DEPARTMENT of HEALTH and HUMAN SERVICES

Fiscal Year 2022

General Departmental Management
Medicare Hearings and Appeals
Office for Civil Rights
National Coordinator for Health Information Technology
Health Insurance Reform Implementation Fund
No Surprises Act 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 2022	
	FTE	**Budget Authority**
General Departmental Management	922	$576,981,000
PHS Evaluation Set-Aside – Public Health Service Act	182	$84,328,000
GDM Program Level[1]	***1,104***	***$661,309,000***
Medicare Hearings and Appeals (MHA)[2]		
Office of Medicare Hearings and Appeals (OMHA)	1,135	$172,381,000
Departmental Appeals Board (DAB)	132	$23,619,000
MHA Program Level	***1,267***	***196,000,000***
Office for Civil Rights (OCR)	180	$47,931,000
Office of the National Coordinator for Health IT (ONC) Program Level	177	$0 $86,614,000
Service and Supply Fund	1,395	$0
TOTAL, Departmental Management	**4,123**	**991,854,000**

[1] The FY 2022 GDM Program level does not include estimated reimbursable budget authority and associated FTE, HCFAC associated FTE, or MACRA PTAC associated FTE unless otherwise indicated.
[1] 2021 and 2022 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 2022 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 2022 Congressional Justifications and accompanying Online Performance Appendices contain the updated FY 2022 Annual Performance Report and FY 2022 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 Acting 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 2022 request totals $992 million to support:

- Teen Pregnancy Prevention and Sexual Risk Avoidance: $137 million, the same as FY 2021, to support community efforts to reduce teen pregnancy through grants to replicate programs that have been proven effective, as well as for sexual risk avoidance programs, and an embryo adoption campaign.
- Minority Health: $62 million, the same as FY 2021, for the Office of Minority Health to lead, coordinate, and collaborate on minority health activities across the Department, including leadership in coordinating policies, programs, and resources to reduce health care disparities and advance health equity in America.
- Minority HIV/AIDS: $55 million, the same as FY 2021, for the Minority HIV/AIDS Fund to reduce new HIV infections, improve HIV-related health outcomes, and reduce HIV-related health disparities for racial and ethnic minority communities.
- Policy Coordination: $40 million in new funding to ensure coordination and implementation of key priority areas across the Department, including areas associated with over 30 new Executive Orders.
- Women's Health: $35 million, the same as FY 2021, for the Office on Women's Health to fund prevention and maternal health initiatives addressing health disparities for women and health communication activities.
- Administrative Funds: $29 million above FY 2021, for a total of $240 million, to ensure the Secretary has oversight of the largest budget in the federal government. Funding supports program integrity oversight and operations and management costs in the Office of the Secretary; areas historically underfunded. Planning, Research, and Evaluation: $20 million in PHS Evaluation funding above FY 2021, for a total of $84 million, to create the Office of Climate Change and Health Equity in the Office of the Secretary, ensure implementation and compliance with the Executive Order on Health Equity, and to ensure research is at the forefront of leadership decision making.

- Electric Vehicles: $8 million to create a Department-wide Electric Vehicle Fleet program.
- The Office of Medicare Hearings and Appeals (OMHA) and Departmental Appeals Board (DAB): $196 million, $4 million above FY 2021, to expand support for the two offices to maximize progress to reduce the Medicare appeals backlog;
- The Office for Civil Rights (OCR): $10 million above FY 2021, for a total of $48 million, to enforce federal civil rights laws, conscience and religious protections, the Health Insurance Portability and Accountability Act Privacy, Security, and Breach Notification Rules, and the Patient Safety Act and Rule. 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 IT (ONC): funded entirely from PHS Evaluation Funds for a total of approximately $87 million, or approximately $25 million above FY 2021, to ensure policy development on value-based, data-driven health system transformation and unique expertise for guiding and facilitating cutting edge technology and standards initiatives that target Federal coordination and investments to spur the development and promotion of an interoperable nationwide health IT infrastructure.

The Secretary looks forward to working with the Congress toward the enactment and implementation of the FY 2022 Budget.

Sincerely,

/Norris Cochran/

Norris Cochran
Acting Assistant Secretary for Financial Resources

Departmental Management Overview

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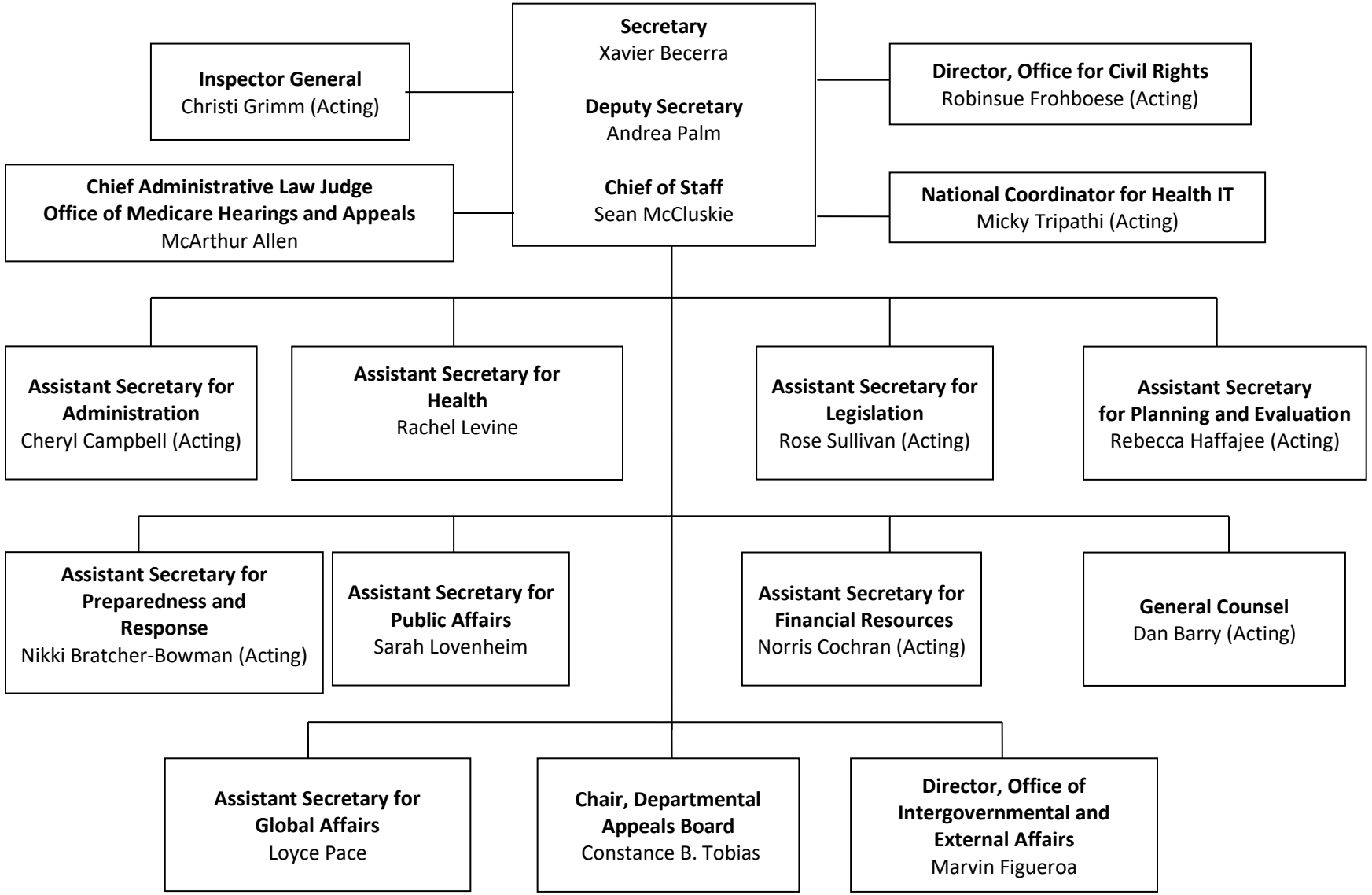
DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF THE SECRETARY



ORGANIZATIONAL CHART: TEXT VERSION

Department of Health and Human Services

- Secretary Xavier Becerra
  - Deputy Secretary Andrea Palm
  - Chief of Staff Sean McCluskie

The following offices report directly to the Secretary:

- Inspector General
  - Christi Grimm (Acting)
- Chief Administrative Law Judge of the Office of Medicare Hearings and Appeals
  - McArthur Allen
- Director of the Office for Civil Rights
  - Robinsue Frohboese (Acting)
- National Coordinator for Health Information Technology
  - Micky Tripathi
- Assistant Secretary for Administration
  - Cheryl Campbell (Acting)
- Assistant Secretary for Health
  - Rachel Levine
- Assistant Secretary for Legislation
  - Anne Tatem (Acting)
- Assistant Secretary for Planning and Evaluation
  - Rebecca Haffajee (Acting)
- Assistant Secretary for Preparedness and Response
  - Nikki Bratcher-Bowman (Acting)
- Assistant Secretary for Public Affairs
  - Sarah Lovenheim
- Assistant Secretary for Financial Resources
  - Norris Cochran (Acting)
- General Counsel
  - Dan Barry (Acting)
- Assistant Secretary for Global Affairs
  - Loyce Pace
- Chief of the Departmental Appeals Board
  - Constance B. Tobias
- Director of the Office of Intergovernmental and External Affairs
  - Marvin Figueroa

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 PHS Evaluation Funds); and
- Service and Supply Fund (revolving fund)

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 2022 President's Budget request for DM totals $991,854,000 in program level funding, including 4,123 full-time equivalent (FTE) positions, an increase of $148,186,000 above the FY 2021 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 $661,309,000 and 1,104 FTE.

Medicare Hearings and Appeals (MHA) supports the Office of Medicare Hearings and Appeals (OMHA) and Departmental Appeals Board (DAB). The FY 2022 President's Budget adopts the new FY 2020 appropriations language and requests $196,000,000 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 $23,619,000. These allocations are subject to change based on actual incoming appeal receipt levels and statuses of appeal backlogs at each level. Overall, this funding enables OMHA and DAB to increase adjudication capacity and reduce the backlog of appeals.

The **Office for Civil Rights (OCR)** enforces federal civil rights laws, conscience and religious protections, the Health Insurance Portability and Accountability Act (HIPAA) Privacy, Security, and Breach Notification Rules, and the Patient Safety Act and Rule. The FY 2022 President's Budget request for OCR is $47,931,000 in budget authority and 180 FTE. The Budget supports OCR's essential programmatic focus on protecting the American people's fundamental rights of nondiscrimination, and health information privacy. 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 2022 President's Budget request for ONC is $86,614,000 in PHS Evaluation Funds and 177 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 to improve the health and care of all Americans and their communities.
ONC's FY 2022 request explains the Office's plan to implement a portfolio of activities driven by congressional requirements and ONC's bipartisan authorities.

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 $1,313,840 and usage of 1,395 FTE.

DEPARTMENTAL MANAGEMENT
BUDGET BY APPROPRIATION
(Dollars in thousands)

Details	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Budget
General Departmental Management	479,629	485,794	576,981
PHS Evaluation Funds	64,828	64,828	84,328
Subtotal, GDM Program Level	**544,457**	**550,622**	**661,309**
Medicare Hearings and Appeals			
Office of Medicare Hearings and Appeals	172,381	172,381	172,381
Departmental Appeals Board	19,500	19,500	23,619
Subtotal, MHA Program Level	**191,881**	**191,881**	**196,000**
Office for Civil Rights	38,798	38,798	47,931
Office of the National Coordinator for Health Information Technology Program Level	60,367	62,367	0 86,614
Total, Departmental Management	**835,503**	**843,668**	**993,754**

General Departmental Management

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APPROPRIATIONS HISTORY TABLE

Fiscal Year	Details	Budget Estimates to Congress	House Allowance	Senate Allowance	Appropriations
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
	Rescission	-	-	-	-$1,050,000
	Transfers	-	-	-	-$1,050,000
	Subtotal	***$478,812,000***	***$365,009,000***	***$444,919,000***	***$458,529,000***
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	$459,959,000	$489,879,000	$485,794,000
	Transfers	-	-	-	-$1,443,490
	Subtotal	***$347,105,000***	***$459,959,000***	***$489,879,000***	***$484,350,510***
2022	Appropriation	$576,981,000	-	-	-
	Subtotal	***$576,981,000***	***-***	***-***	***-***

APPROPRIATIONS LANGUAGE

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 [research studies under section 1110 of the Social Security Act] *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*, [$485,794,000]*$576,981,000*, together with]$64,828,000] *$84,328,000* 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, $55,400,000 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 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
[research studies under section 1110 of the Social Security Act] *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*	Updated language proposed.
[$485,794,000]*$576,981,000*, together with]$64,828,000] *$84,328,000*	Update to amounts to be appropriated for GDM and PHS evaluation.

AUTHORIZING LEGISLATION

(Dollars in thousands)

Details	FY 2021 Amount Authorized	FY 2021 Amount Appropriated	FY 2022 Amount Authorized	FY 2022 President's Budget
General Departmental Management (GDM)	-	-	-	-
Reorganization Plan No. 1 of 1953 (Federal Funds)	Permanent	$155,243	Permanent	$234,943
P.L. 116-260, Consolidated Appropriations Act, 2021 (Embryo, MAIF, TPP, Kidney, SRA)	Indefinite	$197,400	Indefinite	$197,400
Subtotal, GDM Appropriation		***$352,643***		***$432,343***
Office of the Assistant Secretary for Health (OASH)	-	-	-	-
Public Health Service Act, Title III, Section 301 (OASH) (Above Federal Funds –DHPA-AOH)	Permanent	$27,840	Permanent	$38,075
Public Health Service Act, Title, II, Section 229 (OWH)	Expired 2014	$35,140	Expired 2014	$35,140
Public Health Service Act, Title XVII, Section 1701 (DPHP)	Expired 2002	$7,894	Expired 2002	$9,134
Public Health Service Act, Title XVII, Section 1707 (OMH)	Expired 2016	$61,835	Expired 2016	$61,835
Public Health Service Act, Title XVII, Section 1708 (OAH)	Expired 2000	$442	Expired 2000	$454
Subtotal, OASH	-	***$133,151***	-	***$144,638***
-	-	-	-	-
Total GDM Appropriation	-	**$485,794**	-	**$576,981**

APPROPRIATIONS NOT AUTHORIZED BY LAW

Program	Last Year of Authorization	Authorization Level	Appropriations in Last Year of Authorization	Appropriations in FY 2022
GDM	-	-	-	-
Acquisition Reform	2019	-	$1,750,000	-
Related Funding	-	-	-	-
Pregnancy Assistance Fund	2019	-	$25,000,000	-

AMOUNTS AVAILABLE FOR OBLIGATION

Detail	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Budget
Annual appropriation	$479,629,000	$485,794,000	$576,981,000
-	-	-	-
Total Obligations	**$479,629,000**	**$484,350,000**	**$576,981,000**

SUMMARY OF CHANGES

(Dollars in Thousands)

Budget Year and Type of Authority	Dollars	FTE
FY 2020 Final	479,629	789
FY 2021 Enacted	485,794	837
FY 2022 President's Budget	576,981	922
Net Changes	**+91,187**	**+85**

Increases	FY 2021 Enacted Level	FY 2022 Request Change from Base
Immediate Office of the Secretary	12,500	3,300
Assistant Secretary for Legislation	4,100	111
Assistant Secretary for Public Affairs	8,408	1,254
Departmental Appeals Board	4,500	1,662
Office of the General Counsel	31,100	2,424
Assistant Secretary for Financial Resources	31,035	3,680
Quality Services Management Offices (QSMO)	-	6,000
Rent, Operations, Maintenance, and Related Services	15,314	5,000
Center for Faith Opportunities and Initiatives	1,299	35
Office of Intergovernmental and External Affairs	10,625	1,827
Assistant Secretary for Administration	17,858	482
Office of Global Affairs	6,026	676
Shared Operating Expenses - Overhead	10,478	2,268
Secretarial Initiatives and Innovations	2,000	3,000
Electric Vehicle Program	-	7,981
Executive Order Implementation	-	40,000
Office of the Assistant Secretary for Health	36,176	11,487
Total	**-**	**+91,187**

Total Changes	FY 2022 President's Budget	FY 2022 Enacted FTE	FY 2022 Request Change from Base	FY 2022 FTE Change from Base
Total Increases	576,981	922	+91,187	+85
Total Decreases	-	-	-	-
Total Net Change	**-**	**-**	**+91,187**	**+85**

BUDGET AUTHORITY BY ACTIVITY - DIRECT

(Dollars in Thousands)

Details	FY 2020 FTE	FY 2020 Final	FY 2021 FTE	FY 2021 Enacted	FY 2022 FTE	FY 2022 President's Budget
Immediate Office of the Secretary	65	14,200	63	12,500	78	15,800
Assistant Secretary for Legislation	25	4,100	23	4,100	23	4,211
Assistant Secretary for Public Affairs	38	8,408	40	8,408	47	9,662
Departmental Appeals Board	17	4,500	17	4,500	24	6,162
Office of the General Counsel	148	31,100	143	31,100	145	33,524
Assistant Secretary for Financial Resources	140	30,101	132	30,101	141	33,465
Financial Information Systems	-	934	-	934	-	1,250
Grants Quality Service Management Office	-	-	-	-	8	6,000
Office of Intergovernmental and External Affairs	53	10,625	53	10,625	63	12,452
Center for Faith and Opportunity Initiatives	5	1,299	5	1,299	5	1,334
Assistant Secretary for Administration	66	16,558	66	17,858	66	18,340
Office of Global Affairs	24	6,026	20	6,026	20	6,702
Shared Operating Expenses	-	10,478	-	10,478	-	12,746
Secretarial Initiatives and Innovations	-	2,000	-	2,000	-	5,000
Rent, Operations, Maintenance and Related Services	-	15,314	-	15,314	-	20,314
Kidney X	-	5,000	1	5,000	1	5,000
Office of the Assistant Secretary for Health	118	35,776	130	36,176	157	47,663
Electric Vehicle Program	-	-	-	-	-	7,981
Executive Order Implementation	-	-	-	-	-	40,000
Total, GDM Federal Funds	**699**	**196,419**	**693**	**196,419**	**778**	**287,606**
OASH PPAs	**-**	**-**	**-**	**-**	**-**	**-**
Teen Pregnancy Prevention	16	101,000	18	101,000	18	101,000
Office of Minority Health	39	58,670	57	61,835	57	61,835
Office on Women's Health	34	33,640	44	35,140	44	35,140
Subtotal, OASH PPAs	***89***	***193,310***	***119***	***197,975***	***119***	***197,975***
OS PPAs	**-**	**-**	**-**	**-**	**-**	**-**
Embryo Adoption Awareness Campaign	-	1,000	-	1,000	-	1,000
Sexual Risk Avoidance	-	35,000	-	35,000	-	35,000
Minority HIV/AIDS Fund	1	53,900	25	55,400	25	55,400
Subtotal OS PPAs	***1***	***89,900***	***25***	***91,400***	***25***	***91,400***
Total, All PPAs	**90**	**283,210**	**144**	**289,375**	**144**	**289,375**
Total, GDM Discretionary Budget Authority	**789**	**479,629**	**837**	**485,794**	**922**	**576,981**

BUDGET AUTHORITY BY OBJECT CLASS – DIRECT

(Dollars in Thousands)

Object Class Code	Description	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Budget
11.1	Full-time permanent	85,541	88,786	99,848
11.3	Other than full-time permanent	4,060	4,199	4,332
11.5	Other personnel compensation	852	919	950
11.7	Military personnel	3,127	3,748	3,955
Subtotal	***Personnel Compensation***	**93,580**	**97,652**	**109,085**
12.1	Civilian personnel benefits	29,088	33,025	37,339
12.2	Military benefits	713	1,058	1,101
13.0	Benefits for former personnel	-	-	-
Total	***Pay Costs***	**123,381**	**131,734**	**147,525**
21.0	Travel and transportation of persons	2,094	1,533	1,659
22.0	Transportation of things	92	73	76
23.1	Rental payments to GSA	20,634	20,865	23,223
23.3	Communications, utilities, and misc. charges	1,538	1,458	1,390
24.0	Printing and reproduction	1,179	1,158	1,158
25.1	Advisory and assistance services	31,391	31,094	29,951
25.2	Other services from non-Federal sources	28,027	25,373	30,282
25.3	Other goods and services from Federal sources	124,301	124,986	192,941
25.4	Operation and maintenance of facilities	2,183	3,200	4,359
25.5	Research and development contracts	-	-	-
25.6	Medical care	-	-	-
25.7	Operation and maintenance of equipment	2,562	2,074	2,087
25.8	Subsistence and support of persons	18	18	18
26.0	Supplies and materials	505	480	516
31.0	Equipment	735	687	730
32.0	Land and Structures	-	-	-
41.0	Grants, subsidies, and contributions	140,988	141,061	141,066
42.0	Insurance claims and indemnities	-	-	-
44.0	Refunds	-	-	-
Total	***Non-Pay Costs***	**356,248**	**354,060**	**429,456**
Total	**Budget Authority by Object Class**	**479,629**	**485,794**	**576,981**

SALARIES AND EXPENSES

(Dollars in Thousands)

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25.1	Advisory and assistance services	31,391	31,094	29,951
25.2	Other services from non-Federal sources	28,027	25,373	30,282
25.3	Other goods and services from Federal sources	124,301	124,986	192,941
25.4	Operation and maintenance of facilities	2,183	3,200	4,359
25.5	Research and development contracts	-	-	-
25.6	Medical care	-	-	-
25.7	Operation and maintenance of equipment	2,562	2,074	2,087
25.8	Subsistence and support of persons	18	18	18
Subtotal	***Other Contractual Services***	***193,386***	***190,967***	***263,921***
26.0	Supplies and materials	505	480	516
Subtotal	***Non-Pay Costs***	***193,891***	***191,447***	***264,437***
Total	**Salary and Expenses**	**317,272**	**323,181**	**411,962**
Total	**Direct FTE**	**789**	**837**	**922**

GENERAL DEPARTMENTAL MANAGEMENT
ALL PURPOSE TABLE

(Dollars in Thousands)

GDM	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Budget	FY 2022 +/- FY 2021
Budget Authority	**479,629**	**485,794**	**576,981**	**+91,187**
Related Funding	-	-	-	-
PHS Evaluation Set-Aside – Public Health Service Act	64,828	64,828	84,328	+19,500
Program Level	**544,457**	**550,622**	**661,309**	**+110,687**
FTE[1]	**912**	**982**	**1,104**	**+122**

[1] The FY 2022 GDM Program level does not include estimated reimbursable budget authority and associated FTE.

GENERAL DEPARTMENTAL MANAGEMENT

Overview of Performance

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 staff division (STAFFDIV) within GDM, managing thirteen cross-cutting program offices, coordinating public health policy and programs across HHS operating (OPDIVs) and STAFFDIVs, and ensuring the health and well-being of Americans.

The FY 2022 President's Budget reflects decisions to streamline performance reporting by eliminating previous measurements that are no longer relevant or have been retired. 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 the Office of the Assistant Secretary for Administration (ASA), and the Office of the Assistant Secretary for Health (OASH).

The FY 2022 President's Budget request includes individual program narratives that describe accomplishments for most of the GDM components. The request also includes performance tables that provide performance data for specific GDM components: ASA, OASH, and the Departmental Appeals Board (DAB).

OVERVIEW OF BUDGET REQUEST

The FY 2022 President's Budget for General Departmental Management (GDM) includes $576,981,000 in appropriated funds and 1,104 full-time equivalent (FTE) positions. This request is +$91,187,000 above the FY 2021 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.

Administrative (+$25,719,000) – The FY 2022 President's Budget request provides an increase of $25,719,000 above the FY 2021 Enacted Level. The FY 2022 request will provide funding to GDM staff divisions for pay increases and help support program integrity oversight and operations and management costs in the Office of the Secretary; areas historically underfunded.

Grants Quality Service Management Office (QSMO) (+$6,000,000) – The FY 2022 President's Budget request is $6,000,000 which is $6,000,000 above the FY 2021 Enacted Level. The FY 2022 request will enable the Grants QSMO to successfully implement its multi-year vision and mission, providing for appropriate staffing levels needed to drive success in the Grants QSMO's lines of business, continuation of needed project management office support, as well as needed funds to support the development and incubation of innovative grants management solutions critical to the creation of a successful Marketplace of modern grants solutions that address both recipient and awarding agency needs and challenges.

Executive Orders (+$40,000,000) –The FY 2022 President's Budget request for the Executive Order Implementation is $40,000,000, which is the initial request for these resources. Funds will be used by Office of the Secretary Staff Divisions to implement Executive Orders for which they serve as a lead or supporting agency.

Electric Vehicles (+7,981,000) – The FY 2022 President's Budget request for the Electric Vehicle Program is $7,981,000, which is the initial request for these resources. These funds will be used to expand leadership, direction, policy, and management guidance to an enterprise-wide approach for sustainable zero-emission vehicle program, and invest in infrastructure and vehicles with the goal of transforming the HHS fleet to electric vehicles.

Office of the Assistant Secretary for Health (+$11,487,000) – The FY 2022 President's Budget request is $47,663,000 which is $11,487,000 above the FY 2021 Enacted Level. The request provides additional resources to increase support key Administration and Department initiatives and priorities, including addressing issues and gaps in health equity, addressing climate change, combatting the Nation's substance abuse epidemic and the misuse of pain medication, ending the *HIV epidemic in the U.S*. initiative, and developing plans and disseminating information on prevention and health promotion. The request supports the Assistant Secretary for Health to respond to new and expanding needs and allows ODPHP to ensure that its programs are best able to help the nation establish greater resilience through enhancements and quality improvements to the tools and resources that optimize implementation of its key programs – *Healthy People*, Dietary Guidelines, Physical Activity Guidelines for Americans, health literacy, and the health.gov platform.

IMMEDIATE OFFICE OF THE SECRETARY

Budget Summary

(Dollars in Thousands)

Immediate Office of the Secretary	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Budget	FY 2022 +/- FY 2021
Budget Authority	14,200	12,500	15,800	+3,300
FTE	65	63	78	+15

Authorizing Legislation……Reorganization Plan No. 1 of 1953
FY 2022 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 ensuring key issues are brought to leadership's attention in a timely manner and facilitating discussions on policy issues. Documents requiring Secretarial action are reviewed 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 impacting all HHS activities.

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 Executive Secretariat, the Office of National Security (ONS), and the Office of the Chief Technology Officer (CTO). The CTO was reorganized at the end of FY 2020, moving health data initiatives to the Office of the Assistant Secretary for Administration (ASA) Office of the Chief Information Officer (OCIO) and moving health initiatives such as KidneyX to the Office of the Assistant Secretary for Health (OASH).

Five Year Funding Table

Fiscal Year	Amount
FY 2018	$14,200,000
FY 2019	$14,200,000
FY 2020	$14,200,000
FY 2021 Enacted	$12,500,000
FY 2022 President's Budget	$15,800,000

Budget Request

The FY 2022 President's Budget request for IOS is $15,800,000, which is an increase of $3,300,000 above FY 2021 Enacted. The FY 2022 President's Budget allows IOS to increase staffing to support ongoing and

emerging health care issues and to focus on new Presidential and Secretarial priorities, especially health equity, and mental health treatment. The request will allow IOS to add personnel in three key areas. First, it will allow for a small increase in the number of advisors to the Secretary to better address emerging healthcare and human services issues in an increasingly complex healthcare landscape. Second, IOS will invest in staff to support Departmental oversight and policy coordination. Third, after years of relying on detailees to provide administrative support, IOS will build much needed administrative capacity to support core operational functions. These changes support IOS's ability to respond to emerging health care issues, provide essential staffing for all IOS components, and modernize the organization.

SECRETARIAL INITIATIVES AND INNOVATIONS

Budget Summary
(Dollars in Thousands)

Secretarial Initiatives and Innovations	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Budget	FY 2022 +/- FY 2021
Budget Authority	2,000	2,000	5,000	+3,000
FTE	-	-	-	-

Authorizing Legislation.....Reorganization Plan No. 1 of 1953
FY 2022 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 allows 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 2018	$2,000,000
FY 2019	$2,000,000
FY 2020	$2,000,000
FY 2021 Enacted	$2,000,000
FY 2022 President's Budget	$5,000,000

Budget Request

The FY 2022 President's Budget request for Secretarial Initiatives and Innovations is $5,000,000, which is $3,000,000 above the FY 2021 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 the Secretary's priorities to address new and existing critical health issues.

ASSISTANT SECRETARY FOR ADMINISTRATION

Budget Summary

(Dollars in Thousands)

Assistant Secretary for Administration	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Budget	FY 2022 +/- FY 2021
Budget Authority	16,558	17,858	18,340	+482
FTE	66	66	66	-

Authorizing Legislation..... Reorganization Plan No.1 of 1953
FY 2022 Authorization.....Indefinite
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 (ASAIO), Office of Human Resources (OHR), Office of Equal Employment Opportunity, Diversity and Inclusion(EEODI), Office of the Chief Information Officer (OCIO), Office of Business Management and Transformation (OBMT), National Labor Relations Office (NRLO), 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.

Equal Employment Opportunity, Diversity & Inclusion (EEODI)

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 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

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

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 creating a work environment that acknowledges, accepts and encourages employees from all backgrounds to do their best. This is accomplished through Special Emphasis programming, implementation of structured diversity and inclusion awareness and engagement activities, diversity and inclusion education/training, and workforce analysis (statistical trend monitoring). In support of these activities, EEODI is responsible for collecting workforce demographic information and performing periodic cultural climate assessments to target recruitment and other activities.

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 guidance and provides assistance 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 support, including the coordination process for reorganization and delegation of authority proposals that require the Secretary's or designee's signature. OBMT leads Departmental and cross-government initiatives that promote innovation and implement effective management practices within the Department.

National Labor Relations Office (NLRO)

NLRO's primary function has been negotiations and arbitrations on contractual matters. Operating Divisions manage their own labor and relations programs, while NLRO provides oversight and ensures that labor relations approaches in regard to negotiations are in harmony with the administration's vision.

Five Year Funding Table

Fiscal Year	Amount
FY 2018	$17,458,000
FY 2019	$17,458,000
FY 2020	$16,558,000
FY 2021 Enacted	$17,858,000
FY 2022 President's Budget	$18,340,000

Budget Request

The FY 2022 President's Budget request for ASA is $18,340,000, which is an increase of $482,000 above the FY 2021 Enacted Level. The requested resources will allow ASA to fund administrative costs and support pay directly; and continue administrative and oversight responsibilities that support the HHS mission. At the requested level, ASA will maintain current management functions with the ability to fund inflationary pay and non-pay cost increases.

Chief Technology Officer- Outputs and Outcomes Table

Program/Measure	Year and Most Recent Result Target for Recent Result (Summary of Result)	FY 2021 Target	FY 2022 Target	FY 2022 +/- FY 2021
1.1 Increase the number of strategically relevant data sets published across the Department as part of the Health Data Initiative	FY2020: 4,858 Target: 4,000 (Target Exceeded)	5,000	-	-
1.2 Increase the number of opportunities for the public to co-create solutions through open innovation	FY2020: 36 Target: 25 (Target Exceeded)	30	-	-
1.3 Increase the number of innovation solutions identified across the Department in collaboration with the HHS Chief Technology Officer	FY2020: 150 Target: 200 (Target Not Met)	200	-	-
1.4 Expand Access to the Results of Scientific Research funded by HHS	FY2020: 30 million Target: 5.5 million (Target Exceeded)	33 million	-	-

Performance Analysis

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

Pursuant to the Foundations for Evidence-Based Policymaking Act (or OPEN Government Data Act Pub. L. 115–435), HHS is requires to modernize its data management practices with machine-readable data that is "open by default". This includes developing Application Programming (APIs) interfaces to 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 entrepreneurship and new businesses, accelerates scientific discovery and research, and powers digital products and applications 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 December 2020, there are 4,652 datasets from HHS and federated sources on HealthData.gov. This year, there was enhanced access to ONC, FDA, and CMS datasets through

HealthData.gov with 206 COVID-19 datasets published.

Unleashing open data is the first step in creating value and actionable insights. Government must transform its raw data into knowledge and understanding. Often, this involves developing digital tools, such as data visualizations and dashboards for decision makers. As part of its efforts to transform HHS data into evidence-based decision-making, the HHS CTO co-hosted the tenth Health Datapalooza in February 2020. The office hosted two Open Data Roundtables on social determinants of health, one of which focused on COVID-19 and social determinants of health.

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. The goal is to appeal to a broad array of innovators to bring fresh thinking and technology-driven approaches to this space. This includes crowdsourcing, citizen science, prizes, challenges, and innovative collaborations or partnerships.

During FY20, HHS's CTO completed and/or launched four KidneyX prize challenges with over $13 million in purse prizes for the KidneyX Innovation Accelerator. These innovation milestones included the:

- Artificial Kidney Prize (phase 1)
- COVID-19 Kidney Care Challenge
- Redesign Dialysis (phase 2)
- Patient Innovator Challenge
- KidneyX Summit 2020

Emulating the success of KidneyX, HHS CTO established a new partnership—the LymeX Innovation Accelerator (LymeX) for Lyme and tick-borne diseases—with a $25-million-dollar commitment from the Steven & Alexandra Cohen Foundation. Both KidneyX and LymeX advance innovation with patients involved in every step of the innovation process.

As part of its human-centered-design innovation, HHS CTO created the Health+ ("health plus") model for co-creating solutions with the citizens HHS serves. The Indian Health Service (IHS) used HHS CTO Health+ methods for its IHS Health Information Technology (IT) Modernization Initiative. HHS CTO also completed a Health+ cycle for sickle cell disease in collaboration with the HHS Office of the Assistant Secretary for Health (OASH). This delivered:

- Health+ IHS listening sessions, workshops, roundtables, personas/archetypes, journey maps, human-centered-design report, and "healthathon"
- Health+ sickle-cell-disease listening sessions, workshops, roundtables, user personas/archetypes, journey maps, human-centered-design report, and"healthathon"

In response to the COVID-19 pandemic, HHS CTO led the first-ever COVID-19 At-Anywhere Diagnostics "Design-A-Thon". This fast-paced innovation sprint used a crowdsourcing platform to engage 1,000 problem solvers and dozens of industry-led teams. Over 30 teams submitted "capstone projects" related to SARS-CoV-2 diagnostic tests for built-in, automated, harmonized data capture and wireless transmission capabilities. Judges selected 16 winning Design-A-Thon teams to join HHS in an eight-week technology sprint to develop these digital tools. Each of the 16 winners offers unique pathways for the public to co-create solutions with HHS, using the CTO crowdsourcing platform and open innovation pipeline.

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 FY20 through outreach capabilities and knowledge of programs across the Department. In FY20, CTO established the HHS Data Science CoLab and taught four cohorts. Over 1,650 employees applied to participate in the CoLab's six-week, structured training program to up-skill and re-skill with coding and quantitative methods. Given resource constraints, the HHS CTO could only accept 150 CoLab participants — and 150 completed their own HHS projects with innovative solutions/analysis in collaboration with the CTO.

The CoLab methods build upon the CTO Ignite Accelerator program, which is an internal incubator program to build innovation capacity within HHS. Due to the pandemic and resources shifting from innovation to COVID-19, the HHS CTO did not run Ignite Accelerator cohorts in FY20. HHS CTO Demo Days, Startup Days, Tech Days, and other events had to be cancelled due to the COVID-19 emergency.

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

CTO represented HHS headquarters and served on the White House National Science and Technology Council (NSTC) Subcommittee on Open Science (SOS) to advance public access to open science. CTO continues to implement the HHS Public Access Plans published in February 2015 the framework for increasing 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 30 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.

CTO also led interagency efforts on risk management for open science. Specifically, how should federal agencies identify and manage risks to responsibly share data/information in order to optimize expected benefits (e.g., fuel American discovery, entrepreneurship, and innovation) vs. expected risks (e.g., harm to national security, U.S. intellectual property, and PII/privacy)? To answer this, CTO submitted a 10x proposal, which the General Services Administration (GSA) selected and executed. This 10x project helped CTO to publish underlying data from PubMed citations to HealthData.gov, home of HHS open data (performance metric #1.1). Both the CTO and GSA 10x teams worked with the White House NSTC SOS to identify and share best practices and develop tools to mitigate risks and responsibly unlock datasets as part of the open science movement.

ASA Outputs and Outcomes Table:

Measure	Year and Most Recent Result Target for Recent Result (Summary of Result)	FY 2021 Target	FY 2022 Target	FY 2022 Target +/- FY 2021 Target
2.6 Increase HHS employee engagement through Employee Viewpoint Survey.	FY 2020: 76.5% employee engagement Target: 75% employee engagement (Target Exceeded)	73% employee engagement	73% employee engagement	Maintain
2.8 Decrease the cycle time to hire new employees.	FY 2020: 83 days Target: 80 days (Target Not Met but Improved)	80 days	80 days	Maintain
3.3 Increase the percentage of systems with an Authority to Operate (ATO).	FY 2020: 97% Target: 98% (Target Met)	100%	100%	Maintain
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 2020: 70% Target: 90% (Target Not Met)	Discontinued	Discontinued	N/A
3.5 Decrease the Percentage of Susceptibility among Personnel to Phishing.	FY 2020: 4.7% Target: 6.5% (Target Exceeded)	6.2%	6.0%	-0.2%
3.6 Maintain the number of days since last major incident of PII breach.	FY 2020: 366 days Target: 366 days (Target Met)	365 days	365 days	Maintain

Performance Analysis

2.6 Increase HHS employee engagement through the Federal Employee Viewpoint Survey (FEVS).
The Office of Personnel Management (OPM) FEVS measures employee engagement because it drives performance. Engaged employees look at the whole of the organization and understand their purpose within the agency's mission. This understanding leads to better decision-making. The FEVS survey usually opens in May each year; however, due to COVID-19 and workplace disruptions, OPM postponed the survey twice. The late release of the survey and results impacted HHS's ability to meet the performance reporting deadline of December 31, 2020. Furthermore, the delayed release coupled with the need to focus on COVID response and the lack of in-person events, decreased the level of FEVS promotion communications compared to FY 2019. Despite these challenges, HHS significantly improved its Department-wide Employee Engagement Index score, rising from 73.5% in FY 2019 to 76.5% for the FY 2020 survey. In FY 2021 and 2022, HHS will continue to use FEVS data to monitor the impact of its efforts to support organizational improvement.

2.8 Decrease the cycle time to hire new employees
During FY 2020, the customer base grew due to a surge in hiring in response to the COVID-19 crisis. Overall HHS hiring increased more than 14% in FY 2020 compared to FY 2019 and more than 52% from FY 2018. Even with more customers and hardships brought by the COVID-19 crisis, HHS made marked improvements in meeting the Time to Hire target. HHS HR operations transitioned well to maximum telework with no loss of productivity in the recruitment process. The expanded use of shared certificates enabled by the maturation of the HireNow resume search tool, the launch of definitive shared certificate policies, and the acculturation to shared certificate use among HR Centers and customers led to a dramatic increase in shared certificate utilization. More than 61% of all HHS hires in FY 2020 were additional selections from existing certificates of eligible applicants that selected a candidate.

3.3 Increase the percentage of systems with an Authority to Operate (ATO)
Although the target is set for 97%, HHS strives to meet the 100% Federal Information Security Management Act (FISMA) cross agency goal. The slight increase in HHS performance this fiscal year is due to implementing customer engagement teams to assist customers through the ATO process as well as an emergency authorization response policy. In FY 2021, HHS will continue to implement changes to strengthen its enterprise wide information security program. HHS will work with the OpDivs to enhance its enterprise risk management strategy and program to integrate governance functions for information security, strategic planning and reviews, internal control activities, and applicable mission/business areas.

3.4 Improve the score to an "A" in each of the Federal IT Acquisition Reform Act (FITARA) related Scorecard Metrics, per the GAO and House Oversight and Government Reform Committee.
FITARA scorecard results demonstrate the connection of technology capability to agency leadership and the agency's ability to use technology to drive change. HHS received a 70% on the most recent scorecard released in June 2020. While grades may be flat, they signal a connection of the technology capability to the leadership of the agency and using technology to truly drive change. HHS will continue to work to combat cyber threats and incidents as well as work towards a holistic view of the enterprise.

Throughout the history of the scorecard, sub-category measures of the scorecard have changed or retired. The House Committee on Oversight and Reform has signaled several more changes over the coming year creating uncertainty that would challenge HHS's ability to execute on such a broad goal. Recommend discontinuing this goal to focus on other priorities that provide better metrics (e.g., increase percentage of systems with an ATO) in measuring performance across HHS. Specific and meaningful contributions to FITARA are accounted for in other performance metrics and goals as documented in other parts of the budget justifications.

3.5 Decrease the percentage of susceptibility among personnel to phishing
Statistics suggest phishing attacks remain one of the main threat vectors targeting the healthcare industry. Data from Google, CheckPoint, Gartner, and others indicate that both phishing attacks in general and those on registered COVID-19 related domains skyrocketed. HHS trains and educates its personnel to reduce the likelihood of staff mistaking phishing email attempts for legitimate communications through a combination of training, education, and tools. The response rates to phishing training drills remain well below the industry average. HHS will continue this program in FY 2021 and strive to improve user reporting and resistance rates.

3.6 Maintain the number of days since the last major incident of Personally Identifiable Information (PII) breach
If an employee misuses, loses, or otherwise compromises PII, the action may result in steep financial costs and damage to the Department's reputation. This measure serves as an enterprise-wide countdown since the last breach, based on the OMB definition of a major incident in the Department. HHS has not reported a major breach in more than 967 days. HHS works closely with OPDIV privacy programs to continue to protect PII that is collected, used, maintained, shared, and disposed of by HHS information systems. HHS will continue to work with privacy programs across the Department to ensure staff training in protecting and safeguarding PII.

ASSISTANT SECRETARY FOR FINANCIAL RESOURCES

Budget Summary

(Dollars in Thousands)

Assistant Secretary for Financial Resources	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Budget	FY 2022 +/- FY 2021
Assistant Secretary for Financial Resources	30,101	30,101	33,465	+3,364
Financial Systems Integration	934	934	1,250	+316
FTE	140	132	141	+9

Authorizing Legislation:..... Reorganization Plan No. 1 of 1953
FY 2022 Authorization.....Permanent
Allocation Method.....Direct Federal

Program Description and Accomplishments

The mission of the Assistant Secretary for Financial Resources (ASFR) is to advise the Secretary on all aspects of budget, grants, financial management, acquisition, and to provide direction of these activities throughout HHS. In addition, ASFR leads the development and implementation of HHS's Enterprise Risk Management capabilities, including running HHS ERM Council and the leading the development of the annual HHS Risk Profile.

Office of Budget (OB)

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

The OB manages the performance budget and prepares the Secretary to present the budget to OMB, the public, the media, and Congressional committees; and manages HHS apportionment activities, which provide funding to the HHS Operating Divisions and Staff Divisions (OpDivs and StaffDivs). The 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. The OB prepares guidelines and coordinates the execution of reprogramming, transfers between accounts, and other crosscutting funding methods, and provides recommendations in managing and processing crosscutting funding proposals.

Additionally, the OB leads the Service and Supply Fund (SSF) 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. The OB also manages all phases of HHS performance budget improvement activities required under the Government Performance and Results Modernization Act (GPRAMA).

The OB played a key role in helping HHS to secure and manage the resources needed to respond to COVID-19. This included making $105 million in funding available through the Infectious Disease Rapid Response Fund and redirecting $135 million to support CDC, ASPR, and other parts of HHS in their initial response efforts through the Secretary's transfer authority. As the number of COVID-19 cases grew and response effort escalated, Congress passed a series of emergency supplemental appropriations providing $484 billion to HHS. These appropriations include targeted funding for new and complex appropriations such as the Provider Relief Fund, and flexible funding to support a range of activities, including rapid development of vaccines and therapeutics by HHS. The OB helped the policy team quickly identify options for

structuring the Provider Relief Fund and worked closely with policy leadership in ASFR and the Office of the Secretary to align program needs with new appropriations and enabled HHS to support critical investments in cybersecurity, the Commissioned Corps, vaccines and testing and other areas across a wide range of authorities and funding.

The OB supported the critical development of new vaccines and therapeutics. The OB developed the tracking system and lead the bi-weekly updates on contracting projections and execution to ensure funding decisions by HHS are fully informed and funds availability is never an obstacle to executing these critical contracts. The OB coordinates the development and review of congressionally mandated and more detailed spend plans covering multiple activities across HHS supported by four separate emergency supplemental bills.

Office of Finance (OF)

The Office of Finance (OF) provides financial management leadership to the Secretary through the ASFR/Chief Financial Officer (CFO) and CFO Community. The OF leads the HHS-wide financial management efforts for responsible stewardship, accountability, and transparency by issuing the HHS Agency Financial Report to OMB, Treasury, Government Accountability Office, Congressional committees, and the public, in coordination with HHS OpDivs and StaffDivs. The OF manages and directs the development and implementation of financial policies, standards, and internal control practices, including risk assessments; and prepares the HHS annual consolidated financial statements and coordinates related audits, in accordance with the CFO Act, OMB Circulars, Federal Managers Financial Integrity Act, and Federal Accounting Standards Advisory Board standards. The OF provides HHS-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.

The 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 over a decade, 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. The OF successfully produced the Agency Financial Report on-time in compliance with Federal requirements and, for the eighth year in a row, earned the prestigious Certificate of Excellence in Accountability Reporting for the FY 2020 HHS Agency Financial Report.

Office of Acquisitions (OA)

The Office of Acquisitions (OA) provides HHS-wide leadership and management direction in acquisitions, small business policy development, suspension and debarment, performance measurement, oversight and workforce training. The OA also fosters collaboration, innovation and accountability in the administration, management and execution of acquisitions and non-procurement instruments as well as small business functions throughout HHS. OA also supports the financial accountability and transparency initiatives such as those associated with the Federal Funding Accountability and Transparency Act (FFATA), the DATA Act and the HHS Contract Writing Systems.

The OA led multiple initiatives to improve acquisition oversight and governance responsibilities across HHS. The OA played a critical role in the execution of contract resources needed to respond to COVID-19. This included standing up a procurement management office to surge contract operations and meet immediate contract support needs in the early stages of the pandemic. The OA also provided oversight for and facilitated the obligation of over $40.6 billion on contracts in FY 21 across HHS, an increase of $14.1 billion from FY 20. Of the $40.6 billion obligated on contracts in FY 21, $13.2 billion were direct COVID-19 procurements of PPE, equipment, COVID-19 testing services, and critical development of therapeutics and vaccines. Because the COVID-19 cases continued to grow, there was also a significant economic impact to

the financial posture of American businesses. The OA was a key authority to ensuring HHS contract operations were equipped with appropriate guidance and oversight in the execution of relief provisions to HHS industry partners. In accordance with Section 3610 of the CARES Act, this effort aided in reimbursements to HHS contract holders to keep its employees or subcontractors in a ready state, including to protect the life and safety of Government and contractor personnel.

Further, as a result of the pandemic, HHS experienced a significant increase in contract actions and obligations across the agency in support of COVID-19 which highlighted key oversight and policy areas requiring improvements. Correspondingly, multiple initiatives have been implemented to improve stewardship and governance in the procurement and non-procurement lines of business. OA is leading the update to the HHS Acquisition Regulation and reshaping and improving the HHS Procurement Management Oversight program. The OA continues to reshape and update acquisition and non-procurement related internal controls and performance measures; provide technical assistance and oversight to foster stewardship, transparency, and accountability in HHS acquisition and non-procurement programs; respond to acquisition-oriented GAO and OIG audits; lead Department-wide Category Management, Green Procurement and Government Purchase Card Programs.

The OA provided management direction for the HHS' suspension and debarment (S&D) program. The OA led HHS program, acquisition, and non-procurement fraud prevention oversight and outreach, training, and OpDiv and StaffDiv engagements, which promote the use of S&D as an effective administrative remedy in ensuring that HHS conducts business with responsible parties at all stages in the acquisition and federal assistance life cycles. The OA developed S&D policy and published coordination processes necessary to provide guidance to program staff and the acquisition workforce. The OA is also leading an initiative to receive, process and include final suspension and debarment case adjudication in a single repository to promote transparency, streamline research, facilitate case documentation, S&D Official decision-making and case close out.

Office of Grants (OG)

The Office of Grants (OG) is the financial assistance line of business manager for HHS and is responsible for building and maintaining the organizational infrastructure needed to promote performance and accountability for HHS grants, loan, and payment programs. The OG leads through innovation and collaboration, working with OpDivs and StaffDivs, as well as external stakeholders to deliver policy direction, strategic guidance, training, and other tools. OG is also responsible for managing and operating Grants.gov and GrantSolutions, two of the Federal Government's largest shared, fee-based services that together support 33 federal-grant making agencies and more than 1 million registered users.

The OG is responsible for formulating department-wide grants policies. The OG leads the preparation of HHS and government-wide positions on proposed legislation or government-wide policies affecting grants and represents the Department's operational and mission interests in cross-governmental committees and working groups. The OG has been instrumental in recommending applicant and recipient relief options that informed COVID-19 guidance for grant award and administration. The OG provided subsequent policy leadership and technical assistance to OpDivs and StaffDivs as they navigated an unparalleled effort to award trillions in supplementary COVID-19 related funding. In addition, the OG has significantly contributed to the implementation of nine Executive Orders, as well as Presidential and OMB Memoranda in CY 21, supporting implementation through updated policy guidance and technical assistance provision to HHS awarding divisions. The OG is also working to establish its oversight and evaluation functional capability to identify cross-agency and cross-program trends; evaluate recipient risk and grant/program performance; and to detect operational inefficiencies in financial assistance fund award and management.

The OG is the HHS lead for federal electronic grant efforts and supports key financial accountability and transparency initiatives such as the Federal Funding Accountability and Transparency Act (FFATA), the 2014 The Digital Accountability and Transparency (DATA) Act, and the 2019 Grant Reporting Efficiency and Agreements Transparency (GREAT) Act, and submission of grant records to USASpending.gov. In November 2020, OMB designated HHS as the Grant Standards Setting Agency, per the GREAT Act, and OG leads this effort with responsibility for retaining the Grants Federal Integrated Business Framework (FIBF) and Standard Data Elements for the Federal grants community. Federal Agencies' incremental but progressive adoption of the FIBF and the associated Standard Data Elements will increase transparency to the public, performance accountability, and cross-governmental grant system interoperability. In April 2021, OG submitted version 2 of the FBIF to the General Services Administration's Business Standards Council for review and approval. Updates to the submitted data elements are aimed in part at addressing some of the key data quality issues identified by the Pandemic Response Accountability Committee (PRAC) in their ongoing review of pandemic fund administration and management.

In FY 21, OG assumed system ownership of the user fee supported GrantSolutions system. This organizational change ensures management of financial assistance: policy, workforce training, data standards, and major grant system management under OG's single organizational umbrella. Consolidation of these functional responsibilities is aimed at promoting a consistent, integrated approach to financial assistance management for the Department and enhances HHS's focus on effective policy, and recipient performance and compliance for the trillions in grant funds it manages annually.

Financial Systems Integration (FSI)

The OF manages HHS's overall financial management systems environment, including projects to address security and control weaknesses, increase automation, improve user experience, and develop a Financial Business Intelligence System to enhance HHS-wide analytic capabilities and support decision making. The OF continues to implement its strategic roadmap; increase effectiveness and efficiency; and improve access to accurate, reliable, and timely information.

The OF continues to drive innovation across the Department, standardizing financial accounting across HHS and implementing government-wide financial management requirements. The OF developed a comprehensive HHS-wide Digital Accountability and Transparency Act of 2014 (DATA Act) solution, the first in the federal government, that improved data quality and integration across enterprise-wide systems and provided transparency to the over $1.3 trillion HHS budget (in addition to funding related to the COVID-19 response). This solution is used to meet the new monthly financial reporting requirements included in the Coronavirus Aid, Relief, and Economic Security (CARES) Act as well as the American Rescue Plan. HHS ranked second overall out of 24 CFO Act agencies for the highest quality data published on USASpending.gov during an FY 19 DATA Act audit with an error rate under 1.5%.

The OF also began implementing the Department-wide electronic invoicing solution, with CMS going live in August 2020. When complete, this solution will automate over 300,000 invoices resulting in a $200 million cost avoidance over ten years yielding a 295% return on investment.

Furthermore, the OF initiated a digital workforce using Robotics Process Automation (RPA) in the financial management environment to automate low-value manual processes saving thousands of labor hours across the Department.

Lastly, the OF started planning for the Department-wide implementation of Treasury's G-invoicing solution that would improve data accuracy and bring efficiencies across HHS and help the federal government

resolve its long-standing material weakness in its financial statement.

The OF continued efforts to mature the systems environment by strengthening the security, accessibility, and reliability of the financial systems, as evidenced by *no material weaknesses* reported by the independent auditors in FY 20 for the *third consecutive year*.

Five Year Funding Table[2]

Fiscal Year	Amount
FY 2018	$30,444,000
FY 2019	$31,035,000
FY 2020	$31,035,000
FY 2021 Enacted	$31,035,000
FY 2022 President's Budget	$34,715,000

Budget Request

The FY 2022 President's Budget request for ASFR is $33,465,000, which is $3,364,000 above the FY 2021 Enacted Level. At this level, ASFR will invest in grants and acquisition oversight in support of program integrity priorities of the Department.

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

The OF 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 and coordinating various financial audits. The OF will continue to modernize HHS-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 be supported, as outlined below, to ensure they can fulfill their policy missions while providing adequate oversight to the OpDivs and StaffDivs to ensure stewardship of HHS grants, financial assistance, acquisition, and small business programs. FY 2022 requests an additional +9 FTE to be distributed between OG and OA, determined by the ASFR. New OG staff will promote more effective financial assistance management, oversight, evaluation, award-making. New OA staff will facilitate timely process guidance related to contract operations and improved business arrangements, and allow for extensive contract reviews.

Office of Grants

Policy. The OG is responsible for formulating department-wide grants policies and common procedures; providing technical assistance to HHS awarding agencies on complex financial assistance matters; conducting key operational functions such as reviewing notices of funding opportunity for compliance with statute, regulation, and policy; and preparing positions on proposed legislation or government-wide

[2] Funding history includes ASFR and FIS combined.

policies affecting financial assistance. The OG also represents the Department's interests in cross-governmental committees and working groups. , The OG is currently funded at a level supporting seven grant policy staff. Additional OG staff will promote more effective financial assistance award-making and management for the Department.

Oversight and Evaluation. HHS has long considered the oversight and evaluation of its financial assistance programs, investments, and processes as core to its mission and commitment to excellence. HHS awarding divisions monitor their grant awards and conduct programmatic evaluations of their programs or specific investments; however, there remains a need to conduct these activities consistently across the Department and at the enterprise-wide level to identify cross-agency and cross-program performance trends; detect operational inefficiencies; and to proactively identify Departmental and recipient compliance risk in the grant and financial assistance arena. It is also important to have staff who work with the HHS audit liaison and GAO/OIG reviewers to resolve recommendations and analyze findings to make cross-cutting, systemic improvements to financial assistance management practices for the Department. The OG is currently responsible for performing all of these activities. Additional OG FTEs will ensure financial assistance oversight and evaluation**.**

Office of Acquisitions
Policy. The OA establishes uniform Department-wide acquisition procedures which implements or supplements the Federal Acquisition Regulation and other agency policies and statutory requirements; establishes and implements critical policies for the agency to fulfill immediate and long-term acquisition goals and priorities; serves as a key enabler to create a procurement system which supports and promotes the achievement of federal business goals and strategies; and facilitates improved taxpayer service delivery by prioritizing quality, performance, technology and cost. The OA also represents Departmental interests in cross-governmental councils, committees and working groups. To accomplish these broad and complex functions and provide policies that impacts the day-to-day procurement operations across HHS, OA is currently funded at a level supporting three acquisition policy staff. Successful implementation of HHS Acquisition Regulation and common supplemental policies requires extensive and evolving expertise of regulatory and statutory changes that need to be communicated and disseminated to the HHS acquisition workforce. Additional OA FTEs will facilitate timely regulatory and process guidance necessary to promote more effective contract operations and improved business arrangements across HHS.

Oversight: HHS calls upon its federal acquisition workforce to deliver acquisition solutions in an increasingly complex and fast-paced environment and consequently, the oversight, accountability and program integrity of the HHS acquisition system remains a critical function of OA. While Heads of Contracting within HHS evaluate their programs periodically, there is a wide-spread need to conduct periodic evaluative reviews across HHS contract operations to identify and analyze performance trends, capability gaps, inefficiencies and support the improvement and maturity of existing compliance programs. These evaluative reviews have not been conducted for the HHS acquisition enterprise since 2015, which presents significant risks to identifying deficiencies, making systematic improvements and prevention of waste, fraud and abuse in the Federal procurement and non-procurement system. It is critical to have staff to work with HHS contracting offices on a day- to-day basis to ensure regulatory compliance, provide process guidance, ensure compliance with specific laws and mitigate malfeasance and gross misconduct in the execution of HHS programs. Currently, staff reviews are typically conducted during the pre-award phase for HHS anticipated contracts of high interest and/or at very high dollar thresholds. Additional resources will allow OA to focus reviews beyond only very high dollar threshold and high interest contracts.

Investment will support OA's responsibility for the management direction, oversight and accountability for acquisition operations across HHS and the HHS Suspension & Debarment program. Additional OA FTEs will

establish a comprehensive oversight and assessment program for the HHS acquisition enterprise and suspension and debarment programs

Budget Request for Financial Systems Integration.
The FY 2022 President's Budget request for Financial Systems Integration is $1,250,000, which is $316,000 above the FY 2021 Enacted Level.

The OF will continue to lead its multi-year strategy to mature its financial systems environment in collaboration with the HHS CFO, CIO and CISO communities. OF will continue this work and build on the progress made over the past five years by developing a ten-year vision and strategy continuing to mature HHS's financial systems (including an internal controls and risk management framework) that manages approximately $1.3 trillion portfolio.

GRANTS QUALITY SERVICE MANAGEMENT OFFICE

Budget Summary

(Dollars in Thousands)

Grants Quality Service Management Office	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Budget	FY 2022 +/- FY 2021
Budget Authority	-	-	6,000	+6,000
FTE	-	-	8	+8

Authorizing Legislation..... Reorganization Plan No. 1 of 1953
FY 2022 Authorization.....Permanent
Allocation Method.....Direct Federal

Program Description and Accomplishments

Grants Quality Service Management Office (QSMO)

The Grants Quality Service Management Office (QSMO) was established under the Office of Management and Budget (OMB) Memorandum M-19-16, *Centralized Mission Support Capabilities for the Federal Government*, which created QSMO's for select mission-support functions. HHS received full designation from OMB to be the Grants QSMO in December 2020, providing HHS and the federal government with the mechanism to operationalize a vision for federal award assistance that empowers and enables applicants, recipients, and federal awarding agencies to efficiently and effectively deliver on mission.

Through three key roles – Market Coordinator, Solution Manager, and Community Builder – the Grants QSMO facilitates reductions in applicant and recipient burden, equal access to federal financial assistance, government-wide efficiencies, responsiveness to customer needs, and use of data as a strategic asset:

- As a Market Coordinator, the Grants QSMO is establishing a Marketplace of user-centered solutions and services and coordinating with agencies and OMB on investment advisory and review in alignment with updated OMB Circular A-11 guidance.
- As a Solution Manager, the Grants QSMO will bring innovative, customer-focused shared solutions to the Marketplace and provide direction to drive continued modernization and improved customer experience across QSMO-approved solutions.
- As a Community Builder, the Grants QSMO is fostering a community of practice across the federal grant ecosystem to share market research and agency best practices – maximizing government-wide resources, creating community focus on pressing issues and business needs, and minimizing duplication of effort.

The Grants QSMO's role is particularly essential given the federal response to COVID-19, which increased government-wide grant funding from $750 billion to over $2 trillion through supplemental funding. As outlined in OMB Memorandum M-21-20 implementation guidance, the Grants QSMO plays a central role in supporting execution of the *American Rescue Plan Act* (ARP) through technology investment advisory and review. ARP and other supplemental appropriations utilize grant funding as a primary tool to sustain and jumpstart the economy; facilitate greater equity in accessing government funding, programs, and opportunities; and, of course, provide necessary health and community services in response to the pandemic. In this environment, the Grants QSMO's efforts beyond investment review are equally critical, as the Grants QSMO works to enable improved mission outcomes by enhancing service quality for applicants, recipients, and agencies; streamlining and modernizing the grants system landscape; and better leveraging the buying power of the government through shared solutions.

The Grants QSMO is continuing to execute against its 5-Year Implementation Plan and has already had a material impact on the federal grants management landscape. The Grants QSMO maintains an inter-

governmental executive Steering Committee, as well as separate inter-governmental working groups for service providers and awarding agencies. The Grants QSMO also drives its shared services mission through broad engagement with federal grants management, industry, and applicant/recipient community forums. The value and need for the drive towards grants management shared services is clear, as evidenced in FY21 with four awarding agencies – responsible for $6.2 billion in annual grant funding – migrating to a shared grants management solution. The Grants QSMO serves as a catalyst to drive further adoption and modernization of grants management shared services, enabling more strategic and common investments through shared solutions and system footprint reduction.

To coordinate transformative initiatives across agencies, the Grants QSMO is working with other agencies to establish an online collaboration forum and Innovation Hub – a central repository of grants management innovation and pilot solutions. Supporting this type of innovation, the Grants QSMO is actively working with service providers to create a seamless recipient user experience (RUX), driving use of single sign-on through Login.gov to enable development of a recipient portal – resulting in recipients needing only a single set of credentials and providing a single point of access to navigate multiple grants management systems in the ecosystem today. RUX development is supported by ongoing human-centered design sessions with applicants and recipients, with the goal of reducing recipient burden and increasing equity among recipients by better enabling access to federal funding and improving the transparency of grant processes and grant management requirements.

Five Year Funding Table

Fiscal Year	Amount
FY 2018	$0
FY 2019	$0
FY 2020	$0
FY 2021 Enacted	$0
FY 2022 President's Budget	$6,000,000

Budget Request

The FY 2022 President's Budget request for the Grants Quality Service Management Organization is $6,000,000 which is $6,000,000 above the FY 2021 Enacted Level. This level of funding will enable the Grants QSMO to successfully implement its multi-year vision and mission, providing for appropriate staffing levels needed to drive success in the Grants QSMO's lines of business, continuation of needed project management office support, as well as needed funds to support the development and incubation of innovative grants management solutions critical to the creation of a successful Marketplace of modern grants solutions that address both recipient and awarding agency needs and challenges.

This funding provides for the Federal leadership and staff salaries and operating expenses, as well as program management support, required to manage and execute the key roles of Market Coordinator, Solution Manager, and Community Builder, supporting: QSMO responsibilities for QSMO governance oversight; agency coordination; and management of solution providers to build and sustain a viable Marketplace. The QSMO will also undertake efforts to support acquisition and facilitate access to surge support and helpdesk resources needed to expediently process grant funding and support the American public while maintaining appropriate reporting and controls – an effort made timelier and more impactful as HHS and other agencies manage the influx of grant funding in response to COVID-19.

This request enables the Grants QSMO to continue to innovate and develop modern solutions for the Marketplace. In alignment with government-wide goals, identified business needs, and input from the grant recipient community, the Grants QSMO is developing a seamless recipient user experience solution

(RUX) that will enable a single interface for applicants and recipients to manage compliance with requirements across the grant lifecycle. This request supports further solution development (from existing prototype to functioning, scalable solution) and facilitates the transition of recipient-facing government systems to a common single sign-on provider for authentication and access management.

ASSISTANT SECRETARY FOR LEGISLATION

Budget Summary
(Dollars in Thousands)

Assistant Secretary for Legislation	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Budget	FY 2022 +/- FY 2021
Budget Authority	4,100	4,100	4,100	+29
FTE	25	23	23	--

Authorizing Legislation..... Reorganization Plan No. 1 of 1953
FY 2022 Authorization Status.....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 Department's principal interface with Congress, communicating 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, Office and Management and Budget (OMB), other Executive Branch Departments, Members of the Congress and their staffs, and the Government Accountability Office (GAO).

ASL informs the Congress of the Department's views, priorities, actions, grants and contracts, and provides information and briefings that support the Administration's priorities and the substantive informational needs of the Congress. The office also reviews all departmental documents, issues, and regulations requiring Secretarial action.

In FY 2020, ASL coordinated and prepared Departmental witnesses to testify at over 40 hearings and responded to questions for the record that follow each hearing. Throughout FY 2020, ASL prioritized responsiveness and proactive outreach to Members of Congress and their staffs.

Immediate Office of the Assistant Secretary for Legislation
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 relating to health and human services; managing the Senate confirmation process for the Secretary and the 18 other Presidential appointees requiring Senate confirmation; transmitting the Administration's legislative proposals to the Congress; working with Members of Congress and staff on legislation for consideration by appropriate Committees and by the full House and Senate; and coordinating congressional activities and relations among the operating division and staff divisions of the Department, including congressional hearing prep, testimony and questions for the record (QFR) clearances, Member and staff briefings, and responses to congressional correspondence.

Office of Health Legislation
The Office of Health Legislation assists in the legislative agenda and serves as liaison for mandatory and discretionary health programs. The portfolio for the discretionary health team includes the health science-oriented operating divisions, the Agency for Health Research and Quality (AHRQ), Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), National Institutes of Health

(NIH), and Substance Abuse and Mental Health Services Administration (SAMHSA); and staff divisions including the Office of the Assistant Secretary for Preparedness and Response (ASPR), Office of the Assistant Secretary of Health (OASH), Office of the Surgeon General (SG), and the Office of Civil Rights (OCR). This office also covers cybersecurity and Continuity of Operations (COOP) activities. The portfolio for the mandatory health team includes Medicare, Medicaid, the Affordable Care Act, and the Children's Health Insurance Program (CHIP), as well as private sector insurance and legislative matters affecting the Office of Medicare Hearings and Appeals (OMHA) and the Department Appeals Board (DAB). This office is the liaison for health services and health care financing and handles Centers for Medicare and Medicaid Services (CMS) and health care reform. In FY 2020, the Office of Health Legislation had 100 requests for technical assistance, an increase of 10% from FY 2019.

Office of Human Services Legislation
The Office of Human Services Legislation assists in the legislative agenda and serves as the liaison for human services and income security policy. The portfolio includes the operating divisions the Administration of Children and Families (ACF), Administration for Community Living (ACL), Indian Health Service (IHS), Health Services Resources Administration (HSRA), and Office of the National Coordinator (ONC). In FY 2020, significant issues within the human services team included maintaining funding for mandatory programs and administration of programs relative to at-risk populations such as the Special Diabetes Program for American Indian and Alaska Natives, child support enforcement, adoption and foster care, runaway and homeless youth, and organ allocation.

These offices develop and work to enact the Department's legislative and administrative agenda and successfully communicate the Administration's health and human services legislative agenda to the Congress. ASL works to secure the necessary legislative support for the Department's initiatives and provides guidance on the development and analysis of Departmental legislation and policy.

Congressional Liaison Office
The 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 clearinghouse for member and Congressional staff questions and requests. This office maintains the Department's advance notification system to Members of Congress to inform them of grant and contract awards from Departmental programs to entities within their district or state. In FY 2020, 33,000 grant notifications were sent to Members of Congress. The office is responsible for notifying and coordinating with Congress regarding the Secretary's travel and event schedule. 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 the Office of the Assistant Secretary for Financial Resources to coordinate budget distribution, briefings and hearings.

Office of Oversight and Investigations
The Office of Oversight and Investigations (O&I) is 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. In FY 2020, O&I worked together with the Office of the General Counsel to clear letters and transmit documents to requesting congressional committees with oversight jurisdiction. Throughout FY 2020, O&I reduced a backlog of 200 congressional oversight letters by adjusting timelines within their current standard operating procedures and communicated

those changes to HHS staff and operating divisions with equities involved in the clearance process.

HHS has received hundreds of new audit inquiries and more than 400 recommendations that require corrective actions.

Five Year Funding Table

Fiscal Year	Amount
FY 2018	$4,100,000
FY 2019	$4,100,000
FY 2020	$4,100,000
FY 2021 Enacted	$4,100,000
FY 2022 President's Budget	$4,211,000

Budget Request

The FY 2022 President's Budget request for ASL is $4,211,000, which is $111,000 above the FY 2021 Enacted level. This increase will support pay increases and non-pay inflationary costs. 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.

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 2020 Final	FY 2021 Enacted	FY 2022 President's Budget	FY 2022 +/- FY 2021
Budget Authority	8,408	8,408	9,662	+1,254
FTE	38	40	47	+7

Authorizing Legislation:.....Reorganization Plan No. 1 of 1953
FY 2022 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). APSA serves as HHS's principal public affairs office, leading communications efforts in support of the HHS mission, Secretarial initiatives, and other priorities. ASPA accomplishes this mission by building and maintaining relationships with the public through multiple communications channels including the news media, websites, broadcast, social media, journals, speeches, meetings/events, and the Freedom of Information Act (FOIA). The information communicated supports leadership and program priorities and represents a comprehensive view of the Department.

ASPA's FY 2021 accomplishments include:

- The COVID-19 Pandemic intensified HHS's public relations activities. Americans looked to HHS for real-time updates and guidance in a time of uncertainty and fear, and ASPA delivered. ASPA managed over 1,025 Coronavirus-related updates to HHS.gov and created a COVID-19 website hub for HHS. User feedback was used to continually improve COVID-19 communications on the web and in social media. ASPA managed social media campaigns that reached at least 60 million U.S. adults and generated over 400 million impressions and approximately 200,000 engagements on this content. ASPA also co-led Federal-wide COVID-19 web coordination and coordinated digital communications teams across HHS in relation to COVID-19 messaging. The HHS TV Studio Team expanded hours of operation to support COVID-19 communications and developed a continuity of operations plan (COOP) to ensure communications continued if the HHS studio needed to shut down for health and safety reasons. Nearly three-quarters of the year have focused on COVID-19 communication responses.

- ASPA led the communication efforts of the unprecedented $175 billion Provider Relief Fund Program. The Provider Relief Fund supports American families, workers, and the heroic healthcare providers in the battle against the COVID-19 Pandemic. HHS is distributing funding to hospitals and healthcare providers on the front lines of the coronavirus response. ASPA stood up a new public database to ensure transparency in disclosing the recipients of provider relief funding; held multiple press calls with the Secretary and senior HHS officials; and issued 20 press releases with each round of new funding. ASPA continues to coordinate the stewardship of the program with HRSA and others. The ASPA studio created a "5 Things to Know About the Provider Relief Fund" with the Secretary that has received over 16,000 views.

- ASPA FOIA and Privacy Act Division realigned resources to focus on litigations, appeals backlog, and initial requests backlog. The FOIA Division is working closely with OGC to respond to approximately 55 litigations representing more than 120 FOIA requests, which is an increase of about 40% from last fiscal year.

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 2018	$8,408,000
FY 2019	$8,408,000
FY 2020	$8,408,000
FY 2021 Enacted	$8,408,000
FY 2022 President's Budget	$9,662,000

Budget Request

The FY 2022 President's Budget request for ASPA is $9,662,000 which is $1,254,000 above the FY 2021 Enacted level.

The additional funds allow ASPA to increase its number of public affairs specialists to aid the health communications outreach efforts, and FOIA analysts to address the longstanding FOIA backlog and recent spike in FOIA litigations.

At this level, the investment allows ASPA to support the new initiatives and priorities of the Administration, namely providing transparent access to critical information and empowering Americans to lead healthy and productive lives.

OFFICE OF THE GENERAL COUNSEL

Budget Summary

(Dollars in Thousands)

Office of the General Counsel	FY 2020 Enacted	FY 2021 Enacted	FY 2022 President's Budget	FY 2022 +/- FY 2021
Budget Authority	31,100	31,100	33,524	+2,424
FTE	143	143	145	+2

Authorizing Legislation:.....Reorganization Plan No. 1 of 1953
FY 2022 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 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 Investigations; and Legislation.

The Children, Families, and Aging Division (CFAD) provided intensive litigation support and legal review to the Administration for Children and Families (ACF) Office of Refugee Resettlement (ORR) on several litigation cases, numerous class actions, and provided support for the unprecedented influx at the Southern border. CFAD worked closely with the new administration in examining litigation challenging the Adoption and Foster Care and Reporting System (AFCARS). CFAD has supported ACF and Administration for Community Living (ACL) as they implemented the Coronavirus Aid, Relief, and Economic Security Act (CARES) Act, including a new grant program for water administered by the Office of Community Services (OCS) and significant funding increases for the Child Care Development Fund. CFAD provided crucial advice to ACF and ACL regarding Stafford Act flexibilities for grantees for addressing the COVID-19 pandemic. CFAD's expert on the equal treatment rule, at 45 C.F.R. Part 87, continues to engage with the White House and the Department on changes made to that rule. CFAD also continues to support the Temporary Assistance for Needy Families (TANF) program, Office of Child Support Enforcement, the Office of Head Start, the Office of Trafficking in Persons, Children's Bureau, Office of Child Care, and Office for Human Services Emergency Preparedness and Response (OHSEPR).

The Centers for Medicare and Medicaid Services Division (CMSD) provided advice to numerous Centers for Medicare and Medicaid Services (CMS) components in support of their responses to Presidential and Departmental emergency declarations to address the COVID-19 pandemic. CMSD provided counsel on a wide variety of topics in the context of Medicare, Medicaid, and the Children's Health Insurance Program. CMSD provided guidance on issues related to section 1135 waivers, adjustments to permissible sites of care, increased payment for treatment of COVID-19 and access to testing vaccines. CMSD advised CMS on telehealth rules, Emergency Medical Treatment and Labor Act (EMTLA) requirements, survey and certification processes, provider/supplier enrollment, accelerated and advanced payments, and debt recovery requirements. CMSD provided CMS support on adjustments to audits of Medicare Part C and D organizations, improper payment measurement processes, waivers of the Stark Law, and other fraud and abuse requirements. CMSD has provided exceptionally expeditious responses to support the urgent

enactment of new statutes and clearance of emergency rules, including four interim final rules with comment periods, rulings, responses to petitions for rulemaking, and sub-regulatory guidance.

OGC Region IV (Region IV) contributed to the success of the HHS pandemic response by advising CDC's Office of Acquisition Services (OAS) on numerous issues involving modifications to McKesson's COVID-19 vaccine distribution contract for the US states and its territories. The contract modification, funded just under $178 million, will aid in the distribution of COVID-19 vaccine that will continue through January 2022. OGC Region IV provided legal advice and litigation support in the procurement of a COVID-19 Vaccine Distribution and Administrating Tracking software system. The contract is valued at $16,000,000, which includes a mobile application in the early stages and integration of existing electronic health record systems in the later phases. Region IV provided guidance in the procurement of a task order for Data Center Managed Services Migration and Provider services, valued at $60,000,000. Lastly, Region IV assisted the CDC OAS in developing appropriate corrective action that led to the Government Accounting Office (GAO) dismissing a protest of one of the unsuccessful bidders in the clinical trials and clinical research on the treatment, diagnosis and prevention of tuberculosis during a ten-year performance period. The value of the contract, including 5-10 awardees working at different sites, is over $61,000,000. Region VI also advised CDC on its response to a related Congressional inquiry.

Region IV recovered $97,000,000 for the Centers for Medicare and Medicaid Services, Medicaid program. In that case, CMS disallowed payments made to hospitals under Florida's demonstration waiver program, which Departmental Appeals Board (DAB) sanctioned. Region IV also recovered $84,000,000 in unauthorized payments made under the Children's Health Insurance Program Reauthorization Act (CHIPRA) to the State of Alabama. A provision of this act provided bonuses for states to offset the cost of increased child enrollment in the program.

OGC's General Law Division (GLD) has been instrumental in advising the Department's policy makers regarding the administration of their core programs, including advising them on relevant fiscal and procurement laws. Working closely with the Assistant Secretary for Preparedness and Response (ASPR), GLD played a central role in assisting the Department procure critical therapeutics, diagnostics, personal protective equipment (PPE), and vaccines in record time. GLD has also had a key role in providing legal advice to ACF ORR on leases and licenses for facilities, procurements for a myriad of services necessary for providing adequate care, and details for additional assistance from within and outside the Department for unaccompanied children crossing the Southern border. GLD has taken the lead in providing advice on the Federal Advisory Committee Act (FACA), as well as providing advice on the disclosure, retention, and withholding of information requested through various mechanisms. GLD has also adjudicated claims for the Department, including claims filed under the Federal Tort Claims Act (FTCA), Military Personnel and Civilian Employees Claims (MPCE) Act, and Federal Medical Care Recovery Act (FMCRA), and, provided federal court litigation support as necessary. Finally, GLD has provided employment and labor law advice to senior policy makers. GLD has represented the Department in administrative litigation before the Equal Employment Opportunity Commission (EEOC), Merit Systems Protection Board (MSPB), and other litigation matters, including federal court litigation support as appropriate.

The OGC Public Health Division (PHD) is the lead OGC division advising multiple parts of the Department on a myriad of issues related to the COVID-19 pandemic response. It advises on legal matters including those related to the Public Readiness and Emergency Preparedness Act and the Provider Relief Fund; COVID-19 legislation and the development and distribution of vaccines; acceptance of donations and gifts; back to school legal issues; testing and therapeutics; and the implementation of various orders issued pursuant to Sec. 361 of the Public Health Service Act. PHD advises staff supporting the COVID-19 Health Equity Task Force established by Executive Order 13995 and the Disparities Council. PHD also helped the Office of

Minority Health to establish a new $40,000,000 program to fight COVID-19 in racial and ethnic minority, rural and socially vulnerable communities. Finally, PHD handles numerous questions related to the distribution of COVID-19 vaccine in Indian Country, particularly through the Indian Health Service system, the largest rural healthcare system in America.

PHD provides legal advice to clients on many high priority Administration initiatives, such as defending the revised family planning service grant rules, and developing drug pricing control policies. The division continues to advise and assist the NIH on many important and complex matters including its work with its large research grants portfolio, intellectual property, technology transfer, genomic data sharing, biodefense research, addressing undue foreign influence in research, and promoting diversity and inclusion initiatives. PHD also continues to provide copious legal services to the CDC, on matters such as the Federal Select Agent Program, Chronic Disease Prevention, Injury Prevention and Control, Global Health Security, and environmental matters in addition to the extensive COVID-19 work.

PHD also acts as lead and co-lead to regional offices on many federal court cases at every level of the court system. PHD continues to be engaged in significant litigation involving many clients and matters including the 2019 Title X Final Rule, the 340B Discount Drug Program's Alternative Dispute Resolution Final Rule, and challenges to Organ Transplantation Program policies. The Division remains a source of expertise and consultation regarding questions on faith- and community-based organizations and has assisted and opined on the litigation of the Department of Interior and the Department of Treasury.

As part of the national effort to address the opioid crisis, PHD continues to advise agency leadership on a comprehensive and novel public-private partnership involving the National Institutes of Health (NIH), other Federal agencies, private pharmaceutical companies, and representatives from patient advocacy groups. PHD's legal advice has successfully implemented NIH's Helping End Addiction Long-Term initiative and award many grants to address the opioid epidemic. PHD also advises numerous other agencies in their efforts related to the opioid crisis, in particular the Substance Abuse and Mental Health Services Administration (SAMHSA), Health Resources and Services Administration (HRSA), and Office of the Assistant Secretary for Health (OASH) and Centers for Disease Control and Prevention (CDC). As an example, PHD provides significant and ongoing expert legal advice and guidance within the Department, multiple other departments and the White House on Practice Guidelines for the Administration of Buprenorphine for Treating Opioid Use Disorder. PHD continues 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. Furthermore, PHD works alongside the Department of Justice (DOJ) to pursue claims against opioid manufacturers on behalf of the Indian Health Service (IHS), under the authorities of the Federal Medical Care Recovery Act, the Indian Health Care Improvement Act, and the False Claims Act. To date, these efforts have resulted in recoveries for IHS as part of DOJ's $2.8 billion civil settlement agreement with Purdue Pharma L.P. and $225 million civil settlement agreement with the Sackler family.

PHD will continue to advise clients seeking to revise and update program guidance, such as those for the HRSA health professional shortage designation, the Office of Human Research Protection's Common Rule, and the 340B Drug Pricing Program. 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.

PHD will continue to lead OGC teams negotiating over $3,200,000,000 in Indian Self-Determination and Education Assistance Act (ISDEAA) agreements with Indian Tribes and Tribal organizations. PHD has negotiated settlements in over 1,700 IHS contract support costs claims brought under the Contract Disputes Act seeking over $2,200,000,000, with a savings of over $1,200,000,000 over amounts claimed. The Division provides extensive legal advice to the IHS to help operate its large rural health care system

and urban programs.

OGC's National Complex Litigation and Investigations Division (NCLID) is the in-house counsel for the Department on large, complex cases from across the HHS litigation portfolio. These cases include class actions, administrative litigation challenging health care privacy or other enforcement actions, disputes involving tens of millions of dollars in grant funding, and conducting internal investigations on matters that could lead to litigation. NCLID administers the OGC-wide e-Discovery technology, with other HHS staff and operating divisions. In addition, the NCLID 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 2018	$31,100,000
FY 2019	$31,100,000
FY 2020	$31,100,000
FY 2021 Enacted	$31,100,000
FY 2022 President's Budget	$33,524,000

Budget Request

OGC's FY 2022 President's Budget request is $33,524,000; an increase of $2,424,000 above the FY 2021 Enacted level.

In FY 2022, OGC will continue to provide effective and efficient legal support to the Department as the Department continues to pursue the strategic goals. The funding will allow OGC to continue to provide sound and timely legal advice and counsel to the Secretary and the Department, and to effectively manage the legal challenges and provide support for the Department's initiatives and programs.

OGC's request includes funding increase to continue the important contract work underlying OGC's managed discovery program. OGC's often high-profile and complex work on behalf of the Department leverages the contractor's large-scale capabilities and tools for processing, analyzing and producing data from many sources Department-wide. In particular, the contract supports significant litigation and oversight work critical to the HHS clients whom OGC proudly serves.

In FY 2022, OGC will continue to provide Department-wide legal support for all agency acquisitions including: fiscal law and federal real property; general information and administrative law support; claims processing**,** adjudication**,** federal court litigation support for medical malpractice claims under the Federal Tort Claims Act (FTCA); and labor and employment law advice, litigation, and representation.

OGC continues to assist in providing advice on new procurements as may be needed as well as the administration and claims associated with existing contracts, including pandemic response contracts. OGC anticipates a continued relationship with ASPR in furtherance of new contract authority to coordinate the acceleration of countermeasures, product advanced research, and development in preparation for other emerging threats. OGC also anticipates continued support of the Department's programs to care for unaccompanied children crossing the Southern border. In the labor and employment law area, OGC continues litigating a number of employment discrimination cases, MSPB appeals, labor arbitrations, and providing extensive advice concerning Departmental policies, Executive Orders, hiring and pay authorities, performance and conduct actions, and other employment related matters as required. OGC continues its processing and adjudication of claims and providing the necessary federal court litigation support.

OGC continues to assist the CMS with annual Medicare fee-for-service payment and Medicare Advantage/Part D rules, as well as annual and expedited Affordable Care Act (ACA) rulemakings, while also providing CMS with strategic advice on Medicaid demonstration initiatives. OGC is working with the Department of Justice and CMS to represent this Administration's policy preferences in the *Gresham* (work requirements) Supreme Court litigation in a way that will maximize its ability to implement those preferences, and also helping CMS advance this Administrations' policy initiatives, e.g., roll-back of the Georgia 1332 waiver program. OGC continues to defend the Department in numerous challenges to the Secretary's policies: payment rule changes and implementation of statutory changes to inpatient payment rates; payments to disproportionate share hospitals; ACA implementation rules; and price transparency initiatives. OGC expects to focus its litigation efforts on these priorities in the future.

DEPARTMENTAL APPEALS BOARD

Budget Summary

(Dollars in Thousands)

Departmental Appeals Board[3]	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Budget	FY 2022 +/- FY 2021
Budget Authority	4,500	4,500	6,162	+1,662
FTE	17	17	24	+7

Authorizing Legislation……Reorganization Plan No. 1 of 1953
FY 2022 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. The DAB's Medicare claims adjudication costs are funded out of the same Medicare Hearings and Appeals appropriation as the Office of Medicare Hearings and Appeals (OMHA). Congress created the Medicare Hearings and Appeals account in FY 2020 to consolidate the costs of the adjudicative expenses associated with appeals of Medicare claims brought by beneficiaries and health care providers. Details regarding that appropriation are not included in this section, which accounts specifically for 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. Outside parties who disagree with a determination made by an HHS agency or its contractor initiate cases. 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. The Secretary appoints all of the judges (Board Members, Administrative Law Judges (ALJs), and Administrative Appeals Judges (AAJs). The DAB's organizes into the following four Divisions, in addition to having an Immediate Office of the Chair and an Administration 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. The total value of grant disallowance appeals received in FY 2020 was approximately $249,000,000. The total value of decisions issued in grant disallowance cases for FY 2020 was approximately $48,000,000.

In FY 2020, the Board/Appellate Division received 111 cases and closed 82 cases, 47 by decision.

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

[3] Funding levels displayed represent non-Medicare appeals related activities in DAB for FY 2020 -FY 2022.

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 percent 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 transaction 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 involve 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 children.

In FY 2020, CRD received a total of 3,169 new cases and closed 3,961 (98%), of which 1,109 were by decision. Of these cases, CRD received 2,377 FDA cases and closed 2,921 FDA cases, of which 813 were 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 2020, the ADR Division closed 90% of cases open during the fiscal year 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, individual claims for Medicare coverage, and claims for payments filed by beneficiaries or health care providers and suppliers. The costs of Medicare claims adjudication are funded out of the Federal Hospital Insurance and Federal Supplementary Medical Insurance 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) year-to-date case receipt and closure data for FY 2021, (2) the retirement of a Board Member at the beginning of FY 2020, (3) the addition of one new Board Member in late FY 2020, (4) the departure of one staff attorney in FY 2020 and two attorneys in FY 2021, (5) the loss of a long-time administrative support staff member in FY 2020, (6) the addition of three new staff attorneys in FY 2021, (7) the anticipated retirement of the longest serving Board Member at the end of FY 2021, and (8) 2 new staff attorneys in FY 2022.

APPELLATE DIVISION CASES – Chart A			
Cases	**FY 2020**	**FY 2021**	**FY 2022**
Open/start of FY	103	132	133
Received	111	83	116
Cases Closed by Decisions	47	40	60
Total Closed	82	82	90
Open/end of FY	132	133	159

Administrative Law Judges – Civil Remedies Division, FDA Tobacco Program

Chart B shows caseload data for the CRD, FDA Tobacco Program. All FDA Tobacco Program data are projected based on historical trends and certain assumptions, including the extension of the interagency agreement in FY 2022 to hear FDA cases, and no major regulatory changes. In March 2020, FDA suspended tobacco inspections following the COVID-19 Public Health Emergency, resulting in a decrease in the number of enforcement actions filed in the second half of FY 2020 and continuing into FY 2021. FDA has since resumed inspections and anticipates a gradual increase in the number of enforcement actions later in FY 2021, and a return close to pre-COVID numbers of enforcement actions in FY 2022.

CIVIL REMEDIES DIVISION, TOBACCO CASES – Chart B			
Cases	**FY 2020**	**FY 2021**	**FY 2022**
Open/start of FY	593	52	302
Received	2,380	1,000	4,200
Decisions	813	250	975
Total Closed	2,921	750	3,950
Open/end of FY	52	302	552

Five Year Funding Table[4]

Fiscal Year	Amount
FY 2018	$14,000,000
FY 2019	$14,000,000
FY 2020	$4,550,000
FY 2021 Enacted	$4,550,000
FY 2022 President's Budget	$6,162,000

Budget Request

The FY 2022 President's Budget for the DAB is $6,162,000 in discretionary budget authority from the General Departmental Management appropriation, which is $1,662,000 above the FY 2021 Enacted level.

The FY 2022 President's Budget allows the DAB to hire seven additional FTE. The additional staff increases the DAB's adjudication capacity for non-Medicare appeals related work. DAB will add two staff attorneys to the Appellate Division to help tackle its diverse workload. The remaining five FTEs will support the Immediate Office and the Administration Division, where they will serve critical roles in supporting leadership, enhancing operational and adjudicatory functions, and improving overall DAB efficiency. The FY 2022 increase in funding will also help account for inflation and other annual cost increases.

In addition to the increase in funding, the DAB will continue to improve recently implemented and improved IT-based solutions which lead to adjudicative efficiencies, including e-filing, digitization of paper claim files, and case systems database enhancements. The DAB's goal is to continue 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 2021 and FY 2022, the DAB will continue to focus on cutting-edge IT enhancements, such as artificial intelligence and data analytics as tools to collect, manage, and analyze case data.

Further, the DAB will continue to support the President's Executive Orders issued since the start of his Administration.

Outputs and Outcomes Table

Measure	Year and Most Recent Result Target for Recent Result (Summary of Result)	FY 2021 Target	FY 2022 Target	FY 2022 +/- FY 2021
1.1.1 Percentage of Board Decisions with net case age of six months or less	FY 2020: 68% 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 2020: 100% Target: 90% (Target Exceeded)	100%	90%	Decrease by 10%
1.5.1 Number of conflict resolution seminars conducted for HHS employees.	FY 2020: 10 Target: 10 Sessions (Target Met)	15	15	Maintain
1.5.2 Cases closed in a fiscal year as a percentage of cases open in the same fiscal year.	FY 2020: 90% Target: 90% (Target Met)	90%	90%	Maintain

[4] 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.

Performance Analysis

The 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 2020, 68 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 2021 and FY 2022, the target for Measure 1.1.1 remains 50 percent, due to the loss of productivity caused by the departure of one staff attorney at the beginning of FY 2021, the anticipated retirement of a long-serving staff attorney in the second half of 2021, the anticipated retirement of the DAB's longest-serving Board Member at the end of FY 2021, and the need to train three new staff attorneys and one new Board Member in FY 2022. The Appellate Division expects to meet the target for Measure 1.1.1 in both fiscal years

In FY 2020, 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 2021, the target returns to 100 percent as productivity increases after the addition of a new Board Member in late FY 2020. The target for Measure 1.2.1 decreases to 90% for FY 2022 due to the loss of productivity caused by anticipated staff retirements and training demands. The Appellate Division expects to meet the target level for Measure 1.2.1 in both FY 2021 and FY 2022. However, there is the potential that the Board may receive additional types of appeals in the foreseeable future that could affect its ability to reach the targets for both Measures 1.1.1 and 1.2.1 and in the next fiscal years.

Alternative Dispute Resolution (ADR) Division

In FY 2020, ADR met the target of 10 conflict resolution seminars offered to HHS employees for Measure 1.5.1. In FY 2021 and FY 2022, the target increases to 15 seminars due to advances in how the Division offers trainings. Specifically, ADR has been able to leverage the fully functional virtual platform it launched in FY 2020 to increase its offerings to HHS staff and others. ADR expects to meet the target for Measure 1.5.1 in both FY 2021 and FY 2022.

In FY 2021, ADR also met the target for Measure 1.5.2 to close 90% of cases open in that fiscal year. In FY 2021 and FY 2022, ADR expects to continue to meet Measure 1.5.2 by maximizing its virtual resources and by adding one new attorney in FY 2022.

OFFICE OF GLOBAL AFFAIRS

Budget Summary

(Dollars in Thousands)

Office of Global Affairs	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Budget	FY 2022 +/- FY 2021
Budget Authority	6,026	6,026	6,702	+676
FTE	24	20	20	-

Authorizing Legislation……Reorganization Plan No. 1 of 1953
FY 2022 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 by advancing HHS's global strategies and partnerships, and by working with HHS divisions and other U.S. Government (USG) agencies in the coordination of global health policy and international engagement. Guided by Administration priorities such as those laid out in National Security Memorandum on *United States Global Leadership to Strengthen the International COVID-19 Response and to Advance global Health Security and Biological Preparedness* (NSM-1), 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 already present in HHS to address needs and opportunities overseas, while providing knowledge and analysis of international developments for the benefit of the Secretary and the Department. 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 agencies as well as more than 200 Ministries of Health. Key multilateral organizations with whom OGA engages 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 United Nations Children's Fund (UNICEF); the Organization for Economic Cooperation and Development (OECD); and the GAVI Alliance.

Significant recent accomplishments include:

- Led efforts on behalf of the U.S. government to develop and negotiate a reform package designed to strengthen WHO's response to future global health threats by increasing accountability and transparency of relevant multilateral mechanisms. As the chair of the G7, OGA used discussions with G7 Health ministers and put forward a roadmap for discussion with the intent to reach consensus with partner countries to develop a comprehensive set of tools to make the WHO more fit-for-purpose.
- Worked with the Department of State and USAID on comprehensive reform at the Pan-American Health Organization to increase transparency and accountability. Reforms included: replacing the Deputy Director; initiating an independent investigation into a closed program and all aspects of its

execution; and coordinating an agreement with PAHO secretariat and Member States on governance reforms of the organization.

- Convened calls with Ministries of Health around the world to share pandemic updates, a key effort in global coordination to the Coronavirus epidemic and the USG response to global supply needs. Additionally, convened weekly calls, led by the Secretary, with Health Ministries of the G7 to share best practices on public health response.
- Continued to support the growth of the Africa Centers for Disease Control and Prevention (Africa CDC) by working closely with key actors within the African Union (AU) to ensure this important institution can operate independently from undue influence and improve its capacity to detect and respond to infectious disease in the region. In close collaboration with the White House, Department of State and the U.S. Centers for Disease Control and Prevention (CDC) OGA is working to find a solution that serves the public health interest and security concerns of the Africa region and the United States.
- Worked with the CDC along the U.S.-Mexico Border through the U.S.-Mexico Border Health Commission to advance the global health security agenda (GHSA) and AMR objectives, including Coronavirus surveillance, through projects on the border.
- Convened new Health Policy Dialogues with key regional partners, Brazil and Canada, to strengthen bilateral cooperation on a range of shared priorities, including strengthening immunization rates; tackling the challenge of influenza preparedness; reducing rates of vaping in youth; combating the opioid epidemic; and collaborating more closely on preventing anti-microbial resistance.
- Through diplomatic efforts, worked with counterparts in India to strengthen surveillance systems for AMR and Hospital Acquired Infections and to engage with Indian stakeholders on regulatory pathways for new antimicrobials.
- Provided critical and timely inputs on behalf of the USG at the Global Fund board meeting to ensure that the Global Fund remains focused on its mission statement of eradicating Malaria, HIV, and TB and advocated to expand the role of the Global Fund's Inspector General to include an evaluation of the effectiveness of its programs. To this end, the Global Fund Board approved the Principal Deputy Director for OGA to serve as Vice Chair on the Inspector General Selection Committee, which is now engaged in the search for a new Global Fund Inspector General.

Five Year Funding Table

Fiscal Year	Amount
FY 2018	$6,026,000
FY 2019	$6,026,000
FY 2020	$6,026,000
FY 2021 Enacted	$6,026,000
FY 2022 President's Budget	$6,702,000

Budget Request

The FY 2022 President's budget request for OGA is $6,702,000, which is an increase of $676,000 from the FY 2021 enacted level. This increase allows OGA to fully support critical activities related to global health security and AMR and address emerging issues. The increase will also support required pay raise estimates and other inflationary costs.

At this level, OGA will also be able to 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 carry out this mission

focused on three key principles championed by the Biden-Harris Administration, namely a commitment to health equity and inclusion, with attention to disparities based on gender, race, and sexual orientation and gender identity, balancing crisis response (such as COVID and Ebola) with strengthening health systems and achieving universal health coverage, and approaching health holistically, including understanding connections among environmental, animal and human health.

With this budget, OGA will maintain its efforts to coordinate government policy and programs through political and diplomatic channels both with Embassies in Washington and Health Ministries in foreign capitals, and coordinate and facilitate the involvement of HHS Operational and Staff Divisions 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*. OGA 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 continue to provide Secretarial and senior HHS officials with support for global engagements, including planning and coordinating international travel, providing on-the-ground logistical support in collaboration with U.S. Embassies, and supporting bilateral and multilateral engagements with Secretarial counterparts.

This budget also allows OGA to continue 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 2020 Final	FY 2021 Enacted	FY 2022 President's Budget	FY 2022 +/- FY 2021
Budget Authority	10,625	10,625	12,452	+1,827
FTE	53	53	63	+10

Authorizing Legislation:..... Reorganization Plan No. 1 of 1953
FY 2022 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 HHS, state, local, territorial and tribal governments, and non-governmental organizations to facilitate communication related to HHS initiatives with stakeholders. IEA serves as a conduit reporting stakeholder interests and positions to the Secretary for use in the HHS policymaking process.

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, and 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.

IEA is actively involved in leading the educational outreach and stakeholder engagement on the Secretary's priorities related to the COVID-19, Unaccompanied Children (partnering with ACF/ORR and FEMA), 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. IEA's efforts have proven to be hugely successful in improving the communication, timeliness, and relationships with stakeholders across the country.

IEA has conducted intergovernmental outreach on a weekly basis to governors, state health officials, and other state and local leaders regarding COVID-19 focus on:

- Surge testing to states in need of increased capacity
- Notifications to states regarding CRAFT deployment and allocation
- Calls with states regarding the COVID-19 response (testing supplies, PPE, etc.)
- Coordinated engagements with state lab directors and the FDA to help triage technical lab issues
- Status calls with state testing teams to help triage testing and supply issues
- Daily email highlighting all news releases and activities across the Department related to COVID-19
- Compiles and distributes state-specific response and recovery information on a weekly basis.
- Leads outreach and technical assistance on vaccine distribution to jurisdictions in conjunction with the CDC and the Operation, including updated priority populations, innovative delivery models, and other needs

IEA has run or helped facilitate many stakeholder calls and meetings with external organizations regarding Department initiatives and rollouts.

- Facilitate calls with external stakeholders, covering topics including COVID-19, rural health, adoption, tobacco policy, opioids, drug pricing and other HHS initiatives.
- Monthly calls with racial and ethnic minority groups on COVID-19, OWS, and other HHS initiatives.

IEA leads external affairs for the Department on the breadth of its portfolio.

- Coordinates outreach to external organizations on the needs of the Department, including on healthcare coverage, COVID-19, Executive Orders, and other priorities.
- Leads outreach with companies that seek to do business with the Department on COVID-19
- Build coalitions of stakeholders to address policy decisions that the Department needs to make
- Collaborates with the White House on outreach activities on behalf of the administration, including creative direction, logistics, and SME support

IEA plays a key role in the UC program.

- IEA performs notification of state and local elected officials whenever there is an influx of unaccompanied children requiring emergency influx shelters (EIS) or temporary influx care facilities (ICF) beyond the permanent beds ACF currently has or can bring online.
- In addition, IEA notifies appropriate state and local officials of a community at each stage of the process and to coordinate a “community leaders briefing” should HHS reach a stage in the process where such an engagement is called for.
- This protocol would generally be used whether we are considering use of a military base, or non-military facility in a community.
- IEA notifies the appropriate Governor’s office, usually the Governor’s chief of staff or state-federal relations contact.
- HHS Regional Director notifies the appropriate chief elected official of the community in which the potential site is located. This could be a state legislator, county executive, county commissioners, a mayor, a city manager, or all five.
- If there is a request for a community leaders meeting/briefing, IEA Regional Director would then work with the ACF Regional Administrator in setting up the briefing and helping to identify the appropriate officials to invite.
- If after assessing the site, ACF decides to move forward with the facility, IEA will work to schedule a community leader briefing. IEA Regional Director’s office, in partnership with the ACF Regional Administrator, will work with the chief elected official to schedule a briefing for county and city elected officials, state officials, congressional representatives, and local business, community and faith leaders.
- IEA has also worked with the National Governors Association to set up educational briefings and informational briefings for governors’ Washington staffs and state-federal representatives.
- IEA has worked with the U.S. Conference of Mayors and its 1,400 big city municipalities to setup educational briefings for mayors.
- IEA has also provided some assistance in reviewing requests for tours of facilities housing unaccompanied children. In emergency situations, IEA Regional offices have provided tours onsite of emergency intake shelters (EIS) or Influx Care Facilities (ICF) during “all-hands-on-deck” situations.

IEA played a pivotal role in the development of the HHS-wide Maternal Health initiative.

- IEA hosted five roundtables in Washington, DC, with Senior Leadership and key stakeholder groups to gather information regarding innovations, quality, and standards of care.
- IEA organized and held four listening sessions in New Jersey, North Carolina, Louisiana, and South Dakota to inform the Maternal Health strategy through consideration of state leadership and best practices for care.
    - Created a roll-out plan and hosted a release event for the HHS Maternal Health Action Plan that included participation from nearly 3,000 stakeholders
- IEA leads and operates a Public-Private Partnership with March of Dimes targeted towards advancing equity and improving maternal health outcomes.

IEA led engagements on a wide range of public health issues identified as priorities by the Administration and the Secretary.

- Planned and executed appearances by former HHS Secretary Alex Azar on priority topics such as opioids (University of Kentucky HEAL Kick-off Summit) and kidney health (National Academy of Sciences Fireside Chat).
- Planned and hosted roundtables with former HHS Secretary Alex Azar and the White House on organ procurement, tobacco, and interoperability.
- Developed an HHS fact sheet on HHS activities that support racial and ethnic minority communities during COVID-19.
- Led with ASPA and IOS the launch of the AAKH Public Awareness Campaign starting in March 2020.
- Planned and partnered with former ASH Brett Giroir surrounding the announcement and implementation of the Gilead PrEP donation, subsequent EHE funding announcements, and submission of jurisdictional plans.

IEA has played a pivotal role in communication, education, and case work related to the disbursement of Provider Relief Fund.

- Organized and hosted three PRF webinars with HRSA for providers, tribal, and faith communities
- Created and maintained a hospitalcovid19@hhs.gov RFI email account to respond to external questions and concerns regarding PRF.
- Worked closely with HRSA and ASPA to send targeted communications to providers throughout the disbursement period
- Hosted multiple stakeholder calls with external groups regarding PRF
- Prepared responses to over 400 letters from external groups regarding PRF
- Served as the programs/Departments point of contact for all external stakeholders and providers to triage and address casework, policy questions, hold meetings and address other PRF related issues.

IEA continues to play a key role across CMS-specific issues including Marketplace outreach and enrollment, Surprise billing, ARP provisions and Medicaid waivers

- IEA plays an integral role in sharing information with external stakeholder groups on all health care related issues by hosting Secretary and other senior leadership calls, webinars and disseminating toolkits and messages
- Works in concert with the Regional Offices to ensure all information from headquarters is shared and disseminated to broader audiences and local leaders
- Convenes a key group of ACA advocacy organizations to coordinate efforts across the Department and with external partners (in coordination with CMS)

IEA's Tribal team has done extensive outreach to tribes across the country.

- Hosted the Annual HHS Tribal Budget Consultation, virtually
- Hosted annual HHS Regional Tribal Consultations

- Held two Secretary's Tribal Advisory Committee Meetings one in person and virtually
- Organized and coordinated several HHS leadership visits to Indian Country: South Dakota, New Mexico, Wisconsin, and Alaska.
- Responsible for developing a weekly email to Tribes regarding COVID-19 from HHS.
- Developed an HHS COVID-19 Tribal Fact Sheet.
- Assisted and Facilitated the White House with their bi-weekly COVID-19 call with Indian Country
- Led weekly meetings with IHS, FEMA, ASPR regarding COVID-19 response to Indian Country
- Participation in ICNAA executive committee meetings and bi-annual meetings

IEA has done extensive outreach with the COVID-19 Federal Vaccine Effort (the Operation), formerly Operation Warp Speed (OWS):

- IEA convened two Vaccine Consultation Panel (VCP) groups, one with intergovernmental partners and another with external groups, to communicate with key partners about the Operation/OWS and to discuss messaging best practices around a successful vaccination campaign. Calls were held once a month with the intergovernmental group and twice a month with the external group.
- IEA partners with U.S. Army personnel and Operation/OWS leadership on engagement with industry leaders on distribution, administration, and IT for the implementation of the Operation/OWS vaccine distribution plan.
- IEA provides comprehensive technical assistance on behalf of the Operation and the COVID-19 Response to jurisdiction and external partners.

Five Year Funding History

Fiscal Year	Amount
FY 2018	$10,625,000
FY 2019	$10,625,000
FY 2020	$10,625,000
FY 2021 Enacted	$10,625,000
FY 2022 President's Budget	$12,452,000

Budget Request

The FY 2022 President's Budget request for the IEA is $12,452,000, which is an increase of +$1,827,000 above the FY 2021 Enacted level. At this level, IEA can effectively carry out mission critical activities that include soliciting and coordinating input regarding Presidential Executive Orders, intergovernmental responsibilities to state, local and Tribal nations involving all Departmental initiatives and priorities. In the past year, IEA directly supported the White House in communication efforts, playing key roles in providing information, responses, and guidance on COVID-19 efforts to government and external organizations. Successful communication and coordination of healthcare and human services policy issues and other priority initiatives of the Department, Secretary, and the Administration are the critical mission priorities for IEA. In FY 2020, IEA completed an internal budget review to assess the most critical needs of the division, in addition to identifying ways to reduce spending. As a result, IEA developed a new staffing model that would ensure adequate staff in HQ and Regional Offices, while maximizing opportunities to reduce travel costs and improve communication. The increase will allow IEA to continue mission critical activities, securing an additional 10 FTE who are knowledgeable about the complexity and sensitivity of various HHS programs, which include health insurance marketplace, consumer/population distinctions, governmental organizations, and external organizations.

CENTER FOR FAITH AND OPPORTUNITY INITIATIVES

Budget Summary

(Dollars in Thousands)

Center for Faith and Opportunity Initiatives	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Budget	FY 2022 +/- FY 2021
Budget Authority	1,299	1,299	1,334	+35
FTE	5	5	5	-

Authorizing Legislation..... Reorganization Plan No. 1 of 1953
FY 2022 Authorization.....Permanent
Allocation 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 (e.g. YMCA of the USA, Lion's Club, Seventh-day Adventist Church, Boys & Girls Clubs of America, Islamic Relief, and the Southern Baptist Convention.) The Partnership Center is committed to the public health and human services 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 such as Lutheran Services of America, Key Ministry, National Alliance on Mental Illness, the Salvation Army, Jewish Family Services, Seventh-day Adventist Church, Adult & Teen Challenge USA, American Muslim Health Professionals 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 (e.g. 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 2020/2021, the Center accomplishments included:

- Weekly and monthly e-newsletters that connect thousands of faith and community leaders, and providers with the most up-to-date information, resources, and practical strategies for addressing the opioid crisis, the COVID-19 pandemic, mental health, and related public health and human service issues. More than 4,000 individuals were added to the Center's primary distribution list.
- To strengthen the response of faith and community partners to critical public health issues including opioid and substance use disorders, serious mental illness, and better integrate the connection between health care providers and community health assets, the Partnership Center produced practical videos and print resources including:

- *Compassion in Action: Guide for Faith Communities Serving People Experiencing Mental Illness and Their Caregivers;*
- *Faith & Community Roadmap to Recovery Support: Getting Back to Work; and the*
- 4th Edition of *The Opioid Crisis Practical Toolkit for Faith and Community Leaders.*

- Through 2020 and 2021, the Partnership Center worked with trusted messengers within underserved, minority, and rural communities to equip them with credible, engaging, and culturally relevant information and communication strategies, best practices, and tools and resources including; rapid response materials providing up-to-date responses to FAQs, guidance on preventive practices as they relate to faith or community's activities and traditions; webinar trainings that build local capacity and highlight models and practices that are working to address inequities in vaccine access; create events in coordination with highly visible and influential faith and community leaders as co-hosts to CDC or HHS experts COVID-19.
- Produced materials and webinars that address needs and concerns related to COVID-19, in English and in Spanish, including more than 9,000 registrants to webinars on mental health challenges and solutions during COVID-19 and multiple resources explaining how faith and community leaders could understand and address the disease in their respective communities.
- Amplified the work of HHS reaching faith and community leaders including promoting efforts lead and coordinated through Office for Civil Rights, National Institutes of Health, Assistant Secretary for Health, Administration for Children and Families, and others.
- Partnered with HHS Assistant Secretary for Preparedness and Response (ASPR) and FEMA to help distribute over 57 million face coverings to community and faith-based partners in response to CDC's COVID-19 prevention recommendations.
- Hosted 16 educational webinars that supported and expounded upon our mental health, COVID-19, and addiction resources. These webinars averaged over 1,500 registrants each.
- Strengthened our social media presence by establishing a branded YouTube Channel with more than 570 new subscribers during this timeframe and nearly 9,502 views to date.
- Participated in-person and through online conference and community presentations to educate, equip, and engage faith and community leaders and providers about HHS and Partnership Center priorities and activities.
- Supported the Campaign to End HIV/AIDS by engaging hard-to-reach community influencers in regional areas experiencing the highest level of new diagnoses in order to create relevant and culturally appropriate strategies.
- Facilitated, encouraged, and supported internal efforts to highlight faith-based and community leaders and providers in additional agency programs, including foster care and adoption, women's and maternal health.

Five Year Funding History:

Fiscal Year	Amount
FY 2018	$1,299,000
FY 2019	$1,299,000
FY 2020	$1,299,000
FY 2021 Enacted	$1,299,000
FY 2022 President's Budget	$1,334,000

Budget Request

The FY 2022 President's Budget request for the Partnership Center is $1,334,000, which is an increase of $35,000 above the FY 2021 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; maintain current staffing levels; and leverage new, innovative technology to accommodate additional faith-based and community partners.

OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH

Budget Summary

(Dollars in Thousands)

Office of the Assistant Secretary for Health	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Budget	FY 2022 +/- FY 2021
Budget Authority	283,986	290,551	302,038	+11,487
FTE	208	274	301	+27

Authorizing Legislation:.....PHS Act, Title II, Section 301
FY 2022 Authorization .....Permanent
Allocation Method.....Direct Federal

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 lead America to healthier lives. The OASH accomplishes its mission by providing leadership and coordination across the Department on various priority initiatives such as promoting health equity, addressing climate change, ending the HIV epidemic in America, healthcare transformation through disease prevention and health promotion, maternal health, immunization policy, and emerging public health challenges related to infectious diseases.

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, disparities, and health equity 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.

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

- Eight 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 2020 FTE	FY 2020 Final	FY 2021 FTE	FY 2021 Enacted	FY 2022 FTE	FY 2022 President's Budget
Immediate Office of the Assistant Secretary for Health	57	13,178	64	13,578	89	23,428
Office of Infectious Disease and HIV AIDS Policy	11	7,552	15	7,552	15	7,756
Office of Disease Prevention and Health Promotion	23	7,894	25	7,894	27	9,134
Office for Human Research Protections	24	6,243	24	6,243	24	6,412
Office of Adolescent Health	2	442	1	442	1	454
Public Health Reports	1	467	1	467	1	479
Teen Pregnancy Prevention	16	101,000	18	101,000	18	101,000
Office of Minority Health	39	58,670	57	61,835	57	61,835
Office on Women's Health	34	33,640	44	35,140	44	35,140
Office of Research Integrity (Non-Add)	*26*	*8,588*	*27*	*8,986*	*27*	*8,986*
Minority HIV/AIDS Fund	1	53,900	25	55,400	25	55,400
Embryo Adoption Awareness Campaign	-	1,000	-	1,000	-	1,000
Subtotal, GDM	**208**	**283,986**	**274**	**290,551**	**301**	**302,038**
PHS Evaluation Set-Aside	-	-	-	-	-	
OASH	-	4,285	2	4,885	3	7,885
Teen Pregnancy Prevention Initiative	-	6,800	-	6,800	-	6,800
Office of Climate Change and Health Equity	-	-	-	-	8	3,000
Subtotal, PHS Evaluations	**-**	**11,085**	**2**	**11,685**	**11**	**17,685**
Total Program Level	**208**	**295,071**	**276**	**302,236**	**312**	**319,723**

IMMEDIATE OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH

Budget Summary

(Dollars in Thousands)

Immediate Office of the Assistant Secretary for Health	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Budget	FY 2022 +/- FY 2021
Budget Authority	13,178	13,578	23,428	+9,850
FTE	57	64	89	+25

Authorizing Legislation……PHS Act, Title II, Section 301
FY 2022 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 includes the Office of the Surgeon General, the OASH-Office of the Chief Information Officer, Office of Science and Medicine, and 10 regional offices. 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 promoting health equity, addressing climate change, the *Ending the HIV Epidemic in the U.S.* initiative, 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. OASH serves as the lead in coordinating efforts that cut across departmental agencies with different legislative authorities. To effectively serve as a coordinating lead, OASH must be well versed on how legislative authorities and/or policy impact the ability of agencies to implement new areas.

The Office of the Surgeon General (OSG) is responsible for the management of the U.S. Public Health Service (USPHS) Commissioned Corps, including the USPHS Ready Reserve, and supports the Surgeon General serving as America's Doctor to communicate, engage, and provide tools to better prevent public health challenges and respond to public health emergencies. It is a priority for the Administration to strengthen and expand the mission and impact of the Office of the Surgeon General. When President Biden announced his nominee for Surgeon General on December 8, 2020, he noted that this Office would be charged with restoring "public trust and faith in science and medicine," necessitating the enhancement of the Office of the Surgeon General's role to be a public leader that restores public trust while addressing challenges that prevent people in America from living full, health, and safe lives.

The Office of Science and Medicine (OSM) contains the OASH Chief Medical Officer and the InnovationX unit. The InnovationX unit partners with scientists, public health experts, technologists, and designers to leverage emerging technologies and deliver evidence-based, data-driven solutions to drive better, more equitable health outcomes across America. Currently, InnovationX manages two programs: Kidney and Lyme Innovation Accelerator. The Kidney Innovation Accelerator (KidneyX), is a public-private partnership between HHS and the American Society for Nephrology (ASN) to catalyze innovation in the prevention, diagnosis, and treatment of kidney diseases. The Lyme Innovation Accelerator (LymeX), is a public-private partnership between HHS and the Steven & Alexandra Cohen Foundation (SACF) to strategically advance Lyme and tick-borne disease solutions in direct collaboration with Lyme patients, patient advocates, and diverse stakeholders across academia, nonprofits, industry, and government. Both Accelerator programs

utilize 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 and next-generation diagnostics for Lyme disease.

The Office of Regional Health Operations (ORHO) provides support for public health projects and events in the ten HHS regional offices and serves as liaison for the Secretary and Assistant Secretary for Health with Federal, State and local officials. Representing senior public health officials in the region, ORHO also serves as a central point of contact for public health activities for the regions, coordinating and partnering with other HHS operational division regional leads to support and assist with regional responses to public health and other national-level events. In addition, ORHO convenes meetings and works with regional and national associations and other public and private organizations to increase access to clinical, social, and public health services for all. Their role within the regions has continued to expand to include coordination of vaccine efforts, COVID-19 testing, and other key public health areas including HIV.

In November 2019, OASH established an OASH-Office of the Chief Information Officer (OASH-OCIO). In creating this office, OASH sought to address inconsistent and unmanaged information technology (IT) investments that burdened mission organizations with the specialized expertise required for IT management, including ensuring compliance with Federal Information Security Modernization Act (FISMA) and Federal Information Technology Acquisition Reform Act (FITARA). The OASH-OCIO functions as a subordinate IT entity that has accountability and reporting responsibility to the ASH, PDASH, and the HHS Office of the Chief Information Officer (HHS-OCIO).

Accomplishments in FY 2020 include:

- Led HHS efforts to combat the opioid and substance use epidemic through continued execution of a comprehensive strategy, advancing evidence based-interventions, supporting novel research, developing new guidelines, developing a detailed cross- departmental strategy to counter the growing methamphetamine abuse crisis, publishing a new guide for appropriate tapering or discontinuation of long-term opioid use, including leading Coordination of an Interdepartmental Opioid Rapid Response Team (ORRT);
- Continued implementation of *Ending the HIV Epidemic in the U.S.*, in coordination with CDC, HRSA, NIH, and IHS, among others;
- Oversaw execution of the modernization of the U.S. Public Health Service Commissioned Corps (Corps) implementing various new policies and procedures to ensure the Corps is more capable and better equipped for emergency response and humanitarian missions including the initiation of a trained and deployable Ready Reserve Corps to provide surge capacity in response to domestic and global public health emergencies;
- Led and coordinated COVID-19 testing efforts including Community Based Testing Sites and COVID-19 diagnostic testing efforts among Public Health Service agencies, state and local public health authorities, and private/public clinical laboratories;
- Spearheaded the development of a first-ever COVID-19 State Public Health Lab Supply Chain Dashboard and in collaboration with other agencies developed a “Risk Comparison Model” to project the 4- days and 7-days risk for developing COVID-19 across the country;
- Initiated and directed key collaborations with HHS partners to analyze actions taken across Operating and Staff Division in response to COVID-19 to determine suitable and permanent innovations and between the HHS Office of the Inspector General, Drug Enforcement Administration (DEA), CDC, and the Corps to address short-term public health and clinical needs following law enforcement closure of an illegal pain clinic;
- Between 2013 and 2020, Corps officers were deployed 9,629 times, contributing to 197,561

deployments days for 154 different missions. As of April 16, 2021, the Corps has deployed two-thirds of all officers in support of COVID-19 with 429,425 deployment days;

- Led efforts to gain a more comprehensive understanding of how organizations, networks, non-federal government agencies, and other relevant stakeholders operationally defined "resilience" in their respective components of the health system and to identify opportunities to strengthen the U.S. healthcare system, as a whole, through public-private partnerships in data sharing and comprehensive analytics;
- Continued federal interagency workgroup efforts to improve survival of patients with sickle cell disease by 10 years within 10 years;
- Led an HHS-wide response to Congress examining the reasons for higher rates of death by suicide in African American children compared to White children and authored an HHS Interagency Report to Congress on African American Youth Suicide outlining approaches to preventing suicide in children and youth;
- Convened experts from Federal agencies, non-profit organizations, and academia and consolidated a partnership with Milken Institute in order to develop a novel, empirical, data- driven, and reliable model to help identify, forecast, and prioritize critical health innovation gaps that need to be addressed (the Landscape Analysis Project);
- Developed a method for measuring innovation activity that includes collecting data on patent applications, public and private funding levels (including venture capital), clinical trials activity, and newly approved drugs, devices and biologics;
- Led KidneyX innovation efforts including the Kidney-COVID working group subcommittee on policy and processes to ensure appropriate care for patients with chronic kidney disease during the pandemic;

Five Year Funding Table

Fiscal Year	Amount
FY 2018	$11,678,000
FY 2019	$11,678,000
FY 2020	$13,178,000
FY 2021 Enacted	$13,578,000
FY 2022 President's Budget	$23,428,000

Budget Request

The FY 2022 President's Budget request for the IO is $23,428,000, which is $9,850,000 above the FY 2021 Enacted Level. With the FY 2022 Budget request, the OASH-IO will continue to lead, coordinate and support key Administration and Department initiatives, including addressing issues and gaps in health equity, addressing climate change, combatting the Nation's substance abuse epidemic and the misuse of pain medication, ending the *HIV epidemic in the U.S*. initiative, and developing plans and disseminating information on prevention and health promotion. The increased FY 2022 request, which includes an additional 25 FTEs, will support the OASH-IO in addressing new and/or expanded needs within the ORHO, OSG, OASH-OCIO, the InnovationX unit and will allow for a new policy unit within the OASH front office. FY 2022 funding will provide OASH-IO with needed support to address increased OASH administrative and inflationary costs, including ensuring funding to address IT security and compliance issues.

With five new FTEs, a policy unit will ensure sufficient expertise to provide support on all policy and/or legislative matters, essential to providing the ASH and OASH leadership with guidance on complex legislative and policy areas and timely assessments of emerging needs and requirements to determine programmatic direction. The policy staff will evaluate outcomes of existing policies, analyze the impact of proposed legislation, draft summaries explaining the changes to current law proposed by legislation for

use by both program staff and general audiences, present analyses, and propose recommendations to leadership. Having an OASH-based capacity to assess legislative authorities and/or policy impact will enhance the ability of OASH to develop and respond to policy inquiries from the Department and support agencies to take action on crosscutting priorities.

The FY 2022 budget provides additional funding for the ORHO for increased travel and contract support to address increased requests by regional partners and HHS for ORHO support, and staff training to be versed in areas requiring additional support. In addition, in FY 2022, OASH IO will hire one new FTE for the InnovationX unit to provide staffing essential to ensure OASH has the skills needed to support HHS in creating opportunities that leverage the unique expertise and levers of HHS to get clinical innovations to patients faster and identifying areas of public health need that may be overlooked by more immediate requirements. Increased funding for the OSG will support seven additional FTEs necessary to lead external engagements, and communications to advancing the Office's mission. The additional staff would allow the OSG to develop additional reports, public facing materials, external engagement, and communications to advance the Office's mission on matters including combating COVID-19, strengthening mental health, combating substance use disorders, and raising awareness of the tolls of social isolation and loneliness among others. Additionally, these resources would allow for new, effective forms of communication and engagement with the public to meet audiences through different mediums and messages on public health matters and more broadly establish a stronger connection and relationship between the Administration and the public.

As OASH IO efforts continue to expand, additional funding for OASH-OCIO is required to ensure systems are in place to prevent and mitigate cybersecurity/privacy breaches and provide IT support to OASH required for new programs. The FY 2022 budget for the OASH-OCIO provides baseline funding for consistent IT staffing of nine FTEs and some platform licensing to enable improvements in IT consistency and to address current and ongoing security and compliance issues. OASH-OCIO will hire nine key staff with the experience and technical knowledge required to support OASH's expanded IT needs, increased needs in managing Cyber Security threats, system development, requirements in IT service contracts to improve the quality of our systems, increased service desk & demand management, increased licensing requirements and Operations and Maintenance (O&M) costs. These funds will enable OASH-OCIO to establish enterprise platforms and processes, migrate mission workloads to a secure and common IT ecosystem, increase system development responsiveness and improve security control compliance.

The expansion of OASH programming also requires funding to support increased administrative and inflationary costs. Between CY 2020 and CY 2021, OASH received and implemented several new programs and will be further expanding in FY 2022 to include program and offices on climate change and health equity and health disparities. Based on the influx of new programs and projected program expansions, OASH has exceeded its capability to provide overall administrative support to an expanding workforce. Increased FY 2022 funding will enable OASH IO to budget for increased administrative costs required to identify, hire, and support new employees, address increased space needs, support additional budget, grant and contract management needs, and other basic needs including training, paying for computers, phones and other centralized functions. Funding will also support three additional FTE to provide administrative support to an increased OASH workforce.

OFFICE OF ADOLESCENT HEALTH

Budget Summary
(Dollars in Thousands)

Office of Adolescent Health	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Budget	FY 2022 +/- FY 2021
Budget Authority	442	442	454	+12
FTE	2	1	1	-

Authorizing Legislation.....PHS Act, Title XVII, Section 1708
FY 2022 Authorization.....Expired
Allocation Method.....Direct federal

Program Description and Accomplishments

The Office of Adolescent Health (OAH) was established in 2010 with the Teen Pregnancy Prevention (TPP) program as its central focus. Beginning in 2019, OAH was moved to within the Office of Population Affairs and now reports to and operates within OPA. OAH funds are used to support staff who oversee implementation of the TPP program and enable OPA to have an enhanced focus on adolescent health through all OPA activities.

Five Year Funding Table

Fiscal Year	Amount
FY 2018	$1,442,000
FY 2019	$1,442,000
FY 2020	$442,000
FY 2021 Enacted	$442,000
FY 2022 President's Budget	$454,000

Budget Request

The FY 2022 President's Budget request for OAH is $454,000, which is $12,000 above the FY 2021 Enacted Level. The FY 2022 budget request will be used to continue to support staff working within OPA to oversee implementation of the TPP program ensuring an enhanced focus on adolescent health throughout all OPA activities.

OFFICE OF DISEASE PREVENTION AND HEALTH PROMOTION

Budget Summary

(Dollars in Thousands)

Office of Disease Prevention and Health Promotion	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Budget	FY 2022 +/- FY 2021
Budget Authority	7,894	7,894	9,134	+1,240
FTE	23	25	27	+2

Authorizing Legislation.....PHS Act, Title XVII, Section 1701
FY 2022 Authorization Status.....Expired
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 the Office of the President's Council on Sports, Fitness and Nutrition (PCSFN) into ODPHP, creating a joint office to achieve complementarity and critical mass, enhance competencies, ensure translation of science to practice, and deliver consistent and reinforcing tools and messages to the public on physical activity, nutrition, and youth sports. This budget request supports the priority set forth by the Office of the Assistant Secretary for Health (OASH) to improve health equity and reduce health disparities through improved health promotion and disease prevention efforts. The COVID-19 epidemic has underscored the need to increase human resilience and build a more solid public health infrastructure with its foundation in science- and evidence-based disease prevention and health promotion policies and programs. As such, ODPHP continues to focus efforts in setting national health goals, supporting programs and initiatives, expanding healthy activities, and increasing availability of health promotion and prevention information across the health system and to the general public, to promote better health outcomes.

ODPHP provides leadership for a healthier America by initiating, coordinating, defining and supporting disease prevention and health promotion activities, programs, policies, and information through collaboration within Health and Human Services (HHS) and across Federal agencies as well as with external partners.

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 fifth iteration of the *Healthy People* objectives, called *Healthy People 2030*, was released in August 2020. The aspiration is that this next iteration will go even further and provide the framework for health in all policies and programs across all sectors of society.

In FY 2020, ODPHP continued to lead the development of *Healthy People 2030* (HP2030), culminating with the release of the objectives. Drawing on user feedback supporting a more streamlined and focused approach, HP2030 provides a significantly reduced number of national objectives (from about 1,200 measurable objectives in the previous iteration to 355 in HP2030). As part of the development process ODPHP managed 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. The Committee, which operated under the Federal Advisory Committee Act until its charter expired in May 2020, submitted its final recommendations to the Secretary prior to being disbanded. As part of the ongoing management of the *Healthy People* initiative, ODPHP also leads a

Federal Interagency Workgroup on *Healthy People*, including representation from agencies and offices across HHS and other Federal Departments.

As a part of the development of HP2030, ODPHP launched the redesigned microsite for *Healthy People 2030* on health.gov, which makes the *Healthy People 2030* information widely available and easily accessible. This innovative web resource gives users a platform from which to learn, collaborate, plan, and implement the national objectives. Partnering with CDC's National Center for Health Statistics (NCHS) and the HHS Office of Minority Health, ODPHP is increasing accessibility and use of disparities data to allow users to easily see where disparities exist among population groups, and to target their resources accordingly. The redesigned website also provides a database of evidence-based resources to help users find interventions and strategies to implement, in order to achieve the *Healthy People 2030* objectives. It features a resource for building customizable lists that can be used to curate objectives that are relevant to specific goals. For example, ODPHP used this tool to develop a list of all objectives directly related to the COVID- 19 pandemic to demonstrate how *Healthy People 2030* is adaptable to emerging health priorities.

In FY 2020, ODPHP completed a series of public webinar-based progress reviews of the *Healthy People* 2020 Leading Health Indicators (LHIs), which allowed OASH, in collaboration with the NCHS, the federal agencies that manage specific objectives, and community-based organizations, to demonstrate progress toward achieving the 10-year targets and identify areas needing additional work. On average, nearly 1,000 sites registered to attend each webinar. In FY 2020, ODPHP continued the development of the *Healthy People 2030* LHIs, which HHS launched in early FY 2021. The Healthy People 2030 LHIs are a small subset of high-priority *Healthy People 2030* objectives selected to drive action and focus resources toward improving health and well-being.

In FY 2021, ODPHP released the Overall Health and Well-being Measures (OHM) which are broad, global outcome measures intended to assess the HP2030 vision, *A society in which all people can achieve their full potential for health and well-being across the lifespan*. HP2030 includes eight OHMs that encompass well-being, healthy life expectancy, and mortality and health.

In FY 2021, ODPHP released an End-of-Decade Snapshot for Healthy People 2020, which provided a high-level overview of progress made in achieving the last decade's national objectives. In FY 2020, in partnership with NCHS, ODPHP initiated the development of the *Healthy People 2020* final review, which provided a more detailed end-of-decade assessment of progress made toward achieving the targets for the national objectives, and demonstrated where disparities persist among different population groups

<u>Dietary Guidelines for Americans</u>

ODPHP coordinates, the development, review, and promotion of the *Dietary Guidelines for Americans (Dietary Guidelines or DGA)* 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 underpins food assistance programs like the Older Americans Act Nutrition Program and regulations on food labeling and fortification. It also serves as the basis of the nutrition and food safety objectives in *Healthy People*.

The process to develop the ninth (2020-2025) edition began in FY 2017 and continued into FY 2021, with much of the costs borne by USDA, the administrative lead for this edition. USDA and HHS released the 2020-2025 Dietary Guidelines in December 2020. The Departments' approach to the 2020-2025 Dietary Guidelines focuses on life stages, including a new focus on women during pregnancy and lactation, and on infants and toddlers from birth to 24 months, as well as a continued focus on eating patterns. In FY 2019, the Departments published the list of topics and scientific questions to inform the review of evidence needed for updating the Dietary Guidelines. The 2020 Dietary Guidelines Advisory Committee began its work reviewing the scientific literature related to the selected topics and questions and submitted its

report to the Secretaries' of HHS and USDA on June 30, 2020. In partnership with the USDA Center for Nutrition Policy and Promotion, ODPHP staff supported the work of the Committee and its subcommittees as Designated Federal Officer representatives, federal liaisons for subcommittees, and logistical/administrative support of the Committee and co-led the development of the government's 2020-2025 Dietary Guidelines. To promote transparency, updated DietaryGuidelines.gov website provided regular updates on public meetings of the Committee, subcommittee progress, and detailed documentation of the evidence review process. On behalf of HHS, beginning in CY 2021, ODPHP will lead the processes and efforts for the next 5-year iteration of the Dietary Guidelines (2025-2030).

Physical Activity Guidelines for Americans

In FY 2019, the ASH 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 PCSFN. Accompanying the launch of the Guidelines was the Move Your Way communications campaign. Expansions to Move Your Way have focused on various populations highlighted in the Guidelines. Twenty related 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 and the physical activity objectives in *Healthy People*. Adherence to these easily met physical activity guidelines could reduce the US premature mortality by 10% and save over $100 billion annually in health care expenditures.

National Youth Sports Strategy

Presidential Executive Order 13824 issued in February 2018 tasked the HHS Secretary with developing the first National Youth Sports Strategy (NYSS). Released in FY 2019, the NYSS, provides a framework for uniting U.S. sports culture around a shared vision: that one day, all youth will have the opportunity, motivation, and access to play sports, regardless of their race, ethnicity, sex, ability, or zip code. Implementation of NYSS in FY 2020 focused on four key areas: communication and promotion of youth sports, partnership and stakeholder coordination, federal government coordination, and measurement of youth sports. ODPHP adjusted projects to adhere to CDC COVID-19 guidance on safe participation in physical activity and sports. Outputs include the development of sport-specific Move Your Way resources (to be released in FY 2021) and social media content to promote National Physical Fitness and Sports Month, which focused on how to safely stay active. ODPHP hosted six virtual regional workshops, connecting with stakeholders on how to safely reintroduce youth sports. ODPHP plans to hold four regional workshops in FY 2021 to connect local organizations with facilitator-driven networks and discussions in pursuit of the NYSS vision. The NYSS Champions program, a partnership opportunity designed to recognize organizations working in alignment with the NYSS vision, was launched at the September 2020 President's Council on Sports, Fitness, and Nutrition meeting. NYSS Champions will be leveraged to further the engagement with youth sports organizations and to continue promotion and dissemination of the NYSS. Additionally, tracking youth sports participation is included for the first time in *Healthy People 2030.*

Move Your Way

In 2018, ODPHP launched the Move Your Way (MYW) campaign. The campaign promotes the recommendations from the second edition of the Physical Activity Guidelines for Americans and supports HHS's strategic goal to protect the health of Americans where they live, learn, work, and play. The campaign now includes over 55 resources in English and Spanish on health.gov. Collaboration with federal partners and external stakeholders continues to be instrumental for the campaign and its associated outcomes. The campaign has been embraced by federal partners and external stakeholders. For example, in FY 2020 and FY 2021:

- The HHS Office on Women's Health partnered with ODPHP to expand the campaign's target audience to include women who are pregnant and postpartum;

- ODPHP entered into an interagency agreement (IAA) with NIH's NCI to support research for the campaign;
- ODPHP collaborated with NIH's National Institute on Aging, the Administration for Community Living (ACL), and CDC's Healthy Brain initiative to develop new resources for aging Americans;
- The USDA Food and Nutrition Service included Move Your Way materials in its WIC Works and SNAP-Ed resource portals;
- An Indian Health Service medical facility displays Move Your Way videos through its closed circuit TV system in waiting areas and patient rooms;
- ODPHP provided technical assistance to the University of Maryland, which used the campaign as part of a campus-wide wellness initiative; and
- The HHS Office of Minority Health featured the MYW campaign as part of National Minority Health Month.

ODPHP is promoting the Move Your Way campaign to consumers through community pilot tests and has completed 15 pilots between FY 2019-2021. ODPHP will support two additional pilots in FY 2022 that will focus on combining physical activity and healthy eating messages. ODPHP continues to evaluate the campaign and implementation strategies, to inform the Move Your Way Community Playbook, which provides community organizations and local health departments with the information and resources needed to implement the campaign locally.

health.gov

ODPHP fulfills its congressional mandate to provide reliable prevention and wellness information to the public through its website. Since 1997, ODPHP has been a key resource for online health information. In FY 2020, ODPHP completed 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. After PCSFN merged with ODPHP, ODPHP adapted the infrastructure project to also merge fitness.gov into health.gov, and completed this work in early FY 2021.

The new website infrastructure unified all these sites under health.gov, reducing ODPHP's digital footprint by approximately 50%. The reduction was accomplished by converting healthypeople.gov and healthfinder.gov to microsites on health.gov, removing content that is duplicative with other federal sites or outdated, and reducing the number of *Healthy People* objectives, thereby reducing the amount of web content required to support *Healthy People 2030*. The new infrastructure updated the technology supporting the site and improved the user interface for ODPHP's MyHealthfinder microsite, which customizes preventive services recommendations for users based on age, sex, and pregnancy status. In FY 2021 ODPHP also restructured its review process of MyHealthfinder content and established a federal stakeholder Steering Committee to diversify input, increase MyHealthfinder engagement, and provide insight for tool research and testing. The new infrastructure also features a robust microsite to support *Healthy People 2030* with an API that will automatically update the data for each of the 355 objectives with timely data.

Additional Move Your Way resources were added and housed on health.gov as ODPHP adapts and user-tests the information architecture to best meet the public's needs. In FY 2020 the NYSS Champions partnership initiative was integrated into health.gov through both static and dynamic tools to highlight organizations working in alignment with the NYSS vision.

Health Literacy

ODPHP continues to play a leadership role in improving health literacy. In FY 2020, ODPHP released an

updated definition of health literacy as part of *Healthy People 2030*. In FY 2021, ODPHP implemented promotion of the definition and began an assessment of health.gov's health literacy section to evaluate its content to align more closely to the updated definition.

ODPHP also partners with the Agency for Healthcare Research and Quality and NIH to support the HHS Health Literacy Workgroup. In FY 2020, the workgroup continued to support health literacy quality improvement projects for each HHS agency.

President's Council on Sports, Fitness, and Nutrition (PCSFN)
In 2018, Executive Order (EO) 13824, renamed and reestablished the PCSFN with the aim to expand and encourage youth sports participation. PCSFN is a federal advisory committee of up to 30 volunteer citizens who serve at the discretion of the President. Unless extended by the President, the current sitting Council will terminate on September 30, 2021.

PCSFN 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. PCSFN 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.

In FY 2020, the focus of PCSFN was to promote physical activity and health in the midst of the COVID-19 pandemic and to build partnerships with youth sports organizations to continue implementation of the National Youth Sports Strategy (NYSS). PCSFN participated in several community outreach events – both in person and virtually – to disseminate the NYSS at the community and regional level and to educate youth, parents, coaches, and mentors about the benefits of youth sports.

In FY 2020, PCSFN also reinstated the Science Board as a subcommittee. This group of 14 volunteer experts in physical activity, youth sports, and nutrition produced a formal report for PCSFN on the state of science and youth sports and additional educational materials on the benefits of youth sports. At a time when public health is even more in the spotlight than normal, PCSFN worked to ensure that social media and other virtual avenues were used to promote the importance of physical activity and nutrition for all Americans.

Five Year Funding Table

Fiscal Year	Amount
FY 2018	$7,894,000
FY 2019	$7,894,000
FY 2020	$7,894,000
FY 2021 Enacted	$7,894,000
FY 2022 President's Budget	$9,134,000

Budget Request:
The FY 2022 President's Budget request for ODPHP is $9,134,000, which is $1,240,000 above the FY 2021 Enacted Level.

The request allows ODPHP to ensure that its programs are best able to help the nation establish greater resilience through enhancements and quality improvements to the tools and resources that optimize implementation of its key programs – *Healthy People*, Dietary Guidelines, Physical Activity Guidelines for Americans, health literacy, and the health.gov platform. ODPHP will continue to support the

Administration and Department initiatives that lead to better systems of prevention and health promotion and result in individual empowerment. ODPHP will continue leveraging its key role in the coordination of activities among Federal partners, to enable HHS to effectively apply scientific, evaluative, and programmatic findings of the agencies for replication and dissemination government wide. Also, critical to ODPHP addressing extant and expanded requirements across the office's portfolio, the budget request will allow ODPHP to address critical staffing shortfalls in the areas of nutrition science and data analytics, increasing the total number of FTEs to 27 and ensure sufficient support for HHS' role of administrative lead for the next iteration of the Dietary Guidelines.

Healthy People

The FY 2022 request will support implementation of the decade's national, 10-year health objectives, *Healthy People 2030* (HP2030). ODPHP will expand its implementation activities aimed at increasing the reach and usefulness of *Healthy People 2030* and the Leading Health Indicators among a more diverse and expanded group of stakeholders across multiple sectors, reaching beyond our traditional health-sector partners. ODPHP will develop innovative, user-tested online tools and resources to facilitate stakeholder use of the national objectives to improve health in a myriad of communities. Both HP2030 and the LHIs are guided by and encompasses the Department and Administration priorities, such as achieving health equity and eliminating health disparities, to ensure alignment with key initiatives, leverage existing resources, and avoid duplication of efforts.

Dietary Guidelines for Americans

As HHS will have the administrative lead for the development of the 2025-2030 edition of the DGA, the FY 2022 budget request will support many activities including finalizing the topics and questions that the 2025-2030 Dietary Guidelines Advisory Committee (DGAC) will focus on, development of the infrastructure for and the selection of the DGAC, and planning for the first DGAC public meeting. Funds in FY 2022 will support the ongoing development of the website, DietaryGuidelines.gov, to enable public transparency of the whole DGA process as well as enhance the ongoing communications plan for implementation of the 2020-2025 DGA, including the ODPHP-developed toolkit for health professionals, to help them share key messages on healthful diets.

Physical Activity Guidelines for Americans/Move Your Way/National Youth Sports Strategy

The FY 2022 budget request will examine sustainability of ODPHP's continued work on the Move Your Way public information campaign, which ODPHP developed to promote the second edition of the Physical Activity Guidelines for Americans (PAG) and encourage Americans to get the physical activity they need to improve their health. ODPHP will explore ways to incorporate healthy eating messages into Move Your Way® campaign materials; and will also implement and evaluate two community pilots promoting the connection between physical activity and healthy eating on overall health. ODPHP will further develop and leverage partnerships to raise awareness of and encourage behavior change that will benefit the health of all Americans. ODPHP will implement the National Youth Sports Strategy (NYSS) through regional community workshops and its NYSS Champions partnership initiative. The request also will support the development of a midcourse report on the PAG, including a more detailed analysis of strategies to increase physical activity among older adults, to be released in FY 2023.

Health.gov and Health Literacy

The FY 2022 request will enable ODPHP to carry out its Congressional mandate to provide health information to professionals and the public. ODPHP will continue to improve health.gov and conduct user research to enhance its ability to deliver high-quality health information to key audiences and stakeholders in English and in Spanish. Additionally, ODPHP will continue to educate the public about the importance of health equity and health literacy; and conduct outreach and partnership-building to strengthen the impact of health literacy on departmental programs and initiatives. The request will allow ODPHP to promote

catching up on preventive services (due to delays during the COVID-19 pandemic) through enhancements on the MyHealthfinder tool.

President's Council on Sports, Fitness & Nutrition

The FY 2022 budget request will support the work of PCSFN to advise the President, through the Secretary of HHS, on programs and partnerships that recognize the benefits of youth sports participation, physical activity, and a nutritious diet in helping create habits that support a healthy lifestyle. This includes the PCSFN's work to continue supporting implementation of the NYSS and convening at least once per year, as is required by their charter. The PCSFN will serve as "health ambassadors" and will have the opportunity to inspire and lead the nation as we work toward recovery in the wake of the COVID-19 pandemic and the establishment of greater human resilience, as a result. ODPHP will also improve on and update PCSFN's programs for physical activity promotion, awards and recognition, and ensure alignment of these programs with the Physical Activity Guidelines for Americans and the Move Your Way campaign.

ODPHP– Key Outputs and Outcomes Table:

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2021 Target	FY 2022 Target	FY 2022 +/- FY 2021
I.b Visits to ODPHP-supported websites (Output)	FY 2020: 15,084,859 Target: 10.5 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 2020: 94% Target: 94% (Target Met)	40%	60%	+20%

PCSFN– Key Outputs and Outcomes Table:

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2021 Target	FY 2022 Target	FY 2022 +/- FY 2021
8.6 Number of social media impressions related to ODPHP's sports, physical activity, nutrition and other health promotion programs	FY 2020: 183,302,301 Target: 102 million (Target Exceeded)	101 Million	4.5 Million	-96.5 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 to health.gov and is increasing its use of social media vehicles, enhancing value to the public and professionals. *Healthy People* provides an online resource with multiple interactive tools for tracking and implementing national health objectives. The second edition of the Physical Activity Guidelines for Americans is promoted through the Move Your Way campaign, which provides resources online to increase the uptake of the guidelines. Outreach for the Dietary Guidelines is primarily web-based as well and ODPHP plans to update web content and resources in FY 2022 to support the uptake of the 10th edition. The online MyHealthfinder tool provides easy-to-understand, customized prevention recommendations to consumers. As the data reflects, 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 across all its programmatic areas. Such growth will provide resources that help Americans to be more effective 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 will allow ODPHP to continue developing user-centered information and web-based tools 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 states' 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 new decade's objectives—*Healthy People 2030*—use is expected to drop as states recalibrate their efforts to align with the national objectives, however, it is expected to again increase in FY 2022. The significant reduction in the number of objectives in Healthy People 2030, which was driven in large part by stakeholder input, is expected to improve the ease of use of the national objectives by states and others as they identify critical health priorities and develop programs to address those needs.

ODPHP is currently running a social media campaign as part of the Move Your Way pilot tests. As this campaign is the current driver of ODPHP's social media impressions related to ODPHP's sports, physical activity, nutrition and other health promotion programs, ODPHP anticipates a steep decrease in FY 2022 when these pilots end.

OFFICE FOR HUMAN RESEARCH PROTECTIONS

Budget Summary
(Dollars in Thousands)

Office of Human Research Protections	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Budget	FY 2022 +/- FY 2021
Budget Authority	6,243	6,243	6,412	+169
FTE	24	24	24	-

Authorizing Legislation.....PHS Act, Title II, Section 301
FY 2022 Authorization .....Permanent
Allocation Method.....Direct Federal

Program Description and Accomplishments

The Office for Human Research Protections (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 and maintains 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 (also referred to as the 2018 Requirements) 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 compliance date for the cooperative research requirement for approval by a single IRB of cooperative research projects that are conducted in the United States was January 20, 2020. The revised Common Rule 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 slowed certain types of research, while adding little in the way of protections for subjects, and (2) where needed, improving protections for subjects (particularly in terms of improved informed consent for higher-risk research).

Below are summaries of OHRP's ongoing programs:

- **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. Recent accomplishments and ongoing priority initiatives include the following:
  - In FY 2020, OHRP issued three key resources: guidance on the 2019 novel coronavirus disease (COVID-19), human subject regulations decision charts related to the 2018 Requirements, and guidance on elimination of IRB review of grant applications and proposals. In response to needs of the regulated community, OHRP also issued a determination of exception to the required use of a single IRB for certain HHS cooperative research subject to the 2018 Requirements.
  - As of April 2021, OHRP has issued an exception to the single IRB review requirements for certain HHS-conducted or -supported cooperative research activities subject to the 2018 Requirements during the COVID-19 public health emergency and guidance on maintaining consistency regarding the applicability of the 2018 or the pre-2018 Requirements. DPA has launched a strategic planning initiative to identify priorities for FY 2022 while proceeding with development of guidance on other key topics related to the 2018 Requirements.
  - DPA administers the process by which institutions submit assurances of compliance with HHS protection of human subjects' regulations and IRB registrations. In FY 2020, DPA processed 3,296 Federal-wide Assurance (FWA) approvals and 2,670 IRB registrations and expects similar numbers in FY 2021. At present, DPA is developing plans to modernize the technical tools and processes to support this responsibility.

- **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), an 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 institutional requests to support webinars and 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 the first half of FY 2021, OHRP launched phase one of the new *Human Research Protection Training*, an interactive 4-lesson online training program that provides foundational training on human research protections under the federal Common Rule at 45 CFR 46 to the research community. We plan to add one new lesson, new quiz questions, and more interactive elements in phase two planned for release in the last quarter. Due to restrictions imposed by the COVID-19 pandemic, outreach activities are primarily done virtually on electronic platforms. OHRP hosted the workshop *Simplifying Informed Consent* at the NIH Office of Extramural Research (OER) Regional Conference on October 30, 2020 and received 648 live views with another 1000 on-demand views through January 10, 2021. OHRP also supported numerous presentations at PRIM&R's AER20 conference in December 2020 and delivered another eight webinars to a variety of research institutions and federal funders of research until the end of March. In June 2021, OHRP will co-host a virtual 2-day Research Community Forum with the University of Texas Southwestern Medical Center covering topics including promoting diversity and supporting community engagement in research. To further facilitate inclusion and diversity in scientific research, OHRP plans to host a half-day workshop in August to advise investigators on how to enable inclusive research involving the native American populations. On September 24, 2021, OHRP will host its 4th Exploratory Workshop, *Review of Third-Party Research Risks: Is There a Role for IRBs?* OHRP continues its effort to educate the general public about research and protections in research participation through its *About Research*

Participation website. In support of the COVID-19 vaccine initiative to engage children, we released a video called *Research with Children: What Parents Need to Know*, in both English and Spanish. To promote public trust, we released a video called *Protecting Your Privacy in Human Research*. Last but not least, DED led and completed the effort to improve user accessibility and experience for the OHRP Regulation pages.

- During FY 2020, DED conducted two full day, in-person educational workshops (one with the NIH at their OER Regional Seminar in Phoenix, AZ in November 2019; one with St. John Medical Center in Tulsa, OK in October 2019). In addition, DED staff spoke at fourteen different events involving institutions including Public Responsibility in Medicine and Research (PRIM&R), the Society for Clinical Research Associates (SOCRA), the Collaborative Institutional Training Initiative (CITI), the Association of Clinical Research Professionals (ACRP), and the NIH, collectively reaching an audience of as many as 3,000 attendees. On April 28, 2020, OHRP supported a live webcast to provide OHRP Guidance in Response to COVID-19. The live event received over 2,500 views. The 3rd OHRP Exploratory Workshop "*Practical & Ethical Considerations for Single IRB Review*" took place on September 17, 2020 and received 1,453 live views. In February 2020, DED completed the project search engine optimization for the *About Research Participation* website on Google. As a result, the site experienced a 119% increase in the videos being viewed. OHRP added four videos in FY 2020. Finally, DED made improvements to the Luminaries Series webpage and added one new video on eConsent.

- **Division of Compliance Oversight (DCO)** is the division within OHRP that conducts compliance evaluations of research and institutions that conduct human subject research under the Federal Policy for the Protection of Human Subjects, as well as IRBs that review and oversee HHS funded human subject research. In FY 2021, DCO began work with a contractor to develop a new compliance activity tracking database and document management system using the OASH endorsed SalesForce platform. The Phase 1 database was launched in December 2020 and is continuing efforts to refine the system and migrate documents and data to the new system. The following describes three primary functions of DCO:
  - Conducts Compliance Evaluations and Investigations – 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, review of a number of IRB-approved protocols and consent documents, observation of an IRB meeting; and when this evaluation is conducted on-site at the institution, it includes interviews with key individuals from the institution's IRB and human research protections program. At the beginning of April 2021, DCO initiated its first site visit of an independent IRB, which is being conducted virtually. DCO also conducts investigations into alleged noncompliance with the Federal Policy for the Protection of Human Subjects. For-cause investigation include the same activities as a surveillance evaluation with a concentration on the alleged non-compliance. DCO currently has 11 active compliance cases.

- Incident report review and follow-up – Federal Policy for the Protection of Human Subjects require that institutions engaged in HHS-funded human subjects research have written procedures to ensure prompt reporting to OHRP of incidents such as unanticipated problems involving risks to subjects or others, any serious or continuing noncompliance with HHS' human subjects protection regulations or IRB determinations, or any suspension or termination of an IRB approval. DCO logs and reviews each report to determine whether the institution and study researchers' remedial actions are adequate to protect human research subjects. DCO communicates with the institution as needed until the incident is resolved. DCO reviews and logs approximately 800-1000 incident reports per year. In FY 2020, DCO received and reviewed over 900 incident reports.

- Evaluates Complaints – DCO reviews allegations (or "complaints") of noncompliance with Federal

Policy for the Protection of Human Subjects and determines whether the complaint involve HHS-funded research and if so, how to resolve the matter (e.g., conduct a for-cause compliance investigation). The majority of these complaints concern what complainants believe to be issues of non-compliance in human subject research. However, for various reasons, once the terms of our regulations are applied, the object of the complaint does not constitute non-compliance, and OHRP acknowledges receipt of the complaint and takes no action. For example, some complaints are about research that is not covered by the regulations enforced by OHRP, and other complaints are from individuals for issues that do not pertain to the requirements of our regulations. Generally, the source of complaints sent to OHRP include, but are not limited to, research subjects and their family members, individuals involved in the conduct of research such as investigators and study coordinators, institutional officials, journalists, or media. DCO evaluates and logs approximately 400-600 complaints per year. In FY 2020, DCO received over 420 complaints.

- **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. The committee has three meetings per year. Examples of recent issues discussed include the interpretation of public health surveillance under the revised Common Rule, the ethical concept of justice in 45 CFR part 46, the draft NIH Data Sharing and Management Policy, and Deceased Donor Intervention Research. In FY 2020, SACHRP approved five sets of recommendations. To date, one set of recommendations has been approved, with more anticipated from the March and July 2021 meetings.

- The HHS Strategic Plan highlights how HHS "works closely with … international partners to coordinate its efforts to ensure the maximum impact for the public." 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, 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. Strategic planning initiatives are underway to identify top policy-related priorities for FY 2022.

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 2018	$6,493,000
FY 2019	$6,493,000
FY 2020	$6,243,000
FY 2021 Enacted	$6,243,000
FY 2022 President's Budget	$6,412,000

Budget Request

The FY 2022 President's Budget request for OHRP is $6,412,000, which is $169,000 above the FY 2021 Enacted Level. At this level, OHRP will help ensure the successful implementation of the revised Common Rule (45 CFR Part 46). The final revised Common Rule includes numerous regulatory changes that require OHRP to develop new resources for the regulated community and to modify existing resources.

In response to President Biden's Executive Orders to advance scientific development and the capacity to rapidly respond to healthcare crisis including COVID-19, and to advance racial equity and support for underserved communities, OHRP requires a robust level of workforce and program support to adequately provide the guidance and educational support, as well as compliance oversight for HHS-funded and supported research activities. Arguably, such efforts are essential pre-requisites for sound and ethical scientific research, and the FY 2022 President's budget request will enable OHRP to support the mandates included in the President's Executive Orders.

OFFICE OF INFECTIOUS DISEASE AND HIV/AIDS POLICY

Budget Summary
(Dollars in Thousands)

Office of Infectious Disease and HIV/AIDS Policy	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Budget	FY 2022 +/- FY 2021
Budget Authority	7,552	7,552	7,756	+204
FTE	11	15	15	-

Authorizing Legislation..... PHS Act, Title II, Section 301; and PHS Act, Title XXVI, Section 2101
FY2022 Authorization.....Permanent; and Expired
Allocation Method.....Direct Federal

Program Description and Accomplishments
The Office of Infectious Disease and HIV/AIDS Policy (OIDP) provides 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 and implementing HHS and federal government-wide policies, programs, and activities related to vaccines and immunization, HIV/AIDS, viral hepatitis, sexually transmitted infections (STIs), vector-borne, and other emerging infectious diseases of public health significance, as well as blood and tissue safety and availability in the United States. OIDP fulfills this role by undertaking department-wide planning, internal assessments, and policy evaluations 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 (FACs) and workgroups. These FACs span the Office's portfolio and include the Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA), Presidential Advisory Council on HIV/AIDS (PACHA), Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PACCARB), National Vaccine Advisory Committee (NVAC), and Tick-Borne Disease Working Group (TBDWG). Through the development of formal reports and recommendations, these committees and workgroups improve the health of the nation.

OIDP provides an online hub for vaccine information across the federal government for consumer audiences. OIDP provides the public a trusted source of information to answer questions and inform decision-making. In 2020, this platform raised awareness of the importance of vaccines by leveraging Twitter Chats, HHS blog posts, and other social media outlets in collaboration with other HHS offices and agencies.

During FY 2020, OIDP created a suite of communication materials to support HHS Catch-Up to Get Ahead efforts to vaccinate children who may have missed a vaccination during the COVID-19 pandemic. Other efforts included creating new content on vaccination rates in specific communities, and the development of graphical gifs to illustrate the concept of community immunity and simply explain how vaccines work to prevent infections. In addition, OIDP conducted a content review to ensure accuracy throughout the site. The online website was accepted into the Vaccine Safety Network, a site devoted to providing credible information about the safety of vaccines.

Health Equity is a focus across OIDP's entire portfolio. Populations disproportionately impacted by these infectious diseases are the same populations that are disproportionately impacted by COVID-19. OIDP has trusted relationships with disproportionately impacted communities and has worked with them to advance awareness of infectious diseases, including COVID-19, and their prevention and treatment, to reduce disparities. In FY 2020-21, OIDP coordinated the development of four National Strategic Plans (2021-2025) – HIV National Strategic Plan, Viral Hepatitis National Strategic Plan, STI National Strategic Plan and Vaccines National Strategic Plan. These Plans were publicly released in December 2020 through January 2021. Each plan has goals on reducing health disparities, advancing health equity by addressing social determinants of health and other structural barriers to health, and indicators to monitor progress. The five federal advisory committees that OIDP manages provide recommendations to advance health equity and inform the National Strategic Plans, including recommendations on vaccine confidence, immunization equity and addressing HIV stigma and discrimination. OIDP also administers the Minority HIV AIDS Fund (MHAF) which is a unique, annual discretionary fund developed to improve racial and ethnic HIV-related health disparities.

COVID-19

OIDP has played important roles in the COVID-19 response in several ways. In FY 2021, OIDP is coordinating HHS COVID-19 vaccine communications through its leadership of the federal Vaccine Communicators Group and participation in the HHS COVID-19 and Flu Public Education Campaign. OIDP communicates with stakeholders and partners on COVID-19 resources, vaccines, messages and policies to promote COVID -19 equity. In FY 2020, OIDP led the development and implementation of the *Catch up to Get Ahead Childhood Vaccination Campaign*. OIDP represents OASH on the CDC ACIP and FDA VRBPAC committees and on committees formed in response to COVID-19 related Executive Orders. In FY 2021, the Presidential Advisory Committee on Combating Antibiotic Resistant Bacteria has reported on the impact of the COVID-19 pandemic on antimicrobial use, resistance and stewardship. Additionally, the National Vaccine Advisory Committee has approved a report with recommendations for improving COVID-19 vaccination efforts. In FY 2021, HIV.gov launched a page on COVID-19, which is continuously updated with content on Federal resources and how COVID-19 affects people with HIV.

Ending the HIV Epidemic in the U.S.

The *Ending the HIV Epidemic in the U.S.* (EHE) initiative is a bold national plan created to end the HIV epidemic in the U.S. by 2030. The initiative leverages critical scientific advances in HIV prevention, diagnosis, treatment, and outbreak response by coordinating the efforts of HHS agencies and offices. 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 which also have a role in addressing the HIV epidemic.

In support of EHE, OIDP, through the MHAF, launched the America's HIV Epidemic Analysis Dashboard (AHEAD), allowing the public transparent access to EHE data and illustrating the nation's progress toward meeting the initiative's goals. AHEAD visualizes data for six HIV indicators at the national and local level for each of EHE's 57 priority geographic areas, including 48 counties, Washington, D.C., and San Juan, Puerto Rico, where more than 50 percent of new HIV diagnoses occurred in 2016 and 2017, and seven states with a disproportionate burden of HIV in rural areas. An interactive version of the Dashboard enabling users to filter indicator and national demographic data was launched February 2021.

Minority HIV/AIDS Fund
OIDP administers the Minority HIV/AIDS Fund (MHAF) on behalf of OASH. The purpose of MHAF 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 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 working to improve the efficiency, effectiveness, and impact of federal investments in HIV programs, activities, and services for racial and ethnic minorities.

HIV National Strategic Plan (Formerly National HIV/AIDS Strategy)
The HIV National Strategic Plan (HIV Plan), released in January 2021, is the culmination of two years of work with a broad spectrum of input, including a federal steering committee of subject matter experts from six federal departments and 12 HHS agencies and offices, as well as stakeholders from the HIV community. OIDP staff solicited public comments through a request for information (RFI) published in the Federal Register and held both in-person and virtual listening sessions to hear from HIV stakeholders about their experiences living with HIV and their recommendations about the federal government's response to HIV.

The HIV Plan focuses strongly on the syndemic—a set of linked health problems involving two or more health problems that excessively affect a population—including HIV, STIs, viral hepatitis, and mental health and substance use disorders. Importantly, this plan was developed concurrently and in alignment with the next iteration of the Hepatitis National Strategic Plan and the inaugural STIs National Strategic Plan. Together, these three plans aim to enhance coordination of the activities of federal agencies and diverse community stakeholders to reduce morbidity and mortality, stigma, discrimination, health inequities, and disparities; improve outcomes; and fortify a strengthened public health and healthcare infrastructure to support prevention, diagnosis, care, and treatment across these infectious diseases.

A companion Federal Implementation Plan will be developed by the federal partners in FY 2021, detailing the actions federal agencies will perform to meet the goals and indicator targets outlined in the Strategic Plan.

Prevention through Active Community Engagement (PACE) Program
In FY 2020, The PACE Program was established in three HHS regions (IV, VI, IX) as part of "Operation Change the Map" to coordinate with federal and non-federal partners in the regions and facilitate community engagement towards reaching the goals of the EHE initiative. The PACE Program is MHAF funded and comprised of the U.S. Public Health Service (USPHS) officers stationed in Atlanta (Region IV), Dallas (Region VI), and Los Angeles (Region IX). Several of the Officers are bi-lingual, enabling the teams to increase engagements with the Latinx/Hispanic communities. In FY 2020, the PACE Program established enhanced partnerships with 15 State Departments of Health and over 30 EHE geographic areas by disseminating best practices for HIV testing, prevention and treatment. Their work included increasing awareness of COVID-19 prevention, testing and care issues and the use of HIV-self testing and telehealth to help achieve the goals of the EHE initiative. On October 1, 2020, the PACE Program was reorganized into OIDP to improve alignment with the HIV, STI and Viral Hepatitis activities.

Presidential Advisory Council on HIV/AIDS

The Presidential Advisory Council on HIV/AIDS (PACHA) provides advice, information, and recommendations to the Secretary regarding programs, policies, and research to promote effective prevention, treatment, and care of HIV disease and AIDS, including common co-morbidities. With the creation of EHE, PACHA has an opportunity to contribute to this historic federal effort by providing recommendations to the Secretary regarding the development and implementation of the EHE initiative, in addition to the HIV National Strategic Plan (formerly the National HIV/AIDS Strategic Plan).

In FY 2020, PACHA convened four full council meetings, two in-person and two virtually, which helped members develop impactful recommendations for the Department's review and consideration. PACHA typically convenes in Washington, D.C., but in an effort to bring *"PACHA-to-the-People",* PACHA convened in Miami, Florida in October 2019. Miami is a priority area indicated in *EHE and* making the effort to convene in a location other than Washington, D.C. reinforced the opportunity for PACHA to serve as a conduit between HHS and community stakeholders. In Miami, PACHA focused on *Ending the Epidemic* in Florida and Puerto Rico. In February 2020, PACHA returned to Washington, D.C., and the meeting focused on *EHE* jurisdictional plans, HIV and women, addressing stigma both globally and domestically, and HHS' *Ready, Set, PrEP* national program. While in Florida and Washington, D.C., PACHA members and federal partners visited community-based organizations to learn firsthand about the best interventions that make the biggest impact on the ground.

Due to the COVID-19 pandemic, PACHA has convened virtually to ensure the work continues but safely. PACHA convened virtually in June 2020, August 2020, December 2020, and March 2021. Topics included ensuring Health Equity with the Ending the HIV Epidemic in the U.S. (EHE) initiative; HIV and COVID-19 and implementing EHE; HIV and women; addressing stigma both globally and domestically; addressing the needs of the community; HHS' *Ready, Set, PrEP* national program; and the syndemic of HIV, Viral Hepatitis, and STIs.

Since March 2019, PACHA has submitted the following resolutions for the Department's review and consideration:

- Resolution in Support of the *Ending the HIV Epidemic in the U.S.;*
- Resolution in Support of Future Funding *for Ending the HIV Epidemic in the U.S.;*
- Resolution in Support of Robust Community Engagement in the *Ending the HIV Epidemic in the U.S.* Initiative;
- Resolution in Support of Innovation to *End the HIV/AIDS Epidemic in the U.S.*;
- Resolution in Support of FY 2021 Budget for *Ending the HIV Epidemic in the U.S.;*
- Resolution on the Impact of COVID-19 on HIV Prevention and Treatment;
- Resolution to Increase Uptake in the *Ready, Set, PrEP* Program;
- Resolution on 1557 Rule;
- Resolution in Appreciation for Beginning Ending the HIV Epidemic in the U.S. Initiative; and
- PACHA Resolution on Ensuring Equity and Justice in Ending the HIV Epidemic in the U.S.

The resolutions, and additional information about PACHA, can be found on the PACHA page on HIV.gov: https://www.hiv.gov/federal-response/pacha/about-pacha

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 has previously included monitoring and reporting on progress towards reaching the goals of the National HIV/AIDS Strategy (2015-2020).

HIV.gov
HIV.gov is a leading source of comprehensive information about the *Ending the HIV Epidemic in the U.S.* initiative and other HIV federal policies, programs, and resources. It is also the source for information on HHS's MHAF-funded *Ready, Set, PrEP* program. HIV.gov also includes, a new resource - America's HIV Epidemic Analysis Dashboard (AHEAD) used to measuring our nation's collective progress in reaching EHE goals.

HIV.gov provides cross-governmental coordination and technical leadership, working to ensure that HIV messaging and resources are consistent across federal programs and reach target audiences with maximum impact. As part of this effort, HIV.gov convenes the Federal HIV Web Council, provides updates on COVID-19 and HIV, and coordinates key HIV Awareness Days and other events. Further, HIV.gov reports through multiple platforms on breaking scientific and policy news from conferences and events to educate multiple audiences. In addition, in partnership with the NIH, HIV.gov is the new dynamic home of the federal HIV medical practice guidelines.

From July 2020 to March 2021, the website had more than 5.7 million unique visits. HIV.gov's Services Locator, which provides geolocation-based information on testing, care, PrEP, and other services was used over 92,000 times. HIV.gov's Locator widget is on more than 1,200 websites and has been used more than 27,000 times. It was recently updated, yielding an 85.3% increase in views and the HIV.gov website is in transition to become a Progressive Web App to increase security and functionalities. HIV.gov has also created standards for web hosting/Internet security that serve as models for HHS.

Immunization Leadership and Coordination
OIDP advances health promotion and disease prevention priorities using vaccines in the United States by providing policy leadership, outreach and coordination on vaccine and immunization-related activities among federal agencies and non-federal stakeholders. OIDP works with partners to develop strategies to increase vaccine uptake, encourage informed vaccine decision-making, and bridge gaps in implementation of immunization programs. OIDP leads the coordination of federal immunization activities, as exemplified by its management of the federal interagency vaccine work group and vaccine communicators call, and collaborates with immunization stakeholders that include state and local governments, non-governmental health groups, healthcare providers, health insurers, vaccine manufacturers, and the public to achieve the goals outlined in the *Vaccines National Strategic Plan 2021–2025* (Vaccine Plan).

In FY 2020, OIDP led the coordination of flu communication research, messaging, and communication materials to ensure HHS and other federal partners were aligned in approach and did not replicate communications materials. OIDP also co-led The Vaccine Confidence Meeting with CDC to create an inventory of work being done to advance vaccine confidence and identify knowledge gaps–such as the relationship between vaccine confidence and acceptance—to enable the community's use of evidence-based approaches to improve vaccine coverage. OIDP continues to grow the vaccine confidence community and will provide meeting opportunities in FY 2021 to expand the work of these professionals.

Leveraging partnerships with government and non-government stakeholders, OIDP administers or provides technical assistance for programs that fill gaps in vaccination implementation practices or policies. Recent examples include collaborating with HHS agencies, professional organizations, healthcare

systems, and advocacy organizations to lead a coordinated effort to increase awareness of and promote catch-up immunizations for children who fell behind in their schedules because of the COVID-19 pandemic; engaging in communication and engagement activities to reach adolescents for human papillomavirus-associated cancer prevention with vaccination in rural and faith-based communities; and partnering with the American Medical Group Association to develop and implement strategies to improve immunization rates in large healthcare systems.

OIDP supports several federal advisory committees, including the Advisory Committee on Immunization Practices, managed by CDC; the Advisory Commission on Childhood Vaccines, managed by HRSA; and Vaccines and Related Biological Products Advisory Committee, managed by the FDA.

Federal Interagency Vaccine Working Group

OIDP convenes and leads the Federal Interagency Vaccine Working Group (IVWG) to coordinate and enhance collaboration among federal government offices and agencies on immunization. IVWG serves as the steering committee for the development of the national strategic plan and accompanying implementation plan, reviews the progress of the national immunization program, and supports the work of the National Vaccine Advisory Committee.

National Adult and Influenza Immunization Summit

OIDP co-chairs, with CDC and the Immunization Action Coalition, the National Adult and Influenza Immunization Summit (NAIIS), an adult immunization coalition of over 700 partner organizations. NAIIS supports work groups to disseminate and promote best immunization practices for adults. The NAIIS conducts weekly informational partner calls, hosts webinars on topics of current interest, and convenes in-person annual summit meetings. Although the COVID-19 pandemic resulted in postponement of the 2020 meeting, NAIIS conducted additional web-based meetings to disseminate information on COVID-19 vaccine development, safety and effectiveness, storage and handling, allocation and distribution, and administration strategies.

Vaccines National Strategic Plan

The Vaccines Plan describes immunization priorities across the lifespan and provides a 5-year framework for a cohesive national program. The plan's goals are to advance vaccine research and development, ensure vaccine safety, promote vaccine confidence, increase access to vaccines, and collaborate in global immunization efforts. The plan includes objectives, strategies under each objective, and representative indicator with targets to monitor progress. In 2021, OIDP, in partnership with federal and non-government experts in the field and stakeholders, is developing a compendium plan for implementation of the Vaccines Plan.

National Vaccine Advisory Committee
OIDP manages the National Vaccine Advisory Committee (NVAC) to advise the Assistant Secretary for Health on vaccine safety, effectiveness, supply, and other issues. NVAC has taken on addressing contemporary challenges associated with vaccine confidence and hesitancy, as well as immunization equity, and COVID-19 vaccination. These initiatives serve as the basis for current and future NVAC considerations on the development and use of COVID-19 vaccines. NVAC's recommendations were taken into consideration in the development of the Vaccines Plan.

Viral Hepatitis National Strategic Plan
OIDP has the lead role in coordinating national efforts and informing policies to prevent, diagnose, and treat viral hepatitis in the United States. OIDP led development of the next iteration of the Viral Hepatitis National Strategic Plan released in January 2021. To ensure that the development of the Plan was inclusive, OIDP convened and led a joint HIV-viral hepatitis federal steering committee, which met regularly and was comprised of representatives across HHS as well as other federal departments. The steering committee's work was 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 an RFI published in the Federal Register. The steering committee oversaw the development of the Viral Hepatitis National Strategic Plan: A Roadmap to Elimination, including vision, goals, objectives, strategies, indicators and quantitative targets to eliminate viral hepatitis as a public health epidemic by 2030. A companion Federal Implementation Plan will also be developed in 2021, detailing the actions federal agencies commit to implement in the Plan.

Viral Hepatitis Implementation Group
OIDP convenes and leads the Viral Hepatitis Implementation Group (VHIG), with more than 20 federal agencies and offices, including HHS, HUD, DOJ, and the VA. Through the VHIG, OIDP monitors and reports on progress implementing the prior National Viral Hepatitis Action Plan (add dates), leads coordination and leveraging of viral hepatitis initiatives across the federal government, and will monitor and report on federal implementation of the current Viral Hepatitis National Strategic Plan.

Hepatitis C Medicaid Affinity Group
OIDP 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 that reach populations highly impacted by Hepatitis C. Through this project, participating states develop and implement action plans to increase the number and percentage of Medicaid beneficiaries diagnosed with hepatitis C who 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, and numerous states have implemented hepatitis elimination plans. 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. The Hepatitis C Medicaid Affinity group initiative is ending in FY 2021.

Sexually Transmitted Infections National Strategic Plan
OIDP led the development of the first *Sexually Transmitted Infections (STI) National Strategic Plan (2021-2025)*, which was released in December 2020. STIs have risen dramatically since 2013 and are widely recognized as a public health epidemic. The STI National Strategic Plan contains quantitative targets and actionable strategies to reach the targets. OIDP convened a federal steering committee which met regularly and included five subcommittees (primary prevention, secondary prevention and care, disparities and coordination, education and communication, and indicators). The steering committee guided the

development of the STI National Strategic Plan and was comprised of five departments and 16 HHS agencies and offices. Its work was also informed by extensive public comment, which has been received through nationwide listening sessions and an RFI published in the Federal Register. The steering committee oversaw the development of the STI Plan, including its vision, goals, objectives, strategies, indicators, and quantitative targets. OIDP developed and launched the hhs.gov/STI website, the public facing portal for the STI National Strategic Plan. OIDP will work with federal partners to develop an implementation plan of activities.

OIDP ensured that the development of the HIV National Strategic Plan, the Vaccines National Strategic Plan, the Viral Hepatitis National Strategic Plan and the STI National Strategic Plan was coordinated and aligned as appropriate, and will do so as well as with the development of the implementation plans and the monitoring of their progress.

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, and OIDP is at the forefront of this mission.

In June 2019, Congress passed the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 (PAHPAIA). Section 209 of this legislation states that the HHS Secretary shall submit to Congress a report containing recommendations related to maintaining an adequate national blood supply. OIDP supported the HHS Secretary, who serves as the HHS Blood Safety Director, in obtaining input from subject matter experts and the public for the development of these recommendations. OIDP also supports the ASH, in facilitating departmental and interagency activities to maintain safety and availability of the nation's blood and tissue supply as part of the COVID-19 response efforts. OIDP also manages the Biennial HHS National Blood Collection and Utilization Survey (NBCUS), which is the primary method for gathering data on blood collection and utilization in the US.

Federal Advisory Committee on Blood and Tissue Safety and Availability
The Federal Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA) advises, assists, and makes recommendations to the Secretary of HHS, through the ASH, on issues related to the safety of blood, blood products, organs, and tissues. During the 50th meeting of the ACBTSA in April, 2019, public and private-sector stakeholders in organ transplantation explored 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. At the 51st meeting of the ACBTSA, held in late August 2020, key stakeholders from across the nation presented on lessons learned during the COVID-19 pandemic, analyzing the strengths and weaknesses of the blood community and blood supply. The committee discussed recommendations to improve the blood community's response to future public health emergencies.

Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria
OIDP manages the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PACCARB). The PACCARB provides information and recommendations to the Secretary regarding programs and policies intended to reduce or combat antibiotic-resistant bacteria that may present a public health threat and improve capabilities to prevent, diagnose, mitigate, or treat such resistance. Activities include support and evaluation of the implementation of Executive Order (EO) 13676, the National Strategy for Combating Antibiotic-Resistant Bacteria (Strategy) and the National Action Plan for Combating Antibiotic-Resistant Bacteria (Action Plan), and the performance of duties consistent with those assigned to the Advisory Council in section 505(b) of Public Law 116-22, PAHPAIA. While primarily established under EO 13676 in 2014, the PACCARB was codified in June 2019 under the PAHPAIA mandate, which formally places the

issue of antibiotic-resistance and this council's work as an issue of national security as well as a public health threat priority. In accordance with both the EO and PAHPAIA authorities, the PACCARB coordinates and works very closely with the interagency CARB Task Force – the federal entity that develops and implements the goals and corresponding objectives included in the CARB National Action Plan.

In FY 2021, the PACCARB formed two working groups to explore two distinct topics: the ubiquity of new modalities of healthcare in response to the global pandemic, including telehealth, and its impact on antibiotic access and use for human and animal health; and the role of AMR in Inter-Professional Education and ways to incentivize its further inclusion in One Health-centric curricula and programs. The reports from both working groups are due for presentation at their upcoming June 2021 public meeting, which will also begin exploring policy options to operationalize the topic of AMR in One Health as it pertains to the COVID-19 pandemic, the integration of environmental justice and ecosystems, and as a continued activity, monitor and report on mortality data due to secondary antibiotic resistant-pneumonia infections.

As evidence of the PACCARB's influence from both activity and membership, their website has averaged ~1,000-2,000 new user access views on a monthly basis.

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 (P.L. 114-255, Section 2062, and Tick-Borne Diseases) are met. The latest report to the HHS Secretary and Congress regarding findings and recommendations for the federal response to tick-borne diseases was released in January 2021.

For the 2020 report, OIDP managed ten TBDWG subcommittees comprising approximately 65 federal and public members. Eight of these reported 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. Each of these reports to the larger committee informed the development of the final report to Congress. Though the remaining two subcommittees (the public comment subcommittee and the federal inventory subcommittee) did not develop specific subcommittee reports, they also informed the final report. OIDP will identify new members to work on the 2022 TBDWG Congressional Report.

Vector-Borne Strategy

The development of a national strategy on vector-borne diseases including tick-borne diseases was mandated by Congress through Section 404 of P.L. 116-94, the Further Consolidated Appropriations Act.

The Kay Hagan Tick Act, in honor of former Senator Kay Hagan following her death from the tick-borne Powassan disease, requires HHS to develop this strategy. OIDP leads this endeavor in collaboration with federal partners.

To inform the national strategy's development, HHS will solicit stakeholder and public input regarding strategic goals, benchmarks, and gaps. Key topics include duplicative federally funded programs; opportunities to enhance coordination of data collection; research, and development of diagnostics, treatments, and vaccines; and other related activities across HHS and other federal departments.

Five Year Funding Table

Fiscal Year	Amount
FY 2018	$7,802,000
FY 2019	$7,802,000
FY 2020	$7,552,000
FY 2021 Enacted	$7,552,000
FY 2022 President's Budget	$7,756,000

Budget Request

The FY 2022 President's Budget request for OIDP is $7,756,000, which is $204,000 above the FY 2021 Enacted Level.

At this funding level, OIDP will 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 ASH. OIDP's primary areas of emphasis include, but are not limited to, vaccines and immunizations; HIV/AIDS; viral hepatitis; tick-borne diseases; STIs, antibiotic-resistant bacteria, COVID 19 and other emerging infectious diseases of public health significance.

The FY 2022 Budget allows OIDP to provide leadership and support on vaccine hesitancy and confidence programs and activities. In addition, OIDP will prioritize vaccination activities across the lifespan in the United States and monitor the strategies developed for the recently released National Vaccine Strategic Plan. OIDP will also lead efforts on developing implementation strategies and monitoring progress on the National Strategies on HIV, Viral Hepatitis, and STIs and continue to lead the five federal advisory committees it manages to ensure all committee meetings, recommendations, reports and other deliverables are executed throughout the year.

OFFICE OF RESEARCH INTEGRITY

Budget Summary
(Dollars in Thousands)

Office of Research Integrity[5]	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Budget	FY 2022 +/- FY 2021
Budget Authority	8,558	8,986	8,986	-
FTE	26	27	27	-

Authorizing Legislation……PHS Act, Title II, Section 301
FY 2022 Authorization …….. Permanent
Allocation Method …….. Direct Federal

Program Description and Accomplishments
Since its establishment 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's 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. Under ORI's 2005 regulation, recipients of PHS funds must foster an environment that promotes the responsible conduct of research (RCR), 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). ORI is funded through an Interagency Agreement with NIH.

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 promote 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 proceedings in order to develop and support HHS findings of research misconduct and proposed administrative actions. The purpose of the administrative actions is remedial, and may include imposition of supervision requirements for the researcher's PHS grants and contracts; exclusion of the researcher's participation in any PHS advisory capacity; and/or the federal-wide suspension or debarment of a researcher for a period of time ranging from one year, up to a lifetime.

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 (OIG) to educate institutional officials about how to deal with misconduct that involves fabrication/falsification/plagiarism of data, violations of human subjects' protections, and/or fraud. ORI convenes periodic meetings with representatives from other agencies and departments responsible for handling allegations of research misconduct (e.g., NIH, the National Science Foundation, and Department of Veterans Affairs). ORI also coordinates efforts when an allegation of research misconduct involves funds from the PHS and another federal department or agency.

Despite the pervasive disruptions of the COVID-19 pandemic, ORI's work has continued unabated. Accomplishments in FY 2020 include:

- Responded to 204 allegations through coordination with their respective institutions as needed.
- Provided technical assistance and guidance to institutions responding to allegations of research

[5] Funded through an interagency agreement with NIH

misconduct in over 360 instances.

- Closed 72 cases, including 11 with findings of research misconduct.
- Continued reporting (begun in 2018) to the National Institutes of Health (NIH), case closures with concerns for inappropriate research practices that did not meet the legal threshold for misconduct findings, averaging about 2 per month. Through its authorities, NIH can apply grant restrictions to institutions that may not be responsible stewards of research funds.
- Completed security and compliance review of a commercial, off-the-shelf secure document transfer capability. This will enable institutions to send electronic case files directly, via an HHS-validated file transfer system that will reduce the burden and improve security for both ORI and the transmitting institutions. ORI anticipates rollout by Summer 2021 as the single sign-on capability is enabled.
- Assured that over 5,100 institutions worldwide attested to having research misconduct policies in place in order to receive PHS funds for research. Monitored their annual reports of research misconduct and their compliance with their own policies for handing allegations of research misconduct.
- Received over 945,000 visitors to the ORI website, with over 2 million-page views from users in more than 136 countries.
- Promoted interactive videos on research integrity in basic and clinical research and many of ORI's 18 infographics, drawing over 100,000-page views.
- Hosted 15 senior institutional officials virtually to discuss key issues they encounter as related to research integrity. Used the perspectives to develop a 3-part virtual meeting for FY 2021. Combined with engagement with stakeholder organizations, such discussions enhances ORI's ability to tailor educational and outreach efforts.
- Offered virtual-only workshops and meetings in early March 2020 and worked with the grantees to postpone their events because of COVID-19 restrictions.
- Offered frequent social media and regular blog postings throughout the year, as well as monthly email updates. Twitter followers increased by approximately 14% in FY 2020.
- Disseminated three new grant Funding Opportunity Announcements seeking meritorious applications for conducting research on, and convening conferences related to, research integrity. To date, ORI grants have yielded over 200 peer-reviewed publications.
- Launched an interagency agreement with the Air Force Research Laboratory (AFRL) in support of Purdue University, to harness artificial intelligence tools to detect falsified digital images or data related to investigative work. NIH has joined ORI in refining and further developing this effort.
- Published a Request for Information soliciting best practices on sequestration of evidence, an area in which institutions are particularly weak. Inadequate sequestration leads to case closures because the evidence is compromised. Prepared Guidance for OASH leadership consideration in FY 2021.
- Fulfilled 21 Freedom of Information Act (FOIA) requests.

In FY 2021, ORI expects these activities to continue at approximately the same levels. Some rescheduling and reformatting for virtual presentation occurred in FY 2020 because of COVID-19 safety precautions. Some planned FY 2020 grant-funded activities were postponed due to the COVID-19 pandemic, but they all have been extended at no cost into the second quarter of FY 2021. We believe we will resume the usual cadence of in-person training, grants performance (conference grants in particular), and engagement with stakeholders in FY 2022. Anticipating continued pandemic-related disruptions into at least the third quarter of FY 2021, ORI will hold a series of four RCR and research integrity webinars in lieu of in-person workshops. Despite these disruptions, ORI staff have sustained momentum in case closures, even while providing guidance and instruction to new ORI staff. In addition, ORI has begun to update its case tracking system, and in FY 2021 will add features to improve file access and facilitate records management. ORI also has begun work on enhancements to its assurance database, envisioning an online system to systematically review institutional policies for handling allegations of research misconduct.

New staff, particularly those in DEI, have brought new approaches and insights into the way in which ORI presents itself on the web as well as through its training, and in FY 2021 DEI will focus on updating and overhauling educational materials. Results from the 2019-2020 assessment of the current scientist investigator job series (health scientist administrator) are informing 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.

ORI arranged a virtual workshop in FY 2020 for ORI and NIH colleagues to view and interact with the developmental artificial intelligence (AI)-driven image analysis tool led by Purdue University. Given the promising utility of the tool in analyzing research grant submissions for potential image falsification, NIH contributed additional FY 2020 and FY 2021 funding to this project through the IAA each fiscal year. ORI anticipates a product ready for evaluation and assessment by late 2021.

In FY 2020, in order to focus resources on the development of the AI-driven tool, ORI refocused investments, reducing the grants portfolio by half, and creating an opportunity for ORI to launch a fresh grants approach in FY 2021 with a focus on replicable models for the responsible conduct of research. For example, a new grant on research data management approaches should yield insights for both investigative procedures and future grant opportunities in FY 2022 and beyond.

Five Year Funding Table

Fiscal Year	Amount
FY 2018	$8,558,000
FY 2019	$8,558,000
FY 2020	$8,558,000
FY 2021 Enacted	$8,986,000
FY 2022 President's Budget	$8,986,000

Budget Request

The FY 2022 President's Budget request for ORI is $8,986,000, which is flat with the FY 2021 Enacted Level. At this level, the budget will support staff needed to conduct investigative and educational activities, including managing the contracts and grants needed to support the updating, development, and dissemination of educational information regarding research integrity. Funds also support training activities aimed at increasing awareness and technical skill in conducting research misconduct proceedings at PHS-funded research institutions. ORI will continue to accelerate its database modernization project with a module to implement enhanced reporting capabilities and case tracking and handling through investment in 21st century technology, including artificial intelligence. ORI will continue to inform NIH about issues of concern in oversight investigations, refer potential criminal behavior to the HHS OIG, participate in NIH regional conferences, and provide presentations for NIH grants management staff.
A preliminary analysis of ORI's findings of research misconduct in FY 2020 revealed that over $100 million in previously awarded PHS research funding was involved. These funds represent lost opportunities, often multiple years of grant dollars squandered by researchers whose work was not trustworthy. Too often the misconduct involved collaborators' research and published papers which must be retracted or corrected. ORI is pursuing more rigorous analysis of the direct and indirect impacts of its research misconduct oversight. Even if ORI cannot recover these funds, ORI's actions against investigators can prevent further waste of research funds on fabricated, falsified, or plagiarized research.

With the FY 2022 Budget, ORI plans to expand ORI website content (https://ori.hhs.gov/) to include more

just-in-time training modules and guidance for research integrity officials and those teaching the responsible conduct of research. ORI will continue to improve and maintain a robust intranet portal and tracking system. ORI's planned website improvements synchronize with OASH's broader efforts to examine web structures, features, and displays, with an eye toward improving efficiency and ease of use. The ORI website provides information about ORI, misconduct case findings, research integrity education, and policies and procedures. Digital/web-based communication is a critical tool for ORI to accomplish program goals and support program activities, as demonstrated by the COVID-19 pandemic experience. The shift to interactive virtual workshop presentations in 2020 and early 2021 provided helpful information about modernizing information and educational materials for ORI stakeholders. To improve efficiency of allegation intake, ORI plans to 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 task while performing other duties of their positions.

In FY 2022, ORI currently plans support of three Boot Camps to train research integrity officers (RIOs) and their legal counsel. Attesting to the national importance of a training program that helps institutions comply with 42 C.F.R. 93, ORI maintains a waiting list for RIOs and institutional counsel interested in such training. When institutions handle the process poorly, ORI is unable to fulfil its regulatory mandate by making research misconduct findings against respondents. In addition, ORI experts provide lectures and technical consultation at the annual Association for Research Integrity Officers (ARIO) meetings. ARIO is an independent, professional association that provides a forum for RIOs across the country to convene. ARIO meetings have moved online in a variety of platforms through at least the second quarter of FY 2021. ORI also collaborated with NIH and Duke University to offer three senior institutional officials roundtables in the second quarter of FY 2021. These sessions grew out of the discussions with 15 such officials in 2020.

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

In FY 2022, ORI plans to support six new grant awards for exploration of critical questions and innovative approaches related to the promotion of research integrity, responsible conduct of research, and the proper stewardship of PHS research funds. ORI envisions implementing multi-year project periods in FY 2022 to more precisely address high-priority gaps in knowledge. ORI plans to host a conference for current and former grantees in 2022 for the purpose of enhancing the distribution and diffusion of knowledge generated by its grant program.

-Grants Award Table:

Grants (whole dollars)	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Budget
Number of Awards	8	4	6
Average Award	$100,000	$100,000	$100,000
Range of Awards	$30,000-$150,000	$50,000-$600,000	$50,000-$150,000

PUBLIC HEALTH REPORTS

Budget Summary
(Dollars in Thousands)

Public Health Reports	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Budget	FY 2022 +/- FY 2021
Budget Authority	467	467	479	+12
FTE	1	1	1	-

Authorizing Legislation: ……PHS Act, Title III, Section 301
FY 2022 Authorization……Permanent
Allocation Method……Direct federal, Contract

Program Description and Accomplishments

Public Health Reports (PHR) is the official journal of the Office of the U.S. Surgeon General (OSG) and the U.S. Public Health Service (USPHS). PHR is the only general public health journal in the federal government. It has been published since 1878, making it one of 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.

PHR is a scholarly, MedLine-indexed, peer-reviewed scientific journal. It is published on a continuous basis electronically and bimonthly in print. Articles in the journal cover three main areas: public health practice, public health research, and viewpoints and commentaries. The journal also publishes 1 to 4 supplemental issues per year. The journal supports HHS priorities by: facilitating the movement of science into public health policy and practice to positively influence the health and wellness of the American public; publishing scholarly manuscripts that inform and advance public health policy and practice by demonstrating actionable results; and publishing evaluations of public health programs that describe models of practice that can be replicated by others and that describe lessons learned. PHR has made great improvements recently in reducing the time from receiving a manuscript to publication, increasing the diversity of content, expanding readership (electronic downloads up by 72% CY20 vs CY19).

The journal provides great value to its target audiences: the public health community, including USPHS Commissioned Corps officers, public health practitioners and policy makers at the local, state, federal, and international levels, and practice-based academics and students. Many issues include a perspective or commentary by the Surgeon General or senior leaders of OASH and HHS. The COVID-19 pandemic is proving the critical importance of having a platform by which public health information can be shared rapidly with healthcare providers and the public health community. This includes the state, local, and tribal governments that depend on HHS for top cover and guidance related to public health policy recommendations and procedures that can be implemented to protect our populations.

Five Year Funding Table

Fiscal Year	Amount
FY 2018	$467,000
FY 2019	$467,000
FY 2020	$467,000
FY 2021 Enacted	$467,000
FY 2022 President's Budget	$479,000

Budget Request

The FY 2022 President's Budget request for Public Health Reports is $479,000, which is $12,000 above the FY 2021 Enacted Level. This funding will allow the Public Health Reports to continue to be published covering pressing public health matters and distributed to key audiences.

TEEN PREGNANCY PREVENTION

Budget Summary

(Dollars in Thousands)

Teen Pregnancy Prevention	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Budget	FY 2022 +/- FY 2021
Budget Authority	101,000	101,000	101,000	-
FTE	16	18	18	-

Authorizing Legislation..... Current Year
FY 2022 Authorization .....Annual
Allocation Method.....Direct Federal

Program Description and Accomplishments

The Teen Pregnancy Prevention (TPP) program is a discretionary grant program to replicate 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 to support demonstration projects to develop, refine, and test additional models and innovative strategies to prevent teenage pregnancy. It is administered by the Office of Population Affairs within the Office of the Assistant Secretary for Health.

Through the TPP program, youth receive the education and supports needed to prevent teen pregnancy and promote positive adolescent development. Competitive grants and contracts supported through TPP are awarded to public and private entities to fund medically accurate and age appropriate programs that reduce teen pregnancy and support the Federal costs associated with administration and evaluation of program activities. OPA also provides TPP grantees with ongoing training and technical assistance to ensure high quality programming and evaluation.

TPP grants to replicate evidence-based programs aim to have a significant impact on improving the health of adolescents and reducing teen pregnancy and sexually transmitted infections by saturating communities with effective programs. TPP replication grants ensure that areas of greatest need are targeted to promote equity in preventing teen pregnancy and STIs and replicate with fidelity effective programs that are culturally appropriate, age appropriate, medically accurate, and trauma informed.

TPP demonstration grants support the development of new and innovative approaches as well as rigorous evaluation of promising approaches. TPP demonstration grantees are rigorously evaluating innovative approaches that have already demonstrated project merit, feasibility of implementation, and readiness for conducting a rigorous evaluation. TPP demonstration grantees are also establishing and supporting multidisciplinary networks of partners to develop and test innovative interventions in several priority areas where investment in innovation and testing is necessary to make an impact on preventing teen pregnancy and STIs, including (1) juvenile justice; (2) foster care/child welfare; (3) caregivers; (4) expectant and parenting youth; (5) youth with disabilities; (6) youth access to and experience with sexual health care; and (7) youth engagement.

Five Year Funding Table

Fiscal Year	Amount
FY 2018	$101,000,000
FY 2019	$101,000,000
FY 2020	$101,000,000
FY 2021 Enacted	$101,000,000
FY 2022 President's Budget	$101,000,000

Budget Request

The FY 2022 President's Budget request for the Teen Pregnancy Prevention program is $101,000,000, which is flat with the FY 2021 Enacted Level. The FY 2022 request funds the final year of programming for TPP grantees competitively selected in FY 2020; provides program support for the grantees, including programmatic and evaluation training and technical assistance; and covers program operating costs.

Key Outputs and Outcomes Table

Program/Measure	Year and Most Recent Result/Target for Recent Result Summary of Result	FY 2021 Target	FY 2022 Target	FY 2022 +/- FY 2021
9.1 Number of youth served by the TPP Program	FY 2020: 173,065 Target: 240,000 (Target Not Met)	100,000	210,000	+110,000
9.2 Number of TPP Program formal or informal partners	FY 2020: 3,223 Target: 3,650 (Target Not Met)	1,600	2,500	+900
9.3 Number of Intervention Facilitators provided new or follow-up training	FY 2020: 6,418 Target: 3,700 (Target Exceeded)	3,700	3,700	+0
9.4 Percent of youth receiving at least 75% of available TPP programming	FY 2020: 84% Target: 80% (Target Exceeded)	80%	80%	+0
9.5 Mean percentage of the effective program being implemented as intended	FY 2020: 92% Target: 95% (Target Not Met)	90%	90%	+0

Grants Award Table

Grants (whole dollars)	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Budget
Number of Awards	95	79	79
Average Award	$900,000	$900,000	$900,000
Range of Awards	$300,000 - $1,860,000	$500,000 - $1,860,000	$500,000 - $1,860,000

OFFICE OF MINORITY HEALTH

Budget Summary
(Dollars in Thousands)

Office of Minority Health	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Budget	FY 2022 +/- FY 2021
Budget Authority	58,670	61,835	61,835	-
FTE	39	57	57	-

Authorizing Legislation..... PHS Act, Title XVII, Section 1707
FY 2022 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, demonstration 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.

OMH Mission and Vision

- OMH's mission is to improve the health of racial and ethnic minority populations through the development of policies and programs that help eliminate health disparities.
- OMH's vision is to improve health outcomes for racial and ethnic minority communities through leadership that strengthens the coordination and impact of HHS initiatives, programs, communities, and stakeholders across the United States.

OMH facilitates the coordination of efforts across the government to address and eliminate health disparities. OMH is the lead office for promoting adoption of the National Standards for Culturally and Linguistically Appropriate Services (National CLAS Standards), which supports the strengthening of cultural competence among healthcare providers throughout the nation.

OMH Strategic Priorities

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:

- Supporting states, territories and tribes in identifying and sustaining health equity-promoting policies, programs and practices.
- Expanding the utilization of community health workers to address health and social service needs within communities of color.
- Strengthening cultural competence among healthcare providers throughout the country. Specific OMH focus areas are: (1) Prevention (physical activity and nutrition); (2) Clinical conditions, such as substance use disorder, HIV, maternal health, sickle cell disease and trait, diabetes (including prevention of peripheral artery and kidney disease), Lupus, Alzheimer's, and cancer prevention; and (3) Individual social needs and social determinants of health.

In addition, OMH plays a critical role in leading the Department's efforts to promote health equity, including supporting the Health Disparities Council and the Health Equity Task Force. OMH also makes important contributions to the Department's response to public health crises, including the HHS response to the COVID-19 pandemic, 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 healthcare system to improve their health.

FY 2020 Key Accomplishments

OMH FY 2020 accomplishments support the HHS strategic goals as described below.

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:

- Supported free continuing education e-learning program courses. During FY 2020, nearly 88,000 health professionals and students enrolled in OMH-supported courses and earned an estimated 376,679 continuing education credits toward their continuing education licensure requirements. OMH's new behavioral health curriculum had 21,431 health professionals and students enroll in the program with 53,081 continuing education credits earned.
- Launched development of the Culturally and Linguistically Appropriate Services (CLAS) in Maternal Health Care e-learning curriculum. The program is designed for providers and students seeking knowledge and skills related to cultural competency, person-centered care and implicit bias across the continuum of maternal health care.
- Launched development of Cultural Competency Deployment Refresher e-learning course for officers of U.S. Public Health Service Commissioned Corps. This course is designed to provide all Commissioned Corps officers an opportunity to take an abbreviated version of ThinkCulturalHealth's disaster preparedness e- learning module prior to their deployment.
- Collaborated with the U.S. Public Health Service Commission Corps and conducted one training session for Commission Corps officers on implementing the National CLAS Standards.

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

- On September 17, 2020, OMH sponsored a virtual symposium: *Advancing the Response to COVID-19: Sharing Promising Programs and Practices for Racial and Ethnic Minority Communities.* A total of 9,575 people registered for the symposium and more than 3,600 people attended. An OMH webpage hosts a closed-captioned recording of the symposium. The webpage received 2,420-page views and 2,319 unique visits in 2020.

- OMH supported the HHS COVID-19 information dissemination response using social media and digital communications to encourage audiences to practice social distancing while remaining virtually connected to resources to help maintain their physical, mental, and emotional wellness. OMH also partnered with CDC to provide translation of COVID-19 materials into the Pacific Island languages of Marshallese, Tongan and Chuukese.
- OMH funds 14 policy demonstration initiatives that support 83 grants and cooperative agreements. In FY 2020, OMH identified 26 Evidence Informed Practices (EIP) among those grants and cooperative agreements. EIPs differ from 'evidence-based' approaches, which only reference evidence from academic research. Scholars have defined EIPs as the use of research, expertise and experience that is already available and has been tested, tried and true. EIPs can be used to design health promotion programs and activities after reviewing information on what has worked for similar programs in the past. It provides OMH the ability to identify potential benefits, harms and costs of programs and interventions. The following are examples of OMH initiatives and identified EIPs:
- The **Partnership for Achieving Health Equity (PAHE)** program is intended to demonstrate that partnerships between Federal agencies and organizations with a nationwide or regional reach, can efficiently and effectively do one of the following: improve access to and utilization of health services; develop innovative models for managing multiple chronic conditions; increase the diversity of the health workforce; and, increase data availability and utilization of data.
  - The University of Chicago, Pritzker School of Medicine, implements an innovative 6-month group visit and text messaging (GV) program in health centers in rural and underserved healthcare areas across eight mid-west states to improve clinical outcomes among individuals with uncontrolled diabetes. Sustainability efforts are evident in that 57% of health centers that completed the initial interventions, continued their diabetes GV programs, and have expanded the model to other health conditions/diseases (i.e. tobacco cessation GV).
  - Northeastern Vermont AHEC implemented a multi-pronged program to increase student engagement, participation, and interest in Science, Technology, Engineering and Mathematics (STEM) related activities. Multi-pronged program includes 1) Strong Partnerships, 2) Mentoring/Coaching, 3) Family Outreach/Support, 4) Paid Student Internships, and, 5) Celebrating success. This partnership framework was identified as a model practice at Vermont School District. As of June 2020, the program resulted in a steady improvement in participant retention rates from 68% to 85% among hard to reach student populations. Approximately 1,400 unduplicated individuals benefitted from program activities in Year 3 of the initiative.
- The **National Workforce Diversity Pipeline (NWDP) program** seeks to address health disparities among racial and ethnic minorities by supporting network of institutions, focused on demonstrated commitment and capacity to establish pipeline programs to increase minority and disadvantaged students' awareness of, and pursuit in, the areas of health care and behavioral health and increase the availability of STEM education programs.
  - Medgar Evers College (MEC) implemented the Health Careers Pipeline Project (HCPP); a program designed to increase high school and college student engagement, participation, and pursuit of STEM and health-related majors. College student participants have received bachelor's degrees in STEM related areas as follows: 23.5% nursing, 24.0% biology, 24.0% psychology, 15.7% computer science, and 13.4% math.
  - Wake Forest University developed and implemented a multi-faceted program and curriculum that has increased student engagement and participation in STEM related activities. Results for program alumni include: 81% currently enrolled in health/biomedical science 2- or 4-year program; and 36% both enrolled in health and biomedical science 2- or 4-year program and employed in the health/biomedical science workforce.

- The **Empowered Communities for a Healthier Nation Initiative (ECI)** focuses on preventing opioid abuse, increasing access to opioid treatment and recovery services, reducing the health consequences of opioid misuse; reducing obesity prevalence and disparities in weight status among children and adolescents; and, reducing the impact of serious mental illness and improving screening for serious mental illness at the primary care level.
  - The City of Huntington implemented a Quick Response Team (QRT) model to address/reduce the number of opioid overdoses. The QRT is comprised of a paramedic (EMS), a counselor/recovery coach, a law enforcement officer, and a faith-based community member. The QRT visits the individuals within 48 hours of an overdose to provide support and assistance in entering treatment. The project has realized a 25% reduction in overdoses since its implementation. The Huntington QRT was selected by the Bureau of Justice Assistance (BJA) as a National "Mentor-Site for First Responder Diversion" Programs.
  - Boston Medical Center implements Project RECOVER (Referral, Engagement, Case management and Overdose prevention Education in Recovery) which employs Peer Recovery Coaches. The first goal of Project RECOVER is to link, engage, and retain people who have an opioid use disorder in outpatient MOUD (medication for opioid use disorder). The peer recovery coaches continue to assist recoverees in making transitions to continuity of treatment services and remain in treatment programs and MOUD. To date, 92% of recoverees have remained in treatment and scheduled/kept appointments.
  - Community Prevention Partnerships of Berks County (CPP) adapted the evidence based Eat, Play Grow curriculum and program model to ensure it was culturally relevant to the targeted participants, more than 90% of whom are Hispanic. The adapted curriculum includes bilingual Promotors & Community Outreach workers; weekly in-home sessions and activities; community activities with families (cooking demos, supermarket trips); physical exercise; and, community engagement/partnerships. Significant changes were noted among participants from intake to completion: increase in fruit consumption (30% to 47%); increase in vegetable consumption (9% to 31%); decrease in simple carbohydrate consumption (35% to 17%); and, decrease BMI among participants ages 2-19 (26% to 18%).
- The **OMH Hepatitis B Demonstration Initiative** supports the identification and development of model comprehensive hepatitis B programs that include, strategic partnerships between community-based organizations servicing communities at-risk to departments of health, perinatal hepatitis B programs safety net providers, research centers, and healthcare facilities that have capacity to deliver widespread vaccination, scale-up testing, care and link/provide treatment services.
  - Regents of the University of California-Davis implements the END B project which seeks to end the transmission of the Hepatitis B virus (HBV) from the perinatal period throughout the lifespan. This project has optimized Electronic Health Systems to identify ethnicities at-risk for HBV by adding prompts to providers to order the 3-key serologic tests. Pilot test resulted in over 80% of patients being screened for Hepatitis B virus.
- The **State Partnership Initiative to Address Health Disparities (SPI)** is intended to demonstrate that partnerships in which: state offices of minority health/health equity and state health agencies, or tribes and tribal health agencies/organizations play a significant role, can efficiently and effectively improve health outcomes in selected geographical hotspots and address health disparities that affect minorities and disadvantaged populations.
  - From FY 2015 to FY 2020, the Nez Perce Tribe implemented the University of Arizona's Evidence-Based Program, BASIC Tobacco Intervention Skills for Native American Communities (BASIC) to impact commercial tobacco use among Native American youth and reduction of commercial tobacco use among Native American adults residing on the Nez Perce Reservation. The percentage of local Native American youth that reported using any commercial tobacco (within the past 30

days) declined from 30.6% in 2015 to 27.8% in 2017. Female youth saw a dramatic decline in the percentage reporting commercial tobacco use in 2017 (20.7%) when compared to 2015 (35.8%). By the time of the 2018 survey, the smokeless tobacco prevalence rate on the Nez Perce Reservation declined to 32.7% from 42.4% in 2015.

- During National Minority Health Month, OMH led the HHS observance activities focused on the steps the nation can take every day in and around the home to stay mentally healthy and physically active, consistent with the social distancing guidelines to stop the spread of COVID-19. Social media dedicated to National Minority Health Month achieved a total reach of over 17.9 million, gained OMH a total of 956 followers, received 6,894 engagements and yielded almost 650,000 impressions. The National Minority Health Month microsite garnered 5,446 unique visits during the observance month in 2020, an increase of 176% over 2019.
- OMH is leading multiple efforts to improve the lives of those living with Sickle Cell Disease, (SCD) which affects 100,000 Americans, the overwhelming majority of whom are African American and Hispanic.
- OMH collaborated with the Centers for Disease Control and Prevention to further support the expansion of the CDC Sickle Cell Data Collection Program from two states to seven states, which will help identify needs for improved clinical care and targeted resources.
- OMH commissioned the National Academies of Sciences, Engineering, and Medicine to convene an interdisciplinary expert committee to develop the nation's first consensus report and strategic plan for addressing SCD. The report was issued in September 2020. The plan includes recommendations for increasing awareness and funding, addressing stigma, developing team-based systems of care, creating clear treatment guidelines, and training healthcare providers.
- OMH awarded two grants designed to help improve the lives of those affected by SCD in FY 2020. OMH awarded a $1.25 million grant for a demonstration project to evaluate the effectiveness of financial incentives for providers in increasing hydroxyurea prescribing and decreasing emergency department visits for children with sickle cell disease. In addition, OMH made a $1 million award to develop and implement a national sickle cell disease clinical data collection platform and create a new sickle cell learning community.
- In November 2019, OMH and the Health Resources and Services Administration (HRSA) launched the Sickle Cell Disease (SCD) Training and Mentoring Program (STAMP) to identify motivated primary care providers and equip them with the appropriate knowledge, skills, and co-management support to care for adult patients living with SCD. The free telehealth program provides trainings on the basics of SCD care and includes a pilot program encouraging primary care providers to co-manage SCD patients with hematologists. Attendance at the 12 STAMP sessions averaged more than 50 participants/session, and included physicians, advanced practice providers, and other healthcare workers.
- OMH funded a SCD special supplement in Annals of Emergency Medicine to raise awareness about SCD and increase the knowledge of emergency physicians in order to improve quality of care. This open-access supplement was published in September 2020 and distributed to 38,000 emergency medicine physicians and trainees.
- OMH has bolstered its social media presence on Twitter, Facebook, Instagram, and YouTube. For FY 2020, OMH has obtained 9,787 new followers across all social media platforms and has posted a total of 5,481 messages. In FY 2019, OMH achieved a total social media reach of over 182 million compared to approximately more than 200 million in FY 2020. Additionally, OMH achieved a total of 6,738,802 social media impressions in FY 2020 compared to 5,111,186 in FY 2019, resulting in an increase of 31%.
- OMH supports the OMH Knowledge Center Library, which has a collection of reports, books, journals, and media along with health information in 40 languages. The database currently

contains 69,414 records. This includes both print and electronic formats. Overall, a total of 58,488 items have been electronically linked to digital content. This represents approximately 84.7 percent of the total database collection.

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

- In collaboration with the CDC's Geospatial Research, Analysis, and Services Program (GRASP), OMH is building a Minority Health Social Vulnerability Index (MH SVI) from the CDC SVI by:
  - expanding racial/ethnic categories and include additional language data (e.g., top 5 common languages other than English spoken at home) to better understand community needs and tailor resources and outreach;
  - adding two themes to the CDC SVI: a) health care facilities and b) chronic conditions known to associate with adverse COVID-19 outcomes to understand COVID-related issues and impact at the county level; and
  - building a dashboard with maps and charts that reflect these six themes for geographic visualization.
- The collaboration between the Office of Minority Health (OMH) and the U.S. Department of Housing and Urban Development (HUD) Jobs Plus Initiative, OMH-HUD Community Health Worker Place-based Approach to Health (CHW PATH) program, began its second year at the end of FY 2020. During Year 1 (FY 2020), the Housing Authority of Baltimore County (Baltimore, Maryland) and the Housing Authority of the City of Los Angeles (Los Angeles, California) successfully recruited, hired and trained four CHWs (two at each site). CHWs conduct health promotion activities in public housing communities. During Year 2, the CHW PATH program will continue to engage the two initial sites, and will expand to include three additional public housing communities in Akron, OH, Chicago, IL, and New Orleans, LA. Year 2 also includes program evaluation and development of a toolkit to support future dissemination of this model.

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

- In collaboration with the Food and Drug Administration's Office of Minority Health and Health Equity's (FDA OMHHE), OMH is leading a Lupus Clinical Trial Diversity Initiative to increase outreach, education and awareness of opportunities to participate in lupus clinical trials (CTs) among minority populations nationally. This initiative builds upon OMH's grant program to address the lack of diversity in lupus clinical trials, the National Lupus Training, Outreach and Clinical Trial Education Program. OMH and FDA OMHHE will use the initiative to identify model strategies for partnering with other federal and non-federal organizations to improve racial and ethnic minority representation in clinical trials.
- OMH developed and hosts the Compendium of Federal Datasets Addressing Health Disparities, a free online resource of publicly available data, relevant to research and programs aiming to reduce health disparities by exploring the relationship between socioeconomic factors and the social determinants of health. The compendium is the product of the Interdepartmental Health Equity Collaborative (IHEC), a partnership of 10 HHS agencies and the following federal departments: Veterans Administration, Agriculture, Justice, Labor, Interior, Commerce and Education.
- OMH identified three promising practices from OMH's American Indian/Alaska Native Health Disparities Grants in the following areas: implementation of a motor vehicle crash injury surveillance system used to modify traffic laws and enhance safety; correction of racial misclassifications of state-based surveillance systems; and development of a Cultural Orientation Training that led to a significant increase in knowledge of culturally appropriate care.

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 2020 include:

- OMH's Performance Improvement and Management System (PIMS) provides support to OMH and OMH grantees through the Evaluation Technical Assistance Center (ETAC) and through 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 completed a FY 2020 Report to Congress Update on the HHS Disparities Action Plan. This report highlighted the implementation of the Action Plan elements in FY 2109 and FY 2020, with particular attention to the following three HHS priority areas: (1) the opioid crisis; (2) maternal health; and (3) COVID-19 response and recovery.

Five Year Funding Table

Fiscal Year	Amount
FY 2018	$56,670,000
FY 2019	$56,670,000
FY 2020	$58,670,000
FY 2021 Enacted	$61,835,000
FY 2022 President's Budget	$61,835,000

Budget Request

The FY 2022 President's Budget request for OMH is $61,835,000, which is flat with the FY 2021 Enacted Level. At this level, OMH will continue to provide leadership for policies, programs, and resources that improve health outcomes, reduce disparities and promote health equity for racial and ethnic minority populations. This work includes coordinating HHS programs and activities that address health disparities; assessing policy and programmatic activities for health disparity implications; building awareness of issues that impact 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. OMH will also continue to collect and analyze data to help support its mission through new and continuing programs. New programs will strengthen the focus on data-driven efforts to promote health equity. Some specific activities will include:

- Continuing support for the Center for Linguistic and Cultural Competency in Health Care (CLCCHC) to implement the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care (the National CLAS Standards).
- Continuing support for information dissemination and education efforts, including the OMH Resource Center (OMHRC), to provide information resources with the goal of increasing awareness of strategies to address health disparities.

Key Outputs and Outcomes Table:

Measure	Year and Most Recent Result Target for Recent Result (Summary of Result)	FY 2021 Target	FY 2022 Target	FY 2022 +/- FY 2021
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 2020: -16.0% Target: 25% Baseline – 182,000 (FY18) (Target Not Met)	27%	27%	0%
4.4.1 Unique visitors to OMH website (Output)	FY 2020: 1,220,202 Target: 500,000 (Target Exceeded)	505,000	510,000	+5,000
4.5.1 Percentage of State and Territorial Offices of Minority Health/Health Equity that have incorporated national disease prevention and health promotion (e.g., Healthy People 2030) and health equity goals in their health disparities/ health equity planning processes. (Output)	FY 2020: 54% Target: 51% (Target Exceeded)	53%	54%	+0%
4.6.1: Percentage of promising approaches, models, and evidence-based practices produced by OMH-funded grantees and cooperative agreement partners (Output)	FY 2020: 62.1% Target: 50% N = 21 (Target Exceeded)	52%	52%	+0%
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	33%	33%	+0%

Performance Analysis

4.2.1: Think Cultural Health (TCH) houses a suite of continuing education e-learning programs designed to build knowledge, skills and awareness of cultural and linguistic competency among health care professionals. FY 2020 saw fewer continuing education (CE) credits awarded compared to the baseline measure, with challenges related to organizational transitions due to the pandemic being likely contributors. With the addition of new e-learning programs and resources for health care and public health professionals to be introduced in FY 2021, and an increased focus on the promotion and adoption of the *National CLAS Standards*, OMH expects to see incremental growth through a 2% increase over the FY 2020 target in FY 2022 in the number of CE credits earned or awarded to enrollees who complete at least one or more of OMH's accredited e-learning programs in their respective fields, over the baseline.

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 over 69,000 records and 84.7% 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 students, researchers, 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 projects and facilitates educational outreach to Black/African American, Hispanic/Latino, American Indian, Alaskan Native, Asian American, Native Hawaiian, and Pacific Islander communities. OMH saw 1,220,202 unique visitors to its main website in FY 2020, far exceeding the projected 500,000. Some of the increased traffic to OMH's website may have been driven by interest sparked by the observed sharp racial and ethnic disparities in COVID-19 morbidity and mortality rates among Black/African Americans, American Indians, Alaskan Natives, and Hispanics. OMH expects the number of unique visitors to return to pre-pandemic levels of 510,000 unique visitors by the end of FY 2022.
- Social Media has been a growing outlet for the dissemination of health information from OMH and its stakeholders. OMH has more than 70,000 followers on its English Twitter handle with an extended reach to more than one million individuals and organizations. The OMH Facebook, Instagram and Spanish Twitter channels also continue to gain in followers and potential reach.

4.5.1: OMH builds strategic partnerships and provides leadership and coordination for State and Territorial Offices of Minority Health/Health Equity. In FY 2022, OMH expects 54% of these entities will have incorporated national disease prevention and health promotion (e.g., *Healthy People 2030*) and health equity goals in their health disparities/health equity planning processes, consistent with what was achieved in FY2020.

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. For FY 2020, OMH grantees achieved a rate of 62.1%, exceeding the target of 50% due to a change in the proportion of initiatives. FY 2021 and FY 2022 are not expected to continue with this increase, but still see incremental growth.

4.7.1: For FY 2021 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.

Grants Award Table:

Grants (whole dollars)	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Budget
Number of Awards	83	102	83
Average Award	$343,479	$312,340	$350,000
Range of Awards	$69,079 - $1,250,000	$175,000 - $625,000	$275,000 - $1,250,000

Program Data Chart:	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Budget
Contracts	-	-	-
OMH Resource Center	4,004,635	1,059,226	2,800,000
Logistical Support Contract	161,608	167,368	250,000
Center for Linguistic and Cultural Competency in Health Care	1,864,130	1,249,790	1,600,000
Community Health Aide Program	404,256	385,639	-
Assistance - Success, Sustainability & Spread of Health Disparity-Reducing Intervention	289,335	-	-
Evaluation	1,036,721	2,423,094	1,509,842
Organizational Development Contract	310,000	-	-
Sickle Cell Disease: National Academy of Science	80,000	-	-
Program Staff Support Services	69,992	-	-
Addressing SDOH in Public Housing	499,929	594,374	594,374
Advancing Sickle Cell Disease Health Plus	49,250	-	-
Language Access	249,726	500,000	500,000
Minority Leadership Fellowship Program – Contract Portion	-	500,000	500,000
Native Hawaiian & Pacific Islander (NHPI) Data Brief	-	70,000	0
Racial and Ethnic Health Disparities – Partnership with NAS	-	1,500,000	0
Special Journal -Physical Activity & Sport Participation in Marginalized Youth	-	50,000	0
Promoting Black Youth Mental Health	-	500,000	600,000
Professional Support for OMH's Data Function	-	100,000	0
Enterprise Service – Cloud Web Platform Project	-	300,000	0
Subtotal, Contracts	**9,019,582**	**9,399,491**	**8,354,216**
Grants/Cooperative Agreements	-	-	-
American Indian/Alaska Native Partnership	911,752	962,000	-
Re-entry Community Linkages (RE-LINK)	2,807,412	-	-
Partnership to Achieve Health Equity	2,386,251	2,425,000	-
Minority Youth Violence Prevention II: Determinants of Health Collaborative Network	4,078,508	-	-
Empowered Communities for a Healthier Nation Initiative (ECI)	1,749,987	-	-
Hepatitis B Demonstration	2,395,482	2,395,482	-
Collaborative Approach for Youth Engagement in Sports	1,987,400	1,987,400	-
State/Tribal/Territorial Partnership Initiative - Reducing Interventions	3,564,811	3,564,811	-
Reducing Cardiac Arrest Disparities Through Data Registries Initiative	139,076	139,076	-
Community-based Approach-Strengthen Economic Support Working Families	9,946,838	9,946,838	9,946,838
Increase Hydroxyurea for Children w/ Sickle Cell Disease via Provider Incentive	1,250,000	1,250,000	1,250,000
SCD Clinical Data Collection Platform	999,563	999,563	-
Center for Indigenous Innovation and Health Equity	-	2,000,000	2,000,000
National Lupus Outreach and Clinical Trial Education Program	-	2,000,000	2,000,000
Social Determinants of Health Data via Local Data Intermediaries Initiative	-	500,000	500,000
Framework - Health Disparities via Collaborative Policy Demonstration Project	-	1,000,000	1,000,000
Framework - Health Disparities via Collaborative Policy Coordinating Center	-	500,000	500,000
Family Centered Approaches to Improving Diabetes Control and Prevention	-	1,500,000	1,500,000
Minority Leadership Fellowship Program – Grant Portion	-	1,500,000	1,500,000
Healthy Families, Healthy Lifestyles	-	-	1,500,000
Promoting Black Youth Mental Health	-	-	3,500,000
Modifying the Impact of Social Determinants of Health	-	-	3,500,000
Positive Steps for Community Health	-	-	2,500,000
Health Equity Initiative/State OMH/State Offices of HEI	-	-	3,564,811
Subtotal, Grants/ Cooperative Agreements	***32,217,080***	***32,670,170***	***34,761,649***
Inter-Agency Agreements (IAAs)	2,912,734	2,980,620	2,500,000
Operating Costs	***14,520,604***	***16,784,719***	***16,219,135***
Total	**58,670,000**	**61,835,000**	**61,835,000**

OFFICE ON WOMEN'S HEALTH

Budget Summary
(Dollars in Thousands)

Office on Women's Health	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Budget	FY 2022 +/- FY 2021
Budget Authority	33,640	35,140	35,140	-
FTE	34	54	54	-

Authorizing Legislation:.....PHS Act, Title II, Section 229
FY 2022 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. OWH provides expert advice and consultation to the Secretary concerning scientific, legal, ethical, and policy issues relating to women's health. OWH establishes short-range and long-range goals and objectives for women's health within the Department of Health and Human Services. OWH coordinates with other appropriate offices on activities within the Department that relate to disease prevention, health promotion, service delivery, research, and public and health care professional education, for issues of particular concern to women throughout their lifespan. As part of its legislative requirements, OWH monitors the Department of Health and Human Services' offices, agencies, and regional activities regarding women's health and identifies needs regarding the coordination of activities. OWH leads the Coordinating Committee on Women's Health and the National Women's Health Information Center.

<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 2020, 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 2020, the CCWH focused on COVID-19 and women and hypertension. Additionally, in FY 2020, 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 maternal health plan launched in December 2020.
- 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 2020, the committee focused on strategic planning to enhance partnerships, coordinate activities, and update goals and strategies. Additionally, in FY 2020, OWH coordinated with the Office of Violence against Women at the Department of Justice for National Women's Health Week.

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.

In FY 2020, OWH granted extensions to the *Prevention of Opioid Misuse in Women: Office on Women's Health Prevention Awards* (OWHPA) in the setting of COVID-19. In FY 2020, the grantees updated their project plans in response to COVID-19. FY 2020 examples of 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.

In FY 2020, OWH developed and 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 led the development of the Maternal Health Data Contract to obtain up to date information on maternal and infant health outcomes to inform our policy and programs.
- OWH partnered with the Office of Infectious Disease and HIV/AIDS Policy (OIDP) to develop targeted enhancement of immunization culture in obstetric care to increase trust in vaccinations across the lifespan.
- OWH partnered with the OASH Deputy Chief Medical Officer to develop the HHS initiative on Neonatal Abstinence Syndrome/Neonatal Opioid Withdrawal Syndrome.
- OWH continued the State-Level Paid Family Leave Policy Project which involves the collection of information and then inform program and policy about new mothers' health, health behaviors, and ability to fulfill their roles in the workplace, family and community.
- 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, and collection and reporting of performance management data across all OWH project and programs. OWH achieved all 4 performance goals by the end of the FY20 3rd quarter.

<u>Innovative and Model Programs on Women's and Girls' Health</u>

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.

- In FY 2020, OWH developed and implemented initiatives to address maternal health disparities and hypertension during pregnancy and postpartum.
- In FY 2020, OWH partnered with ACL for a prize challenge focusing on the impact of COVID-19 on social isolation and loneliness.

- FY 2020 was year two of *Preventing HIV Infection in Women through Expanded Intimate Partner Violence (IPV) Prevention, Screening, and Response Services.* In FY 2020, OWH added a fifth grantee. The grants support the *Ending the HIV Epidemic in the U.S.* (EHE) initiative and builds on previous OWH work on IPV and HIV.
- FY 2020 was year two of OWH's partnership with the Office of Minority Health on *Youth Engagement in Sports: Collaboration to Improve Adolescent Physical Activity and Nutrition (YES Initiative)* that awarded over $4 million in support of improving physical activity and nutrition and promoting the recently updated Physical Activity Guidelines and National Sports Strategy. Grantees funded by OWH focus on engaging girls in sports.
- In FY 2020, OWH collaborated with the Office of Population Affairs for a funding opportunity announcement focusing on preconception care and preventing and addressing hypertension.

Education and Collaboration on Women's and Girls' Health

OWH uses websites, webinars, written materials, 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.

FY 2020 examples of this work include:

- The administration of 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 eighth grade reading level or below, in English and Spanish.
- An update to the "Breastfeeding Guide," which contains how-to information and support to help women breastfeed.
- An update and development of new messaging for "It's only Natural" Campaign to decrease disparities in breastfeeding.
- A Partnership with the Office of Disease Prevention and Health Promotion (ODPHP) on a communication campaign to promote physical activity during and after pregnancy.
- 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 encourage pregnant women and new mothers to seek treatment.
- Implementation of a communications campaign designed to educate and encourage women and men, aged 18-26, 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.
- Celebration of the 21st Annual Observance for National Women's Health Week (NWHW) and the 15th Annual Observance of National Women and Girls HIV/AIDS Awareness Day (NWGHAAD). OWH developed a new observance in FY 2020 focusing on hypertension in women and home blood pressure monitoring. The record outreach and number of ambassadors and partners during National Women's Health Week led OWH to meet its performance measures by Q3 of FY 2020.

Five Year Funding Table

Fiscal Year	Amount
FY 2018	$32,140,000
FY 2019	$32,140,000
FY 2020	$33,640,000
FY 2021 Enacted	$35,140,000
FY 2022 President's Budget	$35,140,000

Budget Request

The FY 2022 President's Budget request for OWH is $35,140,000, which is flat with the FY 2021 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, for instance, through blood pressure control during pregnancy and postpartum. In addition, in FY 2022 OWH will evaluate the impact of maternal health quality improvement implementation in hospitals and continue its programs and policies that support victims of violence. Additionally, OWH will lead national campaigns addressing immunization hesitancy, infertility, breastfeeding disparities, and postpartum depression.

Key Outputs and Outcomes Table

Program/Measure	Year and Most Recent Result/Target for Recent Result Summary of Result	FY 2021 Target	FY 2022 Target	FY 2022 +/- FY 2021
5.5.1 Number of users of OWH's communication channels (Reach)	FY 2020: 32,298,591 Target: 21,000,500 (Target Exceeded)	13,125,000	14,437,500	+1,312,500
5.6.1 Number of occasions that users interact with OWH content (Engagement)	FY 2020: 150,217,685 Target: 28,100,000 (Target Exceeded)	3,675,000	3,858,750	+183,750
5.7.1 Number of OWH interactions for the purpose of health education and training (Outreach)	FY 2020: 1,594 Target: 200 (Target Exceeded)	53	275	+25
5.8.1 Number of individuals served by OWH activities, programs, and partnerships (Outreach)	FY 2020: 34,623,521 Target: 850,000 (Target Exceeded)	420,000	441,000	+21,000

Grants Award Table

Grants	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Budget
Number of Awards	21	10	10
Average Award	$342,972	$462,500	$462,500
Range of Awards	$110,871-$2,400,000	$500,000--$2,400,000	$400,000-$2,400,000

Program Data Chart	FY 2020 Final	FY2021 Enacted	FY 2022 President's Budget
Contracts	-	-	-
Disease Prevention (Formerly Congenital Syphilis)	149,585	1,325,000	1,325,000
National Women's Health Information Center (Formerly Health Communications, National Women's Health Information Center, Exercise in Pregnancy, HPV)	2,998,153	1,177,375	1,177,375
Women's Health Across the Lifespan (Formerly Women's Health Across the Lifespan, Trauma/Violence Against Women, and State Paid Family Leave)	-	475,000	475,000
Health Disparities in Women (Formerly Postpartum Depression)	1,199,594	600,000	600,000
Health Care Service Delivery and Data (Formerly Health Care Services for Women)	1,514,250	7,779,677	7,779,677
Public Education and Health Promotion (Formerly Education and Collaboration on Women's and Girls Health)	1,649,481	1,749,400	1,150,000
Subtotal, Contracts	***7,511,063***	***13,106,452***	***12,507,052***
Grants/Cooperative Agreements	-	-	-
YES Initiative	4,773,022	-	-
Health Disparities in Women (Blood Pressure Initiative)	3,325,000	-	-
Violence Against Women (Formerly Trauma/ Violence Against Women)	3,945,265	5,100,000	5,100,000
Preconception Health (Formerly Education and Collaboration on Women's and Girls' Health (Empowering Women))	2,399,997	5,550,000	5,550,000
Subtotal, Grants/Cooperative Agreements	***14,443,284***	***10,650,000***	***10,650,000***
Inter-Agency Agreements (IAAs)	**1,010,454**	**1,060,140**	1,559,540
Operating Costs	**10,675,199**	**10,323,408**	**10,423,408**
Total	**33,640,000**	**35,140,000**	**35,140,000**

EMBRYO ADOPTION AWARENESS CAMPAIGN

Budget Summary

(Dollars in Thousands)

Embryo Adoption Awareness Campaign	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Budget	FY 2022 +/- FY 2021 Budget
Budget Authority	1,000	1,000	1,000	-
FTE	-	-	-	-

Authorizing Legislation.....PHS Act, Title II, Section 301
FY 2022 Authorization .....Permanent
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 2018	$1,000,000
FY 2019	$1,000,000
FY 2020	$1,000,000
FY 2021 Enacted	$1,000,000
FY 2022 President's Budget	$1,000,000

Budget Request

The FY 2022 President’s Budget request for EAAC is $1,000,000, which is flat with the FY 2021 Enacted Level. At this level, the campaign will continue its education efforts.

MINORITY HIV/AIDS FUND

Budget Summary
(Dollars in Thousands)

Minority HIV/AIDS Fund	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Budget	FY 2022 +/- FY 2021
Budget Authority	53,900	55,400	55,400	-
FTE	1	25	25	-

Authorizing Legislation:..... Current Year Appropriation
FY 2022 Authorization.....Annual
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 MHAF 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 integration of best practices, effective strategies, and promising emerging models. 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, the *Ending the HIV Epidemic in the U.S. (EHE)* was announced. OIDP leads and manages the implementation of this initiative, ensuring collaboration, transparency, and accountability across the operating divisions. The goal of this bold initiative is to decrease new HIV infections by 90%, to less than 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, and IHS– the primary partner agencies for the initiative. In addition, OIDP coordinates with other federal agencies such as SAMHSA who also have a role in addressing the HIV epidemic. In FY 2020, OIDP initiated the *Ready, Set, PrEP* program, providing Pre-exposure prophylaxis (PrEP) medication to prevent HIV transmission to those who lack prescription drug coverage, at no cost to the patient. In addition, as part of its monitoring and oversight role of EHE, OIDP launched the America's HIV Epidemic Analysis Dashboard (AHEAD). This platform allows transparent access to the process of tracking six indicators for each of the EHE geographic areas and the nation's progress toward meeting the EHE goals.

Phase 1 of EHE focuses on the geographic 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 FY 2019, utilizing resources originating from the MHAF, the CDC and IHS published funding opportunities for EHE Phase 1 geographic areas to develop community plans. The goal is to work with Phase 1 communities to bring additional expertise, technology, and resources that will be required to address the HIV epidemic in their locations.

In FY 2020, MHAF support for EHE took the form of scaling up a CDC-led HIV self-testing intervention, as well as funding for capacity building, technical assistance, and training projects led by HRSA and the IHS. The use of the MHAF funds, in service to EHE, continues to signal OASH's commitment to providing leadership, management, oversight and support for the initiative, and collaboration and coordination among HHS agencies, operating divisions, and external stakeholders. As EHE evolves throughout FY 2021 and into FY 2022, OIDP will continue to pursue innovative strategies to address those barriers, including social and structural determinants of health, that are at the center of the persistent racial and ethnic disparities in HIV.

In FY 2020, MHAF funding supported AHEAD and the *Ready, Set, PrEP* program. In addition, in FY 2020 MHAF-funded projects implemented by our federal partners include:

- *Scaling up HIV Prevention Services in STD Specialty Clinics through Training and Technical Assistance* (CDC) – To strengthen the clinical infrastructure and health delivery systems of STD specialty clinics by increasing capacity to offer HIV prevention services and leveraging the National Network of Sexually Transmitted Diseases Clinical Prevention Training Centers.
- *Mass Mailing HIV Self-Tests to Transgender Women and R/E Minority Communities Disproportionately Affected by HIV/AIDS* (CDC) - To accelerate the identification of undiagnosed HIV infections by building on existing strategies for engaging MSM as well as piloting recruitment strategies and mailing of HIV self-tests designed to engage transgender women (TGW) and racial and ethnic minority persons.
- *Ending the HIV Epidemic: Technical Assistance and Training on Stigma and Cultural Humility* (HRSA) - To provide stigma-reduction and cultural humility training and technical assistance directly and through collaborative partnerships to ensure culturally responsive care for people with HIV.
- *Improving Care and Treatment Coordination for Black Women with HIV* (HRSA) - To design, implement, and evaluate a group of evidence-based interventions applied simultaneously to address social, cultural, and environmental health determinants to expand the delivery and utilization of HIV care and treatment and improve health outcomes for Black women with HIV.
- *Building Capacity to Implement Rapid ART Start for Improved Care Engagement in the Ryan White HIV/AIDS Program* (HRSA) - To support 20 implementation sites to promote a "Rapid Start" connection or accelerated entry into HIV medical care and rapid initiation of ART for people with HIV who are newly diagnosed, new to care, or out of care in the Ryan White HIV/AIDS Program.
- *Clinical Innovations in Indian Country* (IHS) - To reduce new HIV infections via biomedical interventions in the areas of greatest need in Indian Country, including enhancing the role of clinical pharmacists in increasing PrEP patient cohorts.
- *Empowering Healthier Tribal Communities* (IHS) - To support communities in reducing new HIV infections, improve HIV-related health outcomes, and to reduce HIV and comorbidity-related health disparities among American Indian/Alaska Native people, including providing ongoing consultation and technical assistance.
- *Project Red Talon* (IHS) - To reach Native teens and young adults and the clinics that serve them, equipping tribes and urban Indian health centers to carry out the EHE four core strategies by building and funding a network of partners who will, in turn, propose and carry out cross-cutting projects to address current EHE gaps.

America's HIV Epidemic Analysis Dashboard (AHEAD)

AHEAD provides the most up-to-date information about EHE progress to help inform national and priority geographic area decision-making on EHE efforts. AHEAD features data for the 48 counties, Washington, D.C., and San Juan, Puerto Rico, as well as seven states that are included in Phase I of EHE.

AHEAD is focused on visualizing baseline data and indicator targets for the six EHE specific indicators. When fully interactive in early 2021, AHEAD will enable stakeholders to conduct analyses to further support decision-making. Through this tool, users can direct resources more strategically towards successful HIV programs, thereby amplifying interventions that show promise to reach the collective goal of EHE.

Ready, Set, PrEP

FY 2020 MHAF resources were also allocated to support EHE efforts to increase the uptake of PrEP. PrEP is a way for people who do not have HIV, but who are at very high risk of getting it, to prevent HIV infection by taking a pill every day. Studies have shown that PrEP reduces the risk of getting HIV from sex. More than one million people in the U.S. could benefit from PrEP, however only a small fraction receives a prescription for it.

Ready, Set, PrEP is a nationwide program that provides free PrEP medications to people who do not have insurance that covers prescription drugs. It expands access to PrEP medications, will reduce the number of new HIV transmissions, and brings us one step closer to ending the HIV epidemic in the U.S. This program has expanded its partnerships to include collaborations with more than 32,000 co-sponsoring pharmacies. OIDP recently expanded options for mail order services using TrialCard, the vendor for the enrollment portal. This option allows health centers and IHS facilities to have the donated medication mailed to patients' homes or other locations directly from the Trialcard pharmacy.

Five Year Funding History

Fiscal Year	Amount
FY 2018	$53,900,000
FY 2019	$53,900,000
FY 2020	$53,900,000
FY 2021 Enacted	$55,400,000
FY 2022 President's Budget	$55,400,000

Budget Request

The FY 2022 President's Budget request for MHAF is $55,400,000, which is flat with the FY 2021 Enacted Level. At this level, OIDP will maintain support, management, oversight, and coordination of the *Ending the HIV Epidemic in the U.S. (EHE)* Initiative. A Chief Operating Officer for the EHE provides day-to-day oversight of the Initiative and works with the Operational Divisions to ensure integration and accountability.

OIDP will maintain current personnel resources and subject matter experts to help manage the MHAF and the EHE Initiative. MHAF will continue in its efforts to provide the necessary supports to the EHE, with an eye on those that other EHE-related OPDIV funding does not cover. Through capacity building, technical assistance and training support, MHAF is positioned to assist geographic areas navigate the EHE opportunity with all the essential tools and resources necessary to be successful. In addition, the COVID-19 pandemic has necessitated the exploration of new outreach, prevention and care strategies from the expanded use of telemedicine to Sexually Transmitted Infection (STI) and HIV self-testing promotion. Some of these strategies and approaches merit ongoing consideration as we move beyond the current COVID-19 reality and may signal new ways of advancing the EHE. MHAF projects and activities will remain at the cutting edge of innovation and new collaborations.

Outputs and Outcomes Table

Measure	Year and Most Recent Result Target for Recent Result (Summary of Result)	FY 2021 Target	FY 2022 Target	FY 2022 +/- FY 2021
7.1.12a: Increase the number of racial and ethnic minority clients who are tested through the Secretary's MHAF programs. (Outcome)	FY 2020: 20,000 FY 20 Target: 19,500 (Target Exceeded)	40,000	40,000	0
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 2020: 910 FY 20 Target: 900 (Target Met)	800	800	0
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 2020: 70% FY 20 Target: 82% (Target Not Met)	80.8%	80.8%	0
7.1.19 Increase the proportion of persons with diagnosed HIV who have achieved viral suppression.	FY 2020: 65% FY 20 Target: 63% (Target Exceeded)	67%	67%	0
7.1.20 Increase the proportion of persons who received PrEP among those for whom PrEP was indicated.	FY 2020: 12% FY 20 Target: 9% (Target Exceeded)	13%	13%	0

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. The fluctuation in HIV testing and diagnoses is impacted by the types of new programs proposed and approved during each fiscal year in addition to the continuation programs funded.

An essential component of HIV testing is the linkage to care activity for those diagnosed with HIV. This activity is captured under *Measure 7.1.15*. Studies continue to show the challenges faced by many clients, including racial and ethnic minorities, in moving along a "continuum of care" from HIV diagnosis to viral suppression. CDC's latest (2018 data) prevalence-based continuum shows: 86% of people with HIV in the U.S. have been diagnosed, 65% received care, 50% retained in care, and 56% are virally suppressed. As the standard of care has moved from 3-months to 1-month for linkage to care, MHAF testing projects will continue to require more attention in order to meet linkage targets, including our push for expediting the linkage process including immediate linkage. In addition, HIV testing is the gateway activity for the two new measures of viral suppression and PrEP. Both measures currently anchor our domestic response to HIV and are fully integrated in both EHE Initiative and the HIV National Strategic Plan.

KIDNEY INNOVATION ACCELERATOR

Budget Summary

(Dollars in Thousands)

Kidney Innovation Accelerator	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Budget	FY 2022 +/- FY 2021
Budget Authority	5,000	5,000	5,000	-
FTE	-	1	1	-

Authorizing Legislation.....Current Year Appropriation
FY 2022 Authorization.....Annual
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 (ASN) 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 OASH. The Executive Order on Advancing American Kidney Health, signed July 10, 2019, established that "It is the policy of the United States to prevent kidney failure whenever possible through better diagnosis, treatment, and incentives for preventive care," and as referenced above, requires KidneyX to "produce a strategy for encouraging innovation in new therapies." KidneyX is fulfilling this mandate to advance the development of an artificial kidney using KidneyX by planning and running prize challenges across each of these broad domains.

To date, KidneyX has completed phases 1 and 2 of its Redesign Dialysis Prize, awarding $4,100,000 to 21 winners from a pool of 235 applicants across both phases. These prize challenges were aimed at solving specific engineering and technology problems towards the development of technologies that can displace dialysis. KidneyX also completed a $70,000 Patient Innovator Challenge (25 winners from 129 submissions) to recognize the innovative capacity of patients and caregivers to inspire and inform medical product development. At this time, two prize challenges are in progress: the final stages of the $300,000 KidneyX COVID-19 Innovation challenge and the $2,500,000 Artificial Kidney Prize "Moonshot," which is laying the foundation for future KidneyX prizes to incentivize innovation so that artificial kidneys will be in human clinical trials by 2024. Across all five of these prize challenges, KidneyX has already delivered success, catalyzing both the HHS Advancing American Kidney Health Initiative and interest among patients, caregivers, doctors, startups, investors, and industry to solve important problems for the real-world benefit of kidney disease patients.

KidneyX federal expenditures to date represent approximately 40 percent of overall program costs, with the remainder consisting of funds raised by ASN. This program sends a strong signal to the innovation community and to patients that advancing artificial kidney development is a top national public health priority, worthy of additional investment.

Five Year Funding Table

Fiscal Year	Amount
FY 2018	-
FY 2019	-
FY 2020	$5,000,000
FY 2021 Enacted	$5,000,000
FY 2022 President's Budget	$5,000,000

Budget Request

The FY 2022 President's Budget request for KidneyX is $5,000,000, which is flat with the FY 2021 Enacted Level.

The request will allow KidneyX to sustain its staffing level of one FTE, and continue program implementation and oversight. 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 continue to seek additional partner funds from the private sector to contribute to the artificial kidney prize.

SEXUAL RISK AVOIDANCE EDUCATION

Budget Summary

(Dollars in Thousands)

Sexual Risk Avoidance	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Budget	FY 2022 +/- FY 2021
Budget Authority	35,000	35,000	35,000	-
FTE	-	-	-	-

Authorizing Legislation:.....Current Year Appropriation
FY 2022 Authorization.....Annual
Allocation Method.....Direct Federal

General Statement

The Sexual Risk Avoidance Education (SRAE) 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.

Program Description and Accomplishments

In FY 2016, Congress provided $10 million to award sexual risk avoidance education grants, also referred to as the General Departmental SRAE Program, through a separate appropriation in the HHS General Departmental Management account. Approximately 10 percent of the funding is reserved for providing training, technical assistance, and data collection activities. In FY 2019 funding was increased to $34.8 million to continue these competitive programs, which funded 30 continuation awards and 22 new grant awards. Continuation awards range from $332,879 to $445,773. The 22 new awards were funded for a 36-month budget and project period, with awards ranging between $760,745 and $958,780. In FY 2020, 20 continuation grants were funded at a total of $12.88 million and 51 new awards totaling $20.8 million. A contract was also funded to provide grantees with in-person topical trainings, webinars, and an annual conference to address programmatic, data collection and evaluation efforts. Technical assistance was provided individually and with small groups of grantees through on-site and off-site interactions by experts in sexual risk avoidance, youth development, youth risk behaviors, data collection, evaluation, and other related areas. Performance measurement and evaluation contracts were funded to provide grantees with technical assistance and support for data capacity building and the SRAE National Evaluation.

Five Year Funding Table

Fiscal Year	Amount
FY 2018	$25,000,000
FY 2019	$35,000,000
FY 2020	$35,000,000
FY 2021 Enacted	$35,000,000
FY 2022 President's Budget	$35,000,000

Budget Request

The FY 2022 President's Budget request for Sexual Risk Avoidance is $35,000,000, which is flat with FY 2021 Enacted, and funds continuation grants and approximately 20 new awards with a three-year project period. Approximately 10 percent of the General Departmental SRAE allocation will be reserved to fund contracts that support grantees with in-person topical trainings, webinars, and an annual conference to address programmatic, data collection and evaluation efforts. Technical assistance contractors will engage grantees in individual and small groups through on-site and off-site sessions with experts in sexual risk avoidance, youth development, youth risk behaviors, data collection, evaluation, and other related areas.

EXECUTIVE ORDER IMPLEMENTATION

Budget Summary

(Dollars in Thousands)

Executive Order Implementation	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Budget	FY 2022 +/- FY 2021
Budget Authority	-	-	40,000	+40,000
FTE	-	-	-	-

Authorizing Legislation.....Reorganization Plan No. 1 of 1953
FY 2022 Authorization.....Permanent
Allocation Method.....Direct federal

Program Description and Accomplishments

The President's Budget requests resources for implementation of a number of important Executive Orders. The Office of the Secretary plays a key coordination and oversight role in managing the Department, and similarly, plays a key role in ensuring furtherance and implementation of Presidential and Secretarial priorities.

The budget includes $40 million in new funding to allow the Office of the Secretary to ensure implementation of over 30 new President Biden Executive Orders, including those on Health and Racial Equity. As part of a "whole-of-government equity agenda," each federal agency must assess whether its programs and policies perpetuate systemic barriers that affect people of color and other underserved groups. A portion of these requested funds will go to ensuring OS Staff Divisions are meeting this call.

National Security Memorandum on United States Global Leadership to Strengthen the International COVID-19 Response and to Advance Global Health Security and Biological Preparedness will also require resources to invest in advancing global health and health security in the post-COVID world.

Overall, these Executive Orders reflect the President's agenda and priorities, and require resources for implementation. In addition, these orders require systemic changes and objective review of current policies and procedures to ensure alignment with administration priorities. They are crucial to the success of these important efforts.

Five Year Funding Table

Fiscal Year	Amount
FY 2018	$0
FY 2019	$0
FY 2020	$0
FY 2021 Enacted	$0
FY 2022 President's Budget	$40,000,000

Budget Request

The FY 2022 President's Budget request for the Executive Order Implementation is $40,000,000, which is the initial request for these resources. Funds will be used by Office of the Secretary Staff Divisions to implement Executive Orders for which they serve as a lead or supporting agency. Implementation of the following Executive Orders will expend the vast majority of the funding, but other less resources intensive orders, memorandums, and proclamations may create operational costs:

Executive Orders listed in numerical order.

EO - 13985	Advancing Racial Equity and Support for Underserved Communities Through the Federal Government
ASPE	ASPE is leading the department's equity impact assessment, development of the department's plan for addressing barriers to full and equal participation in programs, and an equitable data working group.
CFOI	The Partnership Center will work with faith and community leaders in underserved and minority communities to equip them with credible, engaging, and culturally relevant information and communication strategies, best practices, tools, and resources. They will include rapid response materials in the case of public health emergencies (e.g., COVID-19 and opioid/substance use disorders); webinar trainings that build local capacity in addressing chronic conditions (e.g., recovery support, trauma-informed care, heart disease and diabetes); efforts that strengthen the bridge between health care providers and community services to better address the social determinants of health (e.g., access to healthy and affordable food or employment); and the distribution of timely and relevant federal resources and information through weekly and monthly e-communications.
IEA	Solicit and coordinate input from state, territorial, tribal, and/or local governments, or external partners on areas related or adjacent to the U.S. Department of Health and Human Services.
ASPA	ASPA expects to support communications in print, television, radio and digitally in Spanish, English, ASL and any other underserved community and support the Health Equity Task Force meetings through live streaming, recording and editing.
OGC	OGC/CRD has advised OCR on how vaccine providers may rely on federal civil rights laws, specifically Title VI and its implementing regulations, to lawfully collect and submit race and ethnicity data to the Department. Further, OGC/CRD plans to offer assistance to the President's COVID-19 Health Equity Task Force and the HHS Health Disparities Council, in a legal advisement capacity, to help address access to health care issues (including vaccine access and distribution).
ASFR	The Small Disadvantaged Business (SDB) and Historically Underutilized Business Zone (HUBZone) Federal programs exist to expand opportunity for disadvantaged businesses. The HUBZone program has specific features which have made the program inaccessible and widely misunderstood on how to effectively engage. The HHS Office of Small and Disadvantaged Business will invest in increased engagement and support services. Targeted HUBZone programming will include outreach to rural small businesses, collaborating with large business primes to ensure HUBZone subcontracting goals are met, providing HUBZone specific counseling and partnering with acquisition stakeholders for direct access to HUBZone set aside opportunities.

EO - 13988	Preventing and Combating Discrimination on the Basis of Gender Identity or Sexual Orientation
ASA	The Office of the Secretary is the lead for this Executive Order. ASA/EEODI will develop and provide guidance/framework to Opdiv EEO Offices to assist and support.
ASPA	ASPA supports media, press releases, guidance database postings and other communications activities related to agency actions in enforcing the EO. ASPA FOIA Office has already received and processed a high volume of requests for the release of information on gender identity and expects continued interest in FY22.
OGC	OGC/CRD has advised OCR on how vaccine providers may rely on federal civil rights laws, specifically Title VI and its implementing regulations, to lawfully collect and submit race and ethnicity data to the Department. Further, OGC/CRD plans to offer assistance to the President's COVID-19 Health Equity Task Force and the HHS Health Disparities Council, in a legal advisement capacity, to help address access to health care issues (including vaccine access and distribution).

EO - 13989	Ethics Commitments by Executive Branch Personnel
ASPA	Based on past experience, ASPA expects to support media inquiries and FOIA requests involving personnel actions related to this EO.
OGC	This EO is the current Ethics Pledge applicable to all incoming political appointees. OGC/Ethics ensures that all appointees sign the ethics pledge, are briefed about its requirements, and provides ethics advice to appointees when they have questions about its requirements.

EO - 13990	Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis
OGC	BOGC/PHD's Public Health & Science (PH&S) Branch provides legal support to the Office of the Assistant Secretary for Health (OASH)'s environmental justice program that plays a role with implementing this Executive Order at HHS. The CDC Branch is advising the CDC's National Center for Environmental Health (NCEH) and the Agency for Toxic Substances and Disease Registry (ATSDR) on supporting state, tribal, local, and territorial public health agencies as they prepare for specific health impacts of a changing climate.

EO - 13992	Revocation of Certain EOs Concerning Federal Regulations
ASPA	This Executive Order rescinded the Executive Order that established the online Guidance Database that ASPA built and maintains for the Department through SSF funding. The Executive Secretary and senior leadership reviewed the database and determined that it is good government practice to continue operating with it. ASPA continues to maintain and build the Guidance Database.
OGC	OGC/CRD has advised OCR on how vaccine providers may rely on federal civil rights laws, specifically Title VI and its implementing regulations, to lawfully collect and submit race and ethnicity data to the Department. Further, OGC/CRD plans to offer assistance to the President's COVID-19 Health Equity Task Force and the HHS Health Disparities Council, in a legal advisement capacity, to help address access to health care issues (including vaccine access and distribution). OGC Children Families and Aging Division (CFAD) has formed a work group to draft a regulation to repeal 45 CFR Part 1, which had implemented E.O 13891 and E.O 13892. Both E.O. 13891 and E.O. 13821 were revoked bat E.O. 13992. OGC/CRD is reexamining policies and regulations promulgated pursuant to the Executive Orders rescinded by Executive Order 13992. Specifically, OGC/CRD is examining the rule adopted pursuant to Executive Order 13891 (Promoting the Rule of Law Through Improved Agency Guidance Documents), and identifying appropriate next steps, consistent with the Administrative Procedure Act.

EO - 13999	Protecting Worker Health Safety
ASPE	ASPE is taking a supporting role on this EO primarily making connections to the EO on Reopening Schools and Early Childhood Programs where the health and safety of early care and education workforce is primarily being addressed.
OGC	OGC/PHD's PH&S Branch, CDC Branch, and ASPR team has provided extensive advice and guidance on numerous aspects of COVID-19 vaccine administration. The PH&S Branch is also providing ongoing advice regarding behavioral health services for health care providers. The OGC/PHD ASPR team has provided advice regarding worker health and safety issues for the National Disaster Medical System (NDMS) intermittent Federal responders who have been carrying various COVID-19 deployments. Both Branches also advise the Department on issues related to the operation of and appeals brought under Energy Employees Occupational Illness Compensation Program Act of 2000 (EEOICPA).
ASPA	ASPA anticipates providing some media relations/communications and interdepartmental coordination support for this COVID-19-related executive order.

EO - 14000	Reopening Schools and Early Childhood Programs.
ASPE	ASPE is participating on the workgroup being led by ACF/ECD and is active on several milestones working groups including supporting the behavioral and mental health needs of children, families, and staff; building out the early childhood resources section on ED's Best Practices clearinghouse; and convening a series of meetings with federal and external researchers to identify current and planned research on the impact the COVID-19 pandemic has had on young children's development and their families.

EO - 14002	**Economic Relief Related to the COVID-19 Pandemic**
ASPE	In response to this EO, ASPE is leading a long-term milestone to develop an interagency agenda for economic recovery, providing information for a short-term milestone on pandemic flexibilities, and contributing to a medium-term milestone related to pandemic effects and virtual human services delivery.

EO - 14003	**Protecting the Federal Workforce**
ASA	On January 22, 2021, President Biden revoked EOs 13836, 13837, and 13839. In this order, President Biden under section 4 of instruction, ordered Agency Heads to engage in collective bargaining in accordance with Chapter 71 of title 5, USC. HHS is in compliance with this latest order and is currently in the process of asking policy owners to identify any policy changes, guidance, or processes that were impacted by EOs 13836, 13837, and 13839.
OGC	OGC/GLD provided advice on the technical application of EO 14003 as it relates to the Department's collective bargaining obligations. OGC/GLD anticipates fielding similar legal questions from the HHS National Labor Relations Office (NLRO) and OpDivs in the future as they may arise.

EO - 14003	**Protecting the Federal Workforce and Requiring Mask-Wearing**
OGC	OGC/GLD provided advice on the Department's COVID-19 Workplace Safety Plan, required by OMB in furtherance of EO 13991, which the Department finalized. OGC/GLD anticipates fielding legal questions about the Plan as they may arise. OGC/PHD's CDC Branch worked closely with CDC and with other agencies in issuing orders to help ensure masks are worn when appropriate. See Promoting COVID-19 Safety in Domestic and International Travel.
ASPA	ASPA provides proactive and reactive media relations and paid and organic marketing through traditional and digital mediums as well as external stakeholder outreach in coordination with IEA and the WH to encourage mask wearing across the country per the requirements of this EO.

EO - 14005	**Ensuring the Future is Made in All of America by America's Workers**
ASA	ASPA anticipates that GSA may request ASPA collaboration and work products for the Department to provide waivers to GSA to make information publicly available and comply with the EO.
ASFR	To meet the requirements of the Executive Order the Office of Acquisitions will ensure proper implementation and oversight of the Executive Order. ASFR will be tasked with the necessary collaboration with HHS OPDIVs and programs on implementation of this Order. HHS has extensive laboratories and research that depend on developments in science, inventions, and equipment developed around the world to support the health and well-being of the American public.

EO - 14008	Tackling the Climate Crisis at Home and Abroad
ASA	The Office of the Secretary serves as the lead for this Executive Order. ASA/PSC leads quarterly meetings of land holding agencies and reports to CEQ as needed. Additionally, CEQ requests sustainability scorecards annually.
IEA	Solicit and coordinate input from state, territorial, tribal, and/or local governments, or external partners on areas related or adjacent to the U.S. Department of Health and Human Services.

EO 14009	EO on Strengthening Medicaid and the Affordable Care Act
ASPA	ASPA provides extensive proactive and reactive media relations, strategic communications planning, speechwriting, multilingual/equitable communications, WH communication coordination, department communications alignment, strategy and communications, digital communications support, and video and studio support for the ACA.

EO – 14011	Establishment of Interagency Task Force on the Reunification of Families
OGC	OGC/CFAD has two representatives who are participating as part of the reunification workgroup. An initial meeting of the entire inter-agency task force convened on February 11, 2021 and OGC's representatives participated in that meeting. OGC has provided legal advice concerning the preparation of the FY 2022 President's Budget Appendix submission to OMB and new appropriations language within the Refugee and Entrant Appropriation for a "Separated Families Fund" proposal.
ASPA	ASPA provides extensive media relations and studio support to the unaccompanied children program. ASPA FOIA Office received and processed a high volume of requests for the release of information on Reunification of Families (EO 14011).

EO - 14017	America's Supply Chains
IEA	Solicit and coordinate input from state, territorial, tribal, and/or local governments, or external partners on areas related or adjacent to the U.S. Department of Health and Human Services.
OGC	The OGC/PHD ASPR Team has advised the Strategic National Stockpile on a variety of issues related to procurement, stockpiling, deployment of personal protective equipment, and respiratory protection devices.
ASPA	ASPA provides extensive proactive and reactive media relations, strategic communications planning, speechwriting, multilingual/equitable communications, WH communication coordination, department communications alignment, strategy and communications, digital communications support, and video and studio support for all Coronavirus Executive Orders.

EO - #Pending	Memorandum on Advancing the Human Rights of Lesbian, Gay, Bisexual, Transgender, Queer, and Intersex Persons Around the World
IEA	Solicit and coordinate input from state, territorial, tribal, and/or local governments, or external partners on areas related or adjacent to the U.S. Department of Health and Human Services.

EO - #Pending	Promoting Access to Voting
IEA	Solicit and coordinate input from state, territorial, tribal, and/or local governments, or external partners on areas related or adjacent to the U.S. Department of Health and Human Services.

EO - 14020	Establishment of the White House Gender Policy Council
IEA	Solicit and coordinate input from state, territorial, tribal, and/or local governments, or external partners on areas related or adjacent to the U.S. Department of Health and Human Services.
OGA	OGA is engaged in work around gender equity, including the White House Gender Policy Council; health equity; and the intersection of health and climate. OGA will work with international partners and other stakeholders to advance the human rights of lesbian, gay, bisexual, transgender, queer, and intersex persons around the world and to advance Global Health Security and biological preparedness. This work will be accomplished through bilateral engagements and U.S. leadership in and collaboration with multilateral organizations.

EO - #Pending	Memorandum on Tribal Consultation and Strengthening Nation-to-Nation Relationships
ASPA	ASPA anticipates providing media relations support to the Indian Health Service including potential Studio services to produce video products for IHS and other agencies.
IEA	IEA Tribal Affairs team is tasked with leading this effort of HHS. National consultations were held to hear directly from Tribal Nations. IEA will have to develop memos and reports back to OMB/WH as well as to tribal nations on how we plan to improve the nation to nation relations as well as ways to improve and implement HHS actions for Tribal Nations.
OGC	OGC/PHD's PH&S Branch has provided advice and guidance to the Health Resources and Services Administration (HRSA) on the establishment of its tribal advisory committee. In addition, PHD's NIH Branch anticipates advising the NIH on this EO in FY 2022. PHD's NIH Branch anticipates its advisory work will involve conducting Tribal Consultations for NIH research programs, strengthening overall relationships with Tribes for Tribal participation in NIH research programs, and the development of NIH policies that affect Tribes or are specifically focused on relationships with Tribes or Tribal Consultations.

NSM-1	National Security Memorandum on United States Global Leadership to Strengthen the International COVID-19 Response and to Advance Global Health Security and Biological Preparedness
OGA	OGA will support NSM-1 by coordinating with both domestic and international partners, is critical to protecting the health and well-being of Americans, as this outbreak spreads globally. OGA's support to the COVID-19 response includes communicating and coordinating with international health partners, supporting all of the Secretary's international engagements, coordinating National Security Council (NSC) staff policy development work for HHS, participating in international efforts to advance global health and health security, strengthening the WHO, and pursuing assistance to bolster COVID-19 vaccine production capacity, vaccine distribution, and vaccinations.
OGA	OGA will need to expand health diplomacy through an increase in the number of health attachés stationed internationally. Expanding the Health Attaché cadre in targeted locations will ensure the USG maintains highly trained HHS professionals on the ground dealing directly with foreign governments. Increasing Attaché presence is a concrete, strategic, and cost effective way to augment USG global health leadership.
OGC	OGC/PHD's CDC Branch is assisting the agency on reestablishing international connections including with the World Health Organization (WHO) in support of the COVID-19 response and other global health security goals and initiatives. The ASPR team advised the Office of Global Health Affairs on authorities to provide COVID-19 vaccines to foreign countries, liability issues related to deploying vaccines, and other countermeasures to foreign countries

Memo	Establishing the COVID-19 Pandemic Testing Board and Ensuring a Sustainable Public Health Workforce for COVID-19 and Other Biological Threats
OGC	OGC/PHD's CDC Branch is assisting CDC in the establishment and enhancement of a range of public health workforce activities including state, local, territorial and tribal public health departments in training, recruiting, and retaining a sufficient skilled and diverse workforce. PHD's ASPR team has advised ASPR regarding the provision of grants for public health workforce activities.
ASPA	ASPA provides extensive proactive and reactive media relations, strategic communications planning, speechwriting, multilingual/equitable communications, WH communication coordination, department communications alignment, strategy and communications, digital communications support, and video and studio support for all Coronavirus Public Health Executive Orders.

Memo	Memorandum Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking 1/27
ASPA	ASPA anticipates updates to data plans, reports, website content and other agency materials as stakeholders review content. Updates to some of these items may result in media inquiries.
OGC	OGC/PHD's PH&S Branch provides legal support to the Office of Research Integrity (ORI) to root out falsification, fabrication, and plagiarism in Public Health Service supported research. PHD's CDC Branch is working with the CDC's Office of Science to ensure appropriate training on the implementation of its scientific integrity policies and procedures.

Memo	Memorandum on Protecting Women's Health at Home and Abroad 1/28
ASPA	ASPA anticipates extensive media relations, speeches, press releases, studio, and digital communications work related to this memorandum.
OGC	GC/PHD's CDC Branch is working with the Center for Global Health and other CDC programs on advancing and protecting women's health.

Proclamation	Proclamation on National Teen Dating Violence Awareness and Prevention Month 2021
ASPA	ASPA provides media relations, strategic communications planning, department and WH media coordination, department communications alignment, digital communications support, speechwriting, and video support for monthly proclamations.

Proclamation	Proclamation on National Black History Month 2021
ASPA	ASPA provides media relations, strategic communications planning and execution of plans, department and WH media coordination, department communications alignment, digital communications support, speechwriting, and video support for monthly proclamations.

Proclamation	Proclamation on American Heart Month
ASPA	ASPA provides media relations, strategic communications planning and execution of plans, department and WH media coordination, department communications alignment, digital communications support, speechwriting, and video support for monthly proclamations.
OGC	OGC/PHD's PH&S Branch helped ensure the successful rollout of a $3.25 million hypertension prize competition from the OASH Office on Women's Health. The Branch also advised on a planned Office of Minority Health (OMH) and HRSA jointly funded multi-million dollar cooperative agreement to the American Heart Association (AHA) to reduce disparities in uncontrolled and undiagnosed high blood pressure among medically underserved communities and populations, with a focus on racial and ethnic minorities. PHD's CDC Branch provides legal support to the Division for Heart Disease and Stroke Prevention on hypertension and other related public health work.

Proclamation	Ensuring Data-Driven Response to COVID-19 and Future High-Consequence Public Health Threats
OGC	OGC/PHD's PH&S Branch provided legal advice and drafting support to the Agency for Health Care Research and Quality (AHRQ)'s extramural grant program concerning the rapid implementation of several grant-funding initiatives designed to support research focused on the response of U.S. health care systems to the COVID-19 pandemic. OGC/PHD's CDC Branch is advising CDC and the Department on a full-range of data issues including access, use, sharing and obtaining complete timely and accurate data in order to best position the agency to respond to the pandemic and develop the appropriate guidance. In addition, the PHD CDC Branch is advising the CDC on its data modernization initiatives both internally and with respect to partners.
ASPA	ASPA provides extensive proactive and reactive media relations, strategic communications planning, speechwriting, multilingual/equitable communications, WH communication coordination, department communications alignment, strategy and communications, digital communications support, and video and studio support for all Coronavirus Executive Orders. ASPA also supports the posting and use of data openly and transparently on the Department's website. ASPA FOIA Office received and processed a high volume of requests for the release of information related to COVID-19.

Proclamation	**Improving and Expanding Access to Care and Treatment for COVID-19**
OGC	OGC/PHD's PH&S Branch has provided extensive legal support to Health Resources Services Administration (HRSA)'s Health Center Program to ensure access to COVID-19 vaccines in underserved communities and those disproportionally affected by COVID-19. The OGC/PHD ASPR team has provided extensive legal support to ASPR regarding the use of NDMS and other Federal responders to provide care and administer vaccines and therapeutics to at risk-population populations and when states are overwhelmed and request support from the Federal government. The ASPR team has also advised ASPR on a pilot project with Department of Defense (DoD) to provide critical care telemedicine support to COVID-19 patients.
ASPA	ASPA provides extensive proactive and reactive media relations, strategic communications planning, speechwriting, multilingual/equitable communications, WH communication coordination, department communications alignment, strategy and communications, digital communications support, and video and studio support for all Coronavirus Executive Orders. ASPA FOIA Office received and processed a high volume of requests for the release of information related to COVID-19.

Proclamation	Ensuring Equitable Pandemic Response and Recovery
OGC	OGC/PHD's PH&S Branch advised on the development of a $40 million cooperative agreement between the HHS Office of Minority Health and Morehouse School of Medicine to develop a national network of state, territorial, tribal and local public and community-based organizations to help address the impact of COVID-19 among racial and ethnic minority populations. The Branch worked closely with OASH and OMH to establish the COVID-19 Health Equity Task Force and meets regularly with the supporting staff to answer legal questions as they arise for this fast-moving and important Task Force that was created by this Executive Order. The OGC/PHD CDC Branch provided legal guidance related to CDC's grant award to, in part, address disparities in access to COVID-19 related services and support for deploying community health workers to engage with priority populations at highest risk for poor health outcomes.
ASPA	ASPA provides extensive proactive and reactive media relations, strategic communications planning, speechwriting, multilingual/equitable communications, WH communication coordination, department communications alignment, strategy and communications, digital communications support, and video and studio support for all Coronavirus Public Health Executive Orders, including this one that supports the Pandemic Equity Task Force.

	Promoting COVID-19 Safety in Domestic and International Travel
OGC	OGC/PHD's CDC Branch works closely with CDC and with other agencies in issuing orders to help ensure safe travel domestically and internationally including the Global Testing Order, Mask Order, Conditional Sale Order, Contact Tracing Order, as well as issuing a full-range of guidance.
ASPA	ASPA provides proactive and reactive media relations, strategic communications planning, speechwriting, multilingual/equitable communications, WH communication coordination, department communications alignment, strategy and communications, digital communications support, and video and studio support for this EO. ASPA FOIA Office received and processed a high volume of requests for the release of information related to COVID-19

	Supporting the Reopening and Continuing Operation of Schools and Early Childhood Education Programs
OGC	OGC/PHD's NIH Trademark Group advised on the use and registration of the COVID-19 Test Us trademark used in connection with a program for facilitating clinical studies of new tests for detecting the COVID-19 virus. The COVID-19 Test Us program is part of the RADx-Tech program and has a pediatric component (called COVID-19 Test Us Kids) which enrolls children for clinical studies of new tests. OGC PHD's understanding is that one of the goals of this program is to support reopening and continuing operation of schools. OGC/PHD's CDC Branch has advised on a myriad of issues related to the re-opening of schools, including testing prevention measures and vaccination. OGC/CFAD has reviewed and cleared CDC and Department of Education documents related to school reopening. OGC/CFAD anticipates it will continue to receive guidance and other documents related to school reopening for review.
ASPA	ASPA provides proactive and reactive media relations, WH communication coordination, department communications alignment and interagency department coordination to support this EO.

	Organizing and Mobilizing the US Government to Provide a Unified and Effective Response to Combat COVID-19 and to Provide US Leadership on Global Health and Security
OGC	The OGC/PHD ASPR team has provides extensive legal advice to ASPR as the Federal government has responded to COVID-19, including issues related to deploying the NDMS, Public Health Service Commissioned Corps, and other Federal responders; coordinating the Medical Reserve Corps; providing grants to states, hospital associations, and certain health care entities to enhance hospital preparedness for COVID-19; and numerous issues about coordinating with FEMA on Federal mission assignments under the Stafford Act, including staffing Federal vaccination clinics. In addition, the ASPR team has advised on research and development of COVID countermeasures, authority to procure and distribute respiratory protective devices and ventilators, tests, therapeutics and vaccines, and liability protections under the Public Readiness and Emergency Preparedness (PREP) Act for manufacturers, developers and persons who administer tests, devices, and vaccines.

	Condemning and Combating Racism, Xenophobia, and INtolerance Against Asian Americans and Pacific Islanders
ASPA	ASPA anticipates providing media relations and digital communications support to OCR and OMH in support of this EO.

	Organizing and Mobilizing the U.S. Government to Provide a Unified and Effective Response to Combat COVID-19 and to Provide U.S. Leadership on Global Health and Security
ASPA	The ASPA media relations team works extensively with the team established in this EO and then provides the unified response and messaging back to the department communications offices. The ASPA team provides a high level of alignment and coordination to meet the unified mission outlined in this EO. ASPA FOIA Office received and processed a high volume of requests for the release of information related to COVID-19.

RENT, OPERATION, MAINTENANCE AND RELATED SERVICES

Budget Summary

(Dollars in Thousands)

Rent, Operation, Maintenance, and Related Services	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Budget	FY 2022 +/- FY 2021
Budget Authority	15,314	15,314	20,314	+5,000
FTE	-	-	-	-

Authorizing Legislation……Reorganization Plan No.1 of 1953
FY 2022 Authorization……Permanent
Allocation Method……Direct federal

Program Description and Accomplishments

The Rent, Operation, 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 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 2018	$16,089,000
FY 2019	$14,589.000
FY 2020	$15,314,000
FY 2021 Enacted	$15,314,000
FY 2022 President's Budget	$20,314,000

Budget Request

The FY 2022 President's Budget request for Rent is $20,314,000, which is an increase of $5,000,000 above the FY21 Enacted level. Funding will support increasing costs associated with rental charges from GSA and maintaining aging buildings.

The additional $5,000,000 will be used in support of creating a safer, more productive post-pandemic work environment at HHS Headquarters. This effort will focus on de-densifying office space, enacting stricter cleaning protocols, and supporting desk "hoteling." Funding will allow for office configurations and workspace assignments to be adjustable and flexible; targeting savings through use of enhanced telework and hoteling practices.

The Executive Orders require creative solutions to meet new standards for sustainability and climate control. At the same time, support of a reduced footprint that leverages telework, which has been proven to work during the Pandemic, will allow for cost savings in the long-term and social distancing for future emergencies (pandemic, hurricane, etc.) or mission changes requiring nimble adjustment.

ELECTRIC VEHICLE PROGRAM

Budget Summary

(Dollars in Thousands)

	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Budget	FY 2022 +/- FY 2021
Budget Authority	-	-	7,981	+$7,981
FTE	-	-	-	-

Authorizing Legislation.....Reorganization Plan No. 1 of 1953
FY 2022 Authorization.....Permanent
Allocation Method.....Direct federal

Program Description and Accomplishments

In support of the Administration's international engagement to address climate change, the Electric Vehicle Program establishes a Department-wide capability to invest in transforming its fleet to electric. The scientific community has made it clear that the scale and speed of necessary action is greater than previously believed. Responding to the climate crisis will require both significant short-term global reductions in greenhouse gas emissions and net-zero global emissions by mid-century or before.

In implementing—and building upon—the Paris Agreement's three overarching objectives (a safe global temperature, increased climate resilience, and financial flows aligned with a pathway toward low greenhouse gas emissions and climate-resilient development), the United States will exercise its leadership to promote a significant increase in global climate ambition to meet the climate challenge.

A key component of meeting these objectives is by aligning the management of Federal procurement and real property, public lands and waters, and financial programs to support robust climate action. HHS has been asked to support the Council on Environmental Quality (CEQ) to develop programs that provide clean and zero-emission vehicles for Federal, State, local, and Tribal government fleets, including vehicles of the United States Postal Service. The goal is to convert HHS fleet to carbon pollution-free electricity no later than 2035. These resources will be used to provide infrastructure to support, and to the extent practical, replace fossil fuel vehicles by 2035.

To date, HHS has been implementing clean and zero-emission vehicle purchases subject to the availability of funds. This program will leverage existing government infrastructure provided through the General Services Administration's (GSA) Blanket Purchase Agreement (BPA) that offers seven (7) brands of charging stations, and is available to all federal agencies that are authorized to lease or purchase vehicles from the GSA Fleet.

Infrastructure will be made available to support Federal fleet cars at HHS facilities, and for privately owned vehicles in parking areas under HHS control. Charging stations may be used by Federal employees and other authorized users at the user's expense.

Five Year Funding Table

Fiscal Year	Amount
FY 2018	$0
FY 2019	$0
FY 2020	$0
FY 2021 Enacted	$0
FY 2022 President's Budget	7,981,000

Budget Request

The FY 2022 President's Budget request for the Electric Vehicle Program is $7,981,000, which is the initial request for these resources. These funds will be used to expand leadership, direction, policy, and management guidance to an enterprise-wide approach for sustainable zero-emission vehicle program, and invest in infrastructure and vehicles with the goal of transforming the HHS fleet to electric vehicles.

In support of the President's goal of transitioning to a fully Zero Emission Vehicle Federal fleet, this request focuses on zero emission vehicle (ZEV - battery electric, plug-in electric hybrid, and hydrogen fuel cell vehicles) acquisitions and deploying necessary vehicle charging and refueling infrastructure. These acquisitions are a significant step towards eliminating tailpipe emissions of greenhouse gases (GHG) from the HHS fleet and aligning the agency's fleet operations with the goal of achieving a fully ZEV federal fleet. This action is important because tailpipe emissions are currently the leading source of GHG emissions that threaten the planet and harm U.S. communities.

The HHS ZEV acquisitions may include vehicles for both its agency-owned and GSA-leased segments of its vehicle fleet, including incremental costs of leased vehicles and lease payments to GSA for conversion of agency-owned vehicles to GSA's leased fleet where appropriate. To ensure effective and efficient deployment of ZEVs, HHS will undertake preparation and planning for arriving ZEVs at its facilities, properly prioritizing transition to ZEVs where it is simplest and allow time for additional planning where mission demands pose a challenge to transitioning based on current technologies. Integral to this preparation is growth in the number of agency-accessible re-fueling points (vehicle charging stations). In installing this infrastructure on-site to support acquired ZEVs, HHS will take the long-term view to ensure efficiencies and thereby ensure wise infrastructure decisions that limit total expenditures. Using its experienced personnel and lessons learned in the fleet arena, HHS will undertake a process that relies on a cross-functional team of staff from fleets, operations, facilities, finance, and acquisition departments with executive leadership support. The collaboration will not stop with initial deployment, as HHS fleet and facility managers will work closely and employ existing training and tools to control utility costs by managing the overall charging load and thereby ensuring a seamless operation that now will involve building systems and vehicles together. Further, HHS will ensure proper training of personnel to address any initial shortcomings in terms of any necessary ZEV knowledge and operations as the advanced vehicle technologies roll into the HHS fleet.

The Agency is coordinating all of these efforts to meet or exceed the ZEV-related goals set forth in the comprehensive plan developed pursuant to E.O. 14008, Section 205(a). Funds for these ZEV activities are part of a $600 million request in the President's Budget for ZEVs and charging infrastructure that is contained within the individual budgets of 18 Federal agencies, including ZEV Federal fleet dedicated funds at the General Services Administration. This investment will be complemented by Department of Energy funding to provide technical assistance to agencies through the Federal Energy Management

Program as HHS builds and grows its ZEV infrastructure. This investment serves as a down payment to support a multiyear, whole-of-government transformation to convert the Federal motor vehicle fleet to ZEVs and thereby reduce carbon emissions.

SHARED OPERATING EXPENSES

Budget Summary

(Dollars in Thousands)

Shared Operating Expenses	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Request	FY 2022 +/- FY 2021
Budget Authority	10,478	10,478	12,746	+2,268
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 202022 HHS Enterprise Information Technology and Government-Wide E-Gov Initiatives

The Budget includes $89,472 to support government-wide E-Government initiatives.

FY 2021 E-Gov Initiatives and Line of Business*	Original FY 2021 Amount	Revised Amount FY 2021
GSA/IAE-Loans and Grants	$59,585	$49,367
Federal Health Architecture LoB	$0	$0
E-Rulemaking	$23,195	$19,217
Treasury Managing Partner Financial Mgmt - LOB (MOU) FMLoB	$5,031	$4,168
Human Resources Management LoB (HRLoB)	$2,988	$2,476
Disaster Assistance Improvement Plan (DAIP)*	$1,418	$1,175
Budget Formulation and Execution LoB	$2,400	$1,988
Benefits.gov	$10,543	$8,735
Performance Management Line of Business (PMLoB).	$1,741	$1,442
Geospatial LoB	$1,091	$904
FY 2021 E-GOV Initiatives Total	**$107,991**	**$89,472**

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 2018	$11,544,000
FY 2019	$11,544,000
FY 2020	$10,628,000
FY 2021 Enacted	$10,478,000
FY 2022 President's Budget	12,746,000

Budget Request

The FY 2021 request for other Shared Operating Expenses is $12,746,000, which is $2,268,000 above the FY 2021 Enacted. At this level, the request includes increases for the Service and Supply Fund charges as well as shared expenses.

PHS EVALUATION SET-ASIDE

Budget Summary

(Dollars in Thousands)

PHS Evaluation Set-Aside	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Budget	FY 2022 +/- FY 2021
ASPE	43,243	43,243	56,743	+13,500
Public Health Activities	9,400	8,800	8,800	-
ASFR	1,100	1,100	1,100	-
OASH	4,285	4,885	7,885	+3,000
Teen Pregnancy Prevention	6,800	6,800	6,800	-
Office of Climate Change and Health Equity	-	-	3,000	+3,000
Total	**64,828**	**64,828**	**84,328**	**+19,500**
FTE	123	145	182	+37

ASSISTANT SECRETARY FOR PLANNING AND EVALUATION (ASPE)

Budget Summary

(Dollars in Thousands)

Assistant Secretary for Planning and Evaluation	FY 2020 Final[6]	FY 2021 Enacted	FY 2022 President's Budget	FY 2022 +/- FY 2021
Budget Authority	43,243	43,243	56,743	+13,500
FTE	110	124	152	+28

Authorizing Legislation:.....PHS Act, Title II Section 247
FY 2022 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 Department of Health and Human Services (HHS). The Assistant Secretary is the principal advisor to the Secretary of HHS on policy development, data analysis, program evaluation, and strategic planning. 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 immediate need and longer-term policy research and analysis to support leadership decision-making.

ASPE collaborates across the Department in support of the Administration's initiatives, among other priorities, the COVID-19 pandemic response, health care coverage, health and economic equity, maternal health, women's health, child welfare, behavioral health, and emergency response and preparedness. ASPE's analytic efforts include developing legislative and regulatory proposals, research papers, dashboards, and other products to support the Secretary's initiatives.
ASPE maintains a diverse portfolio of intramural and extramural research and evaluation to inform

[6] Excludes supplemental appropriations for COVID-19, permissive transfers or allotments from PHSSEF to GDM.

policy formulation and decision-making regarding the full portfolio of HHS programs. In developing research priorities, ASPE consults across the Department and the Administration so that it focuses on work that is central to their priorities. Emphasis is placed on identifying areas for which ASPE's work will add value. ASPE maintains several simulation models and databases, as well as provides actuarial support and other resources to support timely policy analysis and development for existing agency efforts. ASPE assembles evidence that is critical to the design of departmental programs and makes policy and program decisions based on the best available evidence (or, in the absence of direct evidence, evidence-informed methods like well-calibrated simulation models), using data and analysis about the behavior of program participants, what interventions work, for whom, and under what circumstances. Staff work to understand potential outcomes of policy actions by identifying what programs and interventions are effective, how to improve upon those that are not, and what actions to take when programs do not demonstrate improvement. In this context, analyses involve a range of information sources and methodologies including survey data and analyses, program evaluation, analytical models, and performance data.

ASPE works across the Department, with the Office of Management and Budget (OMB), with 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 as they provide input on HHS priorities. For instance:

- ASPE coordinates HHS implementation of the Foundation for Evidence-Based Policymaking Act of 2018 (the Evidence Act) (discussed in greater detail below).
- ASPE staffs the Secretary in his role as a Trustee on the Social Security and Medicare Trust Funds. ASPE coordinates with the Trustees Working Group including the Departments of Treasury and Labor as well as the Social Security Administration and the Centers for Medicare and Medicaid Services (CMS). ASPE brings both economic and health policy expertise to this body of work identifying key areas of consideration for the Secretary as the reports are developed every year for release to the public.
- 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. ASPE provides technical assistance to the Department's operating and staff divisions on developing and implementing their own strategic plans and maintains a Strategic Planning system to monitor the implementation of plans.

ASPE convenes a number of other Department-wide efforts, such as:

- Coordinating with the Office of the Assistant Secretary for Health (OASH) the Department's response to the Equity Executive Order, including guiding how agencies conduct equity assessments and integrate findings into the Department's Strategic plan.
- Developing and coordinating the implementation of the Department's work to support the Administration's initiative to address the opioid epidemic.
- Leading the implementation of the Administration's National Action Plan to Combating Antibiotic-Resistant Bacteria initiatives. ASPE also coordinates an HHS-wide workgroup to identify economic incentives to promote antimicrobial development in support of the National Action Plan.

The following outlines ASPE's goals and programs which 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; and Reform, Strengthen and Modernize the Nation's Healthcare System.

Foster Sound, Sustained Advances in the Sciences

ASPE maintains a robust research portfolio examining the biomedical research and the development of drugs and devices. ASPE conducts research on the translation of biomedical research into everyday health and health care practice; the development and adoption of innovation in health care; and food, drug, and medical product safety and availability. ASPE engages in an ongoing collaboration with the Food and Drug Administration (FDA), designed to characterize 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. In conjunction with FDA, National Institutes of Health (NIH), the Assistant Secretary for Preparedness Response (ASPR) and others, ASPE continues to examine whether there are appropriate incentives for antimicrobial research and development. Additional research is examining how research is translated into guidelines and guidance issued by private entities, and how guidelines are used by hospitals to make decisions about the use of new antibiotics.

ASPE coordinates the implementation of the Evidence Act, including providing technical assistance within HHS on the development of Evidence Plans and an Evaluation Plan, with an emphasis on making policymaking more evidence based. Ultimately, this work aims to create a culture of learning to ensure evidence-based decision-making throughout HHS. ASPE also conducts a Capacity Assessment of the Department's evaluation and evidence functions.

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), FDA, 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 conducts research and evaluation for important initiatives that relate to American's economic and social well-being across the lifespan, such as increasing economic mobility, addressing the opioid epidemic, and improving behavioral health. In addition, ASPE helps coordinate work to address homelessness across HHS agencies. ASPE's leadership serves as the HHS representative to the U.S. Interagency Council on Homelessness.

ASPE is working to respond to the urgent economic crisis precipitated by the COVID-19 pandemic and continues its longstanding commitment to promote the economic and social well-being of all Americans, with a focus on equity, prevention, and seamless integration of the federal safety net. ASPE conducts cross-cutting work to improve child well-being and promote healthy youth development. For example, ASPE is identifying strategies to invigorate the child-care workforce, which consists primarily of low-income women of color; working with federal partners to align outcome measures across early childhood programs; and exploring promising practices for reconnecting youth to school and work.

To address the economic and social fallout of COVID-19, ASPE developed analyses and tools to enable human services programs and low-income individuals and families (including communities of color, youth, individuals reentering society from incarceration, and others) meet the challenges of the pandemic. This includes providing technical assistance on virtual human services delivery and helping the people HHS serves access new benefits and flexibilities, such as emergency paid family leave and Economic Impact Payments. ASPE has also modeled the effect of the COVID recession on poverty rates and program eligibility and is positioned to model the role of the ARP as well as the Administration's economic proposals on poverty and economic well-being.

ASPE continues to conduct research to ensure racial equity in human services programs and their outcomes. Current projects track inequitable outcomes from the COVID-19 recession, participation and outcomes in child welfare systems (such as foster care placement and termination of parental rights), and how human services programs identify substance use challenges and support of recovery. ASPE also works to enhance federal and state data infrastructure to better understand outcomes across various demographic groups, including race and ethnic groups, LGTBQ status, and other populations. ASPE also engages with key experts in the field to improve equity in human services programs, policy, and research including identifying available policy levers to address disparities.

ASPE takes a vital and unique cross-cutting perspective on human services policy, working in concert with the Administration for Children and Families (ACF) and others to improve the wellbeing of all Americans and strengthen human services programs and policies by identifying and addressing the root causes of systemic social challenges such as poverty, and increasing emphasis on preventing the need for systems involvement. To better align safety net programs, we lead the U.S. Interagency Council on Economic Mobility chaired by HHS, charged with equitable economic recovery and resilience; coordinate HHS homelessness initiatives, reentry, and youth development work; and partner with the Department of Education and ACF to support early childhood development.

ASPE also has numerous projects underway to improve child welfare outcomes both by improving the response of the child welfare program, especially for families with substance use challenges, and preventing system involvement in the first place. The Planning for Child Welfare Prevention Services Toolkit for States has increased the capacity of states to develop prevention services plans that incorporate cross-agency partnerships and are strategic in their use of new resources available after the passage of the Family First Prevention Services Act, which for the first time made Title IV-E funding available for prevention services to keep families together. An extensive portfolio of work on the relationship between parental substance use disorders (particularly opioid use disorders) and families' involvement with the child welfare system showed that nationwide a 10 percent increase in the overdose death rate corresponded to a 4.4 percent increase in the foster care entry rate, with the primary driver of the increase being entries of infants into foster care.

To increase economic security and mobility, ASPE conducts research and analysis on program alignment, including a special focus on reducing the economic risk of program cliffs. 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 will help facilitate an interagency approach to both the Executive Order on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government and the Executive Order on Economic Relief Related to the COVID-19 Pandemic, as well as provide a sustainable platform to promote effective and equitable provision of services.

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 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. This includes connecting youth with resources to help them recover from economic challenges caused by the COVID-19 pandemic. Many of these goals are accomplished through the website www.youth.gov, a one-stop shop for federal information and resources about youth.

ASPE is helping states integrate child welfare and Medicaid data for both operational and research/evaluation purposes, and recognizes that many of the new preventive services child welfare agencies that may now fund through the Family First Prevention Services Act, are also reimbursable in some states under Medicaid. Real time visibility of which programs are paying for which services and for what clients, will enable states to ensure that families get what they need and avoid inefficiencies. Cross-program data will improve program evaluation. ASPE continues work to move the prevention of child maltreatment upstream by addressing family economic issues that often are treated as neglect and divert the attention of the system from addressing cases of abuse. This will address the disproportionate contact among communities of color with the child welfare system.

ASPE leads the Administration's efforts to combat Alzheimer's disease and related dementias. This includes 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. ASPE will continue to work with Departmental stakeholders, the Advisory Councils, outside experts, and contractors to advance dementia care research and understand the impact of COVID-19 on people with dementia, including social isolation.

ASPE is examining various aspects of older adult health and well-being, including residential care alternatives, caregiver support, evidence-based clinical and community-based preventive services, and health disparities. During the COVID-19 pandemic, ASPE has been providing technical and analytic support for policy decision-making to support ASPR and the Secretary on behalf of individuals, families, and communities, particularly with respect to long-term care provider settings including nursing homes and assisted living facilities; and for those receiving home and community-based services.

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 Act (SUPPORT Act, P.L. 115-271). Ongoing research focuses on naloxone utilization and abandonment, and the impact of state naloxone prescribing policies.

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 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.

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 several 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. In addition, ASPE is leading work to effectively and respectfully incorporate lived experience and expertise into human services policy and will focus on developing person-centered wellbeing measures that can be adapted by programs.

ASPE continues 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. ASPE's Patient Centered Outcomes Research Trust Fund is supporting data infrastructure projects that are developing common data elements, natural language processing, common data elements, and real-world evidence with agencies across the Department.

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 OMB, 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 provides analyses to improve the efficiency and effectiveness of programs. The Indian Health Service requested ASPE support to assess the impact of policy changes to address wait times in clinics in response to a GAO audit; review the current alignment of IHS quality measures with existing performance and value-based purchasing program requirements, and identify opportunities for enhanced alignment, as well as consider activities that IHS could undertake to further engage in value based payment arrangements moving forward.

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 also coordinates the process for reviewing Paperwork Reduction Act waivers for voluntary information collections during a Public Health Emergency.

Reform, Strengthen, and Modernize the Nation's Healthcare System

ASPE conducts research and policy analyses to support the Department's objectives in reforming, strengthening, and modernizing the U.S. healthcare system. This work includes Departmental efforts to: measure, monitor and evaluate health insurance coverage in the Marketplace and Medicaid; sustain financing of the Medicare program; enhance nursing home quality; improve the delivery of behavioral health; develop innovative payment and delivery systems; improve care delivery and financing in the Indian Health Service; and understand the growth of pharmaceutical prices and identify ways to reduce costs.

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 meet their needs. Working closely with the CMS and the Assistant Secretary for Public Affairs (ASPA), ASPE supported the Department's efforts to expand access to health insurance coverage under the Affordable Care Act and the American Rescue Plan, with data analysis on the uninsured; evaluation of Medicaid policies; and policy planning around the ACA Marketplace including a potential public option. Specifically, ASPE research on the geographic and demographic characteristics of the uninsured, and the impact of the newly enacted American Rescue Plan, has informed the Administration's outreach strategies to reduce disparities. ASPE analyses of the impact of recent Medicaid demonstrations and continuous coverage will inform policymaking over the coming year.

ASPE works to improve maternal health by updating a Department-wide Action Plan originally issued in December 2020. Updates involve reassessing goals and objectives, identifying opportunities to expedite and track progress, and developing a research and data strategy.

ASPE will identify key strategies to address the growth of health care costs while promoting high-value patient-centered 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 follow-on research ASPE has completed 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 improve the MIPS physician payment program; 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. ASPE's analyses of drug prices support Department policymaking in regulations and legislative proposals. Analyses assess the impact of competition on generic drug prices; impact of exclusivities and patent protections on generic drug entry; trends in spending by source and patient copayments; impacts of biosimilar policies; and changes in Part D benefit structure.

ASPE participates in several interagency workgroups to support the alignment and public reporting of quality measures across HHS programs. One workgroup focuses on ensuring that measures reported by states as part of the Medicaid and CHIP core sets include behavioral health quality measures that are actionable, relevant, and can meaningfully drive improvement in quality of care and outcomes. ASPE also actively participates in National Quality Forum and National Committee on Quality Assurance workgroups to help strengthen and improve behavioral health quality measures used across HHS reporting programs. In recent years, ASPE has partnered with CMS and the Substance Abuse and Mental Health Services Administration (SAMHSA) to develop or modify thirty-two behavioral health quality measures for reporting at the facility level. These measures address important issues such as follow-up after inpatient and emergency room treatment for behavioral health conditions; screening for clinical depression and follow-up; and adherence to psychotropic medications. ASPE is currently using some of these measures as part of their evaluation of the Certified Community Behavioral Health Clinic (CCBHC) demonstration program, and is also studying the feasibility of calculating some of these measures using existing Medicaid claims and encounter data to help support routine program monitoring and quality improvement efforts.

Agencies often request that ASPE undertake specific projects to support HHS priorities, including numerous CMS requests on topics such as: a review of the evidence regarding Medicaid community engagement requirements and the associated impacts on beneficiaries; updated estimates of those without health insurance coverage to inform outreach and enrollment efforts for the Health Insurance Marketplace; analyses of Medicare beneficiaries with COVID-19 who reside in nursing homes to identify infection control and other policy changes that could improve quality of care going forward; the impact of COVID-19 on provider finances to inform the Center for Medicare and Medicaid Innovation (CMMI) payment model evaluations; policy alternatives to support Medicare post-acute bundled payment reforms, insurance market simulation models, and conducting demonstrations to test new models of serving older individuals in home and community-based settings; and an analysis and description of best practices, payment, and coverage of pain management services under the Medicare program.

ASPE has a central role in behavioral health policy, working closely with other staff divisions, operating divisions, and outside stakeholders. For example, ASPE leads the evaluation of the Medicaid CCBHC demonstration along with CMS and SAMHSA. On initiatives related to the behavioral health workforce, ASPE works closely with the Health Resources and Services Administration (HRSA) and SAMHSA. Since enactment of the SUPPORT Act in 2018, ASPE has coordinated Department-wide implementation tracking in close collaboration with the OASH. ASPE participates in National Quality Forum and National Committee on Quality Assurance workgroups to help strengthen and improve behavioral health quality measures used across HHS reporting programs. ASPE has also been engaged in policy changes to increase access to behavioral health care during the COVID-19 pandemic.

ASPE is conducting research on the Department's response to COVID including most recently analyses around vaccine availability, vaccine hesitancy, and vaccine distribution with a special focus on high risk populations including communities of color, the homebound, and those with multiple chronic conditions. ASPE is preparing maps and other tools to inform state and local partners work on vaccine outreach efforts. ASPE research on COVID infection, hospitalization, and mortality has been used by the Centers for Disease Control and Prevention (CDC) to inform state and local partners, and is the foundation for additional research underway with CMS and CDC around infection control in the nursing homes to inform Department policymaking. ASPE is continuing analytic work on the impact of the pandemic on the health care sector including provider finances and populations who may have deferred health care services and now have exacerbated medical conditions. ASPE analyses around Medicare beneficiary use of telehealth services will be updated and used to inform policymaking decisions for upcoming regulatory proposals and the legislative program.

The Teen Pregnancy Prevention (TPP) Evidence Review systematically collects and presents information about program models that have been rigorously evaluated and shown to reduce teen pregnancy, sexually transmitted infections, or associated sexual risk behaviors.

Five Year Funding Table

Fiscal Year	Amount
FY 2018	$41,243,000
FY 2019	$43,243,000
FY 2020[7]	$43,243,000
FY 2021 Enacted	$43,243,000
FY 2022 President's Budget	$56,743,000

Budget Request

The FY 2022 President's Budget request for ASPE is $56,743,000, which is $13,500,000 above the FY 2021 Enacted level. The additional funds support additional staff, the purchase of data, and expansion of research capabilities to address important policy research needs in support of the President's agenda.

[7] Reflects FY 2020 Operating, post-required transfers. Excludes supplemental appropriations for COVID-19. Excludes permissive transfers or allotments from the PHSSEF to GDM which are shown in PHSSEF.

Research – Additional funding for research allows ASPE to expand the evaluation capacity to quickly estimate the impact of a wide range of policy options to support the President's priority to protect and expand access to quality affordable health care; efforts to control the COVID pandemic by studying the impacts of COVID on a variety of at-risk populations including the American Indian/Alaska Native population, people living with HIV, rural populations, persons with disabilities, and vulnerable older adults. Additional funding allows ASPE to expand the capacity to ensure coordinated, equitable, and effective delivery of human services to promote economic recovery; and child and family wellbeing; and expand research capacity to study the link between climate change and human health and welfare.

Data and Modeling –Additional funds allow ASPE to add race and ethnicity data to some existing and new data purchases. This allows to further evaluate the impacts of COVID on racial and ethnic minorities more directly. ASPE will also expand capacity to explicitly incorporate other vulnerable populations (e.g., the working age population with disabilities) and new income support policies (e.g. the enhanced Child and Dependent Care Tax Credit) into core actuarial and microsimulation models. Additional funding will allow ASPE to secure an IT infrastructure in support of scientific and analytical computing capacity and align with HHS cybersecurity policy and continuity of operations.

Staffing - The additional funds allow ASPE to fill 28 vacancies and restore staff capacity for evaluation, data analysis, and coordination activities in support of the President's Executive Order 14009, Strengthening Medicaid and the Affordable Care Act, and numerous legislative proposals being considered for expanding coverage and building on the ACA and the Healthcare Access. ASPE will also hire staff to support the President's emphasis on restoring faith in and integrity of science, staff to support the Medicare team as it addresses long term financial sustainability of the Medicare program, staff in the Immediate Office to support the incoming leadership.
Additional funding allows ASPE to fully fulfill its role in providing 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 makes significant investments in resources that allow responses to immediate requests for information to support policy making, these include:

- Access to Private Sector Databases
- National Poverty Research Center
- Transfer Income Model (TRIM3)
- Health Insurance Microsimulation Model
- Dynamic Simulation of Income Model (DYNASIM4)
- Actuarial Estimation

ASPE will compete a new contract in FY 2021 to update the evidence review. This contract will reassess, refine, and innovate existing TPP Evidence Review criteria and standards through consultation with external and federal experts; identify and assess evidence for a subset of studies published since the previous review, which included literature available through 2016; and update the information available on the TPP Evidence Review website, now hosted at youth.gov. ASPE is partnering with the Office of Population Affairs and the Family and Youth Services Bureau on this work.

ASPE continues support for a mechanism such as a cooperative agreement to promote economic resilience and equitable recovery, and work to end poverty for children, families, and communities. ASPE awards funds to a university to provide timely access to access to cutting edge researchers and high-quality, reliable research, meeting HHS policy research demands in high priority areas including measures of wellbeing, evidence for prevention, and strengthening equity and inclusion as well as policies and programs to increase economic security and identify and address the root causes of poverty. This work also enhances diversity in the poverty research field.

Grants

Grants(whole dollars)	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Budget
Number of Awards	1	1	1
Average Award	$1,565,000	$1,565,000	$1,565,000
Range of Awards	$1,565,000	$1,565,000	$1,565,000

PUBLIC HEALTH ACTIVITIES

Budget Summary

(Dollars in Thousands)

Public Health Activities	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Budget	FY 2022 +/- FY 2021
Budget Authority	9,400	8,800	8,800	--
FTE	13	13	13	-

Authorizing Legislation..... PHS Act, Title II, Section 247
FY 2022 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.

The CTO was reorganized at the end of FY 2020, moving health data initiatives to the OASH. 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.

Five Year Funding Table

Fiscal Year	Amount
FY 2018	$11,400,000
FY 2019	$9,400,000
FY 2020	$9,400,000
FY 2021 Enacted	$8,800,000
FY 2022 President's Budget	$8,800,000

Budget Request

The FY 2022 President's Budget request for PHS Evaluation is $8,800,000, which is flat with the FY 2021 Enacted. The request will continue to provide the Secretary with resources to 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 program integrity and return on investment.

PHS EVALUATION
ASSISTANT SECRETARY FOR FINANCIAL RESOURCES

Budget Summary
(Dollars in Thousands)

Assistant Secretary for Financial Resources	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Budget	FY 2022 +/- FY 2021
Budget Authority	1,100	1,100	1,100	-
FTE	-	-	-	-

Authorizing Legislation: .....PHS Act, Section 241
FY 2022 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 also 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 2018	$1,100,000
FY 2019	$1,100,000
FY 2020	$1,100,000
FY 2021 Enacted	$1,100,000
FY 2022 President's Budget	$1,100,000

Budget Request
The FY 2022 President's Budget request for ASFR PHS Evaluation is $1,100,000, which is flat with the FY 2021 Enacted Level.

The FY 2022 request supports costs associated with the Department's effort to improve the Data Analytics Platform, which captures data for nearly 1,000 HHS program performance measures, funding levels for select crosscutting issues, as well as enterprise risk management and program integrity information. OB manages the implementation of the Government Performance and Results Modernization Act (GPRAMA) and all phases of HHS performance budget improvement activities. The FY 2022 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 Goals (APG) and Strategic Objective Review (SOR) reporting. APGs are near-term goals that focus on key priorities of the Secretary and the Administration. During the SOR 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)

Office of the Assistant Secretary for Health	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Budget	FY 2022 +/- FY 2021
Budget Authority	4,285	4,885	7,885	+3,000
FTE	-	2	3	+1

Authorizing Legislation: .....PHS Act, Title II, Section 247
FY 2022 Authorization.....Permanent
Allocation Method.....Direct Federal

Program Description and Accomplishments
The Office of the 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 the programs and services are working.

FY 2020 funded projects and accomplishments include:

- Developing National Health Objectives – Healthy People 2030 (HP2030)
  - The validation of data sources, data and 10-year targets for the 355 core (or measurable) HP2030 objectives were completed and launched in August 2020. Collaborating with agencies across HHS, the Office of Disease Prevention and Health Promotion (ODPHP) developed and launched in December 2020, eight HP2030 overall health and well-being measures, which are broad, global outcome measures intended to assess the Healthy People 2030 vision.
- Healthy People 2020
  - In December 2020, the "Healthy People 2020: An End of Decade Snapshot" report, highlights the progress made over the decade in meeting the Healthy People 2020 (HP2020) targets and identifies successes and areas for improvement for the next decade. In March 2021, the "HP2020 Final Review Progress Table" was published. It displays the final status of measurable HP2020 objectives.
- Healthy People 2030 - Leading Health Indicators
  - In partnership with HHS agencies and federal departments, ODPHP completed its assessment of HP2030 objectives to identify the Leading Health Indicators (LHI). In December 2020, HHS released the Healthy People 2030 LHIs, which represent a small subset of 23 measurable Healthy People 2030 objectives associated with evidence-based interventions and which address important factors that impact major causes of death and disease across the lifespan, including social determinants of health.

- Modernization of the USPHS Commissioned Corps Evaluation
  - A training needs analysis examining the availability, content, and suitability of existing training for USPHS Commissioned Corps Officers was conducted. The findings report included strategies to close the training gaps, thereby, strengthening the training for the USPHS Commissioned Corps. Through a series of focus groups and interviews, an integrated strategy to recruit, staff, onboard, and market to reservists and other officers was developed. Lastly, a qualitative study was conducted to develop career pathway options for career progression in the clinical care field according to an officer's interests and aspirations.
- Move Your Way Campaign
  - A quantitative study was conducted with over 5,000 participants across 8 distinct pilot communities. Ongoing data analysis examines differences in key outcomes (e.g., awareness of the guidelines, knowledge, self-efficacy, behavior, and behavioral intent) between participants who reported exposure to the Move Your Way® campaign and those who did not report exposure. In addition, a qualitative study was also conducted to identify models, barriers and facilitators to long-term campaign success and to support ongoing strategic planning.
- 2020-2025 Dietary Guidelines for Americans Communications
  - Formative research was completed to inform updates to the existing Dietary Guidelines for Americans healthcare professional toolkit. These updates reflected new content on the 2020-2025 Dietary Guidelines and the breakdown of life stages (infants/toddlers, adolescents, and older Americans).
- National Youth Sports Strategy Implementation
  - The impact of the National Youth Sports Strategy (NYSS) was evaluated and disseminated through a partnership initiative; virtual stakeholder workshops; and a President's Council on Sports, Fitness and Nutrition's Science Board Report on Youth Sports and Benefits of Youth Sports fact sheet. A series of six, 2-hour NYSS workshops were held in different HHS regions, which brought together more than 100 youth sports stakeholders to discuss reintroducing sports in the wake of the COVID-19 pandemic and to unite around the NYSS vision.
- Precision Prevention Project
  - This study examined whether a single-message program versus a multi-message program resulted in any differences in program effectiveness. While no differences were found, it did identify potential moderating variables that should be considered in future analyses. The project is now completed, producing 3 Office of Population Affairs briefs and 2 journal articles.
- Supporting Healthy Aging through Physical Activity Guidelines
  - A formative study was conducted to understand older adults' knowledge, barriers, and information needs related to physical activity. This research influenced the development of a new campaign resource for older Americans focused on the types and intensity of physical activity recommended for adults over 65. ODPHP also supported the implementation and evaluation of a campaign focused on reaching older adults led by a West-Virginia physical activity non-profit.

Projects approved in FY 2021 include:

- Developing National Health Objectives to Evaluate Health Across the Nation: HP2030:
  - Track and monitor data for HP2030 objectives and measures;
  - Disseminate data for public use; and
  - Conduct implementation and communication activities to promote the use of HP2030 objectives with stakeholders to achieve the national targets.
- Developing Leading Health Indicators (LHI): HP2030

- Track LHI and Overall Health and Well-Being Measures (OHM) data on health.gov/healthypeople2030; and
- Disseminate evidence-based practices stakeholders can use in their own communities to adapt the LHI and OHMs to improve the health of their communities.

- Dietary Guidelines for Americans, 2025-2030:
  - Evaluate dietary guidelines; determine gaps and best practices; and
  - Disseminate activities and findings of the Dietary Guidelines Advisory Committee to ensure transparency and feedback from the public.
- Physical Activity Guidelines for Americans Midcourse Report: Strategies to Increase Physical Activity Among Older Adults:
  - Evaluate the current literature on what works and strategies to increase physical activity among older adults;
  - Identify settings where physical activity messaging/encouragement would be relevant to older adults; and
  - Increase the number of older adults who meet the key guidelines for older adults.
- Evaluating a Modernized USPHS Commissioned Corps:
  - Track implementation of the comprehensive evaluation recommendations for a modernized USPHS Commissioned Corps using performance measures;
  - Disseminate high-level communication strategies to support the implementation phase; and
  - Conduct additional assessments to determine trends, gaps, and improvements.
- Evaluate the implementation of the Sexually Transmitted Infections (STI) Strategic Plan:
  - Assess the nation's progress in reaching identified targets to reduce STIs;
  - Implement steps to course correct, if targets are not being met;
  - Evaluate the impact of COVID-19 on underlying health conditions related to STIs; and
  - Analyze and disseminate best practices.
- Evaluation of Health Messaging to Promote COVID-19 Vaccinations among Racial and Ethnic Minority Populations:
  - Evaluate the effectiveness of developed, targeted promotional materials to increase community demand and awareness of COVID-19 vaccination among racial and ethnic minority populations;
  - Assess community perceptions of risk, barriers, and cues to actions (based on the health belief model) related to COVID-9 vaccination among racial and ethnic minority populations.
- OASH Service Inventory and Automation Evaluation:
  - Assess and expand business analytics of public, officer, and administrative services demand within a Single Point of Contact (SPOC) Call Center and workflow automation capability;
  - Identify trends to provide recommendations on how to support, categorize, streamline and resolve high volume requests in a timely manner; and
  - Identify and recommend automation tools that can provide self-service functionality to the officer, recruit, reservist, OASH administrative, and target communities providing an exceptional connection of mission needs to service delivery.

Five Year Funding Table

Fiscal Year	Amount
FY 2018	$4,285,000
FY 2019	$4,285,000
FY 2020	$4,285,000
FY 2021 Enacted	$4,885,000
FY 2022 President's Budget	$7,885,000

Budget Request
The FY 2022 President's Budget request for OASH PHS Evaluation is $7,885,000, which is $3,000,000 above the FY 2021 Enacted 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.

The FY 2022 Budget will also support activities in response to the Administration's Health Equity Executive Order. Activities will support addressing the disproportionate and severe impact of COVID-19 on communities of color and other underserved populations by conducting a demonstration project and related activities for advancing equitable access to COVID-19 resources and services. Building on existing work with States and localities to identify/address barriers to equitable allocation and access to COVID-19 resources and services, OASH and OMH will collaborate with critical partners affiliated with racial and ethnic populations to review documents and disseminate/findings to determine scientific accuracy, cultural and linguistic responsiveness and effectiveness in facilitating access to health-related services.

PHS EVALUATION
TEEN PREGNANCY PREVENTION

Budget Summary
(Dollars in Thousands)

Teen Pregnancy Prevention	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Budget	FY 2022 +/- FY 2021
Budget Authority	6,800	6,800	6,800	-
FTE	-	-	-	-

Authorizing Legislation.....PHS Act, Title II, Section 241
FY 2022 Authorization.....Permanent
Allocation Method.....Direct Federal

Program Description and Accomplishments
The Office of Population Affairs (OPA) and OASH support several research and evaluation activities to build the evidence base to prevent teenage pregnancy and make a significant contribution to the field, including:

- A research-to-practice center to develop and disseminate research-informed practice resources for professionals who work with youth involved in the child welfare and/or justice systems, youth experiencing homelessness, and opportunity youth.
- Research grants examining setting and youth characteristics to determine under what conditions TPP programs are most and least effective, assessing the impact of social determinants of health on reproductive outcomes among Latina adolescents, and determining factors that prevent and reduce disparities in sexual health outcomes.
- The provision of rigorous evaluation training and technical assistance to TPP Program grantees conducting research and evaluation.
- The collection and analysis of program performance measures for monitoring, program improvement and reporting.
- Multiple research projects with the goals of identifying, measuring, and evaluating the effectiveness of core components of TPP programs.
- The HHS TPP Evidence Review to build our understanding of the program models that have been rigorously evaluated and shown to reduce teen pregnancy, sexually transmitted infections, or associated sexual risk behaviors.

Five Year Funding Table

Fiscal Year	Amount
FY 2018	$6,800,000
FY 2019	$6,800,000
FY 2020	$6,800,000
FY 2021 Enacted	$6,800,000
FY 2022 President's	$6,800,000

Budget Request
The FY 2022 President's Budget request for TPP PHS-Evaluation funding is $6,800,000, which is flat with the FY 2021 Enacted Level. The FY 2022 budget will continue to support research and evaluation activities to build the evidence base to prevent teenage pregnancy.

PHS EVALUATION
OFFICE OF CLIMATE CHANGE AND HEALTH EQUITY

Budget Summary

(Dollars in Thousands)

Office of Climate Change and Health Equity	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Budget	FY 2022 +/- FY 2021
Budget Authority	-	-	3,000	+3,000
FTE	-	-	8	+8

Authorizing Legislation.....PHS Act, Title II, Section 241
FY 2022 Authorization.....Permanent
Allocation Method.....Direct federal

Program Description and Accomplishments

HHS is leading the implementation of multiple climate change-related Executive Orders. Within the Office of the Secretary, HHS is establishing the Office of Climate Change and Health Equity described in Executive Order 14008, Tackling the Climate Crisis at Home and Abroad, Section 222 (d)(i) which is charged with "addressing the impact of climate change on the health of the American people." The new office will be supported by OASH, which also leads the work group defined in Section 222, (d) (ii) which calls for the establishment of an Interagency Working Group to Decrease the Risk of Climate Change to Children, the Elderly, People with Disabilities, and the Vulnerable, as well as a biennial health care system readiness advisory council, both of which will report their progress and findings regularly to the National Climate Task Force. In addition to these new initiatives, the office will be responsible for re-starting the HHS Environmental Justice Working Group and developing an environmental justice strategic plan update (last published in 2012), and interim annual progress reports (last published in 2017).

Office of Climate Change and Health Equity: Establishment of the office in the Office of the Secretary will fulfill not only Section 222 (d)(i) of Executive Order 14008, it will facilitate the provision of an agency-wide hub for climate control, climate justice, environmental justice, and environmental health, areas of focus within the seven total environmental health/climate-related executive orders that are relevant to HHS and interconnected to this initiative: 14008, 14013, 13985, 13987, 13990, 13994, and 13995. Meaningful and effective execution of these executive order areas of responsibility will require coordination with all STAFFDIVs and OPDIVS, as well as a significant interagency coordination function.

Interagency Working Group to Decrease the Risk of Climate Change to Children, the elderly, people with disabilities, and the vulnerable (IAWG): The initial task of the working group will be characterization of the gaps between existing recommendations and activities and needs to achieve the desired goals, identify redundancies in efforts, and identify how each function can contribute to decreasing the risk of climate change to children, the elderly, people with disabilities, and the vulnerable, development of a comprehensive plan, including milestones, activities, tools, and strategies, for establishing and supporting key relationships.

Environmental Justice: HHS environmental justice activities date to the 1994 EO 12898, *Federal Actions to Address Environmental Justice in Minority Populations and Low-income Populations,* which directed agencies to make environmental justice part of its missions. In response, HHS issued its first Environmental Justice Strategy in 1995. Federal environmental justice efforts were reinvigorated in 2010 and in 2012 and updated HHS Environmental Justice Strategy and Implementation Plan was

released. Since that time multiple progress reports have been published. Work products since 2012 include:

- HHS Environmental Justice Strategy and Implementation Plan (2012)
- HHS Environmental Justice Implementation Progress Report (2012 to 2017)

Five Year Funding Table

Fiscal Year	Amount
FY 2018	$0
FY 2019	$0
FY 2020	$0
FY 2021 Enacted	$0
FY 2022 President's Budget	$3,000,000

Budget Request

The FY 2022 President's Budget request for the Office of Climate Change and Health Equity is $3,000,000 and is the initial request for this activity. The FY 2022 budget allows the Office to attain full operational capability and successfully achieve its critical goals.

The FY 2022 budget will support key personnel, to include Senior Advisor, Senior Program Manager, Details from other Agencies, and potentially bringing on needed experts through the Intergovernmental Personnel Act (IPA), and required administrative support. The FY 2022 budget will also ensure that the Office of Climate Change and Health Equity has the resources necessary for priorities such as launching the IAWG, and potentially, the biennial health care system readiness advisory council. Additionally, the re-establishment of the HHS EJ working group will require support to launch and meet critical deadlines.

SUPPORTING EXHIBITS

DETAIL OF POSITIONS[8]

Direct Civilian Positions	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Budget
Executive level I	1	1	1
Executive level II	1	1	1
Executive level III	-	-	-
Executive level IV	2	2	2
Executive level V	-	-	-
Subtotal, Positions	**4**	**4**	**4**
Total, Salaries	**$ 765,700**	**$ 773,357**	**$ 780,511**
-	-	-	-
Executive Service	91	98	100
Administrative Appeal Judge	14	17	17
Subtotal, Positions	**105**	**115**	**117**
Total, Salaries	**$ 17,021,466**	**$ 18,594,848**	**$ 19,098,702**
-	-	-	-
GS-15	162	168	178
GS-14	183	203	213
GS-13	119	119	111
GS-12	79	79	89
GS-11	43	43	75
GS-10	3	3	3
GS-9	43	48	75
GS-8	8	8	8
GS-7	6	6	6
GS-6	1	1	1
GS-5	1	1	1
GS-4	1	1	1
GS-3	-	-	1
GS-2	-	-	-
GS-1	-	-	-
Subtotal, Positions	**649**	**680**	**762**
Total Salaries	**$101,753,834**	**$107,559,969**	**$122,589,744**
Total Positions	**758**	**799**	**883**
Average ES Level	ES 00	ES 00	ES 00
Average ES salary	$ 162,109	$ 161,694	$ 163,237
Average GS grade	14.9	14.10	14.10
Average GS Salary	$ 156,786	$ 158,176	$ 160,879

[8] Table does not include Reimbursable or Commissioned Corps FTE.

DETAIL OF FULL-TIME EQUIVALENT (FTE) EMPLOYMENT[9]

Detail	FY 2020 Final CIV	FY 2020 Final CC	FY 2020 Final Total	FY 2021 Enacted CIV	FY 2021 Enacted CC	FY 2021 Enacted Total	FY 2022 President's Budget CIV	FY 2022 President's Budget CC	FY 2022 President's Budget Total
Direct	758	31	789	799	38	837	883	39	922
Reimbursable	517	15	532	559	11	570	595	11	606
Total FTE	**1,275**	**46**	**1,321**	**1,358**	**49**	**1,407**	**1,478**	**50**	**1,528**
-	-	-	-	-	-	-	-	-	-
Average GS Grade Direct	**-**	**-**	**14.9**	**-**	**-**	**14.10**	**-**	**-**	**14.10**

FTES FUNDED BY THE AFFORDABLE CARE ACT

(Dollars in Thousands)

Program	Section	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Pregnancy Assistance Fund Discretionary P.L. (111-148)	Section 10214	25,000	22,825	23,200	23,275	23,300	23,275	23,350	23,350	0	0	0
FTE	**-**	**2**	**2**	**2**	**2**	**2**	**2**	**2**	**2**	**0**	**0**	**0**

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

HHS FTE FYs 2020-2022[10]

FY 2020 Base Actuals			FY 2020 Supplemental Actuals			FY 2020 Total FTEs (MAX Totals)		
CIV	CC	Total	CIV	CC	Total	CIV	CC	Total
1,275	46	1,321	-	-	-	1,275	46	1,321

FY 2021 Base Omnibus			FY 2021 Supplemental Estimates			FY 2021 Omnibus Total (MAX Totals)		
CIV	CC	Total	CIV	CC	Total	CIV	CC	Total
1,351	49	1,400	-	-	-	1,351	49	1,400

FY 2022 Base President's Budget			FY 2022 Supplemental Estimates			FY 2022 Total President's Budget (MAX Totals)			2022 +/- 2020	2022 +/- 2021
CIV	CC	Total	CIV	CC	Total	CIV	CC	Total	Total Base	Total Base
1,471	50	1,521	-	-	-	1,471	50	1,521	+200	+121

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

RENT AND COMMON EXPENSES

(Dollars in Thousands)

Details	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Budget	FY 2022 +/- FY 2021
Rent	-	-	-	-
GDM	9,867	9,867	11,284	+1,417
IOS	204	204	221	+17
ASA	-	-	-	-
ASFR	117	117	118	+1
ASPA	-	-	-	-
CFOI	65	66	67	+1
DAB	431	537	642	+105
IEA	924	924	933	+9
OASH	5,444	5,483	6,238	+755
OGA	450	450	470	+20
OGC	3,132	3,217	3,250	+33
Subtotal	***20,634***	***20,865***	***23,223***	***+2,358***
Operations and Maintenance	-	-	-	-
GDM	448	1,013	1,843	+830
IOS	122	117	120	+3
ASA	838	838	840	+2
ASFR	704	255	262	+7
ASPA	63	63	64	+1
CFOI	14	14	14	-
DAB	140	140	142	+2
IEA	162	182	184	+2
OASH	2,798	2,619	3,180	+561
OGA	172	692	376	-316
OGC	618	629	636	+7
All Other GDM	204	170	175	+5
Subtotal	***6,283***	***6,732***	***7,836***	***+1,104***
Service and Supply Fund	-	-	-	-
GDM Shared Services	7,210	7,210	7,210	-
IOS	1,713	1,799	1,889	+90
ASA	5,477	5,751	6,038	+287
ASFR	1,532	1,609	1,689	+80
ASPA	658	691	725	+34
CFOI	152	160	168	+8
DAB	389	408	429	+21
IEA	589	618	649	+31
OASH	6,663	6,996	7,346	+350
OGA	441	463	486	+23
OGC	2,998	3,148	3,305	+157
Subtotal	***27,822***	***28,853***	***29,934***	***+1,081***

PHYSICIANS' COMPARABILITY ALLOWANCE (PCA)

Office of the Assistant Secretary for Health

Physician Categories	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Budget
1) Number of Physicians Receiving PCAs	3	3	5
2) Number of Physicians with One-Year PCA Agreements	-	-	-
3) Number of Physicians with Multi-Year PCA Agreements	3	3	5
4) Average Annual PCA Physician Pay (without PCA payment)	$86,000	$86,000	$144,000
5) Average Annual PCA Payment	$28, 666	$28,666	28,666
6) Number of Physicians' Receiving PCA's by Category (non-add) Category I Clinical Position	-	-	-
Number of Physicians' Receiving PCA's by Category (non-add) Category II Research Position	-	-	-
Number of Physicians' Receiving PCA's by Category (non-add) Category III Occupational Health	-	-	-
Number of Physicians' Receiving PCA's by Category (non-add) Category IV-A Disability Evaluation	-	-	-
Number of Physicians' Receiving PCA's by Category (non-add) Category IV-B Health and Medical Admin.	3	3	5

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.

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), Office of Grants, manages the Grants.gov system, website, and program management office as a reimbursable service for Federal grant-making agencies. Grants.gov is the Federal government's single "find and apply" portal for federal financial assistance funding opportunities required by P.L. 106-107. Originally assigned to HHS by the Office of Management and Budget (OMB) in 2003, ASFR has continuously operated the system and collected the costs through reimbursable agreements. Each year, 30+ Federal Partner Agencies post over 4,300 funding opportunity listings totaling nearly $140B in available competitive financial assistance funding to Grants.gov. In FY 2020, Grants.gov exceeded 1M unique, registered users, and received over 270,000 grant applications.

The Grants.gov system enables federal agencies to publish grant funding opportunities and application packages in a single, government-wide online location that may be searched by any organization, e.g., state, local, and tribal governments, education and research entities, or non-profits, and individuals. For participating Federal agency opportunities, Grants.gov also hosts workspaces that allow organizations to complete and submit grant application materials.

The initiative provides service to grant-making Federal agencies including, but not limited to:

- 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 the Interior
- Department of Justice
- Department of Labor
- Department of State
- U.S. Agency for International Development
- Department of Transportation
- Department of the Treasury
- Department of Veterans Affairs
- Environmental Protection Agency
- National Aeronautical and Space Administration
- National Archives and Records Administration
- National Science Foundation
- Small Business Administration
- Social Security Administration
- AmeriCorps
- Institute of Museum and Library Services
- National Endowment for the Arts
- National Endowment for the Humanities

For almost 20 years, Grants.gov has been a national resource for the public to find the financial assistance opportunities that support programs, research projects, and other activities offered by agencies across the Federal government.

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 Register, from identification through resolution. This online register is accessible to all Grants.gov team members and is updated regularly, in keeping with a continuous risk management process. The Risk Register 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 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.

Risk 1: Grants.gov transactions and website traffic increased substantially with the increase of available financial assistance funding in response to the COVID-19 pandemic.

- Grants.gov saw a 97% increase in new user registrants from March 2020 to Jan 2021 when compared to the same timeframe, 2019-2020.
- During this same time-period, the completed application volume increased 21%, with the largest month-to-month growth occurring between March 2020 and Jan 2021, with the largest increase in May 2020 (+69%).
- The new Grants.gov users coupled with the growth in applications submitted resulted in substantial in-bound call increases for the Grants.gov Contact Center of 21% from March 2020 to Jan 2021, with the largest month-to-month growth occurring in April 2020 of 53% as compared to April 2019. Email volume increased 76% overall, with the largest percent increase occurring in May 2020 of 134% as compared to May 2019.
- During Spring 2020, Grants.gov users reported severe system degradation on two occasions, resulting in the Grants.gov application being inaccessible to users for a short period of time.

These increases have placed a significant strain on the Grants.gov system and operation resources. Despite the unprecedented pressure, Grants.gov maintained core operations and continues to be responsive to user and grantor needs. Nonetheless, ageing hardware and software threatens to diminish system performance for users in the future.

Risk mitigation response:

To address these risks, HHS began a multi-year effort in 2016 to modernize the Grants.gov hardware and software. In FY 2022, this includes migrating the Grants.gov system to a cloud-computing environment in FY 2022Migrating to the cloud will:

- Stabilize the Grants.gov application in the short-term.
- Reduce the risks of unplanned downtime or system outages.
- Provide a quickly scalable environment with the capacity to support increased user loads.
- Improve the management of security controls.
- Significantly reduce costs for continued operations and maintenance of hardware.

FUNDING: Grants.gov's operational costs are funded largely by annual agency contributions. Cost recovery is based on an algorithm that factors in annual figures for agency size (in terms of discretionary dollars awarded) and number of applications and opportunities each agency posts. These collections cover operational costs including: salaries and expenses for staff; contracts or agreements for system integration; hardware platforms; upgrades; software licenses; Independent Verification and Validation; outreach and liaison work; contact center; performance metrics monitoring; and a modicum of office support.

The amount of Grants.gov planned Partner collections for FY 2022 is listed in the table below.

GRANTS.GOV

FY 2020 to FY 2022 Agency Collections

Agency	Total FY 2020	Total FY 2021	Total FY 2022
CNCS	26,000	25,000	25,000
DHS	289,000	290,000	295,000
DOC	366,000	377,000	391,000
DOD	621,000	670,000	711,000
DOE	418,000	423,000	425,000
DOI	1,339,000	1,370,000	1,390,000
DOL	93,000	92,000	277,000
DOS	444,000	482,000	535,000
DOT	294,000	301,000	308,000
ED	423,000	436,000	446,000
EPA	331,000	335,000	347,000
HHS	7,036,000	7,156,000	7,226,000
HUD	277,000	275,000	278,000
IMLS	63,000	66,000	70,000
NARA	28,000	28,000	29,000
NASA	74,000	73,000	75,000
NEA	198,000	205,000	209,000
NEH	163,000	167,000	172,000
NSF	325,000	323,000	326,000
SBA	46,000	47,000	47,000
SSA	21,000	21,000	21,000
TREAS	57,000	58,000	59,000
USAID	284,000	279,000	278,000
USDA	484,000	496,000	510,000
USDOJ	473,000	457,000	292,000
VA	143,000	150,000	152,000
Grand Total	**14,316,000**	**14,602,000**	**14,894,000**

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 2021 Funding
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.	$7,786,842
Center for Health Innovation	The Center for Health Innovation (CHI) addresses health innovation priorities, gaps, and opportunities by identifying specific gaps that need to be addressed and develop a coordinated plan to address these critical health gaps through public-private partnerships that span government, non-profit, and private sectors.	$1,342,360
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).	$17,929,722
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.	$743,195
Grants Quality Service Management Office (QSMO) Project Management Office	The Office of Management and Budget (OMB) has designated HHS as the Grants QSMO, as established under the OMB Memorandum M-19-16 *Centralized Mission Support Capabilities for the Federal Government*. The Grants QSMO facilitates reductions in applicant and recipient burden, equal access to federal financial assistance, government-wide efficiencies, responsiveness to customer needs, and use of data as a strategic asset.	$1,046,000
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*).	$337,404
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.	$2,230,650
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
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
Secretary's Policy System (SPS)	The official records repository of the Immediate Office of the Secretary (IOS), it is used to manage regulations, reports to Congress, correspondence, memoranda, invitations, and other documents. The SPS system ensures compliance with laws, directives, and Executive Orders, and provides HHS leadership assurance that all documents, policies, or regulations that require review and approval are tracked, reviewed, and recorded for future reference.	$537,691
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
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.	$396,000

DIGITAL MODERNIZATION

Modernization of the Public-Facing Digital Services – 21st Century Integrated Digital Experience Act

The 21st Century Integrated Digital Experience Act (IDEA) was signed into law on Dec. 20, 2018. It 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 working 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. In FY 20, HHS Digital Communications Leaders began implementation of the Strategy in alignment with IDEA, beginning to align budgets to modernization requirements.

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,
- Continue developing estimated costs and impact measures for achieving IDEA.

Over the next four 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 2021 Joint Explanatory Statement – Division H (page 105)

Minority Leadership Fellowship.—The agreement includes $500,000 for OMH to establish a Minority Leadership Fellowship grant program, as described in House Report 116-450….. The Committee is concerned there is a shortage of minority leaders in senior positions within HHS agencies. The purpose of the Minority Leadership Fellowship Program is to support a year-long fellowship program within HHS, including a curriculum of health care policy, leadership skill building, lectures, panels, case studies, cultural competence, and exchanges with national health care leaders who direct Federal health policy and programs that impact the health and wellness of minority populations.

Action Taken or To Be Taken

The intent of the Minority Leadership Fellowship Program (MLFP or program) is to assist in filling a gap of a lack of racial and ethnic minority leaders in senior positions within HHS agencies and offices. The program will develop a curriculum focused on health care policy, leadership skills building, lectures, panels, case studies, and cultural competence. In addition, the MLFP will integrate training modules to deliver curriculum content on health care policy and leadership skills using a cultural competency framework to address health disparities throughout the U.S. The program will also include an evaluation component to determine the impact of the MLFP on both the emerging leaders and the host sites. As part of the fellowship experience, participants will engage in active exchanges with national health care leaders who direct Federal health policy and programs that impact the health and wellness of minority populations. The program is currently in development with the initial cohort of fellows expected to begin in FY22.

House Report (page 217)

Racial and Ethnic Health Inequities.—The Committee includes $1,500,000 for the Office of Minority Health to enter into an agreement with the National Academies of Sciences, Engineering, and Medicine to provide an evidence-based, non-partisan analysis of Federal policies that contribute to racial and ethnic health inequities, as well as potential solutions. The study should review current Federal policies that contribute to health inequities, including those policies that impact the social determinants of health. Based on that review, the analysis should identify the most effective or promising strategies to eliminate or modify to advance racial and ethnic health equity. The analysis should be inclusive of all racial and ethnic minority populations in the United States, including Black or African American, Hispanic or Latino, American Indian, Alaska Native, Asian American, Native Hawaiian, and Pacific Islander.

Action Taken or To Be Taken

The purpose of the National Academies of Sciences, Engineering, and Medicine (NASEM) contract is the development of a *Racial and Ethnic Health Inequities* report. The report will provide an evidence-based, non-partisan analysis of Federal policies that contribute to racial and ethnic health inequities, including those policies that impact the social determinants of health, as well as potential solutions. Based on that review, the report also will identify the most effective or promising strategies to eliminate or

modify Federal policies to advance racial and ethnic health equity. The initiative is currently in development. OMH expects to award the NASEM contract by fall 2021 and anticipates the final report to be available by late FY22.

House Report (page 209)

Global Health Research.— The Committee requests an update in the fiscal year 2022 congressional budget justification outlining how CDC, FDA, BARDA, and NIH, including the Fogarty International Center, jointly coordinate global health research activities with specific measurable metrics used to track progress and collaboration toward agreed upon health goals.

Action Taken or To Be Taken

Global health research is coordinated across CDC centers with NIH Institutes, FDA, and ASPR/BARDA in areas of mutual interest with broad implications for public health. CDC actively participates on the Fogarty International Center's (FIC) Advisory Board, which provides coordination for the entire NIH global health research portfolio. These collaborative activities address the HHS Global Health Objectives to enhance surveillance, prevent health threats, prepare for emergencies, strengthen international standards, catalyze research, strengthen health systems and address changing disease patterns.

CDC participates in a broad inter-agency partnership with NIH and FDA, coordinated by ASPR/BARDA, for the advanced development of influenza vaccines leading to the eventual development of a "universal vaccine" that would offer better, broader and longer-lasting protection against seasonal influenza viruses as well as novel influenza viruses. These types of advances are applicable to vaccines for other infectious diseases, such as Ebola, Zika, dengue, and chikungunya.

CDC is engaged in the development of new, innovative laboratory diagnostic tools, ranging from point-of-care diagnostics to advanced molecular tests, for diseases of public health importance, including diseases of outbreak concern such as Ebola and other viral hemorrhagic fever viruses. CDC works with its HHS partners including NIH and ASPR/BARDA as part of overall USG coordination that includes DoD, for the approval for use process. These activities help detect infectious disease threats at an early stage and also prevent them from reaching the United States. Additionally, the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) provides global interagency coordination between CDC, FDA, BARDA and NIH to enhance chemical, biological, radiological and nuclear threats and emerging infectious disease preparedness. In this capacity CDC, FDA, and other USG Departments are active members of the US Interagency 1540 Working Group, supporting UN Resolution 1540 on non-proliferation and coordinating our whole of government activities with other USG partners.

CDC works with NIH on broader collaborations with DoD, USAID and the State Department, in developing and enhancing global health security in order to improve prevention, detection and response for disease threats. These efforts include the design and development of sustainable networks with surveillance, epidemiology and laboratory support. These efforts enable more rapid detection and characterization of potential infectious disease threats of significant concern to the United States. CDC collaborates with ASPR/BARDA in procuring and managing medical countermeasures for the Strategic

National Stockpile and organizing effective response measures in the event of a public health emergency.

Federal partners of the SARS-CoV-2 Interagency Group (SIG) include CDC, NIH, FDA, ASPR/BARDA, and DoD. CDC coordinates the SIG, which works to rapidly characterize emerging variants and actively investigate their potential impact on SARS-CoV-2 vaccines, therapeutics, and diagnostics. The purpose of the SIG is to maintain a consistent, cohesive U.S. government approach to the assessment of SARS-CoV-2 variants. The SIG coordinates information sharing and is developing a landscape analysis of USG efforts to support genomic sequencing globally. Additionally, the SIG leads USG coordination with international partners to discuss how we can better coordinate globally on the assessment of SARS-CoV-2 variants, including recommendations and decisions that impact the global community, such as potential vaccine decisions, a globally coordinated surveillance system, and classification of variants. COVID-19 response collaborations outside of DHHS include technical and funding support to low- and middle-income countries to support COVID-19 vaccine program planning, implementation, and evaluation coordinated by CDC and USAID.

Other Examples of HHS FY22 Global Health Activities

Ebola vaccines and therapeutics: As part of ASPR/BARDA's efforts to develop and stockpile medical countermeasures to protect the nation from public health emergencies caused by Ebola virus, they partner extensively with WHO, MSF, ALIMA and the Ministries of Health within several African nations who are in constant threat of new spillovers or resurgence of persistent infections. During outbreaks, ASPR/BARDA plays an integral role in ensuring that vaccines and therapeutics that they have developed is sufficient to meet the demands of the US and global response. An ASPR/BARDA-supported vaccine (Ervebo, from Merck) has been extremely effective in ring vaccination efforts to blunt spread of Ebola. Our therapeutics (Inmazeb, from Regeneron, and Ebanga, from Ridgeback) are a critical component of patient care showing significant benefit for patients. The impact of these efforts can be seen in the current responses in Guinea and DRC where both outbreaks have entered the countdown toward end of transmission. BARDA efforts in FY22 will continue these efforts with industry partners (Merck, Ridgeback and Regeneron) and international partners (WHO, GAVI, and UNICEF) to ensure the availability of these critical medical countermeasures should additional Ebola outbreaks occur.

Marburg and Sudan vaccines: In FY22, ASPR/BARDA's CBRN Vaccines will be developing at least two vaccine candidates for Marburg virus, and at least two for Sudan ebolavirus. There is now a licensed vaccine against Zaire ebolavirus, but Marburg and Sudan represent priority threats. This portfolio is being developed in close coordination with NIH/NIAID/DMID, DoD, and CEPI.

Smallpox vaccines: In FY22, BARDA's CBRN Vaccines will continue to procure doses of the smallpox vaccine JYNNEOS® as well as pursue licensure of a more stable formulation. JYNNEOS® is also licensed to protect against monkeypox virus, the only vaccine indicated as such, and may be part of the global response if a sizable monkeypox virus outbreak were to occur.

CARB-X: In 2016, ASPR/BARDA established CARB-X, a five-year commitment to establish a pipeline of innovative antibacterial candidates to combat the global threat of antimicrobial resistant bacterial infection and accelerate the most promising candidate through preclinical development and into the clinic. CARB-X, lead by Boston University, represents a true international collaboration that includes NIH, Wellcome Trust, Bill and Melinda Gates Foundation, the UK Government and the German Government

as partners and funders. Over the past five years, CARB-X has supported over 90 different companies developing the most innovative diagnostics, preventatives, vaccines and therapeutic drugs targeting drug-resistant bacteria. In FY22, ASPR/BARDA intends to renew its commitment to supporting a biopharmaceutical accelerator through partnerships with current European partners with the possibility of expanding the number of international partners.

World Health Organization Biologics FDA/CBER-WHO Cooperative Agreement : The goal of the FDA/CBER-WHO Cooperative Agreement is to enhance technical collaboration between FDA/CBER, WHO, and its Member States to facilitate strengthening regulatory capacity and increase global access to safe and effective biological products that meet international standards, support innovative research to advance development of vaccines and other biological products important for global public health, and enhance preparedness for public health emergencies.
The four main objectives of this collaboration are:

- Contribute to regulatory systems strengthening
- Enhance post-market surveillance of vaccine safety
- Develop international norms and standards
- Support regulatory research and other activities to promote development and increased access to safe and effective biological products; increase preparedness for responding to emerging and re-emerging infectious diseases.

World Health Organization Regulatory Systems Strengthening Agreement: The FDA/OGPS-WHO Cooperative Agreement currently has four workstreams, Substandard and Falsified Medical Products, Artificial Intelligence in Health, CURE ID for innovative treatments, and Food Safety. Current deliverables under each item are below. In addition to these workstreams for FY22 FDA is considering new workstreams to evaluate how substandard or falsified goods are sold in informal markets, and on the linkage between strong regulatory systems and economic development.

For each workstream, the funding proposals from the World Health Organization are tied to specific deliverables, which FDA tracks as milestones.

NIH-funded global health research: Global infectious disease and pandemic preparedness, chronic non-communicable diseases, climate change and health, data science.

Global Infectious Disease and Pandemic Preparedness: The COVID-19 pandemic has demonstrated the importance of a swift global response to address emerging infectious diseases to protect the health and safety of Americans. Infectious diseases continue to impose a tremendous health burden in LMICs, claiming millions of lives annually and inflicting severe morbidity that results in significant losses in economic productivity and social progress. NIH-funded research will lead to a better understanding of relevant pathogens and effective prevention measures.

Chronic, Non-Communicable Diseases (NCDs): NCDs are collectively responsible for roughly 70 percent of all deaths worldwide. Some of these diseases are also predisposing factors for infectious diseases, such as more severe COVID-19. NIH will continue to invest in research that will lead to better health outcomes abroad and inform prevention and treatment of diseases in the United States, such as Alzheimer's Disease, cancer, mental illness, and cardiovascular disease. In one such funded study, the American University in Beirut (AUB) will form a multidisciplinary collaboration to examine and address the social, cultural and biological determinants of diabetes and cardiovascular disease in Lebanon and throughout the Middle East and North African region.

Climate Change and Health: NIH will support research to study the health impacts of climate change (e.g., the spread of infectious disease, mental health and trauma, increased risk of NCDs), including in highly vulnerable LMIC populations. NIH will also fund the design and testing of interventions to build health resilience and protect public health. Multi-disciplinary training of scientists in the United States and LMICs will expand the climate and health research workforce.

Data Science: Rapid advances in data science are transforming health research and improving health outcomes. NIH's new initiative, Data Science for Health Discovery and Innovation in Africa, will leverage data science technologies and prior NIH investments to develop solutions to the continent's most pressing public health problems through a robust ecosystem of new partners from academic, government, and private sectors.

Metrics to Measure Progress of NIH-funded Global Health Research: In addition to traditional NIH metrics such as scientific publications and grant application success rates, relevant indicators for global health research include: 1) development of effective interventions for international and when possible, U.S. populations, 2) increased scientific research capacity in LMICs and U.S. global health investigators, 3) sustainable locally led research in LMICs, 4) the extent to which NIH global health research investments have impacted health outcomes globally and in the United States, and 5) changes in public health policies or programs globally and domestically.

House Report (page 208)

Evidence-Based Grants and Policy.—The Committee requests an update in the fiscal year 2022 Congressional Budget Justification on implementation of the Foundations for Evidence-based Policymaking Act (P.L. 115–435) and implementation plans for the coming year. The Committee encourages the Secretary to develop guidance to ensure relevant participants and grantees are involved in the Department-wide process of prioritizing evidence needs, including participating in Department-led evaluations. Consistent with program statutes, the Committee encourages the Secretary to ensure that evidence of effectiveness is a consideration in grant opportunities.

Action Taken or To Be Taken

The need to leverage data as a strategic asset has never been more vital than it is today. As evident in the HHS' role in the national response to COVID-19, it is critical that HHS collects, manages, uses, shares, and protects relevant data to support mission functions, inform decision-making, promote transparency, and develop evidence for the most informed decision-making possible. HHS has been engaged across the Department's Operating and Staff Divisions in efforts to implement the Foundations for Evidence-Based Policymaking Act of 2018 (Evidence Act).

We have been developing the HHS Evidence Building Plan and the initial draft Capacity Assessment as well as the Evaluation Plan to meet the 2021 submission and publication deadlines. This work is coordinated by the Office of the Assistant Secretary for Planning and Evaluation working through the

Evaluation and Evidence Council, with broad representation and stakeholder input across HHS as well as through HHS participation in the relevant Evidence Act Councils chaired by OMB.

In addition to developing the required deliverables for Title 1, HHS has been working collaboratively to implement Titles II and III of the Act, including constituting a Data Governance Body and conducting an assessment of agency data skills to ensure agency staff have the skills and competencies needed to effectively support evidence-building activities.

Through the federal response to the COVID-19 pandemic, CDC and HHS supported the development of systems to provide visibility into the COVID-19 pandemic and HHS re-launched HealthData.gov, the home for open data assets (both COVID-19 related and across all the Department's missions).

In the coming year, Departmental implementation will:

- Continue to build on the agency key questions that were identified as priorities for evidence-building;
- Maintain and expand the Open Data Plan;
- Incorporate actions outlined in the Federal Data Strategy;
- Finalize the multi-year learning agenda in the Evidence Plan; and
- Publish the annual Evaluation Plan

House Report (page 213)

Social Media and Negative Outcomes.—The Committee supports efforts by the Secretary to investigate whether there is a relationship between the use of social media and negative social and individual outcomes, including clinical and undiagnosed depression; self-harm, such as suicide, attempted suicide, and suicidal intent; harm to others; cyber bullying; chronic anxiety; or social isolation. Such investigation should consider the role of content and presentation in social media that is linked to negative outcomes, as well as the design of algorithms to prioritize user engagement. The Committee requests an update on this topic within 180 days of enactment of this Act.

Action Taken or To Be Taken

Various studies have linked social media with mental health issues such as depression, anxiety, and social isolation. Additionally, research literature is emerging in the area of social media and self-harm, suicide, attempted suicide, and suicidal intent . Increased accessibility to social media, coupled with routine utilization, introduces cyber-bullying opportunities, which produces new challenges and opportunities for health policy.

SAMHSA supports the agency investigating the role of content and presentation in social media linked to negative outcomes and the design of algorithms to prioritize user engagement by offering behavioral health subject matter expertise in collaboration with other HHS Operating and Staff Divisions. SAMHSA recommends a thorough review of the literature, as well as expert and field consensus around this vital topic through 1) formation of university partnerships to conduct systematic reviews of the literature on this topic examining impacts of social media on mental health, public health implications, individual and community prevention strategies as well as treatment interventions; 2) collection of representative stakeholder input, including from medical academies (e.g., AAP, APA, etc.), health and behavioral health practitioners, schools and colleges, field experts, and those with lived experience; and 3) creation of an

interagency board to provide technical assistance for ways to create awareness about, prevent, treat, and cope with negative mental health outcomes related to social media.

House Report (page 206)

Awareness of Sickle Cell Trait.— The Committee supports the efforts to provide Americans with screening for sickle cell trait, a known health disparity among African Americans and Hispanic/ Latino Americans. The Committee urges the Secretary of Health and Human Services, in collaboration with NIH and CDC, to submit an action plan within 180 days of enactment of this Act to address the lack of awareness of sickle cell trait and the prevalence of testing for sickle cell trait.

Action Taken or To Be Taken

CDC appreciates the Committee's interest in and support of sickle cell trait (SCT) screening for Americans. CDC works with national partners and subject matter experts to maintain resources about SCT such as a toolkit, factsheet, screening infographic, and a link to recommendations on screening of student athletes for SCT. While CDC recognizes the importance of education and awareness on SCT, CDC's programmatic focus is on addressing sickle cell disease (SCD) surveillance. CDC's Sickle Cell Data Collection (SCDC) program collects and analyzes surveillance data to better understand how people with SCD are accessing and using health care. These data are used to target and develop strategies to improve access to the healthcare system and, ultimately, to improve the health and lengthen the lives of people living with SCD. CDC also works with the Association of Public Health Laboratories to provide public health technical assistance with SCD screening activities, including needs assessments for laboratories, as well as education for patients, caregivers, and healthcare workers on hemoglobinopathy screening programs.

House Report (page 206)

Advertising Contracts.—In addition, the Committee encourages the Department to consider using local media in their advertising, including local television, radio broadcast stations, and newspapers to the greatest extent possible. The Committee directs the Department to include in its fiscal year 2022 Congressional Budget Justification details on expenditures on local media advertising for the prior two fiscal years.

Action Taken or To Be Taken

HHS is committed to providing critical COVID-19 information to as many people as we possibly can using local media in advertising, including local television, radio broadcast stations, and newspapers to the greatest extent possible. The HHS COVID-19 Public Education Campaign (Campaign) will use more than 5,000 media vendors across the country to enable us to get clear, accurate, and actionable information to the largest possible percentage of the population, to help them combat COVID-19 and to encourage confidence in authorized COVID vaccines. In FY 2020, ASPA dedicated $11 million to both radio and out-of-home (digital billboards) advertising. The major advertising investments of the Campaign began in FY 2021 and are still underway and will be reported once reconciled.

Senate Report (page 169)

Chronic Fatigue Syndrome Advisory Committee.—The Committee looks forward to reviewing HHS's plan regarding myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS) as requested in House Report 116–62. In the interim, the Committee encourages HHS to foster interagency and stakeholder collaboration in addressing the crisis in ME/CFS clinical care and accelerating drug development for ME/CFS.

Action Taken or To Be Taken

HHS continues to recognize the importance of fostering interagency and stakeholder collaborations to address the needs of the myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS) community. In 2020, the Interagency ME/CFS Working Group was formed by the National Institutes of Health (NIH), led by the National Institute of Neurological Disorders and Stroke (NINDS), and the Centers for Disease Control and Prevention (CDC). To date, the Interagency ME/CFS Working Group has hosted two meetings, which focused on a wide array of topics, such as federal agency updates on ME/CFS related efforts, workforce development and education of ME/CFS healthcare providers, and activities to address prolonged illness following COVID-19. Several federal agencies participated in these discussions, including the NIH, CDC, the Department of Defense, Veterans Affairs, the Social Security Administration, and the Centers for Medicare and Medicaid Services. Community stakeholders, such as nonprofit organizations and ME/CFS researchers, were also invited to participate in both Interagency Working Group meetings. Moving forward, the NIH and CDC will continue to coordinate recurring meetings to promote interagency and stakeholder collaboration and communication through the Interagency ME/CFS Working Group.

Furthermore, the NIH holds regular telebriefings to inform the ME/CFS community of its research efforts and to answer questions from ME/CFS stakeholders. The NIH also recently launched the Post-Acute Sequelae of SARS-CoV-2 Infection (PASC) Initiative to study long-COVID. The cohorts that will be enrolled for the long-COVID studies will look at the difference between people who recovered from COVID-19 and those who did not. This information could then be applied to understanding the underlying mechanisms that lead to ME/CFS. In addition, the protocol will be designed to identify individuals with long-covid who also are diagnosed with ME/CFS, which will be informative for future studies. The Trans-NIH ME/CFS Working Group is also planning a workshop on clinical trials readiness that will help to address the needs of the research community to conduct clinical trials for ME/CFS.

House Report (page 207)

Customer Service.—The Committee continues to support efforts to improve customer service in accordance with Executive Order 13571—Streamlining Service Delivery and Improving Customer Service. The Committee directs the Secretary to develop standards to improve customer service and incorporate the standards into the performance plans required under 31 U.S.C. 1115. The Committee further directs the Department to include an update on the progress of these efforts in the fiscal year 2022 Congressional Budget Justification.

Action Taken or To Be Taken

The Secretary is developing standards to improve customer service as required under 31 U.S.C. 1115.

House Report (page 217)

Health Disparities Education Program.—The Committee strongly encourages the Office of Minority Health to establish and coordinate a health and health care disparities education program. The health and health care disparities education program should collaborate with public, private, and nonprofit stakeholder organizations on education, outreach, and public awareness campaigns targeting the general public and the medical community. In addition, the program should disseminate scientific evidence for the existence and extent of racial and ethnic disparities in health care; new research findings to health care providers and patients to assist them in understanding, reducing, and eliminating health and health care disparities; information about the impact of linguistic and cultural barriers on health care quality; and information about the importance and legality of data collection and analysis according to race, ethnicity, disability status, socioeconomic status, sex, gender identity, sexual orientation, and primary language.

Action Taken or To Be Taken

The HHS Office of Minority Health (OMH) is developing a plan to enhance health disparities education and information dissemination, to include partnerships with diverse stakeholders.

House Report (pages 217-218)

Underserved Populations Along the U.S.-Mexico Border.—The Committee urges the HHS Office of Minority Health to examine how it can support health professions schools at Hispanic Serving Institutions along the United States-Mexico border, including ways to engage community partnerships that utilize cancer prevention tools including screening, education, and diagnostics to meet the healthcare needs of underserved populations along the border. The Committee further encourages OMH to work with the CMS Office of Minority Health to support these types of cancer prevention activities.

Action Taken or To Be Taken

The HHS Office of Minority Health (OMH) is developing a strategy to increase outreach to and engagement of HSI medical schools first and then HSIs more broadly, to include HSIs along the U.S.-Mexico border. HHS OMH will be providing a written report to the Appropriations Committee outlining these efforts. HHS OMH also will explore with CMS OMH colleagues how we can support dissemination of information on CMS resources for cancer prevention to HSIs, including those along the U.S.-Mexico border.

FY 2021 Joint Explanatory Statement – Division H (page 106)

OWH.—The agreement includes $5,100,000 to combat violence against women through the State partnership initiative, an increase of $1,000,000 above the fiscal year 2020 enacted level. The agreement directs OWH to account for geographical diversification in decisions on additional awards.

Action Taken or To Be Taken

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 focus on advancing the science on effective women's health interventions. Programs will focus on violence against women impacting maternal morbidity and mortality. OWH will make every effort under grants policy to ensure equitable geographic distribution.

FY 2021 Joint Explanatory Statement (page 102)

Lung Cancer in Women.—The agreement encourages the Secretary, in consultation with DoD and VA, to conduct an interagency study to evaluate the status of research on women and lung cancer and make recommendations for additional research on the disparate impact of lung cancer in women who never smoked. The study should make recommendations regarding increased access to lung cancer preventive services and strategic public awareness and education campaigns related to lung cancer. The agreement requests an update on these activities in the fiscal year 2022 congressional justification.

Action Taken or To Be Taken

Women's health research is an important part of the National Cancer Institute's (NCI) portfolio, including gender-related differences in lung cancer risk factors, incidence, and mortality. In July 2020, the U.S. Preventive Services Task Force (USPSTF), an independent body that offers clinical guidance about preventive health care, published a draft recommendation that would double the number of people eligible for annual CT scans to screen for lung cancer. The task force reviewed several randomized clinical trials and cohort studies, including results from the NCI-supported National Lung Screening Trial (NLST) and Cancer Intervention and Surveillance Modeling Network (CISNET), modeling studies as well as a large European trial. The recommendation lowers the age of starting annual exams from 55 to 50 years, and is expected to lead to higher screening rates among women, who tend to smoke fewer cigarettes than men, as well as Black patients, who are at higher risk of lung cancer.[11] Research has shown that approximately 20 percent of women who have never smoked develop lung cancer compared with about 9 percent of nonsmoking men. In 2019, NCI began the Sherlock-lung study.[12] This study is a comprehensive genomic epidemiologic study of lung cancer in never smokers. It aims to identify processes involved in lung tumorigenesis to develop a more refined classification of lung cancer in never smokers and provide insights into prognosis and treatment strategies. Preliminary data is beginning to emerge highlighting the large differences in the molecular landscape of lung cancer in never-smokers from that of smokers. The study will collect data from 2,500 never smokers. We also recognize that 80% of lung cancers among women can be attributed to smoking. Therefore, NCI's ongoing efforts to reduce the uptake and use of tobacco, also remain paramount in female lung cancer

[11] www.uspreventiveservicestaskforce.org/uspstf/draft-update-summary/lung-cancer-screening-2020
[12] dceg.cancer.gov/research/cancer-types/lung/sherlock-lung-study

prevention. NCI continues its efforts related to *Smokefree Women*, part of the larger Smokefree.gov website,[13] and remains committed to supporting research and resources to prevent lung cancer and advance progress for all cancer patients, whether their diagnosis is tobacco-related or not.
Currently, NCI is funding nearly a dozen individual investigator-initiated grants focused on women and lung cancer or lung cancer gender differences. Two investigator-initiated grants are examining the digital environment related to tobacco and younger people, specifically the projects are studying increased resistance to tobacco marketing among young adult sexual minority women, and electronic pediatric office systems to support treatment for parental tobacco use.[14] Multiple projects investigating cancer risk and the biological mechanisms of lung cancer are underway, including an investigation of adipose (fat) and lean soft tissue depots associated cancer risk and mortality in postmenopausal women.[15] In addition, an R37 MERIT (Method to Extend Research in Time) award[16], to an Early Stage Investigator is focused on examining disparities in access to and outcomes of cancer surgery for rural Medicare patients with lung and other cancers.[17]
There is also ongoing lung cancer research in NCI-supported programs such as the Specialized Programs of Research Excellence (SPOREs) and the Cancer Intervention and Surveillance Modeling Network (CISNET). Lung cancer was an early focus of the SPORE Program and presently there are five lung cancer SPORE programs.[18] CISNET conducts research on the impact of tobacco control policies and screening in lung cancer with a focus on disparities.[19]

House Report (page 211)

Performance Measures.—Directs the Department to comply with title 31 of the United States Code, including the development of organizational priority goals and outcomes such as performance outcome measures, output measures, efficiency measures, and customer service measures. The Committee further directs the Department to include an update on the progress of these efforts in the fiscal year 2022 Congressional Budget Justification.

Action Taken or To Be Taken

The U.S. Department of Health and Human Services (HHS) is the United States government's principal agency for protecting the health of all Americans and providing essential human services. Operating Divisions (OpDivs), including agencies in the United States Public Health Service and human service agencies, administer HHS programs. Staff Divisions (StaffDivs) provide leadership, direction, and policy and management guidance to the Department.

The scope of HHS's work to ensure the health and safety of our nation has never been more evident than in the central role HHS has played in the government-wide response to the COVID-19 pandemic. HHS has mobilized resources across the Department to address the full scope of this once-in-a-century event, including deploying medical personnel to staff field hospitals and care for those afflicted with the virus; providing financial support and distributing equipment such as ventilators, respirators, surgical

[13] smokefree.gov
[14] projectreporter.nih.gov/project_info_description.cfm?aid=10170999; projectreporter.nih.gov/project_info_description.cfm?aid=9865418
[15] projectreporter.nih.gov/project_info_description.cfm?aid=10050524
[16] www.cancer.gov/grants-training/grants-funding/funding-opportunities/merit
[17] projectreporter.nih.gov/project_info_description.cfm?aid=9948356;
[18] trp.cancer.gov/spores/lung.htm
[19] cisnet.cancer.gov/lung/

masks, and gloves to our hospitals and health care providers; purchasing and ensuring domestic prioritization of supplies to help states increase testing; investing in research to develop vaccines and therapeutics; and supporting human service needs such as child care and meals for older adults. HHS will continue to work with our partners both inside and outside the Federal government to address this public health emergency and apply lessons learned from the pandemic to ensure readiness for future threats.

Through its programming and other activities, HHS works closely with state, local, and U.S. territorial governments. The Federal Government has a unique legal and political government-to-government relationship with tribal governments and provides health services for American Indians and Alaska Natives consistent with this special relationship. HHS works with tribal governments, urban Indian organizations, and other tribal organizations to facilitate greater consultation and coordination between state and tribal governments on health and human services.

HHS also has strong partnerships with the private sector and nongovernmental organizations. The Department works with industries, academic institutions, trade organizations, and advocacy groups to leverage resources from organizations and individuals with shared interests. By collaborating, HHS accomplishes its mission in ways that are the least burdensome and most beneficial to the American public. Private sector grantees, such as academic institutions and faith-based and neighborhood partnerships, provide HHS-funded services at the local level. In addition, HHS works closely with other federal departments and international partners to coordinate efforts and ensure the maximum benefit for the public.

HHS is currently developing the Strategic Plan for FY 2022-2026 that will align with the Administration and the Department's priorities. The Annual Performance Plan and Report provides information on the Department's progress towards achieving the goals and objectives described in the HHS Strategic Plan. The measures relayed to the FY 2022-2026 Strategic Plan will be reported in the FY 2023 Annual Performance Plan and Report. The COVID-19 pandemic is impacting HHS programs in a variety of ways, and in some cases those impacts are still evolving given the dynamic nature of the situation. The pandemic may impact the ability of some HHS programs to achieve projected targets, or result in the need to revise targets in future years.

House Report (page 218)

Menstrual Hygiene Products.—The Committee is concerned with the affordability and accessibility of menstrual hygiene products and information regarding these products, which are basic health care necessities. Per the report requested in House Report 116–62, the Committee encourages the Office on Women's Health to include in the report the number of individuals who experience problems with affordability and accessibility of menstrual hygiene products by race, socioeconomic status, and age. The Committee encourages OWH to include in the study an assessment of the availability and accessibility of menstrual hygiene products within institutions, including public schools, colleges, and universities, and provide a price comparison on fair market costs of menstrual products.

Action Taken or To Be Taken

OWH is compiling a report on Menstrual Hygiene Products to Congress as included in the House Report 116–62 on the affordability and accessibility of menstrual hygiene products. OWH plans to submit the report in the Fall 2021.

House Report (page 210)

Maternal Mental Health.—The Committee looks forward to receiving a report, as directed in House Report 116–62, on the roles of Department agencies in addressing gaps in maternal mental health.

Action Taken or To Be Taken

The Maternal Mental Health report required under House Report 116–62 was transmitted to the Hill on April 21, 2021.

FY 2021 Joint Explanatory Statement – Division H (page 20)

Rapid HIV Self Test.— CDC is encouraged to incorporate rapid HIV self-testing into established activities and emerging efforts of the Ending the HIV Epidemic initiative.

Action Taken or To Be Taken

CDC will use the increases received in FY 2021 to strengthen EHE's capacity to adapt to the challenges faced by the COVID-19 pandemic by supporting integration of rapid HIV self-testing into established activities using community-based organizations to expand access.

FY 2021 Joint Explanatory Statement – Division H (page 104)

Tribal Set-Aside.—The agreement includes $1,500,000 as a Tribal set-aside within the Minority HIV/ AIDS Prevention and Treatment program.

Action Taken or To Be Taken

To build a holistic plan to End the HIV Epidemic in Indian Country by supporting national-level strategic planning and using an environmental scan to assess the current landscape of HIV-related prevention, care, and management activities and community-based assessment framework that works across all Indian Health Service areas including Urban Indian Organizations. The effort would identify gaps and find best-practices from across Indian Country through the collection and examination of HIV-related data, including surveillance, epidemiology, clinical practices, community interventions, academic and grey literature. This project will also allow AI/AN stakeholders to formulate their own response to HIV in their own communities by incorporating local leadership and knowledge with federal strategic plans and best practices. IHS will garner input from stakeholders in the field, including people working in public health, clinical health care, government, community-based organizations, research, and academia. The ETHIC Plan will serve as a process-based roadmap for all stakeholders to guide the development of policies, services, programs, initiatives, and other actions to achieve the nation's vision of ending the HIV epidemic by 2030.

Nonrecurring Expenses Fund
Assistant Secretary for Administration

Budget Summary
(Dollars in Thousands)

Assistant Secretary for Administration	FY 2020[2]	FY 2021[34]	FY 2022[5]
Notification[1]	31,997	25,400	TBD

Authorizing Legislation……..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.

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.

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.

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.

Program Support Center (PSC)
PSC is a multi-function shared service provider to predominantly HHS components. PSC provides support services related to accounting, acquisitions, grants and finance administration, health and wellness, supply chain management, physical security and facilities programs. This includes oversight of the HHS real property inventory and the management of facilities projects that support the mission and improve efficiency. PSC is currently managing four NEF funded projects that will reduce the agencies footprint and result in a significant savings in rent and rent related cost. This includes the Chicago, San Francisco, Boston and Atlanta regional office projects.

Budget Allocations
For FY 2021, Office of the Assistant Secretary for Administration plans to continue to make investments that support information technology cybersecurity enhancements and facilities infrastructure. Current NEF projects and accomplishments across the ASA are:

Continuous Diagnostics and Mitigation (CDM) - $1,250,963
As directed by Department of Homeland Security (DHS), HHS is in the process of implementing the CDM program. Due to funding shortfalls, DHS was unable to provide all software licenses required to achieve full deployment of Phase I tools. In order to meet DHS requirements and better-enhance security at the Department, HHS acquired 91 software licenses across four distinct operating systems and completed the initiative in FY 2018.

Cybersecurity Database & Application Scanning - $7,987,000
FY 2020, HHS Office of Information Security (OIS) implemented a new capability to enable vulnerability scanning for databases and applications. This capability enables HHS to more proactively identify potential sources of eventual data or network compromise while also replacing outdated tools. In addition, this capability complements the suite of CDM tools identified and procured via DHS.
I.
II. Both the CDM and Cybersecurity Database & Application Scanning satisfied the following mandates:

- Federal Information Security Modernization Act (FISMA) of 2014
- OMB CIO IT Modernization Policy
- Cross Agency Priority (CAP) Goals
- Cybersecurity Strategy and Implementation Plan (CSIP)
- Joint Continuous Monitoring Working Group (JCMWG), United States Government Concept of Operations (CONOPS) for Information Security Continuous Monitoring
- Federal Information Processing Standard (FIPS) 200 Minimum Security Requirements for Federal Information and Information Systems
- Continuous Diagnostics and Mitigation (CDM) Program Implementation

Cybersecurity Projects - $46,564,000
OCIO OIS Cybersecurity enhancement projects were completed in FY 2017 and FY 2018.

eGRC - $6,000,000
In FY 2019, OCIO OIS completed the Enterprise Governance, Risk, and Compliance (eGRC) solution, which supports HHS in managing security policies, controls, risks, assessments, and weaknesses through a single platform. The goal was to develop a single repository to document and store security information, allowing HHS to review and assess the security stance of systems. This approach facilitates real-time approval, monitoring, and reporting for all HHS systems. An automated GRC tool allows system owners, information system security officers (ISSOs), privacy officers and security analysts to easily identify system weaknesses and issue resolutions with improved efficiencies.

Email-as-a-service CMS and FDA - $14,973,928
Email Service Consolidation was completed for CMS in FY 2017 and FDA in FY 2018. HHS utilized NEF resources to upgrade the existing email infrastructure to a cloud-based service model. Moving email to one provider improved the quality of email service and provided universal access to collaboration tools across the Department.

Enterprise Network Consolidation and TIC Migration - $5,000,000
The Office of Operations (Ops) and Office of Information Security (OIS) within OCIO are the business owners for the HHS Enterprise Intranet (HHSNet), the Trusted Internet Connection (TIC), and Internet services for HHS. OIS manages government owned infrastructure for the TIC, HHSNet, and Internet services and demonstrates an opportunity for improved operations, security, cost savings and cost predictability for the Department. Additionally, OCIO works with the OpDivs' identified efficiencies migrating to a Managed Trusted Internet Protocol Service (MTIPS).

OIS requested and received funds for a continued investment to identify efficiencies in enterprise security components, fund lifecycle refresh for TIC and Internet security components, support HHS internet requirements and migration cost to MTIPS. These updates strengthened OMB mandated TIC cyber security capabilities. OIS continues to leverage remaining funds for the initiative.

TIC Accomplishments include:

- Major Incident response in March 2020 with successful mitigation at TIC Access Points, no major service disruption.
- OCIO Tiger Team packaged and awarded emergency funds for HHS TIC Managed Trusted Internet Protocol Service. Inception to award in one month to Verizon.
- MTIPS migration kick off April 2020, unprecedented accomplishment of coordination of OpDivs led by OCIO, first successful cutovers August 2020.
- MTIPS benefits: dedicated SOC, managed security stack (FW, IPS, PCAP, EINSTEIN) DOS/DDOS Shield mitigation services, enriched intelligence feeds.
- Network enhancements: 40Gbps redundant circuits in DC, 20Gbps redundant circuits in ATL
- HHS TIC network resiliency intact after failure of Verizon to execute stable MTIPS cutovers.
- Reestablished Department traffic through HHS TIC Access Points without major disruption.
- Completed PA Panorama/PA firewalls upgrade to 9.1.6. This version improves support for zone protection & policy effectiveness
- UFMS Treasury traffic integration through HHS TIC
- Lumen DDOS integration and Internet 2 traffic to route through HHS TIC (ATL)
- Established plan for HHS Security and Network Operations Center under direction from HHS CIO to implement TIC modernization efforts.

Year	Inbound (Avg/Max/Total)	Outbound (Avg/Max/Total)
2020	8Gbps/41.5Gbps/16.2PB	8.5Gbps/39Gbps/17.2PB
2019	6.4Gbps/23.95Gbps/13.15PB	3.8Gbps/14Gbps/9.17PB
2018	8425 Mbps/21077 Mbps/33211 TB	4588 Mbps/11428 Mbps/18085 TB
2017	8334 Mbps/20444 Mbps/32853 TB	3953 Mbps/9914 Mbps/15583 TB
2016	8469 Mbps/14926 Mbps/33385 TB	4684 Mbps/15602 Mbps/18464 TB
2015	5128 Mbps/12554 Mbps/20215 TB	2389 Mbps/5564 Mbps/9417 TB
2014	3668 Mbps/8582 Mbps/14459 TB	1474 Mbps/3066 Mbps/5811 TB
2013	2019 Mbps/3942 Mbps/7959 TB	998 Mbps/1889 Mbps/3934 TB

Medicare Hearings and Appeals

I am pleased to present the Office of Medicare Hearings and Appeals (OMHA's) Fiscal Year (FY) 2022 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.

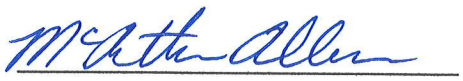
Since beginning operations in July 2005, OMHA has been committed to continuous innovation in the Medicare appeals process through responsible stewardship and an accomplished and resilient adjudication workforce. This commitment continues to inspire OMHA's mission. Between FY 2010 and FY 2014, OMHA experienced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

Increased support and investment in adjudication capacity in the fiscal year 2018, and 2019 appropriations enabled OMHA to undertake an Adjudication Expansion Initiative to alleviate the appeals backlog. In 18 months, OMHA established four new field offices (Albuquerque, New Mexico; Atlanta, Georgia; New Orleans, Louisiana; and Phoenix, Arizona), increased adjudication capacity by roughly 70 administrative law judges (ALJs), 500 adjudicatory, and support staff positions.

OMHA will resolve the backlog and return to the 90-day statutory adjudication time frame in FY 2022. Importantly, the FY 2022 request will enable the Department to meet the mandamus order in the November 1, 2018 Federal District Court ruling in *American Hospital Association v. Becerra*. The mandamus order required the Secretary to achieve specific annual reduction targets in the appeals backlog, leading to total elimination of the backlog. To date, OMHA has met each target and is on schedule to meet the final mandamus order target of eliminating the backlog by the end of FY 2022.

The FY 2022 request also supports continued case processing efficiencies enabled by the Electronic Case Adjudication Processing Environment (ECAPE). ECAPE implementation, completed in November 2019, automates OMHA's adjudicatory business processes from management of documents and correspondence related to requests for hearing exhibits to preparation; scheduling and managing hearings and issuing appeal decisions. ECAPE also enables OMHA to improve reporting of caseload analytics and provides an electronic public portal for appellants to file an appeal, submit evidence, and access information about pending appeals.

OMHA leadership remains committed to 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.



McArthur Allen
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 Allen's letter, the surge in Medicare appeals resulted in a large backlog at the Office of Medicare Hearings and Appeals, which 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, however, without additional resources, case receipts will continue to outpace adjudication capacity and a significant backlog of Medicare appeals will remain at the DAB. Incoming appeals are projected to increase in FY 2021 as a result of OMHA's recent expansion. OMHA has now opened and staffed four new offices and has significantly increased 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 2020 to FY 2021. This trend is expected to continue into FY 2022.

At the end of FY 2020, MOD had a backlog of 18,619 cases and an adjudication capacity of only 5,000 cases annually. The DAB will use the additional funding provided by the FY 2021 appropriation along with additional funding in FY 2022 to continue to address this backlog. Specifically, additional funding in FY 2022 allows the DAB to hire new attorneys, judges, and support staff, giving MOD the opportunity to handle incoming appeals and make even more progress towards 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 and, as a result a backlog has developed that will also be addressed using the requested funding increase in FY 2022. CRD will use those additional funds to hire new attorneys, judges, and support staff to work its backlog and handle incoming cases.

The backlog at the DAB impacts 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 2021, the average appeal in MOD was $43,000, for a total Medicare Appeals backlog value of over $770 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 2021 and FY 2022, 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 Tobias

Digitally signed by Constance Tobias
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Constance B. Tobias
Chair, Departmental Appeals Board

INTRODUCTION – MEDICARE HEARINGS AND APPEALS

The FY 2022 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; and
- Departmental Appeals Board (DAB), which represents the fourth level of the Medicare appeals process.

The FY 2022 Budget request for MHA is $196,000,000 in discretionary funding, which is an increase of $4,119,000 above FY 2021 Enacted. The Office of Medicare Hearings and Appeals and the Departmental Appeals Board access this program level funding to address Medicare related work as follows:

Medicare Hearings and Appeals (MHA)	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Budget	FY 2022 +/- FY 2021
OMHA Discretionary Budget Authority	172,381	172,381	172,381	-
DAB Discretionary Budget Authority	19,500	19,500	23,619	+4,119
TOTAL Medicare Hearings and Appeals /1	191,881	191,881	196,000	+4,119

2/ 2020, 2021, and 2022 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 the MMA, OMHA began operations 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. OMHA requests $172,381,000 in program level funding and 1,135 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. The Medicare Hearings and Appeals appropriation funds DAB's Medicare-related work. The DAB requests $23,619,000 in program level funding and 132 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.

Appropriations Language Analysis

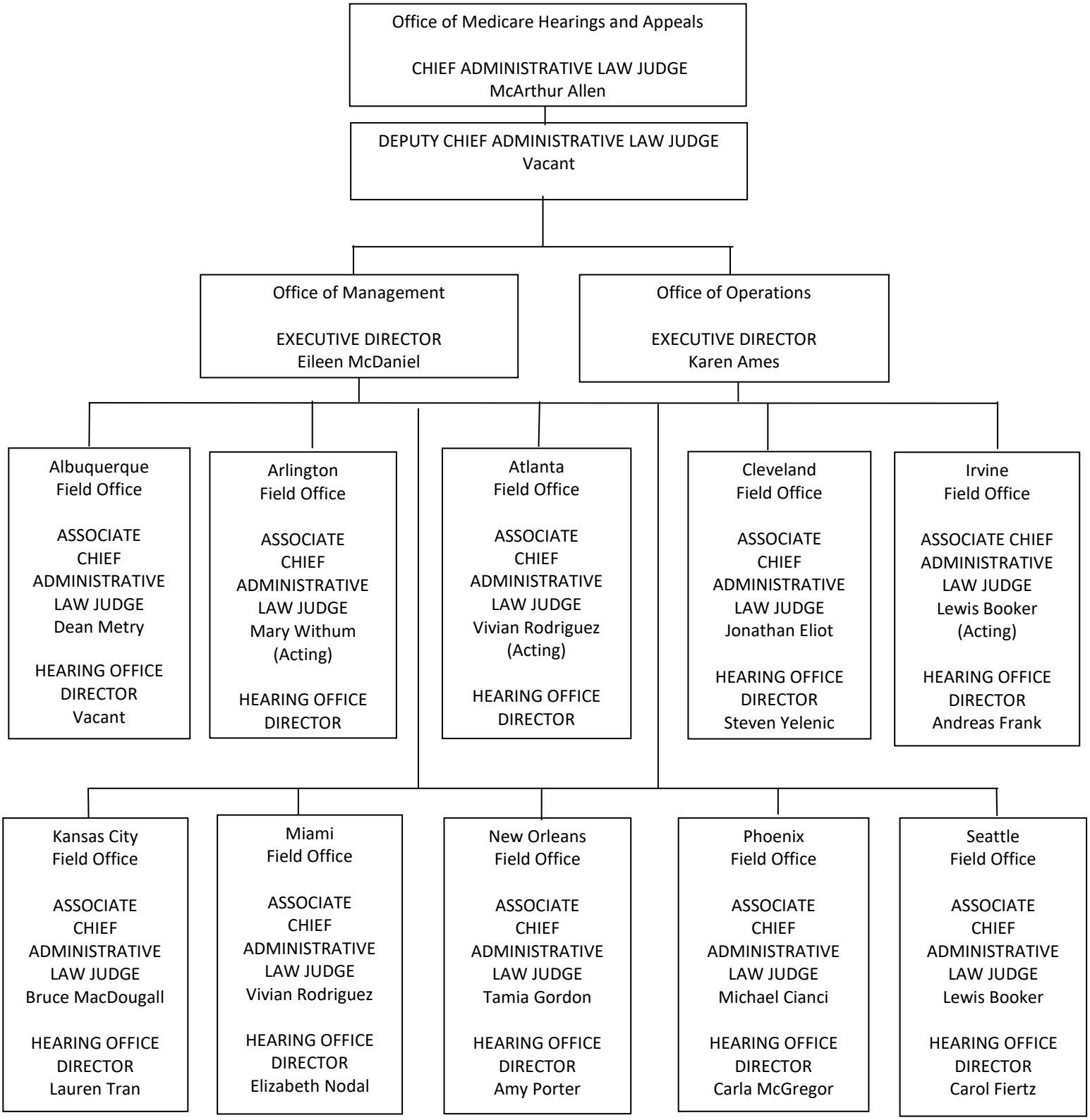
The FY 2022 appropriations language requests $196,000,000 in discretionary budget authority for the "Medicare Hearings and Appeals" appropriation from which OMHA is allocated $172,381,000 and DAB is allocated $23,619,000. These allocations are subject to change.

Appropriations Language

MEDICARE HEARINGS AND APPEALS

For expenses necessary for Medicare hearings and appeals in the Office of the Secretary, [$191,881,000] *$196,000,000* shall remain available until September 30 [2022], *2023*, to be transferred in appropriate part from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund.

OMHA - Organizational Chart



Organizational Chart (Text Version)

Office of Medicare Hearings and Appeals

- Chief Administrative Law Judge, McArthur Allen
- Deputy Chief Administrative Law Judge, Vacant

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, Dean Metry
  - Hearing Office Director, Vacant
- Arlington Field Office
  - Associate Chief Administrative Law Judge, Mary Withum (Acting)
  - Hearing Office Director, Carlton Drew
- Atlanta Field Office
  - Associate Chief Administrative Law Judge, Vivian Rodriguez (Acting)
  - 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, Lewis Booker (Acting)
  - Hearing Office Director, Andreas Frank
- Kansas City Field Office
  - Associate Chief Administrative Law Judge, Bruce MacDougall
  - Hearing Office Director, Lauren Tran
- Miami Field Office
  - Associate Chief Administrative Law Judge, Vivian Rodriguez
  - Hearing Office Director, Elizabeth Nodal
- New Orleans Field Office
  - Associate Chief Administrative Law Judge, Timothy Stewart
  - 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 2022 President's Budget request for OMHA is $172,381,000 at a program level. With this budget request level, OMHA will be able to sustain a staffing level of approximately 155 ALJ teams and 1,135 FTE. The sustainment of this staffing level ensures OMHA's ability to fully eliminate the backlog as currently projected in FY 2022. 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 grew dramatically, most significantly between FY 2010 and FY 2014 when appeals grew by 1,222 percent, it was impossible for the agency to achieve timeliness goals for adjudicating appeals within the statutory 90 day time frame required by the Medicare, Medicaid and SCHIP Benefit Improvement and Protection Act of 2000 (BIPA). The exponential growth resulted in a backlog of appeals that could not be adjudicated within the 90-day time frame. The dramatic increase in appeals and lack of capacity to handle the appeals 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 Procedures Act on disputed Medicare claims. There are four primary factors for 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 (and other Medicare program integrity initiatives).

The ongoing backlog increased OMHA's average processing time. OMHA has not met the statutorily required 90 days for issuing decisions BIPA appeals since 2010 (excluding beneficiary appeals that are given high priority). The average processing time on closed workload increased to 1,430 days in FY 2020 (as of end of FY 2020). The average age of pending appeals at OMHA increased to 1,047 days (as of end of FY 2020).

The drastic growth in the backlog and increased processing time resulted in a lawsuit, *American Hospital Association v. Becerra*. Pursuant to a November 2018 ruling, the Secretary of HHS is operating under a mandamus order, directing specific backlog reduction targets leading to total elimination of the backlog in FY 2022.

In response to the increasing backlog and deteriorating processing time, HHS implemented departmental initiatives and OMHA increased its adjudicatory capacity, as well as changed its prioritization of beneficiaries.

Action: Departmental Initiatives

Several departmental initiatives improved OMHA's pending appeals backlog by resolving appeals through action in addition to hearings for the record. Such initiatives include the Centers for Medicare & Medicaid Services (CMS) Part A Hospital Appeals Settlement Process and OMHA's Settlement Conference Facilitation (SCF) with State Medicaid agencies. The largest initiatives have resulted in significant one-time reductions of OMHA's pending workload which were possibly due to economies of scale.

Unfortunately, these dramatic, one-time reductions are not repeatable for two reasons. First, settlement of appeals, without a reasonable review of the underlying claims, undermines Medicare's responsibility to protect the Medicare Trust Fund and can result in unnecessary costs to the taxpayer. And second, the settlement of a large numbers of appeals without consideration of the merits of the underlying claims encourages the filing of meritless appeals and could increase the number of appeals filed at OMHA.

As the balance of adjudication capacity with receipt levels has been restored by recent budget increases, the backlog has steadily declined. HHS's administrative actions address the growing receipt levels, but sustained funding is still needed to support the appropriate adjudication capacity levels.

Action: Adjudication Capacity

OMHA has increased adjudicatory capacity through the addition of six field offices and the hiring of adjudicatory and administrative support personnel to address the backlog of Medicare appeals. OMHA completed its Adjudication Expansion Initiative in FY 2019. The current adjudicatory capacity positions OMHA to resolve the backlog and in FY 2022 as required by the final mandamus order target of eliminating the backlog by the end of FY 2022 and return to the 90-day statutory adjudication time frame.

OMHA has also sought to increase its adjudication capacity 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 hearings, which only ALJs may conduct. 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, OMHA's other administrative initiatives aimed at increasing productivity (e.g., settlement conference facilitations, statistical sampling, etc.) are similarly dependent on appellants opting to participate in a given administrative initiative.

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 65 days for appeals filed in FY 2020.

Impact: Productivity, Processing Time, and Backlog

Adjudication teams have more than doubled their productivity since 2009. In addition, solutions implemented as part of HHS's administrative initiatives, have reduced the agency's pending backlog by over 81%, from a high of approximately 900,000 pending appeals at the end of FY 2015 to 165,263 as of the end of FY 2020.

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. OMHA independently and with CMS communicates with the appellant community stakeholders through conferences, meetings, open door calls, and email listserv messages.

A primary goal of the stakeholder outreach efforts is to be as transparent as possible about processing times and 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 appeal.

Feedback: Customer Surveys

OMHA 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 on a 5-point scale 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, 1 representing the lowest score (very dissatisfied), and 5 representing the highest score (very satisfied). In FY 2020, OMHA achieved a 3.9 score for appellant satisfaction on the Five-Question OMHA Satisfaction Score, exceeding the FY 2019 score of 3.4.

Despite the overall satisfaction level, 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. The non-beneficiary appellants rated this part of the process only a 2.4 out of a possible 5, bringing down 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, 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.

Medicare Hearings and Appeals (OMHA)

All Purpose Table

(Dollars in Millions)

OMHA	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Budget	FY 2022 +/- FY 2021 Enacted
Total, OMHA Discretionary Budget Authority	**172,381**	**172,381**	**172,381**	-

Authorizing Legislation……Titles XVIII and XI of the Social Security Act
FY 2022 Authorization……Indefinite
Allocation Method……Direct Federal

Appropriations Language

MEDICARE HEARINGS AND APPEALS

For expenses necessary for Medicare hearings and appeals in the Office of the Secretary, [$191,881,000] *$196,000,000* shall remain available until September 30 [2022], *2023*, to be transferred in appropriate part from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund.

Appropriations Language Analysis

The FY 2022 appropriations language requests $196,000,000 in discretionary budget authority for the Medicare Hearings and Appeals" appropriation from which OMHA is allocated $172,381,000 and DAB is allocated $23,619,000. These allocations are subject to change.

Medicare Hearings and Appeals (OMHA)

Amounts Available for Obligation

OMHA Detail	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Budget
Trust Fund Discretionary Appropriation			
OMHA Discretionary Appropriation	172,381	172,381	172,381
Total, Discretionary Appropriation	172,381	172,381	172,381
Unobligated balance lapsing	-	-	-
Total Obligations	-	172,381	172,381

Medicare Hearings and Appeals (OMHA)
Summary of Changes

Budget Year and Type of Authority	Dollars	FTE
FY 2021 Enacted	172,381	1,143
FY 2022 President's Budget	172,381	1,135
Net Change	-	-8

Total Changes	FY 2022 FTE	FY 2022 PB	FY 2022 +/- FY 2021 FTE	FY 2022 +/- FY 2021 BA
Total Increases	-	--	-	-
Total Decreases	-8	-	-8	-
Total Net Change	-8	--	-8	-

Medicare Hearings and Appeals (OMHA)

Budget Authority by Activity – Direct

(Dollars in Thousands)

Activity	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Budget
Discretionary Budget Authority	172,381	172,381	172,381
Discretionary Budget Authority, FTE	**1,165**	**1,143**	**1,135**

Medicare Hearings and Appeals (MHA)

Authorizing Legislation

(Dollars in Thousands)

Medicare Hearings and Appeals	FY 2021 Amount Authorized	FY 2021 Amount Appropriated	FY 2022 Amount Authorized	FY 2022 President's Budget
Medicare Hearings and Appeals, Social Security Act, Titles XVIII and XI	Indefinite	191,881	Indefinite	196,0000
Total Appropriation	-	**191,881**	-	**196,000**

Medicare Hearings and Appeals (MHA)
Appropriations History Table

Details	Budget Estimates to Congress	House Allowance	Senate Allowance	Appropriation
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	191,881,000	191,881,000	191,881,000
Subtotal	196,381,000	191,881,000	191,881,000	191,881,000
2022				
Trust Fund Appropriation	196,000,000			
Subtotal	**196,000,000**			

Narrative by Activity

Program Description and Accomplishments

Introduction

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) requires that most 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 for 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 have allowed OMHA to handle the volume of appeals received, and a backlog of appeals awaiting disposition developed.

OMHA serves a broad sector of the public, including Medicare service providers, 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.

Changes Affecting Backlog

At the time OMHA was established, it was anticipated 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 has seen an increased caseload due to the expansion of its original jurisdiction to include areas not originally planned 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.

Beyond changes in original jurisdiction, OMHA's backlog also was affected by changes to improve program integrity. OMHA 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 2020; OMHA received only 774 RAC appeals in FY 2018, 485 RAC appeals in FY 2019, and 1,202 in FY 2020. This decrease occurred for two reasons, the RAC program was paused while contracts were re-competed and requirements for higher accuracy scores on claims, incentive payment structure, and longer review time were implemented, which reduced output.

Not only did the expansion of appeals from the RAC workload exacerbate OMHA's backlog, but OMHA's non-RAC (traditional) workload also increased significantly. Between FY 2013 and FY 2014, OMHA received over 380,000 non-RAC appeals as CMS contractors (for example, Medicare Administrative Contractors and Zone Program Integrity Contractors) increased pre- and post-payment reviews.

Actions to Respond to Backlog

OMHA continues to recognize the importance of timely resolution of Medicare disputes. Besides increasing the number of field offices and personnel, OMHA has taken a number of steps to reduce the backlog by maximizing the productivity of its ALJ teams and improve the quality and timeliness of its services. These include:

- Development of the Electronic Case Adjudication Processing Environment (ECAPE) – Full implementation agency-wide completed in December 2019

- Opening four new field offices (Atlanta, Albuquerque, Phoenix, New Orleans) and hire and train approximately 70 new ALJs and 500 new positions agency-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, (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 2020

- Development of the OMHA Case Policy Manual (OCPM) initiative to standardize OMHA-wide common business practices for the adjudicative process

- Requiring 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

- Improving 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

- Implementing the Statistical Sampling Pilot to resolve large groups of appeals

- Implementing Settlement Conference Facilitation (SCF) as a less costly alternative to ALJ hearings

- Implementing a Senior Attorney screening program to assist with identification and resolution of appeals which can be resolved without a hearing

- Utilizing the Senior ALJ program which allows for the reemployment of retired ALJs on a temporary and part-time basis

Medicare Hearings and Appeals (OMHA)

5 Year Funding Table

Fiscal Year	Amount
FY 2018	$182,381,000
FY 2019	$182,381,000
FY 2020	$172,381,000
FY 2021	$172,381,000
FY 2022 President's Budget	$172,381,000

FY 2022 Budget Request

The FY 2022 President's Budget request for the Office of Medicare Hearings and Appeals (OMHA) is $172,381,000 in two-year discretionary budget authority, which is the same as the HHS allocated FY 2021 funding level. At this level, OMHA will sustain approximately 155 ALJ teams and 1,135 FTE.

Given the employee and fixed cost heavy structure of the agency, OMHA's projected staffing level in FY 2022 assumes normal employee attrition levels in FY 2021 and FY 2022 to manage within the funding level. 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 baseline staff.

During the past few years, Department efforts to eliminate the backlog have resolved more straightforward Medicare appeals at lower levels. In the future, OMHA anticipates a capacity per adjudicator of approximately 800 appeals per ALJ team to maintain. At this capacity OMHA will meet the mandamus order to resolve the backlog in FY 2022, return to adjudicating appeals within the 90-day BIPA requirement, and adjudicate appeals resulting from re-started program integrity initiatives.

<u>Summary</u>
The FY 2022 budget request positions OMHA to continue the significant progress made in reducing the backlog of pending appeals. The sustained investment in adjudicatory resources and two-year availability of funding enables OMHA to re-balance capacity with incoming receipts.

Medicare Hearings and Appeals (OMHA)

Outputs and Outcomes Table

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2021 Target	FY 2022 Target	FY 2022 Target +/-FY 2021 Target
Reduce the percentage of decisions reversed or remanded on appeals to the Medicare Appeals Council. (Outcome)	FY 2020: 0.3% 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 2020: 3.96 Target: 3.4 (Target Exceeded)	3.4	3.4	Maintain

Medicare Hearings and Appeals (OMHA)

Budget Authority by Object Class

(Dollars in Thousands)

Object Class Code	Description	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Budget	FY 2022 +/- FY 2021
11.1	Full-time permanent	105,000	93,000	97,038	4,038
11.5	Other personnel compensation	-	2,000	1,630	-370
Subtotal	***Personnel Compensation***	105,000	95,000	98,668	3,668
12.1	Civilian personnel benefits	37,000	34,000	35,685	1,685
Total	***Pay Costs***	142,000	129,000	134,353	5,353
21.0	Travel and transportation of persons	-	-	-	-
22.0	Transportation of things	-	-	-	-
23.1	Rental payments to GSA	8,000	9,000	8,931	-69
23.3	Communications, utilities, and misc. charges	8,000	7,000	7,000	-
24.0	Printing and reproduction	1,000	1,000	659	-341
25.2	Other services from non-Federal sources	9,000	12,000	9,912	-2,088
25.3	Other goods and services from Federal sources	11,000	11,000	9,744	-1,256
25.4	Operation and maintenance of facilities	1,000	1,000	1,000	-
25.7	Operation and maintenance of equipment	5,000	1,381	19	-1,362
26.0	Supplies and materials	1,000	1,000	656	-344
31.0	Equipment	-	-	107	107
32.0	Land and Structures	1,000	-	-	-
42.0	Insurance claims and indemnities	-	-	-	-
Total	***Non-Pay Costs***	45,000	43,381	38,028	-5,353
Total	**Budget Authority by Object Class**	**187,000**	**172,381**	**172,381**	**-**

Medicare Hearings and Appeals (OMHA)

Salaries and Expenses
(Dollars in Thousands)

Object Class Code	Description	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Budget	FY 2022 +/- FY 2021
11.1	Full-time permanent	105,000	93,000	97,038	4,038
11.5	Other personnel compensation	-	2,000	1,630	(370)
Subtotal	**Personnel Compensation**	**105,000**	**95,000**	**98,668**	**3,668**
12.1	Civilian personnel benefits	37,000	34,000	35,685	1,685
Total	**Pay Costs**	**142,000**	**129,000**	**134,353**	**5,353**
21.0	Travel and transportation of persons	-	-	-	-
22.0	**Transportation of things**	**-**	**-**	**-**	**-**
23.3	Communications, utilities, and misc. charges	8,000	7,000	7,000	-
24.0	**Printing and reproduction**	**1,000**	**1,000**	**659**	**(341)**
25.2	Other services from non-Federal sources	9,000	12,000	9,912	(2,088)
25.3	**Other goods and services from Federal sources**	**11,000**	**11,000**	**9,744**	**(1,256)**
25.4	Operation and maintenance of facilities	1,000	1,000	1,000	-
25.7	**Operation and maintenance of equipment**	**5,000**	**1,381**	**19**	**(1,362)**
Subtotal	**Other Contractual Services**	**35,000**	**33,381**	**28,334**	**(5,047)**
26.0	**Supplies and materials**	**1,000**	**1,000**	**656**	**(344)**
Subtotal	**Non-Pay Costs**	**36,000**	**34,381**	**28,990**	**(5,391)**
Total	**Salary and Expenses**	**178,000**	**163,381**	**163,343**	**(38)**
23.1	Rental payments to GSA	8,000	9,000	8,931	(69)
Total	**Salaries, Expenses, and Rent**	**186,000**	**172,381**	**172,274**	**(107)**
Total	**Direct FTE**	**1,165**	**1,143**	**1,135**	**(8)**

Medicare Hearings and Appeals (OMHA)

Detail of Full Time Equivalents

Detail	FY 2020 Actual Civilian	FY 2020 Actual Military	FY 2020 Actual Total	FY 2021 Estimate Civilian	FY 2021 Estimate Military	FY 2021 Estimate Total	FY 2022 Estimate Civilian	FY 2022 Estimate Military	FY 2022 Estimate Total
Direct	1,165	-	1,165	1,143	-	1,143	1,135	-	1,135
Reimbursable	-	-	-	-	-	-	-	-	-
Total FTE	**1,165**	**-**	**1,165**	**1,143**	**-**	**1,143**	**1,135**	**-**	**1,135**

5 Year History of Average GS Grade

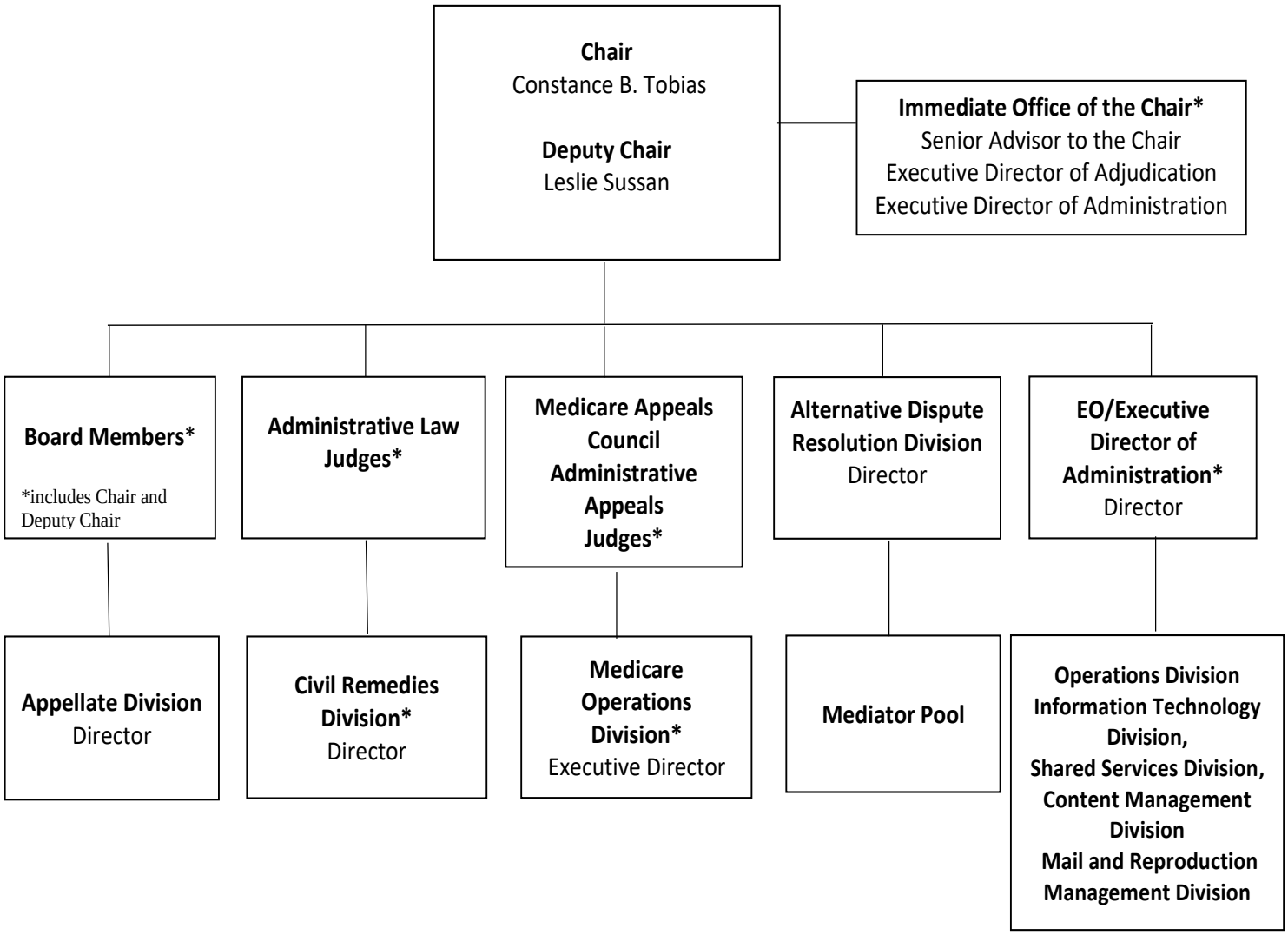
Fiscal Year	Average GS
FY 2018	11/6
FY 2019	12/1
FY 2020	11/2
FY 2021	11/3
FY 2022	11/4

Medicare Hearings and Appeals (OMHA)

Detail of Positions

Detail of Positions	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Budget
ALJ I	0	1	1
ALJ II	11	11	11
ALJ III	152	149	146
Subtotal	163	161	158
Total – ALJ Salaries	27,950,400	28,208,628	28,211,902
ES	2	2	2
Total - ES Salaries	394,600	402,985	411,044
GS-15	18	18	18
GS-14	45	50	50
GS-13	91	96	96
GS-12	268	274	274
GS-11	145	141	141
GS-10	-	-	-
GS-9	52	35	35
GS-8	201	235	235
GS-7	91	74	74
GS-6	52	46	46
GS-5	16	19	19
GS-4	3	2	2
GS-3	-	-	-
GS-2	-	-	-
GS-1	-	-	-
Subtotal	982	990	990
Total - GS Salary	74,698,447	77,688,207	79,241,972
Total Positions	1,147	1,153	1,150
Total FTE	1,165	1,143	1,135
Average ALJ Salary	171,475	175,209	178,556
Average ES salary	197,300	201,492	205,522
Average GS grade	11/2	11/3	11/4
Average GS Salary	76,068	78,473	80,042

DAB Organizational Chart



*Denotes Divisions and staff performing Medicare-related work.

Organizational Chart (Text Version)

Departmental Appeals Board

- Chair, Constance B. Tobias
- Deputy Chair, Leslie Sussan
- Immediate Office of the Chair

The following offices report directly to the Chair:

- Board Members (includes the Chair and Deputy Chair)
    - Appellant Division
- Administrative Law Judges
    - Civil Remedies Division Director
- Medicare Appeals Council Administrative Appeals Judges
    - Medicare Operations Division Director
- Alternate Dispute Resolution Division Director
    - Mediator Pool
- Executive Director of Administration
    - Operations Division Information Technology Division,
    - Shared Services Division,
    - Content Management Division
    - Mail and Reproduction Management Division

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. Outside parties who disagree with a determination made by an HHS agency or its contractor initiate cases. Outside parties include States, universities, Head Start grantees, hospitals, 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. The Secretary appoints all of DAB's judges (Board Members, Administrative Law Judges (ALJs), and Administrative Appeals Judges (AAJs)).

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.

Overview of Budget Request

The FY 2022 President's Budget requests $23,619,000 at the program level, which is +$4,119,000 above the FY 2021 Enacted level. This request will allow the DAB to increase staff by 26 percent and adjudication capacity by 11 percent.

The DAB has a large backlog of pending appeals as a result of increased Department program enforcement and integrity efforts. 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. While additional resources received in FY 2020 helped the DAB in its effort to manage the backlog, MOD is still unable to adjudicate incoming appeals within the 90-day statutory deadline. Additionally, an increase in appeals prioritized by the Council, such as agency referrals from CMS and beneficiary appeals, further delayed MOD's ability to reallocate staff resources to adjudicate backlog cases. As the final level of administrative 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 2020 is more than $770 million.

Based on available data, MOD's receipts are estimated to increase from a total of 3,809 appeals in FY 2020 to 6,918 appeals in FY 2021. Therefore, it is projected that MOD will continue to receive more appeals than it can adjudicate each year. DAB's investment will build the adjudicatory capacity needed to outpace case receipts. The additional funding allows DAB an opportunity to begin to reduce the Medicare appeals backlog 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 12 percent of MOD's annual receipts and for approximately 7 percent of the existing backlog. Although the DAB continues to make 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 2016 to FY 2020) is 623 days. The average age of pending beneficiary appeals is 671 days. In FY 2020, the average age of pending beneficiary appeals increased by 30 percent from FY 2019. This increase is the result of MOD adjudicating appeals docketed in prior fiscal years. In addition to beneficiary appeals, MOD receives other types of appeals that it must prioritize, requiring MOD to reallocate its 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, including statistical sampling and multi-claim overpayment cases, which require significant staff time to review and adjudicate. 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.

Similarly, the DAB's Civil Remedies Division (CRD) received substantially more appeals due to increased CMS program enforcement and integrity efforts. Specifically, CRD's case receipts increased by 50 percent from FY 2016 to FY 2018, and in FY 2019, receipts remained above historic numbers with 23 percent more cases received than in FY 2016. Moreover, CMS and other Department program enforcement and integrity efforts over the last several years have continued to expand CRD jurisdiction, with new types of appeals being directed to CRD's ALJs (and the DAB's Board Members) for review. This growing workload also contributed to substantial delays in adjudication in recent fiscal years.

In FY 2020, receipts returned to historical numerical expectations, and CRD received additional resources to help tackle the unprecedented appeals backlog. Consequently, CRD has been able to focus on adjudicating the particularly complex skilled nursing facility enforcement appeals that accumulated during prior fiscal years. With adjudication capacity improved as a result of the additional resources received in FY 2020 and FY 2021, plus additional funds planned in FY 2022, DAB will hire four new staff (2 ALJs, 2 attorneys). CRD expects that it will begin reducing time periods for case adjudication by the end of FY 2022. Any reduction in adjudication time will depend on whether CRD also receives an expected significant increase in projected receipts due to increased enforcement and program integrity efforts in FY 2021 and FY 2022, comparable to those experienced from FY 2016 to FY 2019.

All Purpose Table

(Dollars in Thousands)

Departmental Appeals Board*	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Budget	FY 2022 President's Budget +/- FY 2021
Total, DAB Discretionary Budget Authority	19,500	19,500	23,619	+4,119

*2020, 2021, and 2022 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.

MEDICARE HEARINGS AND APPEALS

Amounts Available for Obligation

DAB Detail	FY 2020 Final*	FY 2021 Enacted	FY 2022 President's Budget
Trust Fund Discretionary Appropriation			
DAB Discretionary Appropriation	19,500	19,500	23,619
Total Obligations**	19,500	19,500	23,619

** 2020, 2021, 2022 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 Final	19,500	67
FY 2021 Enacted	19,500	102
FY 2022 President's Budget	23,619	132
Net Change	+4,119	+30

DAB Increases (+) and Decreases (-)	FY 2021 Final	– FY 2021 Enacted FTE	FY 2022 President's Budget	FY 2022 +/- FY 2021 FTE	FY 2022 +/- FY 2021 BA
Full-time permanent	10,163	102	12,770	+30	+2,607
Other personnel compensation		-		-	
Civilian personnel benefits	3,570	-	4,034	-	+464
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	-			+30	+4,119

DAB Total Changes	– FY 2022 FTE	FY 2022 President's Budget	FY 2022 +/- FY 2021 FTE	FY 2022 +/- FY 2021
Total Increases (+)	102	23,619	+30	+4,119
Total Decreases (-)	-	-	-	-
Total Net Change			+30	+4,119

Medicare Hearings and Appeals (DAB)

Budget Authority by Activity – Direct

(Dollars in Thousands)

Activity	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Budget
Discretionary Budget Authority	19,500	19,500	23,619
Discretionary Budget Authority, FTE	**67**	**102**	**132**

Medicare Hearings and Appeals (MHA)

Authorizing Legislation

(Dollars in Thousands)

Medicare Hearings and Appeals	FY 2021 Amount Authorized	FY 2021 Amount Appropriated	FY 2022 Amount Authorized	FY 2022 President's Budget
Medicare Hearings and Appeals, Social Security Act, Titles XVIII and XI	Indefinite	191,881	Indefinite	196,000
Total Appropriation	-	**191,881**	-	**196,000**

Medicare Hearings and Appeals (MHA)

Appropriations History Table

Details	Budget Estimates to Congress	House Allowance	Senate Allowance	Appropriation
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	191,881,000	191,881,000	191,881,000
Subtotal	196,381,000	191,881,000	191,881,000	191,881,000
2022				
Trust Fund Appropriation	196,000,000			
Subtotal	**196,000,000**			

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 was replaced in FY 2020 by a similar dual-eligible beneficiary project, called the "New York Integrated Appeals and Grievances Demonstration," and MOD will continue adjudicating these types of appeals for each fiscal year that CMS renews its agreement with the DAB. 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 2020, MOD received 3,809 appeals and adjudicated 1,783. MOD also closed an additional 368 cases pursuant to administrative settlement agreements between CMS and certain categories of appellants. At the end of FY 2020, MOD had 18,619 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 in enforcement cases. CRD ALJs hear appeals of CMS or OIG determinations to exclude providers, suppliers, or other healthcare practitioners from participating in Medicare, Medicaid, and other federal healthcare programs. The ALJs also hear cases

appealing the imposition of civil monetary penalties (CMPs) for fraud and abuse in Medicare, Medicaid, and other federal healthcare programs, as well as various other types of CMPs. CRD jurisdiction also includes appeals from Medicare providers or suppliers of enrollment determinations, as well as appeals of sanctions 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 skilled nursing facility 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 2020, CRD received 799 new cases and closed 1,040, of which 296 were by decision. Approximately 88% 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:

- 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 adjudication capacity by up to 30 percent;
- Increases in personnel in FY 2021 (+10 FTE) and FY 2022 (+19 FTE);
- An additional 100 cases closed in FY 2020 pursuant to administrative settlements;
- A reduction in case receipts if State Medicaid Agency settlements resume in FY 2022;
- An increase in case receipts in FY 2022 as a result of increases in adjudications at OMHA;
- Increased overpayment cases (including Recovery Audit (RA) and statistical sampling cases);
- Increased CMS demonstration projects across the country (e.g., Part A: Home Health Demonstration tentatively scheduled for August 2022);
- Participation in Department-wide administrative initiatives to improve efficiency within the Medicare appeals process and to adjudicate 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 2020	FY 2021	FY 2022
Open/start of FY	16,961	18,619	20,487
Received	3,809	6,859	6,843
Cases Closed	1,783	5,000	5,520
Administrative Settlements	368	-	-
Open/end of FY	18,619	20,487	21,810

Administrative Law Judges – Civil Remedies Division

Chart B shows caseload data for CRD. Approximately 88% of CRD casework is specific to Medicare related issues. All data are projected based on historical trends and certain assumptions, including:

- CMS' increased use of data analysis techniques to detect provider/supplier fraud and noncompliance, and continued implementation of new enforcement authorities;
- 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;
- An increase in the number of skilled nursing facility hearing requests, relative to historic expectations, based on unprecedented impact that the COVID-19 pandemic has had on those facilities and CMS' response prioritizing infection control enforcement;
- No major regulatory changes; and
- No increase in personnel in FY 2021, and 2 new FTEs (2 ALJs) in FY 2022.

CIVIL REMEDIES DIVISION CASES – Chart B

Cases	FY 2020	FY 2021	FY 2022
Open/start of FY	701	460	630
Received	799	1,242	1,242
Decisions	296	226	264
Total Closed	1,040	1,072	1,250
Open/end of FY	460	630	622

5 Year Funding Table - DAB

Fiscal Year	Amount
FY 2018*	-
FY 2019*	-
FY 2020	$19,500,000
FY 2021 Enacted	$19,500,000
FY 2022 President's Budget	$23,219,000

***Funded by the General Departmental Management appropriation.**

Budget Request

The FY 2022 President's Budget for the Departmental Appeals Board (DAB) requests $23,619,000, which is an increase in funding of +$4,119,000 above the FY 2021 Enacted level.

At the FY 2022 President's Budget funding level, the DAB will devote a majority of the additional resources to MOD to continue growing its adjudication capacity. Specifically, MOD will add 19 new attorneys. Additional funding, along with the proposed legislative change to the Council's standard of review, increases the Council's adjudication capacity to approximately 7,176 cases per year, a 44 percent increase over the FY 2021 adjudication capacity level of 5,000. Importantly, this will mark the first period in over a decade where projected receipts in FY 2022 (6,843) will be less than MOD's adjudication capacity. The additional resources and legislative changes will enable MOD to keep pace with incoming appeals, while achieving measurable progress in reducing its Medicare appeals backlog. The DAB expects adjudication capacity in the out-years to increase once more recently hired and incoming staff are fully trained and reach expected levels of productivity.

The FY 2022 President's Budget will also enable CRD to add two new staff members (ALJs) and increase adjudication capacity from 1,072 to 1,250 case closures. This enables CRD to continue to ensure that ALJs can adjudicate cases within statutory and regulatory timeframes and to reduce the adjudication delays experienced in the past several fiscal years. CRD will continue to match its adjudication efforts with the Department's sustained expansion of program integrity measures and the resulting expansion of CRD ALJ jurisdiction.

The DAB continues to leverage existing resource levels and staff members in the Immediate Office of the DAB Chair and Administration Division that support Medicare-related adjudication efforts. All DAB policy, oversight, information technology (IT), and administrative operations including budget, procurement, and human capital management are consolidated into these two divisions. The increase of seven additional staff members to the Administration Division who support operational activities has enhanced efficiencies across the DAB. The additional staff, consolidate and streamline essential aspects of agency functionality, such as FOIA request processing, records management, mail and reproduction services, performance and awards, coordinate hearings and recordings, provide shared services, generate standard operating procedures, and oversee facilities management projects.

This structure allows judges and attorneys to focus solely on legal work, ensuring maximum productivity. These divisions are poised to continue successful operations in FY 2022 and apply additional funding to increase administrative efficiency, improve oversight of the DAB's adjudicatory divisions, and address a myriad of other program challenges driven by growing workload demands. The DAB remains dedicated to developing and implementing new and updated IT solutions, including improved e-filing options, document generation system enhancements, case management systems innovations and resources, and

ongoing IT development in the areas of artificial intelligence and data analytics as tools to collect, manage, and analyze case data.

Outputs and Outcomes Table

Measure - DAB	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2021 Enacted	FY 2022 President's Budget	FY 2022 +/- FY 2021
1.1.1 Percentage of CRD decisions issued within all applicable statutory and regulatory deadlines.	FY 2020: 100% Target 90% (Target Exceeded)	90%	90%	Maintain
1.1.2 Cases closed in a fiscal year as a percentage of total cases open in the fiscal year.	FY 2020: 69% 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 2020: 337 days Target: 737 days (Target Exceeded)	727 days	727 days	Maintain
1.2.2 Number of MOD dispositions.	FY 2020: 1,750 +872 (CMS Settlements) Target: 2,120 (Target Exceeded)	5,000	7,176	+2,176

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 2020. The target for this Measure will remain the same in FY 2021 and FY 2022.

Measure 1.2.1 tracks cases closed as a percentage of all cases open during the fiscal year. CRD exceeded its FY 2020 target by closing 68.5 percent of cases open that year. The FY 2021 and FY 2022 targets remain unchanged because many cases are complex, resulting in longer adjudication times, and CRD expects to receive an increase in appeals in both years. While CRD anticipates meeting Measure 1.2.1 in both years due to increased adjudication capacity resulting from additional resources in FY 2020 and FY 2021, the Division may struggle if receipts greatly exceed expectations.

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. MOD focuses on closing high priority cases, including Part C and D pre-service cases and beneficiary appeals, which is designed to reduce the average time it takes to close a case. New staff in FY 2021 and 2022, 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. MOD exceeded its target in FY 2020 and expects to continue to meet or exceed its targets in FY 2021 and FY 2022, using additional resources to increase adjudication capacity.

MEDICARE HEARING AND APPEALS (DAB)

BUDGET BY OBJECT CLASS

(Dollars in Thousands)

Object Class Code	Description	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Budget	FY 2022 +/- FY 2021
11.1	Full-time permanent	8,685	9,365	14,290	+5,525
11.3	Other than full-time permanent	-	-	-	-
11.5	Other personnel compensation	-	-	-	-
11.7	Military personnel	-	-	-	-
Subtotal	***Personnel Compensation***	***8,685***	***9,365***	***14,290***	***+4,925***
12.1	Civilian personnel benefits	2,730	3,864	4,469	+605
12.2	Military benefits	-	-	-	-
13.0	Benefits for former personnel	-	-	-	-
Total	***Pay Costs***	***11,414***	***13,228***	***18,759***	***+5,530***
21.0	Travel and transportation of persons	-	45	45	-
22.0	Transportation of things	-	5	15	+10
23.1	Rental payments to GSA	1,249	1,380	1,500	+120
23.3	Communications, utilities, and misc. charges	150	170	170	-
24.0	Printing and reproduction	5	5	10	+5
25.1	Advisory and assistance services	-	-	-	-
25.2	Other services from non-Federal sources	4,259	2,686	2,300	-386
25.3	Other goods and services from Federal sources	2,293	1,900	740	-1,160
25.4	Operation and maintenance of facilities	-	-	-	-
25.5	Research and development contracts	-	-	-	-
25.6	Medical care	-	-	-	-
25.7	Operation and maintenance of equipment	-	-	-	-
25.8	Subsistence and support of persons	-	-	-	-
26.0	Supplies and materials	98	30	30	-
31.0	Equipment	30	50	50	-
32.0	Land and Structures	-	-	-	-
41.0	Grants, subsidies, and contributions	-	-	-	-
42.0	Insurance claims and indemnities	-	-	-	-
44.0	Refunds	-	-	-	-
Total	***Non-Pay Costs***	***8,086***	***6,271***	***4,860***	***-1,411***
Total	**Budget Authority by Object Class**	**19,500**	**19,500**	**23,619**	**4,119**

*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.

MEDICARE HEARINGS AND APPEALS (DAB)

Salaries and Expenses

(Dollars in Thousands)

Object Class Code	Description	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Budget	FY 2022 +/- FY 2021
11.1	Full-time permanent	8,685	9,365	14,290	+4,925
11.3	Other than full-time permanent	-	-	-	-
11.5	Other personnel compensation	-	-	-	-
11.7	Military personnel	-	-	-	-
Subtotal	***Personnel Compensation***	***8,685***	***9,365***	***14,290***	***+ 4,925***
12.1	Civilian personnel benefits	2,730	3,864	4,469	+605
12.2	Military benefits	-	-	-	-
13.0	Benefits for former personnel	-	-	-	-
Total	***Pay Costs***	***11,414***	***13,228***	***18,759***	***+ 5,530***
21.0	Travel and transportation of persons	-	45	45	-
22.0	Transportation of things	-	5	15	10
23.1	Rental payments to GSA	1,249	1,380	1,500	120
23.3	Communications, utilities, and misc. charges	150	170	170	-
24.0	Printing and reproduction	5	5	10	5
25.1	Advisory and assistance services	-	-	-	-
25.2	Other services from non-Federal sources	4,259	2,686	2,300	-386
25.3	Other goods and services from Federal sources	2,293	1,900	740	-1,160
25.4	Operation and maintenance of facilities	-	-	-	-
25.5	Research and development contracts	-	-	-	-
25.6	Medical care	-	-	-	-
25.7	Operation and maintenance of equipment	-	-	-	-
25.8	Subsistence and support of persons	-	-	-	-
26.0	Supplies and materials	98	30	30	-
31.0	Equipment	30	50	50	-
32.0	Land and Structures	-	-	-	-
41.0	Grants, subsidies, and contributions	-	-	-	-
42.0	Insurance claims and indemnities	-	-	-	-
44.0	Refunds	-	-	-	-
Total	***Non-Pay Costs***	***8,086***	***6,271***	***4,860***	***-1,411***
Total	**Budget Authority by Object Class**	**19,500**	**19,500**	**23,619**	**4,119**

5 Year History of Average GS Grade

Fiscal Year	Average GS
FY 2018	12/4
FY 2019	12/9
FY 2020	13/1
FY 2021	13/1
FY 2022	13/2

Detail of Full Time Equivalents

DAB Detail	FY 2020 Actual Civilian	FY 2020 Actual Military**	FY 2020 Actual Total*	FY 2021 Estimate Civilian	FY 2020 Estimate Military	FY 2021 Estimate Total	FY 2022 Estimate Civilian	FY 2021 Estimate Military	FY 2022 Estimate Total
Direct	67	-	67	102	-	102	132	-	132
Reimbursable	-	-	-	-	-	-	-	-	-
Total FTE	**67**	**-**	**67**	**102**	**-**	**102**	**132**	**-**	**132**

MEDICARE HEARINGS AND APPEALS (DAB)
Detail of Positions

Direct Civilian Positions	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Budget
Executive level I	3	4	1
Executive level II	1	5	5
Executive level III	7	1	6
Executive level IV	4	4	8
Executive level V	1	1	8
Subtotal, Positions	**16**	**15**	**28**
Total, Salaries	**$3,478,721**	**$2,731,673**	**$3,172,028**
-	-	-	-
Executive Service Positions	**0.5**	**0.5**	**1.15**
Total, Salaries	**$99,650**	**$99,650**	**$215,505**
-	-	-	-
GS-15	4	9	8
GS-14	10	11	17
GS-13	10	15	17
GS-12	11	13	27
GS-11	11	30	21
GS-10	-	-	-
GS-9	1	5	10
GS-8	3	3	3
GS-7	-	-	-
GS-6	-	-	-
GS-5	-	-	-
GS-4	-	-	-
GS-3	-	-	-
GS-2	-	-	-
GS-1	-	-	-
Subtotal, Positions	**50**	**86**	**103**
Total - GS Salary	**$6,234,658**	**$9,947,027**	**$14,270,103**
Total Positions	**67**	**102**	**132**
Average ES level	AA	AA	AA
Average ES salary	**$183,300**	**$183,300**	**$183,300**
Average GS grade	13 Step 5	13 Step 1	13 Step 2
Average GS salary	**$116,353**	**$103,690**	**$107,146**
Average Special Pay categories	-	-	-

Office for Civil Rights

DEPARTMENT of HEALTH and HUMAN SERVICES

Fiscal Year
2022

Office for Civil Rights

Justification of Estimates for
Appropriations Committees

I am pleased to present the Office for Civil Rights' (OCR) Fiscal Year 2022 Congressional Justification. The enclosed budget request supports our mission to ensure that individuals receiving services from HHS-funded or conducted programs are not subject to discrimination, to protect the privacy and security of individuals' health information, and to advance the President's and Secretary's priorities.

OCR has been a leader in protecting civil rights, non-discrimination, and health information privacy and security during the COVID-19 public health emergency. At the start of the pandemic, OCR was the first federal agency to issue a statement on non-discrimination and HIPAA flexibilities to ensure consumers receive equal treatment and to give health care providers flexibility to meet health care demands while continuing to protect privacy and comply with civil rights laws. Throughout COVID-19, OCR has investigated complaints and conducted compliance reviews to assess and address allegations of discrimination in the provision of services and treatment, and published numerous guidance documents and bulletins to educate the public and covered about rights and obligations.

OCR is currently playing a critical role in advancing the Administration's priorities, including priorities under EO 13985: *Advancing Racial Equity and Support for Underserved Communities Through the Federal Government*; Executive Order (EO) 13988: *Preventing and Combating Discrimination on the Basis of Gender Identity or Sexual Orientation*; and EO 13995: *Ensuring an Equitable Pandemic Response and Recovery*. Notably, OCR is leading the Department's response to EO 13988, facilitating cross-departmental coordination and collaboration to provide a robust response.

In addition to responding to the ongoing COVID-19 public health emergency and supporting the Administration's priorities, OCR has continued its core work enforcing prohibitions against discrimination based on race, color, national origin, disability, age, sex, and religion. OCR has responded to a growing number of complaints and continues to reach settlements that vindicate individuals' rights, issue policies, and conduct education and outreach activities to ensure awareness of and compliance with civil rights and non-discrimination laws. In addition to its civil rights and nondiscrimination work, OCR continues to promote and enforce HIPAA privacy and security protections, including by supporting public and private sector efforts to improve health care quality and reduce costs. OCR's initiatives aid in 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 patient safety by helping to facilitate confidential analyses of medical errors and other patient safety events.

Through its activities, OCR continues its commitment to rooting out discrimination in the provision of HHS-funded services and protect the privacy and security of, and access to, health information to empower individuals and families, strengthen the integrity of the health care system, and advance the HHS mission of improving the health and well-being of all Americans.

Robinsue Frohboese

Robinsue Frohboese, J.D., Ph.D.
Acting Director and Principal Deputy Director
Office for Civil Rights
U.S. Department of Health and Human Services

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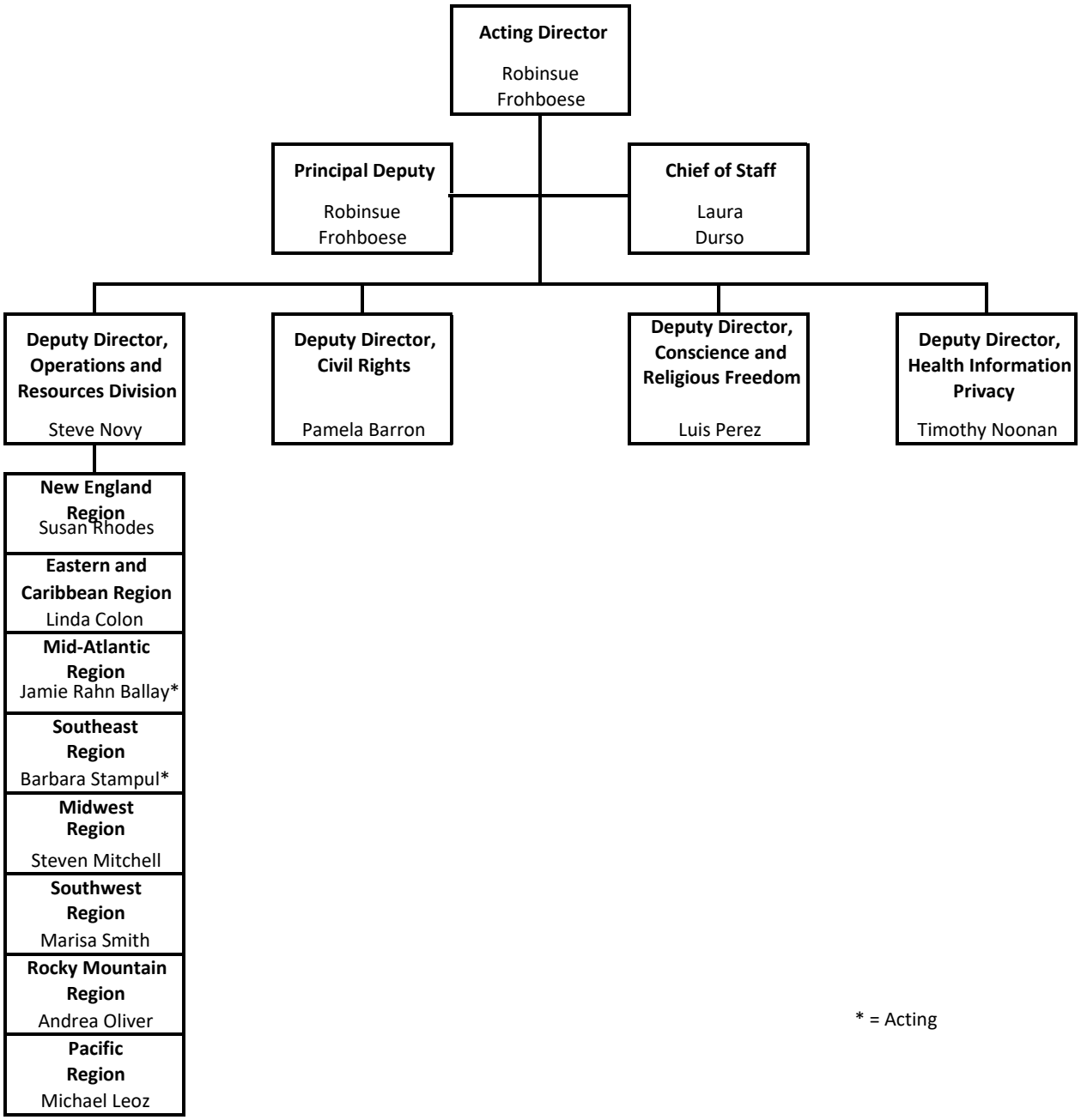
Section 1: Introductory Items

Organization Chart

(April 2021)



* = Acting

Organizational Chart: Text Version

Office for Civil Rights

- Acting Director Robinsue Frohboese
- Principal Deputy Robinsue Frohboese
- Chief of Staff Laura Durso

The following offices report directly to the Director:

1 Deputy Director, Operations and Resources
1.2 Steve Novy
2 Deputy Director, Civil Rights Division
2.2 Pamela Barron
3 Deputy Director, Conscience and Religious Freedom
3.2 Luis Perez
4 Deputy Director, Health Information Privacy
4.2 Timothy Noonan

The following regional managers report to the Deputy Director, Operations and Resources:

- 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 2: 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-funded or conducted programs are not subject to discrimination and that the privacy and security of individuals' health information is protected. By working to root out discrimination in the provision of HHS-funded services and by protecting the privacy and security of, and access to, health information, OCR empowers individuals and families, strengthens the integrity of the health care system, and advances the HHS mission of improving the health and well-being of all Americans.

Mission

As a law enforcement agency, OCR investigates complaints, conducts compliance reviews, develops policy, promulgates regulations, provides technical assistance, and educates the public about federal civil rights and conscience laws that prohibit recipients of HHS federal financial assistance from discriminating on the basis of race, color, national origin, disability, age, sex, and religion. It also ensures that the practices of health care providers, health plans, healthcare clearinghouses, and their business associates comply with the Federal privacy, security, and breach notification laws and regulations that OCR enforces through the investigation of complaints and breach reports, compliance reviews, and audits. Through its work, OCR helps to ensure equal and non-discriminatory access, promotes positive change throughout our nation's social service and health care systems to advance equity and accountability, and provides tools for covered entities and individuals to understand their rights and obligations under the law.

Vision and Values

Through enforcement of laws prohibiting discrimination and protecting the rights of individuals to the privacy and security of, and access to, their health information, OCR helps ensure that all persons have an equal right to access federal programs and services and works to address the histories of marginalization and structural discrimination that have had a disproportionately negative impact on people of color, immigrants and refugees, religious minorities, LGBTQ+ communities, people with disabilities, individuals with limited English proficiency, and other underserved communities. OCR believes that achieving its goals requires active and strong collaboration with other federal partners, community leaders and community-based organizations, and members of the regulated community.

Overview of Budget Request

The FY 2022 President's Budget request for the Office for Civil Rights is $47,931,000 in discretionary funding, which is $9,133,000 above the FY 2021 Enacted level. At this level, OCR will expand its capacity to defend the public's right to nondiscriminatory access to HHS-funded health and human services while continuing to protect access to and the privacy and security of protected health information. OCR will also implement additional civil rights enforcement activities to support the Administration's efforts to advance equity in health and human services programs. The increased funding will allow OCR to add 39 FTEs who will augment OCR's civil rights policy and enforcement work, including supporting OCR's efforts to revitalize civil rights work in the areas of race, disability, and sex discrimination, child welfare, and environmental justice. It will also allow OCR to evaluate and further assess the impact of HHS policies and regulatory role in health equity barriers for underserved groups. OCR will use $19,531,000 in settlement funding for its HIPAA activities, which is $7,323,000 below the FY 2021 level.

There are several key factors contributing to OCR's need for increased funding to advance our mission to protect the civil rights and privacy of all persons in health care and human services. *First*, complaints to OCR have increased exponentially in recent years while total numbers of staff have decreased. From 2003 to 2020, OCR experienced a 1,775% increase in annual cases, from 1,948 cases in 2003 to 36,544 in 2020. At the same time, OCR experienced a 36% reduction in staff, from 121 investigators in 2003 to 77 investigators in 2020. As a result, OCR is limited in the number of complaints per year that it resolves through a full investigative process, as well as the number of compliance reviews it can initiate.

Given the trend in complaints to OCR as well as the priorities articulated by the Administration, discussed further below, OCR anticipates a significant increase in the number of civil rights complaints. OCR plans to proactively address these issues by initiating compliance reviews and using additional staff in the regional offices to respond to the complaints in a timely and impactful way. This budget request includes supporting up to 20 regional investigators to resolve new civil rights cases, address the backlog of civil rights complaints, and initiate compliance reviews in areas of the Administration's priorities.

Second, the investments ensure OCR's ability to meet its existing oversight and enforcement obligations as well as advance the President's priorities, including priorities under Executive Order (EO) 13988: *Preventing and Combating Discrimination on the Basis of Gender Identity or Sexual Orientation*; EO 13985: *Advancing Racial Equity and Support for Underserved Communities Through the Federal Government*; EO 14009: *Strengthening Medicaid and the Affordable Care Act (ACA)*; EO 13995: *Ensuring an Equitable Pandemic Response and Recovery*; EO 13997: *Improving Access to Care and Treatments for COVID-19*; EO 13930: *Strengthening the Child Welfare System for America's Children*; *EO 14008: Tackling the Climate Crisis at Home and Abroad*; and EO 13990: *Protecting Public Health and the Environment and Restoring Science To Tackle the Climate Crisis.* Compliance with these EOs requires a significant expansion in OCR's, policy, technical assistance, and outreach efforts. It also requires coordinated enforcement nationwide. OCR will add 19 FTEs with appropriate subject matter expertise to address these broader requirements.

Third, OCR plans to continue expanding its work on high-impact cases, which require significant time and resources. OCR works on the development and review of approximately 100 active high-impact cases, which are a joint effort between our Regional Offices and Headquarters. These high-impact cases involve critical civil rights issues that have a national impact. Settlement agreements in high-impact cases often bring about systemic change across states, hospitals and health systems, medical practices, and child welfare programs; and are used as models by health care providers, social service agencies, and universities to inform and protect the public. The Administration has clearly laid out a set of priorities that are squarely in line with OCR's mission and areas of expertise, and OCR can play a critical role in meeting these goals and

serving communities in need. The investment is necessary to strengthen civil rights work, effectively advance the Administration's vision, and ensure adequate resources to protect the civil rights of all individuals in HHS services they receive.

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 and protect the privacy and security of personally identifiable health information	A. Increase access to, and receipt of, non-discriminatory quality health and human services 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 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 2022 targets:

Program/Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2021 Target	FY 2022 Target	FY 2022 Target +/- FY 2021 Target
#1 The number of covered entities taking corrective actions as a result of OCR intervention per year (Outcome)	FY 2020: 1,606 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 2020: 296 Target: 250 (Target Exceeded)	250	250	Maintain
#3 Percent of closure for civil rights cases / cases received each year (Outcome)	FY 2020: 95% Target: 90% (Target Exceeded)	90%	90%	Maintain
#4 Percent of closure for health information privacy cases / cases received each year (Outcome)	FY 2020: 99% Target: 90% (Target Exceeded)	90%	90%	Maintain
#5 Percentage of closures for conscience and religious freedom cases / cases received each year (Outcome)	FY 2020: 68% Target: 6% (Target Exceeded)	21%	Combined with #3.	Combined with #3.
#6 Percent of civil rights complaints requiring formal investigation resolved within 365 days (Output)	FY 2020: 84% Target: 50% (Target Exceeded)	70%	80%	Revised +10%
#7 Percentage of civil rights complaints not requiring formal investigation resolved within 180 days (Output)	FY 2020: 81% Target: 95% (Target Not Met)	95%	85%	Revised -10%
#8 Percentage of health information privacy complaints requiring formal investigation resolved within 365 days (Output)	FY 2020: 79% Target: 70% (Target Exceeded)	70%	80%	Revised +10%
#9 Percentage of health information privacy complaints not requiring formal investigation resolved within 180 days (Output)	FY 2020: 97% Target: 95% (Target Exceeded)	95%	95%	Maintain
#10 Percentage of conscience and religious freedom complaints requiring formal investigation resolved within 365 days (Output)	FY 2020: 100% Target: 5% (Target Exceeded)	5%	Combined with #6	Combined with #6
#11 Percentage of conscience and religious freedom complaints not requiring formal investigation resolved within 180 days (Output)	FY 2020: 32% Target: 5% (Target Exceeded)	7%	Combined with #7	Combined with #7

OCR exceeded 10 of its 11 performance measures during FY 2020. This accomplishment is made even more significant because COVID-19 greatly increased OCR's enforcement, policy, and outreach workload as OCR has been a national leader in HIPAA and civil rights areas throughout the pandemic. In particular, OCR was at the forefront of drafting national guidance and participating in national conferences, webcasts, and listening sessions related to the public health emergency to ensure that the regulated community continued to provide access to health care in a non-discriminatory way and without violating the privacy of patients. OCR quickly worked to ensure that HIPAA is not a barrier to the exchange of essential information, to respond effectively to structural shifts in the provision of health care, such as the increase in use of telehealth, and to ensure that consumers get needed COVID-19 testing, treatment, and vaccination.

During FY 2020, OCR received 36,592 complaints (more than 5,000 were COVID-19 related) and resolved 35,777 complaints (which included carry over from the prior year). OCR's performance measures focus on OCR's enforcement activities through complaint investigations and compliance reviews. These investigations and reviews entail in-depth investigations and issuing letters of findings, notices of violation, and notices of proposed determination. OCR works to resolve complaints through voluntary resolution agreements, informal early resolution, technical assistance, and further enforcement action or referral as appropriate. As a result of OCR's efforts, in FY 2020, OCR exceeded the target for resolving health information privacy, civil rights, and conscience and religious freedom cases through the investigative process within 365 days (#8, FY 2020 Target: 70%, Actual: 79%; #6, FY 2020 Target: 50%, Actual 84%; #10, FY2020 Target: 5%, Actual 100%, respectively). The timely completion of complaints through formal investigation represents a meaningful measure of the continued improvements being made by OCR towards fulfilling its core mission because these investigations provide needed relief for complainants and other impacted persons. OCR's civil rights investigations frequently involve statewide reforms and the final disposition in these, as well as OCR's HIPAA cases, serve as a model and instructional tool for other covered entities and the regulated community. OCR further exceeded its overall productivity and closure targets by closing a high percentage of all civil rights, conscience and religious freedom, and HIPAA cases received (#3, FY 2020 Target: 90%, Actual 95%; #4, FY 2020 Target: 90%, Actual 99%; #5 FY2020 Target 6%, Actual 68%, respectively). OCR also exceeded its target for the performance objective of investigated complaints/reviews/breaches resulting in corrective action (#1, FY 2020 Target: 1,000, Actual: 1,606), and the number of covered entities making substantive policy changes (#2, FY 2020 Target: 250, Actual: 296).

OCR resolves a large number of complaints without a formal investigation through the provision of technical assistance to the named entity. These complaints involve straight-forward issues that can easily and quickly be addressed by the entity and yield timely relief for complainants. The use of technical assistance to resolve these types of complaints is an efficient and effective way for OCR to use its resources by notifying the regulated community about potential compliance deficiencies and requesting that entities take steps to address noncompliance. Consequently, OCR exceeded its target for conscience and religious freedom and HIPAA cases not requiring formal investigation resolved within 180 days (#9, FY 2020 Target: 95%, Actual: 97 %; #11, FY2020 Target 5%, Actual: 32%, respectively). With regard to the disposition of civil rights cases not requiring a formal investigation, OCR did not meet this measurement in FY 2020 (#7, FY 2020 Target: 95%, Actual: 81%). Additional resources will help OCR meet this measure for civil rights. OCR has adjusted the performance measure for FY 2022 as capacity is built to maximum efficiency, including combining civil rights authorities with conscience and religious freedom authorities to enhance coordination, integration, and resources across all nondiscrimination areas.

All Purpose Table

(Dollars in Thousands)

Office for Civil Rights	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Budget	FY 2022 +/- FY 2021
Discretionary Budget Authority	38,798	38,798	47,931	+9,133
OCR Civil Monetary Settlement Funding	12,431	26,854	19,531	-7,323
Total, OCR Program Level	**51,229**	**65,652**	**67,462**	**+1,810**
FTE - Discretionary Budget Authority	136	141	180	+39
FTE - OCR Civil Monetary Settlement Funding	6	49	49	-
Total FTE, OCR Program Level	**142**	**190**	**229**	**+39**

Section 3: Office for Civil Rights

Appropriations Language

For expenses necessary for the Office for Civil Rights, **[$38,798,000]** *$47,931,000*.

Amounts Available for Obligation

(Dollars in Thousands)

Detail	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Budget
Appropriation	38,798	38,798	47,931
Subtotal, Adjusted Appropriation	38,798	38,798	47,931
Transfer of Funds	-	-	-
Subtotal, Adjusted General Fund Discretionary App	38,798	38,798	47,931
Total, Discretionary Appropriation	**38,798**	**38,798**	**47,931**

Summary of Changes

(Dollars in Thousands)

Budget Year and Type of Authority	Dollars	FTE
FY 2021 Enacted	38,798	141
FY 2022 President's Budget	47,931	180
Net Change	**+9,133**	**+39**

Program Increases	FY 2021 Enacted FTE	FY 2021 Enacted BA	FY 2022 President's Budget FTE	FY 2022 President's Budget BA	FY 2022 +/- FY 2021 FTE	FY 2022 +/- FY 2021 BA
Full-time permanent	141	16,631	180	22,330	+39	+5,699
Civilian personnel benefits	-	5,978	-	8,184	-	+2,206
Other services from non-fed sources	-	2,219	-	2,774	-	+555
Travel and transportation of persons	-	115	-	600	-	+485
Other than full-time permanent	-	615	-	1,053	-	+438
Other personnel compensation	-	436	-	581	-	+145
Supplies and materials	-	50	-	125	-	+75
Equipment		691	-	765	-	+74
Rental payments to GSA	-	3,601	-	3,666	-	+65
Operation and maint. of equipment	-	261	-	280	-	+19
Benefits for former personnel	-	135	-	150	-	+15
Printing and reproduction	-	162	-	175	-	+13
Operation and maint. of facilities	-	92	-	100	-	+8
Comms, utilities, and misc. charges	-	91	-	96	-	+5
Military personnel	-	128	-	130	-	+2
Military benefits	-	8	-	9	-	+1
Transportation of things	-	5	-	5	-	-
Total Increases	**141**	**31,213**	**180**	**41,023**	**+39**	**+9,805**

Program Decreases	FY 2021 Enacted FTE	FY 2021 Enacted BA	FY 2022 President's Budget FTE	FY 2022 President's Budget BA	FY 2022 +/- FY 2021 FTE	FY 2022 +/- FY 2021 BA
Other G&S from federal sources	-	7,580	-	6,908	-	-672
Total Decreases	-	7,580	-	6,908	-	-672

Program Totals	FY 2021 Enacted FTE	FY 2021 Enacted BA	FY 2022 President's Budget FTE	FY 2022 President's Budget BA	FY 2022 +/- FY 2021 FTE	FY 2022 +/- FY 2021 BA
Total Increases	141	31,218	180	41,023	+39	+9,805
Total Decreases	-	7,580	-	6,908	-	-672
Total Net Change	**141**	**38,798**	**180**	**47,931**	**+39**	**+9,133**

Budget Authority by Activity

(Dollars in Thousands)

Activity	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Budget
Discretionary Budget Authority	**38,798**	**38,798**	**47,931**
Discretionary FTE	**136**	**141**	**180**

Authorizing Legislation

(Dollars in Thousands)

Authorizing Legislation	FY 2021 Amount Authorized	FY 2021 Amount Appropriated	FY 2022 Amount Authorized	FY 2022 President's Budget
Office for Civil Rights	Indefinite	$38,798	Indefinite	$47,931
Appropriation	-	$38,798	-	$47,931

OCR Legal Authorities

- 21st Century Cures Act of 2016, Public Law 114-255, sections 2063 (42 U.S.C. § 1320d-2 note), 4005(c) (42 U.S.C. § 300jj-14 note), 4006(a) (42 U.S.C. § 300jj-19(c)(2)-(4)) and 11003-11004 (42 U.S.C. § 1320d-2 note).
- 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.
- Charitable Choice Provision of the Community Service Block Grants, 42 U.S.C. § 9920 and its implementing regulation at 45 C.F.R. part 1050.
- Charitable Choice Provision of the Temporary Aid for Needy Families, 42 U.S.C. § 604a and its implementing regulation at 45 C.F.R. § 260.34.
- Charitable Choice Provisions applicable to discretionary & formula grants of the Substance Abuse Mental Health Services Administration to prevent or treat substance abuse, 42 U.S.C. §§ 290kk-290kk-3, 300x-65 and implementing regulations at 42 C.F.R. parts 54 and 54a.
- Church Amendments, 42 U.S.C. § 300a-7.
- Coats-Snowe Amendment, 42 U.S.C. § 238n.
- Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970, Pub.L. 91-616, Title VI, § 603, renumbered Pub.L. 94-371, § 7
- Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act Amendments of 1974, Pub.L. 93-282
- Comprehensive Health Manpower Training Act of 1971, Pub.L. 92-157, Title I, Subpart III, Part H §110
- 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.
- 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, *see e.g.*, 22 U.S.C. § 2151b(f).
- Provisions related to Medicare and Medicaid, including 42 U.S.C. §§ 14406(1)-(2), 1395w-22(j)(3)(B), 1396u-2(b)(3)(B); 1395cc(f), 1396a(w)(3), 1320a–1(h), 1320c–11, 1395i–5, 1395x(e), 1395x(y)(1), 1396a(a), & 1397j–1(b)).
- Conscience protections from compulsory health care or services, 42 U.S.C. §§ 1396f, 5106i(a), 280g–1(d), 1396s(c)(2)(B)(ii), 290bb–36(f); & 29 U.S.C. § 669(a)(5).
- Conscience Regulation, 45 C.F.R. pt. 88 (effective 2011).
- Coronavirus Aid, Relief, and Economic Security Act of 2020 (CARES), Public Law 116-136, sections 3221(i) (42 U.S.C. § 290dd–2) and 3224.
- Drug Abuse Prevention, Treatment and Rehabilitation Act of 1972, 21 U.S.C. § 1101
- Equal Treatment of Faith-Based Organizations for Mentoring Children of Prisoners, 42 U.S.C. § 629i.
- Establishment Clause and Free Exercise Clause of the First Amendment to the U.S. Constitution as they apply to HHS.

- 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.
- HHS Equal Treatment Regulation, 45 C.F.R. pt. 87, including its application at 45 C.F.R. §§ 75.218, 96.18.
- Hill-Burton Community Service Assurance (creed) 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).
- Improving America's Schools Act of 1994, Part E, Pub.L. 103-382
- National Research Service Award Act of 1974, Pub.L. 93-348
- Nondiscrimination for Traditional Indian Religious Use of Peyote, 42 U.S.C. § 1996a(b)(1).
- Nondiscrimination Provisions on the basis of creed in certain HHS-funded programs (*e.g.*, Head Start, 42 U.S.C. § 9849, Migrant Health Services, 42 C.F.R. § 56.110, and Community Health Services, 42 C.F.R. § 51c.109).
- Nurse Training Act of 1971, Pub.L. 92-158, renumbered Pub.L. 111-148, 42 U.S.C. § 296g
- Omnibus Budget Reconciliation Act of 1981, Pub.L. 97-35 [civil rights provisions pertaining to HHS Block Grants only]
- Public Health Service Act of 1944; 42 U.S.C. Chapter 6A; Title VI, 42 U.S.C. §291 (known, in combination with Title XVI, as the Hill-Burton Act); Title XVI, 42 U.S.C. § 300 (known, in combination with Title VI, as the Hill Burton Act); Section 533, 42 U.S.C. §290; Section 542, 42 U.S.C. § 290dd-1; Section 794, 42 U.S.C. § 295m; Section 855, 42 U.S.C. § 296g,. Section 1908, 42 U.S.C. §300w-7, Section 1947, 42 U.S.C. § 300x-57
- Public Telecommunications Financing Act of 1978, Pub.L. 95-567
- Religious Freedom Restoration Act, 42 U.S.C. § 2000bb *et seq.*
- Religious Nondiscrimination and Equal Treatment Provisions of the Child Care and Development Block Grants, 42 U.S.C. §§ 9858l, 9858n(2), and certain implementing regulations at 45 C.F.R. pt. 98.
- Religious Nondiscrimination Component of the Equal Employment Opportunity Provision of the Public Telecommunications Financing Act of 1978, Section 309, as amended, 47 U.S.C. § 398(b).
- Religious Nondiscrimination Provision and Charitable Choice Provisions of the Projects in Assistance to Transition from Homelessness Program, 42 U.S.C. §§ 290c-33, 290kk-290kk-3, 300x-65 and implementing regulations at 42 C.F.R. pts. 54 and 54a.
- Religious Nondiscrimination Provision and Charitable Choice Provision of the Substance Abuse Prevention and Treatment Block Grant 42 U.S.C. §§ 300x-57, 300x-65 and implementing regulations at 42 C.F.R. pts. 54 and 54a.
- Religious Nondiscrimination Provision in Disaster Assistance, 42 U.S.C. § 5151 and its implementing regulation at 44 C.F.R. § 206.11, to the extent such programs are administered by HHS, and implementing regulations for crisis counseling assistance and training at 42 C.F.R. § 38.6.
- Religious Nondiscrimination Provision of Programs of All–Inclusive Care for the Elderly, 42 CFR § 460.112.
- Religious Nondiscrimination Provisions of Block Grant Programs for Maternal and Child Health Services, 42 U.S.C. § 708; Preventive Health and Health Services, 42 U.S.C. § 300w-7; and Community Mental Health Services, 42 U.S.C. § 300x-57.
- Religious Nondiscrimination Provisions of the Family Violence Prevention and Services Act Program, as amended, 42 U.S.C. § 10406; in Refugee Assistance and Resettlement Programs, 8 U.S.C. § 1522(a)(5); of the Comprehensive Community Mental Health Services for Children with Serious Emotional Disturbances, 42 U.S.C. § 290ff-1(e)(2)(C); and of the Community Schools Youth Services and Supervision Program, 34 U.S.C. § 12161(g)(3), (i).

- Religious Nondiscrimination Requirements for Patient Visitation in Certain Health Care Facilities, (*e.g.*, 42 C.F.R. §§ 482.13(h), 485.635(f)).
- Sections 1303, 1411, 1553, and 1557 of the Affordable Care Act of 2010, 42 U.S.C. §§ 18023(b)(1)(A) and (b)(4), 18081, 18113, 18116.
- Sections 504 and 508 of the Rehabilitation Act of 1973, 29 U.S.C. § 794; 29 U.S.C. § 794(d)
- Small Business Job Protection Act of 1996, 42 U.S.C. § 1996b (Interethnic adoption)
- Social Security Act of 1934, Section 508; 42 U.S.C. § 708 (known as Maternal and Child Health Services Block Grant)
- Social Security Act, section 1173(d), as added by HIPAA § 262(a), 42 U.S.C. § 1320d-2(d).
- Statutory and public policy requirements governing HHS awards, 45 C.F.R. 75.300.
- The Age Discrimination Act of 1975, 42 U.S.C. § 6101 et seq.
- The Communications Act of 1934; 47 U.S.C. § 151 et seq.
- The Community Services Block Grant Act of 1981, 42 U.S.C. § 9918(c)(1)
- The Family Violence Prevention and Services Act of 2010, formerly part of the Child Abuse Amendments of 1984; 42 U.S.C. §10406(c)(2)(B)(i)
- The Low-Income Home Energy Assistance Act of 1981, 42 U.S.C. § 8625(a)
- Title I of the Genetic Information Nondiscrimination Act of 2008 (GINA), Public Law 110-233, section 105, 42 U.S.C. § 1320d-9.
- Title II of the Americans with Disabilities Act of 1990, 42 U.S.C. § 12131 et seq.
- Title IX of the Education Amendments of 1972, 20 U.S.C. § 1681 et seq.
- Title VI of the Civil Rights Act of 1964, 42 U.S.C. § 2000d et seq.
- Weldon Amendment to the Annual Labor, HHS, & Education Appropriations Act and to Medicare Advantage.

Appropriations History

Details	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
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	38,798,000	-	38,798,000
Subtotal	30,286,000	38,798,000	-	38,798,000
2022				
Appropriation				
Base	47,931,000	-	-	-
Subtotal	47,931,000	-	-	-

Narrative by Activity

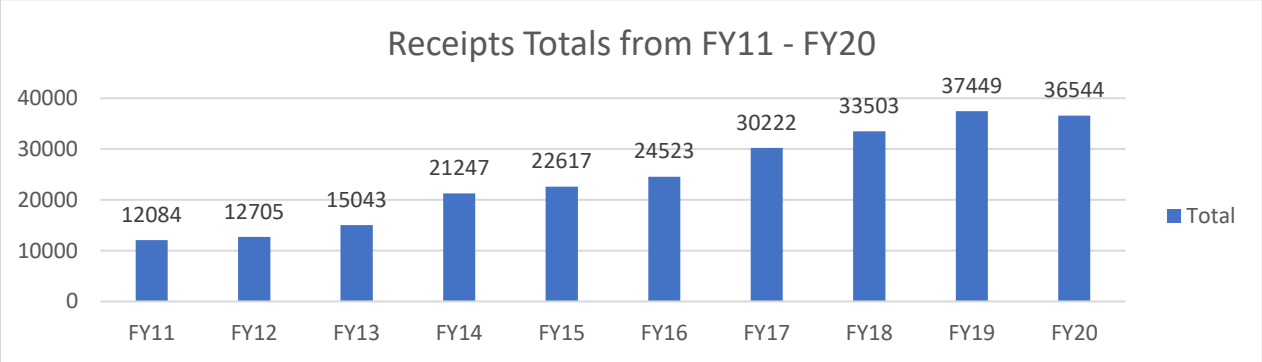
Program Description

The Office for Civil Rights (OCR) defends the public's right to nondiscriminatory access to and receipt of federally funded health and human services and ensures that the privacy of their health information is protected while promoting access to care. Through prevention and elimination of unlawful discrimination and by protecting the privacy of individually identifiable health information, OCR helps HHS carry out its overall mission of improving the health and well-being of all people impacted by the Department's many programs. OCR accomplishes its mission through enforcement, policy work, and education and outreach.

Enforcement

Members of the public can file complaints through OCR's online complaint portal or by mail, fax, or email. Complaints are assessed to determine which can be closed without formal investigation (e.g., where OCR does not have enforcement authority or where the provision of minor technical assistance will resolve the complaint) 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.

Significant process redesign and automation improvements have enabled OCR to increase efficiency, despite a nearly 290 percent increase in the number of complaints since OCR's online complaint portal went live in FY 2012 (36,592 in FY 2020 versus 12,705 in FY 2012).



Although there was a small decrease in the number of new complaints received in FY 2020, OCR attributes this decline to stay-at-home orders, which included some healthcare providers, and the reluctance of some individuals to seek in-person healthcare during the pandemic; consequently, fewer complaints about healthcare services were filed. OCR anticipates that as the public returns to pre-pandemic activities, a rise in the number of cases received and visibility in civil rights activities is likely.

Civil rights and health information privacy and security complaint investigations, breach report investigations, and compliance reviews are conducted by OCR regional offices. [1] Each regional office is staffed with highly skilled investigators responsible for examining allegations of discrimination or health information privacy or 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 laws and regulations OCR enforces. Investigations can result in a finding of no violation, the provision of technical assistance to address specific

[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).

problem areas, corrective action by the covered entity, or, where there are indications of systemic or egregious noncompliance, more formal enforcement action, including the negotiation of settlement agreements.

Where OCR's investigation reveals that a covered entity has egregious or longstanding noncompliance with federal civil rights or health information privacy and security laws under OCR's jurisdiction, or the entity has been unwilling to take prompt and effective measures to address the indicated violations, OCR takes enforcement action. The regional office works closely with OCR Headquarters and HHS's Office of the General Counsel to review the evidence and produce a letter of findings. When OCR sends the letter of findings to a regulated entity, OCR may engage in a settlement negotiation with a corrective action plan and, where appropriate, impose a civil money payment. In instances where entities are uncooperative, OCR can, depending on the statute at issue, refer the matter to the HHS funding component, seek rescission of HHS funding to the covered entity, pursue civil money penalties, or refer the case to the U.S. Department of Justice for consideration of further action.

In addition to complaints submitted by the public, OCR is authorized to open compliance reviews when it has reason to believe that a covered entity may have violated certain 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 a covered entity. Also, as required by the Health Insurance Portability and Accountability Act of 1996 (HIPAA), OCR initiates investigations in all cases where a covered entity has reported a health information privacy breach affecting 500 or more individuals. These compliance reviews and breach report investigations 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 outcomes, follow the same processes noted above for complaint resolution.

Policy

OCR's policy work consists of drafting regulations, guidance, technical assistance, toolkits, and training materials. In addition to OCR's work to ensure compliance through investigations, OCR promotes voluntary compliance through outreach to the regulated community. OCR provides information, guidance, and technical assistance to covered entities to encourage understanding of, and adherence to, their legal responsibilities under nondiscrimination and privacy and security laws. For example, since the launch of its free, web-based video training program on Medscape, *An Individual's Right to Access and Obtain their Health Information Under HIPAA,* OCR has trained over 100,000 health care providers and allied health professionals through this program. OCR's civil rights medical school curriculum educates future health care practitioners in collaboration with the Association of American Medical Colleges on how OCR's compliance work promotes equal access to health care and combats racial and ethnic health disparities.

In addition, throughout COVID-19, OCR was a national leader in providing practical guidance to providers about how to comply with both civil rights and HIPAA obligations to facilitate the Department's efforts to provide testing, treatment, and vaccinations.

Education and Outreach

Our public outreach informs and educates consumers, advocacy groups, and other stakeholders about the laws that OCR enforces, obtains input about potential impediments to accessing healthcare faced by the public, potential violations on which OCR should focus, and ensures that individuals are aware of their rights under the laws and regulations for which OCR is responsible. Greater investment in these activities would significantly increase OCR's ability to reach additional audiences and promote greater compliance with federal civil rights and privacy laws.

OCR conducts nationwide outreach through participation 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 providers about their obligations and consumers about their rights; and convening or participating in various working groups. The goals of this outreach is to educate consumers and covered entities, build relationships, create opportunities for dialogue, and provide opportunities for input on OCR's work.

Highlights of OCR's recent and planned priority activities for FY 2022 include:

1. Civil Rights and Nondiscrimination

Enforcing Prohibitions against Race, Color, and National Origin Discrimination. Title VI of the Civil Rights Act of 1964 prohibits race, color, and national origin discrimination in federally funded programs. Section 1557 prohibits race, color, and national origin discrimination in certain health programs and activities. OCR's activities under these and related authorities include:

- Leading the HHS nondiscrimination activities under EO 13995: *Ensuring an Equitable Pandemic Response and Recovery* 13985.
- Collaborating with HHS agencies to address race discrimination and health care disparities which disproportionately affect racial and ethnic minority communities. Since 2011, CRD has contributed to the HHS Office of Minority Health's (HHS OMH) biennial "Report to Congress on Minority Health Activities." Similarly, for several years, OCR has actively participated in the Interdepartmental Health Equity Collaborative (IHEC), a platform for collaboration to better address health disparities, alongside representatives from HHS OMH, other HHS agencies, and several Executive Departments. OCR also participates in the intra-agency HHS Health Disparities Council, which coordinates the implementation of the "HHS Action Plan to Reduce Racial and Ethnic Health Disparities." OCR contributed to the "2020 Update to the HHS Action Plan" and served on the advisory committee for OMH's e-course, "Culturally and Linguistically Appropriate Services (CLAS) in Maternal Health Care," which was published in March 2021 to address health disparities experienced by African-American women and other women of color.
- Chairing the HHS Language Access Steering Committee, which oversees and coordinates ongoing Departmental efforts to improve language access services. OCR serves as a model for the Department by enhancing its website accessibility for persons with limited English proficiency (LEP). To serve as an HHS and federal government leader, OCR increased accessibility to its website by posting consumer information in the 15 most frequently spoken languages and making it easier for LEP individuals to reach our complaint portal. As a result, LEP individuals can now click on their language of choice at the top of our webpage and immediately access information to understand their rights and can file a complaint in their own language.
- Collaborating across HHS agencies to address national origin discrimination and ensure that health care and human service grant recipients take reasonable steps to provide meaningful access to programs and services for LEP individuals. For example, OCR works to ensure that during emergency evacuation, response, and recovery activities, qualified interpreter services, and translated documents are available in languages prevalent in affected areas.

Enforcing the Prohibitions against Sex Discrimination. Two federal statutes that OCR enforces contain sex discrimination prohibitions. Title IX of the Education Amendments Act of 1972 prohibits sex discrimination in federally funded education programs and activities. Section 1557 of the ACA prohibits sex discrimination in certain health programs and activities. OCR enforces both statutes where there is overlap in jurisdiction. In FY 2018, HHS provided more than $33 billion to fund STEM research and development, including grants

to colleges, universities, and medical schools. Pursuant, in part, to a memorandum of understanding with the National Institutes of Health (NIH), OCR fulfils its Title IX and Section 1557 responsibilities through a combination of enforcement and technical assistance:

- OCR evaluates the sexual harassment prevention efforts of NIH-funded universities through sexual harassment investigations and periodic compliance reviews. As part of a National Initiative to enforce Title IX and Section 1557 to protect athletes, students, and patients from sexual harassment, OCR currently leads investigations at nine universities and university hospitals. Similarly, NIH exercises its grants compliance authority to ensure that NIH-funded institutions comply with the terms and conditions of NIH awards.
- Within their respective programs, grants compliance, and enforcement authorities, NIH and OCR conduct outreach and provide technical assistance to help NIH-funded universities implement practices designed to prevent and resolve sexual harassment through:
    - OCR's redesigned and updated Title IX and sex discrimination webpages;
    - An Effective Practices list, which provides guidance on preventing sexual harassment to entities that receive funds through HHS; and
    - Listserv announcements to more than 500 university Title IX coordinators, including the Effective Practices list and OCR's voluntary resolution agreement with Michigan State University (MSU), which established, throughout MSU's 40 faculty medical practices and clinics, new informed consent, privacy, and chaperone policies for sensitive examinations.

Coordinating Government-wide Compliance with the Age Discrimination Act of 1975. The Age Discrimination Act of 1975 ("Age Act") provides the Secretary with coordinating authority over federal departments' and agencies' implementation of the Age Act. Each year, OCR drafts a government-wide report on federal compliance with the Age Act, which HHS submits to Congress. OCR 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 activities that address age discrimination, including new complaints, carry-over complaints, mediation efforts, compliance reviews, training, technical assistance, outreach, and regulation development.

Protecting the Civil Rights of People with HIV. From 2010 to 2016, OCR participated in the Federal Interagency Working Group to implement the National HIV/AIDS Strategy. OCR currently participates in the Viral Hepatitis/HIV National Strategic Plan Joint Federal Steering Committee, along with the HHS Office of Infectious Disease and HIV/AIDS Policy (OIDP), in the Office of the Assistant Secretary for Health (OASH), and representatives from 15 Executive Departments. OCR investigates and resolves HIV discrimination complaints; trains HHS staff and recipients on protecting the civil rights of people with HIV; and provides technical assistance to HHS agencies producing HIV-related educational materials.

Child Welfare: Protecting the Rights of Birth Parents, Prospective Parents and Children. In early January 2017, OCR entered into a memorandum of understanding (MOU) with the Federal Coordination and Compliance Section of DOJ's Civil Rights Division. This MOU memorialized an ongoing partnership between CRD, DOJ, and the HHS Administration for Children and Families (ACF) to safeguard the civil rights of parents, prospective parents, caretakers, 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 OCR has conducted outreach at key national child welfare conferences with stakeholders. In FY 2020, OCR participated in the Interagency Task Force on Trauma-Informed Care, which works to develop best practices for the identification, referral, and support of children and families who have experienced trauma.

Protecting the Freedom of Religion and the Rights of Religious Minorities. Through these activities, OCR supports the Administration's "whole-of-government" approach to equity, inclusive of activities to protect the rights of individuals who experience multiple forms of discrimination because of their membership in stigmatized religious, racial, ethnic, or other groups. In FY 2022, OCR will combine these activities and conscience protections for health care providers with civil rights to enhance program coordination and promote a comprehensive equity agenda.

Protecting Civil Rights during the COVID-19 Public Health Emergency. To protect civil rights during the COVID-19 pandemic, OCR investigates complaints and initiates compliance reviews to assess and address allegations of discrimination in various aspects of COVID-19 services and treatment from triaging limited resources to testing, treatment, and vaccination. In addition, OCR continues to issue multiple guidance documents and bulletins to prevent discrimination during COVID-19.[2] Most recently, in response to requests, including Congressional requests, OCR issued guidance on disability nondiscrimination in COVID-19 vaccinations. OCR also resolves cases through resolution agreements, corrective action closure letters, and early case resolution procedures; and collaborates on virtual outreach with DOJ, the Federal Emergency Management Agency (FEMA), the Office of the Surgeon General, the National Academies of Sciences, Engineering, and Medicine (National Academies), and racial and ethnic minority stakeholders, including the NAACP, the National Urban League, the League of United Latin American Citizens (LULAC), the Mexican American Legal Defense and Educational Fund , and the Hispanic Medical Association .

2. Health Information Privacy

Through its innovative efforts to promote and enforce HIPAA privacy and security protections, OCR supports public and private sector efforts to improve health care quality and reduce costs. Our initiatives aid in 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 patient safety by helping to facilitate confidential analyses of medical errors and other patient safety events.

Promoting patients' rights to access their medical records.
OCR announced the HIPAA Right of Access Enforcement Initiative in February 2019, to support individuals getting timely access to their medical records, and for a reasonable, cost-based fee. Investigations were initiated across the country, and to date, 17 enforcement actions have been completed with successful resolution agreements, and corrective action plans with the covered entities. This initiative empowers patients to be aware of their health status and active participants in their health care treatment and decision-making.

Enforcing HIPAA to remedy violations. In FY 2020, OCR completed seventeen enforcement actions, including the imposition of two civil money penalties, and the settlement of fifteen cases with a monetary settlement and corrective action plan, for a total of over $21 million in collections. The cases selected for

[2] *See Civil Rights, HIPAA, and the Coronavirus Disease 2019 (COVID-19)* (Mar. 28, 2020), https://www.hhs.gov/sites/default/files/ocr- bulletin-3-28-20.pdf; *Ensuring the Rights of Persons with Limited English Proficiency in Health Care During COVID-19* (May 15, 2020), https://www.hhs.gov/sites/default/files/lep-bulletin-5-15-2020-english.pdf; and *Civil Rights Protections Prohibiting Race, Color and National Origin Discrimination During COVID-19 – Application of Title VI of the Civil Rights Act of 1964* (July 20, 2020), https://www.hhs.gov/sites/default/files/title-vi-bulletin.pdf.

settlement or enforcement action highlight substantial noncompliance with the HIPAA Rules, or egregious failures to protect individuals' HIPAA rights. Highlights include cases involving individual's right to receive a copy of their medical records as part of OCR's Right of Access Initiative, and breach investigations involving hacking, ransomware, PHI stored on unsecured servers, failure to provide proper breach notification to HHS, and impermissible disclosures of PHI on social media. These high-profile cases sent important messages to the public about their HIPAA rights and to covered entities and business associates about their obligation to protect health information.

Ensuring HIPAA facilitates the provision of healthcare during COVID-19. OCR has been at the forefront of ensuring public awareness of individuals' rights under HIPAA during COVID-19 and the flexibility that providers have to meet health care demands while protecting privacy. As soon as the COVID-19 public health emergency was declared, OCR issued a Bulletin on HIPAA Privacy and COVID-19 to inform the public on how HIPAA permits protected health information during an emergency. OCR continues to take proactive actions that target key pandemic response actions, including the provision of telehealth, the sharing of health data with public health agencies, disclosures to first responders, and how health care entities can notify patients about plasma donation opportunities. 3Historically, the HHS.gov/HIPAA pages have averaged 300,000+ visitors a month. However, following the creation of a HIPAA and COVID-19 webpage identifying all the press releases and HIPAA policy and guidance documents issued during this public health emergency, visitors to the HHS.gov/HIPAA pages have increased substantially, averaging over 450,000 visits a month.

Updating HIPAA regulations. The HIPAA Privacy and Security Rules were initially written and implemented more than a decade ago, and much has changed in health care, including the means through which individuals and health care systems access, use, and disclose health information. Recognizing that well-intended regulations can lose their efficacy with the passage of time, and that regulatory complexity can contribute to noncompliance, OCR continuously reviews its regulations and significant sub-regulatory guidance to identify, modify, or eliminate regulatory provisions and interpretations that are no longer effective, that increase complexity for the regulated community without a corresponding benefit to health information privacy or security protections, or that disempower individuals. Based on comments received as a result of a Request for Information, OCR published a Notice of Proposed Rulemaking on Modifications (NPRM) to the HIPAA Privacy Rule in FY 2021. The NPRM requests public comment proposals to: strengthen individuals' rights to access their own health information, including electronic information; improve information sharing for care coordination and case management for individuals; facilitate family and caregiver involvement in the care of individuals experiencing emergencies or health crises; enhance flexibilities for disclosures in emergency or threatening circumstances, such as the Opioid and COVID-19 public health emergencies; and reduce administrative burdens on HIPAA covered health care providers and health plans. The estimated total cost saving from this proposed regulatory reform is $3.2 billion over five years. In addition, OCR is currently working to implement provisions of the Health Information Technology for Economic and Clinical Health (HITECH) Act, the 21st Century Cures Act, and the CARES Act that mandate new regulations or the issuance of further guidance.

Accomplishments

These selected accomplishments highlight the range of outcomes achieved by OCR in FY20 and FY21 in the service of our mission.

3 https://www.hhs.gov/hipaa/for-professionals/special-topics/hipaa-covid19/index.html

Ensuing nondiscrimination against older adults and individuals with disabilities and older adults in Crisis Standards of Care (CSC) Plans

- Pursuant to Section 504, Title II of the ADA, the Age Act, and Section 1557, OCR has collaborated with the OCR Regional Offices to evaluate allegations of age and disability discrimination in state-wide CSC plans. Through this collaboration, OCR has successfully resolved complaint investigations and compliance reviews of CSC plans in Alabama (April 2020), Pennsylvania (April 2020), Tennessee (June 2020), Utah (August 2020), North Texas (January 2021) and North Carolina (January 2021). In addition, we have provided technical assistance to the Indian Health Service (January 2021) and Southwest Texas (January 2021) on CSC policy. These case resolutions have served as national models and resulted in the implementation of non-discriminatory practices to serve older adults and individuals with disabilities during the COVID-19 national public health emergency.

Ensuring access to support persons with disabilities in hospitals during COVID-19 Pandemic

- OCR provided technical assistance to Connecticut and MedStar Health System to revise their visitation policies during COVID-19 to ensure people with disabilities have access to support persons needed for equal access to health care, effective communication, and the ability to make informed decisions and provide consent. By using OCR's early complaint resolution process, OCR was able to assist in getting speedy relief to individual patients and assist states and hospitals to change their policies in a way that provided needed support and equal access.

Providing technical assistance to hospitals to ensure nondiscrimination based on religion in COVID-19 visitations policies

- Acting in partnership with the Centers for Medicare & Medicaid Services (CMS) during the COVID-19 pandemic, OCR provided technical assistance to the health facilities and systems to permit clergy to visit for religious purposes, such as to facilitate the patients' exercise of religion or otherwise provide compassionate care to patients while also enabling the health care facilities to maintain COVID-19 infection control and prevention practices.

Protecting religious exercise of medical student at Staten Island Hospital.

- OCR facilitated the resolution of a complaint against Staten Island University Hospital after the hospital accommodated the religious exercise of a medical student to keep a beard according to his faith while using personal protective equipment during the COVID-19 pandemic.

Addressing discrimination against parents with developmental disabilities in the administration of Massachusetts' child welfare system

- In November 2020, OCR and DOJ reached an agreement with the Massachusetts Department of Children and Families (DCF) to address discrimination against parents with disabilities. The agreement resolved findings by HHS and DOJ that DCF discriminated against a parent with a developmental disability in the administration of its child welfare program. An investigation of the complaint revealed that DCF denied a mother with a developmental disability an equal opportunity to benefit from appropriate supports and services, including in-home services and her existing family supports, and denied her numerous requests for disability-based accommodations, including hands-on demonstrations of the parenting skills DCF was requiring her to learn. DCF agreed to

work with OCR and DOJ to ensure full compliance with DCF's obligations under Section 504 and the ADA, including ensuring that DCF will base removal decisions on individualized assessments rather than stereotypes or generalizations about persons with disabilities.

Ensuring meaningful access to Arizona's child welfare services for parents with limited English proficiency.

- In January of 2021, OCR entered into a Voluntary Resolution Agreement (VRA) with the Arizona Department of Child Safety (DCS) to protect LEP parents from discrimination and ensure meaningful access to DCS programs and activities, including reunification services. OCR initiated a compliance review after local advocacy groups and affected parties alerted OCR to alleged deficiencies in DCS's provision of language services, including failures to provide LEP individuals with critical information and services in the individuals' primary language. Following data requests and an on-site investigation of DCS regional offices, OCR identified systemic deficiencies in DCS's implementation of its language access programs, policies, and procedures to prevent discrimination against LEP parents. As a result, OCR and DCS reached an agreement to ensure that DCS takes reasonable steps to ensure meaningful access for LEP individuals.

Ensuring non-discrimination based on participating in medication assisted treatment for West Virginia couple.

- OCR investigated a complaint filed by a couple who sought to adopt their young niece and nephew who were in the custody of West Virginia's Bureau of Children and Families Programs (BCF). The aunt and uncle alleged that BCF denied their request for placement of the children based on the uncle being in recovery from opioid use disorder and his long-term use of physician-prescribed Suboxone as part of his medication-assisted treatment (MAT) program. In April 2020, BCF signed a voluntary resolution agreement that requires BCF to update its nondiscrimination policies and procedures and other materials to emphasize that individuals with a substance use disorder are entitled to protections under federal laws prohibiting disability discrimination and create a new disability rights training plan that specifically educates its staff on working with individuals who are in recovery from substance use disorder. BCF also agreed to update the aunt and uncle's case file and notify the family court of the aunt and uncle's allegations and BCF's agreement with OCR, so that the court may consider them before it makes any final custody determination with respect to the children.

Ensuring nondiscrimination based on HIV status for patient seeking orthopedic care in Tampa, Florida.

- Florida Orthopedic Institute (Florida Orthopedic) is a comprehensive orthopedic practice in the Tampa, Florida area. OCR received a complaint that a Florida Orthopedic surgeon allegedly made an offensive comment relating to the patient's HIV status and then refused to perform the patient's scheduled surgery. After informing Florida Orthopedic of the allegations, and before OCR reached a conclusion as to the merits of the claims, Florida Orthopedic prohibited the patient from receiving further care at the practice and cited the patient's OCR complaint as a basis for its decision. OCR secured several corrective actions from Florida Orthopedic, including amending its nondiscrimination policies and revising its procedures for dismissing any patient from the practice. Florida Orthopedic also agreed to provide staff with trainings on HIV, federal nondiscrimination laws, grievance procedures, and the requirement to refrain from retaliatory actions.

Resolution of HIPAA-related violations leading to significant disclosure of 10.4 million individuals' PHI.

- Premera Blue Cross, the largest health plan in the Pacific Northwest, filed a breach report with OCR stating that cyber-attackers had gained unauthorized access to its information technology (IT) system. The hackers used a phishing email to install malware that gave them access to PBC's IT system for nearly nine months. OCR's investigation found systemic noncompliance with the HIPAA Rules, including failures to conduct an enterprise-wide risk analysis, failure to implement risk management measures, and failure to implement audit controls. OCR successfully resolved this investigation with a resolution agreement, corrective action plan, and civil money penalty of $6,850,000.

Jackson Health System – Resolution of HIPAA-related violations leading to loss, sale, and exposure of over 24,000 patients' PHI

- Jackson Health System (JHS), based in Miami, Florida, submitted two breach reports to OCR stating that it had lost paper records containing the protected health information (PHI) of 756 patients, and that an employee had inappropriately accessed over 24,000 patients' records and had been selling them. OCR also initiated a separate, but related, compliance review following a media report that disclosed the PHI of a JHS patient. OCR's investigations revealed systemic noncompliance with the HIPAA Privacy and Security Rules, including failures to comply with the breach notification requirements, security management process, and information access management standards. JHS did not agree to an informal resolution including a corrective action plan, so OCR issued a final determination, and JHS paid a $2,154,000 civil money penalty.

Athens Orthopedic Clinic – Resolution of HIPAA-related violations leading to disclosure of over 200,000 individuals' PHI

- Athens Orthopedic Clinic (Athens), located in Athens, Georgia, filed a breach report with OCR stating that it experienced an external cyberattack to their electronic medical records. The PHI disclosed included the names, dates of birth, addresses, phone numbers, Social Security numbers, and health records of 208,557 individuals. The hacker posted the PHI online and demanded a ransom from Athens. OCR's investigation found systemic noncompliance with the HIPAA Rules, including failures to comply with the risk analysis, risk management, audit controls, policies and procedures, Privacy Rule training, and business associate contracts requirements. OCR resolved this investigation with a resolution agreement, corrective action plan, and civil money penalty of $1,500,000.

Funding History

Fiscal Year	Amount
FY 2018	$38,798,000
FY 2019	$38,798,000
FY 2020	$38,798,000
FY 2021 Enacted	$38,798,000
FY 2022 President's Budget	$47,931,000

Budget Request

The FY 2022 discretionary budget request for the Office for Civil Rights is $47,931,000, which is $9,133,000 above the FY 2021 Enacted Level. OCR will support up to 20 regional investigators, who will ensure that OCR is able to investigate and close the influx of civil rights complaints it receives in a timely manner while advancing the Administration's priorities and work on equity for underserved communities. OCR also will add 19 staff to augment civil rights policy and enforcement work, which will include revitalizing OCR's work in the areas of race, disability, and sex discrimination, child welfare, and environmental justice. Additionally, the increase will fund an evaluation and further assess the impact of HHS policies and regulatory role in health equity barriers for underserved groups.

Section 4: Supplementary Tables

Budget Authority by Object Class

(Dollars in Thousands)

Object Class Code	Description	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Budget	FY 2022 +/- FY 2021
11.1	Full-time permanent	16,053	16,631	22,330	+5,699
11.3	Other than full-time permanent	554	615	1,053	+438
11.5	Other personnel compensation	406	436	581	+145
11.7	Military personnel	127	128	130	+2
Subtotal	***Personnel Compensation***	**17,140**	**17,810**	**24,094**	**+6,284**
12.1	Civilian personnel benefits	5,733	5,978	8,184	+2,206
12.2	Military benefits	7	8	9	+1
13.0	Benefits for former personnel	20	135	150	+15
Total	***Pay Costs***	**22,900**	**23,931**	**32,437**	**+8,506**
21.0	Travel and transportation of persons	145	115	600	+485
22.0	Transportation of things	2	5	5	-
23.1	Rental payments to GSA	3,490	3,601	3,666	+65
23.3	Communications, utilities, and misc. charges	211	91	96	+5
24.0	Printing and reproduction	272	162	175	+13
25.2	Other services from non-federal sources	2,933	2,219	2,774	+555
25.3	Other goods and services from fed sources	7,979	7,580	6,908	-672
25.4	Operation and maintenance of facilities	292	92	100	+8
25.7	Operation and maintenance of equipment	451	261	280	+19
Subtotal	***Other Contractual Services***	**11,655**	**10,152**	**10,062**	**-90**
26.0	Supplies and materials	78	50	125	+75
31.0	Equipment	45	691	765	+74
Total	***Non-Pay Costs***	**15,898**	**14,867**	**15,494**	**+627**
Total	**Budget Authority by Object Class**	**38,798**	**38,798**	**47,931**	**+9,133**

Salaries and Expenses Table

(Dollars in Thousands)

Object Class Code	Description	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Budget	FY 2022 +/- FY 2021
11.1	Full-time permanent	16,053	16,631	22,330	+5,699
11.3	Other than full-time permanent	554	615	1,053	+438
11.5	Other personnel compensation	406	436	581	+145
11.7	Military personnel	127	128	130	+2
Subtotal	***Personnel Compensation***	**17,140**	**17,810**	**24,094**	**+6,284**
12.1	Civilian personnel benefits	5,733	5,978	8,184	+2,206
12.2	Military benefits	7	8	9	+1
13.0	Benefits for former personnel	20	135	150	+15
Total	***Pay Costs***	**22,900**	**23,931**	**32,437**	**+8,506**
21.0	Travel and transportation of persons	145	115	600	+485
22.0	Transportation of things	2	5	5	-
23.3	Communications, utilities, and misc. charges	211	91	96	+5
24.0	Printing and reproduction	272	162	175	+13
25.2	Other services from non-federal sources	2,933	2,219	2,774	+555
25.3	Other goods and services from fed sources	7,979	7,580	6,908	-672
25.4	Operation and maintenance of facilities	292	92	100	+8
25.7	Operation and maintenance of equipment	451	261	280	+19
Subtotal	***Other Contractual Services***	**11,655**	**10,152**	**10,062**	**-90**
26.0	Supplies and materials	78	50	125	+75
31.0	**Equipment**	**45**	**691**	**765**	**+74**
Total	***Non-Pay Costs***	**12,363**	**10,575**	**11,063**	**+488**
Total	***Salary and Expenses***	**35,263**	**34,506**	**43,500**	**+8,994**
23.1	Rental payments to GSA	3,490	3,601	3,666	+65
Total	***Salaries, Expenses, and Rent***	**38,753**	**38,107**	**47,166**	**+9,133**
Total	**Direct FTE**	**136**	**141**	**180**	**+39**

Detail of Full-Time Equivalent (FTE) Employment

Detail	FY 2020 Actual Civilian	FY 2020 Actual Military	FY 2020 Actual Total	FY 2021 Estimate Civilian	FY 2021 Estimate Military	FY 2021 Estimate Total	FY 2022 Estimate Civilian	FY 2022 Estimate Military	FY 2022 Estimate Total
Direct	135	1	136	140	1	141	179	1	180
Reimbursable	6	-	6	49	-	49	49	-	49
Total FTE	**141**	**1**	**142**	**189**	**1**	**190**	**228**	**1**	**229**

Average GS Grade

FY 2018: GS 13
FY 2019: GS 13
FY 2020: GS 13
FY 2021: GS 13
FY 2022: GS 13

Detail of Positions

Detail	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Budget
Executive level I	-	-	-
Executive level II	3	5	5
Executive level III	3	-	-
Executive level IV	-	-	-
Executive level V	-	1	1
Subtotal	**6**	**6**	**6**
Total - Executive Level Salaries	**1,155,235**	**1,164,500**	**1,195,941**
GS-15	22	25	29
GS-14	21	21	31
GS-13	32	32	41
GS-12	41	45	61
GS-11	5	3	3
GS-10	-	-	-
GS-9	7	7	7
GS-8	-	-	-
GS-7	1	1	1
GS-6	-	-	-
GS-5	-	-	-
GS-4	-	-	-
GS-3	-	-	-
GS-2	-	-	-
GS-1	-	-	-
Subtotal	**129**	**134**	**173**
Total - GS Salary	**15,451,765**	**16,081,500**	**22,187,059**
Average ES level	192,539	194,083	199,324
Average ES salary	III	III	III
Average GS grade	13.6	13.6	13.7
Average GS Salary	119,781	120,011	128,8249

National Coordinator for Health Information Technology

DEPARTMENT of HEALTH and HUMAN SERVICES

Fiscal Year

2022

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 2020 – 2025, 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 2022 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 an open platform-based ecosystem that can expand interoperability patterns, enrich data exchange, increase usability, and enable advanced interoperability capabilities to improve quality, cost, safety, and equity in healthcare;
- Contributing to HHS efforts to respond to public health emergencies such as **COVID-19 and the opioid epidemic** through collaborations with public health stakeholders to improve the Nation's critical 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 2022 President's Budget Request

Dear Reader,

I am pleased to present the fiscal year (FY) 2022 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 2022, and also includes annual performance information covering highlights from ONC activities that took place in the most recently concluded fiscal year, FY 2020.

The FY 2022 President's Budget request level for ONC is $86.6 million. With this budget, ONC will continue its focus on critical national priorities to improve the health system by (1) promoting the interoperable exchange of electronic health information, (2) supporting a data-driven response to the COVID-19 pandemic, (3) focusing on health equity when developing new policies and programs, and (4) coordinating health IT activities across the federal government to help government agencies execute on their mission.

In furtherance of these goals, and supported by the FY 2022 President's Budget Request, ONC plans to continue necessary efforts to implement the 21st Century Cures Act (Cures Act), which will enter its sixth year of government-wide implementation in 2022. 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.

Since establishment, ONC has a history of noteworthy successes in implementing Congressional requirements and achieving national goals related to the adoption, exchange and use of health information technology (IT). ONC's team has a track record for leading and coordinating health IT activities that are essential for improving the U.S. health system and patient care. ONC's annual budget is fundamental to supporting ONC's infrastructure and advancing national priorities.

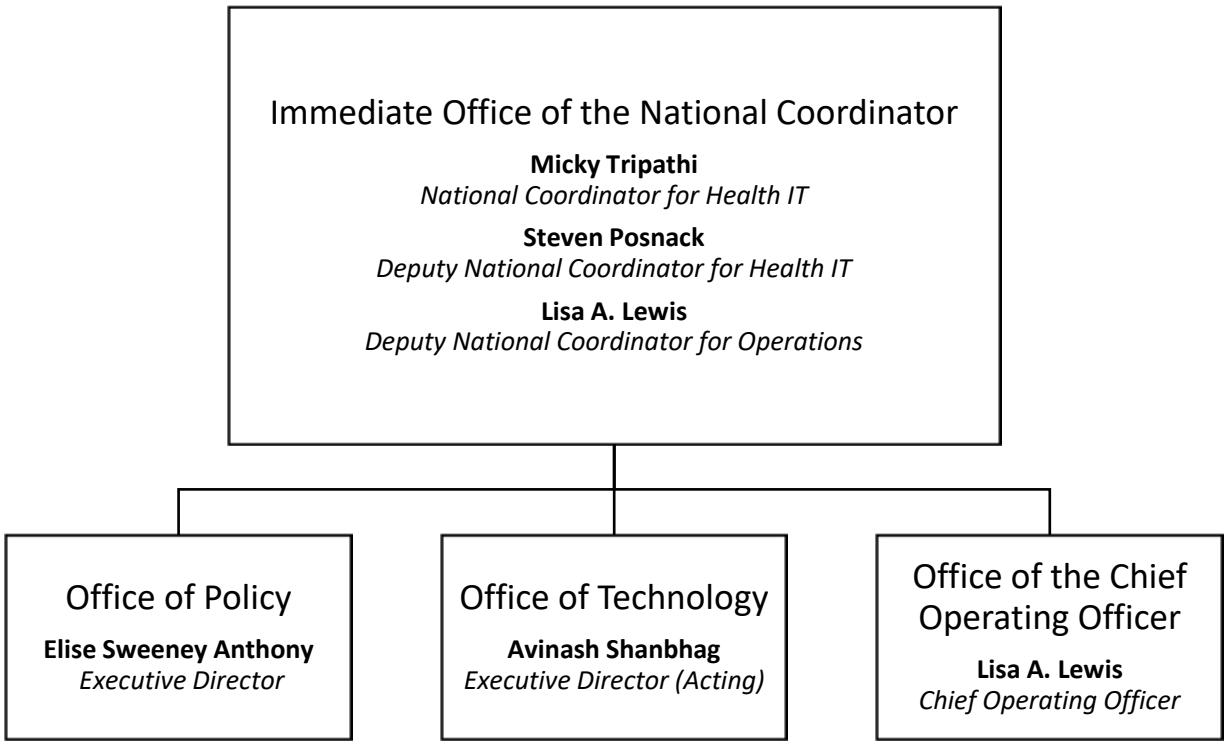
/Micky Tripathi/
Micky Tripathi, Ph.D. M.P.P
National Coordinator for Health IT

FY 2022 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
  - Micky Tripathi, Ph.D. M.P.P. *National Coordinator for Health IT*
  - Steven Posnack, M.S., M.H.S. *Deputy National Coordinator for Health IT*
  - Lisa A. 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, safer, and more equitable 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 small part of Federal spending on healthcare, ONC's activities are central to creating an equitable healthcare system, that works to identify and alleviate health disparities and address social determinants of health.

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).

ONC's program level funding supports 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 over 1.5 million visitors who access the policy and technical assistance materials published at https://HealthIT.gov each year. HHS' holistic approach to its technology-related initiatives centers on putting patients in control of their health information through interoperable health IT.

Interoperability is necessary to combat pandemics and public health emergencies such as COVID-19 and the opioid crisis by providing early detection and readily available health information to clinicians and public health entities. The secure flow of electronic health information can offer insight into health disparities and facilitate longitudinal tracking of health outcomes so that a care provider can have a comprehensive view of a patient's medical history when caring for patients.

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 to make healthcare more equitable through its health IT coordination. ONC's work builds on regulation that incentivized the digitization of medical data which required the first-generation consumer transparency with patient web portals. The standards and interoperability work led by ONC advances the technical infrastructure necessary to support the appropriate and secure flow of clinical data to individuals, caregivers, and their clinicians. ONC is also uniquely situated to coordinate the technical activities among different health standards development organizations as we look to a more equitable future of healthcare.

Overview of Budget Request

The FY 2022 request for ONC is $86.6 million, an increase of $24.3 million in program level. These resources will be entirely available through the Public Health Services Act Evaluation set-aside. ONC's budget, although small compared to the overall Federal healthcare spending, has had transformative impacts on HHS programs and the healthcare system. ONC's FY 2022 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 multifaceted work that weaves together **policy** development on value-based, data-driven health system transformation and unique expertise for guiding and facilitating cutting-edge **technology and standards** initiatives that target Federal coordination and investments to spur the development and promotion of an interoperable nationwide health IT infrastructure.

ONC's program level funding is reported as one line, but the President's Budget request narrative is organized into three chapters, summarized below, to provide greater transparency into ONC's strategy for affecting change.

- ### Policy: Development and Coordination
  Includes 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 and frameworks must be robust and resilient enough to withstand substantial opposition from industry stakeholders and make interoperability a reality.
- ### Technology: Standards, Certification, and Interoperability
  Includes 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 science and innovation and demonstrate advanced uses of health IT which will enable future ONC standards work to support the Administration's equity goals and enable patients to easily access their health information on their smartphones.
- ### Agency-Wide Support
  Includes providing executive, clinical, 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.

ONC's FY 2022 request includes a proposed increase of $23.0 million to improve the Nation's Interoperability Networks for Emergency Response, of which $13.0 million is to further implement Cures Act requirements related to the Trusted Exchange Framework and Common Agreement (TEFCA), and $10.0 million to support ONC's standard's responsibilities, which will build the future healthcare data infrastructure needed to better respond to and prepare for public health emergencies, including the COVID-19 pandemic. The budget request also includes increased funding to allow ONC to support their staff and operational activities needed to keep pace with the agency's growing responsibilities.

Overview of Performance

ONC's Mission, Goals, and Objectives

ONC's mission, adopted from the Federal Health IT Strategic Plan 2020 – 2025, is to improve the health and well-being of individuals and communities using technology and health information that is accessible when and where it matters most. ONC advances progress to its mission by formulating the Federal Government's health IT strategy and promoting coordination of federal health IT policies, technology standards, and programmatic investments. ONC's annual budget request reflects thoughtful and coordinated plans to advance National goals, particularly the objectives outlined in ONC's authorizing and enabling legislation: the Cures Act, MACRA, and the HITECH Act, and the Executive Order on Ensuring a Data-Driven Response to COVID-19 and Future High-Consequence Public Health Threats.

This budget request enables ONC to continue fulfilling its ongoing responsibility as the principal federal entity charged with coordination of nationwide efforts to effectively use health IT and electronic health information exchange to improve healthcare quality, cost, and equity. To this end, ONC leads two priority strategies as part of the HHS Strategic Plan for 2018-22.

Health IT *in the* 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

HHS Priority 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

Summary of Performance Information in the Budget Request

This budget includes performance reporting for the most recently completed year, FY 2020, and budget planning information for the Budget Request level for FY 2022. The performance information in this request includes a combination of contextual measures that describe the extent of nationwide interoperable health information exchange; and milestones and accomplishments that highlight key information about ONC activities that were or need to be taken to implement statutory requirements.

The contextual measures in the budget are the research that ONC conducts with other partners in government to better understand the Nation's Health IT landscape. These projects seek to understand the types of heath IT capabilities that exist and how those capabilities are being used. The measures included in the budget were selected to provide context for ONC's request *and* demonstrate the long-term impact of ONC's past work. This year's budget request maintains support for several necessary survey and data analysis projects that enable ONC to collaborate with public and private sector partners and meet

congressional requirements to evaluate progress toward national goals for interoperable health information exchange.

ONC's Performance Management Process

ONC's performance management process prioritizes a continuous focus on improving program results, finding more cost-effective ways to deliver value to health IT stakeholders nationwide, and increasing the efficiency and effectiveness of Agency operations.

The performance management strategy at ONC consists of four phases: (1) Priority Setting, (2) Strategic Planning, (3) Financial and Performance Management, and (4) Evaluation, Review, and Reporting. Activities aligned to these four phases are coordinated by a workgroup of ONC's leaders who represent the agency in strategy, planning, performance, financial and human capital resources, operations, risk management, data analysis, and program/policy evaluation.

ONC's performance and management processes incorporate requirements from law, procedures from Office of Management and Budget (OMB) circulars, and a range of best practices endorsed by oversight and advisory groups. Example resources that provide a foundation for ONC's management process include:

- Government Performance and Results Act of 1993 and the GPRA Modernization Act of 2010 (Public Law 111-352)
- Federal Mangers' Financial Integrity Act (FMFIA) of 1982 (Public Law 97-255),
- OMB Circular A-11: Preparation, Submission, and Execution of the Budget ("A-11")
- OMB Circular A-123: Management's Responsibility for Enterprise Risk Management and Internal Control ("A-123")
- Government Accountability Office (GAO) Standards for Internal Control in the Federal Government ("The Green Book")
- Performance Improvement Council's Performance Principles and Practices Guide ("P3 Playbook")

Impact of the FY 2022 Budget Request on Performance

ONC's FY 2022 request includes a proposed increase of $23.0 million to improve the Nation's Interoperability Networks for Emergency Response, of which $13.0 million is to further implement Cures Act requirements related to TEFCA (a part of ONC's Policy Development and Coordination activities), and $10.0 million to support ONC's standard's responsibilities (a part of ONC's Standards, Interoperability, and Certification activities).

All-Purpose Table

(Dollars in Thousands)

Activity	FY 2020 Final	FY 2020 Supplemental Funding /1	FY 2021 Enacted	FY 2021 Supplemental Funding /2	FY 2022 President's Budget	FY 2022 President's Budget +/- FY 2021 Enacted
TOTAL, ONC Program Level	$60,253	$10,000	$62,367	$19,500	$86,614	$24,247
TOTAL, ONC Budget Authority	$60,253	$10,000	$62,367	$19,500	$0	($62,367)

1/ Shows supplemental funds post-transfer and post re-allocation from PHSSEF under the CARES Act of 2020, P.L. 116-136.
2/ Shows supplemental funds post-transfer and post re-allocation from PHSSEF under the CARES Act of 2020, P.L. 116-136.

Budget Exhibits

Appropriations Language

From amounts made available pursuant to section 241 of the PHS Act, $86,614,000 shall be for expenses necessary for the Office of the National Coordinator for Health Information Technology, including *for* grants, contracts, and cooperative agreements for the development and advancement of interoperable health information technology, [$62,367,000].

Language Analysis

Language Provision	Explanation
***From amounts made available pursuant to section 241 of the PHS Act, $86,614,000 shall be for* expenses necessary for the Office of the National Coordinator for Health Information Technology, including *for* grants, contracts, and cooperative agreements for the development and advancement of interoperable health information technology, [$62,367,000].**	Provides ONC's budget from PHS Evaluation funding.

Amounts Available for Obligation

	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Budget
General Fund Discretionary Appropriation:			
Appropriation (L/HHS).....	$60,367,000	$62,367,000	$0
Subtotal, Appropriation (L/HHS, Ag, or Interior).....	$60,367,000	$62,367,000	$0
Subtotal, adjusted appropriation.....	$60,367,000	$62,367,000	$0
Real transfer to: (COVID Response).....	($114,000)		
Real transfer to: (ACF).....		($187,000)	$0
Subtotal, adjusted general fund discr. appropriation.....	$60,253,000	$62,180,000	$0
Total, Discretionary Appropriation.....	$60,367,000	$62,367,000	$0
Total Obligations.....	$60,253,000	$62,180,000	$0

Summary of Changes

2021 Enacted	
Total estimated budget authority.....	$62,367,000
Total estimated program level.....	$62,367,000
2022 President's Budget	
Total estimated budget authority.....	$0
Total estimated program level.....	$86,614,000
Net Change in budget authority.....	-$62,367,000
Net Change in program level.....	+$24,247,000

	FY 2021 Enacted		FY 2022 President's Budget		FY 2022 +/- FY 2021	FY 2022 +/- FY 2021
	FTE	BA	FTE	PL	FTE	BA
Increases:						
A. Program:						
1. Health IT, PHS Eval....	177	$0	177	$86,614,000	-	$86,614,000
Subtotal, Program Increases	**177**	**$0**	**177**	**$86,614,000**	**-**	**$86,614,000**
Total Increases	**177**	**$0**	**177**	**$86,614,000**	**-**	**$86,614,000**
Decreases:						
A. Program						
1. Health IT, BA.....	177	$62,367,000	177	$0	-	($62,367,000)
Subtotal, Program Decreases	**177**	**$62,367,000**	**177**	**$0**	**-**	**($62,367,000)**
Total decreases	**177**	**$62,367,000**	**177**	**$0**	**-**	**($62,367,000)**
Net Change	**-**	**-**	**-**	**-**	**-**	**+$24,247,000**

Budget Authority by Activity

(Dollars in Thousands)

	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Budget
1. Health IT			
Annual Budget Authority.....	$60,253	$62,367	$0
Annual Program Level.....	$60,253	$62,367	$86,614
Subtotal, Health IT	$60,253	$62,367	$0
Total, Budget Authority	$60,253	$62,367	$00
Total, Program Level	$60,253	$62,367	$86,814
FTE	157	177	177

Authorizing Legislation

	FY 2021 Amount Authorized	FY 2021 Amount Appropriated	FY 2022 Amount Authorized	FY 2022 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	$62,367,000	Indefinite	$ -
Program Level		$ -		$86,614,000
Total Request Level		$62,367,000		$86,614,000

Appropriations History

Each Year is General Fund Appropriation	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
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	$ -	
Transfers (Secretary's)				($114,000)
Subtotal	$43,000,000	$60,367,000	$60,367,000	$60,253,000
FY 2021				
Annual	$50,717,000	$60,367,000	$60,367,000	$62,367,000
Transfers (Secretary's)	$ -	$ -	$ -	($187,000)
Subtotal	$50,717,000	$60,367,000	$60,367,000	$62,180,000
FY 2022				
Annual	$ -			
PHS Evaluation Funds	$86,614,000			

Subtotal..... $86,614,000

Narrative by Activity

Health IT

	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Budget	FY 2022 +/- FY 2021
BA	$60,253,000	$62,367,000	$0	-$62,367,000
PHS Eval Funds	$0	$0	$86,614,000	$86,614,000
PL	$60,253,000	$62,367,000	$86,614,000	+$24,247,000
FTE	157	177	177	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 were increased by MACRA in 2015 and again by the 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 2022, 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 delegations from the Secretary;
- Supporting secure, standards-based APIs and user-focused technologies to promote an open platform-based ecosystem that can expand interoperability patterns, enrich data exchange, increase usability, and enable advanced interoperability capabilities to improve quality, cost, safety, and equity in healthcare;
- Contributing to HHS efforts to respond to public health emergencies such as **COVID-19 and the opioid epidemic** through collaborations with public health stakeholders to improve the Nation's critical health IT infrastructure and health information sharing.

Sub Activities at ONC [1]

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.

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; scientific advisors who support leveraging standardized clinical data to advance discovery and innovation; a stakeholder outreach and media relations function, including management of HealthIT.gov; and the agency's operations and administration functions.

[1] 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.[2] 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 Centers for Medicare & Medicaid Services (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.[3]

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. It was supported widely for its more than 150 detailed commitments and calls to action.[4]

While nationwide stakeholders worked to implement commitments in the *Roadmap*,[5] 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.[6]

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 APIs 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.

Most recently in **March 2020,** ONC published the Cures Act Final Rule which seeks to improve the healthcare delivery system by addressing the technical barriers and business practices that impede the secure and appropriate sharing of data. A central underpinning to the Rule is to facilitate patients' access

[2] Executive Order 13335: https://www.gpo.gov/fdsys/pkg/WCPD-2004-05-03/pdf/WCPD-2004-05-03-Pg702.pdf.
[3] 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.
[4] https://www.healthit.gov/topic/interoperability/interoperability-road-map-statements-support.
[5] https://www.healthit.gov/sites/default/files/12-19-YearInReviewPrezi-508-LowRes.pdf.
[6] https://www.healthit.gov/buzz-blog/health-data/numbers-progress-digitizing-health-care/.

to their electronic health information and empower their healthcare decisions.

Major Accomplishments

The following performance highlights explain how ONC's investments in previous years have resulted in impactful deliverables, noteworthy accomplishments, and continued progress towards national goals for a healthcare system that has higher quality, lower costs, and is more equitable by design.

Policy: Development and Coordination

- **Cures Act Final Rule:** In March 2020, ONC released the Cures Act Final Rule, which included new rules to implement the Cures Act's information blocking provision as well as changes to the ONC Health IT Certification Program. The Rule supports the right of the patient to get their health information electronically[7] and addresses both technical barriers and business practices that impede the secure and appropriate sharing of data. The Rule advances progress on many of ONC's implementation responsibilities in the Cures Act, including information blocking and conditions of certification for health IT developers under the ONC Health IT Certification Program. It also promotes transparency, using modern computers, smartphones, and software to provide opportunities for the American public to regain visibility in the services, quality, and costs of healthcare. The Rule requires 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.

- **Federal Partner Coordination:** ONC coordinated with numerous Federal agencies throughout FY 2020, including working closely with key stakeholders in the HHS Office of the Secretary, Assistant Secretary for Planning and Evaluation (ASPE), Assistant Secretary for Preparedness and Response (ASPR), Administration for Community Living (ACL), Office for Civil Rights (OCR), CMS, Health Resources and Services Agency (HRSA), Agency for Healthcare Research and Quality (AHRQ), National Institutes for Health (NIH), Centers for Disease Control and Prevention (CDC), Indian Health Service (IHS), HHS Office of Inspector General (OIG), as well as Department of Justice (DOJ), Veterans Health Administration (VHA), Department of Defense (DOD), Social Security Administration (SSA), US Postal Service (USPS), Department of Transportation (DOT) and others. Throughout FY 2020, ONC responded to numerous Administration requests to provide targeted senior-executive expertise to key stakeholders, including to the CMS Office of the Administrator, the VHA, NIH, 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.

- **Federal Health IT Coordinating Council:** ONC improved Federal coordination through the Federal Health IT Coordinating Council, a voluntary group of over 20 Federal departments, agencies, and offices that are actively involved in implementing the national health IT agenda. In FY 2020, the Federal Health IT Coordinating Council convened three times including an average of 66 Federal representatives across 20 organizations. In FY 2020, the Coordinating Council addressed the final rules from ONC and CMS to support seamless and secure access, exchange, and use of electronic health information; assisted in drafting the Federal Health IT Strategic Plan FY 2020 – 2025; and Federal health IT coordination activities related to COVID-19. The Coordinating Council helped to form work groups to inform the Patient Identity and Matching Report to Congress and the Trusted Exchange Framework and Common Agreement. In addition, the Coordinating Council established two additional work groups focused on Federal health IT

[7] https://www.healthit.gov/curesrule/

standards coordination, specifically related to Fast Healthcare Interoperability Resources (FHIR®) and the United States Core Data for Interoperability (USCDI).

- **Patient Access to Electronic Health Information:** ONC worked closely with partners in the Department to promote patient access to electronic health information through online resources and awareness campaigns related to the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule (subpart E of 42 CFR 164), as required by the Cures Act in section 4006. ONC continued to disseminate the Guide to Getting and Using Your Health Records (updated in May 2020) and to promote the Get IT, Check IT, and Use IT campaign. ONC also revamped the Patient Access to Health Records landing page on HealthIT.gov[8] to facilitate easy navigation to all access-related resources. To support the Cures Act Final Rule, ONC developed a draft API infographic targeted at both patients and providers to highlight the benefits of standards-based APIs for these target populations.

- **EHR Reporting Program:** ONC continued to implement this program pursuant to Cures Act section 4002 requirements. The EHR Reporting Program will provide publicly available, comparative information about certified health IT products. The Draft Electronic Health Record (EHR) Program User-Reported Criteria were available for public comment form June 2020 to August 2020. The final criteria were posted early in October 2020.

- **Federal Advisory Committee:** ONC continued to administer the Health IT Advisory Committee (HITAC), ONC's Federal Advisory Committee mandated by the Cures Act. Now in its third year, the HITAC serves as a priority method for obtaining routine input from a group of 32 health IT experts, representing a broad and balanced spectrum of the healthcare system. Between October 1, 2019, and September 30, 2020, the full HITAC met eight times and its task forces and work groups met 40 times to develop recommendations addressing the priority areas identified in the Cures Act. In March 2020, the HITAC has published the FY 2019 Annual Report and developed a new task force on Intersection of Clinical and Administrative Data. At the end of FY 2020, there have been eight HITAC Task Forces and Work Groups with differing levels of activity.
    - Active
        - Annual Report Workgroup
        - Intersection of Clinical and Administrative Data Task Force
    - Completed
        - Interoperability Standards Priorities Task Force
        - Trusted Exchange Framework and Common Agreement Task Force
        - U.S. Core Data for Interoperability Task Force
        - Information Blocking Task Force
        - Conditions of Certification Task Force
        - Health IT for the Care Continuum Task Force

- **Trusted Exchange Framework and Common Agreement (TEFCA)**: In late FY 2019, ONC awarded a four-year cooperative agreement for the TEFCA Recognized Coordinating Entity (RCE) to The Sequoia Project. This partnership leverages the RCE's extensive private sector experience to develop, implement, update, and maintain the Common Agreement component of TEFCA. The Common Agreement will create the baseline technical and legal requirements for networks to share electronic health information across the nation. During FY 2020, the RCE has conducted numerous activities to gain valuable public input needed to create a successful Common Agreement. As of mid-2020, this has included hosting 27 public stakeholder

[8] https://www.healthit.gov/topic/patient-access-health-records/

engagements. In May 2020, ONC committed approximately $1.1 million to the cooperative agreement with The Sequoia Project. This funding will support RCE activities from August 2020 to August 2021.

- **U. S. Core Data for Interoperability (USCDI):** ONC took steps to promote modern technology standards and address the interoperability goals of the Cures Act by setting the USCDI (launched in 2019) as a standard in the Final Rule. New versions of the USCDI will feed into the Standards Version Advancement Process (SVAP) and allow health IT developers in the ONC Health IT Certification Program to voluntarily update their products to include National Coordinator-approved newer versions of select standards.[9] The USCDI ONC New Data Element and Class (ONDEC) submission system opened in July 2020 to develop new versions of the USCDI through a predictable, transparent, and collaborative process allowing health IT stakeholders to submit new data elements and classes on a continuous basis. Proposals submitted before October 9, 2020 will be considered for the USCDI Draft v2.
- **Strategic Plan:** In January 2020, ONC released the draft Federal Health IT Strategic Plan 2020- 2025 for public comment. Specifically, this plan explains how the Federal Government intends to use health IT to: 1) Promote Health and Wellness; 2) Enhance the Delivery and Experience of Care; 3) Build a Secure, Data-Driven Ecosystem to Accelerate Research and Innovation; and 4) Connect Healthcare and Health Data through an Interoperable Health IT Infrastructure. The comment period closed in April and ONC received over 90 comments which ONC reviewed and analyzed for consideration in the final publication released in October 2020.
- **Strengthening Public Health via Health Information Exchanges**: In FY 2020, ONC launched the Strengthening the Technical Advancement and Readiness of Public Health via Health Information Exchange (STAR HIE) Program. The program is designed to strengthen and accelerate innovative uses of health information via health information exchanges (HIEs) within states, communities, and regions to support public health agencies' abilities to advance data-driven prevention of, response to, and recovery from public health events, including disasters and pandemics such as COVID-19.
- **ONC COVID-19 Disaster Response Team:** At the end of January 2020, ONC activated its internal disaster response team to assist with coordination of health IT activities and objectives pertaining to the COVID-19 response. The ONC team participates in and provides subject matter expertise to support Federal coordination. Two resources on HealthIT.gov, specific to the health IT community, were created to assist with the COVID-19 response:
    - COVID-19 Response: Tools and Resources for the Health IT and Clinical Community
    - Interoperability for COVID-19 Novel Coronavirus Pandemic
- **Health Data Access for Emergency Responders:** ONC seeks to bolster national resilience through improved access to health information during disasters and public health emergencies such as the COVID-19 pandemic. The Patient Unified Lookup System for Emergencies (PULSE) is a health IT disaster response platform that, when deployed as part of a PULSE program at the state or local level, can allow disaster workers to query and view patient records from connected health care organizations. In FY 2020, ONC developed enhancements to the PULSE platform to better enable first responders and health care volunteers access to vital health information during disasters. The PULSE code is scalable, flexible, non-proprietary and available at no cost to state, territorial, local and tribal governments. The PULSE code enhancements can give state and local

[9] https://www.healthit.gov/buzz-blog/interoperability/uscdi-onc-new-data-element-and-class-submission-system-now-available

governments more flexibility to build upon existing health information exchange infrastructure, create a more customized PULSE program and system, and utilize existing vendor resources. Additionally, it may create a more innovative and competitive market for other PULSE technical solutions.

- **Opioid Epidemic Response, including Support for States:** ONC led collaborations with CMS, CDC, states, and representatives from stakeholder groups to identify the most critical needs for combatting the opioid epidemic through health IT and improved health information interoperability. ONC has been involved in implementation of Section 5042 of the SUPPORT Act, providing support for CMS's enhanced funding to state Medicaid agencies for qualified prescription drug monitoring programs which has resulted in $155 million in standards-based PDMP architecture. In FY 2020, CMS and ONC established an interagency agreement to execute various SUPPORT ACT provisions. This includes creating health IT resources related to neonatal abstinence syndrome, consent management efforts related to Jessie's Law provisions, supporting patient matching for interstate PDMP queries, and direct technical assistance to states with SUPPORT Act implementation. In summer 2020, ONC worked with states to discuss Prescription Drug Monitoring Programs (PDMP) strategies and to create a toolkit that included considerations for enhancing the functionality of PDMPs.[10] The Health IT Playbook continues to be updated and promoted. This resource gives providers information about connecting to state PDMPs, integrating data, and electronic prescribing of controlled substances.[11]
- **Advancing Interoperability of Social Determinants of Health Data (SDOH):** ONC works closely with our Federal and private sector partners on SDOH-related activities. Examples of such activities include but are not limited to: participating in the Gravity Project, a new community-led effort to develop an Health Level Seven (HL7®) FHIR implementation guide for SDOH data and more comprehensive SDOH terminology; supporting public workshops to identify barriers and opportunities on topics as standards-based electronic referrals with community-based organizations; and supporting electronic long-term support services standards development with CMS and HL7® as a component of ONC's collaborative work with CMS, ONC continues to promote usage of the CMS-ONC Health IT Toolkit for Medicaid Funded Home and Community Based Services Programs.[12]
- **Patient Identity and Patient Record Matching:** ONC is currently investigating strategies to improve patient identity and matching to include in a report to Congress on the topic, as required by the 2019 Congressional Appropriations Agreement. This has included seeking stakeholder input and insight into existing challenges, promising innovations, and technical and operational methods that can improve patient identity and matching.[13] In June 2020, a virtual working session was held with 29 presenters and 693 attendees. In July 2020, ONC facilitated a series of working sessions with 21 Federal agencies to better understand their experiences, challenges and needs around patient identity and matching. ONC has also consolidated several patient identity and matching resources into one landing page on HealthIT.gov.
- **Emergency Medical Services Data Interoperability:** On January 29, 2020, the Federal Interagency Committee on Emergency Medical Services (FICEMS), in cooperation with ONC, the Department of Transportation, and the National Highway Traffic Safety Administration (NHTSA), hosted a National Pre-Hospital and Hospital Data Integration and Listening Session Summit. The Summit focused on the routine integration of pre-hospital emergency medical services data into the hospital electronic medical record. Presentations and discussion topics

[10] https://www.nga.org/center/publications/health/strategies-prescription-drug-monitoring/
[11] https://www.healthit.gov/playbook/opioid-epidemic-and-health-it/
[12] https://www.healthit.gov/topic/advancing-interoperability-medicaid
[13] https://www.healthit.gov/topic/patient-identity-and-patient-record-matching

included pre-hospital data collection, hospital data collection, national emergency use cases, and health information exchanges.

- **Burden Reduction:** In February 2020 ONC, in collaboration with CMS, issued the Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs. Reflective of public comment, the report targets burdens tied to regulatory and administrative requirements that HHS can directly impact through the rulemaking process. The report's strategies, recommendations, and policy shifts aim to give clinicians more time to focus on caring for their patients.

Technology: Standards, Interoperability, and Certification

- **ONC Health IT Certification Program:** ONC continued to implement congressional requirements to operate the ONC 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.[14] By the end of FY 2020, the ONC Health IT Certification Program's website, the Certified Health IT Product List (CHPL), listed products from more than 450 health IT developers,[15] and was used to register the EHRs of over 550,000 care providers and hospitals participating in Medicare and Medicaid.[16] At the end of 2020, there were 658 products from 466 developers on the CHPL certified to the 2015 Edition. This means that 98 percent of the hospitals and over 95 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. The Certification Program maintains test procedures and certification companion guides for 58 certification criteria and six conditions and maintenance of certification requirements,[17] used to standardize information across 21 distinct programs and initiatives taking place at CMS, DOD, VHA, HRSA, and the Substance Abuse and Mental Health Services Administration (SAMHSA).[18] ONC's Rule impacts this program which will carry out part of the implementation of the Rule.

  In June of 2020, ONC released ONC Pediatric Health Information Technology Developer Informational Resource (IR) for health IT developers working to support pediatric care and practice settings. The resource outlines ONC's health IT certification criteria related to key clinical priorities and additional technical information that can assist developers working with pediatric healthcare providers. It also includes relevant tools to consider for implementation with a focus on specific recommendations that are aligned to the clinical priorities identified by pediatric healthcare providers.

- **Standards Advisory:** ONC 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 2020 ISA, published in January 2020, added 13 new interoperability needs for a total of 180, providing detailed recommendations for standards, models and profiles to support interoperability including interoperability standards that could support COVID-19 diagnosis and treatment. During the public comment period for the 2020 ISA, ONC received 108 comments with more than 500 individual recommendations for revisions and improvements. In FY 2020, the ISA website was accessed over 95,000 times, slightly more than the 90,000 views in FY 2019. Public

[14] https://www.healthit.gov/topic/certification-ehrs/programs-referencing-onc-certified-health-it.
[15] https://dashboard.healthit.gov/quickstats/pages/FIG-Vendors-of-EHRs-to-Participating-Professionals.php.
[16] https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/DataAndReports.html.
[17] https://www.healthit.gov/topic/certification-ehrs/2015-edition-test-method.
[18] https://www.healthit.gov/topic/certification-ehrs/programs-referhealencing-onc-certified-health-it.

adoption of the FHIR standards work has been rapid. For example, Apple's "Health App" allows iPhone using patients to access their own health information from dozens of healthcare organizations based on FHIR implementation guides supported by ONC funding.

- **Expanding Vocabulary Standards for Public Health Needs**: In FY 2020, ONC launched a five-year program to fund the rapid development and dissemination of LOINC® codes in response to the pandemic that are used to identify laboratory tests. The LOINC codes are critical for clinicians and public health organizations to quickly and accurately order laboratory tests for COVID-19 and receive this and other clinical or laboratory results.
- **Advancement of Standards to Accelerate the Electronic Use of Health Data in Care Delivery:** In FY 2020, ONC launched a five-year program to fund HL7® SDO to develop and maintain standards and implementation guides that can respond to public health pandemics, such as COVID-19. Areas of development and maintenance include public health, social determinants of health, privacy, security, and expanding on other clinical domains within HL7® standards. This work also includes encouraging the adoption of the bulk data implementation guide.
- **Standards for United States Health Care:** In FY 2020, ONC launched a five-year contract with HL7®, to provide governance, program management, administrative support and timely development of standards targeted for US healthcare system including FHIR API standards. HL7® is the exclusive Standards Development Organization (SDO) with the authority and intellectual property to develop and maintain many of the technical standards used for exchanging health information in an interoperable manner. Many HL7® standards are targeted for international use and need to be updated before they can be used in the USA.
- **ONC Tech Forum:** Continuing the summertime tradition of the "Interoperability Forum," ONC hosted an all-virtual, two-day event from August 10-11, 2020. The event brought together nearly 2,000 participants from across the Federal Government as well as stakeholders from the healthcare and technology sectors to discuss technical innovations that are happening in health IT and have the potential to revolutionize the delivery of healthcare in support of improved health outcomes.[19]
- **Precision Medicine:** 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. In addition, ONC is advancing standards development to ease sharing and use of mobile health, sensor, and wearable data. This project aims to standardize the collection and sharing of remotely collected vital sign data by collaborating with organization accelerating work in this area. This project is also leveraging digital tools and questionnaires to advance standardized collection of SDOH data.[20]
- **Research Agenda:** ONC led the development of National Health IT Priorities for Research: A Policy and Development Agenda, which articulates a vision of a health IT infrastructure that supports alignment between the clinical and research ecosystems. The Agenda, developed in collaboration with Federal partners and with input from stakeholders, outlines nine priorities,

[19] https://www.healthit.gov/news/events/2020-onc-tech-forum
[20] https://www.healthit.gov/buzz-blog/precision-medicine/standards-for-everyday-life-integrating-emerging-health-data-to-advance-precision-medicine

including concrete steps that stakeholders can take to achieve that vision and enable research to happen more quickly and effectively. In July 2020, NIH published a notice encouraging NIH-supported clinical programs and researchers to adopt and use the standardized set of healthcare data classes, data elements, and associated vocabulary standards in the USCDI v1 to enable greater interoperable exchange of health information for clinical care and research. USCDI adoption will allow care delivery and research organizations to use the same coding systems for key data elements that are part of the USCDI data classes. USCDI will benefit NIH researchers through increased availability of consistently standardized clinical data for research and will make it easier to aggregate research data sets and enable greater discovery.

- **Leading Edge Acceleration Projects (LEAP):** In FY 2020, ONC announced a Notice of Funding Opportunity and awarded funding to address well-documented and fast emerging challenges that inhibit the development, use, and/or advancement of well-designed, interoperable health IT. It is expected to further a new generation of health IT development and inform the innovative implementation and refinement of standards, methods, and techniques for overcoming major barriers and challenges as they are identified. This funding opportunity is specifically targeted at creating innovative solutions and advances in the following areas:

  Area 1: Advancing Registry infrastructure for Modern API-base Health IT Ecosystem

  Area 2: Cutting Edge Health IT Tools for Scaling Health Research

  Area 3: Integrating Health Care and Human Services Data to Support Improved Outcomes

- **FHIR at Scale Taskforce (FAST)**: Coordinated by ONC, this taskforce brings together motivated healthcare industry stakeholders and health information technology experts to identify HL7® FHIR scalability gaps and possible solutions that will accelerate FHIR adoption at scale nationwide. During 2020, the taskforce's members engaged a wide range of stakeholder and subject matter experts at public meetings and other events to receive feedback on the proposed, scalable solutions. Based on feedback, new versions of the solutions were developed. Taskforce members aim to initiate pilots by the end of this calendar year.

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.
- ONC's websites garnered 1.5 million visitors during FY 2020, an average of over 180,000 sessions per month and 5.4 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, HealthIT.gov, attracted users referred from 7,196 external websites.

Five Year Funding History

Funding History	
FY 2018 Enacted	60,367,000
FY 2019 Enacted	60,367,000
FY 2020 Enacted	60,367,000
FY 2021 Enacted	62,367,000
FY 2022 President's Budget	86,614,000

Budget Request

The FY 2022 President's Budget Request is for $86.6 million, an increase of $24.2 million (38.9 percent) from the FY 2021 Enacted Level of $62.4 million and an increase of $26.2 million (43.5 percent) from the FY 2020 Enacted Level of $60.4 million. The request includes a total of $23.0 million to bolster Interoperability Networks for Emergency Response; of which $13.0 million will be to enhance TEFCA and $10.0 million to support increased standard responsibilities, which will build the future healthcare data infrastructure needed to better respond to and prepare for public health emergencies, including the COVID-19 pandemic. The request also includes an additional $1.0 million to allow ONC to support their staff and operational activities needed to keep pace with the agency's growing responsibilities.

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 2022 Request supports work to advance the technical infrastructure necessary to support safe, equitable, and affordable healthcare; implement the Cures Act, and improve the interoperability of electronic health information.

Policy Development and Coordination

ONC's FY 2022 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 health equity and reduce health disparities.

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.

Planned activities within ONC's FY 2022 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 2022, ONC will continue to promote and facilitate adoption of the TEFCA by major delivery networks and health information exchanges. With the $13.0 million in additional funding ONC will make TEFCA Infrastructure Investments to build the future healthcare data infrastructure needed to better respond to and prepare for public health emergencies, including the COVID-19 pandemic. To do this, ONC will create a cooperative agreement and/or grant program that would provide funding to public health entities, health information networks, health information exchanges, and certain providers to

speed readiness, onboarding, and infrastructure activities related to participation in the network-to-network exchange ecosystem, thereby better enabling health data to be available when and where it is needed. Funding would also be provided to the RCE to accelerate their work, including expanding their network privacy and security enforcement and oversight. This work is part of ONC's cross-cutting Bolstering Interoperability of Health Information Networks for Emergency Response project.

- **Rulemaking –** ONC will continue to publish and implement rules pertaining to sections 4002, 4003, and 4004 of the Cures Act as well as in accordance with Sec. 3004 of the Public health Services Act (PHSA). The Final Rule includes 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. ONC is implementing these provisions through activities in the Standards, Interoperability and Certification portfolio. The implementation of these provisions will advance interoperability; support the access, exchange, and use of electronic health information through secure, standards-based APIs; and enable transparent, uninhibited data sharing. Both interoperability and standards-based APIs are crucial to achieving patient access to their health information, responding to public health emergencies like COVID-19. In addition, ONC is reviewing recent Congressional action to identify where potential rulemaking may be necessary to support health information exchange, standards, and interoperability provisions within recent legislation and consistent with Sec. 3004 of the PHSA.
- **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 efforts on developing reporting criteria for developers of certified health IT, as required by the condition of certification established under the Cures Act.

Stakeholder Coordination

- **Federal Coordination –** As stated previously, ONC will continue leading and engaging agencies which contribute to the Federal Health IT Strategic Plan[21] 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

[21] https://www.healthit.gov/sites/default/files/9-5-Federalhealthitstratplanfinal_0.pdf.

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.

- **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 –** ONC will continue to implement the Federal Health IT Strategic Plan during FY 2022 regularly collaborating with key stakeholder groups (including Congress and the public) to monitor and report progress of priority 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 2022 Budget Request reflects ONC's plans to meet statutory requirements and advance progress toward national goals for equitable, widespread interoperability, which includes implementing the Cures Act related activities and impacts of ONC's rulemaking. The request includes funding for standards coordination and adoption activities, such as enhancements to ONC's Certification Program, that implement changes enacted by the Cures Act and ONC's subsequent rulemaking activities. As well as increase funding for improving interoperability among health information networks to enable them to rapidly support future emergency response. The standards advancement work led by ONC will enhance the technical infrastructure necessary to support the Administration's goals related to an equitable and data-driven response to the pandemic.

The Request also supports the Conditions of Certification program requirements contained in section 4002 of the Cures Act; standards development and coordination work that promote equity by design; 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 for nationally relevant issues included opioid use. These efforts help to respond to the current COVID-19 pandemic and are integral to responding to future public health emergencies.

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 2022, ONC will continue to oversee the ONC-Authorized Testing Labs and ONC-Authorized Certification Bodies, and maintain a library of required certification companion guides, test procedures, and electronic test tools to support developers with creating certified health IT.

- **Performance Measurement –** ONC will continue support for evidence-building activities including the national surveys related to the development, adoption, and use of health IT in order to advance implementation of ONC authorities and responsibilities for strategic planning and evidence-based policy making.

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, equitable, and interoperable health IT systems. The standards and interoperability work led by ONC advances the technical infrastructure necessary to support the Administration's goals to move healthcare to a more equitable future. To do this, ONC will continue to coordinate with private sector standards development organizations and promote innovative industry-led equity by design, 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 2022 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 making healthcare more equitable,
    - Promoting adoption of common health information interoperability standards by accelerating the readiness of interoperability standards for adoption and enhancement of the United States Core Data for Interoperability (USCDI), and
    - Addressing health IT needs for interoperability of social and behavioral health information to support healthcare.

  With the additional $10.0 million, ONC would support increasing interoperability between health information networks/exchanges, public health agencies, healthcare systems, and health plans. Improved connectivity is needed to build the future healthcare data infrastructure needed to better respond to and prepare for public health emergencies, including the COVID-19 pandemic. This work is part of ONC's cross-cutting Bolstering Interoperability of Health Information Networks for Emergency Response project.
    - Health Information Network (HIN) connectivity grants to support state and local HINs increased connections to healthcare system and to public health agencies for a multitude of public health use cases,
    - Expanding the interoperable care continuum by developing new connectivity between health information networks and social services agencies,
- **Demonstrations and Pilots –** As resources permit, ONC will continue to sponsor and encourage demonstration projects and pilots that address fast emerging and future challenges to advance the development and use of interoperable health IT. It is critical that the field of healthcare innovate and leverage the latest technological advancements and breakthroughs far quicker than it currently does to optimize real-time solutions.

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 interoperability related activities led by international organizations include the European Union and the World Health Organization.
- **Innovation –** The Cures Act identifies ONC as a leading agency for advancing interoperability to reduce barriers to scientific innovation. ONC regularly partners with CMS, NIH, FDA, and others, to implement solutions to public health and scientific innovation through projects of national importance. In FY 2022, ONC will continue to coordinate with stakeholders to develop health IT standards that advance interoperability in biomedical and patient-focused, personalized medical research.

Agency-Wide Support

The FY 2022 President's Budget Request reflects the ONC's commitment to continue advancing progress toward national goals for widespread interoperability. The budget request includes an increase of $1.0 million to support HHS's shared costs for shared services, physical and IT security, and legal support. The request also includes communications and engagement, and ONC management activities.

- **Communications and Engagement** – In FY 2022, 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 2022, ONC will continue to implement and improve its existing strategic and operational management processes. ONC's FY 2022 Budget Request includes funding for the HHS's shared costs, 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 16 percent of the Budget.

Output and Outcomes Table

Measure Group / Measure Text	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2021 Target	FY 2022 Target	FY 2022 Target +/- FY 2021 Target
Policy Development and Coordination				
Number of federal agencies actively participating in ONC-led health IT coordination efforts	FY 2020: 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 2020: 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 (ISA) Reference Edition	FY 2020: 2020 reference edition ISA contained 180 (+13) standards and implementation specification[22] (Baseline)	Maintain ISA with necessary updates & Publish annual update by March 2021	Maintain ISA with necessary updates & Publish annual update by March 2022	--
Agency Wide Support				
Number of visitors to ONC's websites to use health IT policy and technology assistance material	FY 2020: 1.5 million Target: Maintain prior year baseline (Target Not Met)	Maintain	Maintain	--

[22] Includes 6 implementation specifications which are considered "profiles and models" and not traditional standards.

Contextual Measures

Measure Area: Provider capability in key domains of interoperable health information exchange.

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.

	Office- based physicians	Non-federal acute care hospitals
• are electronically sending or receiving patient information with any providers outside their organization	47%	91%
• can electronically find patient health information from sources outside their health system	53%	65%
• can easily integrate (e.g. without manual entry) health information received electronically into their EHR	28%	62%
• had necessary patient information electronically available from providers or sources outside their systems at the point of care	32%	56%

Measure Area: Citizen's perspective on consumer access to their electronic health information

- 51 percent of Americans have been given electronic access to any part of their healthcare record by their healthcare provider or insurer.

Nonrecurring Expenses Fund

Budget Summary

(Dollars in Thousands)

	FY 2020[23]	FY 2021[24] [25]	FY 2022[26]
Notification[27]	--	--	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, ONC received $7.0 million in NEF resources to support 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 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.

[23] Notification submitted to the Committees on Appropriations in the House of Representatives and the Senate on July 20, 2020.

[24] Notification submitted to the Committees on Appropriations in the House of Representatives and the Senate on October 22, 2020.

[25] The projects described below are the current list of approved projects through FY 2021. Additional projects may be funded from the FY 2021 notification letter upon approval from OMB.

[26] HHS has not yet notified for FY 2022.

[27] Pursuant to Section 223 of Division G of the Consolidated Appropriation Act, 2008, notification is required of planned use

Supplementary Tables

Budget Authority by Object Class

(Dollars in Thousands)

	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Budget	FY 2022 +/- FY 2021
Personnel compensation:				
Full-time permanent (11.1)	18,972	19,512	20,039	528
Other than full-time permanent (11.3)	508	513	527	14
Other personnel compensation (11.5)	782	790	811	22
Military personnel (11.7)	348	-	-	-
Special personnel services payments (11.8)	-	-	-	-
Subtotal personnel compensation	**20,610**	**20,815**	**21,377**	**574**
Civilian benefits (12.1)	6,957	7,186	7,380	194
Military benefits (12.2)	19	-	-	-
Benefits to former personnel (13.0)	-	-	-	-
Total Pay Costs	**27,589**	**28,001**	**29,209**	**768**
Travel and transportation of persons (21.0)	144	144	144	-
Transportation of things (22.0)	59	59	59	-
Rental payments to GSA (23.1)	2,008	2,008	2,008	-
Rental payments to Others (23.2)	-	-		-
Communication, utilities, and misc. charges (23.3)	228	228	228	-
Printing and reproduction (24.0)	-	-	-	-
Other Contractual Services:				
Advisory and assistance services (25.1)	-	-	-	-
Other services (25.2)	12,075	12,075	12,075	-
Purchase of goods and services from government accounts (25.3)	10,246	10,246	10,246	-
Operation and maintenance of facilities (25.4)	325	325	325	-
Research and Development Contracts (25.5)	-	-	-	-
Medical care (25.6)	-	-	-	-
Operation and maintenance of equipment (25.7)	13	13	13	-
Subsistence and support of persons (25.8)	-	-	-	-
Subtotal Other Contractual Services	**25,098**	**25,098**	**25,098**	**-**
Supplies and materials (26.0)	158	158	158	-
Equipment (31.0)	-	-	-	-
Land and Structures (32.0)	-	-	-	-
Investments and Loans (33.0)	-	-	-	-
Grants, subsidies, and contributions (41.0)	7,451	9,110	32,601	23,491
Interest and dividends (43.0)	-	-	-	-
Refunds (44.0)	-	-	-	-
Total Non-Pay Costs	**7,609**	**9,268**	**32,759**	**23,491**
Total Budget Authority by Object Class	**60,293**	**62,367**	**86,614**	**24,247**

Salaries and Expenses

(Dollars in Thousands)

	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Budget	FY 2022 +/- FY 2021
Personnel compensation:				
Full-time permanent (11.1)	18,972	19,512	20,039	527
Other than full-time permanent (11.3)	508	513	527	14
Other personnel compensation (11.5)	782	790	811	21
Military personnel (11.7)	348	-	-	-
Special personnel services payments (11.8)	-	-	-	-
Subtotal personnel compensation	**20,610**	**20,815**	**21,377**	**562**
Civilian benefits (12.1)	6,957	7,186	7,380	194
Military benefits (12.2)	19	-	-	-
Benefits to former personnel (13.0)	-	-	-	-
Total Pay Costs	**27,589**	**28,001**	**28,757**	**756**
Travel and transportation of persons (21.0)	144	144	144	-
Transportation of things (22.0)	59	59	59	-
Rental payments to GSA (23.1)	2,008	2,008	2,008	-
Rental payments to Others (23.2)	-	-		-
Communication, utilities, and misc. charges (23.3)	228	228	228	-
Printing and reproduction (24.0)	-	-	-	-
Other Contractual Services:				
Advisory and assistance services (25.1)	-	-	-	-
Other services (25.2)	12,075	12,075	12,075	-
Purchase of goods and services from government accounts (25.3)	10,246	10,246	10,246	-
Operation and maintenance of facilities (25.4)	325	325	325	-
Research and Development Contracts (25.5)	-	-	-	-
Medical care (25.6)	-	-	-	-
Operation and maintenance of equipment (25.7)	13	13	13	-
Subsistence and support of persons (25.8)	-	-	-	-
Subtotal Other Contractual Services	**25,098**	**25,098**	**25,098**	**-**
Supplies and materials (26.0)	158	158	158	-
Total Non-Pay Costs	**158**	**158**	**158**	**-**
Total Salary and Expense	**52,842**	**53,257**	**54,013**	**756**
Direct FTE	**157**	**177**	**177**	**-**

Detail of Full-Time Equivalent Employment (FTE)

	2020 Actual Civilian	2020 Actual Military	2020 Actual Total	2021 Est. Civilian	2021 Est. Military	2021 Est. Total	2022 Est. Civilian	2022 Est. Military	2022 Est. Total
Direct:	155	2	157	177	-	177	177	-	177
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	155	2	157	177	-	177	177	-	177
ONC FTE Total	**155**	**2**	**157**	**177**	**-**	**177**	**177**	**-**	**177**

Average GS Grade		
	Grade:	Step:
FY 2018.....	13	8
FY 2019.....	13	7
FY 2020.....	13	9
FY 2021.....	12	9
FY 2022.....	12	10

Detail of Positions

	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Budget
Executive level	-	-	-
Total - Exec. Level Salaries	-	-	-
ES.....	5	6	6
Total - ES Salary	1,163,980	1,410,744	1,448,834
GS-15.....	49	52	52
GS-14.....	46	54	54
GS-13.....	41	43	43
GS-12.....	6	10	10
GS-11.....	8	8	8
GS-10.....	-	-	-
GS-9.....	8	19	19
GS-8.....	-	-	-
GS-7.....	-	-	-
GS-6.....	-	-	-
GS-5.....	-	-	-
GS-4.....	-	-	-
GS-3.....	-	-	-
GS-2.....	-	-	-
GS-1.....	-	-	-
Subtotal	158	186	186
Total - GS Salary	20,145,263	20,937,317	21,502,624
Average ES salary.....	232,796	235,124	241,472
Average GS grade.....	13-8	12-9	12-10
Average GS salary.....	127,502	112,566	115,606

Programs Proposed for Elimination

No programs are proposed for elimination.

Physicians' Comparability Allowance Worksheet

	PY 2020 (Actual)	CY 2021[28] (Estimate)	BY 2022 (Estimate)
Number of Physicians Receiving PCAs	0	1	3
Number of Physicians with One-Year PCA Agreements	0	0	0
Number of Physicians with Multi-Year PCA Agreements	0	0	3
Average Annual PCA Physician Pay (without PCA payment).	$0	$192,190	$159,028
Average Annual PCA Payment	$0	$30,000	$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.

[28] FY 2021 data will be approved during the FY 2022 Budget cycle

Modernization of the Public-Facing Digital Services - 21st Century Integrated Digital Experience Act

The 21st Century Integrated Digital Experience Act (IDEA) was signed into law on Dec. 20, 2018. It 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 working 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. In FY 2020, HHS Digital Communications Leaders began implementation of the Strategy in alignment with IDEA, beginning to align budgets to modernization requirements.

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
- continue developing estimated costs and impact measures for achieving IDEA.

Over the next four 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

FY 2021 House Appropriations Committee, Labor/HHS/Education Subcommittee, H. Rept. 116-450

Assessment of the State of Health Information Technology at Hospitals: The Committee is concerned about the state of health information technology at hospitals in the United States. The Committee directs the ONC, in consultation with State departments of health and other public health entities, to submit a report to the Committee within one year of the date of enactment of this Act. The report should assess the state of electronic medical records at U.S. hospitals and the dependence of hospitals and health systems on technology that is outdated or debunked, as well as barriers associated with updating health information technology, including with respect to hardware, software, administrative burden, staff training, and associated costs. **(Page 218-219, H. Rept. 116-450)**

Action to Be Taken
ONC is coordinating with state and federal partners, as well as, public health entities to develop a strategy assessing the current state of electronic health records technology.

Health Information Technology Surveillance: The Committee understands that ONC is actively coordinating with the Centers for Disease Control and Prevention (CDC) on data collection and surveillance activities during the ongoing COVID–19 outbreak, but that much of the data being shared today are being transmitted via paper or PDF files. To better understand agency surveillance capacity and future needs, the Committee requests a report within 120 days of enactment of this Act on coordination activities to date, the extent to which computable information is being shared with local, State, and Federal authorities, identified barriers to interoperable exchange of electronic surveillance data, and strategies that can be put in place to improve the surveillance technology infrastructure. **(Page 219, H. Rept. 116-450)**

Action to Be Taken
Interagency Task Force on Health and Human Services Information Technology (IT): The Committee recognizes a growing need for the integration and modernization of Federal IT systems and notes that increased investment in IT would greatly improve employee and recipient interactions with Federal health and human service programs while enhancing program efficiency, integrity, analytic capability, and network security. The Committee urges the Chief Information Office and Chief Technology Officer (CTO) of HHS, in collaboration with the White House CTO and U.S. Department of Agriculture (USDA), as well as the Office of the National Coordinator for Health Information Technology (ONC) within HHS, 18F within the General Services Administration (GSA), and the Cybersecurity and Infrastructure security Agency (CISA) within the U.S. Department of Homeland Security, to establish an interagency task force that will examine existing IT infrastructure in federal health human service programs nationwide and identify the barriers to successfully integrating and modernizing health and human services IT, and the network security necessary for health and human services IT interoperability. The task force shall submit to the Committee within 180 days of enactment on this Act a report on its progress and on recommendations for further Congressional action, which should include estimated costs for agencies to make progress on interoperability initiatives. **(Page 219, H. Rept. 116-450)**

Action to Be Taken
The taskforce is the lead author on this report. An ONC cybersecurity representative will continue to provide subject matter expertise and input to the task force examining existing IT infrastructure in federal

health human service programs nationwide and identify the barriers to successfully integrating and modernizing health and human services IT, and the network security necessary for health and human services IT interoperability.

Interoperability: The Committee notes that finalization of the rule to implement the interoperability provisions of the 21st Century Cures Act takes significant steps forward to give patients greater access to their health data and to improve the electronic flow of health information across care settings. The Committee expects ONC to keep the Committee informed of any delays in implementation. **(Page 219, H. Rept. 116-450)**

Action to Be Taken
ONC will provide congressional members and staff regular updates on ongoing efforts to implement the 21st Century Cures Act.

Patient Data Matching: The Committee is concerned that there is no consistent and accurate way to link patients to their health information across the care continuum and notes the serious patient safety concerns that arise when data is mismatched or when important data is missing. Although the Committee continues to prohibit the use of 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. The Committee continues to encourage the Secretary 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 219-220, H. Rept. 116-450)***

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. ONC anticipates releasing this report in Fall 2021.

FY 2021 Conference Report, Labor/HHS/Education Subcommittee, Division H

The agreement includes a $2,000,000 increase to support interoperability and information sharing efforts related to the implementation of Fast Healthcare Interoperability Resources standards or associated implementation standards.

The agreement notes the general provision limiting funds for actions related to promulgation or adoption of a standard providing for the assignment of a unique health identifier does not prohibit the Department from examining the issues around patient matching, and continues to encourage the Department to provide technical assistance to private-sector-led initiatives to develop a coordinated approach that will promote patient safety by accurately identifying patients to their health information. Additionally, the agreement expects to receive the report requested in the explanatory statement accompanying the Further Consolidated Appropriations Act, 2020 (Public Law 116-94) on current methods and recommended actions to increase the likelihood of an accurate match of patients to their health care data.

Action to Be Taken
The additional appropriated funds were allocated for FHIR Standard work (e.g. Version 5), and also on the HL7® US FHIR Core Implementation Guide. Additionally, ONC will fund testing and piloting of the standards, and implementation specifications.

Health Insurance and Implementation Fund

HEALTH INSURANCE REFORM IMPLEMENTATION FUND

Budget Summary

(Dollars in Thousands)

	FY 2020	FY 2021	FY 2022
Obligations*	**-$1,670**	**$2,072**	**$2,148**

* $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 the 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 Marketplaces. 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 the Affordable Care Act.

The Office of Personnel Management (OPM) required funding to plan for implementing and overseeing Multi-State Plan Options for the Marketplaces 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 2021, a net total of $112,764 has been deobligated by agencies within HHS and external federal partners. 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), are leading 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 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 approximately $2 million of the $4,219,658 remaining in FY 2021 to continue support of the Health IT modernization requirements and anticipates continued engagement with IHS and ONC on this effort. This includes the requirement for funds to support engagement with GSA FedSIM for acquisition pilot and planning. It is the Department's current projection that $2,147,658 will be available for obligation in FY 2022. However, given recent recoveries in this account, it is possible that this amount may be higher.

No Surprises Act Implementation Fund

NO SURPRISES IMPLEMENTATION FUND

Budget Summary

Authorizing Legislation……No Surprises Act, Section 118, FY 2021
FY 2021 Authorization……FY 2024
Allocation Method……Direct Federal, Competitive Contract

Program Description and Accomplishments

Section 118 of the No Surprises Act (P.L. 116-260) appropriated $500,000,000 to the No Surprises Implementation Fund for the Department of Health and Human Services (HHS), Department of Labor (DOL), and Department of the Treasury. The purpose of this implementation fund is to carry out the provisions of, and the amendments made by Title I and Title II, Division BB of the FY 2021 Consolidated Appropriations Act (CAA).

Department of Health and Human Services

For efficiency and to ensure coordination, the No Surprises Implementation Fund account has been established within HHS. HHS is coordinating with DOL and Treasury to ensure that each agency receives funding allocations reflecting their most immediate requirements of the No Surprises Act. HHS is working collaboratively with DOL and Treasury, among other agencies, to quickly draft both guidance and forthcoming regulations to explain and help implement the wide-ranging surprise billing and price transparency provisions in time for many of these provisions to begin going into effect on January 1, 2022.

HHS is using implementation funds to primarily support contracts and infrastructure for various provisions, including core enterprise services and analytical capabilities. This includes work to support the upcoming enforcement of statutory surprise billing protections and transparency requirements for plans, issuers, and providers as well as the establishment of processes and systems to certify Independent Dispute Resolution (IDR) entities and collect user fees, as well as support complaints processing and provider enforcement efforts. HHS is also establishing systems to support the collection of agent/broker compensation and prescription drug data required by sections 202 and 204 of Title II, respectively.

HHS is using implementation funds to support salaries and benefits for FTEs that are needed for associated planning and program management support necessary to ensure effective and efficient implementation of provisions. A portion of these funds also support the establishment of an advisory committee on air ambulance quality and patient safety and an advisory committee on ground ambulance and patient billing. These funds also support the forthcoming production of reports to Congress.

Department of Labor

The Consolidated Appropriations Act (CAA) vastly expands DOL responsibilities as the primary regulator of group health plans, including its 2.4 million ERISA-covered group health plans that provide health coverage to approximately 136 million people. The Department's Employee Benefits Security Administration (EBSA), with close support from DOL's Office of the Solicitor (SOL), will be engaging in dozens of new regulatory and subregulatory projects on very tight timelines; dramatically increasing its health enforcement efforts, particularly with respect to MHPAEA; issuing new Congressionally-

mandated reports; providing education, outreach, and assistance to the public; and coordinating its work with numerous stakeholders, advisory committees, state and federal regulators, and others.

Along with the other two Departments, EBSA's immediate focus is on writing guidance and regulations, and enforcing MHPAEA with the new tools provided by the CAA as Congress contemplated in close conjunction with the Office of the Solicitor (SOL). On April 2, 2021 the DOL, HHS, and Treasury released FAQs (FAQs-Part-45 (dol.gov)) notifying the public of the No Surprises Act's new requirements regarding mental health and substance abuse benefits under the Mental Health Parity and Addiction Equity Act (MHPAEA), and the agencies' expectations with respect to health plans' required analyses and non-quantitative treatment limitations (NQTLs).

DOL has been using the new tools provided by the CAA to increase its enforcement of MHPAEA across the group market. DOL created a task force, developed and conducted new training for its investigators, increased technical support and coordination on MHPAEA-related cases, and started the process of hiring additional staff to pursue this important work. Since issuing its guidance, DOL has reviewed its existing inventory of investigations and identified numerous cases involving potential NQTL violations. As of May 10, 2021, it had already identified more than 66 cases involving 140 NQTLs, and has already made requests for comparative analyses covering dozens of NQTLs. In addition, DOL is pursuing potential claims involving an issuer that serves as a claims administrator for self-funded health plans, and has identified that some plans apply a categorical exclusion for Applied Behavior Analysis (ABA) treatment for autism. Thus far, the issuer has identified nearly 1,000 plans that still have an ABA Therapy exclusion, and many more that had the exclusion in the past three years. The task force has already begun to review the comparative analyses received.

A portion of DOL's implementation funds also support the establishment of an advisory committee on all payer claims database reporting.

EBSA's and SOL's budgets have remained flat for seven consecutive years, while having to absorb increasing annual salary and benefit costs. At current staffing levels, EBSA has less than one investigator for every twelve-thousand plans. SOL is similarly understaffed. DOL has leveraged its already limited staff, diverting investigators who oversee a regulatory universe of about 4 million plans, while also hiring experts to assist with the NQTL analyses. DOL has made significant progress in bringing additional enforcement staff on board thus far. DOL will continue to build upon the progress it has made.

Department of the Treasury

As the No Surprises Act amends the Internal Revenue Service (IRS) Code, the Department of the Treasury is involved in drafting guidance and regulations, developing implementation plans, and addressing legal matters as they arise. Specifically, the IRS Chief Counsel's Office represents the Department in tri-agency discussions.

Nonrecurring Expenses Fund

Nonrecurring Expenses Fund
Budget Summary
(Dollars in Thousands)

	FY 2020[2]	FY 2021[3/4]	FY 2022[5]
Notification[1]	$293,000	$300,000	TBD
CDC Allocation	$225,000		-
NIH Allocation	$225,000	$225,000	-
Rescission	-$350,000	-$375,000	-$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 approximately $4.8 billion for projects, including approximately $2 billion for physical infrastructure projects and approximately $2.8 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 2022 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 2020 HHS-wide facility backlog of maintenance and repairs totals approximately $2.8 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 2021)

The NEF has invested approximately $2 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 approximately $757 million in NEF funding since FY 2013 to address facilities construction and improvement projects. In FY 2016, $162 million was invested in renovations for the Clinical Center E-Wing to replace laboratory space that allowed for a vital

clinical program to function in the formerly deficient space. Additionally, in FY 2020 and FY 2021, Congress directly allocated $225 million of NEF funds to NIH, which NIH has directed to the Surgery, Radiology and Lab Medicine Building (SRLM) on the Bethesda campus. This project will construct a new addition and repurpose two floors of the west laboratory wing of the Clinical Research Center (CRC) to develop a facility that supports medical research initiatives to improve the nation's health and strengthen NIH's biomedical research capacity in close proximity to the CRC. The departments included in the renovation will be able to utilize some of the most advanced and technology dependent cutting-edge programs supporting NIH's Translational Research initiatives.

Indian Health Services

IHS has been allocated approximately $550 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. One of the facilities projects funded in FY 2020 was for the Red Lake Hospital which renovated and expanded 46,000 square feet of space for services including primary and pediatric care as well as behavioral health care.

Food and Drug Administration

FDA has been allocated approximately $311 million in NEF funding since FY 2015 to address a range of construction, renovation, and lab revitalization projects. The funds also supported building and site infrastructure improvements at FDA owned locations, such as renovations, building system upgrades, roadway/drainage repairs, and building equipment replacement. Most recently, a $50 million allocation has supported the relocation of FDA's Southeast Laboratory in Atlanta, Georgia. In FY 2021, FDA was allocated $8 million to correct infrastructure deficiencies at FDA's owned Muirkirk Road Complex in Laurel, Maryland.

Centers for Disease Control and Prevention

CDC has been allocated approximately $511 million in NEF funding since FY 2013 to address a number facility construction and improvement projects, including $130 million for the consolidation of the National Institute for Occupational Safety and Health's (NIOSH) Cincinnati Campus. In FY 2021, the NIOSH campus in Pittsburgh received $14 million of NEF funding to provide PPE to the facility.

Additionally, in FY 2020, Congress directly allocated $225 million of NEF funds for the consolidation of CDC's Chamblee Building 108. This project provides a new research support building and replaces laboratory material that will ultimately elicit long term efficiencies and cost savings by co-locating CDC staff onto this campus.

Major NEF IT and Cybersecurity Investments (FY 2013 – FY 2021)

HHS has invested approximately $2.8 billion in NEF funding for major IT infrastructure projects across the Department. The IT projects vary in size and scale; however, many OpDivs are working to migrate to the cloud and to bring human resources, accounting, grants, and contracts systems into the 21st Century.

Office of the Secretary (OS)

OS has received approximately $880 million since 2013 to improve HHS's financial, grants, and acquisition systems and to maintain strong Department-wide cybersecurity posture. In recent years, OS has been using NEF funds to enhance the e-Invoicing system, which will automate manual processes and increase transparency across the platform, coordinating with the Quality Service Management Organization to strategically consolidate its website and grants management systems, and streamline the Department-wide acquisitions system. Each of these projects contribute to the overall efficiency and security of HHS's online systems. NEF funds have also supported Department-wide projects oriented around trusted internet connection and computer security incident response.

Several staff divisions that fall under OS have also utilized NEF funding to expand and enhance IT systems across their staff Division and across the Department as a whole. For instance, 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 is utilizing NEF funds to strengthen mobile application security and increase the confidentiality and availability of sensitive data nationwide as well as integrate new cloud platforms.

Centers for Medicare and Medicaid Services (CMS)

CMS has received approximately $1.5 billion in NEF funding since FY 2013 to address a range of HHS priorities and objectives. Most notably, CMS has invested $332 million in NEF funding to develop and implement cloud computing technologies between FY 2013 and FY 2015. In addition, CMS has utilized NEF funds to implement the Federal Health Care Exchange program and provisions in the Medicare Access and Chip Reauthorization Act, as well as for cybersecurity enhancement and workflow management.

Administration for Community Living (ACL)

In FY 2021, ACL received $12 million in NEF funding to modernize their data systems to better serve both individuals and caregivers. ACL is also continuing to use NEF funds to enhance their grants reporting system, which has allowed for more consistent grants management and oversight across the agency. Additionally, ACL plans to utilize NEF funding to update security controls and monitoring systems in accordance with updated HHS policy regarding system modernizations.

Health Resources and Services Administration (HRSA)

HRSA has received approximately $28 million from the NEF since FY 2013 and has used this funding to improve upon cybersecurity and IT infrastructure since FY 2016. One project that began in FY 2020 provided critical upgrades and enhancements to HRSA's security systems. In FY 2021, they received $3.7 million for three projects that will reengineer database architecture, modernize financial management capabilities to increase data protection, accuracy, and efficiency, and build a more robust business intelligence system.

NEF Notifications and Reductions from 2013-2021 (dollars in thousands)		
Fiscal Year	Notifications and Congressional Allocations	Enacted Rescissions and Transfers Out
2013	$600,000	--
2014	$600,000	--
2015	$650,000	--
2016	$800,000	--
2017	$430,000	-$400,000
2018	--	-$240,000
2019	$600,000	-$400,000
2020	$743,000	-$350,000
2021	$525,000	-$375,000
TOTAL	**$4,948,000**	**-$1,765,000**

[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 July 20, 2020.
[3] Notification submitted to the Committees on Appropriations in the House of Representatives and the Senate on October 22, 2020.
[4]The projects described below are the current list of approved projects through FY 2021. Additional projects may be funded from the FY 2021 notification letter upon approval from OMB.
[5] HHS has not notified Congress for FY 2022.

Service and Supply Fund

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SERVICE AND SUPPLY FUND

(Dollars in Thousands)

SSF	FY 2020 Actual	FY 2021 Board Approved	FY 2022 Board Approved	FY 2022 +/- FY 2021
BA	$1,000,571	$1,526,009	$1,302,598	-$223,411
FTE	963	1,375	1,395	+20

Authorizing Legislation: 42 USC §231
2022 Authorization……Indefinite
Allocation Method ……Contract, Other

Statement of the Budget

The overall FY 2022 current request for the Service and Supply Fund (SSF) is $1,302,598 which is $223,410 below the FY 2021 approved budget. 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) and the Office of the Secretary. 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 FY 2022 SSF activities are described below.

Program Support Center

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.

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.

Financial Management Portfolio (FMP):
The PSC Financial Management Portfolio (FMP) serves as a major foundation of the Department's finance and accounting through: 1) the administration of grant payment management services; 2) accounting and fiscal services; 3) rate review/negotiation/approval 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.

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 percent of FOH's services are provided to Federal agencies outside of HHS.

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 including, but not limited to Real Property Management, Building Operations Services, Physical Security and Emergency Management, and Mail and Publishing Services.

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.

Immediate of the Secretary (IOS)

The Immediate Office of the Secretary is responsible for operations and coordination of the work of the Secretary.

Office of the Chief Technology Officer (OCTO)

The Office of the CTO harnesses the power of data, technology, and innovation to create a more modern and effective government that works to improve the health of the nation.

Healthdata.gov:

In support of the requirements in the Open, Permanent, Electronic, and Necessary (OPEN) Government Data Act1, HealthData.gov is a web-based application that provides easier access and increased data analytics capabilities for public access. Specifically, the OPEN Act "…requires open government data assets made available by federal agencies (excluding the Government Accountability Office, the Federal Election Commission, and certain other government entities) to be published as machine-readable data." Over 4,500 publicly available data sets are housed today fueling innovation, solutions and ideas to uncover new insights, and open data-driven approaches to solve the nation's health problems and enhance outcomes. This is the public facing complement to the HHS Data Insights Initiative (DII) for non-sensitive, open data availability, run by the HHS Office of the Chief Technology Officer (OCTO), which focuses on facilitating internal and external data sharing.

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):
The HPO/CSM group is located organizationally within the Office of Business Management and Transformation. The HPO/CSM supports approximately 60 HHS OpDivs, StaffDivs, and other FAIR Act Inventory reporting organizations. 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. In response to the National Security Presidential Directive (NSPD) 54 and Homeland Security Presidential Directive (HSPD) 23, OCIO partners with OPDIVs at HHS to provide the Trusted Internet Connection (TIC) for all of HHS.

The OCIO provides information technology services for the development, configuration, and integration of multiple systems for HHS and the Office of the Secretary. In addition, OCIO supports the following activities for HHS: Enterprise Strategy & Governance, Vendor Management, Investment Portfolio Management and Control, and Enterprise Architecture. OCIO is organized into five offices: Office of the Chief Product Officer (OCPO), Office of Information Security (OIS), Office of Information Technology Acquisition Management (ITAM), Office of Operations (Ops), and Office of Enterprise Services (OES).

Office of the Chief Product Officer (OCPO):
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 (OPS):

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 (OES):

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.

Office of Information Technology Acquisition Management (ITAM):

To meet the four main Cross Agency Priority (CAP) goals of the President's Management Agenda and to standardize technology across the enterprise that promotes greater collaboration and unified communications we have established the Office of Information Technology Acquisition Management (ITAM) encompassing Enterprise Infrastructure Solutions (EIS). The EIS Program Management Office (PMO) will support the Department's acquisition, transition, and contract administration activities through a centralized model to reduce operational costs and improve HHS spending, while modernizing IT.

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

EEODI 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, EEODI 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. EEODI also administers the ADR program to manage conflict and prevent and resolve disputes through mediation, conflict coaching, group facilitation, and assessments. Additionally, EEODI manages the Reasonable Accommodation program for DHHS which is funded through Inter-Agency Agreements.

National Labor Relations Office (NLRO)

The labor/management relationship is the foundation to a positive and healthy work environment for all employees. In order to ensure that the agency is acting as a single voice in its interactions with the 21 unions currently at U.S. Department of Health and Human Services (HHS), the Office of the Assistant Secretary of Administration (ASA) implemented a coordinated Labor Relations approach. In short, centralized planning and strategizing and decentralized implementation. This allows the agency to maximize and leverage its resources, tools, and experience, while still allowing for OpDivs to maintain their individuality and balance their organization's specific needs. In order to reassert management's rights consistently throughout the agency a coordinated, single voice is necessary. For example, we have many AFGE local bargaining units throughout the various OpDivs. Previously each OpDiv managed those relationships without the benefit of agency guidance or knowledge of how other OpDivs were interacting with a different AFGE local. Thus, resulting in HHS being inconsistent in its approach and less effective in managing the overall HHS labor/management relationship. The AFGE locals are getting their information and direction from a single source and are treating HHS as a single entity, the establishment of NRLO allows HHS to respond in kind and treat all of the AFGE locals as a single entity.

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.

Office of Human Resources (OHR):

OHR 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.

Office of National Security

The Office of National Security (ONS) was established in 2007, and in 2012 was designated by the Secretary of Health and Human Services (HHS) and the Director of National Intelligence (DNI) as the Department's Federal Intelligence Coordinating Office (FICO). In this capacity, ONS is the HHS point of contact for the Intelligence Community (IC), and is responsible for coordination with the IC and for intelligence support to HHS senior policy makers and consumers of intelligence across the Department. Additionally, ONS is responsible for safeguarding classified national security information across the Department and for the appropriate sharing of intelligence, homeland security and law enforcement information externally and, internally within HHS, among the Operating and Staff Divisions. ONS is headed by the National Security Advisor to the Secretary, who reports directly to the HHS Deputy Secretary.

National Security Case Management (NSA):
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: 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):
The Office of Program Audit Coordination (OPAC) serves as the central point of contact for coordinating program audit support through payment accuracy and audit resolution activities across the Department. OPAC, located in the Office of the Secretary/ Assistant Secretary for Financial Resources/Office of Finance, is organized into three Divisions: (1) Audit Resolution Division (ARD), (2) Audit Tracking and Analysis Division (ATAD), and (3) Division of Payment Integrity Improvement (DPII).

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 supports the acquisition related mission needs of the Department, providing tools to ensure 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.

Acquisition Reform Workforce Program:

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. The HHS Acquisition Reform Workforce program which is located in the Office of the Acquisitions is responsible for every aspect of the HHS Acquisition Workforce Program – Federal Certification Management.

Category Management (CM):

Category Management (CM) is a President's Management Agenda-mandated initiative within the purview of the Assistant Secretary for Financial Resources (ASFR). It executes a long-term vision for creating a more modern and responsive Government – one that prioritizes mission outcomes, service delivery, and effective stewardship. Through this initiative, the Government, as a single buyer, has taken advantage of CM principles and reaped the benefits by aggregating volumes of commonly purchases goods and services to achieve best in class pricing, reduce duplications, and leverage shared solutions.

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):

The Department of Health and Human Services' (HHS) Office of Small and Disadvantaged Business Utilization (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. Organizationally, OSDBU is administratively supported by the Office of Acquisition, but reports directly to the Deputy Secretary of HHS. 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.

Division of Workforce Development (DWD):

Division of Workforce Development (DWD), provides career development, training, and oversight support to the HHS grants management community. The customers for the DWD are the grant-making HHS OpDivs and StaffDivs. The DWD will create and offer meaningful career development courses and promote a highly talented grants management workforce at HHS benefiting the customers and their recipient stakeholders. The intent is to design and implement a robust training program that provides comprehensive training and promotes common core competencies and transferable skills across HHS. DWD has collaborated with the ReInvent Grants Management (RGM) initiative as part of the ReImagine

HHS transformation effort established under OMB Memorandum M-17-22 forming a partnership to leverage their Departmental and government-wide research completed over the last year to implement their training recommendations.

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. The Grants.gov program manages the Grants.gov system including associated operations, maintenance, enhancement, user support, and stakeholder communications. Since inception, Grants.gov has consistently met its statutory obligation to transform the federal grants environment by streamlining and standardizing public-facing grant processes, simplifying and improving those processes for both grantees and grantors, and eliminating redundancies. Grants.gov empowers Federal awarding agencies to improve the visibility and reach of their grant programs, process standardization, and cost savings.

GrantSolutions:

The GrantSolutions (GS), a member of the Service and Supply Fund since FY15. GS is a partnership among HHS and other federal agencies and is responsible for delivering end-to-end grants management services to more than fifeteen hundred national programs to award, monitor, and financially report on grants to states, tribes, territories, and other non-profit organizations. GS provides services such as Onboarding/Migration, Pre-Award, Award and Post Award to Agency Grants Management and Program Offices. Through economies of scale, GS has reduced grants technology costs for partners by 20 to 75 percent. GS makes grants administration easier and more cost effective through electronic reporting and providing e-business information services for grantees.
additional or reduced services.

Tracking Accountability in Government Grants System (TAGGS):

The Assistant Secretary for Financial Resources (ASFR), Office of Grants (OG), Division of Systems (DS), directs and coordinates the activities of the Department with respect to the implementation of all electronic grants initiatives. One of these initiatives is HHS' Tracking Accountability in Government Grants Systems (TAGGS).

Since its 1995 inception, TAGGS is the single repository of financial assistance award data for all HHS Operating Divisions (OPDIVs) and Staff Divisions (STAFFDIVs). Currently, TAGGS houses HHS' grant-award data for $1.7 million in distinct awards and over $7 trillion covering the HHS' grants portfolio. Beginning in 2012, TAGGS started to collect additional types of financial assistance data to include Medicare, loans, and loan repayments totaling an additional $4.2 trillion.

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 Digital) mission is to deliver instant and impactful communications through ASPA managed digital communications channels. In addition, ASPA Digital is leading a department-wide process to implement the HHS Digital Communications Strategy that supports the Secretary's vision of a future where our programs and America's healthcare, human services, and public health systems work better for the people we serve.

Freedom of Information Act (FOIA):
The Freedom of Information Act (FOIA) is a federal statute that allows individuals to request access to federal agency records, except to the extent records are claimed as exempt from disclosure under one or more of the nine exemptions of the 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 FOIA 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 seven Public Health Service (PHS) OPDIVs: AHRQ, Centers for Disease Control (CDC)/Agency for Toxic Substances and Disease Registry (ATSDR), 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. The videos produced by the Broadcast Studio are shared with stakeholders, Congress, and the general public directly and via social media channels such as YouTube, Facebook, Twitter and Instagram.

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 list of services offered includes: two daily media coverage briefings, executive briefing by 6AM, full briefing by 7:30AM (20-30 pages), proprietary search engines, and supplemental OpDiv-specific briefings.

Service and Supply Fund
All Purpose Table (APT)
(Dollars in Thousands)

Service and Supply Fund Activities	FY 2020 Actuals	FY 2021 Approved	FY 2022 Approved
PSC			
Acquisition Management Services	27,017	313,884	59,188
Financial Management Portfolio	50,958	49,838	50,731
Occupational Health Portfolio	125,047	150,401	152,953
Real Estate, Logistics and Operations Portfolio	241,042	350,955	311,379
PSC Subtotal	**444,064**	**865,078**	**574,251**
Non-PSC			
Acquisition Integration and Modernization	1,327	2,072	2,072
Acquisition Reform	1,533	2,225	2,247
Category Management	876	3,294	3,311
Commissioned Corps Force Management	23,739	30,333	31,046
Departmental Contract Information System	1,178	1,767	1,767
Departmental Ethics Program	4,202	4,576	4,602
Digital Communications	28,406	32,463	33,739
Digital Communications	85	2,939	3,393
Freedom of Information Act	1,120	2,019	2,354
Grants.gov	6,858	7,156	7,300
GrantSolutions	68,982	86,613	96,914
HHS Broadcast Studio	2,492	2,836	3,504
HHS Consolidated Acquisition Solution	8,960	10,227	10,227
Healthdata.gov 2	380	380	200
HPO & Commercial Services Management	258	344	346
Media Monitoring and Analysis	980	1,079	1,133
National Labor Relations	1,068	1,749	1,759
National Security Case Management	1,854	2,315	2,315
Office of the Chief Product Officer[1]	25,308	31,015	31,159
Office of Enterprise Services	14,931	16,794	17,331
Office of Equal Employment Opportunity, Diversity & Inclusion	4,556	8,284	8,317
Office of the General Council Claims	1,877	2,049	2,064
Office of Human Resources	52,004	74,023	77,738
Office of Information Security	26,796	32,066	32,414
Office of Information Technology Acquisition Management	40,787	95,137	140,638
Office of Operations[2]	112,891	115,733	120,219

[1] Office of Chief Product Officer formerly OEAD
[2] Office of Operations formerly ITIO

Office of Program Audit Coordination	3,162	3,695	3,744
Small Business Center	3,538	3,983	3,983
Strategic Planning System	516	602	602
Tracking Accountability in Government Grants Sys	4,052	6,309	7,559
Unified Financial Management Systems	57,385	76,853	74,349
Non-PSC Subtotal	**502,101**	**660,931**	**728,345**
Reserves	54,406		
Total SSF Revenue	**1,000,571**	**1,526,009**	**1,302,598**

Service and Supply Fund
Object Classification Table – Reimbursable Obligations
(Dollars in Thousands)

Object Class	FY 2020 Actuals	FY 2021 Board Approved	FY 2022 Board Approved
Reimbursable Obligations			
Personnel Compensation:			
Full – Time Permanent (11.1)	110,734	177,657	183,073
Other Than Full – Time Permanent (11.3)	3,491	5,467	7,550
Other Personnel Compensation (11.5)	3,964	5,820	5,920
Military Personnel (11.7)	6,450	6,450	6,450
Special Personnel Services Payments (11.8)	11,459	15,376	15,345
Subtotal, Personnel Compensation	136,098	210,770	218,338
Civilian Personnel Benefits (12.1)	36,750	44,235	50,233
Military Personnel Benefits (12.2)	791	4,000	6,000
Benefits to Former Personnel (13.0)	348	100	-
Subtotal, Pay Costs	173,987	259,105	274,571
Travel (21.0)	618	2,345	2,167.00
Transportation of Things (22.0)	4,937	3,123	6,345
Rental Payments to GSA (23.1)	17,861	19,156	21,135
Rental Payments to Others (23.2)	-		
Communications, Utilities and Miscellaneous Charge (23.3)	59,965	60,000	60,000
Printing and Reproduction (24.0)	3,028	3,028	3,028
Other Contractual Services:			
Advisory and Assistance Services (25.1)	78,359	69,456	69,345
Other Services (25.2)	374,072	763,567	612,345
Purchases from Govt. Accounts (25.3)	126,130	166,234	93,456
Operation & Maintenance of Facilities (25.4)	10,409	15,345	15,456
Research & Development Contracts (25.5)	-		
Medical Services (25.6)	12,776	12,145	12,345
Operation & Maintenance of Equipment (25.7)	68,437	65,160	63,371
Subsistence& Support of Persons (25.8)	-		
Subtotal, Other Contractual Services	670,183	1,091,907	866,318
Supplies and Materials (26.0)	40,212	57,345	39,034
Equipment (31.0)	24,539	30,000	30,000
Grants (41.0)			
Other (32), (42), (61)	5,241		
Subtotal, Non – Pay Costs	826,584	1,266,904	1,028,027
Total, Reimbursable Obligations	**1,000,571**	**1,526,009**	**1,302,598**

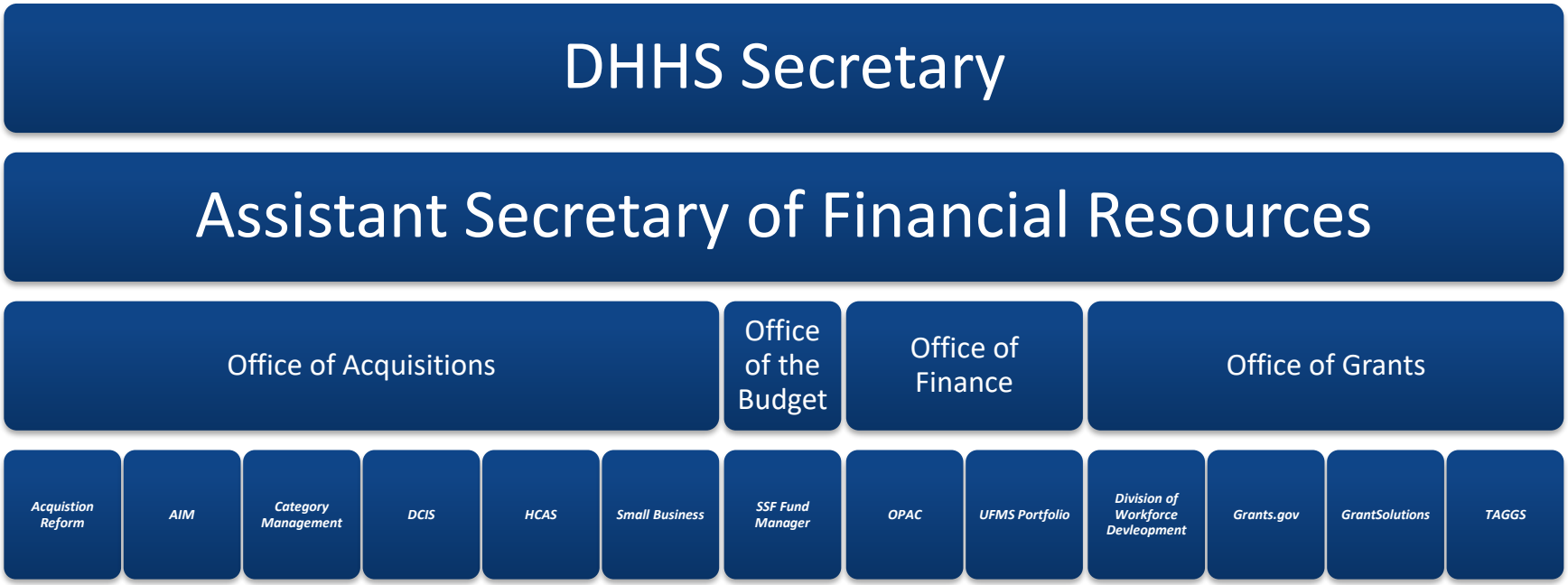
Service and Supply Fund
Assistant Secretary for Administration
Organizational Chart

Acronym Key:
HPO & CMS – High Performing Organizations and Commercial Services Management
ITAM – Office of IT Acquisition Management
OEEODI – Office of Equal Employment Opportunity, Diversity and Inclusion
OCPO – Office of Chief Product Officer
OES – Office of Enterprise Services
OIS – Office of Information Security
OPS – Office of Operations

SSF Activities are italicized

Service and Supply Fund

Non–PSC Activities
Organizational Chart

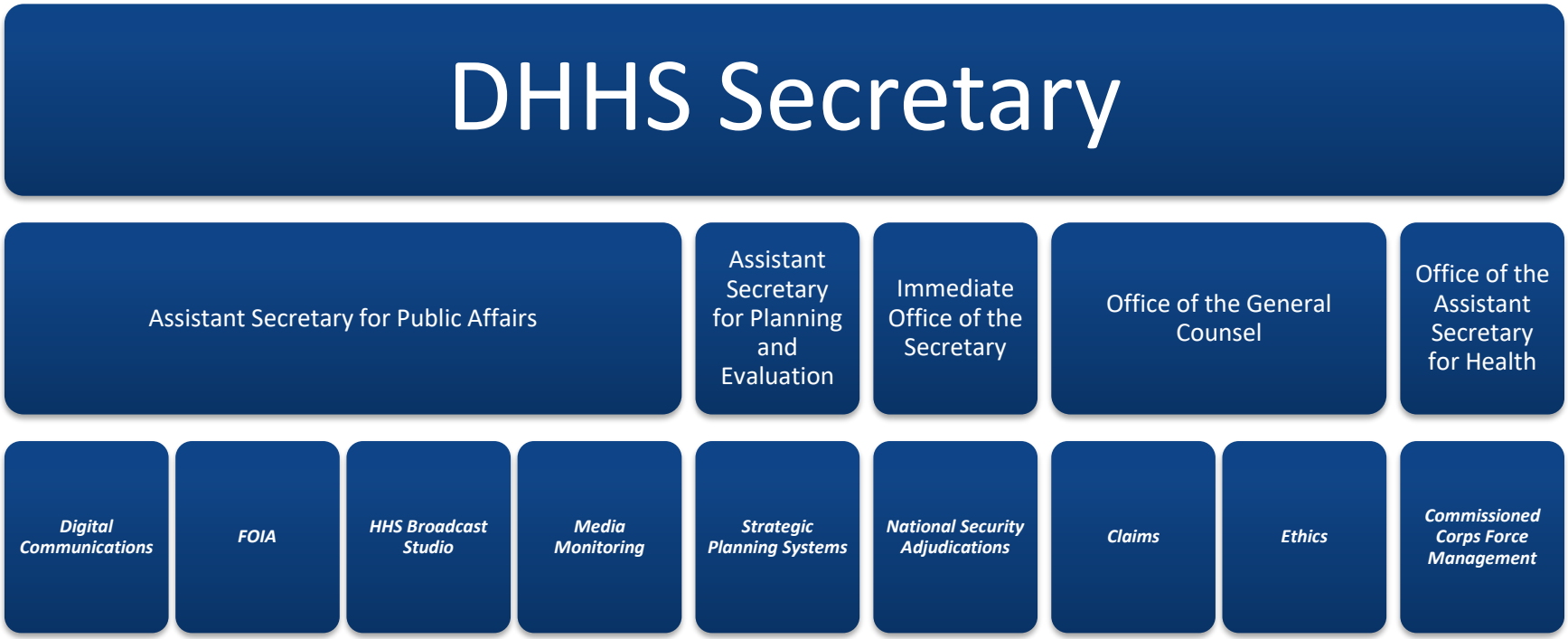


Acronym Key:
AIM – Acquisition Integration and Modernization
DCIS – Departmental Contracts Information System
HCAS – HHS Consolidated Acquisition Solution
OPAC – Office of Program Audit Coordination
TAGGS – Tracking Accountability in Government Grants System
UFMS – Unified Financial Management System

SSF Activities are italicized

Service and Supply Fund

Non-PSC Activities (cont'd)
Organizational Chart



Acronym Key:

FOIA – Freedom of Information Act

SSF Activities are italicized

Service and Supply Fund

Program Support Center (PSC)
Organizational Chart

Retirement Pay & Medical Benefits for Commissioned Officers

RETIREMENT PAY AND MEDICAL BENEFITS FOR COMMISSIONED OFFICERS

	FY 2020	FY 2021 (revised)	FY 2022	FY 2022 +/-FY 2021
Retirement Payments	$511,184,589	$528,449,037	$550,013,086	$21,564,049
Survivor's Benefits	31,629,860	32,262,711	32,908,921	646,210
Medical Care Benefits	99,768,610	95,790,295	90,355,905	-5,434,390
Subtotal	$642,583,059	$656,502,043	$673,277,912	$16,775,869
Accrued Health Care Benefits	$29,112,300	$30,542,700	$35,018,160[1]	4,475,460
Total	**$671,695,359**	**$687,044,743**	**$708,296,072**	**$21,251,329**

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 2022 Authorization……Indefinite.

Rationale for Budget

This appropriation provides for retirement payments to Public Health Service (PHS) Commissioned Corps officers to include active duty and reserve 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 PHS officers 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 DoD Medicare-Eligible Retiree Healthcare Fund for the accrued costs of health care for beneficiaries over the age of 65.

The Accrual Health Care amount is an estimate provided by DoD Office of the Actuary. The PHS FY2021 per capita is $4,911 (full-time members) and $1,952 (part-time members). The PHS FY2022 per capita is $5,506 (full-time members) and $2,138 (part-time members). When multiplied by the FY2021 estimated number of active duty positions of 6,100 and 300 reserve officers, this yields a total budget of $30,542,700. When multiplied by the FY2022 estimated number of active duty positions of 6,360 and 700 reserve officers, this yields a total budget of $36,514,760.

The FY 2021 revised level reflects an amended active duty count to 6,100 and the addition of 300 reserve officers. The FY 2022 estimate is a net increase of $22,417,569 over the FY 2021 revised level. This request reflects decreased costs in medical benefits, an annualization of amounts paid to retirees and survivors in FY 2021, a net increase in the number of retirees and survivors, and increase of the reserves during FY 2022.

[1] FY22 estimate for Accrued Healthcare Benefits does not include related expenses for reserve officers estimated to be 700 in FY22. Total FY22 estimate including reserve officers is $36,514,760 as noted in narrative.

	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Retirement Payments	$572,457,085	$595,816,939	$620,130,023	$644,935,224	$670,732,633
Survivor's Benefits	33,568,073	34,240,429	34,926,251	35,624,776	36,337,272
Medical Care Benefits	90,355,905	90,355,905	90,355,905	90,355,905	90,355,905
Subtotal	$696,381,063	$720,413,273	$745,412,179	$770,915,905	$797,425,809
Accrued Health Care Benefits	37,894,800	40,032,800	41,233,784	42,470,798	43,744,921
Total	**$734,275,863**	**$760,446,073**	**$786,645,963**	**$813,386,702**	**$841,170,731**

HHS General Provisions

GENERAL PROVISIONS

Title II 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**]** *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 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 **[**2021**]** *2022* 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 **[**2021**]** *2022*:

(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 to 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 Research 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 2022 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 2022 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 2022. 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, 2023, 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 for opioid addiction, opioid alternatives, stimulant misuse and addiction, pain management, and addiction treatment to other 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,* 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 the 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**]***221*. 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 non-compliance 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**]***222*. 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**]***223*. 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**]***224*. 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 fiscal year 2021 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 purposes in this, prior, or subsequent fiscal years, shall be available during the period of availability of the Fund for the study of, construction of, demolition of, renovation of, and acquisition of equipment for, facilities of or used by the National Institutes of Health, including the acquisition of real property.**]**

SEC. **[**238**]***225*. Of the unobligated balances in the "Nonrecurring Expenses Fund" established in section 223 of division G of Public Law 110–161, **[**$375,000,000**]** *$500,000,000* are hereby **[**rescinded**]** *permanently cancelled* not later than September 30, 2021.

[SEC. 239. (a) The Chamblee Research Support Building (Building 108) at the Centers for Disease Control and Prevention is hereby renamed as the Johnny Isakson Public Health Research Building.
(b) Section 238 of division A of the Further Consolidated Appropriations Act, 2020 (Public Law 116–94) is amended by inserting "during the period of availability of the Fund" after "shall be available" and by inserting "moving expenses," after "renovation of facilities,".**]**

SEC. 226. For purposes of any transfer to appropriations under the heading "Department of Health and Human Services—Office of the Secretary—Public Health and Social Services Emergency Fund", section 204 of this Act shall be applied by substituting "10 percent" for "3 percent".

SEC. 227. The Secretary of Health and Human Services (Secretary) is authorized to provide, from funds made available in this title for such purposes, mental health and other supportive services, including through grants, contracts, or cooperative agreements, for children, parents, and legal guardians who were separated at the United States-Mexico border between January 20, 2017, and January 20, 2021, in connection with the Zero-Tolerance Policy (as discussed in the Attorney General's memorandum of April 6, 2018, entitled "Zero-Tolerance for Offenses Under 8 U.S.C. 1325(a)") and any other United States Government practice, policy, program, or initiative that resulted in the separation of children who arrived at the United States-Mexico border with their parents or legal guardians during such period. The Secretary may identify the individuals eligible to receive such mental health and other supportive services under this section through reference to the identified members of the classes, and their minor children, in the class-action lawsuits Ms. J.P. v. Barr and Ms. L. v. ICE.

SEC. 228. For fiscal year 2022, 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. 229. (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 the services provided.*

(d) *LIMITATIONS ON FUNDS. A condition or limitation applicable to amounts for grants 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-to services.*

(f) *NO EFFECT ON OTHER LAWS. This section does not affect other laws concerning reimbursable agreements.*

SEC. 230. (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. 231. The unobligated balances of amounts appropriated or transferred to the Centers for Disease Control and Prevention under the heading "Buildings and Facilities" in title II of division H of the Consolidated Appropriations Act, 2018 (Public Law 115–141) for a biosafety level 4 laboratory shall also be available for the acquisition of real property, equipment, construction, demolition, renovation of facilities, and installation expenses, including moving expenses, related to such laboratory: Provided, That no later than September 30, 2022, the remaining unobligated balances of such funds are hereby permanently cancelled, and an amount of additional new budget authority equivalent to the amount cancelled is hereby appropriated, to remain available until expended, for the same purposes as provided in this section, in addition to any other amounts available for such purposes.

SEC. 232. 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. 233. (a) *The Secretary may reserve not more than 0.25 percent from each appropriation made in this Act to the accounts of the Administration for 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. Funds reserved under this section may be transferred to the "Children and Families Services Programs" account for use by the Assistant Secretary for the Administration for Children and Families and shall remain available until expended: Provided, That funds reserved under this section shall not be available for obligation unless the Assistant Secretary submits a plan to the Committees on Appropriations of the House of Representatives and the Senate 15 days in advance of any such transfer describing the evaluations to be carried out.*

(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. 234. (a) *PREMIUM PAY AUTHORITY. If services performed by a Department of Health and Human Services employee during a public health emergency declared under section 319 of the Public Health Service Act are determined by the Secretary of Health and Human Services to be primarily related to preparation for, prevention of, or response to such public health emergency, any premium pay that is provided for such services shall be exempted from the aggregate of basic pay and premium pay calculated under section 5547(a) of title 5, United States Code, and any other provision of law limiting the aggregate amount of premium pay payable on a biweekly or calendar year basis.*

(b) *OVERTIME AUTHORITY. Any overtime that is provided for such services described in subsection (a) shall be exempted from any annual limit on the amount of overtime payable in a calendar or fiscal year.*

(c) *APPLICABILITY OF AGGREGATE LIMITATION ON PAY. In determining, for purposes of section 5307 of title 5, United States Code, whether an employee's total pay exceeds the annual rate payable under such section, the Secretary of Health and Human Services shall not include pay exempted under this section.*

(d) *LIMITATION OF PAY AUTHORITY. Pay exempted from otherwise applicable limits under subsection (a) shall not cause the aggregate pay earned for the calendar year in which the exempted pay is earned to exceed the rate of basic pay payable for a position at level II of the Executive Schedule under section 5313 of title 5, United States Code.*

(e) *DANGER PAY FOR SERVICE IN PUBLIC HEALTH EMERGENCIES. The Secretary of Health and Human Services may grant a danger pay allowance under section 5928 of title 5, United States Code, without regard to the conditions of the first sentence of such section, for work that is performed by a Department of Health and Human Services employee during a public health emergency declared under section 319 of the Public Health Service Act that the Secretary determines is primarily related to preparation for, prevention of, or response to such public health emergency and is performed under conditions that threaten physical harm or imminent danger to the health or well-being of the employee.*

(f) *EFFECTIVE DATE. This section shall take effect as if enacted on September 30, 2020.*

SEC. 235. 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 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. 236. Notwithstanding any other provision of law, the Secretary of Health and Human Services may use $7,981,000 of the amounts appropriated under the heading "Department of Health and Human Services—Office of the Secretary—General Departmental Management" to supplement funds otherwise available to the Secretary for the hire and purchase of electric vehicles and electric vehicle charging stations, and to cover other costs related to electrifying the motor vehicle fleet within HHS: Provided, That electric chargers installed in a parking area with such funds shall be deemed personal property under the control and custody of the component of the Department of Health and Human Services managing such parking area.

SEC. 237. Section 402A(d) of the Public Health Service Act (42 U.S.C. 282a(d)) is amended—
(1) in the first sentence by striking "under subsection (a)" and inserting "to carry out this title"; and
(2) in the second sentence by striking "account under subsection (a)(1)".

SEC. 238. The Secretary of Health and Human Services may waive penalties and administrative requirements in title XXVI of the Public Health Service Act for awards under such title from amounts provided under the heading "Department of Health and Human Services—Health Resources and Services Administration" in this or any other appropriations Act for this fiscal year, including amounts made available to such heading by transfer.

Title V General Provisions

SEC. 501. The Secretaries of Labor, Health and Human Services, and Education are authorized to transfer unexpended balances of prior appropriations to accounts corresponding to current appropriations provided in this Act. Such transferred balances shall be used for the same purpose, and for the same periods of time, for which they were originally appropriated.

SEC. 502. No part of any appropriation contained in this Act shall remain available for obligation beyond the current fiscal year unless expressly so provided herein.

SEC. 503. (a) No part of any appropriation contained in this Act or transferred pursuant to section 4002 of Public Law 111–148 shall be used, other than for normal and recognized executive-legislative relationships, for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, electronic communication, radio, television, or video presentation designed to support or defeat the enactment of legislation before the Congress or any State or local legislature or legislative body, except in presentation to the Congress or any State or local legislature itself, or designed to support or defeat any proposed or pending regulation, administrative action, or order issued by the executive branch of any State or local government, except in presentation to the executive branch of any State or local government itself.

(b) No part of any appropriation contained in this Act or transferred pursuant to section 4002 of Public Law 111–148 shall be used to pay the salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence the enactment of legislation, appropriations, regulation, administrative action, or Executive order proposed or pending before the Congress or any State government, State legislature or local legislature or legislative body, other than for normal and recognized executive-legislative *and State-local* relationships *for presentation to any State or local legislature or legislative body itself,* or participation by an agency or officer of a State, local or tribal government in policymaking and administrative processes within the executive branch of that government.

(c) The prohibitions in subsections (a) and (b) shall include any activity to advocate or promote any proposed, pending or future Federal, State or local tax increase, or any proposed, pending, or future requirement or restriction on any legal consumer product, including its sale or marketing, including but not limited to the advocacy or promotion of gun control.

SEC. 504. The Secretaries of Labor and Education are authorized to make available not to exceed $28,000 and $20,000, respectively, from funds available for salaries and expenses under titles I and III,

respectively, for official reception and representation expenses; the Director of the Federal Mediation and Conciliation Service is authorized to make available for official reception and representation expenses not to exceed $5,000 from the funds available for "Federal Mediation and Conciliation Service, Salaries and Expenses"; and the Chairman of the National Mediation Board is authorized to make available for official reception and representation expenses not to exceed $5,000 from funds available for "National Mediation Board, Salaries and Expenses".

SEC. 505. When issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money, all grantees receiving Federal funds included in this Act, including but not limited to State and local governments and recipients of Federal research grants, shall clearly state—

(1) the percentage of the total costs of the program or project which will be financed with Federal money;

(2) the dollar amount of Federal funds for the project or program; and

(3) percentage and dollar amount of the total costs of the project or program that will be financed by non-governmental sources.

[SEC. 506. (a) None of the funds appropriated in this Act, and none of the funds in any trust fund to which funds are appropriated in this Act, shall be expended for any abortion.

(b) None of the funds appropriated in this Act, and none of the funds in any trust fund to which funds are appropriated in this Act, shall be expended for health benefits coverage that includes coverage of abortion.

(c) The term "health benefits coverage" means the package of services covered by a managed care provider or organization pursuant to a contract or other arrangement.**]**

SEC. **[**507**]***506*. **[**(a) The limitations established in the preceding section shall not apply to an abortion—
(1) if the pregnancy is the result of an act of rape or incest; or
(2) in the case where a woman suffers from a physical disorder, physical injury, or physical illness, including a life-endangering physical condition caused by or arising from the pregnancy itself, that would, as certified by a physician, place the woman in danger of death unless an abortion is performed.**]**

[(b) Nothing in the preceding section shall be construed as prohibiting the expenditure by a State, locality, entity, or private person of State, local, or private funds (other than a State's or locality's contribution of Medicaid matching funds).**]**

[(c) Nothing in the preceding section shall be construed as restricting the ability of any managed care provider from offering abortion coverage or the ability of a State or locality to contract separately with such a provider for such coverage with State funds (other than a State's or locality's contribution of Medicaid matching funds).**]**

[(d)**] [**(1)**]** None of the funds made available in this Act may be made available to a Federal agency or program, or to a State or local government, if such agency, program, or government subjects any

institutional or individual health care entity to discrimination on the basis that the health care entity does not provide, pay for, provide coverage of, or refer for abortions.

[(2)**]** In this **[**subsection**]** *section*, the term "health care entity" includes an individual physician or other health care professional, a hospital, a provider-sponsored organization, a health maintenance organization, a health insurance plan, or any other kind of health care facility, organization, or plan.

SEC. **[**508**]***507*. (a) None of the funds made available in this Act may be used for—

(1) the creation of a human embryo or embryos for research purposes; or (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.204(b) and section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)).

(b) For purposes of this section, the term "human embryo or embryos" includes any organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.

SEC. **[**509**]***508*. (a) None of the funds made available in this Act may be used for any activity that promotes the legalization of any drug or other substance included in schedule I of the schedules of controlled substances established under section 202 of the Controlled Substances Act except for normal and recognized executive-congressional communications.

(b) The limitation in subsection (a) shall not apply when there is significant medical evidence of a therapeutic advantage to the use of such drug or other substance or that federally sponsored clinical trials are being conducted to determine therapeutic advantage.

SEC. **[**510**]***509*. None of the funds made available in this Act may be used to promulgate or adopt any final standard under section 1173(b) of the Social Security Act providing for, or providing for the assignment of, a unique health identifier for an individual (except in an individual's capacity as an employer or a health care provider), until legislation is enacted specifically approving the standard.

SEC. **[**511**]***510*. None of the funds made available in this Act may be obligated or expended to enter into or renew a contract with an entity if—
(1) such entity is otherwise a contractor with the United States and is subject to the requirement in 38 U.S.C. 4212(d) regarding submission of an annual report to the Secretary of Labor concerning employment of certain veterans; and
(2) such entity has not submitted a report as required by that section for the most recent year for which such requirement was applicable to such entity.

[SEC. 512. None of the funds made available in this Act may be transferred to any department, agency, or instrumentality of the United States Government, except pursuant to a transfer made by, or transfer authority provided in, this Act or any other appropriation Act. **]**

SEC. **[**513**]***511*. None of the funds made available by this Act to carry out the Library Services and Technology Act may be made available to any library covered by paragraph (1) of section 224(f) of such

Act, as amended by the Children's Internet Protection Act, unless such library has made the certifications required by paragraph (4) of such section.

[SEC. 514. (a) None of the funds provided under this Act, or provided under previous appropriations Acts to the agencies funded by this Act that remain available for obligation or expenditure in fiscal year 2021, or provided from any accounts in the Treasury of the United States derived by the collection of fees available to the agencies funded by this Act, shall be available for obligation or expenditure through a reprogramming of funds that—

(1) creates new programs;
(2) eliminates a program, project, or activity;
(3) increases funds or personnel by any means for any project or activity for which funds have been denied or restricted;
(4) relocates an office or employees;
(5) reorganizes or renames offices;
(6) reorganizes programs or activities; or
(7) contracts out or privatizes any functions or activities presently performed by Federal employees;

unless the Committees on Appropriations of the House of Representatives and the Senate are consulted 15 days in advance of such reprogramming or of an announcement of intent relating to such reprogramming, whichever occurs earlier, and are notified in writing 10 days in advance of such reprogramming.

(b) None of the funds provided under this Act, or provided under previous appropriations Acts to the agencies funded by this Act that remain available for obligation or expenditure in fiscal year 2021, or provided from any accounts in the Treasury of the United States derived by the collection of fees available to the agencies funded by this Act, shall be available for obligation or expenditure through a reprogramming of funds in excess of $500,000 or 10 percent, whichever is less, that—

(1) augments existing programs, projects (including construction projects), or activities;
(2) reduces by 10 percent funding for any existing program, project, or activity, or numbers of personnel by 10 percent as approved by Congress; or
(3) results from any general savings from a reduction in personnel which would result in a change in existing programs, activities, or projects as approved by Congress; unless the Committees on Appropriations of the House of Representatives and the Senate are consulted 15 days in advance of such reprogramming or of an announcement of intent relating to such reprogramming, whichever occurs earlier, and are notified in writing 10 days in advance of such reprogramming.**]**

SEC. **[**515**]***512*. (a) None of the funds made available in this Act may be used to request that a candidate for appointment to a Federal scientific advisory committee disclose the political affiliation or voting history of the candidate or the position that the candidate holds with respect to political issues not directly related to and necessary for the work of the committee involved.

(b) None of the funds made available in this Act may be used to disseminate information that is deliberately false or misleading.

[SEC. 516. Within 45 days of enactment of this Act, each department and related agency funded through this Act shall submit an operating plan that details at the program, project, and activity level any funding

allocations for fiscal year 2021 that are different than those specified in this Act, the explanatory statement described in section 4 (in the matter preceding division A of this consolidated Act), or the fiscal year 2021 budget request. **]**

[SEC. 517. The Secretaries of Labor, Health and Human Services, and Education shall each prepare and submit to the Committees on Appropriations of the House of Representatives and the Senate a report on the number and amount of contracts, grants, and cooperative agreements exceeding $500,000, individually or in total for a particular project, activity, or programmatic initiative, in value and awarded by the Department on a non-competitive basis during each quarter of fiscal year 2021, but not to include grants awarded on a formula basis or directed by law. Such report shall include the name of the contractor or grantee, the amount of funding, the governmental purpose, including a justification for issuing the award on a non-competitive basis. Such report shall be transmitted to the Committees within 30 days after the end of the quarter for which the report is submitted.**]**

SEC. **[**518**]***513*. None of the funds appropriated in this Act shall be expended or obligated by the Commissioner of Social Security, for purposes of administering Social Security benefit payments under title II of the Social Security Act, to process any claim for credit for a quarter of coverage based on work performed under a social security account number that is not the claimant's number and the performance of such work under such number has formed the basis for a conviction of the claimant of a violation of section 208(a)(6) or (7) of the Social Security Act.

SEC. **[**519**]***514*. None of the funds appropriated by this Act may be used by the Commissioner of Social Security or the Social Security Administration to pay the compensation of employees of the Social Security Administration to administer Social Security benefit payments, under any agreement between the United States and Mexico establishing totalization arrangements between the social security system established by title II of the Social Security Act and the social security system of Mexico, which would not otherwise be payable but for such agreement.

SEC. **[**520**]***515*. (a) None of the funds made available in this Act may be used to maintain or establish a computer network unless such network blocks the viewing, downloading, and exchanging of pornography.

(b) Nothing in subsection (a) shall limit the use of funds necessary for any Federal, State, tribal, or local law enforcement agency or any other entity carrying out criminal investigations, prosecution, or adjudication activities.

SEC. **[**521**]***516*. None of the funds made available under this or any other Act, or any prior Appropriations Act, may be provided to the Association of Community Organizations for Reform Now (ACORN), or any of its affiliates, subsidiaries, allied organizations, or successors.

[SEC. 522. For purposes of carrying out Executive Order 13589, Office of Management and Budget Memorandum M-12–12 dated May 11, 2012, and requirements contained in the annual appropriations bills relating to conference attendance and expenditures:
(1) the operating divisions of HHS shall be considered independent agencies; and
(2) attendance at and support for scientific conferences shall be tabulated separately from and not included in agency totals.**]**

[SEC. 523. Federal agencies funded under this Act shall clearly state within the text, audio, or video used for advertising or educational purposes, including emails or Internet postings, that the communication is printed, published, or produced and disseminated at U.S. taxpayer expense. The funds used by a Federal agency to carry out this requirement shall be derived from amounts made available to the agency for advertising or other communications regarding the programs and activities of the agency.**]**

SEC. **[**524**]***517*. (a) Federal agencies may use Federal discretionary funds that are made available in this Act to carry out up to 10 Performance Partnership Pilots. Such Pilots shall be governed by the provisions of section 526 of division H of Public Law 113–76, except that in carrying out such Pilots section 526 shall be applied by substituting "Fiscal Year **[**2021**]** *2022*" for "Fiscal Year 2014" in the title of subsection (b) and by substituting "September 30, **[**2025**]** *2026*" for "September 30, 2018" each place it appears: *Provided*, That such pilots shall include communities that have **[**experienced civil unrest**]** *been disproportionately impacted by the COVID-19 pandemic*.

(b) In addition, Federal agencies may use Federal discretionary funds that are made available in this Act to participate in Performance Partnership Pilots that are being carried out pursuant to the authority provided by section 526 of division H of Public Law 113–76, section 524 of division G of Public Law 113–235, section 525 of division H of Public Law 114–113, section 525 of division H of Public Law 115–31, section 525 of division H of Public Law 115–141, and section 524 of division A of Public Law 116–94.

(c) Pilot sites selected under authorities in this Act and prior appropriations Acts may be granted by relevant agencies up to an additional 5 years to operate under such authorities.

[SEC. 525. Not later than 30 days after the end of each calendar quarter, beginning with the first month of fiscal year 2021 the Departments of Labor, Health and Human Services and Education and the Social Security Administration shall provide the Committees on Appropriations of the House of Representatives and Senate a report on the status of balances of appropriations: *Provided*, That for balances that are unobligated and uncommitted, committed, and obligated but unexpended, the monthly reports shall separately identify the amounts attributable to each source year of appropriation (beginning with fiscal year 2012, or, to the extent feasible, earlier fiscal years) from which balances were derived. **]**

[SEC. 526. The Departments of Labor, Health and Human Services, or Education shall provide to the Committees on Appropriations of the House of Representatives and the Senate a comprehensive list of any new or competitive grant award notifications, including supplements, issued at the discretion of such Departments not less than 3 full business days before any entity selected to receive a grant award is announced by the Department or its offices (other than emergency response grants at any time of the year or for grant awards made during the last 10 business days of the fiscal year, or if applicable, of the program year).**]**

[SEC. 527. Notwithstanding any other provision of this Act, no funds appropriated in this Act shall be used to purchase sterile needles or syringes for the hypodermic injection of any illegal drug: *Provided*, That such limitation does not apply to the use of funds for elements of a program other than making such purchases if the relevant State or local health department, in consultation with the Centers for Disease Control and Prevention, determines that the State or local jurisdiction, as applicable, is experiencing, or is at risk for, a significant increase in hepatitis infections or an HIV outbreak due to injection drug use, and such program is operating in accordance with State and local law.**]**

[SEC. 528. Each department and related agency funded through this Act shall provide answers to questions submitted for the record by members of the Committee within 45 business days after receipt.**]**

SEC. **[**529**]***518*. Of the unobligated balances made available by section 301(b)(3) of Public Law 114–10, **[**$2,000,000,000**]** *$5,185,000,000* are hereby **[**rescinded**]** *cancelled*.

[SEC. 530. Of any available amounts appropriated under section 2104(a)(24) of the Social Security Act (42 U.S.C. 1397dd) that are unobligated as of September 25, 2021, $1,000,000,000 are hereby rescinded as of such date.**]**

[SEC. 531. Of the unobligated balances made available for purposes of carrying out section 2105(a)(3) of the Social Security Act, $4,000,000,000 shall not be available for obligation in this fiscal year.**]**

SEC. **[**532**]***519*. Of amounts deposited in the Child Enrollment Contingency Fund under section 2104(n)(2) of the Social Security Act and the income derived from investment of those funds pursuant to section 2104(n)(2)(C) of that Act, **[**$14,000,000,000**]** *$19,001,520,000* shall not be available for obligation in this fiscal year.

[SEC. 533. For an additional amount for "Department of Health and Human Services—Administration for Children and Families—Children and Families Services Programs", $638,000,000, to prevent, prepare for, and respond to coronavirus, for necessary expenses for grants to carry out a Low-Income Household Drinking Water and Wastewater Emergency Assistance Program: *Provided*, That the Secretary of Health and Human Services shall make grants to States and Indian Tribes to assist low-income households, particularly those with the lowest incomes, that pay a high proportion of household income for drinking water and wastewater services, by providing funds to owners or operators of public water systems or treatment works to reduce arrearages of and rates charged to such households for such services: *Provided further*, That in carrying out this appropriation, the Secretary, States, and Indian Tribes, as applicable, shall, as appropriate and to the extent practicable, use existing processes, procedures, policies, and systems in place to provide assistance to low-income households, including by using existing programs and program announcements, application and approval processes: *Provided further*, That the Secretary shall allot amounts appropriated in this section to a State or Indian Tribe based on the following (i) the percentage of households in the State, or under the jurisdiction of the Indian Tribe, with income equal to or less than 150 percent of the Federal poverty line, and (ii) the percentage of such households in the State, or under the jurisdiction of the Indian Tribe, that spend more than 30 percent of monthly income on housing: *Provided further*, That up to 3 percent of the amount appropriated in this section shall be reserved for Indian Tribes and tribal organizations: *Provided further*, That such amount is designated by the Congress as being for an emergency requirement pursuant to section 251(b)(2)(A)(i) of the Balanced Budget and Emergency Deficit Control Act of 1985.**]**

SEC. 520. Of the unobligated balances made available by section 2104(f) of the Social Security Act, $114,474,000 are hereby permanently cancelled.

SEC. 521. Evaluation Funding Flexibility

(a) *This section applies to:*

(1) *the Office of the Assistant Secretary for Planning and Evaluation within the Office of the Secretary and the Administration for Children and Families in the Department of Health and Human Services; and*

(2) *The Chief Evaluation Office and the statistical-related cooperative and interagency agreements and contracting activities of the Bureau of Labor Statistics in the Department of Labor.*

(b) *Amounts made available under this Act which are either appropriated, allocated, advanced on a reimburseable basis, or transferred to the functions and organizations identified in subsection (a) for research, evaluation, or statistical purposes shall be available for obligation through September 30, 2026. When an office referenced in subsection (a) receives research and evaluation funding from multiple appropriations, such offices may use a single Treasury account for such activities, with funding advanced on a reimbursable basis.*

(c) *Amounts referenced in subsection (b) that are unexpended at the time of completion of a contract, grant, or cooperative agreement may be deobligated and shall immediately become available and may be reobligated in that fiscal year or the subsequent fiscal year for the research, evaluation, or statistical purposes for which such amounts are available.*