

DEPARTMENT of HEALTH and HUMAN SERVICES

Fiscal Year 2023

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 2023	
	FTE	Program Level
General Departmental Management	993	\$579,839,000
PHS Evaluation Set-Aside – Public Health Service Act	182	\$85,228,000
GDM Program Level ¹	1,175	\$665,067,000
Medicare Hearings and Appeals (MHA) ²		
Office of Medicare Hearings and Appeals (OMHA)	832	\$162,000,000
Departmental Appeals Board (DAB)	193	\$34,000,000
MHA Program Level	1,025	196,000,000
Office for Civil Rights (OCR)	232	\$60,250,000
Office of the National Coordinator for Health IT (ONC) PHS Evaluation Set-Aside	180	\$0 \$103,614,000
Service and Supply Fund	1,518	\$0
TOTAL, Departmental Management ³	4,130	1,024,931,000

¹ The FY 2023 GDM Program level does not include estimated reimbursable budget authority and associated FTE, HCFAC and associated FTE, and MACRA PTAC associated FTE, unless otherwise indicated.

³ The total Department Management level does not include proposed Mental Health Transformation Fund and associated FTE; or PrEP Delivery Program to End the HIV Epidemic and associated FTE unless otherwise indicated.

² 2022 and 2023 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 2023 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 2022 Congressional Justifications and Online Performance Appendices, the Agency Financial Report, and the HHS Citizens' Report. These documents are available at <u>http://www.hhs.gov/budget</u>.

The FY 2023 Congressional Justifications and accompanying Online Performance Appendices contain the updated FY 2023 Annual Performance Report and FY 2023 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

This volume presents 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.

The Budget request supports the Secretary in his role as chief policy officer and general manager of HHS. The FY 2023 request totals \$1 billion to support:

- Teen Pregnancy Prevention and Embryo Adoption Awareness Campaign: \$112 million to support community efforts to reduce teen pregnancy through grants to replicate programs that have been proven effective, and an embryo adoption campaign.
- Minority HIV/AIDS: \$58 million 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.
- Minority Health: \$86 million 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.
- Women's Health: \$42 million for the Office on Women's Health to fund maternal mortality prevention and other maternal health initiatives and communication activities addressing health disparities for women.
- Executive Orders: \$18 million to successfully implement over 30 new Executive Orders, including those on Health and Racial Equity.
- Electric Vehicles: \$5 million to implement a Department-wide Electric Vehicle Fleet program.
- Administrative Funds: \$259 million to provide the Secretary the resources needed for oversight of the largest cabinet department. Funding supports program integrity oversight and operations and management in the Office of the Secretary, areas historically underfunded.
- Planning, Research, and Evaluation: \$85 million in PHS Evaluation Funds to support the Office of Climate Change and Health Equity, ensure implementation and compliance with the Executive Order on Health Equity, and to ensure research is at the forefront of leadership decision making.
- Office of Medicare Hearings and Appeals (OMHA) and Departmental Appeals Board (DAB): \$196 million to fund the Departmental Appeals Board as it continues to maximize progress to reduce the Medicare appeals backlog, and the Office of Medicare Hearings and Appeals

to focus on compliance with the statutorily mandated 90-day adjudicatory timeframe.

- Office for Civil Rights: \$60 million to defend the public's right to nondiscriminatory access to HHS-funded health and human services and the privacy and security of individually identifiable health information. These funds will also support a White House initiative on Asian Americans, Native Hawaiians, and Pacific Islanders; add staff to ensure Departmentwide civil rights compliance and policy development by augmenting technical assistance across HHS; the review of HHS regulations; and training for HHS grantees.
- Office of the National Coordinator for Health IT: \$104 million in PHS Evaluation Funds to ensure policy development on value-based, data-driven health system transformation and to guide and facilitate cutting edge technology and standards initiatives. The investments will 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 2023 Budget.

Norris Cochran

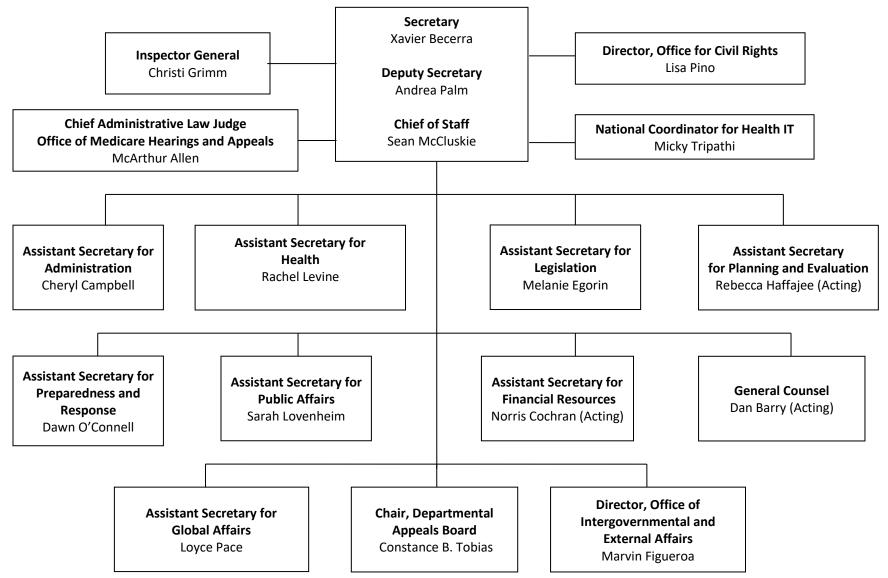
Acting Assistant Secretary for Financial Resources

Departmental Management Overview

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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

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- o Christi Grimm
- Chief Administrative Law Judge of the Office of Medicare Hearings and Appeals
 - o McArthur Allen
- Director of the Office for Civil Rights
 - o Lisa Pino
 - National Coordinator for Health Information Technology
 - Micky Tripathi
- Assistant Secretary for Administration
 - o Cheryl Campbell
- Assistant Secretary for Health
 - Rachel Levine
- Assistant Secretary for Legislation
 - o Melanie Egorin
 - Assistant Secretary for Planning and Evaluation
 - Rebecca Haffajee (Acting)
- Assistant Secretary for Preparedness and Response
 - o Dawn O'Connell
- Assistant Secretary for Public Affairs
 - o 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
 - o 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 2023 President's Budget request for DM totals \$1,024,931,000 in program level funding, including 4,130 full-time equivalent (FTE) positions, an increase of \$181,263,000 above the FY 2022 Annualized Continuing Resolution (CR) 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 2023 President's Budget program level request for GDM includes a total of \$665,067,000 and 1,175 FTE.

Medicare Hearings and Appeals (MHA) supports the Office of Medicare Hearings and Appeals (OMHA) and Departmental Appeals Board (DAB). The FY 2023 President's Budget 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 \$162,000,000 and Departmental Appeals Board (DAB) is allocated \$34,000,000. 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 to focus on compliance with the statutorily mandated 90-day adjudicatory timeframe, and DAB to increase adjudication capacity and reduce the backlog of appeals.

The **Office for Civil Rights (OCR)** defends the public's right to nondiscriminatory access to HHSfunded health and human services, and access to the privacy and security of individually identifiable health information. The FY 2023 President's Budget request for OCR is \$60,250,000 in budget authority and 232 FTE. The Budget provides resources to address existing complaint inventory, ensure Department-wide civil rights compliance and policy development, and training to HHS grantees.

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 2023 President's Budget

request for ONC is \$103,614,000 in PHS Evaluation Funds and 180 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 2023 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 2023 President's Budget request, the SSF, including Debt Collection Center is projecting total revenue of \$1,417,706,000 and usage of 1,518 FTE.

DEPARTMENTAL MANAGEMENT BUDGET BY APPROPRIATION

(Dollars in thousands)

Details	FY 2021 Final	FY 2022 Annualized CR	FY 2023 President's Budget
General Departmental Management	484,351	485,794	579,839
PHS Evaluation Funds	64,828	64,828	85,228
Subtotal, GDM Program Level	549,179	550,622	665,067
Medicare Hearings and Appeals			
Office of Medicare Hearings and Appeals	183,000	172,381	162,000
Departmental Appeals Board	25,500	19,500	34,000
Subtotal, MHA Program Level	208,500	191,881	196,000
Office for Civil Rights	38,682	38,798	60,250
Office of the National Coordinator for Health Information Technology Program Level	62,180	62,367	
PHS Evaluation Funds (ONC)			103,614
Total, Departmental Management	858,541	843,668	1,024,931

General Departmental Management

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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 health or human services research and evaluation activities, including such activities that are similar to activities carried out by other components of the Department, \$579,839,000, together with \$85,228,000 from the amounts available under section 241 of the PHS Act : Provided, That of this amount, \$58,400,000 shall be for minority AIDS prevention and treatment activities: Provided further, That of the funds made available under this heading, \$111,000,000 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, \$7,700,000 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, \$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)).

Note. --A full-year 2022 appropriation for this account was not enacted at the time the budget was prepared; therefore, the budget assumes this account is operating under the Continuing Appropriations Act, 2022 (Division A of P.L. 117-43, as amended). The amounts included for 2022 reflect the annualized level provided by the continuing resolution.

LANGUAGE ANALYSIS

Language Provisions	Explanation
<i>\$579,839,000,</i> together with <i>\$85,228,000</i>	Update appropriated amounts for GDM and PHS evaluation.
\$58,400,000	
	Update appropriated amount for Minority AIDS prevention
\$111,000,000	
	Update appropriated amount for Teen Pregnancy Prevention
\$7,700,000	
	Update appropriated amount for Teen Pregnancy Prevention Evaluation Funds
	Removal of all language related to Sexual Risk Avoidance

AUTHORIZING LEGISLATION

(Dollars in thousands)

Details	FY 2022 Annualized CR Amount Authorized	FY 2022 Annualized CR Amount Appropriated	FY 2023 Amount Authorized	FY 2023 President's Budget
General Departmental Management (GDM)	-	-	-	-
Reorganization Plan No. 1 of 1953 (Federal Funds)	Permanent	\$220,801	Permanent	\$220,801
P.L. 116-260, Consolidated Appropriations Act, 2021 (Embryo, MAIF, TPP, Kidney, SRA)	Indefinite	\$175,400	Indefinite	\$175,400
Subtotal, GDM Appropriation		\$396,201		\$396,201
Office of the Assistant Secretary for Health (OASH)	-	-	-	-
Public Health Service Act, Title III, Section 301 (OASH) (Above Federal Funds –DHPA-AOH)	Permanent	\$41,075	Permanent	\$41,075
Public Health Service Act, Title, II, Section 229 (OWH)	Expired 2014	\$42,140	Expired 2014	\$42,140
Public Health Service Act, Title XVII, Section 1701 (DPHP)	Expired 2002	\$9,134	Expired 2002	\$9,134
Public Health Service Act, Title XVII, Section 1707 (OMH)	Expired 2016	\$85,835	Expired 2016	\$85,835
Public Health Service Act, Title XVII, Section 1708 (OAH)	Expired 2000	\$5,454	Expired 2000	\$5,454
Subtotal, OASH	-	\$183,638	-	\$183,638
-	-	-	-	-
Total GDM Appropriation	-	\$579,839	-	\$579,839

Detail	FY 2021 Final	FY 2022 Annualized CR	FY 2023 President's Budget
Annual appropriation	\$485,794,000	\$485,794,000	\$579,839,000
-	-	-	-
Transfer of funds to Unaccompanied Children (UC)	-\$1,443,490	-\$1,443,490	-
Subtotal, adjusted budget authority	\$484,350,510	\$484,350,510	\$579,839,000
Total Obligations	\$484,350,510	\$484,350,510	\$579,839,000

AMOUNTS AVAILABLE FOR OBLIGATION

SUMMARY OF CHANGES

(Dollars in Thousands)

Budget Year and Type of Authority	Dollars	FTE
FY 2021 Final	484,351	777
FY 2022 Annualized CR	485,794	837
FY 2023 President's Budget	579,839	993
Net Changes	+94,045	+156

Increases	FY 2022 Annualized CR	FY 2023 Request Change from Base
Immediate Office of the Secretary	12,737	3,063
Assistant Secretary for Legislation	4,187	524
Assistant Secretary for Public Affairs	8,577	2,183
Departmental Appeals Board	4,552	1,610
Office of the General Counsel	31,695	2,829
Assistant Secretary for Financial Resources	31,723	4,992
Quality Services Management Office (QSMO)	-	6,000
Rent, Operations, Maintenance, and Related Services	12,321	8,102
Partnership Center for Faith-Based and Neighborhood	1,320	14
Office of Intergovernmental and External Affairs	10,853	1,599
Assistant Secretary for Administration	18,301	539
Office of Global Affairs	6,099	4,503
Shared Operating Expenses - Overhead	10,478	4,000
Secretarial Initiatives and Innovations	2,000	3,000
Electric Vehicle Program	-	5,000
Executive Order Implementation	-	18,000
Office of the Assistant Secretary for Health*	36,576	19,087
ТРР	101,000	10,000
Minority HIV/AIDS	55,400	3,000
ОМН	61,835	24,000
OWH	35,140	7,000
Total	-	+129,045

*OASH includes increases in the Immediate Office only

Decreases	FY 2022 Annualized CR	FY 2023 President's Budget	FY 2023 FTE Change from Base
Sexual Risk Avoidance	35,000	-	-35,000
Total Net Change	-	-	-35,000

Total Changes	FY 2022 Annualized CR	FY 2022 Annualized CR FTE	FY 2022 Request Change from Base	FY 2023 FTE Change from Base
Total Increases	485,794	837	+129,045	993
Total Decreases	35,000	-	-35,000	-
Total Net Change	-	-	+94,045	+156

(Dollars in Thousands)						
	FY		FY		FY	FY 2023
Details	2021 FTE	FY 2021 Final	2022 FTE	FY 2022 Annualized CR	2023 FTE	President's Budget
Immediate Office of the Secretary	63	12,699	63	12,737	78	15,800
Assistant Secretary for Legislation	22	4,175	23	4,187	25	4,711
Assistant Secretary for Public Affairs	37	8,552	40	8,577	55	10,760
Departmental Appeals Board	11	4,539	17	4,552	24	6,162
Office of the General Counsel	149	31,602	143	31,695	152	34,524
Assistant Secretary for Financial Resources	143	31,632	132	31,723	147	36,715
Grants Quality Service Management Office	-	-	-	-	8	6,000
Office of Intergovernmental and External Affairs	49	10,821	53	10,853	68	12,452
Partnership Center for Faith-Based & Neighborhood Partnership	3	1,316	5	1,320	5	1,334
Assistant Secretary for Administration	47	18,247	66	18,301	66	18,840
Office of Global Affairs	16	6,081	20	6,099	28	10,602
Shared Operating Expenses	-	10,448	-	10,478	-	14,478
Secretarial Initiatives and Innovations	-	1,994	-	2,000	-	5,000
Rent, Operations, Maintenance and Related Services	-	12,269	-	12,321	-	20,423
Kidney X	1	5,000	1	5,000	1	5,000
Office of the Assistant Secretary for Health	106	36,469	130	36,576	150	55,663
Electric Vehicle Program	-	-	-	-	3	5,000
Executive Order Implementation	-	-	-	-	10	18,000
Total, GDM Federal Funds	647	195,844	693	196,419	820	281,464
OASH PPAs	-	-	-	-	-	-
Teen Pregnancy Prevention	22	100,697	18	101,000	23	111,000
Office of Minority Health	47	61,649	57	61,835	70	85,835
Office on Women's Health	38	35,035	44	35,140	54	42,140
Subtotal, OASH PPAs	107	197,381	119	197,975	147	238,975
OS PPAs	-	-	-	-	-	-
Embryo Adoption Awareness Campaign	-	997	-	1,000	-	1,000
Sexual Risk Avoidance	-	34,895	-	35,000	-	-
Minority HIV/AIDS Fund	23	55,234	25	55,400	26	58,400
Subtotal OS PPAs	23	91,126	25	91,400	26	59,400
Total, All PPAs	130	288,507	144	289,375	173	298,375
Total, GDM Discretionary Budget Authority	777	484,351	837	485,794	993	579,839

BUDGET AUTHORITY BY ACTIVITY - DIRECT

Fiscal Year	Details	Budget Estimates to Congress	House Allowance	Senate Allowance	Appropriations
	Appropriation	\$301,435,000	-	\$477,208,000	\$458,056,000
2014	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
2015	Subtotal	\$278,800,000	-	\$442,698,000	\$448,034,000
	Appropriation	\$286,204,000	\$361,394,000	\$301,500,000	\$456,009,000
2016	Transfers	-	-	-	-\$516,000
	Subtotal	\$286,204,000	\$361,394,000	\$301,500,000	\$455,493,000
	Appropriation	\$478,812,000	\$365,009,000	\$444,919,000	\$460,629,000
	Rescission	-	-	-	-\$1,050,000
2017	Transfers	-	-	-	-\$1,050,000
	Subtotal	\$478,812,000	\$365,009,000	\$444,919,000	\$458,529,000
	Appropriation	\$304,501,000	\$292,881,000	\$470,629,000	\$470,629,000
	Rescission	-	-	-	-3,128,000
2018	Transfers	-	-	-	-1,141,000
	Subtotal	\$304,501,000	\$292,881,000	\$470,629,000	\$466,360,000
	Appropriation	\$289,545,000	\$379,845,000	\$480,629,000	\$480,629,000
2019	Transfers	-	-	-	\$3,597,121
	Subtotal	\$289,545,000	\$379,845,000	\$480,629,000	\$484,226,121
	Appropriation	\$339,909,000	\$485,169,000	\$490,879,000	\$479,629,000
2020	Subtotal	\$339,909,000	\$485,169,000	\$490,879,000	\$479,629,000
	Appropriation	\$347,105,000	\$459,959,000	\$489,879,000	\$485,794,000
2021	Transfers	-	-	-	-\$1,443,490
	Subtotal	\$347,105,000	\$459,959,000	\$489,879,000	\$484,350,510
	Appropriation	\$576,981,000	\$582,981,000	\$544,090,000	\$485,794,000
2022	Transfers	-	-	-	\$-1,443,490
	Subtotal	\$576,981,000	\$582,981,000	\$544,090,000	\$484,350,510
2022	Appropriation	\$579,839,000	-	-	-
2023	Subtotal	\$579,839,000	-	-	-

APPROPRIATIONS HISTORY TABLE

GENERAL DEPARTMENTAL MANAGEMENT ALL PURPOSE TABLE

GDM	FY 2021 Final	FY 2022 Annualized CR	FY 2023 President's Budget	FY 2023 +/- FY 2022
Budget Authority	484,351	485,794	579,839	+94,045
Related Funding	-	-	-	-
PHS Evaluation Set-Aside – Public Health Service Act	64,828	64,828	85,228	+20,400
Program Level	549,179	550,622	665,067	+114,445
FTE ¹	911	982	1,175	+193

(Dollars in Thousands)

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 2023 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 2023 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 2023 President's Budget for General Departmental Management (GDM) includes \$579,839,000 in appropriated funds and 1,175 full-time equivalent (FTE) positions. This request is +\$94,045,000 above the FY 2022 Annualized Continuing Resolution (CR).

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 – The FY 2023 President's Budget request provides an increase of +\$31,000,000 above the FY 2022 Annualized CR. The FY 2023 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.

Assistant Secretary for Administration - The FY 2023 President's Budget request provides an increase of +\$539,000 above the FY 2022 Annualized CR. At this level, funding will allow ASA to support and expand the implementation efforts of the Competitive Service Act.

Office of Global Affairs - The FY 2023 President's Budget request provides an increase of +\$4,503,000 above the FY 2022 Annualized CR. This level provides an increase for the U.S. Mexico Border Health Commission and provides an additional \$3,000,000 to expand OGA's Health Diplomacy program, responding to the National Security Memorandum-1 section 2.B to review and adjust the United States' health diplomacy personnel overseas.

Grants Quality Service Management Office – The FY 2023 President's Budget request is \$6,000,000 which is +\$6,000,000 above the FY 2022 Annualized CR. The FY 2023 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.

Office of the Assistant Secretary for Health – The FY 2023 President's Budget provides +\$19,087,000 above the FY 2022 Annualized CR. 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.

Electric Vehicles Program – The FY 2023 President's Budget request for the Electric Vehicle Program is \$5,000,000 which is +\$5,000,000 above the FY 22 Annualized CR. 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.

Executive Orders Implementation – The FY 2023 President's Budget request for the Executive Order Implementation is \$18,000,000 which is +\$18,000,000 above the FY 2022 Annualized CR. 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.

Teen Pregnancy Prevention – The FY 2023 President's Budget request provides an increase of +\$10,000,000 above the FY 2022 Annualized CR. The request will support a new national competition for all TPP grant funds, which will result in numerous new grants across the country in communities and among populations most in need. Funds will also support development and testing of new and innovative approaches to preventing teen pregnancy and advancing positive youth development.

Minority HIV/AIDS Fund – The FY 2023 President's Budget request provides an increase of +\$3,000,000 above the FY 2022 Annualized CR. The additional funding will further MHAF efforts to reduce persistent HIV-related health disparities and meet the challenge of promoting health equity.

Office of Minority Health – The FY 2023 President's Budget request provides an increase of +\$24,000,000 above the FY 2022 Annualized CR. The request will be used to provide grant or contracts to community-based organizations with high rates of adverse or significant racial or ethnic disparities in maternal health outcomes. The funds will be used to carry out activities including addressing social determinants of health, promoting evidence-based health literacy, and pregnancy, childbirth, and parenting education program, providing support from perinatal health workers, and providing culturally congruent, linguistically appropriate, and trauma-informed training to perinatal health workers.

Office on Women's Health – The FY 2023 President's Budget request provides an increase of +\$7,000,000 above the FY 2022 Annualized CR. The request will support developing new initiatives focused on prevention and treatment of eating disorders, violence, and substance use disorders, especially in underserved communities. OWH will use additional funds to expand the Maternal Health Data and Analysis Initiative to decrease maternal morbidity and mortality and make the U.S. the safest place to give birth.

Sexual Risk Avoidance - The FY 2023 President's Budget does not request funds for this program.

Mandatory Budget Proposals – The FY 2023 President's Budget also includes two mandatory budget proposals. In support of the President's call for transforming how we deliver mental healthcare, the Budget includes a new \$7.5 billion Mental Health System Transformation Fund to expand access to mental health services through mental health workforce development and service expansion, including the development of non-traditional health delivery sites, the integration of quality mental health and substance use care into primary care settings, and dissemination of evidence-based practices. The budget also creates a national program that invests \$9.8 billion over 10 years to provide a financing and delivery system to ensure everyone has access to pre-exposure prophylaxis, also known as PrEP, via

community providers. The program would include PrEP drugs, associated lab services, and ancillary services to support PrEP uptake and consistent use by clients¹¹.

¹¹Details on the PrEP Delivery Program to End the HIV Epidemic are included in Mandatory Proposals section of the Departmental Management Congressional Justification.

IMMEDIATE OFFICE OF THE SECRETARY

Budget Summary

Immediate Office of the Secretary	FY 2021 Final	FY 2022 Annualized CR	FY 2023 President's Budget	FY 2023 +/- FY 2022	
Budget Authority	12,699	12,737	15,800	+3,063	
FTE	63	63	78	+15	
Authorizing Legislation Reorganization Plan No. 1 of 1953					
FY 2023 AuthorizationPermanent					
Allocation MethodDirect federa					

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). IOS organization components include the Executive Secretariat, and the Office of National Security (ONS). The IOS provides leadership, direction, policy, and management guidance to HHS and supports the Secretary and Deputy Secretary in their roles as representatives of both the Administration and HHS. IOS serves as the central point of coordination and oversight for all HHS activities and the Department's mission of enhancing the health and well-being of Americans.

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

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

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Fiscal Year	Amount				
FY 2019	\$14,200,000				
FY 2020	\$14,200,000				
FY 2021 Final	\$12,699,000				
FY 2022 Annualized CR	\$12,737,000				
FY 2023 President's Budget	\$15,800,000				

Five Year Funding Table

Budget Request

The FY 2023 request for IOS is \$15,800,000 which is an increase of \$3,063,000 above the FY 2022 Annualized CR. At this level IOS can 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 for IOS 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, 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 2021 Final	FY 2022 Annualized CR	FY 2023 President's Budget	FY 2023 +/- FY 2022		
Budget Authority	1,994	2,000	5,000	+3,000		
FTE	-	-	-	-		
Authorizing Legislation Reorganization Plan No. 1 of 1953						
FY 2023 AuthorizationPermanent						
Allocation MethodDirect 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 the impact of these resources will be monitored based on the Secretary's stated goals and objectives for their use.

Fiscal Year	Amount			
FY 2019	\$2,000,000			
FY 2020	\$2,000,000			
FY 2021 Final	\$1,994,000			
FY 2022 Annualized CR	\$2,000,000			
FY 2023 President's Budget	\$5,000,000			

Five Year Funding Table

Budget Request

The FY 2023 request for IOS is \$5,000,000 which is an increase of \$3,000,000 above the FY 2022 Annualized CR. The request 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

Assistant Secretary for Administration	FY 2021 Final	FY 2022 Annualized CR	FY 2023 President's Budget	FY 2023 +/- FY 2022		
Budget Authority	18,247	18,301	18,840	+539		
FTE	47	66	66	-		
Authorizing Legislation						
FY 2023 AuthorizationIndefinite						
Allocation Method				Direct Federal		

(Dollars in Thousands)

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 Operations and Management (OOM), National Labor and Employee Relations Office (NLERO), and Program Support Center² (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, and status as a parent, national origin, age, disability, genetic information, and retaliation. EEODI develops policies and strategies to

² PSC is funded solely through the HHS Service and Supply Fund; it is not included in this request.

provide for the timely resolution and equitable remedies to discrimination complaints. EEODI ensures that all HHS employees and applicants have equal access to services and are able to perform the critical elements of their position by ensuring timely and appropriate reasonable accommodations are provided.

EEODI also manages the Diversity and Inclusion program, which focuses on 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.

National Labor and Employee Relations Office (NLERO)

NLERO is responsible for promoting the development and growth of collaborative labor-management relationships and providing accurate and comprehensive guidance that will empower leaders to make informed decisions as labor challenges arise under the Federal Service Labor-Management Relations Statute. NLERO is charged with the development and delivery of labor and employee relations policies, training, consultation, and operational support solutions that maximize the effectiveness and efficiency across the Department. NLERO consults at the national level with labor organizations, agency managers, and labor relations officials in the development of human resource policy and on government rules, regulations, and binding directives affecting conditions of employment.

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 optimization; 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 Operations and Management (OOM)

OOM, previously Office of Business Management and Transformation, 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. OOM also oversees Department- wide multi-sector workforce management activities. OOM 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. OOM leads Departmental and cross-government initiatives that promote innovation and implement effective management practices within the Department.

Five Year Funding Table

Fiscal Year	Amount
FY 2019	\$17,458,000
FY 2020	\$16,558,000
FY 2021 Final	\$18,247,000
FY 2022 Annualized CR	\$18,301,000
FY 2023 President's Budget	\$18,840,000

Budget Request

The FY 2023 President's Budget request for ASA is \$18,840,000, which is an increase of +\$539,000 above the FY 2022 Annualized Continuing Resolution (CR). At this level, funding will allow ASA to support and expand the implementation efforts of the Competitive Service Act. This includes improvement to the HHS Shared Hiring Certificate program and adoption of successful hiring strategies across the Department; to continue administrative and oversight responsibilities that support the HHS mission; and maintain current management functions with the ability to absorb inflationary pay and non-pay cost increases.

Recruitment Outputs and Outcomes Table

Measure	Year and Most Recent Result Target for Recent Result (Summary of Result)	FY 2022 Target	FY 2023 Target	FY 2023 Target +/- FY 2022 Target
2.8 Decrease the cycle	FY 2021: 110 days			
time to hire new	Target: 80 days	Discontinued	Discontinued	N/A
employees	(Target Not Met)			

Performance Analysis

2.8 Decrease the cycle time to hire new employees

During FY 2021, the customer base continued to grow as increases in hiring continued in response to the COVID-19 crisis. 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.

IT Outputs and Outcomes Table

Measure	Year and Most Recent Result Target for Recent Result (Summary of Result)	FY 2022 Target	FY 2023 Target	FY 2023 Target +/- FY 2022 Target
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 2021: 80% Target: 90% (Target Not Met)	Discontinued	Discontinued	N/A
3.5 Decrease the Percentage of Susceptibility among Personnel to Phishing	FY 2021: 4.8% Target: 6.2% (Target Exceeded)	Discontinued	Discontinued	N/A
3.6 Maintain the number of days since last major incident of PII breach	FY 2021: 365 days Target: 365 days (Target Met)	Discontinued	Discontinued	N/A

Performance Analysis

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 80% on the most recent scorecard released in December 2021. 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.

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 1,332 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

Assistant Secretary for Financial Resources	FY 2021 Final	FY 2022 Annualized CR	FY 2023 President's Budget	FY 2023 +/- FY 2022	
Budget Authority	31,632	31,723	36,715	+4,992	
FTE	143	132	147	+15	
Authorizing Legislation Reorganization Plan No. 1 of 1953					
FY 2023 AuthorizationPermanent					
Allocation MethodDirect 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, and acquisition, and to provide for the direction of these activities throughout HHS. In addition, ASFR leads the development and implementation of HHS's Enterprise Risk Management capabilities.

Office of Acquisitions

The Office of Acquisitions (OA) provides department-wide leadership and management direction of the WHHS procurement system on behalf of the Secretary through the Assistant Secretary for Financial Resources. The OA maintains the HHS acquisition career management program, provides oversight of contract operations, provides department-wide leadership on acquisition/sourcing strategies, and fosters collaboration, innovation, and accountability of the HHS acquisition system.

The OA provides oversight for the second largest federal acquisition portfolio and directs the development and implementation of HHS Acquisition Regulations, procurement policies and standards in accordance with 41 USC §1702, Chief Acquisition Officer & Senior Procurement Executive Statutory Responsibilities. The OA leads HHS acquisition performance measurement, internal controls assessment, data management and analysis, and workforce development including training and federal acquisition certification. The OA supports the financial accountability and transparency initiatives such as those associated with the Federal Funding Accountability and Transparency Act (FFATA), the DATA Act, and sustains the HHS Contract Writing Systems. The OA also serves as the HHS Suspension & Debarment Official and makes responsibility determinations and issues decisions on suspension or debarment for contractors and grant recipients found not to be presently responsible.

Office of Budget

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 the HHS and President's budgets, management of program assessment and performance reporting, presentation of budgets and budgetrelated 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 the OMB, the public, the media, and Congressional committees; and manages HHS apportionment activities, which provide funding to the HHS Operating Divisions and Staff Divisions. The OB coordinates, oversees, and convenes resource managers and financial accountability officials within the Office of the Secretary to update, share, and implement related HHS-wide policies, procedures, operations, rules, regulations, recommendations, and priorities. The OB coordinates and prepares guidelines for 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 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.

Office of Finance

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 accounting principles. 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 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 Grants

The Office of Grants (OG) provides department-wide leadership on grants strategy, policy, and regulations and serves several key government-wide roles, fostering collaboration, innovation, consistency, and accountability in the administration and management of federal grants. In its government-wide roles, the OG is the managing partner of Grants.gov, servicing 35 federal grant-making agencies, GrantSolutions, servicing 13 federal grant-making agencies. OG has played an integral role in revisions to the United States Code of Federal Regulations Title II, Section 200 Uniform Administrative Requirements, and continues to substantially contribute to other government-wide policy and guidance documents. HHS has also been designated the government-wide grant standards setting agency by the Director of OMB under the Grant Reporting Efficiency and Agreements Transparency (GREAT) Act, with OG performing the standards lead function. The OG also continues to be a key partner to OMB and other Federal agencies with on-going government-wide grant initiatives.

The OG formulates department-wide grants policies including uniform administrative rules and provides oversight and review on the implementation of HHS grant policies. The OG provides coordinated leadership in cost policy management and department-wide cost policies and procedures affecting assistance awards. The OG leads the preparation of HHS and government-wide positions on proposed legislation or government-wide policies affecting all aspects of financial assistance and represents the Department's interest regarding internal and external grants management activities. The OG is building the capacity of the HHS financial assistance community through newly developed department-wide trainings to improve the HHS financial assistance workforce by and those who are part of the financial assistance award, monitoring, and closeout processes. The OG is also responsible for financial

assistance DATA Act reporting, submitting hundreds of thousand records to USAspending.gov each year, and providing financial assistance reporting to department executives and external stakeholders.

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 developed a Financial Business Intelligence System (FBIS) to enhance HHS-wide analytic capabilities and support decision-making. The OF continues to drive innovation across the Department, standardizing financial accounting and implementing financial management requirements both in HHS and government wide. A comprehensive HHS Digital Accountability and Transparency Act of 2014 (DATA Act) solution was developed, the first in the federal government that improved data quality and integration across enterprise systems and provided transparency to the over \$1.5 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 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 FY2019 DATA Act audit with an error rate under 1.5 percent.

Partnering with the Centers for Medicare & Medicaid Services (CMS), a department-wide electronic invoicing solution was implemented and went "live" in August 2020. When fully complete, this solution will automate over 300,000 invoices resulting in a \$200 million cost avoidance over ten years yielding a 295 percent return on investment. Additionally, a sound foundation for, and the initiating of, a digital workforce was developed using Robotics Process Automation (RPA) in the financial management environment to automate low-value manual processes saving thousands of labor hours across HHS.

The maturing of the systems environment continues by strengthening the security, accessibility, and reliability of the financial systems, as evidenced by no material weaknesses reported by the Department's independent auditors in FY 2020 for the third consecutive year.

Lastly, planning has started for the department-wide implementation of the Treasury's G-invoicing solution that will improve data accuracy and bring efficiencies to transactions between Federal agencies. When complete, this solution will help the federal government resolve its long-standing material weakness reported by auditors.

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Fiscal Year	Amount	
FY 2019	\$31,035,000	
FY 2020	\$31,035,000	
FY 2021 Final	\$31,632,000	
FY 2022 Annualized CR	\$31,723,000	
FY 2023 President's Budget	\$36,715,000	

Five Year Funding Table³

Budget Request

The FY 2023 President's Budget request for ASFR is \$36,715,000, which is an increase of +\$4,992,000 above the FY 2022 Annualized CR. At this level, ASFR can better fulfill its policy functions and mission to oversee and safeguard the stewardship of HHS's substantial grants, budget, financial, and acquisition portfolios.

³ Funding history includes ASFR and FSI combined.

Office of Acquisitions

The additional funding and staff will focus on oversight improvement activities, acquisition governance, and program integrity across HHS contract operations as well as aid in the build-out of the HHS Suspension and Debarment Program. The staff will also enhance the coordination of acquisition operational needs assessments to address capability gaps, identify process deficiencies, and support the improvement and maturity of existing compliance programs. Further, additional staff will also afford OA the ability to conduct acquisition strategy reviews, supporting Program Management Integrity Act compliance allowing ASFR to identify and execute necessary corrective actions to improve the acquisitions system and stewardship across the enterprise. Critical to the stewardship of HHS contracting dollars is the HHS Acquisition Regulation currently undergoing update, was last updated in2015. The additional staff will also ensure maintenance of the regulation once the update is completed.

Office of Budget

Additional funding and staff will focus on ongoing financial management and oversight, and critical areas in need of investment due to a growing portfolio of accounts. Staff resources have remained constant within the Financial Integrity Team while the number of execution accounts has increased by 32%. Allotment requests and customer billing for reimbursed activities within the Office of the Secretary have steadily risen in the last three years and require resources to support. In addition, increases in oversight of the Office of the Secretary travel reviews under new HHS consolidated travel approval requirements require support. The Office of Budget is relied on by HHS's Operating and Staff Divisions for guidance, financial oversight, and direct assistance. As HHS's role continues to grow, so does the reliance on the staff of the Office of Budget.

Office of Grants

The additional funding and staff will focus on improving the OG policy making and oversight and evaluation capabilities. Additional funding would be used to develop comprehensive grant management and oversight policies for the Department, provide technical assistance to HHS Operating Divisions on complex matters of compliance and performance, and support emerging needs in a timelier manner. Additional staff will also improve OG's oversight and evaluation of its financial assistance programs, investments, and processes. Additional OG staff can work with the HHS audit liaison and GAO/OIG reviewers to resolve recommendations; analyze findings to make cross-cutting, systemic improvements to financial assistance management practices, ensuring cross-agency and cross-program best practices are being leveraged; and proactively identify and mitigate risk to promote program integrity and prevent future audit findings when possible.

GRANTS QUALITY SERVICE MANAGEMENT OFFICE

Budget Summary

(Dollars	in	Thousands)	

Grants Quality Service Management Office	FY 2021 Final	FY 2022 Annualized CR	FY 2023 President's Budget	FY 2023 +/- FY 2022	
Budget Authority	-	-	6,000	+6,000	
FTE	-	-	8	+8	
Authorizing LegislationReorganization Plan No. 1 of 1953					
FY 2023 AuthorizationPermanent Allocation					
Allocation MethodDirect federal					

Program Description and Accomplishments

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 January 2021, providing HHS and the federal government with the mechanism to operationalize a vision for federal grants management that empowers and enables applicants, recipients, and federal awarding agencies to deliver on mission efficiently and effectively.

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 grants, 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. The Grants QSMO also coordinates with and advises agencies and OMB on significant grants IT investments from across government, in alignment with updated OMB Circular A-11 and GSA Investment Planning 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 Grants QSMO-validated solutions.
- As a Community Builder, the Grants QSMO is fostering a community of practice across the federal grants ecosystem to share market research and agency best practices – maximizing governmentwide 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 ongoing federal response to COVID-19, which increased annual 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 advice and reviews. 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 reviews 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 intergovernmental 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) and driving use of a 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.

Fiscal Year	Amount		
FY 2019	-		
FY 2020	-		
FY 2021 Final	-		
FY 2022 Annualized CR	-		
FY 2023 President's Budget	6,000,000		

Budget Request

The FY 2023 President's Budget request for Grants QSMO is \$6,000,000, which is a +\$6,000,000 increase above the FY 2022 Annualized CR. This funding provides for the salaries and operating expenses for Federal leadership and staff for a total of 8 FTE, as well as program management support required to manage and execute the key roles of Market Coordinator, Solution Manager, and Community Builder, supporting: responsibilities for Grants QSMO Marketplace governance and oversight; agency coordination and investment planning; and management of solution providers to build and sustain a viable Marketplace. The Grants QSMO will also undertake efforts to support acquisition and facilitate access to surge support and helpdesk resources needed by agencies 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 a wide range of grant funding.

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 grants lifecycle. This request supports further solution development and human-centered design efforts, as well as facilitates the continued 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 2021 Final	FY 2022 Annualized CR	FY 2023 President's Budget	FY 2023 +/- FY 2022	
Budget Authority	4,175	4,187	4,711	+524	
FTE	22	23	25	+2	
Authorizing Legislation Reorganization Plan No. 1 of 1953					
FY 2023 AuthorizationPermanent					
Allocation MethodDirect 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. ASL, in collaboration with operating divisions, provides technical assistance to Members of Congress and their staff during the development of legislative language. ASL leads Departmental coordination and response to Congressional oversight and investigations. The office also reviews all departmental documents, issues, and regulations requiring Secretarial action.

In FY 2021, ASL coordinated and prepared Departmental witnesses to testify at over 30 hearings and responded to questions for the record that follow each hearing. ASL coordinated over 500 briefings with Departmental experts for Members of Congress and their staff. Since the start of the Biden-Harris Administration, ASL has worked across the Department and with Congress to successfully confirm nine Presidential appointees, and four other nominees are awaiting confirmation on the Senate floor.

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. 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. Significant issues within the health team include COVID-19 response, strengthening the Affordable Care Act, and implementation of major legislative proposals such as the No Surprises Act, the American Rescue Plan, and the Provider Relief Fund. 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 health care financing and health services operating divisions such as the Center for Medicare, the Center for Medicaid and CHIP Services, the CMS Innovation Center (CMMI), the Center for Consumer Information and Insurance Oversight (CCIIO), and the Center for Clinical Standards and Quality (CCSQ), as well as legislative matters affecting the Office of Medicare Hearings and Appeals (OMHA) and the Departmental Appeals Board (DAB).

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). 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. The Human Services team also manages Hill engagement around implementation of the Family First Services Prevention Act (a newly established child welfare entitlement) and proposals and inquiries related to the Unaccompanied Children's program.

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 2021, over 95,000 grant notifications were sent to Members of Congress reflecting over \$90 billion worth of grants to local communities. 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. In FY 2021, ASL updated current standard operating procedures and communicated those changes to HHS staff and operating divisions involved in the clearance process. In FY 2022, ASL continued to improve upon the letter response process across the Department to address the large volume of Congressional letters. 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. O&I works together with the Office of the General Counsel to clear letters and transmit documents to requesting congressional oversight inquiries, which included producing thousands of pages of documents to close 58 oversight letters last year. O&I produces documents on a recurring basis in response to ongoing investigations by the major oversight committees.

Along with increasing Congressional oversight requests, HHS is experiencing significant growth in GAO activity as well. O&I's GAO portfolio has seen a 59 percent increase in intake of GAO engagements over this same time last year. Currently there are 40 active GAO engagements as of February 2022. Additionally, GAO's work resulted in numerous recommendations that require corrective action by the Department. While the Department was able to close 53 recommendations last fiscal year, GAO added 113 recommendations during that time period. In addition to coordinating and monitoring ongoing engagements and recommendations, O&I provided technical assistance across the Department. To assist in tracking and managing this body of work, O&I is also implementing a new audit management system that will not only increase coordination and accountability across all divisions, but it will also make HHS better positioned to respond to future GAO engagements.

Fiscal Year	Amount
FY 2019	\$4,100,000
FY 2020	\$4,100,000
FY 2021 Final	\$4,175,000
FY 2022 Annualized CR	\$4,187,000
FY 2023 President's Budget	\$4,711,000

Five Year Funding Table

Budget Request

The FY 2023 President's Budget request for ASL is \$4,711,000, which is an increase of +\$524,000 above the FY 2022 Annualized Continuing Resolution (CR) level.

Additional funding will allow an increase of 2 FTE to work on coordinating the Department's responses to Congressional requests, including Congressional oversight activities, subject-matter briefings and hearings, letters, and clearance of official Department testimony. 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.

ASSISTANT SECRETARY FOR PUBLIC AFFAIRS

Budget Summary

(Dollars in Thousands)					
Assistant Secretary for Public Affairs	FY 2021 Final	FY 2022 Annualized CR	FY 2023 President's Budget	FY 2023 +/- FY 2022	
Budget Authority	8,552	8,577	10,760	+2,183	
FTE	37	40	55	+15	
Authorizing Legislation					
FY 2023 Authorization				Expired	
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 builds and maintains relationships with the public through multiple communication channels, including the news media, websites, broadcast, social media, speeches, public events, and Freedom of Information Act. The information ASPA communicates provides a comprehensive view of the Department's leadership and strategic goals, while critically informing the public about public health resources and services available – in real time. The information communicated supports leadership and program priorities; and represents a comprehensive view of the Department.

FY 2021 Accomplishments

In FY 2021, ASPA successfully coordinated and amplified key Departmental priorities and initiatives by managing thousands of media interview requests from across HHS, issuing hundreds of press releases and statements, and dozens of fact sheets.

- ASPA prepared hundreds of speeches for Secretary Xavier Becerra and other HHS principals, communicated HHS's policies and guidance through multiple digital channels and hundreds of media outlets, and held dozens of media calls and press events.
- As HHS has issued new rules and policies to support the nation's health and wellbeing, ASPA played a critical role in reaching Americans across the country, with an eye towards equity.
- Communicating on multiple mediums simultaneously, ASPA focuses on amplifying top Departmental priorities. Throughout FY 2021, ASPA has led:
 - A robust and dynamic communications program to tackle COVID-19 and boost vaccine confidence
 - The rollout of new policy initiatives and rules to expand health care access and reduce costs
 - New strategies and policies to strengthen mental and behavioral health

- The narrative around caring for unaccompanied children
- Interagency messaging tied to Afghan repatriation efforts
- o Agency-wide communications focused on return-to-the-workplace efforts

Two examples of how ASPA Lifted Up Departmental Priorities

Health Insurance Marketplace Special Enrollment Period

To help expand access to affordable health coverage, ASPA worked closely with operating division partners to shape the development and implementation of the marketing plan for the Health Insurance Marketplace Special Enrollment Period, resulting in a record-breaking 12.2 million people enrolled—an increase of 1.3 million people compared to last year. ASPA coordinated these efforts with the White House to ensure its messages reached the maximum number of people across the country through national and regional broadcast and print outlets. To increase enrollment in some of America's most vulnerable communities, ASPA built press moments around visits by Secretary Xavier Becerra and other HHS principals to community health centers and focused its messages on affordability. ASPA also translated key messages about getting covered in Spanish and other languages to widen its reach – to support paid and earned media.

Return to Workplace Planning

As Americans increasingly began to get vaccinated across the country, the Administration encouraged every federal agency to begin communicating about its return-to-the-workplace planning. ASPA supported internal communications – drafting weekly emails for HHS's 87,000 employees and the substance for visuals, from graphics to posters, and text messages to employees. The Studio team fully supported the first, HHS-wide Town Hall that included the Secretary, Deputy Secretary Andrea Palm and HHS public health experts – NIH Director Dr. Francis Collins and CDC Director Dr. Rochelle Walensky -- appearing via Zoom to talk about the Department's planning efforts and answer frequently-asked questions. This live event drew over 33,000 views.

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
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Fiscal Year	Amount
FY 2019	\$8,408,000
FY 2020	\$8,408,000
FY 2021 Final	\$8,408,000
FY 2022 Annualized CR	\$8,577,000
FY 2023 President's Budget	\$10,760,040

Budget Request

The FY 2023 President's Budget request for ASPA is \$10,760,000, which is an increase of +\$2,183,000 above the FY 2022 Annualized Continuing Resolution (CR) level. The additional funds will allow ASPA to hire 4 public affairs specialists to aid the health communications outreach efforts and provide additional FOIA analysts and contract support to address the longstanding FOIA backlog and recent spike in FOIA litigations.

ASPA will continue to build on its work and strengthen its tactics to engage the country around key HHS priorities – with the goal of advancing the HHS core mission of improving the health and wellbeing of Americans nationwide. In keeping with the Department's approach to decision-making, ASPA will expand its effort to reach everyone possible across the country by increasing the diversity of its staff to represent the people HHS serves – and launch its communications campaigns and initiatives with an eye towards equity. ASPA will continue to clearly communicate the scope of HHS's work, services, and programs to save lives.

OFFICE OF THE GENERAL COUNSEL

Budget Summary

(Dollars in Thousands)					
Office of the General Counsel	FY 2021 Final	FY 2022 Annualized CR	FY 2023 President's Budget	FY 2023 +/- FY 2022	
Budget Authority	31,602	31,695	34,524	+2,829	
FTE	149	143	152	+9	
Authorizing Legislation:Reorganization Plan No. 1 of 1953					
FY 2023 AuthorizationPermanent					
Allocation MethodDirect 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 an accomplished team of over 400 attorneys and a cohesive 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 legal advice and representation on a wide range of highly visible national issues. OGC's goal is to promote the strategic goals and initiatives of the HHS Secretary and the Department, by providing high quality legal services together with sound and timely legal advice and counsel. OGC is organized with ten regions and eight divisions in the primary practice areas of: Children, Families and Aging; Centers for Medicare and Medicaid Services; Civil Rights; Ethics; General Law; Legislation; National Complex Litigation and Investigations; and Public Health.

The Children, Families, and Aging Division (CFAD) provides 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 support for the unprecedented influx at the Southern border. CFAD works closely with the administration in examining litigation challenging the Adoption and Foster Care and Reporting System (AFCARS). CFAD supports ACF and Administration for Community Living (ACL) as they implement the Coronavirus Aid, Relief, and Economic Security (CARES) Act, including a grant program for water administered by the Office of Community Services and significant funding increases for the Child Care Development Fund. CFAD provides 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 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.

The Centers for Medicare and Medicaid Services Division (CMSD) provides advice to numerous components of the Centers for Medicare & Medicaid Services (CMS) in support of the agency's responses to Presidential and Departmental emergency declarations addressing the COVID-19 pandemic. For example, CMSD advises on Section 1135 waivers, adjustments to permissible sites of care, increased payment for treatment of COVID-19 and access to testing, vaccines, and treatments. These measures ensure that beneficiaries and health insurance enrollees can readily access these lifesaving therapies and services and will not be improperly charged. CMSD also provides advise on permissible incentives to encourage beneficiaries to obtain COVID-19 vaccines and provides extensive program integrity-focused counsel to CMS with respect to nursing home enforcement issues, largely associated with controlling COVID-19's spread among vulnerable Medicare and Medicaid patients

residing in nursing facilities. CMSD assists CMS in promulgating the rule, issued in response to the President's executive order, ensuring the vaccination of employees in facilities receiving Medicare and Medicaid reimbursement, and work closely with the Department of Justice (DOJ) in defending CMS in several lawsuits brought by states challenging the rule. CMSD provides counsel on implementation of various provisions of the No Surprises Act and CMS's continued work on many new innovative payment and service delivery models. CMSD focuses on the numerous issues concerning Medicaid demonstrations, guidance, and related litigation. CMSD reviews and advises on annual Medicare payment rules governing a multitude of complex payment systems, quality reporting requirements, and provider types. CMSD advises CMS on telehealth rules, Emergency Medical Treatment and Labor Act requirements, survey and certification processes, provider/supplier enrollment, accelerated and advanced payments, and debt recovery requirements. CMSD responds expeditiously to support the urgent enactment of new statutes. An example of is the American Rescue Plan Act, which immediately enhanced financial assistance offered through the Affordable Care Act (ACA) Health Insurance Exchanges and the No Surprises Act. Both Acts substantially overhauled the health insurance markets by prohibiting surprise billing and established authority for CMS to effectively regulate health care providers and facilities. CMSD also advises CMS on its operation of the Exchanges, and regulation of the individual and group health insurance markets, including addressing issues with certification of qualified health plans, ACA section 1332 waivers, the requirement for health insurance plans to cover contraceptives, and the complex federal risk adjustment program.

The Civil Rights Division (CRD) assists the Office for Civil Rights (OCR) and the Department in its efforts to expand critical non-discrimination protections in health care in a variety of ways. After the Court issued the Bostock decision, CRD continues to assist OCR in identifying a pathway forward to achieve its policy goals in a complex litigation and regulatory environment. CRD has partnered with the Department of Justice (DOJ) to defend and represent OCR's interests in national litigation surrounding Section 1557, Section 504 as well as in drafting amendments to 45 CFR Parts 160 and 164, and 42 CFR Part 2 required by the CARES Act.

In support of the Department's COVID-19 response, CRD provides key legal advice to OCR, helping to issue key guidance documents clarifying how health information may be shared in response to the public health emergency. These documents are essential in ensuring that HIPAA is not a barrier to providing care during the public health emergency and to managing the spread of the disease.

CRD collaborates with multiple HHS agencies, the National Security Council, Department of Energy, Veterans Affairs, and Department of Defense to coordinate and share health data, research, and artificial intelligence expertise to aid in the fight against COVID-19. CRD assists in drafting HHS Protect agreements which allows a central collection of data from hospitals, public health agencies, and private systems. This work includes the drafting of data use agreements (DUAs) with Oracle, 3M, Epic, Tiberius, FEMA, CVS Pharmacy, and Abbott Laboratories that allows for the ease of flow of diagnostic data between the public and private sectors.

The General Law Division (GLD) is instrumental in advising the Department's policy makers regarding the administration of their core programs, including advising them on relevant fiscal, procurement, claims, and employment law matters. GLD plays 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, employment law advice related to employee details to Emergency Intake Sites and adjudicating a significant number of claims filed under the Federal Tort Claims Act (FTCA). Working closely with the Assistant Secretary for Preparedness and Response (ASPR), GLD plays a central role in the Department's response to the COVID-19 pandemic, assisting in procuring critical therapeutics, diagnostics, personal protective equipment (PPE), vaccines and advancing the agency's response to the vaccine mandate for

HHS return to work policy. In addition, GLD provides critical advice to the Office of the Secretary (OS) and Operating Divisions (OpDivs), on myriad novel, complex, and time-sensitive employment and tort law questions regarding COVID-19. GLD continues to take the lead in advice and litigation matters for the agency in various fora. GLD has provides employment and labor advice to senior policy makers; advice on the Federal Advisory Committee Act (FACA), as well as on the disclosure, retention, and withholding of information requested through various mechanisms; adjudicated claims for the Department, including FTCA, Military Personnel and Civilian Employees Claims (MPCE) Act, and Federal Medical Care Recovery Act (FMCRA), and provide federal court litigation support as necessary. Finally, GLD represents the Department in administrative litigation before the Equal Employment Opportunity Commission (EEOC), Merit Systems Protection Board (MSPB), labor arbitrations, and other litigation matters, including federal court litigation support as appropriate.

The 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 (including the Uninsured Program, Coverage Assistance Fund and ARP-Rural Fund); COVID-19 legislation and the development and distribution of vaccines; countermeasures injury compensation coverage; testing and therapeutics; the implementation of various orders issued pursuant to Section 361 of the Public Health Service Act as well as high-profile litigation challenging these orders. PHD advises staff supporting the Disparities Council and advises and coordinates with other OGC divisions on health equity initiatives. Finally, PHD handles numerous questions related to the distribution of COVID-19 vaccine in Indian Country, particularly through the Indian Health Service (IHS) 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, awarding \$6.6 million through the Title X family planning program to address increased need for family planning services where restrictive laws and policies have impacted reproductive health access, promulgating rules to establish a new Alternative Dispute Resolution process for the 340B Discount Drug Program, and developing drug pricing control policies. PHD also advises on key programs for expanded services in rural health and a new Office for the Advancement of Telehealth. In addition, the Public Health Division serves as the lead office within the Office of the General Counsel for grants-related and intellectual property issues. 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 awarded many grants to address the opioid epidemic. PHD continues to advise on multiagency preparedness efforts related to the opioid epidemic, including public health emergency declarations, grants for treatment and prevention activities, expanding access to buprenorphine for treatment of opioid use disorder, and enhanced distribution processes for Naloxone. Furthermore, PHD works alongside the DOJ to pursue claims against opioid manufacturers on behalf of 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 lead OGC teams negotiating over \$3.2 billion 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 \$2.2 billion, with a savings of over \$1.272 billion over amounts claimed. The

Division provides extensive legal advice to the IHS to help operate its large rural health care system and urban programs.

Five Year Funding Table

Fiscal Year	Amount		
FY 2019	\$31,100,000		
FY 2020	\$31,100,000		
FY 2021 Final	\$31,602,000		
FY 2022 Annualized CR	\$31,695,000		
FY 2023 President's Budget	\$34,524,000		

Budget Request

The FY 2023 President's Budget request for OGC is \$34,524,000, which is an increase of +\$2,829,000 above the FY 2022 Annualized CR Level. At this level OGC will support additional staff, pay increases, and non-pay inflationary costs incurred thereby providing HHS with legal representation on key social, economic, and healthcare issues. This level will provide substantive and extensive legal advice and litigation support in the areas of pandemic response and procurement, Departmental policies and Executive Orders, the advancement of the Secretary's priorities on healthcare, the opioid crisis, and caring for unaccompanied children crossing the Southern border. OGC will continue to manage the legal challenges and keep pace with the Secretary and Department's initiatives, strategic goals, and the following HHS programs.

Children Families and Aging Division

The Children, Families and Aging Division (CFAD) would add one full time equivalent (FTE) to support the Department's ongoing litigation support and legal review to ACF's ORR. CFAD's expert on the equal treatment rule, at 45 C.F.R. Part 87, continues to engage with the White House and Department on changes made to that rule. CFAD continues to support the TANF program, the Office of Child Support Enforcement, the Office of Head Start, the Office of Trafficking in Persons, the Children's Bureau, the Office of Refugee Resettlement, the Office of Child Care, the Office of Community Services, the Office for Human Services Emergency Preparedness and Response, and the Administration for Community Living. Lastly, CFAD will continue to support ACF in their efforts to provide temporary assistance through the Repatriation Program to U.S. citizens and their dependents who are being evacuated from Afghanistan.

CRD HIPPA and General Civil Rights

The Civil Rights Division (CRD) would add one FTE to support the OCR to identify additional authorities throughout the Department to expand critical non-discrimination protections in health care specifically in interpretation of legal policies and regulations of Section 1557 and HIPAA. CRD will continue to assist the Department in its collaboration across government to coordinate and share health data as well as research and artificial intelligence expertise to aid in the fight against COVID-19 while protecting individuals and complying with privacy laws.

CRD continues to advise 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, CRD will continue to support 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). OCR will continue to work collaboratively across HHS to help the Department and the Administration advance critical COVID-19 pandemic efforts to promote public health, while respecting federal health information privacy law.

GLD Procurement Law

The General Law Division (GLD) would add four FTE to provide Department-wide legal support for emerging 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 will continue to assist in providing procurement advice on claims and new and existing contracts, including pandemic response contracts, employment and tort law questions regarding COVID-19, and various fora. GLD will continue to provide legal advice to ACF ORR on leases and licenses for facilities, procurements for a myriad of services necessary for providing adequate care, employment law advice related to employee details to Emergency Intake Sites and adjudicating a significant number of claims filed under the FTCA. GLD will continue to support ASPR in the furtherance of contract authority to coordinate the acceleration of countermeasures, product advanced research, and development in preparation for other emerging threats. GLD will continue to support of the Department's programs to care for unaccompanied children crossing the Southern border. OGC will litigate, as required, employment discrimination cases, MSPB appeals, labor arbitrations, and providing extensive advice concerning Departmental policies, Executive Orders, hiring and pay authorities, and performance and conduct actions. Lastly, GLD will continue to process, adjudicate claims, and provide federal court litigation support.

<u>PHD</u>

As part of the national effort to address the opioid crisis, the Public Health Division (PHD) would add four FTE to advise the agency's leadership on the establishment and structure of 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 will continue to work closely with HHS to finalize revisions to the Title X regulations, promulgating rules to establish new Alternative Dispute Resolution process for the 340B Discount Drug Program and developing drug pricing control policies. PHD continues to provide advice to other HHS components in their efforts related to the opioid crisis, in particular Centers for Disease Control and Prevention (CDC), Health Resources and Services Administration (HRSA), and Office of the Assistant Secretary for Health (OASH).

OFFICE OF GLOBAL AFFAIRS

Budget Summary

(Dollars in Thousands)						
Office of Global Affairs	FY 2021 Final	FY 2022 Annualized CR	FY 2023 President's Budget	FY 2023 +/- FY 2022		
Budget Authority	6,081	6,099	10,602	+4,503		
FTE	16	20	28	+8		
Authorizing LegislationReorganization Plan No. 1 of 1953						
FY 2023 AuthorizationPermanent						
Allocation MethodDirect Federal						

Program Description and Accomplishments

The Office of Global Affairs (OGA) promotes and protects the health of U.S. 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 through health diplomacy. 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, which includes the critical component of HHS Health Attaches in strategic Embassies around the world. OGA coordinates these matters within HHS, across the government, and at multilateral institutions working on major crosscutting global health initiatives.

HHS has a range of relationships with other USG agencies as well as more than 200 Ministries of Health. OGA leads the U.S. government on engagement with the World Health Organization (WHO), the Pan American Health Organization (PAHO), and other WHO regional offices. Other multilateral organizations OGA engages with include 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); one health institutions including the Food and Agriculture Organization of the UN (FAO); the World Organization for Animal Health (OIE); and the GAVI Alliance.

Priority policy and programmatic 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, health systems strengthening including a focus on a stronger and more resilient health workforce, promoting gender equity and reducing barriers to care.

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. These efforts were successful in 2021 as the World Health Assembly established a Working Group on strengthening WHO preparedness and response to health emergencies (WGPR) and U.S. leadership was recognized as the United States was elected to co-chair the negotiations by consensus in July at the WGPR's first meeting.

- Provided support under White House COVID Task Force leadership on the unprecedented U.S. commitment to COVID-19 vaccine sharing including organizing technical inputs from across HHS, working with key partners including WHO, GAVI, and CEPI, and providing important diplomatic communications with counterpart governments on progress or challenges to dose sharing.
- Continued to support the growth of the Africa Centres 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 effectively 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 expand U.S. support to African institutions like the Africa CDC to assist them in achieving their own priority goals and objectives in COVID-19 response and beyond.
- 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. OGA also utilized the insights and expertise of the U.S. members of the Commission to better understand local needs and strategies for collaborative efforts related to COVID-19 in the border region.
 - Existing HHS Health Attachés, as appropriate, have worked with the interagency, counterpart Ministries, other funders, and the WHO to address concerns about readiness, misinformation, lower demand than expected, and vaccine confidence so vaccines make it into arms.
- 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 and advocated to expand the role of the Global Fund's Inspector General to include an evaluation of the effectiveness of its programs.

Fiscal Year	Amount		
FY 2019	\$6,026,000		
FY 2020	\$6,026,000		
FY 2021 Final	\$6,081,000		
FY 2022 Annualized CR	\$6,098,654		
FY 2023 President's Budget	\$10,602,000		

Five Year Funding Table

Budget Request

The FY 2023 President's Budget request for OGA is \$10,602,000, which is an increase of +\$4,503,000 above the FY 2022 Annualized CR. This level provides an increase of \$900,000 for the U.S. Mexico Border Health Commission and provides additional \$3,000,000 to expand OGA's Health Diplomacy program, responding to the National Security Memorandum-1 section 2.B to review and adjust the United States' health diplomacy personnel overseas.

At this budget level, OGA will expand its coordination of government policy and programs through political and health diplomatic channels both with Embassies in Washington and Health Ministries in foreign capitals. OGA will coordinate and facilitate the involvement of HHS Divisions with these entities, which ultimately means more comprehensive coverage and support at the health policy level for the American people with key global partners in critical areas such as infectious disease surveillance and response, cutting edge research, and strengthened regulatory oversight of food and medical products bound for the United States.

In South Africa, Brazil, China, India, Kenya, Switzerland, and Mexico, current HHS health attachés continue to represent HHS and the USG as they work with other government agencies, NGOs, and industry on health and human services, first and foremost on COVID-19 response and recovery. As this program is housed in HHS, it links all domestic health and human service issues with key counterparts overseas, which is critical to not only exchange bilateral and multilateral experiences and best practices, ensure domestic and international policies align, but to inform positions and strategies for regional and global work including for pandemics. Frequently, they are the first point of contact between the U.S. and strategic bilateral and regional partners on matters of health, and therefore serve as a critical resource for not just HHS, but the whole of government. However, HHS Health Attachés are currently only in a limited number of countries, yet COVID-19 is worldwide and has reinforced the importance of global partnerships and the critical role that this staff plays. With the increased funding, OGA will fund health attaché offices in Africa, Asia, and Europe which includes a health attaché and two locally employed staff which will help to maximize current USG investments in health, and ultimately protect the people of the United States. HHS Health Attachés are, and will continue to be, critical to Administration priorities including the COVID-19 response by working with partners and using the relationships with their counterparts to provide support to clinical trials, GlobalVax to assist getting shots in arms, building technical capacity for health workforce and health systems strengthening, global health security, and strengthening multilateral organizations to respond to the next pandemic.

This request includes an increase of \$900,000 to support the U.S. Mexico Border Health Commission. This request mirrors the funding level increase indicated in the FY 2022 House Report and will provide much needed funds to support the Commission's efforts to promote solutions to health issues unique to the Southern border. Additionally, at this level, OGA will continue efforts to ensure the health and well-being of Americans and to improve health and safety across the globe, through bilateral engagement and U.S. leadership in and collaboration with multilateral organizations. OGA will continue to lead work with WHO and its regional offices, and work with organizations such as the Group of Seven (G7) and the Group of Twenty (G20), and others to advance U.S. and HHS priorities. OGA will carry out this mission focused on three key principles championed by the 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.

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. 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. OGA will also 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.

OFFICE OF INTERGOVERNMENTAL AND EXTERNAL AFFAIRS

	(Dollars in Thousand	ls)		
Office of Intergovernmental and External Affairs	FY 2021 Final	FY 2022 Annualized CR	FY 2023 President's Budget	FY 2023 +/- FY 2022
Budget Authority	10,821	10,853	12,452	+1,599
FTE	49	53	68	+15
Authorizing Legislation:		Re	organization Plan	No. 1 of 1953
FY 2023 AuthorizationPermanent				
Allocation Method				Direct Federal

Budget Summary

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 COVID-19, Unaccompanied Children (partnering with ACF/ORR and FEMA), Maternal and Behavioral Health, Access to Healthcare, Health Insurance, and Health Services, and Equity. 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, maternal, and behavioral health, and other HHS initiatives.
- Monthly calls with racial and ethnic minority groups on COVID-19, 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 played a key role in the UC program.

- IEA performed notification of state and local elected officials whenever there was an influx of unaccompanied children requiring emergency influx shelters (EIS) or temporary influx care facilities (ICF) beyond the permanent beds ACF currently had or could bring online.
- In addition, IEA notified appropriate state and local officials of a community at each stage of the process and coordinated a "community leaders briefing" should HHS reach a stage in the process where such an engagement was called for.
- IEA notified the appropriate Governor's office, usually the Governor's chief of staff or state-federal relations contact.
- HHS Regional Director's notified the appropriate chief elected official of the community in which the potential site was located. This included state legislators, county executives, county commissioners, mayors, and city managers.
- Leading the request from community leaders for meetings/briefings, IEA Regional Director's worked with the ACF Regional Administrator to set up the briefing and helped identify the appropriate officials to invite.
- If after assessing the site, ACF decided to move forward with the facility, IEA scheduled community leader briefings. IEA Regional Director's office, in partnership with the ACF Regional Administrator, worked with chief elected official to schedule briefings 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 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:

- IEA convened two Vaccine Consultation Panel (VCP) groups, one with intergovernmental partners and another with external groups, to communicate with key partners 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 partnered with U.S. Army personnel and HHS leadership on engagement with industry leaders on distribution, administration, and IT for the implementation of the vaccine distribution plan.
- IEA provides comprehensive technical assistance on behalf of HHS and the COVID-19 Response to jurisdiction and external partners.

Five	Year	Funding	Table
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Fiscal Year	Amount
FY 2019	\$10,625,000
FY 2020	\$10,625,000
FY 2021 Final	\$10,821,000
FY 2022 Annualized CR	\$10,853,000
FY 2023 President's Budget	\$12,452,000

Budget Request

The FY 2023 President's Budget request for IEA is \$12,452,000, which is an increase +\$1,599,000 above the FY 2022 Annualized Continuing Resolution (CR) level. The increase will allow IEA to continue mission critical activities, securing an additional 15 FTE who are knowledgeable about the complexity and sensitivity of various HHS programs, facilitate communication among key stakeholders, represent intergovernmental and external perspectives of Departmental priorities and initiatives, and serve as a lead in educational outreach and stakeholder engagement.

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, worked with governors, state health officials, and other state and local leaders to address reduction in health care costs, substance abuse and mental health, health disparities, and played a key role in managing public relations for Unaccompanied Children (UC) efforts with the Office of Refugee Resettlement (ORR). 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 the past year, IEA's stakeholder portfolio has increased significantly to include other organizations, institutions, and the private sector to increase awareness, build relationships, and promote awareness to the President's agenda and departmental initiatives and priorities.

THE PARTNERSHIP CENTER FOR FAITH-BASED AND NEIGHBORHOOD PARTNERSHIPS

(Dollars in Thousands)					
Partnership Center for Faith-Based & Neighborhood Partnerships	FY 2021 Final	FY 2022 Annualized CR	FY 2023 President's Budget	FY 2023 +/- FY 2022	
Budget Authority	1,316	1,320	1,334	+14	
FTE	3 5 5		-		
Authorizing Legislation Reorganization Plan No. 1 of 1953					
FY 2023 AuthorizationPermanent					
Allocation MethodDirect Federal					

Budget Summary

Program Description and Accomplishments:

Established in 2001, the Center for Faith-Based and Neighborhood Partnerships (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.

Partnership Center accomplishments to support the Administration and Secretary efforts have included:

- Weekly and monthly e-newsletters that connected thousands of faith and community leaders, and providers with the most up-to-date information, resources, and practical strategies related to public health and human service issues
- Strengthened the response of faith and community partners to critical public health and better integrated the connection between health care providers and community health assets by producing 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*.
- Works 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 COVID-19 experts.
- Produced materials and webinars that addressed 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 educational webinars that supported and expounded upon mental health, COVID-19, and addiction resources. Webinars averaged over 1,500 registrants each.
- Strengthened our social media presence by establishing a branded YouTube Channel.
- 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 Table

Fiscal Year	Amount
FY 2019	\$1,299,000
FY 2020	\$1,299,000
FY 2021 Final	\$1,316,000
FY 2022 Annualized CR	\$1,320,000
FY 2023 President's Budget	\$1,334,000

Budget Request

The FY 2023 President's Budget request for Partnership Center is \$1,334,000, which is an increase +\$14,000 above the FY 2022 Annualized Continuing Resolution (CR) level. The increase in funding for the Partnership Center will support continued efforts to advance the President's priority to expand collaborations between the Center and leaders of different faiths, faith-based and community organizations in addressing national public health and human service concerns identified as priorities for the Department. The funding will also be used to maintain current staffing levels; and leverage new, innovative technology to accommodate additional faith-based and community partners.

DEPARTMENTAL APPEALS BOARD

Budget Summary

	(Dollars in Thousand	ls)		
Departmental Appeals Board	FY 2021 Final	FY 2022 Annualized CR	FY 2023 President's Budget	FY 2023 +/- FY 2022
Budget Authority	4,539	4,552	6,162	+1,610
FTE	11	17	24	+7
Authorizing LegislationReorganization Plan No. 1 of 1953				
FY 2023 AuthorizationPermanent				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. Cases are initiated by outside parties who disagree with a determination made by an HHS agency or its contractor. Outside parties include States, universities, Head Start grantees, nursing homes, clinical laboratories, doctors, medical equipment suppliers, and Medicare beneficiaries. Disputes heard by the DAB may involve over \$1 billion in federal funds in a single year. DAB decisions on certain cost allocation issues in grant programs have government-wide impact because HHS decisions in this area legally bind other Federal agencies. All of the judges (Board Members, Administrative Law Judges (ALJs), and Administrative Appeals Judges (AAJs)) are appointed by the Secretary. The DAB is organized into the following four Divisions, in addition to having an Immediate Office of the Chair and an 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 Administration for Children and Families (ACF), Centers for Medicare & Medicaid Services (CMS), Health Resource & Services Administration (HRSA), Substance Abuse Mental Health Services Administration, Office of the National Coordinator for Health Information Technology, and the Program Support Center, involving discretionary and mandatory grants and cooperative agreements. The total value of grant disallowance appeals received in FY 2021 was approximately \$156,058,618. The total value of decisions issued in grant disallowance cases for FY 2021 was approximately \$161,486,333. In FY 2021, the Board/Appellate Division received 95 cases and closed 76 cases, 35 by decision (the Board issued 34 Decisions in FY 2021, one in a consolidated case, thus closing 35 cases 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 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 88% of CRD's workload is made up of CMS cases. CRD ALJs hear cases appealed from CMS or Office of the Inspector General (OIG) determinations, which exclude providers, suppliers, or other healthcare practitioners from participating in Medicare, Medicaid, and other federal healthcare programs, or impose civil monetary penalties (CMPs) for fraud and abuse in such programs. CRD jurisdiction also includes appeals from Medicare providers or suppliers, including cases under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). ALJs provide expedited hearings when requested in certain types of proceedings, such as provider terminations and certain nursing home CMP cases. These cases typically involve important quality of care issues. ALJs also hear cases that require testimony from independent medical/scientific experts (e.g., in appeals of Medicare Local Coverage Determinations (LCDs) or issues of research misconduct for the purposes of fraudulently obtaining federal grants in cases brought by the Office of Research Integrity (ORI)). Additionally, CRD ALJs hear appeals of CMPs for privacy, security or breach notification violations brought by the Office for Civil Rights (OCR) and transactions violations brought by CMS under HIPAA and/or the Health Information Technology for Economic and Clinical Health (HITECH) Act brought by OCR or CMS.

CRD ALJs also hear appeals of other federal agency enforcement actions through reimbursable interagency agreements. The largest of these workloads 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 2021, CRD received a total of 1,136 new cases and closed 1,112 (98%), of which 266 were by decision. Of these cases, CRD received 12 FDA cases and closed 61 FDA cases, of which 39 were by decision. The FDA did not conduct in person inspections in FY 2021, but has been conducting in person inspections in FY 2022. The FDA cases are expected to increase in FY 2023.

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 2021, the ADR Division closed 90% of cases open during the fiscal year and conducted 15 conflict resolution seminars.

Medicare Appeals Council - Medicare Operations Division (MOD)

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

Workload Statistics

Board Members – Appellate Division

Chart A shows total historical and projected caseload data for the Appellate Division. All data are based on (1) year-to-date case receipt and closure data for FY 2022, (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 six new staff attorneys in FY 2021, (7) the retirement of the longest serving Board Member at the end of CY 2021, and (8) 2 new staff attorneys and one law clerk in FY 2022.

Cases	FY 2020	FY 2021	FY 2022		
Open/start of FY	104	133	152		
Received	111	95	102		
Cases Closed by Decisions	47	34	27		
Total Closed	82	76	60		
Open/end of FY	133	152	194		

APPELLATE DIVISION CASES – Chart A

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 for pre-COVID numbers of enforcement actions in FY 2022.

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

CIVIL REMEDIES DIVISION, TOBACCO CASES – Chart B

Five Year Funding Table

Fiscal Year	Amount
FY 2019	\$14,000,000
FY 2020	\$4,552,402
FY 2021 Final	\$4,539,000
FY 2022 Annualized CR	\$4,552,000
FY 2023 President's Budget	\$6,162,000

Budget Request

The FY 2023 President's Budget request for DAB is \$6,162,000, which is an increase of +\$1,610,000 above the FY 2022 Annualized Continuing Resolution (CR) level. Medicare claims adjudication costs are funded out of the Medicare Hearings and Appeals appropriation.

The FY 2023 increase in funding will allow DAB to hire for the Appellate Division, Immediate Office, and Administration Division, where positions serve critical roles in supporting leadership. The attorneys in the Appellate Division and Immediate Office provide legal assistance, information-gathering, docket management for ever-growing caseloads, and policy advising for leadership, while the analysts in the Administration Division provide budgetary, human capital, acquisition, technical, and logistical management to support the increasing workloads across the DAB.

DAB will absorb mandatory pay increases and inflationary non-pay costs; and manage other operational costs with staff attrition and contractor reduction where needed. DAB will continue seeking other ways to enhance adjudicative efficiency. These currently include recently implemented and improved IT-based solutions, 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 across its adjudicatory divisions into a completely paperless process. 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.

Outputs and Outcomes Table:

Measure	Year and Most Recent Result Target for Recent Result (Summary of Result)	FY 2022 Target	FY 2023 Target	FY 2022 Target +/- FY 2021 Target
1.1.1 Percentage of Board Decisions with net case age of six months or less	FY 2021: 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 2021: 100% Target: 90% (Target Exceeded)	90%	80%	Decrease by 10%
1.5.1 Number of conflict resolution seminars conducted for HHS employees.	FY 2021: 15 Target: 10 Sessions (Target Exceeded)	15	15	Maintain
1.5.2 Cases closed in a fiscal year as a percentage of cases open in the same fiscal year.	FY 2021: 90% Target: 90% (Target Met)	90%	90%	Maintain

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. The DAB is maintaining FY 2022's performance targets, with the exception that the DAB reduced the Board's 1.2.1 target by 10% in FY 2023 to account for staff retirements, personnel changes, and training demands.

Appellate Division

In FY 2021, 62 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 retirement of a long-serving staff attorney in the second half of 2021, the retirement of the DAB's longest-serving Board Member at the end of CY 2021, and the need to train six new staff attorneys in FY 2021, and three new 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 2021, 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 2022, the target remains 90 percent due to the addition of a new Board Member in late FY 2020, but the retirement of the longest-serving Board Members in late 2021, as well as the training demands of six new Staff Attorneys. The target for Measure 1.2.1 decreases to 80% for FY 2023 due to the loss of productivity caused by previous staff retirements and training demands for new Staff Attorneys and Board Members. The Appellate Division expects to meet the target level for Measure 1.2.1 in both FY 2022 and FY 2023. 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 2021, ADR met both its performance targets (Measure 1.5.1 -- number of conflict resolution seminars conducted (15); and Measure 1.5.2 – cases closed in a fiscal year as a percentage of cases open in the same fiscal year (target 90%). Despite losing an ADR attorney in FY 2022, ADR expects to meet both targets in FY 22 and FY 23 through further advances in Information Technology. These advances will be focused on implementing e-filing, developing a new Intranet page, and revising our current Internet page. These advances will allow customers to file requests for cases online, to register for courses online, to review and fill out standard forms used in cases and trainings online, and to provide feedback about our services online.

OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH

Budget Summary

	(Dollars in Thousand	ls)		
Office of the Assistant Secretary for Health	FY 2021 Final	FY 2022 Annualized CR	FY 2023 President's Budget	FY 2023 +/- FY 2022
Budget Authority	290,081	290,951	354,038	+63,087
FTE	236	274	323	+49

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. The mission of OASH is to develop and coordinate the implementation of policies, investments, and frameworks to lead America to healthier lives. OASH accomplishes its mission by providing leadership and coordination across the Department on numerous priority initiatives such as addressing the impacts of Long COVID, advancing health equity, including LGBTQI+ health; addressing the health impacts of climate change and environmental justice; behavioral health, ending the HIV epidemic in America; healthcare transformation through disease prevention, health promotion and resiliency; women's health, including maternal and reproductive health; immunization policy; and emerging public health challenges related to infectious diseases, and others.

In support of this mission, OASH:

- Emphasizes health maintenance, healthy behaviors, prevention, early detection, and evidencebased treatment to achieve optimal health.
- Focuses on ways to improve health outcomes, reduce disparities, and promote 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 and environmental impacts.
- Health Expertise attract, develop, and retain the Nation's best talent.
- Health Innovation foster novel approaches and solutions.
- Health Opportunity advance health opportunities and health equity for all.

As an organization, 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.
- 11 Presidential and Secretarial advisory committees.

OASH SUMMARY TABLE DIRECT

(Dollars in Thousands)

Office of the Assistant Secretary for Health	FY 2021 FTE	FY 2021 Final	FY 2022 FTE	FY 2022 Annualized CR	FY 2023 FTE	FY 2023 President's Budget
Immediate Office of the Assistant Secretary for Health	54	13,793	64	13,978	80	26,428
Office of Infectious Disease and HIV AIDS Policy	10	7,582	15	7,552	15	7,756
Office of Disease Prevention and Health Promotion	20	7,956	25	7,894	27	9,134
Office for Human Research Protections	20	6,225	24	6,243	24	6,412
Office of Adolescent Health	1	443	1	442	3	5,454
Public Health Reports	1	470	1	467	1	479
Teen Pregnancy Prevention	22	100,697	18	101,000	23	111,000
Office of Minority Health	47	61,649	57	61,835	70	85,835
Office on Women's Health	38	35,035	44	35,140	54	42,140
Office of Research Integrity (Non-Add)	26	8,986	27	8,986	28	8,986
Minority HIV/AIDS Fund	23	55,234	25	55,400	26	58,400
Embryo Adoption Awareness Campaign	-	997	-	1,000	-	1,000
Subtotal, GDM	236	290,081	274	290,951	323	354,038
PHS Evaluation Set-Aside						
Office for the Assistant Secretary for Health	-	4,885	2	4,885	5	7,885
Teen Pregnancy Prevention Initiative	-	6,800	-	6,800	1	7,700
Office of Climate Change and Health Equity	-	-	-	-	8	3,000
Subtotal, PHS Evaluations	-	11,685	2	11,685	14	18,585
Total Program Level	236	301,766	276	302,636	337	372,623

IMMEDIATE OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH

(Dollars in Thousands)					
Immediate Office of the Assistant Secretary for Health	FY 2021 Final	FY 2022 Annualized CR	FY 2023 President's Budget	FY 2023 +/- FY 2022	
Budget Authority	13,793	13,978	26,428	+12,450	
FTE	54	64	80	+16	
Authorizing Legislation:PHS Act, Title II, Section 301					
FY 2023 AuthorizationPermanent Allocation					
Method				Direct Federal	

Budget Summary

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, the Office of Science and Medicine, the Office of Policy and Legislation, and the Office of Regional Health Operations, which oversees 10 regional offices. The OASH-IO drives the OASH mission of developing and coordinating the implementation of policies, investments, and frameworks to lead individuals to healthier lives by providing leadership and coordination across both OASH and the Department. Additionally, OASH-IO provides advice and counsel to the Secretary and Administration on cross-cutting priorities to combat public health issues, such as Long COVID, behavioral health and substance use disorders; equity, including LGBTQI+ equity; climate change and environmental justice; and others.

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 a coordinating body across the Department and agencies with different legislative authorities. To effectively serve as a coordinating lead, OASH must also be well-versed on how legislative authorities and/or policies impact public health and the ability of agencies to develop and implement new policies and programs, an important function held in the Office of Policy and Legislation within OASH. This policy unit supports OASH on all policy and/or intergovernmental matters and is essential to providing the ASH and OASH leadership with guidance on complex policy areas and timely assessments of emerging needs and requirements to determine programmatic direction.

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. When President Biden announced his nominee for Surgeon General on December 8, 2020, he noted that this Office will be charged with restoring "public trust and faith in science and medicine." As the Department continues to respond to the COVID-19 pandemic, it is critically important to strengthen and expand the mission and impact of the Office of the Surgeon General in order to restore public trust while addressing challenges that prevent people in America from living full, healthy, and safe lives. The COVID-19 pandemic has exacerbated other longstanding public health challenges including substance use disorder, mental illness, and social isolation and loneliness, issues that require clear, consistent, and empathetic leadership based in science from a trusted messenger.

The Office of Science and Medicine (OSM) harnesses the power of collaboration, data-driven innovation,

and emerging technologies for advancing health equity initiatives within the Department, and leverages data to identify critical health innovation gaps as well as lead and coordinates solutions to address those gaps. OSM contains the Division of the Chief Medical Officer (DCMO) and the InnovationX unit. The DCMO provides policy and programmatic recommendations for critical emerging and long-standing federal issues that impact the medical and environmental determinants of health. This includes identifying ways to better serve the needs of vulnerable communities in urban, rural, and tribal areas affected by opioids and other substance use, as well as support healthy aging, health-related technology development, and social determinants of health. Using collaborative methods, the Division of the DCMO seeks to help provide better understanding of public health problems, unique solution development, and impactful delivery and administration. OSM also leads the interagency development of the first-ever National Strategy on Vector-Borne Diseases due to Congress in 2023, including health equity and climate change challenges.

Currently, InnovationX manages two programs with multi-million-dollar commitments from external partners: Kidney Innovation Accelerator and the Lyme Innovation Accelerator (LymeX), as part of the broader National Strategy on Vector-Borne Diseases. The Kidney Innovation Accelerator is a public-private partnership between HHS and the American Society for Nephrology to catalyze innovation and improve equitable outcomes in the prevention, diagnosis, and treatment of kidney diseases. LymeX is a public-private partnership between HHS and the Steven & Alexandra Cohen Foundation, DARPA, and NASA to launch the LymeX Diagnostics Prize in collaboration with Lyme patients, patient advocates, and diverse stakeholders across academia, nonprofits, industry, and government.

Established in 2021, the Office of Climate Change and Health Equity addresses the impact of climate change on the health of the American people. Exercising powers of convening, coordination and collaboration, the Office serves as a department-wide hub for climate change and health policy, programming, and analysis, in pursuit of environmental justice and equitable health outcomes. As the nation recovers from the COVID-19 pandemic, the negative and compounding effects of long existing health disparities, climate change, and are more apparent than ever. A more detailed discussion of OCCHE funding requests can be found in the EO implementation and the PHS Set Aside Fund sections.

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 and state levels events, and ensuring HHS's mission and priorities are translated, amplified, and implemented at the local, state, tribal, and national levels. In addition, ORHO convenes meetings and works with regional and national associations, other USG agencies, and public and private organizations to increase access to clinical, social, and public health services for all and use their expertise and networks to catalyze action addressing local public health programs, policy, and practice to positively impact leading health indicators and emerging issues.

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 variable information technology (IT) investments, including ensuring OASH IT systems are in compliance with Federal Information Security Modernization Act (FISMA) and Federal Information Technology Acquisition Reform Act (FITARA). OASH-OCIO is responsible for and manages over 33 distinct/disparate systems across program areas including websites; identifies and resolves cyber threats to ensure OASH program data are secure; supports continuity of operations; and provides oversight for IT governance, security, and customer support. OASH-OCIO also identifies and resolves complex business problems through innovative IT

solutions. This prepares and enables OASH to meet the emerging and increasing demands resulting from responding to public health emergencies and global pandemics, including the efforts of the Commissioned Corps.

Accomplishments from FY 2021 and FY 2022 to date:

- Continued to provide leadership and coordination on COVID-19 efforts, including convening HHS agencies and external partners to discuss the current state and clinical presentation of pediatric cases and hospital admissions; represented HHS on the USG coordination effort on Long-COVID led by the White House; and partnered with the U.S. Census Bureau on the Health & COVID-19 category of the Open Data for Good Grand Challenge sponsored by Census Open Innovation Labs (COIL). Additionally, the Surgeon General continued to provide leadership on vaccine confidence, including efforts related the COVID-19 pandemic to drive the public messaging along with trusted messengers.
- Behavioral Health Coordinating Council (BHCC): Led HHS efforts, in partnership with SAMHSA, to break down silos between our agencies and facilitate innovation and collaboration across the Department on behavioral health one of the Department's strategic priorities, including combating the opioid and substance use epidemic. This includes 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 Practice Guidelines for the Administration of Buprenorphine for Treating Opioid Use, and co-chairing and managing with SAMSHA the HHS Behavioral Coordinating Council.
- Mental Health and Substance Use Disorders: in collaboration with national policy experts, clinicians, and researchers developed and implemented an evidence-based strategy to address a historical care gap for maternal-infant dyads with opioid exposure and to publish recommendations on standardizing the clinical definition of opioid withdrawal in the neonate. In collaboration with HHS partners and state leadership teams, completed a follow-up evaluation of state-mandated reporting of neonatal abstinence syndrome (NAS) to improve epidemiologic surveillance. A report was published in the January 14th issue of the *Morbidity and Mortality Weekly Report (MMWR) Series* prepared by HHS/CDC. The U.S. Surgeon General launched a Surgeon General's Advisory on Youth Mental Health Crisis, which outlines the pandemic's unprecedented impacts on the mental health of America's youth and families, as well as the mental health challenges that existed long before the pandemic, and calls for an immediate, whole-of-society response to the crisis and provided a series of recommendations.
 - Established the President's COVID-19 Health Equity Task Force, a federal advisory committee focused on for mitigating the health inequities caused or exacerbated by the COVID-19 pandemic and for preventing such inequities in the future. A final report was issued October 2021. Continued work on mapping of possible HHS actions related to recommendations of the **President's COVID-19 Health Equity Taskforce**.
 - Provide leadership and coordination on **Climate Change and Health Equity**, including the development and inclusion of health equity considerations in the initial HHS Climate Adaptation and Resilience Plan, coordinating HHS responses to the extreme heat crises occurring in the summer of 2021, and the development of the Extreme Heat Interagency Working group under the White House National Climate Task Force. Led the development of US commitments to the COP26 Health Programme on resilient and low-carbon health systems, helping pave the way for coordination of implementation of low-carbon and resilient federal health systems and working through public-private partnership in conjunction with the National Academy of Medicine.
 - Launched the Initiative to Strengthen Primary Health Care to establish a federal foundation for the provision of high-quality primary health care for all; support the achievement of HHS goals on improving health care access and health outcomes and advancing health equity; and develop

an action plan for strengthening primary health care for HHS agencies to advance to the goal state of high-quality primary care by 2030. Thus far, the initiative has engaged 15 HHS agencies and offices as well as the White House Office of Science and Technology Policy and Domestic Policy Council and the Department of Veterans Affairs on an agency activity assessment of their current and planned activities to strengthen primary health care that will be used as a starting point for the next stage of the Initiative workplan, agency action planning.

- Continued execution of the modernization of the U.S. Public Health Service Commissioned Corps (Corps) implementing various new policies and procedures to assure 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. From 2013 to 2021, Corps officers were deployed 10,102 times, contributing to 214,281 deployments days over 222 different missions. As of August 17, 2021, the Corps has deployed two-thirds of all officers in support of COVID-19s, the highest historic deployment of officers to date.
- 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. Led LymeX Innovation Accelerator efforts, including patient-center innovations to identify opportunity areas with actionable recommendations for the future, and crowdsourcing to identify the best educational materials to raise awareness about tick-borne disease prevention.

Five Year Funding Table	unding Table	Fun	Year	Five
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Fiscal Year	Amount
FY 2019	\$11,678,000
FY 2020	\$13,178,000
FY 2021 Final	\$13,793,000
FY 2022 Annualized CR	\$13,978,000
FY 2023 President's Budget	\$26,428,000

Budget Request

The FY 2023 President's Budget request for OASH-IO is \$26,428,000, which is +\$12,450,000 above the FY 2022 Annualized Continuing Resolution (CR). At this funding level, OASH-IO will be better positioned to lead and direct key Administration and Department public health initiatives, including Long COVID response; advancing health equity -- including LGBTQI+ health; addressing the health impacts of climate change and environmental justice; and improving behavioral health and combatting the substance use disorders. OASH-IO will also develop public awareness campaigns to drive messaging on public health issues, through earned media, social media, and engagement with partners and trusted messengers. Funding will also provide OASH-IO with needed support to address administrative and operational needs, including ensuring funding to address IT security and compliance issues.

The budget includes \$3,000,000 in the Immediate Office of the ASH to support the Surgeon General's staffing needs and efforts related to expanding communications and engagement on critical challenges of public health and wellbeing in America. At this level, OSG will be able to hire 1 additional staff to direct public communications, lead digital and other innovative outreach efforts, provide critical engagement with key communities and partners, manage events and effective scheduling, and provide effective analysis of science and policy that will inform the activities of the OSG and OASH. This includes the immediate challenges of the COVID-19 pandemic and the pandemic's long-term effects – the exacerbation of existing challenges including substance use disorder, mental illness, and social isolation

and loneliness, as well as historic areas of OSG leadership including tobacco, obesity, hypertension, and others. The increase in funding will also support an increase in the budget for publications necessary for research and distribution cost of complex Surgeon General publications. Additionally, the increased funding will support the additional operational cost commensurate with expansion of OSG's programs and staff.

As OASH IO efforts continue to expand, funding for OASH-OCIO is required to ensure systems are in place, prevent and mitigate cybersecurity/privacy breaches and provide IT support to OASH required for new programs. The FY 2023 Add-Back level includes an increase of +\$3,600,000 for the OASH-OCIO to enable OASH-OCIO to continue to make significant progress to modernize and consolidate OASH's disparate systems, effectively address increases in Cyber Security threats, update IT service contracts to improve the quality of our systems, increase service desk management capabilities, support increased licensing requirements/needs, and fund continued Operations and Maintenance 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.

OFFICE OF ADOLESCENT HEALTH

Budget Summary

	(Dollars in Thousand	ls)		
Office of Adolescent Health	FY 2021 Final	FY 2022 Annualized CR	FY 2023 President's Budget	FY 2023 +/- FY 2022
Budget Authority	443	442	5,454	+5,012
FTE	1	1	3	+2
Authorizing LegislationPHS Act, Title XVII, Section 1708				
FY 2023 AuthorizationExpired				
Allocation MethodDirect 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 moved within the Office of Population Affairs and now reports to and operates within OPA. OAH engages national partners from healthcare, public health, education, community and out-of-school time programs, faith-based groups, and social services on adolescent health. In FY 2021, OPA/OAH presented at several national conferences on TPP programs and their findings to prevent risky behavior, promote health, and prevent disease.

Five Year Funding Table

Fiscal Year	Amount
FY 2019	\$1,442,000
FY 2020	\$442,000
FY 2021 Final	\$443,000
FY 2022 Annualized CR	\$442,000
FY 2023 President's Budget	\$5,454,000

Budget Request

The FY 2023 President's Budget request for OAH is \$5,454,000, which is \$5,012,000 above the FY 2022 Annualized Continuing Resolution. At this funding level, OAH will finalize development of a first-of-itskind national strategic plan to advance adolescent health. Funds will also allow OAH to update and maintain a National Information Clearinghouse on Adolescent Health; develop and fund an adolescent health research agenda; and support \$3 million in new competitive grants to invest in adolescent health across states, territories, tribes, and communities that focus on increasing protective factors for young people and their families. The FY 2023 budget request will continue to support administration of the TPP program and coordination of adolescent health funding and initiatives across HHS.

OFFICE OF DISEASE PREVENTION AND HEALTH PROMOTION

Budget Summary

(Dollars in Thousands)

Office of Disease Prevention and Health Promotion	FY 2021 Final	FY 2022 Annualized CR	FY 2023 President's Budget	FY 2023 +/- FY 2022
Budget Authority	7,956	7,894	9,134	+1,240
FTE	20	25	27	+2
Authorizing Legislation			.PHS Act, Title XVI	, Section 1701
FY 2023 Authorization StatusExpired				Expired
Allocation Method				Direct Federal

Program Description and Accomplishments

The Office of the Assistant Secretary for Health (OASH), Office of Disease Prevention and Health Promotion (ODPHP), which includes the President's Council on Sports, Fitness and Nutrition (PCFSN), 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. 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 pandemic 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 that expand 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 and well-being for all.

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, *Healthy People 2030*, was released in August 2020. The aspiration is that this new iteration will go even further and provide the framework for health in all policies and programs across all sectors of society. Central to *Healthy People 2030* is its overarching goal to eliminate health disparities, achieve health equity, and attain health literacy to improve health and well-being for all.

Drawing on user feedback supporting a more streamlined and focused approach, Healthy People 2030 provides a significantly reduced number of national objectives (from about 1,200 measurable objectives in the previous iteration to 355 in Healthy People 2030).

In FY 2021, ODPHP released two additional key elements of Healthy People 2030—the Leading Health Indicators (LHIs) and the Overall Health and Well-being Measures (OHMs). The Healthy People 2030 LHIs are a small subset of 23 high-priority *Healthy People 2030* objectives selected to drive action and focus resources toward improving health and achieving the objectives' 10-year targets. The OHMs are broad, global outcome measures intended to assess the Healthy People 2030 vision, *A society in which all people can achieve their full potential for health and well-being across the lifespan. Healthy People 2030* includes eight OHMs that encompass well-being, healthy life expectancy, and mortality and health. New to *Healthy People 2030* is the OHM indicator of well-being. ODPHP collaborated with CDC's National Center for Health Statistics to add a question on life satisfaction to the National Health Interview Survey that will be used to measure well-being at the national level. Together, the *Healthy People 2030* objectives, LHIs and OHMs offer a complete framework for assessing progress in achieving the nation's health and well-being goals.

In FY 2021, ODPHP initiated a Healthy People 2030 Champions program to increase stakeholder engagement and collaboration in achieving Healthy People's vision. The Champions program recognizes public and private organizations that are committed to working toward Healthy People's goals and objectives. In FY 2021, ODPHP continued to collaborate with states and localities through workshops aimed at facilitating establishing their own health improvement plans that incorporated Healthy People 2030 goals of eliminating health disparities, achieving health equity, and addressing the social determinants of health. ODPHP also developed a special supplement on Healthy People 2030 for the Journal of Public Health Practice and Management.

In FY 2021, ODPHP also continued to refine the redesigned microsite for *Healthy People 2030* on health.gov by incorporating additional tools and resources to make the Healthy People 2030 information more widely available and easily accessible and to increase its usefulness and relevance to a broader range of users. This innovative web resource gives users a platform from which to learn, collaborate, plan, and implement the national objectives. Partnering with National Center for Health Statistics 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. In FY 2021, ODPHP released on the microsite detailed data tables showing the latest available data for various population groups, including race/ethnicity, age, sex, sexual orientation, gender identity, geographic location, income and education level, insurance status, country of origin and others. The redesigned microsite also provides a database of evidence-based resources to help users find interventions and strategies to implement, 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 2021, ODPHP released an End-of-Decade Snapshot for Healthy People 2020, which provided a highlevel overview of progress made in achieving the last decade's national objectives. Throughout FY 2021, ODPHP collaborated with NCHS, to produce the *Healthy People 2020* final review, which provided on a rolling basis 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.

Dietary Guidelines for Americans

ODPHP coordinates, on behalf of HHS, 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 of the *Dietary Guidelines* began in FY 2017 and was completed in FY 2021, with much of the costs borne by USDA, the administrative lead for this edition. HHS and USDA released the 2020-2025 *Dietary Guidelines* in December 2020. The Departments' approach to the recent edition focused 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. The focus on these special populations and the entire lifespan will continue in all future editions. 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 then co-led the development of the government's 2020-2025 Dietary Guidelines.

HHS and USDA released a suite of materials with the launch of the *Dietary Guidelines* including a promotional video, 5 infographics, a consumer brochure, and other materials for implementation. In addition, HHS released the updated toolkit for health professionals to align with the current_*Dietary Guidelines*. The updated materials include guidance for health care providers on how to discuss nutrition with patients and complementary fact sheets on healthy eating routines, and reducing intake of saturated fat, added sugars and sodium.

Beginning in FY 2021, ODPHP assumed the administrative lead, and therefore the primary financial responsibility, for the development of the multi-year process to develop the *Dietary Guidelines*, 2025-2030. To promote transparency, the DietaryGuidelines.gov website provides regular updates on the development of topics and questions, public meetings of the Committee, subcommittee progress, and detailed documentation of the evidence review process.

Physical Activity Guidelines for Americans

In FY 2019, the ASH launched the Physical Activity Guidelines for Americans (PAG, or Guidelines), 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. The Guidelines provides evidence-based guidance on how physical activity can help promote health and reduce the risk of chronic disease. 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. The Guidelines serve as the primary basis for physical activity recommendations in the Dietary Guidelines and the physical activity objectives in *Healthy People*. Adherence to the physical activity guidelines could reduce premature mortality by 10% and save over \$100 billion annually in health care expenditures.

In FY 2021, planning began for the PAG Midcourse Report with an anticipated release in FY 2023, 5 years after the second Guidelines edition. The Midcourse Report will focus on older adults who historically have lower rates of meeting the Guidelines. This report will highlight strategies and settings based on the current scientific evidence to encourage more older adults to get the physical activity they need to get and stay healthy.

National Youth Sports Strategy

Released in FY 2019, the National Youth Sports Strategy (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. Implementation of the NYSS focuses on four key areas: communication and promotion of youth sports, partnership and stakeholder coordination, federal government coordination, and measurement of youth sports, all withinput from the HHS implementation steering committee. Previous work included the development of Move Your Way campaign resources to promote the benefits of youth sports and a series of 10 regional workshops to connect local youth sports

organizations with facilitator-driven networking and discussions in pursuit of the NYSS vision. The NYSS Champions program, a partnership initiative, was designed to recognize organizations working in alignment with the NYSS vision and help foster partnership and collaboration across different levels and sectors of society. It was launched at the September 2020 President's Council on Sports, Fitness, & Nutrition meeting and currently includes a growing network of over 165 organizations. The first NYSS Champions workshop was held in FY21 to generate ideas for how NYSS Champions can be meaningfully engaged to support the collective effort to improve the youth sports landscape. NYSS Champions are leveraged to promote and disseminate NYSS and other ODPHP initiatives. Lastly, 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 80 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.

In FY 2021, ODPHP completed new campaign materials for people who are pregnant and postpartum, older adults, and teens and supported targeted pilot campaigns in 5 communities. As of September 2021, implementation of the campaign through 15 pilot tests has resulted in over 191 community events, 300 partnerships, distribution of over 383,000 campaign materials, including factsheets and posters, over 4 million ad views of campaign videoson YouTube, 107 million ad buy impressions across digital and traditional media, and over 350 million impressions of the #MoveYourWay hashtag on Twitter. The campaign has been funded through multiple sources since 2016, including the Office of the Secretary, the Office on Women's Health, and OASH evaluation awards.

ODPHP plans to continue the campaign in FY 2022 by developing new materials that incorporate healthy eating messages, continuing to evaluate the campaign and implementation strategies, and improving 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. ODPHP will also support efforts to identify sustainable options for moving the campaign beyond the pilot stage.

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. ODPHP recently updated health.gov's infrastructure and improved the user interface for the MyHealthfinder microsite, which customizes preventive services recommendations for users with low health literacy based on age, sex, and pregnancy status. Health.gov also features a robust microsite to support Healthy People 2030 with an API that automatically updates the data for each of the 355 objectives. In FY 2021, ODPHP signed an agreement with Google for the use of MyHealthfinder content, 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. ODPHP also added additional features to the Healthy People 2030 microsite and merged fitness.gov, the former website of the PCSFN, with health.gov in FY 2021.

ODPHP plans to launch a promotional campaign for MyHealthfinder in FY 2022 to encourage consumers to catch up on preventive services (due to delays during the COVID-19 pandemic) with the assistance of the MyHealthfinder tool. ODPHP will also add content sections to health.gov, including a section related to long-term recovery and resilience in the wake of the COVID-19 pandemic, support ongoing efforts to

improve website security and content delivery, and make ongoing updates to support programmatic work.

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. In FY 2022, ODPHP plans to make updates to its health literacy resources on health.gov to continue to improve uptake of the new health literacy definition.

ODPHP also partners with the Agency for Healthcare Research and Quality and NIH to support the HHS Health Literacy Workgroup. In FY 2021 the workgroup continued to support health literacy quality improvement projects for each HHS agency. ODPHP plans to continue support of the workgroup in FY2022.

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

President Biden issued amendment to Executive Order (EO) 13265 on September 30, 2021, renewing the President's Council on Sports, Fitness & Nutrition (PCSFN) until September 30, 2023. The PCSFN is a federal advisory committee of up to 30 volunteer citizens who serve at the discretion of the President.

The 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.

Since the release of the National Youth Sports Strategy (NYSS), the PCSFN has been focused on its implementation and building partnerships with youth sports organizations. The most recent amended EO calls for continued promotion of the NYSS and provides for the work of the Council to include a focus on expanding national awareness of the importance of mental health as it pertains to physical fitness and nutrition. The Science Board—a PCSFN subcommittee composed of 14 volunteer experts in physical activity, youth sports, and nutrition—published two commentaries in 2021 that spotlight potential improvements to post-pandemic youth sports to better meet young people's mental, emotional, and social needs.

To further support the PCSFN, repopulating the National Fitness Foundation (NFF) Board of Directors was identified as a key priority in 2021. The NFF was created by Congress in 2010 to assist and strengthen the PCSFN and its mission by facilitating investments and partnerships that engage, educate, and empower all Americans to lead healthy, active lives. NFF board members are appointed by the Secretary of HHS, so ODPHP put together a slate of highly qualified individuals to replace the board members whose terms have expired. The slate will be put forward to Secretary Becerra in early FY 22 for his consideration and appointment.

Five Year Funding Table

Fiscal Year	Amount
FY 2019	\$7,894,000
FY 2020	\$7,894,000
FY 2021 Final	\$7,956,000
FY 2022 Annualized CR	\$7,894,000
FY 2023 President's Budget	\$9,134,000

Budget Request:

The FY 2023 President's Budget request for ODPHP is \$9,134,000, which is +\$1,240,000 above the FY 2022 Annualized Continuing Resolution. At this funding level, ODPHP will be able to ensure that its programs are best able to meet the office's statutory mandate to help the nation establish greater resilience through improved health. This budget will provide for up-to-date enhancements and quality improvements of the tools and resources that optimize implementation of ODPHP's key programs – *Healthy People*, Dietary Guidelines for Americans, 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 improved disease prevention and health promotion and result in individual empowerment. ODPHP will continue leveraging its key role in the coordination of activities among Federal partners, that enable HHS to effectively apply scientific, evaluative, and programmatic findings of agencies, 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, particularly critical, ensuring sufficient staffing for HHS' interagency role as administrative lead for the next iteration of the Dietary Guidelines.

Healthy People

The FY 2023 request will support strategic implementation of the decade's national, 10-year health objectives, Healthy People 2030, which is guided by and encompasses HHS' and the Administration's priorities of achieving health equity, eliminating health disparities, and addressing the social determinants of health. ODPHP will continue to enhance its activities aimed at increasing the reach and usefulness of Healthy People 2030, the Leading Health Indicators, and the Overall Health & Well-being Measures among a more diverse and expanded group of users across multiple sectors, reaching beyond our traditional health-sector partners. ODPHP will leverage its Healthy People 2030 Champions to increase the initiative's reach in addressing critical public health issues. ODPHP will continue to refine its online disparities data display tools, evidence- based resources, and tools for community action and will conduct ongoing reviews of the Healthy People 2030 objectives to ensure they include the nation's critical public health issues.

Dietary Guidelines for Americans (DGA)

With HHS being the current administrative lead for the development of the 2025-2030 edition of the Dietary Guidelines for Americans (DGA), the FY 2023 budget request will support many activities including the appointment of the 2025 Dietary Guidelines Advisory Committee (DGAC), developing the DGAC subcommittee structure and subcommittee support, and holding three public DGAC meetings and numerous subcommittee meetings. Additional federal staff will be brought on to support this large-scale project with national impact. Funds in FY 2023 will support ongoing content development for the website, DietaryGuidelines.gov, to enable public transparency of the entire Dietary Guidelines process.

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

The FY 2023 budget request will support staff to work on the development, launch, and implementation of the Physical Activity Guidelines Midcourse Report focused on strategies to increase physical activity among older adults, to be released in FY 2023. Funds will also support of ODPHP's continued work on the Move Your Way communications campaign, which ODPHP developed to promote the second edition of the Physical Activity Guidelines for Americans (PAG) to 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. 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 continue implementation of the National Youth Sports Strategy (NYSS) through its NYSS Champions partnership initiative and support strategies to create safe, fun, inclusive, developmentally appropriate, and accessible youth sports opportunities.

President's Council on Sports, Fitness & Nutrition

The FY 2023 President's Budget request will support the work of the PCSFN appointed 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 one public meeting 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 to promote physical activity and healthy eating, awards and recognition, and ensure alignment of these programs with the Physical Activity Guidelines for Americans and the Move Your Way campaign, the National Youth Sports Strategy, and the Dietary Guidelines for Americans. Engagement of the PCSFN's Science Board subcommittee ensures the latest scientific evidence is incorporated into all PCSFN deliverables.

ODPHP– Key Outputs and Outcomes Table:

Measure	Year and Most Recent Result Target for Recent Result (Summary of Result)	FY 2022 Target	FY 2023 Target	FY 2023 +/- FY 2022
I.b Visits to ODPHP-supported websites (Output)	FY 2021: 13,222,325 Target: 10.5 Million (Target Exceeded)	10.5 Million	10.5 Million	Maintain
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)	60%	60%	Maintain

ODPHP (including PCSFN)– Key Outputs and Outcomes Table:

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2022 Target	FY 2023 Target	FY 2023 +/- FY 2022
8.6 Number of social media impressionsrelated to ODPHP's sports, physical activity, nutrition and other health promotion programs	FY 2021: 400 million Target: 101 million (Target Exceeded)	4.5 Million	320 million	+315.5 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. Additionally, the National Youth Sports Strategy (NYSS) and the NYSS Champions program provide actionable strategies to increase participation in youth sports, through blogs, regular newsletters, and social media.

Outreach for the Dietary Guidelines is also primarily web-based. ODPHP will continue to update web content and resources in FY 2023 to support implementation of the 2020-2025 DGA as well provide updates on the development of the next edition (2025-2030) of the Dietary Guidelines, including topics and questions, public meetings of the Committee, subcommittee progress, and detailed documentation of the evidence review process.

The online MyHealthfinder tool provides easy-to-understand, customized prevention recommendations to consumers and a targeted promotional effort to encourage Americans to catch up and keep up with preventive services that they might have missed during the COVID-19 pandemic in FY2022 is expected to increase use of the tool. As the data reflects, ODPHP is increasing itsreach 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 wellnessactivities.

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 andprofessional 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. Although web traffic continues to grow, ODPHP expects that the planned archival of the previous decade's website for the *Healthy People* initiative could result in a small decrease in web visits in FY 2022. Additionally, ongoingdenial of service (DDoS) attacks in FY2021 have had a dampening effect on growth in web traffic. For these reasons, ODPHP will maintain a flat target for FY2023, as we monitor possible impacts to web traffic in FY 2022.

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 in FY 2021 dropped, as expected, as states recalibrated their efforts to align with the new national objectives. Further adding to the decrease, was the COVID-19 pandemic, which caused some states to pause their regular health planning efforts. While use is expected to again increase in FY 2022, ODPHP will maintain the FY 2023 target at the FY 2022 leveldue to the uncertainty of possible continued impact of the pandemic. 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 thiscampaign is the current driver of ODPHP's social media impressions, ODPHP anticipates a steep decrease in FY 2022 and in FY2023,

OFFICE FOR HUMAN RESEARCH PROTECTIONS

Budget Summary

(Dollars in Thousands)					
Office for Human Research Protections	FY 2021 Final	FY 2022 Annualized CR	FY 2023 President's Budget	FY 2023 +/- FY 2022	
Budget Authority	6,225	6,243	6,412	+169	
FTE	20	24	24	-	
Authorizing Legislation PHS Act, Title II, Section 301					
FY 2023 Authorization Permanent					
Allocation MethodDirect 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 policy, creates 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 approximately 3,500 Federal Wide Assurances (FWAs) and 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:

OHRP 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:

• To facilitate research during the novel coronavirus disease (COVID-19) pandemic, in October 2020, OHRP 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.

- In November 2020, OHRP issued guidance on maintaining consistency regarding the applicability of the 2018 or the pre-2018 Requirements, which clarifies the options for ongoing collaborative research to add new participating institutions while maintaining regulatory consistency.
- DPA has prepared several items undergoing formal clearance or review by HHS leadership at present, including the following: Guidance on Clinical Trial Consent Form Posting (45 CFR 46.116(h)); Guidance on Demonstration project posting (45 CFR 46.104(d)(5)(i)); Authorization to share Interim Final Rule for Subparts B, C, and D updates; Pre-development decision/approval to draft NPRM for Technical Changes to Subpart A.
- DPA administers the process by which institutions submit assurances of compliance with HHS protection of human subjects' regulations and IRB registrations. To date in FY 21, DPA approved 1582 new Federal-wide Assurance (FWA) applications and 1955 renewed/updated FWA applications. DPA also accepted 380 new IRB Organization registrations, each of which can include multiple registered IRBs. DPA also accepted 2511 renewed/updated IRB Organization registrations and expects similar numbers in FY 2022.
- In September 2021, DPA kicked off an effort to modernize the software supporting FWAs and IRB registrations, including the Human Assurance Tracking System (HATS), Electronic Submission System (ESS), and Search application. In FY22, developers at NIH Center for Information Technology will work with OHRP to characterize OHRP's requirements and create interactive wireframes for OHRP feedback for all three applications. OHRP secured funding for software modernization from partners at NIH, CDC, and FDA through the Joint Funding Arrangement proposal process through a proposal for \$550K over FY22/23 that was approved to receive an initial \$350K in FY22.
- In FY 2021, OHRP pursued renewal of multiple information collection requests with the Office
 of Management and Budget in order to fulfill OHRP's administrative requirements and comply
 with the Paperwork Reduction Act. OHRP is also pursuing a new information collection request
 to correspond to existing regulations for research involving pregnant women, fetuses, or
 neonates, prisoners, or children, where such activities require an HHS consultation process and
 are not otherwise approvable by an IRB. These information collection requests include the
 following: Protection of Human Subjects Assurance Identification/IRB Certification/Declaration
 of Exemption (Common Rule), OMB Control Number 0990-0263, approved June 15, 2021;
 Protection of Human Subjects: Assurance of Compliance with Federal Policy/IRB Review/IRB
 Recordkeeping/Informed Consent/Consent Documentation, OMB Control Number 0990-0260,
 approved August 3, 2021; Institutional Review Board (IRB) Records for HHS/OASH Consultation
 Process, OMB Control Number OS-0990-NEW, 60-day notice concluded September 27, 2021.

OHRP's Division of Education and Development (DED) conducts outreach events and works with institutions around the United States to co-sponsor conferences and workshops to educate and support IRB members and administrators, investigators, institutional officials, and others, in their efforts to protect human subjects in research. The OHRP Research Community Forum (RCF), 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 FY 2021, OHRP launched the new <u>Human Research Protection Training</u>, an interactive 5lesson online training program that provides foundational training on human research protections under the federal Common Rule at 45 CFR 46 to the research community. Due to restrictions imposed by the COVID-19 pandemic, outreach activities were conducted 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 the Public Responsibility in Medicine and Research's annual Advancing Ethical Research Conference in December 2020 and delivered another nineteen webinars to a variety of research institutions and federal funders of research. On June 15-16, 2021, OHRP co- hosted the 2-day virtual Research Community Forum with the University of Texas Southwestern Medical Center, covering topics including promoting diversity and supporting community engagement in research. OHRP staff spoke on three different occasions in this RCF, which was very well received with 560 registered participants. To further facilitate inclusion and diversity in scientific research, OHRP hosted the two-hour workshop Supporting *Ethical Research Involving American Indian/Alaska Native (AI/AN) Populations* with a special address from Admiral Rachel Levine on Thursday, August 26, 2021.

- On September 24, 2021, OHRP hosted its 4th Exploratory Workshop, *Review of Third-Party Research Risks: Is There a Role for IRBs?* In addition, OHRP continued its effort to educate the general public about research and protections in research participation through its <u>About</u> <u>Research Participation</u> website. In support of the COVID-19 vaccine initiative to engage children, OHRP released a video called *Research with Children: What Parents Need to Know*, in both English and Spanish. To promote public trust, a video called *Protecting Your Privacy in Human Research* was released. DED also led and completed the effort to improve user accessibility and experience for the OHRP <u>Regulation pages</u>.
- Projecting into FY 2022, DED plans to host three Research Community Forums (RCFs) in collaboration with Northwell Health System in New York, the University of Nevada in Reno, and Indiana University in Indianapolis. In addition, DED will support four or more virtual webinars with a variety of research and academic institutions. DED plans to release one or more webinars with Common Rule agencies to help the research community understand unique requirements and interesting nuances about how OHRP's Common Rule federal partners apply the regulations. The 5th annual OHRP Exploratory Workshop is scheduled for September 15, 2022 with the topic still under consideration. In FY 2022, DED plans to release a new interactive educational series called Considerations for Reviewing Human Subjects Research. This series will use case examples to help investigators and IRBs understand how to interpret and apply the approval criteria at sec. 46.111 of the Common Rule. DED plans to add five or more videos of plenary lectures given at OHRP RCFs to the Luminaries Lecture series. As for the About Research Participation project that focuses on educating the general public about research participation and protections, DED plans to launch a Voice of Participants' series that provides short audio-recordings of people speaking about their experience related to research and research participation. Moving into the fifth year since its original launch in 2017, DED will reexamine effective communication channels that would help further disseminate the valuable resources on OHRP's About Research Participation website.

OHRP's Division of Compliance Oversight (DCO) DCO is the division within OHRP that conducts compliance investigations in response to indications of noncompliance and valuates human research protections programs at 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. Also, in FY 2021, DCO began work with a contractor to develop a new compliance activity tracking database and document management system using the Salesforce platform. The Phase 1 database was launched in December 2020 and DCO is continuing efforts to refine the system and

migrate data from the old system to the new system. The following describes three primary functions of DCO:

- Conducts Compliance Evaluations and Investigations DCO conducts a program of not-forcause surveillance evaluations of institutions that conduct HHS supported research. 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. In 2021, DCO initiated its first site visit of an independent IRB, which is being conducted virtually, and conducted a second virtual evaluation of an institution's human research protections program in September2021. DCO also conducts investigations into alleged noncompliance with the Federal Policy for the Protection of Human Subjects. For-cause investigation include similar activities as a surveillance evaluation with a concentration on the alleged non- compliance. When evaluations and investigations are conducted remotely (offsite), it is general performed by a single DCO staff person.
- 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 within two business days to determine whether remedial actions are adequate to address the incident and 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 DCO created and published an OMB-approved Incident Reporting Form in July 2021, converted to an on-line form that is now available on OHRP's webpage.
- 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 OHRP's 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.

Secretary's Advisory Committee on Human Research Protections (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 Deceased Donor Intervention Research, Artificial Intelligence and Considerations for IRB Review,

- Reimaging the Concept of "Engagement" and HHS Support, and Considerations for the Principle of Justice in 45 CFR part 46. In FY 2021, SACHRP approved three sets of recommendations that have been or are in process of being forwarded to the Secretary.
- 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.

Fiscal Year	Amount
FY 2019	\$6,493,000
FY 2020	\$6,243,000
FY 2021 Final	\$6,225,000
FY 2022 Annualized CR	\$6,243,000
FY 2023 President's Budget	\$6,412,000

Five Year Funding Table

Budget Request

The FY 2023 President's Budget request for OHRP is \$6,412,000, which is +\$169,000 above the FY 2022 Annualized Continuing Resolution. At this funding level, OHRP will maintain its current activities supporting the conduct of sound and ethical scientific research. Current activities that OHRP expects will be carried out in FY 2023 at this level of funding include the following:

- OHRP plans to continue developing guidance on the revised Common Rule. Priorities for this budget request include incorporating advisory committee recommendations on the ethical principle of justice into guidance efforts; continuing active harmonization efforts with FDA counterparts; identifying gaps in policy and guidance to support trends in the field toward decentralization of clinical research.
- Pursuing rulemaking to address technical issues with the regulations that have resulted in unintended burden on the regulated community.
- Supporting OHRP's ongoing role in managing and improving the processes and tools by which institutions register Institutional Review Boards and obtain assurances to conduct HHS-supported human subjects research.
- Supporting a team of our professionals to maintain its current output of online educational resources on human research protection that has seen a significant increase in demand because of the decentralization of research, and the interest towards diversifying and expanding engagement of the entities supporting research activities and potential participant pools.
- Providing continued support for on-site evaluations of human research protections programs and pay for subject matter experts' (SME) participation in these evaluations. Engaging SMEs during site evaluations continues to be a critical component of OHRP compliance evaluations as they offer institutions expert advice on best practices related to the implementation of and compliance with HHS regulations, along with extra-regulatory matters important to their conduct of human subject research (i.e., diversifying and expanding engagement of the entities supporting research activities).

OFFICE OF INFECTIOUS DISEASE AND HIV/AIDS POLICY

Budget Summary

(Donars in Thousands)				
Office of Infectious Disease and HIV/AIDS Policy	FY 2021 Final	FY 2022 Annualized CR	FY 2023 President's Budget	FY 2023 +/- FY 2022
Budget Authority	7,582	7,552	7,756	+204
FTE	10	15	15	-
Authorizing Legislation	PHS A	ct, Title II, Section	301; PHS Act, Title	e XXI, Section 2101
FY 2023 Authorization			Pe	ermanent; Expired
Allocation Method				Direct Federal

Program Description and Accomplishments

The Office of Infectious Disease and HIV/AIDS Policy (OIDP) within the Office of the Assistant Secretary for Health 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.

Health Equity is a critical component of OIDP's 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. OIDP worked with the White House and released the National HIV/AIDS Strategy for the United States 2022-2025 early in FY2022. The Strategy reflects the Administration's commitment to re-energize and strengthen a whole-of-society response to the epidemic while supporting people with HIV and reducing HIV-associated morbidity and mortality. The Strategy sets bold targets for ending the HIV epidemic in the United States by 2030. To ensure the success of these strategies, OIDP is developing implementation plans to be released in FY2022. 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, equity in antibiotic access and use, and addressing HIV stigma and discrimination. The National Vaccine Advisory Committee (NVAC) also approved a report on immunization equity in FY 2021, and the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PACCARB) issued a report in addressing disparities in antibiotic access and use across the One Health spectrum. 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 coordinated the 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 and prevent the burden of vaccine-preventable disease on the entire country. In FY 2021, OIDP continued its catchup immunization activities by drafting an analytical inventory report of current catch-up immunization activities from federal agencies, advocacy groups, and private entities. In FY 2021, OIDP updated materials supporting efforts to vaccinate children and expanded the messaging to include adults, who may have missed routine immunizations due to the pandemic. In addition, OIDP awarded a contract for a social norming campaign in FY 2021 to further encourage uptake in missed vaccination due to the COVID-19 pandemic and plans to launch the campaign in spring or summer of 2022.

OIDP serves on CDC's Advisory Committee on Immunization Practices (ACIP) as an ex officio member, as well as a member in its COVID-19 work group and COVID-19 vaccine safety technical subgroup. OIDP also serves on FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) as a voting member and was engaged in all discussions and recommendations on emergency use authorizations of COVID-19 vaccines for adults and children. By holding these key positions on scientific advisory committees associated with COVID-19, OIDP provides public health expertise and medical recommendations on the safety, appropriate use, and effectiveness of COVID-19 vaccines.

In FY 2021, the Presidential Advisory Committee on Combating Antibiotic Resistant Bacteria reported on the impact of the COVID-19 pandemic on antimicrobial use, resistance, and stewardship, and continues to address the issue and receive updates at every public meeting. Additionally, the National Vaccine Advisory Committee approved a report with recommendations for improving COVID-19 vaccination efforts and wrote a letter providing recommendations to improve confidence of COVID-19 vaccines and 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. OIDP is in the process of developing a communication campaign to promote blood and plasma donation, as we are currently experiencing severe, life-threatening blood and plasma shortages across the

country.

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, maintains the America's HIV Epidemic Analysis Dashboard (AHEAD). AHEAD is focused on visualizing baseline data and indicator targets for the six EHE specific indicators. In early 2021, OIDP launched an interactive version of AHEAD that allows users to select certain criteria for viewing. OIDP created a step-by-step user guide available on the dashboard to assist users in understanding how to navigate and use the dashboard. In the late summer and fall of 2021, OIDP enhanced AHEAD with stratified data by four key demographic categories at the national, state, and local levels, where data is available. The four demographic categories are age, race/ethnicity, gender/sex at birth, and mode of transmission. Multi-way stratified data will enable stakeholders to view data for selected subpopulations to better understand programmatic gaps and areas where additional focus and resources are needed. Second, OIDP enhanced AHEAD with select social determinants of health, including HIV stigma, housing instability, poverty, education levels and more, to contextualize the six HIV indicator data to inform program planning. In FY22, OIDP plans to add additional useful features to assist stakeholders in reaching the 2025 and 2030 targets that have been established for the EHE initiative.

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.

National HIV/AIDS Strategy for the United States 2022-2025

The National HIV/AIDS Strategy for the United States 2022-2025 (NHAS), released in December 2021, focuses strongly on the syndemics—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.

Prevention through Active Community Engagement (PACE) Program

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. In FY 2021

OIDP, as part of broader community engagement efforts, convened an internal EHE Stakeholder and Partner Engagement Coordination committee focused on engaging: (1) a broad range of health care providers, (2) pharmacists and pharmacies, (3) faith-based organizations, (4) academic and educational institutions, including HBCUs, and (5) community based social support organizations. The aim of this coordination committee is to align and coordinate the PACE Program and EHE work on engaging stakeholders, leveraging shared resources, and avoiding duplication of efforts.

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 and AIDS, including common co-morbidities, as needed to promote effective HIV diagnosis, treatment, prevention, and quality care services. PACHA also advises on the development and implementation of the EHE initiative, in addition to the HIV National Strategic Plan (formerly the National HIV/AIDS Strategic Plan).

In FY2021, PACHA convened virtually in December 2020, March 2021, and August 2021. Topics included ensuring Health Equity with the Ending the HIV Epidemic in the U.S. 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. During PACHA's 71st full council meeting in August 2021, 8 new members and the reappointments for 3 members were sworn-in by ADM Levine, Assistant Secretary for Health, making PACHA's roster reflecting the racial, ethnic, sexual and gender minority, and geographic diversity of the HIV epidemic in the U.S. today. In FY2022, PACHA convened virtually in November 2021 and topics included molecular HIV surveillance, private-sector engagement, and HIV and meeting our 2030 goals. Additional information on, including the Council's recommendations can be found on the PACHA page on HIV.gov: https://www.hiv.gov/federal-response/pacha/about-pacha.

HIV.gov

The HIV.gov website is a leading source of comprehensive information on federal HIV policies, programs, and resources, including the Ending the HIV Epidemic in the U.S. (EHE) initiative and the National HIV/AIDS Strategy for the United States 2022-2025. The site also hosts America's HIV Epidemic Analysis Dashboard (AHEAD), a critical tool that visualizes the nation's collective progress in reaching EHE goals.

The HIV.gov program supports cross-governmental coordination and provides technical leadership to ensure HIV messaging is consistently communicated, and resources are widely available across federal programs to 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. In partnership with NIH, HIV.gov is the dynamic home of the federal HIV treatment guidelines, and often reports on breaking scientific and policy news from conferences and events to educate multiple audiences through multiple platforms.

From October 1, 2021, to January 31, 2022, the website had 3.3 million visits. During this same time, HIV.gov's Locator widget was used on more than 600 websites and more than 7,300 times. The site transitioned to become a Progressive Web App to increase security and functionalities in FY2021 yielding an 19% increase in views. HIV.gov has also created standards for web hosting/Internet security that serve as models for HHS.

Immunization Leadership and Coordination

OIDP leads the coordination of federal immunization activities, 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.

Medical and Public Health Expertise and Strategic Policy Direction on Vaccinations and Immunizations

OIDP sets national vaccine policy by working alongside with other recognized medical and public health experts by serving as a liaison member on the ACIP, which advises the Director of CDC on national policies on the use of vaccines. OIDP is also an ex officio member of the Advisory Commission on Childhood Vaccines which advises HRSA's National Vaccine Injury Compensation Program. By holding these scientific positions, OIDP provides public health expertise and medical recommendations on the safety, appropriate use, and effectiveness of vaccines and immunization schedules for infants, children, adolescents, and adults. OIDP works with federal, state, and local partners as well as nongovernmental entities to provide technical assistance and guidance on vaccination-related issues and priorities.

Immunizations-related Community Grants, Strategic Partnerships and Project Initiatives

In addition to providing medical and public health expertise and policy direction, OIDP oversees two onthe-ground vaccination initiatives. In FY 2021, OIDP awarded six grantees to promote vaccine confidence in local communities, in partnerships with the regional health offices to plan, implement, and evaluate evidence-based strategies and innovation practices to increase vaccine confidence in racial and ethnic minorities and other underserved populations with low vaccination coverage. Leveraging partnerships with government and non-government stakeholders, OIDP administers or provides technical assistance and guidance 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 on their vaccines due to 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.

In FY 2021, 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 continues to grow the vaccine confidence community and will provide meeting opportunities in FY 2022 to expand the work of these professionals.

Vaccines National Strategic Plan

The Vaccines National Strategic Plan establishes a comprehensive five-year strategic framework to promote routinely recommended vaccines and vaccinations. The strategic plan's goals are to advance innovation in vaccine development, ensure vaccine safety, increase public vaccine knowledge and confidence, increase access to and use of vaccines, and support global immunization efforts. The Plan also includes more specific objectives, strategies, and representative indicators with targets to monitor progress. In 2022, OIDP, in partnership with the Federal Interagency Vaccine Work Group (IVWG), will release a Federal Implementation Plan that articulates OIDP's Federal partners' commitments to policies, research, and activities during the fiscal years 2021–2025 to meet the National Strategic Plan's goals.

Federal Interagency Vaccine Work Group

OIDP chairs and convenes the Federal Interagency Vaccine Working Group (IVWG), which functions as the Steering Committee for the Vaccines National Strategic Plan 2021-2025. The IVWG comprises of 25 members representing senior leadership from 15 Departments and agencies with a stake in promoting vaccine development and use. In partnership with OIDP, the IVWG develops and drafts the recommendations for the goals, objectives, and strategies in the National Strategic Plan. The IVWG members identify and develop cross-departmental or agency policies, programmatic initiatives and collaborative approaches to address challenges and gaps as well as capitalize on potential synergistic opportunities. The IVWG facilitates the coordination, collaboration, and accountability of federal efforts and monitors and reports on progress towards the Strategic Plan's goals. Several IVWG members also serve on the National Vaccines Advisory Committee.

National Adult and Influenza Immunization Summit

OIDP co-leads, 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. OIDP cochairs two of four NAIIS workgroups, Access and Provider and Influenza and Adult Immunizations. The NAIIS conducts weekly informational partner calls, hosts webinars on topics of current interest, and convenes in-person annual summit meetings. 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.

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 National Strategic 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 which sets forth a roadmap to eliminate viral hepatitis as a public health threat by 2030. To ensure that the development of the Plan was inclusive, OIDP convened and led a joint HIV-viral hepatitis federal steering committee and three topic specific viral hepatitis subcommittees, which were comprised of representatives across HHS as well as other federal departments. In addition, several hundred sets of public comments received through 18 listening sessions and an RFI published in the Federal Register informed the development of the Plan. In 2021, OIDP disseminated the Plan through postings on HHS websites and through numerous presentations and webinars, reaching a broad range of stakeholders.

A companion Viral Hepatitis Federal Implementation Plan will be released in April 2022. The Federal Implementation Plan sets forth federal partners' commitments to policies, research, and activities during the fiscal years 2021–2025 to meet the National Strategic Plan's goals, pursuant to their respective missions, funding, and resources. OIDP also coordinated opportunities for written and verbal public comment to inform development of the Federal Implementation Plan.

Viral Hepatitis Implementation Working Group

OIDP convenes and leads the Viral Hepatitis Implementation Working Group (VHIWG), with more than 20 federal agencies and offices, including HHS, HUD, DOJ, and the VA. Through the VHIWG, OIDP monitors and reports on progress implementing the prior National Viral Hepatitis Action Plan. This group also serves as a vehicle for coordinating and leveraging viral hepatitis initiatives across the federal government and is currently reconstituted to serve as a subcommittee for the newly established Syndemic Steering Committee to monitor and report on federal implementation of the current Viral Hepatitis National Strategic Plan.

Addressing Reimbursement/Payment Barriers to Integrated Viral Hepatitis Prevention and Care Services

In FY2021 OIDP began a 3-year project to conduct research, through environmental scans, focus group discussions, and partner meetings, to identify barriers to reimbursement and other systemic barriers to integrated viral hepatitis prevention and care services in clinical and non-clinical settings. Expected outcomes will be recommendations for a new or existing efficient payment models or policies to address systemic barriers to integrated viral hepatitis services. OIDP will facilitate collaboration and dissemination of findings to federal, non-federal, health plans, health care systems and providers, community-based groups, and other stakeholders.

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 is working with federal partners to release an implementation plan of activities in May 2022.

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. OIDP continues to monitor the status of the U.S. blood supply and participate in response planning. As of the second quarter of FY2022 the U.S. blood supply is "code red" with less than one-day supply. In FY2022 OIDP will continue to meet with stakeholders from the blood and healthcare industries including the DOD and VA to discuss the actions to alleviate the blood and plasma shortages.

OIDP 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 is planning to launch a National Blood and Plasma Donation Campaign, which was mandated through the 2020 CARES Act, to increase donations and the diversity of donors across the United States. OIDP 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. OIDP serves on the AABB Interorganizational Task Force on Domestic Disaster and Acts of Terrorism that works with the civilian blood counterparts ensuring that blood and tissue products are made available for any natural or man-made disaster contingencies.

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. OIDP was assigned the responsibility for addressing the PAHPAIA, Section 209 Blood Safety Report. Specifically, the report sought to make recommendations related to the challenges associated with the continuous recruitment of blood donors, ensuring the

adequacy of the blood supply in the case of public health emergencies, the implementation of the transfusion transmission monitoring system, and other measures to promote safety and innovation, such as the development, use, or implementation of new technologies, processes, and procedures to improve the safety and reliability of the blood supply. OIDP organized a Working Group of industry experts to provide input and draft the report which was sent to Congress in January 2021. At the 52nd meeting of the ACBTSA, held in October 2021 the committee discussed updating the PHS Guidelines for Reducing HIV, HBV, and HCV in Organ Transplantation to protect the safety of adolescent transplant recipients.

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 antimicrobial resistance (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 were presented to the full council at the June 2021 public meeting. Both reports were deliberated and unanimously approved for transmittal to the Secretary. They are Bridging the Gap: Improving Antimicrobial Access and Use Across One Health and Advancing Interprofessional Education and Practice to Combat Antimicrobial Resistance. The June public meeting included topics that involved policy options to operationalize the topic of AMR in One Health as it pertains to the COVID-19 pandemic, and the integration of environmental justice and ecosystems in AMR narratives.

As evidence of the PACCARB's influence from both activity and membership, their website has averaged approximately 1,000-2,000 new user access views monthly. Additionally, the PACCARB Designated Federal Officer has been and continues to be invited to both local and international fora to provide an overview of the federal advisory committee structure, PACCARB's activities related to providing AMR recommendations, and collaboration with the federal interagency CARB Task Force. These outreach engagements have proven successful through the gradual increases in website attention/traffic and PACCARB public meeting attendees. OIDP will sustain these efforts as the topic of AMR garners further attention as a public health security priority in One Health, especially within the context of environmental justice and specifically, the topic of emerging diseases and climate change.

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 submitted to Congress and released in January 2021. The TBDWG is working to update the third and final report to be submitted to Congress in December 2022. The committee has identified 7 subcommittees with the following topics: 1) Diagnostics, 2) Clinical Presentation and Pathogenesis, 3) Changing Dynamics of Tick Ecology, Personal Protection and Control, 4) Disease Prevention and Treatment, 5) Access to Care and Education, 6) Public Comments, and 7) Federal Inventory. These subcommittees will report back to the full committee in March 2022.

Fiscal Year	Amount
FY 2019	\$7,802,000
FY 2020	\$7,552,000
FY 2021 Final	\$7,582,000
FY 2022 Annualized CR	\$7,552,000
FY 2023 President's Budget	\$7,756,000

Five Year Funding Table

Budget Request

The FY 2023 President's Budget request for OIDP is \$7,756,000, which is +\$204,000 above the FY 2022 Annualized Continuing Resolution. 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. OIDP's primary areas of emphasis include, but are not limited to, vaccines and immunizations, HIV/AIDS, viral hepatitis, tick-borne diseases, blood and tissue safety and availability, STIs, antibiotic-resistant bacteria, COVID 19 and other emerging infectious diseases of public health significance.

The FY 2023 Budget will allow OIDP to provide leadership and support on vaccine hesitancy and confidence programs and activities. OIDP will also lead efforts on implementation strategies and monitoring progress on the National Strategies on HIV, Viral Hepatitis, Vaccines, and STIs. OIDP will 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.

The Budget also includes a mandatory proposal for a transformational PrEP Delivery Program¹⁴. If enacted, the FY 2023 funding request for the "Ready, Set, PrEP" program is still necessary, as there would be a transition period during which the new program is established. OIDP will also work to ensure a seamless transition of current "Ready, Set, PrEP" clients to the new national PrEP Delivery Program⁵.

⁵ Details on the PrEP Delivery Program to End the HIV Epidemic are included in Mandatory Proposals section of the Departmental Management Congressional Justification.

OFFICE OF RESEARCH INTEGRITY Budget Summary

(Dollars in Thousands)				
Office of Research Integrity	FY 2021 Final	FY 2022 Annualized CR	FY 2023 President's Budget	FY 2023 +/- FY 2022
Budget Authority	8,986	8,986	8,986	-
FTE	26	27	28	+1
Authorizing LegislationPHS Act Title II, Section 301				
FY 2023 AuthorizationPermanent				
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. It also aligns directly with the Administration's emphasis on scientific integrity, by way of the 2021 Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking. 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 the National Institutes of Health (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 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 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 (OHRP) 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 (NSF), 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. ORI provided procedures and guidelines as models for the federal-wide scientific integrity efforts led by the White House, culminating in *Protecting the Integrity of Government Science – A Report by the Scientific Integrity Fast-Track Action Committee of the National Science and Technology Council* released January 2022.

ORI's work has continued unabated despite the continuing disruptions of the COVID-19 pandemic. Temporary closures of numerous research institutions since March 2020 have delayed their own work on allegations of research misconduct. ORI's FY 2021 accomplishments include:

- Responded to 222 allegations through coordination with their respective institutions as needed.
- Provided technical assistance and guidance to institutions responding to allegations of researchmisconduct in almost 500 instances.
- Closed 95 cases, including 6 with PHS findings of research misconduct.
- Continued reporting (begun in 2018) to NIH, case closures with concerns for inappropriate research practices that did not meet the legal threshold for misconduct findings, averaging 1-2 per month. Through its authorities, NIH can apply grant restrictions to institutions that may not be responsible stewards of research funds.
- Implemented the ORI File Transfer System on May 3, 2021, for the secure transmittal of assessment, inquiry, or investigation reports and associated files and documentation from institutions to ORI. Through September 30, 2021, 41 institutions had uploaded 5,341 files (48.7 GB) related to 47 unique cases.
- Assured that over 5,300 institutions worldwide attested to having research misconduct policies inplace, a requirement for receiving PHS funds for research. Monitored their annual reports of research misconduct and their compliance with their own policies for handling allegations of research misconduct.
- Received over 1 million visitors to the ORI website, with over 2 million page views from users in domestic and international locations.
- Promoted ORI's learning and teaching resources. Interactive videos on research integrity in basic and clinical research drew over 53,000 page views, and over 5,500 page views of ORI's 18 infographics.
- Sponsored two virtual Boot Camps for Research Integrity Officials with the University of Virginia and with Harvard University.
- Co-hosted a series of 3 virtual roundtables focused on federal and university research leadershipworking together, to protect and promote the integrity and quality of research. Over 150 participants included senior research officials from PHS-funded academic institutions as well as leaders from NIH and ORI. Combined with engagement with stakeholder organizations, such discussions enhance ORI's ability to tailor educational and outreach efforts.
- Co-hosted two virtual meetings with the Association of Research Integrity Officers (ARIO), a key ORI stakeholder group. The first focused on providing guidance and best practices for institutions conducting research misconduct investigations and resulted in ORI developing and releasing an informational document to assist institutions. The second included NIH and featured compliance with NIH's Grants Policies during institutional misconduct proceedings. Each event drew over 100non-federal participants.
- Offered regular social media and blog posts throughout the year, as well as regular email updates.Twitter followers increased by approximately 5% in FY 2021.
- Developed and disseminated two new Notices of Funding Opportunities seeking meritoriousapplications for conducting research related to and developing resources to improve data management, as well as for convening conferences related to research integrity.
- Extended 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. Theteam received COVID-19 funding to support a special modification for certain clinical/scientific images not anticipated in the original system design, which had focused on electrophoresis gels/blots (i.e., western blots), photomicrographs, and data displays (e.g., charts, tables, graphs).

- Published a Request for Information soliciting best practices, challenges, and needs related to teaching the responsible conduct of research, promoting research integrity, and preventing researchmisconduct under 42 C.F.R. Part 93. Individuals, institutions, and organizations responded (35 in total), providing critical information that will inform our efforts to conduct outreach and develop educational resources that best support those in the PHS funded research community.
- Fulfilled 10 Freedom of Information Act (FOIA) requests.
- Updated ORI's records schedule to comport with current guidance of the National Archives and Records Administration. The new schedule enables ORI to align its database improvements with more efficient records management processes, specifically electronic records.

To the extent it can in FY 2022, ORI will continue to capitalize on the use of virtual meeting platforms even as workplaces reopen and in-person gatherings can occur in a post-pandemic environment. Virtual meetings facilitate greater engagement between ORI staff and increased numbers of stakeholders, yet the informal information exchange of in-person gathering remains valued by participants. Thus, even with virtual meetings, ORI plans to resume the usual cadence of in-person training and meetings, as well as grants performance (conference grants in particular) in FY 2022 when it is deemed safe to do so. Despite the unique challenges of teleworking, 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. In FY 2022, ORI will use existing funding for critical enhancements to its aging database systems. Planned improvements include more efficient file access and records management, as well as enhancements to its assurance database. ORI envisioned FY 2022 as a pivotal year to begin migrating its database system with new capabilities such as complete and accessible electronic case records and systematic review of institutional policies for handling allegations of research misconduct, tasks currently conducted manually.

New staff have brought enthusiasm, new approaches, and fresh insights into the way in which ORI carries out its mission. Staff in both divisions contribute to ORI's education and outreach efforts. DEI staff have developed a new approach to assessing compliance with assurance requirements which will roll out in FY 2022. New DIO staff have engaged productively in the development of the image analysis tool, taken advantage of seminars offered by federal partners in complex image analysis, and contributed to the increasing case workload review and closures. In FY 2022, ORI will release new educational materials and plan for the redesign of the website to better support its education and outreach activities.

ORI updated staff and NIH colleagues on 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 funding to this project and increased ORI's budget in FY 2021 for related staffing and other needs. ORI anticipates a product ready for evaluation and assessment by late CY 2022, with full implementation by FY 2025, supported in part by an award of HHS non-recurring expense fund (NEF) monies in FY 2022. In parallel, ORI has worked with a researcher at Syracuse University to evaluate a smaller-scale image analysis tool for which further development remains feasible. ORI plans to conduct a head-to-head evaluation of these systems as well

as one used by some scientific publishers, depending on availability of funding.

ORI received permission early in FY 2022 to begin the public process of overhauling its 2005 regulation, anticipating completion by summer 2024. Anticipated changes in the regulation would bring clearer compliance guidance for research institutions, as well as streamlining some of the investigative and oversight processes. Delaying these changes would continue to burden institutions (and ORI) with an overly-complex regulation that had not envisioned the digital revolution (in data, imagery, and analysis, let alone records retrieval and management) of the past 20 years.

Five Year Funding Table

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Fiscal Year	Amount
FY 2019	\$8,558,000
FY 2020	\$8,558,000
FY 2021 Final	\$8,986,000
FY 2022 Annualized CR	\$8,986,000
FY 2023 President's Budget	\$8,986,000

Budget Request

The FY 2023 President's Budget Request for ORI is \$8,986,000, which is the same level as the FY 2022 Annualized Continuing Resolution. This funding will allow ORI to continue to focus on oversight of institutional research misconduct investigations and processing annual assurance statements from institutions.

ORI --Grants Award Table:

New Grants (whole dollars)	FY 2021 Final	FY 2022 Annualized CR	FY 2023 President's Budget
Number of Awards	4	4	3
Average Award	\$100,000	\$100,000	\$100,000
Range of Awards	\$50,000 - \$600,000	\$50,000 - \$150,000	\$50,000 - \$150,000

PUBLIC HEALTH REPORTS

Budget Summary

(Dollars in Thousands)					
Public Health Reports	FY 2021 Final	FY 2022 Annualized CR	FY 2023 President's Budget	FY 2023 +/- FY 2022	
Budget Authority	470	467	479	+12	
FTE	1	1	1	-	
Authorizing LegislationPHS Act, Title III, Section 301					
FY 2023 AuthorizationPermanent					
Allocation MethodDirect Federa					

Program Description and Accomplishments

Public Health Reports (PHR) is the official journal of the Office of the U.S. Surgeon General (OSG) and the Public Health Service (USPHS). Published since 1878, Public Health Reports is the only general public health journal in the federal government and is one of the oldest journals of public health in the U.S. 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. Some of Public Health Reports recent accomplishments include reducing the time from receiving a manuscript to publication, increasing the diversity of its content, expanding readership (electronic downloads were up by 72% in CY2020 vs CY2019), and improving the journal's impact factor (from 1.764 in CY2019 to 2.792 in CY2020).

Public Health Reports 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 one to four supplemental issues per year. The journal is published through an official agreement with the Association of Schools and Programs of Public Health. The journal has always offered great value to its target audiences: the public health community, including USPHSCommissioned Corps officers; public health practitioners and policy makers at the local, state, federal, and international levels; practice-based academics and students. Many issues include a perspective orcommentary by the Surgeon General or senior leaders of the Office of the Assistant Secretary for Health and HHS. The COVID-19 pandemic has further increased the importance of having a platform by which public health information can be shared rapidly with healthcare providers and the public health community. The journal is a trusted source for state, local, and tribal governments that depend on HHS for up-to-date guidance about public health policy topics that can be implemented to protect Americans.

Five-Year Funding Table

Fiscal Year	Amount		
FY 2019	\$467,000		
FY 2020	\$467,000		
FY 2021 Final	\$470,000		
FY 2022 Annualized CR	\$467,000		
FY 2023 President's Budget	\$479,000		

Budget Request

The FY 2023 President's Budget request for PHR is \$479,000, which is +\$12,000 above the FY 2022 Annualized Continuing Resolution. At this funding level, Public Health Reports will maintain its current staffing levels with one Managing Editor, and capacity for publishing at the rate of six editions per year. This funding will allow the journal to continue to focus on emerging public health concerns and topics, such as disease surveillance, infectious and chronic diseases, occupational disease and injury, immunization, health disparities, substance use disorders, and tobacco use in support of enhancing the health and well-being of all Americans.

TEEN PREGNANCY PREVENTION

Budget Summary

(Dollars in Thousands)

Teen Pregnancy Prevention	FY 2021 Final	FY 2022 Annualized CR	FY 2023 President's Budget	FY 2023 +/- FY 2022	
Budget Authority	100,697	101,000	111,000	+10,000	
FTE	22	18	23	+5	
Authorizing LegislationCurrent Year Appropriation FY 2023 AuthorizationAnnually Allocation					
MethodDirect Federa				,	

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, competitive grants and contracts are awarded to public and private entities to provide medically accurate and age-appropriate programs in communities. Funding also supports grants administration, program evaluation, technical assistance, and training.

TPP replication grants support access to 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. The current cohort of TPP demonstration grants support testing innovative interventions in several priority areas, 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.

Fiscal Year	Amount	
FY 2019	\$101,000,000	
FY 2020	\$101,000,000	
FY 2021 Final	\$100,697,000	
FY 2022 Annualized CR	\$101,000,000	
FY 2023 President's Budget	\$111,000,000	

Five Year Funding Table

Budget Request

The FY 2023 President's Budget request for Teen Pregnancy Prevention program is \$111,000,000, which is +\$10,000,000 above the FY 2022 Annualized Continuing Resolution. At this funding level, OPA will support a new national competition for all TPP grant funds, which will result in numerous new grants across the country in communities and among populations most in need. Funds will also support development and testing of new and innovative approaches to preventing teen pregnancy and advancing positive youth development.

Program/Measure	Year and Most Recent Result Target for Recent Result Summary of Result	FY 2022 Target	FY 2023 Target	FY 2023 +/- FY 2022
9.1 Number of youth served by theTPP Program	FY 2021: 59,244 Target: 100,000 (Target Not Met)	210,000	210,000	-
9.2 Number of TPP Program formalor informal partners	FY 2021: 618 Target: 1,600 (Target Not Met)	2,500	2,500	-
9.3 Number of Intervention Facilitators provided new or follow-up training	FY 2021: 9,009 Target: 3,700 (Target Exceeded)	3,700	3,700	-
9.4 Percent of youth receiving atleast 75% of available TPP programming	FY 2021: 71% Target: 80% (Target Not Met)	80%	80%	-
9.5 Mean percentage of the effective program being implemented asintended	FY 2021: 95% Target: 90% (Target Exceeded)	90%	90%	-

Teen Pregnancy Prevention – Key Outputs and Outcomes Table

Teen Pregnancy Prevention – Grants Award Table

Grants	FY 2021 Final	FY 2022 Annualized CR	FY 2023 President's Budget
Number of Awards	79	79	100
Average Award	\$900,000	\$900,000	\$1,000,000
Range of Awards	\$500,000 - \$1,860,000	\$500,000 - \$1,860,000	\$350,000 - \$2,000,000

Performance Measure 9.1: The COVID-19 pandemic negatively impacted OPA being able to meet the targets for this measure. TPP grantees were unable to implement their programs as planned due to school and after-school closures, group size restrictions, and pivoting to virtual implementation. The FY2022 target is increased because it will reflect data from grantees in their second year of funding and at full implementation.

OFFICE OF MINORITY HEALTH

Budget Summary

(Dollars in Thousands)

Office of Minority Health	FY 2021 Final	FY 2022 Annualized CR	FY 2023 President's Budget	FY 2023 +/- FY 2022
Budget Authority	61,649	61,835	85,835	
FTE	47	57	70	+13
Authorizing Legislation PHS Act, Title XVII, Section 1707				
FY 2023 Authorization Status Expired				
Allocation Method Direct federal				rect 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 Affordable Care Act (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 service 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 throughleadership 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 the 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 is focused on the collective goal of the *success, sustainability, and spread of health equity promoting policies, programs, and practices*. OMH's primary function of promoting policy, program, and practice adoption is supported by additional functions including convening partners; collecting, analyzing, and reporting data; disseminating information; and conducting demonstrations and evaluations. OMH has four overarching programmatic priorities:

- 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.
- Supporting COVID-19 response and recovery within racial and ethnic minority communities.

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. Consequently, specific OMH focus areas are (1) Prevention activities that promote health (e.g., physical activity and nutrition); (2) Clinical conditions (e.g., substance use disorder, HIV, maternal health, sickle cell disease, diabetes, and Lupus); and (3) Individual social needs and social determinants of health. OMH supports and implements initiatives in these focus areas to identify and disseminate innovative and best practices for providing access to quality health care, addressing health disparities, and improving opportunities to achieve optimal health. OMH also 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.

In addition, OMH plays a critical role in leading the Department's efforts to promote health equity, including supporting the HHS Health Disparities Council and the Presidential COVID-19 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.

FY 2021 Key Accomplishments:

OMH FY 2021 accomplishments support the HHS strategic goals as described below.

Strategic Goal 1: Protect and Strengthen Equitable Access to High Quality and Affordable Health Care

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

- Supported free, accredited e-learning programs for health professionals to build knowledge and skills in providing culturally and linguistically appropriate services. During FY 2021, 23,154 health professionals and students completed e-learning programs and earned an estimated 164,740 continuing education credits toward their continuing education licensure requirements.
- OMH's new *Culturally and Linguistically Appropriate Services (CLAS) in Maternal Health Care* e-learning program launched in March 2021, and during the remainder of FY 2021 had 1,501 health professionals and students complete the program and earn 3,002 continuing education credits.

Strategic Goal 2: Safeguard and Improve National and Global Health Conditions and Outcomes

• In February 2021, OMH supported the development and launch of the COVID-19 Health Equity Taskforce (HETF) established by Executive Order 13995, Ensuring an Equitable Pandemic Response and Recovery, which was issued on January 21, 2021, including serving as the Designated Federal Officer (DFO). The Task Force is part of the government-wide effort to identify and eliminate health and social disparities that result in disproportionately higher rates of exposure, illness,

hospitalization, and death related to COVID-19. OMH also developed and launched the COVID-19 HETF microsite to support the Task Force. From February 1 - July 27, 2021, the HETF webpages received 28,240 total views and 23,299 unique views.

- On January 26, 2021, President Biden issued the Memorandum Condemning and Combating Racism, Xenophobia, and Intolerance against Asian Americans and Pacific Islanders in the United States. OMH leads the HHS workgroup that focuses on the response to the memorandum. The workgroup is comprised of representatives from across the Department. Aligned with the Memorandum's directives, the workgroup is supporting efforts to issue guidance on best practices to advance cultural competency, language access and sensitivity toward AAPIs in the context of the federal COVID-19 response.
- One of the activities that OMH coordinated in response to the Presidential memorandum was partnering with the National Park Service (NPS), and the White House Initiative on Asian Americans and Pacific Islanders (WHIAAPI) to host a virtual panel discussion on May 8, 2021 highlighting federal efforts addressing racism and health inequities, including the COVID-19 Health Equity Task Force and the Presidential Memorandum Condemning and Combating Racism, Xenophobia, and Intolerance Against Asian Americans and Pacific Islanders in the U.S. The panel featured contemporary Asian Americans who are leading efforts to protect and empower diverse Asian American and Pacific Islander (AAPI) communities nationwide.
- To address COVID-19 vaccine hesitancy and support vaccine confidence among racial and ethnic minority populations, in early 2021, OMH Director RADM Felicia Collins appeared in a national virtual town hall sponsored by the Black Coalition Against COVID-19 and a Florida-based town hall, sponsored by Onyx Magazine. The town halls had more than 250,000 views, including 140,009 views on YouTube. RADM Collins also conducted a radio interview, which aired on at least12 stations, with a listenership of more than three million.
- OMH utilized its social media channels to promote COVID-19 safety and vaccine information during FY 2021. Social media posts promoting OMH and HHS COVID-19 messaging in FY 2021 reached 29,746,598 individuals and netted 1,477,023 impressions. Digital media, which includes 74 total weekly and monthly newsletters like the Weekly FYI and the Health Equity Link, as well as 45 event and stakeholder announcements focused on COVID-19, have generated 531,916 unique opens and 111,595 unique clicks.
- During National Minority Health Month April 2021, OMH adopted #VaccineReady as the
 observance theme. The goal of the #VaccineReady campaign was to empower communities to
 proactively practice COVID-19 safety measures, get the facts about COVID-19 vaccines, share
 accurate vaccineinformation, participate in clinical trials, and get vaccinated. OMH also supported
 and amplified the launch of the HHS COVID-19 Community Corps as part of its COVID-19 Public
 Education Campaign.
- For AAPI Heritage Month observed in May, OMH created a microsite that served as a central location for stakeholders and partners to gain access to shareable graphics, social media messaging, health resources, events, and blogs. Sections on the microsite such as blogs, social media messaging, and shareable graphics were also made available in multiple Asian languages including Chinese (Traditional), Chinese (Simplified), Japanese, Korean, Tagalog, and Vietnamese. The site had 4,148 total views and 3,638 unique views.
- OMH, in partnership with the Office of the Assistant Secretary for Public Affairs, addressed over 700 community health workers (promotores/as de salud) during two professional conferences by disseminating information in Spanish about the importance of COVID-19 vaccination in Hispanic/Latino communities. The primary purpose of these engagements was to enhance awareness of and share evidence-based material with promotores/as de salud across the U.S.

about the COVID-19 vaccine. OMH discussed the process of approving the use and safety of COVID-19 vaccines, as well as clinical trial protocols, highlighted health disparities related to COVID-19 in Hispanic/Latino communities and the importance of the Hispanic/Latino representation in COVID-19 vaccine and therapeutics clinical trials.

- OMH funds 16 policy demonstration initiatives that support 85 grants and cooperative agreements. In FY 2021, OMH identified 8 Evidence-Informed Practices (EIP) among those grants and cooperative agreements. OMH identified a total number of 34 EIPs FY 2020 2021. 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 Washington recently announced the launch of the Solutions in Health Analytics for Rural Equity across the Northwest (SHARE-NW) website. The website is part of a five-year, collaborative project with public health professionals in four states in the Pacific Northwest (Washington, Idaho, Oregon, and Alaska) to more effectively identify, address, and communicate about health disparities in the rural communities they serve. The website also includes trainings and webinars to help public health professionals develop the skills to make key decisions to improve health equity in the communities they serve. The trainings and webinars are organized by topics that correspond to the data dashboards.
 - 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. Intervention sites successfully implemented the group visit and text messaging programs. Providers and staff had significant improvements in awareness, preparedness, knowledge and confidence to implement group visits. There were improvements in diabetes knowledge, diabetes distress, diabetes social support, satisfaction with diabetes treatment, and receipt of mental health care for group visit patients. Compared to control patients, group visit patients had better processes of care (A1C test, lipid panel, flu vaccine, depression screening, foot exam). A1C improved in both arms. In the intervention arm, A1C improvement was associated with group visit attendance.
 - Northeastern Vermont AHEC implemented a multi-pronged program to increase student engagement, participation, and interest in Science, Technology, Engineering, and Mathematics (STEM) related activities. The 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 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 the capacity to deliver widespread vaccination, scale-up testing, care, and link/provide treatment

services.

- Collectively, the preliminary data alludes to the effectiveness of how OMH Hep B awardees are leveraging its strategic partnerships as evidenced of increase hepatitis b testing from year 1 to year 2 by 13%, increase linkage to care of those who tested positive for hepatitis b in year 1 from 87% to 95% in year 2, increase engaged in hepatitis b directed care in year 1 from 81% to 95% and increased retained in care in year 1 from 61% to 88% in year 2.
- The Asian Health Coalition launched community education and perinatal HBV campaign aimed to encourage the community to know their status, screen for hepatitis b, and vaccinated (including newborns). Campaigns have reached 15,801 and 16,871 individuals for the community education and perinatal HBV campaigns respectively.
- 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. The pilot test resulted in over 80% of patients being screened for Hepatitis B virus.
- The Sickle Cell Disease Clinical Data Collection Platform (SCD Data Collection Platform) initiative
 is designed to determine whether a standardized clinical data collection platform, shared across
 medical centers and other healthcare facilities, can serve as a central repository for analyzing
 data from large patient cohorts, recruiting patients for clinical trials, assessing adherence to
 evidence-based clinical guidelines, and identifying new areas for research. As of October 2021,
 29 sites have enrolled and submitted data into the SCD data hub which includes information on
 over 20,000 SCD patients.
- The Demonstration to Increase Hydroxyurea Prescribing for Children with Sickle Cell Disease Through Provider Incentives initiative is intended to demonstrate the feasibility and effectiveness of providing financial incentives to providers to improve the quality of life of children living with SCD through increased prescription rates of hydroxyurea. To date, the awardee has worked with the information technology (IT) to make necessary adjustments in the Electronic Health Record that will be used to administer the incentive payment model for three provider types (emergency department, primary care, and hematologist). EHR adjustments will ensure adequate documentation, data capture and sharing to track progress and modifications accordingly. In addition, educational modules with appropriate incentives have been developed to ensure shared mental models between the three provider types, community health workers and community-based organizations (CBOs) on the importance of hydroxyurea prescribing for children with SCD.
- The State/Tribal/Territorial Partnership Initiative 2.0 is designed to demonstrate if modifications to existing evidence-informed interventions for selected health issues will significantly improve health outcomes for racial and ethnic minority and disadvantaged populations experiencing health disparities. The awarded projects will help build the capacity of state and tribal governmental health agencies to achieve the following two main goals: (1) test modifications to existing public health programs or practices (interventions) to assess if the modified interventions are successful in significantly improving health outcomes for selected health issues; and (2) develop effective plans to sustain successful interventions after the award period.
 - The Utah Department of Health is funded to implement The Embrace Project Study: Supporting the Wellbeing of Minority Women along Utah's Wasatch Front. UDOH integrates culturally relevant modules and support services for women into The Wellness Bus to improve outcomes related to maternal mortality and morbidity; and diabetes and gestational diabetes among Native Hawaiian/Pacific Islander women of childbearing age living along Utah's Wasatch Front. The project study will include 160 women aged 18-44. Of these 160 women, 102 will identify as Native Hawaiian/Pacific Islander (NHPI) women. The remaining 58 will identify as other racial and ethnic minority women.

- Morehouse School of Medicine Project D.I.N.E. (Dads in Nutrition Education) goals are to prevent maternal and infant mortality and promote healthy eating and breastfeeding. The project will expand statewide partnerships to improve maternal outcomes and father involvement by:
 - Mitigating the social barriers to breastfeeding Black mothers experience and increase the initiation and duration of breastfeeding.
 - Improve fathers' awareness, knowledge, self-efficacy, support, and impact women's intake of micronutrient supplements and dietary diversity.
 - Funded communities actively work together to improve perinatal health outcomes and reduce racial and ethnic disparities by using community-based approaches, such as Healthy Start, Expanded Food and Nutrition Education Program (EFNEP) and WIC to service delivery and facilitating access to comprehensive health and social services for women, infants, and their families. The goals of Project D.I.N.E. are to prevent maternal mortality and promote healthy eating and breastfeeding.
- 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 71,463 records. This includes both print and electronic formats. Overall, a total of 64,478 items have been electronically linked to digital content. This represents approximately 90.2 percent of the total database collection.

Strategic Goal 3: Strengthen Social Well-being, Equity, and Economic Resilience

- In collaboration with the CDC's Geospatial Research, Analysis, and Services Program (GRASP), OMH launched the new Minority Health Social Vulnerability Index (<u>MH SVI</u>). The new MH SVI built upon the existing <u>CDC SVI</u> by:
 - Expanding racial/ethnic categories to align with the 1997 OMB categories and include additional language data (e.g., top five common languages spoken by the limited English proficient population) to better understand community needs and tailor resources and outreach;
 - Adding two themes to the CDC SVI: a) health care infrastructure and b) medical vulnerability to include factors emerged from the literature to associate with adverse COVID-19 outcomes; and
 - Building a dashboard with maps and charts that reflect these six themes (socioeconomic status, household composition, and disability, minority status and language, housing type and transportation, health care infrastructure, and medical vulnerability) of the index 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 (FY2021), the CHW PATH program continues to engage the two initial sites and expands to include three additional public housing communities and 5 newly hired CHWs in Akron, OH, Chicago, IL, and New Orleans, LA. Year 2 also includes program evaluation and a toolkit to support future dissemination of this model.

Strategic Goal 4: Restore Trust and Accelerate Advancements in Science and Research for All

• In collaboration with the Food and Drug Administration's Office of Minority Health and Health Equity (FDA OMHHE), OMH launched a new 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, which includes online and radio ads, patient testimonial videos, and social media outreach, 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 minorityrepresentation in clinical trials.

Strategic Goal 5: Advance Strategic Management to Build Trust, Transparency, and Accountability

OMH supports this goal by maintaining and strengthening OMH's internal performance improvement and management system and evaluating the 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.

- OMH's <u>Performance Improvement and Management System (PIMS)</u> 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 an <u>FY 2020 Report to Congress Update on the HHS Disparities Action Plan</u>. This report highlighted the implementation of the Action Plan elements in FY 2019 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.

Fiscal Year	Amount
FY 2019	\$56,670,000
FY 2020	\$58,670,000
FY 2021 Final	\$61,649,000
FY 2022 Annualized CR	\$61,835,000
FY 2023 President's Budget	\$85,835,000

Five Year Funding Table

Budget Request

The FY 2023 President's Budget request for OMH is \$85,835,000, which is +\$24,000,000 above the FY 2022 Annualized Continuing Resolution. At this funding 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.

The proposed FY 2023 funding of \$85,835,000 will support and enhance ongoing efforts including (see OMH Program Data Chart for details):

- Contracts: A total of \$8,828,074, to support existing OMH contracts. Funding supports the Center for Linguistic and Cultural Competency in Health Care (CLCCHC) to implement the National CLAS Standards, the Minority Leadership Fellowship Program, the OMH Resource Center, evaluation, and logistical support across OMH programs.
- Grants/Cooperative Agreements: A total of \$54,350,000 for demonstration grants or cooperative agreements, including support for the State/Tribal/Territorial Partnership Initiative, national lupus outreach

and clinical trial education program, accessing social determinants of health data through local data intermediate initiative, framework to address health disparities through collaborative policy efforts, family centered approaches to improving diabetes control and prevention, preventative services utilization initiative, and environmental health initiative.

- Inter-Agency Agreements: A total of \$2,000,000 to support both programmatic and operational activities.
- Operating Costs: A total of \$20,656,926 to support staffing and other necessary operating costs for the administration and management of programs, policies, and initiatives proposed in FY 2023.

In FY 2023, the following funding increases (\$24,000,000) above the FY 2022 Annualized Continuing Resolution Budget are proposed for the corresponding grants or cooperative agreements:

- Center for Indigenous Innovation and Health Equity (Center) +\$1,000,000: In FY 2023, the budget request includes a total of \$3 million for continued Center funding and a \$1,000,000 supplement to support a focus on improving health outcomes for indigenous youth. In partnership with institutions of higher education which focus on indigenous health research and policy, the Center will identify culturally relevant positive youth development curriculums and approaches; collaborate with community organizations representative of the indigenous populations to review and assess potential for systems change; and expand data capacity and infrastructure to measure improved health outcomes among youth from indigenous communities. Established in FY 2021, the Center by: (1) managing the Center advisory board; (2) partnering with academic institutions, indigenous leaders, American Indians and Alaska Natives (AI/AN) and Native Hawaiians/Pacific Islander (NHPI) communities on CIIHE activities; (3) identifying and disseminating culturally appropriate evidence-based and/or evidence-informed interventions, and lessons learned; and (4) designing and providing education and training to support community capacity-building.
- Public Health Pilot Program to Address Structural Racism in Public Health \$10,000,000: The budget
 request includes \$10 million for this initiative. OMH will award \$10 million to 20 eligible applicants to
 establish model programs that implement policies and/or programs to address structural racism in public
 health; and assess the effectiveness of coalition building and policy/program activities in addressing
 structural racism and health disparities among racial/ethnic minority populations.
 - OMH will establish a pilot program to address structural racism in public health and promote policies and practices that counter the disparate impact on the health and well-being of racial and ethnic minority populations. The Pilot Program will support coalitions at the community level to identify existing policies, practices and programs that impede equitable access to care and perpetuate health disparities. The initiative will support public and non-profit entities that represent a community coalition to address structural racism in public health.
- Promoting Equitable Language Access 3,000,000: The budget includes \$3 million to provide up to 10 awards under this initiative. OMH will consult with external experts, including organizations with connections to limited English proficient (LEP) communities, to inform the development of an initiative intended to develop, and test methods of informing LEP individuals about their right to and the availability of language access services. Support will be provided to community-level efforts designed to improve health outcomes for LEP individuals by ensuring their access to culturally and linguistically appropriate health services and health care. Specifically, collaborative partnerships that include community-based organizations will be expected to: 1) develop and implement a disparity impact statement to identify LEP populations experiencing barriers to access to care and at greatest risk for health disparities; 2) engage community members to solicit input on language access services, including considerations related to literacy levels of LEP populations, the needs of older adults and speakers of indigenous languages, readability, and the usage of symbols, taglines, translated materials and other methodologies; 4) conduct a process and outcomes evaluation assessing the effectiveness of the methods; 5) document and

disseminate project findings; and 6) develop a sustainability plan.

Achieving Equitable Maternal Health Outcomes Initiative \$10,000,000: In FY 2023, OMH will make awards, in an amount of \$10 million, to community-based and other eligible organizations located in geographic areas with high rates of adverse maternal health outcomes, particularly among racial/ethnic minority families. The awards will support activities that include but are not limited to identifying evidence-based and evidence-informed practices for: addressing social determinants of health; promoting evidence-based health literacy, and pregnancy, childbirth, and parenting education programs; providing support from perinatal health workers; and providing culturally congruent, linguistically appropriate, and trauma-informed training to perinatal health workers.

Measure	Year and Most Recent Result Target for Recent Result (Summary of Result)	FY 2022 Target	FY 2023 Target	FY 2023 +/- FY 2022
4.2.1 Increased percentage of continuing education credits earned or awarded to enrollees who complete at least one or more ofOMH's accredited 'Think Cultural Health" e- learning programs (Output)	FY 2021: -9.5% increase over baseline Target: 27% increase over baseline (Target Not Met) Baseline (FY 2018) – 182,000	27%	29%	+2%
<u>4.4.1 Unique visitors to OMH website (Output)</u>	FY 2021: 1,246,923 Target: 505,000 (Target Exceeded)	510,000	515,000	+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 2021: 54% Target: 53% (Target Exceeded)	54%	55%	+1%
4.6.1: Percentage of promising approaches, models, and evidence-based practices producedby OMH-funded grantees and cooperative agreement partners (Output)	FY 2021: 56% Target: 52% N = 25 (over 45 assessed) (Target Exceeded)	52%	53%	+1%
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%	34%	+1%

Office of Minority Health – Key Outputs and Outcomes Table:

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. During FY 2021, there were fewer continuing education (CE) credits awarded compared to the baseline measure, with likely contributors being potential program participants and supporters being focused onCOVID-19 response needs over continuing education training. 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 seeincremental growth through a 2% increase over the FY 2022 target in FY 2023 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, <u>www.minorityhealth.hhs.gov</u>, is administered through the OMH Resource Center. The website includes access to the OMH Knowledge Center collection, which is a database composed of over 71,400 records and 90.2% 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, Alaska Native, Asian American, Native Hawaiian, and Pacific Islander communities. OMH saw 1,246,923 unique visitors to its main website in FY 2021, far exceeding the projected 505,000. 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, Alaska 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 and increase slightly to 515,000 in FY 2023.
- 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 FY 2021. In FY 2023, OMH expects an increase of 1% over FY 2022, yielding 55% of States and Territories incorporating national disease prevention and health promotion (e.g., *Healthy People 2030*) and health equity goals in their health disparities/health disparities/health equity planning processes, add by OMHsupport through its Advancing Health Equity Policy Analysis Support initiative.

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 supporting 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 promising approaches, models, and evidence-based practices produced by 53% of OMH-funded grantees and cooperative agreement partners in FY 2023. For FY 2021, OMH grantees achieved a rate of 56%, exceeding the target of 52%. The expected performance of this measure is in line with the FY 2023 funding level.

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. In FY 2023, OMH expects an increase of 1% over FY 2022, resulting in 34% of OMH-funded grantees and cooperative agreement partners reporting reliable and valid evidence of a significant reduction in a key health disparity Impact Strategy.

Grants (whole dollars)	FY 2021 Final	FY 2022 Annualized CR	FY 2023 President's Budget
Number of Awards	85	83-91	111 - 120
Average Award	\$372,280	\$350,000	\$400,000
Range of Awards	\$70,000 - \$1,250,000	\$250,000 - \$1,250,000	\$300,000 - \$750,000

Office of Minority Health – Grants Award Table:

Office of Minority Health –Program Data Chart:	FY 2021 Final	FY 2022 Annualized CR	FY 2023 President's Budget
<u>Contracts</u>			
OMH Resource Center	1,059,225	3,225,000	2,800,000
Logistical Support for OMH	262,457	173,373	330,000
Center for Linguistic and Cultural Competency in Health Care	1,305,264	2,770,455	1,900,000
Community Health Aide Program	385,639	0	0
Evaluation	1,280,911	909,842	1,423,074
Organizational Development Contract	0	0	225,000
Addressing SDOH in Public Housing	626,082	0	0
Language Access	499,538	150,000	500,000
Minority Leadership Fellowship Program – Contract Portion	655,754	550,000	550,000
Native Hawaiian & Pacific Islander (NHPI) Data Brief	169,089	0	0
Racial and Ethnic Health Disparities – Partnership with NAS	1,500,000	0	0
Special Journal Issue	0	0	50,000
Promoting Black Youth Mental Health	383,561	0	0
Community Engagement-Addressing HIV Prevention & Treatment	760,000	0	0
Disparity Impact Strategy Implementation Support	401,786	400,000	400,000
Health Equity Policy Analysis Support	599,731	500,000	500,000
National Learning Network for Promoting Health Equity	0	0	150,000
Subtotal, Contracts		8,678,670	8,828,074
Grants/Cooperative Agreements	2,000,001		0,020,071
American Indian/Alaska Native Partnership	961,752	0	0
Partnership to Achieve Health Equity	2,413,315	0	0
Hepatitis B Demonstration	2,495,123	0	0
Collaborative Approach for Youth Engagement in Sports	637,653	0	0
State/Tribal/Territorial; Document & Sustain Disparity-Reducing Interventions	3,299,812	1,000,000	3,000,000
Reducing Cardiac Arrest Disparities Through Data Registries Initiative	138,858	0	0
Community Approach; Strengthening Economic Support for Working Families	9,529,156	9,946,838	0
Increase Hydroxyurea Prescribing Children with Sickle Cell Disease via	1,250,000	1,250,000	0
Incentives	_,,	_,,	-
SCD Clinical Data Collection Platform	998,062	0	0
Center for Indigenous Innovation and Health Equity	1,986,516	2,000,000	3,000,000
National Lupus Outreach and Clinical Trial Education Program	2,034,447	2,034,447	2000,000
Accessing Social Determinants of Health Data Local Data Intermediaries	500,000	500,000	500,000
Address Health Disparities; Collaborative Policy Demonstration Projects	2,150,598	2,150,598	1,500,000
Address Health Disparities; Collaborative Policy Coordinating Center	500,000	600,000	600,000
Family Centered Approaches to Improving Diabetes Control and Prevention	3,401,423	1,500,000	1,500,000
Minority Leadership Fellowship Program – Grant Portion	2,083,203	2,083,203	3,000,000
Effective Policies to Promote Black Youth Mental Health	0	3,500,000	3,500,000
Preventive Services Utilization Initiative	0	5,250,000	5,500,000
Environmental Health	0	0	3,500,000
Trusted Messengers – Demonstration Grants	0	0	5,000,000
Trusted Messengers - Coordination Center	0	0	750,000
Promoting Equitable Language Access – Demonstrations & Coordinating Center	0	0	3,000,000
Community-Based Approaches addressing Structural Racism in Public Health Pilot Programs	0	0	10,000,000

Achieving Equitable Maternal Health Outcomes Initiative		0	0	10,000,000
	Subtotal, Grants/ Cooperative Agreements	34,379,918	31,815,086	56,350,000
Inter-Agency Agreements (IAAs)		2,207,810	2,933,664	2,000,000
Operating Costs		15,358,235	18,407,580	18,656,926
	Total	61,835,000	61,835,000	85,835,000

OFFICE ON WOMEN'S HEALTH

Budget Summary

(Dollars in T	housands)
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Office on Women's Health	FY 2021 Final	FY 2022 Annualized CR	FY 2023 President's Budget	FY 2023 +/- FY 2022	
Budget Authority	35,035	35,140	42,140	+7,000	
FTE	38	44	54	+10	
Authorizing Legislation PHS Act, Title II, Section 229					
FY 2023 Authorization StatusExpired					
Allocation Method				Direct Federal	

Program Description and Accomplishments

The Office on Women's Health (OWH) was established in 1991 and was given new statutory authority by the PatientProtection and Affordable Care Act (ACA) of 2010. OWH provides expert advice and consultation to the Secretary about scientific, legal, ethical, and policy issues relating to women's health, and the Office establishes short-range and long-range goals and objectives for women's health within the Departmentof Health and Human Services. OWH coordinates across the Department on activities relating 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 statutory 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.

Impact National Health Policy as it Relates to Women and Girls OWH coordinates women's health policy, leads and administers committees, and participates ingovernment-wide policy efforts.

OWH continues 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 on current and planned activities across HHS that safeguard and improve the health of women and girls. In FY 2021 and FY 2022, the CCWH focused on COVID-19 and vaccinations. Additionally, the CCWH facilitated and hosted a webinar series on COVID-19 vaccine hesitancy in women and communities of color. Through the CCWH, OWH leads the Maternal Health Working Group which convenes stakeholders from across the Department to share data, programs, and policies related to maternal health.
- OWH co-chairs the HHS Violence Against Women (VAW) Steering Committee with the Administration for Children and Families (ACF). The mission of the Steering Committee is to gather federal stakeholders to learn about and build capacity for initiatives happening across HHS and the federal government that focus on preventing and surviving violence, trauma, and abuse for individuals, families, and communities. In FY21, the Committee focused on strategy planning to enhance partnerships, coordinate activities, and update goals and objectives. In FY22, the Committee will meet throughout the year to engage HHS agencies and collaborate on major initiatives that impact violence prevention.

 OWH supports the Assistant Secretary for Health as the co-chair for the HHS Task Force to Prevent Human Trafficking. In FY22, the Task Force began with the goal to: build the capacity of HHS divisions, programs, and regions to prevent and respond to human trafficking through coordination and information sharing; initiate strategic opportunities to integrate human trafficking prevention and intervention through cross-division collaboration and jointly funded projects; and leverage strengths, reach, and resources of health and human service programs to directly benefit individuals, families, and communities impacted by human trafficking and inform anti-trafficking policies and practices.

In FY 2021 and FY 2022, OWH developed projects to provide insight into emerging issues and utilize policy to improve the health of women and girls. These projects leverage evidence-based data and build partnerships for sustainability.

- Led the recruitment of over 200 hospitals for the Maternal Morbidity and Mortality Data and Analysis Initiative to obtain up-to-date information on maternal and infant health outcomes to inform our policy and programs with a greater understanding of the drivers of maternal mortalityand severe maternal morbidity.
- 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 life course.
- Announced the winners of Phase 1 and Phase 2 of the Breastfeeding and Hypertension Challenges.
- Partnered with the OASH Deputy Chief Medical Officer to develop the HHS initiative on NeonatalAbstinence Syndrome/Neonatal Opioid Withdrawal Syndrome.
- Continued the State-Level Paid Family Leave Policy Project which involves the collection of information to inform program and policy about new mothers' health, health behaviors, and abilityto fulfill their roles in the workplace, family, and community. Data was collected and analyzed from focus groups to examine the relationship of the paid family leave benefit and maternal health, specifically mental health.
- Continued to partner with the CDC to increase the focus and collection of data on women's healthissues by adding specific women's health questions related to benign gynecological conditions and blood pressure control to the National Survey of Family Growth.
- Achieved all 4 performance goals.

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

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

- Developed the Racial Equity in Postpartum Care Challenge in partnership with the Centers for Medicare and Medicaid Services (CMS) to identify innovative ways to improve postpartum care for Black or African American and American Indian or Alaska Native (AI/AN) low-income beneficiaries enrolled in Medicaid or Children's Health Insurance Program (CHIP).
- Developed the HHS Endocrine-Disrupting Chemicals (EDC) Innovator Award Competition: Innovative Methods to Address the Impact of Endocrine-Disrupting Chemicals on Black or African American Women to identify innovative ways to address the impact of endocrine-disrupting chemicals (EDCs) on Black or African American Women.

- Released a \$4.3 million funding opportunity, State, Local, Territorial, and Tribal (SLTT) PartnershipPrograms to Reduce Maternal Deaths due to Violence. The initiative seeks SLTT programs designed to identify and reduce deaths among pregnant and postpartum women due to violence.
- Supported year 3 of *Preventing HIV Infection in Women through Expanded Intimate Partner Violence (IPV) Prevention, Screening, and Response Services.* In FY 2020, OWH added a 5th grantee, which continues through FY 2022.
- Supported year 3 of a 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 therecently updated Physical Activity Guidelines and National Sports Strategy. Grantees funded by OWH focus on engaging girls in sports. The initiative was extended until September 2022 to continue the work due to delays during the COVID-19 pandemic.
- Coordinated and oversaw the National Clinical Care Commission (NCCC) which was charged with evaluating and making recommendations to the U.S. Department of Health and Human Services Secretary and Congress regarding improvements to the coordination and leveraging of federal programs related to diabetes and its complications. In 2021, the NCCC released its final report, which called for additional federal efforts to improve access to health care, address social determinants of health, and improve trans-agency collaboration. The Commission's report the first of its kind since 1975 highlights evidence-based recommendations to address: (1) diabetes prevention and control in the general population; (2) diabetes prevention in populations who are at high risk of developing type 2 diabetes; and (3) treatment of diabetes and its complications. It also underscores the need to address the diabetes epidemic as it cuts across many sectors, including food, housing, commerce, transportation, and the environment.
- Supported the sub-Interagency Policy Committee (IPC) focusing on Pregnant People, Substance Use Disorder and Child Welfare including developing a grant to reduce maternal deaths due to substance use disorder.
- Developed the Self-Measured Blood Pressure (SMBP) Partnership Program to leverage
 partnerships and encourage women to maintain healthy blood pressure levels at every age and
 stage of their lives. The SMBP Program goals are to empower women to take control of their
 heart health, increase access to resources and information, increase knowledge and utilization of
 SMBP activities, increase understanding of blood pressure needs and numbers, and increase
 collaboration with healthcare providers. OWH hosted the SMBP Partnership Program Kickoff
 Meeting with Million Hearts and Hear Her during Heart Health Month with 34 partner
 organizations.
- Collaborated with the Office of Population Affairs for a cooperative agreement to establish the Reproductive Health National Training Center focusing on preconception care and preventing andaddressing hypertension.

Education and Collaboration on Women's and Girls' Health

OWH uses websites, webinars, written materials, social media, partnership outreach, and interactivetraining modules to increase consumer and health care professional knowledge of health issues, research, practices, programs, and policies that affect the health of women and girls. Examples of thiswork 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 8th grade reading level orbelow, in English and Spanish.
- The official launch of the HPV VAX NOW campaign to improve HPV vaccination rates. The campaign focuses on young men and women ages 18 to 26, as well as health care providers, living in Mississippi, South Carolina, and Texas, states with low HPV vaccination rates. HPV VAX NOW's focus on young adults — a group that has largely been overlooked by HPV vaccination activities to date — represents an important strategy to prevent HPV-related cancers and save lives.
- The launch of the Breastfeeding Program for African American Mothers and Families to develop, implement, and evaluate a national program to encourage African American mothers to breastfeed for at least the first six months with support from their families. The program will use the existing OWH materials as core elements, namely It's Only Natural, Mother's Love Mother's Milk, Your Guide to Breastfeeding, Supporting Nursing Moms at Work, and other OWH breastfeeding support materials available through womenshealth.gov. It also includes partnerships with outreach partners, community stakeholders, and the US Department of Health and Human Services' Office of the Assistant Secretary for Health (DHHS OASH) Regional Offices and their <u>partners</u>.
- A partnership with the Office of Disease Prevention and Health Promotion (ODPHP) on a "MoveYour Way" 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 postpartum depression and encourage treatment.
- Celebration of the 22nd Annual Observance for National Women's Health Week (NWHW), 16thAnnual Observance of National Women and Girls HIV/AIDS Awareness Day (NWGHAAD), and 2nd

Annual Observance of National Women's Blood Pressure Awareness Week (NWBPAW).

Fiscal Year	Amount
FY 2019	\$32,140,000
FY 2020	\$33,640,000
FY 2021 Final	\$35,035,000
FY 2022 Annualized CR	\$35,140,000
FY 2023 President's Budget	\$42,140,000

Five Year Funding Table

Budget Request

The FY 2023 President's Budget request for OWH is \$42,140,000, which is +\$7,000,000 above the FY 2022 Annualized Continuing Resolution. At this level, OWH will develop new initiatives focused on prevention and treatment of eating disorders, violence, and substance use disorders, especially in underserved communities. OWH will use additional funds to expand our Maternal Health Data and Analysis Initiative to decrease maternal morbidity and mortality and make the U.S. the safest place to give birth. Additional funds will also be used to develop and implement an Eating Disorder Initiative designed to implement evidence -based strategies and community-based interventions for adolescents and others experiencing eating disorders and address the increase in eating disorders resulting from the COVID-19 pandemic.

At this funding level, OWH will continue to lead public health initiatives with an emphasis on maternal health, mental health, violence against women, vaccines, hypertension, and health equity.

OWH will lead the Improving Maternal Health through Addressing Endometriosis, Fibroids, and/or Polycystic Ovary Syndrome Initiative. This initiative implements and evaluates evidence-based interventions and strategies to comprehensively identify and treat endometriosis, fibroids, and/or polycystic ovary syndrome with a special emphasis on addressing and reducing disparities in underserved communities.

OWH will lead an initiative to improve screening and treatment of patients, during pregnancy and postpartum, who experience substance use disorder and intimate partner violence across healthcare settings by cross-training providers to recognize and treat the signs and symptoms.

Additionally, OWH will lead an initiative to reduce maternal deaths due to substance use disorder. This project is designed to strengthen perinatal and postnatal support structures to optimize maternal health outcomes for individuals with substance use disorder and to reduce deaths during the perinatal and postpartum period due to overdose.

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

Program/Measure	Year and Most Recent Result/Target for Recent Result Summary of Result	FY 2022	FY 2023 Target	FY 2023 +/- FY 2022
5.5.1 Number of users of OWH's communication channels (Reach)	FY 2021: 32,298,591 Target: 13,125,000 (Target Exceeded)	14,437,500	21,656,250	+7,218,750
5.6.1 Number of occasions that users interact with OWH content (Engagement)	FY 2021: 148,176,945 Target: 3,675,000 (Target Exceeded)	3,858,750	100,000,000	+96,141,250
5.7.1 Number of OWH interactions for the purpose of health education and training (Outreach)	FY 2021: 471 Target: 53 (Target Exceeded)	275	415	+140
5.8.1 Number of individuals served by OWH activities, programs, and partnerships (Outreach)	FY 2021: 678,316 Target: 420,000 (Target Exceeded)	441,000	441,000	+0

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

Performance Analysis

As part of its statutory requirements, OWH leads the National Women's Health Information Center to facilitate the exchange, access, and analysis of information regarding matters relating to health information, health promotion, preventive health services, research advances, and education in the appropriate use of health care. OWH's websites and social media platforms are essential to communicating programs and policies to the public and health care professionals. We expand our reach and engagement through innovative programs, national observances, strategic partnerships, and the power of technology and social media to promote the health and well-being of women and girls.

Through our campaigns and key observances, we develop unique strategies to build upon our partners, ambassadors, and sponsors to reach and engage new audiences. For the past years, OWH has consistently exceeded our performance metrics as a result of these efforts. We anticipate continued growth to our online presence by offering social media; interactive learning technologies; data visualization tools; webinars, forums, and other training events; and content syndication of women's health resources and information.

Additionally, OWH developed and implemented initiatives to collect, analyze, and access up-to-date data to identify trends in public health needs by region and develop specialized programs to address health equity. These initiatives allow OWH to continually develop timely, evidence-based tools, resources, and support for the public, community organizations, and health care professionals.

Through OWH's leadership, coordination, and strategic partnerships, we are advancing access to health programs and resources to achieve health equity for women and girls. We develop specialized programs to: achieve a decrease in violence against women, increase blood pressure control in women of all ages, reduce the risk of HPV-related complications including cancer, lead quality improvement interventions to improve maternal health outcomes, educate women on environmental health hazards in commonly used household and personal care products, and address mental health concerns in women and girls.

Office on Women's Health – Grants Award Table

Grants	FY 2021 Final	FY 2022 Annualized CR	FY 2023 President's Budget
Number of Awards	10	10	20
Average Award	\$462,500	\$462,500	\$462,500
Range of Awards	\$500,000\$2,400,000	\$400,000-\$2,400,000	\$300,000-\$2,400,000

Program Data Chart

Activity	FY 2021 Final	FY 2022 Annualized CR	FY 2023 President's Budget
Contracts			
Program Evaluation	-	-	-
Disease Prevention (Formerly Congenital Syphilis)	1,150,000	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)	1,246,583	1,177,375	1,502,375
Women's Health Across the Lifespan (Formerly Women's HealthAcross the Lifespan, Trauma/Violence Against Women, and State	575,616	475,000	3,475,000
Health Disparities in Women (Formerly Postpartum Depression)	646,200	600,000	2,774,677
Health Care Service Delivery and Data (Formerly Health CareServices for Women)	8,179,893	7,779,677	8,550,000
Public Education and Health Promotion (Formerly Education and Collaboration on Women's and Girls Health)	1,749,400	1,150,000	1,315,000
Subtotal, Contracts	13,547,692	12,507,052	18,942,052
Grants/Cooperative Agreements			
Postpartum Depression (PPD) Challenge	1,000,000	-	-
Endocrine Disrupting Chemicals (EDC) Challenge	1,500,000	-	-
Preconception Health	500,000	-	-
YES Initiative	-	-	-
Eating Disorders Initiative			0 745 000
	-	-	3,715,000
Health Disparities in Women (Blood Pressure Initiative)	-	-	3,715,000
	- - 5,100,000	- - 5,100,000	3,715,000 - 5,100,000
Health Disparities in Women (Blood Pressure Initiative)	- - 5,100,000 2,400,000	- - 5,100,000 5,550,000	-
Health Disparities in Women (Blood Pressure Initiative)Violence Against Women (Formerly Trauma/ Violence AgainstPreconception Health (Formerly Education and Collaboration on			- 5,100,000
Health Disparities in Women (Blood Pressure Initiative) Violence Against Women (Formerly Trauma/ Violence Against Preconception Health (Formerly Education and Collaboration on Women's and Girls' Health (Empowering Women))	2,400,000	5,550,000	- 5,100,000 2,400,000
Health Disparities in Women (Blood Pressure Initiative) Violence Against Women (Formerly Trauma/ Violence Against Preconception Health (Formerly Education and Collaboration on Women's and Girls' Health (Empowering Women)) Subtotal, Grants/Cooperative Agreements	2,400,000 10,500,000	5,550,000 10,650,000	- 5,100,000 2,400,000 11,215,000

EMBRYO ADOPTION AWARENESS CAMPAIGN

Budget Summary

(Dol	lars	in	Thousands)	
	001	iais		mousanus	

Embryo Adoption Awareness Campaign	FY 2021 Final	FY 2022 Annualized CR	FY 2023 President's Budget	FY 2023 +/- FY 2022
Budget Authority	997	1,000	1,000	-
FTE	-	-	-	-
Authorizing LegislationPHS Act, Title II, Section 301				
FY 2023 AuthorizationPermanent				
Allocation MethodDirect Federal				

Program Description and Accomplishments

The purpose of the Embryo Adoption Awareness Campaign is to increase public awareness of embryo adoption/donation as a method of family building and provide individuals adopting embryos the medical and administrative services deemed necessary for such adoptions. The program provides funding to 3 grantees annually who provide medical and administrative services to facilitate the use of embryo adoption; increase knowledge, awareness, and understanding of embryo adoption/donation as a method of family formation; monitor and evaluate the outcomes of their activities; and communicate and disseminate about their activities, successes, and lessons learned.

Five Year Funding Table

Fiscal Year	Amount
FY 2019	\$1,000,000
FY 2020	\$1,000,000
FY 2021 Final	\$997,000
FY 2022 Annualized CR	\$1,000,000
FY 2023 President's Budget	\$1,000,000

Budget Request

The FY 2023 President's Budget request for Embryo Adoption Awareness Campaign is \$1,000,000, which is flat with the FY 2022 Annualized Continuing Resolution. At this funding level, the program will continue to support public awareness and medical and administrative services to facilitate the use of embryo adoption and donation as a method of family formation.

MINORITY HIV/AIDS FUND

Budget Summary

Minority HIV/AIDS Fund	FY 2021 Final	FY 2022 Annualized CR	FY 2023 President's Budget	FY 2023 +/- FY 2022
Budget Authority	55,234	55,400	58,400	+3,000
FTE	23	25	26	+1
Authorizing LegislationCurrent Year Appropriation				
FY 2023 AuthorizationAnnually				
Allocation MethodDirect 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 while supporting HHS policies and programs. 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 the context of the syndemic of HIV, hepatitis, substance use, and STIS.

OIDP worked with the White House to publish the <u>National HIV/AIDS Strategy for the United States</u> <u>2022-2025 (NHAS)</u>. The Strategy reflects <u>President Biden's commitment</u> to re-energize and strengthen a whole-of-society response to the epidemic while supporting people with HIV and reducing HIVassociated morbidity and mortality. The Strategy sets bold targets for ending the HIV epidemic in the United States by 2030. To guide the nation toward realizing the vision, the Strategy focuses on four goals and details 21 objectives and 78 strategies for federal and nonfederal stakeholders. The Strategy replaces the HIV National Strategic Plan. OIDP is working with ONAP to develop implementation plans to support the strategy.

Phase 1 of *Ending the HIV Epidemic in the U.S. (EHE)* focuses on the geographic areas of the nation that comprised more than 50% of the newHIV diagnoses in 2016 and 2017, plus seven states with disproportionately high burdens of HIV in rural areas. The goal of the EHE 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 providesoversight 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 partner agencies for the initiative. In addition, OIDP coordinates with other federal agencies who also have a role in addressing the HIV epidemic including the Centers for Medicare and Medicaid Services and the Department of Housing and Urban Development.

As EHE evolved throughout FY 2021 and into FY 2022, OIDP continues to support critical infrastructure and operational activities that provide significant contributions to the EHE initiative. OIDP also continues to pursue innovative strategies to address those barriers, including social and structural determinants of health, that are at the center of the persistent racial andethnic disparities in HIV and a challenge to

achieving health equity.

MHAF funding continues to support AHEAD and the *Ready, Set, PrEP* program.

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. In early 2021, OIDP launched an interactive version of AHEAD that allows users to select certain criteria for viewing. OIDP created a step-by-step user guide available on the dashboard to assist users in understanding how to navigate and use the dashboard. In the late summer and fall of 2021, OIDP enhanced AHEAD with two additional data features. First, OIDP included multi-way stratified data by four key demographic categories at the national, state, and local levels, where data is available. The four demographic categories are age, race/ethnicity, gender/sex at birth, and mode of transmission.Multi-way stratified data will enable stakeholders to view data for selected subpopulations to better understand programmatic gaps and areas where additional focus and resources are needed. Second, OIDP enhanced AHEAD with select social determinants of health, including HIV stigma, housing instability, poverty, education levels and more, to further contextualize other critical factors in the EHE jurisdictions. Further into FY 2022, OIDP will consider other useful features to assist stakeholders in reaching the 2025 and 2030 targets that have been established for the EHE initiative.

Ready, Set, PrEP

FY 2021 MHAF resources supported 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 prescription drug coverage. 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, expanded mail order services and updated enrollment portal for ease of participants. Health centers and IHS facilities can have medications mailed to patients' homes or other locations directly from the program. OIDP also led and coordinated the "I'm Ready" marketing campaign highlighting the diverse stories of real people sharing their personal journeys with PrEP through digital advertising, radio and digital audio spots, videos, posters and shareable graphics. At its launch, Ready, Set, PrEP was designed to provide free medications or pills to those at-risk for HIV. OIDP conducted a needs assessment in FY 2022 that looked at ways to build a PrEP program that will further help to increase participation. The budget also includes a mandatory proposal for a transformational PrEP Delivery Program. If enacted, the FY 2023 funding request for the "Ready, Set, PrEP" program is still necessary, as there would be a transition period during which the new program is established. OIDP will also work to ensure a seamless transition of current "Ready, Set, PrEP" clients to the new national PrEP Delivery Program.

In addition, in FY 2021, MHAF funded projects implemented by federal partners, included:

Several new projects:

- Increasing Retail Clinical Capacity to Improve HIV and STI Prevention, Diagnosis, and Care for Underserved Minorities (CDC) - To expand the reach of HIV/STI diagnosis and prevention services, including PrEP and rapid testing for STI by incorporating Retail Health Clinics into existing networksof HIV/STI care services and leveraging partnerships to enhance the Ready, Set, PrEP program.
- Strategies to Maintain HIV Viral Suppression Among State Prison Inmates Released to the Community (CDC) To support continuity of HIV care for People with HIV (PWH) released from state prisons into the community through health department-based programs that emphasize linkage to and retention in care, ART adherence, and viral suppression assistance and strategies.
- Building the HIV Workforce and Strengthening Engagement in Communities of Color (B-SEC) (HRSA) To increase the number of minority health care professionals providing HIV care services to people of color through the integration of the NHC into curricula of minority serving institutions and through community engagement, anti-stigma, and awareness activities.
- HisStory, HerStory, TheirStory, OurStory: Storytelling As Resistance (IHS) To increase HIV knowledge and awareness among indigenous communities through the tradition of storytelling and the mediums of film, digital technology, and social media platforms. Production of three stories: PWH with an undetectable viral load; person on PrEP; and indigenous elder (50+) PWH.
- Addressing the HIV Epidemic Among Urban AI/AN (IHS) To improve HIV-related health outcomes for urban-based AI/AN and reduce HIV-related health disparities through a supplement Project ECHO model to enhance workforce capacity, provide training and technical assistance, and sharing best practices.
- Strategic Plan to End the HIV Epidemic In Indian Country (The ETHIC Plan) (IHS) To build a holistic plan to End the HIV Epidemic in Indian Country by supporting *national*-level strategic planning and using an environmental scan and community-based assessment framework that works across all Indian Health Service Areas and including Urban Indian Organizations.
- Using Implementation Science to Advance Multidisciplinary Prevention and Treatment Approaches to EHE (NIMHD) - To pilot capacity building efforts of the United States' four Black historical medical schools to respond to the HIV prevention and care needs in the jurisdictions in which they are located and through the use of implementation science to address the gaps in HIV prevention and in the HIV care continuum.
- Assessing HIV and STI Screenings in Title X Service Sites (OASH/OPA) To complete a
 descriptive, qualitative study that explores HIV and STI screenings and linkages to treatment and
 prevention services, including PrEP and PEP and behavior change to assess factors essential to a
 clinic's decision -making in these areas.

Continuation funding for several FY 2020 projects into FY 2021, included:

- Mass Mailing HIV Self-Tests to Transgender Women and R/E Minority Communities Disproportionately Affected by HIV/AIDS (CDC)
- Scaling up HIV Prevention Services in STD Specialty Clinics through Training and Technical Assistance (CDC)
- Ending the HIV Epidemic in the U.S.: Technical Assistance and Training on Stigma and Cultural Humility (HRSA)
- Improving Care and Treatment Coordination for Black Women with HIV (HRSA)
- Building Capacity to Implement Rapid ART Start for Improved Care Engagement in the Ryan WhiteHIV/AIDS Program (HRSA)
- Clinical Innovations in Indian Country (IHS)

- Empowering Healthier Tribal Communities (IHS)
- Project Red Talon (IHS)

Funding History

Fiscal Year	Amount
FY 2019	\$53,900,000
FY 2020	\$53,900,000
FY 2021 Final	\$55,234,000
FY 2022 Annualized CR	\$55,400,000
FY 2023 President's Budget	\$58,400,000

Budget Request

The FY 2023 President's Budget request for MHAF is \$58,400,000, which is +\$3,000,000 above the FY 2022 Annualized Continuing Resolution. At this funding level, MHAF will be able to expand its efforts to integrate additional Administration priorities as detailed in the recently released NHAS, including extensive piloting of strategies and interventions that address social and structural barriers to prevention, treatment and care; piloting of innovative syndemic approaches involving HIV, viral hepatitis, STIs, and substance use disorders; and exploring "status neutral" programming to better meet persons at risk for or living with HIV where they are. The additional funding will further MHAF efforts to reduce persistent HIV-related health disparities and meet the challenge of promoting health equity.

MHAF - Outputs and Outcomes Table

Measure	Year and Most Recent Result / Target for Recent Result / (Summary	FY 2022 Target	FY 2023 Target	FY 2023 Target +/- FY 2022 Target
7.1.12a: Increase the number of racial and ethnic minority clients who are tested through the Secretary's MHAF programs. (Outcome)	FY 2021: 20,330 FY 21 Target: 40,000 (Target Not Met)	40,000	42,000	+2,000
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 2021: 930 Target: 800 (Target Exceeded)	800	820	+20
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 2021: 72% Target: 80.8% (Target Not Met)	80.8%	81%	+0.2%
7.1.19 Increase the proportion of persons with diagnosed HIV who have achieved viral suppression.	FY 2021: 66% FY 2021 Target: 67% (Target Not Met)	67%	68%	+1%
7.1.20 Increase the proportion of persons who received PrEP among those for whom PrEP was indicated.	FY 2021: 14% FY 2021 Target: 13% (Target Exceeded)	13%	15%	+2%

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.

According to <u>CDC data</u> published in May 2021 an estimated 1.2 million people aged 13 and older were living with HIV in the United States at the end of 2019. Of those 1.2 million people, an estimated 87% were diagnosed. That means that 13% of people with HIV (nearly 1 in 7) did not know they had HIV and were therefore not accessing the care and treatment they need to stay healthy and prevent transmitting the virus to their partners. Of those who received an HIV diagnosis in 2019, 81% were linked to care within one month. Approximately 66% had received HIV medical care; 50% were retained in care; and an estimated 57% had achieved viral suppression.

MHAF testing projects will continue to require more attention to meet linkage targets, including our push for expediting the linkage process to 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 the Ending the HIV Epidemic in the U.S. Initiative and the HIV National Strategic Plan. One of our most serious challenges will involve increasing the number of racial and ethnic minorities who are accessing and maintaining use of PrEP services. Enhancements to the Ready, Set, PrEP program or through some other mechanism and continued outreach efforts will be essential. In addition, it is our expectation that our elevated programming around social and structural determinants of health, the syndemic of HIV, viral hepatitis, STIs, and substance use disorders, and a "status neutral" approach will provide benefit to our testing, PrEP, linkage to care, and viral suppression efforts.

KIDNEY INNOVATION ACCELERATOR

Budget Summary

Kidney Innovation Accelerator	FY 2021 Final	FY 2022 Annualized CR	FY 2023 President's Budget	FY 2023 +/- FY 2022
Budget Authority	5,000	5,000	5,000	-
FTE	1	1	1	-
Authorizing LegislationReorganization Plan No. 1 of 1953				
FY 2023 Authorization				Permanent
Allocation MethodDirect Federa				

(Dollars in Thousands)

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 uses 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 13879 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 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 with the goal of having an artificial kidney in human clinical trials in 2024.

For the last two years, with Congressional appropriations beginning 2020, 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 improve dialysis outcomes and patient experience. 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. Two prize challenges launched in 2020 were the \$300,000 KidneyX COVID-19 Innovation challenge and the \$2,500,000 Artificial Kidney Prize "Moonshot," which laid the foundation for future KidneyX prizes to incentivize innovation. Across 2021 and 2022, KidneyX will award \$3,900,000 in prizes to six Moonshot winners. The Moonshot is a multi-phased, multi-year challenge that aims to accelerate the development of artificial kidneys in human clinical trials by 2024. Across all five of these prize challenges, KidneyX has already delivered success, accelerating industry progress and catalyzing 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% of overall program costs, with the remainder consisting of funds raised by ASN. Beyond the prize purses cited above, HHS and ASN have supported overhead costs in the form of personnel and contract labor for the development and administration of prize programs. The specific appropriations language 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 continued investment.

The real running rable	
Fiscal Year	Amount
FY 2019	-
FY 2020	\$5,000,000
FY 2021 Final	\$5,000,000
FY 2022 Annualized CR	\$5,000,000
FY 2023 President's Budget	\$5,000,000

Five Year Funding Table

Budget Request

The FY 2023 President's Budget request for KidneyX is \$5,000,000, which is flat with the FY 2022 Annualized Continuing Resolution. At this funding level, KidneyX will deliver the Artificial Kidney Prize (phase 3) and a series of KidneyX Health Equity innovation activities to deliver on the promise to have an artificial kidney in human clinical trials in 2024 and to accelerate the development of the next generation of digital innovation and technologies for equitable kidney-care solutions accessible to all Americans.

SEXUAL RISK AVOIDANCE

Budget Summary

(Dollars in	Thousands)
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Sexual Risk Avoidance	FY 2021 Final	FY 2022 Annualized CR	FY 2023 President's Budget	FY 2023 +/- FY 2022
Budget Authority	34,895	35,000	-	-35,000
FTE	-	-	-	-
Authorizing Legislation:Current Year Appropriation				
FY 2023 AuthorizationAnnually				
Allocation MethodDirect Federal				

Program Description and Accomplishments

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

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

Five Year Funding Table

Fiscal Year	Amount
FY 2019	\$35,000,000
FY 2020	\$35,000,000
FY 2021 Final	\$34,894,922
FY 2022 Annualized CR	\$35,000,000
FY 2023 President's Budget	-

Budget Request

The FY 2023 President's Budget does not request funds for this program.

EXECUTIVE ORDER IMPLEMENTATION

Budget Summary

(Dollars in Thousands)

Executive Order Implementation	FY 2021 Final	FY 2022 Annualized CR	FY 2023 President's Budget	FY 2023 +/- FY 2022
Budget Authority			18,000	+18,000
FTE	-	-	10	+10
Authorizing LegislationReorganization Plan No. 1 of 1953				
FY 2023 Authorization				Permanent
Allocation Method			D	irect federal

Program Description and Accomplishments

The President's Budget requests resources for implementation of several 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 \$18 million to ensure continued implementation of 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.

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 2019	\$0
FY 2020	\$0
FY 2021 Final	\$0
FY 2022 Annualized CR	\$0
FY 2023 President's Budget	\$18,000,000

Budget Request

The FY 2023 President's Budget level request for Executive Order Implementation is \$18,000,000, which is an increase of +\$18,000,000 above the FY 2022 Annualized CR. Funds will be used by Office of the Secretary Staff Divisions for continued implementation of Executive Orders for which they serve as a lead or supporting agency. Implementation of the following Executive Orders will expend most of the funding, but other less resource intensive orders, memorandums, and proclamations may create operational costs which HHS plans to support with existing resources.

The following Executive Orders and Memoranda will require continued investment to implement their requirements, specifically:

- Executive Order 13985 on "Advancing Racial Equity and Support for Underserved Communities through the Federal Government" where ASPA, ASPE, and IEA will continue to play a leading or supporting role. Funding will help support a Departmental Limited English Proficiency program to ensure effective communication with limited proficiency individuals through identifying services currently provided across the Department, gap analysis, and connecting with stakeholders. Resources will also help support continuation of the HHS Equity Technical Assistance Center, which is currently being established as a tool to provide direct trainings to HHS offices to build their capacity in advancing equity. In addition, these resources will support research and evaluation of federal programs and policies to improve access to services and supports for people with disabilities and behavioral health needs to reduce racial, ethnic, and socioeconomic disparities.
- Executive Order 13990 on "Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis" where ASPE will continue to play a leading or supporting role. Funding will help support studies and policy research projects on Environmental Health and Environmental Justice. Potential projects could include preparing for increased antimicrobial resistance as a result of climate change; study of leafy green supply chain to identify foodborne illness reduction risks, costs, and barriers; a scan of federal human service programs, issues, populations most affects, and potential responses; coordination with agency partners as they prepare for increasing climate related events that disproportionately affect older adults, minority populations, and people with disabilities; among others.
- Executive Order 13999 on "Protecting Worker Health and Safety" and Executive Order 14000 on "Supporting the Reopening and Continuing Operation of Schools and Early Childhood Education Providers" where ASPE will continue to play a leading or supporting role. ASPE recently completed several studies on the immediate and ongoing impacts of the COVID-19 pandemic on direct care workers who assist people with disabilities and older adults. Future work will focus on policies to improve the quality of these jobs through increased compensation and reducing injuries, as well as improving the quality of care received by people with disabilities.
- Executive Order 14002 on "Economic Relief Related to the COVID-19 Pandemic" where ASPE will continue to play a leading or supporting role. ASPE will continue identifying and addressing cross-cutting challenges that impact the well-being of individuals and families, particularly those navigating the complex and fragmented safety net of means-tested federal programs. Through our ongoing coordination of the federal interagency Council on Economic Mobility, ASPE works with partners in the Departments of Agriculture, Education, Housing and Urban Development, Labor, and Treasury, the Social Security Administration, and the Executive Office of the President to collaboratively use our administrative authorities to tackle issues that cannot be solved by one agency alone. For example, these efforts may include encouraging multi-program applications, coordinating technical assistance, and aligning definitions and performance measures across programs. ASPE's research and policy work will continue to prioritize improving program alignment and reducing silos.
- Executive Order 14008 on "Tackling the Climate Crisis at Home and Abroad" where IEA, ASA, and OASH will continue to play a leading or supporting role. Resources will allow for full establishment of the Interagency Working Group to Reduce the Risks of Climate Change to Children, the Elderly, People with Disabilities, and the vulnerable, initiate the Biennial Health Care Preparedness Advisory Council, expand fellowship programs to train scientists and health professional from underrepresented minorities, and expand technical assistance to

disadvantaged communities. Funding will also support the implementation of Justice40 and the development of environmental justice programs, policies, and activities to address the disproportionately high and adverse human health, environmental and cumulative impacts on disadvantaged communities. Funding will support the HHS Facility Vulnerability Study and Adaptation Plan work, which will serve as a model for HHS facilities as they complete vulnerability studies and address climate resilience and adaptation. The plan will identify potential climate risks for the geographical areas and the existing facilities' vulnerabilities to these risks. Resources will support tracking of compliance with environmental laws and executive order directives and mandates through configuring existing HHS systems that are Federal Risk and Authorization Management Program (FedRAMP) authorized for tracking and reporting on sustainability and climate change actions across the HHS enterprises; developing workflows to streamline non-invasive data capture; and developing dashboards to indicate progress towards achieving sustainability, climate change, and/or environmental compliance. In addition, investments will support implementation of the HHS Climate Action Plan (CAP) developed per the requirements identified in EO14008 and the Council on Environmental Quality instructions. Resources will also support pilot regional climate change and health equity collaboratives, expand fellowship programs to train scientists and health professional from underrepresented minorities, and expand technical assistance to communities.

- Executive Order 14009 on "Strengthening Medicaid and the Affordable Care Act" where ASPE will continue to play a leading or supporting role. The Treasury Department and the IRS have concluded there is legal authority to amend the regulations to fix the "family glitch" which renders an employee as well as his/her family members ineligible for subsidized marketplace coverage if self-only coverage for the employee is affordable as defined by the ACA, even if family coverage is not. Funding will support a study examining the impacts of this "family glitch" on Marketplace enrollment, the uninsured and health coverage.
- Executive Order 14020 on "Establishment of the White House Gender Policy Council" where OGA and IEA will continue to play a leading or supporting role. Resources will support implementation of Gender Equity and Human Rights to enable execution on Administration priorities surrounding women's health and empowerment initiatives, responding to Administration priorities under the "build back better world" and "foreign policy for the middle class" initiatives. This funding will enable HHS to truly lead in health diplomatic efforts to promote women's health, evidence-based interventions, and support for better health outcomes for marginalized populations in the United States and around the world.
- Executive Order 14035 on "Diversity, Equity, Inclusion, and Accessibility" where ASA will continue to play a leading or supporting role. Funding will allow focus on advancing HHS' commitment for improving Diversity, Equity, Inclusion, and Accessibility (DEIA) and to provide standards for labor and employee relations pertaining to national policy, oversight, and coordination across the Department. Specifically, development of comprehensive strategies to drive and integrate diversity and inclusion practices throughout HHS to build a more diverse and inclusive workforce strategically focused on recruiting and retaining a diverse workforce drawn from all segments of our population; and deploy a negotiation strategy to ensure labor and employee relation standards are practiced across HHS with the 21 labor unions represented at the Department.
- Memorandum on Restoring Trust in Government where ASPE will continue to play a leading or supporting role. As part of HHS' long-term response to this Memorandum, ASPE will continue to provide leadership and play a coordinating role in ensuring scientific integrity and promoting evidence-based policymaking. ASPE will enhance its support of Operating and Staff Divisions in building a culture of evidence and evaluation, including the development and dissemination of

skill-building materials. As a specific example, ASPE will develop evaluations of the pandemic telehealth waivers both as an example and to provide evidence for post pandemic coverage and payment policy.

 National Security Memorandum 1 on United States Global Leadership to Strengthen the International COVID-19 Response and to Advance Global Health Security and Biological Preparedness where OGA will continue to play a leading or supporting role. Funding will support studies to assess: extant of global vaccine manufacturing and fill and finish capacities for COVID-19 vaccines; timelines and relative cost for expanding and establishing new manufacturing capacity, including utilization of platforms to improve manufacturing flexibility; market sustainability for COVID-19 vaccines in light of global shortages for routine vaccines and epidemic vaccines; manufacturing capacities for critical ancillary supplies; and workforce development needs and sustainability mechanisms. In addition, funding will support expanded and ongoing support to our HHS staff posted overseas starting with current and future Health Attaches covered under the health diplomacy area and also to provide ongoing support to HHS overseas workforce improvement and alignment efforts across Operating and Staff divisions with overseas postings.

RENT, OPERATION, AND MAINTENANCE AND RELATED SERVICES

Budget Summary

Rent, Operation, Maintenance and Related Services	FY 2021 Final	FY 2022 Annualized CR	FY 2023 President's Budget	FY 2023 +/- FY 2022
Budget Authority	12,269	12,321	20,423	+8,102
FTE	-	-	-	-
Authorizing LegislationReorganization Plan No.1 of 1953				
FY 2023 AuthorizationPermanent				Permanent
llocation MethodDirect federal			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).

Fiscal Year	Amount	
FY 2019	\$14,589.000	
FY 2020	\$15,314,000	
FY 2021 Final	\$12,269,000	
FY 2022 Annualized CR	\$12,321,000	
FY 2023 President's Budget	\$20,423,000	

Five Year Funding Table

Budget Request

The FY 2023 President's Budget request for Rent, Operation, Maintenance and Related Services is \$20,423,000 which is an increase of +\$8,102,000 above the FY 2022 Annualized Continuing Resolution (CR) level. Funding will support costs associated with rental charges from GSA and maintaining aging buildings.

Additionally, funding will be used in continuation 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 Administration's 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.

SHARED OPERATING EXPENSES

Budget Summary

Shared Operating Expenses	FY 2021 Final	FY 2022 Annualized CR	FY 2023 President's Budget	FY 2023 +/- FY 2022
Budget Authority	10,447	10,478	14,478	+4,000
FTE	-	-	-	-

Shared/Common Expenses, Service and Supply Fund (SSF) Payment

Shared/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 2023 HHS Enterprise Information Technology and Government-Wide E-Gov Initiatives The Budget includes \$77,388 to support government-wide E-Government initiatives.

FY 2023 E-Gov Initiatives and Line of Business*	Original Amount	Revised Amount 2023
GSA/IAE-Loans and Grants	\$18,715	\$3,337
Federal Health Architecture LoB	\$0	\$1,736
E-Rulemaking	\$7,285	\$1,155
Treasury Managing Partner Financial Mgmt - LOB (MOU) FMLoB	\$1,580	\$39,518
Human Resources Management LoB (HRLoB)	\$939	\$723
Disaster Assistance Improvement Plan (DAIP)*	\$445	\$19,230
Budget Formulation and Execution LoB	\$754	\$1,981
Benefits.gov	\$3,311	\$6,858
Performance Management Line of Business (PMLoB).	\$547	\$940
Geospatial LoB	\$343	\$1,910
FY 2023 E-GOV Initiatives Total	\$33,919	\$77,388

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

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

Fiscal Year	Amount	
FY 2019	\$9,753,000	
FY 2020	\$10,478,000	
FY 2021 Final	\$10,477,212	
FY 2022 Annualized CR	\$10,478,000	
FY 2023 President's Budget	\$14,478,000	

Five Year Funding Table

Budget Request

The FY 2023 President's Budget request for Shared Operating Expenses is \$14,478,000, which is an increase of +\$4,000,000 above the FY 2022 Annualized Continuing Resolution (CR). Funding will support increases for Service and Supply Fund charges and other shared expenses.

ELECTRIC VEHICLE PROGRAM

Budget Summary

(Dollars in Thousands)

Electric Vehicle Program	FY 2021 Final	FY 2022 Annualized CR	FY 2023 President's Budget	FY 2023 +/- FY 2022
Budget Authority	-	-	5,000	5,000
FTE	-	-	3	+3
Authorizing Legislation General Provisions Section 243				
FY 2023 AuthorizationAnnual				
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 2019	\$0
FY 2020	\$0
FY 2021 Final	\$0
FY 2022 Annualized CR	\$0
FY 2023 President's Budget	\$5,000,000

Budget Request

The FY 2023 President's Budget request for the Electric Vehicle Program is \$5,000,000, which is an increase of +\$5,000,000 above the FY 2022 Annualized CR. 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. This funding is necessary to meet or exceed the ZEV-related goals set forth in the comprehensive plan developed pursuant to E.O. 14008, Section 205(a) and Executive Order 14057 which adjusted the timeline to end in FY 2035.

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 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.

PHS EVALUATION SET-ASIDE

Budget Summary

(Dollars in Thousands)

PHS Evaluation Set-Aside	FY 2021 Final	FY 2022 Annualized CR	FY 2023 President's Budget	FY 2023 +/- FY 2022
ASPE	43,243	43,243	56,743	+13,500
Public Health Activities	8,800	8,800	8,800	-
ASFR	1,100	1,100	1,100	-
OASH	4,885	4,885	7,885	+3,000
Teen Pregnancy Prevention	6,800	6,800	7,700	+900
Office of Climate Change and Health Equity	-	-	3,000	+3,000
Total	64,828	64,828	85,228	+20,400
FTE	134	145	182	+37

ASSISTANT SECRETARY FOR PLANNING AND EVALUATION (ASPE)

Budget Summary

(D	ollars in	Inousai	nas)

Assistant Secretary for Planning and Evaluation	FY 2021 Final	FY 2022 Annualized CR	FY 2023 President's Budget	FY 2023 +/- FY 2022
Budget Authority	43,243	43,243	56,743	+13,500
FTE	125	124	149	+25
Authorizing Legislation:PHS Act, Title II Section 247				
FY 2023 Authorization				Permanent
Method				irect 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 maintains a diverse portfolio of intramural and extramural research and evaluation, conducts economic analysis, and estimates the costs and benefits of policies and programs under consideration by HHS or Congress. ASPE's analytic products include legislative and regulatory proposals, research papers and briefs, dashboards, and internal briefing memoranda. Analyses involve a range of information sources and methodologies including survey data and analyses, program evaluation, analytical models, and performance data. To cover this breadth of activities and analytical methodologies, ASPE consists of a diverse group of professionals, including economists, statisticians, demographers, epidemiologists, lawyers, sociologists, scientists, psychologists, and physicians who conduct immediate need and longer-term policy research and analysis to support leadership decisionmaking.

In developing research priorities, ASPE consults across the Department and the Administration so that

its work focuses on their priorities. Emphasis is placed on identifying areas in which ASPE's work will add value. ASPE serves as a convener for interagency collaborations and initiatives around HHS priorities. For example, ASPE coordinates the development of the quadrennial HHS Strategic Plan required by the Government Performance and Results Act (GPRA) of 1993 and the GPRA Modernization Act of 2010. ASPE also staffs the Secretary in his role as a Trustee on the Social Security and Medicare Trust Funds. Other Department-wide efforts coordinated by ASPE include responses to the overdose crisis and behavioral health initiatives; equity and social determinants of health efforts; implementation of the Administration's National Action Plan to Combatting Antibiotic-Resistance Bacteria initiatives; development of the National Plan for Alzheimer's Disease and Related Dementias; and efforts to address maternal health, including development of a maternal health action plan. ASPE also 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's research, evaluation, and policy work spans HHS's mission to enhance and protect the well-being of all Americans by providing effective health and human services; and fostering advances in medicine, public health, and human services. Among other priorities, ASPE's work has focused on emergency preparedness and response, health care reform, maternal and women's health, child welfare, and disability and aging. Below we highlight five key priority areas of recent and renewed focus consistent with current Administration priorities: expanding and strengthening health insurance coverage, responding to the COVID-19 pandemic, enhancing health and economic equity, addressing behavioral health challenges, and promoting scientific integrity and evidence-based policymaking.

Expanding and Strengthening Health Insurance Coverage

The Administration's executive order on health care coverage calls upon a whole of government response to increase and improve health insurance coverage. 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 plays 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 (ACA) and the American Rescue Plan (ARP), with data analysis on the uninsured; evaluation of Medicaid policies including planning for the unwinding of the public health emergency; 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 ARP, has informed the Administration's outreach strategies to reduce disparities. ASPE analyses of the impact of recent Medicaid demonstrations and continuous coverage continue to inform policymaking going forward. ASPE's analyses of the Medicare Advantage program informs rebalancing proposals supported by the Department.

ASPE continues 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, and ASPE led efforts to develop a report pursuant to the

Executive Order 14036 on Promoting Competition in the American Economy that provides a Comprehensive Plan for Addressing High Drug Prices in the U.S. Recommendations, based on research and analyses, discuss ways to foster competition and promote biosimilar and generics; to address the impacts of exclusivities and patent protections on generic drug entry; to reduce spending among patients; to foster transparency; and to advance equity in drug access and affordability, among other topics.

Responding to the COVID-19 Pandemic

ASPE is conducting research on the Department's response to COVID-19. Most recently, ASPE has conducted 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-19 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 Centers for Medicare and Medicaid Services (CMS) and CDC, around infection control in nursing homes, to inform Department policymaking. ASPE conducts analytic work on pandemic impacts 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.

ASPE has undertaken a preliminary assessment of COVID-19 lessons learned from the Department's response to the pandemic. The project assesses whether HHS has the legislative and budgetary flexibilities, data capacity, and governance necessary to support future responses to public health emergencies, specific to the context of testing. Additional funding will result in more robust analyses covering additional functional areas and potential type of public health emergencies, convening of additional key HHS stakeholders and external stakeholders (e.g., states), and implementation of strategies building off the lessons learned.

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) to meet pandemic challenges. This includes providing technical assistance on virtual human services delivery and research on children's mental health and well-being following the start of the pandemic, including children with a COVID-19 diagnosis. ASPE has also modeled the effect of the COVID-19 recession on poverty rates and program eligibility including innovative analyses on the role of the ARP as well as the Administration's economic proposals on poverty and economic well-being.

Enhancing Health and Economic Equity

ASPE 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 the well-being of children and persons with disabilities and promote healthy youth development. For example, ASPE is identifying strategies to invigorate the childcare 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. 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 underserved 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, ASPE coordinates the U.S. Interagency Council on Economic Mobility chaired by HHS, charged with equitable economic recovery and resilience; coordinates HHS homelessness initiatives, and reentry, and youth development work; and partners with the Department of Education and ACF to support early childhood development. ASPE also chairs the Interagency Working Group on Youth Programs, established by Executive Order 13459, Improving the Coordination and Effectiveness of Youth Programs.

ASPE leads analyses and offers guidance on numerous activities related to improving equity and social determinants of health (SDOH). ASPE co-Chairs with the Assistant Secretary for Health, the HHS Health Disparities Council, an umbrella group for equity efforts across the Department. ASPE co-leads the HHS Data Council, which is documenting the landscape of equity data collected and exploring mechanisms to harmonize data. ASPE co-leads coordination of Department-wide bimonthly equity learning sessions and spearheads efforts to meet the requirements of Executive Order 13985 on Advancing Racial Equity and Support for Underserved Communities through the Federal Government. ASPE has established the Equity Technical Assistance Center (ETAC) to extend the work of EO 13985 and institutionalize equity impact assessments, among other equity efforts, in our activities across HHS. ASPE has proposed many data-related changes to better capture SDOH in HHS's data collection going forward, led development of equity impact assessments for legislative proposals, and co-chairs the HHS SDOH working group. Department-wide SDOH and Equity Action Plans are under development under ASPE's leadership.

Addressing Behavioral Health Needs

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 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 certain measures using existing Medicaid claims and encounter data to help support routine program monitoring and quality improvement efforts.

ASPE plays a key role in supporting the Secretary's priorities related to overdose, suicide prevention, and other behavioral health issues. These efforts involve data purchases, contract research, and in-house analyses. 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 CCBHC demonstration evaluation 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 Office of the Assistant Secretary for Health. 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 provides significant subject matter expertise and rigorous analysis to develop policy options and proposals related to addressing the nation's overdose crisis. ASPE staff and leadership synthesize and apply current research to inform policy and programmatic options. This includes leading the development of a new Overdose Prevention Strategy rolled out in Fall 2021, playing a leadership role in the Behavioral Health Coordinating Committee, leading policy work as part of an Interagency Policy Committee related to overdose prevention, and leading evaluation efforts of the HHS buprenorphine prescribing guidelines among other HHS policies. Demand for ASPE's coordination capabilities and subject matter expertise in this domain is likely to grow, as the overdose and mental health crises continue to grow, only exacerbated by COVID-19.

Promoting Scientific Integrity and Evidence-Based Policymaking

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. The work is intended to modernize federal data management practices, evidence-building functions, and statistical efficiency to inform policy decisions. 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. ASPE also participates in the White House's Scientific Integrity Task Force and leads HHS in executing requirements of the Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking. This memorandum calls on agencies to establish and enforce scientific integrity policies that ban improper political interferences and promote transparency in the conduct of scientific research and in the collection of scientific or technological data.

ASPE infuses rigorous methods, high-quality data, and modeling capabilities into analyzing the policies considered and implemented in HHS. For instance, ASPE conducts regulatory impact analyses (RIAs) for the Department through technical assistance, resources, and regulatory review. At this time when significant regulations will need RIAs, methodological improvements enable ASPE to better estimate the effects of regulations on sub-populations of interest and provide insight into important ways to address the Administration's priorities. 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, on behalf of the Secretary, uses the Patient Centered Outcomes Research Trust Fund to support data infrastructure projects that address national health priorities; expand longitudinal data resources; leverage leading technology; and expand socio-economic, environmental, and other data as part of a new strategic plan that will inform real-world evidence development with agencies across the Department.

ASPE analyses are informed by economic, actuarial, and microsimulation modeling to evaluate the impact of policy proposals on health and human services programs. ASPE routinely contracts for actuarial analysis to explore proposed changes to health insurance coverage and reform efforts

associated with long-term services and supports. ASPE also leads the Transfer Income Model and Dynamic Simulation of Income Model (TRIM). These are data-intensive and complex models that simulate changes to major governmental tax, transfer, and health programs that affect the U.S. population, and can produce results at the individual, family, state, and national levels. The models are useful for understanding the implications of broad demographic changes, such as population aging as well as childcare expansions and interactions with tax programs. TRIM can identify the differential impacts of policies on receipt and earnings for different subgroups, including race, ethnicity, geography, and household composition.

Fiscal Year	Amount	
FY 2019	\$41,243,000	
FY 2020	\$43,243,000	
FY 2021 Final	\$43,243,000	
FY 2022 Annualized CR	\$43,243,000	
FY 2023 President's Budget	\$56,743,000	

Five Year Funding Table

Budget Request

The FY 2023 President's Budget request for ASPE is \$56,743,000, which is an increase of +\$13,500,000 above the FY 2022 Annualized Continuing Resolution (CR) level. At the FY 2023 increased funding level, ASPE will be able to purchase additional data, expand research capabilities for critical policy research (including transforming behavioral health services and addressing the overdose crisis), advance interagency coordination of federal economic mobility programs, grow equity efforts, and expand research on the impact of the COVID-19 pandemic on the wellbeing including a focus on children and persons with disabilities. ASPE will be able to lend additional measurement and evaluation support on priority activities in partnership with agencies in the Department. This increase will also allow ASPE to be more agile in support of the increasing research demands coming from the Secretary as well as strategically plan for the most effective and judicious use of funds in support of the Secretary while building and/or capitalizing on economies of scale ASPE has already begun to achieve.

ASPE works carefully to balance the need to hire in-house expertise and skillsets needed to perform existing work, while ensuring that ASPE has the ability to take on the level and breadth of critical research that is required to support the Secretary going forward. The additional funds would allow ASPE to fill many of the vacancies and restore staff capacity for evaluation, data analysis, and coordination activities, including filling vacancies in the Science Policy Division to support efforts in restoring faith in and integrity of science, and promoting scientific discoveries. ASPE will also fill staff vacancies on the Medicare team to address long term financial sustainability of the Medicare program, as well as build sustained capacity to advance equity and conduct short and long-term analysis and evaluation of programs for refugees and unaccompanied children and address key human services issues such as promoting successful return from incarceration. Additionally, ASPE will hire staff to address Administration and Secretarial priorities in behavioral health transformation and related policy and budget commitments, as well as for the Immediate Office to support the ASPE and the Principal Deputy Assistant Secretary.

Grant Award Table

Grants (whole dollars)	FY 2021 Final	FY 2022 Annualized CR	FY 2023 President's Budget
Number of Awards	1	1	1
Average Award	\$1,315,000	\$1,365,000	\$1,365,000
Range of Awards	\$1,315,000	\$1,365,000	\$1,365,000

PUBLIC HEALTH ACTIVITIES

Budget Summary

(Dollars in Thousands)

Public Health Activities	FY 2021 Final	FY 2022 Annualized CR	FY 2023 President's Budget	FY 2023 +/- FY 2022
Budget Authority	8,800	8,800	8,800	
FTE	7	13	13	
Authorizing Legislation:PHS Act, Title II Section 247				
FY 2023 AuthorizationPermanent				
MethodDirect 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.

Fiscal Year	Amount		
FY 2019	\$9,400,000		
FY 2020	\$8,800,000		
FY 2021 Final	\$8,800,000		
FY 2022 Annualized CR	\$8,800,000		
FY 2023 President's Budget	\$8,800,000		

Five Year Funding Table

Budget Request

The FY 2023 request for PHS Evaluation is \$8,800,000 which flat with the FY 2022 Annualized Continuing Resolution. 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 OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH

Budget Summary

(Dollars in Thousands)

Office of the Assistant Secretary for Health	FY 2021 Final	FY 2022 Annualized CR	FY 2023 President's Budget	FY 2023 +/- FY 2022
Budget Authority	4,885	4,885	7,885	+3,000
FTE	-	2	5	+3
Authorizing Legislation:PHS Act, Title II, Section 247				
FY 2023 AuthorizationPermanent				
ocation MethodDirect Federal				eral

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 designed to improve and evaluate the effectiveness of OASH programs funded with the Public Health Service Act. These program evaluations play an integral role in the continuous improvement of OASH programs, and studies supported by these Evaluation Set-Aside funds serve decision makers in federal, state, and localgovernment, and the private sector of the public health research, education, and practice communitiesby providing valuable information about how well the programs and services are working.

The accomplishments and noteworthy activities of FY 2021 evaluation projects include:

- Developing National Health Objectives to Evaluate Health Across the Nation: Healthy People 2030(HP2030):
- Tracked and monitored data for HP2030 objectives and measures;
- Disseminated data for public use via health.gov/healthypeople2030;
- Developed and released HP2030 demographic data charts and tables;
- Initiated the HP2030 Champions program to recognize organization that support the HP2030 vision, goals and objectives;
- o Evaluating states' territories' and local health department's use of HP2030; and,
- Conducting implementation and communication activities to promote the use of HP2030 objectives with stakeholders to achieve the national targets.
 - Developing Leading Health Indicators (LHI) to evaluate progress toward improved health: Healthy People 2030
 - Tracked LHI and Overall Health and Well-Being Measures (OHM) data on health.gov/healthypeople2030;
 - Developed and added a new measure on life satisfaction to the National Health Interview Survey; and,
 - Disseminating evidence-based practices stakeholders can use in their own communities to adapt the LHI and OHMs to improve the health of their communities.
 - Evaluating communications strategies to improve patient understanding of the Dietary Guidelines for Americans (DGA), 2025-2030:
 - Conducted nutrition message testing with health care providers to inform updates to the *Dietary Guidelines* Healthcare provider toolkit and new fact sheets.

- <u>Released an updated the toolkit for health professionals to align with the new Dietary Guidelines</u> including guidance for health care providers on how to discuss nutrition with patients. <u>Interviews with health professionals and user testing informed the development of</u> five new fact sheets on the life stages (infants through older adults) and beverages in English and Spanish.
- *Dietary Guidelines* resources include materials to communicate the dietary recommendations and facilitate implementation through federal programs and public health programs.
- Evaluating strategies to Increase Physical Activity Among Older Adults: Physical Activity Guidelines for Americans Midcourse Report: Evaluating the current literature on what works and strategies to increase physical activityamong older adults in partnership with CDC and
- Identifying settings where physical activity messaging/encouragement would be relevant to older adults with the aim to increase the number of older adults who meet the key PAGs for older adults.
- Evaluating a Modernized USPHS Commissioned Corps:
 - Tracked implementation of the comprehensive evaluation recommendations for amodernized USPHS Commissioned Corps using performance measures;
 - o Disseminating high-level communication strategies to support the implementation phase; and,
 - Conducting additional assessments to determine trends, gaps, and improvements.
- Evaluating the implementation of the Sexually Transmitted Infections (STI) Strategic Plan:
 - o Assessing the nation's progress in reaching identified targets to reduce STIs;
 - o Implementing steps to course correct, if targets are not being met;
 - Evaluating the impact of COVID-19 on underlying health conditions related to STIs; and,
 - Analyzed and disseminating best practices.
- Evaluation of Health Messaging to Promote COVID-19 Vaccinations among Racial and Ethnic Minority Populations:
 - Evaluating the effectiveness of developed, targeted promotional materials to increase community demand and awareness of COVID-19 vaccination among racial and ethnic minority populations; and,
 - Assessing 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:
 - Assessing and expanding business analytics of public, USPHS Commissioned Corps officer, and administrative services demand within a Single Point of Contact (SPOC) Call Center and workflow automation capability;

Identifying trends to provide recommendations on how to support, categorize, streamline and resolve high volume requests in a timely manner; and identifying and recommending automation tools that can enhance self-service functionality of the OASH service automation. Projects approved for the FY22 Public Health Set-Aside program funding include continued evaluations of the Healthy People 2030 and Physical Activity Guidelines, as well as new projects that will evaluate activities related to Long Covid, maternal health, the impacts of climate change on health, primary care, the syndemic of HIV, STIs, viral hepatitis, and substance use disorder, adolescent health, and identifying research misconduct.

The OASH Evaluation Set-Aside program also supports OASH's InnovationX team (formerly the Innovation, Partnerships, and Digital Services of the HHS Office of the Chief Technology Officer [CTO]), which joined OASH's Office of Science and Medicine in 2021. OASH InnovationX harnesses the power of collaboration, data-driven innovation, human-centered design, and emerging technologies to advance human health and equity initiatives for the Office of Science and Medicine. It leads the departmental "open innovation" portfolio, including customer experience (CX), technology sprints, and innovation sprints fueled by open data and open science. InnovationX serves as a hub for HHS public-private partnerships including KidneyX and LymeX, which use grand-prize challenges to accelerate innovation

and scale solutions for real-world impact.

Fiscal Year	Amount
FY 2019	\$4,285,000
FY 2020	\$4,285,000
FY 2021 Final	\$4,885,000
FY 2022 Annualized CR	\$4,885,000
FY 2023 President's Budget	\$7,885,000

Five Year Funding Table

Budget Request

The FY 2023 President's Budget request for OASH Evaluation is \$7,885,000, which is +\$3,000,000 above the FY 2022 Annualized Continuing Resolution. At this funding level, OASH will continue to support robust program evaluation projects 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. Funding will also sustain current staffing levels for InnovationX.

At this level, the PHS Evaluation will continue to support work on Executive Order 13995, Ensuring an Equitable Pandemic Response and Recovery, to conduct a coordinated evaluation of issues contributing to the inequitable U.S. response to COVID-19. Specific activities include the following:

- Retrospective Evaluation of Racial and Ethnic Data Collection during the COVID-19 Pandemic: Establish programmatic activities to evaluate the: (1) Policies/practices that influenced states' data collection, access, and use for racial and ethnic minority demographic data associated with COVID-19 health care utilization and access data; and (2) Corresponding association of these linked demographic and utilization and access data on the states' distribution of COVID-19 resources, access to services and reported health outcomes.
- Data and Policy Briefs/Reports: Develop and implement a plan for producing special analyses and reports describing the evaluation of: (1) States' racial and ethnic minority demographic and social determinants of health (SDOH) data associated with COVID-19 health care utilization and access data; and (2) the corresponding association of these linked demographic, SDOH, utilization and access data on states' distribution of COVID-19 resources, access to services and reported health outcomes.

PHS EVALUATION OFFICE OF CLIMATE CHANGE AND HEALTH EQUITY

Budget Summary

(Dollars in Thousands)

Office of Climate Change and Health Equity	FY 2021 Final	FY 2022 Annualized CR	FY 2023 President's Budget	FY 2023 +/- FY 2022
Budget Authority	-	-	3,000	+3,000
FTE	-	-	8	+8
Authorizing Legislation:PHS Act, Title II Section 247				
FY 2023 AuthorizationPermanent				
MethodDirect Federal				

Program Description and Accomplishments

OASH is the lead or supporting agency for multiple climate change-related Executive Orders. Specifically, the Office of Climate Change and Health Equity (OCCHE) is part of OASH. Section 222(d)(i) of Executive Order 14008, Tackling the Climate Crisis at Home and Abroad, directed the Secretary to establish the Office of Climate Change and Health Equity to "address the impact of climate change on the health of the American people." Section 222 (d)(i) of the EO also directed the Secretary to establish 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.

OCCHE advises the Secretary and the Assistant Secretary for Health on matters relating to protecting disadvantaged communities and vulnerable populations experiencing a disproportionate share of climate impacts and health inequities. Exercising powers of convening, coordination and collaboration, the Office serves as a department-wide hub for climate change policy, programming, and analysis, in pursuit of equitable health outcomes. OCCHE facilitates the use of regulatory and statutory powers of the Department of Health and Human Services (HHS) to address matters affecting disadvantaged communities and vulnerable populations on the frontlines of the climate crisis. It also coordinates climate change and health equity activities among federal agencies and assists in representing US activities on climate change and health equity to the global community.

OCCHE collaborates with the Environmental Justice Team and other HHS colleagues on additional topics that are within the seven total environmental health/climate-related executive orders that are relevant 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.

Initial accomplishments include helping lead the development of the initial HHS Climate Action Plan, coordinating HHS responses to the extreme heat crises occurring in the summer of 2021, and leading the development of the Extreme Heat Interagency Working group under the White House Climate Task Force in partnership with co-chairs from National Oceanic and Atmospheric Administration and Environmental Protection Agency.

Interagency Working Group (IAWG) to Decrease the Risk of Climate Change to Children, the elderly, people with disabilities, and the vulnerable: 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; identifying redundancies in efforts; and identifying how each function can contribute to decreasing the risk of climate change to children, the elderly, people with disabilities, and the vulnerable; and developing a comprehensive plan, including milestones, activities, tools, and strategies for establishing and supporting key relationships.

Five Year Funding Table

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Fiscal Year	Amount
FY 2019	-
FY 2020	-
FY 2021 Final	-
FY 2022 Annualized CR	-
FY 2023 President's Budget	\$3,000,000

Budget Request

The FY 2023 President's Budget request for OCCHE is \$3,000,000 which is a +\$3,000,000 increase over the FY 2022 Annualized Continuing Resolution. At this level, the OCCHE will be able to maintain a staff of subject matter experts and support staff capable of pursuing the Office's goals with partners within HHS and through partnership with our regional offices and other stakeholders.

OCCHE will apply FY 2023 funding to the following key functions:

- Office of Climate Change and Health Equity Personnel: Funds will be dedicated for Office staff, including the Director, Deputy Director, and six additional full-time federal staff, ORISE and Presidential Management Fellows, and Expert Consultants. Staff are needed as SMEs and to manage contracts, cooperative agreements, grant programs, and fellowship administration.
- **Contract Support:** The Office of Climate Change and Health Equity requires and will utilize contract support for technical and logistical support for events and establishment and leadership of new interagency working groups and advisory councils as mandated by E.O. 14008.
- Grants and Cooperative Agreements: The Office of Climate Change and Health Equity will enter into cooperative agreements with public health partners to support fellowships for underrepresented minority students in climate change and health equity. It will also build on an initial mini- and micro-grant program to stimulate innovation and build capacity for resilience in disadvantaged and at-risk communities. This grant program will expand slightly in FY23.

Activity	FY 2021 Final	FY 2022 Annualized CR	FY 2023 President's Budget
Grants/Cooperative Agreements	-	-	\$500,000
Total	-	-	\$500,000

Office of Climate Change and Health Equity – Program Data Chart:

PHS EVALUATION TEEN PREGNANCY PREVENTION

Budget Summary

(Dollars in Thousands)

PHS Evaluation Teen Pregnancy Prevention	FY 2021 Final	FY 2022 Annualized CR	FY 2023 President's Budget	FY 2023 +/- FY 2022	
Budget Authority	6,800	6,800	7,700	+900	
FTE	-	-	1	1	
Authorizing LegislationPHS Act, Title II Section 247					
FY 2023 Authorization				Permanent	
Allocation Method				Direct Federal	

Program Description and Accomplishments

The Office of Population Affairs (OPA) supports several research and evaluation activities that build theevidence base to prevent teenage pregnancy and sexually transmitted infections. OPA supports:

- A research-to-practice center to develop and disseminate research-informed practice resources forprofessionals who work with youth involved in the child welfare and/or justice systems, youth experiencing homelessness, and opportunity youth.
- Research grants examining the settings and youth characteristics to determine under what conditions Teen Pregnancy Prevention (TPP) programs are most and least effective and determiningfactors that prevent and reduce disparities in sexual health outcomes.
- The provision of rigorous evaluation training and technical assistance to TPP Program granteesconducting research and evaluation.
- The collection and analysis of program performance measures for monitoring, programimprovement and reporting.
- Multiple research projects with the goals of identifying, measuring, and evaluating the effectiveness of core components of TPP programs.
- In partnership with the Office of the Assistant Secretary for Planning and Evaluation (ASPE), the HHSTPP 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 2019	\$6,800,000
FY 2020	\$6,800,000
FY 2021 Final	\$6,800,000
FY 2022 Annualized CR	\$6,800,000
FY 2023 President's Budget	\$7,700,000

Budget Request

The FY 2023 President's Budget request for Teen Pregnancy Prevention Evaluation (TPPE) is \$7,700,000, which is +\$900,000 above the FY 2022 Annualized Continuing Resolution. The additional funds will support an independent, systemic, rigorous evidence review of the Teen Pregnancy Prevention evaluation program. At this funding level, OPA will also support competitive grants and contracts that evaluate pregnancy prevention approaches to determine under what conditions TPP programs are most and least effective. These grants and contracts will put an added emphasis on determining factors that prevent and reduce disparities in sexual health outcomes and identifying core components of TPP programs that support effectiveness, as recommended in the 2019 Institutes of Medicine report on the TPP Program.

OPA will also invest in the development of research-to-practice resources to translate research findings into best practices and actionable activities for practitioners and adults who work with adolescents. These funds will also support technical assistance and training for TPP grantees conducting research with rigorous evaluation. Funds will also support the HHS Teen Pregnancy Prevention Evidence Review and related activities to update and expand upon the evidence.

PHS EVALUATION ASSISTANT SECRETARY FOR FINANCIAL RESOURCES

Budget Summary

(Dollars in Thousands)

Assistant Secretary for Financial Resources	FY 2021 Final	FY 2022 Annualized CR	FY 2023 President's Budget	FY 2023 +/- FY 2022
Budget Authority	1,100	1,100	1,100	-
FTE	2	6	6	-
Authorizing Legislation:PHS Act, Title II, Section 24 FY 2023 AuthorizationPermaner MethodDirect feder				

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 2019	\$1,100,000
FY 2020	\$1,100,000
FY 2021 Final	\$1,100,000
FY 2022 Annualized CR	\$1,100,000
FY 2023 President's Budget	\$1,100,000

Budget Request

The FY 2023 President's Budget request for ASFR PHS Evaluation is \$1,100,000, which is flat with the FY 2022 Annualized CR.

Funding will support 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. The Office of Budget manages the implementation GPRAMA and all phases of HHS performance budget improvement activities. Funding 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.

ASPE Strategic Planning System **Nonrecurring Expenses Fund**

Budget Summary

(Dollars in Thousands)

	FY 2021 ⁶	FY 2022 ⁷	FY 2023 ⁸
Notification ⁹		375	
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 use of the funds for capital acquisitions necessary for the operation of the Department, specifically information technology (IT) and facilities infrastructure acquisitions.

The ASPE Strategic Planning System is an enterprise-level resource to support all HHS leaders and staff in their strategic planning efforts. The System secured its Authorization to Operate (ATO) in 2018, is securely accessible through AMS access, and is compliant with federal IT laws and regulations. NEF funds will be applied to a contract that supports the ASPE Strategic Planning System.

FY 2022 NEF funds support implementation of design and usability updates to the ASPE Strategic Planning System to facilitate better reporting of strategic plan implementation by HHS staff, and to better integrate the tracking tool and the best practices offered in the Resource Center, the capacitybuilding module of the Strategic Planning System. These one-time enhancements involve both technical implementation as well as customer engagement to ensure enhancements are responsive to the needs of HHS staff implementing strategic plans. No FY 2022 NEF-funded activities have taken place to date, but work described above will take place during the contract period of performance spanning the remainder of FY 2022.

⁶ Pursuant to Section 223 of Division G of the Consolidated Appropriation Act, 2008, notification is required of planned use.

⁷ Notification submitted to the Committees on Appropriations in the House of Representatives and the Senate on October 22, 2020.

⁸ Notification submitted to the Committees on Appropriations in the House of Representatives and the Senate on June 17, 2021. 9 The NEF CJ indicates the amounts HHS intends to notify for in 2023; these amounts are planned estimates and subject to final approval.

ASPE IT Infrastructure

Nonrecurring Expenses Fund

Budget Summary

(Dollars in Thousands)

	FY 2021 ¹⁰	FY 2022 ¹¹	FY 2023 ¹²
Notification ¹³		1,361	-

Authorizing Legislation:

Authorization	Section 223 of Division G of the Consolidated Ap	propriations 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.

ASPE leadership works in collaboration with the ASPE IT Advisory Committee (ITAC) in their executive oversight of the ASPE IT Solutions contract. The IT Advisory Committee will provide each office, through their committee representatives, a mechanism for laying out their policy requirements; defining metrics for successful outcomes; rely on data to inform decisions; staying up-to-date about contract activities; evaluating and providing input on proposed IT changes; drafting IT-related policies and operating procedures; and conveying, ideas, questions, and concerns to the IT Solutions Team. The committee will increase transparency, engagement, and collaboration across ASPE.

FY 2022 NEF funds are being utilized to modernize and secure ASPE systems and IT infrastructure to align internal systems, the public facing website, and scientific and analytical computing capacity with HHS cybersecurity policy and continuity of operations. Modernizing ASPE's IT infrastructure enables staff to be responsive to rigorous requests from senior leadership within the Office of the Secretary and to disseminate our work to the public. With these funds, ASPE is taking steps to improve our risk posture by:

- Ensuring ASPE's public facing website has Authority to Operate (ATO);
- Purchasing and establishing a low-code solution for ASPE's business operations and ASPE's intranet website; and
- Acquiring or leveraging a cloud solution for scientific and analytical data processing, storage and management.

Initial project activities for FY 2022 are initiated and will continue during the contract period of performance spanning the remainder of FY 2022.

¹⁰ Pursuant to Section 223 of Division G of the Consolidated Appropriation Act, 2008, notification is required of planned use

¹¹ Notification submitted to the Committees on Appropriations in the House of Representatives and the Senate on October 22, 2020.

¹² Notification submitted to the Committees on Appropriations in the House of Representatives and the Senate on June 17, 2021

¹³ The NEF CJ indicates the amounts HHS intends to notify for in 2023; these amounts are planned estimates and subject to final approval.

OASH INTERGRATED DATA PLATFORM Nonrecurring Expenses Fund

Budget Summary

(Dollars in Thousands)

	FY 2021 ²	FY 2022 ³	FY 2023⁴
Notification ¹	-	-	-

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 use of the funds for capital acquisitions necessary for the operation of the Department, specifically information technology (IT) and facilities infrastructure acquisitions.

The COVID-19 Pandemic has exacerbated the significant gaps in the current 20-year-old Corps IT systems used to manage deployments, track personnel, and identify critical skillsets to meet mission requirements during an emergency response.

In August 2020, OASH received \$26.4 million NEF to replace the CCHQ payroll and personnel system which allows for coordination and interaction with HHS civilian HR Systems, such as the Enterprise Human Capital Management (EHCM) and Quality Service Management Office (QSMO).

OASH initiated the project in FY 2021 and conducted system discovery, database analysis and requirement gathering. OASH also established preliminary IT governance and program criteria.

¹Pursuant 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 October 22, 2020.

³Notification submitted to the Committees on Appropriations in the House of Representatives and the Senate on June 17, 2021.

⁴ The NEF CJ indicates the amounts HHS intends to notify for in 2023; these amounts are planned estimates and subject to final approval.

Assistant Secretary for Administration Nonrecurring Expenses Fund

Budget Summary

	FY 2021 ¹⁴	FY 2022 ¹⁵	FY 2023 ¹⁶
Notification ¹⁷	\$24,435	\$17,645	-

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.

Budget Allocations

For FY 2022, Office of the Assistant Secretary for Administration continues to make investments that support information technology, cybersecurity enhancements, and facilities infrastructure. Current and completed NEF projects and accomplishments across the ASA are outlined in the following summarized projects.

HHS IMPACT – Identifying and Mobilizing Personnel Assignments to Critical Tracts - \$3,395,000

OCIO is developing an enterprise federal employee volunteer program and platform to streamline the process by which HHS deploys federal workforce volunteers in response to public health emergencies, surge needs, and crises scenarios. The platform will assist with the mobilization of personnel, rapidly, based on skillset and readiness, and will provide for significant direct human health impacts and positive health outcomes. OCIO is in the beginning phases and is projecting to be fully operational across the Department at the beginning of FY 2023, with development and enhancements continuing through usertesting and specific mission requirements.

PIV Tracking and Access Management - \$950,000

OCIO is in the process of developing a sustainable platform to track and report Personal Identity Verification (PIV) exceptions across the enterprise and leading the assessment and implementation of additional controls pertaining to PIV exceptions to mitigate risk across the Department. In responding to COVID-19, PIV exceptions allowed for a continuance of onboarding federal and contractual personnel in support of HHS' mission under a National Emergency declaration. The exceptions have increased the Department's vulnerability for insider threats requiring mitigation and appropriate corrective actions. In FY 2022, OCIO will implement an enterprise PIV exception tracking and reporting systems along with adding enhanced controls to better mitigate risks.

Debt Management System - \$13,300,000

¹⁴ Pursuant to Section 223 of Division G of the Consolidated Appropriation Act, 2008, notification is required of planned use

¹⁵Notification submitted to the Committees on Appropriations in the House of Representatives and the Senate on October 22, 2020.

¹⁶Notification submitted to the Committees on Appropriations in the House of Representatives and the Senate on June 17, 2021. 17 The NEF CJ indicates the amounts HHS intends to notify for in 2023; these amounts are planned estimates and subject to final approval.

PSC's Debt Collection Center (DCC) provides centralized debt collection and management services to customer agencies. The modernization would include cloud based computing to give users real-time updates to their debt, customer access to transactions and financial standing, and on-demand reporting. The system upgrades will allow for streamlined information communications among agencies such as Treasury CROSS Servicing, credit bureaus, and the Department of Justice. The project is in the beginning phases with a projected operational platform in FY 2024.

Regional Consolidation - Atlanta and Boston Consolidation - \$18,447,842

The Boston and Atlanta regional office projects are now in the early stages of planning. It is anticipated that the design phases for these projects will begin in FY 2022.

Regional Offices - Chicago and San Francisco - \$15,787,158

PSC continues to work with the General Services Administration (GSA) on the new space for the Chicago Regional Office and to renovate existing space in the San Francisco Regional Office. Regional office renovation and consolidation projects consist of multiple phases that generally occur over a three-year period. Phases include the program requirements phase, the design phase, and construction phase. The San Francisco and Chicago projects are currently in the design phase and construction will begin shortly after.

Humphrey Building Renovations - \$7,779,471

NEF funding was approved to GSA for design and construction for the Humphrey Building Cafeteria Renovations. Construction started in November 2021 and scheduled for completion in FY 2022.

Enterprise Network Consolidation and Trusted Internet Connection (TIC) Migration - \$5,000,000

The Office of Operations and Office of Information Security (OIS) within OCIO are the business owners for the HHS Enterprise Intranet. OIS received funds for a continued investment to identify efficiencies in enterprise security components, fund lifecycle refresh for TIC and internet security components, and support HHS internet requirements and migration costs. These updates strengthened OMB mandated TIC cyber security capabilities. OIS continues to leverage remaining funds for the initiative and is scheduled to complete this project in FY 2022.

ReImagine HHS - Better Insight from Better Data - \$19,407,000

Office of the Chief Data Officer (OCDO) has utilized a combination of commercial off-the-shelf products and a customized analytic workspace environment to build a sustainable technology solution that integrates a metadata catalog, analytic workspace, and process flows, now known as HHS Connect. OCIO OCDO implemented an internal portal for collaboration on data and data science across the Department with NEF funding. The platform relies on three integrated software tools to support the data lifecycle: collaborative CRM platform, complete data-lifecycle management solution, and secure cloud-based workspace accessible to all HHS employees.

Optimize Coordination - \$5,000,000

OCIO continues to make investments that support Optimizing Coordination Across HHS. This infrastructure initiative seeks to integrate administrative data into HHS decision making processes. This involves building the infrastructure for a "data hub" that will link existing administrative data sources relating to budget, facilities, human resources, assets, badging, time and attendance, as well as others. Additional features include migrating the on-premise Business Intelligence System to the cloud, and funding contracts to complete other project related tasks, in accordance with leadership priorities

Portfolio Management Tool (PMT) Modernization - \$1,150,000

OCIO completed the PMT modernization project in support of OCIO's mission in facilitating HHS's ability to manage, monitor, and track IT investment costs and projects in accordance with OMB Circular A-11 requirements.

Enterprise Packet Capture Solutions Refresh migration to MTIPS - \$5,499,916

OCIO OIS completed the migration project that included completing requirements, identification, and procurement of the Department's Enterprise Packet Capture Solution, including adjustments to accommodate working from home on a large scale during the pandemic.

HHS Cybersecurity Automation Program (HCAP) - \$20,694,532

HCAP finalized the HCAP Program charter, cybersecurity workflow processes, establishing security information and event management infrastructure, and streamlining multiple tools across the agency.

Office of Human Resources – HRIT, EHCM, and DetailNow - \$103,175,710

The Enterprise Human Capital Management (EHCM) program, has received funding from the NEF since is charged with providing an interoperable HR enterprise solution with common core functionality to support strategic management of human capital and improve delivery of services to HHS employees and managers. OHR continues to implement HHS-wide integrated HR time and attendance solutions. The time and attendance solution will result in the decommissioning of multiple standalone HHS time and attendance applications resulting in a unified, enterprise level solution.

Switzer & Parklawn Projects - \$20,893,760

The PSC project includes a new Conference Center, renovations to the East Lobby and renovations to the Lower Level.

SUPPORTING EXHIBITS BUDGET AUTHORITY BY OBJECT CLASS – DIRECT

(Dollars in Thousands)

Object Class Code	Description	FY 2021 Final	FY 2022 Annualized CR	FY 2023 President's Budget	FY 2023 +/- FY 2022
11.1	Full-time permanent	81,364	86,287	107,757	+21,470
11.3	Other than full-time permanent	4,144	4,144	4,288	+144
11.5	Other personnel compensation	912	912	944	+32
11.7	Military personnel	2,262	3,378	4,053	+676
Subtotal	Personnel Compensation	88,681	94,720	117,042	+22,322
12.1	Civilian personnel benefits	33,607	35,522	43,917	+8,395
12.2	Military benefits	879	1,313	1,576	+263
13.0	Benefits for former personnel	-	-	-	-
Total	Pay Costs	123,168	131,555	162,535	+30,979
21.0	Travel and transportation of persons	1,533	1,533	1,449	-84
22.0	Transportation of things	73	73	70	-3
23.1	Rental payments to GSA	20,865	20,865	21,912	+1,047
23.3	Communications, utilities, and misc. charges	1,458	1,458	1,434	-24
24.0	Printing and reproduction	1,158	1,158	1,172	+14
25.1	Advisory and assistance services	33,627	32,277	37,037	+4,760
25.2	Other services from non-Federal sources	32,737	29,239	34,605	+5,366
25.3	Other goods and services from Federal sources	126,720	124,299	139,385	+15,086
25.4	Operation and maintenance of facilities	3,155	3,207	11,393	+8,186
25.5	Research and development contracts	-	-	-	-
25.6	Medical care	-	-	-	-
25.7	Operation and maintenance of equipment	2,074	2,074	3,094	+1,020
25.8	Subsistence and support of persons	18	18	18	-
26.0	Supplies and materials	480	480	487	+7
31.0	Equipment	687	687	1,373	+686
32.0	Land and Structures	-	-	-	-
41.0	Grants, subsidies, and contributions	136,597	136,870	163,875	+27,005
42.0	Insurance claims and indemnities	-	-	-	-
44.0	Refunds	-	-	-	-
Total	Non-Pay Costs	361,183	354,239	417,304	+63,065
Total	Budget Authority by Object Class	484,351	485,794	579,839	+94,044

BUDGET AUTHORITY BY OBJECT CLASS – REIMBURSABLE

	(Dollars in Thou	sands)			
Object Class Code	Description	FY 2021 Final	FY 2022 Annualized CR	FY 2023 President's Budget	FY 2023 PB +/- FY 2022 CR
11.1	Full-time permanent	48,488	49,898	54,940	+1,410
11.3	Other than full-time permanent	-	-	-	-
11.5	Other personnel compensation	-	-	-	-
11.7	Military personnel	1,410	1,308	1,429	-102
Subtotal	Personnel Compensation	49,898	51,206	56,369	+1,308
12.1	Civilian personnel benefits	17,974	18,238	21,366	+264
12.2	Military benefits	470	431	556	-39
13.0	Benefits for former personnel	-	-	-	-
Total	Pay Costs	68,342	69,875	78,290	+1,533
21.0	Travel and transportation of persons	1,000	1,000	1,010	-
22.0	Transportation of things	-	-	-	-
23.1	Rental payments to GSA	6,000	6,000	8,061	-
23.3	Communications, utilities, and misc. charges	-	-	-	-
24.0	Printing and reproduction	-	-	-	-
25.1	Advisory and assistance services	29,000	29,000	31,796	-
25.2	Other services from non-Federal sources	18,000	18,000	20,683	-
25.3	Other goods and services from Federal sources	104,123	141,995	154,043	+37,872
25.4	Operation and maintenance of facilities	3,000	3,000	2,031	-
25.5	Research and development contracts	-	-	-	-
25.6	Medical care	-	-	-	-
25.7	Operation and maintenance of equipment	5,000	5,000	5,051	-
25.8	Subsistence and support of persons	-	-	-	-
26.0	Supplies and materials	-	-	-	-
31.0	Equipment	1,000	1,000	1,010	-
32.0	Land and Structures	-	-	-	-
41.0	Grants, subsidies, and contributions	3,000	3,000	5,130	-
42.0	Insurance claims and indemnities	-	-	-	-
44.0	Refunds	-	-	-	-
Total	Non-Pay Costs	170,123	207,995	228,815	+37,872
Total	Budget Authority by Object Class	238,465	277,870	307,105	+39,405

(Dollars in Thousands)

SALARIES AND EXPENSES

(Dollars in Thousands)

Object Class Code	Description	FY 2021 Final	FY 2022 Annualized CR	FY 2023 President's Budget	FY 2023 +/- FY 2022
11.1	Full-time permanent	81,364	86,287	107,757	+21,470
11.3	Other than full-time permanent	4,144	4,144	4,288	+144
11.5	Other personnel compensation	912	912	944	+32
11.7	Military personnel	2,262	3,378	4,053	+676
Subtotal	Personnel Compensation	88,681	94,720	117,042	+22,322
12.1	Civilian personnel benefits	33,607	35,522	43,917	+8,395
12.2	Military benefits	879	1,313	1,576	+263
13.0	Benefits for former personnel	-	-	-	-
Total	Pay Costs	123,168	131,555	162,535	+30,979
21.0	Travel and transportation of persons	1,533	1,533	1,449	-84
22.0	Transportation of things	73	73	70	-3
23.3	Communications, utilities, and misc. charges	1,458	1,458	1,434	-24
24.0	Printing and reproduction	1,158	1,158	1,172	+14
25.1	Advisory and assistance services	33,627	32,277	37,037	+4,760
25.2	Other services from non-Federal sources	32,737	29,239	34,605	+5,366
25.3	Other goods and services from Federal sources	126,720	124,299	139,385	+15,086
25.4	Operation and maintenance of facilities	3,155	3,207	11,393	+8,186
25.5	Research and development contracts	-	-	-	-
25.6	Medical care	-	-	-	-
25.7	Operation and maintenance of equipment	2,074	2,074	3,094	+1,020
25.8	Subsistence and support of persons	18	18	18	-
Subtotal	Other Contractual Services	202,554	195,336	229,657	+34,320
26.0	Supplies and materials	480	480	487	+7
Subtotal	Non-Pay Costs	203,034	195,816	230,144	+34,327
Total	Salary and Expenses	326,201	327,372	392,678	+65,307
Total	Direct FTE	777	837	993	+156

(Direct Only)								
Direct Civilian Positions	FY 2021 Actual	FY 2022 Annualized CR	FY 2023 President's Budget					
Executive level I	1	1	1					
Executive level II	1	1	1					
Executive level III	-	-	-					
Executive level IV	1	1	2					
Executive level V	2	1	3					
Subtotal, Positions	5	4	7					
Total, Salaries	\$936,900	\$771,600	\$1,296,399					
-	-	-	-					
Executive Service ¹⁸	67	71	91					
Administrative Appeal Judge ¹⁹	-	-	-					
Subtotal, Positions	67	71	91					
Total, Salaries	\$10,570,859	\$11,136,454	\$14,889,840					
-	-	-	-					
GS-15	165	179	185					
GS-14	210	227	243					
GS-13	119	128	139					
GS-12	79	79	93					
GS-11	43	43	75					
GS-10	3	3	15					
GS-9	43	48	85					
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	-	-	-					
GS-2	-	-	-					
GS-1	-	-	-					
Subtotal, Positions	679	724	852					
Total Salaries	\$108,518,986	\$114,956,343	\$140,718,749					
-	-	-	-					
Total Positions	751	799	950					
-	-	-	-					
Average ES Level	ES 00	ES 00	ES 00					
Average ES salary	\$157,774	\$156,851	\$163,625					
Average GS grade	14.9	14.10	14.10					
Average GS Salary	\$159,823	\$158,778	\$165,163					

DETAIL OF POSITIONS

¹⁸ Executive Service displaying direct only. Prior year's displayed direct and reimbursable combined.

¹⁹ Administrative Appeal Judge designated as reimbursable to GDM or reallocated under Medicare Hearings and Appeals (MHA).

Detail	FY 2021 Final CIV	FY 2021 Final CC	FY 2021 Total	FY 2022 Continuing Resolution (CR) CIV	FY 2022 Continuing Resolution (CR) CC	FY 2022 Continuing Resolution (CR) Total	FY 2023 President's Budget CIV	FY 2023 President's Budget CC	FY 2023 President's Budget Total
Direct	751	26	777	799	38	837	950	43	993
Reimbursable	544	6	550	552	11	563	591	12	603
Total FTE	1,295	32	1,327	1,351	49	1,400	1,541	55	1,596
-	-	-	-	-	-	-	-	-	-
Average Civilian GS Grade Direct	-	-	14.9	-	-	14.10	-	-	14.10

DETAIL OF FULL-TIME EQUIVALENT (FTE) EMPLOYMENT²⁰

²⁰ Abbreviation Key: CIV – Civilian, CC – Commissioned Corps

(Dollars in Thousands)												
Program	Section	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022	FY 2023
Pregnancy Assistance Fund Discretionary P.L. (111-148)	Section 10214	22,825	23,200	23,275	23,300	23,275	23,350	23,350	0	0	0	0
FTE	-	2	2	2	2	2	2	2	0	0	0	0

FTES FUNDED BY THE AFFORDABLE CARE ACT

(Dollars in Thousands)									
	FY 2021	FY 2022	FY 2023	FY 2023 +/-					
Details	Final	Annualized	President's	FY 2021					
		CR	Budget						
Rent									
GDM	10,344	10,344	10,451	+107					
IOS	204	204	221	+17					
ASA	-	-	-	-					
ASFR	117	117	118	+1					
ASPA	-	-	-	-					
CFOI	66	66	67	+1					
DAB	537	537	643	+106					
IEA	-	-	-	-					
OASH	5,483	5,483	6,239	+756					
OGA	450	450	470	+20					
OGC	3,217	3,217	3,250	+33					
Subtotal	20,419	20,419	21,460	+1,041					
Operations and Maintenance	-	-	-	-					
GDM	968	1,020	9,005	+7,985					
IOS	117	117	118	+1					
ASA	838	838	847	+9					
ASFR	255	255	258	+3					
ASPA	63	63	64	+1					
CFOI	14	14	14	-					
DAB	140	140	141	+1					
IEA	81	81	32	-49					
OASH	2,619	2,619	3,926	+1,307					
OGA	692	692	699	+7					
OGC	629	629	636	+7					
All Other GDM	170	170	182	+12					
Subtotal	6,586	6,638	15,922	+9,284					
Service and Supply Fund	-	-	-	-					
GDM Shared Services	7,210	7,210	7,971	761					
IOS	1,713	1,799	1,889	90					
ASA	5,477	5,751	6,038	288					
ASFR	1,532	1,609	1,689	80					
ASPA	658	691	725	35					
CFOI	152	160	168	8					
DAB	389	408	429	20					
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	30,696	+1,843					

RENT AND COMMON EXPENSES

SIGNIFICANT ITEMS

House Report (pages 232)

Advertising Contracts for Small Business Owners - The Committee directs each department and agency to include the following information in its fiscal year 2023 Congressional Budget Justification: expenditures for fiscal year 2021 and expected expenditures for fiscal year 2023 for (1) all contracts advertising services; and (2) contracts for the advertising services of (I) socially and economically disadvantaged small businesses concerns (as defined in section 8(a)(4) of the Small Business Act (15 U.S.C. 637 (a)(4)); and (II) women- and minority-owned businesses.

Action Taken or To Be Taken

For FY 2021, ASPA had two programs that had advertising contracts, i.e., Digital and the COVID-19 Public Education Campaign (PEC) which is funded by the Coronavirus Aid, Relief, and Economic Security Act (CARES).

COVID-19 Public Education Campaign (PEC) - 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 PEC issued a Task Order off of an NIH Indefinite Delivery/Indefinite Quantity contract. The PEC will use more than 5,000 media vendors across the country, the vast majority being local and hyperlocal vendors, 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.

ASPA Digital - ASPA Digital used a small business, as defined by GSA; however, it is not woman owned/disadvantaged or minority owned.

House Report (pages 233)

COVID–19 Services for Medically Underserved Communities - The Committee is concerned about the high rate of COVID–19-related cases, hospitalizations, and deaths of historically medically underserved communities. According to HRSA, more than 18 million people reside in medically underserved areas or populations across the United States. The Committee urges the Secretary develop a strategy to dedicate a specific percentage of COVID–19 funding to community-based organizations proportional to the needs of people living in medically underserved areas.

Action Taken or To Be Taken

As part of the government-wide effort to identify and eliminate health and social disparities, which have resulted in disproportionately higher rates of exposure, illness, hospitalization, and deaths related to COVID-19, President Biden established the COVID-19 Health Equity Task Force (HETF) through Executive Order 13995, on January 21, 2021.

Multiple HETF policy recommendations cite the importance of increased investments in communitybased organizations (CBOs) in improving health equity. Specifically, the HETF recommended HHS provide support to local CBOs to expand vaccinations to underserved groups, as well as provide robust and sustainable funding to CBOs and public health providers for longer-term capacity building. The HETF noted the importance of HHS funding organizations with demonstrated record of working with and for communities of color, people with disabilities, rural communities, immigrants, LGBTQIA+ individuals, and other underserved populations with lived experience.

CBOs have been awarded HHS funding to support the COVID-19 response throughout the pandemic. As part of its comprehensive approach to reach communities with vaccination information, through the American Rescue Plan, HHS/HRSA has provided over \$390 million to 158 CBOs and related organizations serving all 50 states to support trusted messengers conducting tailored local outreach to build vaccine confidence, increase vaccination rates, and address barriers to vaccination among underserved communities and populations, including communities of color and rural areas. HRSA is also investing in new workforce programs to train community health workers and create new rural health networks to better serve these communities and populations. In FY 23, CBOs will be eligible applicants for future HHS COVID-19 response funding consistent with HHS's statutory authority and Congressional appropriations. More generally, HHS will continue to explore ways to partner with community-based organizations to provide key health services to people living in medically underserved areas. These groups will continue to be of critical importance to the Department's response to the COVID-19 pandemic, as well as addressing longer term medical and social needs that create health disparities.

Community-based organizations (CBOs) play an important role in addressing COVID-19 for people living in medically underserved areas and other vulnerable communities. Recognizing the important role that CBOs play in promoting public health, CDC has awarded funds to CBOs in multiple different ways to engage them in supporting the COVID-19 response throughout the pandemic. Early in the pandemic, CDC funded national minority-serving organizations including Historically Black Colleges and Universities (HBCUs) to support hyperlocal COVID-19 prevention strategies. CDC has also provided funding to national organizations who then provide subawards to local CBOs. These local CBOs have used this funding to support the COVID-19 response by working at the local level to improve vaccine confidence and vaccine coverage and to reduce barriers to testing, health care, and vaccines, with a specific focus in increasing vaccine access and uptake among racial and ethnic minority communities. For example, awards were made to local affiliates of national organizations, faith-based organizations and other community-based organizations with the capacity to reduce barriers to testing, health care, and vaccinations. COVID-19 prevention messages were translated into more than 28 different languages and delivered by trusted community messengers. In addition, CDC has also awarded funding to state and local health departments to support the COVID-19 response, and many of these awards specify that a percentage of funding go towards supporting the COVID-19 response at the local level. This locally targeted funding has gone towards supporting local health departments, CBOs, and community health departments, encouraging local health departments to collaborate with community partners in supporting local response needs and reducing COVID-19 disparities in underserved communities.

House Report (pages 235)

Fair Access to Science and Technology Research - The Committee commends the HHS agencies—the Administration for Community Living (ACL), Agency for Healthcare Research and Quality (AHRQ), Assistant Secretary for Preparedness and Response (ASPR), Centers for Disease Control (CDC), Food and Drug Administration (FDA), and National Institutes for Health (NIH)—that have issued plans in response to the White House Office of Science and Technology Policy Directive issued on February 22, 2013. The Committee urges these agencies to continue their efforts toward full implementation of the plan and requests an update in the fiscal year 2023 Congressional Budget Justification.

Action Taken or To Be Taken

<u>ACL</u> - The Administration for Community Living remains committed to ensuring access to scientific publications as directed by the White House Office of Science and Technology Policy (OSTP) Directive of 2013. The ACL Public Access Plan has served as a mechanism for compliance with the OSTP public access policy. ACL/NIDILRR systematically monitors grantees to ensure that published results of NIDILRRfunded research are readily accessible and available in accordance with published guidance. ACL/NIDILRR looks forward to continued collaboration across the HHS research enterprise to fulfill the requirements of the OSTP Directive and to facilitate optimized public access and increased use of research results and scientific data to advance community living outcomes, public policy, and the delivery of services in support of our broad stakeholder networks.

<u>ASPR</u>

As an HHS staff division, ASPR complies with the Department's policies and procedures. These are documented in "POLICIES AND PRINCIPLES FOR ASSURING SCIENTIFIC INTEGRITY", which can be found at <u>https://aspe.hhs.gov/basic-report/policies-and-principles-assuring-scientific-integrity</u>. ASPR coordinates closely with the HHS Office of the Assistant Secretary for Public Affairs. That office then coordinates appropriately across all relevant HHS divisions.

<u>AHRQ</u> - AHRQ has fully implemented the requirement for increasing access to the results of federally funded scientific research. AHRQ published its public access plan in 2015 for establishing a policy for public access to scientific publications and scientific data in digital format resulting from AHRQ funded research (https://www.ahrq.gov/funding/policies/publicaccess/index.html), the Public Access Policy for Scientific Publications in 2016 (https://grants.nih.gov/grants/guide/notice-files/not-hs-16-008.html), and Data Management Plan Policy in 2020 for access to data resulting from AHRQ research funding (https://grants.nih.gov/grants/guide/notice-files/NOT-HS-20-011.html). We are in the process of further refining and implementing data management plan policy compliance measures.

<u>FDA</u> - The FDA has completed phase 1 of the Plan to Increase Access to Results of FDA-Funded Scientific Research through implementing the necessary architecture and user guides entries to meet the requirements. FDA is now working on phase 2, which involves training authors and enhancements to connect the published articles to the datasets in openFDA. OpenFDA can accept public research datasets from FDA researchers and publish them in machine readable format. The FDA Library has implemented Esploro, a commercial FedRAMP approved product from ExLibris, to provide FDA with a mechanism for making the research and scientific outputs accessible. Esploro has been branded the "FDA Research and Expertise Portal". The portal will link the FDA published articles to the datasets that will be located in the existing openFDA system. This initiative is aligned with FDA's Technology Modernization Action Plan and Data Modernization Action Plan.

<u>NIH</u> - NIH is in full compliance with the White House Office of Science and Technology Policy Directive issued on February 22, 2013. NIH has long been a leader in publication availability, through its 2008 Public Access Policy. In 2020, OSP finalized the NIH Policy for Data Management and Sharing (DMS Policy), which will require researchers to prospectively submit plans for managing and sharing their scientific data. These plans will describe what and where data will be shared, how participants' privacy and rights will be respected (for research involving human participants), and anticipated timelines for data preservation and access. Researchers will be expected to maximize data sharing, acknowledging

any limiting legal, ethical, and technical factors. The DMS Policy will go into effect for new and competing awards in 2023. NIH has been working to ensure smooth implementation of the DMS Policy through supplemental information, frequently asked questions, and various other outreach and educational efforts.

House Report (pages 235)

Global Health Research - The Committee requests an update in the fiscal year 2023 Congressional Budget Justification on 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 the Department of Health and Human Services to prevent duplication, as well as complement and augment the work of each division. The National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), Assistant Secretary for Preparedness and Response/ Biomedical Advanced Research and Development Authority (ASPR/BARDA), Office of Global Affairs (OGA), and the Food and Drug Administration (FDA) work in areas of mutual interest and coordinate to assure the broadest returns for public health. The activities of these divisions align with <u>HHS Global Health Objectives</u> to create critical scientific data that underpin public health decisions, enhance surveillance, prevent health threats, prepare for emergencies, strengthen international standards, catalyze research, strengthen health systems, and address changing disease patterns.

NIH supports and conducts groundbreaking biomedical and behavioral fundamental and applied research that aligns with the mission of its 27 Institutes and Centers and is designed to improve health in the United States and globally. The NIH research portfolio includes studies of the causes, diagnosis, prevention, and cure of human diseases; the processes of human growth and development; the biological effects of environmental contaminants; the understanding of mental, addictive and physical disorders; as well as directing programs for the collection, dissemination, and exchange of information in medicine and health. International collaborations are a key component of NIH funded projects. Many NIH Institutes and Centers have strategic programs in global health. The Fogarty International Center (FIC) is the only component at NIH whose mission is focused exclusively on global health. The FIC is also dedicated to advancing and facilitating global health research at NIH. This is accomplished through collaborative funding opportunities for U.S. and international investigators, by building partnerships between health research institutions in the U.S. and abroad and training the next generation of scientists to address global health needs. FIC's Advisory Board, which includes

CDC as an ex officio member, guides its activities in global health research and coordination. CDC has been engaged in the development of new, innovative laboratory diagnostic tools, ranging from point-of-care diagnostics to advanced molecular tests for Ebola and other viral hemorrhagic fever viruses, and most recently for SARS-CoV-2. With regulatory oversight from the FDA, CDC works with its partners, NIH, ASPR/BARDA, and Department of Defense (DoD), for the approval for use process. These activities help detect infectious disease threats at an early stage to decrease their impact here in the United States. CDC is also engaged in the development and evaluation of medical countermeasures (MCMs) such as vaccines and therapeutics. These activities build on disease surveillance infrastructure and include clinical and field trials of MCMs for a broad range of pathogens including Ebola and monkeypox and screening antivirals to inform the development of new MCMs. Additionally, the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) provides global interagency coordination between CDC, FDA, ASPR/BARDA and NIH to enhance preparedness for chemical, biological, radiological and nuclear threats and emerging infectious diseases. CDC is engaged with many partners, including NIH, DoD and the State Department, in the design and development of sustainable forward-deployed laboratories to more rapidly detect and characterize potential infectious disease threats of significant concern to the United States. Working with partners to develop global capacity for genomic sequencing is critical for timely detection of viral variants, and a cornerstone for public health response to pandemics. CDC also works in collaboration with many partners including DoD, NIH, FDA and the World Health Organization on prevention and control of malaria worldwide including safety and efficacy of novel therapeutics and field trials of malaria vaccines and on global schistosomiasis elimination efforts.

FDA is responsible for domestic regulatory oversight of human and veterinary drugs; vaccines and other biological products; medical devices intended for human use; radiation-emitting electronic products; cosmetics; dietary supplements, and tobacco products. FDA works with HHS and USG counterparts on the approval for use process. FDA also supports regulatory research and other activities to promote development and increased access to safe and effective biological products and therapeutic drugs to increase preparedness for responding to emerging and re-emerging infectious diseases.

ASPR/BARDA supports the advanced research, development, regulatory approval, manufacturing and procurement of vaccines, therapeutics, diagnostics and devices to diagnose, prevent and treat the medical consequences caused by Chemical, Biological, Radiological and Nuclear (CBRN) threats, pandemic influenza and emerging infectious diseases. ASPR/BARDA funding bridges the "valley of death" – the transition of preclinical product candidates into clinically viable products that can be evaluated in human trials. ASPR/BARDA's support ensures continuity of funding for the most promising product candidates developed by industry or emerging from fundamental and applied biomedical research, and from preclinical development activities conducted and supported by the NIH. Over the past 16 years, ASPR/BARDA has supported the development of over 400 MCMs, 62 of which have been approved, licensed and/or cleared by the FDA for such CBRN threats as anthrax, Ebola, Zika, smallpox, radiologic injuries, burn injuries due to nuclear blasts, botulism, antibiotic resistant bacteria, and others.

The most vigorous cross-agency collaboration and coordination is in the area of infectious diseases, where pathogens have no geographical boundaries. ASPR/BARDA supported the development, licensure, and subsequent cGMP production of Ebola monoclonal antibodies and vaccine, including advanced development of a monoclonal antibody developed by NIH. These products are the only products licensed to prevent/treat Ebola disease, and are now utilized to support international response efforts to Ebola outbreaks. ASPR/BARDA also coordinates a broad inter-agency partnership with CDC, NIH, and FDA on 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 COVID-19, Ebola, Zika, dengue, and chikungunya. ASPR/BARDA has made significant investments over the past 16 years in new platform technologies for the accelerated discovery, research, development, and commercial scale manufacture of medical counter measures that can be rapidly deployed during a pandemic. Several of those platforms were used in the United States effort to respond to the COVID-19 pandemic, including the Janssen and Moderna vaccine platforms and the Regeneron monoclonal antibody platform. The funding and technical support associated with scaleup, large scale production, regulatory support and, in close collaboration with NIH, global Phase III clinical trials, underpinned the expansion and use of these vaccines throughout the globe. In addition,

the Foundation for the National Institutes of Health, NIH, ASPR/BARDA, CDC, FDA, DoD, and Department of Veterans Affairs; the Countermeasures Acceleration Group (formerly known as Operation Warp Speed); the European Medicines Agency; and representatives from academia, philanthropic organizations, and numerous biopharmaceutical companies formed a public private partnership "Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV)" to develop a coordinated research strategy for prioritizing and speeding development of the most promising treatments and vaccines for COVID-19.

Global engagement in research for these and associated health topics is a critical component for the successful development of effective interventions for persons in the U.S. and abroad. Global engagement is essential for increasing scientific research capacity, for impacting health outcomes, and to affect best practices in public health policies or programs. These will ultimately improve the health and wellbeing of people living in the United States and around the world.

House Report (pages 238-239)

Pain Management - As recommended in the CARA-mandated HHS Pain Management Best Practices Inter-Agency Task Force report, the Committee urges the Department to coordinate with the Department of Defense (DOD) and the VA to launch a public awareness campaign to educate Americans about the differences between acute and chronic pain and available evidence-based non-opioid treatment options. The Committee again urges the Department to widely disseminate the report's recommendations, including the importance of individualized, multidisciplinary, patient-centered care in the treatment of pain to health care providers and other public health stakeholders, and to update relevant pain management policies and educational tools to reflect Task Force recommended best practices across all relevant HHS agencies, including the CDC, CMS and SAMHSA. The Committee urges the Department to include an update on dissemination of these materials and progress on the public awareness campaign in the fiscal year 2023 Congressional Budget Justification.

Action Taken or To Be Taken

The Pain Management Best Practices Inter-Agency Task Force (PMTF) team developed dissemination materials for a wide range of stakeholder groups including providers, individuals, and researchers. While these supplemental materials were removed from their former location, the PMTF Report is currently located here along with a brief, "Fact Sheet: Pain Management Best Practices Inter-Agency Task Force Report." There has been no accompanying public awareness campaign since the PMTF sunset in July 2019, but HHS remains committed to assisting individuals living in pain.

House Report (page 240)

Social Determinants of Health Council —The Committee directs the Social Determinants Council created by H. Rpt. 116–450 to continue to provide technical assistance to State, local, and tribal jurisdictions seeking to develop Social Determinants Accelerator Plans. The Committee directs a report be submitted, no later than 30 days after enactment of this Act, regarding the status of the selection of all Council members outlined in H. Rpt. 116–450.

Action Taken or To Be Taken

HHS agrees with the Congress that addressing the Social Determinants of Health (also known as SDOH) is very important for the health and wellbeing of the nation. SDOH are the conditions where people are born, live, learn, work, play, worship, and age that affect health and wellbeing.

CDC has awarded 20 grants to accelerate actions in state, local, tribal, and territorial jurisdictions that prevent and reduce chronic diseases among people experiencing health disparities. More information regarding CDC and the SDOH Accelerator Plans is available at the following link:

https://www.cdc.gov/chronicdisease/programs-impact/sdoh/accelerator-plans.htm

HHS is taking a strategic approach to addressing SDOH to advance health and wellbeing over the life course. HHS is developing an action plan that will use all of the programmatic authorities of the Department. HHS is working to improve the ability to collect and use better data on social determinants; integrating social and human services in HHS programs and working with other Departments to develop a whole-of-government, multi-sector strategy.

HHS has a long-standing engagement working across the government with the U.S. Interagency Council on Homelessness that is developing a homelessness prevention strategy that will be part of the Federal Strategic Plan to Prevent and End Homelessness. In addition, we are working on a number of initiatives to coordinate HHS programs regarding safe and affordable housing with HUD, food and nutrition services with USDA, and accessible transportation with DOT.

House Report (pages 243)

Tribal Set-Aside - The Committee notes that according to the CDC, HIV-positive status among Native Americans is increasing and nearly one-in-five HIV-positive Native Americans is unaware of their status. In addition, only three-in-five receive care and less than half are virally suppressed. To increase access to HIV/AIDS testing, prevention, and treatment, the Committee includes \$3,000,000 as a tribal set-aside within the Minority HIV/AIDS Prevention and Treatment program.

Action Taken or To Be Taken

The OASH has awarded Tribal Set-Aside funds within the Minority HIV/AIDS Prevention Treatment program to the Indian Health Service (IHS) to conduct national-level strategy planning to End the HIV Epidemic in Indian Country (Indigenized HIV/AIDS Strategy (Indigi-HAS) by using an environmental scan and community-based assessment framework, working across all Indian Health Service Areas and including Urban Indian Organizations.

To date, the Strategy's development has included or will include IHS facilitation of key informant interviews among relevant Tribal government, clinical (I/T/U), and public health stakeholders and the development implementation, and analysis of formative research (e.g., interviews, focus groups, KAP survey) to identify barriers and opportunities for biomedical interventions among 1) Tribal healthcare workers (e.g., physicians, pharmacists, community health representatives) and 2) Tribal community members.

Looking ahead, the Indigenized HIV/AIDS Strategy (Indigi-HAS) goals include: building collaborative partnerships with tribes, tribal organizations, state, federal, universities, and other organizations to communicate and promote Indigi-HAS to reduce new HIV diagnoses by 90%; enhancing capacity and build infrastructure for HIV/HCV/STI prevention and clinical activities through partnerships; and dissemination and implementation of Indigi-HAS in Native communities.

House Report (page 244)

Vaccine and Testing Equity Study - The Committee recognizes that Hispanic and immigrant communities face unique barriers regarding COVID–19 vaccination and testing, including a lack of reliable information in their languages, misinformation, and fear of deportations. The Committee requests a study by the Advisory Committee on Minority Health, within 120 days of enactment of this Act, on further steps and recommendations that can help HHS address vaccine and testing equity in Hispanic and immigrant communities during the COVID–19 pandemic.

Action Taken or To Be Taken

While OIDP does not lead or manage the Advisory Committee on Minority Health, OIDP published the *National Vaccine Strategic Plan 2021-2025* in January 2021 that outlines a vaccine strategy that is national in scope and addresses barriers to vaccination access. OIDP will also release the *Vaccine Federal Implementation Plan 2021-2025* in spring 2022 that will outline federal partners' commitments to policies, research, and activities in the Strategic Plan.

The strategies to increase vaccination access for Hispanic and immigrant communities are complex and depend on the interaction of a host of social determinants of health. Focusing on the specific needs of these sub-populations will ensure tailored appropriate outreach efforts. In addition, this study may uncover policy approaches to address fear of deportation and mistrust of government.

House Report (pages 244)

Viral Hepatitis National Strategic Plan - The Committee urges the Department to implement the strategies laid out in this plan to reverse the rates of viral hepatitis, prevent new infections, improve care and treatment, and ultimately eliminate viral hepatitis as a public health threat.

Action Taken or To Be Taken

The Viral Hepatitis Federal Implementation Plan 2021-2025 will be released in April 2022. This Federal Implementation Plan outlines federal partners' commitments to policies, research, and activities during the fiscal years 2021–2025 to meet the National Strategic Plan's goals, pursuant to their respective missions, funding, and resources. OIDP convenes and leads the Viral Hepatitis Implementation Working Group (VHIWG), with more than 20 federal agencies and offices, including HHS, HUD, DOJ, and the VA. Through the VHIWG, OIDP will monitor and report on federal progress implementing the Viral Hepatitis National Strategic Plan. This group also serves as a vehicle for coordinating and leveraging viral hepatitis initiatives across the federal government.

House Report (pages 245)

National Strategy for Herpes Simplex Virus (HSV), Types 1 and 2—The Committee recognizes that an estimated 1 in 3 Americans has Herpes, and that most Americans with HSV do not have symptoms and do not realize they have it. In light of the national prioritization of ending the HIV/AIDS epidemic, maternal health, neonatal health, and the all-time high of STIs, the Committee urges the Assistant Secretary for Health to develop a national strategy and strategic plan for the treatment and prevention of HSV types 1 and 2.

Action Taken or To Be Taken

In preparation for the development of a national strategy and strategic plan for Herpes Simplex Virus (HSV), Types 1 and 2, the Office of Infectious Disease and HIV/AIDS Policy (OIDP) has or will convene a series of preliminary information-gathering meetings with federal and non-federal stakeholders including, the Centers for Disease Control and Prevention, the National Institutes of Health, the National Coalition of STD Directors, and Herpes Cure Advocacy. In addition, OIDP has begun the development of an on-line instrument to conduct an inventory of all federal programming for HSV. Both the informational meetings and inventory are necessary first steps to inform next steps.

House Report (pages 245)

Public Health Service Corps Eligibility Requirements - The Committee is concerned that the Office of the Surgeon General has not complied with language in the Joint Explanatory Statement for P.L. 116–260 which encouraged the Secretary to update accreditation and eligibility requirements for the Public Health Service Corps to allow access to the best qualified applicants, including those who graduate from Psychological Clinical Science Accreditation System programs. The Committee urges the Department to make the necessary changes to its eligibility requirements.

Action Taken or To Be Taken

The Corps updated its eligibility requirements in its policy in December 2020. The Category Specific Appointment Standards were modified to include those who graduate from Psychological Clinical Science Accreditation System programs. This positively impacts both the Regular and Reserve Corps applicants.

House Report (pages 245-246)

Teen Pregnancy Prevention - The Committee strongly supports the Teen Pregnancy Prevention (TPP) Program and provides \$130,000,000, an increase of \$29,000,000 over the enacted level. The TPP Program has been widely cited as a high-quality evidence-based program, including by the bipartisan Commission on Evidence-Based Policymaking

Action Taken or To Be Taken

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.

TPP grantees aim to have a significant impact on improving the health of adolescents and reducing teen pregnancy and sexually transmitted infections by saturating communities with the greatest need with 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 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.

Since the TPP program was established in 2010, over 1.5 million young people have received evidencebased TPP programs; over 24,000 staff have been trained; and over 20,000 community partnerships have been established. TPP demonstration grants have led to the development of 15 new evidencebased interventions and grantees are currently supporting the development and evaluation of over 100 new interventions.

OPA's current TPP grantees are scheduled to end in June 2023. In FY2023, OPA plans to conduct a new national grant competition, which will result in numerous new grants across the country in communities and populations most in need of support to advance health equity as well as resources for development and testing of new and innovative approaches to preventing teen pregnancy and advancing positive youth development. With an increase in funding, OPA will be able to fund a larger number of grantees to reach even more young people and develop additional interventions.

House Report (pages 246)

Center for Indigenous Innovation and Health Equity - The Committee includes \$3,000,000, an increase of \$1,000,000 to support the work of the Center for Indigenous Innovation and Health Equity. The Committee continues to urge HHS to consider partnering with universities with a focus on Indigenous health research and policy among Native Americans and Alaska Natives, as well as universities with a focus on Indigenous health policy and innovation among Native Hawaiians/Pacific Islanders

Action Taken or To Be Taken

In FY 21, the Office of Minority Health established a grant with a 2-year project period for the Center for Indigenous Innovation and Health Equity (Center). The Center supports efforts including education, service and policy development, and research related to advancing sustainable solutions to address health disparities and advance health equity among American Indian and Alaska Native (AI/AN) and Native Hawaiian and Pacific Islander (NHPI) populations.

Two organizations received FY 21 awards: (1) Oklahoma State University Center for Health Sciences, a university with a focus on Indigenous health research and policy among AI/AN populations; (2) University of Hawaii, a university with a focus on Indigenous health policy and innovation among NHPI populations. For FY 23, HHS is planning continued support for the Center, pending the availability of Congressional appropriations.

House Report (pages 247)

Combating Violence Against Women - The Committee includes \$10,000,000 to combat violence against women through the State partnership initiative and directs the OWH to work in conjunction with the Family Violence Prevention and Services Program office. This program provides funding to State-level public and private health programs to partner with domestic and sexual violence organizations to improve health care providers ability to help victims of violence and improve prevention programs. In addition, the Committee continues to recommend OWH create a State-level pilot program to incentivize substance use disorder treatment providers to be trained on intimate partner violence.

Action Taken or To Be Taken

The OASH Office on Women's Health (OWH) is developing a grant initiative in collaboration with the Family Violence Prevention and Services Program within the HHS Administration for Children and Families (ACF) to implement a state-level pilot program to incentivize substance use disorder treatment providers to be trained on intimate partner violence during pregnancy and the postpartum period. As part of this initiative, OWH plans to foster state and local partnerships with domestic/sexual violence organizations to address the intersection of intimate partner violence and substance use during pregnancy and postpartum time periods. Quality assessment strategies will be established to determine essential programmatic components for successful outcomes, as well as core outcome variables for use across state and local data collection systems.

House Report (pages 257)

Readiness and Training Programs – The Committee requests an assessment of HHS deployable personnel, including but not limited to Public Health Service Commission Corps Officers and National Disaster Medical System intermittent personnel. The assessment should include the coordination of established forces and identification of remaining gaps. The report is to be submitted with the fiscal year 2023 Congressional Budget Justification.

Action Taken or To Be Taken

This is noted. Office of the Surgeon General will collaborate with Assistant Secretary for Preparedness and Response to execute the forementioned HHS deployment assessment to reinforce joint interest for the success of the Commissioned Corps and the Department.

House Report (pages 238)

National Health Care Workforce Commission - The Committee includes \$3,000,000 to establish the National Health Care Workforce Commission, as authorized by the Affordable Care Act. The Commission is intended to serve as a resource on health care workforce policy for Congress, the Administration, States, and localities and is tasked with evaluating health care workforce needs, assessing education and training activities, identifying barriers to improved coordination at the Federal, State, and local levels and recommending changes to address those barriers.

Action Taken or To Be Taken

The FY 2022 Annualized CR did not include funding in the GDM or the HRSA appropriation.

House Report (pages 243)

U.S.-Mexico Border Health Commission – The Committee includes \$2,000,000 for the Commission, an increase of \$900,000. Further, the Committee urges the Secretary to build upon the framework established by Healthy Border 2020 for border region public health goals and the actions needed to improve the health of U.S. and Mexico border residents, and to commence work on Healthy Border 2030 as part of the Department's Healthy People 2030 initiative with a focus on addressing health disparities and to help border communities become more resilient to public health threats.

Action Taken or To Be Taken

Healthy Border is separate and independent from Healthy People. The Border Health Commission is working on a proposal for the development of Healthy Border 2030.

House Report (pages 243)

U.S.-Mexico Border Health Commission Vaccine Deployment Strategy – The Committee encourages the U.S. section of the U.S.-Mexico Border Health Commission to engage with their Mexican counterparts to develop a COVID–19 vaccine deployment strategy for communities on both sides of the border.

Action Taken or To Be Taken

Ending the COVID-19 pandemic is a top priority for this Administration, both domestically and globally, because no country is safe until we are all safe. The federal government has taken firm action to support Mexico's access to COVID-19 vaccines, including by deploying nearly 14 million doses to Mexico so far with additional shipments planned. U.S. local jurisdictions may distribute vaccines to domestic providers serving border communities, if the group administering the vaccine is an approved COVID-19 provider and abides by the provider agreement.

U.S. states, all tribes, and non-federal third parties are not authorized to distribute any vaccine out of the country. Providing international assistance with vaccines authorized for use in the U.S. requires balancing a series of complex legal, regulatory, and logistical issues related to international export and use, which include careful planning and implementation by the U.S. federal government. On the Mexican side, vaccine deployment, distribution and dispensing is managed only by the federal government making it impossible at this time to create distribution strategies at the local level.

Further, the U.S.-Mexico Border Health Commission Act, 22 U.S.C. 290n et seq., does not appear to authorize the U.S.-Mexico Border Health Commission, or the U.S. Section to conduct this type of activity. However, the U.S. – Mexico Border Health Commission is well positioned and able to bring together stakeholders to determine levels of vaccine acceptance in border communities compared with the rest of the population of both countries, observed lessons learned and propose course of actions to increase acceptance as needed.

Lung Cancer in Women - NCI - The agreement requests an update on the status of research on women and lung cancer and the disparate impact of lung cancer in women who have never smoked in the fiscal year 2023 Congressional Justification.

Update

Overall lung cancer incidence and mortality rates continue to decrease in the United States, but important gender and race differences persist. For example, Black women have comparable lung cancer incidence and mortality rates to white women, despite lower smoking rates. For nonsmokers, research has shown that approximately 20 percent of women who develop lung cancer have never smoked compared with about 9 percent of nonsmoking men. The reasons for these disparities are not well understood. The National Cancer Institute (NCI) supports research to understand and eliminate cancer disparities, to increase our understanding of sex differences in cancer, and to advance cancer prevention, detection, and treatment for women.

In 2019, NCI launched the Sherlock-lung study, a comprehensive study that aims to trace lung cancer etiology in never smokers by analyzing genomic data in tumor and surrounding lung tissue.²¹ This molecular characterization will identify exogenous and endogenous processes involved in lung tumorigenesis. The molecular landscape will be integrated with histological and radiological features to develop a more refined understanding of lung cancer in never smokers and provide insights into prognosis and treatment strategies. The study will collect data from approximately 2,500 never smokers. The first results from Sherlock were published in September of 2021 and showed that a majority of the lung tumors analyzed from never smokers arise from the accumulation of mutations caused by natural processes in the body (endogenous).²²

Importantly, the study identified three novel molecular subtypes of lung cancer in people who never smoked. These subtypes were identified from 232 patient samples, 75 percent of whom were women. The study also identified mutations that independently had negative effects on survival, providing information that could lead to personized treatments in the future.

Ongoing NCI-supported research is investigating the role of female hormones in the development of lung cancer. An estrogen metabolite (4-hydroxyestrogen, 4-OHE) is a known carcinogen and was found to exist in higher quantities in lung tumors compared to normal tissue in small cell lung cancer patients. An NCI- funded project is using cell lines and mouse models to determine potential mechanisms for 4-OHE to lead to lung cancer, which could help to identify possible therapeutic inhibitors to prevent lung cancer development for female never-smokers.²³ Another project is studying the effects of estrogen signaling and related inflammation on the development of lung cancer with the goal of developing targeted treatment and prevention options depending on sex and other unique biomarkers.²⁴ A project that recently concluded studied the association between exposure to a type of estrogen (phytoestrogen) and lung cancer risk in women who had never smoked. In this case-control study with long term follow up of approximately 15 years, the researchers found that moderately increasing intake of foods that contain phytoestrogen (foods with soy) had an association with lower lung cancer risk in women who have never smoked.²⁵

²¹ <u>dceg.cancer.gov/research/cancer-types/lung/sherlock-lung-study</u>

²² pubmed.ncbi.nlm.nih.gov/34493867/

²³ reporter.nih.gov/search/IWt72di6wUGBSocZrHU53A/project-details/10338105

²⁴ reporter.nih.gov/search/dG20M9F3IUiAhnAsz8Iykg/project-details/10114231

²⁵ pubmed.ncbi.nlm.nih.gov/34673927/

Eighty percent of lung cancers among women can be attributed to smoking. Along with research in this area, NCI has ongoing efforts to reduce the uptake and use of tobacco. These efforts remain paramount to lung cancer prevention in females. NCI continues to support Smokefree Women, part of the larger Smokefree.gov website,²⁶ 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.

Key NCI-supported programs such as the Specialized Programs of Research Excellence (SPOREs) and the Cancer Intervention and Surveillance Modeling Network (CISNET) focus on lung cancer. There are currently four lung cancer SPORE Programs and three cancer disparities SPORE pilots that include lung cancer as one of the pilot projects.²⁷ CISNET conducts research on the impact of tobacco control policies and screening in lung cancer with a focus on disparities.²⁸ A recently awarded CISNET lung cancer disparities supplement seeks to: use an existing CISNET lung cancer model to study lung cancer incidence and mortality in the non-Hispanic Black (NHB) population; determine the contributions of various factors along the cancer control continuum to disparities in lung cancer mortality in the NHB population relative to the whole population; and evaluate the potential impact of screening and other interventions to reduce lung cancer burden and existing disparities in the NHB population.

NCI continues to support a portfolio of research into ways to increase cancer screenings. A newly funded project is specifically focused on multilevel interventions to increase adherence to lung cancer screening.²⁹ Additionally, results from CISNET and the NCI-supported National Lung Screening Trial (NLST) along with other randomized clinical trials and cohort studies lead to the 2021 U.S. Preventive Services Task Force recommendation that lowered the age of starting annual screening exams for lung cancer from 55 to 50 years of age. This will double the number of people eligible for annual computerized tomography (CT) scans to screen for lung cancer and is expected to lead to higher screening rates among women and Black patients, who are at higher risk of lung cancer.

 ²⁶ <u>smokefree.gov</u>
 ²⁷ <u>trp.cancer.gov/spores/lung.htm</u>

²⁸ cisnet.cancer.gov/lung/

²⁹ reporter.nih.gov/search/EmHMXPNGO0i8Ndp8p3DdeA/project-details/10274176

Legislative Proposals

DISCRETIONARY LEGISLATIVE PROPOSALS

Expand the "Recall to Active Duty" Authority to Allow the Secretary to Recall Retired Public Health Service Officers Involuntarily

This proposal would grant the Secretary of HHS the authority to recall certain retired PHS officers involuntarily to active duty (e.g., those who have unique skills sets that would be required during emergencies or those requiring discipline after being convicted of criminal offenses that occurred while on active duty). Currently retired PHS officers cannot be recalled involuntarily (except when the USPHS Commissioned Corps has been militarized). Consequently, the USPHS Commissioned Corps has no mechanism to recall an officer who posesses subject matter expertise critical to supporting expanding demands to rapidly respond to new challenges. Additionally, the USPHS Commissioned Corps has no statutory mechanism to discipline or take administrative actions against a retired officer who allegedly engaged in misconduct, even if the officer's actions took place while on active duty, let alone after the officer retired. In the military services, such a circumstance could result in the retired officer losing "creditable service" towards retirement. However, retired PHS officers who are convicted of criminal acts currently continue to receive all retirement benefits.

Deeming Training in Emergency Response as a Federal Activity

This proposal would include training for urgent or emergency public health care needs as an authorized activity of a Federal entity to which a PHS officer is detailed or assigned, for purposes of pay, allowances, and benefits. Section 203A of the PHS Act, 42 U.S.C. § 204a, establishes the requirements to ensure the readiness of the USPHS Commissioned Corps to respond to urgent or emergency public health care needs that cannot otherwise be met at the Federal, State, or local levels, and to organize and manage the USPHS Commissioned Corps for deployment. 42 U.S.C. § 204a(c) authorizes that, for purposes of pay, allowances, and benefits, deployment of PHS officers in response to urgent or emergency public health care needs is deemed an authorized activity of the Federal entity to which the officer is detailed or assigned. However, this language does not include training an officer to prepare him/her for such deployments.

Authorize Permissive Constructive Service Credit for Select Candidates

This proposal would change the existing "constructive credit" for new appointees to the Commissioned Corps – crediting them with prior service even if they have not had such service – from mandatory to discretionary. Under current provisions, the USPHS Commissioned Corps must credit candidates for appointment to the Regular Corps, who have no prior uniformed service experience, with extra years of service when calculating pay and benefits as if they had prior uniformed service experience, the constructive credit. This proposal would grant the USPHS Commissioned Corps the flexibility to recruit candidates for higher ranks and increase the salary of new officers based on the needs of the Department, which is currently not an option

<u>Clarify the Surgeon General's Authority to Call the Ready Reserve to Active Duty for Training</u> <u>Voluntarily and Involuntarily</u>

Section 203 of the PHS Act, 42 U.S.C. § 204(c)(2) authorizes the Surgeon General (SG) to mobilize the Ready Reserve Corps. The authority of subsection (A) allows for reservists to be called to active duty for training but does not specifically allow for calls to involuntary service except for during emergencies. This proposal addresses this oversight by authorizing the Surgeon General to order a PHS officer to active duty for training voluntarily and involuntarily.

Authority to Detail PHS Personnel Directly to Certain State, Local, or Nonprofit Health or Mental Health Entities

This proposal would expand the authority of the Surgeon General (SG) to detail PHS officers directly to local health and mental health authorities and to nonprofit health or mental health agencies to provide additional services, including patient care to underserved communities. This proposal would also expand the current purpose of details to include the direct provision of health care services.

Align the USPHS Commissioned Corps' Ready Reserve Corps' Dual Compensation and Leave Rights with those of the Armed Forces

The proposal will allow members of the USPHS Commissioned Corps' Ready Reserve Corps to obtain or retain a federal civil service job and receive dual government pay from their federal job and from their Reserve service. It also allows federal employees who are members of the USPHS Commissioned Corps' Ready Reserve Corps to take leave from their federal jobs for Reserve service or training.

<u>Align the Leave Authorities for the USPHS Commissioned Corps with Those of All Other Uniformed</u> <u>Services</u>

The proposal will expand the types of leave the USPHS Commission Corps can provide its officers to align with those of the other uniformed services (e.g., primary caregiver leave, secondary caregiver leave, and convalescent maternity leave) and allow for expanded carryover of leave (beyond the existing 60 days) at the Secretary's discretion by extending the provisions of title 10, chapter 40 of the U.S. Code (U.S.C.) to Public Health Service (PHS) officers.

MANDATORY LEGISLATIVE PROPOSAL PREP DELIVERY PROGRAM TO END THE HIV EPIDEMIC IN THE UNITED STATES

Budget Summary

(Dollars in Millions)

	FY 2023 President's Budget
Mandatory Proposal – PrEP Delivery Program to End the HIV Epidemic in the United States	\$237
Allocation Method	Direct federal

Program Description and Accomplishments

The FY 2023 President's budget includes a new mandatory Pre-Exposure Prophylaxis Delivery Program to End the HIV Epidemic in the United States ("PrEP Delivery Program"). The PrEP Delivery Program is designed to expand access to PrEP and essential wraparound services for uninsured and underinsured individuals at high risk of HIV infections across the United States. This national program would create a financing and delivery system for PrEP. Currently, there is a patchwork of PrEP access programs for uninsured individuals; this comprehensive new program is a key pillar of the Administration's efforts to meet the commitments laid out in the National HIV/AIDS Strategy for the United States 2022-2025 to reduce HIV infections by 75% by 2025.

PrEP medications, which are typically taken daily, can dramatically reduce the risk of getting HIV from sex or injection drug use. Prior to starting PrEP, individuals are tested for HIV, Hepatitis B and C, other sexually transmitted infections, and kidney function. Screening for these infections and conditions continues while a person is on PrEP. In addition, PrEP is most effective when coupled with proactive adherence support and regular counseling. Connecting individuals to the supportive services that make it possible for them to receive medication and counseling is critical.

FDA approved the first PrEP medication in 2012. The growing availability of PrEP has contributed to an overall decline¹ in new HIV infections yet, there remain significant barriers to prevention, including stigma, medical mistrust, cost and access barriers, and issues associated with social determinants of health (SDOH).² As a result, fewer than 1 in 4 people who could benefit from PrEP are receiving the medication.

There are also significant disparities in PrEP coverage based on race/ethnicity, gender identity and sexual orientation, age, and geographic location. Black and Hispanic/Latino people account for the majority of people for whom PrEP is recommended, but they have the lowest rates of PrEP use among all racial/ethnic groups. Preliminary CDC data show only 9 percent (42,372) of the nearly 469,000 Black people in the United States who could benefit from PrEP received a prescription in 2020 and only 16

¹ Source: <u>https://www.whitehouse.gov/wp-content/uploads/2021/11/National-HIV-AIDS-Strategy.pdf</u> ² Source:

https://www.cdc.gov/socialdeterminants/about.html#:~:text=Social%20determinants%20of%20health%20(SDOH) %20are%20conditions%20in%20the%20places.of%20health%20risks%20and%20outcomes.&text=The%20connecti on%20between%20people's%20access,services%20and%20their%20own%20health.

percent (48, 838) of the nearly 313,000 Hispanic and Latino people who could benefit from PrEP received a prescription.³

These disparities are the result of inequities across the SDOH. SDOH not only affect an individual's likelihood of acquiring an infectious disease, such as HIV, but they further exacerbate inequities in access to preventive measures. For instance, most health insurance plans must cover both PrEP and the full range of laboratory and counseling services that are part of PrEP care without any copay or cost-sharing. However, Black Americans are more likely⁴ to be uninsured than the rest of the population, as are individuals in the LGBTQI+ community⁵. Disparities across other SDOH create further barriers to treatment and care; for example, differences in access to transportation⁶ may be a barrier, given the need for ongoing lab testing as part of PrEP-based care.

The PrEP Delivery Program is designed to advance equitable access to HIV prevention by addressing many of these systemic barriers; the program will guarantee access to PrEP at no cost; eliminate costs for essential associated services; and establish a network of providers in underserved communities that provide culturally and linguistically appropriate services.

The PrEP Delivery Program will create an efficient, systematic approach to drug acquisition and distribution and also provide the critical wrap-around services that make it possible for individuals to successfully participate in the ongoing intervention. The Department will purchase PrEP medications in bulk directly from manufacturers, leveraging its large purchasing power to obtain the lowest possible price, creating a long-term, sustainable model for purchasing medication. Most of the purchased medications can be generic versions of PrEP, which have been available for the last year. The Department will purchase medication from multiple generic companies to reduce potential supply disruptions.

The PrEP Delivery Program will expand PrEP access at clinical settings through on-site dispensing and lab services for those without health care coverage.

Additionally, the PrEP Delivery Program will establish and support PrEP programs for state, tribal, and local public health departments, community-based organizations (CBOs), and health care facilities that serve the highest risk populations, such as the CDC's health department and CBO grantees, tribal-servicing organizations, STI clinics, community health centers, Title X clinics, opioid treatment programs, mobile prevention units, homeless shelters, and domestic violence shelters. These organizations will administer the program for clients and work to implement PrEP education campaigns, medication support services, and provide outreach and education to increase utilization of PEP and PrEP among individuals at risk of HIV infection.

The network of providers, including community-based providers, will help serve as trusted messengers to engage individuals to initiate PrEP; connect individuals with navigators, community health workers and others to support them in accessing ongoing lab services and maintaining their drug regimen; and provide connections and referrals to social services necessary to facilitate participants' well-being.

³ Source: <u>https://www.cdc.gov/nchhstp/newsroom/fact-sheets/hiv/PrEP-for-hiv-prevention-in-the-US-factsheet.html</u>

⁴ Source: <u>https://aspe.hhs.gov/sites/default/files/private/pdf/265286/Uninsured-Population-Issue-Brief.pdf</u>

⁵ Source: <u>https://aspe.hhs.gov/sites/default/files/2021-07/lgbt-health-ib.pdf</u>

⁶ Source: <u>https://health.gov/healthypeople/objectives-and-data/social-determinants-health/literature-summaries/access-health-services</u>

Some of these providers will have co-located prescribers and laboratories, but in other cases the organization's staff will connect individuals with telehealth providers who can then screen patients, prescribe PrEP, and help the patient with necessary lab services. This work will build on lessons learned from the COVID-19 response with a focus on building public confidence in HIV prevention and treatment interventions.

All PrEP Delivery Program participating organizations and providers – including telehealth providers – must agree to accept the program's payments for these services as payment in full and would meet Department-issued standard for participation, including integrity and oversight requirements.

PrEP Delivery Program participating organizations will also be responsible for providing or linking patients to the following services:

- Treatment for those who test positive for HIV or other infectious diseases during either the initial testing or monitoring. Treatment will be paid for by Medicaid or the Ryan White HIV/AIDS program, depending on the patient's insurance status.
- Medication adherence and patient support to educate patients about their PrEP medications, maintain care, help with establishing dosing routines that fit within their work and social schedules; provide reminder systems and tools.
- Medical and non-medical case management, including linking patients to behavioral health providers and assisting eligible patients to enroll in other public and private health and social services.

The PrEP Delivery Program providers and other community-based organizations will screen patients for eligibility, consistent with the eligibility determinations made by community-based HIV prevention programs.

Budget Request

The FY 2023 President's budget request for the PrEP Delivery Program to End the HIV Epidemic in the United States mandatory proposal is \$237,000,000 in FY 2023, with funding increasing in subsequent years resulting in a ten-year program cost of \$9,835,000,000.

MANDATORY LEGISLATIVE PROPOSAL MENTAL HEALTH TRANFORMATION FUND

Budget Summary

(Dollars in Millions)

	FY 2023
Mandatory Proposal – Mental Health Transformation Fund	\$750
Allocation MethodDi	rect federal

Program Description and Accomplishments

The FY 2023 budget includes \$7.5 billion for a Mental Health Transformation Fund in the Office of the Secretary to invest in workforce and delivery. The current behavioral health care system is siloed and vastly under resourced, with significant gaps in access as well in the types of services and supports available to millions of Americans. The current behavioral health system relies on various federal, state, and private funding streams, each with distinct limits in the types of behavioral health services they can offer and without alignment across programs. The current piecemeal funding approach and lack of alignment across programs is confusing, restricts access to services, and limits the reach and potential effectiveness of treatment and the integration of services across settings, making true behavioral health transformation difficult for those providing services on the ground.

The goal of the Mental Health Transformation Fund is to address these gaps, as well as fundamentally re-think and re-design the delivery of behavioral health services. The fund will extend resources to projects and programs where traditional funding does not reach and remove barriers in alignment across systems. The vision of the fund is to allow for the piloting of innovative approaches that bring together all HHS agencies and programs, working across government to build system capacity, integrate settings of care, and connect more, and especially vulnerable, Americans to quality mental health services and supports, where and when they need them. Specifically, the Mental Health Transformation Fund will, through coordination of policy and resources across HHS agencies, fund large-scale projects that improve access to services across the prevention to recovery continuum, promote resilience, and integrate and fund social needs as an essential component to care.

The Fund will be operated with representation and leadership from all HHS agencies to create a unified vision of improving behavioral health care across government. HHS will require all projects funded to implement structures of accountability, fill gaps in the research and evidence base, and have strong outcome measurement and evaluation controls.

In allocating resources from the Mental Health Transformation Fund, the Secretary will prioritize investments that are sustainable, scalable, and that advance integration of behavioral health services across primary care as well as non-traditional delivery settings. The Secretary will also prioritize those investments that advance equity among underserved populations, which include Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by

persistent poverty or inequality, including individuals involved in the child welfare system, runaway and homeless youth, and individuals who have experienced family violence and trafficking. Projects funded will maximize system capacity, extend the reach of existing providers, care for people in their communities, and address behavioral health care – including the inclusion of non-medical supports -- holistically.

Budget Request

The FY 2023 President's budget request for the Mental Health Transformation Fund mandatory proposal is \$7,500,000,000 to be allocated over ten years.

Medicare Hearings and Appeals



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Office of Medicare Hearings and Appeals Office of the Chief Judge 2550 S. Clark Street, Suite 2001 Arlington, VA 22202 (703) 235-0635 Main Line (703) 308-0222 Facsimile

I am pleased to present the Office of Medicare Hearings and Appeals (OMHA's) Fiscal Year (FY) 2023 Congressional Justification. This budget request reflects OMHA's enduring 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 focused on continuous innovation in the Medicare appeals process through an accomplished and resilient adjudication workforce. This commitment continued to inspire OMHA's mission through adversity. Between FY 2010 and FY 2014, OMHA experienced an unprecedented 969 percent surge in appeals, while funding for adjudication increased by only 16 percent. The exponential growth in appeals resulted in a backlog that could not be adjudicated within the 90-day period contemplated by statute.

Congressional support through 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) and increased adjudication capacity by roughly 70 Administrative Law Judges (ALJs) and 500 adjudicatory and support staff positions.

Recent increased capacity, combined with backlog mitigation initiatives implemented in collaboration with other agencies, will enable OMHA to resolve the backlog in FY 2022 as required by the mandamus order in the November 1, 2018 Federal District Court ruling in *American Hospital Association v. Becerra*. This FY 2023 request supports OMHA's efforts to return to the 90-day statutory adjudication time frame once the backlog is resolved and positions the agency to address expected near-term increases in appeals volume.

This request also supports continued refinement of OMHA's Electronic Case Adjudication Processing Environment (ECAPE). Completed in November 2019, ECAPE automates OMHA's adjudicatory business processes, from management of documents and correspondence related to requests for hearing exhibits, to preparation, scheduling and management of hearings, and issuance of appeal decisions. ECAPE also enables OMHA to continuously improve caseload analysis and reporting capabilities 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. This budget request provides enough resources to sufficiently support these commitments in the near-term.

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 (MOD).

The DAB has utilized multiple strategies for eliminating or reducing the backlog in MOD. However, the cumulative effect of an evolving workload that is increasing in complexity makes eliminating the backlog of Medicare appeals an on-going challenge. Appeal receipts at the Council level are projected to increase in FY 2022 as a direct result of OMHA's efforts to meet the Court imposed targeted reductions in response to recent litigation involving Medicare appeals. Additionally, the adjudication of complex cases by OMHA ALJ's will likely result in an increase of complex cases at the Council level.

At the end of FY 2021, MOD had a backlog of 18,740 cases and an adjudication capacity of only 5,000 cases annually. The DAB will direct additional funding provided by the FY 2022 appropriation along with the funding increase in FY 2023 to continue to address the backlog. Specifically, additional funding in FY 2023 will allow the DAB to further its progress in hiring term appointed attorneys and judges, giving MOD the opportunity to adjudicate more incoming appeals within the statutory deadline while simultaneously increasing its efforts to reduce 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 funding received in FY 2021 and FY2022. CRD is using additional funds to hire new attorneys to work its backlog and handle incoming cases and is working to balance its staffing level with the projected increase in receipts.

The backlog at the DAB impacts many constituencies, including beneficiaries, whose appeals are prioritized; the provider supplier community which includes 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 amount in controversy of an appeal pending adjudication in MOD was \$57,032, for a total Medicare Appeals backlog value of over \$749 million. Additional funding enables DAB to increase adjudication capacity which will decrease the average wait time from when an appeal is filed, and a decision is issued.

The DAB continues to seek innovative ways to enhance its adjudicative efficiency. These efforts involve continuing to develop and deploy newly implemented IT-based solutions, including e-filing, digitization of paper claim files, expanding the MOD document generation system, and establishing case management system integration with the other levels of the appeals process via the CMS-owned Medicare Appeals 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 2022 and FY 2023, 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.

Constance B. Tobias Chair, Departmental Appeals Board

INTRODUCTION – MEDICARE HEARINGS AND APPEALS

The FY 2023 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 2023 Budget request for MHA is \$196,000,000 in discretionary funding, which is an increase of +\$4,119,000 above FY 2022 Annualized Continuing Resolution (CR). 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 2021 Final	FY 2022 Annualized	FY 2023 President's	FY 2023 +/-
	11101	CR	Budget	FY 2022
OMHA Discretionary Budget Authority	183,000	172,381	162,000	-10,381
DAB Discretionary Budget Authority	25,500	19,500	34,000	+14,500
TOTAL Medicare Hearings and Appeals /1	208,500 ¹	191,881	196,000	+4,119

1/ 2020, 2021, 2022, and 2023 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 \$162,000,000 in program level funding and 832 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 \$34,000,000 in program level funding and 193 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.

¹ The Total Medicare Hearings and Appeals FY 2021 Final funding level includes carryover from the FY 2020/21 Appropriation.

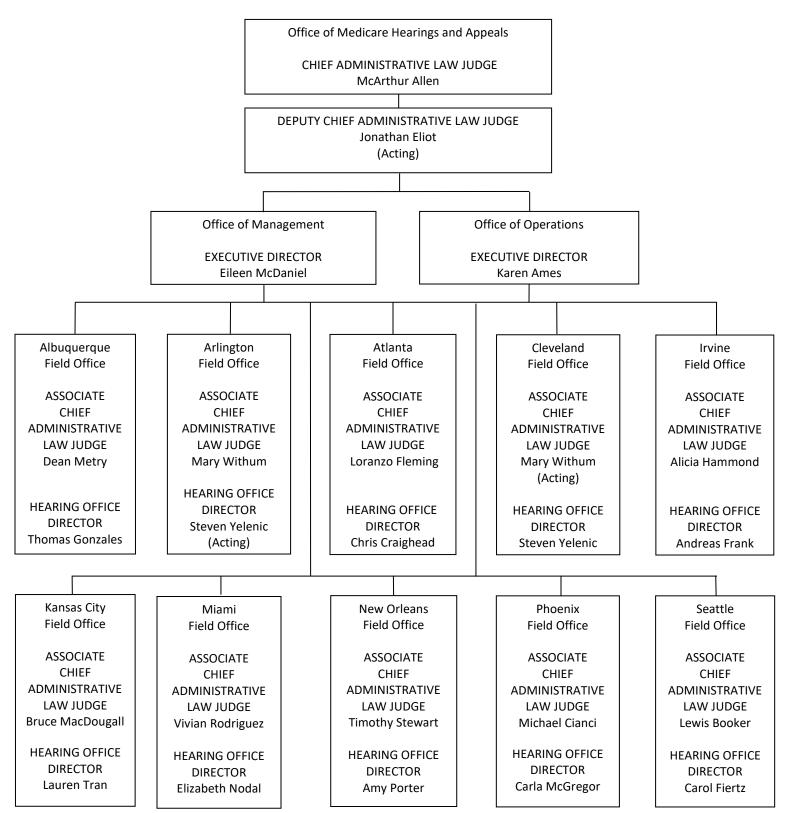
Appropriations Language

MEDICARE HEARINGS AND APPEALS

For expenses necessary for Medicare hearings and appeals in the Office of the Secretary, \$196,000,000 shall remain available until September 30, [2023] *2024*, 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 2023 appropriations language requests \$196,000,000 in discretionary budget authority for the "Medicare Hearings and Appeals" appropriation from which OMHA is allocated \$162,000,000 and DAB is allocated \$34,000,000. These allocations are subject to change.



Organizational Chart

Organizational Chart (Text Version)

Office of Medicare Hearings and Appeals

- Chief Administrative Law Judge, McArthur Allen
- Deputy Chief Administrative Law Judge, Jonathan Eliot (Acting)
- Executive Director, Office of Management, Eileen McDaniel
- Executive Director, Office of Operations, Karen Ames

The following offices report directly to the Deputy Chief Administrative Law Judge:

Albuquerque Field Office

- Associate Chief Administrative Law Judge, Dean Metry
- Hearing Office Director, Thomas Gonzales

Arlington Field Office

- Associate Chief Administrative Law Judge, Mary Withum
- Hearing Office Director, Steve Yelenic (Acting)

Atlanta Field Office

- Associate Chief Administrative Law Judge, Loranzo Fleming
- Hearing Office Director, Chris Craighead

Cleveland Field Office

- Associate Chief Administrative Law Judge, Mary Withum (Acting)
- Hearing Office Director, Steven Yelenic

Irvine Field Office

- Associate Chief Administrative Law Judge, Alicia Hammond
- 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.

<u>Vision</u>

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 2023 President's Budget request for the Office of Medicare Hearings and Appeals (OMHA) is \$162,000,000, which is -\$10,381,000 below the FY 2022 Annualized Continuing Resolution (CR) level and the FY 2022 President's Budget. At this level, OMHA will be able to sustain approximately 117 ALJ teams and 832 FTE agency wide.

Overview of Performance

OMHA remains committed to continuous improvement throughout the Medicare appeals process, and toward that end continues to pursue efforts to enhance the quality and timeliness of its services within its statutory authorities and funding levels. Through Departmental initiatives, process improvements, and targeted addition of adjudicatory and support staff, OMHA has continuously improved performance without sacrificing program integrity.

Background

As OMHA's workloads grew dramatically from FY 2010 to FY 2015, it became impossible for the agency to achieve its timeliness goals. The most significant growth occurred between FY 2010 and FY 2014 when appeal receipts grew by 969 percent, while funding levels increased by only 16 percent. Although the exponential growth in appeals slowed after FY 2014, the end result was a backlog that reached a high of 886,418 appeals at the end of FY 2015. At its peak, the backlog was 11 times greater than OMHA's annual adjudicatory capacity. The dramatic increase in appeals and lack of capacity to handle them had a detrimental impact on OMHA's mission. There were four primary factors behind 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.

Predictably, the ongoing backlog increased OMHA's average processing time. As a result, OMHA has not been able to issue decisions within the statutorily required 90 days for BIPA appeals since 2010 (excluding beneficiary appeals that are given high priority). The average processing time on closed workload rose to a high of 1,448 days in FY 2020, which decreased to 1,260 days in FY 2021 (as of September 30, 2021). Similarly, the average age of pending appeals at OMHA rose to a high of 1,525 days in FY 2019, which decreased to 788 days in FY 2021 (as of September 30, 2021). Both are still far beyond the 90-day adjudication time frame directed by BIPA, but both will fall sharply once the backlog is eliminated, and aged appeal workloads are replaced with new appeal receipts.

The backlog growth and the resulting increased processing times are the subject of a lawsuit by the American Hospital Association. Pursuant to a November 2018 ruling, the Secretary of HHS is operating under a mandamus order directing specific annual reduction targets in the appeals backlog leading to total elimination in 2022.

In response to the backlog and lengthy processing times, HHS implemented collaborative Departmental initiatives while OMHA increased its adjudicatory capacity and changed its prioritization of beneficiaries.

Departmental Initiatives

Various Departmental initiatives had immediate effects on OMHA's pending appeals backlog. Such initiatives included the Centers for Medicare & Medicaid Services (CMS) Part A Hospital Appeals Settlement Process and OMHA's Settlement Conference Facilitation (SCF) efforts with State Medicaid agencies. The largest initiatives resulted in sizable one-time reductions of OMHA's pending workload.

Unfortunately, these dramatic one-time reductions cannot be perpetuated 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 cost to the taxpayer. Second, the settlement of large numbers of appeals without consideration of the merits of underlying claims is arguably not an ideal long-term practice.

Adjudication Capacity

Backlog elimination was a multi-year effort that required not only the continued impacts of Departmental initiatives but also the full adjudicatory impact of FY 2018 and FY 2019 ALJ team expansion efforts. Over the last few years, OMHA has increased adjudicatory capacity by adding 6 new offices (in addition to the 4 legacy offices) and hiring additional personnel, reaching a high of 1,206 staff on-board in December 2019 (FY 2020).

Beneficiary Prioritization

Although adjudication delays at OMHA have impacted almost all categories of appellants, OMHA has supported its most vulnerable stakeholders by prioritizing appeals filed by beneficiaries since 2013. The average wait time to disposition for prioritized beneficiary appeals has decreased from 244 days for appeals filed in FY 2013, to 63 days for appeals filed in FY 2021 (as of September 30, 2021).

Customer Education

In addition, OMHA routinely informs and updates the appellant community on the status of OMHA's efforts, challenges related to the appeals backlog and options available to appellants. Throughout the past year, OMHA organized and participated in presentations, conferences, and meetings with appeals partners to streamline processes in support of the appellant community. OMHA also maintains a web service through which appellants can access information about their specific appeals, and shares updates with the public through announcements on our website and through listserv messages to the appellant community. A primary goal of stakeholder outreach efforts is to be as transparent as possible about the challenges faced by the appeals system and to keep appellants informed of current initiatives and evolving plans designed to address workloads at all levels of the appeals process.

Customer Surveys

OMHA also supports HHS Strategic Goal 5: Advance Strategic Management to Build Trust, Transparency, and Accountability through independent assessments that capture the scope of the OMHA appeals adjudication experience by randomly surveying selected appellants and appellant representatives. The related performance target calls for OMHA to achieve an appellant satisfaction level of 3.4 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, with 1 representing the lowest score (very dissatisfied) and 5 representing the highest score (very satisfied).

In the 2021 survey, OMHA exceeded its target of 3.4 with an overall appellant satisfaction score of 3.53. Despite the overall satisfaction level, adjudication delays have had a predictably detrimental effect on customer satisfaction scores due to non-beneficiary appellants' frustration with the amount of time it takes for cases to be assigned to an adjudicator. Non-beneficiary appellants rated this part of the process at 2.73 out of a possible 5, which significantly decreased OMHA's overall score. As a result, the overall level of appellant satisfaction still falls short of the 4.3 recorded in FY 2010, prior to the increases in processing times that resulted from a backlog of pending appeals.

Results

Thanks to OMHA's ongoing efforts toward continuous improvement, adjudication teams have doubled their productivity since 2009. These efforts, in addition to expansion efforts and initiatives implemented in collaboration with HHS partners, have helped reduce the agency's pending backlog by more than 93% – from a high of 886,418 pending appeals at the end of FY 2015 to 60,062 at the end of FY 2021 (as of September 30, 2021). Current trends suggest the backlog will indeed be eliminated in FY 2022, which will enable OMHA to return to its original, legislatively mandated priority in FY 2023 – its 90-dayprocessing timeframe.

All Purpose Table

(Dollars in Thousands)

ОМНА	FY 2021 Final	FY 2022 Annualized CR ²	FY 2023 President's Budget	FY 2023 +/- FY 2022
Office of Medicare Hearings and Appeals	183,000	172,381	162,000	-10,381
Authorizing Legislation FY 2023 Authorization Allocation Method				,

² Reflects the annualized amounts provided in the continuing resolution ending 12/3/2021 (or any further extension of a continuing resolution)

Amounts Available for Obligation

Detail	FY 2021 Final	FY 2022 CR	FY 2023 President's Budget
Trust Fund Discretionary Appropriation			
OMHA Discretionary Appropriation	172,381	172,381	162,000
Total, Discretionary Appropriation	172,381	172,381	162,000
Unobligated balance lapsing	-	-	-
Total Obligations	183,000	172,381	162,000

Summary of Changes (Dollars in thousands)

FY 2022 CR	
Total estimated budget authority	172,381
(Obligations)	172,381
FY 2023 President's Budget	
Total estimated budget authority	162,000
(Obligations)	162,000
Net Change	(10,381)

	FY 2022 Annualized CR		nualized President's		FY 2023 +/- FY 2022	
	FTE	ВА	FTE	BA	FTE	BA
Full-time permanent	958	96,133	832	82,237	(126)	(13,896)
Other personnel compensation	-	1,630	-	1,596	-	(34)
Civilian personnel benefits	-	35,685	-	30,187	-	(5,498)
Travel and transportation of persons	-	385	-	385	-	-
Transportation of things	-	127	-	127	-	-
Rental Payments to GSA	-	8,931	-	8,428	-	(503)
Communications, utilities, and misc. charges	-	7,338	-	13,878	-	6,540
Printing and reproduction	-	659	-	787	-	128
Advisory and assistance services	-	-	-	2,213	-	2,213
Other services from non-Federal sources	-	9,912	-	6,570	-	(3,342)
Other goods and services from Federal sources	-	9,744	-	13,315	-	3,571
Operation and maintenance of facilities	-	1,021	-	1,021	-	-
Medical Care	-	-	-	22	-	22
Operation and maintenance of equipment	-	19	-	451	-	432
Supplies and materials	-	656	-	631	-	(25)
Equipment	-	107	-	119	-	12
Land and Structures	-	19	-	18	-	(1)
All Other Insurance Claims and Indemnities	-	15	-	15	-	-
Total	958	172,381	832	162,000	-126	(10,381)
Net Change	-	-	-	-	-126	(10,381)

Budget Authority by Activity

(Dollars in Thousands)

Activity	FY 2021 Final	FY 2022 CR	FY 2023 President's Budget
Discretionary Budget Authority	183,000	172,381	162,000
FTE	1,117	958	832

Medicare Hearings and Appeals (MHA)

Authorizing Legislation

(Dollars in Thousands)

Medicare Hearings and Appeals	FY 2022 Amount Authorized	FY 2022 Amount Appropriated	FY 2023 Amount Authorized	FY 2023 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

Appropriations History Table

Fiscal Year	Details	Budget Estimates to Congress	House Allowance	Senate Allowance	Appropriations
2014	Trust Fund Appropriation	82,381,000	-	82,381,000	82,381,000
2014	Subtotal	82,381,000	-	82,381,000	82,381,000
2015	Trust Fund Appropriation	100,000,000	-	-	87,381,000
2015	Subtotal	100,000,000	-	-	87,381,000
2016	Trust Fund Appropriation	140,000,000	-	-	107,381,000
2016	Subtotal	140,000,000	-	-	107,381,000
2017	Trust Fund Appropriation	120,000,000	107,381,000	112,381,000	107,381,000
2017	Subtotal	120,000,000	107,381,000	112,381,000	107,381,000
2019	Trust Fund Appropriation	117,177,000	112,381,000	107,381,000	182,381,000
2018	Subtotal	117,177,000	112,381,000	107,381,000	182,381,000
2010	Trust Fund Appropriation	112,381,000	172,381,000	182,381,000	182,381,000
2019	Subtotal	112,381,000	172,381,000	182,381,000	182,381,000
2020	Trust Fund Appropriation	182,381,000	182,381,000	182,381,000	191,881,000
2020	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
2021	Subtotal	196,381,000	191,881,000	191,881,000	191,881,000
2022	Trust Fund Appropriation	196,000,000	196,000,000	-	-
2022	Subtotal	196,000,000	196,000,000	-	-
2023	Trust Fund Appropriation	196,000,000	-	-	-

Narrative by Activity

Program Description and Accomplishments

OMHA opened its doors in July 2005 pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), which sought to respond to the delays in processing of Medicare appeals that existed at the Social Security Administration (SSA) by establishing an Administrative Law Judge (ALJ) hearing forum dedicated solely to the adjudication of Medicare benefit appeals. According to the Government Accountability Office (GAO), SSA ALJs took an average of 368 days to resolve appeals in 2003. While SSA had no statutory timeframe for case adjudication, the Medicare, Medicaid, and State Children's Health Insurance Program (SCHIP) Benefits Improvement and Protection Act of 2000 (BIPA) envisioned 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 ensure 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 levels that would allow OMHA to manage the volume of appeals being received and a backlog of appeals awaiting disposition developed.

OMHA serves a broad sector of the public, including Medicare service providers and suppliers, and Medicare beneficiaries who are often elderly and/or disabled. Ensuring that providers and suppliers have a forum for independent and timely resolution of their disputes over Medicare payments also contributes to the security of the Medicare system by encouraging the provider and supplier community to continue to provide services and supplies to Medicare beneficiaries. OMHA administers its program in ten field offices, including Albuquerque, New Mexico; Arlington, Virginia; Atlanta, Georgia; Cleveland, Ohio; Irvine, California; Kansas City, Missouri; Miami, Florida; New Orleans, Louisiana; Phoenix, Arizona; and Seattle, Washington.

Changes that Led to the Backlog

At the time of OMHA's establishment, 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 subsequently 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 was also affected by changes to improve program integrity. In 2008, OMHA began to receive a significant volume of appeals 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 all agency appeal receipts) with no 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.

from FY 2015 to FY 2021. OMHA received only 1,202 RAC appeals in FY 2020 and 1,287 in FY 2021. This rapid decrease is also attributable to two factors related to contract administration: First, there was a lengthy pause in the RAC program while contracts were being re-competed. Second, the level of review by contractors and the incentive structure of the new contracts required higher accuracy scores on claims reviewed and overturn rates, which required more time to complete and led to reduced output.

While RAC workloads were reaching their peak, non-RAC workloads kept pace at nearly the same level. Between FY 2013 and FY 2014, OMHA received over 425,000 non-RAC appeals as CMS contractors increased pre- and post-payment reviews. Although the exponential growth in non-RAC appeals has slowed since FY 2014, OMHA has received over 600,000 non-RAC appeals since then (FY 2015 – FY 2021).

Actions in Response to the Backlog

Collaborative efforts to address the backlog began in 2015 with the formation of an interagency workgroup. The efforts of this workgroup, combined with additional funding received in FY 2018 and subsequent years, have put OMHA on pace to eliminate the backlog in FY 2022. The additional funding was primarily directed toward opening four new field offices and hiring approximately 70 new ALJ teams and support staff. Further steps taken by OMHA, alone and in collaboration with the Departmental Medicare Appeals Workgroup, include:

- Developed the Electronic Case Adjudication Processing Environment (ECAPE) Agency-wide implementation began in December of 2018 and was completed in December of 2019.
- Revised 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
- Prioritized beneficiary appeals to ensure timely adjudication The average wait time to disposition for prioritized beneficiary appeals has decreased from 244 days for appeals filed in FY 2013, to 63 days for appeals filed in FY 2021.
- Developed the OMHA Case Policy Manual (OCPM) to standardize OMHA-wide business practices for the adjudicative process
- Required National Substantive Legal Training for new ALJs and attorneys, and yearly judicial education to increase consistency in decision-making and address program integrity issues
- Improved case assignments by assigning appellants with a large number of filings to a single ALJ, facilitating potential consolidated proceedings and more efficient adjudication. These assignments are rotated among ALJs in accordance with the Administrative Procedure Act.
- Implemented a Statistical Sampling Pilot to resolve large groups of appeals
- Implemented Settlement Conference Facilitation (SCF) as a less costly alternative to ALJ hearings

• Implemented an Attorney Adjudicator program to assist with identification and resolution of appeals that can be resolved without a hearing

Fiscal Year	Amount
FY 2019	\$182,381,000
FY 2020	\$172,381,000
FY 2021 Final	\$183,000,000
FY 2022 Annualized CR	\$172,381,000
FY 2023 President's Budget	\$162,000,000

Five Year Funding Table

FY 2023 Budget Request

The FY 2023 President's Budget request for the Office of Medicare Hearings and Appeals (OMHA) is \$162,000,000, which is -\$10,381,000 below the FY 2022 Annualized Continuing Resolution (CR) level. At this level, OMHA would sustain approximately 117 ALJ teams, 832 FTE, and an approximate annual capacity of 87,000 appeal dispositions.

FY 2023 will be a transitional year, falling between the elimination of the backlog and an expected return to pre-backlog annual appeal receipt levels. In this context, OMHA will carefully continue to reduce staffing levels to match projected receipts and remain poised to address increases in appeal receipts as a result of increased CMS program integrity efforts.

An effort to reduce the average number of attorneys per ALJ team from 2 to 1 is currently underway. Decreasing the average size of OMHA's ALJ teams will preserve more teams and keep OMHA poised to address future workload increases. This is now possible as a result of operational efficiencies gained through OMHA's new electronic case adjudication system (ECAPE). ECAPE has automated most aspects of OMHA's adjudicatory business process, especially in the areas of managing and handling documents, exhibiting case processing workflow, generating correspondence, scheduling and managing hearings, and supporting the decision process.

As staff departs, programmatic and administrative teams are reconstituted by drawing on remote assistance from personnel in other offices. OMHA has also pursued short-term and temporary means of decreasing personnel costs, including loaning employees to other agencies on a reimbursable basis.

HHS and CMS workload estimates predict current and pending program integrity efforts will increase OMHA's annual appeal receipts toward 60,000 in FY 2022 and even higher in FY 2023. In addition to increased appeal receipts from current, pending, and proposed program integrity efforts, additional appeal receipts can be expected from changes in provider behavior as average processing times return from a high of 1,448 days in FY 2020 to 90 days. Provided FY 2023 appeal receipts do not exceed 100,000, OMHA's planned adjudicatory capacity for the year will be sufficient to prevent recurrence of a backlog in the near-term. Beyond backlogged appeals and annual receipts, adjudicatory capacity per team affects OMHA's budget as well. Beginning in FY 2022, OMHA projects the average annual capacity per ALJ team will decrease from the prior average of 800 to a new average of 750. Two factors contribute to this small decrease: first, a decrease in the average number of attorneys per ALJ team will have a small but measurable effect on ALJ team productivity, and second, OMHA anticipates a higher percentage of more complex and time-consuming appeals due to CMS programmatic changes that have shifted many less complex appeals from OMHA to CMS for resolution.

Finally, this FY 2023 Budget Request positions OMHA to fully focus on compliance with the statutorily mandated 90-day adjudicatory timeframe. At this level, OMHA can focus on timeliness while strategically constricting to balance staffing with expected near-term receipt levels. Strategic constriction efforts must take care to ensure OMHA remains poised to expand as workloads rebound in subsequent years. The strongest evidence this rebound will inevitably occur is found under Objective 5.2 of the HHS FY 2022-2026 Strategic Plan, which prescribes increased program integrity and improper payment review efforts at CMS and includes multiple related entries in the Performance Goals section. A decade ago, similar efforts at CMS resulted in 474,000 appeals to OMHA in FY 2014 alone.

Outputs and Outcomes Table

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2022 Target	FY 2023 Target	FY 2023 Target +/-FY 2022 Target
1.1.4 Reduce the percentage of decisions reversed or remanded on appeals to the Medicare Appeals Council. (Outcome)	FY 2021: 0.4% Target: 1% (Target Exceeded)	1%	1%	Maintain
1.1.5 Retain average survey results from appellants reporting good customer service on a scale of 1 - 5 at the Medicare Appeals level (Outcome)	FY 2021: 3.9 Target: 3.4 (Target Exceeded)	3.4	3.4	Maintain
1.1.8 Increase the number of Benefits Improvement and Protection Act of 2000 (BIPA) cases closed within the applicable adjudication timeframe. (Outcome)	FY 2023: Result Expected Nov 3, 2023 Target: 70.0 % (Pending)	Not Defined	70.0 %	N/A

Budget Authority by Object Class

(Dollars in Thousands)

Object Class Code	Description	FY 2021 Final	FY 2022 Annualized CR	FY 2023 President's Budget	FY 2023 +/- FY 2022
11.1	Full-time permanent	106,000	96,133	82,237	(13,896)
11.5	Other personnel compensation	-	1,630	1,596	(34)
Subtotal	Personnel Compensation	106,000	97,763	83,833	(13,930)
12.1	Civilian personnel benefits	37,000	35,685	30,187	(5,498)
Total	Pay Costs	143,000	133,448	114,020	(19,428)
21.0	Travel and transportation of persons	-	385	385	-
22.0	Transportation of things	-	127	127	-
23.1	Rental payments to GSA	9,000	8,931	8,428	(503)
23.3	Communications, utilities, and misc. charges	8,000	7,338	13,878	6,540
24.0	Printing and reproduction	1,000	659	787	128
25.1	Advisory and assistance services	-	-	2,213	2,213
25.2	Other services from non-Federal sources	10,000	9,912	6,570	(3,342)
25.3	Other goods and services from Federal sources	9,000	9,744	13,315	3,571
25.4	Operation and maintenance of facilities	1,000	1,021	1,021	-
25.6	Medical care	-	-	22	22
25.7	Operation and maintenance of equipment	2,000	19	451	432
26.0	Supplies and materials	-	656	631	(25)
31.0	Equipment	-	107	119	12
32.0	Land and Structures	-	19	18	(1)
42.0	Insurance claims and indemnities	-	15	15	-
Total	Non-Pay Costs	40,000	38,933	47,980	9,047
Total	Budget Authority by Object Class	183,000	172,381	162,000	(10,381)

Salaries and Expenses

(Dollars in Thousands)

Object Class Code	Description	FY 2021 Final	FY 2022 CR	FY 2023 President's Budget	FY 2023 +/- FY 2022
11.1	Full-time permanent	106,000	96,133	82,237	(13,896)
11.5	Other personnel compensation	-	1,630	1,596	(34)
Subtotal	Personnel Compensation	106,000	97,763	83,833	(13,930)
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25.3	Other goods and services from Federal sources	9,000	9,744	13,315	3,571
25.4	Operation and maintenance of facilities	1,000	1,021	1,021	-
25.6	Medical care	-	-	22	22
25.7	Operation and maintenance of equipment	2,000	19	451	432
Subtotal	Other Contractual Services	31,000	29,205	38,769	9,564
26.0	Supplies and materials	-	656	631	(25)
Subtotal	Non-Pay Costs	31,000	29,861	39,400	9,539
Total	Salary and Expenses	174,000	163,309	155,420	(9 <i>,</i> 889)
Total	Direct FTE	1,117	958	832	(126)

Detail	2021 Actual CIV	2021 Actual Total	2022 Est. CIV	2022 Est. Total	2023 Est. CIV	2023 Est. Total
Direct	1,117	1,117	958	958	832	832
Reimbursable	-	-	-	-	-	-
Total FTE	1,117	1,117	958	958	832	832
Average GS Grade						
FY 2019	12/1					
FY 2020	11/2					
FY 2021	11/4					
FY 2022	11/5					
FY 2023	12/1					

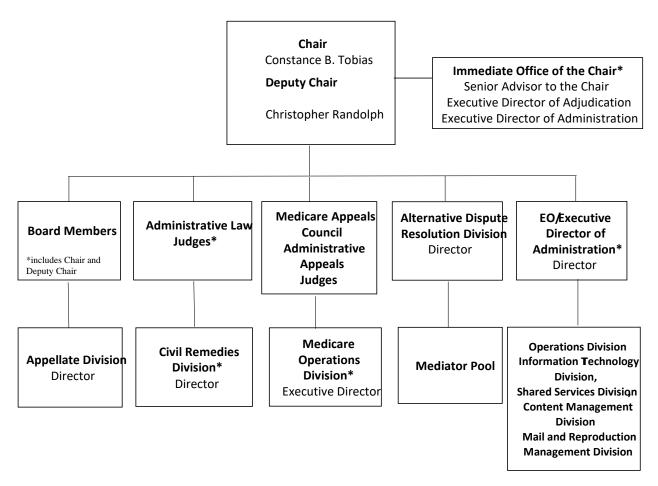
Detail of Full Time Equivalent (FTE) Employment

Detail of Positions

Direct Civilian Positions	FY 2021 Final	FY 2022 CR	FY 2023 President's Budget
AUT	1	1	1
ALI II	8	10	10
	142	124	107
Subtotal, Positions	151	135	118
Total, Salaries	\$26,614,398	\$24,276,165	\$22,077,662
Executive Service Positions	2	2	2
Total, Salaries	\$398,600	\$406,654	\$416,108
GS-15	17	15	15
GS-14	45	42	42
GS-13	93	88	82
GS-12	337	306	267
GS-11	51	47	38
GS-10	-	-	-
GS-9	28	22	18
GS-8	241	212	171
GS-7	51	43	38
GS-6	32	28	24
GS-5	5	3	2
GS-4	1	-	-
GS-3	-	-	-
GS-2	-	-	-
GS-1	-	-	-
Subtotal, Positions	901	806	697
Total - GS Salary	\$72,757,906	\$67,068,473	\$60,341,952
Total Positions	1,054	943	817
Average ALJ salary	\$172,254	\$179,823	\$187,099
Average ES salary	\$199,300	\$203,327	\$208,054
Average GS grade	11/4	11/5	12/1
Average GS salary	\$80,752	\$83,212	\$86,574

DEPARTMENTAL APPEALS BOARD

DAB Organizational Chart



*Denotes Divisions and staff performing Medicare-related work

Organizational Chart (Text Version)

Departmental Appeals Board

- Chair, Constance B. Tobias
- Deputy Chair, Christopher Randolph
- Immediate Office of the Chair

The following offices report directly to the Chair:

- Board Members (includes the Chair and Deputy Chair)
 - o Appellant Division
- Administrative Law Judges
 - o Civil Remedies Division Director
- Medicare Appeals Council Administrative Appeals Judges
 - o Medicare Operations Division Director
- Alternate Dispute Resolution Division Director
 - o Mediator Pool
- Executive Director of Administration
 - o Operations Division
 - o Information Technology Division,
 - o Shared Services Division,
 - o 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.

Budget Summary

(Dollars in Thousands)

	Departmental Appeals Board	FY 2021 Final	FY 2022 CR	FY 2023 President's Budget	+/- FY 2022 Budget
	Budget Authority	25,500	19,500	34,000	+14,500
	FTE	111	132	193	+61
4	Authorizing Legislation				
	FY 2023 AuthorizationIndefinite				
	Allocation MethodDirect federal				

Overview of Budget Request

The FY 2023 budget request for the Departmental Appeals Board (DAB) is \$34,000,000, which is an increase of +\$14,500,000 above the FY 2022 Annualized Continuing Resolution (CR). This request will allow the DAB to devote the additional funding to a temporary staff of term appointment judges and attorneys specifically to work on the reduction of the Medicare Operations Division's (MOD) case backlog, while maintaining the funding level needed to support the increased adjudication capacity of the permanent staff.

The DAB has a large backlog of pending appeals due to 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. The flexibility of the MHA account allowed the DAB \$6 million in additional resources, which were used to initiate a hiring plan for a termappointment attorney backlog reduction force. While significant progress has been made, the hiring plan is on-going and limited staff resources continue to require MOD to balance the goal of reducing the backlog against adjudicating 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 impacted 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 reduced the number of appeals received from repeat filers, the remaining docket is comprised of appeals filed by low-volume filers, present unique or novel legal issues, or involve large dollar amount claims involving multiple beneficiaries, none of which can be easily resolved through large-scale settlements or other Department-wide initiatives. The estimated total amount in controversy of all cases pending in MOD's backlog at the end of FY 2021 is more than \$749 million.

Based on available data, MOD's receipts are estimated to increase from a total of 5,254 appeals in FY 2021 to 5,593 appeals in FY 2022. Therefore, it is projected that MOD's adjudication capacity will exceed incoming receipts for the first time in over a decade in FY 2023. Based on discussions with OMHA, the DAB anticipates a temporary reduction in production beginning in early FY 2023 through

mid-FY 2024, as it adjudicates a large number of overpayment cases. These appeals, which are referred to as "statistical sampling" cases, result from post-payment audits conducted by the HHS Office of Inspector General. Based on historical data, this workload typically includes a large number of claims, a higher-than-average amount in controversy and complex legal arguments challenging the statistical validity of the sample or the correctness of the determination in specific cases identified by the sample (e.g., waiver of liability where medical necessity or custodial care is at issue).

DAB's increased funding during FY 2023 will build the adjudicatory capacity needed to outpace case receipts and prevent the backlog growing further, while the additional funding request allows DAB to strategically reduce the Medicare appeals backlog at the DAB.

The DAB prioritizes beneficiary appeals, which accounted for 14 percent of MOD's annual receipts in FY 2021 and for approximately 8 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 2017 to FY 2021) is 493 days. The average age of pending beneficiary appeals is currently 740 days.

These circumstances have also presented other challenges for MOD. In addition to the complex cases mentioned above, over 75 percent of the cases in the backlog are Part A Inpatient appeals which involve voluminous and complex records and require significant staff time to review and adjudicate. Based on delegated authority from the Secretary, MOD continues to prepare the administrative record for cases appealed to federal court, a process that further strains MOD's already limited staff resources.

The DAB's Civil Remedies Division (CRD) received substantially more appeals due to increased nursing home and covid reporting cases in FY 2021. Specifically, CRD's case receipts increased by 30 percent from FY 2020 to FY 2021. 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 2021, 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, FY 2021, plus additional funds planned in FY 2022, 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

Activity	FY 2021 Final/1	FY 2022 Annualized CR	FY 2023 President's Budget	FY 2023 +/- FY 2022
Departmental Appeals Board	25,500 ³	19,500	34,000	+14,500

(Dollars in Thousands)

*2021, 2022, and 2023 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.

³ DAB's FY 2021 Final funding level includes carryforward from the FY 2020/21 MHA Appropriations

Medicare Hearings and Appeals (MHA) Authorizing Legislation

(Dollars in Thousands)

	FY 2021	FY 2021	FY 2022	FY 2022
Medicare Hearings and Appeals	Amount Authorized	Amount Appropriated	Amount Authorized	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

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 2021, MOD received 6,859 appeals and adjudicated 5,000. At the end of FY 2021, MOD had 20,478 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 2021, CRD received 1,124 new cases and closed 1,051, of which 227 were by decision. Approximately 88% of the CRD casework is Medicare related.

Workload Statistics

<u>Medicare Appeals Council – Medicare Operations Division</u> Chart A shows total historical and projected caseload data for MOD.

Assumptions on which the data are based include:

- 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.

Cases	FY 2020	FY 2021	FY 2022
Open/start of FY	16,961	18,626	20,478
Received	3,816	6,859	6,843
Cases Closed	1,783	5,000	5,520
Administrative Settlements	368	-	-
Open/end of FY	18,626	20,478	21,801

MEDICARE OPERATIONS DIVISION CASES – Chart A

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

Cases	FY 2020	FY 2021	FY 2022	FY 2023	
Open/start of FY	701	458	531	456	
Received	799	1,124	975	1,100	
Decisions	296	227	250	250	
Total Closed	1,042	1,051	1,050	1,050	
Open/end of FY	458	531	456	506	

CIVIL REMEDIES DIVISION CASES – Chart B

Five Year Funding Table

Fiscal Year	Amount
FY 2019	\$19,500,000
FY 2020	\$19,500,000
FY 2021 Final	\$25,500,000
FY 2022 Annualized CR	\$19,500,000
FY 2023 President's Budget	\$34,000,000

Budget Request

The budget request is for \$34,000,000, which is +\$14,500,000 above the FY 2022 Annualized Continuing Resolution (CR) and -10,381,000 below the FY 2022. DAB will devote the additional funding to an increase to its permanent workforce as well as a targeted temporary staff of 10 term appointment judges, and 50 term appointed attorneys, ranging from GS-9 to GS-14. The term appointed staff will specifically work on the reduction of the Medicare Operations case backlog. This structure allows permanent staff to focus on incoming receipts and temporary judges and attorneys to focus solely on the backlog, resulting in an anticipated 50 percent reduction of backlog by the end of FY 2023, with the temporary staff anticipated through mid-FY 2025.

Key Outputs and Outcomes Table:

Measure - DAB	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2022 Target	FY 2023 Target +/- FY 2022 Target
1.1.1 Percentage of CRD decisions issued within all applicable statutory and regulatory deadlines.	FY 2021: 100% Target 90% (Target Exceeded)	90%	Maintain
1.1.2 Cases closed in a fiscal year as a percentage of total cases open in the fiscal year.	FY 2021: 69% Target: 50% (Target Exceeded)	50%	Maintain
1.2.1 Average time to complete action on Requests for Review measured from receipt of the claim file.	FY 2021: 337 days Target: 737 days (Target Exceeded)	727 days	Maintain
1.2.2 Number of MOD dispositions.	FY 2021: 5,000 Target: 7,176 (Target Not Met)	7,176	Maintain

Performance Analysis

DAB has made measurable progress in the strategic management of human capital by reengineering its operations and improving its case management techniques, and is maintaining its FY 2022 targets.

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 2021. The target for this Measure will remain the same in FY 2022 and FY 2023.

Measure 1.1.2 tracks cases closed as a percentage of all cases open during the fiscal year. CRD exceeded its FY 2021 target by closing 66.4 percent of cases open that year. The FY 2022 and FY 2023 targets remain unchanged because many cases are complex, including an increase in the nursing home cases received, and CRD expects to receive an increase in appeals in FY 2022 and FY 2023 when program integrity efforts increase. 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.

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 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 increased its target for FY 2021 and expects to meet or exceed it in FY 2022 once the additional resources to increase adjudication capacity have been onboarded and fully trained.

MEDICARE HEARING AND APPEALS (DAB)

BUDGET AUTHORITY BY OBJECT CLASS – DIRECT

(Dollars in	Thousands)
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Object Class Code	Description	FY 2021 Final	FY 2022 Annualized CR	FY 2023 President's Budget	FY 2023 +/- FY 2022
11.1	Full-time permanent	11,100	11,447	19,296	7,849
11.3	Other than full-time permanent	-	-	-	-
11.5	Other personnel compensation	-	-	-	-
11.7	Military personnel	-	-	-	-
Subtotal	Personnel Compensation	11,100	11,447	19,296	7,849
12.1	Civilian personnel benefits	4,100	3,263	6,433	3,170
12.2	Military benefits	-	-	-	-
13.0	Benefits for former personnel	-	-	-	-
Total	Pay Costs	15,200	14,710	25,729	11,019
21.0	Travel and transportation of persons	45	45	45	-
22.0	Transportation of things	5	5	5	-
23.1	Rental payments to GSA	3,000	1,580	1,380	-200
23.3	Communications, utilities, and misc. charges	165	165	170	5
24.0	Printing and reproduction	5	5	5	-
25.1	Advisory and assistance services	-	-	-	-
25.2	Other services from non-Federal sources	7,000	1,860	4,686	2,826
25.3	Other goods and services from Federal sources	-	1,050	1,900	850
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	30	30	30	-
31.0	Equipment	50	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	10,300	4,790	8,271	3,481-
Total	Budget Authority by Object Class	25,500 ⁴	19,500	34,000	14,500

⁴ DAB's FY 2021 Final funding level includes carryforward from the FY 2020/21 MHA Appropriation

MEDICARE HEARINGS AND APPEALS (DAB)

SALARIES AND EXPENSES

(Dollars in Thousands)

Object Class Code	Description	FY 2021 Final	FY 2022 Annualized CR	FY 2023 President's Budget	FY 2023 +/- FY 2022
11.1	Full-time permanent	11,000	11,447	19,296	7,849
11.3	Other than full-time permanent	-	-	-	-
11.5	Other personnel compensation	-	-	-	-
11.7	Commissioned Corps personnel	-	-	-	-
Subtotal	Personnel Compensation	11,000	11,447	19,296	9,375
12.1	Civilian personnel benefits	4,100	3,263	6,433	3,170
12.2	Commissioned Corps benefits	-	-	-	-
13.0	Benefits for former personnel	-	-	-	-
Total	Pay Costs	15,200	14,710	25,729	11,019
21.0	Travel and transportation of persons	45	45	45	-
22.0	Transportation of things	5	5	5	-
23.3	Communications, utilities, and misc. charges	165	165	170	5
24.0	Printing and reproduction	5	5	5	-
25.1	Advisory and assistance services	-	-	-	-
25.2	Other services from non-Federal sources	7,000	1,860	4,686	2,826
25.3	Other goods and services from Federal sources	-	1,050	1,900	850
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	-	-	-	-
Subtotal	Other Contractual Services	-	-	-	-
26.0	Supplies and materials	30	30	30	-
Subtotal	Non-Pay Costs	7,250	4,841	6,841	3,681
Total	Salary and Expenses	22,450	18,070	32,570	14,700
Total	Direct FTE	111	132	193	+61

DE	DETAIL OF FULL-TIME EQUIVALENT (FTE) EMPLOYMENT								
	2021	2021	2021	2022 Ect	2				

Detail	2021 Actual CIV	2021 Actual CC	2021 Actual Total	2022 Est. CIV	2022 Est. CC	2022 Est. Total	2023 Est. CIV	2023 Est. CC	2023 Est. Total
Direct	111	-	111	132	-	132	193	-	193
Reimbursable	-	-	-	-	-	-	-	-	-
Total FTE	111	-	111	132	-	132	193	-	193
-	-	-	-	-	-	-	-	-	-
Average GS Grade		-	-	-	-	-	-	-	-
FY 2019	12	-	12	12	-	12	12	-	12
FY 2020	13	-	13	13	-	13	13	-	13
FY 2021	13	-	13	13	-	13	13	-	13
FY 2022	13	-	13	13	-	13	13	-	13
FY 2023	13	-	13	13	-	13	13	-	13

Office for Civil Rights



DEPARTMENT of HEALTH and HUMAN SERVICES

Fiscal Year 2023

Office for Civil Rights

Justification of Estimates for Appropriations Committees



DEPARTMENT OF HEALTH & HUMAN SERVICES

I am pleased to present the Office for Civil Rights' (OCR) Fiscal Year 2023 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 is the paramount HHS agency to ensure non-discrimination in the Administration's overall equity efforts. In particular, OCR leads the HHS efforts to implement Executive Order 13988: *Preventing and Combating Discrimination on the Basis of Gender Identity or Sexual Orientation*. OCR also remains a leading force in ensuring civil rights and patient privacy protections during the ongoing COVID-19 public health emergency. From responding to specific pandemic-related complaints, to consulting with States on key aspects of critical care and providing HIPAA flexibilities, OCR is at the forefront of the government-wide effort to support the American People through a safe, effective, and equitable response to the pandemic.

A dramatic rise in caseloads and threats in civil rights and patient privacy policy and enforcement portfolios has led to a steady increase in case inventories over the past decade. OCR is committed to the timely response to all complainants and accordingly requests to raise staffing levels to address the accumulation of cases requiring action. An augmentation of regional staff who work on cases, breaches, and compliance reviews will enable OCR to resolve the situation.

The growth of OCR's Civil Rights Division (CRD) is a crucial goal for FY 2023. The expansion will enable the Division to expand its work on high-impact systemic cases and add staff to ensure Department-wide civil rights compliance and policy development by augmenting technical assistance to HHS components, review of HHS regulations, and training for HHS grantees. Additional funding will also support the expansion of CRD's enforcement work, including race, color, national origin, and sex discrimination policy and enforcement—as well as OCR's new environmental justice initiative. In addition, funding will support CRD's work to implement executive orders on advancing equity in government programs.

The White House Initiative on Asian Americans, Native Hawaiians, and Pacific Islanders (WHIAANHPI), established on May 28, 2021 through Executive Order 14031 and co-chaired by the HHS Secretary also resides in OCR. The Initiative's focus will be on leading change in government programs and creating an interagency working group and regional network that will advise federal agency leadership on the coordination and implementation of a whole-of-government agenda to advance equity, justice, and opportunity.

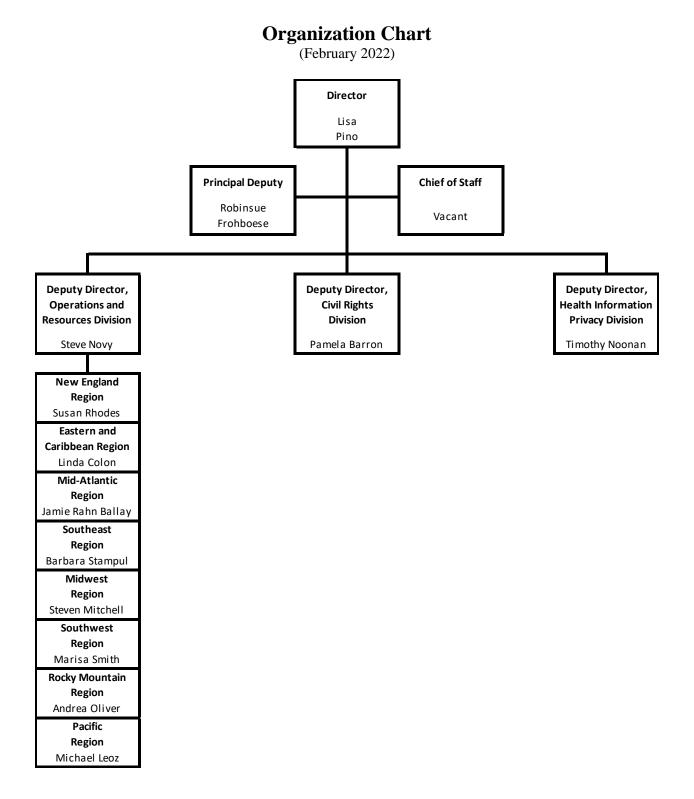
OCR's Fiscal Year 2023 budget request is necessary to continue the momentum of revitalizing the role of non-discrimination in health and human services and maintaining its leadership on consumer access to health information and protection of their information.

Lisa Pino Director, Office for Civil Rights

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Section 1: Introductory Items



Organizational Chart: Text Version

Office for Civil Rights

- Director Lisa Pino
- Principal Deputy Robinsue Frohboese
- Chief of Staff Vacant

The following offices report directly to the Director:

- 1 Deputy Director, Operations and Resources Division
- 1.2 Steve Novy
- 2 Deputy Director, Civil Rights Division
- 2.2 Pamela Barron
- 3 Deputy Director, Health Information Privacy Division
- 3.2 Timothy Noonan

The following regional managers report to the Deputy Director, Operations and Resources Division:

- Susan Rhodes, New England Region
- Linda Colon, Eastern & Caribbean Region
- Jamie Rahn Ballay, Mid-Atlantic Region
- Barbara Stampul, 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, people with disabilities, individuals with limited English proficiency, immigrants and refugees, religious minorities, LGBTQ+ communities, 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 2023 President's Budget request for the Office for Civil Rights is \$60,250,000 which is \$21,452,000 above the FY 2022 Annualized Continuing Resolution. At this level, OCR will continue defending the public's right to nondiscriminatory access to HHS-funded health and human services as well as access to and the privacy and security of individually identifiable health information. OCR will also implement additional civil rights and patient privacy enforcement activities to support the Administration's efforts to ensure all healthcare protections are vigorously enforced. Additionally, OCR will continue to implement the WHIAANHPI.

With a \$21.5 million increase in FY 2023, OCR will invest \$9 million in adding staff to enhance enforcement activities related to dramatic case receipt increases. Funds will also support OCR's civil rights policy and enforcement work in the areas of race, disability, sex discrimination, child welfare, and environmental justice as requested in the FY 2022 budget. Additional investments will be made in other key areas, including:

- +\$8,164,000 for the Operations and Resources Division for additional resources to address the existing complaint backlog;
- +\$2,140,000 for the Civil Rights Division for added staff to ensure Department-wide civil rights compliance and policy development by augmenting technical assistance to HHS components, review of HHS regulations, and training for HHS grantees; and
- +\$2,015,000 for the White House Initiative on Asian Americans, Native Hawaiians, and Pacific Islanders

Overview of Performance

OCR's overarching goals encompass multiple supporting objectives.

	OCR Goal		OCR Supporting Objectives
1.	Raise awareness, increase understanding, and ensure compliance with, all federal laws requiring non- discriminatory access to HHS- funded or conducted programs, protect the privacy and security of personally identifiable health information	А. В. С. D.	Increase access to, and receipt of, non- discriminatory quality health and human services Protect the privacy and security of personally identifiable health information for healthcare consumers (HIPAA Rule activities and enforcement) Provide information, public education activities, and training to representatives of health and human service providers, other interest groups, and consumers 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	А. В. С.	Maximize efficiency of operations by streamlining processes and the optimal allocation of resources Improve financial management and the integration of budget and performance data (Increase resource management process oversight, strengthen internal controls, maintain viable performance objectives) 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:

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2022 Target	FY 2023 Target	FY 2023 Target +/- FY 2022 Target
#1 The number of covered entities taking corrective actions as a result of OCR intervention per year (Outcome)	FY 2021: 2,655 Target: 1,500 (Target Exceeded)	1,500	1,500	No Change
#2 The number of covered entities making substantive policy changes as a result of OCR intervention / year (Outcome)	FY 2021: 298 Target: 250 (Target Exceeded)	250	250	No Change
#3 Percent of closure for civil rights cases / cases received each year (Outcome)	FY 2021: 91% Target: 90% (Target Exceeded)	90%	90%	No Change
#4 Percent of closure for health information privacy cases / cases received each year (Outcome)	FY 2021: 93% Target: 90% (Target Exceeded)	90%	90%	No Change
#5 Percent of civil rights complaints requiring formal investigation resolved within 365 days (Output)	FY 2021: 84% Target: 70% (Target Exceeded)	80%	80%	No Change
#6 Percentage of civil rights complaints not requiring formal investigation resolved within 180 days (Output)	FY 2021: 82% Target: 95% (Target Not Met)	85%	85%	No Change
#7 Percentage of health information privacy complaints requiring formal investigation resolved within 365 days (Output)	FY 2021: 81% Target: 70% (Target Exceeded)	80%	80%	No Change
#8 Percentage of health information privacy complaints not requiring formal investigation resolved within 180 days (Output)	FY 2021: 98% Target: 95% (Target Exceeded)	95%	95%	No Change

OCR exceeded 7 of 8 performance measures during FY 2021 and continued to play a significant role in the Department's response to COVID-19. OCR's performance measures focus on OCR's enforcement activities through reviewing, triaging, and investigating complaints and initiating compliance reviews. Overall, OCR was able to exceed its productivity and closure targets by closing a high percentage of civil rights and HIPAA cases. The issue confronting OCR, however, is a rapid rise in case receipts as caseload grew dramatically in FY 2021 and OCR anticipates receiving approximately 53,000 in FY 2022.

Complaint investigations and reviews may entail in-depth investigations, which may conclude with a letter of findings, a voluntary resolution agreement, or a settlement agreement. Investigations may also resolve through OCR's facilitated early complaint resolution process negotiated between the complainant and the named entity or with voluntary corrective action. In FY 2021, OCR exceeded the target for resolving civil rights and patient privacy complaints through the investigative process within 365 days. OCR also exceeded its target for the performance objective of investigated complaints/reviews/breaches resulting in corrective action and the number of covered entities making substantive policy changes. The timely completion of complaints through formal investigation with corrective action and with substantive policy changes represent meaningful measures of the actions taken by OCR towards fulfilling its core mission of ensuring equal opportunity to access HHS funded health care and social services and the privacy and security of protected health information.

OCR also resolves a large number of complaints that do not require a formal investigation, which includes non-jurisdictional complaints, as well as those for which OCR provided technical assistance to the named entity. Technical assistance is appropriate for complaints involving 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. OCR exceeded its target for HIPAA cases not requiring formal investigation resolved within 180 days.

In FY 2021, OCR took aggressive steps to resolve a significant number of civil rights complaints. However, with regard to the disposition of civil rights cases not requiring a formal investigation, OCR did not meet this metric. The budget request specifically addresses this issue and would remedy the shortfall.

All Purpose Table

(Dollars in Thousands)

Activity	FY 2021 Final	FY 2021 COVID-19 Supplemental	FY 2022 CR ²	FY 2022 Supplemental Funding ³	FY 2023 President's Budget	FY 2023 President's Budget +/- FY 2022 CR
Discretionary Budget Authority	38,682	-	38,798	-	60,250	+21,452
OCR Civil Monetary Settlement Funding	18,229	-	19,531	-	20,693	+1,162
Total, OCR Program Level	57,091	-	58,329	-	80,943	+22,614
FTE - Discretionary Budget Authority	127	-	141	-	232	+91
FTE - OCR Civil Monetary Settlement Funding	54	-	49	-	49	-
Total FTE, OCR Program Level	181	-	190	-	281	+91

¹ This column includes both supplemental funding and mandatory funds appropriated in the American Rescue Plan Act of 2021, P.L. 117-2 post-transfer and post-reallocation and the supplemental appropriation in the Consolidated Appropriations Act, 2021 (P.L. 116-260)

 $^{^{2}}$ Reflects the annualized amounts provided in the continuing resolution ending 12/3/2021 (or any further extension of a continuing resolution)

³ This column includes both supplemental funding and mandatory funds appropriated for FY 2022 in the Infrastructure and Jobs Act and in the Build Back Better Act.

Section 3: Office for Civil Rights

Appropriations Language

For expenses necessary for the Office for Civil Rights, \$60,250,000.

Amounts Available for Obligation (Dollars in Thousands)

Detail	FY 2021 Final	FY 2022 CR	FY 2023 President's Budget
Appropriation	38,798	38,798	60,250
Across-the-board reductions	-	-	-
Subtotal, Appropriation	38,798	38,798	60,250
Transfer of Funds	(116)	-	-
Subtotal, Adjusted General Fund Discretionary App	38,682	38,798	60,250
Total, Discretionary Appropriation	38,682	38,798	60,250

Summary of Changes

(Dollars in Thousands)

FY 2022 CR	
Total estimated budget authority	38,798
FY 2023 President's Budget	
Total estimated budget authority	60,250
Net Change	+21,452

	FY 2	2022 CR		President's Idget	FY 2023 +/- FY 2022	
Increases:	FTE	BA	FTE	BA	FTE	BA
A. Built-in:						
1. Full-time permanent	141	17,237	232	29,694	+91	+12,457
2. Civilian personnel benefits		6,181		10,674		+4,493
3. Other than full-time permanent		367		815		+448
4. Other personnel compensation		480		716		+236
5. Military personnel		134		140		+6
6. Benefits for former personnel		116		120		+4
7. Military benefits		9		10		+1
Subtotal, Built-in Increases		24,524		42,169		+17,645
B. Program:						
1. Other goods and services from Federal sources		6,740		8,154		+1,414
2. Other services from non-Federal sources		2,629		3,496		+867
3. Travel and transportation of persons		88		886		+798
4. Equipment		30		434		+404
5. Rental payments to GSA		3,689		4,021		+332
6. Supplies and materials		78		162		+84
7. Transportation of things		5		10		+5
8. Communications, utilities, and misc. charges		98		100		+2
9. Printing and reproduction		179		181		+2
Subtotal, Program Increases		13,536		17,444		+3,908
Total Increases		38,060		59,613		+21,553
Decreases:						
A. Built-in:						
Subtotal, Built-in Decreases						
B. Program:						
1. Operation and maintenance of facilities		377		351		-26
2. Operation and maintenance of equipment		361		286		-75
Subtotal, Program Decreases		738		637		-101
Total Decreases		738		637		-101
Net Change		38,798		60,250		+21,452

Budget Authority by Activity (Dollars in Thousands)

Activity	FY 2021 Final	FY 2022 CR	FY 2023 President's Budget
Office for Civil Rights	38,682	38,798	60,250
Total, Budget Authority	38,682	38,798	60,250
FTE	127	141	232

Authorizing Legislation

(Dollars in Thousands)

Details	FY 2022 Amount Authorized	FY 2022 Amount Appropriated	FY 2023 Amount Authorized	FY 2023 President's Budget
Office for Civil Rights	Indefinite	38,798	Indefinite	\$60,250
Appropriation	-	38,798	-	\$60,250

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.

- 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 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

Fiscal Year	Details	Budget Estimates to Congress	House Allowance	Senate Allowance	Appropriation
2014	General Fund Appropriation	42,205,000	-	42,205,000	38,798,000
2014	Subtotal	42,205,000	-	42,205,000	38,798,000
2015	General Fund Appropriation	41,205,000	-	38,798,000	38,798,000
2015	Subtotal	41,205,000	-	38,798,000	38,798,000
2016	General Fund Appropriation	42,705,000	-	38,798,000	38,798,000
2016	Subtotal	42,705,000	-	38,798,000	38,798,000
	General Fund Appropriation	42,705,000	38,798,000	38,798,000	38,798,000
2017	Transfers	-	-	-	(90,000)
	Subtotal	42,705,000	38,798,000	38,798,000	38,708,000
	General Fund Appropriation	32,530,000	38,798,000	-	38,798,000
2018	Transfers	-	-	-	(97,000)
	Subtotal	32,530,000	38,798,000	-	38,701,000
	General Fund Appropriation	30,904,000	38,798,000	38,798,000	38,798,000
2019	Transfers	-	-	-	(131,000)
	Subtotal	30,904,000	38,798,000	38,798,000	38,667,000
2020	General Fund Appropriation	30,286,000	38,798,000	38,798,000	38,798,000
2020	Subtotal	30,286,000	38,798,000	38,798,000	38,798,000
	General Fund Appropriation	30,286,000	38,798,000	-	38,798,000
2021	Transfers	-	-	-	(116,000)
	Subtotal	30,286,000	38,798,000	-	38,682,000
	General Fund Appropriation	47,931,000	47,931,000	47,931,000	39,798,000
2022	Transfers	-	-	-	-
	Subtotal	47,931,000	47,931,000	47,931,000	39,798,000
2023	General Fund Appropriation	60,250,000	-	-	-

Office for Civil Rights

(Dollars in Thousands)

Program	FY 2021 Final	FY 2022 CR	FY 2023 President's Budget	FY 2023 +/- FY 2022
Budget Authority				
Discretionary Budget Authority	38,682	38,798	60,250	+21,452
Civil Monetary Settlement Funding	18,229	19,531	20,693	+1,162
Total Program Level	57,091	58,329	80,943	+22,614
FTE				
Discretionary Budget Authority	127	141	232	+91
Civil Monetary Settlement Funding	54	49	49	-
Total Program Level	181	190	281	+91

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, technical assistance and training, rulemaking and guidance, 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 patient 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 261 percent increase in the number of complaints received since OCR's online complaint portal went live in FY 2012 (45,832 year to date in FY 2021 versus 12,701 in FY 2012). In FY 2021, OCR received more complaints than in either FY 2020 or FY 2019.

Civil rights and patient privacy and security complaint investigations, breach report investigations, and compliance reviews are conducted by OCR regional offices.⁴ 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

⁴ 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).

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 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 (OGC) 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 recission 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.

Training and Technical Assistance

OCR provides training and technical assistance to HHS Operating and Staff Divisions to ensure that the Department complies with federal civil rights laws and regulations. For example, OCR has entered into a memorandum of understanding (MOU) with the National Institutes of Health (NIH), where OCR provides training and technical assistance to NIH staff, who in turn refer notices of recipient (including principal investigator) sexual misconduct to OCR for investigation and, if necessary, enforcement. Throughout the summer of 2021, OCR collaborated with the senior leadership of the Centers for Medicare & Medicaid Services (CMS), NIH, and the Office of Intergovernmental and External Affairs (IEA), to provide training on Sections 501, 504, and 508 of the Rehabilitation Act of 1973 and Executive Order 14035: *Diversity, Equity, Inclusion, and Accessibility in the Federal Workforce,* regarding each HHS Agency's responsibility to provide employees and beneficiaries with effective communication via alternate formats.

As noted more fully below, OCR is also HHS's lead agency implementing Executive Order 13988: *Preventing and Combating Discrimination on the Basis of Gender Identity or Sexual Orientation.* Similarly, OCR has provided technical assistance to the Office of the Assistant Secretary for Financial Resources (ASFR), including civil rights content for their July 2021 Equity Guidance, as well as other HHS grant-making agencies updating their Notice of Funding Opportunity (NOFO) announcements to focus on civil rights compliance information; language access requirements for the limited English proficient; protections for members of the Asian American and Native Hawaiian Pacific Islanders (AANHPI) community; and prohibitions on sexual harassment and discrimination. In addition, OCR has provided civil rights and language access content to the Administration for Children and Families (ACF) Office of Human Services Emergency Preparedness and Response for the National Emergency Repatriation Framework and the "welcome packets" provided to U.S. citizens, as well as Burmese and Afghan refugees, entering the United States.

Policy

OCR's policy work consists of drafting regulations, guidance documents, and other materials. This policy work helps ensure the strength and clarity of the regulations implementing OCR's legal authorities; and provides the regulated community with resources to promote compliance with federal law. For example, as discussed in more detail below, OCR is currently developing notices of proposed rulemaking to amend and update the regulations implementing Section 1557 of the Affordable Care Act and Section 504 of the Rehabilitation Act of 1973. In addition, throughout the COVID-19 public health emergency, OCR has been a national leader in providing guidance documents to providers on how to comply with both federal civil rights and HIPAA obligations to facilitate the Department's efforts to provide COVID-19 testing, treatment, and vaccinations.

Education and Outreach

OCR's public outreach informs and educates consumers, advocacy groups, covered entities, 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.

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 more than 100,000 health care providers and allied health professionals through this program. Since 2009, OCR's civil rights medical school curriculum has been presented to educate future health care practitioners in collaboration with the Association of American Medical Colleges on how OCR's work promotes equal access to health care and addresses health care disparities experienced by racial and ethnic minority communities. OCR has presented the medical school curriculum to approximately 8,500 medical school, nursing, and allied health students, including undergraduate and professional school students. Through the Summer Health Professionals Education Program (SHPEP), OCR provides the training to premedical and predental college students at over a dozen universities each year.

OCR conducts nationwide outreach through participating in conferences and inter-agency briefings, as well as listening sessions and smaller meetings; hosting workshops, and webinars; 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 are 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 2023 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: <u>Ensuring an Equitable</u> <u>Pandemic Response and Recovery</u>; and EO 13166: <u>Improving Access to Services for Persons</u> <u>With Limited English Proficiency</u>; and actively supporting the HHS implementation activities under EO 13985: <u>Advancing Racial Equity and Support for Underserved Communities</u> <u>Through the Federal Government</u>; EO 14035: <u>Diversity, Equity, Inclusion, and Accessibility in</u> <u>the Federal Workforce</u>; and EO 13990: <u>Protecting Public Health and the Environment and</u> <u>Restoring Science To Tackle the Climate Crisis</u>.
- Partnering with the Justice Department, in November 2021, to initiate an environmental justice investigation into the wastewater disposal programs, including infectious disease prevention and control, of the Alabama Department of Public Health (DPH) and the Lowndes County Health Department. Under the authority of Title VI, the investigation is examining whether Alabama DPH and Lowndes County operate their wastewater disposal programs in a manner which discriminates against Black residents. The HHS Office of Climate Change and Health Equity is consulting with OCR on the public health aspects of the investigation. In addition, OCR continues to participate in the HHS Environmental Justice Working Group, as well as the Federal Interagency Working Group on Environmental Justice.
- Collaborating with the White House Initiative on Asian Americans, Native Hawaiians, and Pacific Islanders (WHIAANHPI) on the implementation of EO 14031: <u>Advancing Equity</u>, <u>Justice, and Opportunity for Asian Americans, Native Hawaiians, and Pacific Islanders</u>.
- Preventing and addressing discrimination and health care disparities which disproportionately affect racial and ethnic minority communities. For example, in April 2021, OCR secured corrective action from a national pharmacy chain with 1100 locations. During the course of OCR's complaint investigation, the pharmacy chain developed and implemented a written Title VI policy prohibiting race, color, and national origin discrimination; conducted staff training; and posted the new policy in a portal accessible to all employees. For several years, OCR has actively participated in the intra-agency HHS Health Disparities Council, as well as the Interdepartmental Health Equity Collaborative (IHEC), a platform to better address health disparities, alongside representatives from the HHS Office of Minority Health (HHS OMH), other HHS agencies, and several Executive Departments. OCR also collaborated with HHS OMH senior leaders to provide civil rights content for their <u>Think Cultural Health</u> e-courses, "Culturally and Linguistically Appropriate Services (CLAS) in Maternal Health Care" (March 2021), and "Culturally Competent Nursing Care: A Cornerstone of Caring" (October 2021).
- In its compliance with EO 13166 to improve access to services for LEP persons, OCR's operations serve as a model for the Department by producing language enforcement-related communications in the primary languages of complainants and enhancing its website accessibility for LEP individuals. To serve as an HHS and federal government leader, OCR increased accessibility to its enforcement program by posting consumer information in the 15 most frequently spoken languages, which made it easier for LEP individuals to learn about their rights and exercise them through OCR's complaint portal. As a result, LEP individuals can now click on their primary language at the top of the OCR webpage and immediately access information to understand their rights and file a complaint in their primary 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. OCR serves as a member of the HHS All-Hazards Base Plan Working Group to ensure disability and language access services are part of preparedness, response, and recovery planning and execution. For example, OCR works to ensure that during emergencies, qualified interpreter services, and translated documents, are available in languages prevalent in affected areas. Throughout FY 2021, OCR developed bulletins that provided guidance and resources to emergency responders to help them ensure meaningful access for LEP individuals. OCR also deployed several employees during this period to ACF's Office of Refugee Resettlement's (ORR) Texas facilities to support the care and processing of unaccompanied minors who crossed the border from Mexico to the United States. In addition to fulfilling functional roles, staff observed and advised workers on serving Spanish-speaking children and children with disabilities in accordance with applicable civil rights laws.

Enforcing the Prohibitions against Sex Discrimination

Two federal statutes that OCR enforces contain sex discrimination prohibitions. Section 1557 of the Affordable Care Act prohibits sex discrimination in certain health programs and activities; and Title IX of the Education Amendments Act of 1972 prohibits sex discrimination in federally funded education programs and activities.

- The Fall 2021 Unified Agenda reported that OCR will issue a notice of proposed rulemaking to effect changes in the 2020 Final Rule implementing Section 1557. OCR anticipates that this rulemaking with result in significant benefits by providing clear guidance to the covered entity community regarding non-discrimination requirements. OCR also anticipates cost savings as individuals are able to access a range of health care services that will result in decreased health care disparities among historically marginalized groups.
- On May 10, 2021, the Department announced that in light of the U.S. Supreme Court's decision in *Bostock v. Clayton County*, OCR will interpret and enforce Section 1557's and Title IX's prohibitions on discrimination based on sex to include: (1) discrimination on the basis of sexual orientation; and (2) discrimination on the basis of gender identity. OCR's Headquarters and Regional Offices are currently collaborating to expedite investigation of sexual orientation and gender identity discrimination complaints.
- During FY 2021, OCR coordinated the Department's implementation of Executive Order 13988: Preventing and Combating Discrimination on the Basis of Gender Identity or Sexual Orientation, by conducting an inventory of HHS Agency actions to be revised, suspended, or rescinded. To fulfil the Department's responsibilities under the Executive Order, OCR has: consulted with the Justice Department and EEOC; convened 18 HHS Agencies for monthly coordination meetings; submitted an HHS Action Plan detailing the implementation process to the White House, OMB, and the Attorney General; and is currently providing individual consultations to HHS Agencies on revisions to their EEO and Anti-Harassment Policy Statements, EEO Complaint Forms and Instructions, EEO Complaint and Processing Policies, and Affirmative Employment policies.
- OCR serves as a member of the Safety, Justice and Dignity Work Group of the *White House Gender Policy Council*, established by Executive Order 14020, and the Interagency Working Group on Safety, Inclusion, and Opportunity for Transgender Americans. OCR actively provides technical assistance to HHS Agencies as they work to advance gender equity through their policies, and programs.
- Pursuant, in part, to a memorandum of understanding with the National Institutes of Health (NIH), OCR fulfills its Title IX and Section 1557 responsibilities through a combination of technical assistance and training, as well as enforcement:

- 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 eight 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.

Enforcing Prohibitions against Disability Discrimination

OCR is responsible for enforcement of Section 504 of the Rehabilitation Act of 1973, which prohibits disability discrimination in federally funded programs; Title II of the Americans with Disabilities Act, which requires state and local governments to give individuals with disabilities an equal opportunity to benefit from their programs, services, and activities; and Section 1557, which prohibits disability discrimination in certain health programs and activities.

- As reported in the Fall 2021 Unified Agenda reports that OCR will issue a notice of proposed rulemaking to revise the regulations implementing Section 504 to address unlawful disability discrimination in HHS health and human service programs. The rulemaking is to include non-discrimination in organ transplantation, child welfare programs and services, health care value assessment methodologies, accessible medical equipment, and auxiliary aids and services.
- OCR serves on the Interagency Policy Committee (IPC) on Disability with members from the Domestic Policy Council and a number of other federal agencies. OCR has been a part of the IPC Subcommittees focusing on COVID-19, Children with Disabilities, and Long-Term Services and Supports, and will be part of an additional Subcommittee on Accessibility beginning in the fall of 2021. Within HHS, OCR is also a part of the Behavioral Health Coordinating Council and the Interagency Meeting on Vaccination of People with Disabilities headed by the CDC.

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. For example, OCR, joined with FEMA and the Department of Homeland Security's Office of Civil Rights and Liberties to launch compliance reviews of 19 state COVID programs to determine whether LEP individuals in those states have meaningful access to critical COVID testing, vaccination and treatment. In addition, OCR continues to issue multiple guidance documents and bulletins to

prevent discrimination during COVID-19.⁵ Most recently, OCR collaborated with the Justice Department to issue: "Guidance on 'Long COVID' as a Disability Under the ADA, Section 504, and Section 1557," which was included in the July 26, 2021 "White House Fact Sheet: Biden-Harris Administration Marks Anniversary of Americans with Disabilities Act." In response to stakeholder and Congressional requests and complaints received, OCR issued: "Guidance on Federal Legal Standards Prohibiting Race, Color and National Origin Discrimination in COVID-19 Vaccination Programs" (December 22, 2021); "Guidance on Federal Legal Standards Prohibiting Disability Discrimination in COVID-19 Vaccination Programs" (April 13, 2021), and Comprehensive FAQ's on Protections for Persons with Disabilities and Healthcare Provider Nondiscrimination Obligations During COVID -19. (February 4, 2022). OCR also resolves cases through resolution agreements, corrective action closure letters, and early case resolution procedures; and collaborates on virtual outreach with a broad range of stakeholders. Throughout FY 2021, OCR partnered with other HHS Operating Divisions to provide technical assistance in the areas of mask mandates, religious gatherings, and vaccination mandates. OCR provided tribal communities proposed communication strategies to assist in utilizing CDC guidance on COVID-19 safety. OCR also provided technical assistance to religious organizations and health care providers on how to safely accommodate religious visitation in hospitals and nursing homes.

Protecting the Civil Rights of People with HIV

OCR is a member of the Federal Steering Committee for the *National HIV/AIDS Strategy (2022-2025)*, which is convened by the White House Office of National AIDS Policy, in collaboration with the HHS Office of Infectious Disease and HIV/AIDS Policy (OIDP), Office of the Assistant Secretary for Health (OASH), and representatives from 15 Executive Departments. OCR also is a member of the Federal Steering Committee for the *Viral Hepatitis National Strategic Plan (2021-2025)*. OCR investigates and resolves HIV discrimination complaints; trains HHS staff and recipients on protecting the civil rights of people with HIV; provides technical assistance to HHS agencies producing HIV-related educational materials; and regularly contributes civil rights content to HIV.gov. In FY 2022, OCR published a blog post for HIV.gov, "HHS Office for Civil Rights Commemorates World AIDS Day" that indicates examples of OCR's HIV nondiscrimination enforcement efforts.

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 settlement agreement; and OCR has conducted outreach at key national conferences with stakeholders. In April 2021, OCR partnered with the Substance Abuse and Mental Health Services Administration (SAMHSA), ACF, and the National Center on Substance Abuse and Child Welfare (NCSACW), to release a video series informing audiences about the application of federal disability rights laws to child welfare programs and activities, especially as they pertain to Medication-Assisted Treatment (MAT) for Opioid Use Disorder (OUD).

⁵ See <u>Guidance on "Long COVID" as a Disability Under the ADA, Section 504, and Section 1557</u> (July 26, 2021)(joint guidance from the U.S. Department of Health & Human Services and the U.S. Department of Justice); <u>Guidance on Federal Legal Standards Prohibiting Disability Discrimination in COVID-19</u> <u>Vaccination Programs</u> (April 13, 2021).

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 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 2023, OCR will continue its work to enforce the religious nondiscrimination statutes and regulations in its jurisdiction to protect religious minorities and other individuals from discrimination and to promote a comprehensive equity agenda. Pursuant to E.O. 13985, "Advancing Racial Equity and Support for Underserved Communities Through the Federal Government," OCR has researched barriers religious minorities face to health care and has been exploring ways that OCR's legal authorities can help alleviate these challenges.⁶ OCR plans to continue its work on behalf of marginalized or stigmatized religious groups into FY 2023, consulting with stakeholders and experts on the causes of barriers religious minorities and other underserved groups face in healthcare settings and its impact on patient access and outcomes.

2. Health Information Privacy

The collection and sharing of health information is critical to improving the quality and safety of health care and advancing medical discoveries that can improve the health and wellbeing of individuals and populations. However, in the face of increasing cybersecurity threats targeting the health care sector and public concerns about the privacy and security of health data, active education, and enforcement of HIPAA privacy, security, and breach notification regulations are critical to building and maintaining public trust in robust uses and disclosures of protected health information. OCR works to ensure the protection of health information through investigations and enforcement, rulemaking and guidance, and education and outreach.

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, including addressing the opioid crisis; advancing interoperability of digital health information; empowering individuals to make health care decisions; enabling enhanced care coordination; building public trust in health data sharing; helping to build the privacy and security framework for public and private sector research initiatives that yield medical discoveries; supporting public health surveillance and emergency preparedness and response activities; improving the ability of entities subject to HIPAA to prevent and effectively respond to cybersecurity threats; and improving the safety of health care by helping to facilitate confidential analysis of medical errors and other patient safety events.

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

⁶ See, e.g., Padela, Aasim, et al. "Religious Values and Healthcare Accommodations: Voices from the American Muslim Community." J. Gen Intern Med 27(6) at 711 (2011).

medical records, and for a reasonable, cost-based fee. Investigations were initiated across the country, and to date, 25 enforcement actions have been completed with successful resolution agreements, and corrective action plans or the imposition of a civil money penalty. This initiative empowers patients to be aware of their health status and active participants in their health care treatment.

Enforcing the HIPAA Rules to remedy potential violations. In FY 2021, OCR completed twenty enforcement actions, including the imposition of two civil money penalties, and the successful settlement of eighteen cases with a monetary settlement and corrective action plan, for a total of over seven million dollars in collections. The cases selected as enforcement actions demonstrate substantial noncompliance with the HIPAA Rules, or egregious failures to protect individuals' HIPAA rights. Highlights include cases involving individual's right to receive access to their medical records as part of OCR's Right of Access Initiative, and breach investigations involving hacking, PHI left unsecured on servers without login credentials, former employee's access to PHI after leaving employment, and failures to implement basic HIPAA Security Rule requirements such as conducting a risk analysis of the potential risks and vulnerabilities to electronic protected health information (ePHI), and implement risk management to reduce those potential risks and vulnerabilities to a reasonable level.

Updating the HIPAA Rules. The HIPAA Privacy Rule was written and implemented nearly twenty years ago, and much has changed in health care, including the means through which individuals and health care systems access, use, and disclose protected health information. OCR published a Request for Information in December 2018 to solicit public comments on questions about modifying the HIPAA Privacy Rule. In January 2021, OCR published a Notice of Proposed Rulemaking (NPRM) on Modifications to the HIPAA Privacy Rule. The NPRM sought public comments on proposals to strengthen individuals' rights to access their own health information, including electronic health information; improve information sharing for care coordination and case management for individuals; facilitate family and caregiver involvement in the care of individuals experiencing health emergencies or crises; enhance flexibilities for disclosures in emergency and to prevent or lessen serious and reasonably foreseeable threats, such as the Opioid and COVID-19 public health emergencies; and reduce administrative burdens on HIPAA covered entities, while continuing to protect individuals' health information privacy interests. Additionally, OCR is working on additional rulemaking to implement the HITECH Act, and the CARES Act.

Legislative Proposal Submitted for Consideration

"Enhancing HIPAA Protections by Increasing Civil Monetary Penalty Caps and Authorizing Injunctive Relief"

OCR is proposing an increase in the amount of civil money penalties that can be imposed in a calendar year for HIPAA noncompliance and authorize OCR to work with the U.S. Department of Justice to seek injunctive relief in federal court for HIPAA violations. Authorizing higher annual caps would increase OCR's ability to vigorously enforce the HIPAA Rules, create a greater incentive to comply with the health information privacy laws, and effectuate greater industry compliance. In OCR's experience, the current limits on civil money penalties do not create a sufficient deterrent to industry noncompliance.

Accomplishments

These selected accomplishments highlight the range of outcomes recently achieved by OCR in the service of OCR's mission.

Ensuring access to support persons with disabilities in hospitals during the COVID-19 Pandemic

 In February 2021, OCR resolved three disability discrimination complaints to ensure that patients with disabilities are allowed access to necessary support persons in MedStar Health hospitals and care locations despite visitor restrictions during the COVID-19 pandemic. OCR worked with the complainants and MedStar Health to resolve the issues in their complaints through OCR's early complaint resolution process and to provide technical assistance on the application of federal disability law requirements. In response, MedStar Health revised its policy to clearly distinguish between "visitors" and "support persons," who perform specific disability-related functions for patients with disabilities when necessary to have an equal opportunity to obtain and benefit from health care services.

Protecting older adults and individuals with disabilities from discrimination in Crisis Standards of Care (CSC) Plans during the COVID-19 Pandemic

 Pursuant to Section 504, Title II of the ADA, the Age Act, and Section 1557, OCR Regional Offices evaluated allegations of age and disability discrimination in state-wide CSC plans. Through this effort, OCR has achieved case resolutions that serve as models in the implementation of non-discriminatory practices to serve older adults and individuals with disabilities during the COVID-19 national public health emergency.

Supporting the health care industry's response to COVID-19

- In January 2021, OCR issued a Notification of Enforcement Discretion on the use of online or web-based scheduling applications for the scheduling of COVID-19 vaccination appointments. The Notification explains that the exercise of enforcement discretion applies to covered health care providers and their business associates, including web-based scheduling application (WBSA) vendors, when the WBSA is used in good faith and only for the limited purpose of scheduling individual appointments for COVID-19 vaccinations during the COVID-19 nationwide public health emergency.
- In September 2021, OCR issued guidance on HIPAA, COVID-19 Vaccinations, and the Workplace. This guidance addresses common workplace scenarios and answers questions about when the HIPAA Privacy Rule applies to disclosures and requests for information about whether a person has received a COVID-19 vaccine.

Securing access to service animals for persons with disabilities during the COVID-19 Pandemic

• In response to complaints OCR received on behalf of individuals who had travelled to a foreign country with their service animal (a dog trained to perform necessary tasks for the person with a disability), OCR worked with the CDC to help the individuals address obstacles in getting the right documents approved to be able to return to the U.S. with their service animal in a timely fashion. With quick action, and crucial cooperation from the CDC, the travelers with a disability and their family members were able to have the problem resolved before running out of necessary prescription medication, other supplies, or experiencing other potentially harmful consequences.

Providing the ability for HHS employees of all faiths to safely volunteer to serve unaccompanied children

• OCR provided proactive technical assistance to the Office for Refugee Resettlement to ensure that ORR's mask-fitting procedures accommodated employees whose faith requires them to maintain a beard, enabling HHS employees of all religious beliefs to safely volunteer to assist unaccompanied children at the border during the pandemic.

Assuring non-discrimination in admissions to skilled nursing facilities for those participating in medication assisted treatment recovery programs.

- In December 2021, OCR and the United States Attorney's Office for the District of Massachusetts entered into an agreement with The Oaks, a skilled nursing facility operated by Life Care Centers of America, Inc. The complainant alleged that, in violation of Section 1557, Section 504, and Title III of the ADA, he was denied admission to the Oaks because he was taking an FDA-approved medication to treat Opioid Use Disorder (OUD). Under the terms of the agreement, The Oaks will, among other things, revise its admissions policy; and provide training to admissions personnel on Federal civil rights laws and OUD to ensure that, in the future, it will not deny admission to individuals with disabilities because they are taking an OUD medication. Under DOJ's Title III authority, The Oaks also will pay a civil penalty in the amount of \$5,000.00.
- In August 2021, OCR and the United States Attorney's Offices in the Districts of Rhode Island and Massachusetts reached an agreement with twelve skilled nursing facilities in Rhode Island and Massachusetts operated by Genesis HealthCare Inc. to resolve allegations that the facilities denied admission to prospective residents because they were taking an FDAapproved medication assisted treatment to treat OUD, in violation of Section 1557, Section 504, and Title III of the ADA. Under the terms of the agreement, the twelve skilled nursing facilities will, among other things, adopt a non-discrimination policy, and provide training on federal civil rights laws and OUD to admissions personnel. The company will also pay a civil penalty of \$60,000 to DOJ, which will be forgiven if the facilities comply with the terms of the agreement.

Ensuring nondiscrimination based on HIV status for patient seeking orthopedic care in Michigan.

 In March 2021, OCR and the United States Attorney's Office for the Eastern District of Michigan reached an agreement with Great Lakes Surgical Associates (GLSA) to protect patients from discrimination on the basis of HIV status. The complainant, an African-American man and a Medicare beneficiary, filed a complaint after GLSA allegedly refused to fully evaluate him for bariatric surgery or to provide him with surgery due to complainant's HIV status, in violation of the ADA, Section 1557, and Section 504. OCR secured several corrective actions from GLSA, including adoption of a grievance procedure and designation of a Civil Rights Coordinator, implementation of policies and procedures for providing services in a nondiscriminatory manner to persons with disabilities, and an agreement to provide training to all personnel on their obligations to not discriminate against individuals with disabilities. Under DOJ's Title III authority, GLSA will also compensate the complainant in the amount of \$37,000.

Addressing multiple violations of HIPAA which led to the breach of unsecured protected health information affecting more than 9.3 million people

Office for Civil Rights

 Excellus BlueCross BlueShield and Univera Healthcare, Lifetime Health Medical Group, Lifetime Benefit Solutions, Lifetime Care, and The MedAmerica Companies (collectively "Excellus Health Plan") agreed to pay \$5.1 million to OCR to settle a data breach affecting over 9.3 million people. The breach was the result of cyber-attackers gaining unauthorized access and installing malware and conducting reconnaissance activities to Excellus' information technology systems that resulted in the impermissible disclosure of protected health information, including names, addresses, dates of birth, email addresses, Social Security numbers, bank account information, health plan claims, and clinical treatment information. In addition to the \$5.1 million-dollar monetary settlement, Excellus Health Plan agreed to undertake a corrective action plan that includes two years of monitoring and will address its failure to conduct an enterprise-wide risk analysis, and failures to implement risk management, information system activity review, and access controls as required by the Health Insurance Portability and Accountability Act (HIPAA).

Establishing effective communication for deaf individuals seeking medical services

- In November 2021, pursuant to Section 1557, Section 504, and Title III of the ADA, OCR and the United States Attorney's Office for the District of Massachusetts entered into a voluntary resolution agreement with Baystate Medical Center (Baystate) to ensure effective communication with individuals who are deaf or hard of hearing. The Agreement resolves a complaint filed on behalf of a patient who is deaf and uses American Sign Language (ASL) interpreters. According to the complaint, despite receiving a request for an ASL interpreter prior to the patient's scheduled arrival to have labor induced, Baystate failed to take appropriate steps to ensure that the communications with the patient during labor and childbirth were effective. As a result of the HHS OCR and DOJ joint investigation, Baystate agreed to enter into the agreement; affirm its compliance with federal civil rights laws; take steps to ensure the availability of auxiliary aids and services; consent to monitoring; and, under DOJ's ADA Title III authority, pay \$135,000 in compensatory relief.
- In August 2021, OCR successfully resolved a complaint filed by a deaf individual on behalf of his deaf mother alleging that Hudson Valley Radiology Associates (HVRA) denied their requests for an American Sign Language (ASL) interpreter for his mother's scheduled appointment. As a result of OCR's investigation and technical assistance, HRVA committed to reviewing and revising its Patient Communication Policy and procedure for effective communication with persons who are deaf or hard of hearing, including the provision of appropriate auxiliary aids and services and accommodations; notifying staff that they cannot require a family member, advocate or friend of a deaf or hard of hearing patient/companion to interpret or facilitate communications between staff; and training all its staff on all updated policies and procedures.

Supporting the Department of Justice efforts to provide states models for Extreme Risk Protection Orders

On December 20, 2021, OCR issued guidance to help clarify how the HIPAA Privacy Rule permits covered health care providers to disclose protected health information to support applications for extreme risk protection orders that temporarily prevent a person in crisis, who poses a danger to themselves or others, from accessing firearms.

Funding History

Fiscal Year	Amount
FY 2019	\$38,666,634
FY 2020	\$38,798,000
FY 2021 Final	\$38,681,519
FY 2022 CR	\$38,798,000
FY 2023 President's Budget	\$60,250,000

Budget Request

The FY 2023 President's Budget request for the Office for Civil Rights is \$60,250,000 which is \$21,452,000 above the FY 2022 Annualized Continuing Resolution and \$12,319,000. OCR will invest \$9 million in adding staff to enhance enforcement activities related to dramatic case receipt increases. Funds will also support OCR's civil rights policy and enforcement work in the areas of race, disability, sex discrimination, child welfare, and environmental justice as requested in the FY 2022 Budget. Additional investments will be made in other key areas, including:

- +\$8,164,000 for additional resources to address the existing complaint inventory
 - Complaints received by OCR have risen significantly in recent years. Case receipts increased from 1,948 cases in 2003 to 45,832 in fiscal year 2021. As a result, OCR is limited in the number of complaints per year that it is able to resolve through a full investigative process. The trend of case receipts is estimated to further increase in FY 2022 as OCR received nearly 46,000 complaints in FY21. OCR must therefore reevaluate its projection methodology. Historically, OCR has used approximately 10% to approximate future case receipts, but in FY21 the increase was over double that amount. Given the trend in complaints to OCR as well as the priorities articulated by the Administration, OCR anticipates a significant increase in the number of civil rights, information breaches, and cybersecurity complaints.
 - OCR requires this increase in FY 2023 to address the increased levels of complaints as well as breaches of unsecured PHI affecting more than 500 individuals increase every year.⁷
 - During the time that the caseload has risen dramatically, OCR has experienced a large decrease in staffing available to resolve complaints. The number of investigators has dropped from 121 investigators in 2003 to 77 investigators in 2020.
 - 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 new regional investigators to resolve new civil rights and HIPAA cases, address the backlog of complaints, and initiate compliance reviews in the Administration's priority areas.
 - OCR intends to add 37 additional investigators and supervisory investigators in FY 2023. These additional FTEs will be brought on to augment the regional staff who

⁷ OCR received 683 breaches in CY 2020, a 30% increase from the prior year.

work on cases, breaches, compliance reviews, and other enforcement actions. With this increase, OCR estimates it will result in the backlog being eliminated by FY 2026.

- +\$2,140,000 for added staff to ensure Department-wide civil rights compliance and policy development by augmenting technical assistance to HHS components, review of HHS regulations, and training for HHS grantees.
 - Additional resources will ensure OCR's ability to: meet its existing oversight and enforcement obligations; advance the President's Executive Orders increasing equity in government programs and services; and implement recent Supreme Court decisions on federal civil rights. Compliance with these Executive Orders and Supreme Court decisions requires a significant expansion in OCR's case adjudication, compliance, policy, technical assistance, and outreach efforts.
 - OCR will add FTEs with appropriate subject matter expertise to address these broader requirements. An additional 10 staff (FTEs) will provide technical assistance, review of regulations, training for grantees and subject matter expertise to Operating and Staff Divisions in support of a whole-of-government approach to civil rights compliance. This funding will help ensure that the Department is meeting its obligations under existing federal civil rights laws.
 - OCR plans to continue expanding its work on high-impact cases, which require significant time and resources, by initiating compliance reviews in priority areas that have a national impact. Resolutions in high-impact cases often bring about systemic change across states, health systems, and human service programs; and are used as models to inform and protect the public. The Administration has clearly laid out a set of priorities, which encompass OCR's areas of expertise. Consistent with the Administration's vision, OCR can play a critical role by initiating compliance reviews to address inequities in vulnerable communities. Additional investments in OCR are necessary to advance the Administration's vision; strengthen civil rights enforcement; and combat harassment, and discrimination against members of vulnerable communities.
 - OCR anticipates that this funding will support several new sections in the Civil Rights Division, which are likely to include: (1) a new sex discrimination policy section; (2) a new sex discrimination enforcement section, which would ensure internal HHS compliance and external recipient compliance, with Title IX, Section 1557, and Executive Order 13988: *Preventing and Combating Discrimination on the Basis of Gender Identity or Sexual Orientation*; (3) a new race, color, national origin discrimination policy section; and (4) a new race, color, national origin enforcement section, which would ensure internal HHS compliance and external recipient compliance, with Title VI, Section 1557, and Executive Order 13985: *Advancing Equity and Support for Underserved Communities Through the Federal Government*.
- +\$2,015,000 for the White House Initiative on Asian Americans, Native Hawaiians, and Pacific Islanders

Office for Civil Rights

- The White House Initiative on Asian Americans, Native Hawaiians, and Pacific Islanders and President's Advisory Commission on Asian Americans, Native Hawaiians, and Pacific Islanders are both co-chaired by HHS Secretary Xavier Becerra and housed within HHS per Executive Order 14031. Both entities are tasked with developing, monitoring, and coordinating executive branch efforts to advance equity, justice, and opportunity for Asian American, Native Hawaiian, and Pacific Islander (AA and NHPI) communities throughout the entirety of the Federal government by working in close collaboration with the White House.
- The Commission consists of 25 leaders appointed by the President who advise him on ways the public, private, and non-profit sectors can work together to advance equity, justice, and opportunity for AA and NHPI communities.
- The Initiative components include its Interagency Working Group and Regional Network: 1) The Interagency Working Group comprises senior-level Executive Branch officials from more than 35 federal agencies and offices who coordinate the Initiative's work across the federal government. The IWG is tasked with creating and implementing agency plans to increase participation in and access to federal grants, programs, and initiatives in which AA and NHPI communities may be underserved. The Regional Network includes over 300 members in the 10 federal regions, representing dozens of federal agencies. The Regional Network aims to build relationships between the federal government and AA and NHPI communities by coordinating outreach efforts and connecting community stakeholders with federal resources.

Nonrecurring Expenses Fund

Budget Summary

(Dollars in Thousands)

	FY 2021 ²	FY 2022 ³	FY 2023 ⁴
Notification ¹		2,300	

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 use of the funds for capital acquisitions necessary for the operation of the Department, specifically information technology (IT) and facilities infrastructure acquisitions.

OCR received funding in FY 2022 for the OCR Management Information System (OMIS) project, retitled PIMS NEXTGEN for next generation. This project is an in-depth technical assessment of the OCR Program Information Management System (PIMS) which was implemented in 2000. PIMS integrates OCR's various business processes, including all of its compliance activities, correspondence tracking, and records management to allow for real-time access, results reporting and various information management needs in support of its civil rights and patient privacy compliance responsibilities and is the OCR system of record. Although OCR has made several system improvements to PIMS since its original implementation in 2000, many of the application processes are no longer in-sync with OCR business processes. While PIMS has kept up with the requirements of security regulations, PIMS NEXTGEN will allow OCR to incorporate cutting-edge security protocols. This makes the PIMS NEXTGEN project extremely important to OCR's continued mission success.

⁴ HHS has not yet notified for FY 2023.

¹Pursuant 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 October 22, 2020.

³Notification submitted to the Committees on Appropriations in the House of Representatives and the Senate on June 17, 2021.

Section 4: Supplementary Tables

Budget Authority by Object Class

(Dollars in Thousands)

Object Class Code	Description	FY 2021 Final	FY 2022 Annualized CR	FY 2023 President's Budget	FY 2023 +/- FY 2022
11.1	Full-time permanent	15,077	17,237	29,694	+12,457
11.3	Other than full-time permanent	356	367	815	+448
11.5	Other personnel compensation	464	480	716	+236
11.7	Military personnel	131	134	140	+6
Subtotal	Personnel Compensation	16,028	18,218	31,365	+13,147
12.1	Civilian personnel benefits	5,406	6,181	10,674	+4,493
12.2	Military benefits	8	9	10	+1
13.0	Benefits for former personnel	136	116	120	+4
Total	Pay Costs	21,578	24,524	42,169	+17,645
21.0	Travel and transportation of persons	9	88	886	+798
22.0	Transportation of things	2	5	10	+5
23.1	Rental payments to GSA	3,609	3,689	4,021	+332
23.3	Communications, utilities, and misc. charges	95	98	100	+2
24.0	Printing and reproduction	275	179	181	+2
25.2	Other services from non-Federal sources	1,743	2,629	3,496	+867
25.3	Other goods and services from Federal sources	10,648	6,740	8,154	+1,414
25.4	Operation and maintenance of facilities	348	377	351	-26
25.7	Operation and maintenance of equipment	349	361	286	-75
Subtotal	Other Contractual Services	13,088	10,107	12,287	+2,180
26.0	Supplies and materials	25	78	162	+84
31.0	Equipment	1	30	434	+404
Total	Non-Pay Costs	17,104	14,274	18,081	+3,807
Total	Budget Authority by Object Class	38,682	38,798	60,250	+21,452

Salaries and Expenses Table (Dollars in Thousands)

Object Class Code	Description	FY 2021 Final	FY 2022 Annualized CR	FY 2023 President's Budget	FY 2023 +/- FY 2022
11.1	Full-time permanent	15,077	17,237	29,694	+12,457
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25.7	Operation and maintenance of equipment	349	361	286	-75
Subtotal	Other Contractual Services	13,088	10,107	12,287	+2,180
26.0	Supplies and materials	25	78	162	+84
Total	Non-Pay Costs	13,494	10,555	13,626	+3,071
Total	Salary and Expenses	35,072	35,079	55,795	+20,716
23.1	Rental payments to GSA	3,609	3,689	4,021	+332
Total	Salaries, Expenses, and Rent	38,681	38,768	59,816	+21,048
Total	Direct FTE	127	141	232	+91

Detail of Full-Time Equivalent (FTE)

Detail	FY 2021 Actual Civilian	FY 2021 Actual Military	FY 2021 Actual Total	FY 2022 Estimate Civilian	FY 2022 Estimate Military	FY 2022 Estimate Total	FY 2023 Estimate Civilian	FY 2023 Estimate Military	FY 2023 Estimate Total
Direct	126	1	127	140	1	141	231	1	232
Reimbursable	54	-	54	49	-	49	49	-	49
Total FTE	180	1	181	189	1	190	280	1	281

Average GS Grade

FY 2019: GS 13 FY 2020: GS 13 FY 2021: GS 13 FY 2022: GS 13 FY 2023: GS 13

Detail of Positions

Detail	FY 2021 Final	FY 2022 Annualized CR	FY 2023 President's Budget
Executive level I	-	-	-
Executive level II	3	3	3
Executive level III	-	1	1
Executive level IV	-	-	1
Executive level V	1	1	-
Subtotal	4	5	5
Total - Executive Level Salaries	763,625	961,000	1,005,100
GS-15	23	24	32
GS-14	24	26	42
GS-13	32	34	51
GS-12	34	39	88
GS-11	3	3	4
GS-10	-	-	-
GS-9	5	8	8
GS-8	-	-	-
GS-7	1	1	1
GS-6	-	-	-
GS-5	-	-	-
GS-4	-	-	-
GS-3	-	-	-
GS-2	-	-	-
GS-1	-	-	-
Subtotal	122	135	226
Total - GS Salary	14,669,375	16,643,000	29,503,900
Average ES level	190,906	192,200	201,020
Average ES salary	III	III	III
Average GS grade	13.6	13.6	13.6
Average GS Salary	120,241	123,281	131,128

National Coordinator for Health Information Technology



DEPARTMENT of HEALTH and HUMAN SERVICES

Fiscal Year

2023

Office of the National Coordinator for Health Information Technology

> *Justification of Estimates to the Appropriations Committee*



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, coordinating federal health IT policies, technology standards, and programmatic investments, and promoting adoption of health IT and use of health information to enhance the health and well-being of all US residents.

Federal Health IT Strategic Plan Mission

ONC's mission, adopted from the <u>Federal Health IT Strategic Plan 2020 – 2025</u>, 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 2023 Priorities

- 1. Promoting *seamless, secure information-sharing* among providers, patients, and other healthcare stakeholders using modern, open-industry, internet-based technologies
- 2. Building on federal investments in electronic health records *to improve the access, exchange, and use of electronic health information* and advance quality, equitability, safety, efficiency, accessibility, and affordability of US healthcare
- 3. Enabling an *open health IT ecosystem* to ensure a level playing field for innovation and competition to support health IT users, including patients
- 4. Furthering *universal access to secure, usable information exchange technologies* through nationwide networks and application programming interfaces (APIs)
- 5. Fostering the use of health IT and health information to identify and address *health equity* issues in healthcare delivery, public health, and population health
- 6. Facilitating the *success of federal programs* through the effective use of health IT and health information

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 2023 President's Budget Request

Dear Reader,

More than a decade has passed since the HITECH Act set the U.S. health system on a path to creating a truly digital healthcare system. At its passage in 2009, the health system still lagged behind many major industry sectors and industrialized countries with respect to electronic health record (EHR) adoption. Clinicians used pen and paper to capture important information from clinical encounters, which were stored in manila folders and file cabinets. Information sharing for care coordination was limited and at a time when individuals were using the internet throughout their daily lives our health system offered few options for them to easily access their electronic health information.

The foundation set by the HITECH Act and subsequent 21st Century Cures Act dramatically changed this paradigm. The industry has made tremendous progress. By the end of the 2010s the vast majority of hospitals and clinicians use EHRs, clinical data is being captured electronically using common data standards, and electronic health information is routinely being shared via health information networks and, increasingly, modern application programming interfaces (APIs). However, this progress is not universal across the country and is affected by different priorities, resources, and business models among industry actors. Other providers across the care continuum such as long-term and post-acute care, behavioral health, and home and community-based providers who were ineligible for incentive payments lag behind in terms of EHR adoption and, thus, their ability to engage in interoperable exchange.

The COVID-19 pandemic exposed many challenges in the nation's healthcare system, particularly the need for more reliable data, especially to support vulnerable individuals and those persistently marginalized by the medical community. In addition, although significant funding under the HITECH Act propelled EHR adoption among hospitals and physician offices, corresponding levels of resources were not provided to our public health IT systems. As a result, public health agencies at the State, Tribal, Local, and Territorial and federal levels were not able to make full use of the large installed base of EHR systems and we saw one-way data flows, overwhelmed public health data systems, and manual data review that led to limited actional data for decision making and no ability to provide real-time feedback to communities.

As we look towards the future, we are focused on driving change that actively uses the digital foundation built over the past decade. ONC's FY 2023 Budget Request reflects the actions and investments necessary to take these earlier investments to the next level and drive transformation to a "digitally native" healthcare system. ONC will work with partners in the public and private sectors to advance a health IT ecosystem that benefits patients, providers, payers, public health, federal agencies, and developers. This approach will leverage open-industry, platform-based business and technical models that have delivered tremendous efficiency and quality in other parts of the economy and will enable a rich and thriving healthcare app ecosystem to complement the EHR systems in place today to benefit patients as well as providers. Health information networks should operate as information and transaction backbones with high reliability and efficiency and to make basic clinical data available universally across the continuum in a low-cost, consistent way. Most importantly, this system should be built to identify health inequities and facilitate interventions that prevent such inequities from further turning into healthcare disparities.

ONC's FY 2023 Budget Request continues our focus on advancing interoperability, strengthening the public health infrastructure, empowering patients and clinicians with the most advanced information technology, enabling federal agency partners to make the most cost-effective use of health IT, and

accelerating the implementation of the 21st Century Cures Act. Through continued investments in policy development and coordination, along with standards, certification, and interoperability, we will carry out HHS' commitment to ensuring every American can obtain their full health potential.

/Micky Tripathi/ Micky Tripathi, Ph.D. M.P.P National Coordinator for Health IT

FY 2023 Budget Request

Justification of Estimates to the Appropriations Committee Office of the National Coordinator for Health Information Technology

Contents



Organizational Chart

Organizational Chart – Text Version

- Immediate Office of the National Coordinator .
 - o 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 0
 - o Lisa A. Lewis Person, Deputy National Coordinator for Operations
- Office of Policy ٠
 - o Elise Sweeney Anthony, J.D., Executive Director
- Office of Technology ٠
 - o Avinash Shanbhag, Executive Director
- Office of the Chief Operating Officer ٠
 - o Lisa A. Lewis Person, 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.

ONC's mission, goals, and objectives originate from three laws; 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).

While ONC is a small part of Federal spending on healthcare, ONC's activities are central to creating a patient-centric, equitable health system that works to improve the overall quality, safety, efficiency, and affordability of healthcare and identify and address social determinants of health and other health inequities to mitigate health disparities.

The importance of **coordinating** health IT activities across Federal agencies has dramatically increased in recent years. In particular, a growing number of agencies now seek to leverage electronic health records and other health IT capabilities to advance their mission interests in health equity, public health, health services research, drug and device surveillance, integration of healthcare and social services, remote diagnostics, digital therapeutics, telehealth, quality measurement, drug discovery and basic life sciences research, and other areas.

ONC contributes to health IT initiatives led by partners and engages in 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.

The availability of data exchange capabilities in electronic health record (EHR) systems significantly contributes to greater interoperability¹. The ONC **Health IT Certification Program** has become an important part of the health IT ecosystem, motivating baseline consistency in EHR systems in an otherwise highly fragmented and decentralized market, and improved health data interoperability for

¹ Yuriy Pylypchuk, Wesley Barker, William Encinosa, Talisha Searcy. Journal of the American Medical Informatics Association, Volume 28, Issue 9, September 2021, Pages 1866–1873, https://doi.org/10.1093/jamia/ocab083

patient care and patient access. The Health IT Certification Program has contributed to the successful deployment of an infrastructure of EHR systems across the country. ONC remains focused on advancing interoperability across those EHR systems by spurring access, exchange, and use of electronic health information, including through secure, standards-based APIs to enable more transparent, more efficient data sharing. In addition to supporting information exchange among those delivering healthcare, ONC's overall work is crucial to advancing patients' access to their health information and responding to public health emergencies like COVID-19.

The **standards** work led by ONC advances the technical infrastructure necessary to support the appropriate and secure **exchange** of electronic health information to individuals, caregivers, and their clinicians, leading to greater interoperability in healthcare. The secure flow of electronic health information can offer insight into health disparities and facilitate trending longitudinal health outcomes so that a care provider can have a comprehensive view of a patient's medical history when caring for patients. Interoperability in healthcare is necessary to provide high-quality, cost-effective care, identify and reducing healthcare disparities and "digital divides," and 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.

ONC has and will continue to play a critical role in transforming healthcare to be interoperable and more equitable. In fact, as interoperable health IT becomes increasingly vital to the health and well-being of the nation, demand for ONC's assistance is growing rapidly as federal agencies seek to leverage ONC's technical and policy expertise and authorities in coordination, standards, health information exchange and EHR certification. From building on regulations that incentivized the digitization of medical data within electronic health record systems to supporting greater consumer engagement and transparency through technologies, ONC is essential to achieving the Administration's priorities and making health information available when and where it matters most.

Overview of Budget Request

The FY 2023 request is \$103.6 million which is \$17.0 million above the FY 2022 President's Budget and \$41.2 above FY 2022 Annualized Continuing Resolution. This will be entirely available through the Public Health Service Act Evaluation set-aside. ONC's budget, although small compared to the overall Federal healthcare spending, has had transformative impacts on HHS programs, the health system, and private sector investments in health technology. ONC's FY 2023 Budget Request explains the Office's plan to implement a portfolio of activities driven by congressional requirements and ONC's 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 organized into three sections, summarized below, to provide 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. ONC focuses its work in this section on being robust and resilient enough to withstand substantial opposition from industry stakeholders and pragmatically focused on what it takes to make interoperability a reality.

• Technology: Standards, Certification, and Interoperability

Includes administering the ONC Health IT Certification Program; facilitating the development and promotion of technology standards that improve infrastructure and interoperability; and investing in early stage pilot projects, prototypes, and industry challenges to accelerate science and innovation and demonstrate advanced uses of health IT. Taken together, these investments 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 <u>https://HealthIT.gov</u> to promote Federal policy related to health IT; and ensuring effective operations and management through an integrated operations function.

ONC's FY 2023 request includes a proposed increase of +\$17.0 million (19.6 percent) above the FY 2022 President's Budget and a +\$41.2 million (66.1 percent) increase above the FY 2022 Annualized Continuing Resolution. Of the +\$41.2 million increase, \$18.0 million will be allocated to Policy Development and Coordination efforts to target interoperability policy work that will accelerate the exchange of information between health information exchanges by establishing common principles, terms, and conditions through the Trusted Exchange Framework and Common Agreement (TEFCA); and \$22.0 million will be allocated to Standards Coordination and Collaboration to target Federal coordination activities to further its equity-by-design approach to increase interoperability and improve equity. The request also includes an additional \$1.3 million 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 this mission by formulating the Federal Government's health IT strategy and promoting coordination of Federal health IT policies, technology standards, and programmatic investments. As the breadth and depth of Federal activities leveraging health IT have grown, ONC's coordination role has taken on greater importance in identifying areas of potential misalignment and/or opportunities for synergies across Federal agencies. 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 to fulfill 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. ONC efforts advance align to Goal 1: Protect and Strengthen Equitable Access to High Quality and Affordable Healthcare, Objective 1.2: "Reduce costs, improve quality of healthcare services, and ensure access to safe medical devices and drugs" of the draft HHS Strategic Plan for 2022-2026.

While ONC is a small part of Federal spending on healthcare, ONC's activities are central to creating a patient-centric, equitable health system that works to improve the overall quality, safety, efficiency, and affordability of healthcare and identify and address social determinants of health and other health inequities to mitigate health disparities. HHS' holistic approach to its technology-related initiatives centers on enabling healthcare providers and public health agencies to have seamless and timely availability of clinical information and ensuring patients have access to their health information through interoperable health IT. ONC is integral to HHS' approach.

Summary of Performance Information in the Budget Request

This budget includes performance reporting for the current fiscal year and budget planning information for the budget request. 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 reflect 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.

ONC's performance management strategy 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 2023 Budget Request on Performance

ONC's FY 2023 request includes a proposed increase of +\$17.0 million above the FY 2022 President's Budget and a +\$41.2 million increase above the FY 2022 Annualized Continuing Resolution. This provides and additional +\$18.0 million will be allocated to Policy Development and Coordination efforts to target interoperability policy work that will accelerate the exchange of information between health information exchanges by establishing common principles, terms, and conditions through the TEFCA; and an additional + \$22.0 million will be allocated to Standards Coordination and Collaboration to target Federal coordination activities to further its equity-by-design approach to increase interoperability and improve equity. The request also includes an additional \$1.3 million to allow ONC to support their staff and operational activities needed to keep pace with the agency's growing responsibilities.

All-Purpose Table

Activity		FY 2021		FY 2022	FY 2023	FY 2023 President's
	FY 2021	Supplemental	FY 2022	Supplemental	President's	Budget +/- FY 2022
	Final	Funding /1	CR /2	Funding /3	Budget	Enacted
TOTAL, ONC	62,180	\$19,500	\$62,367	\$0	\$103,614	\$41,247
Program Level						
TOTAL, ONC	62,180	\$19,500	\$62,367	\$0	\$0	(\$62,367)
Budget Authority						

(Dollars in Thousands)

1/ This column includes both supplemental funding and mandatory funds appropriated in the American Rescue Plan Act of 2021, P.L. 117-2 post-transfer and post-reallocation and the supplemental appropriation in the Consolidated Appropriations Act, 2021 (P.L. 116-260)

2/ Reflects the annualized amounts provided in the continuing resolution ending 2/18/2022

3/ This column includes both supplemental funding and mandatory funds appropriated for FY 2022 in the Infrastructure and Jobs Act and in the Build Back Better Act.

Budget Exhibits

Appropriations Language

From amounts made available pursuant to section 241 of the PHS Act, \$103,614,000 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.

Language Analysis

Language Provision	Explanation
From amounts made available pursuant to	Provides ONC's budget from PHS Evaluation
section 241 of the PHS Act, \$103,614,000 shall	funding.
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.	

Amounts Available for Obligation

			FY 2023
	FY 2021		President's
	Final	FY 2022 CR	Budget
General Fund Discretionary Appropriation:			
Appropriation (L/HHS)	\$62,367,000	\$62,367,000	\$103,614,000
Subtotal, Appropriation (L/HHS, Ag, or Interior)	\$62,367,000	\$62,367,000	\$103,614,000
Subtotal, adjusted appropriation	\$62,367,000	\$62,367,000	\$103,614,000
Real transfer to: (ACF)	(187,241)		\$0
Subtotal, adjusted general fund discr. appropriation	\$62,179,759	\$62,367,000	\$103,614,000
Total, Discretionary Appropriation	\$62,367,000	\$62,367,000	\$103,614,000
Total Obligations	\$62,179,759	\$62,367,000	\$103,614,000
0			

Summary of Changes

2022 CR	
Total estimated budget authority	\$62,367,000
Total estimated program level	\$62,367,000
2023 President's Budget	
Total estimated budget authority	\$0
Total estimated program level	\$103,614,000
Net Change in budget authority	-\$62,367,000
Net Change in program level	+\$41,247,000

	FY	2022 CR	FY 2023 President's Budget		F	FY 2023 +/- FY 2022	
	FTE	BA	FTE	PL	F	ΓE BA/PL	
Increases:							
A. Program:							
1. Health IT, PHS Eval	180	\$0	180	\$103,614,000	-	\$103,614,000	
Subtotal, Program Increases	180	\$0	180	\$103,614,000	-	\$103,614,000	
Total Increases	180	\$0	180	\$103,614,000	-	\$103,614,000	
Decreases:							
A. Program							
1. Health IT, BA Subtotal, Program	180	\$62,367,000	180	\$0	-	(\$62,367,000)	
Decreases	180	\$62,367,000	180	\$0	-	(\$62,367,000)	
Total decreases	180	\$62,367,000	180	\$0	-	(\$62,367,000)	
Net Change	-	-	-	-	-	+\$41,247,000	

Budget Authority by Activity

(Dollars in Thousands)

	FY 2021 Final	FY 2022 CR	FY 2023 President's Budget
1. Health IT			
Annual Budget Authority	\$62,180	\$62,367	\$0
Annual Program Level	\$62,180	\$62,367	\$103,614
Subtotal, Health IT	\$62,180	\$62,367	\$0
Total, Budget Authority	\$62,180	\$62,367	\$0
Total, Program Level FTE	\$62,180 180	\$62,367 180	\$103,614 180

Authorizing Legislation

	FY 2022 Amount Authorized	FY 2022 Amount Appropriated	FY 2023 Amount Authorized	FY 2023 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 Program Level Total Request Level	Indefinite	\$62,367,000 \$ - \$62,367,000	Indefinite	\$- \$103,614,000 \$103,614,000

Appropriations History

Each Year is General Fund Appropriation	Request to Congress	House Allowance	Senate Allowance	Appropriation
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)				(\$187,241)
Subtotal	\$50,717,000	\$60,367,000	\$60,367,000	\$62,179,759
FY 2022				
Annual				62,367,000
PHS Evaluation Funds	\$86,614,000	\$86,614,000	\$86,614,000	
Subtotal	\$86,614,000	\$86,614,000	\$86,614,000	
FY 2023				
Annual				
PHS Evaluation Funds	\$103,614,000			
Subtotal	\$103,614,000			

Narrative by Activity

	FY 2021 Final	FY 2022 CR	FY 2023 President's Budget	FY 2023 +/- FY 2022
BA	\$62,179,759	\$62,367,000	\$0	-\$62,367,000
PHS Eval Funds	\$0	\$0	\$103,614,000	\$103,614,000
PL	\$62,179,759	\$62,367,000	\$103,614,000	+\$41,247,000
FTE	180	180	180	0

Health IT

Authorizing Legislation

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 2023, ONC will implement its authorities and requirements to accelerate progress to an interoperable nationwide health IT infrastructure by pursuing the following objectives:

- 1. Promoting *seamless, secure information-sharing* among providers, patients, and other healthcare stakeholders using modern, open-industry, internet-based technologies
- 2. Building on federal investments in electronic health records *to improve the access, exchange, and use of electronic health information* and advance quality, equitability, safety, efficiency, accessibility, and affordability of US healthcare
- 3. Enabling an *open health IT ecosystem* to ensure a level playing field for innovation and competition to support health IT users, including patients
- 4. Furthering *universal access to secure, usable information exchange technologies* through nationwide networks and application programming interfaces (APIs)
- 5. Fostering the use of health IT and health information to identify and address *health equity* issues in healthcare delivery, public health, and population health
- 6. Facilitating the *success of federal programs* through the effective use of health IT and health information

Sub Activities at ONC²

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 under relevant statutes and executive orders, including: (1) policy and rulemaking activities, such as writing the rule text to implement the Cures Act; (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 <u>HealthIT.gov</u>; and the agency's operations and administration functions.

² 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: <u>https://www.federalregister.gov/documents/2018/05/02/2018-09361/statement-of-organization-functions-and-delegations-of-authority-office-of-the-national-coordinator.</u>

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.³ At its inception, ONC's primary efforts focused on strategic planning, building the National Health Information Network, supporting health IT certification, and stimulating collaboration on health IT standards 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 incent and guide the development and adoption of a more comprehensive nationwide health IT infrastructure via the Medicare and Medicaid 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.⁴

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.⁵

While nationwide stakeholders worked to implement commitments in the *Roadmap*,⁶ in **2015** Congress placed further emphasis on achieving widespread interoperability in MACRA. With MACRA introduced, the Medicare EHR Incentive Program for eligible professionals 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.⁷

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 prevent anti-competitive business practices related to the access, exchange, and use of electronic health information, which are now referred to as "information blocking." The bipartisan goal was to promote friction-free information-sharing among providers and other healthcare delivery actors, and with patients. We expect increased information-sharing will benefit

³ Executive Order 13335: <u>https://www.gpo.gov/fdsys/pkg/WCPD-2004-05-03/pdf/WCPD-2004-05-03-Pg702.pdf.</u>

⁴ Hospitals: <u>https://dashboard.healthit.gov/evaluations/data-briefs/non-federal-acute-care-hospital-ehr-adoption-2008-2015.php.</u> Physicians: <u>https://dashboard.healthit.gov/quickstats/pages/physician-ehr-adoption-trends.php.</u>

⁵ <u>https://www.healthit.gov/topic/interoperability/interoperability-road-map-statements-support.</u>

⁶ <u>https://www.healthit.gov/sites/default/files/12-19-YearInReviewPrezi-508-LowRes.pdf.</u>

⁷ <u>https://www.healthit.gov/buzz-blog/health-data/numbers-progress-digitizing-health-care/</u>

the entire healthcare system by opening up new technology approaches and business models that also directly engage patients themselves.

In March 2020, ONC released the <u>Cures Act Final Rule</u> 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 of the Rule is to facilitate providers' and patients' access 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

- Advancing Policy and Coordination for Public Health Data Systems: In FY 2021 ONC's policy related work contributed significantly to building a stronger infrastructure to support the intersection of public health with clinical data systems. ONC's HITAC established the Public Health Data Systems Task Force 2021, which consisted of 21 industry and federal experts and provided 52 recommendations on a variety of public health data systems needs. Topics addressed in the recommendations include laboratory and case reporting, immunizations, syndromic surveillance, situational awareness, infrastructure, health equity, and individual engagement. The HITAC recommendations are informing HHS's response to President Biden's Executive Order on Ensuring a Data-Driven Response to COVID-19 and Future High-Consequence Public Health Threats. With funding from the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), the Strengthening the Technical Advancement and Readiness of Public Health Agencies via Health Information Exchange (STAR HIE) Program continued efforts to build innovative health information exchange services available to support communities disproportionately impacted by the COVID-19 pandemic. As of January 2022, the following has been accomplished:
 - Thirteen awardees have signed new or modified existing public health memoranda of understanding or data sharing agreements facilitating easier access to lab reporting, case reporting, and/or immunization data;
 - Seven awardees have developed and offered new enriched data reports and data visualization tools; and
 - Nine awardees have increased data sharing between HIEs and jurisdictional Immunization Information Systems (IIS).

Additionally, new COVID-19 provider notification tools have been deployed under the STAR HIE Program.

 HEALTHeLINK, a regional health information organization covering Western New York, developed an approach to deliver COVID-19 test result notifications via Direct Message (Admission, Discharge, and Transfer alerts) and reports to providers, hospitals, and health departments as needed.

- HealthShare Exchange of Southeastern Pennsylvania (HSX) improved their region's pandemic response by developing bulk reports of patients' vaccine status to organizations doing outreach. Reports are pushed to the organizations several times a week with updated results, compared to one patient at a time lookups from the vaccine registries.
- Bronx RHIO expanded their COVID-19 test result alerts and reporting to include alerts and reporting on vaccination status.

Through the STAR HIE Program, new vaccination reporting tools have also been established.

- Indiana Health Information Exchange (IHIE) successfully launched a COVID-19 vaccination reporting tool.
- The Kansas Health Information Network (KHIN) is reducing physician and public health burden by developing a solution for providers to electronically report COVID-19 lab results to their public health agency.
- The Texas Health Services Authority is demonstrating standards-based, real-time reporting of hospital capacity data for the purpose of reducing burden on hospitals and improving data quality.

Finally, the STAR HIE Program is advancing broader health equity goals.

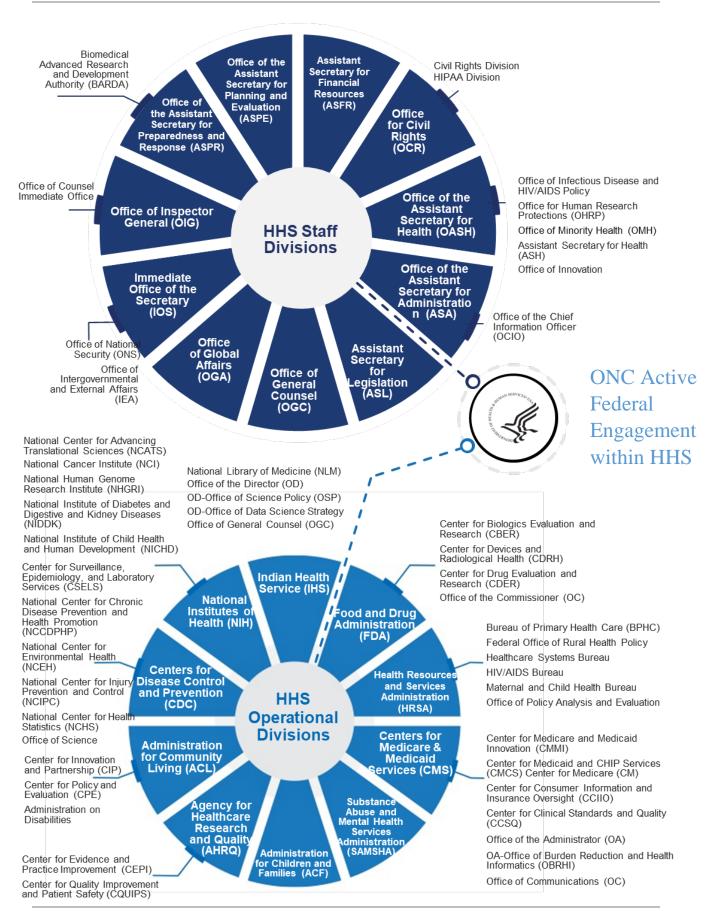
- HSX currently produces surveillance reports for their members, including data on race. The surveillance reports highlight the disproportionate impact on communities of color down to a zip code level to allow their members to identify and address areas for improvement.
- West Virginia Health Information Network (WVHIN) has finalized specifications for race, ethnicity, and geocoding for vaccines to enhance use of this data by public health and to address vaccination hesitancy and outreach to underserved populations.
- **Cures Act Final Rule:** Due to the COVID-19 pandemic, ONC published the <u>Interim Final Rule</u> in November 2020 to extend certain compliance dates and timeframes for Information Blocking and the ONC Health IT Certification Program that were outlined in the ONC Cures Act Final Rule (Final Rule) that was released to the public in March 2020. The Cures Act Final Rule supports a patient's right to get their electronic health information⁸ and addresses both technical barriers and business practices that impede the secure and appropriate sharing of data. The Final 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 seamless, secure information sharing among providers, patients, and other healthcare providers using modern, open-industry, internetbased technologies. The Final Rule requires that certified health IT developers make available in their products secure, standards-based APIs that help to enable an open health IT ecosystem where patients and providers have choices of applications and devices, including mobile devices, that best meet their needs and preferences for accessing, exchanging, and using electronic health

⁸ <u>https://www.healthit.gov/curesrule/</u>

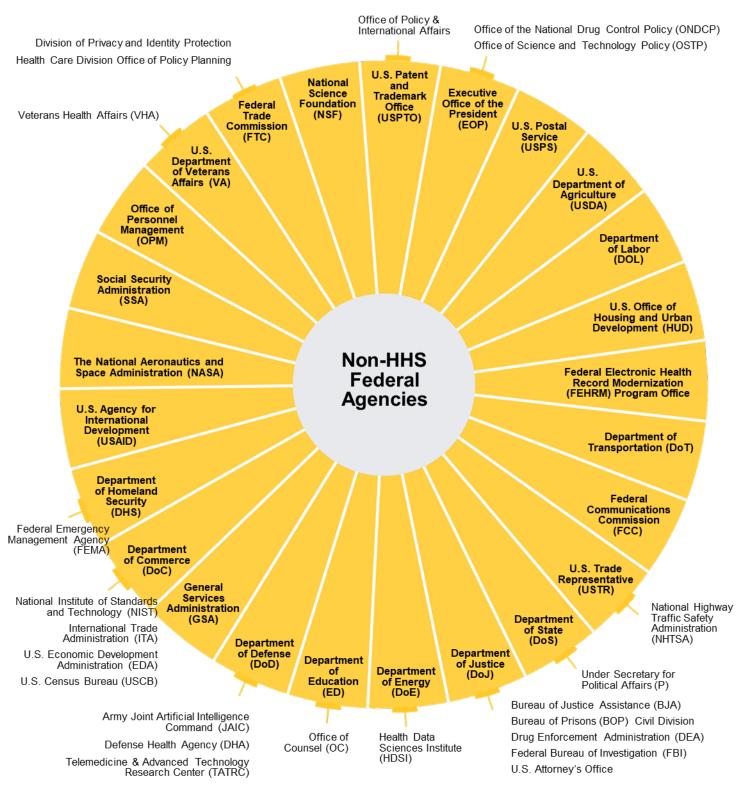
information. The Final Rule also adopts the United States Core Data for Interoperability (USCDI) as a standard to establish the baseline set of information that can be exchanged across health IT for clinical data exchange and patient access.

- Information Blocking Outreach and Engagement: Throughout FY 2021 and FY 2022, ONC emphasized outreach and education to the providers, developers, and health information networks and exchanges who need to understand both what information blocking is and what it is not, specifically in context of what the exceptions established in the Cures Act Final Rule are and how they work. ONC's outreach has included hosting office hours and webinars which are recorded and posted on healthIT.gov, publishing <u>frequently asked questions</u> (FAQs) and fact sheets on the ONC website, and participating in stakeholder-led education sessions on information blocking in general as well as specific topics. ONC's engagement activities in FY 2021 and FY 2022 included listening sessions for a wide variety of stakeholder groups share with us their experiences and questions regarding information blocking.
- Federal Health IT Coordinating Council: ONC improved Federal coordination through the Federal Health IT Coordinating Council, a voluntary group of nearly 40 Federal departments, agencies, and offices that are actively involved in implementing the national health IT agenda. In FY 2021, the Federal Health IT Coordinating Council convened five times including an average of 75 Federal representatives across 22 organizations. In FY 2021, the Coordinating Council influenced draft FHIR Guidance for Federal partners, supported efforts to update the USCDI, shared Federal progress made towards the 2020-2025 Federal Health IT Strategic Plan, and assisted in Federal health IT coordination activities related to COVID-19. The Coordinating Council also convened two work groups focused on Federal health IT standards coordination, specifically related to the FHIR standard and the USCDI.









- 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 fourth year, the HITAC serves as a priority method for obtaining routine input from a group of 27 health IT experts and 6 federal representatives, representing a broad and balanced spectrum of the healthcare system.⁹ Between October 1, 2020, and January 2022, the full HITAC held 13 meetings and its subcommittees met over 70 times to develop recommendations addressing the priority areas identified in the Cures Act. In February 2021, the HITAC published the FY 2020 Annual Report. In FY 2021, there were four HITAC Task Forces and Work Groups that provided recommendations to the National Coordinator on such public health data systems, priority uses of health IT, and health IT standards.¹⁰
 - o Active
 - Annual Report Workgroup
 - Interoperability Standards Priorities Task Force 2021
 - Public Health Data Systems Task Force 2021
 - U. S. Core Data for Interoperability Task Force 2021
 - o Inactive
 - Interoperability Standards Priorities Task Force 2018
 - Intersection of Clinical and Administrative Data Task Force
 - Trusted Exchange Framework Task Force
 - o Sunset
 - Conditions of Certification Task Force
 - Health IT for the Care Continuum Task Force
 - Information Blocking Task Force
 - U.S. Core Data for Interoperability Task Force 2019
 - U.S. Core Data for Interoperability Task Force 2020
- **Trusted Exchange Framework and Common Agreement (TEFCA)**: ONC published the Trusted Exchange Framework and the Common Agreement Version 1 in Q1 of 2022.¹¹ The Common Agreement creates baseline legal and technical requirements that will enable secure, information sharing across different networks nationwide. The publication of TEFCA was made possible due to extensive <u>public engagements</u>, webinars and workgroup sessions conducted under a four-year cooperative agreement with The Sequoia Project as the TEFCA Recognized Coordinating Entity (RCE). This partnership leverages the RCE's extensive private sector experience to develop, implement, update, and maintain the Common Agreement component of TEFCA. As of January 2022, there had been 45 webinars with almost 5,000 total participants. In addition, the RCE received and analyzed public stakeholder feedback to inform several aspects of TEFCA, including the Common Agreement itself, the technical framework for TEFCA, and proposed metrics that will be collected to measure success. As next steps, ONC and the RCE will perform public education activities and will work to inform potential signatories to the Common

¹¹ https://www.healthit.gov/sites/default/files/page/2022-

⁹ https://www.healthit.gov/hitac/committees/health-information-technology-advisory-committee-hitac/membership

¹⁰ <u>https://www.healthit.gov/topic/federal-advisory-committees/subcommittees</u>

 $^{01/}Common_Agreement_for_Nationwide_Health_Information_Interoperability_Version_1.pdf$

Agreement, with the goal of seeing live data sharing before the end of 2022.

Strategic Planning: In October 2020, ONC released the final Federal Health IT Strategic Plan 2020-2025. 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 with Health Data. The plan was developed by the ONC in collaboration with more than 25 Federal organizations and informed by nearly 100 public comment submissions. The Federal EHR Modernization Office used the goals from the Federal Health IT Strategic Plan for the Interoperability Modernization Strategy for the U.S. Department of Defense and U.S. Department of Veterans Affairs. Additionally, 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, including concrete steps that stakeholders can take to achieve that vision and enable research to happen more quickly and effectively.

Technology: Standards, Interoperability, and Certification

- Advancing Standards and Technology for Public Health Data Systems: In FY 2021, ONC's technology related work contributed significantly to building a stronger infrastructure to support the intersection of public health with clinical data systems. Examples include: A report on public health data standards, which solidified the best options for scaling FHIR-based standards and implementation guides to support expansion of interoperable data systems, a review of the technical barriers to bi-directional exchange of immunization data by the Association of State and Territorial Health Officials (ASTHO), and coordination of immunization appointment scheduling with private industries, state government health officials and various U.S. Government systems using the ONC-supported SMART Scheduling specifications to support www.vaccinefinder.org through the use of ONC developed testing infrastructure. ONC issued guidance to industry that enabled FHIR-based eCR Now application developed by the public health community to be relied for use as part of certified health IT module to demonstrate conformance with the electronic case reporting certification criterion in the regulation. This guidance helped providers and hospitals take rapid advantage of the eCR Now application while meeting the requirements of CMS Promoting Interoperability program, in support of addressing COVID-19 efforts. ONC also supported the rapid development of LOINC® codes that have been critical in accurately reporting COVID-19 infections across the country. ONC supported the operations of several standards development organizations, including HL7, IHE and LOINC that enabled health IT industry to rapidly develop solutions to address the public health needs during the pandemic.
- 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 test procedures and certification companion guides and test tools to advance interoperability and support numerous HHS Programmatic goals. The Certification Program updated the compliance timelines for the program in support of ONC's

Interim Final Rule. Additionally, the <u>Certified Health IT Product List</u> (CHPL) website was updated to provide stakeholders with appropriate information on the certification status. The Certification Program published several program resource guides to ensure that health IT industry would be able to meet the regulations efficiently. ONC also continued to make updates to the testing infrastructure that is used by the ONC-Authorized Testing Labs to support conformance to regulations.

As of September 30, 2021, the ONC Health IT Certification Program listed more than 490 certified health IT developer on the CHPL¹² and supported over 550,000 care providers and hospitals participating in Medicare and Medicaid.¹³ At the end of FY 2021, there were 715 products from 490 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 Centers for Medicare & Medicaid Services (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 requirements,¹⁴ used to standardize information across 21 distinct programs and initiatives taking place at CMS, Department of Defense (DOD), Veteran Health Administration (VHA), Health Resources and Services Administration (HRSA), and the Substance Abuse and Mental Health Services Administration (SAMHSA).¹⁵

ONC also developed and received public feedback and HITAC recommendations on draft measures for developers to report under the EHR Reporting Program. ONC intends to implement the EHR Reporting Program via notice and comment rulemaking. Data collected and reported under the program will address information gaps in the health IT marketplace and provide insights on how certified health IT is being used. ONC anticipates the initial set of EHR Reporting Program measures will focus on interoperability of electronic health information.

• United States Core Data for Interoperability (USCDI): In July 2021, ONC finalized and published <u>USCDI Version 2</u> (USCDI v2), a standardized set of health data classes and constituent data elements required in the Cures Rule for nationwide, interoperable health information exchange. As part of the USCDI v2 development process, the health IT community submitted more than 600 data classes and elements for consideration to be added to USCDI. Consistent with the Biden Administration's executive orders, <u>new data elements</u> were included in USCDI v2 to support the Administration's efforts to advance health equity, including data elements for sexual orientation, gender identity, and social determinants of health. USCDI v2 includes three new data classes and a total of 22 new data elements. The new data elements laid the foundation for the provider community to start addressing health equity considerations in the clinical setting. The USCDI Version 3 was released in January 2022. Version 3 builds on previous versions by adding data elements which intentionally address areas of healthcare inequity and disparities, underserved communities, and public health data requirements around reporting, investigations,

¹² https://dashboard.healthit.gov/quickstats/pages/FIG-Vendors-of-EHRs-to-Participating-Professionals.php.

¹³ https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/DataAndReports.html.

¹⁴ https://www.healthit.gov/topic/certification-ehrs/2015-edition-test-method.

¹⁵ https://www.healthit.gov/topic/certification-ehrs/programs-referencing-onc-certified-health-it

and emergency response. These areas align with the Administration's focus in Executive Orders Advancing Racial Equity and Support for Underserved Communities Through the Federal Government and Ensuring a Data-Driven Response to COVID-19 and Future High-Consequence Public Health Threats.

- Standards Version Advancement Process (SVAP): As part of the Cures Act Final Rule, ONC established an annual process to identify and permit certified health IT developers to voluntarily use a more advanced version of standard(s) and implementation specification(s) approved by the National Coordinator than is adopted in the ONC 2015 Edition Certification Criteria, known as SVAP. During the comment period for 2020 SVAP-eligible standards and implementation specifications (September - November 2020), a total of 34 comments were received from stakeholders on 22 standards and implementation specifications. Following a detailed review and assessment, ONC finalized a list of five versions of standards and implementation specifications that can be advanced to under the ONC Health IT Certification Program as of March 12, 2021. As part of ONC's ongoing charge to coordinate health IT across federal and industry stakeholders, we determined it was necessary to adjust our Standards Version Advancement Process (SVAP) timeline to align with standards development activity in standards development organizations. The new SVAP timeline was announced in October 2021 which will allow standards development activities to be completed in a timely manner and enabling industry adoption of latest version of USCDI. As the annual SVAP cycle continues, ONC expects developers will take advantage of newer standards versions, thus promoting interoperability more rapidly than regulatory cycles may otherwise allow.
- 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 ISA is widely used by federal agencies for their programs and serves a useful resource to the broader health IT community. The 2021 ISA, published in January 2021, added a new sub-section on the COVID-19 Novel Coronavirus Pandemic, as well as a Specialty Care and Settings "tag" for COVID-19 related interoperability needs across the ISA. In addition to the COVID-19 sub-section and Specialty Care and Settings listing, ONC added four interoperability needs connected to public health emergency response. These include sections on healthcare personnel status, the use of hospital/facility beds, lab operations (population lab surveillance), and population-level morbidity and mortality. Together, these elements can help emergency officials maintain situational awareness around public health emergencies and optimize emergency operations. The ISA website was accessed over 371,000 times in FY 2021, almost four times the 95,000 views in FY 2020.

In January 2022, ONC published the 2022 Interoperability Standard Advisory (ISA). The 2022 ISA adds two new, interoperability needs related to labs, Representing Laboratory Test Ordered and Representing Laboratory Test Performed. The 2022 ISA also adds a Work Information section with Work Information Templates interoperability need. In addition, the 2022 ISA created a new interoperability need called Representing Mass Vaccination Status within the Vocabulary/Code Set/Terminology: Public Health Emergency Preparedness and Response.

- Advancing Modern Application Program Interface (API) for Health IT: ONC partnered with Health Level Seven (HL7) standards development organization to advance the adoption and use of Fast Healthcare Interoperability Resources (FHIR) API standard. ONC supported the development of US Core, Bulk Data Access, COVID-19 FHIR Profile Library and International Patient Summary implementation guides.
- Precision Medicine Activities: ONC is advancing standards development to improve the interoperability of new and diverse types of health data, with the goal of making them easier to share, curate, aggregate, and synthesize. The Advancing Standards for Precision Medicine (ASPM) project was established to enable the collection and sharing of high-impact data found outside the care such as mobile health, sensor, and wearable data; and social determinants of health (SDOH) data. ONC undertook two demonstration projects to investigate and inform the collection and use of these data. Lessons learned from the development and demonstration projects were disseminated via a final report issued in January 2021. Additionally, ONC continued to lead segments of the Precision Medicine Initiative (PMI), including the Sync for Science and Sync for Genes projects. In November 2020, ONC published a report documenting the experiences of provider sites engaged by ONC to pilot the use of third-party applications and supporting standards-based application programming interfaces to allow patients to share their health data with researchers.

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 2.5 million visitors during FY 2021, an average of over 292,000 sessions per month and 6.8 million page views throughout the year. Over ninety percent of visitors were from outside the National Capitol area (DC, Maryland, and Virginia). Additionally, ONC's main website, <u>HealthIT.gov</u>, attracted users referred from 7,749 external websites

<u>Fiscal Year</u>	<u>Amount</u>
FY 2019 Enacted	60,367,000
FY 2020 Enacted	60,367,000
FY 2021 Final	62,179,759
FY 2022 CR	62,367,000
FY 2023 President's Budget	103,614,000

Five Year Funding History

Budget Request

ONC's FY 2023 request includes a proposed increase of +\$17.0 million (19.6 percent) above the FY 2022 President's Budget and a +\$41.2 million (66.1 percent) increase above the FY 2022 Annualized Continuing Resolution. Of the +\$41.2 million increase above the Annualized Continuing Resolution, \$18.0 million will be allocated to Policy Development and Coordination efforts to target interoperability policy work that will accelerate the exchange of information between health information exchanges by establishing common principles, terms, and conditions through the TEFCA; and \$22.0 million will be allocated to Standards Coordination and Collaboration to target Federal coordination activities to further an equity-by-design approach to increase interoperability and improve health equity. The request also includes an additional \$1.3 million to allow ONC to support their staff and operational activities needed to keep pace with the agency's growing responsibilities.

The FY 2023 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, federal agencies, state/territorial/local/tribal public health agencies, and researchers who rely on health IT. ONC's FY 2023 request supports continuously expanding work to advance the technical infrastructure necessary to support safe, equitable, and affordable healthcare; implement Cures Act requirements, and improve the interoperability of electronic health information.

Policy Development and Coordination

ONC's FY 2023 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. This budget includes an increase of \$18.0 million above the Annualized Continuing Resolution level, which will fund interoperability policy work that will accelerate the exchange of information between health information exchanges by establishing common principles, terms, and conditions through the TEFCA, and build the future healthcare data infrastructure needed to better respond to and prepare for public health emergencies.

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 2023 policy development and coordination portfolio include:

Policy Development and Support

• **Interoperability Policy** – ONC will continue to lead implementation of TEFCA, which seeks to create baseline legal and technical requirements to enable secure information sharing across different healthcare networks nationwide.

In FY 2023, following the publication of the <u>Common Agreement</u> in January 2022, ONC will promote the adoption of TEFCA by a wide range of healthcare entities, including major delivery networks and health information exchanges.

Increased funding will position ONC to make TEFCA-related 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 will 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 created by TEFCA, thereby better enabling health data to be available when and where it is needed.

The effort will accelerate adoption of and wider-scale participation in TEFCA, meaning that patients and providers will have access to more data within electronic health records, resulting in better care and broad reaching impacts to public health. It will also mean that data service companies will be able to offer more accurate and more useful data analytics for providers and payers, resulting in better quality and reduced healthcare costs.

ONC will dedicate funding for the TEFCA Recognized Coordinating Entity (RCE) - ONC's nonprofit partner that leverages its extensive private sector experience to develop, implement, update, and maintain the Common Agreement component of TEFCA - to accelerate work expanding network privacy and security enforcement and oversight. This is especially critical because healthcare networks, similar to other parts of the nation's critical infrastructure (e.g., transportation and energy sectors), are under increasing cyber threat.

ONC will provide resources for the TEFCA to support grants or cooperative agreements to state, territorial, local, and tribal public health agencies that are seeking improved outcomes relating to public health, such as investigations related to outbreaks, disease surveillance, and/or patient outreach related to vaccination efforts. The grants or cooperative agreements will address cost and sustainability barriers preventing funding recipients from leveraging the entirety of the TEFCA network.

• **Rulemaking** – A central underpinning of all ONC rulemakings is to facilitate providers' and patients' access to electronic health information and empower them to make better healthcare decisions. ONC will continue to administer rules that advance interoperability; support the access, exchange, and use of electronic health information.

In FY 2023, ONC will continue to administer rules implementing certain provisions of the Cures Act, as well as in accordance with Sec. 3004 of the Public Health Service Act (PHSA). ONC's next rule includes provisions related to: the EHR Reporting Program condition and maintenance of certification requirements under the ONC Health IT Certification Program; a process for health information networks that voluntarily adopt the TEFCA to attest to such adoption of the framework and agreement; and enhancements to support information sharing under the

information blocking regulations.

The rulemaking would also include proposals for new standards and certification criteria under the Certification Program related to real-time benefit tools and electronic prior authorization and potentially other revisions to the Certification Program.

- 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 the intersection of HIPAA Privacy and Security Rules with health IT. 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. ONC also continues to partner with industry stakeholders to advance privacy and security education.
- EHR Reporting Program ONC intends to implement the EHR Reporting Program via notice and comment rulemaking. ONC will establish the necessary program infrastructure to support data collection and reporting of the EHR Reporting Program measures by certified health IT developers. Data collected and reported under the program will address information gaps in the health IT marketplace and provide insights on how certified health IT is being used. ONC anticipates the initial set of EHR Reporting Program measures will be interoperability focused.

Stakeholder Coordination

• Federal Coordination – As stated previously, ONC will continue leading and engaging agencies which contribute to the Federal Health IT Strategic Plan¹⁶ 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 payment policy and programs, and to engage stakeholders to support provider participation; with HHS OCR to ensure and promote secure patient access to electronic health information and the privacy and security of health IT; and with the HHS OIG, FTC, and DOJ to define and enforce standards for data sharing and prohibiting information blocking.

Federal coordination efforts will also focus on expanding the USCDI standard and the new ONC initiative called USCDI+ to support the identification and establishment of domain or program-specific datasets that will operate as extensions to the existing USCDI. The USCDI+ initiative included USCDI+ Public Health which standardizes public health dataset to improve the U.S. public health data infrastructure; and USCDI+ Quality which improves quality measures to be less burdensome for providers.

ONC is currently coordinating with 16 federal entities on USCDI and USCDI+. USCDI+ is a service that ONC will provide to federal partners who have a need to establish, harmonize, and advance the use of interoperable datasets that extend beyond the core data in the USCDI in order

¹⁶ <u>https://www.healthit.gov/topic/2020-2025-federal-health-it-strategic-plan</u>

to meet agency-specific programmatic requirements. This approach will allow ONC to better serve its federal partners, assure that extensions build from the same core USCDI foundation, and create the opportunity for aligning similar data needs across agency programs. USCDI+ efforts for quality measurement and public health are starting with the Centers for Medicare & Medicaid Services and Centers for Disease Control and Prevention, and more may be added. In addition to USCDI, ONC will continue to coordinate with over 20 federal entities to accelerate the development and use of the FHIR® standard to improve electronic health information exchange needs of federal agencies. Other time limited and topic focused workgroups administered under the Federal Health IT Coordinating Council include, TEFCA, digital health innovations, and federal health IT systems.

- 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. HITAC consists of over 25 members and six federal representatives. In FY 2021, ONC convened the HITAC 10 times and held over 65 subcommittee meetings. HITAC provided over 130 recommendations.¹⁷ In addition to requirements that the HITAC annually addresses updates to the USCDI standard and priority ONC Interoperability Standards Advisory interoperability needs, the HITAC workgroups and recommendations also addressed a range of priority issues, including public health data systems, health equity by design, information blocking, TEFCA, EHR Reporting Program.
- **Health IT Safety** ONC will continue to help address emerging health IT safety challenges and foster the development of tools such as standards, and evidence-based practice guidance to help healthcare providers more effectively use health IT to deliver safe care to all their patients.

Strategic Planning and Reporting

- Federal Health IT Strategic Planning In FY 2023, ONC will start the next update of the
 Federal Health IT Strategic Plan in consultation with the Federal Health IT Coordinating Council.
 ONC will continue to implement the 2020 2025 Federal Health IT Strategic Plan during
 FY 2023, regularly collaborating with key stakeholder groups (including Congress and the
 public) to monitor and report progress of priority activities. Key activities include, but are not
 limited to:
 - Convening federal and industry stakeholders to understand health IT and interoperability needs;
 - Monitoring and reporting progress on the Plan;
 - Coordinating with federal and industry stakeholders on critical health IT infrastructure efforts related to APIs, USCDI, FHIR, information blocking, and electronic health information exchange.
- **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

¹⁷ https://www.healthit.gov/topic/federal-advisory-committees/recommendations-national-coordinator-health-it

Cures Act related to interoperability, privacy and security, and patient access. The HITECH Annual Report provides an update on progress against the Federal Health IT Strategic Plan.

Standards, Interoperability, and Certification

In FY 2023, ONC will continue 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 an additional \$22.0 million in funding above the FY 2022 Annualized Continuing Resolution for standards coordination and adoption activities, such as enhancements to ONC's Health IT Certification Program, which will implement changes enacted by the Cures Act and ONC's subsequent rulemaking activities. It also includes an increase in funding for improving interoperability among health information networks to enable them to participate more comprehensively in TEFCA and adapt to the new standards and implementation guides developed to support facilitated and brokered FHIR exchange. 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 2023, 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.

Increased funding will go towards certification work to implement the Cures Act Final Rule which supports the right of the patient to get their own health information electronically. The additional funds are needed to expand ONC's investment in a robust testing infrastructure that is used by the ONC-Authorized Testing Labs to ensure health IT industry meet the requirements of the Cures Act. Several new capabilities have been identified in the Cure Act Final Rule, including expanding availability of equity enhancing health information for patients and providers, which will require continued advancement of the API by the health IT industry. ONC's investment in robust testing infrastructure enables the health IT industry to focus their investments on improving health IT rather than duplicating testing infrastructure across all the industry. ONC testing is also now a critical part of the feedback standards developers receive to improve standards. Testing generates direct, hands-on implementation experiences and ONC uses those insights work with stakeholders to make future standards versions better. Increased funding enables ONC to develop new testing tools for future certification program requirements including

but not limited to prior authorization, real time prescription drug benefits, and public health certification.

• **Performance Measurement** – ONC will conduct research and analyses to assess the degree to which ONC is advancing an interoperable nationwide health IT infrastructure by meeting its objectives. This includes continuing support for evidence-building activities such as national surveys related to the development, adoption, and use of health IT to advance the 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 and curate the standards, implementation specifications, and common approaches to enable 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 industry led 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 in the FY 2023 budget include:
 - Promoting the use of health IT and health information to address health equity, healthcare delivery, and public health issues by accelerating the readiness of interoperability standards for adoption and enhancing the USCDI by adding data elements to support those efforts, and
 - Ensuring that the next generation of privacy and security standards are ready for widespread adoption by coordinating the development, testing, piloting, and refining them as the nation progresses to widespread adoption of secure APIs in healthcare, which is a key component of making healthcare more equitable,
 - Addressing health IT interoperability challenges related to social and behavioral health information to support healthcare.

With the increased funding requested in the FY 2023 Budget, ONC will further invest in identifying additional equity focused data elements and engaging and investing with the appropriate standards development organizations to create, refine, and release updated standards. In parallel, ONC will work with appropriate stakeholders to rapidly pilot such standards and evaluate their ability to be adopted more broadly. This includes:

Addressing gaps and challenges related to SDOH standards – including social service data among managed by stakeholders and across federal programs. ONC will take an equity-by-design approach to advance the use of interoperable, standardized data to represent social needs and the conditions in which people live, learn, work, and play. Health data, including data on race/ethnicity and SDOH, can help to identify health disparities and to inform efforts to improve health outcomes at an individual and population level.

- ONC will also continue to work on integrating SDOH and human and social services data to help improve the health outcomes and the patient experience.
- **Demonstrations and Pilots** 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. This includes expanding and advancing demonstration sites and pilots under the Leading Edge Acceleration Projects (LEAP) program. The goal of the LEAP program is to advance health IT development as well as to inform the innovative implementation and refinement of standards, methods, and techniques for overcoming major barriers and challenges. LEAP in Health IT projects tackle the creation of new standards, methods, and tools to improve care delivery and advance research capabilities. Through this work, ONC will support real world demonstrations and pilots around health equity, public health, APIs, research, and social determinants of health data exchange through this work.

Science and Innovation

- Scientific Initiatives ONC will continue to foster advancement of health IT by identifying and participating in using innovative technologies such as Artificial Intelligence (Ai) and machine learning. ONC will work closely with stakeholders in the scientific research community to connect their goals and interests to the advancement that ONC has fostered, including standards work in the area of precision medicine. More specifically, ONC will continue to lead and drive the efforts around standardizing and broad adoption of genomic information among laboratories, providers, patients, and researchers.
- Innovation The HITECH Act and reinforced by the Cures Act identifies ONC as a leading agency for advancing interoperability, competition, and innovation in the health IT ecosystem. In FY 2023, ONC will continue to coordinate with stakeholders to develop health IT standards that advance interoperability in less mature areas. This includes leading and working with industry and partners around patient generated health data used by clinicians and researchers and innovative approaches/tools to capturing and integrating data from remote monitoring devices and wearables in EHR systems. It also includes, where applicable, the administration of prize competitions and other industry spotlight engagements to advance novel approaches, standards, and technologies.

Agency-Wide Support

The FY 2023 budget request reflects the ONC's commitment to continue advancing progress toward national goals for widespread interoperability. The budget request includes an increase of \$1.3 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 2023, ONC will continue to maintain its statutorily required website, <u>https://HealthIT.gov/,</u> 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 <u>https://HealthIT.gov/HITAC</u>. Management and Governance – In FY 2023, ONC will continue to implement and improve its existing strategic and operational management processes. ONC's FY 2023 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.

Output and Outcomes Table

	Year and Most Recent Result / Target for Recent Result /			FY 2023
Measure Group / Measure Text	(Summary of Result)	FY 2022 Target	FY 2023 Target	Target +/- FY 2022 Target
Policy Development and Coordinatio Number of federal agencies actively participating in ONC-led health IT coordination efforts	n FY 2021: 22 Target: Maintain Prior Year (Baseline)	Maintain 20+ active agencies	Maintain 20+ active agencies	
Standards, Interoperability, and Cert Number of certification criteria and conditions of maintenance requirements included in the ONC Health IT Certification Program to meet congressional requirements for interoperable health data	FY 2021: 64 criterion in <u>2015</u> <u>edition</u> ¹⁸ Target: Maintain (Target Met) FY 2021: 2021	Maintain Maintain ISA	Maintain Maintain ISA	
areas supported by standards and implementation specifications included in the annual <u>Interoperability Standards</u> <u>Advisory (ISA)</u> Reference Edition	reference edition ISA contained 185 (+5) standards and implementation specification ¹⁹ (Target Met)	with necessary updates & Publish annual update by March 2022	with necessary updates & Publish annual update by March 2023	
Agency Wide Support Number of visitors to ONC's <u>https://healthIT.gov</u> websites to use health IT policy and technology assistance material	FY 2021: 2.5 million Target: Maintain prior year baseline of 1.5M (Target Exceeded)	Maintain	Maintain	

¹⁸ <u>https://www.healthit.gov/topic/certification-ehrs/2015-edition-test-method</u>

¹⁹ 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 that ONC evaluate nationwide progress to widespread health information interoperability.

	Office- based physicians	Non-federal acute care hospitals
• are electronically <u>sending or receiving</u> patient information with any providers outside their organization	42%	93%
• can electronically <u>find</u> patient health information from sources outside their health system	49%	75%
• can easily <u>integrate</u> (e.g., without manual entry) health information received electronically into their EHR	29%	71%
• had necessary patient information electronically <u>available</u> from providers or sources outside their systems at the point of care	47%	53%

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 Millions)

	FY 2021 ²	FY 2022 ³	FY 2023 ⁴
Notification ¹	-	2.750	2.000

Authorizing Legislation:

AuthorizationSection 223 of Division G of the Consolidated Appropriations Act, 2008

Allocation MethodDirect 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 2023, ONC is planning to utilize \$2 million in NEF funding for Certified Health IT Product List (CHPL) enhancements. NEF funds will be used to upgrade the overall CHPL public user interface, as well as a planned public usage and usability analysis. These funds will also allow for the specific development, testing, and implementation of a CHPL reporting module for collecting, verifying, and reporting required information in support of establishing the new EHR Reporting Program as required by the Cures Act.

In FY 2022, ONC will received a total of \$2.750 million in NEF funding to build the Health IT Data Dashboard and the Tool for ISA Comment Transparency and Improved Workflow.

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.

¹ Notification submitted to the Committees on Appropriations in the House of Representatives and the Senate on June 17, 2021.

² Notification submitted to the Committees on Appropriations in the House of Representatives and the Senate on October 22, 2020.

³Pursuant to Section 223 of Division G of the Consolidated Appropriation Act, 2008, notification is required of planed use.

⁴ The NEF CJ indicates the amounts HHS intends to notify for in 2023; these amounts are planned estimates and subject to final approval

Supplementary Tables

Budget Authority by Object Class

(Dollars in Thousands)

	FY 2021 Final	FY 2022 CR	FY 2023 President's Budget	FY 2023 +/- FY 2022
Personnel compensation:				
Full-time permanent (11.1)	22,159	22,757	23,804	1,047
Other than full-time permanent (11.3)	494	507	531	23
Other personnel compensation (11.5)	1,240	1,273	1,332	59
Military personnel (11.7)	-	-	-	-
Special personnel services payments (11.8)	-	-	-	-
Subtotal personnel compensation	23,893	24,538	25,667	1,128
Civilian benefits (12.1)	7,955	8,170	8,546	376
Military benefits (12.2)	-	-	-	-
Benefits to former personnel (13.0)	-	-	-	
Total Pay Costs	31,848	32,708	34,212	1,505
Travel and transportation of persons (21.0)	8	8	8	-
Transportation of things (22.0)	42	42	42	-
Rental payments to GSA (23.1)	1,890	1,890	1,890	-
Rental payments to Others (23.2)	-	-		-
Communication, utilities, and misc. charges (23.3)	20	20	20	-
Printing and reproduction (24.0)	3	3	3	-
Other Contractual Services:				
Advisory and assistance services (25.1)	-			-
Other services (25.2)	11,821	11,821	11,821	-
Purchase of goods and services from		10.001		
government accounts (25.3)	10,391	10,391	10,391	-
Operation and maintenance of facilities (25.4)	282	282	282	-
Research and Development Contracts (25.5)	-	-	-	-
Medical care (25.6)	-	-	-	-
Operation and maintenance of equipment (25.7)	-	-		-
Subsistence and support of persons (25.8)	-	-	-	
Subtotal Other Contractual Services	24,457	24,457	24,457	-
Supplies and materials (26.0)	213	213	213	-
Equipment (31.0)	-	-	-	-
Land and Structures (32.0)	-	-	-	-
Investments and Loans (33.0)	-	-	-	-
Grants, subsidies, and contributions (41.0)	5,590	4,989	44,732	39,743
Interest and dividends (43.0)	-	-	-	-
Refunds (44.0)	-	-	-	-

Total Non-Pay Costs	5,803	5,202	44,945	39,743
Total Budget Authority by Object Class	62,108	62,367	103,614	41,248

Salaries and Expenses

(Dollars in Thousands)

	FY 2021 Final	FY 2022 CR	FY 2023 President's Budget	FY 2023 +/- FY 2022
Personnel compensation:				
Full-time permanent (11.1)	22,159	22,757	23,804	1,047
Other than full-time permanent (11.3)	494	507	531	23
Other personnel compensation (11.5)	1,240	1,273	1,332	59
Military personnel (11.7)	-	-	-	-
Special personnel services payments (11.8)	-	-	-	
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Benefits to former personnel (13.0)	-	-	-	-
Total Pay Costs	31,848	32,708	34,212	1,505
Travel and transportation of persons (21.0)	8	8	8	-
Transportation of things (22.0)	42	42	42	-
Rental payments to GSA (23.1)	1,890	1,890	1,890	-
Rental payments to Others (23.2)	-	-	-	-
Communication, utilities, and misc. charges (23.3)	20	20	20	-
Printing and reproduction (24.0)	3	3	3	-
Other Contractual Services:				
Advisory and assistance services (25.1)	-	-	-	-
Other services (25.2)	11,821	11,821	11,821	-
Purchase of goods and services from				
government accounts (25.3)	10,391	10,391	10,391	-
Operation and maintenance of facilities (25.4)	282	282	282	-
Research and Development Contracts (25.5)	-	-	-	-
Medical care (25.6)	-	-	-	-
Operation and maintenance of equipment (25.7)	-	-	-	-
Subsistence and support of persons (25.8)	-	-	-	-
Subtotal Other Contractual Services	24,457	24,457	24,457	-
Supplies and materials (26.0)	213	213	213	-
Total Non-Pay Costs	213	213	213	-
Total Salary and Expense	56,518	57,378	58,882	1,505
Direct FTE	180	180	180	-

	2021 Actual	2021 Actual	2021 Actual	2022 Est.	2022 Est.	2022 Est.	2023 Est.	2023 Est.	2023 Est.
	Civilian	Military	Total	Civilian	Military	Total	Civilian	Military	Total
Direct:	180	-	180	180	-	180	180	-	180
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	180	-	180	180	-	180	180	-	180
ONC FTE Total	180	-	180	180	-	180	180	-	180

Detail of Full-Time Equivalent Employment (FTE)

Average GS Grade

	Grade:	Step:
FY 2019	13	7
FY 2020	13	9
FY 2021	13	6
FY 2022	13	6
FY 2023	13	6

	FY 2021 Final	FY 2022 Enacted	FY 2023 President's Budget
Executive level	-	-	-
Total - Exec. Level Salaries	-	-	-
ES	6	6	6
Total - ES Salary	1,287,181	1,321,935	1,382,744
GS-15	47	49	49
GS-14	49	53	53
GS-13	46	44	44
GS-12	15	16	16
GS-11	9	16	16
GS-10	-	-	-
GS-9	7	12	12
GS-8	-	-	-
GS-7	-	-	-
GS-6	-	-	-
GS-5	-	-	-
GS-4	1	-	-
GS-3	-	-	-
GS-2	-	-	-
GS-1	-	-	-
Subtotal	174	190	190
Total - GS Salary	22,182,176	22,781,095	23,829,025
Average ES salary	214,530	220,322	230,457
Average GS grade	13-8	13-4	13-6
Average GS salary	127,474	119,900	125,416

Detail of Positions

Programs Proposed for Elimination

No programs are proposed for elimination.

	PY 2021	CY 2022 ²⁰	BY 2023
	(Actual)	(Estimate)	(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	\$159,028	\$159,028
Average Annual PCA Payment	\$0	\$16,000	\$16,000

Physicians' Comparability Allowance Worksheet

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.

 $^{^{20}\,\}mathrm{FY}$ 2022 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 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, 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 usercentric, 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 2022 House Appropriations Committee, Labor/HHS/Education Subcommittee, H.Rept. 117-96

Accessibility of Online Telehealth Platforms: The Committee recognizes that the COVID–19 pandemic led to the increased use of online portals and web services for patients seeking information, scheduling, and accessing remote services. However, the Committee is concerned that many online platforms are not user-friendly, especially for less digitally literate communities, including seniors. The Committee urges the Secretary, working through ONC, to coordinate with the Agency for Healthcare Research & Quality (AHRQ), the Centers for Medicare & Medicaid Services (CMS), and Office for Civil Rights (OCR) on any Federal efforts that can be made to evaluate the accessibility of digital health platforms for Federally-supported providers, including any assessments of how seniors and persons with disabilities are included in the design and testing of the platforms. Further, the Committee directs the Secretary, working through ONC, AHRQ, CMS, and OCR, to establish best practices for healthcare providers to improve their online telehealth platforms for seniors, individuals with disabilities, and individuals with limited English proficiency. (Page 248-249, H. Rept. 117-96)

Public Health Data Utility: The Committee notes the COVID–19 pandemic has exposed serious gaps in our healthcare system and the challenges of responding to major public health threats. Real-time data is essential for responding to a pandemic and for improving public health outcomes broadly. The Committee acknowledges some States have advanced capacities to collect and share real-time data and effectively respond to public health threats through their Health Information Exchange (HIE). These States can lead the way by maximizing current capabilities and sharing across the Nation. The Committee encourages the Office of the National Coordinator, in coordination with the Assistant Secretary for Preparedness and Response, to coordinate with State based health data utilities to better plan and prepare for a public health threat. (Page 249, H. Rept. 117-96)

Recording Vaping in Electronic Health Records: The Committee understands that despite the prevalence of e-cigarette use among youths and the potential risk of serious side effects, consensus on how to screen adolescents for e-cigarette use is lacking. Providers may not ask about use of these devices, and electronic health records (EHRs) currently do not provide options for recording use of e-cigarettes, water pipes, and other types of smoking in consistent computable ways, potentially resulting in underreporting, and a dearth of data that can be used to understand long-term health outcomes. The Committee urges the Secretary, working through the Centers for Disease Control and Prevention, Food and Drug Administration, and ONC, to consider developing strategies to enhance accurate data collection and timely reporting of e-cigarette use, including consideration of the role of EHRs, as aligned with applicable clinical practice guidelines. (**Page 249, H. Rept. 117-96**)

Standards for Interoperability: The recommendation includes not less than \$5,000,000 to support Fast Healthcare Interoperability Resource standards-related activities needed to successfully achieve interoperability and information sharing for better health and health care. (**Page 249, H. Rept. 117-96**)

Action to Be Taken

ONC spent the additional \$2.0 million in funding provided in the FY 2021 bill to support HL7 FHIR standards-related activities. Specifically, funds supported an HL7 cooperative agreement, coordinating FHIR activities with information health exchanges (IHE) (including to support its future use for EMS providers); some funds supported federal FTE time/labor to coordinate public and private sector activities through the FHIR at Scale Taskforce (FAST), leading the Federal Health IT Coordinating Council to help scale the use of FHIR within other Federal agencies, and to lend additional support of Leading Edge Acceleration Projects (LEAP) in Health IT, especially those working to unite community providers and clinicians related to FHIR-based patient consent tools.

Proposed Law

1. Advisory Opinions for Information Blocking

Provide HHS the authority to create an advisory opinion process and issue advisory opinions for information blocking practices governed by section 3022 of the Public Health Service Act (PHSA), 42 USC 300jj-52. The opinion would advise the requester whether, in the Department's view, a specific practice would violate the information blocking statutory and regulatory provisions; it would be binding on the Department, such that the Department would be barred from taking enforcement action against the practice. In addition, provide ONC with the authority to collect and retain fees charged for issuance of such opinions, and to use such fees to offset the costs of the opinion process.

Health Insurance and Implementation Fund

HEALTH INSURANCE REFORM IMPLEMENTATION FUND

Budget Summary

(Dollars in Millions)

	FY 2021	FY 2022	FY 2023	
Obligations*	-\$2	-\$2	-\$2	
* \$1,000,000,000 was appropriated in the Health Care and Education Reconciliation Act of 2010				
Authorizing LegislationAuthorizing Legislation Act, Section 1005, FY 2010				
FY 2020 AuthorizationIndefinite				
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 2022, a net total of \$6,006 has been deobligated by agencies within HHS. It is the Department's current projection that approximately \$6 million will be available for obligation in FY 2023 although, given recoveries in this account, this amount may be higher. In prior years, the HHS Office of the Chief Technology Officer (CTO), in partnership with the Indian Health Service (IHS) and the Office of the National Coordinator for Health IT (ONC), used available funds to lead 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.

No Surprises Act Implementation Fund

NO SURPRISES IMPLEMENTATION FUND

Budget Summary

(Dollars in Millions)

	FY 2021	FY 2022	FY 2023
Obligations	\$63	\$144	\$138

Authorizing Legislation.....Consolidated Appropriations Act, 2021 (Public Law 116-26), or the No Surprises Act.

Program Description and Accomplishments

Section 118 of the No Surprises Act, enacted in the Consolidated Appropriations Act, 2021 (P.L. 116-260), appropriated \$500,000,000 in implementation funding to the Department of Health and Human Services (HHS), Department of Labor (DOL), and Department of the Treasury (the Departments). The implementation fund is available until expended through 2024. The purpose of the implementation fund is to carry out the provisions of, and the amendments made by, Title I (No Surprises Act) and Title II (Transparency), Division BB, of the Consolidated Appropriations Act, 2021 (CAA). At the start of FY 2022, the No Surprises Act implementation fund had a balance of \$436.7 million.

Department of Health and Human Services

For efficiency and to ensure coordination, the No Surprises Implementation Fund account was established within HHS in FY 2021. HHS coordinates with DOL and Treasury to ensure that each agency receives funding allocations reflecting their most immediate requirements of the No Surprises Act.

In FY 2021, HHS obligated \$56.0 million, with the Centers for Medicare & Medicaid Services (CMS) obligating \$54.7 million and the Office of the Assistant Secretary for Planning and Evaluation (ASPE) obligating \$1.3 million.

CMS is responsible for leading the implementation operations and system solutions for the majority of the provisions of Title I (No Surprises Act) and Title II (Transparency) of Division BB of the CAA. CMS engaged in a multitude of concurrent and integrated activities in FY 2021 to ensure implementation of critical legislative provisions and consumer-facing priorities that started in January 2022.

Stakeholder engagement and listening sessions: CMS, in coordination with the Departments of Labor and the Treasury, engaged in more than 20 virtual listening sessions with stakeholder groups in FY 2021. Listening sessions were held with state Departments of Insurance, providers, issuers, consumer groups, employer groups, and independent arbitrators. CMS, along with DOL and the Treasury, met with more than 100 entities through these sessions and accommodated several additional meetings by request.

User Research and Defining Requirements: CMS collaborated with the U.S. Digital Service to conduct research and analyses to understand the business needs and high-level requirements of relevant stakeholders; validate acquisition planning needs; and make informed decisions on whether to build new or leverage existing systems to support operations for the new consumer protections enacted as part of the CAA.

Enforcement Activities: HHS generally has primary enforcement authority over health insurance issuers with regard to the insurance market reform provisions of title XXVII of the Public Health Service (PHS) Act in states that do not have authority to enforce (Texas, Missouri, and Wyoming) – referred to as direct enforcement states – or where HHS determined the state has failed to substantially enforce one or more of the provisions, and over non-Federal governmental group health plans in all states. The CAA amends the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA) to require these plans and issuers to make their non-quantitative treatment limitation (NQTL) comparative analyses available to HHS upon request and requires HHS to request at least 20 NQTL comparative analyses each year for review. CMS carried out HHS's enforcement responsibilities under title XXVII of the PHS Act, including enforcement of MHPAEA. CMS requested 21 NQTL comparative analyses from four non-Federal governmental plan sponsors and from nine issuers in direct enforcement states between May and November 2021.

In FY 2021, CMS also obtained contractor support to enforce other provisions of the CAA applicable to group health plans, issuers of health insurance coverage in the individual and group markets, providers, facilities, and providers of air ambulance services. CMS set up a system for receipt and investigation of complaints of potential violations of the No Surprises Act and Transparency title provisions for individual and group market health plans and issuers, providers, and facilities.

Advisory Committee Activities: CMS engaged in program planning activities toward establishment of the "Advisory Committee to Review Air Ambulance Services" and the "Advisory Committee on Ground Ambulance and Patient Billing". The Federal Register notice establishing the ground ambulance services advisory committee was published on November 23, 2021.¹

Federal Hiring Activities: CMS received approval in FY 2021 to hire up to 58 federal staff to support implementation of the No Surprises Act and Transparency title provisions. CMS onboarded 29 federal staff in FY 2021 and expects to complete hiring efforts for the remaining approved federal staff in FY 2022.

U.S. DEPARTMENT OF LABOR (DOL)

In FY 2021, DOL obligated \$7.0 million, with the Employee Benefits Security Administration (EBSA) obligating \$4.8 million and the Office of the Solicitor (SOL) obligating \$2.2 million. DOL obligations supported the implementation, enforcement, and administration of applicable CAA provisions in FY 2021. Specifically, EBSA supported implementation of the No Surprises Act and Transparency titles in FY 2021 by participating in the development and drafting of the regulations issued. EBSA collaborated with the HHS contractors developing the Independent Dispute Resolution entity (IDRE) systems, reviewed materials and the approval process, and reviewed IDRE applications. EBSA is also collaborating with HHS on the system for receipt and investigation of complaints of potential violations of the No Surprises Act and Transparency title provisions for individual and group market health plans and issuers, providers, and facilities.

Advisory Committees: EBSA established the "State All Payer Claims Databases Advisory Committee" in March 2021, under section 735 of the Employee Retirement Income Security Act (ERISA), as added by the CAA, and provided the necessary support for the Advisory Committee's meetings. On October 27,

¹ 86 FR 66565, <u>https://www.federalregister.gov/documents/2021/11/23/2021-25560/ground-ambulance-and-patient-billing-advisory-committee</u>.

2021, the State All Payer Claims Databases Advisory Committee submitted its final report with recommendations to the Secretary of Labor and Congress.² EBSA also engaged in program planning activities for establishment of the "Advisory Committee on Ground Ambulances and Patient Billing".

Enforcement Actions: The Department of Labor has primary authority for enforcing MHPAEA with respect to private sector employment-based group health plans, which provide benefits to the majority of American workers under age 65. EBSA's MHPAEA jurisdiction and responsibilities extend to approximately two million ERISA-covered group health plans that provide health benefits to an estimated 136.5 million Americans. The CAA gave EBSA important new enforcement tools to ensure that group health plans and issuers comply with the requirements of MHPAEA for parity between NQTLs for medical/surgical services and mental health/substance use disorder (MH/SUD) benefits. Major FY 2021 enforcement activities include:

- *Task Force*. A new Task Force, comprised of experienced investigators, health policy experts, and technical experts from EBSA's regional offices, EBSA's national office, and SOL, worked closely with agency leadership as well as regional offices to develop approaches for implementation of the new provisions. In coordination with the Task Force, EBSA's regional offices conducted a comprehensive review of their existing inventory of investigations involving health plans to identify red flags for potential MHPAEA violations involving NQTLs. Many of the potential NQTLs flagged or requested were NQTLs that EBSA had identified as focus areas in <u>FAQs Part 45</u>.
- *Comparative Analysis Results.* EBSA issued 156 letters to plans and issuers requesting comparative analyses for 216 unique NQTLs spanning 86 investigations.
- *Training.* EBSA expanded staffing and increased staff specialization by hiring or promoting more than 46 FTEs to enhance its enforcement program. Between April and September 2021, the Task Force delivered more than 15 training sessions to groups of between 15 to 500 investigators, managers, customer service staff, leadership, and SOL attorneys.
- Data Systems Upgrades. In FY 2021, EBSA updated its Enforcement Management and Technical Assistance and Inquiry Modules in the agency's ERISA Management System (EMS) to better capture and track inquiries and investigative data relative to MHPAEA.
- Tool Development/Consultants and Experts. EBSA developed new tools for investigators to use in MHPAEA investigations and to better identify red flags for MHPAEA concerns. EBSA retained contractor support for development of tools, access to external sources of reference data for incorporation into the tools, and to advise on specific technical questions raised by comparative analyses provided by plans and issuers.
- Other CAA Enforcement Provisions. EBSA worked on an enforcement plan to implement the new provisions, including the surprise billing, network accuracy, and ERISA section 408(b)(2) disclosure provisions. The enforcement plan, among other things, identifies the enforcement tool modifications and field guidance and training needed to prepare EBSA investigative staff.

U.S. DEPARTMENT OF THE TREASURY (Treasury)

Treasury obligated \$201,000 in FY 2021 for the work of 1.2 FTEs. The Internal Revenue Service (IRS) Chief Counsel's Office supported implementation of the No Surprises Act and Transparency titles in FY 2021 by participating in the development of all the regulations issued. IRS Counsel also collaborated with the HHS contractors developing the IDRE systems, reviewed materials and the approval process, and reviewed IDRE applications.

² <u>https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/about-us/state-all-payer-claims-databases-advisory-committee/final-report-and-recommendations-2021.pdf</u>

TRI-DEPARTMENT RULEMAKING ACTIVITIES

The Departments, along with the Office of Personnel Management (OPM), drafted and published the following rules and guidance to support implementation of the No Surprises Act and the Transparency title of Division BB of the CAA:

- April 2, 2021: The Departments published Frequently Asked Questions³ providing guidance on the amendments to MHPAEA under the CAA.
- July 13, 2021: The Departments published "Requirements Related to Surprise Billing; Part I,"⁴ which implements many of the law's central surprise billing protections.
- August 20, 2021: The Departments published Frequently Asked Questions⁵ providing guidance on implementation of various surprise billing and transparency provisions.
- September 16, 2021: The Departments published "Requirements Related to Air Ambulance Services, Agent and Broker Disclosures, and Provider Enforcement" Notice of Proposed Rulemaking (NPRM),⁶ which would increase transparency by requiring plans, issuers, and providers to submit certain information about air ambulance services. The NPRM would require certain plans to report agent/broker compensation. The NPRM would also establish a process to investigate complaints and enforce violations specific to Title XXVII of the PHS Act by providers and facilities.
- October 7, 2021: The Departments published "Requirements Related to Surprise Billing; Part II,"⁷ which provides additional protections against surprise medical bills, including the establishment of an Independent Dispute Resolution (IDR) process to determine out-of-network payment amounts between providers or facilities and health plans. This regulation also establishes the process for the patient-provider dispute resolution process. The Departments also issued several pieces of sub-regulatory guidance, including guidance on fees for use of the federal IDR process and multiple notices associated with negotiation and initiation of the federal IDR process.
- November 23, 2021: The Departments published "Prescription Drug and Health Care Spending,"⁸ which requires plans and issuers to submit certain information about prescription drugs and health care spending to the Departments. The related "Request for Information Regarding Reporting on Pharmacy Benefits and Prescription Drug Costs",⁹ published on June 23, 2021, solicited comments regarding implementation of the data collection, the data elements to be collected, and the associated impact on plans and issuers.

³ FAQS ABOUT AFFORDABLE CARE ACT AND CONSOLIDATED APPROPRIATIONS ACT, 2021 IMPLEMENTATION PART 45, <u>https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/MHPAEA-FAQs-Part-45.pdf</u> and <u>https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-45.pdf</u>.

⁴ 86 FR 36872, <u>https://www.federalregister.gov/documents/2021/07/13/2021-14379/requirements-related-to-surprise-billing-part-i</u>.

⁵ FAQS ABOUT AFFORDABLE CARE ACT AND CONSOLIDATED APPROPRIATIONS ACT, 2021 IMPLEMENTATION PART

^{49, &}lt;u>https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-49.pdf</u>. ⁶ 86 FR 51730, <u>https://www.federalregister.gov/documents/2021/09/16/2021-19797/requirements-related-to-air-ambulance-services-agent-and-broker-disclosures-and-provider-enforcement.</u>

⁷ 86 FR 55980, <u>https://www.federalregister.gov/documents/2021/10/07/2021-21441/requirements-related-to-surprise-billing-part-ii</u>.

⁸ 86 FR 66662, <u>https://www.federalregister.gov/documents/2021/11/23/2021-25183/prescription-drug-and-health-care-spending</u>.

⁹ 86 FR 32813, <u>https://www.federalregister.gov/documents/2021/06/23/2021-13138/request-for-information-regarding-reporting-on-pharmacy-benefits-and-prescription-drug-costs</u>.

Nonrecurring Expenses Fund

Nonrecurring Expenses Fund

Nonrecurring Expenses Fund

Budget Summary (Dollars in Thousands)

(Donars in Thousands)				
	FY 2021 ²	FY 2022 ³	FY 2023 ⁴	
Notification ¹	\$300,000	\$390,000	\$300,000	
NIH Allocation	\$225,000			
Rescission	\$375,000	\$500,0005	\$500,000 ⁵	

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 use of the funds for capital acquisitions necessary for the operation of the Department, specifically information technology (IT) and facilities infrastructure acquisitions.

HHS was first able to collect expired funds in FY 2013. Since then, HHS has allocated approximately \$5.4 billion for projects, including approximately \$2.5 billion for physical infrastructure projects and approximately \$2.9 billion for IT infrastructure projects. HHS has a wide range of aging IT systems and facilities; the NEF is an asset to helping address these needs across the landholding agencies and to develop, enhance, and maintain IT systems across the Department.

The FY 2023 Budget proposes to cancel \$500 million from the NEF. Remaining NEF balances will fund multiple high-priority projects that address facility and technology needs across the Department. Below is an overview of planned uses of \$300 million from the NEF for FY 2023. The investments listed below are based on approximate funding levels, using current estimates, and are subject to final approval. HHS will provide Congressional notification of specific projects and amounts closer to the beginning of FY 2023.

Budget Allocation FY 2023

<u>Administration for Community Living (ACL) - \$6 million -</u> The NEF will be used to establish a technology framework to enhance communication internally and externally across ACL's portfolio of programs. The project will also include a new customer relationship management tool that will allow ACL to better organize and aggregate information about services to ACL grantees, subgrantees, services providers, and in turn the public.

<u>Agency for Healthcare Research and Quality (AHRQ) - \$2 million -</u> The NEF will be used for a one-time IT development and enhancement project that will modernize the Healthcare Cost and Utilization Project User-Support website's functionality, accessibility, and usability. This system is AHRQ's flagship data project because it provides the largest collection of hospital care data in the United States and is utilized for policy analysis and research for various topics.

<u>Assistant Secretary for Program Evaluation (ASPE) - \$3 million -</u> The NEF will be used to invest in a range of systems and IT infrastructure to align internal systems, modernize the public facing

website, and increase scientific and analytical computing capacity. This project will strengthen the alignment between ASPE's current systems and the Department's cybersecurity requirements by transitioning to a secure, HHS-approved system.

<u>Centers for Disease Control and Prevention (CDC) - \$35 million -</u> The NEF will be used to replace and upgrade essential National Health and Nutrition Examination Survey (NHANES) Mobile Examination Center (MEC) vehicles, equipment, and IT to sustain CDC's public health infrastructure.

<u>Food and Drug Administration (FDA) - \$43 million -</u> The NEF will be used to invest in the consolidation and modernization of a pathology laboratory that houses the National Center for Toxilogical Research and Office of Regulatory Affairs on the FDA-owned Jefferson Laboratory Complex in Arkansas. The NEF will also be used for the construction of a Disaster Recovery Center on the Jefferson Laboratory Complex by transforming office space into a data center.

<u>Health Resources and Services Administration (HRSA) - \$42 million -</u> The NEF will support multiple projects, one of which includes building a new space for the National Hansen's Disease Program Lab Research Branch in Baton Rouge, Louisiana. Funds will also be used to replace existing underlying physical server hardware that has reached the end of its useful life. With up to date equipment, HRSA will be able to better visualize and analyze large health workforce data sets and apply predictive analytic techniques. Lastly, HRSA will complete a previous NEF-funded project to implement solutions for health data collection in rural communities.

<u>Indian Health Service (IHS) - \$38 million -</u> The NEF will support a range of IT and facilities projects for critical facilities projects and to remediate a priority backlog across Indian country. Funding will also be used to modernize IHS' aging health information technology systems.

<u>National Institutes of Health (NIH) - \$63 million -</u> The NEF will be used to improve the safety and electrical power reliability in the Clinical Center Complex through replacement and upgrades of aging services with safe, state-of-of the art, cost effective, contiguous, and secure electrical systems. Additionally, NEF funds will be used for the Rocky Mountain Laboratories campus to improve, centralize, consolidate, and integrate support functions.

<u>Office of the Assistant Secretary for Health (OASH) - \$4 million -</u> The NEF project will build on a previously funded NEF project, allowing OASH to generate a consolidated Human Resources dashboard that will efficiently track and monitor Commissioned Corps personnel across agencies. OASH will then be able to better utilize Corps capabilities and response teams for deployment as needed.

<u>Office of Inspector General (OIG) - \$13 million -</u> The NEF will be used to support the completion of a multi-phase effort to consolidate legacy systems, build new software capabilities on a modern platform, cover upfront security authorization costs for modernization, and provide capability for increased storage and bandwidth.

<u>Office of the National Coordinator for Health Information Technology (ONC) - \$2 million -</u> The NEF will be used to streamline the development, testing, and implementation of the Certified Health IT Product List (CHPL) reporting module. These funds will upgrade the CHPL public user interface by providing structured data in an open format for public use and analysis.

<u>Administration for Children and Families (ACF) - \$50 million -</u> The NEF will be used to invest in facilities that are co-operated with the Department of Homeland Security for the purposes of processing children who arrive with non-parent relatives, as well as other facilities that can address Unaccompanied Children capacity needs. The NEF CJ indicates the amounts HHS intends to notify for in 2023; these amounts are planned estimates and subject to final approval.

Budget Allocation FY 2022

In FY 2022 HHS notified for a total of \$390 million in new NEF investments to support critical IT and facility infrastructure project across the Department to modernize HHS operations and provide a safe, secure, and productive work environment for OpDivs and StaffDivs as they carry out the HHS mission. This included \$64 million in IT infrastructure and \$326 million in facility projects. The facilities total includes \$65 million for CDC to complete construction of the CDC/NIOSH Cincinnati Campus. Additionally, HHS notified for the use of \$15 million to support the implementation of Treasury's G-Invoicing solution and \$100 million for capital acquisition costs to expand and support ACF's capability to care for and shelter Unaccompanied Children.

Budget Allocation FY 2021

In FY 2021 HHS notified for a total of \$300 million in new NEF investments, which included \$69 million in IT infrastructure projects and \$231 million in facilities projects. This included \$194 million to IHS to address critical facilities projects, to help remediate the priority backlog across Indian country, and to modernize IHS' aging health information technology systems. Additionally, HHS notified to use NEF funds modernize and streamline HHS acquisition and grant making systems that improved accountability and management.

NEF Notifications and Reductions from 2013-2023 (dollars in millions)				
Fiscal Year	Notifications	Rescissions		
2013	\$600	-		
2014	\$600	-		
2015	\$650	-		
2016	\$800	-		
2017	\$430	(\$100)		
2018	-	-		
2019	\$600	(\$400)		
2020	\$743	(\$350)		
2021	\$300	(\$375)		
2022	\$390	(\$500)/5		
2023/4	\$300	(\$500)/5		
TOTAL	\$5,413	(\$2,225)		

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 October 22, 2020.

³ Notification submitted to the Committees on Appropriations in the House of Representatives and the Senate on June 17, 2021.

⁴ The NEF CJ indicates the amounts HHS intends to notify for in 2023; these amounts are planned estimates and subject to final approval.

⁵Rescission reflects the President's Budget.

¹ Pursuant to

Service and Supply Fund

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SERVICE AND SUPPLY FUND

(Dollars in Thousands)

SSF*	FY 2021 Actual	FY 2022 Board Approved	FY 2023 Board Approved	FY 2023 +/- FY 2022
BA	983,932	1,313,840	1,417,708	+103,868
FTE		1,421	1,516	+95

*SSF BA and FTE levels include the Debt Collection Center, funded through a separate account.

Authorizing Legislation: 42 USC §231	
2023 Authorization	Indefinite
Allocation Method	Contract, Other

Statement of the Budget

The overall FY 2023 current approved budget for the Service and Supply Fund (SSF) is \$1.4 billion which is \$103,868 above the FY 2022 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 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: Program Support Center (PSC) activities 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 2023 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.

- PSC Acquisition Management Services (AMS): The PSC Acquisition Management Services (AMS) serves as a major foundation of the Department's procurement operations through fully integrated acquisition and strategic support services. AMS provides these services on behalf of the Department and other Federal agencies. AMS offers a range of acquisition support services including simplified, negotiated contracts, and purchase card management services.
- **PSC 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) debt management services; and 4) 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.
- **PSC Occupational Health Portfolio (FOH):** The Federal Occupational Health (FOH) provides comprehensive, high-quality, customer-focused occupational health services in strategic partnership with Federal agencies nation-wide to improve the health, safety, and productivity of the Federal workforce. Approximately 93 percent of FOH's services are provided to Federal agencies outside of HHS. FOH is organized in four service areas: Clinical Health Services, Wellness and Health Promotion Services, Behavioral Health Services, and Environmental Health and Safety Services.
- PSC Real Estate, Logistics, and Operations Portfolio (RLO): Real Estate, Logistics and Operations
 Portfolio (RLO) provides real estate, logistics and a wide range of administrative and technical
 support services to customers within HHS and other federal agencies. RLO is organized in the
 following Service Areas: Real Property Management Services, Supply Chain Management
 Services, Building Operations Services, and Physical Security and Emergency Management
 Services, Mail and Publishing Services, FedResponse Services, Transportation Services, and
 Intake Suitability and Badging Services, and Other Administration 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.

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 Operations Management (OOM)

OOM is responsible for supporting the achievement of the HHS mission by identifying, developing, implementing, and evaluating efficient and effective business practices throughout the Department. OOM also supports the HHS-wide Commercial Services Management (CSM) reporting, the inventory and reporting of the Federal Activities Inventory Reform (FAIR) Act, the active sponsorship of High Performing Organizations (HPO) and provides insourcing consulting services to maximizing return on taxpayer dollars by undertaking initiatives to improve services, reduce costs, and streamline activities across the Department. Additionally, OOM offers organizational redesign services to the Department to promote mission effectiveness, cost-savings, and increase efficiencies.

Office of the Chief Information Officer (OCIO)

The Office of the Chief Information Officer (OCIO) advises the Secretary and the Assistant Secretary for Administration (ASA) on matters pertaining to the use of information and related technologies to accomplish Departmental goals and program objectives. The mission of the OCIO is to establish and provide: assistance and guidance on the use of technology-supported business process reengineering; investment analysis; performance measurement; strategic development and application of information systems and infrastructure; policies to improve management of information resources and technology; and better, more efficiently service our customers and employees.

OCIO supports the HHS mission by leading the development and implementation of an enterprise information technology (IT) infrastructure across HHS. The OCIO is headed by the Deputy Assistant Secretary for Information Technology (DASIT)/HHS Chief Information Officer (CIO), who executes the statutory requirements of the Federal Information Technology Acquisition Reform Act (FITARA) of 2014, to ensure appropriate oversight, monitoring, compliance, and management activities across HHS' \$6.6 billion IT portfolio. The HHS CIO is accountable for other fundamental IT legislation, including the Federal Information Security Modernization Act of 2014 (FISMA), the Making Electronic Government Accountable by Yielding Tangible Efficiencies (MEGABYTE) Act of 2016, and the Modernizing Government Technology (MGT) Act of 2017. Many of these principles are rooted in the Information Technology Management Reform Act (i.e. ITMRA, or Clinger-Cohen) of 1996 to improve federal IT management. OCIO is also responsible for the development and implementation of an enterprise-wide secure and trusted environment in support of HHS' commitment to better health and well-being of the American people. The cybersecurity program supports the Department's HHS-wide security incident response coordination functions, enabling enterprise threat analysis and information sharing efforts. OCIO governed security tools and technologies provide enterprise-wide solutions to monitor HHS' computers, endpoints, and networks for security incidents and attacks; provide for comprehensive intrusion detection and prevention systems; implement network security forensics and analysis capabilities; and assess and leverage other security technologies to best protect HHS. OCIO is currently divided into the following business lines:

- OCIO Office of Application and Platform Solutions (OAPS): OAPS (formerly OCPO) is responsible for modern applications and platforms to support today's digital business challenges through agile development and cloud platforms. The services include hosting, design, development, configuration, integration, implementation, and enterprise support that enables delivery of scalable, reliable, and sustainable applications that will fuel digital transformation. OAPS 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, OAPS provides production reporting and business intelligence query dashboard capabilities for its customers.
- OCIO 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 is currently divided into the following functions: Enterprise Software Licensing, Government Wide E-Gov, IT Vendor Management Office, and Program and Project Management.
- OCIO Office of Information Security (OIS): HHS is the repository for information on biodefense, 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.
- OCIO Office of Information Technology Acquisition Management (ITAM): Enterprise Infrastructure Solutions Program Management Office (PMO) is responsible for the implementation and transition of the Networx, WITS3 and Local Services Agreements (LSA) to the Enterprise Infrastrcture Solutions (EIS) contract with the long-term goal of delivering modern and innovative telecommunications and IT technologies. The EIS vehicle, successor to Networx, WITS3, and Regional Local Service Agreements provides a centralized solution to acquire enterprise telecommunications and IT infrastructure services from a single source verses having to coordinate multiple acquisitions to meet the Departments enterprise needs. HHS is on course to fully transition to the EIS contract vehicle by September FY 2022. The purpose of the contract is to provide a Department wide unified contract vehicle that achieves savings and efficiencies.

- OCIO Office of Operations (Ops): The mission of Ops is to provide efficient and effective delivery of IT services to its customers by providing customer-driven, business-enabling technologies. 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. Ops supports over 22 customer organizations comprised of over 13,000 users, including all HHS Staff Divisions (StaffDivs) and participating Operating Divisions (OpDivs).
- OCIO Office of the Chief Data Officer (OCDO): The HHS OCDO provides leadership for advancing HHS's data and analytics strategy across the totality of the Department's programs. The HHS OCDO uses the regulatory and statutory framework to drive implementation of the HHS data strategy vision and support plans, strategies, and considerations for leadership in the domains of: Data Strategy, Risk Management, and Governance, Data Management and Open Data, Data Utilization and Stakeholder Management, Data Architecture and Delivery.

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 and Employee Relations Office (NLERO)

NLERO is responsible for promoting the efficiency of the service, advance the mission of the Department of Health and Human Services (HHS), and protect and advocate for the Department's rights and interests. Historically, the Labor and Employee relations functions were highly federated with limited consistency or oversight that caused substantial specialization and hindered the common requirements for the Department and were performed individually by organizations within the Human Resources function. In support of *One HHS*, the Department is committed to a cohesive approach to managing our labor and employee relations functions through the coordination of uniform operational practices. This policy is issued to ensure consistent communication and oversight in the execution of these functions and will be communicated in the activities offices under the Assistant Secretary for Administration (ASA).

Office of Human Resources (OHR)

OHR provides Department-wide strategic leadership, policy implementation and governance and operational services for a variety of Human Capital Management functions across the Department including the planning and development of personnel policies and human resource programs supporting the Department's mission. To assist the HHS Operating Divisions (OpDivs) with effectively and efficiently accomplishing their missions, OHR provides technical assistance through improved planning and

recruitment of human resources and serves as the Departmental liaison to central management agencies on related matters.

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. 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. OHR is organized in the below service areas:

- **OHR Enterprise:** OHR Enterprise is responsible for Department-wide policies, programs, and practices relevant to HHS employees including workforce planning, employee relations, performance management, benefits, oversight, recruitment and placement, and human capital planning.
- OHR Staffing and Recruitment Operations Center (SROC): SROC provides customer-focused, efficient, and flexible human resources service delivery to approximately 12,000 federal employees for the HHS Office of the Secretary Staff Divisions (StaffDivs) and several Operating Divisions (OpDivs) including ACF, ACL, and SAMHSA. SROC is responsible for administering and managing various human capital programs to include classification, position management, staffing and strategic recruitment, pay administration, benefits and retirement counseling, processing personnel actions, records management, and employment policy. SROC also provides customer-focused, efficient, and flexible human resources service delivery to approximately 6,000 intermittent employees for the Assistant Secretary for Preparedness and Response (ASPR), National Disaster Medical System (NDMS). OHR is responsible for administering and managing human capital programs for NDMS to include classification, position management, staffing and strategic recruitment, pay administration, pay administration, processing personnel actions, records medical System (NDMS).
- **OHR Human Resources Solutions (HRS):** HRS is responsible for the operations and maintenance of the Enterprise HR information technology system and other HR related systems such as timekeeping and payroll.

Office of National Security

The Office of National Security (ONS) is organizationally within the Immediate Office of the Secretary. 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. ONS is comprised of three operating divisions: Intelligence & Analysis Division (IAD), the Division of Operations Division (DO), and the Personnel Security Division (PSD). The Personnel Security Division within ONS is responsible for national security clearance adjudication (NSA) program as well as classified national security information management, Sensitive Compartmented Information Facility (SCIF) management, communications security, and the safeguarding and sharing of classified information. This operational responsibility is in support of the Intelligence Reform and Terrorism Prevention Act of 2004 (IRTPA); Executive Order 13587, Structural Reforms to Improve the Security of Classified Networks and the Responsible Sharing and Safeguarding of Classified Information; and other relevant Executive Orders (including Executive Order 12333), Presidential Directives and policy guidance. ONS has responsibilities to establish implementing guidance, provide oversight, and manage the Department's policy for the sharing, safeguarding, and the coordinated exchange of information related to national or homeland security with other federal departments and agencies, including law enforcement organizations and the IC, in compliance with HHS policies and applicable laws, regulations, and Executive Orders.

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 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 is located in the Office of the Secretary/Assistant Secretary for Financial Resources/Office of Finance and 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 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 Acquisition Integration and Modernization (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 Office of Acquisitions.
- Acquisition Reform Workforce Program (ARWP): 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 ARWP which is located in the Office of the Acquisitions is responsible for every aspect of the HHS Acquisition Workforce Program – Federal Certification Management. ARWP serves as the Departmental Acquisition Career Manager (ACM) supporting the Operating and Staff Divisions; verifies and validates HHS Acquisition Workforce assuring that each member has met or exceeded requirements for Federal Certification Levels; plans and conduct guarterly ACM/BACM forums; provides advice to BACMs residing in NIH, CMS, CDC, FDA, ACF, AHRQ, HRSA, IHS, ASPR, OIG, PSC, and SAMHSA; represents HHS at Government wide Acquisition Workforce meetings and Government wide Office of Federal Procurement Policy (OFPP) meetings; manages the Centralized Training Program; collaborates with FAI on government-wide AWF training needs and government requirements for certification; and completes and submits the annual Acquisition Human Capital Plan
- Category Management (CM): Category Management (CM) is a strategic business practice aligned to the requirements of OMB Memorandum 19-13 and cross agency priority goal #7, leveraging common contracts and best practices to drive economies of scale and efficiencies. The BUYSMARTER Full Contract Scan AI Tool and the SmartPay®3 Purchase Card Program aligns to CM principles by aggregating volumes of commonly purchased goods and services to achieve best-in-class (BIC) prices, reducing duplications and leveraging shared solutions. As a Federally mandated initiative, to more efficiently manage contract spend through a balance of Government-wide, agency-wide and local contracts, the program is funded by the Operating and Staff Divisions that have contract authority under the Heads of the Contracting Activity (HCA). The service provides the HHS-attributed amount as allocations across the HHS OPDIVs/STAFFDIVs based on the amount of their respective transactions and obligations for the previous fiscal year.

- Departmental Contracts Information System (DCIS): Departmental Contracts Information System (DCIS) program provides procurement data analysis and reporting capabilities to enable the HHS Operating Divisions (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. The DCIS program oversees the HHS FedDataCheck program. The FedDataCheck service is offered to all OPDIV/STAFFDIV HCAs to monitor and improve the accuracy of FPDS data. Since implementing FedDataCheck, there has been continued improvement in HHS FPDS and USAspending data quality. The program also supports hosting and data services that provide for a central repository of accessible HHS acquisition.
- HHS Consolidated Acquisition Solution (HCAS): The HHS Consolidated Acquisition Solution (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. In addition, HCAS supports OA'S efforts to standardize acquisition end-to-end business processes.
- 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. 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 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): DWD develops professional training strategies within the Department and Government-wide; creates a training curriculum and certification program for grants management officials across the Department; and provides performance assessment Department-wide to improve workforce performance. Findings from <u>GAO-18-491</u>: "Actions Needed to Ensure Staff Have Skills to Administer and Oversee Federal Grants", indicated a need for monitoring and evaluating HHS's grants training at the Departmental level. To accomplish this, the Office of Grants established the DWD and the Grants Management Training Academy (GMTA). The GMTA seeks to be the premier training source for grants management related training for HHS staff and Federal funds recipients.

- **Grants.gov:** Grants.gov (www.grants.gov) is the federal government's single site for the public to LEARN, FIND and APPLY for \$140 billion in federal discretionary grants annually. The PMO is responsible for managing: operations, maintenance, and enhancements to the Grants.gov platform/application; user support; and stakeholder communications and engagement. Grants.gov has transformed the federal grants environment by streamlining and standardizing public-facing grant processes, simplifying and improving these processes for both grantees and grantors, and eliminating redundancies. Grants.gov empowers Federal awarding agencies by improving the visibility and reach of grant programs, providing process standardization and enabling cost savings.
- **GrantSolutions:** GrantSolutions (GS) is a partnership among HHS and other Federal awarding agencies. GS is responsible for delivering end-to-end grants management services to more than fifteen hundred national programs awarding, monitoring, and financially reporting on grants and cooperative agreements to states, tribes, territories, and other institutions and organizations. During FY21, GS processed 117,000 award actions totaling over \$204 billion. GS provides services such as Onboarding/Migration, Pre-Award, Award and Post Award to Agency Grants Management and Program Offices. GS makes grants administration easier and more cost effective through electronic reporting and providing e-business information services for grantees.
- Tracking Accountability in Government Grants System (TAGGS): The Office of Grants, Division of Information and Solutions, Data and Systems Project Management Office (PMO or the PMO) provides technical system support and data services across the HHS financial assistance enterprise. The PMO manages the TAGGS System. Since its 1995 inception, TAGGS has been the single repository of financial assistance award data for the Department. TAGGS is the only HHS, non-financial system approved for submitting financial assistance data to Treasury for publication to USASpending.gov. Currently, TAGGS houses HHS's award data for over \$1.7 million distinct grant and cooperative agreement awards totaling over \$7 trillion. Beginning in 2012, TAGGS collects additional types of financial assistance data including Medicare payments, loans, and loan repayments totaling an additional \$4.2 trillion.

Office of the Assistant Secretary for Health (OASH)

OASH oversees the Department's key public health offices and programs, a number of Presidential and Secretarial advisory committees, 10 regional health offices across the nation, and the Office of the Surgeon General and the U.S. Public Health Service Commissioned Corps.

• Commissioned Corps Headquarters (CCHQ): The U.S. Public Health Service Commissioned Corps (Corps) is a mobile, duty bound, all-officer group of health professionals willing to serve anywhere, anytime to meet the nation's most urgent public health needs including public health emergencies, natural disasters, and national security risks. CCHQ is responsible for all functions management of the Corps, to include recruitment, commissioning, transfers, re-assignment, deployment support, medical fitness, credentialing, promotion, policy, career management, adverse actions, separations and retirements. CCHQ is within the Office of the Surgeon General (OSG), and OSG is one of the offices within the Office of Assistant Secretary for Health (OASH). CCHQ analyzes and reports Corps personnel strength and readiness status, supports Corps (active duty and retiree) payroll, and develops policy to support all Corps officers serving throughout Department of Health and Human Services (HHS) and numerous non-HHS agencies.

CCHQ manages and maintains Corps personnel programs, policies, and procedures that impact Corps personnel.

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 Office of the Assistant Secretary for Public Affairs, Digital Communications Division' (ASPA Digital) mission is to deliver instant and impactful communications through ASPA managed digital communications channels (e.g., websites, social media, digital marketing, etc.) In addition, ASPA Digital is leading a department-wide process to implement the HHS Digital Communications Strategy that supports the Department'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. ASPA Digital aligns and coordinates and supports Agencies and Office digital communications and strategies as messages, information and misinformation are shifting in real time.
- Freedom of Information Act (FOIA): ASPA provides FOIA requests and appeals services to multiple HHS Operating Divisions (OpDiv) and one Staff Division. Services include providing FOIA guidance and processing requests and appeals. Specific services provided include: initial requests (working with customer FOIA liaisons with the identification of responsive records, working with customer subject matter experts and Office of General Counsel, making release and denial determinations); and 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 seven Public Health Service OpDivs.

- HHS Broadcast Studio: Under the leadership of ASPA, the HHS Broadcast Studio supports the entire Department with Video 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.
- Media Monitoring and Analysis: The Media Monitoring activity, coordinated by the Office of the Assistant Secretary for Public Affairs, provides the Secretary, department, agency leadership and staff with the latest analysis of what the media is reporting about Department-wide and Agency-specific priorities, initiatives and programs. This Department-wide tool has been effective since 2009. The nature of this service does not dictate the need for day-to-day oversight. The OPDIV-specific requirements and additional levels of effort are provided through a contract vehicle with Bulletin Intelligence.

Office of the Assistant Secretary for Planning and Evaluation

The Assistant Secretary for Planning and Evaluation (ASPE) is the principal advisor to the Secretary of the U.S. Department of Health and Human Services on policy development, and is responsible for major activities in policy coordination, legislation development, strategic planning, policy research, evaluation, and economic analysis.

• **Strategic Planning System:** The Strategic Planning System is a web-based, PIV card protected application that centralizes information about strategic plans that HHS operating and staff divisions are implementing. It was developed in close collaboration with strategic planners, performance officers, program and policy staff, research and evaluation staff, and others with roles in strategic planning from across the Department and is enhanced based on feedback from our accountholders. Approximately 200 strategic plans are currently in the Strategic Planning System. The Strategic Planning System is supported by a contract managed by ASPE.

Office of the General Counsel (OGC)

The Office of the General Counsel (OGC) is the legal team for the Department of Health and Human Services (HHS), providing quality representation and legal advice on a wide range of highly visible national issues. OGC supports the development and implementation of the Department's programs by providing the highest quality legal services to the Secretary of HHS and the organization's various agencies and divisions.

- **OS Claims:** The Office of the General Counsel (OGC) OS Claims program receives all tort claims filed against the Department pursuant to the Federal Tort Claims Act (FTCA). These torts can range from "slips" and "falls" in Departmental facilities, to motor vehicle accidents involving Departmental vehicles, or medical malpractice in health clinics. OGC reviews and processes all of these claims.
- **Departmental Ethics:** The HHS Office of the General Counsel Ethics (OGC Ethics Division) administers the HHS ethics program. Federal ethics laws and regulations seek to ensure that the public can have confidence that the decisions of the federal government are made in the best interests of the public, and not based on the private gain of individual employees. The HHS ethics program is, primarily, a proactive risk management program. OGC Ethics provides ethics

education, training, advice and counseling to employees concerning how their official duties could interact with their personal interests and outside activities. OGC Ethics Division administers the Department's financial disclosure program, to ensure leadership and employees to prevent conflicts of interest between official duties and reported assets, liabilities, outside activities, and reportable gifts.

Service and Supply Fund All Purpose Table (APT)

(Dollars in Thousands)

	FY 2021	FY 2022	FY 2023
Service and Supply Fund Activities	Actuals	Approved	Approved
PSC		_	
Acquisition Management Services	17,848	59,188	27,273
Federal Occupational Health Portfolio	102,989	152,953	137,784
Financial Management Portfolio	37,868	61,974	62,383
Real Estate, Logistics & Operations Portfolio	234,864	311,379	288,205
PSC Subtotal	393,570	585,494	515,645
Non-PSC			
Acquisition Integration and Modernization Program	1,902	2,072	3,035
Acquisition Reform Workforce Program	2,093	2,247	3,582
Category Management	3,134	3,311	3,896
Commissioned Corps Headquarters	24,796	31,046	32,045
Departmental Contract Information System	1,136	1,767	1,767
Departmental Ethics Program	4,239	4,602	4,602
Digital Communications	28,061	33,739	43,629
Division of Workforce Development	1,703	3,393	3,514
Freedom of Information Act	1,668	2,354	1,991
Grants.gov	6,233	7,300	18,192
GrantSolutions	108,073	96,914	122,244
HHS Broadcast Studio	2,169	3,504	3,739
HHS Consolidated Acquisition Solution	9,824	10,227	10,227
Media Monitoring and Analysis	1,062	1,133	1,190
National Labor Relations	1,131	1,759	1,798
National Security Case Management	2,246	2,315	2,895
Office of Operations Management	159	346	256
Office of Chief Information Office Portfolio	247,557	341,962	412,899
Office of Equal Employment Opportunity, Diversity & Inclusion	4,957	8,317	13,526
Office of General Counsel Claims	1,921	2,064	2,064
Office of Human Resources	63,184	77,738	120,033
Office of Program Audit Coordination	3,339	3,744	4,016
Small Business Center	3,603	3,983	4,550
Strategic Planning System	425	602	602
Tracking Accountability in Government Grants System	5,829	7,559	8,704
Unified Financial Management Systems	59,919	74,349	77,066
Non-PSC Subtotal	590,362	728,345	902,062
Total SSF Revenue	983,932	1,313,840	1,417,708

Service and Supply Fund Object Classification Table – Reimbursable Obligations (Dollars in Thousands)

Object Class	FY 2021 Actuals	FY 2022	FY 2023 Board
		Board Approved	воаго Approved
Reimbursable Obligations			Approved
Personnel Compensation:			
Full – Time Permanent (11.1)	117,588	137,885	176,619
Other Than Full – Time Permanent (11.3)	4,431	4,998	6,352
Other Personnel Compensation (11.5)	4,266	4,816	6,225
Military Personnel (11.7)	6,565	8,698	11,311
Special Personnel Services Payments (11.8)	13,880	15,687	19,429
Subtotal, Personnel Compensation	146,730	172,084	219,936
Civilian Personnel Benefits (12.1)	41,000	48,633	61,282
Military Personnel Benefits (12.2)	807	1,531	1,458
Benefits to Former Personnel (13.0)	283	238	403
Subtotal, Pay Costs	188,820	222,486	283,079
Travel (21.0)	145	3,502	3,841
Transportation of Things (22.0)	2,042	1,344	5,605
Rental Payments to GSA (23.1)	21,249	14,447	22,029
Rental Payments to Others (23.2)	-	-	-
Communications, Utilities and Miscellaneous	14,231	30,865	34,385
Charge (23.3) Printing and Reproduction (24.0)	910	3,069	4,376
	510	5,005	4,370
Other Contractual Services:	10.000	20.674	25.020
Advisory and Assistance Services (25.1)	10,000	29,674	35,828
Other Services (25.2)	329,000	566,738	471,019
Purchases from Govt. Accounts (25.3)	174,744	160,056 7,254	201,310 11,739
Operation & Maintenance of Facilities (25.4)	10,160		
Research & Development Contracts (25.5)	-	114	48
Medical Services (25.6)	12,067	11,478	14,660
Operation & Maintenance of Equipment (25.7)	154,733	178,597	214,442
Subsistence& Support of Persons (25.8)	-		
Subtotal, Other Contractual Services	729,181	992,152	1,019,284
Supplies and Materials (26.0)	22,728	24,820	33,303
Equipment (31.0)	43,100	58,794	76,161
Grants (41.0)	-	-	-
Other (32), (42), (61)	103	603	5881
Subtotal, Non – Pay Costs	795,112	1,091,354	1,134,628
Total, Reimbursable Obligations	983,932	1,313,840	1,417,708

Service and Supply Fund Assistant Secretary for Administration Organizational Chart

DHHS Secretary

Assistant Secretary for Administration

National
Labor
RelationsOOMOCIOOEEODIOffice of
Human
Resources

Acronym Key: OOM – Office of Operations Management OCIO – Office of the Chief Information Officer OEEODI – Office of Equal Employment Opportunity, Diversity and Inclusion SSF Activities are italicized Service and Supply Fund

Non–PSC Activities Organizational Chart

DHHS Secretary

Assistant Secretary of Financial Resources

Office of Acquisitions				Office Budget	Office of Finance		Office of Grants					
Acquistion Reform	AIM	Category Management	DCIS	HCAS	Small Business	SSF Fund Manager	OPAC	UFMS Portfolio	Division of Workforce Devleopment	Grants.gov	GrantSolutions	TAGGS

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

DHHS Secretary



Acronym Key: FOIA – Freedom of Information Act SSF Activities are italicized Service and Supply Fund Program Support Center (PSC) Organizational Chart

Program Support Center

Acquisition Managment Services Federal Occupational Health Portfolio Financial Management Portfolio Real Estate Logistics Operations Portfolio Retirement Pay & Medical Benefits for Commissioned Officers

RETIREMENT PAY AND MEDICAL BENEFITS FOR COMMISSIONED OFFICERS

(Dollars in Thousands)								
	FY 2021	FY 2022 (revised)	FY 2023	FY 2023 +/-FY 2022				
Retirement Payments	\$528,449	\$549,563	\$573,441	\$23,878				
Survivor's Benefits	32,263	34,821	35,964	1,142				
Medical Care Benefits	95,790	104,076	100,922	-3,154				
Subtotal	\$656,502	\$688,461	\$710,327	\$21,866				
Accrued Health Care Benefits <u>*</u>	\$29,883	\$35,852	\$36,964	\$1,112				
Total	\$686,385	\$724,313	\$747,291	\$22,978				

*The funding levels in FY 2022 and FY 2023 accrued health care benefits are estimates and subject to change.

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 2023 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 Accrued Health Care Benefits amount is an estimate provided by DoD Office of the Actuary. The PHS FY2022 per capita is \$5,506 (full-time members) and \$2,138 (part-time members). The PHS FY2023 per capita is \$5,795 (full-time members) and \$2,279 (part-time members). The total budget is estimated by multiplying the per capita amount with the number of activity-duty positions and part-time (reserve) officers. The FY2022 estimated number of active-duty positions of 6,395 and 300 reserve officers yields a total estimated budget of \$35.8 million. The FY2023 estimated number of active positions of 6,300 and 200 reserve officers yields a total estimated budget of \$37.0 million.

The FY 2023 estimate is a net increase of \$23.0 million over the FY 2022 level. This request reflects increase cost due to the annualization of amounts paid to retirees and survivors in FY 2022, a net increase in the number of retirees and survivors and increase of the reserves during FY 2022.

(dollars in thousands)	FY 2024	FY 2025	FY 2026	FY 2027	FY 2028
Retirement Payments	\$598,356	\$624,354	\$651,481	\$679,787	\$709,323
Survivor's Benefits	37,143	38,361	39,619	40,918	42,260
Medical Care Benefits	102,941	104,999	107,099	109,241	111,426
Subtotal	\$738,440	\$767,714	\$798,200	\$829,947	\$863,009
Accrued Health Care Benefits	\$40,000	\$42,000	\$46,000	\$48,000	\$50,000
Total	\$778,440	\$809,714	\$844,200	\$877,947	\$913,009

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 this section shall not apply to the Head Start program.

SEC. 203. Notwithstanding section 241(a) of the PHS Act, such portion as the Secretary shall determine, but not more than 2.55 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. 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. 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 2023 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. 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. 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. 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. 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. 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 2023:

(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. 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. 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. 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. 214. Not to exceed 1 percent of funds appropriated by this Act to the offices, institutes, and centers of the National Institutes of Health may be 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. 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. 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. 217. Effective during the period beginning on November 1, 2015 and ending January 1, 2024, any provision of law that refers (including through crossreference 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. 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. 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. 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. 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 noncompliance with paragraph (1) if the Secretary certifies and provides a report to Congress on the contractor's or grantee's good-faith efforts and progress towards compliance;
- (3) not more than four consecutive waivers under paragraph (2) may be granted to a contractor or grantee with respect to a specific facility;
- (4) ORR shall ensure full adherence to the monitoring requirements set forth in section 5.5 of its Policies and Procedures Guide as of May 15, 2019;
- (5) for any such unlicensed facility in operation for more than three consecutive months, ORR shall conduct a minimum of one comprehensive monitoring visit during the first three months of operation, with quarterly monitoring visits thereafter; and
- (6) not later than 60 days after the date of enactment of this Act, ORR shall brief the Committees on Appropriations of the House of Representatives and the Senate outlining the requirements of ORR for influx facilities including any requirement listed in paragraph (1)(A) that the Secretary has determined are not applicable to non-State licensed facilities.

SEC. 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. 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. 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 219 of this Act at costs not in excess of those paid for or reimbursed by the Department of Defense.

SEC. 225. Of the unobligated balances in the "Nonrecurring Expenses Fund" established in section 223 of division G of Public Law 110–161, \$500,000,000 are hereby permanently cancelled not later than September 30, 2023.

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. For fiscal year 2023, 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. 228.

Section 340B of the Public Health Service Act (42 U.S.C. 256b) is amended (a) in subsection (a)(5)(C)

- (1) by striking "A covered entity shall permit" and inserting "(i) DUPLICATE DISCOUNTS AND DRUG RESALE. A covered entity shall permit"; and
- (2) by inserting at the end the following:

"(*ii*) USE OF SAVINGS. A covered entity shall permit the Secretary to audit, at the Secretary's expense, the records of the entity to determine how net income from purchases under this section are used by the covered entity."

"(iii) RECORDS RETENTION. Covered entities shall retain such records and provide such records and reports as deemed necessary by the Secretary for carrying out this subparagraph.".

(b) by adding at the end the following new subsection: "(f) REGULATIONS. The Secretary may promulgate such regulations as the Secretary determines appropriate to carry out the provisions of this section.".

SEC. 229. (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 administer and 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 describing the evaluations to be carried out 15 days in advance of any such transfer.

(b) The accounts referred to in subsection (a) are: "Low Income Home Energy Assistance", "Refugee and Entrant Assistance", "Payments to States for the Child Care and Development Block Grant", and "Children and Families Services Programs".

SEC. 230. (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, 2021.

SEC. 231. 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. 232. Notwithstanding any other provision of law, the Secretary of Health and Human Services may use \$5,000,000 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 zero emission passenger motor vehicles and supporting charging or fueling infrastructure, and to cover other costs related to electrifying the motor vehicle fleet within HHS: Provided, That supporting charging or fueling infrastructure 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. 233. 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. 234. 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.

SEC. 235. 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 and 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. 236. (a) Amounts made available to the Department of Health and Human Services in this or any other Act under the heading "Administration for Children and Families—Refugee and Entrant Assistance" may in this fiscal year and hereafter be used to provide, including through grants, contracts, or cooperative agreements, mental health and other supportive services, including access to legal services, to children, parents, and legal guardians who were separated at the United States-Mexico border between January 20, 2017, and January 20, 2021: Provided, That such services shall also be available to immediate family members of such individuals if such family members are in the United States and in the same household: Provided further, That amounts made available to the Department of Health and Human Services for refugee and entrant assistance activities in any other provision of law may be used to carry out the purposes of this section: Provided further, That the Secretary of Health and Human Services may identify the children, parents, and legal guardians eligible to receive mental health and other supportive services described 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; Provided further, the Secretary has sole discretion to identify the individuals who will receive services under this section due to their status as immediate family members residing in the same household of class members or class members' minor children, and such identification shall not be subject to judicial review.

(b) Notwithstanding any other provision of law, in this fiscal year and hereafter, individuals identified in subsection (a), including immediate family members of such individuals residing in the same household if such immediate family members are identified by the Secretary in accordance with such subsection, shall be eligible for resettlement assistance, entitlement programs, and other benefits available to refugees admitted under section 207 of the Immigration and Nationality Act (8 U.S.C. 1157) to the same extent, and for the same periods of time, as such refugees.

SEC. 237. During this fiscal year, an Operating or Staff Division in HHS may enter into a reimbursable agreement with another major organizational unit within HHS or of another agency under which the ordering agency or unit delegates to the servicing agency or unit the authority and funding to issue a grant or cooperative agreement on its behalf: Provided, That the head of the ordering agency or unit must certify that amounts are available and that the order is in the best interests of the United States Government: Provided further, That funding may be provided by way of advance or reimbursement, as deemed appropriate by the ordering agency or unit, with proper adjustments of estimated amounts provided in advance to be made based on actual costs: Provided further, That an agreement made under this section obligates an appropriation of the ordering agency or unit, including for costs to administer such grant or

cooperative agreement, and such obligation shall be deemed to be an obligation for any purpose of law: Provided further, That an agreement made under this section may be performed for a period that extends beyond the current fiscal year.

SEC. 238. Section 317G of the Public Health Service Act (42 U.S.C. 247b–8) is amended by adding at the end the following: "The Secretary may, no later than 120 days after the end of an individual's participation in such a fellowship or training program, and without regard to any provision in title 5 of the United State Code governing appointments in the competitive service, appoint a participant in such a fellowship or training program to a term or permanent position in the Centers for Disease Control and Prevention.".

SEC. 239. In the event of a public health emergency declared by the Secretary of Health and Human Services under section 319 of the Public Health Service Act, or where the Secretary determines that there is a significant potential for such an emergency to exist that will affect national security or the health and security of United States citizens domestically or internationally, the Director of the Centers for Disease Control and Prevention may enter into transactions other than contracts, grants, and cooperative agreements that are directly related to preparing for or responding to such emergency or potential emergency.

SEC. 240. a) The Public Health Service Act (42 U.S.C. 201 et seq.), the Controlled Substances Act (21 U.S.C. 801 et seq.), the Comprehensive Smoking Education Act (15 U.S.C. 1331 et seq.), the Comprehensive Addiction and Recovery Act of 2016 (Public Law 114–198), the Drug Abuse Prevention, Treatment, and Rehabilitation Act (21 U.S.C. 1101 et seq.), the Omnibus Crime Control and Safe Streets Act of 1968 (34 U.S. C. 10101 et seq.), and title 5 of the United States Code are each amended—

- (1) by striking "National Institute on Drug Abuse" each place it appears and inserting "National Institute on Drugs and Addiction"; and
- (2) by striking "National Advisory Council on Drug Abuse" each place it appears and inserting "National Advisory Council on Drugs and Addiction".

(b) Title IV of the Public Health Service Act (42 U.S.C. 281 et seq.) is amended—

(1) in section 464H(b)(5), by striking "National Institute of Drug Abuse" and inserting "National Institute on Drugs and Addiction";

(2) in sections 464L, 464M(a), 464O, and 494A, by striking "drug abuse" each place it appears and inserting "drug use";

- (3) in section 464L(a), by striking "treatment of drug abusers" and inserting "treatment of drug addiction";
- (4) in section 464M(a), by striking "prevention of such abuse" and inserting "prevention of such use";
- (5) in section 464N—
 - (A) in the section heading, by striking "DRUG ABUSE RESEARCH CENTERS" and inserting "DRUGS AND ADDICTION RESEARCH CENTERS";
 - (B) in subsection (a)—

(i) in matter preceding paragraph (1), by striking "National Drug Abuse Research Centers" and inserting "National Drugs and Addiction Research Centers"; and

(*ii*) in paragraph (1)(C), by striking "treatment of drug abuse" and inserting

"treatment of drug addiction"; and

(C) in subsection (c)—

(i) by striking "DRUG ABUSE AND ADDICTION RESEARCH" and inserting "DRUGS AND ADDICTION RESEARCH CENTERS";

(*ii*) in paragraph (1), by striking "National Drug Abuse Treatment Clinical Trials Network" and inserting "National Drug Addiction Treatment Clinical Trials Network"; and

(iii) in paragraph (2)(H), by striking "reasons that individuals abuse drugs, or refrain from abusing drugs" and inserting "reasons that individuals use drugs or refrain from using drugs"; and

- (6) in section 464P—
 - (A) in subsection (a)—

(*i*) in paragraph (1), by striking "drug abuse treatments" and inserting "drug addiction treatments"; and

(*ii*) in paragraph (6), by striking "treatment of drug abuse" and inserting "treatment of drug addiction"; and

(B) in subsection (d)—

(i) by striking "disease of drug abuse" and inserting "disease of drug addiction";
(ii) by striking "abused drugs" each place it appears and inserting "addictive drugs"; and

(iii) by striking "drugs of abuse" and inserting "drugs of addiction".

- (c) Section 464N of the Public Health Service Act (42 U.S.C. 2850–2), as amended by subsection (b)(5), is further amended by striking "drug abuse" each place it appears and inserting "drug use".
- (d) Any reference in any law, regulation, map, document, paper, or other record of the United States to the National Institute on Drug Abuse shall be considered to be a reference to the National Institute on Drugs and Addiction.

SEC. 241. (a) The Public Health Service Act (42 U.S.C. 201 et seq.) and the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970 (42 U.S.C. 4541 et seq.) are each amended—

- (1) by striking "National Institute on Alcohol Abuse and Alcoholism" each place it appears and inserting "National Institute on Alcohol Effects and Alcohol-Associated Disorders"; and
- (2) by striking "National Advisory Council on Alcohol Abuse and Alcoholism" each place it appears and inserting "National Advisory Council on Alcohol Effects and Alcohol-Associated Disorders".

(b) Title IV of the Public Health Service Act (42 U.S.C. 281 et seq.) is amended—

- (1) in section 464H—
 - (A) in subsection (a)—

(i) by striking "prevention of alcohol abuse" and inserting "prevention of alcohol misuse"; and

(*ii*) by striking "treatment of alcoholism" and inserting "treatment of alcohol associated disorders"; and

(B) in subsection (b)—

(i) in paragraph (3)—

(I) in subparagraph (A), by striking "alcohol abuse and domestic violence" and inserting "alcohol misuse and domestic violence";
(II) in subparagraph (D), by striking "abuse of alcohol" and inserting "misuse of alcohol";

(III) by striking subparagraph (E) and inserting "(E) the effect of social pressures, legal requirements regarding the use of alcoholic beverages, the cost of such beverages, and the economic status and education of users of such beverages on the incidence of alcohol misuse, alcohol use disorder, and other alcohol-associated disorders,"; and

(ii) in paragraph (5), by striking "impact of alcohol abuse" and inserting "impact of alcohol misuse";

(2) in sections 464H(b), 464I, and 494A, by striking "alcohol abuse and alcoholism" each place it appears and inserting "alcohol misuse, alcohol use disorder, and other alcohol-associated disorders";

(3) in sections 464H(b) and 464J(a), by striking "alcoholism and alcohol abuse" each place it appears and inserting "alcohol misuse, alcohol use disorder, and other alcohol-associated disorders"; and

(4) in section 464J(a)—

(A) by striking "alcoholism and other alcohol problems" each place it appears and inserting "alcohol misuse, alcohol use disorder, and other alcohol-associated disorders";

(B) in the matter preceding paragraph (1), by striking "interdisciplinary research related to alcoholism" and inserting "interdisciplinary research related to alcohol-associated disorders"; and

(C) in paragraph (1)(E), by striking "alcohol problems" each place it appears and inserting "alcohol misuse, alcohol use disorder, and other alcohol-associated disorders".

(c) Any reference in any law, regulation, map, document, paper, or other record of the United States to the National Institute on Alcohol Abuse and Alcoholism shall be considered to be a reference to the National Institute on Alcohol Effects and Alcohol-Associated Disorders.

SEC. 242. (a) The Public Health Service Act (42 U.S.C. 201 et seq.) is amended—

- (1) by striking "Substance Abuse and Mental Health Services Administration" each place it appears and inserting "Substance use And Mental Health Services Administration";
- (2) by striking "Center for Substance Abuse Treatment" each place it appears and inserting "Center for Substance Use Services"; and
- (3) by striking "Center for Substance Abuse Prevention" each place it appears and inserting "Center for Substance Use Prevention Services".

(b) Title V of the Public Health Service Act (42 U.S.C. 290aa et seq.) is amended—
(1) in the title heading, by striking "SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION" and inserting "SUBSTANCE USE AND MENTAL HEALTH SERVICES ADMINISTRATION";
(2) in section 501(A) in the section heading, by striking "SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION" and inserting "SUBSTANCE USE AND MENTAL HEALTH SERVICES ADMINISTRATION"; and

(B) in subsection (a), by striking "(hereafter referred to in this title as the Administration)" and inserting "(hereafter referred to in this title as SAMHSA or the Administration)";

(3) in section 507, in the section heading, by striking "CENTER FOR SUBSTANCE ABUSE TREATMENT" and inserting "CENTER FOR SUBSTANCE USE SERVICES"; (4) in section 513(a), in the subsection heading, by striking "CENTER FOR SUBSTANCE ABUSE TREATMENT" and inserting "CENTER FOR SUBSTANCE USE SERVICES"; and

(5) in section 515, in the section heading, by striking "CENTER FOR SUBSTANCE ABUSE PREVENTION" and inserting "CENTER FOR SUBSTANCE USE PREVENTION SERVICES".

(c) Section 1932(b)(3) of the Public Health Service Act (42 U.S.C. 300x–32(b)(3)) is amended in the paragraph heading by striking "CENTER FOR SUBSTANCE ABUSE PREVENTION" and inserting "CENTER FOR SUBSTANCE USE PREVENTION SERVICES".

(d) Section 1935(b)(2) of the Public Health Service Act (42 U.S.C. 300x–35(b)(2)) is amended in the paragraph heading by striking "CENTER FOR SUBSTANCE ABUSE PREVENTION" and inserting "CENTER FOR SUBSTANCE USE PREVENTION SERVICES".

(e) The Indian Alcohol and Substance Abuse Prevention and Treatment Act of 1986 (25 U.S.C. 2401 et seq.) is amended by striking "Substance Abuse and Mental Health Services Administration" each place it appears and inserting "Substance use And Mental Health Services Administration".

(f) The Social Security Act is amended in sections 1861, 1866F, and 1945 (42 U.S.C. 1395x, 1395cc-6, 1396w-4) by striking "Substance Abuse and Mental Health Services Administration" each place it appears and inserting "Substance use And Mental Health Services Administration".
(g) Section 105(a)(7)(C)(i)(III) of the Child Abuse Prevention and Treatment Act (42 U.S.C. 5106(a)(7)(C)(i)(III)) is amended by striking "Substance Abuse and Mental Health Services Administration".
(h)

(1) Except as provided in paragraph (2), any reference in any law, regulation, map, document, paper, or other record of the United States to the Substance Abuse and Mental Health Services Administration, the Center for Substance Abuse Treatment of such Administration, or the Center for Substance Abuse Prevention of such Administration shall be considered to be a reference to the Substance use And Mental Health Services Administration, the Center for Substance Use Services of such Administration, or the Center for Substance Use Services of such Administration, or the Center for Substance Use Prevention Services of such Administration, respectively.
(2) Paragraph (1) shall not be construed to alter or affect section 6001(d) of the 21st Century Cures Act (42 U.S.C. 290aa note), providing that a reference to the Administration shall be construed to be a reference to the Assistant Secretary for Mental Health and Substance Use.

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, 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 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 is authorized to make available for official reception and representation expenses not to exceed \$5,000 from funds available for "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."

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 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.

(b) In this 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. 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. 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. 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. 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. 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. 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. 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. 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. 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. 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 2023" for "Fiscal Year 2014" in the title of subsection (b) and by substituting "September 30, 2027" for "September 30, 2018" each place it appears: Provided, That such pilots shall include communities that have 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. 518. 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 that 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, 2027: Provided, That when an office referenced in subsection (a) receives research and evaluation funding from multiple appropriations, such office 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.

SEC. 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, \$19,860,000,000 shall not be available for obligation in this fiscal year.

SEC. 520. Of the unobligated balances made available for purposes of carrying out section 2105(a)(3) of the Social Security Act, \$6,017,000,000 shall not be available for obligation in this fiscal year.

SEC. 521. Of the unobligated balances made available by section 2104(f) of the Social Security Act that are no longer available for the purposes described in such section, \$114,474,000 are hereby permanently cancelled.

SEC. 522. Of the unobligated balances made available by section 301(b)(3) of Public Law 114–10, \$1,185,000,000 are hereby permanently cancelled.

SEC. 523. Of the unobligated balances made available by section 3002(b)(2) of Public Law 115–120, \$4,999,000,000 are hereby permanently cancelled.