, private institutions, academia, private sector and labor unions of the various healthcare related programs and have proven to be hugely successful in improving the communication, timeliness and ultimately the relationships with stakeholders across the country.

In 2019, IEA accomplished the following in support of the Secretary's Initiatives:

- Formulated and executed Secretary's engagement with a broad spectrum of stakeholders, particularly around the Opioid Crisis and Drug Pricing, organizing 85 individual meetings, roundtables, and calls with external groups.
- Organized 58 individual meetings and roundtables with external groups for the Deputy Secretary, Chief of Staff, and Senior Advisors.
- Develop and staffed eight trips for the Secretary, Deputy Secretary, and other senior HHS leaders. On occasion, this travel also includes the President and Vice President.
- Led 10 Secretarial level rollouts of major policy items.
- State Profiles – Manage and update profiles on all states covering HHS programs to support Secretarial and senior level meetings, planning, and briefings.
- IEA received recognition and acknowledgement from ED's leadership for coordinating with 8 federal agencies that participated in a two-day workshop to support rural community colleges. ED is excited to repeat the event for another cohort in September 2019.

- Regularly interact with state legislators, county commissioners, and mayors to resolve issues related to clarification of policies regarding the implementation of the Child Care Development Fund, Family First Prevention Services Act, and matters related to Unaccompanied Alien Children.
- Coordinate and manage IEA's Policy Summit with HHS' intergovernmental and select external partners on sharing the Secretary's priorities. Moreover, throughout the year the Secretary monitors feedback received and apprise leadership of potential challenges that the administration and HHS could encounter from states, counties, cities, and nongovernment entities.
- Planned, executed, and staffed the Administration's "Advancing American Kidney Health" initiative. The 560-person event at the Ronald Reagan International Trade Center comprised of a speech from the President of the United States, an executive order-signing, a press conference, and a policy-focused breakout session.
- Organized quarterly Secretary's Travel Advisory Committee meetings and Indian Country travel
- Supported the ReImagine HHS Initiative including convening Optimizing Regional Performance Initiative meetings and worked with the team to develop performance standards and standard operating procedures for Regional Directors.

Five Year Funding Table

Fiscal Year	Amount
FY 2017	$10,625,000
FY 2018	$10,625,000
FY 2019	$10,625,000
FY 2020	$10,625,000
FY 2021 Request	$10,625,000

Budget Request

The FY 2021 President's Budget request for Office of Intergovernmental and External Affairs is $10,625,000, which is flat with the FY 2020 Enacted Level. At this level, IEA will continue coordination of a wide range of outreach activities, and facilitate crosscutting initiatives.

IEA will continue mission critical activities via personnel who are knowledgeable about the complexity and sensitivity of various HHS programs including health insurance marketplace, consumer/population distinctions, governmental organizations, and external organizations, to ensure successful communication and coordination of healthcare and human services policy issues and other priority initiatives of the Department, Secretary, and the Administration. IEA will continue to utilize electronic avenues to reduce travel costs, improve communication, timeliness, and relationships with stakeholders across the country.

CENTER FOR FAITH AND OPPORTUNITY INITIATIVES

Budget Summary

(Dollars in Thousands)

Center for Faith and Opportunity Initiatives	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget	FY 2021 +/- FY 2020
Budget Authority	1,299	1,299	1,299	-
FTE	5	5	5	-

Authorizing Legislation..... Reorganization Plan No. 1 of 1953
FY 2021 Authorization.....Permanent
Method.....Direct Federal

Program Description and Accomplishments:

Established in 2001, the Center for Faith and Opportunity Initiatives (the Partnership Center) partners with faith and community organizations to address national public health and human service issues (i.e.: the YMCA, Teen Challenge USA, the Boys and Girls Clubs of America, and the Southern Baptist Convention). The Partnership Center is committed to the clinical priorities of the Secretary and the Administration, as well as the priority of finding, exposing, and removing every barrier to full and active engagement of the faith community in the work of HHS.

The Partnership Center is strategically positioned to advance the Secretary's priorities across the vast array of faith-based and community organizations around the nation. This is being achieved through internal coordination with the various agencies of the Department and with regional offices across the nation, and externally through targeted outreach, education, capacity building, and community health asset alignment.

The Partnership Center supports the priorities of the Secretary, HHS, and the Administration by:

- Serving as an "open door" for faith and community-based partners, including service providers including Catholic Charities, National Alliance on Mental Illness' FaithNet, the Salvation Army, and Jewish Family Services, Seventh-day Adventist Church, and others to connect with and support the priorities of the Secretary and HHS.
- Building and strengthening relationships between The Patient Center, IEA, HHS, and diverse faith and community partners and providers.
- Developing educational opportunities (i.e.: webinars, videos, toolkits, and collaborative gatherings) that leverage the Department's subject-matter expertise, and the expertise of community leaders around the country. As a result, the Center continues to grow and strengthen a constituency base of national and local leaders, who are effectively implementing informed strategies to positively affect their communities.
- Communicating key messages, resources, grant opportunities, and awards relevant to faith and community partners.

In 2018-2019, the Center accomplishments, included:

- Connected thousands of faith and community leaders and providers with information, resources, and practical strategies for addressing the opioid crisis in their communities, including access to clinical services, workforce development, and strengthening recovery support services.
- Partnered with faith leaders to address the stigma of serious mental illness and how best to foster inclusion within faith communities.

- Collaborated with SAMHSA to strengthen the cultural competency of clinical providers and build their capacity to address the religious and spiritual concerns of their patients.
- Participated in more than 58 conference and community presentations with the goal to help educate, equip, and engage faith and community leaders and providers about HHS and Partnership Center priorities and activities.
- Supported the goals of the Ending the HIV Epidemic strategy by engaging hard to reach community influencers, in the areas with highest cases of new HIV diagnoses, with relevant and culturally appropriate messages.
- Facilitated, encouraged, and supported internal efforts to highlight faith-based and community leaders and providers in additional agency programs, including unaccompanied minors, foster care and adoption, women's health, and vaccinations.

Five Year Funding Table

Fiscal Year	Amount
FY 2017	$1,299,000
FY 2018	$1,299,000
FY 2019	$1,299,000
FY 2020	$1,299,000
FY 2021 Request	$1,299,000

Budget Request

The FY 2021 President's Budget request for Center for Faith and Opportunity Initiatives is $1,299,000, which is flat with the FY 2020 Enacted Level. At this level the Partnership Center will continue to support the efforts of faith-based and community organizations in addressing national public health and human service concerns identified as priorities for the Department; and leverage new software to accommodate more faith-based and community partners who desire to participate in webinars and other social media engagements hosted by the Partnership Center.

OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH

Budget Summary

(Dollars in Thousands)

Office of the Assistant Secretary for Health	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget	FY 2021 +/- FY 2020
Budget Authority	279,659	283,986	183,712	-100,274
FTE	229	252	229	-23

Agency Overview

The Office of the Assistant Secretary for Health (OASH), headed by the Assistant Secretary for Health (ASH), is a Staff Division of the Office of the Secretary in the U.S. Department of Health and Human Services (HHS). The ASH serves as the senior advisor for public health and science to the Secretary and coordinates public health policy and programs across the Operating and Staff Divisions of HHS. OASH is charged with leadership in development of policy recommendations on population-based public health and science and coordination of public health issues and initiatives that cut across the Operating and Staff Divisions of HHS. OASH provides leadership on population-based public health and clinical preventive services, ensuring the health and well-being of all Americans. The mission of OASH is to develop and coordinate the implementation of policies, investments, and frameworks to transform the current "sick-care system" into a "health-promoting system."

In support of this mission, OASH:

- Emphasizes health maintenance, healthy behaviors, prevention, early detection, and evidence-based treatment to achieve optimal health.
- Focuses on needy populations and disparities, as well as initiatives on health issues that can function as "exemplars" for more complex future initiatives.
- Demonstrates pathways to implement OASH priorities in a value-based health care environment.

In Leading America to Healthier Lives, OASH will focus on the following strategies:

- Health Transformation – catalyze a health promoting culture.
- Health Response – respond to emerging health challenges.
- Health Expertise – attract, develop and retain the Nation's best talent.
- Health Innovation – foster novel approaches and solutions.
- Health Opportunity – advance health opportunities for all.

As an organization, OASH represents a wide, cross-cutting spectrum of public health leadership including:

- 8 core public health offices – including the Office of the Surgeon General and U.S. Public Health Service (USPHS) Commissioned Corps – and 10 regional health offices around the nation.
- 13 Presidential and Secretarial advisory committees.

OASH SUMMARY TABLE – DIRECT

(Dollars in Thousands)

Office of the Assistant Secretary for Health	FY 2019 FTE	FY 2019 Final	FY 2020 FTE	FY 2020 Enacted	FY 2021 FTE	FY 2021 President's Budget
Immediate Office of the Assistant Secretary for Health	54	11,678	50	13,178	50	16,678
Office of Integrated Health						
Office of Infectious Disease and HIV AIDS Policy	18	7,802	18	7,552	18	5,937
Office of Disease Prevention and Health Promotion	28	7,894	29	7,894	29	7,894
Office for Human Research Protections	30	6,493	31	6,243	31	6,993
Office of Adolescent Health	4	1,442	4	442	-	-
Public Health Reports	2	467	2	467	-	-
Teen Pregnancy Prevention	16	100,562	17	101,000	-	-
Office of Minority Health	40	56,424	57	58,670	57	58,670
Office on Women's Health	36	32,001	43	33,640	43	33,640
Office of Research Integrity (Non-Add)	***28***	***8,558***	***28***	***8,558***	***28***	***9,414***
Minority HIV/AIDS Fund	1	53,900	1	53,900	1	53,900
Embryo Adoption Awareness Campaign	-	996	-	1,000	-	-
Subtotal, GDM	***229***	***279,659***	***252***	***283,986***	***229***	***183,712***
PHS Evaluation Set-Aside	-	-	-	-	-	-
OASH	-	4,285	-	4,285	-	4,285
Teen Pregnancy Prevention Initiative	-	6,800	-	6,800	-	-
Subtotal, PHS Evaluations	***-***	***11,085***	***-***	***11,085***	***-***	***4,285***
Total Program Level	**229**	**290,744**	**252**	**295,071**	**229**	**187,997**

IMMEDIATE OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH

Budget Summary

(Dollars in Thousands)

Immediate Office of the Assistant Secretary for Health	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget	FY 2021 +/- FY 2020
Budget Authority	11,678	13,178	16,678	+3,500
FTE	54	50	50	-

Authorizing Legislation.....PHS Act, Title II, Section 201
FY 2021 Authorization.....Permanent
Allocation Method.....Direct Federal

Program Description and Accomplishments

The Assistant Secretary for Health (ASH) and the Immediate Office of the Assistant Secretary for Health (OASH-IO) serve in an advisory role to the Secretary on issues of public health and science. The OASH-IO drives the OASH mission to lead America to healthier lives by providing leadership and coordination across the Department in public health and science, and advice and counsel to the Secretary and Administration on various priority initiatives such as combatting the opioid crisis, ending the HIV epidemic in America, value-based healthcare transformation through disease prevention and health promotion, maternal health, immunization policy, and emerging public health challenges related to infectious diseases.

Senior public health officials within the OASH-IO work to ensure a public health and prevention perspective is addressed in Secretarial and Presidential priorities through effective networks, coalitions, working groups, and partnerships that identify public health concerns and undertake novel and innovative projects.

Accomplishments in FY 2019 included:

- Led HHS efforts to combat the opioid and substance use epidemic by developing a comprehensive strategy, advancing evidence based-interventions, supporting novel research, developing new guidelines and highlighting voiceless victims through efforts such as the HHS National Convening on Neonatal Abstinence Syndrome, and developing a detailed cross- departmental strategy to counter the growing methamphetamine abuse crisis;
- Developed *Ending the HIV Epidemic: A Plan for America*, in coordination with CDC, HRSA, NIH, and IHS, among others; worked with OIDP, CDC, and IHS to kick off the implementation phase by (1) awarding grants to 32 CDC-funded state and local health departments to develop comprehensive *Ending the HIV Epidemic* plans that are tailored by and for each community, and (2) awarding grants to four jurisdictions to jumpstart activities to further reduce the number of new HIV transmissions
- Completed a comprehensive self-assessment of the U.S. Public Health Service Commissioned Corps (Corps), in coordination with the Office of the Surgeon General and Corps Headquarters, establishing a clearly-defined strategy and mission for the 21st Century Corps;
- Implemented various new policies and procedures to assure that the Commissioned Corps is more capable to achieve emergency response and humanitarian missions;
- Established a new federal interagency steering committee and workgroup on maternal health with the goal of making the United States one of the safest countries in the world to give birth. The workgroup includes CMS, HRSA, CDC, NIH, IHS and multiple other agencies;
- Published and disseminated the Physical Activity Guidelines for America;
- Published and launched the National Youth Sports Strategy with the White House and Secretary;

- Reorganized OASH including its regional operations to be better able to develop and implement public health priorities efficiently and effectively; and
- Established a new federal interagency workgroup with the specific objective of improving survival of patients with sickle cell disease by 10 years within 10 years. The workgroup includes NIH, FDA, CMS, HRSA, CDC, and multiple other agencies.

Five Year Funding Table

Fiscal Year	Amount
FY 2017	$11,678,000
FY 2018	$11,678,000
FY 2019	$11,678,000
FY 2020	$13,178,000
FY 2021 Request	$16,678,000

Budget Request

The FY 2021 President's Budget request for OASH's Immediate Office (IO) is $16,678,000, which is a $3,500,000 increase above FY 2020 Enacted Level. At this level, OASH will maintain support for the OASH-IO, which is the SG, and 10 regional offices. The OASH-IO will continue support for Administration and Department initiatives, including combatting the Nation's substance abuse epidemic and the misuse of pain medication, ending the HIV epidemic in America, and developing plans and disseminating information on prevention and health promotion. Critical strategies under development include Health People 2030, the National Vaccine Plan, the National HIV/AIDS Strategy, the National Viral Hepatitis Strategy, the first National Plan for Sexually Transmitted Diseases, and with the Department of Agriculture the Dietary Guidelines for America.

Reforming and Improving the U.S. Public Health Service Commissioned Corps

The Budget will continue to fund the modernization of the Corps and implementation of the Corps Ready Reserve. The Ready Reserve will provide surge capacity for public health emergencies, to deploy in response to a public health emergency and/or backfill critical positions left vacant during Regular Corps deployments.

Through the Public Health and Social Services Emergency Fund (PHSSEF), the President's Budget provides the Corps with funding for readiness training to improve the Corps' ability to respond to public health emergencies and ensure the Corps is a highly trained, always ready, fully-deployable national asset. The Budget also provides funds in PHSSEF and HRSA to cover the costs associated with a potential deployment of Corps staff to support homeless individuals.

The Budget also includes a mandatory proposal, effective FY 2022, which shifts the Commissioned Corps retirement pay and survivors' benefits costs from the current mandatory indefinite structure to a discretionary structure and charges agencies their share of these costs on a prospective basis.

<u>Proposed Law – Modernization of the Commissioned Corps/Alignment of Authorities with Other Uniformed Services</u>

The Budget also includes the following legislative proposals to modernize the Corps by updating legislative authorities to align the Corps with other uniformed services in support of improved force management:

Align the Corps' Leave Authorities with All Uniformed Services: This proposal would align the Corps' leave authorities with the other uniformed services by extending only the basic provisions of title 10, chapter 40 of the U.S. Code, including parental and adoption leave to Corps officers.

Expand the Recall-to-active-duty Authority to allow the Secretary to Involuntarily Recall Retired Corps Officers: This proposal grants the Secretary of HHS the authority to exercise an involuntary recall to active duty of retired Corps officers to face appropriate disciplinary actions if warranted. The Corps currently has no mechanism to recall a retired officer to face disciplinary actions if an officer had engaged in a conduct, while on active duty but not discovered until after retirement, that results in the conviction of a criminal offence.

OFFICE OF ADOLESCENT HEALTH

Budget Summary

(Dollars in Thousands)

Office of Adolescent Health	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget	FY 2021 +/- FY 2020
Budget Authority	1,442	442	-	-442
FTE	4	4	-	-4

Authorizing Legislation: ……PHS Act, Title XVII, Section 1708
FY 2021 Authorization……Expired
Allocation Method……Direct federal

Program Description and Accomplishments

Office of Adolescent Health (OAH) was established in 2010 with the Teen Pregnancy Prevention (TPP) program as its central focus. OAH convenes the Adolescent Health Working Group and supports efforts to reduce teen pregnancy and help pregnant and parenting teens become self-sufficient.

As part of the FY 2019 congressionally notified OASH reorganization, OAH merged with the Office of Population Affairs.

Five Year Funding Table

Fiscal Year	Amount
FY 2017	$1,442,000
FY 2018	$1,442,000
FY 2019	$1,442,000
FY 2020	$442,000
FY 2021 Request	-

Budget Request

The FY 2021 President's Budget does not request funding for this program.

OFFICE OF DISEASE PREVENTION AND HEALTH PROMOTION

Budget Summary

(Dollars in Thousands)

Office of Disease Prevention and Health Promotion	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget	FY 2021 +/- FY 2020
Budget Authority	7,894	7,894	7,894	-
FTE	28	29	29	-

Authorizing Legislation.....PHS Act, Title XVII, Section 1701
FY 2021 Authorization.....Permanent
Allocation Method.....Direct Federal

Program Description and Accomplishments

The Assistant Secretary for Health (ASH) has consolidated the Office of Disease Prevention and Health Promotion (ODPHP) and President's Council on Sports, Fitness and Nutrition (PCSFN) into ODPHP, which creates a joint office to assure critical mass, enhance competencies, assure science to practice, and deliver consistent and reinforcing tools and messages to the public on physical activity, nutrition and youth sports. The ODPHP FY 2021 Budget Request supports the priority set forth by the Office of the Assistant Secretary of Health (OASH) to reduce health disparities and improve health promotion and disease prevention efforts. ODPHP continues to focus efforts in setting national health goals, supporting programs and initiatives expanding healthy activities, and availability of health promotion and prevention information across the health system and to the public to promote stronger health outcomes.

Office of Disease Prevention and Health Promotion (ODPHP)

ODPHP provides leadership for a healthier America by initiating, coordinating, and supporting, disease prevention and health promotion, activities, programs, policies, and information through collaboration with HHS and other federal agencies.

Healthy People

ODPHP meets its Congressional mandate to establish health goals for the Nation by leading the development and implementation of *Healthy People*. *Healthy People* provides science-based national objectives, with 10-year targets, for improving the health of all Americans at all stages of life. It underpins HHS priorities and strategic initiatives, and provides a framework for prevention and wellness programs for a diverse array of federal and non-federal stakeholders. Many state and local health departments draw on *Healthy People* to develop their own health plans. The fourth iteration of the *Healthy People* objectives was released in 2010, as *Healthy People 2020*. ODPHP plans to launch the next generation of the objectives—*Healthy People 2030*—in mid-FY 2020.

In FY 2019, ODPHP continued to lead the development of Healthy People 2030. Drawing on user feedback supporting a more streamlined and focused approach, HP2030 will provide a significantly reduced number of national objectives (from about 1,200 to less than 400). As part of the development process, ODPHP manages the Secretary's Advisory Committee on National Health Promotion and Disease Prevention Objectives for 2030, comprised of 13 non-federal subject matter experts in various public health related fields. In FY 2019, the full Committee met three times via webinar and its subcommittees met 30 times. In FY 2019, the Committee provided recommendations to the HHS Secretary on the Leading Health Indicators (a subset of HP2030 objectives); target setting methodologies; stakeholder engagement and communication; and provided an assessment of the

proposed HP2030 objectives; and a series of seven issues briefs to inform the development and implementation of HP2030.

In FY2019, ODPHP published a *Federal Register* notice requesting public comments on the proposed slate of HP2030 objectives, which garnered 4,724 comments. Each of the comments was reviewed and vetted by the various lead agencies across HHS and other Departments that manage specific objectives. As part of the ongoing management of the current initiative (HP2020) and development of HP2030, ODPHP leads a Federal Interagency Workgroup on Healthy People, which includes representation from agencies and offices across HHS and other Federal Departments.

In FY 2019, ODPHP continued to improve and expand the reach of its award winning *Healthy People 2020* website (http://www.HealthyPeople.gov), which makes *Healthy People 2020* information widely available and easily accessible. This innovative web tool gives users a platform from which to learn, collaborate, plan, and implement objectives. Partnering with CDC's National Center for Health Statistics (NCHS) and the HHS Office of Minority Health, ODPHP increased accessibility and uptake of a disparities tool that allows users to easily see where disparities exist among population groups, and target their resources accordingly.

In FY 2019, the office continued a series of public webinar-based progress reviews of the *Healthy People* 2020 Leading Health Indicators (a subset of *Healthy People* objectives representing high-priority health issues), which allowed the OASH, in collaboration with the NCHS, the federal agencies that manage specific objectives, and community-based organizations, to demonstrate progress toward achieving the ten-year targets and identify areas needing additional work. On average, nearly 1,000 sites registered to attend each webinar.

Dietary Guidelines for Americans

ODPHP coordinates, on behalf of HHS, the development, review, and promotion of the *Dietary Guidelines for Americans* as required by Congress (P.L. 101-445). Published jointly every five years by HHS and the Department of Agriculture (USDA), the Dietary Guidelines is the basis of federal nutrition policy, programs, standards, and education for the general public. It also serves as the basis of the nutrition and food safety objectives in Healthy People 2020.

The process to develop the ninth edition (2020-2025 Dietary Guidelines) began in FY 2017 and continued in FY 2019, with much of the costs borne by USDA, the administrative lead. The Departments' approach to the next edition focuses on life stages, including a new focus on women during pregnancy and infants and toddlers from birth to 24 months, and a continued focus on eating patterns. In FY 2019, the Departments published the final list of topics and scientific questions that will inform the review of evidence supporting the development of the Dietary Guidelines. Additionally, the call for nominations and appointment of 20 members to the 2020 Dietary Guidelines Advisory Committee was completed. The Committee began its work reviewing the scientific literature related to the selected topics and questions. In FY 2019, the Departments hosted two of five public meetings of the Committee—March and July 2019—the second of which included time for 76 oral comments from the public. In partnership with the USDA Center for Nutrition Policy and Promotion, ODPHP staff support the work of the Committee and its subcommittees as Designated Federal Officer representatives, federal liaisons for subcommittees, logistical/administrative support, and general oversight of the Committee. The Committee's work will conclude in 2020, with submission of a scientific report to the Secretaries that will provide scientific evidence to support the development of the 2020-2025 Dietary Guidelines.

To promote transparency, an updated DietaryGuidelines.gov website includes regular updates on the public meetings of the Committee, subcommittee progress, and detailed documentation of the evidence review process. ODPHP will continue to support the process for the development of the 2020-2025 Dietary Guidelines, which is expected to be released in 2020.

Physical Activity Guidelines for Americans

In FY 2019, the Assistant Secretary for Health launched the Physical Activity Guidelines for Americans (PAG), 2nd edition at the American Heart Association Scientific Sessions. This was a multi-year project led by ODPHP in collaboration with CDC, NIH, and the President's Council on Sports, Fitness, & Nutrition. Accompanying the launch of the Guidelines was the Move Your Way communications campaign. Twenty manuscripts have been published since the launch, by Advisory Committee members and/or federal staff to further the reach of the Guidelines. The PAG serves as the primary basis for physical activity recommendations in the Dietary Guidelines for Americans and the physical activity objectives in Healthy People. Adherence to these easily met physical activity guidelines could reduce US premature mortality by 10% and save over $100B annually in health care expenditures.

Move Your Way

In November 2018, ODPHP launched the Move Your Way campaign to promote the recommendations from the second edition of the Physical Activity Guidelines for Americans. Move Your Way supports HHS's strategic goal to protect the health of Americans where they live, learn, work, and play. The campaign includes over 40 resources in English and Spanish on health.gov. The campaign has been embraced by federal partners and external stakeholders. For example, in FY2019:

- CDC invited ODPHP to include the Move Your Way campaign in its State and Community Health Media Center. This will enable CDC grantees to create customized versions of the campaign resources for distribution.
- ODPHP provided technical assistance to the University of Maryland, which used the campaign as part of a campus-wide wellness initiative with nearly 900,000 estimated impressions and an estimated 47% of students reporting exposure to the campaign.
- The HHS Office of Minority Health featured the campaign as part of National Minority Health Month.
- The campaign garnered awards for clear communication and digital health information.

ODPHP is promoting the Move Your Way campaign to consumers through community pilot tests. For the first round of pilot tests, ODPHP recruited lead organizations in Las Vegas, NV and Jackson, MS. These lead organizations were chosen from states with low levels of leisure time physical activity and informed by recommendations from CDC. Cumulatively, the community pilots resulted in more than 7,400 attendees getting active at local campaign events, more than 5,500 posters and fact sheets distributed within the communities, more than 26 million impressions from customized social media ads, and over 2 million completed views of the campaign videos. The pilots also garnered earned media coverage from local radio and television stations.

ODPHP is completing a full evaluation of the pilot tests to inform a second round of eight additional pilots for FY 2020. ODPHP also will focus on building new partnerships to promote the campaign and integrating it into the National Youth Sports Strategy.

National Youth Sports Strategy

Presidential Executive Order 13824 issued in February 2018 tasked the HHS Secretary with developing a National Youth Sports Strategy (NYSS). The Executive Order outlined four key pillars that form the foundation and focus areas of the NYSS:

1. Increase awareness of the benefits of participation in sports and regular physical activity, as well as the importance of good nutrition.
2. Promote private and public sector strategies to increase participation in sports, encourage regular physical activity, and improve nutrition.
3. Develop metrics that gauge youth sports participation and physical activity to inform efforts that will improve participation in sports and regular physical activity among young Americans.
4. Establish a national and local strategy to recruit volunteers who will encourage and support youth participation in sports and regular physical activity, through coaching, mentoring, teaching, or administering athletic and nutritional programs.

In FY 2019, ODPHP initiated the development of and launched the NYSS. To develop the strategy, ODPHP assembled a federal executive committee with staff from OASH, CDC, and NIH to oversee the project. Additionally, a larger federal steering committee with representatives from 17 different HHS offices is engaged throughout the NYSS development. The Federal Steering Committee formed four work groups, each of which focused on one key pillar. In FY 2019, ODPHP convened a public listening session to learn from organizations about coaching recruitment and training, programming, best practices, and strategies to engage underserved populations. There were two rounds of public comment, one on the key pillars and one on a draft of the NYSS. ODPHP also received input on the draft NYSS from academic peer reviewers and federal staff across HHS. ODPHP launched the NYSS in September 2019.

health.gov

ODPHP fulfills its congressional mandate to provide reliable prevention and wellness information to the public through its websites. Since 1997, ODPHP has been a key resource for online health information. In FY 2019, ODPHP began an initiative to streamline and improve its online health information through a comprehensive website infrastructure project to integrate and update its existing web properties: health.gov, healthfinder.gov, and healthypeople.gov.

The new website infrastructure will unify all the sites under health.gov using Drupal as a content management system, and reduce ODPHP's digital footprint by approximately 50%. The reduction will be accomplished by removing content that is duplicative with other federal sites or outdated and by reducing the number of Healthy People objectives, thereby reducing the amount of web content required to support Healthy People 2030. The new infrastructure will update the technology supporting the three sites and improve the user interface for ODPHP's myhealthfinder tool, which customizes preventive services recommendations for users based on age, sex, and pregnancy status. The new infrastructure will also feature a robust data dashboard to support Healthy People 2030 with an API that will automatically update each of the approximately 400 objectives with timely data.

In FY 2019, ODPHP completed planning for the new website infrastructure and in FY 2020 plans to complete web development and testing. ODPHP plans to launch the new infrastructure in mid-FY 2020, timed with the release of Healthy People 2030.

Health Literacy

ODPHP continues to play a leadership role in improving health literacy. In FY 2019, ODPHP led an effort to update the definition of health literacy as part of the planning process for Healthy People 2030. As part of this process, ODPHP published a *Federal Register* notice seeking public comments on the definition, which ODPHP plans to release with Healthy People 2030. ODPHP also partners with AHRQ to co-lead the HHS Health Literacy Workgroup. In FY 2019, the workgroup initiated health literacy quality improvement projects for each HHS agency.

President's Council on Sports, Fitness, and Nutrition (PCSFN)

On February 27, 2018, President Trump issued Executive Order (EO) 13824, "President's Council on Sports, Fitness, and Nutrition." The EO renamed and reestablished the PCSFN and detailed the Administration's aim to expand and encourage youth sports participation. The Council is a federal advisory committee of up to 30 volunteer citizens who serve at the discretion of the President.

The Council advises the President, through the Secretary of HHS, on programs, partnerships and initiatives that increase access to opportunities for all Americans to lead active, healthy lives. Council members, in consultation with offices within HHS and across the Federal government--as well as the private and non-profit sectors—have the delegated authority from ODPHP to promote sports participation among youth of all backgrounds and abilities and healthy and active lifestyles for all Americans.

I Can Do It!

I Can Do It! (ICDI) was effectively transitioned to the Administration for Community Living (ACL) on July 31, 2019. This follows the intent of the ASH to develop and implement novel programs, and then transition them to the appropriate Operational Division for expansion and further dissemination. Given ACL's expertise in administering programs and initiatives for individuals with a disability, they are uniquely positioned to advance the goals and objectives of ICDI.

Five Year Funding Table

Fiscal Year	Amount
FY 2017	$7,894,000
FY 2018	$7,894,000
FY 2019	$7,894,000
FY 2020	$7,894,000
FY 2021 Request	$7,894,000

Budget Request

The FY 2021 President's Budget request for ODPHP is $7,894,000, which is flat with the FY 2020 Enacted level. At this level, ODPHP will support the Administration and Department initiatives to create better systems of prevention, early detection, and patient empowerment that require the coordination of activities among Federal partners to enable HHS to leverage the scientific, evaluative, or programmatic findings of one agency for replication and dissemination through other agencies and government-wide.

ODPHP & PCSFN– Key Outputs and Outcomes Table:

Program/Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2020 Target	FY 2021 Target	FY 2021 Target +/- FY 2020 Target
ODPHP **I.b Visits to ODPHP-supported websites (Output)**	FY2019: 13,709,953 Target: 7.28 Million (Target Exceeded)	10.5 Million	10.5 Million	No Change
II.a Percentage of States that use the national disease prevention and health promotion objectives in their health planning process (Outcome)	FY 2019: 94% Target: 90% (Target Exceeded)	94%	40%	-54%
PCSFN **8.6 Number of social media impressions resulting from the promotion of sports, physical activity and promotion**	FY 2019: 110,779,596 Target: 1 Million (Target Exceeded)	1.2 Million	101 Million	99.8 Million

Performance Analysis

ODPHP has a congressional mandate to provide health information to professionals and the public. ODPHP continues to consolidate and move a substantial amount of program activities online and is increasing its use of social media vehicles, enhancing the value to the public and professionals. Healthy People provides an online resource with multiple interactive tools for tracking and implementing national health objectives (HealthyPeople.gov). The second edition of the Physical Activity Guidelines for Americans' Move Your Way campaign provides resources online to increase the uptake of the guidelines. Outreach for the Dietary Guidelines for Americans is primarily web-based as well. The online myhealthfinder tool provides easy-to-understand, customized prevention recommendations to consumers. As the data reflect, ODPHP is increasing its reach and engagement with Americans and exceeding performance targets. As a result, the public and professionals have more evidence-based tools, resources, and support for their prevention and wellness activities.

ODPHP expects to continue to grow its online presence. The initiative will allow Americans to be more productive in their prevention and wellness activities by offering social media, interactive learning technologies, data visualization tools, content syndication of prevention and wellness information, and forums that have proven to increase public and professional engagement. It also allows ODPHP to continue developing user-centered information and websites based on health literacy and plain language principles, extending the reach and impact to those who are not savvy users of health information or the internet.

ODPHP expects State use of Healthy People's national disease prevention and health promotion objectives to mirror the uptake seen with the previous decade's objectives. With the launch in FY 2020 of the next decade's objectives—Healthy People 2030—use will drop as States recalibrate their efforts to align with the national objectives.

OFFICE FOR HUMAN RESEARCH PROTECTIONS

Budget Summary

(Dollars in Thousands)

Office for Human Research Protections	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget	FY 2021 +/- FY 2020
Budget Authority	6,493	6,243	6,993	+750
FTE	30	31	31	-

Authorizing Legislation.....PHS Act, Title II, Section 301
FY 2021 Authorization.....Permanent
Allocation Method.....Direct Federal

Program Description and Accomplishments

OHRP was created in June 2000 to lead HHS's efforts to protect human subjects in biomedical and behavioral research, and to provide leadership for all federal agencies that conduct or support human subjects research under the Federal Policy for the Protection of Human Subjects, also known as the Common Rule. OHRP replaced the Office for Protection from Research Risks (OPRR), which was created in 1972 and was part of the National Institutes of Health (NIH). In June 2000, HHS established the National Human Research Protections Advisory Committee (NHRPAC) to provide HHS with expert advice and recommendations on human subject protections matters.

OHRP provides clarification and guidance, develops educational programs and materials, maintains regulatory oversight through compliance activities, provides advice on ethical and regulatory issues in biomedical and behavioral research, and administers assurance of compliance and Institutional Review Board (IRB) registration programs. These program activities include processing more than 3,500 Federal-wide Assurances (FWAs) and more than 3,000 IRB registrations each fiscal year. The office also supports the Secretary's Advisory Committee on Human Research Protections (SACHRP), which advises the HHS Secretary on issues related to protecting human subjects in research. SACHRP replaced NHRPAC on January 3, 2003 with similar responsibilities. OHRP has oversight over an estimated 13,000 institutions in the United States and worldwide that conduct HHS-supported non-exempt human subjects research (Authorizing Legislation Sections 491 and 492A of the Public Health Service Act).

On January 19, 2017, HHS and 15 other departments and agencies issued a revised Common Rule that was amended on January 22, 2018 and June 19, 2018. The general compliance date of the revised Common Rule was January 21, 2019. The revised Common Rule (also referred to as the 2018 Requirements) represents the first major set of changes to the federal human subjects protection system in over 20 years. These changes accomplish two important goals: (1) eliminating inappropriate regulatory burdens that have served to slow down certain types of research without providing meaningful protections for subjects, and (2) where needed, improving protections for subjects (particularly in terms of improved informed consent for higher-risk research).

- Policy and Guidance Development – OHRP's Division of Policy and Assurances (DPA) develops policy and guidance documents related to HHS regulations for the protection of human subjects (45 CFR Part 46). These documents address topics that the research community has indicated warrant additional clarification, an alternative regulatory interpretation, or regulatory change. The key goal of the policy and guidance documents are to help ensure that human research subjects are appropriately protected from harm, and to reduce unnecessary regulatory burden. Critical to meeting these goals is an active partnership with the Food and Drug Administration (FDA), the HHS agencies that conduct or support human subject research, and the other federal departments and agencies that have adopted the Common Rule. The recent revisions to the Common Rule include numerous regulatory changes that require OHRP to develop a number of new resources for the regulated community and to modify existing resources, including guidance documents. OHRP is developing more than two dozen new guidance documents and modifying more than three dozen of its existing guidance documents. During FY 2019, DPA issued two new draft guidance documents and new FAQs on two topics related to the revised Common Rule. The two draft guidance documents are on the topics of: public health surveillance activities deemed not to be research and the revised Common Rule compliance dates and transition provision, respectively. Both draft documents received positive responses from the regulated community. The FAQs are on the topics of: newborn dried blood spot; and, how IRBs should approach the continuing review of research that remains active beyond long-term follow-up or data analysis, but that is eligible for expedited review under categories 8(b) or 9 on the 1998 OHRP expedited review list in light of a new provision in the revised Common Rule (CR) that eliminated the requirement for continuing review of such research, respectively.

- Assurances of Compliance and Registering Institutional Review Boards – DPA administers the assurances of compliance with HHS protection of human subjects regulations and registrations of institutional review boards (IRB). During FY 2019, DPA processed 3,703 FWA approvals, and 3,296 IRB registrations. So far in FY 2020, DPA has processed 614 FWA approvals and 590 IRB registrations.

- OHRP's Division of Education and Development (DED) conducts outreach events and works with institutions around the United States to co-sponsor conferences and workshops to educate and support IRB members and administrators, investigators, institutional officials, and others, in their efforts to protect human subjects in research. The OHRP Research Community Forum (RCF), a two-day event organized in collaboration with research establishments, is the flagship DED education and outreach activity. DED sponsors two to three RCFs each year. DED also accepts up to about six institutional requests a year to support full or half-day Educational Workshops. Furthermore, DED develops online educational materials including videos and infographics for the general public to educate them about research participation, and for the research community to educate them about regulatory protections of human research subjects.

- In FY 2020, OHRP will sponsor three RCFs, co-host five to six one-day educational workshops, host one exploratory workshop, and speak at numerous events, projecting a reach to over 7,000 participants. OHRP also plans to post five new educational videos in FY 2020. In its first quarter, DED already supported two educational workshops (one with the NIH in Phoenix Arizona and the other with St. John's Health System in Tulsa, OK), provided staff speakers at four events including the 2019 Annual Meeting of Public Responsibility in Medicine and Research (PRIM&R), and posted a new video entitled "*How is Medical Research Different from Medical Care*?"

- For FY 2019, DED conducted six full day educational workshops (two with the NIH at their OER Regional Seminars; one with Regional Health of Rapid City, SD; one with Spectrum Health in Grand Rapids, MI; one with Leidos Biomedical Research, Inc. at the Frederick National Lab for Cancer Research in Frederick, MD; and another with the Uniformed Services University of the Health Sciences in Bethesda, MD) and provided staff to speak at nine different events including the Fellowship Course on Comparative Effectiveness Research hosted by the Association of Health Care Journalists; the NIH OER Regional Seminars; the conference on Healthcare in the Era of Big Data: Opportunities and Challenges hosted by the New York Academy of Sciences at New York University, NY; Human Subjects Training on Informed Consent conducted by the New York University Langone, NY; the IRB Educational Day at the Morehouse School of Medicine in Atlanta, GA; the 2018 Annual Conference of the Public Responsibility in Medicine and Research (PRIM&R) in San Diego, CA; the NCI ENRICH Forum on two separate occasions; and the 2019 Annual Conference of the Society for Clinical Research Associates (SOCRA) in San Antonio, TX, together reaching an audience of over 4,000 attendees. The 2nd OHRP Exploratory Workshop entitled "*Privacy & Health Research in a Data-Driven World*" was a tremendous success receiving 5,055 live views. The summary report and the archived videos for this event are now posted on OHRP website. Lastly, DED posted four new videos on the About Research Participation website and two educational videos on DED's Luminaries Lecture Series.

- OHRP's Division of Compliance Oversight (DCO) reviews allegations of noncompliance involving human subject research projects conducted or supported by HHS or that are otherwise subject to the regulations, and determines whether to conduct compliance investigations. DCO operates with two full-time subject matter experts. In FY 2019, DCO evaluated 174 complaints about research and allegations of non-compliance.

    - For-Cause Compliance Evaluations – DCO conducts inquiries and investigations into alleged noncompliance with HHS regulations for the protection of human subjects. These activities include conducting compliance inquiries, investigations, and preparing investigative reports, making determinations of noncompliance when appropriate, and requiring or recommending remedial or corrective action plans, as necessary. OHRP may choose to use other mechanisms to address allegations or indications of noncompliance rather than conducting a for-cause evaluation. For example, OHRP and its Compliance Division worked closely with NHLBI to resolve several concerns raised by complainants regarding the NHLBI funded study titled, Crystalloid Liberal or Vasopressors Early Resuscitation in Sepsis Trial (CLOVERS). After months of discussions with NHLBI, the protocol and consent documents were revised to resolve those concerns.

    - Not-for-Cause Compliance Site Visits - DCO conducts a program of not-for-cause surveillance evaluations of institutions. These evaluations, when conducted on site by several OHRP staff and expert consultants, involve an extensive review of IRB records and resources, review of a sample of IRB-approved protocols, and interviews with institutional officials, IRB administrators or human subject protections administrators, IRB members, IRB staff, and investigators. In FY 2019, DCO conducted a not-for-cause site visit to Vanderbilt University Medical Center to evaluate their human research protections program implementation of the revised common rule. In FY 2020, DCO plans to conduct approximately four on-site evaluations.

    - Incident report review and follow-up – DCO reviews incident reports submitted by institutions, and acknowledges or requests additional information from institutions, when needed. HHS regulations for the protection of human subjects (45 CFR Part 46), require that institutions

engaged in HHS-conducted or -supported human subjects research have written procedures, to ensure that they promptly submit, to OHRP, reports on incidents related to unanticipated problems involving risks to subjects or others, any serious or continuing noncompliance with HHS regulations or IRB determinations, or any suspension or termination of an IRB approval. In FY 2019, DCO received and reviewed 913 incident reports from regulated institutions.

- DCO is revising its evaluation procedures to address recommendations made by the Office of the Inspector General to clarify for the public how OHRP determines when it may choose to use other mechanisms to address allegations or indications of noncompliance rather than conducting a for-cause evaluation.

- SACHRP consists of eleven members that provide expert advice and recommendations to the Secretary and the ASH on issues relating to the protection of human research subjects, with particular emphasis on special populations, such as neonates and children, prisoners and the decisionally impaired; pregnant women, embryos, and fetuses; individuals and populations in international studies; populations in which there are individually identifiable samples, data, or information; and investigator conflicts of interest. Examples of recent issues discussed include the "HIPAA Exemption," under the Revised Final Rule, "Broad Consent," under the Revised Final Rule, and single IRB review for multisite research. In FY 2019, SACHRP approved 2 sets of recommendations. As of the first quarter of FY 2020, SACHRP has approved one set of recommendations.

- The HHS Strategic Plan highlights how HHS "works closely with…international partners to coordinate its efforts to ensure the maximum impact for the public." To this end, OHRP maintains oversight responsibility for over 3,800 institutions located outside the United States which conduct HHS-funded research. In support of this responsibility, OHRP publishes the International Compilation of Human Research Standards, coordinates a federal-wide International Working Group, serves as a resource to other federal agencies and to researchers conducting research in other countries, provides technical advice on draft international documents, and hosts international delegations.

Key Priority

OHRP will continue to develop new guidance and educational materials and modify existing guidance material for the regulated community in follow-up to issuance of the 2018 Requirements. OHRP supports the HHS and OASH strategic goals by contributing to the following measures:

- Increase the number of local, state, and national health policies, programs, and services that strengthen the public health infrastructure, and the number of policies in research institutions that improve the research enterprise.
- Increase the reach and impact of OASH communications related to strengthening the public health and research infrastructures.
- Increase the number of substantive commitments to strengthening the public health and research infrastructure on the part of governmental and non-governmental organizations.
- Increase knowledge about the public health and research infrastructure, including research needs, and improve data collection needed to support public health decision.

Five Year Funding Table

Fiscal Year	Amount
FY 2017	$6,493,000
FY 2018	$6,493,000
FY 2019	$6,493,000
FY 2020	$6,243,000
FY 2021 Request	$6,993,000

Budget Request

The FY 2021 President's Budget request for OHRP is $6,993,000, which is an increase of $750,000 above the FY 2020 Enacted Level. At this level, OHRP will support the Administration and Department initiatives to create better systems of prevention, early detection, and patient empowerment that require the coordination of activities among Federal partners to enable HHS to leverage the scientific, evaluative, or programmatic findings of one agency for replication and dissemination through other agencies and government-wide.

OFFICE OF INFECTIOUS DISEASE AND HIV/AIDS POLICY

Budget Summary

(Dollars in Thousands)

Office of Infectious Disease and HIV/AIDS Policy	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget	FY 2021 +/- FY 2020
Budget Authority	7,802	7,552	5,937	-1,615
FTE	18	18	18	-

Authorizing Legislation..... PHS Act, Title II, Section 301
FY 2021 Authorization.....Permanent
Allocation Method.....Direct Federal

Program Description and Accomplishments

The Office of the Assistant Secretary for Health (OASH) oversees the Department's key public health offices and programs, a number of Presidential and Secretarial federal advisory committees, 10 regional health offices across the nation, the Office of the Surgeon General, and the U.S. Public Health Service Commissioned Corps. As part of the *HHS ReImagine Initiative*, the Assistant Secretary for Health (ASH) announced a new structure for OASH intended to strengthen its portfolio with a more streamlined organization, poised to provide stronger cross-cutting, science-based, health-promoting leadership on our nation's most important public health topics. These structural changes, which went into effect in June 2019, have improved the integrity and quality of OASH's programs, increased operational efficiencies, better aligned technical and programmatic expertise to meet the future challenges of public health, and better positioned OASH to support bold initiatives, including the *Ending the HIV Epidemic: A Plan for America* (EHE). Ultimately, the new OASH structure will achieve maximal productivity and creativity of personnel, while improving efficiency in order to realize the OASH mission— to lead America to healthier lives.

As part of the OASH reorganization, the ASH consolidated the former National Vaccine Program Office (NVPO) and Office of HIV/AIDS and Infectious Disease Policy (OHAIDP) into the Office of Infectious Disease and HIV/AIDS Policy (OIDP). The mission of the new office is to provide strategic leadership and management, while encouraging collaboration, coordination, and innovation among federal agencies and stakeholders to reduce the burden of infectious diseases.

OIDP plays a vital role in directing HHS and federal government-wide policies, programs, and activities related to vaccines and immunization, HIV/AIDS, viral hepatitis, sexually transmitted, tick-borne, and other emerging infectious diseases of public health significance, as well as for blood and tissue safety and availability in the U.S. OIDP fulfills this role and supports these subject areas by undertaking department-wide planning, internal assessments, and policy evaluations which identify opportunities to maximize collaboration, eliminate redundancy, and enhance resource alignment to address strategic priorities.

OIDP also leverages expert advice to prevent infectious diseases through management of five federal advisory committees and workgroups. These workgroups span the Office's portfolio, and include the Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA), President's Advisory Council on HIV/AIDS (PACHA), Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PACCARB), National Vaccine Advisory Committee (NVAC), and the Tick-Borne Disease Working Group (TBDWG). Through the development of formal reports and recommendations, these committees and

workgroups contribute materially to the public health thought leadership provided by the Office and Department.

Ending the HIV Epidemic: A Plan for America

In February 2019, the President announced a robust plan to *End the HIV Epidemic in America.* OIDP leads and manages the implementation of this Presidential Initiative, ensuring collaboration, transparency and accountability across the operational divisions. The goal of this bold Initiative is to decrease new HIV infections by 90%, to <3,000 per year, by 2030. OIDP leads the Operational Leadership Team (OLT), which provides oversight to all operational aspects of the Initiative. As such, OIDP is responsible for coordinating the activities and work of the CDC, HRSA, NIH, IHS, and SAMHSA – the primary agencies for the Initiative. In addition, OIDP coordinates with other Departments who also have a role in addressing the HIV epidemic.

Phase 1 of EHE focuses on areas of the nation that comprised more than 50% of the new HIV diagnoses in 2016 and 2017, plus seven states with disproportionately high burdens of HIV in rural areas. In FY19, utilizing resources originating from the Minority HIV/AIDS Fund (MHAF), the CDC and IHS published funding opportunities for EHE Phase I jurisdictions to develop community plans. The goal is to work with phase I communities to bring additional expertise, technology, and resources that will be required to address the HIV epidemic in their communities.

In addition, utilizing MHAF funds, awards were made to four jurisdictions to jumpstart activities and implement the Initiative on an expedited basis. Metrics/indicators for the Initiative have been developed and adopted by the OLT and Policy Leadership Council. Through the use of the MHAF funds, the OASH has signaled its commitment to provide leadership, management, oversight and support for, and collaboration and coordination among HHS agencies, operating divisions, and external stakeholders.

National HIV Strategic Plan

OIDP is currently leading the development of the next iteration of the National HIV Strategy, which is due to be released in 2020. OIDP leads a federal steering committee that includes three subcommittees (prevention and care, disparities and coordination, and indicators), with partners from across HHS as well as numerous other federal departments, and meets regularly and guides development of the Strategy. Extensive public comment was gathered through 18 listening sessions and a Request for Information published in the Federal Register, has informed the work of the steering committee. The steering committee is aligning its work with the *Ending the HIV Epidemic: A Plan for America*, and has developed an updated vision and goals. In addition, the steering committee has adopted the EHE indicators. A companion Federal Implementation Plan will also be developed, detailing the actions federal agencies will perform to meet the metrics outlined in the Strategic Plan.

Minority HIV/AIDS Fund (MHAF)

OIDP administers the Minority HIV/AIDS Fund (MHAF) on behalf of the OASH. The purpose of the Minority HIV/AIDS Fund is to reduce new HIV infections, improve HIV-related health outcomes, and to reduce HIV-related health disparities for racial and ethnic minority communities by supporting innovation, collaboration, and the integration of best practices, effective strategies, and promising emerging models in the response to HIV among minority communities. In addition, the MHAF is focused on transforming HIV prevention, care, and treatment for communities of color by bringing federal, state, and community organizations together to design and pilot innovative solutions that address critical emerging needs and work to improve the efficiency, effectiveness, and impact of federal investments in HIV programs, activities, and services for racial and ethnic minorities.

Presidential Advisory Council on HIV/AIDS (PACHA)

The Presidential Advisory Council on HIV/AIDS (PACHA) provides advice, information, and recommendations to the Secretary regarding programs, policies, and research to promote effective treatment, prevention and cure of HIV disease and AIDS, including considering common co-morbidities, to promote effective HIV prevention, treatment and quality services to persons living with HIV disease and AIDS. With the creation of the *Ending the HIV Epidemic: A Plan for America,* PACHA has an opportunity to contribute to this historic federal effort by providing recommendations to the Secretary regarding the development and implementation of the Initiative, in addition to the National HIV/AIDS Strategy. In FY 2019, PACHA convened three full council meetings and established three subcommittees in order to provide focused analysis and recommendations regarding prioritized topical areas: *Ending the HIV Epidemic: A Plan for America* and the Updated National HIV Strategy Subcommittee, Stigma and Disparities Subcommittee, and the Global Subcommittee. Since March 2019, PACHA has submitted four resolutions for the Department's review and consideration:

- Resolution in Support of the *Ending the HIV Epidemic: A Plan for America;*
- Resolution in Support of Future Funding *for Ending the HIV Epidemic: A Plan for America;*
- Resolution in Support of Robust Community Engagement in the *Ending the HIV Epidemic* Initiative;
- Resolution in Support of Innovation to End the HIV/AIDS Epidemic.

Federal Interagency Working Group on HIV/AIDS

OIDP convenes and leads the Federal Interagency Working Group on HIV/AIDS (FIW), to ensure coordination of the work being done throughout the federal government on HIV. This includes monitoring and reporting on progress towards reaching the goals of the current National HIV/AIDS Strategy. In 2018, 96% of the 167 action items committed to by federal partners were completed or ongoing as planned. The FIW is in the process of preparing the 2019 report and will continue to monitor and report on progress for the next iteration of the National HIV Strategic Plan, to be released in 2020.

HIV.gov

HIV.gov is a leading source of information about the *Ending the HIV Epidemic: A Plan for America* initiative and information on HIV prevention and care and federal policies, programs, and resources. HIV.gov also became the lead federal source for information on the Ready, Set, PrEP program.

HIV.gov also provides:

- Cross-government coordination and technical leadership: HIV.gov works to ensure that federal messaging on HIV is consistent and reaches target audiences with maximum impact. We convene the Federal HIV Web Council and the awareness days to ensure that federal messaging from the HHS Secretary and the White House are promoted consistently across the U.S. Government.
- Cross-government marketing: We report through multiple platforms on breaking scientific news and federal resources from senior government officials to educate our federal and public audiences from major conferences and key events.

In FY2019, the HIV.gov website was visited more than 4.9 million times. The HIV.gov Services Locator, which provides geolocation-based information about testing and care services providers was used over 168,000 times. The HIV.gov Services Locator tool was also updated with a more user-friendly interface that yielded an 85.3% increase in views. We also converted the Locator to a Progressive Web App, which increased the speed at which it loads by 94%.

HIV.gov has also created standards for web hosting and internet security that serve as models for OASH and other federal agencies.

Vaccines and Immunizations
In 1987, Congress created the NVPO to provide policy leadership and coordination on vaccine and immunization-related activities among federal agencies and non-federal stakeholders (state and local government, non-governmental health groups, healthcare providers, health insurers, vaccine manufacturers and the public). In 2019, the scope of the NVPO was integrated into OIDP, which is now responsible for administering and implementing the statutory responsibilities of the National Vaccine Program.

As part of its vaccines and immunization-focused responsibilities, one of OIDP's core functions is to advance Departmental priorities for disease prevention by promoting health and wellness through immunization and optimization of the vaccine and immunization enterprise in the U.S. OIDP leads the coordination of federal immunization activities to ensure they are carried out in an efficient and consistent manner, and also works with non-federal stakeholders—domestic and international—to achieve the goals outlined in the 2010 National Vaccine Plan (NVP), that provides the framework—goals, objectives, and strategies—for pursuing the prevention of infectious diseases through immunizations. This includes federal government efforts towards vaccine research and development, vaccine confidence and safety, immunization coverage, supply, financing, education and communications, and global vaccine and immunization initiatives. OIDP also works with non-federal partners to develop and implement strategies for achieving the highest possible level of prevention of vaccine-preventable diseases. OIDP ensures coordination by taking a cross-cutting view to identify and bridge research gaps in immunization activities through various projects.

Viral Hepatitis
OIDP has the lead role in coordinating national efforts and informing policies to prevent, diagnose, and treat viral hepatitis in the United States.

OIDP leads development of the next iteration of the National Viral Hepatitis Strategic Plan, to be released in 2020. OIDP has convened and leads a joint HIV-viral hepatitis federal steering committee, which meets regularly and is comprised of representatives across HHS as well as other federal agencies. The steering committee's work is informed by three viral hepatitis subcommittees (prevention and care, disparities and coordination, and indicators), as well as the several hundred sets of public comments received through 18 listening sessions and a Request for Information published in the Federal Register. The steering committee has adopted and updated vision, goals, indicators and targets. A companion Federal Implementation Plan will also be developed, detailing the actions federal agencies commit to implement the Strategic Plan.

OIDP convenes and leads the Viral Hepatitis Implementation Group (VHIG), with more than 20 federal agencies and offices, including Departments of Health and Human Services, Housing and Urban Development, Justice, and Veterans Affairs. Through the VHIG, OIDP monitors and reports on progress implementing the current National Viral Hepatitis Action Plan (NVHAP) and will monitor and report on federal implementation of the next Strategic Plan.

OIDP also convenes the Hepatitis C Medicaid Affinity Group in collaboration with federal partners (CDC, CMS, HRSA, SAMHSA) and state Medicaid, public health and other state programs with populations highly impacted by Hepatitis C. Through this project, participating states develop and implement action plans to increase the number and percentage of Medicaid patients diagnosed with hepatitis C that are successfully treated and cured, which also decreases transmission of the hepatitis C virus. State-led

solutions and promising strategies are shared among the states to leverage and adapt each other's efforts. States that have participated include Louisiana and Washington, which have both implemented innovative pharmacy contracts to reduce the cost of hepatitis C treatment. Common strategies include data improvement, provider capacity expansion, reducing barriers to treatment and cure, expanding focused screening, diagnosis and treatment for the state's most impacted populations, and linkage to care upon release from prison.

Sexually Transmitted Infections

OIDP is leading the development of the first Sexually Transmitted Infections (STI) Federal Action Plan, which is expected to be released in 2020. STIs have risen dramatically since 2013 and are widely recognized as a public health epidemic. The STI Plan will contain targets and actionable strategies to reach them. In 2019, OIDP convened a federal steering committee which meets regularly and includes five subcommittees (primary prevention, secondary prevention and care, disparities and coordination, education and communication, and indicators). The steering committee guides development of the STI Plan and is comprised of about 20 federal agencies and offices. Its work is also informed by extensive public comment, which has been received through nationwide listening sessions and a Request for Information (RFI) published in the Federal Register. The steering committee has adopted a vision, goals, indicators, and targets for the STI Plan. OIDP developed and launched the hhs.gov/STI website, the public facing portal for the STI Plan. OIDP will work with federal partners to develop an implementation plan of activities. In addition, each participating federal agency will commit to establish an ongoing STI working group to continue collaboration and support implementation progress throughout the federal government, and OIDP will monitor implementation of the STI Plan.

Development of the National HIV Strategy, the National Vaccine Plan, the National Viral Hepatitis Strategy and the STI Federal Action Plan are all coordinated and aligned with each other, as well as with the *Ending the HIV Epidemic: A Plan for America* Initiative.

Vaccines and Immunizations

In 1987, Congress created the National Vaccine Program Office (NVPO) to provide policy leadership and coordination on vaccine and immunization-related activities among federal agencies and non-federal stakeholders (state and local government, non-governmental health groups, healthcare providers, health insurers, vaccine manufacturers and the public). In 2019, the scope of the NVPO was subsumed by the OIDP, which is now responsible for administering and implementing the statutory responsibilities of the National Vaccine Program.

As part of its vaccine system and immunization-focused responsibilities, one of OIDP's core functions is to advance Departmental priorities for disease prevention by promoting health and wellness through immunization and optimization of the vaccine and immunization enterprise in the U.S. OIDP leads the Interagency Vaccine Working Group and coordinates federal immunization activities to ensure they are carried out in an efficient and consistent manner, and also works with non-federal stakeholders—domestic and international—to achieve the goals outlined in the 2010 National Vaccine Plan (NVP). The 2010 NVP provides the framework—goals, objectives, and strategies—for pursuing the prevention of infectious diseases through immunizations. This includes federal government efforts towards vaccine research and development, vaccine safety, immunization coverage, supply, financing, education and communications, and global vaccine and immunization initiatives. OIDP also works with non-federal partners to develop and implement strategies for achieving the highest possible level of prevention of vaccine-preventable diseases. OIDP also works to respond to exigent circumstances within this domain. For example, in response to the recent, global resurgence of measles, OIDP is leading and coordinating

collaborative intra- and inter-agency initiatives with the goal of increasing public confidence in the U.S.'s vaccine and immunization enterprise. These activities are being carried out in order to meet NVP population level targets for all routinely Advisory Committee on Immunization Practices (ACIP) recommended vaccines. Additionally, OIDP takes a cross-cutting view to identify research gaps, mitigate potential duplication in resources utilized, and promotes robust coordination with stakeholders for all Office project initiatives.

2020 National Vaccine Plan (NVP)

OIDP is developing the next iteration of the NVP, which will recommend vaccine strategies across the lifespan and prioritize actions from 2020-2025. The development of this plan is being coordinated with the Interagency Vaccine Working Group (IVWG) and other federal partners. In addition, recommendations from the National Vaccine Advisory Committee (NVAC) have been taken into consideration. As part of this activity, a Request for Information (RFI) was published in the Federal Register, in order to solicit public input on strengthening and improving the nation's response to vaccine preventable diseases and strategies to address infectious diseases through vaccination. Comments from stakeholders and the general public on the priorities, goals, and objectives for the next iteration of the NVP have been received. Results from this analysis will be combined with other stakeholder input to inform the development of a concise, actionable five-year plan that will recommend vaccine strategies across the lifespan, guide priority actions for 2020-2025, and emphasize indicators to measure progress towards plan goals. The next iteration of the NVP will be released in October 2020.

National Vaccine Advisory Committee (NVAC)

OIDP serves as Executive Secretariat for NVAC, which advises and makes vaccine-related recommendations to the ASH, in his capacity as the Director of the National Vaccine Program. NVAC was established in 1987 to comply with Title XXI of the Public Health Service Act (P.L. 99-660) (Section 2105). The Committee's responsibilities pertain to encouraging the availability and adequacy of vaccination products in the U.S., recommending research priorities, advising the ASH on the implementation of, and areas for collaboration pertaining to the National Vaccine Program and the National Vaccine Plan.

In FY 2019, OIDP convened three NVAC meetings. During FY 2019, the ASH assigned three charges to the committee, each of which will result in a report to the ASH. The first charge asked NVAC to assess and prioritize existing goals from the *National Vaccine Plan* (2010) and *National Adult Immunization Plan* (2016), and propose new goals, priorities, and stakeholders for the 2020 NVP. This charge was completed this fiscal year and the recommendations from this NVAC report were taken into consideration in the development of the 2020 NVP. The second charge was to review and summarize factors that contribute to vaccination disparities and then deliver a set of system-wide recommendations for overcoming drivers of immunization disparities and reducing gaps in coverage. The third charge was to assess how confidence in vaccines impacts the optimal use of all recommended vaccines in the U.S. Both the vaccine confidence and the immunization equity reports will be voted on at the September 2020 NVAC meeting.

Communicating the Importance of Vaccines Across the Lifespan

In 2011, the National Vaccine Program established Vaccines.gov as a hub for vaccine information from across the federal government for consumer audiences. Through Vaccines.gov, OIDP provides the public a trusted voice and extensive information on vaccines and vaccine information across the lifespan. In 2019, Vaccines.gov reached nearly 5 million people with evidence-based, credible information, and raised awareness of the importance of vaccines by leveraging Twitter Chats, HHS blog posts, and other social media outlets in collaboration with the Office of the Assistant Secretary for Health, the Office of

the Surgeon General, and other offices. OIDP also worked with Twitter to direct users seeking vaccine information on Twitter to Vaccines.gov. OIDP led an OASH-wide group that developed a comprehensive communication plan to support the HHS strategy to improve HPV vaccination rates, which included partner engagement, dissemination of an HPV toolkit on Vaccines.gov, and adding 3,000 HPV vaccination locations to the Vaccine Finder Widget on Vaccines.gov. In 2019 OIDP also migrated Vaccines.gov's English and Spanish content to a more secure, easier to use, and cost-saving content management system. This update will help ensure Vaccines.gov remains a top search result on Google and other search engines for vaccine information while also enhancing the user experience for the site when viewed across mobile and tablet devices.

Encouraging Adult Immunization

Reducing vaccine-preventable diseases in adults is a national health priority. Adult vaccination coverage rates remain low for most routinely recommended vaccines, and fall well below Healthy People 2020 targets. As part of ongoing activities intended to implement *National Adult Immunization Plan* (NAIP) objectives, in 2019, OIDP held stakeholder meetings in Regions 1, 2, 4, and 10 to collaborate and discuss practices and barriers on priority immunization topics. Key accomplishments from the series included providing training on immunization registries and optimizing their use for HPV vaccination; raising awareness of funds for adult immunization and best practices for their utilization; forging partnerships among state health departments and correctional facilities to enhance vaccination among correctional facility populations; and initiating action planning around linking state immunization and substance use programs to improve Hepatitis A vaccination rates and reduce the threat of existing outbreaks in the northeast.

Reducing the Incidence of Preventable Human Papillomavirus (HPV) Associated Cancers through Immunization

Recognizing the urgent need to lower the incidence of HPV infections that lead to HPV-associated cancers through the use of the ACIP-recommended HPV vaccine, the Assistant Secretary for Health established and prioritized the goal to increase HPV vaccination series completion rates to 80% by 2025. In response, OIDP has developed a two year strategic investment that targets critical nodes and geographic regions in the national health care system. This collaborative blueprint is intended to foster and facilitate efforts to strengthen system-wide focus on HPV vaccination. The OIDP strategy has three components to achieve this goal, and in 2019 initiated activities intended to optimize existing health system infrastructure to further the reach and utilization of the HPV vaccination. These activities include: coordination of an HHS-wide communications and engagement strategy through social, digital, and traditional communications platforms; dissemination of evidence-based practices and engaging integrated health care delivery networks; addressing provider needs in rural areas; and outreach to faith-based communities, including a 100 congregation-wide initiative in Region IV that was developed and implemented in the last quarter of 2019.

Understanding the importance of engagement and collaboration with large health systems to meet the 2025 goal, OIDP initiated a collaborative 24 month project in 2019, with the American Cancer Society's National HPV Vaccination Roundtable, CDC, and the American Medical Group Association (AMGA) to improve HPV vaccination rates. This project is intended to develop and implement evidence-based strategies and interventions to improve HPV vaccination rates in multi-specialty medical groups, integrated health systems, or integrated delivery networks (IDN) with a focus on adolescents. The collaborative will create a community of knowledge that can help participants accelerate systematic change and develop care processes to address HPV vaccinations. The AMGA team will make site visits in 2020 to the eight awarded health systems to assist with and analyze the adaptation and implementation

of established best practices for increasing HPV vaccination uptake across the systems. Throughout the project, ongoing lessons will be shared with IDN staff, creating a feedback loop for greater dissemination and organizational learning. The work of the collaborative will be carefully documented, with the potential to develop at least one peer-reviewed publication on the collaborative findings. The findings will also be featured on a national webinar hosted by the HPV Roundtable, and ongoing lessons learned will be communicated on the HPV Roundtable website for dissemination by other large national medical groups and integrated delivery networks.

Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PACCARB)
The Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PACCARB) is managed by OIDP. PACCARB provides advice, information, and recommendations to the Secretary regarding programs and policies intended to support and evaluate the implementation of U.S. government activities related to combating antibiotic-resistant bacteria, including the National Strategy for Combating Antibiotic-Resistant Bacteria (Strategy) and the National Action Plan for Combating Antibiotic-Resistant Bacteria (Action Plan). While primarily established under Executive Order 13676 in 2014, the PACCARB was codified in June 2019 under the Pandemic and All Hazards Preparedness and Advancing Innovation Act, thus emphasizing the issue of antibiotic resistance as a public health security threat.

During Fiscal Year 2019, the PACCARB hosted a 2-day public meeting, at the Secretary's request, with a range of stakeholders from human, animal, and environmental health domains, to gain public feedback regarding the Department's antimicrobial resistance (AMR) related activities. This meeting helped to inform the development of a PACCARB report regarding priorities for consideration for the next iteration of the National Action Plan on Combating Antibiotic Resistant Bacteria: 2020-2025. Another public meeting was held, virtually, to vote on and discuss a PACCARB one-page report supporting the inclusion of antibiotic stewardship programs in CMS Conditions of Participation. Finally, a third public meeting was convened and focused on a range of topics, including: antifungal-resistant fungi, human and animal health provider behavior change, innovations in diagnostics and avian influenza, and AMR information dissemination through public education.

Blood and Tissue Safety and Availability
Ensuring that safe blood and tissue products are available when they are needed is important to the health and wellbeing of Americans. OIDP coordinates HHS activities related to blood and tissue safety and availability, and has a number of accomplishments within this domain.
The Federal Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA) advises, assists, and makes recommendations to the Secretary of HHS, through the Assistant Secretary for Health, on issues related to the safety of blood, blood products, organs, and tissues. The 50th meeting of the ACBTSA was held in April, 2019. For this meeting, public- and private-sector stakeholders in organ transplantation were seeking to explore potential important updates to the 2013 *PHS Guideline for Reducing Human Immunodeficiency Virus, Hepatitis B Virus, and Hepatitis C Virus Transmission Through Organ Transplantation* in order to maintain accordance with current health sector circumstances. To improve policies around transplantation so that Americans in need of organs have the greatest possible chance of receiving one, the ACBTSA developed 12 recommendations.

Since 1971, national surveys have been administered intermittently in the U.S. to estimate blood collection and utilization. OIDP manages the Biennial HHS National Blood Collection and Utilization Survey (NBCUS). The biennial NBCUS has been the primary method of gathering these data in the U.S. since 1997. All US blood collection centers and all U.S. acute care hospitals performing at least one hundred inpatient surgical procedures per year and located within the 50 states and the District of Columbia are asked to participate.

Tick-Borne Disease Working Group

OIDP is responsible for convening the Tick-Borne Disease Working Group (TBDWG) to ensure requirements of the 21st Century Cures Act (Section 2062, Tick-Borne Diseases) are met. The next report to the HHS Secretary and Congress regarding findings and recommendations for the federal response to tick-borne diseases is due December 2020.

For the 2020 report, OIDP manages ten TBDWG subcommittees comprising approximately 65 federal and public members who will report to the TBDWG on the following topics: 1) tick biology, ecology, and control; 2) pathogenesis and physiology of Lyme disease; 3) clinical aspects of Lyme disease; 4) training and education; 5) alpha-gal syndrome; 6) rickettsiosis; 7) ehrlichiosis and anaplasmosis; and 8) babesiosis and tick-borne viruses. OIDP is also working with the TBDWG to develop three Topic Development Briefs to gather a preliminary understanding of three topics: 1) What are the causes for the increased number of tick-borne disease cases in the U.S? 2) What are the causes of persistent symptoms of Lyme disease? and, 3) What are the current diagnostic tests available for tick-borne diseases, and what is the state of the tests?

Five Year Funding Table

Fiscal Year	Amount
FY 2017	$7,802,000
FY 2018	$7,802,000
FY 2019	$7,802,000
FY 2020	$7,552,000
FY 2021 Request	$5,937,000

Budget Request

The FY 2021 President's Budget request for OIDP is $5,937,000 which is $1,615,000 below the FY 2020 Enacted Level. This request will allow OIDP to continue its critical role in directing HHS and federal government-wide policies, programs, and activities related to infectious diseases as delegated by the Secretary to the Assistant Secretary for Health (ASH). OIDP's primary areas of emphasis include, but are not limited to: vaccines and immunizations; HIV/AIDS; viral hepatitis; tick-borne diseases; sexually transmitted infections (STIs), antibiotic-resistant bacteria and other emerging infectious diseases of public health significance.

OFFICE OF RESEARCH INTEGRITY

Budget Summary

(Dollars in Thousands)

Office of Research Integrity	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget	FY 2021 +/- FY 2020
Budget Authority	8,558	8,558	9,414	+856
FTE	28	28	28	-

Authorizing Legislation.....PHS Act, Title II, Section 301
FY 2021 Authorization.....Permanent
Allocation Method.....Direct Federal

Program Description and Accomplishments

Since its inception in 1992, the Office of Research Integrity (ORI) has worked to promote integrity in biomedical and behavioral research, reduce research misconduct, and maintain the public's confidence in research supported by funds of the U.S. Public Health Service (PHS) agencies – supporting HHS' goal to lead in health and biomedical science and innovation.

ORI's mission directly supports the Office of the Assistant Secretary for Health's national leadership on the quality of public health systems. Recipients of PHS funds are required by ORI's 2005 regulation to foster an environment that promotes the responsible conduct of research, implement policies and procedures to respond to allegations of research misconduct, protect the health and safety of the public, and conserve public funds (42 C.F.R. Part 93).

Funded through an Interagency Agreement with NIH, ORI functions through two divisions. The Division of Education and Integrity (DEI) manages programs to ensure that PHS-funded institutions have policies and procedures in place for handling allegations of research misconduct, provides educational resources to help institutions in promoting research integrity, and evaluates trends in research integrity lapses. The Division of Investigative Oversight (DIO) handles allegations of research misconduct and monitors institutional research misconduct processes in order to develop and support HHS findings of research misconduct and proposed administrative actions.

ORI leads or collaborates in cross-departmental training and oversight activities. ORI works with HHS's Office for Human Research Protections and Office of Inspector General to educate institutional officials about how to deal with misconduct that involves research misconduct, violations of human subjects' protections, and/or fraud. ORI convenes periodic meetings with representatives from other departments and agencies responsible for handling allegations of research misconduct, including the National Science Foundation, Department of Veterans Affairs, Department of the Interior, Environmental Protection Agency, and Department of Defense. As needed, ORI coordinates efforts when an allegation of research misconduct involves funds from the PHS and another federal agency. Most significantly, in 2019, ORI continued its relationship with the Office of Extramural Research at the National Institutes of Health (NIH), reporting case closures with concerns for inappropriate research practices that did not meet the legal threshold for misconduct findings. Having reported 10 such cases in 2019, ORI anticipates reporting more than a dozen such cases in 2020, strengthening HHS' ability to protect PHS funding through NIH's grants administrative functions. Through its own authorities, NIH is able to apply certain grant restrictions to institutions that may not be responsible stewards of research funds.

When ORI makes a finding of research misconduct, it usually has taken a year or more of in-depth analysis of the evidence. Analysis typically proceeds with the assistance of the research institution's Research Integrity Officer (RIO) providing additional information, and the advice of the HHS Office of General Counsel (OGC). Research misconduct findings lead to HHS administrative actions published in the *Federal Register*.

Administrative actions taken by PHS agencies may include one or more of the following: suspension or termination of a PHS grant; special review of all institutional requests for PHS funding; imposition of supervision requirements for all grants and contracts to a researcher; exclusion of participation by a researcher in any advisory capacity to the PHS; notification to journals for the correction/retraction of publications; and/or suspension or debarment of a researcher for one year up to lifetime. The purpose of these administrative actions is remedial and to prevent the misuse of PHS funds by the person found to have engaged in research misconduct ("the respondent") and to improve the oversight of an institution's responsibilities as a recipient of PHS funds

ORI makes a majority of its findings through a negotiated settlement between ORI and the respondent. If the respondent declines the settlement, HHS' OGC develops a charge letter notifying the respondent of the findings of research misconduct and any HHS administrative actions. The respondent has 30 days to contest the charge and request a formal hearing. If that happens, the case goes to an Administrative Law Judge (ALJ) on HHS' Departmental Appeals Board. ALJs issued decisions supporting ORI findings in three significant cases in 2018 and 2019, continuing the trend of HHS' success in presenting cases to the ALJ since 2005. ORI has no cases pending before the ALJ as of December 2019.

ORI receives allegations of research misconduct from the public and institutional officials via phone, email, and mailed documents. ORI records all allegations in an electronic case tracking database. ORI assesses entries in this database for jurisdiction and timeliness under the statute of limitations specified in ORI's regulation. For allegations that are both credible and within ORI jurisdiction (involves PHS funding), ORI refers allegations to institutional officials for further assessment or formal inquiry. Over the past five years, ORI has handled 200-450 accessions each year, opening 25-40 cases per year in response to institutional investigation reports, and closing 20-50. ORI closes cases with either findings of research misconduct or a determination that the evidence is not strong enough to pursue. Currently, ORI has almost 200 active allegations, including over 30 active cases.

ORI funds research grants to improve understanding of institutional, social, and behavioral factors associated with research misconduct, to develop tools to better detect research misconduct, and to develop and evaluate effective approaches to promoting the responsible conduct of research. ORI also funds grants to institutions to provide a forum for discussion and production of tangible outcomes related to at least one of several themes related to ORI's mission: (1) training on responsible conduct of research; (2) fostering an environment that promotes research integrity; (3) prevention of research misconduct; (4) handling of research misconduct allegations; (5) whistleblowing; (6) international issues in research integrity; or (7) other topics clearly linked to research integrity and compliance with 42 C.F.R. Part 93. To date, ORI grants have yielded over 200 peer-reviewed publications.

ORI's accomplishments in FY 2019 have furthered the goal of promoting research integrity as follows:

- Responded to 235 allegations.
- Opened 38 cases.
- Administratively closed 26 allegations that were not substantiated, including 13 received in 2019.
- Closed 40 cases, including 8 with findings of research misconduct.
- Assured that almost 6,000 institutions worldwide attested to having research misconduct policies in place in order to receive PHS funds for research, along with monitoring their annual reports of research misconduct and their compliance with their policies for handing allegations of research misconduct.
- Fulfilled 11 Freedom of Information Act (FOIA) requests.
- Received over 100 website visits from each of more than 138 countries.
- Promoted interactive videos on research integrity in basic and clinical research and a number of infographics which were viewed more than 82,000 times.
- Hosted conferences and workshops on research integrity in 2019, including:
    a. Two RIO Boot Camps for institutional officials (March and August 2019) to teach them research integrity basics;
    b. A Responsible Conduct of Research (RCR) Instructor Workshops (September 2019), a train-the-trainer format so institutional officials can transfer appropriate knowledge and skills to their staff and students ; and
    c. Senior Institutional Officials Meeting on Research Integrity (May 2019).
- Offered frequent social media and regular blog postings throughout the year, as well as monthly email updates.
- Disseminated two new grant Funding Opportunity Announcements seeking meritorious applications for conducting research on, and convening conferences related to, research integrity.

In FY 2020, ORI expects these activities to continue at approximately the same levels, although only one RCR workshop is anticipated. In addition, ORI has begun to update its case tracking system, adding features to improve file access, and enabling a secure document transfer capability without compromising confidentiality. This latter improvement alone will enable institutions to send electronic files directly, versus the current methods which rely on external media (CD or flash drive), reducing burden and improving security for both ORI and the sending institutions. Further, having the electronic versions immediately available will ensure timely updating of the case tracking system. ORI also has begun work on enhancements to its assurance database, envisioning an online system to systematically review institutional policies or allegations of research misconduct. These changes should be initiated by the close of fiscal year 2021. ORI convened other federal agencies with research misconduct policies in 2019, to assess interest in jointly completing development of image analysis technology that would use artificial intelligence to analyze the multiple (sometimes hundreds) of images involved in a research misconduct investigation. Since image manipulation comprises about 80% of allegations of falsification or fabrication of research results, automating the initial identification of suspect images will greatly increase efficiency. The interagency meeting also surfaced best practices in improving case reporting and alignment for data comparability. Finally, results from the 2019-2020 assessment of the current scientist investigator job series (health scientist administrator) will help determine ORI's future hiring of these positions to better identify candidates with critical skills to evaluate allegations of research misconduct, oversight of institutional investigations, and the forensic examination of biomedical data, images, and computer hardware.

Five Year Funding Table

Fiscal Year	Amount
FY 2017	$8,558,000
FY 2018	$8,558,000
FY 2019	$8,558,000
FY 2020	$8,558,000
FY 2021 Request	$9,414,000

Budget Request

The FY 2021 President's Budget request for ORI is $9,414,000, which is $856,000 above the FY 2020 Enacted Level. At this level, ORI will continue to accelerate its database modernization project with a module to implement enhanced reporting capabilities and case tracking. The budget will support pay and non-pay inflationary costs and maintain staff needed to conduct investigative and educational activities. This includes managing contracts and grants needed to support the dissemination of educational information regarding research integrity, and training activities aimed at increasing awareness and technical skill in conducting research misconduct proceedings at PHS-funded research institutions. ORI will enhance internal case handling processes through investment in 21st century technology. ORI will continue to inform NIH when we identify issues of concern in our oversight investigations, participate in NIH regional conferences, and provide presentations for NIH grants management staff.

ORI supports database and website development, including updating and enhancing the ORI website (https://ori.hhs.gov/), but will maintain a robust intranet portal and tracking system. Digital/web-based communication is a critical tool for ORI to accomplish program goals and support program activities. The ORI website receives over 2.2 million page views per year from users around the world, seeking information about ORI, misconduct cases, research education, and policies and procedures. To improve efficiency of allegation intake, ORI will replace its current "Ask ORI" resource mailbox with a web-based form enabling the submitter to complete fields that would aid ORI staff in triage and immediate assignment of allegations. Current manual processes to triage 30 – 50 daily emails often require significant time to categorize and determine the appropriate jurisdiction, with staff attending to this while performing other duties of their positions.

The ORI website requires intensive maintenance to ensure compliance with Federal Web Policies and HHS Web Communications and New Media Policies and Standards. A migration to the cloud in 2019 required ORI to meet significant information security demands, but now that effort is in maintenance mode. Finally, the ORI Intranet Portal contains a Case Tracking System, used by the ORI investigative division to monitor and document the progress of research misconduct allegations and cases. While ORI is updating this system for the near-term, ORI anticipates a full transition into a paperless, initiation-to-close case management system, with continuation of that work through 2021.

ORI will support three Boot Camps to train RIOs and their legal counsel. ORI maintains a waiting list for RIOs and institutional counsel interested in this program, which helps institutions comply with 42 C.F.R. 93. When institutions handle the process poorly, ORI is unable to fulfil its regulatory mandate by making research misconduct findings against respondents. Attesting to the national importance of this training program, the Boot Camps have led to the creation of an independent professional association, the Association for Research Integrity Officers (ARIO), to provide a forum for RIOs across the country to convene. ORI experts provide lectures and technical consultation at the annual ARIO meetings.

ORI anticipates collaboration with OIG, NSF, and NIH to provide collective training either through two workshops, briefer but more frequent webinars, or other means yet to be determined, for RCR instructors, in order to fulfill our regulatory requirement to promote research integrity at PHS-funded institutions.

ORI plans to offer a senior institutional leadership workshop or meeting in 2021, for which the proceedings will inform modifications to, or additional, ORI educational efforts. Institutional officials benefit from hearing from their peers about best practices in research integrity, which should help reduce the incidence of research misconduct as well as foster a broader culture of responsible conduct of research.

ORI plans to support twelve new grant awards for exploration of critical questions related to the promotion of research integrity and the proper stewardship of PHS research funds.

Grant Awards Table:

Grants (whole dollars)	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget
Number of Awards	11	12	12
Average Award	$100,000	$100,000	$100,000
Range of Awards	$50,000-$150,000	$50,000-$150,000	$50,000-$100,000

PUBLIC HEALTH REPORTS

Budget Summary

(Dollars in Thousands)

Public Health Reports	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget	FY 2021 +/- FY 2020
Budget Authority	467	467	-	-467
FTE	2	2	-	-2

Authorizing Legislation: .....PHS Act, Title II, Section 301
FY 2021 Authorization.....Permanent
Allocation Method.....Direct

Program Description and Accomplishments

Public Health Reports (PHR) is the official, peer-reviewed scientific journal of the Office of the Surgeon General of the U.S. Public Health Service Commissioned Corps and U.S. Public Health Service. PHR is the only general public health journal in the federal government. It has been published since 1878, making it one it the oldest journals of public health in the U.S. The journal is published through an official agreement with the Association of Schools and Programs of Public Health.

Five Year Funding Table

Fiscal Year	Amount
FY 2017	$467,000
FY 2018	$467,000
FY 2019	$467,000
FY 2020	$467,000
FY 2021 Request	-

Budget Request

The FY 2021 President's Budget does not request funding for this program.

TEEN PREGNANCY PREVENTION

Budget Summary

(Dollars in Thousands)

Teen Pregnancy Prevention	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget	FY 2021 +/- FY 2020
Budget Authority	100,562	101,000	-	-101,000
FTE	16	17	-	-17

Authorizing Legislation: .....Current Year Appropriation
FY 2021 Authorization.....Annually
Allocation Method.....Direct Federal

Program Description and Accomplishments

The Teen Pregnancy Prevention program is a discretionary grant program to reduce teenage pregnancy, behavioral risk factors underlying teenage pregnancy, or other associated risk factors. It is administered by the Office of Adolescent Health within the Office of the Assistant Secretary for Health.

Five Year Funding Table

Fiscal Year	Amount
FY 2017	$101,000,000
FY 2018	$101,000,000
FY 2019	$101,000,000
FY 2020	$101,000,000
FY 2021 Request	-

Budget Request

The FY 2021 President's Budget does not request funding for this program.

OFFICE OF MINORITY HEALTH

Budget Summary

(Dollars in Thousands)

Office of Minority Health	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget	FY 2021 +/- FY 2020
Budget Authority	56,424	58,670	58,670	-
FTE	40	57	57	-

Authorizing Legislation……PHS Act, Title XVII, Section 1707
FY 2021 Authorization……Expired
Allocation Method……Direct federal

Program Description and Accomplishments

The Office of Minority Health (OMH) was created in 1986 as a result of the 1985 *Secretary's Task Force Report on Black and Minority Health*. OMH was subsequently established in statute by the Disadvantaged Minority Health Improvement Act of 1990 (PL 101-527), re-authorized under legislation in 1998 (PL 105-392), and most recently re-authorized under the 2010 federal health law (PL 111-148). OMH's statutory authority requires that OMH work to improve the health of racial and ethnic minority groups through supporting research, demonstrations projects and evaluations; disseminating information and education regarding prevention and service delivery to individuals from disadvantaged backgrounds; contracting to increase primary health services providers' ability to provide culturally and linguistically appropriate health care; and supporting a national minority health resource center.

<u>OMH Mission and Vision</u>

- OMH's mission is to improve the health of racial and ethnic minority populations through the development of policies and programs that help eliminate disparities.
- OMH's vision is to improve the health of racial and ethnic minority communities by focusing on prevention, putting people and communities at the center of its work, and providing leadership and coordination to strengthen the HHS programs and actions of communities of stakeholders across the United States.

OMH serves as the lead office for coordinating efforts across the government to address and to eliminate health disparities. OMH convenes, and provides guidance, to HHS operating and staff divisions and other Federal departments, to identify health disparity and health equity policy and programmatic actions. This targeted leadership improves performance through coordination on crosscutting public health initiatives, minimizes programmatic duplication, and leverages funds to reduce health disparities.

<u>OMH Strategic Priorities</u>

OMH focuses on translating core minority health and health disparity programs into strategic activities and policies at the federal, state, tribal, territorial, and local levels. OMH's strategic priorities are:

- Support Departmental initiatives, programs and partnerships that provide access to quality health care;
- Support of the Department's strategic priorities, the drug overdose and substance misuse crises, ending the HIV epidemic in the US, value-based care; and
- Support the Office of the Assistant Secretary for Health's (OASH) and OMH's strategic priorities directly impacting racial and ethnic minorities, such as sickle cell disease, maternal mortality and

morbidity, increasing physical activity via youth sports and increasing access to health care and social services via community health workers.

In addition, OMH plays a critical role in helping the Department respond effectively to public health crises, which often disproportionately affect OMH's statutorily mandated populations of focus. OMH supports and implements initiatives that provide access to quality health care, address health disparities, and improve opportunities to achieve optimal health. OMH also seeks to sustain and spread successful policies, programs and practices that reduce health disparities among racial and ethnic minority population. Racial and ethnic minorities are less likely to receive preventive care, have higher rates of many chronic conditions, have fewer treatment options, have the highest rates of uninsured, and are less likely to receive quality health care. OMH addresses these issues through educational outreach and collaboration with strategic partners and stakeholders to increase these populations' understanding of health coverage, health care, and how to effectively and efficiently use the health care system to improve their health.

FY 2019 Key Accomplishments

OMH promotes integrated approaches, evidence-based programs, and best practices to reduce health disparities. FY 2019 accomplishments support the Secretarial strategic goals as well as illustrate OMH's commitment to enhancing and assessing the impact of all policies and programs on racial and ethnic health disparities.

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

OMH furthered the adoption, implementation, and evaluation of the *National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care (National CLAS Standards).* Key accomplishments include:

- OMH presented at four national conferences and coordinated and conducted two training sessions and two webinars for organizations on implementing culturally and linguistically appropriate services using the National CLAS Standards.
- During FY 2019, nearly 61,935 health professionals and students enrolled in OMH's free, continuing education e-learning programs courses and earned an estimated 235,329 continuing education credits towards their continuing education licensure requirements.
- Completed development of a new e-learning program for behavioral health professionals. OMH launched the Behavioral Health E-Learning Program on June 25, 2019. As of September 30, 2019, 5,389 individuals had completed at least one course within the program and 2,774 users had completed the entire program.

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

- Implemented the Empowered Communities for a Healthier Nation Initiative, designed to reduce significant health disparities impacting racial and ethnic minorities and/or disadvantaged populations through implementing evidence-based strategies with the greatest potential for impact. In FY 2019, the program served approximately 3,000 residents, health care providers, and first responders in communities disproportionately impacted by the opioid epidemic; conducted youth and family-based obesity prevention programs that reached more than 1,300 participants; and trained and mentored primary care providers in the care of patients with serious mental illness.
- To support disease prevention, OMH coordinated to increase use of the seasonal flu vaccination through its *2018 – 2019 Walgreens – HHS Influenza Vaccination Initiative*: A Co-Sponsorship Agreement between HHS and Walgreens Assistance, Inc., a 501(c)(3) private operating foundation (Walgreens), was established during the 2010 – 2011 influenza season to increase prevention

among the number of uninsured or underserved individuals against seasonal influenza by improving access to seasonal quadrivalent influenza vaccines. During the 2018 -2019 season, 160,000 vouchers were printed and distributed to 49 states, District of Columbia, and Puerto Rico. Of the 160,000 influenza vaccination vouchers, a total of 106,793 vouchers (66.7%) were redeemed.

- To assist the HHS response to the opioid and substance misuse crisis, OMH utilized social media channels to promote HHS substance misuse-related resources. In May, OMH hosted its first of a three-part webinar series for providers aimed at addressing and raising awareness about opioid-related disparities among racial and ethnic minority populations. Of the 1,000 individuals registered, 576 (58%) attended the webinar. Social media posts focused on opioids garnered a reach of 2.2 million in FY 2018 and increased by 427.2 percent in FY 2019 with a reach of more than 11.6 million people. In November, OMH recognized National Recovery Month, which celebrated the success of those who have overcome substance use disorders. OMH also supported National Drugs and Alcohol Facts Week launched by the National Institute on Drug Abuse (NIDA) in January by sharing materials that debunk the myths about drugs and alcohol among teenagers.
- During National Minority Health Month, OMH led the HHS observance activities, including organizing a national Active & Healthy Challenge to promote the Physical Activity Guidelines and the Office of Disease Prevention and Health Promotion's Move Your Way Campaign. The challenge was co-sponsored by the Louisiana Department of Health's Bureau of Minority Health Access. During the 30-day challenge, OMH had 76 participants in the Individual Challenge and 27 teams in the Team Challenge. Participants recorded 40,272,460 steps, which equals 19,068 miles. Activities included the NMHM Kickoff event, a weekly #ActiveandHealthyTuesdays walk and the NIMHD Minority Health Month 5K Walk/Run. The National Minority Health Month webpage garnered 3,088 (34%) more unique visits during the observance month in 2019 in comparison to 2018.
- OMH is leading a national effort to improve the lives of those living with Sickle Cell Disease, which affects 100,000 Americans, the overwhelming majority of whom are African American or Hispanic. OMH collaborated with the Centers for Disease Control and Prevention to fund the expansion of the CDC Sickle Cell Data Collection program from two states to seven states, which will help identify where SCD patients live and help target resources for improved clinical care. OMH commissioned the National Academies to convene an interdisciplinary expert committee to develop the nation's first SCD consensus report. The report will be issued in January 2020 and serve as a strategic plan and blueprint for addressing SCD. OMH collaborated with HRSA to develop a SCD Training and Mentoring Program for Primary Care Providers (STAMP). In November 2019, OMH launched the free telehealth program, which provides trainings on the basics of SCD care and a pilot program encouraging primary care providers at Historically Black Colleges and Universities (HBCUs) and other sites to co-manage SCD patients with hematologists.
- As part of the HHS's Sickle Cell Disease (SCD) Initiative, OMH continued to promote HHS and OMH messaging via its webpages and social media platforms. In February 2019, OMH conducted the Holistic *Health and Sickle Cell Disease: A Focus on Mental and Behavioral Health* webinar in observance of Rare Disease Day. Of the 665 individuals registered, 376 (57%) attended the webinar. Additionally, in June 2019, OMH highlighted World Sickle Cell Day to recognize the significant impact that sickle cell disease has on minority communities. To help further spread awareness, OMH produced and promoted a blog authored by the Secretary of the Department of Health and Human Services, Alex Azar, and Assistant Secretary for Health, Admiral Brett P. Giroir. The blog focused on the current efforts that are underway to find a cure for SCD within the department, the nation and the world and the medical advances that are making a cure for sickle cell a possibility within the next 10 years. In September, as part of Sickle Cell Awareness Month, OMH coordinated a radio interview for ADM Giroir with the Tom Joyner Morning Show, the No. 1 one syndicated urban morning radio show in the nation with a listening audience of nearly 8 million. Sickle cell-related social media posts

in FY 2019 garnered an estimated reach of more than 8.1 million people, a 3.8 percent increase over FY 2018 (7.8 million). The Sickle Cell Disease microsite garnered a total of 11,862 page views during September 2019, a 569% increase from 2018 (1,773).

- OMH has a social media presence on Twitter, Facebook, Instagram, and YouTube. In FY 2019, OMH obtained 4,934 new followers and posted a total of 3,154 messages. Additionally, OMH has seen growth in both reach and impressions in FY 2019 compared to FY 2018. In FY 2018, OMH achieved a total social media reach of 166,063,528 compared to 182,978,394 in FY 2019, resulting in a 10% increase. Moreover, in FY 2018, OMH achieved 4,216,083 in total social media impressions compared to 5,111,186 in FY 2019, resulting in an increase of 21.2%.
- The Office of Minority Health Knowledge Center Library has a collection of reports, books, journals and media along with health information in 40 languages. The database currently contains 67,502 records. This includes both print and electronic formats. Overall, a total of 52,760 items have been electronically linked to owned content. This represents approximately 78.2 percent of the total database collection.

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

- OMH coordinated its Youth Health Equity Model of Practice (YHEMOP), using an eight-lesson curriculum focusing on skills needed to be an effective health equity leader. The 2019 summer cohort included 27 Health Equity Fellows. The Health Equity Fellows were chosen from a pool of approximately 151 applications. Fellows are matched to health equity projects in organizations nationwide including federal agencies, state and county health departments, non-profit organizations, and academic institutions. Fellows participate in a number of activities (e.g. webinars with Federal leaders, development of tailored Health Equity projects), and each present their work to OMH at the conclusion of the placement period.

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

- OMH published an article in the May-June supplemental issue of *Public Health Reports,* "Understanding and Addressing Health Disparities and Health Needs of Justice-Involved Populations." Articles in this supplement examine the health of the justice-involved population and their families, propose policies and interventions to address their health needs, assess how population health surveys can provide better information about the justice-involved population and identify opportunities for bridging knowledge gaps on health disparities and health needs. The OMH article was authored by Juliet Bui, Minh Wendt and Alexis Bakos.

Strategic Goal 5: Promote Effective and Efficient Management and Stewardship

OMH supports this goal by maintaining and strengthening OMH's internal performance improvement and management system and evaluating implementation of the HHS Disparities Action Plan and the National CLAS Standards. OMH has also added processes to improve its internal controls and is working to identify strategies that will help improve efficiencies throughout the office. Key accomplishments in FY 2019 include:

- OMH's *Performance Improvement and Management System (PIMS)* provides support to OMH and OMH grantees through the Evaluation Technical Assistance Center (ETAC) and the collection of performance measures. The ETAC provides tailored evaluation support for OMH grantees and supports OMH's identification of promising approaches and best practices for reducing health disparities.
- OMH's leadership of implementation of the *HHS Disparities Action Pla***n** included
    - Evaluation of health disparity impact statements for policies and programs.

- Evaluation and assessment of the development of a multifaceted health disparities data collection strategy across HHS, as outlined in the HHS Disparities Action Plan.
- Development of a framework for the long-term evaluation of National CLAS Standards and providing a tips and resources tool kit to assist health care providers of all types in evaluating implementation of the National CLAS Standards at the local level (https://minorityhealth.hhs.gov/assets/PDF/Evaluation_of_the_Natn_CLAS_Standards_Toolkit_PR3599_final.508Compliant.pdf).
- In collaboration with NCHS, assessing patient experience with culturally competent health care using five specially development measures in the National Health Interview Survey (NHIS), a nationally representative survey of the civilian noninstitutionalized population of the United States. Data regarding patient experiences and perceptions regarding health care were released in fall of 2018.

Five Year Funding Table

Fiscal Year	Amount
FY 2017	$56,541,000
FY 2018	$56,670,000
FY 2019	$56,670,000
FY 2020	$58,670,000
FY 2021 Request	$58,670,000

Budget Request

The FY 2021 President's Budget request for OMH is $58,670,000, which is flat with the FY 2020 Enacted level. At this level, OMH will continue to provide leadership in coordinating policies, programs, and resources related to racial and ethnic minorities. OMH will also continue coordinating HHS health disparity programs and activities; assessing policy and programmatic activities for health disparity implications; building awareness of issues impacting the health of racial and ethnic minorities; developing guidance and policy documents; collaborating and partnering with agencies within HHS, across the federal government, and with other public and private entities; funding demonstration programs; and supporting projects of national significance.

Office of Minority Health – Key Outputs and Outcomes Table:

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2020 Target	FY 2021 Target	FY 2021 Target +/- FY 2020 Target
4.2.1 Increased percentage of continuing education credits earned or awarded to enrollees who complete at least one or more of OMH's accredited 'Think Cultural Health" e-learning programs (Output)	FY 2019: 29% Target: 20% (Target Exceeded)	25%	27%	+2%
4.4.1 Unique visitors to OMH-supported websites (Output)	FY 2019: 863,750 Target: 850,000 (Target Exceeded)	500,000	505,000	+5,000
4.5.1 Increased percentage of State and Territorial Offices of Minority Health/Health Equity that have incorporated national disease prevention and health promotion (e.g., Healthy People 2020) and health equity goals in their health disparities/ health equity planning processes. (Output)	FY 2019:59% Target: 49% (Target Exceeded)	51%	53%	+2%
4.6.1: Increase the percentage of promising approaches, models, and evidence-based practices produced by OMH-funded grantees and cooperative agreement partners (Output)	FY 2019: 48.1% Target: 45% (Target Exceeded)	50%	52%	+2%
4.7.1 Recommended Measure A: Promote effective interventions that reduce health disparities (Outcome) Measure 1: Proportion of completed research and demonstration grant projects that demonstrate a reduction in a key health disparity.	N/A	30%	33%	+3%

Performance Analysis

4.2.1: Think Cultural Health (TCH) houses a suite of continuing education e-learning programs dedicated to advancing health equity at every point of contact. The focus is on increasing provider awareness and, over time, changing beliefs and attitudes that will translate into better health care. With the addition of new e-learning programs and resources for more health care and public health professionals and service providers, and sustained focus on the promotion and adoption of the *National CLAS Standards*, OMH expects to see a 25% increase in the number of continuing education (CE) credits earned or awarded to enrollees who complete at least one or more of OMH's accredited Think Cultural Health e-learning programs in their respective fields.

4.4.1: OMH's main website, www.minorityhealth.hhs.gov, is administered through the OMH Resource Center. The website includes access to the OMH Knowledge Center collection, which is a database composed of 68,000 records and almost 76% of the content is in digital format. The database contains minority health and health disparities data and literature, information on national and local minority health organizations, as well as resources for community- and faith-based organizations and institutions of higher education (including minority-serving institutions), and information about OMH.

- The website supports community organizations and health disparities researchers in assembling accurate and comprehensive information and articles for use in program development and grant writing. The website serves as an information dissemination tool for OMH initiatives and project and facilitates educational outreach to Black/African American, Hispanic/Latino, American Indian, Alaskan Native, Asian American, Native Hawaiian, and Pacific Islander communities. OMH expects to see at least 850,000 unique visitors to its main website in FY 2019 and 525,000 in FY 2020. As noted in previous reports, this decreased number over its previously established target of 850,000 unique visitors in 2019 reflects a change in the method used to measure "unique" visitors to OMH's website. The WebLog Expert tool has been phased out and we are now using Google Analytics (GA) through a HHS provided account. This gives OMH a more reliable and accurate count of unique visitors by eliminating "bots" and "spiders." The new estimate of unique visits includes additional viewers brought in via OMH's burgeoning social media accounts on Twitter, Facebook, YouTube and Instagram, and continual improvement of website content and features.
- Social Media has been a growing outlet for the dissemination of health information from OMH and its stakeholders. OMH has more than 67,000 followers on its English Twitter handle with an extended reach to more than 1+ million individuals and organizations. The OMH Facebook and Instagram pages, and Spanish Twitter handle are growing in followers.

4.5.1: OMH builds strategic partnerships and provides leadership and coordination for State and Territorial Offices of Minority Health/Health Equity. OMH expects to see a 2% increase in the percentage of these entities that have incorporated national disease prevention and health promotion (e.g., *Healthy People 2020*) and health equity goals in their health disparities/health equity planning processes.

4.6.1: OMH is charged with advising the Secretary and the Department on the effectiveness of community-based programs and policies impacting health disparities and to support research, demonstrations and evaluations to test new and innovative models. OMH funds demonstration grants to develop, test, and implement interventions to reduce health disparities. Results from these demonstration programs play a critical role in supporting the HHS Disparities Action Plan and the Department priority goal to eliminate health disparities and achieve health equity. Additionally, OMH is charged with ensuring on-the-ground implementation of initiatives and programs that provide access to quality health care and HHS Disparities Action Plan strategies. OMH expects to see a 2% increase in the percentage of promising approaches, models, and evidence-based practices produced by OMH-funded grantees and cooperative agreement partners per year. The expected performance of this measure is in line with the FY 2020 funding level.

In addition, OMH has proposed a new outcome measure, which reflects OMH's focus on identifying programs, policies, and practices that reduce health disparities. The proposed measure, *Promote effective interventions that reduce health disparities*, will be assessed by documenting the proportion of completed research and demonstration grant projects and cooperative agreements that demonstrate a significant reduction in a key health disparity. In recent years and going forward, OMH's research and demonstration grant projects and cooperative agreements will concentrate on identifying programs that significantly reduce key health disparities compared with current practices.

Grant Awards Table:

Grants (whole dollars)	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget
Number of Awards	114	102	102
Average Award	$290,207	$312,340	$312,340
Range of Awards	$175,000 - $525,000	$175,000 - $625,000	$175,000 - $625,000

Program Data Chart:

Activity	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget
Contracts			
OMH Resource Center	2,997,000	2,836,500	3,100,000
Logistical Support Contract	150,000	250,000	250,000
Center for Linguistic and Cultural Competency in Health Care	1,830,477	1,830,477	1,566,972
Community Health Aide Program		2,000,000	2,000,000
HHS Action Plan to Reduce Racial and Ethnic Health Disparities	-	-	-
Evaluation	803,542	804,000	870,276
Disparities Health Prevention	-	-	-
Sickle Cell Disease	-	4,000,000	4,000,000
Viral Hepatitis: Primary Care Physicians Capacity Building Model	-	-	-
Maternal Mortality		2,000,000	2,000,000
Subtotal, Contracts	*5,781,019*	*13,720,977*	*13,787,248*
Grants/Cooperative Agreements			
State Partnership Programs	4,148,876	6,000,000	6,000,000
American Indian/Alaska Native Partnership	961,752	960,117	962,000
Specified Project – Lupus	1,749,967	250,000	-
Communities Addressing Childhood Trauma (ACT)	-	-	-
Re-entry Community Linkages (RE-LINK)[3]	2,807,412	2,800,000	2,807,412
National Workforce Diversity Pipeline Program (NWDP)	6,151,121	-	-
Partnership to Achieve Health Equity	2,326,818	2,326,818	2,326,818
Minority Youth Violence Prevention II: Social Determinants of Health Collaborative Network	4,078,508	3,922,263	4,078,508
Empowered Communities for a Healthier Nation Initiative (ECI)	7,225,619	2,098,164	2,100,000
Hepatitis B Demonstration	2,953,234	3,000,000	3,000,000
Collaborative Approach for Youth Engagement in Sports	2,000,000	2,000,000	2,000,000
Social Determinants of Health	-	850,000	3,500,000
Supporting Resilience in Minority Youth	-	1,600,000	-
Healthy Families, Healthy Lifestyles	-	1,500,000	1,500,000
Mental Health Initiative	-	500,000	500,000
Subtotal, Grants/Coop	*34,403,307*	*27,807,362*	*28,774,738*
Inter-Agency Agreements (IAAs)	1,715,000	3,253,765	2,522,805
Operating Costs	*14,524,674*	*13,887,896*	*13,585,209*
Total	56,424,000	58,670,000	58,670,000

OFFICE ON WOMEN'S HEALTH

Budget Summary

(Dollars in Thousands)

Office on Women's Health	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget	FY 2021 +/- FY 2020
Budget Authority	32,001	33,640	33,640	-
FTE	36	43	43	-

Authorizing Legislation:.....PHS Act, Title II, Section 229
FY 2021 Authorization.....Expired
Allocation Method.....Direct Federal

Program Description and Accomplishments

The Office on Women's Health (OWH) was established in 1991 and statutorily authorized by the Patient Protection and Affordable Care Act (ACA) of 2010. The mission of OWH is to provide national leadership to improve the health of women and girls through policy, education, and innovative programs. OWH seeks to impact policy and to produce educational and innovative programs that providers, communities, agencies, and other stakeholders across the country can replicate and expand. To achieve these goals, the office works with many partners, including federal agencies; nonprofit organizations; consumer groups; associations of health care professionals; tribal organizations; and state, county, and local governments.

<u>Impact National Health Policy as it Relates to Women and Girls</u>

OWH coordinates women's health policy, leads and administers committees, and participates in government-wide policy efforts.

In FY 2019, OWH continued its leadership role on HHS and interagency committees and workgroups that advance policies to improve the health of women and girls.

- The HHS Coordinating Committee on Women's Health (CCWH), chaired by OWH, advises the Assistant Secretary for Health (ASH) on current and planned activities across HHS that safeguard and improve the health of women and girls. In FY 2019, the CCWH coordinated the HHS Maternal Health Work Group comprised of senior level representatives from across HHS to develop an HHS-wide plan for maternal health. The Work Group compiled information on current and past efforts to improve maternal health and eliminate preventable deaths that will inform HHS's next steps.
- OWH co-chairs the HHS Violence against Women (VAW) Steering Committee along with the Administration for Children and Families (ACF). The mission is to lead HHS in developing a blueprint for communities free from violence against women and girls, and to integrate the work of each HHS agency into its implementation. In FY 2019, the committee focused on strategic planning to enhance partnerships, coordination of activities and update goals and strategies.

OWH continued work to address the ongoing impact of the opioid epidemic on women's health. Through this work, OWH has examined the prevention, treatment, and recovery issues for women who misuse, have use disorders, and/or overdose on opioids. Examples of accomplishments in FY 2019 include:

- OWH funded the second year of a partnership with HRSA on an initiative to produce a care coordination model for women impacted by opioids who receive health care services via HRSA-funded programs.
- OWH hosted three regional consultations to obtain stakeholder and provider perspectives on how HHS-funded programs can better meet the needs of these women. The meetings were held in San Francisco, CA; Rockville, MD; and Kansas City, MO and included participants representing a diverse range of health care and community service providers, researchers, and local and state government agencies – including HRSA and OWH grantees.
- OWH and HRSA used the feedback from these consultations to develop a draft care coordination model, which will be refined in fiscal year 2020 with additional stakeholder consultations. The model and accompanying implementation toolkit will include specific resources for providers on how to support the care coordination and recovery needs of women across the life course – including specific attention to the needs of pregnant and parenting women.

OWH funded the third year of the *Prevention of Opioid Misuse in Women: Office on Women's Health Prevention Awards* (OWHPA), 20 cooperative agreements that support primary and secondary prevention activities. Examples of FY 2019 accomplishments include:

- The grantees made progress in community partnership building; developing tools and resources to train health professionals; the use of Screening, Brief Intervention, and Referral to Treatment (SBIRT) model when caring for women and girls; development of health information campaigns; instruction on the use of Naloxone; introduction of alternative methods for the management of chronic pain that reduce the need for pharmacological therapy; and more.
- Grantees have also developed gender-specific SBIRT training, instructive webinar series, online and print information campaigns, and created an alert system embedded into electronic health records.
- The grantees are continuing to implement their projects while increasing their focus on partnership and sustainability of their efforts after the funding period ends.
- OWH will convene a meeting September 18-19 in Washington, DC to highlight the community-level prevention activities of the grantees and other offices throughout OASH, HHS and the larger federal space. The meeting will show the impact of these collective efforts towards preventing opioid misuse among women and girls and how we are accomplishing the HHS Five-Point Strategy to Combat the Opioid Crisis.

In FY 2019, OWH continued projects to provide insight into emerging issues and new opportunities to utilize policy to improve the health of women and girls. These projects will leverage the best available data and build partnerships for sustainability.

- OWH continued the State-Level Paid Family Leave Policy Project which involves the collection of information to inform program and policy about new mothers' health, health behaviors, and ability to fulfill their roles in the workplace, family and community.
- The Data and Policy Analysis Project is a two-year endeavor designed to analyze data and policy for the purpose of identifying emerging issues/trends, uncovering disparities, and examining sex/gender and other social determinants of health in order to make recommendations to fill gaps in research, policy, and practice of improving women's health outcomes.
- OWH led the development of the Guidance for HHS Nursing Mothers.
- OWH continued to partner with the CDC to increase the focus and collection of data on women's health issues by adding specific women's health questions to the National Survey of Family Growth.
- OWH continued to support evaluation, collection, and reporting of performance management data across all OWH project and programs.

Innovative and Model Programs on Women's and Girls' Health

OWH supports activities and programs aimed at gathering evidence on effective strategies to help women and girls of all ages live healthier lives. OWH programs also focus on advancing the science on effective women's health interventions.

- OWH initiated a new grant program, *Preventing HIV Infection in Women through Expanded Intimate Partner Violence (IPV) Prevention, Screening, and Response Services*, that awarded over $3.1 million to 4 grantees. The grants support the President's initiative to end HIV and builds on previous OWH work on IPV and the intersection of IPV and HIV.
- OWH initiated a new grant program in partnership with the Office of Minority Health. The program, *Youth Engagement in Sports: Collaboration to Improve Adolescent Physical Activity and Nutrition (YES Initiative)*, awarded over $4 million in support of the Assistant Secretary's priority to improve physical activity and nutrition and promote the recently updated Physical Activity Guidelines and National Sports Strategy. Grantees funded by OWH will focus on engaging girls in sports.

Education and Collaboration on Women's and Girls' Health

OWH uses websites, webinars, written materials, Grand Round lectures, social media, partnership outreach, and interactive training modules to increase consumer and health professional knowledge of health issues, research, practices, programs, and policies that affect the health of women and girls. Examples include:

- OWH administers the National Women's Health Information Center to provide health information to women across the nation. These resources allow women and girls to find scientifically accurate and reliable health information written at the 8th grade reading level or below, in English and Spanish.
- OWH is partnering with ODPHP on a communication campaign to promote physical activity during and after pregnancy.
- In FY 2019, OWH continued the development of a communication campaign to educate women and their loved ones of the risks of postpartum depression. The campaign will create PSAs, social media content, and written materials designed to destigmatize the disorder and promote treatment seeking in pregnant women and new mothers.
- In FY 2019, OWH continued to fund a targeted communications campaign designed to educate and encourage women and men, 18 -26-years of age, living in Texas, Mississippi, and South Carolina (the states with the lowest rates of HPV vaccination) about the health benefits of completing the HPV vaccine series.
- OWH continues to organize nationwide observances including National Women's Health Week (NWHW) and National Women and Girls HIV/AIDS Awareness Day.

o National Women's Health Week (NWHW) is held every May, this event encourages women to prioritize their health and take five simple steps improve their health at any age. In FY 2019:

- NWHW generated more than 770 million media impressions from April 1 through May 28.
- OWH's "Find Your Health" tool received nearly 31,500 page views between May 8 and May 29.
- NWHW reached up to 36 million accounts on Twitter alone from April 23 through May 17.
- Sixteen federal partners, 21 national supporters and 5 ambassadors helped OWH spread the word about NWHW by sharing messaging with their audiences.

- National Women and Girls HIV/AIDS Awareness Day (NWGHAAD) is an observance created to share information and empower women and girls to learn the importance of HIV and AIDS prevention, care, and treatment. In 2019, target audiences included U.S. women and girls who are living with HIV, HIV-negative, and African American and Latina women. OWH distributed messages across multiple digital platforms, including the NWGHAAD website, womenshealth.gov blog, social media, and email blasts. There were 165 media stories (blogs, television shows, organization websites, and

news websites) mentioning NWGHAAD, resulting in 76,675,895 media impressions from February 15 - March 31, 2019. From February 15-March 31, 2019:

- NWGHAAD website received 22,350 page views
- 2019 NWGHAAD blog post received 580 page views
- A total of 59 paid and organic social media posts resulted in 1,144,095 social media impressions; 121,752 social media engagements; and 7,923 link clicks
- A total of three e-blasts reached:
  - 49,790 recipients on March 5
  - 91,096 recipients on March 8
  - 49,812 recipients on March 10

In FY 2019, OWH engaged with public and private sector stakeholders through a variety of meetings and consultations on critical issues impacting women's health.

- In March, OWH partnered with the Eating Disorders Coalition to convene *How to Talk about Healthy Weight and Healthy Eating: A Cross-Disciplinary Dialogue on Messaging to Promote Health Behaviors and Positive Body Image*, which brought together experts in the fields of obesity prevention and eating disorder prevention to address issues of mutual concern around healthy behaviors and body image. The meeting identified the appropriate messaging that isn't stigmatizing or opposing to either field and the knowledge gaps that exist for message development for target audiences (e.g., parents/caregivers, young women and girls).
- In August, OWH hosted the *Female Genital Mutilation/Cutting Dissemination & Transition Meeting*, which facilitated the effective dissemination of findings from OWH-funded work and subject matter experts regarding promising practices and innovative approaches that address the needs of individuals and communities impacted by female genital cutting, a form of gender-based violence impacting U.S. women and girls. The meeting encouraged further collaboration between former grantees, other subject matter experts, and sister federal agencies.
- In September, OWH convened *Combating Opioid Misuse among Women and Girls: Prevention Strategies at Work*, which brought together HHS key leadership, federal staff, and OWH grantees, as well private sector and community leaders working in opioid misuse and overdose prevention, particularly among women and girls. The meeting highlighted how the Department is addressing prevention as a part of the HHS 5-Point Strategy to Combat the Opioid Crisis and the impact of investment and community engagement in the effort to combat the opioid crisis.

Five Year Funding Table

Fiscal Year	Amount
FY 2017	$32,067,000
FY 2018	$32,140,000
FY 2019	$32,140,000
FY 2020	$33,640,000
FY 2021 Request	$33,640,000

Budget Request

The FY 2021 President's Budget request for OWH is $33,640,000, which is flat with the FY 2020 Enacted level. At this level, OWH will continue support for existing projects that focus on OASH's priorities with a special emphasis on maternal health initiatives to include addressing health disparities in women through blood pressure control. Highlights for OWH activities for FY 2021 include:

OWH will continue to lead the CCWH Maternal Health Work Group and focus on improving not only mortality, but also the tens of thousands of serious complications to mothers and their newborns that occur annually. Most are preventable with a multi-disciplinary, multi-sectoral effort. OWH will continue to support regional and national projects to promote women's health through prevention initiatives and/or women's health information dissemination.

OWH seeks to empower women to understand the natural menstrual cycles of their bodies and destigmatize menstruation. Between 2017 and 2018, fertility rates declined for non-Hispanic black, non-Hispanic white, and Hispanic women. The goal is to diagnose common conditions that affect a woman's menstrual cycle and impact this 5th unique women's vital sign. Women will be better informed to recognize common menstrual cycle abnormalities with the goal of early diagnoses, reduced maternal morbidity and mortality, and overall health improvement for women of reproductive age. Through understanding the effects that common health conditions (such as obesity, diabetes, and polycystic ovarian syndrome) and social determinants of health can have on this fundamental aspect of women's health, women will better recognize factors that can impact their fertility. This grant will educate providers at federally qualified health centers, Title X programs, and academic medical centers in order to empower women to understand, destigmatize, and appreciate the natural menstrual cycle and its impacts on female physiology.

Additionally, OWH will address maternal mortality and maternal health by coordinating efforts across HHS to improve blood pressure control for women of reproductive age from 62% (national average) to 80% by 2022.

OWH's health communications activities help OWH to achieve its mission of providing national leadership and coordination to improve the health of women and girls through policy, education, and model programs. OWH administers the National Women's Health Information Center to provide health information to women across the nation. These resources allow women and girls to find scientifically accurate and reliable health information written at the 6th to 8th grade reading level in English and Spanish.

Office on Women's Health – Key Outputs and Outcomes Table

Program/Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2020 OMB Target	FY 2021 OMB Target	FY 2021 OMB Target +/- FY 2020 OMB Target
5.7.1 Number of OWH interactions for the purpose of health education and training (Outreach)	FY19: 2,803 Target: 150 (Target Exceeded)	200	53	-147
5.8.1 Number of individuals served by OWH activities, programs, and partnerships (Outreach)	FY19: 292,199 Target: 750,000 (Target Not Met)	850,000	420,000	-430,000
5.5.1 Number of users of OWH's communication channels (Reach)	FY19: 18,516,812 Target: 19,751,540 (Target Not Met)	21,000,500	13,125,000	-7,875,500
5.6.1 Number of occasions that users interact with OWH content (Engagement)	FY19: 5,005,617 Target: 26,076,320 (Target Not Met)	28,100,000	3,675,000	-24,425,000

Grant Awards Table

Grants (whole dollars)	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget
Number of Awards	37	25	25
Average Award	$342,972	$679,166	$462,500
Range of Awards	$65,944-$1,033,333	$325,000-$1,033,333	$325,000-$600,000

Program Data Chart

Activity	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget
Contracts	-	-	-
Program Evaluation	1,753,449	1,800,000	750,000
Health Communications (National Women's Health Information Center)	5,614,870	3,000,000	1,265,500
Women's Health Across the Lifespan	1,945,525	1,945,525	1,500,000
Trauma/Violence Against Women	347,850	300,000	-
Health Disparities in Women	1,200,000	1,598,950	-
Health Care Services for Women	300,000	900,000	-
Education and Collaboration on Women's and Girls' Health	222,060	500,000	-
Postpartum Depression	-	-	1,500,000
HPV	-	-	1,100,500
Congenital Syphilis	-	-	500,000
Exercise in Pregnancy	-	-	1,250,000
State Paid Family Leave	345,525	-	-
Subtotal, Contracts	***11,729,279***	***10,044,475***	***7,866,000***
Grants/Cooperative Agreements	-	-	-
Health Care Services for Women (Opioids)	1,961,178	-	-
YES Initiative	2,000,000	4,734,877	-
Health Disparities in Women (Blood Pressure Initiative)	-	1,845,525	5,250,000
Trauma/Violence Against Women	3,100,000	3,100,000	3,100,000
Education and Collaboration on Women's and Girls' Health (Empowering Women)	-	-	3,500,000
Subtotal, Grants/Cooperative Agreements	***7,061,178***	***9,680,402***	***11,850,000***
Inter-Agency Agreements (IAAs)	2,784,386	2,015,123	2,000,000
Operating Costs	***10,425,657***	***11,900,000***	***11,924,000***
Total	**32,000,500**	**33,640,000**	**33,640,000**

EMBRYO ADOPTION AWARENESS CAMPAIGN

Budget Summary

(Dollars in Thousands)

Embryo Adoption Awareness Campaign	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget	FY 2021 +/- FY 2020
Budget Authority	996	1,000	-	-
FTE	-	-	-	-

Authorizing Legislation.....Current Year Appropriation
FY 2021 Authorization.....Annually
Allocation Method.....Direct Federal

Program Description and Accomplishments

The purpose of the embryo donation/adoption awareness campaign (EAAC) is to educate the American public about the existence of frozen embryos created through in-vitro fertilization (IVF) that could be available for adoption by infertile individuals or couples and identify strategies to reduce the number of frozen embryos.

Five Year Funding Table

Fiscal Year	Amount
FY 2017	$1,000,000
FY 2018	$1,000,000
FY 2019	$1,000,000
FY 2020	$1,000,000
FY 2021 Request	-

Budget Request

The FY 2021 President's Budget does not request funds for this program.

MINORITY HIV/AIDS FUND

Budget Summary

(Dollars in Thousands)

Minority HIV/AIDS Fund	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget	FY 2021 +/- FY 2020
Budget Authority	53,900	53,900	53,900	-
FTE	1	1	1	-

Authorizing Legislation:.....Current Year Appropriation
FY 2021 Authorization.....Annually
Allocation Method.....Direct Federal

Program Description and Accomplishments

The Office of Infectious Disease and HIV/AIDS Policy (OIDP) administers the Minority HIV/AIDS Fund (MHAF) on behalf of the Office of the Assistant Secretary of Health (OASH). The purpose of the Minority HIV/AIDS Fund is to reduce new HIV infections, improve HIV-related health outcomes, and to reduce HIV-related health disparities for racial and ethnic minority communities by supporting innovation, collaboration, and the integration of best practices, effective strategies, and promising emerging models in the response to HIV among minority communities. In addition, the MHAF is focused on transforming HIV prevention, care, and treatment for communities of color by bringing federal, state, and community organizations together to design and pilot innovative solutions that address critical emerging needs and work to improve the efficiency, effectiveness, and impact of federal investments in HIV programs, activities, and services for racial and ethnic minorities.

In February 2019, HHS released the *Ending the HIV Epidemic (EHE): A Plan for America* initiative, a bold new Presidential initiative designed to reduce new HIV infections in the United States by 75 percent in five years and by 90 percent by 2030. The EHE provides the hardest hit communities with the additional expertise, technology, and resources required to address the HIV epidemic. Phase 1 of EHE focuses on the areas of the nation that comprised more than 50% of the new HIV diagnoses in 2016 and 2017, plus the seven states with rural areas that carry a disproportionately high burden of HIV. Through the use of the MHAF in service to the initiative, the OASH signals its commitment to provide leadership, management, oversight and support for, and collaboration and coordination among HHS agencies, operating divisions, and external stakeholders.

In support of the initiative, in FY 2019, OASH committed more than $33M for community planning, jurisdictional jumpstarts, and infrastructure building, and staffing support including:

Community Planning

CDC's Accelerating HIV Planning to End the HIV Epidemic - Supported health departments in Phase 1 jurisdictions to conduct a rapid planning process to engage the community, HIV prevention and care providers, and other partners in aligning resources and activities.

HRSA's State Collaborative Partnerships - Supported the identification of key stakeholders in the 7 states with high rural HIV burden (Mississippi, South Carolina, Alabama, Arkansas, Kentucky, Missouri, and Oklahoma) and establishes collaborative partnerships in each state to develop communication structures and short-term action plans to prepare for EHE. Specifically, the project worked to identify key stakeholders in the 7 states and establish "State teams" to quickly and successfully implement the

EHE initiative in FY 2020 by developing a short term action plan to address administrative and data infrastructure, capacity development, partnership, and communications needs.

IHS's Empowering Healthier Tribal Communities - Provided the IHS network of 12 Tribal Epidemiology Centers (TECs) with ongoing consultation and technical assistance to plan, implement, and evaluate each component of their respective programs. This effort developed or accelerated customized community plans, ensuring that community-specific social norms and unique epidemic attributes are addressed and will develop collaborative partnerships between TECs and state and local health departments, IHS, tribal, and urban Indian healthcare (I/T/U) clinical communities, and community-based organizations to expand and routinize HIV diagnosis, treatment, prevention, and response, as per the EHE.

NIH's Strategic Partnerships to End the HIV Epidemic in America's R/E Minority Populations: A Collaboration with NIH Centers - Supported implementation science activities through the collaboration of CFAR and ARC investigators with local partners and HHS agencies to develop local plans to reduce incidence, improve HIV-related outcomes and reduce disparities in the highest-risk racial and ethnic minority communities.

Jurisdictional Jumpstarts

CDC's Community Ramping Pilots - Supported the capacity building and implementation of ramping up activities in three Ending the HIV Epidemic Phase 1 jurisdictions (DeKalb County, GA; East Baton Rouge Parrish, LA; & Baltimore, MD) in order to jumpstart each of the four operational strategies of diagnose, treat, protect and respond. Activities were also to develop the HIV Workforce needed to fully implement jurisdictional initiative plans. The funding played a critical role in jumpstarting the initiative with additional resources to allow the health departments to expand access to services and begin implementing key parts of the initiative, including providing treatment for those living with HIV, increasing HIV testing, and expanding preventative services, including PrEP.

IHS's Ending the HIV Epidemic in Cherokee Nation - Supported ramping up activities in Cherokee Nation through the expansion of HIV screening and case management capacity for engagement and retention in care within Cherokee Nation Health Services facilities; established a robust PrEP program utilizing clinical pharmacists; and implements a public education campaign centered on HIV care and prevention.

Infrastructure and Staffing Support

Additional EHE infrastructure and staffing supports managed within OASH and OIDP included: the development of the *Data Analysis and Visualization System*, an EHE indicators dashboard for tracking and reporting EHE progress and performance with regard to several leading performance indicators as well as serving as a decision support tool to help communities identify the right strategies to achieve the goals of the initiative; support for the *PACE Regional HIV Program* to assist the regional offices and state and local partners to conduct HIV-related needs assessments and develop and execute public health interventions through collaborative relationships between federal and non-federal partners; and support for the *Pre-exposure prophylaxis (PrEP) Implementation and Dissemination Services Project* to establish and administer a customized solution to facilitate the integrated process of distribution of donated PrEP medications to qualified eligible recipients. In addition, OIDP has worked to develop and execute a stakeholder education & awareness campaign (*Ready, Set, PrEP*) designed to raise awareness and educate key audiences about the PrEP donation program.

Throughout FY 2019, OIDP worked to provide oversight to the MHAF funded projects and lead, coordinate and implement the Ending the HIV Epidemic Initiative. In FY 2019, the office established the organizational structure for this initiative, coordinated activities and led working groups to ensure a timely implementation of the Initiative. OIDP also managed the FY 2019 Minority HIV/AIDS Funds and awarded these dollars to the OPDIVs for community plan development and jump starting the program in select jurisdictions as previously described.

As the Initiative ramps up and becomes fully operational throughout FY 2020 and into 2021, there will be an increased need for additional coordination, communication, leadership and accountability. The OASH is leading this Initiative through the OIDP. OIDP, in collaboration with the OPDIVs and with approval by the EHE Policy Leadership Team has adopted an organizational structure that will help ensure integration of activities and appropriate financial and programmatic oversight. OIDP will continue to lead and coordinate all aspects of this initiative through this organizational structure. To date, OIDP has led the Indicator Working group (WG), the Dashboard WG and established the operational leadership team. OIDP has also begun to coordinate the diagnose, treat, prevent and respond workgroup activities. In addition, An Ending the HIV Epidemic Plan Indicator WG comprised of subject matter experts from CDC, HRSA HAB, HRSA BPHC, SAMHSA, NIH, IHS and OIDP has developed ambitious performance targets for the next 10 years in order to meet the goal of a 90% reduction in new HIV infections by 2030. The 2021 MHAF targets support the Ending the HIV Epidemic initiative goals of: a 15% reduction in new HIV infections; a 15% increase in linkage to HIV medical care within one month of diagnosis; and 15% increase in the number of persons with indications for PrEP who are prescribed PrEP by the end of 2021 as compared to 2017.

Five Year Funding Table

Fiscal Year	Amount
FY 2017	$53,900,000
FY 2018	$53,900,000
FY 2019	$53,900,000
FY 2020	$53,900,000
FY 2021 Request	$53,900,000

Budget Request

The FY 2021 President's Budget request for MHAF is $53,900,000, which is flat with FY 2020 Enacted Level. At this flat level, OIDP will maintain support, management, oversight, and coordination of the President's *Ending the HIV Epidemic: A Plan for America*.

MHAF - Outputs and Outcomes Table

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2020 Target	FY 2021 Target	FY 2021 Target +/- FY 2020 Target
7.1.12a: Increase the number of racial and ethnic minority clients who are tested through the Secretary's MHAF programs. (Outcome)	FY 2018: 73,585 Target: 20,000 (Target Exceeded)	19,500	40,000	+20,500
7.1.12b: Increase the diagnosis of HIV-positive racial and ethnic minority clients through HIV testing programs supported by the Secretary's MHAF programs. (Outcome)	FY 2018: 1,011 Target: 1,000 (Target Exceeded)	900	800	-100
7.1.15: Increase the proportion of newly diagnosed and re-diagnosed HIV-positive racial and ethnic minority clients' linkage to HIV medical care within 1 month of diagnosis or re-diagnosis through the Secretary's MHAF programs. (Outcome)	FY 2018: 47% Target: 80% (Target Not Met)	79.1%	80.8%	+1.7%
7.1.19 Increase the proportion of persons with diagnosed HIV who have achieved viral suppression. **(NEW)**	-	63%	67%	+4%
7.1.20 Increase the proportion of persons who received PrEP among those for whom PrEP was indicated. **(NEW)**	-	9%	13%	+4%

Performance Analysis

HIV testing is at the center of *Measures 7.1.12.a & 7.1.12b.* The measures identify the number of racial and ethnic minorities tested for HIV and the numbers diagnosed HIV-positive.

An essential component of HIV testing is the linkage to care activity for those who are diagnosed HIV-positive. This activity is captured under *Measure 7.1.15*. Studies continue to show the challenges the U.S. is having along a "continuum of care" from HIV diagnosis to viral suppression of clients – estimates show 84% are linked to care; 56.5% are retained in care; 95.4% are prescribed antiretroviral medication; and only 57.9% are virally suppressed. . In addition, HIV testing is the gateway activity for the two proposed new measures of viral suppression and PrEP. Both measures currently anchor our domestic response to HIV and our fully integrated in both the *Ending the HIV Epidemic: A Plan for America* and the National HIV/AIDS Strategy.

SEXUAL RISK AVOIDANCE

Budget Summary

(Dollars in Thousands)

Sexual Risk Avoidance	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget	FY 2021 +/- FY 2020
Budget Authority	34,848	35,000	-	-35,000
FTE	-	-	-	-

Authorizing Legislation:.....Current Year Appropriation
FY 2021 Authorization.....Annually
Allocation Method.....Direct Federal

Program Description and Accomplishments

The Sexual Risk Avoidance program consists of competitive, discretionary grants to provide sexual risk avoidance education for adolescents.

Grantees use an evidence-based approach and/or effective strategies through medically accurate information referenced in peer-reviewed publications to educate youth on how to avoid risks that could lead to non-marital sexual activity. Projects are implemented using a Positive Youth Development (PYD) framework as part of risk avoidance strategies, to help participants build healthy life skills, build on or enhance individual protective factors that reduce risks, and empower youth to make healthy decisions.

Five Year Funding Table

Fiscal Year	Amount
FY 2017	$15,000,000
FY 2018	$25,000,000
FY 2019	$35,000,000
FY 2020	$35,000,000
FY 2021 Request	-

Budget Request

The FY 2021 President's Budget does not request funds for this program.

RENT, OPERATION, AND MAINTENANCE AND RELATED SERVICES

Budget Summary

(Dollars in Thousands)

Rent, Operation, and Maintenance and Related Services	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget	FY 2021 +/- FY 2020
Budget Authority	14,589	15,464	18,589	+3,125-
FTE	-	-	-	-

Authorizing Legislation……Reorganization Plan No.1 of 1953
FY 2021 Authorization……Permanent
Allocation Method……Direct federal

Program Description and Accomplishments

The Rent/Operation and Maintenance and Related Services account supports headquarters facilities occupied by the OS STAFFDIVS funded by the GDM account. Descriptions of each area follow:

- Rental payments (Rent) to the General Services Administration (GSA) includes rental costs of office space, non-office space, and parking facilities in GSA-controlled buildings.

- Operation and Maintenance includes the operation, maintenance, and repair of buildings for which GSA has delegated management authority to HHS; this includes the HHS SW Complex headquarters, (i.e.: Hubert H. Humphrey Building, Wilbur J. Cohen Federal Building, and The Mary E. Switzer Building.)

- Related Services includes non-rent activities in GSA-controlled buildings (e.g., space management, events management, guard services, other security, and building repairs and renovations).

Five Year Funding Table

Fiscal Year	Amount
FY 2017	$16,089,000
FY 2018	$16,089,000
FY 2019	$14,589.000
FY 2020	$15,464,000
FY 2021 Request	$18,589,000

Budget Request

The FY 2021 President's Budget request for Rent is 18,589,000, which is $3,125,000 above the FY 2020 Enacted Level. This level includes funding to support increasing costs associated with rental charges from GSA and maintaining aging buildings.

SHARED OPERATING EXPENSES

Budget Summary

(Dollars in Thousands)

Shared Operating Expenses	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Request	FY 2021 +/- FY 2020
Budget Authority	9,330	10,628	11,753	+1,125
FTE	-	-	-	

*The FY 2019 Final does not reflect Secretary's Transfer amounts to the Administration for Children and Families or in from the Centers for Medicare and Medicaid Services.

Common Expenses/ Service and Supply Fund (SSF) Payment

Common Expenses include funds to cover administrative items and activities which cut across and impact all STAFFDIVs under the GDM appropriation. The major costs in this area include:

- Worker's Compensation
- Federal Employment Information and Services
- Records storage at the National Archives and Records Administration
- Radio Spectrum Management Services
- Federal Executive Board in Region VI
- Telecommunications (e.g., FTS and commercial telephone expenses)
- CFO and A-123 audits
- Federal Laboratory Consortium
- Postage and Printing
- Unemployment Compensation

Payments to the SSF are included in the overall Common Expenses category, but are broken out separately here for display purposes. These payments cover the usage of goods and services provided through the SSF:

- Personnel and Payroll Services
- Finance and Accounting activities
- Electronic communication services (e.g., voice-mail and data networking)
- Unified Financial Management System (UFMS) Operations and Maintenance

FY 2019 HHS Enterprise Information Technology and Government-Wide E-Gov Initiatives

The Budget includes $33,919 to support government-wide E-Government initiatives.

FY 2021 E-Gov Initiatives and Line of Business*	Original Amount	Revised Amount 2021
GSA/IAE-Loans and Grants	$18,715	$18,715
Federal Health Architecture LoB	$0	$0
E-Rulemaking	$7,285	$7,285
Treasury Managing Partner Financial Mgmt - LOB (MOU) FMLoB	$1,580	$1,580
Human Resources Management LoB (HRLoB)	$939	$939
Disaster Assistance Improvement Plan (DAIP)*	$445	$445
Budget Formulation and Execution LoB	$754	$754
Benefits.gov	$3,311	$3,311
Performance Management Line of Business (PMLoB).	$547	$547
Geospatial LoB	$343	$343
FY 2019 E-GOV Initiatives Total	**$33,919**	**$33,919**

* Specific levels presented here are subject to change, as redistributions to meet changes in resource demands are assessed.

Government-wide e-Gov initiatives provide benefits, such as standardized and interoperable HR solutions, coordinated health IT activities among federal agencies providing health and healthcare services to citizens; financial management processes; and performance management. They also improve sharing across the federal government of common budget formulation and execution practices and processes resulting in improved practices within HHS.

Five Year Funding Table

Fiscal Year	Amount
FY 2017	$11,544,000
FY 2018	$11,544,000
FY 2019	$9,753,000
FY 2020	$10,628,000
FY 2021 Request	$11,753,000

Budget Request

The FY 2021 President's Budget request for other Shared Operating Expenses is $11,753,000, which is $1,125,000 above the FY 2020 Enacted Level. At this level the request includes inflationary increases for Service and Supply Fund charges and other shared expenses.

PHS EVALUATION SET-ASIDE

Budget Summary

(Dollars in Thousands)

PHS Evaluation Set-Aside	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget	FY 2021 +/- FY 2020
ASPE	43,243	43,243	43,243	-
Public Health Activities	9,400	9,400	20,212	+10,812
Artificial Intelligence Initiative	-	-	5,000	+5,000
ASFR	1,100	1,100	1,100	-
OASH	4,285	4,285	4,285	-
Teen Pregnancy Prevention	6,800	6,800	-	-6,800
Total	64,828	64,828	73,840	+9,012
FTE	115	129	138	+9

ASSISTANT SECRETARY FOR PLANNING AND EVALUATION (ASPE)

Budget Summary

(Dollars in Thousands)

Assistant Secretary for Planning and Evaluation	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget	FY 2021 +/- FY 2020
PHS Evaluation	43,243	43,243	43,243	-
FTE	110	124	124	-

Authorizing Legislation:.....PHS Act, Title II Section 247
FY 2021 Authorization.....Permanent
Allocation Method.....Direct Federal

Program Description and Accomplishments

The Office of the Assistant Secretary for Planning and Evaluation (ASPE), headed by the Assistant Secretary for Planning and Evaluation, is a Staff Division of the Office of the Secretary in the U.S. Department of Health and Human Services (HHS). The Assistant Secretary is the principal advisor to the Secretary of HHS on policy development, and ASPE's staff lead initiatives for the Secretary and provide direction for HHS strategic, legislative, and policy planning. ASPE conducts policy research, evaluation, and economic analysis and estimates the costs and benefits of policies and programs under consideration by HHS or Congress. ASPE consists of a diverse group of professionals, including economists, statisticians, epidemiologists, lawyers, sociologists, scientists, psychologists, and physicians who conduct quick turnaround and longer term policy research and analysis to support leadership decision-making.

ASPE works in concert with others in the Department in support of the Administration's drug pricing initiative. ASPE's analytic efforts include developing legislative and regulatory proposals, research papers, drug list price change dashboards, international drug price comparisons, prescription drug pricing Report to Congress and other products as part of the Secretary's initiative to reduce drug list prices. ASPE's Part D benefit model is being used to simulate the impacts of legislation being considered by the Congress as well as proposals being considered by the Administration.

ASPE took the lead in preparing a report, Advancing American Kidney Health, which synthesized efforts across the Department into a cohesive vision to transform kidney care. This work helped to clarify what strategies would contribute to addressing Departmental goals, as well as refining the goals. Several ASPE research papers support this initiative. ASPE is similarly coordinating Department efforts to improve maternal health by developing a Department wide strategic framework including goals and objectives, identifying opportunities to expedite and track progress, and developing a research and data strategy.

ASPE leads the development, coordination of the implementation of the Department's work to support the Administration's initiative to address the opioid epidemic and serves as the HHS lead to coordinate the implementation of the Administration's National Action Plan to Combating Antibiotic-Resistant Bacteria initiative. ASPE also coordinates an HHS-wide workgroup to identify economic incentives to promote antimicrobial development in support of the National Action Plan.

ASPE has a central role in behavioral health and works with Substance Abuse and Mental Health Services Administration (SAMHSA), National Institute of Mental Health, and other stakeholders to address serious mental illness and leads significant mental health initiatives required by Congress in the 21st Century Cures Act. During a public health emergency or infectious disease outbreak, ASPE participates in efforts led by the Assistant Secretary for Preparedness and Response (ASPR), to ensure that HHS and Administration policies are implemented efficiently and effectively. ASPE works closely with the Administration for Children and Families (ACF) to identify and test strategies that advance the health, safety, and well-being of Americans, and leads the U.S. Interagency Council on Economic Mobility chaired by HHS, charged with promoting employment, personal responsibility, and economic independence. ASPE research has played a central role in HHS efforts to assure that all Americans have access to quality, affordable health care, through insurance coverage and health care safety-net programs that work for them and meets their needs. ASPE analyses of regulatory burden have played a central role in the Department's efforts to reduce burden, put patients first, and increase state flexibility in health insurance markets.

ASPE maintains a diverse portfolio of intramural and extramural research and evaluation to inform policy formulation and decision-making regarding the full portfolio of HHS programs. In addition, ASPE maintains a number of simulation models, databases, actuarial support, and other resources to support timely policy analysis and development. In developing research priorities, ASPE consults across the Department and the Administration so that it focuses on work that is central to Department priorities. Emphasis is placed on identifying areas for which ASPE's work will add value to existing agency efforts and/or fill gaps, and where ASPE's contributions will be meaningful. Agencies often request that ASPE undertake specific projects to support HHS priorities, including numerous CMS requests on topics such as: Medicare drug prices compared to international drug prices, Medicare post-acute bundled payments, insurance market simulation models, evaluation of new interventions (like assisted outpatient treatment) to serve people with serious mental illness, and conducting demonstrations to test new models of serving older individuals in home and community- based settings. The Indian Health Service requested ASPE support to assess current alignment of IHS quality measures with existing performance and value-based purchasing program requirements, identify opportunities for enhanced alignment, and consider activities that IHS could undertake to further engage in value based payment arrangements moving forward.

ASPE works across the Department, with the Office of Management and Budget, agencies throughout the federal government, and other stakeholders to develop analytic capacity to evaluate federal

investments and support evidence-informed policies. ASPE's work in these areas is enhanced by participation at all levels in interagency collaborations, and ASPE convenes many operating and staff divisions which provide input on HHS priorities. ASPE will coordinate HHS implementation of the Foundation for Evidence-Based Policymaking Act of 2018.

ASPE coordinates the development of the quadrennial HHS Strategic Plan. A strategic plan is one of three main elements required by the Government Performance and Results Act (GPRA) of 1993 (P.L. 103-62) and the GPRA Modernization Act of 2010 (P.L. 111-352). An agency's strategic plan defines its mission, goals, and the means by which it will measure its progress in addressing specific national problems over a four-year period.

The following outlines ASPE's goals and programs continuing from FY 2019. The goals align with Department goals to Foster Sound, Sustained Advances in the Sciences; Strengthen the Economic and Social Well-being of Americans Across the Lifespan; Promote Effective and Efficient Management and Stewardship; Foster Sound, Sustained Advances in the Sciences; and Reform, Strengthen and Modernize the Nation's Healthcare System.

Foster Sound, Sustained Advances in the Sciences
In FY 2020, ASPE continues to manage and upgrade the Strategic Planning System to track progress on the Department's implementation of the CARB (Combating Antimicrobial Resistant Bacteria) Strategic Plan, as well as plans on other Departmental priorities. The Strategic Planning System houses a Resource Center which provides guidance and insight to the Department's OpDivs and StaffDivs on developing and implementing their own strategic plans.

ASPE continues to respond to requests from Congress, and develop an overall strategy to evaluate HHS programs that serve people with serious mental illness and other behavioral health needs.
Other priority projects under this goal include research and analysis to support regulatory risk assessment and management; the translation of biomedical research into every day health and health care practice; the development and adoption of innovation in health care; and food, drug, and medical product safety and availability. ASPE will build on an existing collaboration with the Food and Drug Administration (FDA), which is characterizing the activities and costs associated with validating new biomarkers for use in drug development. Information gleaned from this project may be useful to inform efforts to encourage biomarker validation, with the goal of facilitating the speed and efficiency of drug development so new therapies reach patients sooner. ASPE is also partnering with FDA on research to assess the costs of clinical trials, with a goal to identify policy interventions to improve the efficiency of the clinical trial process and encourage innovation. Additional research focuses on understanding the costs of generic drug development and approval.

ASPE coordinates an HHS-wide initiative to build data capacity for patient-centered research. ASPE convenes agency leaders, researchers, data experts, and research networks to collect, link, and analyze real world data for research on a wide spectrum of issues. FY 2021 projects will address Secretarial priorities and may include Substance use (including opioid use disorders), patient-centered health information technology and data, mental health, and maternal morbidity and mortality.

ASPE's coordination of efforts to build data capacity across HHS strengthens its research, analyses, and public reporting programs, while simultaneously reducing unnecessary duplication, inefficiencies, and reporting burdens on patients or health care providers.

ASPE leads an HHS-wide Analytics Team to provide recommendations for strengthening regulatory analysis, and provides technical assistance on regulatory impact analysis development to HHS agencies and offices. ASPE works in close partnership with HHS operating divisions on regulatory priorities and regulatory reform, and with the White House, the Office of Management and Budget, and the Federal Trade Commission to continue efforts to introduce more experimental evidence into decision making in the design of regulations. For example, ASPE has developed guidelines for HHS on analyzing the impact of regulations to improve the transparency and quality of regulatory decision making, and is leveraging the Analytics Team to provide thought leadership on regulatory costs and benefits under the rubric of Regulatory Reform, as newly required by Executive Order 13771, Reducing Regulations and Controlling Regulatory Costs, and Executive Order 13777, Enforcing the Regulatory Reform Agenda.

ASPE will be coordinating the implementation of the Foundations for Evidence-based Policymaking Act of 2018 (Evidence Act), including providing technical assistance to within HHS on the development of Evidence Plans and an Evaluation Plan, with an emphasis on making policymaking more evidence-based.

Finally, ASPE convenes and works collaboratively with other HHS operating and staff divisions, and statistical centers, such as Office of National Coordinator for Health Information Technology (ONC), Food and Drug Administration (FDA), Centers for Medicare & Medicaid Services (CMS) and Centers for Disease Control's (CDC) National Center for Health Statistics (NCHS) to advance the goal of an electronic, nationwide interoperable healthcare system. This includes crafting health IT policies that support the development and use of standardized data to improve patient safety. Two examples of this type of work are ASPE's contributions to the development of FDA's unique device identifier for tracking medical devices, and the evaluation and development of comparability ratios when converting to new standard data classifications (ICD9-ICD10) in NCHS national surveys for tracking population health.

Strengthen the Economic and Social Well-being of Americans across the Lifespan

ASPE's priorities are to provide actionable research to support the Secretary's goal to advance the health, safety, and well-being of Americans through self-sufficiency and work that increases personal responsibility, independence, economic mobility, and – most importantly – family stability. Understanding how to help parents work and care for their children is reflected in ASPE's efforts to strengthen workforce development, identify and address the barriers to find and keep unsubsidized employment, leverage social capital, improve child support enforcement, and increase access to child care. In addition, ASPE analyzes methods to improve access to healthcare, promote the healthy development of children, and increase opportunities for learning and school success. When at risk families need more help, ASPE provides for the study of strategies to improve the safety and well-being of children involved in the child welfare system, refugee and homeless families, and families affected by incarceration. ASPE is a leader in on-going research and study of poverty and youth programs, and is also leading research and coordination to enhance human services programs' ability to combat the impact of the opioid crisis on low income families.

ASPE is examining residential care alternatives for older adults, caregiver support, evidence-based clinical and community-based preventive services, mental health and substance use disorder programs, and disparities in health. During public health emergencies and infectious disease outbreaks, ASPE will provide technical and analytic support for policy decision-making to support ASPR and the Secretary on behalf of individuals, families, and communities.

ASPE provides analytic support for efforts to reduce Opioid mortality and morbidity, and coordinates HHS efforts to implement the Substance Use Disorder Prevention that Promotes Opioid Recovery and

Treatment for Patients and Communities (SUPPORT) Act.

ASPE assembles evidence that is critical to the design of departmental programs, and makes policy and program decisions based on the best available evidence, using data and analysis about the behavior of program participants, what interventions work, for whom, and under what circumstances. In the absence of direct evidence, ASPE uses the evidence-informed methods (such as well-calibrated simulation models) to expand approaches that work and fine-tune programs and interventions that may have mixed results. Staff work to anticipate potential outcomes of policy actions, what programs and interventions work, improve upon what does not, and understand what actions to take when programs do not demonstrate improvement. In this context, analyses involve a range of information sources including survey data and analyses, program evaluation, analytical models and methods, as well as performance data and scientific evidence generated at multiple levels of study. ASPE will continue this work as it coordinates the implementation of the Evidence Act. This will include working with HHS operating and staff divisions to create a culture of learning to ensure evidence-based decision- making is the norm throughout HHS.

ASPE conducts research and evaluation for important initiatives, such as increasing economic mobility, behavioral health (including early psychosis intervention), and addressing the opioid epidemic. In addition, ASPE helps coordinate work to address homelessness across HHS agencies. ASPE leadership serves as the HHS representative to the U.S. Interagency Council on Homelessness (USICH).

ASPE coordinates behavioral health parity implementation across HHS and other federal agencies working on parity, notably the Departments of Labor and Treasury. A number of ASPE-identified action steps were included in the 21st Century Cures legislation, including that the Secretary of HHS host a public meeting on behavioral health parity. ASPE hosted this tri-Department listening session last summer and will complete an Action Plan this coming year based on the listening session.

ASPE leads the Administration's efforts to combat Alzheimer's disease and related dementias, including operating the National Advisory Council on Alzheimer's Research, Care, and Services, which involves all HHS leaders engaged in dementia-related work, as well as 12 national experts from the private sector. The group produces and updates an annual National Alzheimer's Plan. In the coming year, ASPE will coordinate Departmental stakeholders, the Advisory Council, outside experts and contractors to convene a national summit on dementia care research on the NIH campus.

ASPE leads the U.S. Interagency Council on Economic Mobility to maximize the efficiency and coordination of the nearly 100 federal public benefit programs that focus on employment and economic mobility. The Council executes a component of the 2018 Government Reform Plan and HHS' *ReImagine* Initiative (Aim for Independence). It implements the policy objectives outlined in several Executive Orders related to employment and economic mobility, including Reducing Poverty in America by Promoting Opportunity and Economic Mobility (April 2018). The Council will increase program alignment, efficiency, and accountability of work and welfare programs federal government, and provide a sustainable platform for moving towards an aligned outcomes orientation.

ASPE chairs the Interagency Working Group on Youth Programs, established by Executive Order 13459, Improving the Coordination and Effectiveness of Youth Programs. The Working Group coordinates with the First Lady's Be Best initiative, and leverages the activities of 20 federal agencies and offices in order to improve youth outcomes, promote positive youth development and successful transition to

adulthood, disseminate evidence- based practices, and strengthen youth engagement and youth/adult partnerships and increase efficiency across the federal government. Many of these goals are accomplished through the website www.youth.gov, a one-stop shop for federal information and resources about youth.

Promote Effective and Efficient Management and Stewardship
Specific projects under this goal include developing metrics for performance measurement, understanding needs of individuals with disabilities, determining the common components of effective youth prevention programs, research addressing the new Medicare quality payment program for physicians, and evaluating the impact of social risk factors in Medicare's quality and resource use measures in value based purchasing programs. ASPE will coordinate HHS data collection and analysis activities; ensure effective long-range planning for surveys and other investments in major data collection; and will proactively identify opportunities for transparency, data sharing, and dissemination through electronic posting of datasets on healthdata.gov and other means.

ASPE maintains several databases, which allow for short-term monitoring and evaluation of existing and newly-implemented policies. ASPE's staff routinely work with colleagues in other HHS agencies, Departments, and private organizations to improve data collection for policy development, analysis, and evaluation. It also extensively uses unique data sets, acquired from private vendors, to better monitor, evaluate, and track trends in important areas such as prescription drug policies; use of mental health and substance use disorder services; and employer sponsored health insurance.

ASPE supports the Department in its goals to enhance internal and external information sharing in accordance with privacy and civil liberties policies. ASPE reviews and advises on privacy policy involving the protection of individually identifiable information. Our goals are to ensure fairness and confidentiality while ensuring data is available for research, administration, and policy decision making.

Foster Sound, Sustained Advances in the Sciences
ASPE maintains a small team focused on improving evaluation and the use of evidence across the Department through collaboration, coordination, and consultation with staff and leadership in operating and staff divisions. ASPE provides a number of products and services that advance these goals in multiple programs. The newly enacted Evidence Act specifically proposes strengthening Federal evaluation government-wide, including administrative improvements to increase capacity to conduct evaluation. ASPE is developing enhanced and strategic learning activities in order to effectively address the Secretary's and the Departments' priorities. While ASPE has recently improved data access relevant to these priorities, particularly in the areas of opioids and drug pricing, data itself cannot provide the contextual and causal information that formal evaluations can.

ASPE will continue to lead efforts to leverage HHS administrative data for research, policy, statistical, program and performance management and evidence building purposes. For example, ASPE is conducting a review to identify and document the major privacy issues or other limitations in accessing, using, and sharing administrative data for other purposes. Identification of limitations is a first step in the ability to reform policies, guidance, and procedures for linking administrative data for use in research, evaluation, or program improvement; disseminating results; and making available data sets for public use. ASPE is also leading efforts by the HHS Data Council to examine existing data use agreements with the goal of standardizing and streamlining data use agreements across the Department. These activities will support the development of efforts to navigate potential limitations and increase access to administrative data.

Reform, Strengthen and Modernize the Nation's Healthcare System
Priority projects under this goal include providing analysis and developing data to measure, monitor and evaluate the Department's efforts to address pharmaceutical pricing, stabilize the individual and small group health insurance markets, encouraging state innovation to develop patient-centered reforms to health care delivery, enhancing price and quality transparency, improving health care and nursing home quality, developing innovative payment and delivery systems, analyzing the performance of safety net and workforce distribution programs, identifying the best ways to serve individuals who are dually eligible for Medicare and Medicaid, modernizing Medicaid, and improving care delivery in the Indian Health Service.

ASPE will identify key strategies to reduce the growth of health care costs while promoting high-value, consumer-driven, effective care. Priority projects will produce the measures, data, tools, and evidence that health care providers, insurers, purchasers, consumers, and policymakers need to improve the value and affordability of health care and to reduce disparities in costs and quality between population groups and regions. These projects include research required under the IMPACT ACT to determine the relationship between social risk (socioeconomic) factors and quality measures used in Medicare's value based purchasing programs; research to support the implementation of new physician payment approaches under The Medicare Access and CHIP Reauthorization Act of 2015; and research to support development of post-acute care payment models required by the IMPACT ACT.

ASPE will continue to develop advanced capacity to track, analyze and compare drug prices and utilization across U.S. payers and internationally. Analyses include the impact of competition on generic drug prices; impact of exclusivities and patent protections on generic drug entry; analyzing trends in spending by source and patient copayments; analysis of biosimilar policy issues; and analysis of changes in Part D benefit structure.

ASPE participates in interagency workgroups to support the alignment and public reporting of quality measures across HHS programs. One workgroup focuses on public reporting across HHS agencies. A second workgroup focuses on quality measure endorsement and input on the National Quality Strategy. ASPE has partnered with SAMHSA, CMS, and NIMH over the past few years to develop additional quality measures for behavioral health care. The measures address important issues regarding follow-up after inpatient and emergency room treatment, screening and care for co-morbid conditions, screening for risk of suicide or other violent behavior, and fidelity to evidence-based treatments. ASPE has worked together to develop and promote these measures for use in various programs throughout the Department including the meaningful use measures used by the ONC and the reporting requirements used by CMS for the inpatient psychiatric facility prospective payment system in Medicare. In addition, ASPE has worked together to sponsor a study by the Institute of Medicine on developing quality standards for psychosocial interventions.

Five Year Funding Table

Fiscal Year	Amount
FY 2017	$41,243,000
FY 2018	$41,243,000
FY 2019	$43,243,000
FY 2020	$43,243,000
FY 2021 Request	$43,243,000

Budget Request
The FY 2021 President's Budget request for ASPE if $43,243,000 which is flat with the FY 2020 Enacted Level. At this level, ASPE will continue to support the economic analysis and reports on drug pricing, including international drug prices. ASPE will absorb pay increases by reducing contracts.

ASPE provides planning and research support to the department to meet regular business needs, such as strategic planning, evaluation and program effectiveness, FACA compliance, interagency work groups, and many others. ASPE prioritizes work to support the latest set of Secretarial initiatives: combating the opioid crisis; bringing down the high cost of prescription drugs; addressing the cost and availability of health insurance; transforming our healthcare system to a value-based system, supporting establishment of the Council on Economic Mobility (in collaboration with other relevant Agencies) to implement certain aspects of the previously-titled "Council on Public Assistance" as recommended in Delivering Government Solutions in the 21st Century and *ReImagine HHS*.

In addition, ASPE continues to work on activities that support HHS's mission more broadly, especially as outlined in the HHS Strategic Plan. Addressing these priorities and informing decision-making accurately, thoroughly, and objectively requires access to increasingly costly data, software, programming, and expert analytic support. In addition to the critical Secretarial initiatives, ASPE has responded to a series of White House Executive Orders around regulatory reform, rural health, welfare reform, prisoner reentry, health care choice and competition, price transparency, Medicare reform, and kidney disease.

Key research topics from the last Fiscal Year have included:
- Prescription drug pricing
- Understanding Recent Trends in Generic Drug Prices (intramural)
- Health Insurance Reform
- Medicare Value Based Purchasing Programs
- Kidney Care Initiative: Medicare immunosuppressive drugs, Special Diabetes Program for Indians, Analysis of Home vs. Facility-Based Dialysis, and developing a Department-wide vision
- HIV: Comparing trends over time in health status, outcomes, spending, and utilization of services for older people living with HIV
- Behavioral Health and Substance Disorder Treatment
- Analysis of Disability and Aging Programs
- Estimating the Risk and Use of Long-Term Services and Supports
- Incentives for Antibacterial Drug Development
- Implementing electronic health record default settings to reduce opioid overprescribing
- Synthetic Data Initiative to support President's Executive Order on Improving Price and Quality, Transparency in American Healthcare to Put Patient's First.

In addition, ASPE makes significant investments in resources that allow us to respond to immediate requests for information to support policy-making. These include:

- Access to Prescription Drug Data, Patient Level Drug Utilization Data, and Drug Sales Data for the Purposes of On-going Research
- National Poverty Research Center
- Transfer Income Model (TRIM3)

- Health Insurance Microsimulation Model (RAND COMPARE)
- Private Health Plan Claims data (Marketscan)
- Dynamic Simulation of Income Model (DYNASIM4)
- Actuarial Estimation

This request will also support and expand ASPE's role in coordinating departmental implementation of the Strategy to address the opioid epidemic through continued research into addiction, prevention, treatment, and recovery services. ASPE currently plays an important role in providing coordination and departmental involvement in critical policy decisions with a focus on expediting the discovery, development, and delivery of new therapies, making significant reforms to the mental health system, and increasing health care choice, access and quality. To further the Secretary's focus on serious mental illness, ASPE will develop and implement work related to education, screening, treatment, community engagement, and research.

ASPE anticipates continuing its role in coordinating departmental implementation of the 21st Century Cures Act, given the cross-cutting nature of the law's provisions. ASPE also coordinates implementation of the SUPPORT Act, the Evidence Act, and the Government Performance and Results Modernization Act. ASPE plays an important role in providing coordination and department involvement in critical policy decisions related to authorities and mandates affecting HHS agencies with a focus on expediting the discovery, development, and delivery of new therapies, making significant reforms to the mental health system, and increasing health care choice, access and quality.

ASPE will continue support for a cooperative agreement to address barriers to economic mobility for children, families, and communities. ASPE awards $2,565,000 per year to a university-based poverty research center to provide timely access to access to cutting edge researchers and high-quality, reliable research products, meeting HHS policy research demands in high priority areas including economic mobility and building strong families as well as policies and programs to increase independence.

ASPE will continue to coordinate with the workgroup leading the Department's efforts to implement the "Executive Order on Advancing American Kidney Health" and implementation of the activities described in the Advancing American Kidney Health report. ASPE will also continue to work closely with OASH and other divisions on developing a Department-wide vision for improving maternal health; rural health; and the impact of social determinants on health.

Grants

Grants (whole dollars)	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget
Number of Awards	1	1	1
Average Award	$1,565,000	$2,565,000	$2,565,000
Range of Awards	$1,565,000	$2,565,000	$2,565,000

PHS EVALUATION
PUBLIC HEALTH ACTIVITIES

Budget Summary
(Dollars in Thousands)

PHS Evaluation – Public Health Activities	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget	FY 2021 +/- FY 2020
PHS Evaluation	9,400	9,400	20,212	+10,812
FTE	2	5	13	+8

Authorizing Legislation……PHS Act, Title II, Section 301
FY 2021 Authorization……Permanent
Allocation Method……Direct Federal

Program Description and Accomplishments
The Immediate Office of the Secretary provides leadership, direction, policy, and management guidance to HHS and establishes Department priorities for evaluation of Public Health Service programs. These priorities include evaluating program effectiveness across HHS to improve the quality of public health and human service programs.

PHS Evaluation funding allows the Secretary the necessary flexibility to identify, refine, and implement programmatic and organization goals in response to evolving needs. With these funds, staff research and evaluate health and human services activities and operations; serving HHS and the Administration decision makers, as well as state and local government, private sector public health research, education, and practice communities by providing valuable information on the factors contributing to the determining program effectiveness.

A key priority of the Secretary is to evaluate HHS investments in data collection and management. Diverse sets of data assets include administrative, research, and public health data, all of which have the potential for tremendous value. These funds will support program review by the Office of the Chief Technology Officer (CTO) to evaluate the effectiveness of HHS efforts for uniform collection, storage and optimized use of HHS data assets. This effort enables HHS to make the best use of its wealth of data to identify, evaluate, and improve program performance, to prioritize investments, and to improve how HHS measures associated impact.

Five Year Funding Table

Fiscal Year	Amount
FY 2017	$12,005,000
FY 2018	$11,400,000
FY 2019	$9,400,000
FY 2020	$9,400,000
FY 2021 Request	$20,212,000

Budget Request
The FY 2021 President's Budget Request for Secretary's Public Health Activities is $20,212,000, which is $10,812,000 above the FY 2020 Enacted Level. This will allow the Secretary to fund other priority areas such as Health Insurance Reform, lowering prescription drug prices and out-of-pocket costs, and Value-Based Care.

In FY 2021, the Secretary will proactively respond to the needs of the Department, as it improves programs and services authorized in the U.S. Public Health Service Act by evaluating the implementation and effectiveness of these programs, to ensure the return on the investment of program funding through meaningfully leveraging data to enable new insights for targeted interventions and programmatic improvement.

Strengthening Health Care
FY 2021 priority projects for Public Health Activities include providing analysis and developing data to measure, monitor, and evaluate the Department's efforts to stabilize the individual and small group health insurance markets, respect and promote the patient-doctor relationship, empower patients and promote consumer choice, enhance affordability, return regulatory authority to the states, and reduce unwarranted regulatory and economic burden.

The Secretary identifies key strategies to promote high-value, consumer-driven, effective care that lowers total health care cost growth. Priority projects are intended to produce new or streamline the performance measures, data, tools, and evidence that health care providers, insurers, purchasers, consumers, and policymakers need to improve the value and affordability of health care and to reduce disparities in costs and quality between population groups and regions. These projects include research required under the Improving Medicare Post-Acute Care Transformation (IMPACT) Act to determine the relationship between social risk (socioeconomic) factors and quality measures used in Medicare's value based purchasing programs; research to support the implementation of new physician payment approaches under the Medicare Access and CHIP Reauthorization Act of 2015; and research to support development of post-acute care payment models required by the IMPACT Act.

Data Innovation
The Office of the CTO leads HHS enterprise data efforts. HHS evaluates the value and impact of data developed by the Department and that of stakeholders to more effectively gain insights which advance HHS initiatives, such as combating the national opioid epidemic. Focusing on the Secretary's priorities, the Office of the CTO works across HHS to evaluate how data can be used to establish practical solutions to crosscutting problems. CTO advances best practices and data driven solutions to address issues such as the opioid crisis, reduction in provider burden, and data sharing across states.

CTO will also seeks to accelerate evaluation of improved access to HealthData.gov, the public gateway to Department health and human datasets. In FY 2021, CTO plans to develop the HealthData.gov strategy and execution plan, to increase utilization of HHS data for novel health research and solutions.

PHS EVALUATION
ARTIFICIAL INTELLIGENCE
Budget Summary
(Dollars in Thousands)

PHS Evaluation Artificial Intelligence	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget	FY 2021 +/- FY 2020
PHS Evaluation	-	-	5,000	+5,000
FTE	-	-	1	+1

Authorizing Legislation……Title III of the PHS Act
FY 2021 Authorization……Indefinite
Allocation Method……Direct Federal

Program Description and Accomplishments
Executive Order (EO) 13859 on Maintaining American Leadership in Artificial Intelligence (AI) provides that the Secretaries of Defense, Commerce, Health and Human Services and Energy, the Administrator of the National Aeronautics and Space Administration, and the Director of the National Science Foundation shall, to the extent appropriate and consistent with applicable law, prioritize the allocation of high-performance computing resources for AI related applications through increased assignment of discretionary allocation of resources and resource reserves or any other appropriate mechanisms.

HHS will establish a committee to address AI investments and identify best opportunities for the use of these funds Department-wide to pursue the five pillars of the EO. The five pillars include: Research and Development, Standards and Resources, Workforce, Governance and International Engagement.
A centralized approach and direction is needed, especially when working to identify the impacts of increased access by the non-Federal AI community to Federal data and models, while ensuring safety, security, and privacy. The committee will focus on ensuring AI investments Department-wide are focused on lowering costs, using real-world evidence, and enhancing interoperability.

Five Year Funding Table

Fiscal Year	Amount
FY 2017	-
FY 2018	-
FY 2019	-
FY 2020	-
FY 2021 Request	$5,000,000

Budget Request
The FY 2021 President's Budget request for Secretary's Artificial Intelligence is $5,000,000, which is $5,000,000 above the FY 2020 Enacted Level. The use of PHS Evaluation funding will allow the committee to provide oversight and direction to HHS Operating Divisions as they work to meet the goals of the EO.

PHS EVALUATION
ASSISTANT SECRETARY FOR FINANCIAL RESOURCES

Budget Summary
(Dollars in Thousands)

PHS Evaluation – Assistant Secretary for Financial Resources	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget	FY 2021 +/- FY 2020
Budget Authority	1,100	1,100	1,100	-
FTE	-	5	13	+8

Authorizing Legislation: ……PHS Act, Section 241
FY 2021 Authorization……Indefinte
Method……Direct federal, Contract

Program Description and Accomplishments

Office of Budget (OB)
OB manages the performance budget and prepares the Secretary to present the budget to the Office of Management and Budget (OMB), the public, the media, and Congressional committees. OB manages the implementation of the Government Performance and Results Modernization Act (GPRAMA) and all phases of HHS performance budget improvement activities.

Five Year Funding Table

Fiscal Year	Amount
FY 2017	-
FY 2018	$1,100,000
FY 2019	$1,100,000
FY 2020	$1,100,000
FY 2021 Request	$1,100,000

Budget Request
The FY 2021 President's Budget request is $1,100,000, which is flat with the FY 2020 Enacted Level. At this level, ASFR will support costs associated with the Department's effort to improve program performance through the collection, analysis and reporting of HHS program performance data. The FY 2021 request will be used to fund program performance measurement activities within the ASFR Office of Budget. The Office of Budget manages the implementation of the Government Performance and Results Modernization Act (GPRAMA) and all phases of HHS performance budget improvement activities. These funds will cover staff costs focused on program evaluation activities in the preparation of performance reports for OMB, the Congress, and the public. Funds will also go towards the coordination of Agency Priority Goal (APG) and Strategic Review reporting. APGs are near-term goals that focus on key priorities of the Secretary and the Administration. During the Strategic Review process, HHS reports interim and end of year progress on meeting the goals and objectives of the HHS Strategic Plan.

PHS EVALUATION
OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH

Budget Summary

(Dollars in Thousands)

OASH – Public Health Service Evaluation	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget	FY 2021 +/- FY 2020
PHS Evaluation	4,285	4,285	4,285	-
FTE	-	-	-	-

Authorizing Legislation: .....PHS Act, Title II, Section 241
FY 2021 Authorization.....Permanent
Allocation Method.....Direct federal

Program Description and Accomplishments

The Office of Assistant Secretary for Health (OASH) Immediate Office coordinates the Evaluation Set-Aside program for OASH. Each fiscal year, OASH program offices submit proposals in an effort to improve and evaluate Public Health Service Act funded programs effectiveness. Studies supported by these Set-Aside funds serve decision makers in federal, state, and local government, and the private sector of the public health research, education, and practice communities by providing valuable information about how well programs and services are working. Projects approved in FY 2019 are listed below:

- Monitoring and Evaluating Progress in Achieving our National Health Objectives: Healthy People 2020 (HP2020):
  - Assess progress in achieving the HP2020 targets.
  - Identify population health disparities and gaps in data collection.
  - Identify and communicate evidence-based practices and programs that support achievement of the HP2020 objectives, across multiple sectors and levels.

- Developing National Health Objectives to Evaluate Health Across the Nation: Healthy People 2030 (HP2030):
  - Conduct a comprehensive evaluation of data supporting exiting national objectives, emerging critical public health issues that impact policy and program development and implementation, within and outside the federal government.
  - Lead committee and subcommittee meetings.
  - Develop a formal public comment process on the proposed HP2030 objectives
  - Finalize the framework and objectives for HP2030 by the Healthy People Federal Interagency Workgroup.
  - Gain input from ODPHP's management of the processes to yield the HP2030 objectives and Leading Health Indictors (LHIs) in time for the launch in 2020.

- Evaluation of core competencies for Scientist Investigators:
  - Identify key skills of present and past successful scientist investigators at ORI.
  - Identify opportunities to bolster skills through training, job shadowing, other mechanisms.
  - Use findings to develop an assessment for use in the hiring process for new scientist investigators, as well as a tool for investigators' career development over time.

- Physical Activity Guidelines for Americans, 2018:
  - Evaluate current science to develop the second edition of the Physical Activity Guidelines for Americans.
  - Encourage adoption of the recommendations in the second edition of the Physical Activity Guidelines for Americans through communications strategies and educational resources based on formative audience research.
  - Evaluate awareness of the recommendations from the second edition of the Physical Activity Guidelines and behavior change among target audiences.

- Evaluation of the National Sports Strategy:
  - Evaluate methods to disseminate information from National Youth Sports Strategy among target audiences.
  - Explore partnerships and opportunities to expand federal efforts to promote youth sports with both public and private partners.
  - Increase awareness of the benefits of youth sports participation through communications strategies and educational resources.

- Sickle Cell Database Expansion
  - Identify up to 3 additional states for Sickle Cell Database Expansion
  - Collect comprehensive SCD data collection via CDC
  - Conduct oversight, including site visits, of respective states; and
  - Complete data analysis and data dissemination efforts, including CDC Sickle Cell annual reports.

- Evaluation of Monitoring and Oversight Activities and Strategies for the Title X Family Planning Projects:
  - Assess activities and strategies that Title X grantees currently use to monitor and conduct oversight of their sub-recipients.
  - Identify, document, and rate monitoring and oversight strategies, including training, electronic tools, checklists and other documents, and experiences that can be directly used or adapted for the Title X family planning program.
  - Develop an implementation strategy addressing current challenges, best practices, processes, and metrics/performance measures to establish a comprehensive monitoring and oversight program for the Title X family planning program.

- Evaluating a Modernized USPHS Commissioned Corps:
  - Execute an implementation plan for the top 20 recommendations.
  - Develop ongoing key messages that support the implementation plan and the modernization of the USPHS Commissioned Corps.

- Office of the Assistant Secretary for Health Strategic Plan:
  - Assist with conducting the development of the OASH strategic plan.
  - Support implementation strategies and activities that align with the final OASH strategic plan.

Five Year Funding Table

Fiscal Year	Amount
FY 2017	$4,285,000
FY 2018	$4,285,000
FY 2019	$4,285,000
FY 2020	$4,285,000
FY 2021 Request	$4,285,000

Budget Request

The FY 2021 President's Budget request is $4,285,000, which is flat with the FY 2020 Enacted Level. At this level, OASH will continue to support robust program evaluation projects selected from proposals to improve and evaluate public health programs and identify ways to improve their effectiveness. The evaluation projects will continue to serve decision makers in, federal, state, and local government, as well as support OASH priorities and the HHS Strategic Plan.

PHS EVALUATION
TEEN PREGNANCY PREVENTION

Budget Summary

(Dollars in Thousands)

Teen Pregnancy Prevention – Public Health Service Evaluation	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget	FY 2021 +/- FY 2020
PHS Evaluation	6,800	6,800	-	-6,800
FTE	-	-	-	-

Authorizing Legislation.....PHS Act, Title II, Section 247
FY 2021 Authorization.....Permanent
Allocation Method.....Direct Federal

Program Description and Accomplishments

The Office of Adolescent Health (OAH) supports several evaluation activities to build the evidence base to prevent teenage pregnancy and to support expectant and parenting youth and their families. OAH supports projects that make a significant contribution to these fields including Federal program evaluations, economic evaluations, the provision of rigorous training and technical assistance to evaluation grantees. Additionally, OAH collects and analyzes performance measures.

Five Year Funding Table

Fiscal Year	Amount
FY 2017	$6,800,000
FY 2018	$6,800,000
FY 2019	$6,800,000
FY 2020	$6,800,000
FY 2021 Request	-

Budget Request

The FY 2021 President's Budget does not request funds for this program.

PREGNANCY ASSISTANCE FUND

Budget Summary

(Dollars in Thousands)

Pregnancy Assistance Fund	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget	FY 2021 +/- FY 2020
Budget Authority	23,350	-	-	-
FTE	2	-	-	-

Authorizing Legislation.....Patient Protection and Affordable Care Act, Section 10214
FY 2020 Authorization.....Expired
Allocation Method.....Mandatory Federal

Program Description and Accomplishments

The Pregnancy Assistance Fund (PAF) is a competitive grant program for States and Tribes to develop and implement projects to improve the health, educational, social, and economic outcomes of expectant and parenting teens, women, fathers, and their families.

Five Year Funding Table

Fiscal Year	Amount
FY 2017	$25,000,000
FY 2018	$25,000,000
FY 2019	$25,000,000
FY 2020	-
FY 2021 Request	-

Budget Request

The FY 2021 President's Budget Request does not request funds for this program.

Department of Health and Human Services
Office of the Assistant Secretary for Health
FY 2021 Discretionary State Grants

Pregnancy Assistance Fund (PAF)

State/Territory	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget	FY 2021 +/- FY 2020
Alabama	$928,496	-	-	-
Alaska	$744,329	-	-	-
Arizona	$1,220,613	-	-	-
California	$1,388,075	-	-	-
Connecticut	$780,486	-	-	-
Kansas	$941,475	-	-	-
Maryland	$970,000	-	-	-
Massachusetts	$970,000	-	-	-
Michigan	$970,000	-	-	-
Minnesota	$970,000	-	-	-
Mississippi	$970,000	-	-	-
Montana	$970,000	-	-	-
Nebraska	$796,696	-	-	-
New Mexico	$970,000	-	-	-
New York	$970,000	-	-	-
Oklahoma	$851,320	-	-	-
Oregon	$970,000	-	-	-
Pennsylvania	$744,306	-	-	-
Rhode Island	$885,739	-	-	-
South Carolina	$970,000	-	-	-
Virginia	$931,296	-	-	-
Washington	$970,000	-	-	-
Wisconsin	$970,000	-	-	-
New Grant Awards – TBD		-	-	-
Subtotal States/Tribes	**$21,852,831**	-	-	-
Program Support	**$1,497,169**	-	-	-
Total Resources	**$23,350,000**	-	-	-

SUPPORTING EXHIBITS
DETAIL OF POSITIONS[4]

Direct Civilian Positions	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget
Executive level I	1	1	1
Executive level II	1	1	1
Executive level III	-	-	-
Executive level IV	3	3	3
Executive level V	-	-	-
Subtotal, Positions	**5**	**5**	**5**
Total, Salaries	$ 961,000	$ 961,000	$ 961,000
-	-	-	-
Executive Service	72	72	72
Administrative Appeal Judge	10	10	10
Subtotal, Positions	**82**	**82**	**82**
Total, Salaries	$ 13,207,000	$ 13,207,000	$ 13,207,000
-	-	-	-
GS-15	129	132	129
GS-14	203	213	203
GS-13	127	134	127
GS-12	142	145	139
GS-11	41	46	41
GS-10	21	25	21
GS-9	35	35	35
GS-8	30	30	30
GS-7	12	12	12
GS-6	6	6	6
GS-5	2	2	2
GS-4	1	1	1
GS-3	-	-	-
GS-2	-	-	-
GS-1	-	-	-
Subtotal, Positions	**749**	**781**	**746**
Total Salaries	**$ 101,211,353**	**$111,577,748**	**$ 107,553,552**
Total Positions	**836**	**868**	**833**
Average ES Level	ES 00	ES 00	ES 00
Average ES salary	$ 164,239	$ 164,239	$ 164,239
Average GS grade	**14.5**	**14.7**	**14.7**
Average GS Salary	**$ 135,129**	**$ 142,865**	**$ 144,174**

[4] Table does not include Reimbursable of Commissioned Corps FTE.

DETAIL OF FULL-TIME EQUIVALENT (FTE) EMPLOYMENT

Detail[5]	FY 2019 Final CIV	FY 2019 Final CC	FY 2019 Final Total	FY 2020 Enacted CIV	FY 2020 Enacted CC	FY 2020 Enacted Total	FY 2021 President's Budget CIV	FY 2021 President's Budget CC	FY 2021 President's Budget Total
Direct	836	25	861	868	22	890	833	24	857
Reimbursable	491	15	506	486	15	501	507	13	520
Total FTE	**1,327**	**40**	**1,367**	**1,354**	**37**	**1,391**	**1,340**	**37**	**1,377**
-	-	-	-	-	-	-	-	-	-
Average GS Grade	**-**	**-**	**14.5**	**-**	**-**	**14.7**	**-**	**-**	**14.7**

[5] Abbreviation Key: CIV – Civilian, CC – Commissioned Corps

FTES FUNDED BY THE AFFORDABLE CARE ACT

(Dollars in Thousands)

Program	Section	FY 2011	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017	FY 2018	FY 2019	FY 2020	FY 2021
Pregnancy Assistance Fund Discretionary P.L. (111-148)	Section 10214	25,000	25,000	22,825	23,200	23,275	23,300	23,275	23,350	23,350	0	0
FTE	**-**	**2**	**2**	**2**	**2**	**2**	**2**	**2**	**2**	**2**	**0**	**0**

RENT AND COMMON EXPENSES

(Dollars in Thousands)

Details	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget	FY 2021 +/- FY 2020
Rent	-	-	-	-
GDM	8,792	9,867	10,284	+417
IOS	191	191	193	+2
ASPA	-	-	-	-
ASFR	-	-	-	-
ASA	-	-	-	-
IEA	828	800	808	+8
CFOI	59	59	60	+1
OGC	3,320	3,320	3,354	+34
DAB	2,500	2,500	2,500	-
OGA	392	392	396	+4
OASH	4,622	4,836	4,674	-162
Subtotal	***20,704***	***21,965***	***22,269***	***+304***
Operations and Maintenance	-	-	-	-
GDM	3,634	3,434	4,118	+684
IOS	129	129	118	-
ASPA	64	64	65	-
ASFR	648	648	655	+7
ASA	157	157	159	+2
IEA	156	186	188	-
CFOI	17	17	17	-
OGC	841	841	849	+8
DAB	500	284	287	+3
OGA	69	69	70	+1
OASH	2,543	2,950	2,976	+26
Subtotal	***8,757***	***8,778***	***9,501***	***+731***
Service and Supply Fund	-	-	-	-
GDM Shared Services	7,210	7,210	7,210	-
GDM	2,163	2,163	4,187	+2,024
IOS	-	-	-	-
ASFR	5,436	5,708	5,993	+285
ASFR	-	-	-	-
ASA	2,120	2,226	2,337	+111
IEA	-	-	-	-
CFOI	-	-	-	-
OGC	6,972	7,321	7,687	+366
DAB	1,113	1,168	1,227	+58
OGA	965	1,014	1,064	+51
OASH	7,527	7,903	8,299	+395
Subtotal	***26,296***	***27,503***	***30,794***	***+3,291***

PHYSICIANS' COMPARABILITY ALLOWANCE (PCA)

Office of the Assistant Secretary for Health

Physician Categories	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget
1) Number of Physicians Receiving PCAs	9	15	15
2) Number of Physicians with One-Year PCA Agreements			
3) Number of Physicians with Multi-Year PCA Agreements	9	15	15
4) Average Annual PCA Physician Pay (without PCA payment)	$200,000	$380,000	$380,000
5) Average Annual PCA Payment	$22,222	$25,333	$25,333
6) Number of Physicians' Receiving PCA's by Category (non-add) Category I Clinical Position	0	0	0
Number of Physicians' Receiving PCA's by Category (non-add) Category II Research Position	0	0	0
Number of Physicians' Receiving PCA's by Category (non-add) Category III Occupational Health	0	0	0
Number of Physicians' Receiving PCA's by Category (non-add) Category IV-A Disability Evaluation	0	0	0
Number of Physicians' Receiving PCA's by Category (non-add) Category IV-B Health and Medical Admin.	9	15	15

There is a shortage of qualified licensed medical doctors federal government-wide. OASH leads initiatives that require the qualifications and experience of licensed physicians (i.e., opioid, infectious diseases, immunization, disease prevention, as well as a host of presidential and secretarial federal advisory committees to focus on health disparities, pain management, etc.).

The use of PCA and direct hire granted by OPM affords OASH the ability to compete with the private sector to attract and retain licensed medical doctors. OASH typically loses 2 plus highly qualified physicians per year due to competing offers from the private sector. Most positions go unencumbered for a period of not less than 6 months. Due to the shortage, OASH projects to encumber 6 accessions (medical officers) this year.

OASH consistently monitors staffing levels to include planned and unplanned vacancies. Succession planning is based on current and projected needs which align with the priorities of the Secretary and Department.

GRANTS.GOV

The following is presented pursuant to Sections 737(b) and (d) of the Consolidated Appropriations Act of 2008 (P.L. 110-161).

The Assistant Secretary for Financial Resources (ASFR) manages the Grants.gov program on behalf of the 26 federal grant-making agencies. Grants.gov is the Federal government's hub for grant applications and information on over 1,000 grant programs and approximately $120 billion awarded by the agencies and other organizations. The program enables federal agencies to publish grant funding opportunities and application packages online, while allowing the grant community of over one million organizations (state, local, and tribal governments, education and research organizations, non-profit organizations, public housing agencies, and individuals) to search for opportunities and download, complete, and electronically submit applications.

Using Grants.gov, the agencies are able to provide the public with increased access to government grant programs and are able to reduce operating costs associated with online posting and application submissions of grants. Additionally, agencies are able to improve their operational effectiveness using Grants.gov by increasing data accuracy and reducing processing cycle times.

The initiative provides benefits to the following agencies:

Corporation for National Community Service
Department of Agriculture
Department of Commerce
Department of Defense
Department of Education
Department of Energy
Department of Health and Human Services
Department of Homeland Security
Department of Housing and Urban Development
Department of Justice
Department of Labor
Department of State
Department of the Interior
Department of the Treasury
Department of Transportation
Department of Veterans Affairs
Environmental Protection Agency
Institute of Museum and Library Services
National Aeronautical and Space Administration
National Archives and Records Administration
National Endowment for the Arts
National Endowment for the Humanities
National Science Foundation
Small Business Administration
Social Security Administration
U.S. Agency for International Development

From its inception in 2003, Grants.gov has transformed the federal grants environment by streamlining and standardizing public-facing grant processes, thus facilitating an easier application submission process for our applicants. The Grants.gov Program Management Office (PMO) works with agencies on system adoption, utilization, and customer satisfaction.

RISK MANAGEMENT OVERVIEW: Risks are categorized and prioritized to facilitate and focus risk management activities. Risk categories are aligned with OMB risk management guidance, ensuring comprehensive consideration of possible risks and simplifying program reporting. Risk prioritization is based on the probability of occurrence and potential impact, and focuses project resources where they are most needed.
All risks are tracked in the Grants.gov Risk Management Database, from identification through resolution. This online database is accessible to all Grants.gov team members and is updated regularly, in keeping with a continuous risk management process. Although physically separate, the Risk Management Database is considered an integral part of the Grants.gov Risk Management Plan.

Risks are categorized to facilitate analysis and reporting. The Grants.gov risk categories are aligned with Office of Management and Budget (OMB) guidance on risk assessment and mitigation. The risk category describes potentially affected areas of the program, and helps put individual risks into context when assessing their severity. The categories are also used to drive risk identification: the lack of identified risks in a given category may indicate overlooked risks. The following risks have been identified to OMB:

Risk 1: The global financial crisis (2008-present) has dramatically reduced federal revenues and increased the federal deficit. Widespread calls to reduce federal spending could result in decreased funding for Grants.gov. The Grants.gov PMO operations, funded entirely by agency contributions, include salaries and expenses for full-time staff, and support contracts for system integration, hardware platforms, upgrades, software licenses, Independent Verification and Validation, outreach and liaison, contact center, performance metrics monitoring, and office support. If the PMO does not receive sufficient funding, or if the agency contributions are not provided in a timely manner, the PMO would have to limit or stop providing the services it offers to its stakeholders.

Risk mitigation response: Grants.gov risk mitigation is a multifaceted approach that includes internal actions as well as external entities. Internally, the PMO times the majority of its contract actions toward the 3rd and 4th quarter of the fiscal year, to accommodate the speed of incoming contributions. Additionally, if sufficient funding is not available, the PMO can reduce the scope of its contracts, reprioritize contract awards, and/or postpone awarding of contracts. All contract actions and award decisions are made in the context of ensuring full, reliable functionality of the Grants.gov system. The PMO closely monitors contract expenditures and PMO activities such as training and travel expenditures to ensure the available budget will cover the actual expense. By the end of the 1st quarter, the PMO develops and sends documentation to each funding agency to initiate funding transfers and then reports (monthly) the status of agency contributions to the Financial Assistance Committee for E-Government (FACE), and OMB.

Risk 2: A fundamental concept of electronic commerce is the standardization of a common set of terms to be used by trading partners during business communications. Grants.gov requires common data processes in order to function. The inability to define common data and processes could impede program goals.

Risk mitigation response: The Grants.gov system was developed in accordance with the electronic standards for core grants data, Transaction Set 194, which were developed by the Inter-Agency Electronic Grants Committee (IAEGC). The Grants.gov PMO worked with the PL 106-107 workgroup and IAEGC to build consensus, and continues to work to minimize the required changes to agency and applicant processes. Agencies are being encouraged to simplify their forms and if possible develop a common set of forms and data definitions. To meet that goal, Grants.gov is consolidating already existing forms and working with Agencies for adoption to avoid duplicate forms used across the agencies. Grants.gov is also working to ensure compliance with DATA Act, Federal Integrated Business Framework (FIBF) Grants Management Standards, and the GREAT Act and Uniform Guidance requirements as they are finalized.

FUNDING: The total development cost of the Grants.gov initiative by fiscal year -- including costs to date, estimated costs to complete development to full operational capability, and estimated annual operations and maintenance costs -- are included in the table below. Also, included are the sources and distribution of funding by agency, showing contributions to date, and estimated future contributions through FY 2021.

GRANTS.GOV

FY 2019 to FY 2021 Agency Contributions

Agency Contributions	Total FY 2019	Total FY 2020	Total FY 2021
CNCS	31,320	26,000	25,000
DHS	202,102	289,000	290,000
DOC	342,232	366,000	377,000
DOD	755,095	621,000	670,000
DOE	410,979	418,000	423,000
DOI	1,933,644	1,339,000	1,370,000
DOL	152,190	93,000	92,000
DOS	451,018	444,000	482,000
DOT	216,587	294,000	301,000
ED	321,448	423,000	436,000
EPA	275,652	331,000	335,000
HHS	6,315,818	7,036,000	7,156,000
HUD	201,977	277,000	275,000
IMLS	96,506	63,000	66,000
NARA	38,792	28,000	28,000
NASA	103,383	74,000	73,000
NEA	324,578	198,000	205,000
NEH	256,841	163,000	167,000
NSF	233,849	325,000	323,000
SBA	63,924	46,000	47,000
SSA	25,895	21,000	21,000
USAID	139,162	284,000	279,000
USDA	473,087	484,000	496,000
USDOJ	458,850	473,000	457,000
USDOT	91,396	57,000	58,000
VA	118,826	143,000	150,000
Grand Total	**14,035,151**	**14,316,000**	**14,602,000**

CENTRALLY MANAGED PROJECTS

The GDM Staff Divisions are responsible for administering certain centrally managed projects on behalf of all Operating Divisions in the Department. Authority for carrying out these efforts is authorized by either specific statute or general transfer authority (such as the Economy Act, 31 USC 1535). The costs for centrally managed projects are allocated among the Operating Divisions in proportion to the estimated benefit to be derived.

Project	Description	FY 2020 Funding
The Digital Accountability and Transparency Act	DATA Act operations and maintenance services, an allocation by financial system, determined to be the most reflective of the law, and the area of greatest impact to HHS business operations.	$707,805
Bilateral and Multilateral International Health Activities	Office of Global Affairs activities leading the U.S. government's participation in policy debates at multilateral organizations on health, science, social welfare policies, advancing HHS's global strategies and partnerships, support of coordination of global health policy, and setting priorities for international engagements across USG agencies.	$7,411,842
Department-wide CFO Audit of Financial Statements	HHS financial statements annual audit (as required by the CFO Act of 1990), and stand-alone audit of the CMS producing Department-wide financial statements, and coordinating the HHS audit process (i.e.: FISMA).	$17,157,628
HHS Biosafety and Biosecurity Coordinating Council	HHS efforts to confront threats posed by the accidental or deliberate release of high-consequence biological agents/toxins, and aligns with the principles articulated in the *National Health Security Strategy;* the *National Strategy for Countering Biological Threats,* and EO 13546 *(Optimizing the Security of Select Agents and Toxins*).	$331,112
Intradepartmental Council on Native American Affairs	HHS-wide tribal consultation, gathering information towards developing policies affecting the Native American communities served by the department. Coordination of activities throughout HHS and works to improve coordination, outreach, and communication on American Indian/Alaska Native, Tribal Government, Native Hawaiian, and other Pacific Islander issues at HHS.	$201,820
National Clinical Care Commission	The Commission evaluates and makes recommendations on coordination and leveraging programs within HHS and Federal agencies focusing on preventing and reducing the incidence of diabetes and other autoimmune diseases relating to insulin and other disease complications. Authorized is provided by the National Clinical Care Commission Act (Public Law 115-80).	$720,000
National Science Advisory Board for Bio-Security (NSABB)	NSABB provides guidance and recommendations to researchers; develops strategies for enhancing interdisciplinary bio-security and outreach; engages journal editors on policy review and international engagement; and develops Federal policy for life sciences research oversight at the local level.	$2,472,000
NIH Negotiation of Indirect Cost Rates	NIH expanded its capacity to negotiate on behalf of all HHS OPDIVs, indirect cost rates with commercial (for-profit) organizations receiving HHS contract and grant awards, to ensure indirect costs are reasonable, allowable, and allocable.	$1,425,957
Office of Business Management and Transformation	ReImagine HHS coordinates innovation across HHS to identify targets, leverage existing authorities, and contract support addressing new requirements established through the President's Executive Order on Reorganizing the Federal Government and OMB Memoranda 17-22(M-17-22) released in April 2017; funds contribute to HHS goal of improving operations and performance while reducing duplication and unnecessary costs.	$3,203,382

President's Advisory Council on Combating Antibiotic-Resistant Bacteria	**EO 13676 directs the Secretary of Health and Human Services to establish the Advisory Council in consultation with the Secretaries of Defense and Agriculture. The Council provides advice on programs and policies to preserve the effectiveness of antibiotics, to strengthen surveillance of antibiotic-resistant bacterial infections, and the dissemination of up-to-date information on the appropriate and proper use of antibiotics to the public, human, and animal healthcare providers.**	**$1,125,000**
ReInvent Grants Management	ReInvent Grants Management Initiative will create a single user experience through improved grants management administration and enhance grants performance measurement, resulting in an environment that is more transparent and less duplicative for internal and external stakeholders. This will allow HHS to be more efficient and optimize resource usage.	$589,156
Regional Health Administrators (RHAs)	The RHAs provide senior-level leadership in health, bringing together the Department's investments in public health and prevention by providing a health infrastructure across the ten HHS regions. Particularly in the areas of prevention, preparedness, coordination and collaboration, the RHA's represent the Secretary, Assistant Secretary for Health and Surgeon General in the Regions, and are key players in managing ongoing public health challenges.	$2,772,090
Secretary's Advisory Committee on Blood and Tissue Safety and Availability	Committee advises the Secretary on a broad range of public health, ethical and legal issues related to blood transfusion and transplantation safety. Activities ensure HHS coordination of transfusion and transplantation safety and availability, for relevant U.S. Public Health Service (PHS) agencies to prevent adverse events that occur during the donation and transfusion/ transplantation processes.	$1,500,000
Tick-Borne Disease Working Group	Congress established the Tick-Borne Disease Working Group in December 2016 as part of the 21st Century Cures Act. The Office of the Assistant Secretary for Health (OASH) convenes, coordinates, and supports the Tick-Borne Federal Advisory Committee for ongoing tick-borne research, programs, and policies, including those related to causes, prevention, treatment, surveillance, diagnosis, diagnostics, duration of illness, and intervention of individuals with tick-borne diseases.	$600,000
Interdepartmental Substance Use Disorders Coordinating Committee	The Committee will identify areas for improved coordination related to substance abuse, including research, services, and support and prevention activities across all relevant Federal agencies. Funds support critical activities to ensure that policy making related to Substance Use Disorders is coordinated, informed, and promulgated by internal and external experts who can provide an effective and robust responses to this epidemic. The Substance Use-Disorder Prevention that Promotes Opioid recovery and Treatment for Patients and Communities Act (SUPPORT Act, PL 115-271) establish the Committee.	$1,228,438
Secretary's Tribal Advisory Committee (STAC)	The STAC develops a coordinated, HHS-wide strategy for incorporating Tribal recommendations on HHS priorities, policies, and budgets, improving the Government-to-Government relationship, and ensuring that mechanisms to improve services to Indian tribes are in place. The STAC's primary purpose is to seek consensus, exchange views, share information, provide advice and/or recommendations, or facilitate any other interaction related to intergovernmental responsibilities or administration of HHS programs.	$301,000

DIGITAL MODERNIZATION

Modernization of the Public-Facing Digital Services – 21st Century Integrated Digital Experience Act
On Dec. 20, 2018, President Trump signed the 21st Century Integrated Digital Experience Act (IDEA), which requires data-driven, user-centric website and digital services modernization, website consolidation, and website design consistency in all Executive Agencies. Departments across the federal landscape are beginning to implement innovative digital communications approaches to increase efficiency and create more effective relationships with their intended audiences. The American public expects instant and impactful communications – desired, trusted content available when they want it, where they want it, and in the format they want it. If the consumer is not satisfied they move on and our opportunity for impact is lost.

Modernization Efforts
In FY 2019 HHS engaged Department leadership and developed a Digital Communications Strategy that aligns with the requirements of IDEA. As the result of a comprehensive review of costs associated with website development, maintenance, and their measures of effectiveness, HHS will prioritize:

- modernization needs of websites, including providing unique digital communications services, and
- develop estimated costs for achieving performance metrics.

Over the next five years HHS will continue to implement IDEA by focusing extensively on a user-centric, Digital First approach to both external and internal communications and developing performance standards. HHS will focus on training, hiring, and tools that drive the communication culture change necessary to successfully implement IDEA.

Over the next year, HHS Agencies and Offices will work together to continue to implement IDEA and the HHS Digital Communications Strategy across all communications products and platforms.

SIGNIFICANT ITEMS

FY 2020 Joint Explanatory Statement P.L. 116-94

Antibiotic Development
The agreement encourages HHS to be closely involved with the update of the National Action Plan for Combating Antibiotic Resistant Bacteria. HHS shall include in the fiscal year 2021 Congressional Justification a detailed update on progress implementing such plan. National Action Plan for Combating Antibiotic Resistant Bacteria.

Action taken or to be taken

HHS is currently implementing activities under the fifth and final year of the original National Action Plan for Combating Antibiotic-Resistant Bacteria (CARB), which covered 2015 to 2020. Highlights of progress include increasing antibiotic stewardship programs from 39% of hospitals in 2014 to 76% in 2017, launch of FDA's new five-year plan for Supporting Antimicrobial Stewardship in Veterinary Settings, and approval of three new BARDA-supported antimicrobial products. HHS is also leading the development of the next CARB Plan, covering 2020-2025. These efforts include developing guidance, criteria, and a timeline for the plan development, leading an in-depth review and assessment of progress and challenges experienced while implementing the first CARB Plan, and coordinating inter-agency collaboration on the development of new objectives and measures. HHS also facilitated public stakeholder engagement in the development of the new CARB Plan via the Presidential Advisory Council on Combating Antibiotic Resistant Bacteria. HHS anticipates that the new CARB Plan will be published in Spring 2020.

FY 2020 Joint Explanatory Statement (pages 88-89)

P.L. 116-94

Surgeon General's Report on Oral Health

The Committee appreciates NIDCR's contributions to the Surgeon General's 2020 Report on Oral Health and looks forward to the much-needed update of the seminal Oral Health in America report from 2000.

Action taken or to be taken

The Office of the Surgeon General under the Office of the Assistant Secretary for Health will issue the 2020 Surgeon General's Report on Oral Health in December 2020. With hundreds of contributors representing academia, organized dentistry, federal agencies, state oral health programs, and other key stakeholder groups, this report will show progress made since 2000 in oral health, challenges that still persist in achieving oral health, and key actions to improve the oral health of the country over the next few decades. It will describe oral health across the

lifespan, including children, adolescents, adults, and older adults; the integration of oral health and primary care and workforce issues; the relationships between oral health and substance abuse disorders, the opioid epidemic, high-risk behaviors, and mental health; the effect of oral health on the community, overall well-being, and the economy; and emerging technologies and promising science that will transform oral health in the future.

FY 2020 Joint Explanatory Statement (page 121)

P.L. 116-94

Regulation Reform

Regulation reform— The agreement directs the Secretary to include in the fiscal year 2021 Congressional Justification any plan to repeal guidance documents or any plans to repeal or revise regulations that the Department believes are duplicative.

Action taken or to be taken

HHS is committed to streamlining the regulatory process and evaluating necessary steps to eliminate or change regulations that impose unnecessary burden. Burdensome regulations can drive up costs of healthcare, while poorly designed regulations can come between doctors and patients, reducing the quality of care and the essential trust to that relationship. From FY 2017 to FY 2019, HHS succeeded in cutting the economic burden of its regulations by $25.7 billion through 46 deregulatory actions. HHS had the largest deregulatory impact of any Cabinet agency during this time period.

HHS is using the power of new cognitive technologies for greater operational effectiveness and research insights, including regulatory reduction. HHS used an Artificial Intelligence-driven regulation analysis tool and expert insight to analyze the Code of Federal Regulations, seeking potential opportunities to modernize regulations. HHS since launched a Department-wide Regulatory Clean-Up Initiative to implement changes based on these findings, by reviewing and – where a change is warranted – addressing incorrect citations and eliminating the submission of triplicate or quadruplicate of the same citation.

HHS is working to implement the provisions of the Executive Order on *Promoting the Rule of Law through Improved Agency Guidance Documents*. This Executive Order will accomplish important policy goals that will improve HHS guidance practices in the long term. Prior to the issuance of this Executive Order, several federal agencies issued internal memoranda regarding the appropriate use of guidance. The Executive Order requires agencies to now go a step further and codify certain good guidance practices and policies into federal regulations. By August 27, 2020, each agency must finalize regulations to set forth processes and procedures for issuing guidance documents. In addition, by February 28, 2020, federal agencies must establish a single, searchable database on its website that contains, or links to, all of the agency's guidance documents currently in effect. Any guidance document not included in the guidance website is deemed rescinded. HHS is committed to meeting the President's timelines.

House Report (page 161)
P.L. 116-94

Advertising Contracts

The Committee understands that, as the largest advertiser in the United States, the federal government should work to ensure fair access to its advertising contracts for small disadvantaged businesses and businesses owned by minorities and women. The Committee directs the Department to include the following information in its fiscal year 2021 budget justification: Expenditures for fiscal year 2019 and expected expenditures for fiscal years 2020 and 2021, respectively, for (1) all contracts for advertising services; and (2) contracts for the advertising services of (I) socially and economically disadvantaged small business concerns (as defined in section 8(a)(4) of the Small Business Act (15 U.S.C. 637(a)(4)); and (II) women- and minority-owned businesses.

Action taken or to be taken

In fiscal year 2019, the Department of Health and Human Services executed 513 contract actions for advertising services totaling $296.94 million. Awards to women owned and small disadvantaged businesses totaled $8.94 million and $77,407 respectively. The expected fiscal years 2020 and 2021 HHS expenditures for advertising services is $9.7 million and $5.9 million respectively. Additionally, expenditures to women owned and small disadvantaged businesses are expected to reach $3 million and $77,000 respectively in fiscal years 2020 and 2021.

Department of Health and Human Services

FY 2019 Good Accounting Obligation in Government Act Report

February 10, 2020

Executive Summary

The Good Accounting Obligation in Government Act (GAO-IG Act; Public Law 115-414) requires each agency to include, in its annual budget justification, a report that identifies each public recommendation issued by the Government Accountability Office (GAO) and federal Offices of Inspectors General (OIG), which has remained unimplemented for one year or more from the annual budget justification submission date. In compliance with this act, the Department of Health and Human Services (HHS) has developed a report listing each public recommendation from GAO and HHS OIG. As of September 30, 2019, HHS recognizes a combined total of 927 public recommendations that were open for more than one year. Additionally, this report identifies the 201 closed, unimplemented recommendations that HHS non-concurred with or did not implement due to legislative or budgetary constraints.

Background

Congress enacted the GAO-IG Act to enhance transparency into open and unimplemented public recommendations issued by GAO and the agency's OIG. In addition to reporting on unimplemented public recommendations over a year old, the Act requires a reconciliation between the agency records and the OIG's Semiannual Report to Congress (SAR report).

For recommendations with which HHS concurred, this report provides timelines for full implementation of the planned corrective actions, as well as updates and constraints for the recommendations, in Appendix 1. These are considered to be "In Progress." For recommendations that HHS believes have been implemented, but the auditor lists as open, this report indicates their status as "Awaiting disposition" as these recommendations are pending auditor validation and close out. For recommendations HHS non-concurred with or did not implement due to legislative or budgetary constraints, Appendix 2 identifies the reasons for the "Closed, unimplemented" status.

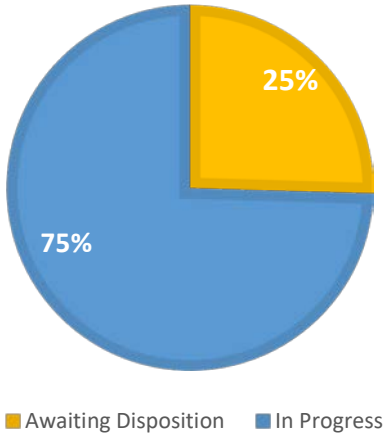
HHS has a combined total of 927 recommendations open for more than one year. Of these, 296 were issued by the GAO during the period July 12, 2002 through September 30, 2018. The remaining 631 were issued by the HHS OIG during the period September 11, 2001 through September 30, 2018. The GAO online database reflects 293 open recommendations; this variance in recommendation totals reported by HHS and GAO is the result of closures between September 30, 2019 and publication of this report. The HHS OIG SAR lists 764 open recommendations. The discrepancy of 135 such recommendations is explained by several duplicative recommendations to multiple HHS Operating and Staff Divisions (OpDivs and StaffDivs) that HHS combined as this report is a collaborative effort, as well as recommendations assigned to the Centers for Medicare & Medicaid Services (CMS) and the Administration for Children and Families (ACF) that are actually specific State or grantee responsibilities. Table 1 summarizes this information.

Table 1: Open Recommendation Reconciliation Data

Recommendations	OIG/GAO Total	Adjustment	HHS Total
GAO	293	3	**296**
OIG	764	-133	**631**
Total Open Recommendations	1,057	-130	**927**

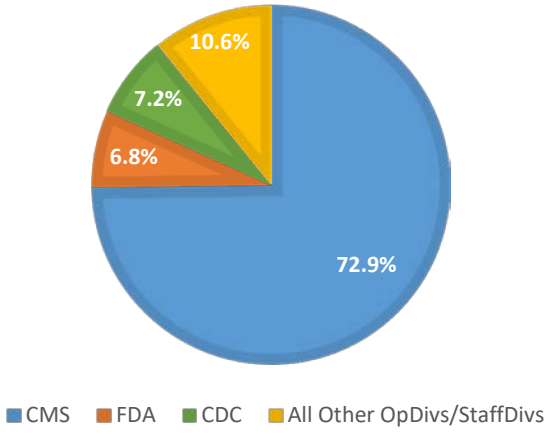
The Department has made a good faith effort to implement these recommendations and in many cases HHS believes the required action has been completed and the auditors should close the recommendation. Of the 927 open recommendations, HHS classified 236 as "Awaiting disposition," which represents 25 percent of all recommendations. Of these, 95 were issued by the GAO and 141 by the HHS OIG. After the auditors review HHS information and updates, many of these recommendations can be closed and removed from future reports. The remaining 75 percent of recommendations are in progress as shown in Figure 1.

Figure 1: Implementation Status of All GAO and OIG Public Recommendations



In accordance with OMB Circular A-50, HHS is committed to preparing prompt, responsive, constructive corrective actions in response to OIG and GAO audit report findings and recommendations. HHS considers audit recommendation follow-up to be an integral part of good management. Due to the potential improvements in operations, efficiency, and effectiveness as a result of implementing GAO and OIG recommendations, there has been increased effort dedicated to closing recommendations at several OpDivs and StaffDivs. Figure 2, below, identifies the percentage of GAO and OIG public recommendations that are awaiting disposition with the GAO or the HHS OIG.

Figure 2: Percent of GAO/OIG Public Recommendations Awaiting Disposition Presented by OpDiv/StaffDiv



GAO and OIG also identify top issues and recommendations (known as Priority Recommendations or Top Unimplemented Challenges) that they believe could help to significantly improve HHS's program operations. In Appendix 1, HHS also identified 110 GAO Priority Recommendations or OIG Top Unimplemented Challenges among the open recommendations; of those 110 recommendations, 16 are awaiting disposition and the remaining 93 percent are in progress.

Reporting Methodology and Report Structure

As required by the GAO–IG Act, this report includes GAO and OIG recommendations open at least one year as of September 30, 2019.[1] The details include the implementation status of each public recommendation, a timeline for full implementation, and any updates and/or constraints. For several recommendations, the Department believes it has completed final action and is awaiting GAO or OIG concurrence and closure of the recommendations. The report has been broken out by each Operating Division and Staff Division in their individual Congressional Justification (CJ).

[1] Disclaimer: The current reporting methodology and structure are subject to change in future years if OMB issues further guidance on how agencies shall implement the GAO-IG Act.

GOOD ACCOUNTING OBLIGATION IN GOVERNMENT ACT (GAO-IG ACT) REPORT

The information below addresses the requirements of the Good Accounting Obligation in Government Act (GAO-IG Act; Public Law 115-414) to provide a report identifying each public recommendation issued by the Government Accountability Office (GAO) and federal Offices of Inspectors General (OIG) which remains unimplemented for one year or more from the annual budget justification submission date. The recommendations below apply specifically to this division of HHS. Please refer to the General Departmental Management budget justification for more information on the Department's overall progress in implementing GAO and OIG recommendations.

ASA

Appendix 1: OIG-GAO Open Recommendations							
Report Number	**Report Title**	**Report Date**	**Recommendation Text**	**Concur / Non-Concur**	**Implementation Timeline**	**Implementation Status**	**Implementation Updates and Constraints**
GAO-16-128	Federal Research Opportunities: DOE, DOD, and HHS Need Better Guidance for Participant Activities	1/20/2016	The Secretaries of Energy, Defense, and Health and Human Services should develop detailed guidance to ensure that ORISE program coordinators, mentors, and research participants are fully informed of the prohibition on nonfederal employees performing inherently governmental functions	Concur	2021	In Progress	
GAO-16-548	Federal Workforce: Opportunities Exist to Improve Data on Selected Groups of Special Government Employees	8/15/2016	To help ensure HHS has reliable data on SGEs not serving on federal boards, the Secretary of HHS should take steps to improve the reliability of data on SGEs not serving on boards. For example, the agency could reconcile human capital data with general counsel and ethics office data, or issue clarifying guidance to human capital staff on appropriately identifying SGEs in human capital databases.	Concur	2021	In Progress	

Appendix 1: OIG-GAO Open Recommendations							
Report Number	**Report Title**	**Report Date**	**Recommendation Text**	**Concur / Non-Concur**	**Implementation Timeline**	**Implementation Status**	**Implementation Updates and Constraints**
GAO-14-84	Minority AIDS Initiative: Consolidation of Fragmented HIV/AIDS Funding Could Reduce Administrative Challenges	11/22/2013	In order to reduce the administrative costs associated with a fragmented MAI grant structure that diminishes the effective use of HHS's limited HIV/AIDS funding, and to enhance services to minority populations, HHS should consolidate disparate MAI funding streams into core HIV/AIDS funding during its budget request and allocation process.	Non-Concur	NA	Awaiting Disposition	OASH greatly appreciates GAO's input and recommendations. Over the last two fiscal years, OASH has worked to ensure that the Minority HIV/AIDS Fund (MHAF) functions to reduce new HIV infections, improve HIV-related health outcomes, and to reduce HIV-related health disparities for racial and ethnic minority communities by supporting innovation, collaboration, and the integration of best practices, effective strategies, and promising emerging models in the response to HIV among minority communities. In addition, the MHAF is focused on transforming HIV prevention, care, and treatment for communities of color by bringing federal, state, and community organizations together to design and pilot innovative solutions that address critical emerging needs and work to improve the efficiency, effectiveness, and impact of federal investments in HIV programs, activities, and services for racial and ethnic minorities. In February 2019, HHS released Ending the HIV Epidemic (EHE): A Plan for America to address the hardest hit communities with the additional expertise, technology, and resources required to address the HIV epidemic in their communities. Phase 1 of the Ending the HIV Epidemic Plan focuses on the areas of the nation that comprised more than 50% of the new HIV diagnoses in 2016 and 2017, plus the seven states with rural areas that carry a disproportionately high burden of HIV. Through

							the use of the MHAF in service to the initiative, OASH is committed to providing leadership, management, oversight and support for, and collaboration and coordination among HHS agencies, operating divisions, and external stakeholders.
GAO-14-84	Minority AIDS Initiative: Consolidation of Fragmented HIV/AIDS Funding Could Reduce Administrative Challenges	11/22/2013	In order to reduce the administrative costs associated with a fragmented MAI grant structure that diminishes the effective use of HHS's limited HIV/AIDS funding, and to enhance services to minority populations, HHS should seek legislation to amend the Ryan White Comprehensive AIDS Resources Emergency Act of	Non-Concur	NA	Awaiting Disposition	OASH greatly appreciates GAO's input and recommendations. Over the last two fiscal years, OASH has worked to ensure that the Minority HIV/AIDS Fund (MHAF) functions to reduce new HIV infections, improve HIV-related health outcomes, and to reduce HIV-related health disparities for racial and ethnic minority communities by supporting innovation, collaboration, and the integration of best practices, effective strategies, and promising emerging models in the response to HIV among minority communities. In addition, the MHAF is focused on transforming HIV prevention, care, and treatment for communities of color by bringing federal, state, and community organizations together to design and pilot innovative solutions that address critical emerging needs and work to improve the efficiency, effectiveness, and impact of federal investments in HIV programs, activities, and services for racial and ethnic minorities. In February 2019, HHS released Ending the HIV

			1990 or other provisions of law, as necessary, to achieve a consolidated approach.				Epidemic (EHE): A Plan for America to address the hardest hit communities with the additional expertise, technology, and resources required to address the HIV epidemic in their communities. Phase 1 of the Ending the HIV Epidemic Plan focuses on the areas of the nation that comprised more than 50% of the new HIV diagnoses in 2016 and 2017, plus the seven states with rural areas that carry a disproportionately high burden of HIV. Through the use of the MHAF in service to the initiative, OASH is committed to providing leadership, management, oversight and support for, and collaboration and coordination among HHS agencies, operating divisions, and external stakeholders.
GAO-15-590	Federal Supply Schedules: More Attention Needed to Competition and Prices	8/10/2015	To help foster competition for FSS orders consistent with the FAR, the Secretary of HHS should assess reasons that may be contributing to the high percentage of orders with one or two quotes--including the practice of narrowing the pool of potential vendors--and if necessary, depending on the results of the assessment,	Concur	NA	In Progress	To address the finding in GAO Report 15-590 to assess reasons that may be contributing to the high percentage of orders with one or two quotes, and to ensure that appropriate procedures for competing and awarding Federal Supply Schedule (FSS) orders are currently being practiced, the Senior Procurement Executive guidance issued in December 2017 to the OPDIV acquisition staff on the appropriate procedures. Additionally the HHS OPDIVs have been tasked to conduct an assessment of their FY 2017 and FY 2018 FSS awards. These assessments are to identify any gaps in procedure regarding competition that have not been resolved. These assessments are due by 30 Nov 2019 for analysis.

			provide guidance to help ensure contracting officials are taking reasonable steps to obtain three or more quotes above the simplified acquisition threshold.				
GAO-17-159	Single Audit: Improvements Needed in Selected Agencies' Oversight of Federal Awards	2/16/2017	The Secretary of Health and Human Services should direct the Assistant Secretary for Financial Resources to revise policies and procedures to reasonably assure that management decisions contain the required elements and are issued timely in accordance with OMB guidance.	Concur	2019	Awaiting Disposition	HHS has made the requested changes in their policies and procedures and has requested closure of this recommendation.
GAO-17-159	Single Audit: Improvements Needed in Selected Agencies' Oversight of	2/16/2017	The Secretary of Health and Human Services should direct the Assistant Secretary for	Concur	2019	Awaiting Disposition	HHS has incorporated a risk based approach in their policies and procedures and has requested closure of this recommendation.

	Federal Awards		Financial Resources to design and implement policies and procedures for identifying and managing high-risk and recurring single audit findings using a risk-based approach.				
GAO-17-159	Single Audit: Improvements Needed in Selected Agencies' Oversight of Federal Awards	2/16/2017	The Secretary of Health and Human Services should direct the Administrator of the Centers for Medicare and Medicaid Services to design and implement policies and procedures for identifying and managing high-risk and recurring single audit findings using a risk-based approach.	Concur	2019	Awaiting Disposition	HHS has incorporated a risk based approach in their policies and procedures and has requested closure of this recommendation.

GAO-17-398	Service Contracts: Agencies Should Take Steps to More Effectively Use Independent Government Cost Estimates	5/17/2017	To ensure that IGCEs contain key information consistent with good cost estimating practices, the Secretaries of Education, Health and Human Services, Housing and Urban Development, and Labor should revise or clarify guidance to require that IGCEs document data sources, methodology, and assumptions, and take steps to help ensure that guidance is followed by, for example, providing training or issuing reminders to officials to include this information when developing IGCEs.	Concur	NA	In Progress	ASFR is actively working to address this recommendation.

GAO-17-398	Service Contracts: Agencies Should Take Steps to More Effectively Use Independent Government Cost Estimates	5/17/2017	To ensure that IGCEs are optimized as a tool in the procurement planning process, the Secretaries of Defense, Education, Health and Human Services, Homeland Security, Housing and Urban Development, and Labor should take steps to ensure that, when appropriate, contracting staff document differences between IGCE and final contract award value in the contract file.	Concur	NA	In Progress	ASFR is actively working to address this recommendation.
GAO-17-738	Federal Contracting: Additional Management Attention and Action Needed to Close Contracts and Reduce Audit Backlog	9/28/2017	To enhance management attention to closing out contracts, the Secretary of Health and Human Services should develop a means for department-wide	Concur	NA	In Progress	HHS has developed a reporting format and instruction for quarterly reporting from the OPDIVs. The metrics monitored are contracts completed, contracts closed in a timely manner, contracts not closed timely, and total backlog for each quarter.

			oversight into components' progress in meeting their goals on closing contracts and the status of contracts eligible for closeout.				
GAO-18-323	Railroad Retirement Board: Additional Controls and Oversight of Financial Interchange Transfers Needed	5/21/2018	The Secretary of HHS should, consistent with its existing statutory authority, take additional steps to provide oversight of financial interchange calculations at the individual-case level. If the Secretary concludes that there are limitations in its authority in this area, the Secretary should seek to obtain the necessary additional authority.	Non-Concur	NA	Awaiting Disposition	HHS has determined that the Secretary does not have the necessary statutory authority and the Office of the General Counsel has asked that CMS stop action related to this recommendation.

GAO-18-491	Grants Workforce: Actions Needed to Ensure Staff Have Skills to Administer and Oversee Federal Grants	9/20/2018	The Secretary of HHS should establish a process to monitor and evaluate HHS's grants training at the central office level. This process should include (1) a method for identifying all employees working on grants across the agency, and (2) oversight procedures to evaluate the sufficiency of sub-agencies' grants training efforts including the incorporation of leading practices related to assessing competencies, training approaches, accountability, and training results.	Concur	2020	In Progress	Currently, efforts are underway through the ReInvent Grants Management (RGM) Initiative, part of ReImagine HHS, to develop and implement a department-wide financial assistance training and certification program to improve the functional effectiveness of the financial assistance management workforce in the areas of internal controls and risk mitigation. HHS met with GAO after the report was issued and provided an outline letting them know this was a long-term project Since then, HHS provided GAO with quarterly updates. As the RGM initiative comes to a close at the end of FY2020, HHS is working to transition grants workforce efforts to Departmental owners. Specifically, HHS is reviewing the funding implications of moving this activity to the Office of Grants within ASFR.

OEI-03-14-00230	Federal Marketplace: Inadequacies in Contract Planning and Procurement	1/20/2015	HHS should revise its guidance to include specific standards for conducting past performance reviews of companies under consideration during contract procurement	Concur	2020	In Progress	ASFR is actively working to address this recommendation.
OEI-04-11-00530	Vulnerabilities in the HHS Small Business Innovation Research Program	4/22/2014	Ensure compliance with SBIR eligibility requirements	Concur	2019	Awaiting Disposition	ASFR has met all required eligibility checks and has created processes to continue to do so. ASFR has requested closure of this recommendation.
OEI-04-11-00530	Vulnerabilities in the HHS Small Business Innovation Research Program	4/22/2014	Improve procedures to check for duplicative awards	Concur	2019	Awaiting Disposition	ASFR has developed robust procedures to prevent duplicative awards. ASFR has requested closure of this recommendation.
GAO-16-366	Medicare Fee-For-Service: Opportunities Remain to Improve Appeal Process	6/9/2016	To reduce the number of Medicare appeals and to strengthen oversight of the Medicare FFS appeals process, the Secretary of Health and Human Services should direct CMS, OMHA, or DAB to modify the various Medicare appeals	Concur	NA	In Progress	The DAB continues to explore the feasibility of tracking allowed amounts at Level 4. However, one constraint for the DAB is access to this type of data; this data must be provided to the DAB by prior levels or included in the record on appeal. In the meantime, DAB has started recording and tracking billed amounts in MODACTS, based on the information that is available in the record for each appeal.

			data systems to capture the amount, or an estimate, of Medicare allowed charges at stake in appeals in Medicare Appeals System (MAS) and Medicare Operations Division Automated Case Tracking System (MODACTS).				

GAO-16-366	Medicare Fee-For-Service: Opportunities Remain to Improve Appeal Process	6/9/2016	To reduce the number of Medicare appeals and to strengthen oversight of the Medicare FFS appeals process, the Secretary of Health and Human Services should direct CMS, OMHA, or DAB to modify the various Medicare appeals data systems to collect consistent data across systems, including appeal categories and appeal decisions across MAS and MODACTS	Concur	2018	Awaiting Disposition	CMS recommends closure on both recommendation 3 & 4 based on the following: MAS CR 747 was released in November 2016 and included revised Level 3 Appeal Categories. This functionality allows for consistent appeal categories at case closure when ECAPE transmits closed Level 3 appeals back to the appeals system of records, MAS. As of the end of April 2017, all Part A MACs were successfully onboarded to MAS. Since CMS' last reporting date, all MACs had passed their transition period and had attested to readiness in MAS and their desire to continue processing within the MAS environment and not roll back to their previous legacy systems. CMS continues efforts to seek funding for onboarding the remaining MACs (Part B and DME) onto MAS. Recently, CMS received FY18 funding for a pilot to partially onboard 1 Part B and 1 DME MAC to MAS for data collection, reporting, and case file transfers only. With this approach, MACs would continue to be able to innovate and experience in-house developed operational efficiencies using their internal workflow and correspondence systems, while also allowing CMS to explore enhanced monitoring of MAC Part B and DME workload. This solution will control MAC operational costs by incrementally allowing for seamless integration into their current workflow and not negatively impact current MAC operating budgets. Web services would assist MACs with updating MAS with data from their internal systems. To account for the complexity of incorporating this new type of workload in MAS, this pilot would allow all MAC jurisdictions to assist in the development of business requirements. In addition, as of the most recent MAS release in May 2018, CMS

							implemented CR 752 and the functionality to allow MAC users visibility into appeals histories at Levels 1, 2, and 3, associated to their organization's contract. This will greatly assist in data reporting consistency and allows MACs the ability to report on cases promoted to Level 3 that may not have been processed within MAS by their organization, but rather through a legacy system or the previous MAC jurisdiction contract holder that was uploaded to MAS by a Level 2 QIC contractor." The DAB continues to work towards developing system interoperability with OMHA's ECAPE system, which will help standardize and integrate data between Levels 3 and 4. Currently, the DAB is working with its IT contractor to developed APIs capable of importing and exporting data from ECAPE. In addition, the DAB actively participated in "IT Sprint," an interagency project led by the HHS Office of the Chief Technology Officer, which explored ways to integrate appeals data across all levels of review. Most recently, the project developed a prototype for a dashboard that would enable various stakeholders to obtain the status of individual or collective claims. The DAB has also established connectivity with CMS contractors for the electronic transfer and upload of claim files for appealed cases.

GAO-16-366	Medicare Fee-For-Service: Opportunities Remain to Improve Appeal Process	6/9/2016	To reduce the number of Medicare appeals and to strengthen oversight of the Medicare FFS appeals process, the Secretary of Health and Human Services should direct CMS, Office of Medicare Hearings and Appeals (OMHA), or Departmental Appeals Board (DAB) to modify the various Medicare appeals data systems to collect information on the reasons for appeal decisions at Level 3.	Concur	2020	Awaiting Disposition	OMHA recommends closure on this recommendation. In the July 2017 interim release of the Electronic Case Adjudication and Processing Environment (ECAPE) system, OMHA added a "Reason for Disposition" data field for most dispositions issued by an adjudicator. Because the "Reason for Disposition" data field limits the number of reasons that can be selected, OMHA added more categories in later releases. As of November 2019, ECAPE has been implemented in all of OMHA's field offices and its satellite office. Information on the reasons for Level 3 appeal decisions can currently be reported within ECAPE. DAB recently added new data fields and case categories to its case management system to capture more detail about pending cases, including the reasons for ALJ dismissals at level 3. In addition, DAB continues to work towards developing system interoperability with ECAPE. Once baseline interoperability is established, DAB will work with OMHA to explore the feasibility of incorporating level 3 "Reason for Disposition" data into its new system.

Appendix 2: OIG-GAO Closed, Unimplemented Recommendations

Report Number	Report Title	Report Date	Recommendation Text	Implementation Status	Reason for non-implementation
GAO-11-548R	Mentor-Protégé Programs Have Policies that Aim to Benefit Participants but Do Not Require Post agreement Tracking	6/15/2011	To more fully evaluate the effectiveness of their mentor-protégé programs, the OSDBU and Mentor-Protégé Program Directors of DHS, DOE, DOS, EPA, FAA, GSA, HHS, SBA, Treasury, and VA should consider collecting and maintaining protégé post completion information	Closed, Unimplemented	Non-concur, recommendation is no longer valid

OCIO

Appendix 1: OIG-GAO Open Recommendations							
Report Number	**Report Title**	**Report Date**	**Recommendation Text**	**Concur / Non-Concur**	**Implementation Timeline**	**Implementation Status**	**Implementation Updates and Constraints**
GAO-12-791	Organizational Transformation: Enterprise Architecture Value Needs to Be Measured and Reported	9/26/2012	To enhance federal agencies' ability to realize enterprise architecture benefits, the Secretaries of the Departments of Health and Human Services and Housing and Urban Development should ensure that enterprise architecture outcomes are periodically measured and reported to top agency officials.	Concur	NA	In Progress	OCIO is actively working to implement the recommendation.
GAO-15-431	Telecommunications: Agencies Need Better Controls to Achieve Significant Savings on Mobile Devices and Services	5/21/2015	To help the department effectively manage spending on mobile devices and services, the Secretary of Health and Human Services should ensure procedures to monitor and control spending are established department-wide. Specifically, ensure that (1) procedures include assessing devices for zero, under, and over usage; (2) personnel with authority and responsibility for performing the procedures are identified; and (3) the specific steps to be taken to perform the process are documented.	Concur	2020	In Progress	OCIO is actively working to implement the recommendation.
GAO-16-323	Data Center Consolidation: Agencies Making Progress, but Planned Savings Goals Need to Be Established	3/3/2016	The Secretaries of the Departments of Agriculture, Commerce, Defense, Education, Energy, Health and Human Services, Homeland Security, Housing and Urban Development, the Interior, Labor, State, Transportation, the Treasury, and Veterans Affairs; the Attorney General of the United States; the Administrators of the	Concur	2020	Awaiting Disposition	This recommendation was based on metrics from M-16-19 which is no longer in effect and has been replaced M-19-19. OCIO has

			Environmental Protection Agency, General Services Administration, National Aeronautics and Space Administration, and U.S. Agency for International Development; the Director of the Office of Personnel Management; the Chairman of the Nuclear Regulatory Commission; and the Commissioner of the Social Security Administration should take action to improve progress in the data center optimization areas that we reported as not meeting OMB's established targets, including addressing any identified challenges.				worked closely with OMB to define new metrics and therefore believes this recommendation should be closed.
GAO-16-325	Cloud Computing: Agencies Need to Incorporate Key Practices to Ensure Effective Performance	4/7/2016	To help ensure continued progress in the implementation of effective cloud computing SLAs, the Secretaries of Health and Human Services, Homeland Security, Treasury, and Veterans Affairs should direct appropriate officials to develop SLA guidance and ensure key practices are fully incorporated as the contract and associated SLAs expire.	Concur	NA	In Progress	OCIO is actively working to implement the recommendation.
GAO-16-468	Information Technology: Federal Agencies Need to Address Aging Legacy Systems	5/25/2016	The Secretary of Health and Human Services should direct the CIO to identify and plan to modernize or replace legacy systems as needed and consistent with OMB's draft guidance, including time frames, activities to be performed, and functions to be replaced or enhanced.	Concur	NA	Awaiting Disposition	OCIO is actively working to implement the recommendation.
GAO-16-469	Information Technology Reform: Agencies Need to Increase their use of Developmental Practices	9/15/2016	To improve the certification of adequate incremental development, the Secretaries of Defense, Education, Health and Human Services, and the Treasury should direct their CIOs to establish a department policy and	Concur	NA	In Progress	OCIO is actively working to implement the recommendation. We have submitted a draft

			process for the certification of major IT investments' adequate use of incremental development, in accordance with OMB's guidance on the implementation of the Federal Information Technology Acquisition Reform Act.				policy that GAO believes will satisfy the recommendation when it is approved in early 2020.
GAO-16-494	IT Dashboard: Agencies Need to Fully Consider Risks When Rating Their Major Investments	6/2/2016	To better ensure that the Dashboard ratings more accurately reflect risk, the Secretaries of the Departments of Agriculture, Education, Energy, Health and Human Services, the Interior, State, and Veterans Affairs; and the Director of the Office of Personnel Management should direct their CIOs to factor active risks into their IT Dashboard CIO ratings.	Concur	NA	In Progress	OCIO is actively working to implement the recommendation.
GAO-16-494	IT Dashboard: Agencies Need to Fully Consider Risks When Rating Their Major Investments	6/2/2016	To better ensure that the Dashboard ratings more accurately reflect risk, the Secretary of the Department of Health and Human Services, should direct their CIOs to ensure that their CIO ratings reflect the level of risk facing an investment relative to that investment's ability to accomplish its goals.	Concur	NA	In Progress	OCIO is actively working to implement the recommendation.
GAO-16-511	Information Technology: Agencies Need to Improve Their Application Inventories to Achieve Additional Savings	9/29/2016	To improve federal agencies' efforts to rationalize their portfolio of applications, the heads of the Departments of Agriculture, Commerce, Education, Energy, Health and Human Services, Housing and Urban Development, the Interior, Labor, State, Transportation, the Treasury, and Veterans Affairs; and heads of the Environmental Protection Agency; National Aeronautics and Space Administration; National Science	Concur	2020	Awaiting Disposition	OCIO has contacted ASL about closing this recommendation based on the information provided earlier to GAO.

			Foundation; Nuclear Regulatory Commission; Office of Personnel Management; Small Business Administration; Social Security Administration; and U.S. Agency for International Development should direct their Chief Information Officers (CIOs) and other responsible officials to improve their inventories by taking steps to fully address the practices we identified as being partially met or not met.				
GAO-17-448	Data Center Optimization: Agencies Need to Address Challenges and Improve Progress to Achieve Cost Savings Goal	9/6/2017	The Secretaries of Agriculture, Commerce, Defense, Homeland Security, Energy, HHS, Interior, Labor, State, Transportation, Treasury, and VA; the Attorney General of the United States; the Administrators of EPA, GSA, and SBA; the Director of OPM; and the Chairman of NRC should take action to, within existing OMB reporting mechanisms, complete plans describing how the agency will achieve OMB's requirement to implement automated monitoring tools at all agency-owned data centers by the end of fiscal year 2018.	Concur	2020	Awaiting Disposition	This recommendation was based on metrics from M-16-19 which is no longer in effect and has been replaced M-19-19. OCIO has worked closely with OMB to define new metrics and therefore believes this recommendation should be closed.
GAO-17-8	IT Workforce: Key Practices Help Ensure Strong Integrated Program Teams; Selected Departments Need to Assess Skill Gaps	11/30/2016	To facilitate the analysis of gaps between current skills and future needs, the development of strategies for filling the gaps, and succession planning, the Secretary of Health and Human Services should require the Chief Information Officer, Chief Human Capital Officer, and other senior managers as appropriate to address	Concur	NA	In Progress	OCIO is actively working this recommendation with the Office of Grants and Acquisition Policy and Accountability (OGAPA).

			the shortfalls in IT workforce planning noted in this report, including the following actions: (1) establish and maintain a workforce planning process inclusive of all staff; (2) develop staffing requirements for all positions; (3) assess staffing needs regularly; (4) assess gaps in competencies and staffing for all components of the workforce; (5) develop strategies and plans to address gaps in competencies and staffing; (6) implement activities that address gaps, including an IT acquisition cadre, if justified and cost-effective; (7) monitor the department's progress in addressing competency and staffing gaps; and (8) report to department leadership on progress in addressing competency and staffing gaps.				
GAO-18-381	Paperwork Reduction Act: Agencies Could Better Leverage Review Processes and Public Outreach to Improve Burden Estimates	8/10/2018	The Secretary of Health and Human Services should review the policies, procedures, and related control activities to ensure that the agency's Paperwork Reduction Act review process is operating effectively.	Concur	NA	In Progress	OCIO is actively working this recommendation.
GAO-18-381	Paperwork Reduction Act: Agencies Could Better Leverage Review Processes and Public Outreach to Improve Burden Estimates	8/10/2018	The Secretary of Health and Human Services should leverage existing consultation with stakeholders and the public to explicitly seek input on the estimated burden imposed by information collections.	Concur	NA	In Progress	OCIO is actively working this recommendation.

GAO-18-42	Information Technology: Agencies Need to Involve Chief Information Officers in Reviewing Billions of Dollars in Acquisitions	1/10/2018	The Secretary of HHS should ensure that IT acquisition plans or strategies are reviewed and approved according to OMB's guidance.	Concur	2020	In Progress	OCIO is actively working this recommendation and has shared information with GAO.
GAO-18-93	Federal Chief Information Officers: Critical Actions Needed to Address Shortcomings and Challenges in Implementing Responsibilities	8/2/2018	The Secretary of Health and Human Services should ensure that the department's IT management policies address the role of the CIO for key responsibilities in the six areas we identified.	Concur	NA	In Progress	OCIO is actively working this recommendation and has shared information with GAO.

ASPE

Appendix 1: OIG-GAO Open Recommendations							
Report Number	**Report Title**	**Report Date**	**Recommendation Text**	**Concur / Non-Concur**	**Implementation Timeline**	**Implementation Status**	**Implementation Updates and Constraints**
GAO-15-190	Older Adults: Federal Strategy Needed to Help Ensure Efficient and Effective Delivery of Home and Community-Based Services and Supports	5/20/2015	The Secretary of the Department of Health and Human Services should facilitate development of a cross-agency federal strategy to help ensure that federal resources from Administration for Community Living, CMS, USDA, HUD, and DOT are effectively and efficiently used to support a comprehensive system of HCBS and related supports for older adults. Through such a strategy the agencies could, for example, define common outcomes for affordable housing with supportive services, non-medical transportation, and nutrition assistance at the federal level; develop lessons learned for the local networks that area agencies on aging and community-based organizations are forming; and develop strategies for leveraging limited resources.	Concur	2017	Awaiting Disposition	In August 2017, HHS provided GAO a list of activities that would remediate the recommendation. HHS has considered this recommendation closed as implemented. HHS continues to collaborate with HUD, USDA and DOT.
GAO-15-211	Antipsychotic Drug Use: HHS Has Initiatives	3/2/2015	The Secretary of HHS should expand its outreach and educational efforts aimed at reducing antipsychotic drug use among older adults with	Concur	2019	In Progress	In April 2019, HHS released "Guidance on Inappropriate Use of Antipsychotics: Older Adults and People with Intellectual and Developmental Disabilities in Community Settings." The guidance was

	to Reduce Use among Older Adults in Nursing Homes, but Should Expand Efforts to Other Settings		dementia to include those residing outside of nursing homes by updating the National Alzheimer's Plan.				developed in partnership with SAMHSA, CMS, HRSA, and ACL and is intended for physician and other prescribers, support staff, administrators, and caregivers of people with dementia and/or people with intellectual and developmental disabilities in community.
GAO-16-17	Health Care Workforce: Comprehensive Planning by HHS Needed to Meet National Needs	1/11/2016	To ensure that HHS workforce efforts meet national needs, the Secretary of Health and Human Services should develop a comprehensive and coordinated planning approach to guide HHS's health care workforce development programs--including education, training, and payment programs--that (1) includes performance measures to more clearly determine the extent to which these programs are meeting the department's strategic goal of strengthening health care; (2) identifies and communicates to stakeholders any gaps between existing programs and future health care workforce needs identified in the Health Resources and Services Administration's workforce projection reports; (3) identifies actions needed to address identified gaps; and (4) identifies and communicates to	Concur	NA	In Progress	As HHS has noted in the past, the legislative and budget cycles provide an annual opportunity for coordination of workforce issues across the Department with priorities identified through the Department's budget request and legislative program. Our legislative program and budget are informed by input from formal mechanisms such as statutory advisory committees and consultation with the Tribes and interactions that arise from Agency program and project activities. Our budget contains a major proposal restructuring CMS Graduate Medical Education (GME) programs into a discretionary grant program. Such a restructuring would allow the Department to set expectations for program performance in CMS GME and allow the kind of tracking HRSA has been able to implement in the Children's Hospital GME program and its Teaching Hospital GME program. However, Congress has not responded to this request.

			Congress the legislative authority, if any, the Department needs to implement the identified actions.				

GAO-18-240	Physician Workforce: HHS Needs Better Information to Comprehensively Evaluate Graduate Medical Education Funding	3/29/2018	The Secretary of HHS should coordinate with federal agencies, including VA, that fund GME training to identify information needed to evaluate the performance of federal programs that fund GME training, including the extent to which these programs are efficient and cost-effective and are meeting the nation's health care workforce needs.	Concur	NA	In Progress	The President's FY 2020 budget contains a major proposal to restructure the Department's Graduate Medical Education (GME) programs located in the Centers for Medicare and Medicaid Services (CMS) and the Health Resources and Services Administration (HRSA) into a single capped grant program. Such a restructuring would allow the Department to set expectations for program performance in CMS's GME programs and allow the kind of tracking HRSA has been able to implement in the Children's Hospital GME program. However, Congress has not authorized this activity. More specifically, should necessary authorization language be passed, the Administration has assigned responsibility for reforming and administering GME jointly to CMS and HRSA. As specified in the Department's budget, this proposal would consolidate federal graduate medical education spending from Medicare, Medicaid, and the Children's Hospital Graduate Medical Education Program into a single grant program for teaching hospitals. Total funds available for distribution in FY 2020 would equal the sum of Medicare and Medicaid's 2017 payments for graduate medical education, plus 2017 spending on Children's Hospital Graduate Medical Education, adjusted for inflation. This amount would then grow at the CPI-U minus one percentage point each year. Payments would be distributed to hospitals based on the number of

							residents at a hospital (up to its existing cap) and the portion of the hospital's inpatient days accounted for by Medicare and Medicaid patients. This grant program would be funded out of the general fund of the Treasury. The Secretary would have authority to modify the amounts distributed based on the proportion of residents training in priority specialties or programs (e.g., primary care, geriatrics) and based on other criteria identified by the Secretary, including addressing health care professional shortages and educational priorities. Enactment of this proposal would give the Department new opportunities to monitor performance in its biggest GME investments. Should Congress decide to authorize this activity, CMS and HRSA can further consider how the recommendations from GAO may be addressed.

GAO-18-240	Physician Workforce: HHS Needs Better Information to Comprehensively Evaluate Graduate Medical Education Funding	3/29/2018	The Secretary of HHS should coordinate with federal agencies to identify opportunities to improve the quality and consistency of the information collected within and across federal programs, and implement these improvements.	Concur	NA	In Progress	The President's FY 2020 budget contains a major proposal to restructure the Department's Graduate Medical Education (GME) programs located in the Centers for Medicare and Medicaid Services (CMS) and the Health Resources and Services Administration (HRSA) into a single capped grant program. Such a restructuring would allow the Department to set expectations for program performance in CMS's GME programs and allow the kind of tracking HRSA has been able to implement in the Children's Hospital GME program. However, Congress has not authorized this activity. More specifically, should necessary authorization language be passed, the Administration has assigned responsibility for reforming and administering GME jointly to CMS and HRSA. As specified in the Department's budget, this proposal would consolidate federal graduate medical education spending from Medicare, Medicaid, and the Children's Hospital Graduate Medical Education Program into a single grant program for teaching hospitals. Total funds available for distribution in FY 2020 would equal the sum of Medicare and Medicaid's 2017 payments for graduate medical education, plus 2017 spending on Children's Hospital Graduate Medical Education, adjusted for inflation. This amount would then grow at the CPI-U minus one percentage point each year. Payments would be distributed to hospitals based on the number of

							residents at a hospital (up to its existing cap) and the portion of the hospital's inpatient days accounted for by Medicare and Medicaid patients. This grant program would be funded out of the general fund of the Treasury. The Secretary would have authority to modify the amounts distributed based on the proportion of residents training in priority specialties or programs (e.g., primary care, geriatrics) and based on other criteria identified by the Secretary, including addressing health care professional shortages and educational priorities. Enactment of this proposal would give the Department new opportunities to monitor performance in its biggest GME investments. Should Congress decide to authorize this activity, CMS and HRSA can further consider how the recommendations from GAO may be addressed.
GAO-18-44	Opioid Use Disorders: HHS Needs Measures to Assess the Effectiveness of Efforts to Expand Access to Medication-Assisted Treatment	10/31/2017	The Assistant Secretary for Planning and Evaluation should establish performance measures with targets related to expanding access to MAT for opioid use disorders.	Concur	NA	In Progress	The Secretary's Opioid Initiative is no longer active, as this was an Initiative under the Obama Administration. Under the current Administration, the Department has a new 5-Point Opioid Strategy, and its implementation is being led by the Senior Advisor for Opioid Policy, not ASPE. Regarding metrics, the Agency Priority Goal on opioids sets out clear metrics and targets for the Department's efforts to reduce opioid-related morbidity and mortality, including measures explicit to expanding access to medication assisted treatment,

							the focus of GAO's inquiry. Quarterly progress reports are available publically on at https://www.performance.gov/health_and_human_services/APG_hhs_2.html From HHS' perspective, this recommendation has been implemented.

DAB

Appendix 1: OIG-GAO Open Recommendations							
Report Number	**Report Title**	**Report Date**	**Recommendation Text**	**Concur / Non-Concur**	**Implementation Timeline**	**Implementation Status**	**Implementation Updates and Constraints**
GAO-16-366	Medicare Fee-For-Service: Opportunities Remain to Improve Appeal Process	6/9/2016	To reduce the number of Medicare appeals and to strengthen oversight of the Medicare FFS appeals process, the Secretary of Health and Human Services should direct CMS, OMHA, or DAB to modify the various Medicare appeals data systems to capture the amount, or an estimate, of Medicare allowed charges at stake in appeals in Medicare Appeals System (MAS) and Medicare Operations Division Automated Case Tracking System (MODACTS).	Concur	NA	In Progress	The DAB continues to explore the feasibility of tracking allowed amounts at Level 4. However, one constraint for the DAB is access to this type of data; this data must be provided to the DAB by prior levels or included in the record on appeal. In the meantime, DAB has started recording and tracking billed amounts in MODACTS, based on the information that is available in the record for each appeal.

GAO-16-366	Medicare Fee-For-Service: Opportunities Remain to Improve Appeal Process	6/9/2016	To reduce the number of Medicare appeals and to strengthen oversight of the Medicare FFS appeals process, the Secretary of Health and Human Services should direct CMS, OMHA, or DAB to modify the various Medicare appeals data systems to collect consistent data across systems, including appeal categories and appeal decisions across MAS and MODACTS	Concur	2018	Awaiting Disposition	CMS recommends closure on both recommendation 3 & 4 based on the following: MAS CR 747 was released in November 2016 and included revised Level 3 Appeal Categories. This functionality allows for consistent appeal categories at case closure when ECAPE transmits closed Level 3 appeals back to the appeals system of records, MAS. As of the end of April 2017, all Part A MACs were successfully onboarded to MAS. Since CMS' last reporting date, all MACs had passed their transition period and had attested to readiness in MAS and their desire to continue processing within the MAS environment and not roll back to their previous legacy systems. CMS continues efforts to seek funding for onboarding the remaining MACs (Part B and DME) onto MAS. Recently, CMS received FY18 funding for a pilot to partially onboard 1 Part B and 1 DME MAC to MAS for data collection, reporting, and case file transfers only. With this approach, MACs would continue to be able to innovate and experience in-house developed operational efficiencies using their internal workflow and correspondence systems, while also allowing CMS to explore enhanced monitoring of MAC Part B and DME workload. This solution will control MAC operational costs by incrementally allowing for seamless integration into their current workflow and not negatively impact current MAC operating budgets. Web services would assist MACs with updating MAS with data from their internal systems. To account for the complexity of incorporating this new type of workload in MAS, this pilot would allow all MAC jurisdictions to assist in the development of business requirements. In addition, as of the most recent MAS release in May 2018, CMS implemented CR 752 and the functionality to allow MAC users visibility into

							appeals histories at Levels 1, 2, and 3, associated to their organization's contract. This will greatly assist in data reporting consistency and allows MACs the ability to report on cases promoted to Level 3 that may not have been processed within MAS by their organization, but rather through a legacy system or the previous MAC jurisdiction contract holder that was uploaded to MAS by a Level 2 QIC contractor." The DAB continues to work towards developing system interoperability with OMHA's ECAPE system, which will help standardize and integrate data between Levels 3 and 4. Currently, the DAB is working with its IT contractor to developed APIs capable of importing and exporting data from ECAPE. In addition, the DAB actively participated in "IT Sprint," an interagency project led by the HHS Office of the Chief Technology Officer, which explored ways to integrate appeals data across all levels of review. Most recently, the project developed a prototype for a dashboard that would enable various stakeholders to obtain the status of individual or collective claims. The DAB has also established connectivity with CMS contractors for the electronic transfer and upload of claim files for appealed cases.

GAO-16-366	Medicare Fee-For-Service: Opportunities Remain to Improve Appeal Process	6/9/2016	To reduce the number of Medicare appeals and to strengthen oversight of the Medicare FFS appeals process, the Secretary of Health and Human Services should direct CMS, Office of Medicare Hearings and Appeals (OMHA), or Departmental Appeals Board (DAB) to modify the various Medicare appeals data systems to collect information on the reasons for appeal decisions at Level 3.	Concur	2020	Awaiting Disposition	OMHA recommends closure on this recommendation. In the July 2017 interim release of the Electronic Case Adjudication and Processing Environment (ECAPE) system, OMHA added a "Reason for Disposition" data field for most dispositions issued by an adjudicator. Because the "Reason for Disposition" data field limits the number of reasons that can be selected, OMHA added more categories in later releases. As of November 2019, ECAPE has been implemented in all of OMHA's field offices and its satellite office. Information on the reasons for Level 3 appeal decisions can currently be reported within ECAPE. DAB recently added new data fields and case categories to its case management system to capture more detail about pending cases, including the reasons for ALJ dismissals at level 3. In addition, DAB continues to work towards developing system interoperability with ECAPE. Once baseline interoperability is established, DAB will work with OMHA to explore the feasibility of incorporating level 3 "Reason for Disposition" data into its new system.

OGC

Appendix 1: OIG-GAO Open Recommendations							
Report Number	**Report Title**	**Report Date**	**Recommendation Text**	**Concur / Non-Concur**	**Implementation Timeline**	**Implementation Status**	**Implementation Updates and Constraints**
OEI-04-10-00010	Conflict-of-Interest Waivers Granted to HHS Employees in 2009	8/24/2011	Require OPDIVs and STAFFDIVs to document conflict-of interest waivers as recommended in Government wide Federal ethics regulations and the Secretary's instructions.	Concur	2021	In Progress	
OEI-04-10-00010	Conflict-of-Interest Waivers Granted to HHS Employees in 2009	8/24/2011	Take action to revise the conflict-of-interest waivers in our review that were not documented as recommended in Government wide Federal ethics regulations and the Secretary's instructions, if the waivers are still in effect.	Concur	2019	In Progress	These waivers are no longer in effect and a request will be made to close this recommendation.
OEI-04-10-00010	Conflict-of-Interest Waivers Granted	8/24/2011	Require all employees to sign and date, or similarly	Concur	2019	In Progress	OGC requires all employees to sign and date a waiver that has been granted, in which the employee acknowledges the waiver and agrees to abide by the terms of the waiver.

	to HHS Employees in 2009		document, their conflict of interest waivers.				

OASH

Appendix 1: OIG-GAO Open Recommendations							
Report Number	**Report Title**	**Report Date**	**Recommendation Text**	**Concur / Non-Concur**	**Implementation Timeline**	**Implementation Status**	**Implementation Updates and Constraints**
OEI-01-15-00350	OHRP Generally Conducted Its Compliance Activities Independently, But Changes Would Strengthen Its Independence	7/27/2017	HHS should address factors that may limit OHRP's ability to operate independently	Concur	2021	In Progress	See SWIFT #Swift 05302019B002. SACHRP was asked to make recommendations regarding the four specific ways identified in the OIG report that HHS could address the factors that limit or appear to limit OHRP's ability to operate independently. OHRP forwarded SACHRP's recommendations to OASH and provided the link on our website to the SACHRP's recommendations.
OEI-01-15-00351	OHRP Should Inform Potential Complainants of How They Can Seek Whistleblower Protections	9/18/2017	Request that HHS consider the adequacy of whistleblower protections for complainants who make disclosures to OHRP about human subjects protections	Concur	2021	In Progress	See SWIFT #07252017B004. In a memo dated August 28, 2017, from Dr. Wright (then acting ASH) to Inspector General Levinson. Dr. Wright indicated that he "will ask HHS leadership to consider the adequacy of the proposed whistleblower protections for complainants making disclosures about human subject protections to OHRP."
OEI-05-10-00050	Guidance and Standards on Language Access Services: Medicare Providers	7/1/2010	In addition, to help Medicare providers offer language access services, we recommend that: OMH offer model translated written materials and signs to providers.	Concur	2020	In Progress	No current OMH staff have awareness of this commitment. OMH will coordinate with CMS to determine the specific need and best path forward.

GAO-16-645	Female Genital Mutilation/Cutting: Federal Efforts to Increase Awareness Need Improvement	8/1/2016	To make the best use of federal resources directed toward combating FGM/C in the United States, the Attorney General and the Secretaries of Education, Health and Human Services, Homeland Security, and State should each develop a written plan that describes the agency's approach for conducting education and outreach to key stakeholders in the United States regarding FGM/C.	Concur	2019	Awaiting Disposition	OASH is preparing to submit an update to GAO with a request that this recommendation be closed as implemented. This request is based on the significant work that OASH and CDC have done in this area since 2016, including a grant program, public and stakeholder meetings, and the upcoming CDC FGM/C prevalence study. Although HHS did not complete a comprehensive written plan, we believe that the planning and implementation of these activities has accomplished the intent of the GAO recommendation.
GAO-16-645	Female Genital Mutilation/Cutting: Federal Efforts to Increase Awareness Need Improvement	8/1/2016	To make the best use of federal resources directed toward combating FGM/C in the United States, the Attorney General and the Secretaries of Education, Health and Human Services, Homeland Security, and State should each communicate the plan with other relevant federal	Concur	2019	Awaiting Disposition	OASH is preparing to submit an update to GAO with a request that this recommendation be closed as implemented. This request is based on the significant work that OASH and CDC have done in this area since 2016, including a grant program, public and stakeholder meetings, and the upcoming CDC FGM/C prevalence study. Although HHS did not complete a comprehensive written plan, we believe that the planning and implementation of these activities has accomplished the intent of the GAO recommendation.

			agencies and stakeholder groups, as appropriate.				

OHRP

Appendix 1: OIG-GAO Open Recommendations					
Report Date	**Recommendation Text**	**Concur / Non-Concur**	**Implementation Timeline**	**Implementation Status**	**Implementation Updates and Constraints**
7/27/2017	OHRP should post the following on its website: (a) a description of its approach to oversight and (b) data (in aggregate) on the full array of its compliance activities	Concur	2021	In Progress	Partially implemented. OHRP is now posting aggregate data on an array of its compliance activities. The data posted is limited by the current DCO tracking system. OHRP is continuing to have internal discussions regarding the first part of this recommendation, which advised that OHRP develop a separate section on its website to include "(a) a description of its approach to oversight," that specifically addresses "OHRP's alternatives to conducting a compliance evaluation...".

OFFICE OF THE SECRETARY

Appendix 1: OIG-GAO Open Recommendations							
Report Number	**Report Title**	**Report Date**	**Recommendation Text**	**Concur / Non-Concur**	**Implementation Timeline**	**Implementation Status**	**Implementation Updates and Constraints**
A-03-13-03002	HHS Did Not Identify and Report Antideficiency Act Violations	5/12/2017	Collaborate with ASFR to identify changes to UFMS to ensure that contract expenditures for each program year are paid using the appropriate program year obligations	Concur	2020	In Progress	The PSC change request (CR 0001163) that will satisfy OIG's request to, "develop automated controls in the UFMS system to ensure that contract expenditures for each program year are paid using the appropriate program year obligations" has been scheduled for a December 2020 release.
A-03-13-03002	HHS Did Not Identify and Report Antideficiency Act Violations	5/12/2017	Use product/service codes that accurately reflect the contract statement of work	Concur	2019	In Progress	Product service codes are at the discretion of the Contracting Officer but PSC will continue to work with Contracting Officers to ensure they choose the most appropriate code.
A-03-13-03002	HHS Did Not Identify and Report Antideficiency Act Violations	5/12/2017	Use "no cost" contract extensions for severable services contracts only when they do not extend the period of performance for a program year to more than 12 months	Concur	2019	In Progress	Additional trainings for acquisitions workforce (contracting, budget, and program staff) implemented. Both online and in-person trainings are offered specific to "no cost" extensions for severable service contracts.
A-03-13-03002	HHS Did Not Identify and Report Antideficiency Act Violations	5/12/2017	Work with the HHS Office of the Secretary to report Antideficiency Act expenditure violations totaling $29,188,270	Concur	2021	In Progress	Working with OpDivs to accurately determine which issues Congress was constructively notified of in 2011, which are correctible

							errors, and which may require additional notifications under the Antideficiency Act.
A-03-13-03002	HHS Did Not Identify and Report Antideficiency Act Violations	5/12/2017	Work with the HHS Office of the Secretary to report Antideficiency Act obligation violations totaling $20,256,755	Concur	2021	In Progress	Working with OpDivs to accurately determine which issues Congress was constructively notified of in 2011, which are correctible errors, and which may require additional notifications under the Antideficiency Act.
A-03-13-03003	HHS Agencies Did Not Accurately Report Some Conference Costs for Fiscal Year 2012	12/9/2014	We recommend that the Department direct HHS agencies to provide greater oversight to ensure that officials who approve travel costs do not authorize unallowable costs for meals that are provided as part of the conference.	Concur	2019	Awaiting Disposition	HHS submitted an update10/10/19 requesting closing this recommendation as implemented.
A-03-13-03003	HHS Agencies Did Not Accurately Report Some Conference Costs for Fiscal Year 2012	12/9/2014	We recommend that the Department provide additional guidance to its agencies on awarding contracts, grants, and cosponsorship agreements that appropriately identify the costs paid by the Government for each conference.	Concur	2019	Awaiting Disposition	HHS submitted an update10/10/19 requesting closing this recommendation as implemented.

A-12-17-00002	The Office of the Secretary of Health and Human Services Did Not Comply with Federal Regulations for Chartered Aircraft and Other Government Travel Related to Former Secretary Price	7/11/2018	Train responsible HHS personnel and put controls in place to ensure that the following requirements are met for future travel: conducting a cost analysis and maintaining documentation to support each use of chartered aircraft that is consistent with each charter justification and ensure compliance with the FTR and the HHS Travel Policy Manual; following the HHS Travel Policy Manual when making travel decisions for the Secretary and accompanying staff when they are not traveling from or to their official duty stations; ensuring authorizations and vouchers are completed in accordance with the FTR and the HHS Travel Policy Manual; cancelling travel reservations to ensure that the value of an unused ticket is not charged to HHS's centrally billed account and then paid, in accordance with the FTR; ensuring existing and newly assigned individuals complete all required training before Government travel in compliance with OMB Circular No. A-123 and the HHS Travel Policy Manual; and ensuring HHS individuals responsible for approving travel receive initial and refresher training to comply with OMB Circular No. A-123 and the HHS Travel Policy Manual.	Concur	2020	In Progress	OS and HHS travel personnel are actively reviewing the HHS Travel Policy Manual and increasing trainings for staff involved in scheduling, preparing, procuring, and approving travel. Additional reporting requests for chartered aircraft have also been implemented

A-12-17-00002	The Office of the Secretary of Health and Human Services Did Not Comply with Federal Regulations for Chartered Aircraft and Other Government Travel Related to Former Secretary Price	7/11/2018	Assess the roles, responsibilities, and actions of Federal personnel involved in scheduling, preparing, procuring, and approving the use of chartered aircraft for former Secretary Price's travel and take all appropriate actions related to their performance or conduct.	Concur	2020	In Progress	The Office of the Secretary (OS) is actively working towards resolving this recommendation. OS is currently working with the Office of the General Counsel (OGC).
A-12-17-00002	The Office of the Secretary of Health and Human Services Did Not Comply with Federal Regulations for Chartered Aircraft and Other Government Travel Related to Former Secretary Price	7/11/2018	Train responsible HHS personnel and put controls in place to ensure that the following requirements are met for future procurements: preparing and maintaining documentation regarding the rationale for quote selections when the lowest quote is not selected is prepared and included in the contract file as required by the FAR; and verifying that sole-source justification requirements are adhered to and documentation related to sole-source awards is prepared in accordance with the FAR.	Concur	2020	In Progress	OS and HHS travel personnel are actively reviewing the HHS Travel Policy Manual, identifying what training and how much training need to be implemented for staff involved in scheduling, preparing, procuring, and approving travel. Additional reporting requests for chartered aircraft have also been implemented.

A-12-17-00002	The Office of the Secretary of Health and Human Services Did Not Comply with Federal Regulations for Chartered Aircraft and Other Government Travel Related to Former Secretary Price	7/13/2018	We recommend that the Office of the Secretary review the lack of compliance with the OMB Circular A-126, Federal Travel Regulations, and HHS Travel Policy Manual related to the authorization and use of chartered aircraft during former Secretary Price's tenure, and on the basis of the review, determine and take appropriate administrative actions to recoup $333,014 of identified waste, including: the $12,178 for the June 6 trip to Nashville for which the chartered aircraft was not cancelled after receiving confirmation that the White House event would not occur providing an opportunity for the use of commercial flights, the $36,313 for the June 24–26 trip to San Diego, Aspen, and Salt Lake City that included only 3.5 hours of official engagements, the $10,001 for the September 15 trip to Philadelphia for not using options other than chartered aircraft, the $12,346 for the Raleigh to Brunswick travel leg in which former Secretary Price used the chartered aircraft to attend an event in a personal capacity, the net cost of the cancelled leg of approximately $8,675 from the Marathon and Stillwater trip starting on September 18, and	Concur	2020	In Progress	The Office of the Secretary (OS) is actively working towards resolving this recommendation. OS is currently working with the Office of the General Counsel (OGC).

			the remaining $253,501 for not comparing the cost of chartered aircraft to the cost of commercial travel and not selecting the most cost-effective mode of travel.				

A-12-17-00002	The Office of the Secretary of Health and Human Services Did Not Comply with Federal Regulations for Chartered Aircraft and Other Government Travel Related to Former Secretary Price	7/13/2018	Review the lack of compliance with the HHS Travel Policy Manual related to travel that started or ended in locations other than former Secretary Price's official duty station, and on the basis of the review, determine and take appropriate administrative actions to recoup $4,926 identified as waste: the $818 for the July 6 trip to Chattanooga in travel costs for an employee to travel to Atlanta on July 5, the $580 for the Raleigh to Brunswick leg in which HHS travelers had to fly commercially back to DC because former Secretary Price used the chartered aircraft to attend an event in a personal capacity, and the $3,528 for the September 18 trip to Marathon and Stillwater.	Concur	2020	In Progress	The Office of the Secretary (OS) is actively working towards resolving this recommendation. OS is currently working with the Office of the General Counsel (OGC).
A-12-17-00002	The Office of the Secretary of Health and Human Services Did Not Comply with Federal Regulations for Chartered Aircraft and Other Government Travel Related to Former Secretary Price	7/13/2018	Review the lack of compliance with the FTR and the HHS Travel Policy Manual related to other excess travel costs, and on the basis of the review, determine and take appropriate action to recoup $2,960 of identified waste: the $1,568 of excess lodging costs that were not pre-authorized, the $727 of excess costs incurred for a rental vehicle and pre-paid fuel, and the $665 to Government travelers for travel costs that included unallowable meal costs and	Concur	2020	In Progress	The Office of the Secretary (OS) is actively working towards resolving this recommendation. OS is currently working with the Office of the General Counsel (OGC).

			incorrect amounts entered on vouchers.				
A-12-17-00002	The Office of the Secretary of Health and Human Services Did Not Comply with Federal Regulations for Chartered Aircraft and Other Government Travel Related to Former Secretary Price	7/13/2018	Request a repayment totaling $716 for former Secretary Price's wife's use of one flight aboard a chartered aircraft.	Concur	2020	In Progress	The Office of the Secretary (OS) is actively working towards resolving this recommendation. OS is currently working with the Office of the General Counsel (OGC).

OEI-06-14-00011	Indian Health Service Hospitals: Longstanding Challenges Warrant Focused Attention to Support Quality Care	10/6/2016	As part of OS' newly formed Executive Council, lead an examination of the quality of care delivered in IHS hospitals and use the findings to identify and implement innovative strategies to mitigate IHS's longstanding challenges	Concur	2019	Awaiting Disposition	HHS has submitted documentation requesting this recommendation be closed as implemented. The Executive Council is no longer active but the work of the Council has been institutionalized in the IHS Office of Quality effective January 2019. The IHS Office of Quality will provide leadership and promote consistency in health care quality across the agency by consolidating and enhancing oversight of these efforts at IHS headquarters working to mitigate historical IHS challenges. In addition, earlier this year the Department reinstituted the Intradepartmental Council on Native American Affairs (ICNAA), which had been dormant for almost a decade. The ICNAA is statutorily authorized by the Native American Programs Act of 1974 and serves as the internal body within the Department for coordination of health and human services issues, including developing and promoting Departmental policies to provide greater access to quality services for American Indians and Alaska Natives.

GAO-16-305	High–Containment Laboratories: Comprehensive and Up-to-Date Policies and Stronger Oversight Mechanisms Needed to Improve Safety	4/19/2016	To ensure that federal departments and agencies have comprehensive and up-to-date policies and stronger oversight mechanisms in place for managing hazardous biological agents in high-containment laboratories and are fully addressing weaknesses identified after laboratory safety lapses, the Secretary of Health and Human Services should develop department policies for managing hazardous biological agents in high-containment laboratories that contain specific requirements for training and inspections for all high-containment component agency laboratories and not just for their select-agent-registered laboratories; or direct the Director of CDC to provide these requirements in agency policies.	Concur	2020	In Progress	Guidance pulled from clearance for revisement to remove lab training section and embed in overall CDC training policy. Internal comments have been addressed in clearance process.

GAO-16-305	High–Containment Laboratories: Comprehensive and Up-to-Date Policies and Stronger Oversight Mechanisms Needed to Improve Safety	4/19/2016	To ensure that federal departments and agencies have comprehensive and up-to-date policies and stronger oversight mechanisms in place for managing hazardous biological agents in high-containment laboratories and are fully addressing weaknesses identified after laboratory safety lapses, the Secretary of Health and Human Services should direct the Director of NIH and the Commissioner of FDA to require routine reporting of the results of agency laboratory inspections--and in the case of FDA, require routine reporting of select agent inspection results--to senior agency officials.	Concur	NA	In progress	FDA has a standing policy for managing hazardous biological agents in high-containment laboratories that includes reporting requirements (SMG 2130.8 and Directive 201710.2). In 2019, FDA began piloting a standardized Agency-wide laboratory safety inspection checklist to ensure that all laboratories are inspected rigorously and consistently. As part of the pilot, all laboratories are to be inspected during Q1-Q3 of the calendar year. Any corrective/preventative actions will be tracked and resolved locally during this inaugural year. The results of the inspections will be aggregated, and trends and significant findings will be reported to Agency senior leadership in Q4 of 2019. Beginning in 2019, OLS is committed to independently inspecting all high-containment and select agent laboratories and 1/3 of all other laboratories each year to ensure compliance with all laws, regulations, and consensus standards. (In other words, all laboratories will be inspected at least once every three years)

GAO-16-305	High–Containment Laboratories: Comprehensive and Up-to-Date Policies and Stronger Oversight Mechanisms Needed to Improve Safety	4/19/2016	To ensure that federal departments and agencies have comprehensive and up-to-date policies and stronger oversight mechanisms in place for managing hazardous biological agents in high-containment laboratories and are fully addressing weaknesses identified after laboratory safety lapses, the Secretary of Health and Human Services should develop department policies for managing hazardous biological agents in high-containment laboratories that contain specific requirements for reporting laboratory incidents to senior department officials, including the types of incidents that should be reported, to whom, and when, or direct the Director of CDC and the Commissioner of FDA to incorporate these requirements into their respective policies.	Concur	NA	In progress	FDA has a standing policy for managing hazardous biological agents in high-containment laboratories that includes reporting requirements (SMG 2130.8, Directives 201710.2 and 2019.3). FDA also implemented a mechanism for incident reporting electronically to facilitate the investigation, resolution, and reporting of incidents. FDA continues to work with the Biosafety and Biosecurity Coordinating Council to establish a process for the routine reporting of the results of agency and select agent laboratory inspections to senior department officials.

GAO-16-305	High–Containment Laboratories: Comprehensive and Up-to-Date Policies and Stronger Oversight Mechanisms Needed to Improve Safety	4/19/2016	To ensure that federal departments and agencies have comprehensive and up-to-date policies and stronger oversight mechanisms in place for managing hazardous biological agents in high-containment laboratories and are fully addressing weaknesses identified after laboratory safety lapses, the Secretary of Health and Human Services should require routine reporting of the results of agency and select agent laboratory inspections to senior department officials.	Concur	NA	In Progress	NIH has provided documentation to GAO as evidence they have implemented this recommendation.
GAO-16-305	High–Containment Laboratories: Comprehensive and Up-to-Date Policies and Stronger Oversight Mechanisms Needed to Improve Safety	4/19/2016	To ensure that federal departments and agencies have comprehensive and up-to-date policies and stronger oversight mechanisms in place for managing hazardous biological agents in high-containment laboratories and are fully addressing weaknesses identified after laboratory safety lapses, the Secretary of Health and Human Services should require routine reporting of incidents at CDC, FDA, and NIH laboratories to senior department officials.	Concur	NA	In progress	In August 2019, FDA reported that it continues to work with the Biosafety and Biosecurity Coordinating Council to establish a process for the routine reporting of these results but had not yet completed its actions.

Medicare Hearings and Appeals

I am pleased to present the Office of Medicare Hearings and Appeals (OMHA's) Fiscal Year (FY) 2021 Congressional Justification. This budget request reflects OMHA's strong commitment to providing a responsive and independent forum for the fair, credible, and efficient adjudication of Medicare appeals for beneficiaries and other parties.

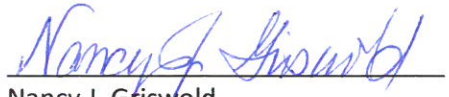
Since beginning operations in July 2005, OMHA has been committed to continuous innovation in the Medicare appeals process through responsible stewardship and an accomplished and resilient adjudication workforce. This commitment continues to inspire OMHA's mission. However, between FY 2010 and FY 2014, OMHA experienced an unprecedented 1,222 percent surge in appeals, while funding for adjudication increased by only 16 percent. Although the exponential growth in appeals has slowed since the FY 2014 peak, the result of that growth has been a backlog of appeals (292,517 appeals as of end of FY 2019) that could not be adjudicated within the 90-day period contemplated by statue.

Thanks to Congress's support and investment through a 70 percent budget increase in March of 2018, which was sustained in OMHA's FY 2019 appropriation, OMHA has completed its Adjudication Expansion Initiative. In the span of just 18 months, OMHA opened four new field offices (Albuquerque, New Mexico; Atlanta, Georgia; New Orleans, Louisiana; and Phoenix, Arizona) and increased adjudication capacity by roughly 80 administrative law judges (ALJs) and 700 adjudicatory and support staff positions.

With the continued sustainment of OMHA's adjudicatory capacity in the FY 2021 budget request, OMHA will be able to handle its projected incoming receipts and continue the process of resolving its backlog of pending appeals. Most importantly, the sustainment of adjudicatory capacity will enable OMHA to maintain its projected backlog elimination efforts, which are mandated by the November 1, 2018 Federal District Court ruling in *American Hospital Association v. Azar*. Pursuant to that ruling, the Secretary of HHS is operating under a mandamus order, directing specific annual reduction targets in the appeals backlog, leading to total elimination in 2022. OMHA has already reduced the appeals backlog by approximately 27% in FY 2019 which surpassed the Court's annual reduction target of 19%.

Another exciting development at OMHA is the establishment of the Electronic Case Adjudication Processing Environment (ECAPE), which adds long-overdue efficiencies in case processing. ECAPE began a phased implementation roll out in December 2018, which was completed in November 2019. ECAPE automates most aspects of OMHA's adjudicatory business process, especially in the areas of managing and handling documents, exhibiting case processing workflow, generating correspondence, scheduling and managing hearings, and supporting the decision process. ECAPE will also enable OMHA to improve its analytics, and provide an electronic public portal for appellants to file an appeal, submit evidence, and access information about pending appeals.

Despite the significant workload challenges facing the agency, OMHA leadership remains committed to OMHA's key priorities: timely adjudication of appeals, maximizing efficiency through continued innovation and technological improvements, and providing exceptional value to the public through superior customer service and quality adjudication.



Nancy J. Griswold
Chief Administrative Law Judge

The Departmental Appeals Board (DAB) provides impartial, independent hearings and appellate reviews, and issues Federal agency decisions under more than 60 statutory and regulatory provisions governing HHS programs. A large percentage of the DAB's work is the result of Medicare claims appeals. As noted in Judge Griswold's letter, the surge in Medicare appeals resulted in a large backlog at the Office of Medicare Hearings and Appeals, which has triggered a similar impact on the workload of the Medicare Appeals Council in the DAB's Medicare Operations Division's (MOD).

The DAB has tried to utilize multiple strategies for eliminating or reducing the backlog in MOD, but ultimately the lack of increased staffing capacity has proven insurmountable. While incoming appeals were lower in FY 2019 due to the impact of HHS settlements, incoming appeals are projected to increase again in FY 2020, following and as a result of OMHA's recent expansion. OMHA has now opened and staffed four new offices, and will begin significantly increasing its case output. This increase in OMHA adjudications is projected to more than double the number of appeals to the DAB's MOD from FY 2019 to FY 2020. This trend is expected to continue into FY 2021.

At the end of FY 2019, MOD had a backlog of 17,682 cases and an adjudication capacity of only 1,920 cases annually. With the additional funding provided by the FY 2020 Enacted bill, the DAB will continue the process of addressing its backlog. Additional funding in FY 2021 allows the DAB to hire new attorneys, judges, and support staff, giving MOD the opportunity to handle incoming appeals and continue to make progress on reducing the backlog.

A similar situation has developed in the DAB's Civil Remedies Division (CRD), where approximately 90% of the workload is made up of CMS cases. The receipts in CRD rose over the last few years, while staffing decreased. As a result, a backlog has developed that will also be addressed by the requested funding increase in FY 2021. CRD will use additional funds to hire new attorneys, judges, and support staff to work its backlog and handle incoming cases.

The backlog at the DAB impact many constituencies, including beneficiaries whose appeals are prioritized, physicians, hospitals, home health agencies, skilled nursing facilities, ambulance suppliers, and medical equipment companies. These constituents currently face long wait-times to receive a final decision. At the beginning of FY 2020, the average appeal in MOD was $43,000, for a total Medicare Appeals backlog value of over $760 million. Additional funding enables DAB to increase adjudications, and decrease the average wait time.

The DAB continues to seek other ways to enhance its adjudicative efficiency. These efforts involve continuing to improve newly implemented IT-based solutions, including e-filing, digitization of paper claim files, cloud-based data storage, expanding the new MOD document generation system, working to establish case management system integration with CMS, and developing ongoing enhancements to MOD's case processing system. The DAB's goal is to build upon its existing e-filing and electronic record systems, and transform case processing in all of its adjudicatory divisions into a completely paperless process. In FY 2020 and FY 2021, the DAB will also focus on cutting-edge IT enhancements, such as artificial intelligence and data analytics, as tools to collect, manage, and analyze case data. The DAB has also proposed a change to the Medicare Appeals Council's standard of review that would increase MOD's adjudicatory capacity by up to 30%.

Constance B. Tobias

Constance B. Tobias
Chair, Departmental Appeals Board

Table of Contents

Introduction - Medicare Hearings and Appeals

The FY 2021 Medicare Hearings and Appeals (MHA) justification is a consolidated display that deals with the Medicare hearings and appeals related work carried out by two Office of the Secretary Staff Divisions:

- Office of Medicare Hearings and Appeals (OMHA), which represents the third level of the Medicare appeals process;
- Departmental Appeals Board (DAB), which represents the fourth level of the Medicare appeals process.

The FY 2021 Budget request for MHA is $198,808,000 in program level funding, an increase of $6,927,000 above FY 2020 Enacted. This program level funding is accessed by the Office of Medicare Hearings and Appeals and the Departmental Appeals Board to address Medicare related work as follows:

Medicare Hearings and Appeals (MHA)	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget	FY 2021 President's Budget +/- FY 2020
Total Program Level Funding (OMHA)	182,381	172,381	173,908	+1,527
Proposed User Fee Collections (Mandatory)	-	-	1,527	+1,527
OMHA Discretionary Budget Authority	182,381	172,381	172,381	-
Total Program Level Funding (DAB) /1	-	19,500	24,900	+5,400
Proposed User Fee Collections (Mandatory) /1	-	-	900	+900
DAB Discretionary Budget Authority /1	-	19,500	24,000	+4,500
TOTAL Medicare Hearings and Appeals /2	182,381	191,881	198,808	+6,927

1/ For display purposes, FY 2019 DAB funding levels are reflected in the GDM section of the Congressional Justification.
2/ 2020 and 2021 funding levels for OMHA and DAB represent HHS allocations from the overall MHA appropriation, which are subject to change based on actual incoming appeal receipt levels and statuses of appeal backlogs at each organization.

The **Office of Medicare Hearings and Appeals (OMHA)** was created in response to the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA). As mandated by MMA, OMHA began operation on July 1, 2005, to hear Medicare appeals at the Administrative Law Judge (ALJ) level, for cases brought under titles XVIII and XI of the Social Security Act. For FY 2021, the President's Budget requests $173,908,000 in program level funding and 1,245 FTE.

The **Departmental Appeals Board (DAB)** provides impartial, independent hearings and appellate reviews, and issues federal agency decisions pursuant to more than 60 statutory provisions governing HHS programs. DAB's Medicare-related work is funded from the Medicare Hearings and Appeals appropriation. For FY 2021, the President's Budget requests $24,900,000 in program level funding and 94 FTE for such Medicare-related work.

OMHA and DAB's Medicare adjudicative related expenses are funded from the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds. This request also includes a suite of legislative re-proposals to address the backlog of Medicare appeals and to improve the Medicare appeals process.

Appropriations Language Analysis

The FY 2020 "Labor, Health and Human Services, Education, and Related Agencies" appropriation changed the language of OMHA's appropriation to allow all costs of Medicare Hearings and Appeals in the Office of the Secretary to be charged to a new appropriation. The two offices within the Office of the Secretary that are funded by this new appropriation are the Office of Medicare Hearings and Appeals (OMHA) and the Departmental Appeals Board (DAB). Funding between these two offices will be allocated each year by the Secretary and are subject to change based on actual incoming appeal and receipt levels and statuses of appeal backlogs at each organization.

The FY 2021 President's Budget adopts the new appropriations language and requests $196,381,000 in discretionary budget authority for the "Medicare Hearings and Appeals" appropriation from which OMHA is allocated $172,381,000 and DAB is allocated $24,000,000. An additional $1,527,000 and $900,000 is proposed for user fees to address OMHA and DAB administrative costs from unfavorable non-beneficiary appeals, respectively. These allocations are subject to change.

Appropriations Language

MEDICARE HEARINGS AND APPEALS

For expenses necessary for Medicare hearings and appeals in the Office of the Secretary, [$191,881,000] *$196,381,000* shall remain available until September 30 [2021], *2022*, to be transferred in appropriate part from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund.

Legislative Proposals

The 2021 President's Budget request includes the following legislative re-proposals to improve the Medicare appeals system:

Change the Medicare Appeal Council's Standard of Review
Change the standard of review for the DAB Medicare Appeals Council ("Council") from de novo to an appellate-level standard of review. Under the proposal, the Council may grant a request for review of a decision by an administrative law judge (ALJ) or other OMHA adjudicator of Medicare claims only if (1) there is an abuse of discretion; (2) there is an error of law material to the outcome of the case; (3) the findings of fact are not supported by substantial evidence; or (4) there is a need to clarify an important question of law, policy, or fact. The proposal also clarifies that the Council may deny a request for review.

Establish Post-Adjudication User Fee for Level 3 & 4 Unfavorable Medicare Appeals
Institute a post-adjudication user fee for all Medicare appeals (other than beneficiary appeals) which are denied, or otherwise receive unfavorable disposition, by the Office of Medicare Hearings and Appeals (the 3rd level of appeals), and the Departmental Appeals Board (the 4th level of appeals). The user fee amount will support a portion of administrative costs required to adjudicate appeals and will serve as a disincentive for frivolous appeals.

Expedite Procedures for Claims with No Material Fact in Dispute
Allow the Office of Medicare Hearings and Appeals to issue decisions without holding a hearing if there is no material fact in dispute. These cases include, for example, appeals in which Medicare does not cover the cost of a particular drug or the Administrative Law Judge (ALJ) cannot find in favor of an appellant due to binding limits on authority. Because the decision would be unfavorable to the appellant, the appellant could request review by the Medicare Appeals Council of the Departmental Appeals Board.
Increase Minimum Amount in Controversy for Administrative Law Judge Adjudication of Claims to Equal

Amount Required for Judicial Review
Increase the minimum amount in controversy required for adjudication by an Administrative Law Judge (ALJ) to the Federal Court amount in controversy requirement ($1,670 in CY 2020) (see Social Security Act § 1869(b)(1)(E)). The minimum amount in controversy would increase annually, consistent with the adjustment methodology set forth in section 1869(b)(1)(E)(iii). Appeals not reaching the proposed minimum amount in controversy, but that have an amount in controversy greater than $170 (annually adjusted), will be adjudicated by a Medicare magistrate. Also, the proposal would require appeals that are aggregated to meet the amount in controversy requirement at the OMHA level to be processed as a single action at the ALJ and subsequent levels of appeal. Additionally, the proposal would adjust the calculation of the amount in controversy to be based on the established Medicare payment amount rather than the billed amount when the payment amount is available to more accurately represent the amount in dispute. Beneficiaries would be protected with an additional provision that would exempt their claims from the established payment amount in controversy calculation method if the beneficiary would be liable for the billed amount. This proposal would apply only to Medicare Parts A and B fee-for-service claims.

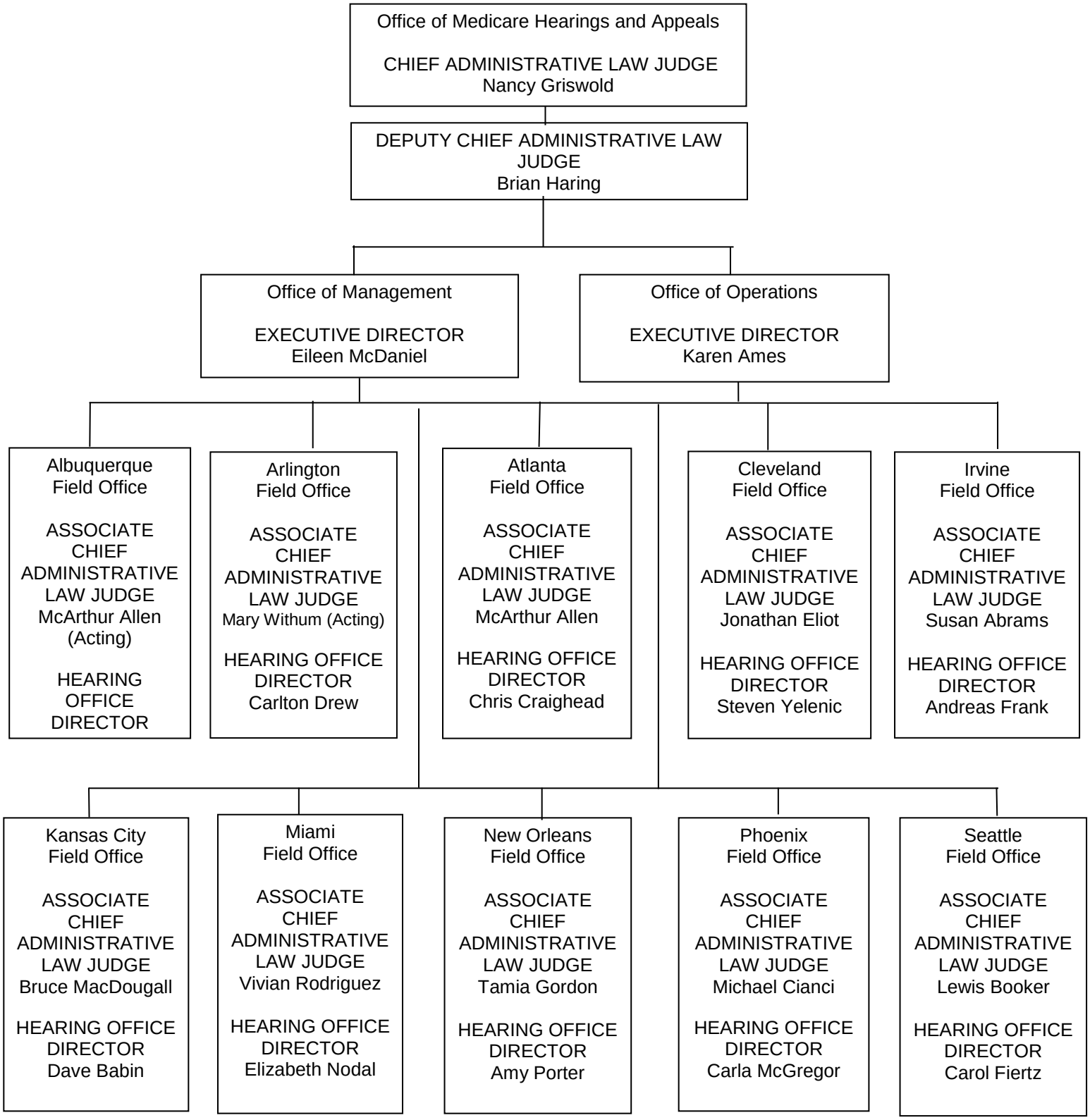
Establish Magistrate Adjudication for Claims with Amount in Controversy Below New Administrative Law Judge Amount in Controversy Threshold
Allow the Office of Medicare Hearings and Appeals (OMHA) to use Medicare Magistrates for Medicare Part A and Part B appeals below the federal district court amount in controversy threshold ($1,670 in calendar year 2020 and updated annually) and above $170.

Limit Appeals When No Documentation is Submitted
Under this proposal, the QIC or ALJ would dismiss a provider's or supplier's appeal of a Medicare fee-for-service claim denied at the redetermination level if no documentation was submitted to the QIC to support the items or services billed. An exception would exist for appeals filed by a beneficiary who has been determined financially responsible for the items or services. If no documentation is submitted to the Qualified Independent Contractor (QIC) at Level 2 of the appeals process, the request for reconsideration is dismissed by the QIC. If a provider or supplier appeals the QIC dismissal, an OMHA attorney adjudicator will perform a limited scope review, to ensure the basis for the QIC dismissal was correct.

Remand Appeals to the Redetermination Level with the Introduction of New Evidence
With this proposal, a Medicare appeal could be remanded to the redetermination (first) level of review at a Medicare Administrative Contractor (MAC) when new documentary evidence is submitted into the administrative record at the second or subsequent level of appeal. Exceptions may be made if evidence was provided to the lower level adjudicator but erroneously omitted from the record, or an adjudicator denies an appeal on a new and different basis from earlier determinations.
Require a Good-Faith Attestation on All Appeals

This proposal would (a) require all appellants or representatives of appellants to attest in their initial appeal filing that they are submitting the appeal under an objectively reasonable and good-faith belief that they are entitled to receive Medicare payment based on having provided a medically necessary service to a Medicare beneficiary; and (b) authorize the Secretary to sanction or impose civil monetary penalties on appellants who submit attestations that are found to be either unreasonable or made in bad faith. Beneficiaries are excluded from this proposal.

OMHA - Organizational Chart



Organizational Chart (Text Version)

Office of Medicare Hearings and Appeals

- Chief Administrative Law Judge, Nancy Griswold
- Deputy Chief Administrative Law Judge, Brian Haring

The following offices report directly to the Chief Administrative Law Judge:

- Executive Director, Office of Management, Eileen McDaniel
- Executive Director, Office of Operations, Karen Ames
- Albuquerque Field Office
  - Associate Chief Administrative Law Judge, McArthur Allen (Acting)
  - Hearing Office Director, Larry Brenden
- Arlington Field Office
  - Associate Chief Administrative Law Judge, Mary Withum (Acting)
  - Hearing Office Director, Carlton Drew
- Atlanta Field Office
  - Associate Chief Administrative Law Judge, McArthur Allen
  - Hearing Office Director, Chris Craighead
- Cleveland Field Office
  - Associate Chief Administrative Law Judge, Jonathan Eliot
  - Hearing Office Director, Steven Yelenic
- Irvine Field Office
  - Associate Chief Administrative Law Judge, Susan Abrams
  - Hearing Office Director, Andreas Frank
- Kansas City Field Office
  - Associate Chief Administrative Law Judge, Bruce MacDougall
  - Hearing Office Director, David Babin
- Miami Field Office
  - Associate Chief Administrative Law Judge, Vivian Rodriguez
  - Hearing Office Director, Elizabeth Nodal
- New Orleans Field Office
  - Associate Chief Administrative Law Judge, Tamia Gordon
  - Hearing Office Director, Amy Porter

- Phoenix Field Office
  - Associate Chief Administrative Law Judge, Michael Cianci
  - Hearing Office Director, Carla McGregor

- Seattle Field Office
  - Associate Chief Administrative Law Judge, Lewis Booker
  - Hearing Office Director, Carol Fiertz

Introduction and Mission

The Office of Medicare Hearings and Appeals (OMHA), headed by the Chief Administrative Law Judge, is a Staff Division of the Office of the Secretary in the U.S. Department of Health and Human Services (HHS). OMHA administers the third level of appeals, nationwide, for the Medicare program. OMHA ensures that Medicare beneficiaries, providers, and suppliers have access to an independent forum and opportunity for a hearing conducted pursuant to the Administrative Procedure Act on disputed Medicare claims. By providing a timely and impartial review of Medicare appeals, OMHA encourages providers and suppliers to continue to provide services and supplies to Medicare beneficiaries. Such access to timely adjudication of disputes is essential to the integrity of the Medicare system. On behalf of the Secretary of HHS, the Administrative Law Judges (ALJs) within OMHA conduct impartial hearings and issue decisions on claim determination appeals involving Medicare Parts A, B, C, D, as well as Medicare entitlement and eligibility appeals.

Mission

OMHA is a responsible forum for fair, credible, and timely decision-making through an accomplished, innovative, and resilient workforce. Each employee makes a difference by contributing to shaping American health care.

Vision

World class adjudication for the public good.

Statutory Decisional Timeframe

The Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) envisions that OMHA will issue decisions on appeals of Part A and Part B Qualified Independent Contractor (QIC) reconsiderations within 90 days after a request for hearing is filed.

Overview of Budget Request

The FY 2021 President's Budget request for OMHA is $173,908,000 at a program level, which is $1,527,000 above the HHS allocated FY 2020 funding level. The request is composed of $172,381,000 in two-year discretionary budget authority and $1,527,000 in proposed user fee collections (mandatory budget authority). This request also includes a suite of eight legislative re-proposals to improve the efficiency and integrity of the Medicare appeals process. With this budget request level and projected FY 2020 carryover funding, OMHA will be able to sustain a staffing level of approximately 155 ALJ teams and 1,245 FTE. The sustainment of this staffing level is critical to OMHA's ability to eliminate the backlog of appeals, as currently projected in FY 2022, and restore a balance with future annual receipt levels. OMHA also requests the continuation of two-year appropriation, which allows OMHA to be more flexible to demand changes and provides a mechanism to address uncertain annual receipt levels in the out-years.

Overview of Performance

Introduction

OMHA remains committed to continuous improvement in the Medicare appeals process by implementing initiatives to enhance the quality and timeliness of its services within its statutory authorities and funding levels. Through Departmental initiatives, increased process efficiency, and targeted addition of support staff, OMHA has streamlined its business processes and has implemented a number of new initiatives to improve performance without sacrificing program integrity.

Issue: Backlog Growth and Processing Time

As OMHA's workloads continued to grow dramatically for many years, it became impossible for OMHA to achieve its timeliness goals. The most significant growth occurred between FY 2010 and FY 2014, when appeals grew by 1,222 percent, while funding levels increased by only 16 percent. Although the exponential growth in appeals has slowed since FY 2014, the result has been a backlog of appeals that could not be adjudicated within the 90-day period as required by statute. The dramatic increase in appeals and lack of capacity to handle the appeals has had a detrimental impact on OMHA's mission of ensuring that Medicare beneficiaries, providers, and suppliers have access to an independent forum and opportunity for a hearing conducted pursuant to the Administrative Procedure Act on disputed Medicare claims. There are four primary drivers of the increase in appeals volume: (1) increases in the number of beneficiaries; (2) updates and changes to Medicare and Medicaid coverage and payment rules; (3) growth in appeals from Medicaid State Agencies with respect to dual eligible beneficiaries; and (4) national implementation of the Medicare Fee-for-Service Recovery Audit Contractor (RAC) Program.

The ongoing backlog has predictably increased OMHA's average processing time. OMHA has not been able to issue decisions within the statutorily required 90 days for BIPA appeals since 2010 (excluding beneficiary appeals that are given top priority). The average processing time on closed workload rose to 1,372 days in FY 2019 (data as of end of FY 2019). The average age of pending appeals at OMHA has also risen, and measures 1,525 days (data as of end of FY 2019), far above the 90-day adjudication time frame directed by BIPA. These statistics indicate that processing times will continue to increase in the short-term until the backlog of pending appeals has been substantially reduced.

The drastic backlog growth and increasing processing time is the subject of a lawsuit, *American Hospital Association v. Azar*. Pursuant to a November 2018 ruling, the Secretary of HHS is operating under a mandamus order, directing specific annual reduction targets in the appeals backlog leading to elimination in 2022.

In response to the increasing backlog and deteriorating processing time, HHS implemented Departmental initiatives and OMHA increased its adjudicatory capacity. OMHA also prioritized beneficiary appeals in order to ensure timely adjudication of their appeals.

Action: Departmental Initiatives

Various Departmental initiatives have improved OMHA's pending appeals backlog in the short term. Such initiatives include the Centers for Medicare & Medicaid Services (CMS) Part A Hospital Appeals Settlement Process and OMHA's Settlement Conference Facilitation (SCF). The largest initiatives have resulted in sizable one-time reductions in OMHA's pending workload, which were possible due to economies of scale.

Unfortunately, these dramatic, one-time reductions are not repeatable for several reasons. First, a large percentage of the appeals remaining unresolved at OMHA were filed by appellants that are currently the subject of program integrity investigations and, therefore, ineligible for settlement. Second, settlement of appeals, without a reasonable review of the underlying claims, undermines Medicare's responsibility to protect the Medicare Trust Funds and can result in unnecessary cost to the taxpayer. Third, the settlement of large numbers of appeals without consideration of the merits of the underlying claims would encourage the filing of future meritless appeals, and could increase the number of frivolous appeals filed at OMHA.

Even if these concerns are overcome, the settlement of large numbers of appeals without taking contemporaneous steps to sustain the current level of adjudication capacity at OMHA to handle incoming receipts achieves only temporary relief. Without maintaining adjudication capacity sufficient to handle the level of annual appeal receipts – which has been achieved in recent budget increases – the backlog will grow again. HHS's administrative actions address the growing receipt levels, but sustained funding is still necessary to support appropriate adjudication capacity levels.

Action: Adjudication Capacity

Appeals backlog elimination is a multi-year effort that requires not only continued reductions achieved by Departmental administrative initiatives, but also requires that the full adjudicatory capacity of the FY 2018 and FY 2019 ALJ team expansions be maintained. Over the past two years, OMHA has increased adjudicatory capacity through the opening of four new offices and the hiring of additional personnel, for a total of approximately 1,300 staff, roughly double the agency staffing level in FY 2017.

OMHA has also sought to increase its adjudication capacity by repurposing some of its most experienced attorneys as adjudicators with limited authority through regulatory change, but its ability to do so is limited. On March 20, 2017, OMHA gained regulatory authority for an Attorney Adjudicator program allowing senior attorneys (attorney-adjudicators) to decide cases which do not require a hearing, issue remands, dismiss a request for hearing when the appellant withdraws, and dismiss a request for review for any reason. This program frees ALJs to devote more time to actual hearings, which is a task that only an ALJ may perform under current law. However, the impact of the attorney adjudicator process is largely limited by appellants' willingness to waive the right to a hearing.

Because the Social Security Act provides appellants a right to a hearing before an ALJ, the success of OMHA's other administrative initiatives aimed at increasing productivity (e.g., settlement conference facilitations, statistical sampling, etc.) are similarly at the discretion of appellants.

Action: Beneficiary Prioritization

Although adjudication delays at OMHA have impacted almost all categories of appellants, OMHA is able to support its most vulnerable stakeholders by prioritizing appeals filed by beneficiaries. The average wait time to disposition for prioritized beneficiary appeals has decreased from 244 days for appeals filed in FY 2013, to 66 days for appeals filed in FY 2019. This processing time supports the conclusion that, when properly resourced, OMHA is able to resolve most pending appeals within the required statutory timeframe.

Impact: Productivity, Processing Time, and Backlog

Adjudication teams have more than doubled their productivity since 2009. In addition, creative solutions implemented as part of HHS's administrative initiatives, combined with ALJ team productivity increases, have reduced the agency's pending backlog by over 65%, from a high of approximately 900,000 pending appeals at the beginning of FY 2016 to 292,517 as of end of FY 2019.

Transparency: Customer Education

In addition, OMHA routinely informs and educates the appellant community on the status of the OMHA program, challenges related to the appeals backlog, and available options for appellants. Throughout the past year, OMHA organized and participated with CMS in dozens of presentations, conferences, meetings, open door calls, and listserv messages to the appellant community. A primary goal of the stakeholder outreach efforts is to be as transparent as possible about the challenges faced by the appeals system and to keep appellants informed about current initiatives, pending pilots, demonstration projects, and evolving plans designed to address the workload at all levels of Medicare appeals.

Feedback: Customer Surveys

OMHA also continues its support of the HHS Strategic Goal 5: Promote Effective and Efficient Management and Stewardship, in part through ongoing evaluation of its customer service through an independent assessment that captures the scope of the OMHA appeals adjudication experience by randomly surveying selected appellants and appellant representatives. This strategic goal calls for OMHA to achieve a 3.4 level of appellant satisfaction, to ensure appellants and related parties are satisfied with their Medicare appeals experience, regardless of the outcome of their appeal. The measure is evaluated on a scale of 1 to 5, with 1 representing the lowest score (very dissatisfied) and 5 representing the highest score (very satisfied). In FY 2019, OMHA achieved a 3.5 level of overall appellant satisfaction, exceeding the FY 2019 target. Despite meeting the overall satisfaction level goal, the delays in adjudication have had a predictably detrimental impact on satisfaction scores, as the non-beneficiary appellants' frustration with the amount of time it takes for cases to be assigned to an adjudicator continues to rise. Here, the non-beneficiary appellants rated this part of the process only a 2.5 out of a possible 5, decreasing OMHA's satisfaction scores in other areas. Moreover, the overall level of appellant satisfaction still falls short of the 4.3 recorded in FY 2010, prior to increases in processing times that resulted from the backlog of pending appeals.

Summary

The combination of Departmental initiatives, adjudication capacity increases, legislative changes, and sustained resources is the best solution for improving OMHA's performance. This multi-faceted approach is anticipated to eliminate the appeals backlog, comply with court orders, and improve customer satisfaction in the upcoming years. Moreover, the increased productivity will facilitate the long-term achievement of the legislatively mandated 90 day processing time for hearings.

All Purpose Table

(Dollars in Thousands)

OMHA /1	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget	FY 2021 President's Budget +/- FY 2020
Total, Program Level Funding	182,381	172,381	173,908	+1,527
Less: Proposed User Fee Collections (Mandatory)	-	-	1,527	+1,527
Total, OMHA Discretionary Budget Authority	182,381	172,381	172,381	-

1/ 2020 and 2021 funding levels for OMHA and DAB represent HHS allocations from the overall MHA appropriation, which are subject to change based on actual incoming appeal receipt levels and statuses of appeal backlogs at each organization.

Authorizing Legislation……..Titles XVIII and XI of the Social Security Act
FY 2021 Authorization……Indefinite
Allocation Method……..Direct Federal

Amounts Available for Obligation

OMHA Detail	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget
Trust Fund Discretionary Appropriation			
OMHA Discretionary Appropriation	182,381	172,381	172,381
Total, Discretionary Appropriation	182,381	172,381	172,381
Mandatory Appropriation			
Proposed User Fee Collections	-	-	1,527
Unobligated balance lapsing	*	-	-
Total Obligations	*164,000	172,381	173,908

*FY 2019 is a two-year appropriation. OMHA will obligate such appropriations until expended in FY 2020.
**2020 and 2021 funding levels for OMHA and DAB represent HHS allocations from the overall MHA appropriation, which are subject to change based on actual incoming appeal receipt levels and statuses of appeal backlogs at each organization. *This approach is assumed in all further tables.*

Summary of Changes

OMHA Budget Year and Type of Authority	Dollars	FTE
FY 2020 Enacted	172,381	1,300
FY 2021 President's Budget	173,908	1,245
Net Change	+1,527	-55

OMHA Increases and Decreases	FY 2020 Enacted	FY 2021 PB FTE	FY 2021 PB BA	FY 2021 +/- FY 2020 FTE	FY 2021 +/- FY 2020 BA
Full-time permanent	94,370	1,245	103,883	-55	+9,513
Other personnel compensation	927	-	1,024	-	+97
Civilian personnel benefits	30,678	-	34,060	-	+3,382
Travel and transportation of persons	440	-	280	-	-160
Transportation of things	600	-	240	-	-360
Rental Payments to GSA	9,750	-	8,337	-	-1,413
Communications, utilities, and misc. charges	8,200	-	7,784	-	-416
Printing and reproduction	139	-	638	-	+499
Other services from non-Federal sources	13,100	-	2,315	-	-10,785
Others goods and services from Federal sources	9,000	-	10,445	-	+1,445
Operation and maintenance of facilities	1,500	-	1,220	-	-280
Operation and maintenance of equipment	2,000	-	3,115	-	+1,115
Supplies and materials	927	-	504	-	-423
Equipment	750	-	63	-	-687
Total Increases	172,381	1,245	173,908	-55	+1,527

Budget Authority by Activity - Direct

(Dollars in Thousands)

OMHA Activity	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget
Discretionary Budget Authority	182,381	172,381	172,381
Discretionary Budget Authority, FTE	853	1,300	1,245

Authorizing Legislation

(Dollars in Thousands)

Medicare Hearings and Appeals	FY 2020 Amount Authorized	FY 2020 Amount Appropriated	FY 2021 Amount Authorized	FY 2021 President's Budget
Medicare Hearings and Appeals, Social Security Act, Titles XVIII and XI	Indefinite	191,881	Indefinite	196,381
Total Appropriation	-	**191,881**	-	**196,381**

Appropriations History Table

OMHA Details	Budget Estimates to Congress	House Allowance	Senate Allowance	Appropriation
2012	-	-	-	-
Trust Fund Appropriation	81,019,000	71,147,000	71,147,000	72,147,000
Rescissions (P.L. 112-74)	-	-	-	(136,000)
Subtotal	81,019,000	71,147,000	71,147,000	72,011,000
2013	-	-	-	-
Trust Fund Appropriation	84,234,000		79,908,000	72,010,642
Rescissions (P.L. 113-6)	-	-	-	(144,021)
Sequestration (P.L. 112-25)	-	-	-	(3,622,567)
Transfers	-	-	-	1,200,000
Subtotal	84,234,000	-	79,908,000	69,444,054
2014	-	-	-	-
Trust Fund Appropriation	82,381,000	-	82,381,000	82,381,000
Subtotal	82,381,000	-	82,381,000	82,381,000
2015	-	-	-	-
Trust Fund Appropriation	100,000,000	-	-	87,381,000
Subtotal	100,000,000	-	-	87,381,000
2016	-	-	-	-
Trust Fund Appropriation	140,000,000	-	-	107,381,000
Subtotal	140,000,000	-	-	107,381,000
2017	-	-	-	-
Trust Fund Appropriation	120,000,000	107,381,000	112,381,000	107,381,000
Subtotal	120,000,000	107,381,000	112,381,000	107,381,000
2018			-	-
Trust Fund Appropriation	117,177,000	112,381,000	107,381,000	182,381,000
Subtotal	117,177,000	112,381,000	107,381,000	182,381,000
2019				
Trust Fund Appropriation	112,381,000	172,381,000	182,381,000	182,381,000
Subtotal	112,381,000	172,381,000	182,381,000	182,381,000
2020*	182,381,000			
Trust Fund Appropriation	182,381,000	182,381,000	182,381,000	191,881,000
Subtotal	182,381,000	182,381,000	182,381,000	191,881,000
2021*				
Trust Fund Appropriation	196,381,000			
Subtotal	196,381,000			

*For the first time, FY 2020 Enacted included a new Medicare Hearings and Appeals appropriation, which consolidated resources for OMHA and DAB's Medicare hearings and appeals related activities. The FY 2021 Budget level is for MHA overall.

Narrative by Activity

Program Description and Accomplishments

OMHA opened its doors in July 2005, pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), which sought to respond to the delays in processing of Medicare appeals that existed at the Social Security Administration (SSA) by establishing an Administrative Law Judge (ALJ) hearing forum dedicated solely to the adjudication of Medicare benefit appeals. According to the Government Accountability Office (GAO), SSA ALJs took on average 368 days to resolve appeals in 2003. While SSA had no statutory timeframe for case adjudication, the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) envisioned that Medicare appeals would be decided by OMHA within 90 days of filing. Furthermore, the MMA provided for the addition of ALJs and staff as needed to insure the "timely action on appeals before administrative law judges" (MMA § 931(c), 117 Stat. 2398–99). However, from FY 2010 to FY 2017, funding was not appropriated at a level which would allow OMHA to handle the volume of appeals being received, and a backlog of appeals awaiting disposition developed.

OMHA serves a broad sector of the public, including Medicare service providers and suppliers and Medicare beneficiaries who are often elderly and/or disabled. Ensuring that providers and suppliers have a forum for independent and timely resolution of their disputes over Medicare payments also contributes to the security of the Medicare system by encouraging the provider and supplier community to continue to provide services and supplies to Medicare beneficiaries. OMHA administers its program in ten field offices, including Albuquerque, New Mexico; Arlington, Virginia; Atlanta, Georgia; Cleveland, Ohio; Irvine, California; Kansas City, Missouri; Miami, Florida; New Orleans, Louisiana; Phoenix, Arizona; and Seattle, Washington.

At the time of OMHA's establishment, it was envisioned that OMHA would receive a traditional workload of Medicare Part A and Part B fee-for-service benefit claim appeals, and Part C Medicare Advantage program organization determination appeals. However, OMHA experienced an increased caseload, due to the legislative expansion of its original jurisdiction to include areas not originally envisioned to be within its authority. In 2007, OMHA was also given additional responsibility for conducting hearings and issuing decisions in Medicare Part B Income-Related Monthly Adjustment Amount (IRMAA) appeals.

OMHA also began receiving new cases as a result of the CMS Recovery Audit Contractor (RAC) program, which was piloted in six states beginning in 2007. This program included RAC reviews of Medicare Part A and Part B claims on a post-payment basis, and reviews for Medicare Secondary Payer recoupments. In January 2010, the RAC program became permanent and was expanded to all 50 States. As a result of this expansion, OMHA received nearly 433,000 RAC appeals between FY 2013 and FY 2014, 50 percent of the total agency appeal receipts, without receiving additional resources to handle this new workload. Although the RAC expansion legislation provided funding for the administrative costs of the program at CMS, OMHA is functionally and fiscally independent of CMS, and OMHA's administrative costs were not covered by the legislation. The number of RAC appeals has rapidly declined from FY 2015 to FY 2019; OMHA received only 774 RAC appeals in FY 2018 and just 485 RAC appeals in FY 2019. This rapid decrease is for two reasons: First, there was a lengthy pause in the RAC program while contracts were being re-competed. Second, the level of reviews by the contractors and the incentive structure of the

new contracts required higher accuracy scores on claims reviewed and overturn rates, which required more time to complete and reduced output.
Not only has the expansion of appeals from the RAC workload exacerbated OMHA's workload challenges, but OMHA's non-RAC (traditional) workload also increased significantly. Between FY 2013 and FY 2014, OMHA received 380,000 non-RAC appeals as CMS contractors (for example, Medicare Administrative Contractors and Zone Program Integrity Contractors) increased pre- and post-payment reviews. Although the exponential growth in non-RAC appeals has slowed since FY 2014, OMHA has still averaged roughly 75,000 non-RAC receipts the past three fiscal years.

Recognizing the importance of timely resolution of Medicare disputes, OMHA has taken a number of steps to maximize the productivity of its ALJ teams and improve the quality and timeliness of its services. These include:

- Development of OMHA's Electronic Case Adjudication Processing Environment (ECAPE) – Full implementation agency-wide began December 2018 and completed November 2019 using Nonrecurring Expenses Fund (NEF) resources. The NEF supported ECAPE development and partial Regional Office expansion by providing a total of $39 million to these efforts since 2013 through NEF notifications 2, 3, and 4A.

- Construction and opening of 4 new field offices (Atlanta, Albuquerque, Phoenix, New Orleans) and the hiring and training of approximately 80 new ALJs and 700 new positions office-wide.

- Revision of governing regulations (effective March 20, 2017) which (1) expanded OMHA's ability to process Level 3 appeals by authorizing attorney adjudicators to decide appeals that can be resolved without a hearing before an ALJ with appellant consent, (2) adopted a number of processing efficiencies at OMHA, and (3) resolved many areas of confusion among stakeholders.

- Prioritization of beneficiary appeals to optimize timely adjudication of beneficiary appeals – The average wait time to disposition for prioritized beneficiary appeals has decreased from 244 days for appeals filed in FY 2013, to 66 days for appeals filed in FY 2019.

- OMHA Case Policy Manual (OCPM) initiative to develop OMHA-wide common business practices for the adjudicative process.

- National Substantive Legal Training Program for new ALJs and attorneys and yearly judicial education to increase consistency in decision-making and address program integrity issues.

- Strategic case assignments to assign appellants with a large number of filings to a single ALJ (these "big box" assignments are then rotated among ALJs in accordance with the Administrative Procedure Act), facilitating potential consolidated proceedings and more efficient adjudication.

- Statistical Sampling Pilot to resolve large groups of appeals with appellant consent.

- Settlement Conference Facilitation (SCF) as a less costly alternative to ALJ hearings.

- Senior Attorney screening program to assist with identification and resolution of appeals which can be resolved without a hearing.

- Utilization of the Senior ALJ program, which allows for the reemployment of retired ALJs on a temporary and part-time basis.

5 Year Funding Table - OMHA

Fiscal Year	Amount
FY 2017	**$107,381,000**
FY 2018	$182,381,000
FY 2019	$182,381,000
FY 2020	$172,381,000
FY 2021 President's Budget	$173,908,000

1/ 2020 and 2021 funding levels for OMHA and DAB represent HHS allocations from the overall MHA appropriation, which are subject to change based on actual incoming appeal receipt levels and statuses of appeal backlogs at each organization.

FY 2021 Budget Request

The FY 2021 President's Budget request for the Office of Medicare Hearings and Appeals (OMHA) is $173,908,000, comprised of $172,381,000 in two-year discretionary budget authority and $1,527,000 in proposed user fee collections (mandatory budget authority), which is $1,527,000 above the HHS allocated FY 2020 funding level. This request also includes a suite of eight legislative re-proposals to improve the efficiency and integrity of the Medicare appeals process. At this budget request level and with projected FY 2020 carryover funds, OMHA will be able to staff approximately 155 ALJ teams and 1,245 FTE. The sustainment of this staffing level is critical to OMHA's ability to eliminate the backlog of appeals as currently projected in FY 2022, and restore an adjudicatory capacity balance with future annual appeal receipt levels.

To manage the flat funding allocation level, OMHA plans to leverage the high proportion of employee and fixed costs relative to total costs within a legal services agency. OMHA's projected staffing level in FY 2021 assumes normal employee attrition levels in FY 2020 and FY 2021. Consequently, OMHA projects that the cost savings realized from attrition will offset non-pay inflationary cost increases as well as career ladder and within-grade step increases for remaining staff.

The appropriate funding of OMHA is complicated by the elastic demand for its services. One factor that affects demand elasticity is program integrity decisions. The current projection to eliminate the backlog by FY 2022 assumes that receipts do not increase more rapidly than are currently reflected in HHS's workload estimates. These workload estimates are based on the assumption that the "status quo" will continue and that HHS will not undertake any additional program integrity efforts which would impact appeal receipt levels at OMHA. Some program integrity decisions could have a major impact on the number of appeal receipts.

Another factor that affects demand elasticity is the average processing times for appeals. The existence of processing times in excess of 1,000 days in recent years has had a deterrent effect on the quantity of incoming appeals. In the coming years, we expect the agency average processing time will decrease. Consequently, as the average processing time is reduced, it is anticipated beneficiaries and service providers may appeal in higher volumes, and therefore, appeal receipts may increase. Even if annual

receipts return to FY 2016 levels (which were not as large as FY 2014 levels), OMHA's current adjudicatory capacity projections could be insufficient to meet the demand, at least in the short term.

Besides elasticity in the number of appeals, the complexity of appeals also affects OMHA's ability to determine the funding necessary to address backlogs. During the past few years, HHS's backlog elimination efforts have resolved more straightforward Medicare appeals at lower levels. In the future, OMHA anticipates that a higher concentration of more complex and time-consuming appeals at its level will have a negative impact on total adjudication capacity per adjudicator. OMHA projects that the increased complexity of the appeals mix will reduce adjudication capacity per adjudicator from the prior ceiling of approximately 1,000 to approximately 800 appeals per ALJ team annually beginning in FY 2020.

Therefore, OMHA also requests additional program flexibility to address both the challenge of the elastic demand of its annual workload as well as the changing complexity of cases. Specifically, OMHA requests a continued two-year appropriation. With uncertain receipt levels in the out-years, the agency needs to be agile in staffing when demand vastly outstrips supply and, conversely, when receipt levels fall below expected projections. The ability to manage the ebb and flow of staffing with carryover funding would enable sustainment of an effective staffing level from year-to-year, with an ability to also fund surge capacity quickly. Agility in appropriations is also needed in funding the transition to more time-consuming and costly complex cases.

Summary

The FY 2021 President's Budget request positions OMHA to continue the significant progress made in reducing the backlog of pending appeals. With the sustainment of the significant investment in additional adjudicatory resources added in 2018 and 2019, OMHA will be able to eliminate the backlog, re-balance capacity with incoming receipts, and ultimately return to the 90-day processing times envisioned by statute in the coming years.

Outputs and Outcomes Table
OMHA

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2020 Target	FY 2021 Target	FY 2021 Target +/-FY 2020 Target
Reduce the percentage of decisions reversed or remanded on appeals to the Medicare Appeals Council. (Outcome)	FY 2019: 0.2% Target:1% (Target Exceeded)	1%	1%	Maintain
Retain the average survey results from appellants reporting good customer service on a scale of 1 - 5 at the Administrative Law Judge Medicare Appeals level (Outcome)	FY 2019: 3.5 Target: 3.4 (Target Exceeded)	3.4	3.4	Maintain

Budget Authority by Object Class
(Dollars in Thousands)

OMHA	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget	FY 2021 +/- FY 2020
Personnel Compensation:				
Full-time permanent (11.1)	77,000	94,370	103,883	+9,513
Other personnel compensation (11.5)	-	927	1,024	+97
Subtotal Personnel Compensation	77,000	95,297	104,907	+9,610
Civilian personnel benefits (12.1)	27,000	30,678	34,060	+3,382
Total Pay Costs	**104,000**	**125,975**	**138,967**	**+12,992**
Travel and transportation of persons (21.0)	1,000	440	280	-160
Transportation of things (22.0)	1,000	600	240	-360
Rental payments to GSA (23.1)	5,000	9,750	8,337	-1,413
Communications, utilities, and misc. charges (23.3)	4,000	8,200	7,784	-416
Printing and reproduction (24.0)	-	139	638	+499
Other Contractual Services:				
Other services from non-Federal sources (25.2)	13,000	13,100	2,315	-10,785
Other goods and services from Federal sources (25.3)	19,000	9,000	10,445	+1,445
Operation and maintenance of facilities (25.4)	5,000	1,500	1,220	-280
Operation and maintenance of equipment (25.7)	1,000	2,000	3,115	+1,115
Subtotal Other Contractual Services	**38,000**	**25,600**	**17,095**	**-8,505**
Supplies and materials (26.0)	3,000	927	504	-423
Equipment (31.0)	8,000	750	63	-687
Total Non-Pay Costs	**60,000**	**46,406**	**34,941**	**-11,466**
Total Budget Authority by Object Class*	**164,000**	**172,381**	**173,908**	**+1,527**

*Reflects program level funding.

Salaries and Expenses

(Dollars in Thousands)

OMHA	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget	FY 2021 +/- FY 2020
Personnel Compensation:				
Full-time permanent (11.1)	77,000	94,370	103,883	+9,513
Other personnel compensation (11.5)	-	927	1,024	+97
Subtotal Personnel Compensation	77,000	95,297	104,907	+9,610
Civilian personnel benefits (12.1)	27,000	30,678	34,060	+3,382
Total Pay Costs	**104,000**	**125,975**	**138,967**	**+12,992**
Travel and transportation of persons (21.0)	1,000	440	280	-160
Transportation of things (22.0)	1,000	600	240	-360
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Printing and reproduction (24.0)	-	139	638	+499
Other Contractual Services:				
Other services from non-Federal sources (25.2)	13,000	13,100	2,315	-10,785
Other goods and services from Federal sources (25.3)	19,000	9,000	10,445	+1,445
Operation and maintenance of facilities (25.4)	5,000	1,500	1,220	-280
Operation and maintenance of equipment (25.7)	1,000	2,000	3,115	+1,115
Subtotal Other Contractual Services	**38,000**	**25,600**	**17,095**	-8,505
Supplies and materials (26.0)	3,000	927	504	-423
Total Non-Pay Costs	**52,000**	**45,656**	**34,878**	**-10,778**
Total Salary and Expense	**156,000**	**171,631**	**173,845**	**+2,214**
Direct FTE	**853**	**1,300**	**1,245**	**-55**

Detail of Full Time Equivalents

OMHA Detail	FY 2019 Actual Civilian	FY 2019 Actual Military	FY 2019 Actual Total	FY 2020 Estimate Civilian	FY 2020 Estimate Military	FY 2020 Estimate Total	FY 2021 Estimate Civilian	FY 2021 Estimate Military	FY 2021 Estimate Total
Direct	853	-	853	1,300	-	1,300	1,245	-	1,245
Reimbursable	-	-	-	-	-	-	-	-	-
Total FTE	**853**	**-**	**853**	**1,300**	**-**	**1,300**	**1,245**	**-**	**1,245**

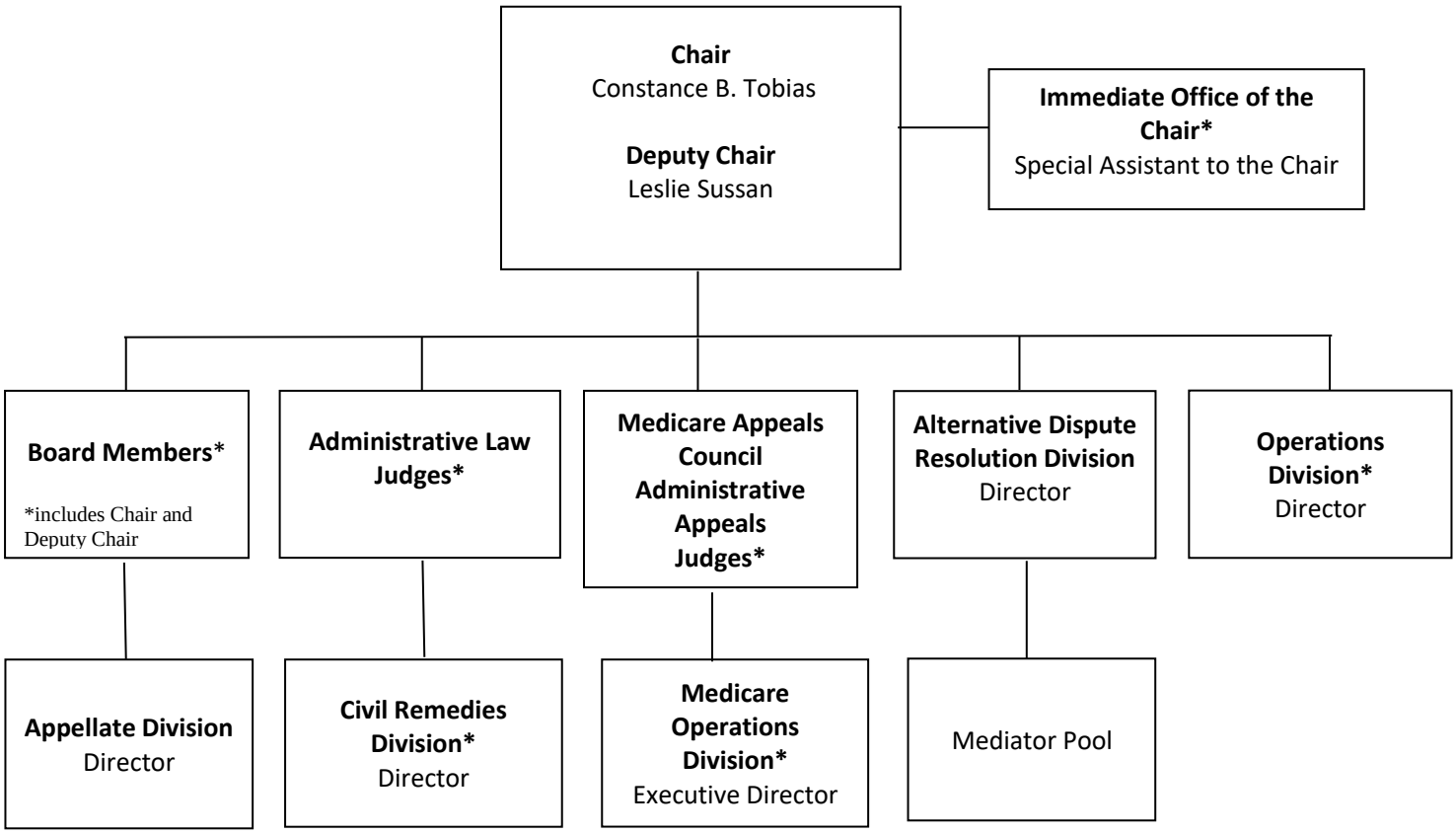
5 Year History of Average GS Grade - OMHA

Fiscal Year	Average GS
FY 2017	11/3
FY 2018	11/6
FY 2019	11/1
FY 2020	11/2
FY 2021	11/3

Detail of Positions

OMHA Detail	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget
ALJ I	1	1	1
ALJ II	11	11	11
ALJ III	154	155	155
Subtotal	166	167	167
Total – ALJ Salaries	21,144,203	27,811,445	28,368,674
ES	3	3	3
Total - ES Salaries	551,331	562,358	573,605
GS-15	16	16	16
GS-14	46	48	48
GS-13	80	86	94
GS-12	247	296	274
GS-11	93	123	152
GS-10	-	-	-
GS-9	161	172	156
GS-8	144	156	150
GS-7	104	116	122
GS-6	63	86	76
GS-5	30	44	38
GS-4	11	8	4
GS-3	-	-	-
GS-2	-	-	-
GS-1	-	-	-
Subtotal	995	1,151	1,130
Total - GS Salary	55,304,466	83,827,586	83,974,707
Total Positions	1,164	1,321	1,300
Total FTE	853	1,300	1,245
Average ALJ Salary	163,270	166,536	169,872
Average ES salary	183,777	187,453	191,202
Average GS grade	11/1	11/2	11/3
Average GS Salary	71,402	72,830	74,314

DAB Organizational Chart



*Denotes Divisions and staff performing Medicare-related work.

Introduction and Mission

The Departmental Appeals Board (DAB), a staff division within the Office of the Secretary, provides impartial, independent hearings and appellate reviews, and issues federal agency decisions pursuant to more than 60 statutory provisions governing HHS programs. The DAB provides high-quality adjudication and other conflict resolution services in administrative disputes involving HHS. Cases are initiated by outside parties who disagree with a determination made by an HHS agency or its contractor. Outside parties include States, universities, Head Start grantees, nursing homes, clinical laboratories, doctors, medical equipment suppliers, and Medicare beneficiaries. Disputes heard by the DAB may involve over $1 billion in federal funds in a single year. DAB decisions on certain cost allocation issues in grant programs have government-wide impact because HHS decisions in this area legally bind other Federal agencies. All of DAB's judges (Board Members, Administrative Law Judges (ALJs), and Administrative Appeals Judges (AAJs)) are appointed by the Secretary.

Mission

DAB's mission is to provide the best possible dispute resolution services for the people who appear before us, those who rely on our decisions, and the public.

The following principles guide us:

- We provide a great work environment for each other, we treat each other with respect, and we take pride in what each of us, and all of us, do.
- We are fair and impartial, and we always try to assure that our customers perceive us so.
- We do our job as promptly as possible.
- We deliver products which are thorough, well-reasoned, and written in concise, clear English.
- We value creativity and innovation, and we always seek better ways to do things in every part of our job.
- We each take personal responsibility for assuring that customers' needs are met.
- We help parties economize in case preparation.
- We empower parties to narrow and resolve issues on their own, or with the help of mediation or other alternative dispute resolution.

All Purpose Table

(Dollars in Thousands)

Departmental Appeals Board**	FY 2019 Final*	FY 2020 Enacted	FY 2021 President's Budget	FY 2021 +/- FY 2020
Total Program Level Funding		19,500	24,900	+5,400
Less: Proposed User Fee Collections (Mandatory)	-	-	900	+900
Total, DAB Discretionary Budget Authority		19,500	24,000	+4,500

*Funded by General Departmental Management in FY 2019. For display purposes, FY 2019 DAB funding levels are reflected in the GDM section of the Congressional Justification.

**2020 and 2021 funding levels for OMHA and DAB represent HHS allocations from the overall MHA appropriation, which are subject to change based on actual incoming appeal receipt levels and statuses of appeal backlogs at each organization.

Authorizing Legislation……..Titles XVIII and XI of the Social Security Act

FY 2021 Authorization……Indefinite

Allocation Method……..Direct Federal

Amounts Available for Obligation

DAB Detail	FY 2019 Final*	FY 2020 Enacted	FY 2021 President's Budget
Trust Fund Discretionary Appropriation			
DAB Discretionary Appropriation		19,500	24,000
Total, Discretionary Appropriation	-	19,500	24,000
Mandatory Appropriation			
Proposed User Fee Collections	-	-	900
Unobligated balance lapsing	-	-	-
Total Obligations**		19,500	24,900

* Funded by General Departmental Management in FY 2019. For display purposes, FY 2019 DAB funding levels are reflected in the GDM section of the Congressional Justification.

** 2020 and 2021 funding levels for OMHA and DAB represent HHS allocations from the overall MHA appropriation, which are subject to change based on actual incoming appeal receipt levels and statuses of appeal backlogs at each organization.

Summary of Changes

DAB Budget Year and Type of Authority	Dollars	FTE
FY 2020 Enacted	19,500	76
FY 2021 President's Budget	24,000	94
Net Change	+4,500	+18

DAB Increases (+) and Decreases (-)	FY 2020 Enacted	FY 2021 PB FTE	FY 2021 PB BA	FY 2021 +/- FY 2020 FTE	FY 2021 +/- FY 2020 BA
Full-time permanent	10,163	94	12,770	+18	+2,607
Other personnel compensation		-		-	
Civilian personnel benefits	3,570	-	4,415	-	+845
Travel and transportation of persons	5	-	5	-	-
Transportation of things	5	-	5	-	-
Rental Payments to GSA	2,000	-	2,000	-	-
Communications, utilities, and misc. charges	16	-	20	-	+4
Printing and reproduction	12	-	15	-	+3
Other services from non-Federal sources	1,040	-	1,771	-	+731
Others goods and services from Federal sources	1,116	-	1,216	-	+100
Operation and maintenance of facilities	1,523	-	1,723	-	+200
Operation and maintenance of equipment	-	-	-	-	-
Supplies and materials	50	-	60	-	+10
Equipment	-	-	-	-	-
Total Increases	-		+4,500	+18	

DAB Total Changes	FY 2021 FTE	FY 2021 PB	FY 2021 +/- FY 2020 FTE	FY 2021 +/- FY 2020 BA
Total Increases (+)	94	24,000	+18	+4,500
Total Decreases (-)	-	-	-	-
Total Net Change			+18	+4,500

Budget Authority by Activity - Direct

(Dollars in Thousands)

DAB Activity	FY 2019 Final*	FY 2020 Enacted	FY 2021 President's Budget
Discretionary Budget Authority **	-	19,500	24,000
Discretionary Budget Authority, FTE	-	76	94

*Funded by General Departmental Management in FY 2019. For display purposes, FY 2019 DAB funding levels are reflected in the GDM section of the Congressional Justification.

****** 2020 and 2021 funding levels for OMHA and DAB represent HHS allocations from the overall MHA appropriation, which are subject to change based on actual incoming appeal receipt levels and statuses of appeal backlogs at each organization**.**

Program Description and Accomplishments

Medicare Appeals Council – Medicare Operations Division (MOD)

MOD provides staff support to the Administrative Appeals Judges (AAJs) on the Medicare Appeals Council (Council). The Council provides the final administrative review within HHS of claims for entitlement to Medicare and individual claims for Medicare coverage and payment filed by beneficiaries or health care providers and suppliers. Under current law, Council decisions are based on a *de novo* review of decisions issued by ALJs in the Office of Medicare Hearings and Appeals (OMHA). CMS (or one of its contractors) and SSA may also refer ALJ decisions to the Council for own-motion review. In the majority of cases, the Council has a statutory 90-day deadline by which it must issue a final decision.

An appellant may also file a request with the Council to escalate an appeal from the OMHA ALJ level if the ALJ has not completed his or her action on the request for hearing within any adjudication deadline. In addition, the Council reviews cases remanded back to the Secretary from Federal court. MOD is responsible for preparing and certifying the administrative records of cases appealed to Federal court.

Cases may involve complex issues of law, such as appeals arising from overpayment determinations, non-sample audits, or statistical sampling extrapolations involving thousands of claims and high monetary amounts. Some cases, particularly those filed by enrollees in Medicare Advantage and prescription drug plans, require an expedited review (e.g., pre-service authorization for services or procedures or prior authorization for prescription drugs).

Since FY 2015, through a reimbursable agreement with CMS, MOD has adjudicated appeals filed under a CMS demonstration project with the State of New York. The demonstration project, called "Fully Integrated Duals Advantage" Plan (FIDA), offered an estimated 170,000 Medicare-Medicaid enrollees in New York an opportunity for more coordinated care. FIDA provided a streamlined appeals process which gave beneficiaries the opportunity to address denials of items and services through a unified system that included all Medicare and Medicaid protections. The FIDA project ended in December 2019. However, it has been replaced by a similar dual-eligible beneficiary demonstration project in FY 2020 for the State of New York, and MOD will continue adjudicating these types of appeals. The FIDA and new demonstration project cases are not included in the MOD workload chart below because of the low volume of these appeals at this time.

In FY 2019, MOD received 2,898 appeals and adjudicated 2,387. MOD also closed an additional 802 cases pursuant to administrative settlement agreements between CMS and certain categories of appellants. At the end of FY 2019, MOD had 17,682 pending appeals.

Administrative Law Judges – Civil Remedies Division (CRD)
DAB Administrative Law Judges (ALJs), supported by CRD staff, conduct adversarial hearings and issue decisions on the record in a wide variety of proceedings, including proceedings that are critical to HHS healthcare program integrity efforts to combat fraud, as well as quality of care concerns. Hearings in these cases may last a week or more. Cases may raise complex medical or clinical issues. Some cases require presentation of evidence to prove allegations of complicated fraudulent schemes. Cases may also raise legal issues of first impression, such as appeals of enforcement cases. CRD ALJs hear cases appealed from CMS or OIG determinations which exclude providers, suppliers, or other healthcare practitioners from participating in Medicare, Medicaid, and other federal healthcare programs, or impose civil monetary penalties (CMPs) for fraud and abuse in such programs. CRD jurisdiction also includes appeals from Medicare providers or suppliers, including cases under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). ALJs provide expedited hearings when requested in certain types of proceedings, such as provider terminations and certain nursing home CMP cases. These cases typically involve important quality of care issues. ALJs also hear cases that require testimony from independent medical/scientific experts (e.g., in appeals of Medicare Local Coverage Determinations (LCDs)).

In FY 2019, CRD received 1,142 new cases and closed 1,173, 247 by decision. Approximately 90% of the CRD casework is Medicare related.

Workload Statistics

Medicare Appeals Council – Medicare Operations Division
Chart A shows total historical and projected caseload data for MOD.

Assumptions on which the data are based include:

- In FY 2019, the retirement and departure of 4 Administrative Appeals Judges (AAJs) within a short time-period, resulting in a decrease in adjudication capacity for that year;
- In FY 2020, a 33 percent reduction in case receipts due to the impact of State Medicaid Agency settlements;
- In FY 2021, pursuant to the proposed legislation, a change in the Council's standard of review from "de novo" to an appellate level standard of review, increasing the adjudication capacity by approximately 30 percent;
- Increases in personnel in FY 2020 (24 FTE) and FY 2021 (16 FTE);
- An additional 708 cases closed in FY 2020 pursuant to administrative settlements;
- An increase in case receipts in FY 2020 and FY 2021 as a result of additional adjudications at OMHA;
- Increased overpayment cases (including Recovery Audit (RA) and statistical sampling cases);
- Increased CMS demonstration projects across the country;
- Participation in Department-wide administrative initiatives to improve efficiency within the Medicare appeals process and to address appeals as

early as possible; and

- Increased requests for certified administrative records in cases appealed to Federal court.

MEDICARE OPERATIONS DIVISION CASES – Chart A

Cases	FY 2019 (actual)	FY 2020	FY 2021
Open/start of FY	17,973	17,682	17,249
Received	2,898	4,275	6,618
Cases Closed	2,387	4,000	6,864
Administrative Settlements	802	708	-
Open/end of FY	17,682	17,249	17,003

Administrative Law Judges – Civil Remedies Division

Chart B shows caseload data for CRD. Approximately 90% of CRD casework is specific to Medicare related issues. All data are projected based on historical trends and certain assumptions, including:

- CMS's increased use of data analysis techniques to detect provider/supplier fraud and noncompliance, and continued implementation of new enforcement authorities;
- A slight increase, relative to historic baseline numbers, in the number of provider/supplier cases due to CMS's prioritization of program integrity enforcement efforts;
- New types of hearing requests, such as appeals pursuant to agreements under the Medicare Part D Prescription Drug Coverage Gap Discount Program, CMPs imposed under the 340B drug pricing program, appeals from individuals and entities placed on the preclusion list for Medicare Advantage and Part D plans, and appeals of CMPs imposed based on Medicare market conduct examinations;
- The Inspector General's increased focus on exclusion cases;
- An increase in the number of skilled nursing facility hearing requests, relative to historic expectations, based on the inflation adjustment of CMPs in those cases;
- No major regulatory changes; and
- An increase in personnel in FY 2021 of 2 FTEs (2 ALJs).

CIVIL REMEDIES DIVISION CASES – Chart B

Cases	FY 2019 (actual)	FY 2020	FY 2021
Open/start of FY	733	702	665
Received	1,142	1,142	1,142
Decisions	247	247	285
Total Closed	1,173	1,179	1,342
Open/end of FY	702	665	465

5 Year Funding Table - DAB

Fiscal Year	Amount
FY 2017*	-
FY 2018*	-
FY 2019*	-
FY 2020	$19,500,000
FY 2021 Request	$24,900,000

***Funded by the General Departmental Management appropriation.**
For display purposes, FY 2017 – FY 2019 DAB funding levels are reflected in the GDM section of the Congressional Justification.

FY 2021 Budget Request

The DAB has a large backlog of pending appeals as a result of increased Department program enforcement and integrity efforts. Most significantly, since FY 2010, the Medicare Operations Division (MOD) has received more appeals each year than it has the resources to adjudicate. As a result, MOD has a significant backlog of cases, even after recent settlements between appellants and CMS, and other administrative initiatives intended to decrease the number of appeals moving upstream to the third and fourth levels of appeal. As the final level of review, MOD maintains a complex, appellate-level docket with a diverse pool of appellants. While settlements and administrative initiatives have helped reduce the number of appeals involving repeat filers and recurring issues, most of MOD's remaining appeals involve low-volume filers, unique issues, or large dollar amounts, which cannot be easily resolved through large-scale settlements or other initiatives. The estimated total amount in controversy of all cases pending in MOD's backlog at the end of FY 2019 is more than $760 million.

The backlog in MOD is further complicated by the fact that OMHA received a substantial funding increase in FY 2018, while the DAB received no additional funding in FY 2018 or FY 2019. There is a direct correlation between OMHA dispositions and MOD receipts; due to the projected increase in OMHA's adjudication capacity, MOD's receipts are projected to increase to 6,618 appeals in FY 2021. It is projected that MOD will continue to receive more appeals than it can adjudicate each year. Without more resources, case receipts will continue to outpace adjudications and a large backlog of Medicare appeals will remain at the DAB.

Because of the backlog, MOD is unable to adjudicate appeals within the statutory 90-day timeframe. The DAB prioritizes beneficiary appeals, which typically account for 10 to 15 percent of MOD's annual receipts and for approximately 5 percent of the existing backlog. Although the DAB has recently made progress on these appeals, the backlog has still resulted in substantial delays for beneficiaries to receive decisions. The average adjudication time (from the date of filing to the date of adjudication) for beneficiary appeals over the last five years (FY 2015 to FY 2019) is 442 days. The average age of pending beneficiary appeals is 518 days. In addition to beneficiary appeals, MOD receives other types of appeals that it must prioritize, requiring MOD to reallocate its limited resources to address constantly changing adjudication priorities. For example, MOD must prioritize agency referrals filed by CMS, requiring MOD to redirect resources to these appeals, and away from beneficiary appeals, as soon as the referrals are

received. Similarly, MOD must prioritize Part C and D pre-service and expedited appeals, due to the medical urgency of these appeals, which delays the adjudication of other beneficiary appeals.

These circumstances have also presented other challenges for MOD. For example, because of large-scale payment recovery efforts by CMS contractors, many of the cases in the backlog are voluminous and complex statistical sampling and multi-claim overpayment cases, which require significant staff time to review and process. Similarly, while recent administrative settlements have removed a significant portion of cases from MOD's backlog, the process of identifying, collecting, closing, and shipping these settled cases has required a considerable amount of staff time. MOD must also prepare the administrative record for cases appealed to federal court, a process that further strains MOD's already limited staff resources.

The DAB's Civil Remedies Division (CRD) is also receiving substantially more appeals because of increased CMS program enforcement and integrity efforts. CRD's case receipts increased by 50 percent from FY 2016 to FY 2018. In FY 2019, receipts remained above historic numbers, as CRD received 23 percent more cases than in FY 2016. Further, CMS and other Department program enforcement and integrity efforts have also resulted in an ever-expanding jurisdiction for CRD, with new types of appeals being directed to CRD's ALJs (and the DAB's Board Members) for review. This growing workload has led to substantial delays in adjudication. Without corresponding resources, CRD ALJs will soon be unable to adjudicate cases within statutory and regulatory timeframes.

Budget Request

The FY 2021 President's Budget request for the Departmental Appeals Board (DAB) is $24,900,000 at a program level, which is $5,400,000 above the HHS allocated FY 2020 funding level. The request is composed of $24,000,000 in two-year discretionary budget authority and $900,000 in proposed user fee collections (mandatory budget authority). This request also includes legislative re-proposals to change the standard of review in Medicare appeals and implement an administrative user fee that impact DAB directly, as well as legislative re-proposals that aim to implement improvements to the overall appeals process.

At the FY 2021 Budget funding level, the DAB will be able to devote significant resources to MOD and CRD to increase the adjudication capacity of those divisions. Specifically, MOD will add AAJs, attorneys, and program support positions. These additional resources, along with the proposed legislative change to the Council's standard of review will increase the Council's adjudication capacity to approximately 6,864 cases per year, a 71 percent increase over the FY 2020 adjudication capacity level of 4,000. Importantly, while projected receipts in FY 2021 (6,618) will still be greater than MOD's adjudication capacity, receipt and adjudication levels will be more closely aligned than they have been since the backlog started. This will put MOD in a better position to keep pace with incoming appeals and make progress towards reducing the Medicare appeals backlog. DAB expects adjudication capacity in the out-years to increase once new staff are fully trained and are on-board for the full fiscal year.

With the additional funding in FY 2021, CRD will also add ALJs and supporting attorneys. This will reduce the average ALJ caseload from 176 cases per ALJ in FY 2019 and FY 2020 to 134 cases per ALJ in FY 2021. This enables CRD to reduce delays in adjudication and ensure that ALJs can adjudicate cases within statutory and regulatory timeframes. Further, with the Department's increased prioritization of program integrity efforts, and the resulting expansion of jurisdiction of CRD ALJs, the request puts CRD in a better position to meet its existing adjudication obligations; recover from the significant increase in

cases relative to historic receipts that occurred in FY 2017, FY 2018, and FY 2019; and meet its obligations in its new areas of jurisdiction.

The DAB will also add staff to the Immediate Office of the DAB Chair and Operations Division that support Medicare-related adjudication efforts. All DAB policy, oversight, information technology (IT), and administrative operations (e.g., budget, procurement, and human capital management) are consolidated into these two divisions. This structure allows judges and attorneys to focus solely on legal work, ensuring maximum productivity. A portion of the FY 2021 resources will be devoted to increasing administrative efficiency, improving oversight of the DAB's adjudicatory divisions, and addressing a myriad of other program challenges driven by growing workload demands. Similarly, the DAB has implemented several important IT solutions, including e-filing, digitization of paper claim files, cloud-based data storage, a new document generation system, case management systems integration with CMS, and ongoing enhancements to MOD's case processing system, and will direct resources to continued IT development, particularly in the areas of artificial intelligence and data analytics, as tools to collect, manage, and analyze case data. Another important IT goal for the DAB is to build upon its existing e-filing and electronic record systems and transform case processing in all of its adjudicatory divisions into a completely paperless process, and FY 2021 resources will be directed towards achieving this goal. Funding will also be directed to fund additional space costs associated with the increase in FTE.

Outputs and Outcomes Table

Measure - DAB	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2020 Enacted	FY 2021 President's Budget	FY 2021 +/- FY 2020
1.1.1 Percentage of CRD decisions issued within all applicable statutory and regulatory deadlines.	FY 2019: 59% Target 50% (Target Exceeded)	50%	50%	Maintain
1.1.2 Cases closed in a fiscal year as a percentage of total cases open in the fiscal year.	FY 2019: 82% Target: 50% (Target Exceeded)	50%	50%	Maintain
1.2.1 Average time to complete action on Requests for Review measured from receipt of the claim file.	FY 2019: 378 days Target: 1,036 days (Target Exceeded)	737 days	727 days	-10
1.2.2 Number of MOD dispositions.	FY 2019: 2,387 +802 (CMS Settlements) Target: 1,920 (Target Exceeded)	4,000	6,864	+2,864

Performance Analysis

DAB has made measurable progress in the strategic management of human capital by reengineering its operations and improving its case management techniques.

Civil Remedies Division

Measure 1.1.1 tracks the percentage of CRD decisions issued within all applicable statutory and regulatory deadlines. CRD exceeded Measure 1.1.1 in FY 2019. The target for this Measure will remain the same in FY 2020 and FY 2021. Without additional staff in FY 2020 to help reduce the growing backlog of pending appeals, CRD is at risk of failing to meet the target in FY 2020. However, with additional staff in FY 2021, CRD will be better positioned to meet the target in FY 2021.

Measure 1.2.1 tracks cases closed as a percentage of all cases open during the fiscal year. CRD exceeded its FY 2019 target by closing 63 percent of cases open that year. The FY 2020 and FY 2021 targets remain unchanged because many cases are complex, resulting in longer adjudication times. CRD expects to meet Measure 1.2.1 in both years, but will be challenged to do so if case receipts increase and/or if DAB is unable to add additional staff in FY 2020.

Medicare Operations Division

Measure 1.2.1 tracks how long it takes to close a case after MOD receives the claim file. However, MOD does not request the claim file until staff is available to work on the case. Therefore, the measure only reflects how long it takes MOD to close a case after the claim file for the case is received, not how long it takes from the date MOD receives the request for review to the date the Council issues a final decision. The larger the backlog, the longer it takes for MOD staff to be available to work on a new case and the longer the overall time for HHS to resolve Medicare claims. While the focus on closing high priority cases,

including Part C and D pre-service cases and beneficiary appeals, is designed to reduce the average time it takes to close a case, this effort was negated in FY 2019 by the consistent rate of growth of the Medicare appeals backlog and the loss of critical staff. New staff in FY 2020 and 2021, as well as the proposed legislative change in the standard of review, will improve the DAB's ability to address that trend moving forward.

Measure 1.2.2 tracks case closures, which are directly proportional to staffing. Projected case closures decreased in FY 2019 because of staff departures, but MOD was able to make up for some of those losses by implementing internal initiatives, including a new motions practice that streamlines the adjudication of cases involving procedural issues.

Budget Authority by Object Class

(Dollars in Thousands)

DAB	FY 2020 Enacted	FY 2021 President's Budget	FY 2021 +/- FY 2020
Personnel Compensation:			
Full-time permanent (11.1)	10,163	12,770	+2,607
Other personnel compensation (11.5)	-	-	-
Subtotal Personnel Compensation	10,163	12,770	
Civilian personnel benefits (12.1)	3,570	4,415	+845
Total Pay Costs	**13,733**	**17,185**	**+3,452**
Travel and transportation of persons (21.0)	5	5	-
Transportation of things (22.0)	5	5	-
Rental payments to GSA (23.1)	2,000	2,000	-
Communications, utilities, and misc. charges (23.3)	16	20	+4
Printing and reproduction (24.0)	12	15	+3
Other Contractual Services:			
Other services from non-Federal sources (25.2)	1,040	1,771	+731
Other goods and services from Federal sources (25.3)	1,116	1,216	+100
Operation and maintenance of facilities (25.4)	1,523	1,723	+200
Operation and maintenance of equipment (25.7)			
Subtotal Other Contractual Services	3,679	4,710	**+1,031**
Supplies and materials (26.0)	50	60	+10
Equipment (31.0)			
Total Non-Pay Costs	**5,767**	**6,715**	**+948**
Total Budget Authority by Object Class*	**19,500**	**24,000**	**+4,500**

*2020 and 2021 funding levels for OMHA and DAB represent HHS allocations from the overall MHA appropriation, which are subject to change based on actual incoming appeal receipt levels and statuses of appeal backlogs at each organization. This approach is assumed in all further tables.

Salaries and Expenses

(Dollars in Thousands)

DAB	FY 2020 Enacted	FY 2021 President's Budget	FY 2021 +/- FY 2020
Personnel Compensation:			
Full-time permanent (11.1)	10,163	12,770	2,407
Other personnel compensation (11.5)			
Subtotal Personnel Compensation	10,163	12,770	
Civilian personnel benefits (12.1)	3,570	4,415	+845
Total Pay Costs	**13,733**	**17,185**	**+3,452**
Travel and transportation of persons (21.0)	5	5	-
Transportation of things (22.0)	5	5	-
Rental payments to GSA (23.1)	2,000	2,000	-
Communications, utilities, and misc. charges (23.3)	16	20	+4
Printing and reproduction (24.0)	12	15	+3
Other Contractual Services:			
Other services from non-Federal sources (25.2)	1,040	1,771	+731
Other goods and services from Federal sources (25.3)	1,116	1,216	+100
Operation and maintenance of facilities (25.4)	1,523	1,723	+200
Operation and maintenance of equipment (25.7)			
Subtotal Other Contractual Services	3,679	4,710	+1,031
Supplies and materials (26.0)	50	60	+10
Total Non-Pay Costs			
Total Salary and Expense	**19,500**	**24,000**	**+4,500**
Direct FTE	**76**	**94**	**+18**

Detail of Full Time Equivalents

DAB Detail	FY 2019 Actual Civilian*	FY 2019 Actual Military**	FY 2019 Actual Total*	FY 2020 Estimate Civilian	FY 2020 Estimate Military	FY 2020 Estimate Total	FY 2021 Estimate Civilian	FY 2021 Estimate Military	FY 2021 Estimate Total
Direct	-	-	-	76	-	76	94	-	94
Reimbursable	-	-	-	-	-	-	-	-	-
Total FTE	**-**	**-**	**-**	**76**	**-**	**76**	**94**	**-**	**94**

* For display purposes, FY 2019 FTE levels are reflected in the GDM section of the Congressional Justification.

Good Accounting Obligation in Government Act (GAO-IG Act) Report

The information below addresses the requirements of the Good Accounting Obligation in Government Act (GAO-IG Act; Public Law 115-414) to provide a report identifying each public recommendation issued by the Government Accountability Office (GAO) and federal Offices of Inspectors General (OIG) which remains unimplemented for one year or more from the annual budget justification submission date. The recommendations below apply specifically to this division of HHS. Please refer to the General Departmental Management budget justification for more information on the Department's overall progress in implementing GAO and OIG recommendations.

Appendix 1: OIG-GAO Open Recommendations							
Report Number	**Report Title**	**Report Date**	**Recommendation Text**	**Concur / Non-Concur**	**Implementation Timeline**	**Implementation Status**	**Implementation Updates and Constraints**
GAO-16-366	Medicare Fee-For-Service: Opportunities Remain to Improve Appeal Process	6/9/2016	To reduce the number of Medicare appeals and to strengthen oversight of the Medicare FFS appeals process, the Secretary of Health and Human Services should direct CMS, OMHA, or DAB to modify the various Medicare appeals data systems to capture the amount, or an estimate, of Medicare allowed charges at stake in appeals in Medicare Appeals System (MAS) and Medicare Operations Division Automated Case Tracking System (MODACTS).	Concur	NA	In Progress	The DAB continues to explore the feasibility of tracking allowed amounts at Level 4. However, one constraint for the DAB is access to this type of data; this data must be provided to the DAB by prior levels or included in the record on appeal. In the meantime, DAB has started recording and tracking billed amounts in MODACTS, based on the information that is available in the record for each appeal.

GAO-16-366	Medicare Fee-For-Service: Opportunities Remain to Improve Appeal Process	6/9/2016	To reduce the number of Medicare appeals and to strengthen oversight of the Medicare FFS appeals process, the Secretary of Health and Human Services should direct CMS, OMHA, or DAB to modify the various Medicare appeals data systems to collect consistent data across systems, including appeal categories and appeal decisions across MAS and MODACTS	Concur	2018	Awaiting Disposition	CMS recommends closure on both recommendation 3 & 4 based on the following: MAS CR 747 was released in November 2016 and included revised Level 3 Appeal Categories. This functionality allows for consistent appeal categories at case closure when ECAPE transmits closed Level 3 appeals back to the appeals system of records, MAS. As of the end of April 2017, all Part A MACs were successfully onboarded to MAS. Since CMS' last reporting date, all MACs had passed their transition period and had attested to readiness in MAS and their desire to continue processing within the MAS environment and not roll back to their previous legacy systems. CMS continues efforts to seek funding for onboarding the remaining MACs (Part B and DME) onto MAS. Recently, CMS received FY18 funding for a pilot to partially onboard 1 Part B and 1 DME MAC to MAS for data collection, reporting, and case file transfers only. With this approach, MACs would continue to be able to innovate and experience in-house developed operational efficiencies using their internal workflow and correspondence systems, while also allowing CMS to explore enhanced monitoring of MAC Part B and DME workload. This solution will control MAC operational costs by incrementally allowing for seamless integration into their current workflow and not negatively impact current MAC operating budgets. Web services would assist MACs with updating MAS with data from their internal systems. To account for the complexity of incorporating this new type of workload in MAS, this pilot would allow all MAC jurisdictions to assist in the development of business requirements. In addition, as of the most recent MAS release in May 2018, CMS implemented CR 752 and the functionality to allow MAC users visibility into appeals histories at Levels 1, 2, and 3, associated to their organization's contract. This will greatly assist in data reporting consistency and allows MACs the ability to report on cases promoted to Level 3 that may not have been processed within MAS by their organization, but rather through a legacy system or the previous MAC jurisdiction contract holder that was uploaded to MAS by a Level 2 QIC contractor." The DAB continues to work towards developing system interoperability with OMHA's ECAPE system, which will help standardize and integrate data between Levels 3 and 4. Currently, the DAB is working with its IT contractor to developed APIs capable of importing and exporting data from ECAPE. In addition, the DAB actively participated in "IT Sprint," an interagency project led by the HHS Office of the Chief Technology Officer, which explored ways to integrate appeals data across all levels of review. Most recently, the project developed a prototype for a dashboard that would enable various stakeholders to obtain the status of individual or collective claims. The DAB has also established connectivity

							with CMS contractors for the electronic transfer and upload of claim files for appealed cases.

GAO-16-366	Medicare Fee-For-Service: Opportunities Remain to Improve Appeal Process	6/9/2016	To reduce the number of Medicare appeals and to strengthen oversight of the Medicare FFS appeals process, the Secretary of Health and Human Services should direct CMS, Office of Medicare Hearings and Appeals (OMHA), or Departmental Appeals Board (DAB) to modify the various Medicare appeals data systems to collect information on the reasons for appeal decisions at Level 3.	Concur	2020	Awaiting Disposition	OMHA recommends closure on this recommendation. In the July 2017 interim release of the Electronic Case Adjudication and Processing Environment (ECAPE) system, OMHA added a "Reason for Disposition" data field for most dispositions issued by an adjudicator. Because the "Reason for Disposition" data field limits the number of reasons that can be selected, OMHA added more categories in later releases. As of November 2019, ECAPE has been implemented in all of OMHA's field offices and its satellite office. Information on the reasons for Level 3 appeal decisions can currently be reported within ECAPE. DAB recently added new data fields and case categories to its case management system to capture more detail about pending cases, including the reasons for ALJ dismissals at level 3. In addition, DAB continues to work towards developing system interoperability with ECAPE. Once baseline interoperability is established, DAB will work with OMHA to explore the feasibility of incorporating level 3 "Reason for Disposition" data into its new system.

Office for Civil Rights

DEPARTMENT of HEALTH and HUMAN SERVICES

Fiscal Year
2021

Office for Civil Rights

Justification of Estimates for
Appropriations Committees

I am pleased to present the Office for Civil Rights' (OCR) Fiscal Year 2021 Congressional Justification. The enclosed budget request supports our mission to ensure compliance with our nation's civil rights, conscience and religious freedom, and health information privacy and security laws and the President's and Secretary's priority initiatives.

OCR continues to be a leader in advancing the President's 2017 Executive Order requiring the government to "*vigorously enforce Federal law's robust protections for religious freedom*," through its Conscience and Religious Freedom Division, which is charged with robust enforcement and policy making over conscience and religious freedom laws affecting HHS funded and conducted programs.

OCR is also a vital part of the Department's efforts to combat the opioid crisis through (1) a national public education and enforcement campaign to safeguard the civil rights of persons seeking treatment for opioid use disorder, and (2) by empowering medical professionals with knowledge about how they may share health information to help persons suffering an opioid crisis, consistent with Health Insurance Portability and Accountability Act (HIPAA). OCR's civil rights enforcement efforts underscore the Department's commitment to non-discrimination in the programs it funds and operates. Our Sex Discrimination Initiative focuses on some of the most egregious cases of sex abuse and harassment in HHS-funded programs, including medical schools, and our disability non-discrimination initiatives have led to important corrective actions to eliminate stereotypical actions that treat parents and patients with disabilities as somehow less worthy of receiving vital health or human services.

OCR supports the Secretary's initiative to transform our health system to pay for value and promote coordinated care through HIPAA policymaking and targeted enforcement actions. OCR also supports a new Right of Access Initiative that focuses on preserving the right of patients to get their medical information in a timely manner and without being overcharged. Informed patients are empowered to make better health care decisions and to choose and pay for value, which leads to improved health outcomes.

Finally, OCR has undertaken a number of initiatives to support the Administration's regulatory reform efforts. In December 2018, as part of HHS's Regulatory Sprint to Coordinated Care, OCR published a Request for Information, seeking recommendations and input from the public on how the HIPAA Rules, especially the HIPAA Privacy Rule, could be modified to promote coordinated, value-based health care and in June 2019, OCR published a notice of proposed rulemaking to reform regulations issued under Section 1557 of the Affordable Care Act that would result in billions of dollars in reduced regulatory costs for providers and insurers over five years – savings that may be passed on to consumers and patients.

OCR is impacting outcomes in all of its program areas, and will continue to work hard to sustain these advances under law. The American people deserve nothing less.

Roger Severino
Director, Office for Civil Rights

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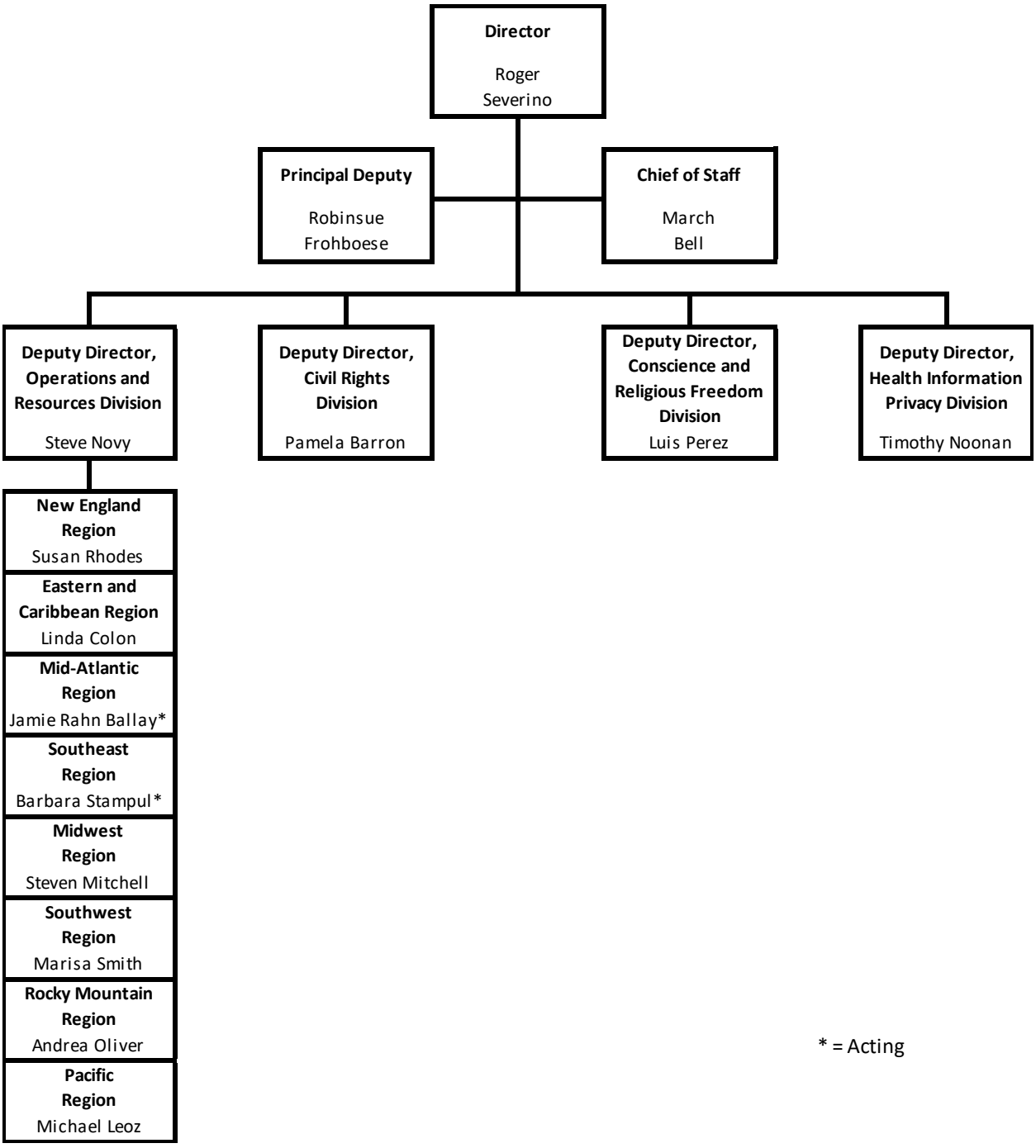
Section I: Performance Budget Overview

Organization Chart

(January 2020)



* = Acting

Organizational Chart: Text Version

Office for Civil Rights

- Director Roger Severino
- Principal Deputy Robinsue Frohboese
- Chief of Staff March Bell

The following offices report directly to the Director:

1 Deputy Director, Operations and Resources Division
1.2 Steve Novy
2 Deputy Director, Civil Rights Division
2.2 Pamela Barron
3 Deputy Director, Conscience, and Religious Freedom Division
3.2 Luis Perez
4 Deputy Director, Health Information Privacy Division
4.2 Timothy Noonan

The following regional managers report to the Deputy Director, Operations and Resources Division:

- Susan Rhodes, New England Region
- Linda Colon, Eastern & Caribbean Region
- Jamie Rahn Ballay (Acting), Mid-Atlantic Region
- Barbara Stampul (Acting), Southeast Region
- Steven Mitchell, Midwest Region
- Marisa Smith, Southwest Region
- Andrea Oliver, Rocky Mountain Region
- Michael Leoz, Pacific Region

Section II: Executive Summary

Introduction and Mission

The Office for Civil Rights (OCR), a staff division in the Office of the Secretary of the U.S. Department of Health and Human Services (HHS), ensures that individuals receiving services from HHS-conducted or HHS-funded programs are not subject to unlawful discrimination, individuals and entities can exercise their conscience and religious freedom rights, and people can trust the privacy, security, and availability of their health information. By rooting out discrimination and removing unlawful barriers to HHS-conducted or funded services, OCR helps to carry out the HHS mission of improving the health and well-being of all Americans and providing essential human services. By ensuring individuals and institutions can exercise their conscience and religious freedom rights, OCR vindicates the interests of justice while furthering diversity and tolerance in a pluralistic society. By protecting the privacy, security, and access to health information, OCR empowers people's health care decision-making and helps ensure the integrity of the health care system, both of which promote better health outcomes for the nation.

Mission

As an HHS enforcement agency, OCR investigates complaints, conducts compliance reviews, vindicates rights, develops policy, promulgates regulations, provides technical assistance, and educates the public concerning our nation's civil rights, conscience and religious freedom, and health information privacy and security laws. OCR accomplishes this by:

- Ensuring that recipients of HHS federal financial assistance comply with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, sex, and religion.
- Ensuring that HHS, state and local governments, health care providers, health plans, and others comply with federal laws that guarantee the protection of conscience and free exercise of religion, and prohibit coercion and religious discrimination, in HHS- conducted or funded programs.
- Ensuring the practices of health care providers, health plans, healthcare clearinghouses, and their business associates adhere to federal privacy, security, and breach notification regulations under the Health Insurance Portability and Accountability Act (HIPAA) and the Health Information Technology for Economic and Clinical Health (HITECH) Act, through the investigation of complaints, self-reported breaches, compliance reviews, and audits.

Vision

OCR enforces civil rights laws and conscience and religious freedom laws; and protects the privacy, security, and availability of individuals' health information. Through these mechanisms, OCR helps to ensure equal access to health and human services, protects the exercise of religious beliefs and moral convictions by individuals and institutions participating in HHS programs, advances the health and well-being of all Americans, protects individuals' health information, and provides the tools for provider awareness and full engagement of individuals in decisions related to their health care.

Overview of Budget Request

OCR's FY 2021 budget request of $30,286,000 is $8,512,000 below the FY 2020 Enacted Level. At this level, OCR will continue defending the public's right to nondiscriminatory access to HHS funded health and human services, conscience and religious freedom, access to and the privacy and security of personally identifiable health information.

Program Changes:

Civil Rights Division

- The Civil Rights Division discretionary budget request of $4,522,000 is $425,000 above the FY 2020 Enacted Level. The increase relates to minor adjustments and cost increases as well as general inflationary costs.

Conscience and Religious Freedom Division

- The Conscience and Religious Freedom Division discretionary budget request of $5,116,000 is $227,000 above the FY 2020 Enacted Level. The increase will support an additional 3 FTEs and associated overhead costs as corresponding contractor support decreases.

Health Information Privacy Division

- The Health Information Privacy Division discretionary budget request of $722,000 is $3,606,000 below the FY 2020 Enacted Level.
- OCR plans to expend $8,607,000 in settlement funding which is $3,944,000 more than the previous year.
- Total program level is $9,329,000.

Operations and Resources Division

- The Operations and Resources Division discretionary budget request of $19,926,000 is $5,558,000 below the FY 2020 Enacted Level.
- OCR plans to expend $18,117,000 in settlement funding which is $ 8,216,000 more than the previous year.
- Total program level is $38,043,000.

Overview of Performance

OCR's overarching goals encompass multiple supporting objectives.

OCR Goal	OCR Supporting Objectives
1. Raise awareness, increase understanding, and ensure compliance with all federal laws requiring non-discriminatory access to HHS funded or conducted programs, protect health care provider conscience rights, and protect the privacy and security of personal health information	A. Increase access to, and receipt of, non-discriminatory quality health and human services while protecting conscience and the integrity of HHS federal financial assistance B. Protect the privacy and security of personally identifiable health information for healthcare consumers (HIPAA Rule activities and enforcement) C. Provide information, public education activities, and training to representatives of health and human service providers, other interest groups, and consumers (civil rights, conscience, and health information privacy mission activities) D. Increase the number of covered entities that take corrective action, including making substantive policy changes or developing new policies as a result of review and/or intervention
2. Enhance operational efficiency	A. Maximize efficiency of operations by streamlining processes and the optimal allocation of resources B. Improve financial management and the integration of budget and performance data (Increase resource management process oversight, strengthen internal controls, maintain viable performance objectives) C. Advance human capital management (Provide training, develop and mentor subordinates, promote effectiveness)

The following Outputs and Outcomes Table presents the current OCR performance measures and results along with the proposed FY 2021 targets:

Program/Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2020 Target	FY 2021 Target	FY 2021 Target +/- FY 2020 Target
#1 The number of covered entities taking corrective actions as a result of OCR intervention per year (Outcome)	FY 2019: 2,029 Target: 1,000 (Target Exceeded)	1,500	1,500	Maintain
#2 The number of covered entities making substantive policy changes as a result of OCR intervention / year (Outcome)	FY 2019: 261 Target: 250 (Target Exceeded)	250	250	Maintain
#3 Percent of closure for civil rights cases / cases received each year (Outcome)	FY 2019: 96% Target: 90% (Target Exceeded)	90%	90%	Maintain
#4 Percent of closure for health information privacy cases / cases received each year (Outcome)	FY 2019: 113% Target: 90% (Target Exceeded)	90%	90%	Maintain
#5 Percentage of closures for conscience and religious freedom cases / cases received each year (Outcome)	FY 2019: 29% Target: 6% (Target Exceeded)	6%	21%	Revised +15%
#6 Percent of civil rights complaints requiring formal investigation resolved within 365 days (Output)	FY 2019: 79% Target: 50% (Target Exceeded)	50%	70%	Revised +20%
#7 Percentage of civil rights complaints not requiring formal investigation resolved within 180 days (Output)	FY 2019: 74% Target: 95% (Target Not Met)	95%	95%	Maintain
#8 Percentage of health information privacy complaints requiring formal investigation resolved within 365 days (Output)	FY 2019: 77% Target: 70% (Target Exceeded)	70%	70%	Maintain
#9 Percentage of health information privacy complaints not requiring formal investigation resolved within 180 days (Output)	FY 2019: 95% Target: 95% (Target Met)	95%	95%	Maintain
#10 Percentage of conscience and religious freedom complaints requiring formal investigation resolved within 365 days (Output)	FY 2019: 20% Target: 5% (Target Exceeded)	5%	5%	Maintain
#11 Percentage of conscience and religious freedom complaints not requiring formal investigation resolved within 180 days (Output)	FY 2019: 40% Target: 5% (Target Exceeded)	5%	7%	Revised +2%

OCR regularly communicates with the regulated community, advocacy groups, individuals, and the general public about the laws that OCR enforces and OCR's priorities through outreach and training, regulatory activities, and investigations and compliance reviews that may lead to formal letters of findings and resolution agreements.

OCR experienced significant challenges throughout the year, including a significant reduction in experienced staff due to retirements. Nevertheless, in FY 2019, OCR exceeded its target for resolving health information privacy (HIP) and civil rights cases through the investigative process within 365 days (#8, FY 2019 Target: 70%, Actual: 77%; #6, FY2019 Target: 50%, Actual: 79%). The timely resolution of complaints through formal investigation represents one of the most meaningful indicators of OCR's continued and improving ability to fulfill its core mission. Moreover, OCR has a robust outreach program, which is another proactive method of educating covered entities on their HIP and civil rights obligations that encourages and induces HIP and civil rights compliance without the expenditure of enforcement resources.

Additionally, OCR exceeded its overall productivity and closure targets by closing a high percentage of all HIP cases received (#4, FY 2019 Target: 90%, Actual 113%) and exceeded its target for closing all civil rights cases received (#3, FY 2019 Target: 90%, Actual: 96%). This is notable because OCR continues to see an annual increase in the receipt of health information privacy and civil rights cases (11.5% increase in complaint receipts from FY 2019 to FY 2020).

The Patient Protection and Affordable Care Act, including Section 1557 enforced by OCR, has been the subject of ongoing legal challenges. Of particular note, in December 2016, the Northern District Court of Texas in *Franciscan Alliance, Inc. et al v. Burwell,* preliminarily enjoined HHS from enforcing, on a nationwide basis, the provisions of the regulation implementing Section 1557 of the Affordable Care Act that prohibits discrimination based on gender identity or termination of pregnancy. The court subsequently entered a final order vacating those portions of the rule. As a result, OCR must conduct an additional review of all incoming civil rights complaints to determine if they are subject to the District Court's Order. During the fiscal year, OCR took several proactive measures to process, and where possible, close cases not subject to the injunction, and streamlined its review process to identify enjoined cases in an expedited manner.

Additionally, to permanently address the concerns specified in the injunction, as well as others raised by the regulated community, OCR published a notice of proposed rulemaking that would make changes to the Section 1557 regulation to comply with the law and significantly reduce unnecessary costs imposed on health care providers and insurers, as well as conforming changes to other OCR and departmental regulations.

Legal challenges to OCR's enforcement of the HIPAA Rules and guidance have required deployment of additional resources that has slowed resolution of more complex cases in this area.

OCR exceeded its target for the performance objective of investigated complaints/reviews/breaches resulting in corrective action (#1, FY 2019 Target: 1,000, Actual: 2,029), and the number of covered entities making substantive policy changes (#2, FY 2019 Target: 250, Actual: 261). OCR also continues to effectuate corrective action in other ways. OCR resolves a large number of complaints without a formal investigation, through the provision of technical assistance to the named entity. These complaints involve simple issues that, if substantiated, the entity can often address quickly with

voluntary corrective action. The use of technical assistance to resolve these types of complaints is an efficient way for OCR to use its resources by notifying the regulated community about potential compliance deficiencies and requesting that entities take any necessary voluntary corrective action. OCR met its target for HIP cases not requiring formal investigation resolved within 180 days (#9, FY 2019 Target: 95%, Actual: 95%). With regard to the disposition of civil rights cases not requiring a formal investigation, which can include the provision of technical assistance, OCR did not meet this measurement (#7, FY 2019 Target: 95%, Actual: 74%), partially as result of the aforementioned court injunction.

These aggressive targets continue to present OCR a significant challenge because, as stated above, OCR projects an 11.5% increase in complaint receipts from FY 2019 to FY 2020. However, filling regional vacancies, including critical managerial positions, and continued innovations within the CCMO, where all new cases are triaged, and improvements in the electronic case management system has enabled OCR to sustain greater efficiencies in case processing than realized in previous fiscal years. OCR continues to work faster without sacrificing its ability to identify and pursue "high impact" casework.

OCR's Conscience and Religious Freedom Division (CRFD) conducts OCR's nationwide outreach, and policymaking activities under HHS's conscience and religious freedom authorities. While these functions are similar to the HIP and civil rights division, CRFD differs in that it is also the principal investigator and enforcer of the laws assigned to it. Fiscal Year 2021 represents the third year for which CRFD has had the opportunity to set targets for this program. OCR informed its FY 2021 targets based on OCR's anticipation that CRFD's capacity-building efforts in FY 2019 and FY 2020 will positively impact the percentage of complaints resolved in FY 2021 and the timeliness with which they are resolved. These capacity-building efforts included hiring career staff with the appropriate skills and experience, establishing the appropriate leadership and management structures, and strengthening the efficiency of CRFD's case intake and case management practices, which all brought greater stability to CRFD.

CRFD exceeded all of its targets for FY 2019. CRFD closed cases received in prior fiscal years during FY 2019, representing 29% of its cases received in FY 2019, which is +23 percentage points above the target (#5, FY 2019 Target: 6%, Actual: 29%). Of CRFD's cases closed in FY 2019 that did not require formal investigation, 40% were resolved within 180 days (#11, FY 2019 Target: 5%, Actual: 40%). OCR aims to increase its performance for measure #5 at an annual rate of 50% relative to its FY 2019 target. CRFD's target of 21% for measure #5 in FY 2021 is 15 percentage points above the FY 2020 target of 6%, a 250% increase. OCR aims to increase its performance for measure #11 by one percentage point each year, relative to its FY 2019 target, which results in a target of 7% in FY 2021, which is a relative increase of 40% from the FY 2020 target of 5%.

As mentioned earlier, CRFD is unique among OCR divisions in that it handles not only outreach and policymaking, but also processing and investigation for laws assigned to it. Cases investigated and resolved by CRFD in FY 2019, such as complaints resolved against the State of California and the State of Hawaii, were primarily initiated in prior fiscal years. Thus, only 20% of CRFD's investigated closures in FY 2019 were resolved within 365 days. Because CRFD has limited performance data on investigated closures to inform this target, it is premature to increase the FY 2021 target until CRFD has additional years of performance data with respect to metric #10.

All Purpose Table

(Dollars in Thousands)

Division	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget	FY 2021 +/- FY 2020
Discretionary Budget Authority				
Operations and Resources Division	28,096	25,484	19,926	-5,558
Civil Rights Division	3,755	4,097	4,522	+425
Conscience and Religious Freedom Division	2,852	4,889	5,116	+227
Health Information Privacy Division	3,964	4,328	722	-3,606
Total, OCR Discretionary Budget Authority	**38,667**	**38,798**	**30,286**	**-8,512**
Civil Monetary Settlement Funding				
Operations and Resources Division	4,756	9,901	18,117	+8,216
Health Information Privacy Division	2,076	4,663	8,607	+3,944
Total, OCR Civil Monetary Settlement Funding	**6,832**	**14,564**	**26,724**	**+12,160**
Total Program Level				
Operations and Resources Division	32,852	35,385	38,043	+2,658
Civil Rights Division	3,755	4,097	4,522	+425
Conscience and Religious Freedom Division	2,852	4,889	5,116	+227
Health Information Privacy Division	6,040	8,991	9,329	+338
Total, OCR Program Level	**45,499**	**53,362**	**57,010**	**+3,648**

Section III: Office for Civil Rights

Appropriations Language

For expenses necessary for the Office for Civil Rights, **[$38,798,000]** *$30,286,000*.

Amounts Available for Obligation

(Dollars in Thousands)

Detail	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget
Appropriation	38,798	38,798	30,286
Across-the-board reductions	-	-	-
Subtotal, Adjusted Appropriation	38,798	38,798	30,286
Transfer of Funds	-131	-	-
Subtotal, Adjusted General Fund Discretionary App	38,667	38,798	30,286
Total, Discretionary Appropriation	**38,667**	**38,798**	**30,286**

Summary of Changes

(Dollars in Thousands)

Budget Year and Type of Authority	Dollars	FTE
FY 2020 Enacted	38,798	151
FY 2021 President's Budget	30,286	141
Net Change	**-8,512**	**-10**

Program Increases	FY 2020 Enacted FTE	FY 2020 Enacted Level BA	FY 2021 President's Budget FTE	FY 2021 President's Budget BA	FY 2021 +/- FY 2020 FTE	FY 2021 +/- FY 2020 BA
Benefits for former personnel	-	20	-	146	-	+126
Civilian personnel benefits		5,702		5,790		+88
Printing and reproduction	-	139	-	162	-	+23
Other than full-time permanent	-	742	-	751	-	+9
Military personnel	1	98	1	101	-	+3
Military benefits	-	37	-	38	-	+1
Total Increases	**-**	**6,738**	**-**	**6,988**	**-**	**+250**

Program Decreases	FY 2020 Enacted FTE	FY 2020 Enacted BA	FY 2021 President's Budget FTE	FY 2021 President's Budget BA	FY 2021 +/- FY 2020 FTE	FY 2021 +/- FY 2020 BA
Other G&S from federal sources	-	8,168	-	4,466	-	-3,702
Rental payments to GSA	-	3,539	-	1,146	-	-2,393
Other services from non-fed sources	-	1,821	-	749	-	-1,072
Full-time permanent	150	16,606	140	15,933	-10	-673
Travel and transportation of persons	-	467	-	191	-	-276
Equipment	-	254	-	65	-	-189
Operation and maint. of equipment	-	400	-	261	-	-139
Supplies and materials	-	135	-	50	-	-85
Operation and maint. of facilities	-	175	-	92	-	-83
Other personnel compensation	-	324	-	246	-	-78
Comms, utilizes, and misc. charges	-	143	-	91	-	-52
Transportation of things	-	28	-	8	-	-20
Total Decreases	**-**	**32,060**	**-**	**23,298**	**-**	**-8,762**

Program Totals	FY 2020 Enacted FTE	FY 2020 Enacted BA	FY 2021 President's Budget FTE	FY 2021 President's Budget BA	FY 2021 +/- FY 2020 FTE	FY 2021 +/- FY 2020 BA
Total Increases	-	6,738	1	6,988	-	+250
Total Decreases	-	32,060	-	23,298	-	-8,762
Total Net Change	**151**	**38,798**	**141**	**30,286**	**-10**	**-8,512**

Budget Authority by Activity

(Dollars in Thousands)

Activity	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget
Operations and Resources Division	28,096	25,484	19,926
Civil Rights Division	3,755	4,097	4,522
Conscience and Religious Freedom Division	2,852	4,889	5,116
Health Information Privacy	3,964	4,328	722
Total, Budget Authority	**38,667**	**38,798**	**30,286**
FTE	**139**	**151**	**141**

Authorizing Legislation

(Dollars in Thousands)

Authorizing Legislation	FY 2020 Amount Authorized	FY 2020 Amount Appropriated	FY 2021 Amount Authorized	FY 2021 President's Budget
Office for Civil Rights	Indefinite	$38,798	Indefinite	$30,286
Appropriation	-	$38,798	-	$30,286

OCR Legal Authorities

[Refer to authority listings by activity on pages 26, 32, and 39.]

Appropriations History

Details	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
2012				
Appropriation				
Base	44,382,000	41,016,000	41,016,000	41,016,000
Rescission	-	-	-	(78,000)
Subtotal	44,382,000	41,016,000	41,016,000	40,938,000
2013				
Appropriation				
Base	38,966,000	-	38,966,000	40,938,000
Sequestration	-	-	-	(2,059,000)
Rescission	-	-	-	(82,000)
Transfers	-	-	-	(182,000)
Subtotal	38,966,000	-	38,966,000	38,615,000
2014				
Appropriation				
Base	42,205,000	-	42,205,000	38,798,000
Subtotal	42,205,000	-	42,205,000	38,798,000
2015				
Appropriation				
Base	41,205,000	-	38,798,000	38,798,000
Subtotal	41,205,000	-	38,798,000	38,798,000
2016				
Appropriation				
Base	42,705,000	-	38,798,000	38,798,000
Subtotal	42,705,000	-	38,798,000	38,798,000
2017				
Appropriation				
Base	42,705,000	38,798,000	38,798,000	38,798,000
Transfers	-	-	-	(90,000)
Subtotal	42,705,000	38,798,000	38,798,000	38,708,000
2018				
Appropriation				
Base	32,530,000	38,798,000	-	38,798,000
Transfers	-	-	-	(97,000)
Subtotal	32,530,000	38,798,000	-	38,701,000

Appropriations History (Continued)

Details	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
2019				
Appropriation				
Base	30,904,000	38,798,000	38,798,000	38,798,000
Transfers	-	-	-	-131,000
Subtotal	30,904,000	38,798,000	38,798,000	38,667,000
2020				
Appropriation			-	-
Base	30,286,000	38,798,000	38,798,000	38,798,000
Subtotal	30,286,000	38,798,000	38,798,000	38,798,000
2021				
Appropriation			-	-
Base	30,286,000	-	-	-
Subtotal	30,286,000	-	-	-

Summary of the Request

OCR's budget request consists of four narratives, one for each of its Divisions. The below table summarizes the discretionary budget authority requests:

Division	FY 2020 Enacted	FY2021 President's Budget	FY 2021 +/- FY 2020
Operations and Resources Division (ORD)	25,484	19,926	-5,558
Civil Rights Division (CRD)	4,097	4,522	+425
Conscience and Religious Freedom Division (CRFD)	4,889	5,116	+227
Health Information Privacy Division (HIPD)	4,328	722	-3,606

Operations and Resources Division

(Dollars in Thousands)

Program	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget	FY 2021 +/- FY 2020
Budget Authority				
Discretionary Budget Authority	28,096	25,484	19,926	-5,558
Civil Monetary Settlement Funding	4,756	9,901	18,117	+8,216
Total Program Level	**32,852**	**35,385**	**38,043**	**+2,658**
FTE				
Discretionary Budget Authority	104	110	108	-2
Civil Monetary Settlement Funding	-	-	-	-
Total Program Level	**104**	**110**	**108**	**-2**

Legal Authorities

The Operations and Resources Division (ORD) acts as OCR's primary enforcement arm for civil rights and health information privacy and security complaints. In that capacity, ORD enforces the civil rights and health information privacy and security legal authorities listed on pages 26 and 39 respectively.

Program Description

ORD consists of OCR's eight regional offices,[1] the Centralized Case Management Operations (CCMO), and headquarters support personnel. As described below, the regions and CCMO have key operational responsibilities in OCR enforcement, technical assistance, and outreach activities and other ORD personnel provide nationwide support for OCR's operations.

Operations

Complaint Processing

The enforcement lifecycle begins with CCMO, which receives complaints alleging the violation of one or more of OCR's legal authorities by a covered entity. Members of the public can file complaints through OCR's online complaint portal, mail, fax, and email. Complaints are assessed to determine which can be closed without formal investigation (e.g., as non-jurisdictional or with the provision of minor technical assistance) and which civil rights and health information privacy and security complaints should be transferred to an OCR regional office for further deliberation and possible investigation. CCMO resolves a majority of OCR's case receipts with administrative closures and technical assistance closures. Significant process redesign and automation improvements have enabled OCR to increase efficiency, despite being on track to receive nearly triple the amount of complaints (36,591 in FY 2019 versus 12,705 in FY 2012) since OCR's online complaint portal went live in FY 2012.

[1] The regional offices include New England Region (Boston), Eastern and Caribbean Region (New York), Mid-Atlantic Region (Philadelphia), Southeast Region (Atlanta), Midwest Region (Chicago and Kansas City), Southwest Region (Dallas), Rocky Mountain Region (Denver), and Pacific Region (San Francisco, Seattle, and Los Angeles).

Investigation
OCR's regional offices conduct Civil Rights and Health Information Privacy and Security complaint investigations, breach report investigations, and compliance reviews. Each regional office utilizes highly skilled investigators responsible for examining allegations of discrimination or health information privacy/security violations and determining the appropriate action. Through understanding and application of OCR's legal authorities and jurisdiction, the staff conducts comprehensive fact-finding investigations to determine a covered entity's compliance with the regulations OCR enforces. Investigations can result in a finding of no violation, the provision of technical assistance to address specific problem areas, or, where there are indications of noncompliance, more formal enforcement action, including the negotiation of settlement agreements.

Enforcement
When OCR determines there has been a violation of one or more of its legal authorities, OCR takes enforcement action. When a regional investigator finds a violation, the regional office works closely with OCR Headquarters and the Office of the General Counsel to review the facts of the investigation and produce a letter of findings. When OCR sends the letter of finding to an entity, OCR may offer to provide technical assistance to promote voluntary compliance or engage in a settlement negotiation with a corrective action plan and, where appropriate, monetary payments. In instances where entities are uncooperative, OCR can, depending on the statute at issue, seek rescission of HHS funding to the entity, pursue civil money penalties, or refer the case to the Department of Justice for further proceedings.

In addition to complaints submitted by the public, OCR has authority to open compliance reviews of specific entities when it has reason to believe that an entity may have violated certain of the laws that OCR enforces. OCR learns of such potential violations from a variety of sources, including media reports and situations in which significant numbers of individual complaints have been filed against an entity. Also, as required by HIPAA, OCR initiates an investigation in all cases where an entity has reported a health information privacy breach affecting 500 or more individuals. These compliance reviews and breach report investigations can enable OCR to evaluate compliance issues and focus on systemic reform. The investigation and enforcement process for compliance reviews and breach report investigations, along with their outcome, follow the same processes noted above for complaint resolution.

Technical Assistance and Outreach
In addition to OCR's work to ensure compliance through enforcement, OCR promotes voluntary compliance through technical assistance and outreach. OCR delivers impact through strong technical assistance to covered entities. This collaboration across OCR teams ensures that covered entities can receive the information, guidance, and support required to achieve voluntary compliance with their legal responsibilities under civil rights and privacy/security laws.

Another major component of OCR's compliance portfolio includes outreach. A robust outreach program informs and educates individuals, consumer groups, advocacy groups, and other stakeholders of civil rights, religious freedom and conscience, and health information privacy and security laws, obtains input about challenges and potential violations on which OCR should focus, and provides guidance on means to ensure compliance. This is accomplished through HQ and our regions participating in conferences and briefings as well as smaller meetings and listening sessions; hosting workshops, webinars, and trainings; disseminating materials in a variety of forums; training law and medical students and other stakeholders; and convening and participating in various working groups. OCR's regional staff also participate in inter-agency and intra-agency activities and work collaboratively with federal partners. OCR's nationwide outreach efforts

educate and provide guidance to federal agencies, States, covered entities, consumers, and other stakeholders. These efforts allow OCR to build relationships, create opportunities for dialogue, provide opportunities for input on OCR's work, and ensure that OCR is able to anticipate future challenges.

Resources and Services Support
ORD's resources staff supports all OCR operations by assisting all four divisions, including the regional offices, by providing budget, information technology, human resources, acquisition, security, property management, travel, ethics, Freedom of Information Act (FOIA), continuity of operations (COOP), and other related administrative support. The Budget Team, Human Resources Team, Information Technology Team, and the Executive Secretariat provide critical support to all programmatic staff to allow them to focus their attention on mission requirements.

Accomplishments
Allergy Associates of Hartford, P.C. (Allergy Associates) is comprised of three doctors at four locations across Connecticut. In February 2015, a patient of Allergy Associates contacted a local television station to speak about a dispute that had occurred between the patient and an Allergy Associates' doctor. The reporter subsequently contacted the doctor for comment and the doctor discussed the patient's health information with the reporter. OCR's investigation found that the doctor impermissibly disclosed the patient's protected health information (PHI) with the reporter and that Allergy Associates failed to take any disciplinary action against the doctor or take any corrective action following the impermissible disclosure to the media. Allergy Associates agreed to pay a $125,000 monetary settlement and adopt a corrective action plan (CAP). In the CAP, Allergy Associates agreed to develop/revise policies and procedures that address permissible and impermissible uses and disclosures of PHI, appropriate administrative, technical, and physical safeguards to protect PHI from any intentional or unintentional use or disclosure, define individually identifiable health information and PHI, develop workforce-training protocols, and distribute to all workforce members.

Advanced Care Hospitalists PL (ACH) provides contracted internal medicine physicians to hospitals and nursing homes in west central Florida and has been in operation since 2005. Between November 2011 and June 2012, ACH engaged the services of an individual that represented himself to be a representative of a Florida-based company named Doctor's First Choice Billings, Inc. (First Choice). The individual provided medical billing services to ACH using First Choice's name and website, but allegedly without any knowledge or permission of First Choice's owner. In February 2014, a local hospital notified ACH that patient information was viewable on the First Choice website, including name, date of birth and social security number. ACH filed a breach notification report with OCR, stating that 400 individuals were affected; however, after further investigation, stated that an additional 8,855 patients could have been affected. OCR's investigation revealed that ACH never entered into a business associate agreement with the individual providing medical billing services to ACH, failed to adopt any policy requiring business associate agreements until April 2014, and had not conducted a risk analysis or implemented security measures or any other written HIPAA policies or procedures before 2014. ACH agreed to pay a $500,000 monetary settlement and entered into a CAP to provide an accounting of its business associates and copies of related business associate agreements, conduct an enterprise-wide risk analysis and risk management plan, develop Privacy and Security Rule policies, distribute the polices to workforce members and provide training.

Pagosa Springs Medical Center (PSMC) is a critical access hospital that, at the time of OCR's investigation, provided more than 17,000 hospital and clinic visits annually and employs more than 175 individuals. OCR received a complaint that alleged a former PSMC employee continued to have remote access to PSMC's web-based scheduling calendar, which contained patients' electronic protected health information (ePHI),

after separation of employment. OCR's investigation revealed that PSMC impermissibly disclosed the ePHI of 557 individuals to its former employee and to the web-based scheduling calendar vendor without a required business associate agreement in place. PSMC agreed to pay a $111,400 monetary settlement and adopt a CAP to update its enterprise-wide risk analysis and risk management plan, revise its uses and disclosures of PHI and business associates' policies and procedures, and provide training to workforce members.

Cottage Health operates Santa Barbara Cottage Hospital, Santa Ynez Cottage Hospital, Goleta Valley Cottage Hospital, and Cottage Rehabilitation Hospital, in California. OCR received two notifications from Cottage Health regarding breaches of unsecured ePHI affecting over 62,500 individuals. The first breach arose when ePHI on a Cottage Health server was accessible from the internet. OCR's investigation determined that security configuration settings of the Windows operating system permitted access to files containing ePHI without requiring a username and password. As a result, patient names, addresses, dates of birth, diagnoses, conditions, lab results, and other treatment information were available to anyone with access to Cottage Health's server. The second breach occurred when a server was misconfigured following an IT response to a troubleshooting ticket, exposing unsecured ePHI over the internet. This ePHI included patient names, addresses, dates of birth, social security numbers, diagnoses, conditions, and other treatment information. OCR's investigation revealed that Cottage Health failed to conduct an accurate and thorough assessment of the potential risks and vulnerabilities to the confidentiality, integrity, and availability of the ePHI; failed to implement security measures sufficient to reduce risks and vulnerabilities to a reasonable and appropriate level; failed to perform periodic technical and non-technical evaluations in response to environmental or operational changes affecting the security of ePHI; and failed to obtain a written business associate agreement with a contractor that maintained ePHI on its behalf. Cottage Health agreed to pay a $3 million monetary settlement and enter into a CAP. In the CAP, Cottage Health agreed to conduct an enterprise-wide risk analysis and risk management plan, develop a written process to evaluate any environmental or operational changes that affect the security of Cottage Health's ePHI, develop/revise Privacy and Security policies implicated by the breaches, and provide training to workforce members.

Touchstone Medical Imaging (Touchstone) provides diagnostic medical imaging services in Nebraska, Texas, Colorado, Florida, and Arkansas. The Federal Bureau of Investigation (FBI) and OCR notified Touchstone that one of its FTP servers allowed uncontrolled access to its patients' ePHI and permitted search engines to index the PHI of Touchstone's patients, which remained visible on the Internet even after the server was taken offline. OCR's investigation revealed that the ePHI of more than 300,000 patients was exposed including names, birth dates, social security numbers, and addresses. OCR's investigation found that Touchstone did not thoroughly investigate the security incident until several months after the FBI and OCR notified it of the breach. Consequently, Touchstone's notification to individuals affected by the breach was untimely. OCR's investigation further found that Touchstone failed to conduct an accurate and thorough risk analysis of potential risks and vulnerabilities to the confidentiality, integrity, and availability of all of its ePHI, and failed to have business associate agreements in place with its vendors, including its IT support vendor and a third-party data center provider. Touchstone agreed to pay a $3,000,000 settlement and adopt a CAP to provide an accounting of its business associates and related business associate agreements, conduct an enterprise-wide risk analysis and risk management plan, revise Privacy and Security policies and procedures, and provide training to its workforce members.

Medical Informatics Engineering, Inc. (MIE) is an Indiana company that provides software and electronic medical record services to healthcare providers. MIE filed a breach report with OCR following a discovery that hackers used a compromised user ID and password to access the ePHI of approximately 3.5 million people. OCR's investigation revealed that MIE did not conduct a comprehensive risk analysis prior to the

breach. MIE paid a $100,000 monetary settlement and entered into a CAP to a complete an enterprise-wide risk analysis and risk management plan.

Mid-Maryland Musculoskeletal Institute (MMI) is an orthopedic practice in Maryland that provides a full-range of orthopedic services, including onsite physical therapy. OCR initiated an investigation into a complaint alleging that MMI failed to provide a qualified American Sign Language interpreter to a deaf six-year-old requiring physical therapy, in violation of both Section 504 of the Rehabilitation Act of 1973 (Section 504) and Section 1557 of the Patient Protection and Affordable Care Act (Section 1557). The complaint was the fifth one received by OCR alleging that MMI failed to effectively communication to individuals who are deaf or hard of hearing. OCR and MMI entered into a voluntary resolution agreement and MMI agreed to take steps to improve and upgrade its review and assessment of sign language interpreters, provide staff training in effective communication and OCR will provide MMI with substantive technical assistance and feedback in response to reports MMI will be sending to OCR regarding its ongoing compliance activities.

University of North Carolina Health Care System (UNC Health Care) is a public academic medical center comprised of North Carolina Memorial Hospital, North Carolina Children's Hospital, North Carolina Neurosciences Hospital, and North Carolina Women's Hospital. OCR used its Early Complaint Resolution process to work with UNC Health Care to resolve a complaint alleging a denial of the opportunity to be considered for placement on the United Network for Organ Sharing list on the basis of an individual's disability. The complaint alleged that an individual with an intellectual disability was in need of a heart transplant but was not considered for placement on the waiting list for a transplant based on this disability and the fact that the individual did not live independently. OCR used the Early Complaint Resolution process to achieve a successful resolution of this matter. This process entails a facilitated negotiation between the parties to an OCR complaint with the goal of achieving a resolution that quickly provides a remedy to the individual that has been allegedly discriminated against as well as securing additional measures that can be implemented to reduce the likelihood of future incidents of alleged discrimination. UNC Health Care agreed that the individual was eligible to be considered for placement on the waiting list and that it would ensure its policies and procedures were in compliance with federal civil rights requirements for persons with disabilities.

Funding History

Fiscal Year	Amount
FY 2017	$30,027,000
FY 2018	$27,852,000
FY 2019	$28,096,000
FY 2020	$25,484,000
FY 2021 Request	$19,926,000

Budget Request

The FY 2021 discretionary request for the Operations and Resources Division of $19,926,000 is $5,558,000 below the FY 2020 Enacted Level. OCR will offset reductions with $18,117,000 in settlement funding, $8,216,000 more than planned in FY 2020. OCR will reduce staffing by 2 FTEs to allow flexibility and maximum support to enforcement efforts.

Civil Rights Division

(Dollars in Thousands)

Program	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget	FY 2021 +/- FY 2020
Budget Authority				
Discretionary Budget Authority	3,755	4,097	4,522	+425
Civil Monetary Settlement Funding	-	-	-	-
Total Program Level	**3,755**	**4,097**	**4,522**	**+425**
FTE				
Discretionary Budget Authority	14	15	15	-
Civil Monetary Settlement Funding	-	-	-	-
Total Program Level	**14**	**15**	**15**	**-**

Legal Authorities

- Title VI of the Civil Rights Act of 1964, as amended, 42 U.S.C. § 2000d *et seq.*
- Section 504 of the Rehabilitation Act of 1973, as amended, 29 U.S.C. § 794.
- Section 508 of the Rehabilitation Act of 1973, as amended, 29 U.S.C. § 794d.
- Title IX of the Education Amendments of 1972, as amended, 20 U.S.C. § 1681 *et seq.*
- Age Discrimination Act of 1975, as amended, 42 U.S.C. § 6101 *et seq.*
- Hill-Burton Community Service Assurance, Titles VI and XVI of the Public Health Service Act (PHSA), as amended. The community service assurances are in §§ 603(e), 1621(b)(1)(K) of the PHSA (codified as amended at 42 U.S.C. §§ 291c(e), 300s-1(b)(1)(K)(i)).
- Low-Income Home Energy Assistance Act of 1981, 42 U.S.C. § 8625 *et seq.*
- Title II of the Americans with Disabilities Act, as amended, 42 U.S.C. § 12131 *et seq.*
- Section 1557 of the Affordable Care Act, 42 U.S.C. § 18116.
- Multi-Ethnic Placement Act, 42 U.S.C. § 5115a, as amended by Section 1808 of the Small Business Job Protection Act of 1996, 42 U.S.C. § 1996b.
- Sections 799A and 855 of the Public Health Service Act, 42 U.S.C. §§ 295m and 296g.
- Section 321, Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment and Rehabilitation Act of 1970, as amended, 42 U.S.C. § 4581.
- Section 1947, Substance Abuse Prevention and Treatment Block Grant and Community Mental Health Services Block Grant, 42 U.S.C. § 300x-57.
- Admission of Substance Abusers to Private and Public Hospitals and Outpatient Facilities, 42 U.S.C. § 290dd-1.
- Community Services Block Grant Programs, 42 U.S.C. § 9908.
- Equal Employment Opportunity Provision in the Public Telecommunications Financing Act of 1978, Section 309, as amended, 47 U.S.C. § 398(b).
- Maternal and Child Health Services Block Grant Nondiscrimination Provision, 42 U.S.C. § 708.
- Preventive Health and Health Services Block Grants, 42 U.S.C. § 300w-7.
- Projects in Assistance to Transition from Homelessness Project Grants, Nondiscrimination Provision, 42 U.S.C. § 290c-33.
- Family Violence Prevention and Services Act, as amended, 42 U.S.C. §10406.

Program Description

OCR's Civil Rights Division (CRD) aggressively enforces our Nation's civil rights laws to ensure that all individuals – regardless of race, color, national origin, age, disability, religion, or sex – have equal access to health and human services. CRD's work advances HHS Strategic Goal 1: Reform, Strengthen, and Modernize the Nation's Healthcare System; Strategic Objective 1.3: Improve Americans' access to healthcare and expand choices of care and service options; Strategic Objective 1.4: Strengthen and expand the health care workforce to meet America's diverse needs; HHS Strategic Goal 3: Strengthen the Economic and Social Well-Being of Americans across the Lifespan; Strategic Objective 3.3: Support strong families and healthy marriage, and prepare children and youth for healthy, productive lives; Strategic Objective 3.4: Maximize the independence, well-being, and health of older adults, people with disabilities, and their families and caregivers.

CRD accomplishes its mission by:

(1) undergirding the work of the OCR Director, who serves as the Secretary's principal advisor on civil rights. CRD conducts civil rights reviews of the Department's rulemaking and policy guidance; drafts regulations and guidance to better implement the civil rights protections under OCR's jurisdiction; and represents the OCR Director on HHS and inter-agency workgroups that address civil rights issues;
(2) providing direction and subject matter expertise to regional staff and ensuring legal and policy coordination in the formulation of enforcement actions, including investigative plans for complaints and compliance reviews, corrective action closure letters, voluntary resolution agreements, violation letters of finding and settlement agreements;
(3) sponsoring national outreach initiatives for stakeholders and covered entities to urge civil rights compliance; and
(4) rescinding and amending regulations and sub-regulatory guidance issued by OCR and other HHS components where the civil rights benefits are outweighed by the burden imposed.

Focus Areas

Coordinating Government-wide Compliance with the Age Discrimination Act of 1975

- The Age Discrimination Act of 1975 provides the Secretary with coordinating authority over Federal departments' and agencies' implementation of the Act. Each year, CRD submits to Congress a government-wide report on Federal compliance. CRD collects information from 28 Federal departments and agencies; analyzes the data; and prepares the government-wide report. The report provides quantitative and qualitative analysis of new and ongoing age activities, including new complaints, carry-over complaints, mediation efforts, compliance reviews, training, technical assistance, outreach, and regulation development. CRD submitted the FY 2018 Report to Congress on March 29, 2019. In FY 2018, OCR closed 184 Age Discrimination Act complaints.

Protecting the Rights of Individuals with Disabilities and Limited English Proficient (LEP) Persons during Natural Disasters and National Emergencies

- During Hurricane Florence in the fall of 2018, CRD issued guidance to ensure equal access to emergency services for LEP persons and individuals with disabilities. In the guidance, CRD urged first responders to:
    - employ qualified interpreter services to assist LEP persons and individuals who are deaf or hard of hearing, during evacuation, response and recovery activities;
    - make emergency messaging available in languages prevalent in the affected area(s) and in multiple formats, such as audio, large print, and captioning;

- make use of multiple outlets and resources for messaging to reach LEP persons and individuals with disabilities and members of diverse faith communities;
- consider the needs of individuals with mobility impairments and individuals with assistive devices or durable medical equipment in providing transportation for evacuation;
- identify and publicize accessible sheltering facilities;
- avoid separating people from their sources of support, such as caregivers, service animals, durable medical equipment, medication, and supplies; and
- stock shelters with items that will help people to maintain independence, such as hearing aid batteries, canes, and walkers.

CRD continues to serve on emergency preparedness task forces convened by the Assistant Secretary for Preparedness and Response (ASPR), the Federal Emergency Management Agency (FEMA) and the American Red Cross.

Ensuring Language Access Services in Health and Human Service Settings

- CRD collaborates across the HHS family of agencies to ensure that health care and human service grant recipients take reasonable steps to provide meaningful access to programs and services for individuals with limited English proficiency (LEP). The OCR Director chairs the HHS Language Access Steering Committee, which oversees and coordinates ongoing Departmental efforts to improve language access services. In 2019, the Steering Committee worked with all HHS grant-making agencies to update their Funding Opportunity Announcements (FOAs) to focus on civil rights compliance information, including language access requirements; protections for conscience and religious freedoms; and prohibitions on sexual harassment and discrimination.

Enforcing Title IX's and Section 1557's Prohibition on Sex Discrimination

- Title IX of the Education Amendments Act of 1972 prohibits discrimination on the basis of sex in federally funded education programs and activities. In 2016, HHS provided approximately $21 billion in federal funding for grant recipients performing academic research and development. OCR fulfils its responsibilities to enforce Title IX through a combination of complaint investigations and initiation of compliance reviews.

Protecting the Civil Rights of Birth Parents, Prospective Parents and Children in the Child Welfare System

- CRD has an ongoing partnership with the Department of Justice (DOJ) and the HHS Administration for Children and Families (ACF) to safeguard the civil rights of parents, prospective parents, and children in the child welfare system. OCR, DOJ, and ACF have issued joint guidance to prevent and address disability and race discrimination; initiated joint complaint investigations and compliance reviews; issued a joint violation letter of finding; and have conducted joint outreach at key national conferences with stakeholders.

Raising Awareness and Enhancing Public Education

- CRD provides outreach to raise awareness of the federal civil rights statutes that OCR enforces and to provide technical assistance to covered entities regarding compliance with civil rights in the health and human services context. During FY 2019, CRD has participated in more than two dozen civil rights related outreach events at a number of associations' meetings and national civil rights conferences. These events have included participation in meetings sponsored by the Association for Successful Parenting, the Association of American Medical Colleges, the Child Welfare League of America, the Kaiser Family Foundation, the Kansas Department of Children and Family Services, the League of United

Latin American Citizens (LULAC), the Louisiana Court Improvement Project, the Maryland Court Appointed Special Advocate, the National Association of Counsel for Children, the National Disability Rights Network, the North Carolina Department of Health and Human Services, the Oregon Department of Human Services and 13 colleges and universities.

Accomplishments

In August 2019, OCR entered into a voluntary resolution agreement with Michigan State University, the MSU Health Team, and MSU Health Care, Inc. (MSU). The agreement resolves CRD's and the Midwest Region's compliance review of MSU, pursuant to Title IX and Section 1557. The review was initiated after Lawrence G. Nassar, a former MSU physician, pled guilty to felony criminal sexual conduct arising from his sexual abuse of patients. In the agreement, the MSU entities agreed to:

- revise their non-discrimination notices and sexual misconduct policies to clarify Title IX's and Section 1557's prohibitions on sex discrimination;
- improve their processes for investigating and resolving Title IX and Section 1557 complaints (including for MSU-students, non-MSU-student patients, faculty and staff);
- designate a responsible official to coordinate the acceptance, investigation and resolution of Title IX and Section 1557 complaints;
- institute a new chaperone policy requiring authorized members of the health care team to be present during sensitive medical examinations and allowing patients to request chaperones according to sex;
- when conducting sensitive examinations, provide the patient with an appropriate gown, privacy for undressing and dressing, and sensitive draping to maximize physical privacy; and
- conduct all-staff training and provide bi-annual reports to HHS OCR during the three year term of the agreement.

In June 2019, OCR published a notice of proposed rulemaking (NPRM) intended to reform regulations issued under Section 1557 of the Affordable Care Act. The proposed rule would maintain vigorous civil rights enforcement on the basis of race, color, national origin, disability, age, and sex, while revising certain provisions of the current Section 1557 rule that a federal court has said is likely unlawful. The proposed rule also would retain protections that ensure physical access for individuals with disabilities to healthcare facilities, and appropriate communication technology to assist individuals who are visually or hearing-impaired. Moreover, the proposed rule would retain protections for non-English speakers, including the right to meaningful language access to healthcare, qualification standards for translators and interpreters, and limitations on the use of minors and family members as translators in healthcare settings, while proposing to eliminate requirements that impose significant costs without corresponding language access benefits. In addition, regulated entities would continue to be required to provide written assurance to the Department that they will comply with Section 1557's civil rights provisions and the proposed regulation.

In the summer of 2019, CRD continued a long-standing collaboration with the Association of American Medical Colleges (AAMC), whose membership includes all 154 accredited U.S. medical schools. CRD, in partnership with AAMC and OCR Regional Offices, taught a 90 minute civil rights compliance training to pre-medical and pre-dental college students. Focusing on Title VI's race, color, and national origin discrimination prohibition, the primary goal of the training is for students to learn that providing equal access to patients, including LEP patients, is required by law and necessary to provide safe and effective health care. Earlier this year, OCR staff members delivered the presentation to approximately 1,000 students at Charles R. Drew University of Medicine and Science; Columbia; Howard; Rutgers; UCLA; University of Alabama; University of Florida; University of Iowa; University of Louisville; University of Nebraska; University of Texas Health Science Center; University of Washington; and Western University of Health Sciences. OCR also piloted a new disability rights training to approximately 160 pre-medical and

pre-dental students at Howard and Rutgers on effective communication requirements for persons who are deaf or hard of hearing under Section 504, Section 1557, and Title II of the ADA.

In FY 2018, OCR launched an initiative to conduct compliance reviews of STEM programs at universities that were grant recipients of the National Institutes of Health (NIH). Using neutral selection criteria, CRD and OCR Regional Offices conducted three compliance reviews of NIH funded universities. OCR did not find evidence of Title IX violations during the reviews, but provided the universities with technical assistance on notice requirements, including informing students and staff that they may file complaints with HHS OCR, in addition to the Department of Education OCR and the universities' Title IX offices.

In October 2018, CRD, in collaboration with HIP and the Office of the OCR Director, launched a public education campaign on civil rights protections in response to the national opioid crisis. The campaign materials inform the public about civil rights protections that may apply to a person in recovery from an opioid addiction and ensure that covered entities are aware of their obligations to comply with federal nondiscrimination laws. The campaign materials include an interview with the OCR Director and a new OCR video which discusses important nondiscrimination laws that may protect individuals with opioid use disorders.

In December 2018, CRD and ASPR spearheaded the HHS Language Access Steering Committee's efforts to develop a civil rights compliance tool for natural disasters and national emergencies. The compliance tool, "Ensuring Language Access and Effective Communication During Response and Recovery: A Checklist for Emergency Responders," includes recommendations, specific action steps, and resources to assist first responders and emergency managers in communicating effectively in disasters and providing on-the-ground language assistance. This compliance tool continues OCR's long history of leadership and collaboration with other HHS agencies to ensure the protection of civil rights during emergency response and recovery.

CRD participates in the Agency Priority Goal (APG) Developmental Workgroup: Ending the HIV Epidemic, the Federal Steering Committee Meetings on the National HIV/AIDS Strategy and the National HIV/AIDS Strategy Federal Interagency Working Group, along with the HHS Office of HIV/AIDS and Infectious Disease Policy (OHAIDP) and representatives from the 15 Executive Departments. In 2018, OCR resolved HIV-related discrimination complaints against a Michigan dental office and an Oklahoma health insurance provider. In the Oklahoma matter, the patient alleged that his health insurer did not afford him an equal opportunity to receive healthcare coverage (e.g., genotypic resistance testing to identify his drug-resistant strains of HIV and guide his choice of antiretroviral therapy), in violation of Section 504 of the Rehabilitation Act and Section 1557 of the Affordable Care Act. During the course of OCR's investigation, the health insurer voluntarily agreed that the patient could submit a letter of medical necessity for consideration during the re-processing of the insurance claim. After the claim was re-processed, the health insurer agreed to cover the HIV genotypic resistance testing. Moreover, in a subsequent letter of assurance to OCR, the health insurer advised that due to the evolution of treatment standards, it now routinely covers HIV genotypic resistance testing.

Funding History

Fiscal Year	Amount
FY 2017	$4,525,000
FY 2018	$4,056,000
FY 2019	$3,755,000
FY 2020	$4,097,000
FY 2021 Request	$4,522,000

Budget Request

The FY 2021 request for the Civil Rights Division of $4,522,000 is $425,000 above the FY 2020 Enacted Level. At this level OCR will continue to aggressively enforce anti-discrimination laws with existing staff. The increase supports FY 2021 non-pay inflationary increases and other minor programmatic adjustments.

Conscience and Religious Freedom Division

(Dollars in Thousands)

Program	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget	FY 2021 +/- FY 2020
Budget Authority				
Discretionary Budget Authority	2,852	4,889	5,116	+227
Civil Monetary Settlement Funding	-	-	-	-
Total Program Level	**2,852**	**4,889**	**5,116**	**+227**
FTE				
Discretionary Budget Authority	6	12	15	+3
Civil Monetary Settlement Funding	-	-	-	-
Total Program Level	**6**	**12**	**15**	**+3**

Legal Authorities

- Church Amendments, 42 U.S.C. § 300a-7.
- Coats-Snowe Amendment, 42 U.S.C. § 238n.
- Weldon Amendment to the Annual Labor, HHS, & Education Appropriations Act and to Medicare Advantage, *e.g.*, Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019, Public Law 115-245, Division B, Title V, § 507(d) (Labor, HHS, Education), § 209 (Medicare Advantage).
- Religious Freedom Restoration Act, 42 U.S.C. § 2000bb *et seq.*
- Conscience protections in the Affordable Care Act, including Sections 1303, 1411, and 1553, 42 U.S.C. §§ 18023(b)(1)(A) and (b)(4), 18081, 18113.
- Conscience protections for participants in the Medicare and/or Medicaid Programs, including 42 U.S.C. § 14406(1) & (2), 42 U.S.C. §§ 1395w-22(j)(3)(B) and 1396u-2(b)(3)(B), 42 U.S.C. §§ 1395cc(f), 1396a(w)(3), 42 U.S.C. §§ 1320a–1(h), 1320c–11, 1395i–5, 1395x(e), 1395x(y)(1), 1396a(a), and 1397j–1(b)).
- Conscience and nondiscrimination protections for organizations related to Global Health Programs, to the extent such funds are administered by the Secretary of HHS, 22 U.S.C. § 7631(d).
- Conscience protections attached to Federal funding, to the extent such funding is administered by the Secretary, regarding abortion and involuntarily sterilization, 22 U.S.C. § 2151b(f), see, e.g., the Consolidated Appropriations Act, 2019, Pub. L. 116–6, Div. F, sec. 7018.
- Conscience protections from compulsory health care or services, 42 U.S.C. §§ 1396f and 5106i(a), 42 U.S.C. § 280g–1(d), 29 U.S.C. § 669(a)(5), 42 U.S.C. § 1396s(c)(2)(B)(ii), 42 U.S.C. § 290bb–36(f).
- Equal Employment Opportunity Provision of the Public Telecommunications Financing Act of 1978, Section 309, as amended, 47 U.S.C. § 398(b).
- Hill-Burton Community Service Assurance in Title VI, Sec. 603(e) of the Public Health Service Act (codified as amended at 42 U.S.C. § 291c(e)), and Title XVI, Secs. 1621(b)(1)(K) and 1627 of the Public Health Service Act (codified as amended at 42 U.S.C. §§ 300s-1(b)(1)(K)(i)), 300s-6).
- Nondiscrimination Provision of the Family Violence Prevention and Services Act Program, as amended, 42 U.S.C. § 10406.
- Nondiscrimination Provision of the Maternal and Child Health Services Block Grant Program, 42 U.S.C. § 708.

- Nondiscrimination Provision of the Preventive Health and Health Services Block Grant Program, 42 U.S.C. § 300w-7.
- Nondiscrimination Provision of the Projects in Assistance to Transition from Homelessness Program, 42 U.S.C. § 290c-33.
- Nondiscrimination Provision of the Substance Abuse Prevention and Treatment Block Grant and Community Mental Health Services Block Grant Programs, 42 U.S.C. § 300x-57.

Program Description

The OCR Conscience and Religious Freedom Division (CRFD) implements OCR's national conscience and religious freedom programs, including compliance with, and enforcement of, laws protecting conscience and the free exercise of religion and prohibiting coercion and religious discrimination. CRFD aims to encourage widespread respect and support for the Federal health care conscience and religious freedom rights of all Americans. CRFD seeks to make its vision a reality by vigorously promoting, implementing, and enforcing the health care conscience and religious freedom laws of the United States with respect to HHS's programs and activities.

Established in FY 2018 as a component of OCR's Headquarters operations, CRFD provides the organizational structure to elevate conscience and religious freedom to an equal status with OCR's civil rights and health information privacy programs. CRFD centralizes OCR and HHS-wide conscience and religious freedom efforts in Headquarters. OCR adopted a similar centralized model when it began administering its new health information privacy responsibilities in the early 2000s. This model maximizes OCR's ability to build expertise and capacity in handling complex, sensitive, and novel policy and enforcement questions of first impression.

CRFD supports the President's Executive Order 13798, 82 FR 21675 (May 8, 2017), to "vigorously enforce Federal law's robust protections for religious freedom" — the Nation's first freedom, as well as guidance issued by the Attorney General of the United States regarding federal law protections for religious liberty, including protection of the right to perform or refrain from performing certain physical acts in accordance with one's beliefs, in HHS's programs and activities. CRFD also support HHS's efforts to enhance respect for the role of religious people and institutions in everything HHS does. As Executive Order 13798 explains, "[t]he Founders envisioned a Nation in which religious voices and views were integral to a vibrant public square, and in which religious people and institutions were free to practice their faith without fear of discrimination or retaliation by the Federal Government."

The Federal laws in CRFD's portfolio implicate conscience and religious nondiscrimination laws in health and human services programs.

Examples of the conscience laws that OCR enforces include the Church, Coats-Snowe, and Weldon Amendments; and Sections 1303(b)(1)(A) and (b)(4) and 1553 of the Affordable Care Act. Collectively, these laws protect health care professionals (current and those in training) and other entities from being discriminated against on certain bases, such as for not providing, paying for, referring for, performing, or assisting in certain services, such as abortions, sterilizations, or assisted suicide.

Examples of the religious freedom laws that OCR enforces include those that collectively protect participation in, afford accommodations to, or protect receipt of benefits from, certain federally funded or administered programs. For instance, provisions of the Social Security Act, as amended, afford accommodations for religious nonmedical health care institutions to participate in Medicare

and Medicaid. OCR also enforces the religious nondiscrimination requirement of several grant programs, including the Maternal and Child Health Block Grant, Community Mental Services Health Block Grant, Substance Abuse and Mental Health Treatment Block Grant, Preventive Health and Health Services Block Grant, and Family Violence Prevention Services Act Programs, among others.

Finally, CRFD has delegated authority to promote compliance with the Religious Freedom Restoration Act (RFRA) with respect to HHS programs and activities. RFRA prohibits the Federal government from "substantially burdening a person's exercise of religion" unless the burden to the person furthers a compelling governmental interest and is the least restrictive means of doing so. 42 U.S.C. § 2000bb-1(a), (b). As interpreted by the U.S. Supreme Court, under RFRA, a substantial burden with respect to an adherent's religious observance or practice includes the banning of, compelling an act inconsistent with, or substantially pressuring the modification of, such religious observance or practice. *Sherbert* v. *Verner,* 374 U.S. 398, 405-06 (1963).

Capacity Building

In FY 2019, OCR made substantial progress towards its staffing goals to hire career staff with the appropriate skills and experience. As career staff came on-board, the contract support utilized by CRFD decreased. The on-board strength of CRFD's career staff was equivalent to 6 FTEs in FY 2019 and OCR projects to be near 11 FTE at the beginning of FY 2020, which includes CRFD's leadership and management team, which CRFD had in place by the end of April 2019.

Program Tools to Promote Compliance

CRFD uses a variety of tools to improve compliance with laws that protect the exercise of conscience and prohibit discrimination based on religion, such as one's religious observance and practice.

Complaint Examination, Investigation, and Management

CRFD conducts OCR's nationwide investigation activities under HHS's conscience and religious freedom authorities and manages the life-cycle of a conscience or religious nondiscrimination complaint from intake through to case resolution. Examples of complaints alleging a violation of one's exercise of conscience include a health care entity being subject to a State law that assess fines if the health care entity refuses to provide certain notices, or refer for, or make arrangements for, abortion. An example of a complaint alleging a religious freedom violation include an organization alleging that an HHS regulatory requirement for participation in an HHS program has substantially burdened a person's exercise of religion by forcing the person to choose between participating in the HHS program and comply with the regulatory requirement or living out the person's sincerely held religious beliefs.

Based on case data from OCR's system of record as of December 12, 2019, OCR received over 1,760 cases during FY 2019 in which the complainant alleged a conscience or religious discrimination violation. Of these cases, including CRFD's pre-FY 2019 caseload, CRFD closed 29% of its complaints received in FY 2019 and resolved within 180 days about 40% of the cases it closed that did not require formal investigation. This performance exceeded FY 2019 targets. Federal non-management staff, with contractor support as needed, handle this workload.

CFRD continues to handle and investigate cases received in previous fiscal years, including high-impact cases, which constitute a relatively small proportion of CRFD's complaint docket. These cases are highly complex and sensitive cases of national significance implicating sophisticated covered entities or dealing with previously unenforced areas of law. These cases warrant a disproportionate

amount of staff resources, relative to lower-impact cases, on legal research, case strategy, case theory development, investigation planning and execution, and case resolution strategies.

Policy Development and Implementation

In coordination with the HHS Center for Faith and Opportunity Initiatives, CRFD provides subject-matter expertise, analytic support, and leadership throughout HHS on the development, impact, and implementation of regulatory and Congressional actions regarding conscience and religious freedom matters in health and human services. CRFD also serves as a clearinghouse for policy and program issues involving conscience and religious freedom.

With regard to regulatory matters, CRFD engages in rulemaking, policy development, guidance drafting, and technical assistance to fill gaps in the implementation and enforcement of Federal conscience and religious freedom laws. In FY 2019, OCR finalized a regulation to enhance compliance with statutory conscience and associated nondiscrimination rights in health care, including an additional 22 conscience protections for which the Secretary or Congress delegated authority to OCR to handle. *See* 84 FR 23170 (May 21, 2019). CRFD has drafted technical assistance, education, and outreach materials on the 2019 Conscience Rule to facilitate regulated entities' voluntary compliance and individuals' and entities' awareness of their rights.

In FY 2021, CRFD will continue work in coordination with the HHS Center for Faith and Opportunity Initiatives to provide subject-matter expertise and regulation drafting support to HHS components who seek OCR's analysis of how Federal conscience and religious nondiscrimination laws may impact components' program decisions. CRFD will also continue its review of HHS components' draft rulemaking and guidance documents for consistency with Federal conscience and religious freedom laws and policy, such as RFRA. These efforts will ensure that, from the beginning of a contemplated action, HHS components assess the implications of conscience and religious freedom laws on their programs, and act to minimize or eliminate any burden that the action may impose on the exercise of religion, consistent with the law and the Attorney General's Memorandum.

With regard to Congressional actions, CRFD provides subject-matter expertise and analytic support to HHS's Office of the Assistant Secretary for Legislation and Office of the Assistant Secretary for Financial Resources in responding to Congressional oversight letters, requests for information, and technical assistance on Federal legislation. In FY 2021, CRFD will continue this work, which benefits not only OCR but also ensures other HHS components are aware of, and engaged on, these matters as "one HHS."

Compliance and Enforcement

CRFD is responsible for promoting the Department's own compliance with applicable Federal conscience and religious freedom laws and OCR's compliance with Freedom of Information Act (FOIA) requests that implicate conscience and religious nondiscrimination matters. To that end, CRFD educates, coordinates with, and collaborates with HHS components, including staff divisions within the Office of the Secretary, to ensure that the relationships and systems are in place to effectively and efficiently accomplish HHS's own internal compliance. Because OCR's 2019 Conscience Rule relies on OCR using HHS's existing mechanisms for enforcing terms and conditions of HHS grants and contracts and conditions of participation under programs such as Medicare and Medicaid, CRFD's continued coordination in FY 2021 with HHS and component-level offices that award and manage these instruments is critical to HHS's robust and informed enforcement of these laws.

CRFD provides critical leadership throughout HHS to further the Department's own compliance with the applicable conscience and religious freedom laws and regulations, such as the federal conscience statutes and RFRA. More specifically, CRFD provides HHS-wide technical assistance, training, and interagency coordination to assure consistent and effective implementation and compliance.

In FY 2019 and FY 2020, CRFD processed thousands of pages to respond to high-volume FOIA requests under a monthly production schedule. CRFD, like all of OCR's divisions, takes its legal obligation under the Freedom of Information Act seriously and processes FOIA requests as expeditiously as possible and as required by law.

Outreach Activities to Raise Awareness and Enhance Compliance Education

CRFD is at the forefront in changing public awareness to recognize that conscience and religious freedom violations are serious infractions that transgress basic human dignity and fundamental rights. CRFD's education and outreach efforts communicate the principle that it is fundamentally unfair to coerce, treat differently, persecute, or penalize an individual or organization for acting in accord with its religious or moral beliefs when those actions constitute protected conduct under Federal law.

CFRD faces significant challenges including conscience and religious freedom issues in health and human services are not easily understood and frequently misrepresented in public discourse. Federal laws protect the exercise of moral convictions and religious beliefs, and giving life to those laws fosters greater tolerance and diversity in HHS programs.

In coordination with the HHS Center for Faith and Opportunity Initiatives, CRFD educates and informs the public of the historical underpinnings of conscience and religious freedom laws and the scope of existing protections under Federal law with respect to HHS programs and activities. These education and training activities seek to illuminate the positive impact of conscience and religious freedom protections, such as preventing the harm health care providers would experience from moral injury, which is "a sense of complicity in doing wrong" and "a deep anguish that comes from the nature of those circumstances [of the provider's work environment] as systemic, persistently recurrent, and pervasively productive of crises of conscience."[2] Some of the best providers of health care and human services are motivated by their religious beliefs or moral convictions, and they should not be driven out of Federal programs because of those convictions.

CRFD conducts its outreach and education efforts closely with OCR's media unit and also works closely with the HHS Center for Faith and Opportunity Initiatives to liaise and build relationships with national advocacy, beneficiary, and provider groups; religious organizations; faith-based organizations; state and local governments; for-profit and non-profit organizations; and other Federal departments and agencies. CRFD also raises awareness of how individuals or entities who believe their rights have been violated can file complaints with OCR.

Accomplishments

During CRFD's short tenure, it has already demonstrated a variety of accomplishments across key

[2] 2019 Conscience Rule, 84 FR 23170, 23249 (May 21, 2019) (elaborating on the literature of moral distress). Substantial academic literature documents the existence among health care providers of moral injury, which functions as a pressure on providers to leave the health care profession. *See, e.g.*, *id*.

areas:

Rulemaking to Enhance Compliance with Statutory Conscience Rights in Health Care: On May 21, 2019, HHS issued a final rule substantially revising its existing health conscience regulation. The revised regulation protects the statutory rights of individuals and entities to refrain from certain activities without discrimination or retaliation related to health care services implicating abortion, sterilization, and assisted suicide, among others. This regulation implements the full spectrum of Federal health conscience and associated anti-discrimination statutory provisions (25 in all), and articulates the scope of enforcement tools otherwise available in existing HHS regulations to address violations of Federal law and resolve complaints. To ensure recipients of Federal financial assistance and other HHS funds comply with their legal obligations, the regulation requires certain recipients to maintain records; cooperate with OCR's investigations, reviews, or other proceedings; and submit written assurances and certifications of compliance to HHS. This rule was vacated before its effective date by a Federal District court. The Department of Justice has filed a notice of appeal on behalf of HHS.

Raising Awareness and Enhancing Compliance Education: In FY 2019, CRFD engaged in significant outreach that raised awareness of CRFD's formation and of the Federal health conscience and religious nondiscrimination laws it enforces. These initiatives informed the public of OCR's complaint process and brought a renewed focus to covered entities' obligations and persons' rights under Federal laws. These efforts, which CRFD conducted in coordination with the Center for Faith and Opportunity Initiatives, honored an important bipartisan commitment to use education and outreach programs to facilitate compliance with all Federal civil rights laws, including those protecting the rights of individuals and entities to be free from coercion or discrimination on account of religious beliefs or moral convictions.

In FY 2019, the CRFD-specific portion of the OCR website received an average of approximately 4,300 site visits every month. The announcement of the 2019 Conscience Rule and of CRFD's resolution of high-impact complaints raised public awareness of OCR and its conscience and religious nondiscrimination work to unprecedented levels.

Establishing a Rigorous National Enforcement Program: CRFD has built a nationwide program to handle, investigate, and enforce conscience and religious freedom authorities from OCR Headquarters. CRFD is unique among HQ Divisions in that it handles case processing and investigation for the Federal conscience and religious freedom laws within OCR's purview in addition to handling policymaking functions.

In FY 2019, CRFD favorably resolved three high-profile matters of national significance, resulting in the enforcement of laws passed by Congress, the protection of the conscience rights of American citizens, and a heightened public awareness of CRFD and the law it enforces. For instance, OCR issued a letter notifying the State of Hawaii that complaints against the state regarding Hawaii's Act 200, a 2017 law that required certain pregnancy centers to disseminate a government-scripted notice that promotes abortion, were satisfactorily resolved when Hawaii's Attorney General issued a memorandum to the Department of the Attorney General for the State of Hawaii, which is charged with enforcing Act 200, stating that it will not enforce Act 200's notice provisions against any limited

service pregnancy center, and also notified Hawaii's legislature of its decision not to enforce Act 200's notice requirements.[3]

As another example, OCR issued a letter notifying the State of California that it had violated the Weldon Amendment and the Coats-Snowe Amendments by enacting the Reproductive Freedom, Accountability, Comprehensive Care, and Transparency Act (currently enjoined), which subjected certain pregnancy centers to potential fines if they refused to provide certain notices that refer for or make arrangements for abortion.[4]

Finally, HHS has undertaken major policy changes to protect religious freedom, including issuing a Secretarial delegation for OCR to ensure compliance with the Religious Freedom Restoration Act ("RFRA") in HHS's federally funded programs and activities. In FY 2019, OCR worked with the Administration for Children and Families to satisfactorily resolve a request from the State of South Carolina for a waiver or exception from certain HHS regulations, in order to permit the State to continue working with a particular faith-based foster care provider and all similarly situated faith-based providers; OCR recommended granting the exception to order to ensure compliance with RFRA.

In terms of major open enforcement actions, during the Fiscal Year, OCR issued a notice of violation to a major medical center in the State of Vermont notifying it that it had violated the Church Amendments by forcing a nurse to assist in an elective abortion procedure over the nurse's conscience-based objections. OCR also found that the medical center had violated the Church Amendments by having discriminatory policies that assign or require employees to assist in abortion procedures even after they had recorded their religious or moral objections to assisting in the performance of such abortions.

Funding History

Fiscal Year	Amount
FY 2017	-
FY 2018	$3,927,000
FY 2019	$2,852,000
FY 2020	$4,889,000
FY 2021 Request	$5,116,000

Budget Request

The FY 2021 request for the Conscience and Religious Freedom Division of $5,116,000 is $227,000 above the FY 2020 Enacted Level. The increase reflects the addition of 3 FTEs and associated overhead costs. This FTE level is the minimum necessary to keep pace with the increasing conscience and religious freedom complaints and maintain operations of other program activities in the current structure within CRFD. This FTE increase seeks to bring parity with other Headquarters Divisions, which have similar FTE counts, and that do not handle their own intake and investigation of cases, as CRFD does.

[3] https://www.hhs.gov/about/news/2019/03/22/ocr-issues-notice-resolution-state-hawaii-after-hawaii-takes-action-safeguarding-conscience.html.

[4] https://www.hhs.gov/about/news/2019/01/18/ocr-finds-state-california-violated-federal-law-discriminating-against-pregnancy-resource-centers.html.

Health Information Privacy Division

(Dollars in Thousands)

Program	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget	FY 2021 +/- FY 2020
Budget Authority				
Discretionary Budget Authority	3,964	4,328	722	-3,606
Civil Monetary Settlement Funding	2,076	4,663	8,607	+3,944
Total Program Level	**6,040**	**8,991**	**9,329**	**+338**
FTE				
Discretionary Budget Authority	15	14	3	-11
Civil Monetary Settlement Funding	-	6	15	+9
Total Program Level	**15**	**20**	**18**	**-2**

Legal Authorities

- Administrative Simplification Provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), section 264, Public Law 104-191, 42 U.S.C. §1320d-2 (note).
- Social Security Act, section 1173(d), as added by HIPAA §262(a), 42 U.S.C. §1320d-2(d).
- Confidentiality provisions of the Patient Safety and Quality Improvement Act of 2005 (PSQIA), Public Law 109-41, 42 U.S.C. §299b-21 – 299b-26.
- Title I of the Genetic Information Nondiscrimination Act of 2008 (GINA), Public Law 110-233, section 105, 42 U.S.C. §1320d-9.
- Health Information Technology for Economic and Clinical Health Act (HITECH), American Recovery and Investment Act of 2009, Public Law 111-5, sections 13400- 13423, 42 USC §§17921-17953, as amended.
- 21st Century Cures Act of 2016, Public Law 114-255, Sections 4006(a) and (b), 11003, and 11004.

Program Description

The collection and sharing of health information is critical to improving the quality and safety of health care and advancing medical discoveries that can improve the health and wellbeing of individuals and populations. However, in the face of increasing cybersecurity threats targeting the health care sector and public concerns about the privacy and security of health data, active education, and enforcement of privacy and security regulations are critical to building and maintaining public trust in robust uses and disclosures of health information. HIP works to ensure the protection of health information privacy from unauthorized uses and disclosures, and to enforce the right of individual patients to access their health information.

Through its innovative efforts to promote and enforce HIPAA privacy and security protections, HIP supports public and private sector efforts to improve health care quality and reduce costs, including addressing the opioid crisis; advancing interoperability of digital health information; empowering individuals to make health care decisions; enabling enhanced care coordination; building public trust in health data sharing; helping to build the privacy and security framework for public and private sector research initiatives that yield medical discoveries; supporting public health surveillance and emergency preparedness and response activities; improving the ability of entities subject to HIPAA to prevent and effectively respond to cybersecurity threats; and improving the safety of health care by helping to facilitate confidential analysis of medical errors and other patient safety events.

HIP improves compliance with the HIPAA privacy, security, and breach notification regulations through:

(1) Robust policy guidance and outreach to the public and industry stakeholders including actively addressing common questions about HIPAA's regulations and how the rules apply to novel circumstances and new technologies;
(2) Periodic audits, as required by law, to proactively identify and address vulnerabilities before they result in breaches, unauthorized disclosures, or other HIPAA violations;
(3) Support to the Director in advising Departmental leadership on cross-cutting issues involving HIPAA privacy and security;
(4) Partnerships with OCR's regional offices to exercise OCR's enforcement and civil money penalty authority to hold entities financially accountable for systemic or egregious compliance failures and to obtain corrective action; and
(5) Reform of regulatory provisions for which the benefit to health information privacy and security is outweighed by the burden imposed.

Policy

The HIPAA Privacy and Security Rules were initially written and implemented more than a decade ago, and much has changed in health care, including access, use, and disclosure of health information. Recognizing that well-intended regulations can lose their efficacy with the passage of time and regulatory complexity can contribute to noncompliance, OCR is reviewing its regulations and significant sub-regulatory guidance to identify and modify or eliminate regulatory provisions and interpretations that are no longer effective or increase complexity for the regulated community without a corresponding benefit to health information privacy or security protections, or empowerment of individuals. At the same time, OCR is actively working to implement provisions of HITECH Act and the 21st Century Cures Act that mandate new regulations or the issuance of further guidance. OCR will seek input from the public as it undertakes this review, both informally as well as through applicable Administrative Procedure Act notice and comment processes.

Audit Program

OCR examines the HIPAA compliance of randomly selected entities through OCR's audit program, to help promote compliance with the HIPAA regulations. HIP's audit program, required under the HITECH Act, is a proactive and systemic look at industry compliance. Following the comprehensive evaluation conducted in the first pilot phase of OCR's audit program, Phase 2 (conducted in 2016 and 2017) focused on desk audits of over 200 covered entities and business associates who submitted documentation of their efforts to comply with selected provisions of the HIPAA regulations. In 2018 and beyond, OCR will continue to use the audit program as a tool for obtaining HIPAA compliance from selected entities, and the identification of compliance issues for future OCR activities including outreach and sub-regulatory guidance.

Raising Awareness and Enhancing Public Education

HIP provides outreach and technical assistance to covered entities, business associates, and consumers regarding compliance with the HIPAA rules and individuals' rights under HIPAA.

- During FY 2019, the Director and HIP participated in over 60 outreach events nationwide. These events include keynote addresses and important plenary sessions at major industry conferences, including the American Health Lawyers Association, the American Bar Association, HIPAA Summit, and the Healthcare Information and Management Systems Society.

- HIP cosponsored its 11th annual conference in FY 2019 focusing on best practices for compliance with the HIPAA Security Rule with the National Institute of Standards and Technology (NIST) of the U.S. Department of Commerce. The event attracted over 1,000 participants over two days, through both its in-person conference and live webcast.

- HIP continues to generate substantial news as OCR and its enforcement or policymaking activities have been referenced in over 160 national and local news stories since April 2019, including in the Wall Street Journal, Politico, Bloomberg Law, Kansas City Star, Minneapolis Star Tribune, and others. HIP also handles approximately 200 press queries a year on all aspects of the HIPAA Privacy, Security, and Breach Notification Rules.

Accomplishments

In early FY 2019, OCR settled the largest U.S. healthcare data breach with the largest HIPAA settlement in OCR history with the $16 Million settlement with Anthem, Inc. The investigation found that after a series of cyber-attacks against Anthem's IT system, almost 79 million individuals' electronic protected health information had been exposed. OCR determined that Anthem failed to implement appropriate measures for detecting hackers who had gained access to their IT system to harvest passwords and steal people's health information.

In December 2018, OCR issued a Request for Information (RFI) as part of the Department's "Regulatory Sprint to Coordinated Care." The RFI sought public comments on how OCR could amend the HIPAA Privacy Rule to remove regulatory obstacles and decrease regulatory burdens in order to facilitate efficient care coordination and/or case management and to promote the transition of the health care system to a value-based system, while preserving the privacy and security of protected health information. OCR sought comment on (1) promoting information sharing for treatment, care coordination and/or case management; (2) encouraging covered entities to share treatment information with parents, loved ones, and caregivers of adults facing health emergencies; (3) implementing the HITECH Act requirement to include in an accounting of disclosures, disclosures for treatment, payment and health care operations from an electronic health record; and (4) eliminating or modifying the requirement for covered health care providers to make a good faith effort to obtain individuals' written acknowledgment of receipt of providers' Notice of Privacy Practices.

In April 2019, OCR issued a new frequently asked questions (FAQ) document to address the HIPAA right of access as it relates to apps designated by individual patients and application programming interfaces (APIs) used by a healthcare provider's electronic health record (EHR) system. The FAQs clarify that once protected health information has been shared with a third-party app, as directed by the individual, the HIPAA covered entity will not be liable under HIPAA for subsequent use or

disclosure of electronic protected health information, provided the app developer is not itself a business associate of a covered entity or of other business associate.

In April 2019, OCR issued a Notification of Enforcement Discretion Regarding HIPAA Civil Money Penalties that, consistent with statutory limitations, reduced the maximum annual limit for identical violations in a calendar year for three of the four culpability tiers as a better reading of the requirements of the HITECH Act.

In May 2019, OCR issued a new fact sheet that provides a clear compilation of all provisions through which a business associate can be held directly liable for compliance with certain requirements of the HIPAA Privacy, Security, Breach Notification, and Enforcement Rules, in accordance with the HITECH Act of 2009.

In June 2019, OCR issued a new frequently asked questions (FAQ) document that clarifies how the HIPAA Privacy Rule permits health plans to share protected health information (PHI) in a manner that furthers the HHS Secretary's goal of promoting coordinated care. The FAQ explains when and how one health plan can share PHI about individuals in common with a second health plan for care coordination purposes under the Privacy Rule. The FAQ also clarifies that, in certain circumstances, the Privacy Rule permits a health plan to use PHI to inform individuals about a replacement for health insurance, even if the plan received the PHI for a different purpose, without the communication being deemed marketing.

In December 2019, OCR issued updated joint guidance with the U.S. Department of Education addressing the application of the Family Educational Rights and Privacy Act (FERPA) and the HIPAA Privacy Rule to records maintained on students. The revised guidance includes additional frequently asked questions and answers addressing when a student's health information can be shared without the written consent of the parent or eligible student under FERPA, or without written authorization under the HIPAA Privacy Rule.

In CY 2019, OCR completed ten enforcement actions including the imposition of two civil money penalties, and the settlement of eight cases with a monetary settlement and corrective action plan, for a total of $12.2 million in collections. The cases selected for settlement or enforcement action highlight substantial noncompliance with the HIPAA Rules, or egregious failures to implement or protect individuals' HIPAA rights. Highlights include settling two cases involving an individual's right to receive a copy of their medical records as part of OCR's Right of Access Initiative, and breach investigations involving PHI on unsecured servers, unencrypted mobile devices, failure to provide proper breach notification to HHS, and impermissible disclosures on social media. These high profile cases require substantial deployments of OCR resources and send important messages to the public about their HIPAA rights and to industry stakeholders about their obligation to protect health information. Cases resolved through formal agreements and settlements, however, represent a relatively small proportion of OCR's total HIP docket. OCR initiates investigations through complaints received from the public, compliance reviews based upon information received from other sources, and the breaches reported to HHS by regulated entities. OCR closes most (>95%) of its cases after investigation, through the provision of technical assistance, or the confirmation of corrective actions.

OCR audited 166 covered entities and 41 business associates pursuant to phase 2 of the HITECH audit program. The phase 2 audits focused on the HIPAA Security Rule risk analysis and risk management provisions, the HIPAA Breach Notification Rule requirements to notify individuals and

HHS of breaches of health information, and the HIPAA Privacy Rule requirements to provide individuals with a Notice of Privacy Practices and to provide individuals with access to their health information. In FY 2019, individual reports were sent to each audited entity, and a comprehensive report to the public identifying best practices as well as the recurring patterns of noncompliance that OCR will consider for future guidance, outreach, and compliance reviews is planned for FY 2020.

Funding History

Fiscal Year	Amount
FY 2017	$4,156,000
FY 2018	$2,866,000
FY 2019	$3,964,000
FY 2020	$4,328,000
FY 2021 Request	$722,000

Budget Request

The FY 2021 discretionary budget request for the Health Information Privacy Division of $722,000 is $3,606,000 below the FY 2020 Enacted Level. OCR will offset reductions with $8,607,000 in settlement funding, $3,944,000 more than in FY 2020. OCR will continue health information privacy, security, and breach notification activities.

Section IV: Supplementary Tables

Budget Authority by Object Class

(Dollars in Thousands)

Object Class Code	Description	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget	FY 2021 +/- FY 2020
11.1	Full-time permanent	15,808	16,606	15,933	-673
11.3	Other than full-time permanent	752	742	751	+9
11.5	Other personnel compensation	263	324	246	-78
11.7	Military personnel	97	98	101	+3
Subtotal	***Personnel Compensation***	**16,920**	**17,770**	**17,031**	**-739**
12.1	Civilian personnel benefits	5,218	5,702	5,790	+88
12.2	Military benefits	36	37	38	+1
13.0	Benefits for former personnel	142	20	146	+126
Total	***Pay Costs***	**22,316**	**23,529**	**23,005**	**-524**
21.0	Travel and transportation of persons	461	467	191	-276
22.0	Transportation of things	1	28	8	-20
23.1	Rental payments to GSA	3,362	3,539	1,146	-2,393
23.3	Communications, utilities, and misc. charges	137	143	91	-52
24.0	Printing and reproduction	295	139	162	+23
25.2	Other services from non-Federal sources	259	1,821	749	-1,072
25.3	Other goods and services from fed sources	11,103	8,168	4,466	-3,702
25.4	Operation and maintenance of facilities	240	175	92	-83
25.7	Operation and maintenance of equipment	333	400	261	-139
Subtotal	***Other Contractual Services***	**11,935**	**10,564**	**5,568**	**-4,996**
26.0	Supplies and materials	131	135	50	-85
31.0	Equipment	29	254	65	-189
Total	***Non-Pay Costs***	**16,351**	**15,269**	**7,281**	**-7,988**
Total	**Budget Authority by Object Class**	**38,667**	**38,798**	**30,286**	**-8,512**

Salaries and Expenses Table

(Dollars in Thousands)

Object Class Code	Description	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget	FY 2021 +/- FY 2020
11.1	Full-time permanent	15,808	16,606	15,933	-673
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12.1	Civilian personnel benefits	5,218	5,702	5,790	+88
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21.0	Travel and transportation of persons	461	467	191	-276
22.0	Transportation of things	1	28	8	-20
23.3	Communications, utilities, and misc. charges	137	143	91	-52
24.0	Printing and reproduction	295	139	162	+23
25.2	Other services from non-Federal sources	259	1,821	749	-1,072
25.3	Other goods and services from fed sources	11,103	8,168	4,466	-3,702
25.4	Operation and maintenance of facilities	240	175	92	-83
25.7	Operation and maintenance of equipment	333	400	261	-139
Subtotal	***Other Contractual Services***	**11,935**	**10,564**	**5,568**	**-4,996**
26.0	Supplies and materials	131	135	50	-85
Total	***Non-Pay Costs***	**12,960**	**11,476**	**6,070**	**-5,406**
Total	***Salary and Expenses***	**35,276**	**35,005**	**29,075**	**-5,930**
23.1	Rental payments to GSA	3,362	3,539	1,146	-2,393
Total	***Salaries, Expenses, and Rent***	**38,638**	**38,544**	**30,221**	**-8,323**
Total	**Direct FTE**	**139**	**151**	**141**	**-10**

Detail of Full-Time Equivalent (FTE) Employment

Detail	FY 2019 Actual Civilian	FY 2019 Actual Military	FY 2019 Actual Total	FY 2020 Estimate Civilian	FY 2020 Estimate Military	FY 2020 Estimate Total	FY 2021 Estimate Civilian	FY 2021 Estimate Military	FY 2021 Estimate Total
Direct	138	1	139	150	1	151	140	1	141
Reimbursable	1	-	1	2	-	2	1	-	1
Total FTE	**139**	**1**	**140**	**152**	**1**	**153**	**141**	**1**	**142**

Average GS Grade

FY 2017: GS 13
FY 2018: GS 13
FY 2019: GS 13
FY 2020: GS 13
FY 2021: GS 13

Detail of Positions

Detail	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget
Executive level I	-	-	-
Executive level II	3	3	3
Executive level III	3	3	3
Executive level IV	-	-	-
Executive level V	-	-	-
Subtotal	***6***	***6***	***6***
Total - Executive Level Salaries	**$1,124,000**	**$1,149,000**	**$1,176,000**
GS-15	26	29	28
GS-14	21	23	20
GS-13	31	32	29
GS-12	41	44	44
GS-11	5	6	4
GS-10	-	-	-
GS-9	7	8	7
GS-8	-	-	-
GS-7	1	1	1
GS-6	-	1	1
GS-5	-	-	-
GS-4	-	-	-
GS-3	-	-	-
GS-2	-	-	-
GS-1	-	-	-
Subtotal	**132**	**144**	**134**
Total - GS Salary	**$15,436,000**	**$16,199,000**	**$15,508,000**
Average ES level	III	III	III
Average ES salary	$187,333	$191,500	$196,000
Average GS grade	13.6	13.5	13.6
Average GS Salary	$116,939	$112,493	$115,731

Section V: Significant Items

OCR Response to Appropriations Committee Report

None

Good Accounting Obligation in Government Act (GAO-IG Act) Report

The information below addresses the requirements of the Good Accounting Obligation in Government Act (GAO-IG Act; Public Law 115-414) to provide a report identifying each public recommendation issued by the Government Accountability Office (GAO) and federal Offices of Inspectors General (OIG) which remains unimplemented for one year or more from the annual budget justification submission date. The recommendations below apply specifically to this division of HHS. Please refer to the General Departmental Management budget justification for more information on the Department's overall progress in implementing GAO and OIG recommendations.

Appendix 1: OIG-GAO Open Recommendations							
Report Number	**Report Title**	**Report Date**	**Recommendation Text**	**Concur / Non-Concur**	**Implementation Timeline**	**Implementation Status**	**Implementation Updates and Constraints**
GAO-16-771	Electronic Health Information: HHS Needs to Strengthen Security and Privacy Guidance and Oversight	9/26/2016	To improve the effectiveness of HHS guidance and oversight of privacy and security for health information the Secretary of Health and Human Services should update security guidance for covered entities and business associates to ensure that the guidance addresses implementation of controls described in the National Institute of Standards and Technology Cybersecurity Framework.	Concur	2021	In Progress	OCR has fully implemented this GAO recommendation. In 2016, OCR created the NIST Cybersecurity Framework to HIPAA Security Rule Crosswalk in collaboration with the HHS Office of the National Coordinator for Health Information Technology (ONC) and the National Institute of Standards and Technology (NIST). This tool can be used by HIPAA covered entities and business associates to understand how the HIPAA Security Rule requirements can be "mapped" to specific NIST Cybersecurity Framework subcategories, thus informing an organization of its level of framework adoption based on its HIPAA compliance. Organizations that have already aligned their security programs to either the NIST Cybersecurity Framework or the HIPAA Security Rule can use this crosswalk to identify and remediate potential gaps in their security programs. OCR, in collaboration with ONC, maintains the Security Risk Assessment (SRA) Tool. This tool helps HIPAA covered entities and business associates identify risks to the confidentiality, integrity, and availability to their electronic protected health information (ePHI). The SRA Tool has undergone several revisions, including a major update in 2018 that included a new user-friendly interface and additional guidance for protecting ePHI and ensuring compliance with the HIPAA Security Rule. Revisions in 2019 incorporated references to the NIST Cybersecurity Framework to assist organizations that want to incorporate Framework components into their security program. The 2019 revisions also made the tool easier to use, particularly for small health care providers that may not have the resources to support dedicated information systems security staff. The tool diagrams HIPAA Security Rule safeguards and provides enhanced functionality to document how an organization implements safeguards to mitigate, or plans to mitigate, identified risks. OCR also participates in HHS Cybersecurity Task Force activities to promote awareness and use of the NIST Cybersecurity Framework. The Task Force was established by HHS in accordance with the Cybersecurity Act of 2015 to address the challenges the health care industry faces securing and protecting itself against cybersecurity threats. As a member of the Task Force Steering Committee, OCR collaborates with other federal agencies providing input and guidance to Task Force members for their work products including the Health Industry Cybersecurity Practices: Managing Threats and Protecting Patients documents released in 2018. The purpose of these documents is to improve the cybersecurity practices of healthcare entities by sharing best practices that align with the NIST Cybersecurity Framework and are consistent with HIPAA and HITECH requirements. The Task Force continues to draft new documents building upon the best practices documents released in 2018. OCR reviews drafts of these new work products to ensure consistency of NIST recommended best practices with the HIPAA Rules.

GAO-16-771	Electronic Health Information: HHS Needs to Strengthen Security and Privacy Guidance and Oversight	9/26/2016	To improve the effectiveness of HHS guidance and oversight of privacy and security for health information the Secretary of Health and Human Services should update technical assistance that is provided to covered entities and business associates to address technical security concerns.	Concur	2019	In Progress	OCR has fully implemented this GAO recommendation. OCR offers many tools to assist entities in their HIPAA compliance efforts. For example, entities can consult the recently updated HHS SRA Tool for help in evaluating whether they have a compliant risk analysis and risk management plan. OCR's access guidance and other HHS resources provide clarity for how entities can improve patients' access to their health information by implementing improved policies and procedures and digital technologies. OCR issues technical assistance in the form of quarterly Cybersecurity Awareness Newsletters to help HIPAA covered entities and business associates remain in compliance with the HIPAA Security Rule by identifying emerging or prevalent issues, and highlighting best practices to safeguard ePHI. Topics covered in past OCR's Cybersecurity Newsletters include: ransomware, phishing, patching vulnerabilities, security training, authentication, audit logs, and risks of using third-party software. These Cybersecurity Newsletters are available on OCR's website, which also includes many other helpful technical assistance and guidance documents topics relating to information security, including new threats and new technologies, to assist covered entities and business associates in protecting ePHI in compliance with HIPAA. For example, OCR posted detailed guidance on how to prevent, detect, and respond to ransomware attacks and explaining an entity's breach reporting obligations with respect to ransomware attacks. This guidance was supplemented by OCR's Fall 2019 Cybersecurity Newsletter that provided updates on the evolving threat of new types of ransomware attacks and technical assistance on how to counter these threats. OCR has also provided detailed guidance regarding the use of cloud service providers to host ePHI on behalf of covered entities and business associates. This guidance offered technical assistance regarding the use of business associate contracts and service level agreements to ensure that safeguards to protect ePHI are in place and clearly communicated. OCR collaborated with ONC, the Federal Trade Commission (FTC), and the Food and Drug Administration (FDA) to develop a tool to assist health app developers in determining which laws apply to them, including HIPAA and FTC's Health Breach Notification Rule. Additionally, OCR maintains a health app developer portal that provides technical assistance and guidance on HIPAA compliance and protecting ePHI. In addition to providing a set of health app use scenarios describing the circumstances in which HIPAA applies to health app developers, the portal provides an opportunity for the health app developer community to ask technical and compliance related questions and receive answers and feedback in a moderated forum. Although geared to the health app developer community, the portal is viewable and searchable by the public and offers technical guidance and compliance information applicable to covered entities and business associates more generally. OCR also provides technical assistance in the form of outreach activities directed toward HIPAA covered entities, business associates, and their counsel that provided technical assistance and guidance on complying with the HIPAA Rules and protecting PHI. OCR regularly

							participates in industry conferences to discuss emerging issues in health information privacy and security. Many of these conferences are hosted by national associations including the American Bar Association, American Health Law Association, Health Care Compliance Association, Public Responsibility in Medicine and Research, Workgroup for Electronic Data Interchange (WEDI), Sedona Conference, and Association of American Medical Colleges. Additionally, OCR cosponsors an annual cybersecurity and HIPAA conference with NIST that provides attendees with an opportunity to interact with and receive technical assistance directly from OCR and NIST cybersecurity experts and leadership as well as experts from other federal agencies and private industry. In 2019, there were over 1000 in-person and web streaming attendees.OCR frequently collaborates with other federal agencies in conducting outreach activities for stakeholders. For example, OCR, along with ONC, hosted three webinars in 2019 focused on using the updated SRA Tool and conducting an accurate and thorough risk analysis. Each of these webinars hosted over 600 attendees. OCR also conducts outreach activities with the HHS Office of the Chief Information Officer (OCIO) to support that office's engagement efforts with the healthcare sector to promote the use of the NIST Cybersecurity Framework and related best practices to protect PHI. Several of these events occurred in 2019, with more scheduled in 2020.

GAO-16-771	Electronic Health Information: HHS Needs to Strengthen Security and Privacy Guidance and Oversight	9/26/2016	To improve the effectiveness of HHS guidance and oversight of privacy and security for health information the Secretary of Health and Human Services should revise the current enforcement program to include following up on the implementation of corrective actions.	Concur	2019	In Progress	OCR has fully implemented this GAO recommendation. In cases resolved with settlement agreements, OCR already requires monitoring of corrective actions by the regulated entity. OCR monitors the implementation of identified corrective actions over a 1 to 3 year period, depending on the identified compliance concerns. These cases highlight ongoing compliance issues in the health care industry, systemic or egregious conduct, or other important considerations under the HIPAA Rules. In most instances, as the GAO noted (94% of the cases that GAO reviewed), OCR investigations were not closed until evidence of corrective actions had been presented to OCR. In order to fully address this recommendation, in 2019, OCR implemented the requirement that in all investigations where OCR determines that corrective actions are needed, the investigations will remain open until the entities provide sufficient evidence that the corrective actions have been implemented.
GAO-16-771	Electronic Health Information: HHS Needs to Strengthen Security and Privacy Guidance and Oversight	9/26/2016	To improve the effectiveness of HHS guidance and oversight of privacy and security for health information the Secretary of Health and Human Services should establish performance measures for the Office of Civil Rights (OCR) audit program	Concur	2020	In Progress	OCR's implementation of this GAO recommendation remains in progress.OCR created an audit program to measure compliance with the HIPAA privacy, security, and breach notification requirements by regulated entities. OCR finished field work in 2013 and spent the balance of the year conducting a formal program evaluation. The evaluation concluded in 2014. The evaluation noted strengths of the program design and suggestions that were utilized in the next round of audits. OCR launched Phase 2 of the audit program in 2014. Key activities included updating the audit protocols, refining the pool of potential auditees, and implementing a screening tool to assess size, entity type, and other information about potential audit subjects. Selected entities received notification and data requests in spring 2016. OCR completed Phase 2 of the Audit Program in 2017. OCR finalized the results of Phase 2 and developed final reports for the regulated community based on the data collected in 2018. These reports included measurable performance goals for each entity. OCR is currently evaluating the two previous audits to develop new performance measures for the next audits. One of the objectives of the first two phases of the audit program was to ascertain whether there were compliance or enforcement concerns that were not being captured by other aspects of the enforcement program. The results of the audits largely mirrored the trends seen in the enforcement program generally. For example, most covered entities that maintained a website about their customer services or benefits also satisfy the requirement to prominently post their Notice of Privacy Practices (NPP) on their website. However, the audits revealed that most covered entities failed to meet other selected provisions, adequately safeguarding protected health information, ensuring the individual right of access and providing appropriate content in a Notice of Privacy Practices. The audits also found that covered entities and business associates failed to implement the HIPAA Security Rule requirements for risk analysis and risk management. As OCR is developing the next phase of the audit program, OCR will consult with

							GAO to ensure that the program incorporates the performance measures contemplated in the recommendation.
GAO-18-211	Critical Infrastructure Protection: Additional Actions Are Essential to Assessing Cybersecurity Framework Adoption	2/15/2018	The Secretary of Health and Human Services, in cooperation with the Secretary of Agriculture, should take steps to consult with respective sector partner(s), such as the SCC, DHS and NIST, as appropriate, to develop methods for determining the level and type of framework adoption by entities across their respective sector.	Concur	2020	In Progress	OCR's implementation of this GAO recommendation remains in progress. OCR has conferred with agencies and sector partners regarding methods to determine framework adoption. In 2019, OCR consulted with HHS agencies and participated in Healthcare SCC activities (i.e., the Healthcare Sector Coordinating Council Cybersecurity Working Group) regarding a survey to determine adoption of the NIST Cybersecurity Framework of HSCC members. Survey results were collated by the HSCC Cybersecurity Director and distributed to HSCC Cybersecurity Workgroup members in June 2019. In addition to using a survey to determine framework adoption, OCR notes that HIPAA covered entities and business associates can use the HIPAA Security Rule to NIST Cybersecurity Framework to assess their own adoption with the framework by leveraging their current HIPAA compliance posture.

OEI-09-10-00510	OCR Should Strengthen Its Oversight of Covered Entities' Compliance With the HIPAA Privacy Standards	9/28/2015	OCR should fully implement a permanent audit program	Concur	2020	In Progress	OCR's implementation of this GAO recommendation remains in progress. The HITECH Act required OCR to perform periodic audits. In 2011, OCR conducted comprehensive on-site audits of 115 covered entities. Findings included a pattern of insufficient risk analyses, poor security of mobile electronic devices, improper disposal, inadequate physical access safeguards and insufficient training of workforce members. In 2016, OCR conducted desk audits of 166 covered entities and 41 business associates on selected provisions of the HIPAA Privacy, Security and Breach Notification Rules. The audits gave OCR an opportunity to examine mechanisms for compliance, identify promising practices for protecting the privacy and security of health information, and discover risks and vulnerabilities that may not have been revealed by OCR's other enforcement activities. These audits were designed to complement OCR's enforcement program, which investigates specific covered entities or business associates through complaint investigations and compliance reviews, seeks resolution of potential violations through corrective action plans and settlements, and in some instances, imposes civil money penalties. OCR developed a comprehensive audit protocol for use in the desk audits to analyze an entity's compliance with the processes, controls, and policies relating to the HIPAA Rules. The audit protocol addresses every standard of the HIPAA Rules and provides measurable criteria and key questions an entity can apply when developing and reviewing its compliance activities. Findings included a pattern of insufficient risk analysis and risk management and inconsistent provision of an individual's right of access to their medical records. OCR has sent individual reports to each auditee notifying the entity of OCR's findings, and OCR is presently finishing a report to the industry that will discuss OCR's findings in each provision of the HIPAA Rules that was audited. The next phase of OCR's audit program will build upon the lessons learned from the first two phases of the audits. Additionally, OCR has publicly announced the indefinite continuation of the audit program as an enforcement tool. OCR will provide GAO with additional information to confirm that the OCR audit program is permanent and will continue to conduct periodic audits.

GAO-16-771	Electronic Health Information: HHS Needs to Strengthen Security and Privacy Guidance and Oversight	9/26/2016	To improve the effectiveness of HHS guidance and oversight of privacy and security for health information the Secretary of Health and Human Services should establish and implement policies and procedures for sharing the results of investigations and audits between OCR and Centers for Medicare & Medicaid Services to help ensure that covered entities and business associates are in compliance with the Health Insurance Portability and Accountability Act of 1996 and the Health Information Technology for Economic and Clinical Health Act.	Concur	2020	In Progress	Upon the completion of the last Medicare meaningful use audit, CMS shall obtain from the HITECH meaningful use audit contractor within 14 business days (but no later than 10/31/17) a report of all providers that failed a meaningful use audit and the "protection of electronic health information" measure was deemed not met. The report will be vetted to ensure the providers identified as not having met the "protection of electronic health information" measure were also not associated with a HITECH meaningful use appeal, which may have reversed the audit determination of not met for that measure. On October 30, 2017 the Meaningful Use Audit Contract was closed. In mid-November 2017, Office of Financial Management transferred all data containing results of meaningful use audits including HIPAA compliance to the Centers for Clinical Standards and Quality (CCSQ).

National Coordinator for Health Information Technology

DEPARTMENT of HEALTH and HUMAN SERVICES

Fiscal Year

2021

Office of the National Coordinator for Health Information Technology

Justification of Estimates
to the Appropriations Committees

ABOUT ONC

Departmental Mission

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

Agency Description

The Office of the National Coordinator for Health Information Technology (ONC), a staff division of the HHS Office of the Secretary, is charged with formulating the Federal Government's health information technology strategy and promoting coordination of federal health IT policies, technology standards, and programmatic investments.

Federal Health IT Strategic Plan Mission

ONC's mission, adopted from the Federal Health IT Strategic Plan 2015 – 2020, is to improve the health and well-being of individuals and communities through the use of technology and health information that is accessible when and where it matters most.

ONC's FY 2021 Priorities

- Advancing the, accessibility, **interoperability**, and **usability** of electronic health information and electronic health records (EHRs) by developing the necessary regulatory frameworks and implementing the programs and responsibilities necessary to implement ONC's statutory authorities and delegations from the Secretary;
- Supporting secure, standards-based application programming interfaces (APIs) and user-focused technologies to promote a mobile health app economy that can increase **transparency, competition, and consumer choice** in healthcare;
- Contributing to HHS efforts to combat the **opioid epidemic and other substance use disorders** through collaboration with HHS partners to improve health IT infrastructure and health information sharing.

ONC's Authorizing and Enabling Legislation

Health Information Technology for Economic and Clinical Health Act ("HITECH" Pub. L. No: 111-5), Medicare Access and CHIP Reauthorization Act ("MACRA" P.L. 114-10), 21st Century Cures Act ("Cures Act" P.L. 114-255)

U.S. Department of Health and Human Services

Message from the National Coordinator for Health IT

FY 2021 President's Budget Request

Dear Reader,

I am pleased to present the fiscal year (FY) 2021 President's Budget Request, Justification of Estimates to Appropriations Committees for the Office of the National Coordinator for Health Information Technology (ONC). This budget request outlines a proposed funding level and some expected outcomes for ONC at the President's Budget request level in FY 2021, and also includes annual performance information covering highlights from ONC activities that took place in the most recently concluded fiscal year, FY 2019.

The FY 2021 President's Budget request level for ONC is $50.7 million. With this budget, ONC will continue its longstanding focus on two critical national priorities for the health care industry: (1) the interoperable exchange of electronic health information, and (2) reducing the administrative burdens facing health care providers.

In furtherance of these goals, and supported by the FY 2021 President's Budget Request, ONC plans to continue necessary efforts to implement the 21st Century Cures Act (Cures Act), which will enter its fifth year of government-wide implementation in 2021. In particular, ONC will prioritize activities that address Congressional requirements related to: (1) facilitating the development and promotion of technology standards that improve infrastructure and interoperability, (2) administering the ONC Health IT Certification Program, (3) enabling trusted and secure health information exchange, and (4) ensuring patients have access to and control of electronic health information stored in their medical records through modern technological approaches such as smartphone applications using application programming interfaces.

Since establishment, ONC has a history of noteworthy successes in implementing Congressional requirements and achieving national goals. ONC's team has a track record for leading efforts that are essential for improving the U. S. health system. ONC's annual discretionary appropriation is fundamental to supporting ONC's infrastructure and advancing national priorities for improving health and health care by empowering patients with their health information, relieving regulatory and administrative burdens hampering providers, building the foundation to support price and product transparency, and promoting an innovative and competitive health care marketplace in the United States.

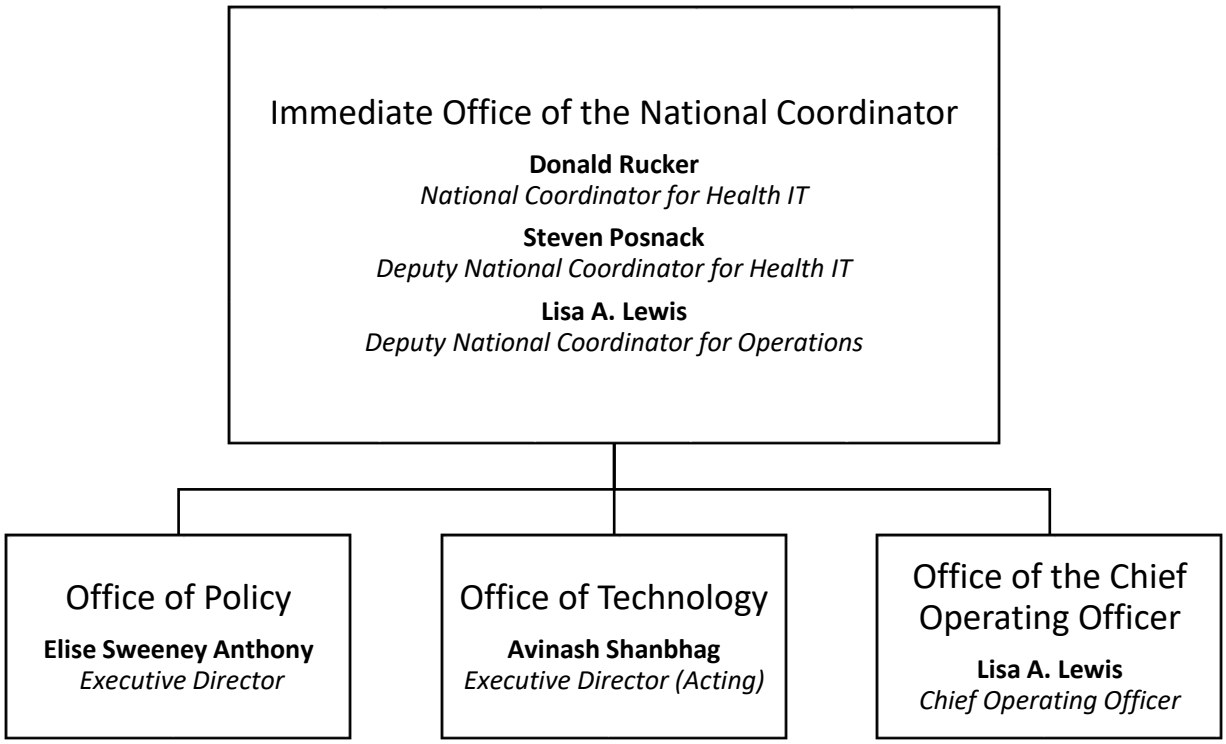
/Donald W. Rucker/
Donald W. Rucker, M.D.
National Coordinator for Health IT

FY 2021 President's Budget

Justification of Estimates to the Appropriations Committees
Office of the National Coordinator for Health Information Technology

Contents

Organizational Chart



Organizational Chart – Text Version

- Immediate Office of the National Coordinator
  - Donald Rucker, M.D. *National Coordinator for Health IT*
  - Steven Posnack, M.S., M.H.S. *Deputy National Coordinator for Health IT*
  - Lisa Lewis, *Deputy National Coordinator for Operations*
- Office of Policy
  - Elise Sweeney Anthony, J.D., *Executive Director*
- Office of Technology
  - Avinash Shanbhag, *Executive Director (Acting)*
- Office of the Chief Operating Officer
  - Lisa Lewis, *Chief Operating Officer*

Executive Summary

Mission and Introduction

ONC Mission

Improve the health and well-being of individuals and communities through the use of technology and health information that is accessible when and where it matters most.

ONC Overview

The Office of the National Coordinator for Health Information Technology (ONC) is charged with formulating the Federal Government's health information technology (IT) strategy and leading and promoting effective policies, programs, and administrative efforts to advance progress on national goals for better and safer healthcare through a nationwide *interoperable* health IT infrastructure. ONC is a staff division within the U.S. Department of Health and Human Services (HHS) that reports directly to the Immediate Office of the Secretary for HHS. While ONC is a very small part of federal spending on healthcare, ONC's activities are central to transforming U.S. healthcare into a competitive, patient led system where patients have a support right to their medical records, the necessary price information, and the quality information needed to make informed decisions about their healthcare.

ONC's mission, goals, and objectives originate from three laws, including the Health Information Technology for Clinical and Economic Health Act (2009); Medicare Access and CHIP Reauthorization Act of 2015; and the 21st Century Cures Act (2016).

HHS is taking a holistic approach to its technology related initiatives. This approach centers on putting patients in charge of their own data with interoperable health IT, which will empower patients with the information they need to search for the lowest costs and the highest-quality care. To accomplish this goal, HHS is using multiple policy levers across different agencies and staff divisions. A cornerstone of this work is the implementation of key provisions in title IV of the 21st Century Cures Act (Cures Act). In 2019, ONC issued a proposed rule to implement and support seamless and secure access, exchange, and use of electronic health information. Once finalized, ONC will implement the rule through its programs and activities, including through the Health IT Certification Program, which will continue to drive the electronic access, exchange, and use of health information to both providers and patients.

This proposed rule seeks to inject competition into the healthcare delivery system by addressing the technical barriers and business practices that impede the secure and appropriate sharing of data. A central underpinning of the proposed rule is to facilitate patient access to their electronic health information on their smartphone, growing a nascent patient- and provider-facing app economy, and building the foundation to support price and product transparency. The proposed rule also aims to support the data necessary to promote new business models of care and the clinical information and chart portability that patients need to shop for their care.

For the past decade, national leaders have pursued an agenda that promotes innovation in healthcare built on widespread, interoperable health information. ONC has and will continue to play a transformative role in helping the transition to transparency in healthcare through its health IT coordination. ONC's work builds on the incentives that made medical data electronic and its regulations that required first generation consumer transparency with patient web portals. The standards and interoperability work led by ONC advances the technical infrastructure necessary to support product and price transparency. ONC is also uniquely situated to coordinate the technical activities among different healthcare standards development organizations as we look to a future where a patient's health information is aligned with its related cost information.

Interoperable health information will improve health and healthcare by increasing market transparency and efficiency, and empowering patients and their providers with access to actionable health information from different sources. Improvements in interoperability and the evolution of health IT tools that put health information in practice will ensure patients can access and control their electronic health information, facilitate value-based transformation of the healthcare delivery system, and increase healthcare market competition.

In FY 2019, ONC's appropriated budget authority of $60.4 million supported a diverse staff and a network of contracted experts spanning a wide range of healthcare, technology, policy, public health, and public administration specialties. ONC staff specialists collaborate with leaders in healthcare, health, and technology in government and industry. This includes contributing to health IT initiatives led by partners and strategic coordination with partner agencies, states, and an extensive network of current and former grantees, leading healthcare sector companies, public interest groups, clinicians, and the congressionally mandated Health IT Advisory Committee (HITAC). ONC promotes the lessons learned from these stakeholder encounters to nearly 2 million visitors who access the policy and technical assistance materials published at https://HealthIT.gov each year.

Overview of Budget Request

The FY 2021 President's Budget Request for ONC is $50.7 million, which is a $9.7 million (16 percent) reduction from the FY 2020 Enacted Level. ONC's efforts in FY 2021 will continue to emphasize implementation of national priorities as outlined in the HHS Strategic Plan:

HHS Strategic Plan, 2018-2022

Goal 1	Reform, Strengthen, and Modernize the Nation's Healthcare System
Objective 2	Expand safe, high-quality healthcare options, and encourage innovation and competition

Priority Health IT Strategies:

- Advance interoperable clinical information flows so patients, providers, payers, and others can efficiently send, receive, and analyze data across primary care, acute care, specialty care including behavioral healthcare, and post-acute care settings
- Promote implementation of understandable, functional health information technology tools to support provider and patient decision-making, and to support workflows for healthcare providers

ONC will also prioritize actions necessary to meet congressional goals expressed in the Cures Act, the President's October 12, 2017 Executive Order 13813 on **healthcare choice and competition** and the June 24, 2019 Executive Order on **healthcare price and quality transparency**; Secretary Azar's 4-part strategy for value-based care; and the HHS 5-point strategy to combat the opioids crisis.

ONC's FY 2021 President's Budget Request explains the office's plan to implement a portfolio of activities driven by congressional requirements and ONC's bipartisan authorities. ONC's budget organization highlights its multifaceted work that weaves together cutting edge policy development on health system transformation with ONC's unique expertise for guiding and facilitating technological innovation through the development and promotion of health information interoperability standards and the operation of the ONC Health IT Certification Program. ONC's budget, although small compared to overall federal healthcare spending, has a transformative impact on the healthcare system. The lack of interoperability and related lack of price and product transparency are massive costs to the U.S. public. ONC's work to rapidly address these issues through its policy development and coordination work, and its standards, certification, and interoperability work is sound public policy.

In FY 2021, ONC will continue to a play a pivotal role in providing the regulations and standards needed to increase transparency in healthcare by empowering patients with access to their personal health information they need to search for the lowest costs and the highest-quality care. Performance planning and reporting, and budget request information is organized into the following sections:

- **Policy: Development and Coordination**, including strategic and policy planning, developing regulatory frameworks and administrative procedures, maintaining a Federal Advisory Committee, and conducting coordination with public and private stakeholder groups. These policies are frameworks must be robust and resilient enough to withstand substantial opposition and make interoperability a reality.

- **Technology: Standards, Certification, and Interoperability**, including managing the ONC Health IT Certification Program; facilitating the development and promotion of technology standards that improve infrastructure and interoperability; and sponsoring pilot projects and

industry challenges to accelerate innovation and demonstrate advanced uses of health IT which will enable future ONC standards work to support the Administration's price transparency goals and enable patients to easily access to their health information on their smartphones.

- **Agency-Wide Support**, including providing executive, clinical, and scientific leadership, and coordinating outreach between ONC and key federal stakeholders; maintaining https://HealthIT.gov to promote federal policy related to health IT; and ensuring effective operations and management through an integrated operations function.

Overview of Performance

Description of ONC's Performance Management Process

ONC's performance management process prioritizes a continuous focus on improving program results, increasing the efficiency and effectiveness of operations, and finding more cost-effective ways to deliver value through policy, program, and management leadership to health IT stakeholders nationwide.

ONC's routine performance management processes are led by a Strategic Management Council that sets the tone and big picture management plan for ONC's planning efforts. The Council is comprised of ONC's experts in planning, performance measurement, operations, resource allocation, risk management, data analysis, and evaluation. Throughout ONC's performance management process, executives and leaders throughout the organization strive to create a culture of performance management by regularly conducting strategic planning; goal setting, and prioritization; measure development; performance monitoring; data analysis; and strategic communications and reporting activities.

Summary of Performance Information in the Budget Request

Performance information in the President's Budget Request for ONC includes a combination of (1) environmental measures that describe the extent of nationwide interoperable health information exchange and patient and provider access to electronic health information, and (2) agency milestones and measures that highlight key information about activities necessary to implement statutory requirements.

Environmental Measures

ONC often measures the extent and performance of health interoperability. During FY 2019, ONC continued a number of survey and data analysis projects necessary to meet congressional requirements to evaluate progress towards national goals for health system modernization through interoperable health IT. These efforts make possible national-level estimates for the following priority indicators:

Patient Access to Electronic Health Information: [1]

- 51 percent of Americans had been given **electronic access** to any part of their healthcare record by their healthcare provider or insurer by 2018.

Health Information Interoperability: [2, 3]

- 47 percent of physicians and 90 percent of hospitals are **sending or receiving** patient information to providers outside their organization via an EHR.
- 53 percent of physicians and 61 percent of hospitals can **find** patient health information from sources outside their health system through their EHR.
- 28 percent of physicians and 53 percent of hospitals can **integrate** (e.g., without manual entry) health information received electronically into their EHR.
- 32 percent of physicians and 51 percent of hospitals reported having necessary patient information electronically **available** at the point of care through their EHR.

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1 Patel V & Johnson C. (April 2018). Individuals' use of online medical records and technology for health needs. ONC Data Brief, no.40. Office of the National Coordinator for Health Information Technology: Washington DC. https://www.healthit.gov/sites/default/files/page/2018-03/HINTS-2017-Consumer-Data-Brief-3.21.18.pdf

2 Health Information National Trends Survey (HINTS), National Institutes of Health (NIH), 2016.

3 These measures were selected to meet MACRA § 106(b) requirements to evaluate progress to widespread interoperability. Physician data are as of 2017; hospital data are as of 2017. 2018 estimates for both measures are expected to become available during calendar year 2019. https://www.healthit.gov/sites/default/files/fulfilling_section_106b1c_of_the_medicare_access_and_chip_reauthorization_act_of_2015_06.30.16.pdf.

Noteworthy ONC Accomplishments

Highlights of key ONC accomplishments from FY 2019 illustrate how the office helps to lead nationwide interoperability and improvements in health IT usability:

- ONC continued to prioritize the transformative requirements set in the **Cures Act**, including undertaking stakeholder coordination and outreach, rulemaking, and policy activities related to:
    - Section 4001: Reduction in Burdens Goal; Certification of Health IT for Medical Specialties and Sites of Service; and Meaningful Use Statistics
    - Section 4002: Enhancements to Certification and EHR Reporting Program
    - Section 4003: Support for Interoperable Network Exchange and Provider Digital Contact Information Index
    - Section 4004: Information Blocking
    - Section 4005: Treatment of Health IT Developers with respect to Patient Safety Organizations
    - Section 4006: Patient Access
- Specific highlights related to Cures Act implementation during FY 2019 include:
    - In February 2019, ONC issued a Proposed Rule to support the right of the patient to get their medical records electronically and on their smartphone.[4] The Rule seeks to **inject digitally-based competition** into the healthcare delivery system by addressing both technical barriers and business practices that impede the secure and appropriate sharing of data. The Proposed Rule advances progress on many of ONC's implementation responsibilities for the Cures Act, including information blocking and conditions of certification, which can also facilitate investments in the technical infrastructures and data necessary for broader Administration goals such as price and product transparency. Within the rule, we propose that certified health IT developers make available in their products secure, standards-based APIs that could be used to facilitate patients' use of smartphones (or other mobile devices) for accessing electronic health information at no cost.
    - The TEFCA was released for a second round of public comment in April 2019. The TEFCA is designed to provide a single "on-ramp" to nationwide connectivity and advance a landscape where information securely follows the patient where and when it is needed. In September 2019, ONC announced that The Sequoia Project has been awarded a cooperative agreement to serve as the Recognized Coordinating Entity responsible for developing, updating, implementing, and maintaining the Common Agreement in collaboration with ONC.[5] This Common Agreement will create the baseline technical and legal requirements for networks to share electronic health information across the nation. Additionally, ONC released the first draft of the Qualified Health Information Network Technical Framework,[6] which describes technical and functional requirements to implement the Common Agreement and enable health information networks to connect to each other.
    - ONC led the development of the draft Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs, which was released for public comment in November 2018 and closed in January 2019. During the public

4 https://www.healthit.gov/topic/laws-regulation-and-policy/notice-proposed-rulemaking-improve-interoperability-health

5 https://www.hhs.gov/about/news/2019/09/03/onc-awards-the-sequoia-project-cooperative-agreement.html

6 https://www.healthit.gov/buzz-blog/interoperability/moving-beyond-closed-networks-an-update-on-trusted-exchange-of-health-information

commenting period ONC received 208 comments with the majority of submissions commenting on health IT usability and user experience.[7]

- ONC continued to implement congressional requirements to operate the **Health IT Certification Program** by maintaining a suite of certification criteria – including automated test procedures and certification companion guides – used to standardize information across **21 federal efforts**.[8] By the end of FY 2018, the ONC Health IT Certification Program's website, the Certified Health IT Product List (CHPL), listed products from more than 700 health IT developers,[9] and was used to register the EHRs of 550,000 care providers and hospitals participating in Medicare and Medicaid.[10] At the end of 2019, there were 497 2015 Edition products from 342 developers on the CHPL. This means that 98 percent of the hospitals and 94 percent of the clinicians participating in CMS programs have access to a health IT product or upgrade from their current developer that has the latest capabilities outlined by Congress and codified into the ONC Health IT Certification Program's 2015 Edition Certified Health IT.

- ONC continued to evolve and promote the adoption of a wide range of interoperability standards, including Release 4 of HL7 FHIR standard, which is used to enable API-based access, a key component in increasing interoperability in the app economy, promoting product transparency, and enabling patient access to their health information on their smartphones. ONC also coordinated standards awareness and use through the publication and maintenance of the Interoperability Standards Advisory (ISA), a resource listing **health information standards, models, and profiles** fitting into more than 60 sub-sections divided by topic/use (e.g., public health, patient information, coordination, clinical care, administration). The 2019 ISA, published in January 2019, added 16 new interoperability needs for a total of 167, providing detailed recommendations for standards, models and profiles to support interoperability. It also includes two new cross-cutting views of recommended standards targeted to assist providers in specialty care and clinical settings including pediatrics and opioids. During the public comment period for the 2019 ISA, ONC received 74 comments with more than 400 individual recommendations for revisions and improvements. In FY 2019, the ISA website has been accessed over 90,000 times, suggesting it is on pace to parallel the over 100,000 views in FY 2018. Public adoption of the FHIR standards work has been rapid. Apple's "Health App" allows iPhone using patients to access their own health information from dozens of healthcare organizations based on the FHIR implementation guides supported by ONC funding.

- ONC continued to administer the Health IT Advisory Committee (HITAC), ONC's **Federal Advisory Committee** mandated by the Cures Act. Now in its second year, the HITAC serves as a priority method for obtaining routine input from a group of 29 health IT experts, representing a broad and balanced spectrum of the healthcare system. Between October 1, 2018, and August 1, 2019, the full **HITAC met 11 times** and its **task forces and work groups met 113 times** to develop recommendations addressing the priority areas identified in the Cures Act. The full HITAC plans to meet at least one more time this fiscal year and three more times before the end of CY 2019. To date, the HITAC has completed a Policy Framework, published the FY 2018 annual report, and provided recommendations on the draft TEFCA and the U.S. Core Data for Interoperability (USCDI), among other topics. As of December 2019, the following HITAC Task Forces and Work Groups meet regularly:
    - Trusted Exchange Framework and Common Agreement Task Force

7 https://www.healthit.gov/burdencomments
8 https://www.healthit.gov/topic/certification-ehrs/programs-referencing-onc-certified-health-it.
9 https://dashboard.healthit.gov/quickstats/pages/FIG-Vendors-of-EHRs-to-Participating-Professionals.php.
10 https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/DataAndReports.html.

  - U.S. Core Data for Interoperability Task Force
  - Interoperability Standards Priorities Task Force
  - Annual Report Workgroup
  - Information Blocking Task Force
  - Conditions of Certification Task Force
  - Health IT for the Care Continuum Task Force

- ONC continued to promote improved **federal coordination** through the Federal Health IT Coordinating Council, a voluntary group of **25 agencies** that are actively involved in implementing the national health IT agenda. In FY 2019, the Federal Health IT Coordinating Council convened to address the draft *Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs* and the proposed rules from ONC and CMS to support seamless and secure access, exchange, and use of electronic health information. Leveraging federal partner interest in diving deeper into solving problems with health information interoperability, ONC hosted a Federal Interoperability Summit in April 2019 that included 81 representatives from 23 federal organizations. In June 2019, the Coordinating Council met to discuss the update to the *Federal Health IT Strategic Plan FY 2020 – 2025*.

All-Purpose Table

(Dollars in Thousands)

Activity	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget	FY 2021 President's Budget +/- FY 2020 Enacted
TOTAL, ONC Program Level	$60,163	$60,367	$50,717	$(9,650)
TOTAL, ONC Budget Authority	$60,163	$60,367	$50,717	$(9,650)

Budget Exhibits

Appropriations Language

For expenses necessary for the Office of the National Coordinator for Health Information Technology, including grants, contracts, and cooperative agreements for the development and advancement of interoperable health information technology, [$60,367,000] *$50,717,000*.

Language Analysis

Language Provision	**Explanation**
For expenses necessary for the Office of the National Coordinator for Health Information Technology, including grants, contracts, and cooperative agreements for the development and advancement of interoperable health information technology, [$60,367,000] ***$50,717,000*****.**	Provides ONC's budget from Budget Authority.

Amounts Available for Obligation

	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget
General Fund Discretionary Appropriation:			
Appropriation (L/HHS)	$60,367,000	$60,367,000	$50,717,000
Subtotal, Appropriation (L/HHS, Ag, or Interior)	$60,367,000	$60,367,000	$50,717,000
Subtotal, adjusted appropriation	$60,367,000	$60,367,000	$50,717,000
Real transfer to: (ACF)	($204,397)	$0	$0
Subtotal, adjusted general fund discr. appropriation	$60,162,603	$60,367,000	$50,717,000
Total, Discretionary Appropriation	$60,367,000	$60,367,000	$50,717,000
Total Obligations	$60,162,603	$60,367,000	$50,717,000

Summary of Changes

2020 Enacted	
Total estimated budget authority	$60,367,000
2021 President's Budget	
Total estimated budget authority	$50,717,000
Net Change	($9,650,000)

	FY 2020 Final	FY 2021 PB FTE	FY 2021 PB BA	FY 2021 +/- FY 2020 FTE	FY 2021 +/- FY 2020 BA
Decreases:					
A. Program:					
1. Health IT	$60,367,000	164	$50,717,000	-	($9,650,000)
Subtotal, Program Decreases	**$60,367,000**	**164**	**$50,717,000**	**-**	**($9,650,000)**
Total Decreases	**$60,367,000**	**164**	**$50,717,000**	**-**	**($9,650,000)**

Budget Authority by Activity

(Dollars in Thousands)

	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget
1. Health IT			
Annual Budget Authority	$60,163	$60,367	$50,717
Subtotal, Health IT	$60,163	$60,367	$50,717
Total, Budget Authority	$60,163	$60,367	$50,717
FTE	158	164	164

Authorizing Legislation

	FY 2020 Amount Authorized	FY 2020 Amount Appropriated	FY 2021 Amount Authorized	FY 2021 President's Budget
Health IT				
1. Title XXX of PHS Act as added by the HITECH Act (PL 111-5) and the Cures Act (PL 114-255)	Indefinite	$ -	Indefinite	$ -
Budget Authority	Indefinite	$60,367,000	Indefinite	$50,717,000
Total Request Level		$60,367,000		$50,717,000

Appropriations History

Each Year is General Fund Appropriation	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
FY 2012				
Annual	$57,013,000	$ -	$42,246,000	$16,446,000
PHS Evaluation Funds	$21,400,000	$28,051,000	$19,011,000	$44,811,000
Rescissions (P.L. 112-74)	$ -	$ -	$ -	$(31,000)
Subtotal	$78,413,000	$28,051,000	$61,257,000	$61,226,000
FY 2013				
Annual	$26,246,000	$16,415,000	$16,415,000	$16,415,000
PHS Evaluation Funds	$40,011,000	$44,811,000	$49,842,000	$44,811,000
Rescissions (P.L. 113-6)	$ -	$ -	$ -	$(33,000)
Sequestration	$ -	$ -	$ -	$(826,000)
Subtotal	$66,257,000	$61,226,000	$66,257,000	$60,367,000
FY 2014				
Annual	$20,576,000	$ -	$20,290,000	$15,556,000
PHS Evaluation Funds	$56,307,000	$ -	$51,307,000	$44,811,000
User Fee	$ 1,000,000	$ -	$1,000,000	$ -
Subtotal	$77,883,000	$ -	$72,597,000	$60,367,000
FY 2015				
Annual	$ -	$61,474,000	$61,474,000	$60,367,000
PHS Evaluation Funds	$74,688,000	$ -	$ -	$ -
Subtotal	$74,688,000	$61,474,000	$61,474,000	$60,367,000
FY 2016				
Annual	$ -	$60,367,000	$60,367,000	$60,367,000
PHS Evaluation Funds	$91,800,000	$ -	$ -	$ -
Subtotal	$91,800,000	$60,367,000	$60,367,000	$60,367,000
FY 2017				
Annual	$ -	$65,367,000	$60,367,000	$60,367,000
PHS Evaluation Funds	$82,000,000	$ -	$ -	$ -
Transfers (Secretary's)	$ -	$ -	$ -	$(140,000)
Subtotal	$82,000,000	$65,367,000	$60,367,000	$60,227,000
FY 2018				
Annual	$38,381,000	$38,381,000	$60,367,000	$60,367,000
PHS Evaluation Funds	$ -	$ -	$ -	$ -
Transfers (Secretary's)	$ -	$ -	$ -	$(150,000)
Subtotal	$38,381,000	$38,381,000	$60,367,000	$60,217,000
FY 2019				
Annual	$38,381,000	$42,705,000	$60,367,000	$60,367,000
Transfers (Secretary's)	$ -	$ -	$ -	$(204,397)
Subtotal	$38,381,000	$42,705,000	$60,367,000	$60,162,603
FY 2020				
Annual	$43,000,000		$60,367,000	$60,367,000
PHS Evaluation Funds		$60,367,000		
Subtotal	$43,000,000	$60,367,000	$60,367,000	$60,367,000
FY 2021				
Annual	$50,717,000			
Subtotal	$50,717,000			

Narrative by Activity

Health IT

	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget	FY 2021 +/- FY 2020
BA	$60,162,603	$60,367,000	$50,717,000	$(9,650,000)
FTE	158	164	164	0

Enabling Legislation Citation ..... Title XXX of PHS Act as added by the HITECH Act (PL 111-5) and amended by the Cures Act (PL 114-255)
Enabling Legislation Status ..... Permanent
Authorization of Appropriations Citation ..... No Separate Authorization of Appropriations
Allocation Method ..... Direct Federal, Contract, Cooperative Agreement, Grant

Program Description

ONC was established in 2004 through Executive Order 13335 and statutorily authorized in 2009 by the HITECH Act. ONC's responsibilities for leading national health IT efforts was increased by MACRA in 2015 and again by the 21st Century Cures Act in 2016. The range of authorities and requirements assigned to ONC through its authorizing and enabling legislation establish a framework of actions for the agency related to (1) Policy Development and Coordination and (2) Technology Standards, Certification, and Interoperability, and (3) Agency-Wide Support.

In FY 2021, ONC will implement its authorities and requirements to accelerate progress to an interoperable nationwide health IT infrastructure by pursuing the following objectives:

- Advancing the accessibility, **interoperability**, and **usability** of electronic health information and electronic health records (EHRs) by developing the necessary regulatory frameworks and implementing the programs and responsibilities necessary to implement ONC's statutory authorities and delegation from the Secretary;
- Supporting secure, standards-based APIs and user-focused technologies to promote a mobile health app economy that can increase **transparency, competition, and consumer choice** in healthcare;
- Contributing to HHS efforts to combat the **opioid epidemic and other substance use disorders** through collaborations with HHS partners to improve health IT infrastructure and health information sharing.

Component Activities at ONC [11]

ONC's authorities and requirements are implemented through a budget and organizational structure emphasizing the following key components:

Policy: Development and Coordination

Within the Office of Policy, ONC undertakes a range of policy development and coordination activities including: (1) policy and rulemaking activities, such as writing the rule text to implement the Cures Act, MACRA, the HITECH Act, and Executive Order 13335; (2) supporting ONC's domestic policy initiatives; (3) coordinating with executive branch agencies, federal commissions, advisory committees, and external partners; (4) conducting analysis and evaluation of health IT policies for ONC and HHS, including in the areas of interoperability, information blocking, care transformation, privacy and security, and quality improvement; and (5) operating the HITAC, established in the Cures Act. Because a number of the interoperability and pro-consumer requirements of the Cures Act affect large parts of the healthcare delivery system, effective and fair rule-writing that is robust enough to make interoperability a reality is a resource intensive activity. Once a final rule or regulation is complete, it is implemented through ONC's technology activities outlined below.

Technology: Standards, Interoperability, and Certification

Within the Office of Technology, ONC undertakes a range of coordination, technical, and program activities including: (1) executing provisions of law including those in the HITECH Act, MACRA, and the Cures Act; (2) providing technical leadership and coordination within the health IT community to identify, evaluate, and influence the development of standards, implementation guidance, and best practices for standardizing and exchanging electronic health information; (3) coordinating with federal agencies and other public and private partners to implement and advance interoperability nationwide; (4) leading the development of electronic testing tools, resources, and data to achieve interoperability, enhanced usability, and aid in the optimization of health IT; (5) administering the ONC Health IT Certification Program, including the Certified Health IT Product List; and (6) leveraging a team of medical professionals and information scientists that provide leadership to ONC's technical interoperability interests and investments.

Agency-Wide Support

Led by the Immediate Office of the National Coordinator and the Office of the Chief Operating Officer, ONC undertakes a range of agency-wide support activities, including providing overall leadership, executive, strategic, and day-to-day management direction for the ONC organization. Agency-wide support also includes a team of expert clinician advisors who support the National Coordinator and ONC policy and technology leadership; a stakeholder outreach and media relations function, including management of https://HealthIT.gov/; and the agency's operations and administration functions.

[11] For a more complete explanation of the alignment of ONC's organizational chart to its responsibilities, see the May 2018 Statement of Organization, Functions, and Delegations of Authority; Office of the National Coordinator for Health Information Technology: https://www.federalregister.gov/documents/2018/05/02/2018-09361/statement-of-organization-functions-and-delegations-of-authority-office-of-the-national-coordinator.

Agency Background

Since its establishment by Executive Order 13335 in **2004**, ONC has been tasked with providing leadership to stakeholders across the Federal Government and the healthcare and health IT industries in the shared effort to advance nationwide implementation of an interoperable health IT infrastructure.[12] At its inception, ONC's primary efforts focused on strategic planning, establishing the Federal Health Architecture, building the National Health Information Network, and stimulating collaboration among a growing network of federal agencies interested in health IT.

After 5 years of progress implementing its founding mission, Congress statutorily authorized ONC when it enacted the HITECH Act of **2009**. The Act codified the responsibilities outlined in the Executive Order and provided ONC and CMS with financial resources to incentivize and guide the development and adoption of a more comprehensive nationwide health IT infrastructure via the Medicare EHR Incentive Program, commonly referred to as meaningful use. During the time that CMS and ONC implemented HITECH programs, the availability and use of certified EHR technology significantly increased, and EHR adoption among hospitals and office-based professionals increased to more than three quarters.[13]

Throughout **2014-15**, ONC built upon the Nation's momentum toward widespread health information interoperability and its position of leadership by working closely with stakeholders to develop and publish a *Shared Nationwide Interoperability Roadmap*. The *Roadmap* was developed through extensive coordination across the government and industry, and was supported widely for its more than 150 detailed commitments and calls to action.[14]

While nationwide stakeholders worked to implement commitments in the *Roadmap*,[15] in **2015** Congress placed further emphasis on achieving widespread interoperability in MACRA. With MACRA introduced, the Medicare EHR Incentive Program (meaningful use) was transitioned to become one of the four components of the new Merit-Based Incentive Payment System (MIPS), which itself is part of MACRA. CMS's implementation of MACRA, and ONC's continued progress to fulfill requirements outlined in HITECH and MACRA, contributed substantially to the progress of nearly all hospitals and three quarters of physicians using certified EHRs.[16]

In **2016**, the Nation's health IT agenda received continued congressional direction through the landmark 21st Century Cures Act, which addressed key barriers to interoperability. Among the Cures Act requirements, Congress charged ONC with enhancing its Health IT Certification Program to require modern standards-based application programming interfaces and in parallel preventing anti-competitive business practices related to health information exchange (e.g., information blocking). The bipartisan goal was to promote patient access to and control of their personal electronic health information. We expect patients' electronic control of their medical record will help patients to shop for care and simultaneously allow new business models of lower cost and better healthcare.

12 Executive Order 13335: https://www.gpo.gov/fdsys/pkg/WCPD-2004-05-03/pdf/WCPD-2004-05-03-Pg702.pdf.

13 Hospitals: https://dashboard.healthit.gov/evaluations/data-briefs/non-federal-acute-care-hospital-ehr-adoption-2008-2015.php. Physicians: https://dashboard.healthit.gov/quickstats/pages/physician-ehr-adoption-trends.php.

14 https://www.healthit.gov/topic/interoperability/interoperability-road-map-statements-support.

15 https://www.healthit.gov/sites/default/files/12-19-YearInReviewPrezi-508-LowRes.pdf.

16 https://www.healthit.gov/buzz-blog/health-data/numbers-progress-digitizing-health-care/.

Most recently, Executive Order 13877, "Improving Price and Quality Transparency in American Healthcare to Put Patients First," was signed in June **2019.**[17] This Executive Order outlines lack of patient access to price and quality information as major barrier to patients making fully informed decision about their care. ONC activities to promote interoperability and patient access to data through the development of secure, standards-based APIs is fundamental to transparency around both the healthcare product and service offered as well as its cost.

FY 2019 Major Accomplishments

Policy: Development and Coordination

- ONC continued to **coordinate federal partners** throughout FY 2019, including working closely with key stakeholders in the HHS Office of the Secretary, Assistant Secretary for Planning and Evaluation (ASPE), Office for Civil Rights (OCR), Centers for Medicare & Medicaid Services (CMS), Health Resources and Services Agency (HRSA), National Institutes for Health (NIH), Centers for Disease Control and Prevention (CDC), and HHS Office of Inspector General (OIG). Throughout FY 2019, ONC responded to numerous Administration requests to provide targeted senior-executive expertise to key stakeholders, including to the CMS Office of the Administrator, the Veterans Health Administration, and the Department of Commerce. ONC has a long history of lending the expertise of its leaders to key stakeholders during times of critical importance.
- ONC worked closely with partners in the Department to promote patient access to electronic health information through public assistance materials and awareness campaigns related to the Privacy Act and patient rights as required by the Cures Act. This is a crucial first step to enable price and product transparency and patient access to their health information on their smart phone. ONC continued to disseminate the Guide to Getting and Using Your Health Information and to promote the Get IT, Check IT, and Use IT campaign as part of the All of Us Research Program. Additionally, ONC developed and launched an ad campaign to promote patient access.
- In February 2019, ONC issued a detailed Proposed Rule to support the seamless and secure access, exchange, and use of electronic health information as required by the Cures Act.[18] The Rule seeks to **inject competition** into the healthcare delivery system by addressing both technical barriers and business practices that impede the secure and appropriate sharing of data. The Proposed Rule sets as key expectation that certified health IT developers make available in their products secure, standards-based APIs that could be used to facilitate patients' use of smartphones (or other mobile devices) for accessing electronic health information at no cost. Importantly the proposed rule builds out the regulatory framework to allow patients control of their information in a secured protected way. Using APIs patients control their medical data and which applications get to access that data.
- ONC received 2,013 comment submissions on the Proposed Rule to improve the interoperability of health information. Comment will be synthesized and considered as a part of the final publication.
- ONC continued to plan the implementation of the **EHR Reporting Program** pursuant to Cures Act section 4002 requirements. The EHR Reporting Program will provide publicly available, comparative information about certified health IT products. ONC has taken multiple steps to obtain stakeholder input to develop the program's criteria including holding **seven listening session** across the country in 2019 and issuing a Request for Information (RFI) which comment period closed in October 2018.

[17] Executive Order 13877: https://www.federalregister.gov/documents/2019/06/27/2019-13945/improving-price-and-quality-transparency-in-american-healthcare-to-put-patients-first

[18] https://www.healthit.gov/topic/laws-regulation-and-policy/notice-proposed-rulemaking-improve-interoperability-health

In response to the RFI, ONC received 77 public comment submissions from health IT developers and provider organizations representing all major segments of the provider community, payers and health plans covering millions of beneficiaries, and consumer and quality improvement organizations representing patients and consumers.

- In March 2019, ONC organized a full day HITAC hearing in collaboration with the National Committee on Vital Health Statistics, which focused on better understanding the landscape, burdens and potential solutions related to prior authorization. ONC continues to meet with industry stakeholders to learn about how we can support emerging technologies and standards that enable seamless electronic prior authorization to occur to substantially reduce provider burden and allow for improved patient care.
- Pursuant to Cures Act section 4001, ONC and CMS jointly led a team of policy experts and clinicians to produce a draft Strategy to Reduce Regulatory and Administrative Burdens affecting healthcare providers. Throughout FY 2018, ONC communicated extensively with patients, providers, health IT developers, and federal partners to better understand challenges and opportunities. ONC hosted multiple listening sessions to better understand stakeholders' issues. The input ONC garnered from stakeholders informed collaborations between ONC and CMS and contributed to making much needed progress at easing burdens and improving clinician experiences with health IT. The draft strategy was released for public comment in November 2018 and closed in January 2019. The Burden Reduction Strategy received widespread public comment and support from stakeholder across the spectrum. Burden reduction work has been initiated in federally required patient note documentation requirements, the prior authorization process, and federal requirements for quality measurement.

★ - Stakeholder Feedback & Action Planning on Burden Reduction Efforts - ★

ONC was tasked by Congress through the 21st Century Cures Act section 4001 to work with healthcare stakeholders and CMS to reduce clinician burden associated with health IT. CMS and ONC heard from stakeholders – specifically physicians, nurse practitioners, physician assistants, and other clinicians who bill Medicare – that the *evaluation and management documentation requirements* create a large amount of administrative burden and are frequently medically unnecessary.

Through research, stakeholders learned that the "boilerplate" template generated text that the current Evaluation & Management code billing requirements generate makes ambulatory office notes in the United States four times as long as those in the rest of the world (4,000 vs. 1,000 characters). Stakeholders agree that the clutter squanders national resources not only in the efforts required to generate the text but in trying to find actual clinical facts when reading the notes.[19]

In response this information, ONC and CMS worked together to address the burdens generated by the underlying 1995 regulation. On November 1, 2018, the 2019 Medicare Physician Fee Schedule Final Rule was published in the Federal Register.[20] The Final Rule adopts a number of documentation, coding, and payment changes recommended in the draft Strategy to Reduce Regulatory and Administrative Burdens to *improve flexibility and reduce documentation requirements* associated with office/outpatient evaluation and management (E/M) visits.

[19] Reference: Ann Intern Med. 2018 Jul 3;169(1):50-51. doi: 10.7326/M18-0139. Epub 2018 May 8. Physician Burnout in the Electronic Health Record Era: Are We Ignoring the Real Cause? Downing NL1, Bates DW2, Longhurst CA3.

[20] https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/.

These historic changes will take place from 2019 to 2021 with immediate savings beginning in 2019. These changes may result in significantly less documentation burden for clinicians treating Medicare beneficiaries. This historic shift should lead to more efficient, effective use of EHRs in clinicians' offices by improving the workflows needed to support patient-centered care instead of a focus on documentation for billing requirements.[21]

- ONC continued to administer the Health IT Advisory Committee (HITAC), ONC's **Federal Advisory Committee**. To date, the HITAC has completed a Policy Framework, published the FY 2018 annual report, and provided recommendations on the TEFCA and the USCDI, among other topics.
- Between March and May 2019, the HITAC held six full committee meetings and 72 Task Force meetings – all to deliberate and provide commendations to support the final publication of the proposed rule to improve interoperability of health information.
- The **Trusted Exchange Framework and Common Agreement** (TEFCA) was released for a second round of public comment in April 2019. The Trusted Exchange Framework will establish a set of common principles, terms, and conditions that facilitate exchange between health information networks. These principles support the ability of stakeholders to access, exchange, and use relevant electronic health information across different networks and sharing arrangements. The terms and conditions focus on the areas of variation among currently existing trust agreements that impede nationwide interoperability. The Sequoia Project was awarded a cooperative agreement to serve as the Recognized Coordinating Entity responsible for developing, updating, implementing, and maintaining the **Common Agreement** in collaboration with ONC.[22] Additionally, ONC released the first draft of the **Qualified Health Information Network** Technical Framework.[23]
- The second draft of the Trusted Exchange Framework garnered over 100 public comments, which are being considered as a part of the final product.
- ONC took steps to **promote modern technology standards** and address the interoperability goals of the Cures Act by proposing the U.S. Core Data for Interoperability (USCDI) (launched in 2019) as a standard in the Proposed Rule. The USCDI identifies a common set of healthcare record data classes that are required for interoperable exchange. ONC's Certification Program will test that health IT products meet this new standard. The USCDI has been developed through close coordination with a dedicated HITAC task force that is providing recommendations on data class priorities and a process and proposed frequency for expanding the USCDI.[24]
- ONC continued to provide health IT and policy expertise and technical assistance by leading the Health IT Resource Center project, which collaborates closely with CMS support to 15 CMS State Innovation Model (SIM)/All-Payer states and Medicaid Innovation Accelerator Program awardees. ONC's policy and technical assistance addressed many topics, including the Cures Act, the Trusted

21 https://www.healthit.gov/buzz-blog/health-it/onc-supports-cms-proposed-cy-2019-physician-fee-schedule/.
22 https://www.hhs.gov/about/news/2019/09/03/onc-awards-the-sequoia-project-cooperative-agreement.html
23 https://www.healthit.gov/buzz-blog/interoperability/moving-beyond-closed-networks-an-update-on-trusted-exchange-of-health-information
24 https://www.healthit.gov/hitac/committees/us-core-data-interoperability-task-force.

Exchange Framework, substance use disorders and 42 CFR Part 2 considerations,[25] health information exchange, and global budget models.

- In alignment with The President's Commission on Combating Drug Addiction and the Opioid Crisis, ONC led collaborations with CMS, CDC, numerous states, and representatives from **first responder groups** to identify the most critical stakeholder needs for combatting the opioid epidemic through health IT and improved health information interoperability. As part of this work, ONC and CMS collaborated closely, and in June 2018, CMS published **a letter to State Medicaid Directors** that detailed recommendations for integrating Prescription Drug Monitoring Programs (PDMPs) and EHR data; deploying predictive models coupled with targeted case management; leveraging telehealth-enabled medication assisted therapy; and combining emergency medical system data with other data sources for better care coordination.[26] ONC also continued to promote its Health IT Playbook which contains resources giving providers information about connecting to state PDMPs, integrating data, and electronic prescribing of controlled substances.[27]

★ - Technical Assistance from ONC Experts - ★

ONC continued to provide technical assistance to CMS State Innovation Model (SIM) participants. In FY 2019, ONC responded to **38** SIM Technical Assistance Request Cases, **15** All-Payer Model Technical Assistance Requests, participated in **18** SIM Virtual and In-Person State visits, attended **three** All-Payer In-Person State Visits, Hosted **four** Meeting Events, **three** Learning Events, **three** Affinity Groups, and developed **three** resources. The Health IT Resource Center also provided support for **32** SIM Operation Plan and Document Reviews, and **13** SIM Quarterly Progress Report Reviews.

Technology: Standards, Interoperability, and Certification

- ONC continued to implement the statutorily required **ONC Health IT Certification Program** during FY 2019. Pursuant to requirements in the Cures Act (including sections 4001 through 4004), ONC has updated the Certification Program to establish technical and organizational requirements aimed at transparent data sharing, including prohibiting information blocking, publishing APIs, and conducting real world testing of certified products.

  The Certification Program maintains test procedures and certification companion guides for 60 certification criteria,[28] used to standardize information across 21 distinct programs and initiatives taking place at CMS, the Department of Defense (DOD), the Veterans Health Administration (VHA), the Health Resources and Services Administration (HRSA), and the Substance Abuse and Mental Health Services Administration (SAMHSA).[29] ONC's Proposed Rule impacts this program which will carry out part of the implementation of the finalized rule. Additionally, the Health IT Certification Program website, the Certified Health IT Product List (CHPL), grew to include more than 700 health IT developers' products, and was used to register the EHR products of more than 550,000 healthcare providers and hospitals participating in Medicare and Medicaid programs.[30]

25 https://www.samhsa.gov/newsroom/press-announcements/201805020200.
26 "Leveraging Medicaid Technology to Address the Opioid Crisis," https://www.medicaid.gov/federal-policy-guidance/downloads/smd18006.pdf.
27 https://www.healthit.gov/playbook/opioid-epidemic-and-health-it/.
28 https://www.healthit.gov/topic/certification-ehrs/2015-edition-test-method.
29 https://www.healthit.gov/topic/certification-ehrs/programs-referencing-onc-certified-health-it.
30 https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/DataAndReports.html.

By CY 2018, nearly all hospitals and over half of office-based physicians in the nation had implemented a health IT product certified through the capabilities prioritized by Congress and included in the "2014 edition" certification standards. The most current edition of certified health IT products, dubbed the "2015 Edition," also became increasingly available for upgrade throughout 2018. At the end of FY 2019, there were 497 2015 Edition products from 342 developers on the CHPL, meaning that there is an EHR product with the latest capabilities available for 98 percent of the eligible hospitals and 94 percent of the eligible clinicians in CMS programs. Widespread adoption of 2015 edition EHRs among providers participating in the CMS programs is expected throughout the FY 2018-2020 timeframe.

- ONC continued to evolve and promote the adoption of a wide range of interoperability standards, including Release 4 of Health Level Seven International's (HL7) **Fast Healthcare Interoperability Resources** (FHIR®) standard, which is used to enable API-based access. ONC also coordinated standards awareness and use through the publication and maintenance of the Interoperability Standards Advisory (ISA), a resource listing **health information standards, models, and profiles** fitting into more than 60 sub-sections divided by topic/use (e.g., public health, patient information, coordination, clinical care, administration). During the public comment period for the 2019 ISA, ONC received 74 comments with more than 400 individual recommendations for revisions and improvements. In FY 2019, the ISA website has been accessed over 90,000 times, suggesting it is on pace to parallel the over 100,000 views in FY 2018.

★ - Third National Interoperability Forum - ★

ONC hosted the third national Interoperability Forum that took place from August 21 – 22, 2019 and brought together nearly 1,000 health IT stakeholders, to learn about recent effort to advance interoperability nationwide and to identify concrete actions in response to interoperability barriers.

During the 2-day event, participants from across the Federal Government and healthcare and technology sectors collaborated to identify barriers, showcase demonstrations and innovative health IT solutions, and partake in workgroups focused on various aspects of interoperability, such as the deployment of APIs, improving clinicians' experience with interoperability, patient matching, and health IT security.

- ONC continued to lead segments of the Precision Medicine Initiative (PMI), including the Sync for Science and Sync for Genes projects. In collaboration with partners at NIH, ONC established pilot sites and improved coordination for the PMI effort. Additional ONC-led activities were targeted to increase health information exchange, develop Implementation Guides for data standards, and finalize a FHIR Release 4 Clinical Genomic Standard. The project team also conducted needs assessments and provided advanced technical guidance to policy leaders to determine gaps that could affect the future of widespread electronic sharing of genomic information for research and healthcare.

★ - Leading Edge Acceleration Projects - ★

In March 2019, ONC announced an Interest in Applications for a **Leading Edge Acceleration Projects** (LEAP) funding opportunity to address standardization of patient information for seamless access, exchange, and use. The grant advances 21st Century Cures Act's requirements related to improving the interoperability of health information, facilitating information exchange, addressing barriers to interoperability, and reducing clinician burden relative to EHRs. This funding opportunity is specifically targeted at creating innovative solutions and advances in the following areas:

Area 1: Standardization and Implementation of Scalable HL7 FHIR Consent Resource.

Area 2: Design, Develop, and Demonstrate Enhanced Patient Engagement Technologies for Care and Research.

Agency-Wide Support

- ONC continued to implement workplace improvement initiatives to maintain recent increases in employee engagement. ONC's commitment to employee engagement is aligned with the goals in the HHS Annual Performance Plan Goal 5, Objective 2 related to managing human capital. In FY 2018, ONC established the Workforce Engagement (WE) Team to continue to enrich employee experience within the organization. In 2019, ONC achieved an Employee Engagement Index of 77 percent and Global Satisfaction Index of 72 percent. Additionally, ONC achieved an official response rate of 93 percent on the 2019 Federal Employee Viewpoint Survey, the highest of any HHS StaffDiv.
- ONC's websites garnered 1.2 million visitors so far during FY 2019, an average of over 188,000 sessions per month and 4.3 million page views throughout the year. Almost ninety percent of visitors were from outside the National Capitol area (DC, Maryland, and Virginia). Additionally, ONC's main website, https://HealthIT.gov, attracted users referred from 6,880 external websites.

Five Year Funding History

Funding History	
FY 2017 Enacted	60,367,000
FY 2018 Enacted	60,367,000
FY 2019 Enacted	60,367,000
FY 2020 Enacted	60,367,000
FY 2021 President's Budget	50,717,000

Budget Request

ONC's budget is a very small portion of federal healthcare spending, yet it has made a transformative impact on the U.S. healthcare system. The lack of interoperability and related, extensive lack of price and product transparency are massive costs to the U.S. public. These deficits keep patients from accessing their medical records, limits patients' ability to be engaged in their healthcare choices, and dramatically reduces market competition at high cost to the American public. ONC's work to rapidly address these issues through its policy development and coordination work, and its standards, certification, and interoperability work is sound public policy to promote quality healthcare in the US.

The ONC FY 2021 President's Budget Request is for $50.7 million, a decrease of $9.7 million (16 percent) from the FY 2020 Enacted Level. The Budget Request outlines activities required by the Cures Act, MACRA, and HITECH Act, and continues ONC's longstanding commitment to engage and respond to the needs of patients, providers, public health agencies, and researchers who rely on health IT. ONC's FY 2021 Request supports work to advance the technical infrastructure necessary to support price and product transparency and implement the Cures Act, and improve the interoperability of electronic health information. This work would move the healthcare system into a future where financial and clinical data about patients are more aligned. The FY 2021 President's Budget does not include dedicated funding for the national surveys related to the development, adoption, and use of health IT, or to support ONC's work related to combatting the opioid epidemic.

No additional FTEs are requested.

Policy Development and Coordination

ONC's FY 2021 Budget Request reflects ONC's continued commitment to achieving the Nation's goals by effectively implementing available policy and coordination levers mandated and necessary to fulfill requirements outlined in the Cures Act, MACRA, and HITECH Act; and work to promote transparency and patient access to their health information. ONC's progress in promoting and advancing nationwide interoperability depends on the coordinated action of its stakeholders, and the budget request shows how ONC will work closely with partners to advance toward these goals through health IT policy development and coordination. Priorities within ONC's FY 2021 policy development and coordination portfolio include:

Policy Development and Support

- **Interoperability Policy –** ONC will continue to lead implementation of the TEFCA, which seeks to accelerate health information exchange by establishing common principles, terms, and conditions to facilitate trust between health information networks. In 2021, ONC will continue to promote and facilitate adoption of the TEFCA by major delivery networks and health information exchanges.

- **Rulemaking –** ONC will publish and implement rules pertaining to sections 4002, 4003, and 4004 of the Cures Act. The proposed rules and regulations include provisions on conditions and maintenance of certification requirements for health IT developers under the ONC Health IT Certification Program, the voluntary certification of health IT for use by pediatric healthcare providers, health information network voluntary attestation to the adoption of the TEFCA in support of network-to-network exchange, and defining reasonable and necessary activities that do not constitute information blocking. Upon the publication of the finale rule ONC must implement these provisions through activities in the Standards, Interoperability and Certification portfolio. The implementation of these provisions will advance interoperability and support the access, exchange, and use of electronic health information through secure, standards-based APIs and transparent and uninhibited data sharing. Both interoperability and standards-based APIs are crucial to achieving patient access to their health information and price transparency, enabling patients to shop for care in the future.
- **Usability and Burden Reduction –** ONC will seek to advance implementation of recommendations included in the Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs.
- **Privacy and Security –** ONC will continue to work closely with OCR in response to Cures Act requirements and to address emerging challenges related to HIPAA and the privacy and security of electronic health information. ONC remains unwavering in its long standing goal to promote and ensure secure patient access to, and exchange of, electronic health information. A fundamental part of ONC's interoperability efforts is ensuring the privacy and security of patient data. For patient data to be shared it must be requested and directed by patients. ONC is encouraging and permitting entities to educate patients on the risks of sharing their medical data, as well as things they should consider before sharing their data with anyone.
- **EHR Reporting Program –** ONC will continue necessary activities to develop and implement the EHR Reporting Program. This includes the development of the technical infrastructure to collect confidential feedback and information on reporting program criteria; the development of detailed and summary reports based on information collected; and using the data collected and experiences gained in the previous performance periods, develop and submit to ONC an evaluation report with recommendations for enhancements and mechanisms to move forward with the program.

Stakeholder Coordination

- **Federal Coordination –** As stated previously, ONC will continue leading and engaging agencies which contribute to the Federal Health IT Strategic Plan[31] and participate in the Federal Health IT Coordinating Council. Within these collaborative forums, ONC will prioritize projects required by the Cures Act, MACRA, and HITECH Act, including work with CMS to reform existing programs and fee schedules, and to engage stakeholders to support provider participation; with HHS OCR to ensure and promote secure patient access to electronic health information and the privacy and security of health IT; and with the HHS OIG, FTC, and DOJ to define and enforce standards for data sharing and prohibiting information blocking.

[31] https://www.healthit.gov/sites/default/files/9-5-federalhealthitstratplanfinal_0.pdf.

- **Federal Advisory Committee –** ONC will continue to lead and engage the HITAC to inform the development of federal health IT policies and the implementation of its programs impacted by the policies and HHS and administration priorities.

Strategic Planning and Reporting

- **Federal Health IT Strategic Planning –** As stated previously, ONC plans to update the Federal Health IT Strategic Plan during FY 2019 – 2020. To create the new plan, ONC will coordinate with federal agencies and seek contributions from key stakeholders group including Congress and the public. Upon publication of the plan, ONC will begin regular collaboration with key stakeholders to plan, monitor, and report progress in support of priority implementation activities.
- **Congressional Reports –** ONC will continue to meet requirements for preparing and submitting annual reports to Congress, including the HITECH Annual Report describing actions taken to address barriers to accomplishing national health IT goals, and to support the HITAC in producing its Annual Report describing progress toward priority target areas identified in the Cures Act related to interoperability, privacy and security, and patient access.

Standards, Interoperability, and Certification

The FY 2021 Budget Request reflects ONC's plans to meet statutory requirements and advance progress toward national goals for widespread interoperability, which includes implementing the impacts of ONC's rulemaking. The request includes funding for coordination and technical activities, such as updates to ONC's Certification Program, that implement changes enacted by the Cures Act and ONC's subsequent rulemaking activities. The standards and interoperability work led by ONC advance the technical infrastructure necessary to support the Administration's price and product transparency goals and enables individuals to get access to their health information on their smartphones.

The Request supports the Conditions of Certification program requirements contained in section 4002 of the Cures Act; standards development and coordination work that promote product transparency and value-based care; development, promotion, and adoption of common standards, with a focus on next generation privacy, security, and interoperability standards; integration of social and behavioral data into electronic health records; and improving patient matching and promote interoperability of data in PDMPs.

Health IT Certification, Testing, and Reporting

- **ONC Health IT Certification Program –** ONC will continue to operate the Certification Program according to statutory requirements. ONC will make updates to the Certified Health IT product list and testing tools, and continue to implement the Conditions of Certification program requirements from section 4002 of the Cures Act, which necessitates substantial program oversight change.

  In FY 2021, ONC will continue to oversee the ONC-Authorized Testing Labs and ONC-Authorized Certification Bodies, and maintain a library of useful certification companion guides, test procedures, and electronic test tools to help developers with creating certified health IT.
- **Performance Measurement –** ONC will end support for the national surveys related to the development, adoption, and use of health IT in order to shift funding to critical work implementing the Cures Act such as the Proposed Rule, and Certification Program.

Standards Development and Technology Coordination

- **Standards Development Coordination –** ONC will continue to play a key role as a leader and convener of the health IT community to identify best practices and common approaches to implementing secure, interoperable health IT systems. The standards and interoperability work led by ONC advance the technical infrastructure necessary to support the Administration's price and product transparency goals, empowering patients with the information they need to search for the lowest costs and the highest-quality care. As part of this effort, ONC will continue to coordinate with private sector standards development organizations and promote innovative industry-led projects that improve adoption of mature standards, implement secure APIs, and promote standardized approaches for population level access to health data. Specific projects included in the 2021 Budget include:
    - Ensuring that the next generation of privacy and security standards are ready for widespread adoption as the Nation progresses to widespread adoption of APIs in healthcare, which is a key component of increasing price and product transparency,
    - Promoting adoption of common health information interoperability standards by accelerating the readiness of interoperability standards for adoption into the U.S. Core Data for Interoperability (USCDI), and
    - Addressing growing demand for a national strategy, resources, and demonstrable progress with integrating social and behavioral data and measures into EHRs.
- **Demonstrations and Pilots –** As resources permit, ONC will continue to sponsor and encourage demonstration projects and pilots that tackle critical interoperability challenges. ONC will prioritize projects that emphasize clinical uses of health IT related to the identification and harmonization of existing technical specifications.

Scientific Innovation

- **Scientific Initiatives –** ONC will continue to provide leadership to partners and foster healthcare advancement by anticipating, identifying, and participating in innovation projects spanning health IT development and use. ONC will work closely with stakeholders responsible for implementing the Precision Medicine Initiative (PMI), patient-centered outcomes research (PCOR), artificial intelligence, and international projects.
- **Innovation –** The Cures Act identifies ONC as a leading agency for advancing interoperability to reduce barriers to scientific innovation. ONC's Chief Scientist and clinical experts regularly partner with CMS, NIH, FDA, and others, to implement solutions to public health and scientific innovation through projects of national importance. In FY 2021, ONC will continue to coordinate with stakeholders to develop health IT policy and standards that advance interoperability in biomedical and health services research.

Agency-Wide Support

The FY 2021 President's Budget Request reflects the ONC's commitment to continue advancing progress toward national goals for widespread interoperability. The request includes coordination and ONC management activities that implement changes enacted in the Cures Act.

- **Communications and Engagement** - In FY 2021, ONC will continue to maintain its statutorily required website, https://HealthIT.gov/, as a key method of coordinating and disseminating best practices to common challenges facing health IT policymakers, providers, and consumers. ONC

will also continue to maintain a required repository of Federal Advisory Committee meeting documents at https://HealthIT.gov/HITAC.

- **Management and Governance -** In FY 2021, ONC will continue to implement and improve its existing strategic and operational management processes. ONC's FY 2021 Budget Request includes funding for the HHS-controlled shared services that ONC is mandated by HHS to pay for and use, including fees for financial and grants management systems, contract management, and ONC's office space located in HHS's Southwest Complex. ONC will continue to identify opportunities for savings and efficiencies by improving the management of central costs through negotiations with service providers. At this level, department controlled shared services make up about 15 percent of the available budget.

Output and Outcomes Table

Measure Group / Measure Text	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2020 Target	FY 2021 Target	FY 2021 Target +/- FY 2020 Target
Policy Development and Coordination				
Number of federal agencies actively participating in ONC-led health IT coordination efforts	FY 2019: 25 Target: Maintain (Target Met)	Maintain	Maintain	--
Standards, Interoperability, and Certification				
Number of interoperable data elements included in certification criteria adopted into the ONC Health IT Certification Program to meet congressional requirements	FY 2019: 60 criterion in 2015 edition Target: Maintain (Target Met)	Increase related to Cures Act Implementation	Maintain	--
Number of interoperability needs areas supported by standards and implementation specifications included in the annual Interoperability Standards Advisory Reference Edition	FY 2019: 2019 reference edition ISA published in January contained 167 (+16) standards and implementation specifications[32] (Baseline)	Maintain ISA & Publish annual update by March 2020	Maintain ISA & Publish annual update by March 2021	--
Agency Wide Support				
Number of visitors to ONC's websites to use health IT policy and technology assistance material	FY 2019: 1.8 million (Baseline)	Maintain	Maintain	--

[32] Includes 6 implementation specifications which are considered "profiles and models" and not traditional standards.

Environmental Measures

Measure: Provider capability in key domains of interoperable health information exchange[33]

	Office- based physicians	Non-federal acute care hospitals
• are electronically sending or receiving patient information with any providers outside their organization	47%	90%
• can electronically find patient health information from sources outside their health system	53%	61%
• can easily integrate (e.g. without manual entry) health information received electronically into their EHR	28%	53%
• had necessary patient information electronically available from providers or sources outside their systems at the point of care	32%	51%

Measure: Citizen's perspective on consumer access

- 51 percent of Americans have been given electronic access to any part of their healthcare record by their healthcare provider or insurer.

[33] These measures were selected to meet MACRA § 106(b) requirements to evaluate progress to widespread interoperability. Physician data are as of 2015; hospital data are as of 2017. 2018 estimates for both measures are expected to become available during calendar year 2019. https://www.healthit.gov/sites/default/files/fulfilling_section_106b1c_of_the_medicare_access_and_chip_reauthorization_act_of_2015_06.30.16.pdf.

Nonrecurring Expenses Fund

Budget Summary

(Dollars in Thousands)

	FY 2019[34]	FY 2020[35]	FY 2021[36]
Notification[37]	$7,000	TBD	TBD

Authorization ..... Section 223 of Division G of the Consolidated Appropriations Act, 2008
Allocation Method .....Direct Federal, Competitive Contract

Program Description and Accomplishments

The Nonrecurring Expenses Fund (NEF) permits HHS to transfer unobligated balances of expired discretionary funds from FY 2008 and subsequent years into the NEF account. Congress authorized use of the funds for capital acquisitions necessary for the operation of the department, specifically information technology (IT) and facilities infrastructure acquisitions.

In FY 2019, NEF resources supported the development of electronic (software-based) testing tools for the Health IT Certification Program and software development associated to build a data-reporting platform. These two interdependent IT infrastructure capacity-building activities directly tie to implementing Section 4002 of the 21st Century Cures Act. To support these activities, ONC awarded non-severable contracts to software development firms. An additional contract for this work will be issued in early FY 2020. The new testing tools and the reporting platform will allow ONC to conduct oversight and continuous monitoring of targeted electronic health record technologies and "real world testing" of certified products, and to build a data-reporting platform to capture and publish new data elements as required by the Act.

[34] Pursuant to Section 223 of Division G of the Consolidated Appropriation Act, 2008, notification is required of planned use
[35] Notification submitted to the Committees on Appropriations in the House of Representatives and the Senate on December 4, 2018
[36] HHS has not yet notified for FY 2020
[37] HHS has not yet notified for FY 2021

Supplementary Tables

Budget Authority by Object Class

(Dollars in Thousands)

	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget	FY 2021 +/- FY 2020
Personnel compensation:				
Full-time permanent (11.1)	18,686	19,265	19,265	-
Other than full-time permanent (11.3)	940	969	969	-
Other personnel compensation (11.5)	746	769	769	-
Military personnel (11.7)	253	261	269	8
Special personnel services payments (11.8)	9	9	9	-
Subtotal personnel compensation	**20,634**	**21,274**	**21,281**	**8**
Civilian benefits (12.1)	6,229	6,422	6,422	-
Military benefits (12.2)	107	110	114	3
Benefits to former personnel (13.0)	-	-	-	-
Total Pay Costs	**26,970**	**27,806**	**27,817**	**11**
Travel and transportation of persons (21.0)	330	330	330	-
Transportation of things (22.0)	-	-	-	-
Rental payments to GSA (23.1)	1,934	1,934	1,934	-
Rental payments to Others (23.2)	-			-
Communication, utilities, and misc. charges (23.3)	137	137	137	-
Printing and reproduction (24.0)	-	-	-	-
Other Contractual Services:				
Advisory and assistance services (25.1)	37	37	37	-
Other services (25.2)	12,931	12,931	10,748	(2,184)
Purchase of goods and services from government accounts (25.3)	11,309	11,309	9,126	(2,184)
Operation and maintenance of facilities (25.4)	284	284	284	-
Research and Development Contracts (25.5)	-	-	-	-
Medical care (25.6)	-	-	-	-
Operation and maintenance of equipment (25.7)	-	-	-	-
Subsistence and support of persons (25.8)	-	-	-	-
Subtotal Other Contractual Services	**26,962**	**26,962**	**22,595**	**(4,367)**
Supplies and materials (26.0)	286	286	286	-
Equipment (31.0)	19	19	19	-
Land and Structures (32.0)	-	-	-	-
Investments and Loans (33.0)	-	-	-	-
Grants, subsidies, and contributions (41.0)	5,739	5,294	-	(5,294)
Interest and dividends (43.0)	-	-	-	-
Refunds (44.0)	-	-	-	-
Total Non-Pay Costs	**6,044**	**5,599**	**305**	**(5,294)**
Total Budget Authority by Object Class	**59,976**	**60,367**	**50,717**	**(9,650)**

Salaries and Expenses

(Dollars in Thousands)

	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget	FY 2021 +/- FY 2020
Personnel compensation:				
Full-time permanent (11.1)	18,686	19,265	19,265	-
Other than full-time permanent (11.3)	940	969	969	-
Other personnel compensation (11.5)	746	769	769	-
Military personnel (11.7)	253	261	269	8
Special personnel services payments (11.8)	9	9	9	-
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Subsistence and support of persons (25.8)	-	-	-	-
Subtotal Other Contractual Services	**26,962**	**26,962**	**22,595**	**(4,367)**
Supplies and materials (26.0)	286	286	286	-
Total Non-Pay Costs	**286**	**286**	**286**	**-**
Total Salary and Expense	**54,218**	**55,054**	**50,698**	**(4,356)**
Direct FTE	**158**	**164**	**164**	**-**

Detail of Full-Time Equivalent Employment (FTE)

	2019 Actual Civilian	2019 Actual Military	2019 Actual Total	2020 Est. Civilian	2020 Est. Military	2020 Est. Total	2021 Est. Civilian	2021 Est. Military	2021 Est. Total
Direct:	156	2	158	162	2	164	162	2	164
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	156	2	158	162	2	164	162	2	164
ONC FTE Total	**156**	**2**	**158**	**162**	**2**	**164**	**162**	**2**	**164**

Average GS Grade		
	Grade:	Step:
FY 2017.....	13	9
FY 2018.....	13	8
FY 2019.....	13	7
FY 2020.....	13	7
FY 2021.....	13	7

Detail of Positions

	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget
Executive level	-	-	-
Total - Exec. Level Salaries	-	-	-
ES	6	6	6
Total - ES Salary	1,195,222	1,223,011	1,223,011
GS-15	46	46	46
GS-14	41	41	41
GS-13	43	44	44
GS-12	10	10	10
GS-11	5	12	12
GS-10	-	-	-
GS-9	7	16	16
GS-8	-	-	-
GS-7	-	1	1
GS-6	-	-	-
GS-5	-	1	1
GS-4	-	-	-
GS-3	-	-	-
GS-2	-	-	-
GS-1	-	-	-
Subtotal	152	171	171
Total - GS Salary	19,750,966	20,210,176	20,210,176
Average ES salary	199,204	203,835	203,835
Average GS grade	13-10	13-6	13-6
Average GS salary	129,941	118,188	118,188

Programs Proposed for Elimination

No programs are proposed for elimination.

Physicians' Comparability Allowance Worksheet

	PY 2019 (Actual)	CY 2020 (Estimate)	BY 2021 (Estimate)
Number of Physicians Receiving PCAs	1	3	3
Number of Physicians with One-Year PCA Agreements	0	0	0
Number of Physicians with Multi-Year PCA Agreements	0	3	3
Average Annual PCA Physician Pay (without PCA payment).	$192,190	$159,028	$159,028
Average Annual PCA Payment	$30,000	$16,000	$16,000

Explain the recruitment and retention problem(s) justifying the need for the PCA pay authority.

ONC needs physicians with a strong medical background to engage clinical stakeholders and to provide an in-depth clinically based perspective on ONC policies and activities such as EHR safety, usability, clinical decision support, and quality measures.

Without the PCA, it is unlikely that ONC could have recruited and maintained its current physicians, nor is it likely that ONC would be able to recruit and maintain physicians without PCAs in future years.

Explain the degree to which recruitment and retention problems were alleviated in your agency through the use of PCAs in the prior fiscal year.

ONC was able to retain physicians with strong medical background so the agency was better able to engage clinical stakeholders and provide a clinically based perspective on ONC policies and activities such as EHR safety, reducing administrative burden on providers, usability, clinical decision support, and quality measures.

Modernization of the Public-Facing Digital Services - 21st Century Integrated Digital Experience Act

On Dec. 20, 2018, President Trump signed the 21st Century Integrated Digital Experience Act (IDEA), which requires data-driven, user-centric website and digital services modernization, website consolidation, and website design consistency in all Executive Agencies. Departments across the federal landscape are beginning to implement innovative digital communications approaches to increase efficiency and create more effective relationships with their intended audiences. The American public expects instant and impactful communications – desired, trusted content available when they want it, where they want it, and in the format they want it. If the consumer is not satisfied they move on and our opportunity for impact is lost.

Modernization Efforts

In FY 2019 HHS engaged Department leadership and developed a Digital Communications Strategy that aligns with the requirements of IDEA. As the result of a comprehensive review of costs associated with website development, maintenance, and their measures of effectiveness, HHS will prioritize:

- modernization needs of websites, including providing unique digital communications services, and
- develop estimated costs for achieving performance metrics.

Over the next five years HHS will continue to implement IDEA by focusing extensively on a user-centric, Digital First approach to both external and internal communications and developing performance standards. HHS will focus on training, hiring, and tools that drive the communication culture change necessary to successfully implement IDEA.

Over the next year, HHS Agencies and Offices will work together to continue to implement IDEA and the HHS Digital Communications Strategy across all communications products and platforms.

Significant Items in Appropriation Committee Reports

Patient Data Matching: *The Committee is aware that one of the most significant challenges inhibiting the safe and secure electronic exchange of health information is the lack of a consistent patient data matching strategy. With the passage of the Health Information Technology for Economic and Clinical Health (HITECH) Act, a clear mandate was placed on the Nation's healthcare community to adopt electronic health records and health exchange capability. Although the Committee continues to carry a prohibition against HHS using funds to promulgate or adopt any final standard providing for the assignment of a unique health identifier for an individual until such activity is authorized, the Committee notes that this limitation does not prohibit HHS from examining the issues around patient matching. Accordingly, the Committee continues to encourage the Secretary, acting through the ONC and CMS, to provide technical assistance to private-sector-led initiatives to develop a coordinated national strategy that will promote patient safety by accurately identifying patients to their health information.* ***(Page 168, H.Rept. 116-62)***

Action to Be Taken
ONC will continue to provide technical assistance to private-sector-led initiatives to develop a coordinated national strategy that will promote patient safety by accurately identifying patients to their health information.

Good Accounting Obligation in Government Act Report

The information below addresses the requirements of the Good Accounting Obligation in Government Act (GAO-IG Act; Public Law 115-414) to provide a report identifying each public recommendation issued by the Government Accountability Office (GAO) and federal Offices of Inspectors General (OIG) which remains unimplemented for one year or more from the annual budget justification submission date. The recommendations below apply specifically to this division of HHS. Please refer to the General Departmental Management budget justification for more information on the Department's overall progress in implementing GAO and OIG recommendations.

Appendix 1: OIG-GAO Open Recommendations

Report Number	Report Title	Report Date	Recommendation Text	Concur / Non-Concur	Implementation Timeline	Implementation Status	Implementation Updates and Constraints
GAO-17-305	Health Information Technology: HHS Should Assess the Effectiveness of Its Efforts to Enhance Patient Access to and Use of Electronic Health Information	3/15/2017	To help ensure that its efforts to increase patients' electronic access to health information are successful, the Secretary of HHS should direct ONC to use the information these performance measures provide to make program adjustments, as appropriate. Such actions may include, for example, assessing the status of program operations or identifying areas that need improvement in order to help achieve program goals related to increasing patients' ability to access their health information electronically.	Concur	NA	In Progress	ONC continues to take actions in response to and to close out GAO's recommendation. Specifically, in our latest open recommendation update, ONC noted it currently uses program data to reassess and improve upon its initiatives. For example, the Patient Engagement Playbook for providers is updated on a quarterly basis through user feedback to provide relevant and timely information. Similarly, the Blue Button Connector website for consumers is currently being redesigned to create a more engaging and beneficial experience for users seeking their health information. In each of these projects and when developing other tools and resources focused on increasing electronic access to health information, ONC will continue to implement user-centered design principles to ensure that all products and materials developed are effective and impactful. Additionally, ONC will rely on web metrics, stakeholder feedback and input, comments and feedback from users, and internal program analysis to update and improve these efforts. ONC is committed to leveraging data from its program evaluations to facilitate program improvement.
OEI-01-11-00570	Not All Recommended Fraud Safeguards Have Been Implemented in Hospital EHR Technology	12/9/2013	Audit logs be operational whenever EHR technology is available for updates or viewing.	Concur	2020	Awaiting Disposition	ONC submitted an NFA to OIG in 2016 informing OIG no further action would be taken, but OIG has not yet closed out the recommendations.
OEI-01-11-00570	Not All Recommended Fraud Safeguards Have Been Implemented in Hospital EHR Technology	12/9/2013	ONC and CMS strengthen their collaborative efforts to develop a comprehensive plan to address fraud vulnerabilities in EHRs.	Concur	2020	Awaiting Disposition	ONC submitted an NFA to OIG in 2019 informing OIG no further action would be taken, but OIG has not yet closed out the recommendations.

Report Number	Report Title	Report Date	Recommendation Text	Concur / Non-Concur	Implementation Timeline	Implementation Status	Implementation Updates and Constraints
GAO-14-207	Electronic Health Record Programs: Participation Has Increased, but Action Needed to Achieve Goals, Including Improved Quality of Care	3/6/2014	To ensure that CMS and ONC can effectively monitor the effect of the EHR programs and progress made toward goals, the Secretary of Health and Human Services should direct the agencies to develop performance measures to assess outcomes of the EHR programs--including any effects on health care quality, efficiency, and patient safety and other health care reform efforts that are intended to work toward similar outcomes.	Concur	2020	Awaiting Disposition	In its latest open recommendation update, ONC noted, in-depth, efforts to implement this recommendation, including: (1) regularly/publically reporting on how program participants are progressing in the program and related impacts; (2) funding a series of external program evaluations designed to assess the impact of the programs funded under HITECH, including the EHR Incentive Programs; and, (3) continuing to explore potential outcome measures to incorporate into EHR programs. GAO responded to ONC's update noting "to fully implement this recommendation, CMS needs to develop performance measures that enable the agency to assess whether the Promoting Interoperability programs are improving outcomes, . . ." CMS has indicated that the new scoring submission window ends in the Spring of 2020 and the final data, for the first year, should be available by late 2020.
GAO-14-207	Electronic Health Record Programs: Participation Has Increased, but Action Needed to Achieve Goals, Including Improved Quality of Care	3/6/2014	To ensure that CMS and ONC can effectively monitor the effect of the EHR programs and progress made toward goals, the Secretary of Health and Human Services should direct the agencies to use the information these performance measures provide to make program adjustments, as appropriate, to better achieve program goals.	Concur	2021	Awaiting Disposition	In addition to actions taken in response to recommendation GAO-14-207-2, to implement recommendation GAO-14-207-3, the information gathered through the monitoring activities noted above was used to inform ONC and CMS programs. For example, information collected was regularly presented to ONC's Federal Advisory Committees to inform their decision-making. CMS and ONC have continued to leverage information gathered through previously noted program monitoring activities to inform rulemaking necessary to implement requirements under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) and the 21st Century Cures Act (CURES). Both of these legislations build upon the requirements under HITECH and thus might alter the anticipated outcomes of current programs going forward. GAO responded to ONC's update noting "to fully implement this recommendation, CMS needs to develop outcome-oriented performance measures and then demonstrate it is using them to make appropriate program adjustments. . . ." CMS indicated that they expect to be able to close this recommendation once HHS has identified the performance based measures. CMS will not receive the 2019 reporting period data until spring of 2020 and the final validated data until late 2020.

Report Number	Report Title	Report Date	Recommendation Text	Concur / Non-Concur	Implementation Timeline	Implementation Status	Implementation Updates and Constraints
GAO-17-184	Electronic Health Records: HHS Needs to Improve Planning and Evaluation of Its Efforts to Increase Information Exchange in Post-Acute Care Settings	2/27/2017	To improve efforts to promote EHR use and electronic exchange of health information in post-acute care settings, the Secretary of Health and Human Services should direct the Centers for Medicare & Medicaid Services (CMS) and ONC to evaluate the effectiveness of HHS's key efforts to determine whether they are contributing to HHS's goal for increasing the use of EHRs and electronic exchange of health information in post-acute care settings.	Concur	2019	Awaiting Disposition	In its latest open recommendation update, ONC noted, in-depth, the efforts taken to implement this recommendation, including but not limited to, noting ONC conducted activities to evaluate HIT adoption and interoperability for PAC settings, including conducting and analyzing the results of 3 surveys regarding rates of interoperability among skilled nursing facilities and home health agencies. These surveys established important baseline data for EHR adoption and interoperability by skilled nursing home and home health; the results of these analyses were published by ONC in 2 data briefs published in 2017 and 2018; and, ONC presented the results of these analyses to CMS and the public. Also in July 2015, ONC issued 12 two-year cooperative agreements to state-designated entities and state government agencies under the Advance Interoperable Health Information Technology Services to Support Health Information Exchange (AHIE) program. The awards funded efforts to provide training, education, and technical assistance to support clinical and non-clinical caregivers with incorporating HIE into their existing workflows. The goal was to leverage investments and lessons learned from the initial State HIE projects to increase the adoption and use of interoperable HIT to improve care coordination. Each awardee was asked to develop a set of measures unique to their projects that would demonstrate their progress toward these milestones and an evaluation of awardee efforts was also conducted. ONC believes it has addressed the recommendations made in the GAO report that are within ONC's authority and considers the recommendation fully implemented. In August 2019 CMS submitted the Data Element Library response to GAO. It is our understanding that ONC will provide a response regarding the State Medicaid matching funds and additional responses related to their efforts.The program area is hopeful that this closes out both recommendations of this audit for CMS.

Report Number	Report Title	Report Date	Recommendation Text	Concur / Non-Concur	Implementation Timeline	Implementation Status	Implementation Updates and Constraints
GAO-17-184	Electronic Health Records: HHS Needs to Improve Planning and Evaluation of Its Efforts to Increase Information Exchange in Post-Acute Care Settings	2/27/2017	To improve efforts to promote EHR use and electronic exchange of health information in post-acute care settings, the Secretary of Health and Human Services should direct CMS and ONC to comprehensively plan for how to achieve the department's goal related to the use of EHRs and electronic information exchange in post-acute care settings. This planning may include, for example, identifying specific actions related to post-acute care settings and identifying and considering external factors.	Concur	2019	Awaiting Disposition	ONC noted the following in its latest open recommendation update. In 2015, ONC published a federal strategic plan to advance the adoption and interoperability of HIT, including in post-acute care (PAC) settings: Federal Health IT Strategic Plan 2015 – 2020 (the Plan). Contributors to the Plan included representatives from across the federal government, including CMS. The Plan: (1) addresses the federal HIT strategy for all health care industry segments that are health information exchange partners, including long-term care and post-acute; (2) explains how the federal government is working to achieve the mission of 'improving the health and well-being of individuals and communities through the use of technology and health information that is accessible when and where it matters most'; (3) applies broadly to stakeholders across the care continuum, including PAC providers, and aims to modernize the U.S. HIT infrastructure so individuals, providers, and communities can use it to help achieve health and wellness goals; (4) includes goals, objectives, and strategies intended to drive the actions needed to improve HIT adoption and PAC interoperability; and, (5) states "long-term and post-acute care plays an integral role in helping to keep individuals healthy and have numerous situations that necessitate collaboration and sharing of information with the greater health community." ONC has also taken actions to advance HIT adoption and interoperability for PAC providers through outreach/collaboration, supports for HIT adoption, and standards/initiatives specific to PAC. ONC believes it has addressed the recommendations made in the GAO report that are within ONC's authority and considers the recommendation fully implemented. In August 2019 CMS submitted the Data Element Library response to GAO. It is our understanding that ONC will provide a response regarding the State Medicaid matching funds and additional responses related to their efforts. The program area is hopeful that this closes out both recommendations of this audit for CMS.

Report Number	Report Title	Report Date	Recommendation Text	Concur / Non-Concur	Implementation Timeline	Implementation Status	Implementation Updates and Constraints
GAO-17-5	Health Care Quality: HHS Should Set Priorities and Comprehensively Plan Its Efforts to Better Align Health Quality Measures	10/13/2016	To make it more likely that HHS will achieve its goals to reduce quality measure misalignment and associated provider burden, the Secretary of HHS should direct CMS and the Office of the National Coordinator for Health Information Technology to prioritize their development of electronic quality measures and associated standardized data elements on the specific quality measures needed for the core measure sets that CMS and private payers have agreed to use.	Concur	2020	Awaiting Disposition	CMS does prioritize the development of electronic quality measures and associated standardized data elements on the specific quality measures needed in the cores sets. We have highlighted leveraging the Core Quality Measures Collaborative in our strategic approach for measure development priorities for MACRA, as noted in the CMS Quality Measure Development Plan (https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/Final-MDP.pdf). The following section and language throughout the MDP is documentation of that prioritization: "CMS intends to prioritize the development of electronic measures in a manner that ensures relevance to patients, improves measure quality, increases clinical data availability, accelerates development cycle times, and drives innovation. Specifically, CMS, in concert with ONC and the private sector, is championing electronic measure development in the areas of standards, tools, and processes that are open to all measure developers." In addition, we anticipate soon awarding an Eligible Clinician (EC) eCQM maintenance and development contract where the contractor shall identify clinical quality measure concepts for eCQMs that reflect the following CMS priorities: 1) improve quality, safety, and efficiency and reduce health disparities, 2) engage patients and families, 3) improve care and coordination, 4) ensure adequate privacy and security protections for personal health information, and 5) improve population and public health. Measure concepts will be for the EC setting as well as for other health care settings, such as post-acute care setting like skilled nursing facilities, home health, and dialysis facilities. We note that up to 4 new (de novo or retooled) Eligible Clinician eCQMs may be developed during each period of performance of the contract, according to the QPP, Agency and HHS needs and priorities. Although CMS has implemented measures from the Core Quality Measures Collaborative's agreed-upon measure sets, ONC understands that only some of the measures across all of the agreed-upon core sets have been fully developed and specified for EHR reporting. ONC has implemented the 2015 Edition Health IT Certification Criteria (2015 Edition) and its associated testing and certification procedures to support the efforts of CMS and other measure developers who are prioritizing development of core measures, including private payers and clinical specialty societies. Certification to the 2015 Edition ensures a health IT product is capable of capturing and exchanging a defined catalog of data elements in conformance with interoperability standards, all identified in our regulations. Thus, the 2015 Edition provides a foundational set of standardized data elements that CMS and other measure developers can use to develop and specify additional measures for EHR reporting. ONC continues to prioritize interoperability of health data to support patient choice, clinical care, public health, value-conscious purchasing and improved care value. ONC does not plan to take further action(s), other than those actions previously taken, in response to this recommendation. ONC believes efforts to prioritize CMS' development of measures from the core measure sets that they and private payers have agreed to use should be addressed by CMS.

Health Insurance and Implementation Fund

HEALTH INSURANCE REFORM IMPLEMENTATION FUND

Budget Summary

(Dollars in Thousands)

	FY 2019	FY 2020	FY 2021
Obligations*	**$493**	**$574**	**$1,871**

* $1,000,000,000 was appropriated in the Health Care and Education Reconciliation Act of 2010

Authorizing Legislation……Health Care and Education Reconciliation Act, Section 1005, FY 2010
FY 2020 Authorization……Indefinite
Allocation Method……Direct Federal, Competitive Contract

Program Description and Accomplishments

Section 1005 of the Health Care and Education Reconciliation Act of 2010 (P.L. 111-152) appropriated $1,000,000,000 to the Health Insurance Implementation Fund within the Department of Health and Human Services (HHS). The Fund was used for Federal administrative expenses necessary to carry out the mandates of the Patient Protection and Affordable Care Act of 2010 (P.L. 111-148) and the Health Care and Education Reconciliation Act of 2010.

HHS used implementation funds to primarily support salaries, benefits, contracts, and infrastructure for various provisions, including rate review and medical loss ratio. A portion of these funds also supported the establishment of the Exchanges, including the building of IT systems.

The Department of Treasury required funding to implement multiple tax changes, including the Small Business Tax Credit, expanded adoption credit, W-2 changes for loan forgiveness, charitable hospital requirements, and planning for Exchanges. The Department of Labor required funds to conduct compliance assistance; modify or develop IT systems that support data collection, reporting, policy and research; and develop infrastructure for the newly required Multiple Entity Welfare Arrangements reporting and registration within Obamacare.

The Office of Personnel Management (OPM) required funding to plan for implementing and overseeing Multi-State Plan Options for the Exchanges and allowing Tribes and tribal organizations to purchase Federal health and life insurance for their employees. OPM also assisted HHS by implementing an interim Federal external appeals process prior to the establishment of a permanent Federal appeals process.

Budget Request

In FY 2019, $493,311 of this funding was spent by the HHS Office of the Chief Technology Officer (CTO), who, in partnership with the Indian Health Service (IHS) and the Office of the National Coordinator for Health IT (ONC), led a project to conduct a baseline assessment of IHS and tribal health IT needs and recommend a detailed approach to modernizing the IHS's health IT. CTO is also using this funding to lead an effort to update IHS's quality reports to include new measures and recommend a detailed approach to streamlining and enhancing the quality reporting process. CTO plans to spend another $573,825 of the $2,444,603 remaining in FY 2020 to continue this work. It is the Department's current projection that $1,870,778 will be available for obligation in FY 2021. However, given the steady rate of recoveries in this account year of year, it is possible that this amount may be higher.

Nonrecurring Expenses Fund

Nonrecurring Expenses Fund
Budget Summary
(Dollars in Thousands)

	FY 2019[2]	FY 2020[3]	FY 2021[4]
Notification[1]	$600,000	TBD	TBD
CDC Allocation	-	$225,000	-
NIH Allocation	-	$225,000	-
Rescission	($400,000)	($350,000)	($500,000)

Authorizing Legislation:
Authorization……Section 223 of Division G of the Consolidated Appropriations Act, 2008
Allocation Method……Direct Federal, Competitive Contract

Program Description and Accomplishments

The Nonrecurring Expenses Fund (NEF) permits HHS to transfer unobligated balances of expired discretionary funds from FY 2008 and subsequent years into the NEF account. Congress authorized the use of these funds for capital acquisitions necessary for the operation of the Department, specifically information technology (IT) and facilities infrastructure acquisitions.

Since FY 2013, HHS has allocated over $3.6 billion for projects, including $1.1 billion for physical infrastructure projects and $2.5 billion for IT infrastructure projects. The NEF helps to address infrastructure needs across HHS's four landholding agencies and to develop, enhance, and maintain important IT systems across the Department.

The 2021 Budget proposes to cancel $500 million from the NEF. With available balances, the NEF will support multiple high-priority projects that address facility and technology needs across the Department. For example, the FY 2021 HHS-wide facilitates backlog of maintenance and repairs totals nearly $2.4 billion. Each year that HHS does not address its infrastructure problems, backlog grows. HHS receives millions in new funding requests each year from its OPDIVs for IT project support.

Major NEF Facilities Investments (FY 2013 – FY 2019)

The NEF has invested over $1.1 billion in facilities projects across the Department. The funding has been used to improve laboratories, medical centers and storage spaces to safely store substances from high-contaminants to food and medical products.

<u>National Institutes of Health</u>

NIH has been allocated $319 million in NEF funding since FY 2013 to address facilities construction and improvement projects. Most notably, $162 million was invested in renovations for the Clinical Center E-Wing in FY 2016. This project will provide new research laboratory space that replaces existing laboratories, and will replace a vital clinical program

now functioning in deficient space. Additionally, in FY 2020 Congress allocated $225 million of NEF funds to NIH for facilities projects.

Indian Health Services

IHS has been allocated $332 million in NEF funding since FY 2013 to address the Health Care Facilities Construction Priority List backlog and support improvement projects to meet accreditation standards and accommodate population growth. These investments will facilitate improved access to modern facilities and data systems for health care providers, support accurate clinical diagnosis, and effective therapeutic procedures to assure the best possible health outcomes across Indian Country.

Food and Drug Administration

FDA has been allocated $244 million in NEF funding since FY 2013 to address a range of construction, renovation, and lab replacement projects. This includes $36 million for the Denver District Laboratory Replacement project, which will provide a new modern space for food safety, dietary supplements, and pharmaceutical testing. In addition, FDA has invested $39 million from the NEF for renovations to various buildings located at the Jefferson Laboratory in Arkansas to address and prevent further deterioration to facilities critical to food and medical product safety.

Centers for Disease Control and Prevention

CDC has been allocated $272 million in NEF funding since FY 2013 to address a number facility construction and improvement projects and IT infrastructure projects, most notably to provide $130 million for the construction and consolidation of the National Institute for Occupational Safety and Health's (NIOSH) Cincinnati Campus. Additionally, CDC used $5 million of NEF funds to expedite the renovation of a deactivated biosafety lab to address the critical need for improvements in laboratory safety training with high-contaminant substances. Without NEF funds, HHS may not have been able to quickly support this critical need.

Additionally, CDC received $240 million, as directed by Congress, to support their Biosafety Level 4, high containment lab. In FY 2020, Congress also allocated $225 million of NEF funds for the Chamblee Building 108 campus consolidation, which will provide a new research support building and a replacement laboratory material handling facility. This investment elicits long term efficiencies and cost savings by co-locating CDC staff onto this campus.

Major NEF IT and Cybersecurity Investments (FY 2013 – FY 2019)

HHS has invested over $2.5 billion in NEF funding for major IT infrastructure projects across the Department. The funding has been used to improve HHS's financial, grants, and acquisition systems and to maintain strong Department-wide cybersecurity posture.

System Modernizations:

Over $158 million has been allocated from the NEF to improve the Unified Financial Management System (UFMS) and modernize outdated financial systems across the Department, ensuring financial integrity and improving Departmental compliance with the Federal Financial Management Improvement Act. Additionally, $340 million has been allocated for projects to move HHS's IT systems to the cloud, and to bring human resources, accounting, grants, and contracts systems into the 21st Century, in alignment with the Cross-Agency Priority Goal of Modernizing Information Technology.

Cybersecurity:

$163 million of NEF funds has been allocated to support urgent and critical cybersecurity initiatives to protect the Department from continually evolving threats and to address evolving Continuous Diagnostic and Mitigation requirements from the Department of Homeland Security. In FY 2019, HHS notified for $65 million to IHS to modernize the aging health IT systems and support other IT initiatives including Health IT Systems and Support. The Assistant Secretary for Administration developed the HHS Cybersecurity Automation Program, which established a cybersecurity solution, as well as governance, leadership, and operational capabilities for the system. Additionally, the Office of Inspector General received $11 million in funding from the NEF to strengthen mobile application security and increase the confidentiality and availability of sensitive data nationwide. NEF funds have also supported Department-wide projects oriented around trusted internet connection and computer security incident response.

NEF Notifications and Reductions from 2013-2020
(dollars in millions)

Fiscal Year	Notifications and Congressional Allocations	Enacted Rescissions and Transfers Out
2013	$600	
2014	$600	
2015	$650	
2016	$800	
2017	$430	($400)
2018	-	($240)
2019	$600	($400)
2020	$450	($350)
TOTAL	**$4,130**	**($1,390)**

[1] Pursuant to Section 223 of Division G of the Consolidated Appropriation Act, 2008, notification is required of planned use
[2] Notification submitted to the Committees on Appropriations in the House of Representatives and the Senate on December 4, 2018
[3] HHS has not yet notified for FY 2020
[4] HHS has not yet notified for FY 2021

Service and Supply Fund

Service and Supply Fund Table of Contents

SERVICE AND SUPPLY FUND

(Dollars in Thousands)

SSF	FY 2019 Actuals	FY 2020 Board Request	FY 2021 Current Estimate	FY 2021 +/- FY 2020
BA	$1,502,269	$1,785,253	$1,385,164	-$400,089
FTE	998	1,262	1,262	-

Authorizing Legislation.....42 USC §231
2021 Authorization.....Indefinite
Allocation Method .....Contract, Other

Statement of the Budget

The overall FY 2021 current estimate for the Service and Supply Fund (SSF) is $1,385,164 which is $400,089 below the FY 2020 Board request. Details can be found in the narratives below.

Service and Supply Fund Overview and Activity Narratives

This section describes the activities funded through the HHS' Service and Supply Fund (SSF), which is a revolving fund authorized under 42 USC §231. The SSF provides consolidated financing and accounting for business-type operations which involve the provision of common services to customers. The SSF is governed by a Board of Directors, consisting of representatives from each of the Department's ten Operating Divisions (OPDIV), the Program Support Center (PSC), and the Office of the Secretary (OS). A representative from the Office of Inspector General (OIG) serves as a non-voting member of the SSF Board.

The SSF does not have its own annual appropriation but is funded entirely through charges to its customers (OPDIVs and Staff Divisions (STAFFDIV) in addition to other federal departments and agencies) for their usage of goods and services. The SSF is comprised of two categories of activities: the Program Support Center and those activities which are performed by other OS components (Non-PSC). Each activity financed through the SSF is billed to the Fund's customers by either fee-for-service billing, which is based upon actual service usage, or by an allocated methodology. Details of the 2020 Board Request, and 2021 Estimates and FY 2019 actuals are described below.

Program Support Center

PSC Portfolios	FY 2020 Board Request	Adjustments (+/-)	FY 2021 Current Estimate
Acquisition Management Services	$688,433,085	-$400,089	$288,344,090
Financial Management Portfolio (FMP)	$63,428,497	$0	$63,428,497
Occupational Health Portfolio (FOH)	$199,725,272	$0	$199,725,272
Real Estate, Logistics & Operations Portfolio (RLO)	$328,613,085	$0	$328,613,085
Total	**$1,280,199,939**	**-$400,089**	**$880,110,384**

The Program Support Center (PSC) organizationally resides under the Assistant Secretary for Administration, Office of the Secretary and operates under authorizing legislation 42 USC §231 as amended. The PSC is committed to providing the best value in terms of cost and service quality to its customers.

PSC tracks performance in terms of its strategic goals. These goals focus primarily on delivering products and services that are recognized both as high quality, and as providing value. The organization strives to achieve three primary outcomes: higher service quality, lower operating costs and reduced rates for customers. By working to reach these outcomes, PSC supports the Department's efforts for responsible stewardship and effective management. Details are outlined in the performance review section.

PSC's FY 2021 current estimate of $880,110,384 which is $400,089 below the FY 2020 Board request of $1,280,199,939.

PSC Acquisition Management Services (AMS):

The PSC Acquisition Management Services (AMS) serves as a major foundation of the Department's procurement operations through fully integrated acquisition and strategic support services. AMS provides these services on behalf of the Department and other Federal agencies. AMS offers a range of acquisition support services including simplified and negotiated contracts.

PSC Financial Management Portfolio (FMP):

The PSC Financial Management and Procurement Portfolio (FMP) serves as a major foundation of the Department's finance, accounting, and procurement operations through: the administration of grant payment management services; accounting and fiscal services; debt management services; rate review/negotiation/approval services; and fully integrated acquisition and strategic support services. FMP provides these services on behalf of the Department and other Federal agencies. Fiscal and technical guidance is offered to assist in implementing new initiatives across HHS and other agencies and to ensure compliance with regulatory requirements. FMP also provides guidance and oversight for HHS Financial Policy, and ensures compliance where appropriate.

FMP continues to be a leader in supporting the Department's clean audit opinions from independent audit firms. FMP services are organized into three Service Areas:

- **Accounting Services** – covers a range of financial support services associated with Unified Financial Management System (UFMS) and includes accounting, debt collection and financial reporting.
- **Grants Finance and Administration Services** – provides federal grant funding support, negotiating indirect costs for grant providers and issuing grant payments to grantees.

PSC Occupational Health Portfolio (FOH):

The Federal Occupational Health (FOH) provides comprehensive, high-quality, customer-focused occupational health services in strategic partnership with Federal agencies nation-wide to improve the health, safety, and productivity of the Federal workforce. Approximately 93% of FOH's services are provided to Federal agencies outside of HHS. FOH is organized in four Service Areas:

- **Clinical Health Services (CHS)** consists of seven cost centers: Exams and Clinical Outreach, FedStrive Advantage, Onsite Occupational Health Centers, Medical Surveillance/Clearance Reviews, Medical Employability and Workers Compensation Management and Psychological Testing which has been moved from Behavioral Health to better align with the Medical Review oversight required. CHS provides services which includes exams and related procedures, health screenings to prevent illness, immunizations for illness prevention and work related activities, reasonable accommodation request, workers compensation management reviews, medical surveillance and clearance required based upon an employee's job duties and other medical services.

- **Wellness and Health Promotion Services (WHP)** is a single cost center which provides fitness center oversight and health promotion activities, such as health coaching, health education, and promotion of programs to support healthy behaviors which contributes to increased employee productivity through better health behaviors.

- **Behavioral Health Services (BHS)** consists of two cost centers: Employee Assistance Program / Work Life Services and Organizational Development and Leadership. Psychological Testing was part of this service area in FY17 and has been moved to Clinical Health Services for FY18. BHS provides professional services for: assessment, short-term counseling, referral, and critical incident response. This improves the well-being of federal employees, and helps employees better manage their personal and professional responsibilities which in turn helps improve productivity.

- **Environmental Health and Safety Services (EHS)** consists of two cost centers Environmental Health and Safety (EHS) and the Automated External Defibrillator (AED) program. EHS offers a wide variety of services including environmental and occupational safety compliance, industrial hygiene assessments, laboratory analysis of environmental samples, urgent response management, and other environmental consulting services. In addition, EHS provides the mandatory policy services to HHS. The AED program helps agencies set up a program within

their facility aiding them in the procurement of devices, certification training, and ensuring the appropriate medical oversight is provided.

PSC Real Estate, Logistics and Operations Portfolio (RLO):

Real Estate, Logistics and Operations Portfolio (RLO) provides real estate, logistics and a wide range of administrative and technical support services to customers within HHS and other federal agencies. RLO is organized in the following Service Areas:

- **Real Property Management Services** provides space design planning, utilization and compliance, management for transfer of surplus real property to non-profit entities (McKinney-Vento Homeless Assistance Act), and real property oversight.

- **Supply Chain Management Services** provides personal property management, warehousing, distribution, medical supply fulfillment, publication fulfillment, personal property disposal and labor services;

- **Building Operations Services** provides facilities operations, maintenance, shredding, parking services, regional support services and conference room services;

- **Intake, Suitability and Badging Services** fulfills the Homeland Security Presidential Directive 12 (HSPD-12) for the HHS, developing and issuing guidelines in conjunction with federal laws and regulations prescriptive to identity, credential, and access management;

- **Physical Security and Emergency Management Services** provides Department-wide leadership, coordination and oversight for the Physical Security and Emergency Management programs throughout the Department to ensure the safety and security of HHS employees and assets;

- **Mail and Publishing Services** provides digital conversion services, printing procurement, Departmental forms management, HHS printing guidance, mail screening, mail operations, and HHS mail services;

- **FedResponse Services** consists of the Contact Center and HHS Toll Free Hotline;

- **Transportation Services** provides transit subsidy program management, executive drivers, coordination of travel policy, travel program management, travel charge card management, purchase card management, fleet card management, fleet guidance, vehicle leasing services; and

- **Other Administrative Support** - Board for Corrections of the USPHS Commissioned Corps.

Non-PSC Activities

Non-PSC activities differ from those provided by the PSC in their predominate focus, which is helping HHS components comply with law, regulations, or other federal management guidelines, as well as targeted workforce management. The non-PSC activities support all components of HHS, providing support in areas such as acquisitions management, audit resolution, responding to and processing Federal tort claims, collecting and managing grants data to ensure HHS' ability to respond to regulatory requirements, providing human resources and equal employment opportunity services, and providing IT support and devices.

Agency for Children and Families

The Administration for Children and Families (ACF) promotes the economic and social well-being of children, families, individuals and communities with leadership and resources for compassionate, effective delivery of human services.

GrantSolution Center of Excellence:
GrantSolutions (GS), a Center of Excellence, is a partnership between the Department of Health and Human Services (HHS)and a number of cabinet level and independent agencies. GS is located within the HHS Administration for Children and Families (ACF). The President's budget for FY 2007 codified GrantSolutions as one of three shared service providers for the grants management line of business e-gov initiative. GS is responsible for awarding, monitoring, and financially reporting on grants to states, tribes, territories, and other non-profit organizations.

GS is comprehensive; supporting both discretionary and mandatory awards through all 14 stages of a grant's lifecycle. GS offers its partners services associated with 8 different modules, multiple interfaces to partner specific and government-wide systems and support for all aspects of the grants management business lifecycle. GS makes grants administration simpler and cost effective through electronic reporting and information access for grantees, allowing grantees to focus more fully on program goals. Through economies and technologies of scale, GS has reduced grants management technology cost for its customers by 20 to 75 percent.

Office of the Assistant Secretary for Administration (ASA)

The Assistant Secretary for Administration provides leadership for HHS departmental administration, including human resource policy, information technology, and departmental operations. The ASA also serves as the operating division head for the HHS Office of the Secretary.

Office of Business Management and Transformation (OBMT)

OBMT supports the HHS mission by identifying, developing, implementing, and evaluating efficient and effective business practices throughout the Department. OBMT acts as an internal consulting group to other parts of HHS, maximizing return on taxpayer dollars by undertaking initiatives to improve services,

reduce costs, and streamline bureaucracy. Its projects are often team-based and cross-functional in ways that include staff from supported organizations.

High Performing Organizations, Commercial Services Management Reporting (HPO&CSM):
OBMT High Performing Organizations, Commercial Services Management Reporting & Insourcing supports HHS-wide Commercial Services Management reporting (CSM), the inventory and reporting of the Federal Activities Inventory Reform (FAIR) Act inventory, the active sponsorship of High Performing Organizations (HPO), and insourcing through central service activities. Additionally, this program offers organizational redesign services to the Department to promote mission effectiveness, cost-savings and increase efficiencies.

Office of the Chief Information Officer (OCIO)

OCIO supports the HHS mission by leading the development and implementation of an enterprise information technology (IT) infrastructure across HHS. The OCIO is responsible for providing a reliable, cost effective, scalable, and flexible enterprise computing platform that supports the enhancement of customer IT needs and capabilities from requirements gathering through design, development, testing, and implementation.

The OCIO is also responsible for the development and implementation of a cybersecurity program which includes the security technologies that provide an enterprise-wide capability to monitor HHS' computers and networks for security incidents and attacks through HHS' secure Internet gateways, intrusion detection systems, network security forensics and analysis, and other enterprise security technologies throughout HHS.

Office of the Chief Product Officer (formerly OEAD):
OCPO provides information technology services for the development, configuration, and integration of enterprise services and systems for HHS and the Office of the Secretary. In addition, OCPO provides production reporting and business intelligence query/dashboard capabilities for its many customers. The development capabilities provided by CPO include collaboration and workflow automation technologies that promote the deployment of repeatable business processes in order to achieve customer efficiencies and effectiveness. OCPO's Integration services collects and renders data for systems and end user consumption and reporting that help to improve decision making across the department. Its support functions provide OCPO customers with cost effective Operations & Maintenance, systems administration, and database support services that ensure applications and platform availability for secure and continuous business operations.

Office of Information Security (OIS):
HHS is the repository for information on bio-defense, development of pharmaceuticals, and medical information for one hundred million Americans, among a great deal of other sensitive information. As a result, HHS information is a target for cyber criminals seeking economic gain, as well as nation states who might seek to compromise the security of government information and gain economic, military, or political advantage.

OIS assures that all automated information systems throughout HHS are designed, operated, and maintained with the appropriate information technology security and privacy data protections.

OIS is tasked with implementing a comprehensive, enterprise-wide cybersecurity program to protect the critical information with which the Department is entrusted.

Office of Operations (formerly ITIO):
The mission of OCIO-OPS is to provide efficient and effective delivery of IT services to its customers by providing customer-driven, business-enabling technologies.

OCIO-Ops is responsible for providing a reliable, cost effective, scalable and flexible enterprise computing platform that supports and enhances customer IT needs and capabilities from requirements gathering through design, development, testing, implementation, and ongoing lifecycle asset refreshment for end user computers and printers. OCIO-Ops supports over 22 customer organizations comprised of over 11,000 users, including all HHS Staff Divisions (STAFFDIVs) and participating Operating Divisions (OPDIVs), across 16 Technology and Business Management (TBM) services.

Office of Enterprise Services (formerly OSPG):
The Office of Enterprise Services (OES) is the Executive Office responsible for ensuring HHS IT investments are smart, customer-centric, and compliant with federal laws and regulations such as FITARA, e-Gov and MGT Act, thereby spending according to mission capability, managed risk, and delivered value. OES's Program and Project Management (PPM) Cost Center, directs the following activities: Enterprise Strategy & Governance, Investment Portfolio Management and Control, Legislative Compliance and Implementation and Enterprise Architecture. Additionally, the PPM Cost Center provides support for the Office of the Secretary's IT governance, policy, strategy, and investment management. The Office of Enterprise Services serves as HHS's E-Government (E-Gov) Coordinator and provides a central funding point for OMB-mandated contributions to Government-wide E-Gov initiatives.

EEO Compliance and Operations Division (EEOCO):
EEOCO works to promote a discrimination–free work environment focused on serving DHHS by preventing, resolving, and processing EEO discrimination complaints in a timely and high-quality manner. In compliance with the Civil Rights Act of 1964 as amended, and other federal laws, regulations, directives, and policies prohibiting discrimination and harassment of protected individuals, EEOCO processes EEO complaints for DHHS employees, applicants for employment, and former employees. Complaint processing services include counseling, Alternative Dispute Resolution (ADR), procedural determinations, and investigations. EEOCO also administers the ADR program to manage conflict and prevent and resolve disputes through mediation, conflict coaching, group facilitation, and assessments. Additionally, EEOCO manages the Reasonable Accommodation program.

Office of the Assistant Secretary for Human Resources (OHR)

The Office of Human Resources (OHR) provides leadership for the development, execution, and management of the human resources program to ensure the Department builds and retains a highly skilled and diverse workforce. In coordination with the Operating Divisions (OPDIVs) OHR provides human resource programs and policies developed to support and enhance the HHS mission.
OHR also provides leadership in creating and sustaining a diverse workforce and an environment free of discrimination. OHR works proactively to enhance the employment of women, minorities, veterans, and people with disabilities through efforts that include policy development, program oversight, complaint resolution, diversity outreach, commemorative events, and standardized education and training

programs. OHR also provides technical assistance to the HHS Operating Divisions (OPDIVs) to effectively and efficiently accomplish the OPDIV's mission through improved planning and recruitment of human resources and serves as the Departmental liaison to central management agencies on related matters. In addition, OHR works in collaboration with the various HHS Equal Employment Opportunity offices on conducting Department-wide program reviews to determine barriers to diversity and inclusion.

National Security Case Management (formerly Office of Security and Strategic Information (OSSI)):
NSA is headed by the Assistant Deputy Secretary for National Security, who reports directly to the Deputy Secretary and also serves as the Secretary's Senior Intelligence Official on intelligence and counterintelligence issues. OSSI is comprised of three operating divisions: the Intelligence & Analysis Division (IAD), the Division of Operations Division (DO), and the Personnel Security Division (PSD). These divisions are responsible for integrating intelligence and security information into HHS policy and operational decisions; assessing, anticipating, and warning of potential security threats to the Department and our national security, while providing policy guidance on and managing the Office of the Secretary's implementation of the Department's national security, intelligence (including cyber intelligence), and counterintelligence (including insider threat) programs. OSSI's programs include national security adjudication, classified national security information management, secure compartmented information facilities management, communications security, safeguarding and sharing of classified information.

Office of the Assistant Secretary for Financial Resources (ASFR)

The Office of the Assistant Secretary for Financial Resources (ASFR) provides advice and guidance to the Secretary on all aspects of budget, financial management, grants and acquisition management, and provides for the direction and implementation of these activities across the Department.

Office of the Deputy Assistant Secretary of Finance

The mission of the Office of Finance is to provide financial accountability and enhance program integrity through leadership, oversight, collaboration, and innovation.

Office of Program Audit Coordination (OPAC) (formerly Audit Resolution):
The Office of Program Audit Coordination (OPAC), located in the Office of the Secretary/ Assistant Secretary for Financial Resources/Office of Finance, is organized into three Divisions: (1) the Audit Resolution Division (ARD), (2) the Audit Tracking and Analysis Division (ATAD), and (3) the Division of Payment Integrity Improvement (DPII).

OPAC's ARD provides Departmental leadership in the area of Single Audit. This OPAC division is also responsible for reviewing, resolving, and coordinating, where necessary, the Single Audit findings of award recipients that affect the programs of more than one HHS Operating Division/Staff Division (OpDiv/StaffDiv) or other Federal entity. To implement the Shared Vision described above, OPAC's ATAD has begun work to develop an automated, enterprise-wide audit tracking and analysis system to capture, at a minimum, data related to Single Audits, HHS' Office of Inspector General (OIG) audits, and the U.S. General Accountability Office audits. In addition to ensuring HHS' compliance with OMB's Uniform Guidance, this new system will serve as a tool to (a) automate existing standardized processes; (b) streamline audit resolution processes across HHS; (c) enable more efficient and timely assignment of Single Audit findings to OpDivs/StaffDivs for resolution; (d) provide HHS grants and program managers

access to Single Audit data, metrics, and reports that could assist them in their grant-related decisions; and (e) enable the analysis of Single Audit data.

DPII coordinates HHS' implementation of the *Improper Payments Information Act of 2002* (IPIA), as amended, and related OMB implementing guidance contained in Appendix C of OMB Circular A-123, "*Management's Responsibility for Enterprise Risk Management and Internal Control*." Specifically, the DPII team works with OpDivs/StaffDivs to complete risk assessments of programs, employee pay, and charge cards to determine susceptibility to significant improper payments, and to assist OpDivs/StaffDivs in complying with the IPIA, as amended, and OMB implementing guidance.

Unified Financial Management Systems (UFMS):

The UFMS environment including the Unified Financial Management Systems, the Consolidated Financial Reporting System (CFRS), the Financial Business Intelligence System (FBIS), and the governance function are under the purview of the DAS OF within the Office of the Assistant Secretary for Financial Resources. The UFMS environment provides the Department a secure, stable platform for effectively processing and tracking its financial and accounting transactions. UFMS is the core accounting system for 10 Operating Divisions and 18 Staff Divisions. UFMS integrates with over 50 program, business, and administrative systems (i.e., mixed systems) to create a secure, reliable, and highly available financial management environment.

Office of the Deputy Assistant Secretary of Acquisitions

The mission of the Office of Acquisitions is to provide leadership, guidance and oversight to constituent organizations, and coordinates long and short-range planning for HHS' acquisition practices, systems and workforce.

Acquisition Integration and Modernization (AIM):

The AIM Program was created to capture knowledge, create standardization and provide one source for the HHS Acquisition Workforce (HHSAW) to access policies, guidance, and other acquisition tools. The program support the acquisition related mission needs of the Department, providing tools to insure that the acquisition lifecycle processes are efficiently executed and complies with statutory requirements. The AIM program is managed by the Office of Acquisition Policy within the Division of Acquisition, under the Office of Grants and Acquisition Policy and Accountability, which is within the office of the Assistant Secretary for Financial Resources.

Category Management (CM):

CM is a purchasing approach in which spending is organized into common categories and managed strategically. Fortune 500 companies and several governments have adopted category management in the last 20-30 years because it's a commercial best practice for buying and selling. In accordance with the Federal Acquisition Regulation (FAR) and further reinforced via the Office of Management and Budget (OMB) Memorandums 17-22 and M-17-26, to the maximum extent practicable, [HHS] shall use existing contract solutions such as: a) Federal Supply Schedules; b) Government-wide acquisition contracts; c) multi-agency contracts; d) and any other procurement instruments intended for use by multiple agencies (e.g. Best-In-Class) for common supplies and services. Leveraging these sources: (a) decreases administrative costs; (b) prevents repetitive/ unnecessary contract actions; (c) permits acquisition staff to focus on high-priority and agency unique procurements/ requirements; and (d)

enables agencies to better manage spending through such actions as standardization, participating in volume buying events, and applying best practices.

Departmental Contracts Information System (DCIS):
DCIS provides procurement data collection and reporting capabilities to enable the HHS OPDIVs to comply with requirements under Public Law 93-400 and FAR Subpart 4.6 regarding the reporting of contract actions to the Federal Procurement Data System (FPDS) and DATA Act. DCIS provides a single system capability within HHS that collects, edits, and stores information on the individual procurement and contracting actions executed by Operating Divisions (OPDIVs) and other offices of HHS totaling more than $24 billion and consisting of more than 88,000 individual actions. In addition, the DCIS program oversees the HHS FedDataCheck program. The FedDataCheck service is offered to all OPDIV/STAFFDIV HCAs to monitor and improve FPDS data. Since implementing FedDataCheck, there has been a 10% improvement in HHS FPDS and USAspending data quality.

HHS Consolidated Acquisition Solution (HCAS):
HCAS was launched in 2009 and provides consolidated acquisition functionality, capabilities and critical to the contract execution operations for seven of the Department's ten Contracting Activities. This is a Commercial-Off-The-Shelf software application called "PRISM" which allows end-users to formulate, administer and distribute contractual documents that comply with the Federal Acquisition Regulation. In addition, HCAS supports OGAPA's efforts to standardize acquisition end-to-end business processes through the launch of Health and Human Services Acquisition Lifecycle Framework (HALF) and the HHS Acquisition Lifecycle – Consolidated Acquisition Management System (HALF-CAMS)

Office of Small and Disadvantaged Business Utilization (OSDBU):
OSDBU was established in October 1979 pursuant to Public Law 95-507. OSDBU is the focal point for the Department's policy formulation, implementation, coordination, and management of small business programs. The office ensures that small businesses are given a fair and transparent opportunity to compete for contracts that provide goods and services to HHS; establishes, manages and tracks small business goal achievements; provides technical assistance and small business program training to OPDIV contracting and program officials; and conducts outreach and provides marketing and technical guidance to small businesses on contracting opportunities with HHS.

Office of the Deputy Assistant Secretary for Grants

The mission of the Office of Grants is to provide Department-wide leadership, guidance, and oversight to constituent organizations, and coordinates long and short-range planning for HHS' grants management policies, practices and systems and workforce.

Grants.gov:
The Grants.gov system (www.grants.gov) is the federal government's single site for the public to find and apply for federal discretionary grants. FY2015 marked the first year Grants.gov became a part of the Service and Supply Fund (SSF). Prior to FY2015, it was part of the Government-wide E-Gov Initiatives. The Grants.gov program manages the Grants.gov system including associated operations, maintenance, enhancement, user support, and stakeholder communications.

The Grants.gov program is governed by the 26 federal grant-making agencies through the Financial Assistance Committee on eGovernment (FACE) and the Council on Financial Assistance Reform (COFAR), and HHS serves as the managing partner. The program operates within HHS's Office of the Assistant Secretary for Financial Resources. The program is funded by the participating agencies, each providing support commensurate with its usage of Grants.gov and its overall grants program volume according to a formula approved by the FACE & the Service and Supply Fund.

Tracking Accountability in Government Grants System (TAGGS):

Since 1995, the Department of Health and Human Services (HHS) has tracked and reported grant spending online via TAGGS. This product provides a central repository for all HHS financial assistance information and continues to add needed data sets for additional business needs.

The TAGGS system is maintained in a manner that supports: the Open Government Initiative, adherence to federal reporting requirements, and ensures the availability of HHS data for internal and external stakeholders use. TAGGS continues to serve as a central data repository for grants business information and reporting of grant award data generated by HHS's Staff Divisions and Operating Divisions.

Office of the Assistant Secretary for Public Affairs (ASPA)

ASPA serves as the Secretary's principal counsel on public affairs. The Office of the Assistant Secretary for Public Affairs conducts national public affairs programs, provides centralized leadership and guidance for public affairs activities within HHS' Staff and Operating Divisions and regional offices, manages the Department's digital communications, and administers the Freedom of Information and Privacy Acts. The Division leads the planning, development, and implementation of emergency incident communications strategies and activities for the Department. The ASPA reports directly to the HHS Secretary.

Digital Communications Division (DCD):

The Digital Communications Division in the Office of the Assistant Secretary for Public Affairs (ASPA), Department of Health and Human Services, leads ASPA's Social Media and Website projects. In FY 2018 ASPA built the foundation for an aggressive engagement strategy in support of the Secretary's four priorities for HHS – combat opioid misuses, reduce drug prices, health insurance reform and value-based care.

In support of these priorities and the HHS strategic plan ASPA Digital manages HHS.gov, the HHS Intranet, and numerous OS websites, as well as multiple topic-oriented websites. All promote Agency and cross-federal agency work. Overall, ASPA Digital manages the tools, content and infrastructure that in 2017 supported 973,588 Twitter followers, 433,706 Facebook followers, 7,706,737 YouTube views, 749,464 email subscribers, 27,874,424 unique website visitors, and 78,527,426 website page views. ASPA Digital also coordinates digital communications leaders and community, and digital communications policy and guidance across the Department.

Freedom of Information Act (FOIA):

SSF FOIA performs initial requests including identification of responsive records, release and denial determinations for the Program Support Center (PSC), Agency for Healthcare Research and Quality (AHRQ), and all components of the Office of the Assistant Secretary for Health (ASH). SSF FOIS also performs administrative appeals of initial FOIA determinations, reviewing the OPDIV's denial action to determine consistency with the FOIA, HHS FOIA regulations, and case law, for the eight (8) Public Health

Service (PHS) OPDIVs: AHRQ, Centers for Disease Control (CDC)/Agency for Toxic Substances and Disease Registry (ATSDR), Food and Drug Administration (FDA), Health Resources and Services Administration (HRSA), Indian Health Service (IHS), National Institutes of Health (NIH), ASH, and Substance Abuse and Mental Health Services Administration (SAMHSA).

HHS Broadcast Studio:

The HHS Broadcast Studio supports the entire Department with video production and AV Services. The services provided to the Department range from multi-camera studio productions; audio-visual support in the Humphrey Auditorium, Great Hall and Room 800; video streaming via HHS.gov/live and Facebook Live; satellite media tours; motion graphics and video editing, and delivery to multiple social media platforms and channels. In FY2016 we performed 2,338 unique services for our customers; that is a 73% increase over FY2015 (1,351).

Media Monitoring and Analysis:

Media Monitoring and Analysis provides the Secretary, Department, agency leadership and staff with the latest analysis of what the media is reporting about Department-wide and Agency-specific priorities, initiatives and programs. This Department-wide tool has been effective since 2009. The nature of this service does not dictate the need for day-to-day oversight. The OPDIV-specific requirements and additional levels of effort are provided through a contract vehicle.

Office of the Assistant Secretary for Planning and Evaluation

The Assistant Secretary for Planning and Evaluation (ASPE) is the principal advisor to the Secretary of the U.S. Department of Health and Human Services on policy development, and is responsible for major activities in policy coordination, legislation development, strategic planning, policy research, evaluation, and economic analysis.

Strategic Planning System (SPS):

SPS is a web-based, password-protected application that centralizes information about strategic plans that agencies within HHS are implementing. The SPS was built in response to a request from the Deputy Secretary and is supported by a contract managed by ASPE. More than 150 strategic plans are currently included in the SPS.

Office of the General Counsel (OGC)

The Office of the General Counsel (OGC) is the legal team for the Department, providing quality representation and legal advice on a wide range of highly visible national issues. OGC supports the development and implementation of the Department's programs by providing the highest quality legal services to the Secretary of HHS and the organization's various agencies and divisions.

Departmental Ethics Program;

The Departmental Ethics Program was established in 2004, pursuant to 5 C.F.R. § 2638.202(a) and Executive Order 12731, § 301(e), to ensure that operating and staff divisions' decision-making is untainted by improper bias or the influence of special interests. The Ethics Division provides ethics advice, it administers the financial disclosure program, and it ensures lobbying activities comply with the applicable rules. Its goals include strengthening grant and procurement integrity; ensuring human

subject protections; enhancing public confidence in health science research and drug approval and monitoring; and inviting acceptance of healthcare reform because policy determinations–ranging from coverage and financing decisions to health information technology improvements–are made by administrators and regulators free of financial and personal conflicts and affiliations that would otherwise lead reasonable persons to question their impartiality.

Office of the General Counsel (OGC) Claims:
OGC Claims receives all tort claims filed against the Department. These torts can range from "slips" and "falls" in Departmental facilities, to motor vehicle accidents involving Departmental vehicles, or medical malpractice in health clinics. OGC reviews and processes all of these claims. Two clients typically account for approximately ninety-six percent of the Claims Activity workload: the Health Resources and Services Administration (83%) and the Indian Health Service (13%).

Service and Supply Fund
All Purpose Table (APT)
(Dollars in Thousands)

Service and Supply Fund Activities	FY 2019 Actuals	FY 2020 Board Request	FY 2021 Current Estimate	FY 2021 +/- FY 2020
PSC				
Acquisition Management Services	492,305	688,433	288,344	400,089
Financial Management Portfolio	48,675	63,428	63,428	-
Occupational Health Portfolio	179,259	199,725	199,725	-
Real Estate, Logistics & Operations Portfolio[1]	304,850	328,613	328,613	-
PSC Subtotal	**1,025,089**	**1,280,199**	**880,110**	**400,089**
Non-PSC				
AIM	1,323	1,484	1,484	-
Category Management	677	959	959	-
CCFM	25,553	29,695	29,695	-
Departmental Ethics	4,120	4,553	4,553	-
DCIS	1,273	1,767	1,767	-
Digital Communications	26,694	28,063	28,063	-
Equal Employment Opportunity	4,918	4,918	4,918	-
Freedom of Information Act	1,123	1,368	1,368	-
Grants.gov	5,999	7,036	7,036	-
GrantsSolutions Center of Excellence	66,118	67,041	67,041	-
HHS Broadcast Studio	2,195	2,517	2,517	-
HCAS	8,998	8,227	8,227	-
HPO & CSM	271	271	271	-
Media Monitoring and Analysis	989	1,281	1,281	-
National Security Case Management	1,748	2,315	2,315	-
Office of Chief Product Officer	23,656	26,951	26,951	-
Office of Enterprise Services	13,884	16,791	16,791	-
Office of General Counsel Claims	2,094	1,709	1,709	-
Office of Human Resources	59,730	61,286	61,286	-
Office of Information Security	37,609	32,750	32,750	-
Office of Operations	121,003	122,002	122,002	-
OPAC (formerly Audit Resolution)	3,131	3,515	3,515	-
Small Business Consolidation	3,115	3,844	3,844	-
Strategic Planning System	525	525	525	-
TAGGS	3,823	4,409	4,409	-

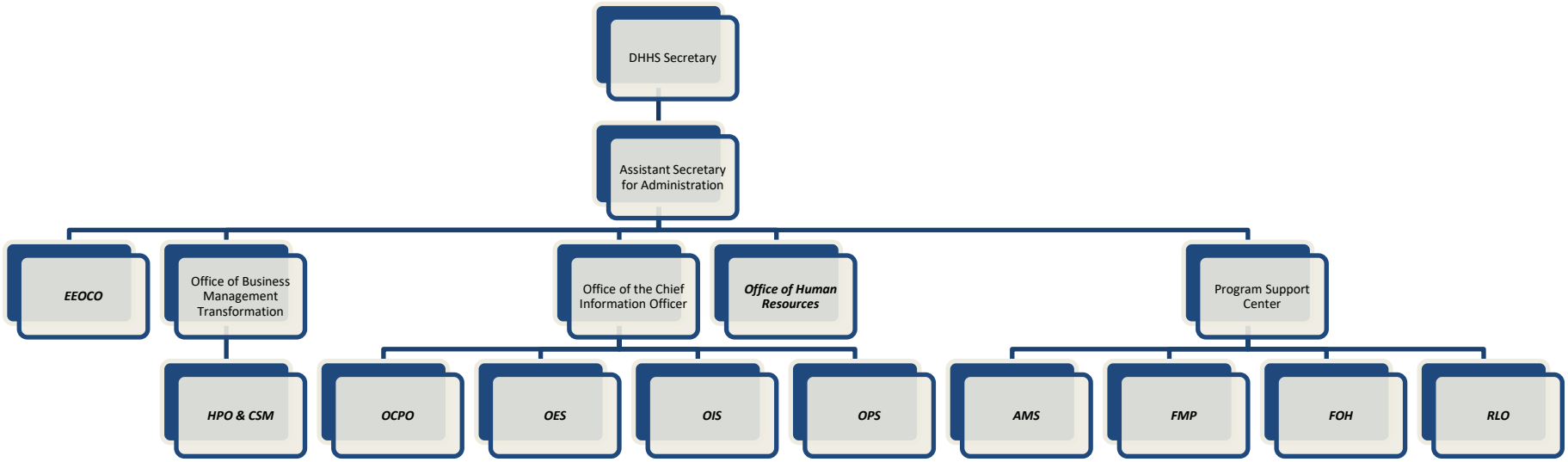
UFMS	57,319	69,776	69,776	-
Non-PSC Subtotal	**477,089**	**505,053**	**505,053**	**-**
Total SSF Revenue	**1,502,269**	**1,785,253**	**1,385,163**	**400,089**

1- Formerly a part of the Financial Management Portfolio

Service and Supply Fund
Object Classification Table – Reimbursable Obligations
(Dollars in Thousands)

Object Class	FY 2019 Actuals	FY 2020 Board Request	FY 2021 Current Estimate
Reimbursable Obligations			
Personnel Compensation:			
Full – Time Permanent (11.1)	102,907	116,610	123,435
Other Than Full – Time Permanent (11.3)	3,216	3,341	3,341
Other Personnel Compensation (11.5)	3,717	3,372	3,372
Military Personnel (11.7)	4,738	7,618	7,958
Special Personnel Services Payments (11.8)	10,456	10	12
Subtotal, Personnel Compensation	**125,034**	**141,669**	**150,538**
Civilian Personnel Benefits (12.1)	33,536	38,358	41,987
Military Personnel Benefits (12.2)	2,320	2,655	2,894
Benefits to Former Personnel (13.0)	491	138	138
Subtotal, Pay Costs	**161,381**	**182,820**	**195,557**
Travel (21.0)	2,057	2,527	2,527
Transportation of Things (22.0)	1,687	3,112	3,112
Rental Payments to GSA (23.1)	20,897	17,606	17,606
Rental Payments to Others (23.2)	1		
Communications, Utilities and Miscellaneous Charge (23.3)	9,156	8,758	8,758
Printing and Reproduction (24.0)	5,034	6,077	6,077
Other Contractual Services:			
Advisory and Assistance Services (25.1)	135,809	196,904	196,904
Other Services (25.2)	932,496	1,192,408	779,582
Purchases from Govt. Accounts (25.3)	64,525	21,359	21,359
Operation & Maintenance of Facilities (25.4)	22,238	13,750	13,750
Research & Development Contracts (25.5)	196		
Medical Services (25.6)	19,774	32,446	32,446
Operation & Maintenance of Equipment (25.7)	71,172	51,011	51,011
Subsistence& Support of Persons (25.8)			
Subtotal, Other Contractual Services	**1,246,210**	**1,507,878**	**1,095,052**
Supplies and Materials (26.0)	54,095	49,889	49,889
Equipment (31.0)	1,257	5,604	5,604
Grants (41.0)			
Other (32), (42), (61)	494	982	982
Subtotal, Non – Pay Costs	1,304,888	1,602,433	1,189,607
Total, Reimbursable Obligations	**1,502,269**	**1,785,253**	**1,385,164**

ASA SSF Organizational Chart



Acronym Key:

AMS – Acquisition Management Services

EEOCO – Equal Employment Opportunity Compliance and Operations

FMP – Financial Management Portfolio

FOH – Federal Occupational Health Portfolio

HPO & CMS – High Performing Organizations and Commercial Services Management

RLO – Real Estate and Logistics Portfolio

OCPO – Office of Chief Product Officer

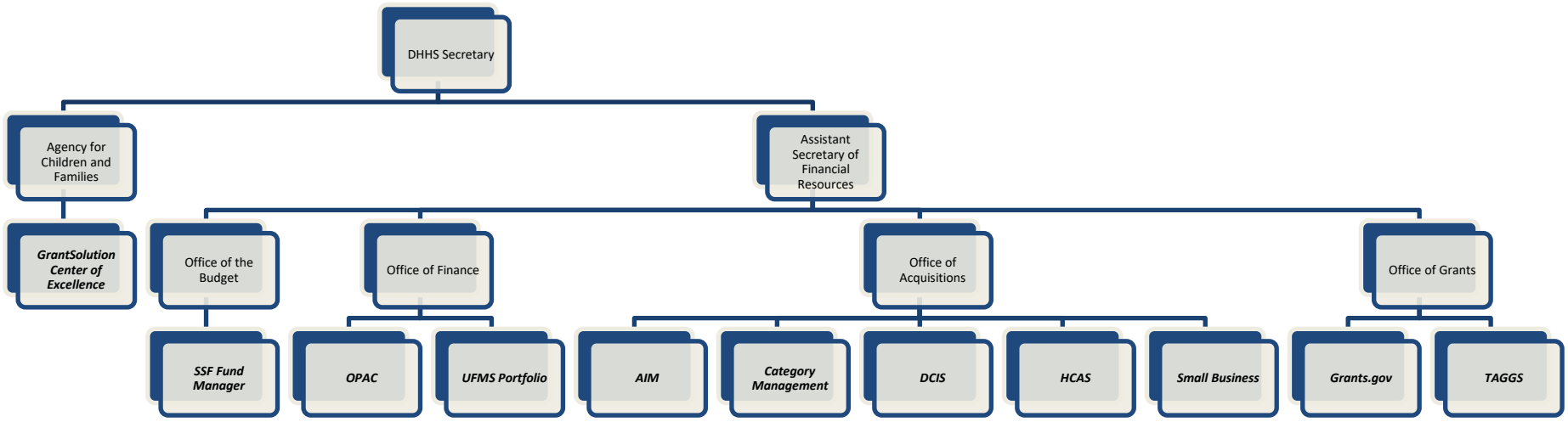
OES – Office of Enterprise Services

OIS – Office of Information Security

OPS – Office of Operations

SSF Activities are italicized

Non ASA SSF Organizational Chart



Acronym Key:

AIM – Acquisition Integration and Modernization

DCIS – Departmental Contracts Information System

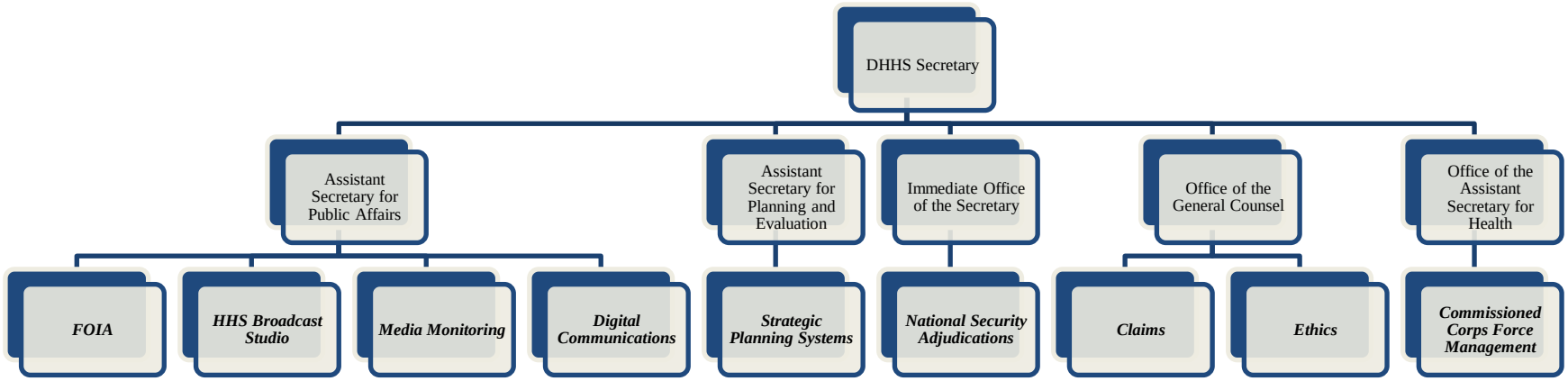
HCAS – HHS Consolidated Acquisition Solution

OPAC – Office of Program Audit Coordination

TAGGS – Tracking Accountability in Government Grants System

UFMS – Unified Financial Management System

Non ASA Organizational Chart (Cont'd)



Acronym Key:

FOIA – Freedom of Information Act

SSF Activities are italicized

Retirement Pay & Medical Benefits for Commissioned Officers

RETIREMENT PAY AND MEDICAL BENEFITS FOR COMMISSIONED OFFICERS

	FY 2019	FY 2020	FY 2021	FY 2021 +/-FY 2020
Retirement Payments	$487,926,929	$506,024,064	$524,818,431	$18,794,367
Survivor's Benefits	$30,843,244	$31,414,321	$31,925,240	$510,919
Medical Care Benefits	$104,320,284	$99,768,610	$96,280,093	($3,488,517)
Sub Total	**$623,090,457**	**$637,206,995**	**$653,023,765**	**$15,816,770**
Accrued Health Care Benefits	$28,891,602	$29,112,300	$30,944,211	$1,831,911
Total	**$651,982,059**	**$666,319,295**	**$683,967,976**	**$17,648,681**

Authorizing Legislation 42 U.S.C., Chapter 6A; 10 U.S.C., Chapter 73; 10 U.S.C., Chapters 55; and Section 229(b) of the Social Security Act.

FY 2021 Authorization……Indefinite.

Rationale for Budget

This appropriation provides for retirement payments to Public Health Service (PHS) Commissioned Corps officers who are retired for age, disability, or a specific length of service as well as payments to survivors of deceased retired officers who had elected to receive reduced retirement payments.

This appropriation also funds the provision of medical care to active duty and retired members of the Corps under the age of 65, dependents of active duty and retired members, and dependents of deceased members. This account includes payments to the Department of Defense (DoD) Medicare-Eligible Retiree Healthcare Fund for the accrued costs of health care for beneficiaries over the age of 65.

The Accrual Health Care Benefits amount is an estimate of $4,911 per officer, provided by the DoD Office of the Actuary, multiplied by the estimated total number of active duty positions (6,301 in FY 2021), for a baseline contribution of $30,944,211. The FY 2021 estimate is an increase of $1,831,911 over the FY 2020 level.

The overall request reflects decreased costs in medical benefits, an average increase of 4% over the past five years in Retired Pay, an estimated increase in active duty positions, and a net increase in the number of retirees and survivors during FY 2020.

	FY 2022	FY 2023	FY 2024	FY 2025	FY 2026
Retirement Payments[1]	$544,311,338	$564,528,255	$585,496,072	$607,242,679	$629,797,003
Survivor's Benefits[1]	$32,444,374	$32,971,950	$33,508,105	$34,052,978	$34,606,711
Medical Care Benefits	$96,280,093	$96,280,093	$96,280,093	$96,280,093	$96,280,093
Sub Total	**$ 673,035,806**	**$ 693,780,298**	**$ 715,284,270**	**$ 737,575,750**	**$ 760,683,808**
Accrued Health Care Benefits	$36,000,000	$37,000,000	$39,000,000	$41,000,000	$44,000,000
Total*	**$ 709,035,806**	**$ 730,780,298**	**$ 754,284,270**	**$ 778,575,750**	**$ 804,683,808**

[1] The Budget includes a mandatory proposal, effective FY 2022, which shifts the Commissioned Corps retirement pay and survivors' benefit costs from the current mandatory indefinite structure to a discretionary structure. Agencies would pay their share of these costs on a prospective basis. With this proposal, the payments for retirement pay and survivors' benefits come from a new account, which affected agencies would contribute to.

HHS General Provisions

GENERAL PROVISIONS

SEC. 201. Funds appropriated in this title shall be available for not to exceed $50,000 for official reception and representation expenses when specifically approved by the Secretary.

SEC. 202. None of the funds appropriated in this title shall be used to pay the salary of an individual, through a grant or other extramural mechanism, at a rate in excess of Executive Level **[**II: *Provided*, That none of the funds appropriated in this title shall be used to prevent the NIH from paying up to 100 percent of the salary of an individual at this rate**]** *V, except that this section shall not apply to the Head Start program*.

[SEC. 203. None of the funds appropriated in this Act may be expended pursuant to section 241 of the PHS Act, except for funds specifically provided for in this Act, or for other taps and assessments made by any office located in HHS, prior to the preparation and submission of a report by the Secretary to the Committees on Appropriations of the House of Representatives and the Senate detailing the planned uses of such funds.**]**

SEC. **[**204**]***203*. Notwithstanding section 241(a) of the PHS Act, such portion as the Secretary shall determine, but not more than **[**2.5**]***2.9* percent, of any amounts appropriated for programs authorized under such Act shall be made available for the evaluation (directly, or by grants or contracts) and the implementation and effectiveness of programs funded in this title.

SEC. **[**205**]***204*. Not to exceed 1 percent of any discretionary funds (pursuant to the Balanced Budget and Emergency Deficit Control Act of 1985) which are appropriated for the current fiscal year for HHS in this Act may be transferred between appropriations, but no such appropriation shall be increased by more than 3 percent by any such transfer: *Provided*, That the transfer authority granted by this section shall not be used to create any new program or to fund any project or activity for which no funds are provided in this Act: *Provided further*, That the Committees on Appropriations of the House of Representatives and the Senate are notified at least 15 days in advance of any transfer.

SEC. **[**206**]***205*. In lieu of the timeframe specified in section 338E(c)(2) of the PHS Act, terminations described in such section may occur up to 60 days after the effective date of a contract awarded in fiscal year **[**2020**]***2021* under section 338B of such Act, or at any time if the individual who has been awarded such contract has not received funds due under the contract.

SEC. **[**207**]***206*. None of the funds appropriated in this Act may be made available to any entity under title X of the PHS Act unless the applicant for the award certifies to the Secretary that it encourages family participation in the decision of minors to seek family planning services and that it provides counseling to minors on how to resist attempts to coerce minors into engaging in sexual activities.

SEC. **[**208**]***207*. Notwithstanding any other provision of law, no provider of services under title X of the PHS Act shall be exempt from any State law requiring notification or the reporting of child abuse, child molestation, sexual abuse, rape, or incest.

SEC. **[**209**]***208*. None of the funds appropriated by this Act (including funds appropriated to any trust fund) may be used to carry out the Medicare Advantage program if the Secretary denies participation in such program to an otherwise eligible entity (including a Provider Sponsored Organization) because the entity informs the Secretary that it will not provide, pay for, provide coverage of, or provide referrals for

abortions: *Provided*, That the Secretary shall make appropriate prospective adjustments to the capitation payment to such an entity (based on an actuarially sound estimate of the expected costs of providing the service to such entity's enrollees): *Provided further*, That nothing in this section shall be construed to change the Medicare program's coverage for such services and a Medicare Advantage organization described in this section shall be responsible for informing enrollees where to obtain information about all Medicare covered services.

SEC. **[**210**]***209*. None of the funds made available in this title may be used, in whole or in part, to advocate or promote gun control.

[SEC. 211. The Secretary shall make available through assignment not more than 60 employees of the Public Health Service to assist in child survival activities and to work in AIDS programs through and with funds provided by the Agency for International Development, the United Nations International Children's Emergency Fund or the World Health Organization.**]**

SEC. **[**212**]***210*. In order for HHS to carry out international health activities, including HIV/AIDS and other infectious disease, chronic and environmental disease, and other health activities abroad during fiscal year **[**2020**]** *2021*:

(1) The Secretary may exercise authority equivalent to that available to the Secretary of State in section 2(c) of the State Department Basic Authorities Act of 1956. The Secretary shall consult with the Secretary of State and relevant Chief of Mission to ensure that the authority provided in this section is exercised in a manner consistent with section 207 of the Foreign Service Act of 1980 and other applicable statutes administered by the Department of State.

(2) The Secretary is authorized to provide such funds by advance or reimbursement to the Secretary of State as may be necessary to pay the costs of acquisition, lease, alteration, renovation, and management of facilities outside of the United States for the use of HHS. The Department of State shall cooperate fully with the Secretary to ensure that HHS has secure, safe, functional facilities that comply with applicable regulation governing location, setback, and other facilities requirements and serve the purposes established by this Act. The Secretary is authorized, in consultation with the Secretary of State, through grant or cooperative agreement, to make available to public or nonprofit private institutions or agencies in participating foreign countries, funds to acquire, lease, alter, or renovate facilities in those countries as necessary to conduct programs of assistance for international health activities, including activities relating to HIV/AIDS and other infectious diseases, chronic and environmental diseases, and other health activities abroad.

(3) The Secretary is authorized to provide to personnel appointed or assigned by the Secretary to serve abroad, allowances and benefits similar to those provided under chapter 9 of title I of the Foreign Service Act of 1980, and 22 U.S.C. 4081 through 4086 and subject to such regulations prescribed by the Secretary. The Secretary is further authorized to provide locality-based comparability payments (stated as a percentage) up to the amount of the locality-based comparability payment (stated as a percentage) that would be payable to such personnel under section 5304 of title 5, United States Code if such personnel's official duty station were in the District of Columbia. Leaves of absence for personnel under this subsection shall be on the same basis as that provided under subchapter I of chapter 63 of title 5, United States Code, or section 903 of the Foreign Service Act of 1980, to individuals serving in the Foreign Service.

SEC. **[**213**]***211*. The Director of the NIH, jointly with the Director of the Office of AIDS Research, may transfer up to 3 percent among institutes and centers from the total amounts identified by these two Directors as funding for research pertaining to the human immunodeficiency virus: *Provided*, That the

Committees on Appropriations of the House of Representatives and the Senate are notified at least 15 days in advance of any transfer.

SEC. **[**214**]***212*. Of the amounts made available in this Act for NIH, the amount for research related to the human immunodeficiency virus, as jointly determined by the Director of NIH and the Director of the Office of AIDS Research, shall be made available to the "Office of AIDS Research" account. The Director of the Office of AIDS Research shall transfer from such account amounts necessary to carry out section 2353(d)(3) of the PHS Act.

SEC. **[**215**]***213*.
(a) AUTHORITY.—Notwithstanding any other provision of law, the Director of NIH ("Director") may use funds authorized under section 402(b)(12) of the PHS Act to enter into transactions (other than contracts, cooperative agreements, or grants) to carry out research identified pursuant to or research and activities described in such section 402(b)(12).
(b) PEER REVIEW.—In entering into transactions under subsection (a), the Director may utilize such peer review procedures (including consultation with appropriate scientific experts) as the Director determines to be appropriate to obtain assessments of scientific and technical merit. Such procedures shall apply to such transactions in lieu of the peer review and advisory council review procedures that would otherwise be required under sections 301(a)(3), 405(b)(1)(B), 405(b)(2), 406(a)(3)(A), 492, and 494 of the PHS Act.

SEC. **[**216**]***214*. Not to exceed **[**$45,000,000**]***1 percent* of funds appropriated by this Act to the *offices,* institutes*,* and centers of the National Institutes of Health may be **[**used for alteration, repair, or improvement of facilities, as necessary for the proper and efficient conduct of the activities authorized herein, at not to exceed $3,500,000 per project**]** *transferred and merged with funds appropriated under the heading "National Institutes of Health-Buildings and Facilities": Provided, That the use of such transferred funds shall be subject to a centralized prioritization and governance process: Provided further, That the Director of the National Institutes of Health shall notify the Committees on Appropriations of the House of Representatives and the Senate at least 15 days in advance of any such transfer: Provided further, That this transfer authority is in addition to any other transfer authority provided by law*.

SEC. **[**217**]***215*. Of the amounts made available for NIH, 1 percent of the amount made available for National Research Service Awards ("NRSA") shall be made available to the Administrator of the Health Resources and Services Administration to make NRSA awards for research in primary medical care to individuals affiliated with entities who have received grants or contracts under sections 736, 739, or 747 of the PHS Act, and 1 percent of the amount made available for NRSA shall be made available to the Director of the **[**Agency for Healthcare**]***National Institute for* Research *on Safety* and Quality to make NRSA awards for health service research.

SEC. **[**218**]***216*.
(a) The Biomedical Advanced Research and Development Authority ("BARDA") may enter into a contract, for more than one but no more than 10 program years, for purchase of research services or of security countermeasures, as that term is defined in section 319F-2(c)(1)(B) of the PHS Act (42 U.S.C. 247d–6b(c)(1)(B)), if–

(1) funds are available and obligated–

(A) for the full period of the contract or for the first fiscal year in which the contract is in effect; and

(B) for the estimated costs associated with a necessary termination of the contract; and

(2) the Secretary determines that a multi-year contract will serve the best interests of the Federal Government by encouraging full and open competition or promoting economy in administration, performance, and operation of BARDA's programs.

(b) A contract entered into under this section–

(1) shall include a termination clause as described by subsection (c) of section 3903 of title 41, United States Code; and

(2) shall be subject to the congressional notice requirement stated in subsection (d) of such section.

[SEC. 219.

(a) The Secretary shall publish in the fiscal year 2021 budget justification and on Departmental Web sites information concerning the employment of full-time equivalent Federal employees or contractors for the purposes of implementing, administering, enforcing, or otherwise carrying out the provisions of the ACA, and the amendments made by that Act, in the proposed fiscal year and each fiscal year since the enactment of the ACA.

(b) With respect to employees or contractors supported by all funds appropriated for purposes of carrying out the ACA (and the amendments made by that Act), the Secretary shall include, at a minimum, the following information:

(1) For each such fiscal year, the section of such Act under which such funds were appropriated, a statement indicating the program, project, or activity receiving such funds, the Federal operating division or office that administers such program, and the amount of funding received in discretionary or mandatory appropriations.

(2) For each such fiscal year, the number of full-time equivalent employees or contracted employees assigned to each authorized and funded provision detailed in accordance with paragraph (1).

(c) In carrying out this section, the Secretary may exclude from the report employees or contractors who–

(1) are supported through appropriations enacted in laws other than the ACA and work on programs that existed prior to the passage of the ACA;

(2) spend less than 50 percent of their time on activities funded by or newly authorized in the ACA; or

(3) work on contracts for which FTE reporting is not a requirement of their contract, such as fixed-price contracts.**]**

[SEC. 220. The Secretary shall publish, as part of the fiscal year 2021 budget of the President submitted under section 1105(a) of title 31, United States Code, information that details the uses of all funds used by the Centers for Medicare & Medicaid Services specifically for Health Insurance Exchanges for each fiscal year since the enactment of the ACA and the proposed uses for such funds for fiscal year 2021. Such information shall include, for each such fiscal year, the amount of funds used for each activity specified under the heading "Health Insurance Exchange Transparency" in the explanatory statement described in section 4 (in the matter preceding division A of this consolidated Act).**]**

[SEC. 221. None of the funds made available by this Act from the Federal Hospital Insurance Trust Fund or the Federal Supplemental Medical Insurance Trust Fund, or transferred from other accounts funded by this Act to the "Centers for Medicare & Medicaid Services-Program Management" account, may be used for payments under section 1342(b)(1) of Public Law 111–148 (relating to risk corridors).**]**

[SEC. 222.

(a) Within 45 days of enactment of this Act, the Secretary shall transfer funds appropriated under section 4002 of the ACA to the accounts specified, in the amounts specified, and for the activities specified under the heading "Prevention and Public Health Fund" in the explanatory statement described in section 4 (in the matter preceding division A of this consolidated Act).
(b) Notwithstanding section 4002(c) of the ACA, the Secretary may not further transfer these amounts.
(c) Funds transferred for activities authorized under section 2821 of the PHS Act shall be made available without reference to section 2821(b) of such Act.**]**

SEC. **[**223**]***217*. Effective during the period beginning on November 1, 2015 and ending January 1, 2022, any provision of law that refers (including through cross-reference to another provision of law) to the current recommendations of the United States Preventive Services Task Force with respect to breast cancer screening, mammography, and prevention shall be administered by the Secretary involved as if–

(1) such reference to such current recommendations were a reference to the recommendations of such Task Force with respect to breast cancer screening, mammography, and prevention last issued before 2009; and

(2) such recommendations last issued before 2009 applied to any screening mammography modality under section 1861(jj) of the Social Security Act (42 U.S.C. 1395x(jj)).

[SEC. 224. In making Federal financial assistance, the provisions relating to indirect costs in part 75 of title 45, Code of Federal Regulations, including with respect to the approval of deviations from negotiated rates, shall continue to apply to the National Institutes of Health to the same extent and in the same manner as such provisions were applied in the third quarter of fiscal year 2017. None of the funds appropriated in this or prior Acts or otherwise made available to the Department of Health and Human Services or to any department or agency may be used to develop or implement a modified approach to such provisions, or to intentionally or substantially expand the fiscal effect of the approval of such deviations from negotiated rates beyond the proportional effect of such approvals in such quarter.**]**

SEC. **[**225**]***218*. The NIH Director may transfer **[**funds specifically appropriated**]** *discretionary amounts identified by the Director as funding* for opioid addiction, opioid alternatives, pain management, and addiction treatment **[**to other**]***among* Institutes and Centers of the NIH to be used for the same purpose 15 days after notifying the Committees on Appropriations *of the House of Representatives and the Senate*: *Provided*, That the transfer authority provided in the previous proviso is in addition to any other transfer authority provided by law.

[SEC. 226.
(a) The Secretary shall provide to the Committees on Appropriations of the House of Representatives and the Senate:

(1) Detailed monthly enrollment figures from the Exchanges established under the Patient Protection and Affordable Care Act of 2010 pertaining to enrollments during the open enrollment period; and

(2) Notification of any new or competitive grant awards, including supplements, authorized under section 330 of the Public Health Service Act.
(b) The Committees on Appropriations of the House and Senate must be notified at least 2 business days in advance of any public release of enrollment information or the award of such grants.**]**

[SEC. 227. In addition to the amounts otherwise available for "Centers for Medicare & Medicaid Services, Program Management", the Secretary of Health and Human Services may transfer up to

$305,000,000 to such account from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund to support program management activity related to the Medicare Program: *Provided*, That except for the foregoing purpose, such funds may not be used to support any provision of Public Law 111–148 or Public Law 111–152 (or any amendment made by either such Public Law) or to supplant any other amounts within such account.**]**

[SEC. 228. The Department of Health and Human Services shall provide the Committees on Appropriations of the House of Representatives and Senate a biannual report 30 days after enactment of this Act on staffing described in the explanatory statement described in section 4 (in the matter preceding division A of this consolidated Act).**]**

SEC. **[**229**]***219*. Funds appropriated in this Act that are available for salaries and expenses of employees of the Department of Health and Human Services shall also be available to pay travel and related expenses of such an employee or of a member of his or her family, when such employee is assigned to duty, in the United States or in a U.S. territory, during a period and in a location that are the subject of a determination of a public health emergency under section 319 of the Public Health Service Act and such travel is necessary to obtain medical care for an illness, injury, or medical condition that cannot be adequately addressed in that location at that time. For purposes of this section, the term "U.S. territory" means Guam, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the Virgin Islands, American Samoa, or the Trust Territory of the Pacific Islands.

SEC. **[**230**]***220*. The Department of Health and Human Services may accept donations from the private sector, nongovernmental organizations, and other groups independent of the Federal Government for the care of unaccompanied alien children (as defined in section 462(g)(2) of the Homeland Security Act of 2002 (6 U.S.C. 279(g)(2))) in the care of the Office of Refugee Resettlement of the Administration for Children and Families, including *monetary donations and* medical goods and services, which may include early childhood developmental screenings, school supplies, toys, clothing, and any other items *and services* intended to promote the wellbeing of such children.

[SEC. 231.
(a) None of the funds provided by this or any prior appropriations Act may be used to reverse changes in procedures made by operational directives issued to providers by the Office of Refugee Resettlement on December 18, 2018, March 23, 2019, and June 10, 2019 regarding the Memorandum of Agreement on Information Sharing executed April 13, 2018.
(b) Notwithstanding subsection (a), the Secretary may make changes to such operational directives upon making a determination that such changes are necessary to prevent unaccompanied alien children from being placed in danger, and the Secretary shall provide a written justification to Congress and the Inspector General of the Department of Health and Human Services in advance of implementing such changes.
(c) Within 15 days of the Secretary's communication of the justification, the Inspector General of the Department of Health and Human Services shall provide an assessment, in writing, to the Secretary and to Committees on Appropriations of the House of Representatives and the Senate of whether such changes to operational directives are necessary to prevent unaccompanied children from being placed in danger.**]**

[SEC. 232. None of the funds made available in this Act under the heading "Department of Health and Human Services-Administration for Children and Families-Refugee and Entrant Assistance" may be obligated to a grantee or contractor to house unaccompanied alien children (as such term is defined in

section 462(g)(2) of the Homeland Security Act of 2002 (6 U.S.C. 279(g)(2))) in any facility that is not State-licensed for the care of unaccompanied alien children, except in the case that the Secretary determines that housing unaccompanied alien children in such a facility is necessary on a temporary basis due to an influx of such children or an emergency, provided that–

(1) the terms of the grant or contract for the operations of any such facility that remains in operation for more than six consecutive months shall require compliance with–

(A) the same requirements as licensed placements, as listed in Exhibit 1 of the Flores Settlement Agreement that the Secretary determines are applicable to non-State licensed facilities; and

(B) staffing ratios of one (1) on-duty Youth Care Worker for every eight (8) children or youth during waking hours, one (1) on-duty Youth Care Worker for every sixteen (16) children or youth during sleeping hours, and clinician ratios to children (including mental health providers) as required in grantee cooperative agreements;

(2) the Secretary may grant a 60-day waiver for a contractor's or grantee's noncompliance with paragraph (1) if the Secretary certifies and provides a report to Congress on the contractor's or grantee's good-faith efforts and progress towards compliance;

(3) not more than four consecutive waivers under paragraph (2) may be granted to a contractor or grantee with respect to a specific facility;

(4) ORR shall ensure full adherence to the monitoring requirements set forth in section 5.5 of its Policies and Procedures Guide as of May 15, 2019;

(5) for any such unlicensed facility in operation for more than three consecutive months, ORR shall conduct a minimum of one comprehensive monitoring visit during the first three months of operation, with quarterly monitoring visits thereafter; and

(6) not later than 60 days after the date of enactment of this Act, ORR shall brief the Committees on Appropriations of the House of Representatives and the Senate outlining the requirements of ORR for influx facilities including any requirement listed in paragraph (1)(A) that the Secretary has determined are not applicable to non-State licensed facilities.**]**

[SEC. 233. In addition to the existing Congressional notification for formal site assessments of potential influx facilities, the Secretary shall notify the Committees on Appropriations of the House of Representatives and the Senate at least 15 days before operationalizing an unlicensed facility, and shall (1) specify whether the facility is hard-sided or soft-sided, and (2) provide analysis that indicates that, in the absence of the influx facility, the likely outcome is that unaccompanied alien children will remain in the custody of the Department of Homeland Security for longer than 72 hours or that unaccompanied alien children will be otherwise placed in danger. Within 60 days of bringing such a facility online, and monthly thereafter, the Secretary shall provide to the Committees on Appropriations of the House of Representatives and the Senate a report detailing the total number of children in care at the facility, the average length of stay and average length of care of children at the facility, and, for any child that has been at the facility for more than 60 days, their length of stay and reason for delay in release.**]**

[SEC. 234. None of the funds made available in this Act may be used to prevent a United States Senator or Member of the House of Representatives from entering, for the purpose of conducting oversight, any facility in the United States used for the purpose of maintaining custody of, or otherwise housing, unaccompanied alien children (as defined in section 462(g)(2) of the Homeland Security Act of 2002 (6 U.S.C. 279(g)(2))), provided that such Senator or Member has coordinated the oversight visit with the Office of Refugee Resettlement not less than two business days in advance to ensure that such visit would not interfere with the operations (including child welfare and child safety operations) of such facility.**]**

[SEC. 235. Not later than 14 days after the date of enactment of this Act, and monthly thereafter, the Secretary shall submit to the Committees on Appropriations of the House of Representatives and the Senate, and make publicly available online, a report with respect to children who were separated from their parents or legal guardians by the Department of Homeland Security (DHS) (regardless of whether or not such separation was pursuant to an option selected by the children, parents, or guardians), subsequently classified as unaccompanied alien children, and transferred to the care and custody of ORR during the previous month. Each report shall contain the following information:

(1) the number and ages of children so separated subsequent to apprehension at or between ports of entry, to be reported by sector where separation occurred; and

(2) the documented cause of separation, as reported by DHS when each child was referred.**]**

SEC. **[**236**]***221*. Funds appropriated in this Act that are available for salaries and expenses of employees of the Centers for Disease Control and Prevention shall also be available for the primary and secondary schooling of eligible dependents of personnel stationed in a U.S. territory as defined in section 229 of this Act at costs not in excess of those paid for or reimbursed by the Department of Defense.

[SEC. 237. Of the unobligated balances available in the "Nonrecurring Expenses Fund" established in section 223 of division G of Public Law 110–161, $225,000,000, in addition to any funds otherwise made available for such purpose in this or subsequent fiscal years, shall be available for buildings and facilities at the National Institutes of Health.**]**

[SEC. 238. Of the unobligated balances available in the "Nonrecurring Expenses Fund" established in section 223 of division G of Public Law 110–161, $225,000,000, shall be available for acquisition of real property, equipment, construction, demolition, installation, renovation of facilities, and related infrastructure improvements for the Centers for Disease Control and Prevention's Chamblee Campus.**]**

SEC. 222. Amounts made available in section 238 of division A of Public Law 116–94 shall remain available until September 30, 2024 for installation expenses, including moving expenses, related to the Centers for Disease Control and Prevention's Chamblee Campus.

SEC. **[**239**]***223*. Of the funds provided under the heading "CDC-Wide Activities and Program Support", **[**$85,000,000**]** *$50,000,000*, to remain available until expended, shall be available to the Director of the CDC for deposit in the Infectious Diseases Rapid Response Reserve Fund established by section 231 of division B of Public Law 115–245: *Provided*, That such amount may be available for Ebola preparedness and response activities without regard to the limitations in the third proviso in such section 231.

SEC. **[**240**]***224*. Of the unobligated balances *available* in the "Nonrecurring Expenses Fund" established in section 223 of division G of Public Law 110–161, **[**$350,000,000**]***$500,000,000* are hereby **[**rescinded not later than September 30, 2020**]** *permanently cancelled*.

SEC. 225.

(a) *IN GENERAL. Under the conditions listed in subsection (b), the Secretary or the head of a major organizational unit within the Department may in this fiscal year enter into a reimbursable agreement with the head of another major organizational unit within the Department or of another agency under which –*

(1) *the head of the ordering agency or unit delegates to the head of the servicing agency or unit the authority to issue a grant or cooperative agreement on behalf of the ordering agency or unit;*

(2) *the servicing agency or unit will execute or manage a grant or cooperative agreement on behalf of the ordering agency or unit; and*

(3) *the ordering agency or unit will reimburse the servicing unit or agency for the amount of the grant or cooperative agreement and for the service of executing or managing the grant or cooperative agreement.*

(b) *CONDITIONS. The conditions for making an agreement described in subsection (a) are that -*

(1) *amounts are available;*

(2) *the head of the ordering agency or unit decides the agreement is in the best interest of the United States Government; and*

(3) *the agency or unit to execute or manage the grant or cooperative agreement is able to provide that service.*

(c) *PAYMENT. Payment shall be made promptly through the Intra-governmental Payment and Collection system at the request of the agency or unit providing the service. Payment may be in advance or on providing all or part of the service, and shall be for any part of the estimated or actual cost as determined by the agency or unit providing the service. A bill submitted or a request for payment is not subject to audit or certification in advance of payment. Proper adjustment of amounts paid in advance shall be made as agreed to by the heads of the agencies or units on the basis of the amount of the grant or cooperative agreement and the actual cost of service provided.*

(d) *LIMITATIONS ON FUNDS. A condition or limitation applicable to amounts for grant or cooperative agreements of the ordering agency or unit applies to an agreement made under this section and to a grant or cooperative agreement made under such agreement.*

(e) *OBLIGATION OF APPROPRIATIONS. An agreement made under this section obligates an appropriation of the ordering agency or unit. The amount obligated is deobligated to the extent that the agency or unit providing the service has not incurred obligations, before the end of the period of availability of the appropriation, in*

(1) *awarding the grant or cooperative agreement; or*

(2) *providing the agreed-on services.*

(f) *NO EFFECT ON OTHER LAWS. This section does not affect other laws about reimbursable agreements.*

SEC. 226.

(a) *IN GENERAL. A State or tribal organization which receives grant funds attributable to appropriations under the heading "Department of Health and Human Services, Administration for Community Living, Aging and Disability Services Programs" to carry out programs under parts B, C, D, or E of title III (with respect to States) or under title VI (with respect to tribal organizations) of the Older Americans Act of 1965 (OAA) may elect to transfer up to 100 percent of such received funds among such title III or title VI programs (respectively), subject to OAA sections 306(a)(9) and 307(a)(9) but notwithstanding any otherwise-applicable limitations on such transfers under the OAA or such heading.*

(b) *NOTIFICATION OF PROPOSED TRANSFER; SECRETARIAL APPROVAL. A State or tribal organization which elects to make a transfer under subsection (a) shall notify the Secretary of Health and Human Services of such proposed transfer, including a description of the amount to be transferred, the purposes of the transfer, the need for the transfer, and the impact of the transfer on the provision of services from which the funding would be transferred. The Secretary shall approve any such transfer unless the Secretary determines that such transfer is not consistent with the objectives of the OAA.*

(c) RULES OF CONSTRUCTION. No transfer of grant funds by a State or tribal organization under this section shall be construed–

(1) as inconsistent with the authorized use of such funds under the OAA, including for purposes of OAA administration and oversight by the Secretary; or

(2) to relieve the State or tribal organization from applicable reporting requirements under the OAA regarding the use of such funds.

SEC. 227. Funds appropriated in this Act to accounts that received appropriations in title II of division A of Public Law 116–94 for the administrative expenses of programs or activities for which appropriations are not provided in this Act shall be available for necessary expenses to carry out the closure of such programs or activities.

SEC. 228. Section 340B of the Public Health Service Act (42 U.S.C. 256b) is amended —
(a) in subsection (a)(5)(C) —
(1) by striking "A covered entity shall permit" and inserting "(i) DUPLICATE DISCOUNTS AND DRUG RESALE. A covered entity shall permit"; and
(2) by inserting at the end the following:
"(ii) USE OF SAVINGS. — A covered entity shall permit the Secretary to audit, at the Secretary's expense, the records of the entity to determine how net income from purchases under this section are used by the covered entity.
"(iii) RECORDS RETENTION. — Covered entities shall retain such records and provide such records and reports as deemed necessary by the Secretary for carrying out this subparagraph.".
(b) by adding at the end the following new subsection:
"(f) REGULATIONS. — The Secretary may promulgate such regulations as the Secretary determines appropriate to carry out the provisions of this section.".

SEC. 229. For fiscal year 2021, the notification requirements described in sections 1804(a) and 1851(d) of the Social Security Act may be fulfilled by the Secretary in a manner similar to that described in paragraphs (1) and (2) of section 1806(c) of such Act.

SEC. 230. Any assessment or user fee charged pursuant to section 1311(d)(5)(A) of the Patient Protection and Affordable Care Act credited to the "Centers for Medicare and Medicaid Services, Program Management" account shall be available for any other Federal administrative expenses the Secretary incurs for activities related to the Exchange program, in addition to any other purposes authorized by law, and shall remain available until expended for the purposes described in this section.

SEC. 231. There is hereby established in the Treasury a fund to be known as the "Federal Emergency Response Fund" (the "Fund"). Amounts in the Fund shall be available, in addition to any other amount appropriated for such purposes, to carry out titles II, III, and XVII of the PHS Act, and domestic preparedness activities and global health; to prevent, prepare for, or respond to a chemical, biological, radiological, or nuclear defense threat; or to prevent, prepare for, or respond to an emerging infectious disease; and may be used to purchase or lease, and provide for the insurance of, passenger motor vehicles for official use in foreign countries. Amounts in the Fund may only be used for such threats or emergencies that the Secretary determines have significant potential to occur and potential, on occurrence, to affect national security or the health and security of United States citizens, domestically or internationally. The Secretary may transfer to the Fund such amounts as are necessary from any discretionary amounts (pursuant to the Balanced Budget and Emergency Deficit Control Act of 1985) appropriated in this Act, provided that no such appropriation is reduced by more than 1 percent. Such transferred amounts shall remain available until expended. When implementing response activities, amounts in the Fund may be transferred to other accounts of the Department of Health and Human Services for the purposes provided in this section. The Committees on Appropriations of the House of Representatives and the Senate shall be notified promptly of the initiation of response activities under

this authority, and of any transfer made under the authority provided in this subsection. The Committees on Appropriations of the House of Representatives and the Senate shall receive a report not later than 45 days after the end of each quarter in the fiscal year on the unobligated balances in the Fund and all actual obligations incurred for the fiscal year, including obligations by program, project, or activity. The transfer authorities in this section are in addition to any other transfer authority otherwise available to the Department of Health and Human Services. Products purchased using amounts in the Fund may, at the discretion of the Secretary of Health and Human Services, be deposited in the Strategic National Stockpile under section 319F-2 of the PHS Act.

SEC. 232.
(a) The Secretary may reserve not more than 0.25 percent from each appropriation made available in this Act to the accounts of the Administration of Children and Families identified in subsection (b) in order to carry out evaluations of any of the programs or activities that are funded under such accounts. Any such funds reserved under this section may be transferred to "Children and Families Services Programs" for use by the Assistant Secretary for the Administration for Children and Families and shall remain available until expended: Provided, That such funds shall only be available if such Assistant Secretary submits a plan to the Committees on Appropriations of the House of Representatives and the Senate describing the evaluations to be carried out 15 days in advance of any such transfer.
(b) The accounts referred to in subsection (a) are: "Low Income Home Energy Assistance", "Refugee and Entrant Assistance", "Payments to States for the Child Care and Development Block Grant", and "Children and Families Services Programs".

SEC. 233. Section 2813 of the Public Health Service Act (42 U.S.C. 300hh–15) is amended —

(1) by redesignating subsection (i) as subsection (j); and

(2) by inserting after subsection (h) the following new subsection:

"(i) TORT CLAIMS AND WORK INJURY COMPENSATION COVERAGE FOR CORPS VOLUNTEERS. —

"(1) IN GENERAL — If under section 223 and regulations pursuant to such section, and through an agreement entered into in accordance with such regulations, the Secretary accepts, from an individual in the Corps, services for a specified period that are volunteer and without compensation other than reasonable reimbursement or allowance for expenses actually incurred, such individual shall, during such period, have the coverages described in paragraphs (2) and (3).

"(2) FEDERAL TORT CLAIMS ACT COVERAGE. — Such individual shall, while performing such services during such period —

"(A) be deemed to be an employee of the Department of Health and Human Services, for purposes of claims under sections 1346(b) and 2672 of title 28, United States Code, for money damages for personal injury, including death, resulting from the performance of functions under such agreement; and

"(B) be deemed to be an employee of the Public Health Service performing medical, surgical, dental, or related functions, for purposes of having the remedy provided by such sections of title 28 be exclusive of any other civil action or proceeding by reason of the same subject matter against such individual or against the estate of such individual.

"(3) COMPENSATION FOR WORK INJURIES. Such individual shall, while performing such services during such period, be deemed to be an employee of the Department of Health and Human Services, and an injury sustained by such an individual

shall be deemed 'in the performance of duty' for purposes of chapter 81 of title 5, United States Code, pertaining to compensation for work injuries.".

SEC. 234. Funds made available to the Secretary of Health and Human Services (HHS) in this or any other or prior Acts that are available for acquisition of real property or for construction or improvement of facilities shall also be available to make improvements on non-federally owned property located directly adjacent to property owned by HHS or a component thereof, provided that the primary benefit of such improvements accrues to HHS or the component thereof funding the improvements.
(Department of Health and Human Services Appropriations Act, 2020.)