

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FISCAL YEAR

2009

General Departmental Management
Office of Medicare Hearings and Appeals
National Coordinator for Health Information Technology
Public Health and Social Services Emergency Fund
HHS General Provisions

Justification of Estimates for Appropriations Committees

Introduction

This FY 2009 Congressional Justification is one of several documents that fulfill the performance planning and reporting requirements for the Department of Health and Human Services (HHS). HHS agencies achieve full compliance with the Government Performance and Results Act of 1993, and with Office of Management and Budget Circulars A-11 and A-136, through the FY 2009 Congressional Justifications and Online Performance Appendices, the Agency Financial Report, and the HHS Performance Highlights.

The Performance Highlights document briefly summarizes key past and planned performance and financial information. The Agency Financial Report provides fiscal and high-level performance results. The FY 2009 Congressional Justifications fully integrate HHS's FY 2007 Annual Performance Report and FY 2009 Annual Performance Plan, and are supplemented by the Online Performance Appendices. The Justifications focus on key performance measures and summarize program results, while the Appendices provide more detailed performance information for all HHS measures.

The Congressional Justification and Online Performance Appendix for Departmental Management can be found at: http://www.hhs.gov/budget/docbudget.htm



Message from the Assistant Secretary for Resources and Technology

I am pleased to present the Congressional Justification for Departmental Management (DM) activities within the Office of the Secretary. This budget request represents the Administration's initiatives, as well as the Secretary's priorities in guiding the Department of Health and Human Services to fulfill the President's vision of a healthier, safer and more hopeful America.

The DM budget request supports the Secretary in his role as chief policy officer and general manager of HHS. In total, DM activities are requesting \$1,859 million and 2,433 full-time equivalent (FTE) staff in FY 2009. These levels will ensure the Secretary's ability to achieve excellence in management throughout the important programs and activities administered by the Department.

The FY 2009 budget for DM includes funding increases for the transformation and expansion of the U.S. Public Health Service Commissioned Corps, and to continue the Department's efforts at strengthening our ability to protect the American people in the event of an influenza pandemic. The request also increases investments for emergency preparedness, including enhancements to our emergency response capabilities, and research and development of promising medical countermeasures with the greatest potential for acquisition for the Strategic National Stockpile. Additionally, the request includes funds for the Secretary's Health Diplomacy Initiative, and to continue efforts at making electronic health records available to most Americans.

Overall, the DM budget request reflects a fiscally prudent budget, holding down costs in most areas with a few key increases. Reductions reflect the completion of certain programs and efforts to hold down rent and operations and maintenance costs.

The Secretary and I look forward to working with the Congress toward the enactment and implementation of a 2009 budget that continues our progress for the health and well-being of the American people.

Charles E. Johnson

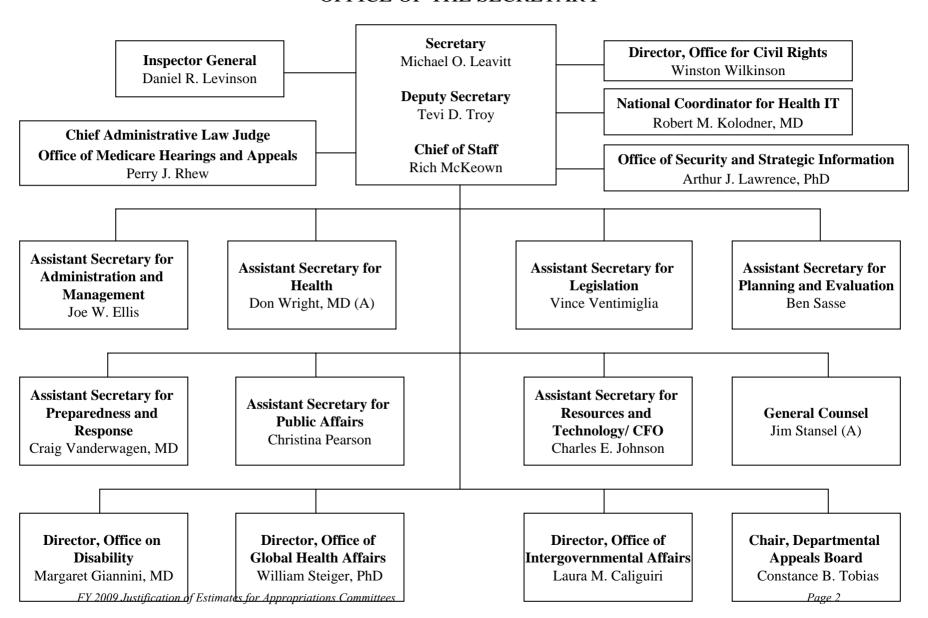
Assistant Secretary for Resources

and Technology

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DEPARTMENT OF THE ALTHUMAN SERVICES OFFICE OF THE SECRETARY



DEPARTMENTAL MANAGEMENT Executive Summary

Agency Mission

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

- General Departmental Management;
- Office of Medicare Hearings and Appeals:
- Office of the National Coordinator for Health Information Technology; and
- Public Health and Social Services Emergency Fund.

The **mission** of 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.

Overview of Budget Request

The FY 2009 budget request for DM – including Pandemic Influenza amounts – totals \$1,859,190,000 in appropriated budget authority, and 2,433 full-time equivalent (FTE) positions. When Pandemic Influenza amounts are excluded, the total of \$1,274,099,000 is an increase of \$160,109,000 (or 14.4 percent) above the comparable FY 2008 Enacted level; please see the DM Budget by Appropriation table on page 5.

The **General Departmental Management** (GDM) appropriation supports those activities associated with the Secretary's roles 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 twelve Staff Divisions (STAFFDIVs), including the Immediate Office of the Secretary, the Departmental Appeals Board, and the Offices of: Public Affairs; Legislation; Planning and Evaluation; Resources and Technology; Administration and Management; Intergovernmental Affairs; General Counsel; Global Health Affairs; Disability; and Public Health and Science.

The **Office of Medicare Hearings and Appeals** (OMHA) was created in response to the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA). As mandated by MMA, OMHA opened its doors on July 1, 2005, to hear Medicare appeals at the Administrative Law Judge level, for cases under titles XVIII and XI of the Social Security Act. OMHA is funded entirely from the Medicare Hospital Insurance and Supplemental Medical Insurance Trust Funds, and requests \$65,344,000 and 374 FTE in FY 2009.

The Office of the National Coordinator for Health Information Technology (ONC) was created in response to Executive Order 13335, signed by President Bush on April 27, 2004. ONC became fully operational on August 19, 2005, and requests budget authority of \$18,151,000 (program level of \$66,151,000) and 28 FTE in FY 2009 to accomplish its mission of expanding the use of health information technology nationwide, by facilitating the

development of an interoperable Health IT infrastructure. The goal is to reduce medical errors, improve healthcare quality, and produce greater value in healthcare expenditures.

The **Public Health and Social Services Emergency Fund** (PHSSEF) provides resources in support of a comprehensive program to respond to the health and medical consequences of bioterrorism and other public health emergencies, including all funding for the Office of the Assistant Secretary for Preparedness and Response (ASPR). ASPR directs the Department's efforts in preparing for, protecting against, responding to, and recovering from all acts of bioterrorism and other public health emergencies that affect the civilian population. The PHSSEF also includes the Department's resources for administering its Pandemic Influenza programs, cyber-security efforts, Office of Security and Strategic Information, and Medical Reserve Corps (part of the USA Freedom Corps initiative).

Program increases:

Commissioned Corps Transformation (+\$26 million)

The increase for Commissioned Corps will support a number of Commissioned Corps initiatives, including: strengthening recruitment, training and career development to promote officer retention; creating two Health and Medical Response (HAMR) teams; supporting the salary and benefits of the current eight positions that are involved in program management and oversight; training development and coordination; response coordination; information technology development and maintenance; and contracted support for the learning management system (necessary to provide ongoing web-based readiness training for all 6,000 Commissioned Officers).

<u>Health Diplomacy Initiative (+\$3.5 million)</u>

The Health Diplomacy Initiative supports the continued strengthening and expansion of the Presidential Western Hemisphere Initiative for Social Justice and Secretarial Health-Diplomacy Initiative in Latin America. Funds will support additional health care services in Latin American through deployment of USPHS Officers on humanitarian and medical training missions, strengthen the Regional Health Care Training Center to increase skill sets and expertise for students from communities at highest-risk and needs in a range of public health areas, including influenza preparedness, oral health, and maternal/child health, and increase collaboration with non-governmental organizations to ensure sustainability and positive impact.

Preparedness and Emergency Operations (+\$17.6 million)

Preparedness and Emergency Operations will strengthen HHS' capabilities to deploy, coordinate, and communicate effectively during a response. Funding will support improved regional response coordination, including the development of scenario-based response plans tailored to individual geographic regions; systems upgrades and infrastructure enhancements in the Secretary's Operations Center; and the development of emergency response capabilities, including training and exercises.

National Disaster Medical System (+\$7 million)

The increase will support headquarters operations as well as medical response assets including teams, supplies, and equipment.

Advanced Research and Development (+\$148.5 million)

Funds will support efforts to evaluate, assess and develop candidate medical countermeasures with the long-term potential to qualify for acquisition as medical countermeasures for the Strategic National Stockpile. These funds are requested with two years of fiscal availability.

Advanced Development of Next Generation Ventilators (+\$25 million)

The increase will support advanced development of next generation ventilators. Ventilators would have a significant impact during an influenza pandemic, and gap analysis of domestic manufacturing surge capacity for ventilators demonstrated that pandemic preparedness could not be accommodated by present capacities for existing types of ventilators.

Policy, Strategic Planning, and Communication (+\$1 million)

This increase will support the development of the National Health Security Strategy as required by the Pandemic and All-Hazards Preparedness Act.

Program Decreases:

Embryo Adoption Awareness Campaign (-\$1.9 million)

The FY 2009 request for Embryo Adoption Awareness Campaign is consistent with the FY 2008 President's Budget. The FY 2009 request provides continued funding only for embryo adoption public awareness information and education activities, which have been the core of the program since its inception. Funds are not included for medical and administrative services related to embryo adoption.

Hospital Preparedness (-\$61.7 million)

The formula grant level for awards to States, cities, and territories will be reduced due to a shortening of the grant cycle from twelve months to nine months, three weeks. This is a technical adjustment, not a reduction in grant awards on a monthly basis.

Office of Minority Health (-\$6.1 million)

The FY 2009 Budget does not include funds for the continuation of three grant programs: Morehouse Male Health Project, Youth Empowerment Program, and the Health Disparities in Mississippi project.

Office on Women's Health (-\$2.6 million)

The FY 2009 Budget reflects the fact that some of the programs funded in 2008 were targeted for one-year funding only. These include the Regional Women's Master Contract, the 2008 Woman Challenge, and the Institute of Medicine (IOM) study on women's health research.

DEPARTMENTAL MANAGEMENT

BUDGET BY APPROPRIATION

(Dollars in thousands)

	FY 2007 <u>Actual</u>		FY 2008 Enacted		FY 2009 <u>Estimate</u>	
	FTE	Amount	FTE	<u>Amount</u>	<u>FTE</u>	Amount
General Departmental Management	1,313	\$364,490	1,280	\$354,015	1,388	\$379,864
Service and Supply Fund (OS portion)	109	_	126	_	127	-
Office of Medicare Hearings and Appeals	356	\$59,727	374	\$63,864	374	\$65,344
Office of the National Coordinator for Health Information Technology	23	\$42,402	28	\$41,661	28	\$18,151
Public Health and Social Services Emergency Fund (PHSSEF): Non-Pandemic Flu portion	287	<u>\$716,733</u>	404	<u>\$654,450</u>	469	<u>\$810,740</u>
Subtotal, Budget Authority	1,998	\$1,183,352	2,222	\$1,113,990	2,386	\$1,274,099
PHSSEF: Pandemic Influenza	10		36	<u>\$74,809</u>	<u>47</u>	<u>\$585,091</u>
TOTAL, Budget Authority	2,098	\$1,183,352	2,248	\$1,188,799	2,433	\$1,859,190
[Trust Fund transfers included above for GDM and OMHA]		[\$65,520]		[\$69,555]		[\$71,195]
PHS Evaluation Funds		\$58,452		\$65,656		\$94,756
HCFAC Funds		<u>\$5,131</u>		<u>\$5,714</u>		<u>\$5,714</u>
TOTAL, Program Level		\$1,222,676		\$1,260,169		\$1,959,660

General Departmental Management

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APPROPRIATIONS LANGUAGE

GENERAL DEPARTMENTAL MANAGEMENT

For necessary expenses, not otherwise provided, for general departmental management, including hire of six sedans, and for carrying out titles III, XVII, XX, and XXI of the Public Health Service Act, the United States-Mexico Border Health Commission Act, and research studies under section 1110 of the Social Security Act, [\$355,518,000] \$374,013,000, together with [\$5,792,000] \$5,851,000 to be transferred and expended as authorized by section 201(g)(1) of the Social Security Act from the *Federal* Hospital Insurance Trust Fund and the [Supplemental] Federal Supplementary Medical Insurance Trust Fund, and \$46,756,000 from the amounts available under section 241 of the Public Health Service Act to carry out national health or human services research and evaluation activities: Provided, That of the funds made available under this heading for carrying out title XX of the Public Health Service Act, \$13,120,000 shall be for activities specified under section 2003(b)(2), all of which shall be for prevention service demonstration grants under section 510(b)(2) of title V of the Social Security Act, as amended, without application of the limitation of section 2010(c) of said title XX: Provided further, That of this amount, \$51,891,000 shall be for minority AIDS prevention and treatment activities; and [\$5,892,000] \$5,789,000 shall be to assist Afghanistan in the development of maternal and child health clinics, consistent with section 103(a)(4)(H) of the Afghanistan Freedom Support Act of 2002; and [\$1,000,000 shall be transferred, not later than 30 days after enactment of this Act, to the National Institute of Mental Health to administer the Interagency Autism Coordinating Committee: Provided further, That specific information requests from the chairmen and ranking members of the Subcommittees on Labor, Health and Human Services, and Education, and Related Agencies, on scientific research or any other

manner and within the time frame specified in the request: *Provided further*, That scientific information, including such information provided in congressional testimony, requested by the Committees on Appropriations and prepared by government researchers and scientists shall be transmitted to the Committees on Appropriations, uncensored and without delay: *Provided further*, That funds provided in this Act for embryo adoption activities may be used to provide, to individuals adopting embryos, through grants and other mechanisms, medical and administrative services deemed necessary for such adoptions: *Provided further*, That such services shall be provided consistent with 42 CFR 59.5(a)(4): *Provided further*, That \$4,138,000 shall be available for the projects and in the amounts specified in the explanatory statement described in section 4 (in the matter preceding division A of this consolidated Act)] \$3,545,000 shall be for a Health *Diplomacy Initiative and may be used to carry out health diplomacy activities such as health training, services, education, and program evaluation provided directly, through grants, or through contracts.*

(Department of Health and Human Services Appropriations Act, 2008.)

LANGUAGE ANALYSIS

Language Provision

"from the *Federal* Hospital Insurance Trust Fund and the [Supplemental] *Federal Supplementary* Medical Insurance Trust Fund"

"\$1,000,000 shall be transferred, not later than 30 days after enactment of this Act, to the National Institute of Mental Health to administer the Interagency Autism Coordinating Committee:"

"Provided further, That funds provided in this Act for embryo adoption activities may be used to provide, to individuals adopting embryos, through grants and other mechanisms, medical and administrative services deemed necessary for such adoptions: *Provided further*, That such services shall be provided consistent with 42 CFR 59.5(a)(4):"

"Provided further, That \$4,138,000 shall be available for the projects and in the amounts specified in the explanatory statement described in section 4 (in the matter preceding division A of this consolidated Act)"

"\$3,545,000 shall be for a Health Diplomacy Initiative and may be used to carry out health diplomacy activities such as health training, services, education, and program evaluation provided directly, through grants, or through contracts"

Explanation

These changes are necessary in order to correct and standardize all HHS appropriations language which references the HI and SMI Trust Funds.

This language was for a one-time-only action and is no longer needed.

This language is no longer needed.

This language was for a one-time-only action and is no longer needed.

This language specifies funding and parameters for the Secretary's Health Diplomacy Initiative.

AMOUNTS AVAILABLE FOR OBLIGATION 1

	FY 2007	FY 2008	FY 2009
	Actual	Enacted	Estimate
General funds:			
Annual appropriation\$		\$355,518,000	\$374,013,000
Rescission pursuant to PL 110-28	-500,000	_	_
Rescission pursuant to PL 110-161		-6,211,000	
Subtotal		349,307,000	374,013,000
Comparable transfer from:			
PHSSEF, for Transformation of Commissioned			
Corps	+8,726,000	_	_
Comparable transfer to:			
PHSSEF, for Office of Security and Strategic			
Information	-474,000	_	_
Actual transfer to:			
NIMH for Interagency Autism Coordinating Cmte		-983,000	<u> </u>
Subtotal, adjusted general funds	358,697,000	348,324,000	374,013,000
-			
Trust funds:	5 702 000	5 702 000	5 051 000
Annual appropriation	5,793,000	5,792,000	5,851,000
Rescission pursuant to PL 110-161Subtotal, adjusted trust funds	5,793,000	<u>-101,000</u> 5,691,000	5,851,000
Subtotal, adjusted trust runds	3,793,000	3,091,000	3,831,000
Subtotal, adjusted budget authority	364 490 000	354,015,000	379,864,000
Subtotal, adjusted budget authority	504,470,000	334,013,000	377,004,000
Unobligated balance lapsing	-781,000		
Total obligations\$	363,709,000	\$354,015,000	\$379,864,000

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 $^{^1}$ Excludes the following amounts for reimbursable activities carried out by this account: FY 2007 - \$218,111,000; FY 2008 - \$212,090,000; FY 2008 - \$215,000,000.

SUMMARY OF CHANGES

2008	General funds adjusted appropriation				\$348,324,000 <u>5,691,000</u>
	Total adjusted budget authority				354,015,000
2009	Request – General funds				374,013,000 <u>5,851,000</u>
	Total estimated budget authority				379,864,000
	Net change				+25,849,000
		200	8 Estimate	Chang	e from Base
		(FTE)	Budget Authority	(FTE)	Budget Authority
Increa	ses:				
A. Bu	ilt-in:				
1.	Anualization of January 2008 pay raise (3.5%)	(1,280)	\$123,160,000	()	+1,078,000
2.	Effect of January 2009 pay raise (3.0%)	(1,280)	123,160,000	()	+2,833,000
3.	Within-grade increases and career ladder promotions	(1,280)	123,160,000	()	+1,231,000
4.	Total Common Expenses/ Service and Supply Fund payments	()	18,861,000	()	+3,550,000
	Subtotal				+8,692,000
B. Pro	ogram:				
1.	Office of Public Health and Science: Commissioned Corps Transformation and expansion	(23)	4,119,000	(+117)	+26,040,000
2.	Office of Global Health Affairs: Health Diplomacy Initiative	()	0	(-1)	+3,545,000
3.	National Commission on Children and Disasters	()	500,000	()	+500,000
	Subtotal			(+116)	+30,085,000
	Total Increases			(+116)	+38,777,000
Decre	ases:				
B. Pro	ogram:				
1.	Office of Public Health and Science: net reduction in grants	()	66,142,000	()	-5,684,000
2.	One-time Congressional projects included in FY 2008 GDM appropriation	()	3,501,000	()	-3,501,000
3.	Embryo Adoption Awareness Campaign	()	3,930,000	()	-1,950,000
4.	UFMS Payment	()	1,187,000	()	-1,187,000
5.	Net decrease in other non-salary administrative costs	(1,280)	230,855,000	()	-421,000
6.	Office of the General Counsel	(365)	36,427,000	(-8)	-185,000
	Total Decreases			(-8)	-12,928,000

BUDGET AUTHORITY BY ACTIVITY

(Dollars in Thousands)

	FY 2007 Actual			FY 2008 Enacted		2009 timate
	<u>FTE</u>	<u>Amount</u>	<u>FTE</u>	<u>Amount</u>	<u>FTE</u>	<u>Amount</u>
Immediate Office of the Secretary	68	\$9,959	66	\$9,960	66	\$10,048
Public Affairs	28	4,008	27	3,909	27	3,944
Legislation	28	3,187	24	3,108	24	3,135
Planning and Evaluation	97	6,787	97	_	97	_
Resources and Technology	141	20,662	140	20,152	140	20,534
Administration and Management	114	15,458	113	15,341	113	15,984
Intergovernmental Affairs	33	5,762	32	5,620	32	5,670
General Counsel	376	37,347	365	36,427	357	36,242
Departmental Appeals Board	60	9,600	59	9,363	59	9,445
Disability	4	739	4	721	4	728
Global Health Affairs	43	9,796	38	9,693	37	16,723
Public Health and Science	305	153,791	300	144,716	417	162,932
Embryo Adoption Awareness Campaign	_	1,980	_	3,930	_	1,980
President's Council on Bioethics	10	_	9	_	90	_
Center for Faith-Based Initiatives	6	_	6	_	6	_
Rent/Operations & Maintenance ¹	_	15,249	_	16,882	_	16,850
Common Expenses/SSF Payment ¹	_	16,740	_	18,861	_	22,411
UFMS Payment	_	1,187	_	_	_	_
Enterprise IT	_	347	_	347	_	347
Minority HIV/AIDS	_	51,891	_	50,984	_	51,891
Congressional Projects	_	_	_	3,501	_	_
Commission on Children & Disasters				500		_1,000
Subtotal	1,313	\$364,490	1,280	\$354,015	1,388	\$379,864
OS Service and Supply Fund	109		126		127	
Total budget authority	1,422	\$364,490	1,406	\$354,015	1,515	\$379,864
[Trust Fund transfers included above]		[\$5,793]		[\$5,691]		[\$5,851]
[Evaluation Funds; non-add]		[\$39,552]		[\$46,756]		[\$46,756]

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 $^{^{1}}$ Excludes OGC, OPHS, IGA, DAB and OGHA shares; see narrative for Rent and Common Expenses.

BUDGET AUTHORTY BY OBJECT

	2008	2009	Increase or
	Estimate	Estimate	<u>Decrease</u>
Personnel Compensation:			
Full-time permanent (FTP)	86,869	89,391	+2,522
Other than FTP	3,129	3,171	+42
Other personnel compensation	1,990	2,058	+68
Military personnel compensation	6,088	19,034	+12,946
Subtotal	98,076	113,654	+15,578
Civilian personnel benefits	23,275	23,881	+606
Military personnel benefits	1,799	4,354	+2,555
Benefits to former personnel	10	15	+5
Subtotal, Pay Cost	123,160	141,904	+18,744
, •			
Travel	2,354	2,782	+428
Transportation of things	198	251	+53
Rental payments to GSA	20,698	20,267	-431
Rental payments to others	105	115	+10
Communications, utilities, misc. charges	1,186	1,269	+83
Printing and reproduction	984	1,046	+62
Other contractual services:			
Advisory and assistance services	2,419	3,221	+802
Other services	29,813	35,097	+5,284
Purchase of goods and services from government	_,,,,,	,-,	,
accounts	39,699	44,724	+5,025
Operation and maintenance of facilities	2,547	3,050	+503
Research and Development Contracts	255	255	-
Medical Care	0	0	-
Operation and maintenance of equipment	2,949	1,900	-1,049
Subsistence and support of persons	0	0	-
Subtotal Other Contractual Services	77,682	88,247	+10,565
Supplies and materials	1,907	2,185	+278
Equipment	706	1,397	+691
Grants, subsidies, and contributions	125,035	120,401	-4,634
Subtotal, Non-pay costs	230,855	237,960	+7,105
Total, Budget Authority	354,015	379,864	+25,849

SALARIES AND EXPENSES

	2008	2009	Increase or
	<u>Estimate</u>	Estimate	<u>Decrease</u>
Personnel Compensation:	06.060	00.201	. 0. 500
Full-time permanent (FTP)	86,869	89,391	+2,522
Other than FTP	3,129	3,171	+42
Other personnel compensation	1,990	2,058	+68
Military personnel compensation	6,088	19,034	
Special personnel services	- 00.07/	112.654	. 15 570
Subtotal	98,076	113,654	+15,578
Civilian personnel benefits	23,275	23,881	+606
Military personnel benefits	1,799	4,354	+2,555
Benefits to former personnel	10	15	+5
Subtotal, Pay Cost	123,160	141,904	+18,744
Travel	2,354	2,782	+428
Transportation of things	198	251	+53
Rental payments to others	105	115	+10
Communications, utilities, misc. charges	1,186	1,269	+83
Printing and reproduction	984	1,046	+62
Other contractual services:			
Advisory and assistance services	2,419	3,221	+802
Other services	29,813	35,097	+5,284
Purchase of goods and services from government			
accounts	39,699	44,724	+5,025
Operation and maintenance of facilities	2,547	3,050	+503
Research and Development contracts	255	255	-
Operation and maintenance of equipment	2,949	1,900	-1,049
Subsistence and support of persons			
Subtotal Other Contractual Services	77,682	88,247	+10,565
Supplies and Materials	1,907	2,185	+278
Total, Salaries and Expenses	207,576	237,799	+30,223

AUTHORIZING LEGISLATION

	2008		2009	2009
	Amount	2008	Amount	Budget
	Authorized	Enacted	Authorized	Request
General Departmental Management, except accounts below: Reorganization Plan No. 1 of 1953	Indefinite	\$209,299,000) Indefinite	\$216,932,000
Office of Public Health and Science:				
Public Health Service Act,				
Title III, Section 301	Indefinite	52,402,000) Indefinite	75,739,000
Title XVII, Section 1701 (ODPHP)		7,097,000) 1	7,159,000
Title XVII, Section 1707 (OMH)		48,738,000		42,686,000
Title XX, Section 2010 (AFL)		29,778,000		30,307,000
Title XXI (NVPO)	4	6,701,000	<u>)</u> 4	6,841,000
Subtotal		144,716,000)	162,932,000
Total appropriation		\$354,015,000)	\$379,864,000

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¹ Authorizing legislation under Section 1701(b) of the PHS Act expired September 30, 2002. Reauthorization will be proposed.

 $^{^2}$ Authorizing legislation under Section 1707 of the PHS Act expired September 30, 2002. Reauthorization will be proposed.

 $^{^3}$ Authorizing legislation under Section 2010 of the PHS Act expired September 30, 1985. Reauthorization will be proposed.

 $^{^4}$ Authorizing legislation under Title XXI, Subtitle 1, of the PHS Act expired September 30, 1995. Reauthorization will be proposed.

APPROPRIATIONS HISTORY TABLE

(Non-Comparable)

	Budget			
	Estimate	House	Senate	
	to Congress	Allowance	Allowance	Appropriation
<u>FY 2000</u>				
Appropriation	\$185,561,000	\$171,936,000	\$193,203,000	\$207,051,000
Rescission	_	_	_	-1,478,000
Trust Funds	6,851,000	5,851,000	6,517,000	5,851,000
FY 2001				
Appropriation	223,741,000	206,780,000	204,266,000	285,224,000
Rescission	_	_	_	-438,000
Trust Funds	5,851,000	5,851,000	5,851,000	5,851,000
FY 2002				
Appropriation	415,348,000	333,036,000	416,361,000	341,703,000
Rescissions	_	_	_	-1,667,000
Trust Funds	5,851,000	5,851,000	5,851,000	5,851,000
FY 2003				
Appropriation	387,880,000	352,600,000	368,535,000	361,364,000
Rescission	_	_	_	-2,349,000
OER Transfer	_	_	_	-13,856,000
Trust Funds	5,851,000	5,851,000	5,851,000	5,851,000
Rescission	_	_	_	-38,000
FY 2004				
Appropriation	348,100,000	343,284,000	344,808,000	357,358,000
Rescissions	_	_	_	-3,174,000
Trust Funds	5,851,000	5,851,000	5,851,000	5,851,000
Rescission	_	_	, , , <u>– </u>	-35,000
FY 2005				
Appropriation	431,971,000	349,298,000	376,704,000	371,975,000
Rescissions	_	_	_	-3,530,000
Trust Funds	5,851,000	5,851,000	5,851,000	55,851,000
Rescission	_	_	_	-447,000
SSA Transfer	_	_	_	-49,600,000
FY 2006				
Appropriation	353,325,000	338,695,000	353,614,000	352,703,000
Rescission	_	· —	_	-3,527,000
Trust Funds	5,851,000	5,851,000	5,851,000	5,851,000
Rescission	_	_	_	-58,000

APPROPRIATIONS HISTORY TABLE

(Cont.)

	Budget Estimate to Congress	House <u>Allowance</u>	Senate <u>Allowance</u>	Appropriation
FY 2007				
Appropriation	\$362,568,000	_	_	\$350,945,000
Rescission	_	_	_	-500,000
KLL Supplemental	13,512,000	_	_	_
Trust Funds	5,851,000	_	_	5,793,000
FY 2008				
Appropriation	386,705,000	342,224,000	386,053,000	355,518,000
Rescission	_	_	_	-6,211,000
NIMH Transfer	_	_	_	-983,000
Trust Funds	5,851,000	5,851,000	5,851,000	5,792,000
Rescission	_	_	_	-101,000
FY 2009				
Appropriation	374,013,000			
Trust Funds	5,851,000			

GENERAL DEPARTMENTAL MANAGEMENT

	FY 2007	FY 2008	FY 2009	FY 2009
	<u>Actual</u>	Enacted	<u>PB</u>	<u>+/- FY 2008</u>
Budget Authority	\$364,490,000	\$354,015,000	\$379,864,000	+\$25,849,000
FTE (including reimbursables)	1,313	1,280	1,388	+108
FY 2009 Authorization	• • • • • • • • • • • • • • • • • • • •			Indefinite
Allocation Method	• • • • • • • • • • • • • • • • • • • •			Direct Federal

Overview of Budget Request

The FY 2009 budget request for General Departmental Management (GDM) includes \$379,864,000 in appropriated funds and 1,388 full-time equivalent (FTE) positions. This request is \$25,849,000 (7.3 percent) and 108 FTE higher than the comparable FY 2008 Enacted level.

The GDM appropriation supports those activities associated with the Secretary's roles as chief policy officer and general manager of the Department. These activities are carried out through twelve Staff Divisions (STAFFDIVs), including the Immediate Office of the Secretary, the Departmental Appeals Board, and the Offices of: Public Affairs; Legislation; Planning and Evaluation; Resources and Technology; Administration and Management; Intergovernmental Affairs; General Counsel; Global Health Affairs; Disability; and Public Health and Science.

The largest single STAFFDIV within GDM is the Office of Public Health and Science (OPHS). OPHS serves as the focal point for leadership and coordination across the Department in public health and science, and provides advice and counsel to the Secretary on public health and science issues. OPHS also exercises management responsibility for twelve cross-cutting program offices, including: Surgeon General, HIV/AIDS Policy, Adolescent Family Life, Disease Prevention and Health Promotion, President's Council on Physical Fitness and Sports, Minority Health, Women's Health, Human Research Protections, Commissioned Corps Initiatives, National Vaccine Program Office, Public Health Reports, and Research Integrity.

This justification includes narrative sections describing the activities of each STAFFDIV funded under the GDM account, plus the Rent and Common Expenses accounts. (Resource tables reflect only funding provided from the GDM appropriation. FTE figures include full-time, part-time, and temporary employees.) This justification also includes selected performance information; however, the majority of performance-related information for GDM can be found in the On-line Performance Appendix at http://www.hhs.gov/budget/docbudget.htm.

The FY 2009 request for GDM reflects the following significant changes from previous years:

• Funding for **Transformation of the Commissioned Corps** (+\$26 million over FY 2008) is requested in order to centralize funding for all US Public Health Service (USPHS) Commissioned Corps Initiatives in one location, and to protect the health of the American people by transforming the Corps into a force that is ready to respond rapidly to the most

dramatic public health challenges and health care crises. Please see the Commissioned Corps narrative for additional information.

- Funding is requested for a **Health Diplomacy Initiative** (+\$3.5 million) to support the President's commitment to advancing U.S. global leadership in the Western Hemisphere, and investing in public health and diplomacy abroad, by delivering direct patient care and training local health workers in Central America. This initiative will be coordinated by the Office of Global Health Affairs (OGHA); please see the OGHA narrative for additional information.
- The FY 2009 request for **Embryo Adoption Awareness Campaign** (-\$1.9 million) is consistent with the FY 2008 President's Budget. The FY 2009 request provides continued funding only for embryo adoption public awareness information and education activities, which have been the core of the program since its inception. Funds are not included for medical and administrative services related to embryo adoption.
- Funding for the **Office of Minority Health** (-\$6.1 million) does not include funds for the continuation of three grant programs: Morehouse Male Health Project, Youth Empowerment Program, and the Health Disparities in Mississippi project.
- Funding for the **Office on Women's Health** (-\$2.6 million) reflects the fact that some of the programs funded in 2008 were targeted for one-year funding only. These include the Regional Women's Master Contract, the 2008 Woman Challenge, and the Institute of Medicine (IOM) study on women's health research.

Non-comparable appropriated funding for GDM during the last five years, including amounts available for obligation from both general funds and trust fund transfers, has been as follows:

Fiscal Year	<u>Funds</u>	<u>FTE</u>
2004	\$360,000,000	1,408
2005	\$423,849,000	1,499
2006	\$354,725,000	1,335
2007	\$355,764,000	1,297
2008	\$354,015,000	1,280

In addition to appropriated funds, the GDM budget uses other sources and types of funding, including: transfers from the federal Health Insurance and Supplementary Medical Insurance trust funds; inter-departmental delegations of authority; inter-agency reimbursements; and funds from the Health Care Fraud and Abuse Control (HCFAC) account. GDM also conducts centrally-managed projects which benefit the Department's OPDIVs and STAFFDIVs, under the authority of the Economy Act (31 USC 1535) or other specific statutes. Costs for these activities are distributed among the OPDIVs and STAFFDIVs on a proportional basis, using established cost distribution formulas.

The President's FY 2009 appropriation request of \$379,864,000 for the GDM account represents current law requirements. No proposed law amounts are included.

IMMEDIATE OFFICE OF THE SECRETARY

	FY 2007	FY 2008	FY 2009	FY 2009
	<u>Actual</u>	Enacted	<u>PB</u>	<u>+/- FY 2008</u>
Budget Authority	\$9,959,000	\$9,960,000	\$10,048,000	+\$88,000
FTE	68	66	66	
FY 2009 Authorization				Indefinite
Allocation Method				Direct federal

Program Description and Accomplishments

The Immediate Office of the Secretary (IOS) provides leadership, direction, policy, and management guidance to the Department, and support for the Secretary and Deputy Secretary in their roles as representatives of both the Administration and the Department of Health and Human Services (HHS). IOS serves as the nucleus for HHS activities.

The Immediate Office serves to advocate the Administration's health and human services agenda and drives the Department's formulation of policy. IOS achieves this objective by ensuring key issues are brought to leaderships' attention in a timely manner, facilitating discussions on policy issues, reviewing documents requiring Secretarial action for policy consistent with that of the Secretary and the Administration, and coordinating the appropriate release of regulatory documents. IOS works with other Departments to coordinate analysis of and input on policy decisions impacting activities that fall within their purview. IOS also ensures White House policymakers are afforded a timely opportunity to participate in decisions impacting high-profile issues.

IOS activities include:

- Providing advisory management services and executive level staff support essential for the Secretary to manage and direct the myriad of programs in the Department. For example, the Executive Secretariat coordinates and facilitates policy decisions within the Department by ensuring that the relevant decision makers have an opportunity to provide input into the decision making process and policy implementation. This office works with the relevant component to develop comprehensive briefing documents, facilitates discussions between staff and operating divisions, and ensures the final document reflects policy decisions.
- Providing assistance, direction and coordination to the White House and other Cabinet agencies on HHS issues. For example, IOS took the lead on establishing an interagency workgroup on import safety IOS also regularly reaches out to relevant cabinet agencies as policy documents work their way through the clearance process to garner their input.
- Setting the Department's regulatory agenda and review of all new regulations and

regulatory changes to be issued by the Secretary; performing an on-going review of regulations which have already been published, with particular emphasis on reducing the regulatory burden.

- Increasing the efficiency and cost-effectiveness of the Department through improved management of resources, operations and implementation of the President's Management Agenda. Evaluating the potential for cost savings through the introduction of a centralized approach to developing, operating and maintaining automated administrative systems.
- Providing continuing Departmental leadership in implementing the Medicare Modernization Act of 2003, which is the largest program expansion of Medicare since its inception more than 40 years ago. IOS has coordinated the publication of several regulations to address issues that have arisen since the benefit took effect. IOS has also worked with the Social Security Administrations and others to ensure a unified message regarding the success of the benefit and any changes.

Funding History

FY 2004	\$7,759,000
FY 2005	\$7,872,000
FY 2006	\$7,872,000
FY 2007	\$9,959,000
FY 2008	\$9,960,000

Budget Request

The FY 2009 request for IOS is \$10,048,000, an increase of \$88,000 above the FY 2008 President's Budget. This will partially cover increased personnel costs such as the annualization of the January 2008 pay raise and the anticipated January 2009 pay raise.

The budget request for IOS will be used to achieve all of the oversight and management of a range of programs. The responsibilities associated with policies and issues that the Secretary and HHS must confront daily include more than 300 programs, covering a wide spectrum of activities.

The mission of the office involves coordinating all Departmental documents, issues and regulations requiring Secretarial action; mediating the resolution of differences between Departmental components; communicating Secretarial decisions; and ensuring the implementation of those decisions. The budget also supports overseeing the operations and functions of IOS entities including: Scheduling and Advance, the Executive Secretariat and the White House Liaison.

ASSISTANT SECRETARY FOR PUBLIC AFFAIRS

	FY 2007	FY 2008	FY 2009	FY 2009
	<u>Actual</u>	Enacted	<u>PB</u>	+/- FY 2008
Budget Authority	\$4,008,000	\$3,909,000	\$3,944,000	+\$35,000
FTE	28	27	27	
FY 2009 Authorization				Indefinite
Allocation Method				Direct federal

Program Description and Accomplishments

The Assistant Secretary for Public Affairs (ASPA) serves as the Department's principal public affairs office, communicating information on the Secretary's initiatives and HHS's mission and activities to the general public. ASPA plays an important role by:

- Serving the Secretary in advising and preparing public communications.
- Providing timely, accurate, consistent and comprehensive public health information to the public.
- Coordinating public health and medical communications across all levels of government and with international and domestic partners.
- Providing public affairs counsel in the HHS policymaking process.
- Acting as the central HHS press office handling media requests, clearing all press releases and interviews, and managing news issues that cut across Agencies; produce electronic clips for the Secretary and senior staff; and compile a Department-wide report on each day's media affairs.
- Managing and maintaining the content of the HHS Web site and counsel on outreach utilization of New Media and the Web.
- Overseeing the extensive daily public affairs activities that take place throughout the Department.
- Supporting the Secretary's television and radio appearances; manage the HHS studio, producing and distributing radio and television outreach materials and monitoring television news; and provide HHS photographer.
- Producing speeches and articles for the Secretary, Deputy Secretary and other Department principals as needed.
- Maintaining HHS FOIA/Privacy Act operations and activities.

ASPA provides communications support for Secretarial initiatives which cut across program and operating agency lines within the Department. Among these initiatives are public affairs campaigns to support the following: Value-Driven Health Care, Health Information Technology, Medicaid Modernization, Medicare Rx, rebuilding of the New Orleans Health Care System, Personalized Health Care, Obesity Prevention, Protecting and Preparing the Nation for Pandemic Influenza, and Emergency Preparedness and Response.

In FY 2007, ASPA organized, convened and coordinated more than two dozen briefings for the media to gain support of the Secretary's initiatives; created reports, postcards, brochures and other leave-behind tools written and produced to complement the Secretary's Initiatives; published and distributed "Public Health Emergency Response: A Guide for Leaders and Responders," a reference guide designed to inform elected officials (e.g., mayors, county executives, governors) and first responders (e.g. police, fire, EMS, etc.) about the role of public health in emergency response; and conducted tabletop exercises on pandemic flu response in six U.S. cities with media representatives and senior Federal, State and local officials.

ASPA also continues to lead the development of a consolidated, U.S. government-wide public Web portal to provide citizens with access to timely information on how to prepare for a possible outbreak of avian influenza. In addition, Web staff are upgrading, modernizing, and enhancing the Department's internal and external Web presence, to allow Web access to the vital health and human service programs that reside within HHS. This has necessitated establishing a governance organization to evaluate the content and timeliness of agency Websites, and to coordinate them with the Department's Website.

Funding History

FY 2004	\$3,988,000
FY 2005	\$3,929,000
FY 2006	\$3,931,000
FY 2007	\$4,008,000
FY 2008	\$3,909,000

Budget Request

The FY 2009 request for ASPA is \$3,944,000, an increase of \$35,000 above the FY 2008 President's Budget. This will partially cover increased personnel costs such as the annualization of the January 2008 pay raise and allow ASPA to anticipated January 2009 pay raise. Personnel costs make up 80 percent of ASPA's GDM budget. As in the previous several years, annual cost-of-living increases for personnel costs have not been fully funded, and were absorbed within the enacted ASPA GDM funding levels. Given the proposed increase of \$35,000 for FY 2009, which is below what was requested to cover anticipated personnel costs, ASPA will again need to absorb the costs above that increased amount from other critical program areas that support the Secretary and the Department, such as Secretarial travel staffing, daily media monitoring, and teleconference and transcription services for press conferences.

In FY 2008 ASPA plans to develop more than a dozen new public service announcements for local media to use during emergency and disaster response or to heighten awareness of pressing health care issues; redesign the HHS Newsroom site with more interactive or comprehensive features such as web videos, promote awareness of the Secretary's blog, and conduct a pandemic flu response tabletop exercise with bloggers and senior Federal, State and local officials.

In FY 2009 ASPA will continue to work on several key areas including: improving the effectiveness of Departmental education and marketing campaigns, producing and distributing

health messages to television and radio station outlets, and improving the efficiency of processing Freedom of Information Act (FOIA) requests based on current laws.

Overall the budget request for ASPA will be used to conduct Department-wide public affairs programs; synchronize Departmental policy and activities with communications; oversee the planning, management and execution of communication activities throughout HHS, and administer the Freedom of Information Act (FOIA) and Privacy Act programs on behalf of the Department. The budget also supports overseeing the operations and functions of ASPA including: communication with the public on vital health issues by providing new releases, Webbased materials, speeches, rapid responses and other materials to national and regional media, including minority media.

ASSISTANT SECRETARY FOR LEGISLATION

	FY 2007	FY 2008	FY 2009	FY 2009 +/-
	<u>Actual</u>	Enacted	<u>PB</u>	FY 2008
BA	\$3,187,000	\$3,108,000	\$3,135,000	+\$27,000
FTE (includes Reimb.)	28	24	24	
FY 2009 Authorization				Indefinite
Allocation Method				Direct federal

Program Description and Accomplishments

The Office of the Assistant Secretary for Legislation (ASL) serves as the principal advocate before Congress for the Administration's health and human services initiatives; serves as chief HHS legislative liaison and principal advisor to the Secretary and the Department on Congressional activities; and maintains communications with executive officials of the White House, OMB, other Executive Branch departments, Members of the Congress and their staffs, GAO, non-governmental organizations and associations, and selected legislative programs. The office consists of six divisions that help ASL accomplish this mission: Immediate Office of the Assistant Secretary for Legislation, Office of the Deputy Assistant Secretary for Budget and Health Science, Office of the Deputy Assistant Secretary for Health Entitlement Programs, Office of the Deputy Assistant Secretary for Human Services, Congressional Liaison Office, Office of Oversight and Investigations.

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. Below are examples of activities:

- 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 14 other Presidential appointees (HHS) who must be confirmed by the Senate.

The Deputy Assistant Secretary for Legislation for Budget and Health Science assists in the legislative agenda and liaison for discretionary health programs. This portfolio includes health-science-oriented operating divisions (the Food and Drug Administration, the National Institutes of Health, the Centers for Disease Control and Prevention, the Agency for Healthcare Research and Quality), health IT, private-sector health insurance, medical literacy and patient safety, and bio-defense. The Office coordinates the activities of Office of the Assistant Secretary for Legislation and the Department with respect to the Congressional Budget Process, and assists the ASL in budget affairs of the Office of the Assistant Secretary for Legislation.

The Deputy Assistant Secretary Legislation for Health Entitlement Programs assists in the legislative agenda and liaison for health services and health care financing operating divisions

(Centers for Medicaid and Medicare Services, Indian Health Service and Health Resources and Services Administration).

The Deputy Assistant Secretary for Legislation for Human Services assists in the legislative agenda and liaison for human services and income security policy. This portfolio includes the Administration for Children and Families; the Administration on Aging; and, the Substance Abuse and Mental Health Services Administration. Below are examples of activities:

- Developing, transmitting, providing information about, and working to enact the Department's legislative and administrative agenda;
- Coordinating meetings and communications of the Secretary and other Department officials with Members of Congress;
- Notifying and coordinating with Congress regarding the Secretary's travel and event schedule:
- Preparing witnesses and testimony for Congressional hearings;

The Director of the Congressional Liaison Office assists in the legislative agenda and liaison for bioethics, faith-based, and special projects. The office maintains the Department's program grant notification system to Members of Congress (public access at: <u>GrantsNet</u> and <u>TAGGS</u>), and is responsible for notifying and coordinating with Congress regarding the Secretary's travel and event schedule. In addition, CLO provides staff support for the Assistant Secretary for Legislation coordinating responsibilities to the HHS regional offices, and coordinates the Continuity of Operations Plan (COOP). Below are examples of activities:

- Responding to Congressional inquiries and notifying Congressional offices of grant awards (GrantsNet, TAGGS) made by the Department.
- Providing technical assistance regarding grants and legislation to Members of Congress and their staff and facilitating informational briefings relating to Department programs and priorities.

The Office of Oversight and Investigations reports to the Assistant Secretary for Legislation and has responsibility for all matters related to Congressional oversight and investigations, including those performed by the Government Accountability Office, and assists in the legislative agenda and liaison for special projects. Below are examples of activities:

- Coordinating Department response to Congressional oversight and investigations.
- Acting as Departmental liaison with the Government Accountability Office (GAO) and coordinating responses to GAO inquiries.

ASL has successfully advocated the Administration's health and human services legislative agenda before the Congress. ASL worked to secure the necessary legislative support for Department's initiatives and provided guidance on the development and analysis of Departmental legislation and policy.

Funding History

FY 2004	\$3,044,000
FY 2005	\$2,732,000
FY 2006	\$3,110,000
FY 2007	\$3,187,000
FY 2008	\$3,108,000

Budget Request

The FY 2009 request for ASL is \$3,135,000 a net increase of \$27,000 above the FY 2008 President's budget level. This will partially cover increased personnel costs such as the annualization of the January 2008 pay raise and the anticipated January 2009 pay raise. The mission of the office involves coordinating all Departmental documents, issues and regulations requiring Secretarial action; mediating the resolution of differences between Departmental components; communicating Secretarial decisions; and ensuring the implementation of those decisions.

The budget request for ASL will support facilitating communication between the Department and Congress. The office also informs the Congress of the Department's views, priorities, actions, grants and contracts. In FY 2009, ASL will continue to work on several key areas with Members of Congress, Congressional staff and Committees, and with the Government Accountability Office (GAO) including: managing the Senate confirmation process for Department nominees; preparing witnesses and testimony for Congressional hearings; improving Congressional awareness of issues relating to pandemic influenza and emergency preparedness; and advising Congress on the status of key HHS priority areas such as health information technology and value-driven healthcare.

ASSISTANT SECRETARY FOR PLANNING AND EVALUATION

	FY 2007	FY 2008	FY 2009	FY 2009 +/-
	<u>Actual</u>	Enacted	<u>PB</u>	FY 2008
Budget Authority	\$6,787,000	0	0	0
PHS Evaluation	\$34,500,000	\$41,243,000	\$41,243,000	0
FTE	97	117	117	0

Program Description and Accomplishments

ASPE serves as the principal advisor to the Secretary of the Department of Health and Human Services (HHS) on policy development in health, disability, aging, human services, and science, and provides advice and analysis on economic policy. ASPE leads special initiatives on behalf of the Secretary, and provides direction for HHS-wide strategic, evaluation, legislative and policy planning. ASPE conducts research and evaluation studies; provides critical policy analysis, development, and advice; provides policy planning, coordination, and management; conducts research, evaluation, and data collection; and estimates the costs and benefits of policies and programs under consideration by HHS or the Congress.

Four policy offices within ASPE (Health Policy, Science and Data Policy, Human Services Policy, and Disability and Long Term Care Policy) perform these functions with a focus on their primary population or issue of interest. ASPE develops and reviews issues with a perspective that is broader in scope than that of any one Operating Division or Staff Division. When appropriate, ASPE divisions collaborate with HHS Operating Divisions and Staff Divisions, as well as other federal agencies, state and local partners, and non-governmental groups, in performing these functions. Working with these partners enables ASPE to leverage available resources more effectively, achieve efficiencies, and assist the translation of research to practice. ASPE also coordinates and manages data and information policy within HHS, and coordinates crosscutting policy-related activities within, and sometimes outside, HHS.

ASPE's accomplishments are numerous. Analytical, evaluation, and policy development efforts in the health, science and data, and human services policy areas have led to major improvements in information for decision-making in policy formation in health and human services, science policy and program management and evaluation across HHS. ASPE's policy support services provided simulation modeling, statistical analysis, and other technical and analytic services needed in order to carry out policy research. ASPE seeks to ensure efficient, reliable, and timely analytic support, while offsetting increases in costs through the introduction of cost-saving technologies. These services supported internal Department-wide data policy and coordination in data policy, including interagency data collection and data standards, and collaborative efforts between HHS and the health industry.

ASPE supports the Department's mission and works to implement the Strategic Goals from the FY 2007-2012 HHS Strategic Plan, as described below.

Goal 1: Improve the safety, quality, affordability and accessibility of health care, including behavioral health care and long-term care through:

- Leading and conducting policy research and economic analyses that led to the President's Electronic Health Record initiative and Executive Order, as well as the HHS Secretary's health information technology initiative. This work has resulted in acceptance of new health information technology standards, and shaped private sector standards for the function of a nursing home Electronic Health Record System known as the HL7 Nursing Home EHR-S Functional Profile.
- Conducting policy analyses used in developing the President's proposal to expand health care
 access to every American by establishing new avenues for states to enact reforms through the
 Affordable Choices initiative. ASPE also conducted research and analysis that resulted in a
 modification of the Medicaid law to provide all states with the option to implement the LongTerm Care Partnership. ASPE now provides leadership to ensure the timely completion of
 the federal guidance and regulations implementing the Partnership. Twenty states have
 modified their Medicaid plans to include Partnership programs.
- Leading the implementation of the Long-Term Care Awareness Campaign. The campaigns in fifteen states have led to significant increases in planning activities related to long-term care, such as the purchase of the long-term care insurance, with a 15% increase in policies purchased in the campaign states.
- Co-chairing the HHS Data Council that has developed the web-based Gateway to HHS Statistics and Data on the Web, an integrated, one stop HHS-wide website that provides user-friendly access to the wide range of statistics and data developed by HHS agencies. The Gateway includes the ability to search and display relevant information, a metadirectory of HHS Statistical Resources, and links to data policy websites and is designed to provide information for policy development and decision making in health and human services. The Gateway has been expanded to include minority data and health insurance data websites.

Goal 2: Prevent and control disease, injury, illness, and disability across the lifespan, and protect the public from infectious, occupational, environmental and terrorist threats by:

- Conducting several studies related to national vaccine policy and economics including a cost benefit analysis of influenza vaccine; a study to better understand vaccine shortages; a series of analyses relating to the demand, supply and economics of the vaccine production and distribution in the U.S., and a project with FDA to develop and evaluate a system for the rapid post approval assessment of the safety of a pandemic vaccine.
- Co-sponsoring a workshop at the National Academies on Nutritional Risk Assessment.
- Developing cost-benefit analyses comparing screening and treating refugees for communicable diseases prior to or after entry into the U.S.
- Providing support for the Secretary's efforts to improve emergency preparedness efforts throughout the Department. ASPE surveyed HHS Operating and Staff Divisions and six other federal departments and agencies on programs and disaster needs, which was used to inform the Department's response to the White House report, "The Federal Response to Hurricane Katrina: Lessons Learned." ASPE developed a Request for Information to solicit input from the public and private sectors about creating a new electronic benefit transfer system for distributing human services benefits to disaster victims.

Goal 3: Promote the economic and social well-being of individuals, families and communities by:

- Providing policy research and analysis in TANF, Head Start, and Violence Against Women
 Act areas to inform and support legislative proposals, regulations, and reauthorization. ASPE
 developed a model to estimate the impacts of welfare reauthorization provisions on state
 work participation rates. ASPE's analysis of research data on health and employment of
 TANF recipients contributed to policies that were incorporated in interim final regulations.
- Supporting the President's Healthy Marriage agenda by researching the effects of marriage on family economic well-being. Research provided a robust indication that married parents tend to be better off than both single and cohabitating parents and that these benefits extend to disadvantaged families.
- Supporting the First Lady's Helping America's Youth initiative. ASPE leads a workgroup that created and enhanced the web-based Community Guide to Helping America's Youth (HAY) ASPE had a key role in planning five regional HAY conferences to train local partnerships to use the Community Guide.
- Conducting research projects on post-adoption services and adoption subsidies and on involving fathers in child welfare case management. Results of these projects are being used extensively by state and local agencies to change policies and practices.

Funding History

<u>GDM</u>	
FY 2004	\$6,730,000
FY 2005	\$6,851,000
FY 2006	\$6,726,000
FY 2007	\$6,787,000
FY 2008	\$0

PHS Evaluation Set-Aside

FY 2004	\$36,467,000
FY 2005	\$35,000,000
FY 2006	\$35,000,000
FY 2007	\$34,500,000
FY 2008	\$41,243,000

FY 2008 reflects transfer of all GDM funding for ASPE into PHS Evaluation funds.

Budget Request

The FY 2009 request for the Office of the Assistant Secretary for Planning and Evaluation (ASPE) is level-funded at \$41,243,000. This will allow ASPE to continue a variety of independent policy research and evaluation activities across the spectrum of the Department's programs, with particular attention to specific crosscutting initiatives, the breadth and depth of which are described in this submission. ASPE's work directly supports the Department's mission and achievement of the Strategic Goals. When the FY 2009 research portfolio is finalized, it is anticipated that the following activities, organized by Strategic Goal, will be

included.

Goal 1: Improve the safety, quality, affordability and accessibility of health care, including behavioral health care and long-term care by:

- Ensuring that the President's goal of accelerating the use of electronic health records as well as the Secretary's initiative to transform health care through health information technology is addressed in the FY 2009 research agenda.
- Conducting research and analysis in support of the Secretary's initiative to promote a Valuedriven Health Care system.
- Supporting the expansion and further development of community collaboratives such as the Recognized Community Leader and Chartered Value Exchange.
- Furthering the concept of personalized health care, by building upon existing efforts, providing leadership and program and policy coordination across HHS, and carrying out a program of policy research, analysis and evaluation in support of the Department's personalized health care efforts.
- Working with internal partners to foster the use of Medicare data to support efforts of local quality measurement.

Goal 2: Prevent and control disease, injury, illness, and disability across the lifespan, and protect the public from infectious, occupational, environmental and terrorist threats by:

- Implementing, with other agencies, the President's Emergency Preparedness Plan and Pandemic Flu Plan.
- Coordinating and carrying out research and analyses to improve emergency preparedness, response and recovery efforts, support White House and Departmental "lessons learned" activities and assessments, and develop policies and procedures for future efforts.
- Conducting policy research, evaluation and data development for assuring and assessing prevention, preparedness and response capabilities for planning, preparing, and responding to a variety of public health threats, such as bioterrorism, natural disasters, and a potential disease pandemic. This includes efforts to understand how states and localities plan for the needs of vulnerable populations in their emergency preparedness plans.
- Conducting evaluation and policy development efforts in chronic disease prevention and health promotion, with a focus on increasing physical activity and preventing obesity.

Goal 3: Promote the economic and social well-being of individuals, families and communities by:

- Supporting the President's Healthy Marriage agenda by researching the effects of marriage on family economic well-being.
- Conducting research on poverty, low-income populations and government policies that foster self-reliance and reward work, including welfare, supports for working families, and child support enforcement.

Public Health Service Act Evaluation Funds: ASPE's Research and Evaluation Program

ASPE's Research and Evaluation program, funded under section 241 of the U.S. Public Health Service Act, has a significant impact on the improvement of HHS policies, programs and services, as earlier described. Set-aside funds are used to conduct research and evaluation

studies; data collection; and estimate the costs and benefits of policies and programs under consideration by HHS or the Congress.

In FY 2009 ASPE will conduct the following activities in support of HHS's four Strategic Goals.

Goal 1: Improve the safety, quality, affordability and accessibility of health care, including behavioral health care and long-term care. Priority projects for FY 2009 under this goal include promoting health care value incentives and health information technology; modernizing Medicaid; and strengthening and improving Medicare. A more detailed description of projects is included listed below.

- Medicare modernization. Conduct research on Medicare Modernization Act (MMA) implementation issues, including an evaluation of the potential of competitive bidding strategies or other efficiency or effectiveness reforms to address the response required by triggering of the Medicare funding warning. ASPE will continue to strengthen and improve Medicare by conducting analyses on methods of refining Medicare's fee-for-service payment system, especially in post-acute care settings.
- **Medicaid sustainability.** Provide analytical support for policy initiatives to ensure the sustainability of the Medicaid program through analyses of enrollment and spending growth.
- **SCHIP sustainability.** Analyze options to ensure the continuation and sustainability of the State Children's Health Insurance Program.
- Value-driven health care. Support the Value-driven Health Care Initiative, through assessing ongoing public and private initiatives and analyzing local area health markets to better understand health care costs and quality transparency issues. ASPE will develop and refine policies to promote and facilitate the adoption of Value-driven Health Care throughout the healthcare system and increase the use of value-based purchasing principles in Medicare and other HHS-administered health programs.
- **Health information technology.** Initiate evaluation efforts for improving the effectiveness and efficiency of the health system through the accelerated adoption of health information technology. ASPE will continue its leadership role in evaluating activities to support the President's and the Secretary's priority to accelerate the development and use of information technology in health care, long-term care, and public health. Areas of focus include safety net providers, public birth data exchange, physician adoption, personal health records and improving the tools for communicating patient information during transitions from hospitals to nursing homes and post-acute care settings.
- Access to health insurance coverage. Provide continuing analytical support for efforts to expand access to health insurance coverage to every American. These efforts include continued policy development for the Affordable Choices initiative and other health care reform proposals including coordination with federal tax incentives to purchase insurance.
- **Health care marketplace competition.** Investigate the impacts of health care marketplace competition, and research the effects of health care spending on the economy.
- **Efforts to improve quality.** Continue to research, develop and analyze policy options to improve the quality of health care for all Americans.
- Long-term care needs and services. Continue research efforts to study, analyze, and evaluate consumer-driven options for organizing, delivering and financing home- and community-based support for people who use long-term care services. ASPE will develop and analyze policy options and identify barriers, with the goal of expanding long-term care

- planning opportunities for individuals.
- Long-term care workforce. Support new and ongoing research activities to address the recruitment and retention of a qualified, stable frontline workforce to provide long-term supports in institutional and community settings, including strengthening the basic data infrastructure.
- **Ryan White.** Continue to work on issues related to the implementation of the Ryan White HIV/AIDS Modernization Act of 2006, and working with HRSA and ASL to respond to inquiries from Congress about progress implementing new provisions of the Act.
- **Independent living supports.** Support research on home modifications that enable older individuals with disabilities to live in their homes more safely for longer periods of time.
- Advance directives and hospice services. Continue to support Congressionally-requested research on advance directives and hospice services, to provide policymakers with sound information on death and dying related issues, and to advance medical research and science.
- **Disability in the aging population.** Develop and analyze policy options and data sources for measuring and describing the aging of the population and the incidence and prevalence of disability in the aging population.
- Goal 2: Prevent and control disease, injury, illness and disability across the lifespan, and protect the public from infectious, occupational, environmental and terrorist threats. Priority projects for FY 2009 under this goal include promoting emergency preparedness, response and recovery planning efforts; preventing chronic disease and promoting healthy behaviors; and reducing health disparities. A more detailed description of projects is included listed below.
- **PEPFAR.** Collaborate with the Department of State on the reauthorization of the President's Emergency Plan for AIDS Relief.
- Emergency preparedness. Work closely with other agencies on the implementation of the President's Emergency Preparedness Plan and Pandemic Flu Plan, with special attention to evaluation, data and policy analysis. ASPE will coordinate and carry out research and analyses to support White House and Departmental "lessons learned" activities and assessments to improve preparedness, response and recovery efforts and to develop policies and procedures for future efforts.
- Emergency preparedness. Conduct policy research, evaluation and data development for assuring and assessing prevention, preparedness and response capabilities for planning, preparing, and responding to a variety of public health threats, such as bioterrorism, natural disasters, and a potential disease pandemic. ASPE will conduct research to understand how states and localities plan for the needs of vulnerable populations in their emergency preparedness plans.
- **Mental health and substance abuse programs.** Conduct evaluation efforts targeted at the effectiveness of mental health and substance abuse programs.
- Chronic disease prevention and health promotion. Conduct evaluation and policy development efforts in chronic disease prevention and health promotion, with a focus on increasing physical activity and preventing obesity.
- **Health disparities.** Continue to research, develop and analyze policy options to reduce racial and ethnic health disparities.

Goal 3: Promote the economic and social well-being of individuals, families and communities. Priority projects for FY 2009 under this goal include promoting economic independence and

social well-being of individuals and families; protecting the safety and fostering the well-being of children and youth; and addressing the needs of other vulnerable populations, including human trafficking victims.

- Economic self-sufficiency. Conduct research, evaluation and analyses on poverty; low-wage workers; welfare; child support enforcement; and policies to enhance the economic well-being of low-income families and their children, foster self-reliance and reward work, and support capacities for ownership, including improved strategies for helping the hard-to-employ. ASPE will continue support for the Poverty Research Centers to examine causes, consequences and remedies of poverty.
- Marriage and fatherhood. Build on research in support of healthy two-parent married families to improve economic self-sufficiency, family stability, child well-being and public health. ASPE will study family strengths associated with marriage, the long-term health consequences of family structure, the contributions of fathers, and strategies for improving delivery of healthy marriage services to specific subgroups. In partnership with ACF, evaluate programs for incarcerated and re-entering fathers and their partners.
- **Human trafficking.** Continue research on both targeted and mainstream HHS programs serving human trafficking victims to develop information about how they address the needs of victims of human trafficking, including domestic victims, with a priority focus on youth.
- **Healthy youth development.** Promote healthy youth development through research and data on positive youth development and risk-based adolescent behaviors, support interdepartmental collaborations to assist at-risk youth, and continue to build evaluation capacity to improve abstinence education programs.
- Early childhood development and child well-being. Continue to examine programs and policies that affect child well-being, early childhood development, early childhood education, child protection, and foster and adoptive home supply. ASPE will examine ways to improve permanency planning for at-risk children, and assess child welfare privatization efforts.
- Homelessness. ASPE will continue to fund research and evaluations and serve as the
 Department's interface with the U.S. Interagency Council on Homelessness in developing
 strategies to assist policymakers and providers to improve programs and services for
 homeless persons.
- **Faith-based and community partnerships.** Continuing research to support state efforts to expand faith-based and community partnerships in providing effective health and human services.

Goal 4: Advance scientific and biomedical research and development related to health and human services. Priority projects for FY 2009 under this goal include conducting research and evaluation efforts and translating them into practice, especially in the areas of food, drug and medical product safety, and personalized health care.

- **Personalized health care.** Support policy research and analytical efforts to further the concept of personalized health care by building upon existing efforts, provide leadership and program and policy coordination across HHS, and carry out a program of policy research, analysis and evaluation in support of departmental personalized health care efforts.
- Food, drug, and medical product safety. Conduct evaluation and analytical efforts, and support policy research and analytical efforts, in issues related to national vaccine policy; food, drug, and medical product safety; national prescription drug policy including pharmaceutical economic, drug cost, and utilization studies; international drug studies; and

- pharmaceutical research and development issues.
- **Risk assessment and management.** Conduct evaluation and analytical efforts in risk assessment, risk management, and risk communication, regulatory science, and the impact of biomedical investment and related issues in science and technology policy.

ASSISTANT SECRETARY FOR RESOURCES AND TECHNOLOGY

	FY 2007	FY 2008	FY 2009	FY 2009 +/-
	<u>Actual</u>	Enacted	<u>PB</u>	FY 2008
Budget Authority	\$20,662,000	\$20,152,000	\$20,534,000	+ \$382,000
FTE (includes Reimb.)	141	140	140	
FY 2009 Authorization				Indefinite
Allocation Method			Direct fee	leral: Contracts

Program Description and Accomplishments

The Assistant Secretary for Resources and Technology (ASRT) advises the Secretary on all aspects of budget, grants, financial management and information technology, and provides for the direction of these activities throughout the Department. In carrying out these functions, the Assistant Secretary has several formal and informal roles, including Chief Financial Officer, Chief Infrastructure Assurance Officer, the Department's audit follow-up official, and leading officials for budget and grants. The ASRT is also a close advisor to the Secretary on all policy issues. ASRT accomplishes its work through four offices:

Office of Budget (OB) – The OB manages the preparation of the Department's annual performance budget, and prepares the Secretary to present and defend the budget to the public, the media, and Congressional committees. The Office prepares analyses, options, and recommendations on all budget and management issues for the Department and works with OMB and Congress to accomplish his priorities. For FY 2007, the OB provided budget guidance to the HHS Operating Divisions in a timely manner and successfully submitted the FY 2008 Congressional Justifications on time. In addition, the OB successfully managed the major workloads required in support of the annual performance budget and other program budget analysis and estimates that occurred throughout the year. Guidance and technical assistance were provided in a timely manner. Budget and performance justifications were carefully reviewed and distributed in a timely manner prior to hearings.

The Office also manages the implementation of the Government Performance and Results Act (GPRA) and the Performance Improvement Initiative under the President's Management Agenda (PMA). This involves preparing the HHS Annual Plan, working on the Performance and Accountability Report, managing Operating Division development of integrated performance budgets, coordinating performance measurement information as well as additional performance management products. The FY 2008 HHS Annual Plan was submitted on time meeting the FY 2007 target.

Office of Finance (OF) –The Office of Finance (OF) provides financial management leadership to the Secretary through the Chief Financial Officer and the Operating Division CFOs. The OF manages and directs the development of financial policies and standards consistent with major financial management legislation, the Federal Accounting Standards Advisory Board (FASAB), and the requirements of OMB Circular A-123. The OF prepares the annual HHS Performance and Accountability Report (PAR), which includes the HHS annual financial statements and auditor's opinion, as well as the report on performance, as required by GPRA. In FY 2007, the OF participated in the OMB PAR pilot and successfully submitted the Agency Financial Report on time. HHS has consistently met its target since FY 1999, with exception to FY 2004. The Department also once again received an unqualified audit opinion in FY 2007. HHS has earned unqualified (clean) audit opinions on its consolidated financial statements every year since FY 1999.

The OF develops department-wide policies and standards for financial and mixed financial systems, including participation in the Capital Planning and Investment Control CPIC process and development of business cases for departmental financial efforts. The OF leads the development and business management of the Unified Financial Management System (UFMS). UFMS is a single integrated financial management system that operates across HHS' 12 Operating Divisions and six Departmental accounting centers. In addition to financial system activities, the Office of Finance coordinates the HHS activities related to the PMA initiatives to improve financial performance and eliminate improper payments in Federal programs. In FY2007, HHS met its UFMS performance targets for the year completing: data conversion and system deployment at the Indian Health Service; successful year-end close at the Program Support Center; and developing and implementing the global acquisition and personal property automated solutions. HHS is continuing UFMS stabilization efforts and focusing significant resources to ensure the successful implementation of UFMS Core Financials at the Indian Health Service. The Healthcare Integrated General Ledger Accounting System (HIGLAS) implementation continues on schedule and HHS is working toward the incorporation of Medicare Part C/D financial accounting into the system. As one of HHS' six accounting centers, NIH' Business System integrates accounting and property management data to ensure comprehensive financial management practices. In June 2007, NIH's Business System deployed the Property and Acquisition solution via "Sunflower Assets Property Management." This capital investment facilitates full tracking capability for the acquisition/ property management lifecycle as well as interfaces from Sunflower to the General Ledger for management of personal property and posting of depreciation expense.

OF's audit resolution function carries out the requirements of OMB Circular A-133 to ensure that external entities using HHS/federal grant dollars are using funds for right purpose and in accordance with government rules and regulations. The Office resolves cross-cutting systemic and monetary issues related to federal audits of State and local governments, Indian tribes, colleges and universities and non-profit organizations. In addition, the OF provides management and technical assistance to the OPDIVs and works with the Office of the Inspector General (OIG) on audit resolution issues.

Office of the Chief Information Officer (OCIO) – The OCIO provides leadership and oversight in the use of information technology (IT)-supported business process re-engineering, investment analysis, performance measurement, strategic planning, and development and application for information systems and infrastructure. The OCIO coordinates enterprise-wide programs such as IT Capital Planning and Investment Control (CPIC), which ensures that IT investments are aligned with the Department's strategic objectives and Enterprise Architecture (EA) that support the HHS IT Budget data collection, analyses and presentation.

Enterprise Architecture (EA) is a discipline used by organizations to perform strategic planning, and develop "blueprints" of their future-state. EA is used by the Federal government as a management tool to ensure planning and budgeting activities (particularly those related to information technology) are aligned with the strategic goals of the organization, and to identify opportunities for collaboration and reuse of resources across an agency and across the government. As part of the PMA, the EA programs of 24 Federal government agencies are reviewed and scored annually against criteria within OMB's Enterprise Architecture Assessment Framework. The Framework assesses the maturity of agencies' EA programs in 13 different categories by scoring them on a scale from one to five. Each of the 13 areas is aggregated into one of three higher-level categories: Completion, Use, and Results. During FY 2007, the HHS EA Program earned an overall rating of "green" for EA, requiring them to earn an average score of 4.0 in Completion, 3.0 in Use, and 3.0 in Results.

The OCIO manages and maintains requirements under the Paperwork Reduction Act and the Clinger-Cohen Act as defined in OMB Circular A-130. In meeting the requirements of the Paperwork Reduction Act (PRA); e.g., eliminate information collection violations per the PRA, HHS had 0 violations in FY 2006 and 6 violations in FY 2007.

The six violations out of the reported 603 collections in FY 2007 were the result of HHS Operating Divisions (OPDIVs) failing to submit an extension/revision request in a timely manner or when OMB knew the expiring collection was a regulatory or federally mandated data collection. As a result, OMB disapproved the OPDIVs emergency extension requests or the OPDIVs discontinuation request. In FY 2007, OMB increased the enforcement of the emergency extension in that the request cannot be used as a bridge from the current clearance date to the next extension date without the proper documentation.

HHS OCIO has put into place reminder e-mail notifications to the OPDIV Reports Clearance Officers (RCOs) to alert them to packages that are scheduled to expire within 30-90 days. In conjunction, the HHS OCIO conducts quarterly meetings with the OPDIV RCOs for risk mitigation to reduce any PRA violations. HHS OCIO is updating the current ICRAS (Information Collection Request Review and Approval System) to automate the initial steps with automatic email notifications to the OPDIVs RCOs that will begin nine months from the expiration date of the collection in the system.

The OCIO also provides liaison with OMB and other Federal Departments, as well as internal coordination in connection with the fulfillment of the PMA objectives relating to e-Government. In addition, the Office has operational responsibility for Departmental IT Services that include Enterprise Email, Security and Capital Planning systems, and information collection tracking systems. Finally, the Office develops policy to provide improved management of information resources and technology, and to provide better, efficient service to HHS clients and employees.

Office of Grants (OG) – The OG advises the Secretary on all aspects of grants administration, a critical function given that HHS is the largest grants making entity in the federal government. The OG develops and promulgates policy regarding pre-award and post-award financial and administrative management for the over \$240 billion awarded annually by the various HHS agencies or Operating Divisions. In addition to grants policy, the OG administers the HHS-wide Grants Officer Training and Certification Program, and Grants Policy Oversight and Evaluation Program. OG also works to develop modern business models and the functional requirements for the electronic systems that centralize information about HHS-wide grants, including the Tracking Accountability in Government Grants System (TAGGS) award reporting system and the new HHS Forecast of Grant Opportunities. In the government-wide arena, OG manages Grants. Gov on behalf of 26 participating federal agencies and also participates in the Grants Executive Board and the Grants Policy Committee joined by 25 federal partners. Grants.Gov received approximately 190,000 grant applications during fiscal year 2007. This number far exceeds the target of 125,000 set at the beginning of the year and shows steady growth over the preceding three years, wherein the program received 92,000, 16,000, and 1,600 applications, respectively.

During FY 2007, OG implemented several major projects, including those related to Grants Policy, Oversight and Evaluation, Cost Policy and Business Process Modeling. For example, in terms of improving efficiency and effectiveness, OG developed the HHS Forecast of Grants Funding Opportunities tool. This tool enables all interested parties, internal and external to HHS, to begin to track programs from the earliest points of their development. This provides enhanced opportunities for HHS senior policy advisors to affect program content before a program announcement is in the final clearance phase. It also, and most importantly, allows potential awardees to have maximum opportunity to prepare to make eventual application for various funds.

The OG also reviews and coordinates cost policy issues with OMB, HHS' Inspector General, and other central agencies as well as the HHS regional Divisions of Cost Allocation related to recipients of Federal financial assistance under HHS programs.

Funding History

FY2004	\$17,969,000
FY2005	\$18,961,000*
FY2006	\$18,943,000
FY2007	\$20,662,000
FY2008	\$20,152,000

*Note: The office of Grants joined ASRT in FY 2005.

Budget Request

The FY 2009 request for the Office of the Assistant Secretary for Resources and Technology (ASRT) is \$21,534,000. This is an increase of +\$382,000 over the FY 2008 appropriation. The request will allow ASRT to maintain support of its ongoing responsibilities, which include improving financial management, expanding electronic government, improving budget and performance integration, improving grants management and operations oversight, and eliminating improper payments.

Office of Budget (OB) – The OB will continue to manage the preparation of the Department's annual performance budget, and prepare the Secretary to present and defend the budget to the public, the media, and Congressional committees. The Office will also continue its efforts to prepare analyses, options, and recommendations on all budget and management issues for the Department and works with OMB and Congress to accomplish HHS priorities. The request will also allow the OB to continue its other responsibilities including the implementation of the Government Performance and Results Act (GPRA) and the Budget and Performance Integration initiative under the President's Management Agenda (PMA).

Office of Finance (OF) -- For the OF, the request will provide increased support for financial reporting needs under the PMA Improve Financial Performance initiative such as resolving outstanding audit findings relating to the accurate and timely preparation of financial statements and the resolution of auditor material weaknesses and reportable conditions related to required financial reconciliations. The request will also provide needed additional support for the implementation of the new OMB Circular A-123 Internal Control over Financial Reporting (ICOFR) requirements in the Office of Finance by addressing any outstanding management and/or auditor identified reportable conditions or material weaknesses resulting from implementation of ICOFR in FY 2006 and FY 2007. OMB Circular A-123, Appendix A requires that managers of Federal agencies take responsibility for conducting a rigorous assessment of internal controls over financial reporting and report on the results of these assessments in assurance statements. Assurance statements are required to be included in the Performance and Accountability Report (PAR).

Office of the Chief Information Officer (OCIO) -- The request will allow the OCIO to provide leadership and oversight in all of its responsibilities by enhancing the quality, availability, and delivery of HHS information and services to citizens, employees, businesses, and governments. In FY 2009, OCIO continues to achieve excellence in IT management processes through the enterprise wide portfolio management tool, certified enterprise architect training, improved acquisition planning and execution with solid earned value management practices and reporting.

OCIO continues to address emerging cyber security threats by employing sound risk management and mitigation controls with appropriate allocation of resources managed by the HHS Secure One office. In FY 2009, the OCIO has planned activities to monitor and mitigate privacy impact violations, secure trusted internet connections and continued enforcement of improved physical security and safety measures.

In FY 2009, the OCIO will also continue to work to achieve the goal of eliminating information collection violations as required by the Paperwork Reduction Act as outlined above with monitoring and risk mitigation strategies and upgrades of automated notices within the ICRAS system.

Office of Grants (OG) – The request will allow the OG to continue to lead HHS in all aspects of grants administration, including the development and promulgation of policy, administration of the HHS-wide Grants Officer Training and Certification Program, the Grants Policy Oversight and Evaluation Program, and the Office of Grants System Modernization, which leads efforts in the development and maintenance of modern business models and the functional requirements for supporting grants related IT systems. In FY 2009, the OG will continue to support major projects, including those related to Grants Policy, Oversight and Evaluation, Cost Policy and Business Process Modeling. For example, the Grants Policy project is examining ways to increase transparency, including simplifying award terms and conditions, merging internal and external policy documents and developing financial/administrative guidance manuals, all of these to be provided through user friendly, web-based formats.

ASSISTANT SECRETARY FOR ADMINISTRATION AND MANAGEMENT

	FY 2007	FY 2008	FY 2009	FY 2009 +/-
	<u>Actual</u>	Enacted	<u>PB</u>	<u>2008</u>
Budget Authority	\$15,458,000	\$15,341,000	\$15,984,000	+\$643,000
FTE (including reimbursables)	114	113	113	
FY 2009 Authorization				Indefinite
Allocation Method				.Direct federal

Program Description and Accomplishments

The Assistant Secretary for Administration and Management (ASAM) advises the Department of Health and Human Services (HHS) Secretary on all aspects of administration; provides leadership, policy guidance, supervision, and coordination of long and short-range planning for HHS; and ensures that HHS meets goals set forth in the President's Management Agenda (PMA). ASAM's responsibilities involve a number of functions in the following major areas: Office of Acquisition Management and Policy, Office of Small and Disadvantaged Business Utilization, Office of Business Transformation, Office of Human Resources, Office of Diversity Management & Equal Employment Opportunity, Office of Facilities Management and Policy and the Office of the Secretary Executive Office. ASAM is also responsible for the Program Support Center (PSC), which is funded through other sources.

- Office of Acquisition Management and Policy (OAMP) Provides performance leadership for HHS business practices through policy development and oversight and management of HHS contracts and logistics. ASAM/OAMP has developed an Acquisition Dashboard which captured performance standards, indicators and assessment criteria for the Acquisition Balanced Scorecard, Acquisition Integration and Modernization initiative, Strategic Sourcing Program and Small Business Program. In FY 2007, ASAM/OAMP successfully implemented the Acquisition Dashboard to formally measure and improve acquisition performance. In FY 2008, OAMP will develop additional performance measures to track and improve competition, performance-based acquisitions, workforce development, contract data reliability and past performance assessments.
- Office of Small and Disadvantaged Business Utilization (OSDBU) Advises the
 Secretary and the Deputy Secretary on services and practices to foster the use of small
 and disadvantaged businesses as Federal contractors pursuant to Public Law 95-507.
 OSDBU's goal is to provide guidance to the small business community on Federal
 contracting processes and contracting opportunities available within HHS. OSDBU
 continues to monitor the performance of acquisition activities by Operating Divisions
 (OPDIVs) as they relate to the Department's small business goals and drives
 improvements through this process.
- Office of Business Transformation (OBT) Provides results-oriented analytical support for key management initiatives. OBT also oversees the implementation of strategic initiatives and competitive sourcing activities Department-wide to generate

savings and improve efficiencies. To date, HHS has conducted competitive sourcing studies for more than 45 percent of its available commercial activities. OBT has successfully implemented three High Performing Organizations (HPOs). In accordance with P.L. 108-199, Section 647(b), HHS reported total accrued savings of \$162 million to Congress on December 17, 2007.

Office of Human Resources (OHR) – Provides leadership in the development and
assessment of the Department's human resources programs and policies that support and
advance the HHS mission and objectives of the PMA. OHR also serves as the
Department liaison to central management agencies exercising jurisdiction over
personnel matters.

The scope of OHR's activities is Department-wide, covering all statutes and regulations relating to human resources, including those under 5 USC and Title 5 CFR. This includes assigning responsibility to develop and implement methodologies to measure, evaluate, and improve human capital results to ensure mission alignment, effective HR management programs, efficient business processes and merit-based decision-making in compliance with laws and regulations. In FY 2007, OHR identified 13 Mission Critical Occupations (MCOs) within the Department and streamlined the process to expedite recruiting.

- Office of Diversity Management and Equal Employment Opportunity (ODME) Provides Departmental leadership in creating and sustaining a diverse workforce and promoting a workplace free of discrimination by establishing Departmental policy, conducting program evaluations, ensuring Equal Employment Opportunity (EEO) compliance, strengthening diversity through outreach, recruitment, and special employment initiatives an OPM requirement. In FY 2007, ODME provided Departmental oversight of EEO and diversity functions, programs and initiatives.
- Office of Facilities Management and Policy (OFMP) Provides mission-enabling facilities and a safe, secure and healthy work environment for all HHS employees. OFMP provides stewardship and fiscal responsibility in managing the Department's real property assets. In FY 2007, 100 percent of HHS' real property acquisitions and disposals were executed in accordance with regulations. OFMP is also focusing on reducing energy consumption at HHS facilities as mandated by the Executive Order (EO) 13423.
- OS Executive Office (OSEO) Provides managerial assistance to the Office of the Secretary on resource management in the areas of budget and financial services, strategic human capital planning, administration and management, information and project management to 16 staff divisions which include approximately 2,100 employees. OSEO provides centralized, cost-effective service delivery that enables staff divisions to execute key functions for the Secretary and the Department. In FY 2007, OSEO established and supported the Inter-Agency Working Group on Import Safety as directed by Executive Order, July 18, 2007.

Funding History

\$15,896,000
\$15,298,000*
\$15,644,000
\$15,458,000
\$15,341,000

^{*}Note: The Office of Grants Moved to the Assistant Secretary for Resources and Technology (ASRT) in FY 2005.

Budget Request

The FY 2009 request for ASAM is \$15,984,000, an increase of \$643,000 above the FY 2008 President's Budget. The increase is needed to cover the mandatory costs of annualization for the January 2008 pay raise and the anticipated January 2009 pay raise. Additionally, the increase will allow for additional support of management initiatives and accomplish the Secretary's priorities. With approval of the funding request in FY 2009, the ASAM will improve operations utilizing the following strategies.

Office of Acquisition Management and Policy (OAMP) will continue to standardize and modernize HHS' acquisition processes and refine the Acquisition Dashboard metrics as needed. Additionally OAMP will:

- Increase the use of full and open competition and increase the appropriate use of performance-based contracts and performance specifications.
- Manage the direction of acquisition and logistics policy (including travel policies) for the Department. Manage and monitor the travel card and e-travel systems, and providing direct travel support staff offices.
- Develop and maintain an acquisition career management program, in concert with Government-wide initiatives.

Office of Small and Disadvantaged Business Utilization (OSDBU) will continue to increase the use of small businesses as HHS contractors by disseminating best practices and policy that ensure sufficient numbers of small businesses are considered during the procurement process.

Office of Business Transformation (OBT) will perform management and administrative analysis and develop policy and guidelines for proposed or ongoing management initiatives to improve effectiveness and gain efficiencies by:

- Leading HHS development of High Performing Organizations (HPOs) as an alternative to public-private competition.
- Providing Department-wide leadership, centralized oversight, policy and guidelines, and coordination support relating to competitive sourcing activities and representing the Department in dealings with OMB, GAO and other Federal agencies.

Office of Human Resources (OHR) will update the Human Capital Accountability Plan and overseeing enterprise-wide recruitment, retention, and succession programs by:

- Providing technical assistance through consolidated Human Resource Centers.
- Evaluating and refining workforce planning processes to ensure they are integrated with agency budget proposals, performance contracts, restructuring plans, hiring

- plans and learning and development plans, including HHS University.
- Supporting HSPD-12 through establishment of policies, programs and procedures to implement required changes in HR administration.
- Achieving full deployment of Enterprise Workflow Information System.

Office of Diversity Management and Equal Employment Opportunity (ODME) will establish policy and conducting program evaluation to ensure Diversity and EEO efforts are integrated, standardized and compliant throughout the Department with regard to legislative and regulatory requirements through:

- Providing technical assistance and coordination with the OHR on management and recruitment initiatives, assessment reviews and OPDIVs review process related to improving Diversity and EEO programs.
- Serving as the Departmental contact in the provision of assistive technology, devices and services to HHS employees with disabilities via the HHS partnership with the DoD Computer/Electronic Assistance Program.
- Reviewing, analyzing and adjudicate complaints of discrimination for purposes of issuing Final Agency Decisions on behalf of the Secretary.
- Providing oversight/technical assistance in connection with Alternate Dispute
 Resolution (ADR)-EEO programs and collaborating with the Departmental Appeals
 Board and others to facilitate the use of ADR techniques in the resolution of EEO
 complaints.

Office of Facilities Management and Policy (OFMP) will develop policies and monitor HHS Occupational Safety, Health and Environmental Programs and provide technical assistance for OPDIV's in accordance with applicable Executive Orders (EO) and Federal, State and local laws and regulations. Specific projects include development of:

- Departmental framework for Environmental Management Systems (per EO 13423)
- HHS real property assets and the facilities capital budget planning and delivery process (per EO 13327).
- Comprehensive Historic Preservation Program to protect and preserve properties in accordance with the National Historic Preservation Act of 1996, as amended.

OSEO will facilitate and enable OS-wide administrative activities to provide an integrated and strategic assessment of functions, procedures and systems that result in higher economies of scale and administrative efficiencies through:

- Streamlining management processes to assure timely performance management that ties to Secretarial priorities, as well as placing a strong emphasis on developing timely assurances for meeting ethical reviews and training.
- Providing budgetary and financial management services in support of its client base.
- Developing and implementing customer outreach initiatives, such as quarterly customer advisory meetings.

OFFICE OF INTERGOVERNMENTAL AFFAIRS

	FY 2007	FY 2008	FY 2009	FY 2009
	<u>Actual</u>	Enacted	<u>PB</u>	<u>+/- FY 2008</u>
Budget Authority	\$5,762,000	\$5,620,000	\$5,670,000	+\$50,000
FTE	33	32	32	
FY 2009 Authorization				Indefinite
Allocation Method				Direct federal

Program Description and Accomplishments

The Office of Intergovernmental Affairs (IGA) is composed of a headquarters office and the ten offices of the Regional Directors. The headquarters office advises Departmental officials on the intergovernmental aspects of HHS policies, programs and initiatives. The headquarters office also coordinates the Department's strategies to strengthen intergovernmental relationships and implement Administration and Secretarial initiatives at various levels of government. The Regional Directors represent the Department in direct official dealings with state, local, and tribal governmental officials and offices, as well as non government organizations. In addition to helping implement Department of Health and Human Services (HHS) initiatives and programs, IGA undertakes a variety of assignments for the White House, the Secretary, and the Deputy Secretary related to the Department's intergovernmental partners. IGA also works closely with individual States, local and tribal officials, and the local and national organizations that represent them, ensuring that lines of communication are maintained among all levels of government.

The Office of Intergovernmental Affairs serves to advocate and facilitate the communication of the Administration's health and human services agenda with State, local and tribal governments and outreach to external organizations. IGA consistently does this by serving as chief HHS liaison and principal advisor to the Secretary and the Department on state, local, and tribal activities. The Office and the ten regional components establish and maintain effective communications with Governors, mayors and tribal governments, and selected external organizations. They are able to effectively provide guidance on the development and analysis of Departmental policy as it relates to state, local and tribal governments.

IGA activities include:

- Providing advice to State and local entities about the potential impact of proposed
 Departmental legislative, regulatory, and administrative decisions. This includes working
 with the HHS Operating Divisions as well as with State local and tribal officials in the
 development and implementation of Federal legislation and regulations on subjects
 ranging from welfare, to Medicare to bioterrorism and other important departmental
 activities.
- Promoting general public understanding of programs, policies, and objectives of the Department through meetings, conferences, informational sessions, and through the dissemination of Departmental materials.

- Designing and implementing an outreach plan for communication with key external groups, such as business advocacy groups, healthcare organizations and other private sector entities impacted by the Secretary's priorities and initiatives.
- Coordinating the Department's tribal consultation responsibilities, pursuant to the Indian Self-Determination and Education Assistance Act (PL 93-638) and presidential Executive Orders on tribal consultation; to provide a single point of contact for nearly 700 American Indian/Alaska Native (AI/AN) tribes to access HHS program information and assistance. IGA also provides general management and supervision of the Secretary's Intradepartmental Council on Native American Affairs and reviews policy and actions to ensure program objectives are achieved.

Funding History

FY 2004	\$5,779,000
FY 2005	\$5,787,000
FY 2006	\$5,931,000
FY 2007	\$5,762,000
FY 2008	\$5,620,000

Budget Request

The FY 2009 request for IGA is \$5,670,000, an increase of \$50,000. This will partially cover increased personnel costs such as the annualization of the January 2008 pay raise, and the anticipated January 2009 pay raise.

The budget request for IGA will be used to coordinate a range of outreach activities and facilitate cross-cutting initiatives in the field. IGA develops close relationships with, and is the Secretary's representative to, governors, State legislators, mayors, tribal leaders, other elected and appointed officials, and their constituencies. IGA also responds with outreach and communication with key external groups, such as business advocacy groups, healthcare organizations and other private sector entities impacted by Departmental Initiatives. In IGA's role the office tracks HHS region-specific, Federal and State legislative actions, and serves as a surrogate for the Secretary and Deputy Secretary in the regions, informing State, local and tribal officials, the media and public of the Administration's and Department's program initiatives and priorities. IGA provides Departmental leadership in the field in several areas, including all top Secretarial priorities and initiatives. IGA also represents the Secretary and the Deputy Secretary in contacts with officials from other Federal agencies, the White House, State, local, and tribal governments, their representative organizations, and other outside parties. IGA solicits a full range of viewpoints from stakeholders, including State, local and tribal officials, district Congressional staffs, business coalitions, interest groups, advocacy groups, the media and other regional constituents to be shared with headquarters and the Office of the Secretary.

OFFICE OF THE GENERAL COUNSEL

	FY 2007	FY 2008	FY 2009	FY 2009 +/-
	<u>Actual</u>	Enacted	<u>PB</u>	<u>2008</u>
Budget Authority	\$37,347,000	\$36,427,000	\$36,242,000	(\$185,000)
FTE (including reimbursables)	347	336	328	
HCFAC	[\$5,131,000]	[\$5,714,000]	[\$5,714,000]	
FTE	29	29	29	
FY 2009 Authorization				Indefinite

Program Description and Accomplishments

The Office of the General Counsel (OGC) litigates cases, provides advice and counsel to its client agencies throughout the Department, reviews proposed regulations and legislative drafting, and provides other legal work that emerges from the policies and programs of the Department, Administration, and the Congress. OGC is the legal team of 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, the Operating Divisions (OPDIVs), and the Staff Divisions (STAFFDIVs).

A team of over 400 attorneys and a comprehensive support staff, OGC is one of the largest and most diverse and talented law offices in the country. Many OGC lawyers are heavily involved in administrative and Federal court litigation. The OGC team also reviews proposed regulations and legislation affecting significant issues of health and human services.

OGC's long-term goal is to provide effective and efficient legal support to the Department. OGC's performance measure for this goal is to support of the Office of the Secretary and program client operations, initiatives, and requests by providing high quality legal services, including sound and timely legal advice and counsel. In FY 2007, OGC provided exceptional legal services in a timely manner in support of the Department's Strategic Plan.

OGC successfully defended the Department's rules governing the Medicare Part A and Part B appeals procedures which included video teleconferencing of ALJ hearings. OGC expects similar challenges in FY 2009 and beyond. OGC has also worked closely with the CMS and DOJ to craft innovative settlements in major products liability cases related Medicare Secondary Payer Litigation. OGC led the effort to recover conditional payments under the MSP in the class action orthopedic bone screw case, and in various class action cases filed nationwide against manufacturers of PCPs. OGC has been integral in the defense of nearly 100 challenges involving ACF issues. OGC works closely with the Department of Justice in Federal Court cases, and independently handles proceedings where the Departmental Appeals Board (DAB) has jurisdiction. Two of the most significant disputes, involving Title IV-E claims involved disallowances of \$162 million (settled) and \$95 million (pending).

OGC's team also plays a key role in the implementation of the Secretary and Department's initiatives. OGC has played a critical role in two HHS initiatives designed to implement one of the "four cornerstones" for an improved health care system set forth in Executive Order 13335: Transparency on the quality of services. OGC developed the legal theories for the "Better Quality Information for Medicare Beneficiaries" (BQI) initiative. A second initiative, involving "Chartered Value Exchanges," involves the aggregation of Medicare claims data with data from other insurers to provide quality information, designed for the benefit of all insurers contributing data, including the Medicare program. This project is expected to be fully underway in FY 2010. Additionally, OGC has participated in the PHS Commissioned Corps Transformation to respond to urgent or emergency public health care needs at the national, state, or local level. OGC has drafted the HHS proposal for legislation, of which the core force management provisions were enacted in 2007. Through technical assistance (including legislative drafting), OGC continues to assist HHS to advance additional proposed authorities needed for broad-based transformation of the Corps. OGC looks forward to continuing to work with the Department in these areas.

Funding History

FY 2004	\$37,364,000
FY 2005	\$37,413,000
FY 2006	\$36,729,000
FY 2007	\$37,347,000
FY 2008	\$36,427,000

Budget Request

The FY 2009 request for the Office of the General Counsel (OGC) is \$36,242,000, a decrease of \$185,000 below the FY 2008 Enacted level. In FY 2009, OGC will continue to provide effective and efficient legal support to the Department. OGC will support the President's Management Agenda, the Department of Health and Human Services Strategic Goals and Top 20, and the Secretary's 500 Day Plan. OGC's goal is to support the Office of the Secretary and the Department by providing high quality legal services, including sound and timely legal advice and counsel. The Budget request for OGC will be used to continue to effectively manage the legal challenges and provide support for the Secretary and Department's initiatives and programs. In addition to the activities financed through the General Departmental Management appropriation, the Office of the General Counsel also provides reimbursable services to HHS components. These services are delivered under agreements between OGC and the entity receiving services. OGC is currently standardizing the agreements supporting these services, moving towards one agreement per client component. This standardization may change some of the reimbursements received in FY 2008 and FY 2009.

In FY 2009, OGC will continue to focus on supporting the Department's Strategic Plan. Select OGC initiatives and programs are outlined below:

1. Improve the safety, quality, affordability and accessibility of health care, including behavioral health care and long-term care.

- *Physician Quality Reporting Initiative*. OGC continues to counsel CMS in the implementation and expansion of the Physician Quality Reporting Initiative (PQRI).
- Health Information Technology. OGC will continue to play a critical role in the Department's health information technology initiatives, specifically: (i) working with the CMS on transparency initiatives; (ii) working with CMS on the rules effectuating the e-prescribing provisions for the Part D program under the Medicare Modernization Act (MMA); and (iii) working with Office of the National Coordinator on the development of the Nationwide Health Information Network.
- Expanding Consumer Choice and Access to Quality Services for Medicare Beneficiaries. Assist CMS efforts to (1) expand the health care coverage options available through the Medicare Advantage program, (2) improve nursing home quality of care; and (3) promote transparency in Part D drug plan compliance with quality standards.
- Maintaining Financial Integrity of Medicare and Medicaid Programs. OGC will continue the enormous amount of work involved in advising CMS with respect to payment system changes, anti-fraud initiatives, implementation of the new Medicaid Integrity Program, and other efforts to protect the financial integrity of the Medicare and Medicaid programs.
- Medicare Modernization Act (MMA) and the Part D Benefit. OGC expects that the implementation of the Medicare Part D benefit and the Regional Medicare Advantage program, both enacted into law with the MMA, will continue to generate a significant amount of litigation challenging various aspects of these programs. OGC is defending five major lawsuits challenging CMS's implementation of Part D and other key provisions of the MMA. OGC will continue to defend all of these lawsuits in the upcoming years. More important, OGC's experience now shows that the enactment of Part D will give rise to future, predictable litigation. Prescription Drug Plans' (PDPs) and MA-PDs' bids are submitted on a yearly cycle, and OGC fully expects that subsequent years will bring additional legal challenges by unsuccessful bidders.
- Patient Safety and Quality Improvement Act of 2005. OGC attorneys assist the Agency for Healthcare Research and Quality and the Office for Civil Rights in implementing the Patient Safety and Quality Improvement Act of 2005.
- 2. Public Health Promotion and Protection, Disease Prevention, and Emergency Preparedness: Prevent and control disease, injury, illness, and disability across the lifespan, and protect the public from infectious, occupational, environmental, and terrorist threats.
 - Public Health Emergency Preparedness. OGC will help prepare the nation for public health emergencies through legal preparedness activities, including drafting international cooperation agreements and advising federal, state, local and tribal officials on legal authorities (e.g., for quarantine or emergency declarations).
 - Pandemic Influenza Preparedness. OGC will advise OGHA and ASPR in their discussions with the World Health Organization and member countries regarding access to pandemic influenza strains originating from developing countries.
 - Expanding Global and Domestic HIV/AIDS and Emerging Infections Programs. OGC advises both CDC and HRSA on the numerous legal issues associated with HHS's expanding international programs including those focused on emerging infections and

those focused on HIV/AIDS and Tuberculosis, consistent with the Secretary's 500-Day Plan. OGC will work with key personnel implementing the reauthorization of the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act. In addition, OGC will work with the Department of State and advises HHS and CDC on development of bilateral agreements with host countries.

- Strategic National Stockpile. OGC will assist the Centers for Disease Control and Prevention with its efforts to expand and maintain the Strategic National Stockpile, providing legal assistance and advice regarding a number of significant issues involving the purchase, stockpiling, and deployment of vital vaccines, drugs, and other medical supplies, including negotiation of deployment agreements, and the management and contracts administration of current and new contracts.
- The Pandemic and All-Hazards Preparedness Act (PAHPA), P.L. 190-417. OGC has provided and continues to provide extensive advice on the implementation of this Act to ASPR and other HHS agencies. OGC advised ASPR on a myriad of issues regarding the return of the NDMS to HHS, employment issues, licensing and credentialing issues, ability of team members to provide support to states or private entities and use of Federal property when NDMS teams have not been activated by the Federal government and storage of pharmaceuticals and other equipment.
- PHS Commissioned Corps Transformation. The Secretary's initiative on the Commissioned Corps seeks to ensure Corps readiness to respond to urgent or emergency public health care needs at the national, State, or local level. OGC has drafted the HHS proposal for legislation, of which the core force management provisions were enacted in 2007. Through technical assistance (including legislative drafting), OGC continues to assist HHS to advance additional proposed authorities needed for broad-based transformation of the Corps.

3. Promote the economic and social well-being of individuals, families and communities.

- Patient Safety and Quality Improvement Act of 2005 (Medical Malpractice). OGC will
 continue to advise and assist AHRQ, OCR, and HHS clients in connection with drafting
 of regulations and other tasks connected with implementation of the recently enacted
 patient safety legislation, designed to encourage reporting of medical errors in order to
 facilitate correction of systemic problems, by ensuring that such reports cannot be used in
 adversarial proceedings.
- Indian Health Care Improvement Act and Indian Self-Determination Act. OGC will assist ASL and IHS in providing technical assistance to the Congress (including legislative drafting assistance) on Congressional bills to update IHS program authorities to respond to changing health care needs of the American Indian/Alaska Native population. Additionally, OGC will participate in contract and compact negotiations under the Indian Self-Determination Act and various IHS consultation workgroups and conferences to assist IHS in transferring control of IHS programs to tribes and tribal organizations.
- President's Health Centers Initiative, and Tort Claims and Tort Litigation. OGC expects an increase in tort claims and litigation under the Federal Tort Claims Act (FTCA). OGC has issued legal opinions about the tort coverage to various clients and has provided assistance to IHS and HRSA especially in the area of "risk management" activities designed to prevent, respond to, or minimize the effects of any alleged medical

malpractice in Federally-funded facilities. This nationwide workload involves medical malpractice allegations relating to care provided at IHS-funded facilities and HRSA-funded Community Health Centers. OGC projects a significant growth in tort claims and tort litigation, especially regarding claims arising from the expansion in the number of HRSA-funded Community Health Centers.

- *Marriage and Fatherhood Grants*. OGC has reviewed and provided guidance in implementation of two major new initiatives promoting Healthy Marriages and Responsible Fatherhood authorized under TANF reauthorization providing \$150 million in annual grant awards.
- TANF and Head Start Reauthorization. OGC assisted ACF in reviewing and clearing interim final rules implementing new tougher work requirements for welfare recipients and creating new penalties for states that fail to implement work participation plans effectively, and is assisting in the issuance of Final Regulations implementing these requirements, which will be published early in 2008.
- Head Start Reauthorization. The Head Start program was reauthorized in late 2007 and OGC is assisting in evaluating the many legal issues raised by the new legislation which will require grantees to re-compete for awards periodically and which make many other changes to the program designed to increase emphasis on the primary objective of school readiness.
- Reauthorization of Trafficking Victims, Torture Victims authorities. OGC will work with ACF and ASL to provide HHS views and technical assistance to the Congress in connection with the development and passage of legislation to reauthorize the Trafficking Victims Protection (TVPA) and Torture Victims statutes. There is a strong likelihood this legislation will be enacted in FY 2008.

4. Advance scientific and biomedical research and development related to health and human services.

- Development and Implementation of the Medicare Clinical Research Policy. OGC has assisted CMS and AHRQ in developing a new national coverage determination that will enable the Medicare program to expand the current clinical trial policy and support research that is particularly beneficial to the Medicare population. OGC has been involved from the outset of this initiative and have been instrumental in developing the legal theories to support expanded coverage under two provisions of the Social Security Act while ensuring compliance with Departmental rules on the protection of human subjects.
- Development of New Vaccines, Drugs and Medical Technology. OGC assists NIH in accelerating private sector development of new vaccines, drugs, and medical technology through contracts, as well as providing legal advice and support on technology transfer and intellectual property. In the technology transfer arena, OGC advises on the execution and enforcement of over 1,000 patent license agreements; collection and administration of more than \$98 million dollars in royalty funds; and protection of HHS intellectual property against infringement.
- Oversight of Biomedical and Behavioral Research and Research Misconduct. OGC assists the Office for Human Research Protections (OHRP) and the Office of Research Integrity (ORI) in their oversight of HHS-conducted or supported biomedical and

behavioral research and research misconduct. OGC also assists NIH to carry out its own intramural programs to ensure research integrity and appropriate human subject protection in research.

5. Other OGC Priorities

- Personnel Legal Activities. OGC attorneys support the Department's managers who take
 action against employee misconduct, and make efforts to improve employee performance
 and, where necessary, take performance-based adverse actions. OGC attorneys defend
 management decisions with respect to employee misconduct or poor performance or
 claims of unlawful discrimination before arbitrators, the MSPB and the EEOC, as well as
 in the Federal courts.
- Early Offers" Pilot". OGC has staffed the "Early Offers" Pilot. Early Offers provides a means of settling meritorious administrative medical malpractice tort claims before claimants and the government incur unnecessary litigation cost. The pilot will maximize OGC's limited staff resources, and result in speedier payment of meritorious claims.
- Ethics Redesign Initiative. OGC administers the Department's ethics program. This includes the public and confidential financial disclosure systems. OGC will focus on completion of ongoing program reviews and implementing enforcement and compliance systems and will reinitiate audits after an appropriate interval to measure improvement.

DEPARTMENTAL APPEALS BOARD

	FY 2007	FY 2008	FY 2009	FY 2009
	<u>Actual</u>	Enacted	<u>PB</u>	<u>+/- FY 2008</u>
Budget Authority	\$9,600,000	\$9,363,000	\$9,445,000	\$82,000
FTE	60	65	65	
FY 2009 Authorizatio	n			Indefinite
Allocation Method				Direct federal

Program Description and Accomplishments

The Departmental Appeals Board (DAB) provides impartial, independent hearings and appellate reviews, and issues Federal agency decisions under more than 60 statutory provisions governing HHS programs. Unlike most other Staff Divisions (STAFFDIVs) in the Office of the Secretary, DAB performs functions that are mandated by statute or regulation. 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, and Medicare beneficiaries. Disputes heard by the DAB may involve over \$1 billion in Federal funds in a single year. DAB decisions have nation-wide impact. In addition, DAB decisions on certain cost allocation issues in grant programs have government-wide impact, since HHS is the agency whose decisions in this area legally bind other Federal agencies.

In general, DAB contributes to the improved management and integrity of HHS programs, and to the quality of health care, by:

- Ensuring compliance with program requirements;
- Promoting consistency in decision-making across HHS;
- Issuing timely decisions that are well-founded, well-reasoned, and clearly communicated;
- Resolving disputes administratively, thereby avoiding costly court proceedings.

DAB has made progress in the strategic management of human capital by re-engineering its operations and improving its case management techniques. DAB shifts resources across its Divisions as needed to meet changing caseloads, where feasible, and targets mediation services to reduce pending workloads.

DAB is organized into four Divisions:

- the Appellate Division supports the Board Members, who preside in various types of cases;
- the Civil Remedies Division supports DAB Administrative Law Judges (ALJs), who conduct evidentiary hearings;
- the Medicare Operations Division supports DAB Administrative Appeals Judges, who review decisions by ALJs from the HHS Office of Medicare Hearings and Appeals (OMHA) or (in some older cases) by Social Security Administration ALJs; and

• the Alternate Dispute Resolution Division, which provides mediation services in DAB cases and provides policy guidance and information on the use of dispute resolution methods throughout HHS to reduce administrative and management costs.

Performance analyses for each Division are based on FY 2007 data to date. Workload assumptions are explained in the charts under Rationale for the Budget Request.

Board Members – Appellate Division

DAB Board Members are appointed by the Secretary, and the Board Chair is also the STAFFDIV Head of DAB. All Board Members are judges with considerable experience who, acting in panels of three, issue decisions with the support of Appellate Division staff. In some cases (such as Head Start terminations and Medicaid disallowances), Board Members conduct *de novo* reviews and hold evidentiary hearings if needed. In other cases, Board Members provide appellate review of decisions by DAB ALJs or other ALJs. Board review ensures consistency of administrative decisions, as well as adequacy of the record and legal analysis before court review. For example, Board decisions in grant cases promote uniform application of OMB cost principles. Board decisions are posted on the DAB Website and provide precedential guidance on ambiguous or complex requirements.

Board jurisdiction affecting Medicare and Medicaid includes:

- Appellate review of DAB ALJ decisions in cases for which a healthcare provider or supplier has a hearing right under section 1866(h)(1) of the Social Security Act and/or 42 C.F.R. Part 498, including cases that raise important quality of care issues such as nursing home enforcement and Clinical Laboratory Improvement Amendments (CLIA) cases.
- Review of Medicare National Coverage Determination policies and review of DAB ALJ
 decisions on Local Coverage Determinations that may affect whether Medicare
 beneficiaries get timely access to new medical technology/procedures, without
 jeopardizing safety or wasting funds.
- Appellate review of DAB ALJ decisions in civil money penalty and exclusion cases brought by the HHS Office of Inspector General (OIG) or Centers for Medicare & Medicaid Services (CMS) to improve program integrity.
- *De novo* review of Medicaid disallowances (i.e., the loss of Medicaid funding) appealed by States pursuant to statute.

States may also request Board review of TANF (welfare) penalties, penalties based on ACF child and family welfare and services reviews, foster care eligibility disallowances, and some other determinations related to financial or program management.

The Secretary appointed a new Board Chair in April 2007, to replace the former Chair who retired on April 1, 2006. The Board Chair spends considerable time on management, administrative, and training activities, or responding to congressional requests for information and coordinating with program agencies on regulation development and related activities. In FY 2007, DAB filled two of this Division's attorney vacancies, but lost one in FY 2008 when an

attorney was transferred to the Medicare Operations Division (described below) to help with that Division's growing backlog of cases.

Performance Analysis: Despite having vacant positions for the first half of FY 2007, the Board/Appellate Division issued decisions in 77 cases and closed an additional 53 cases. The Appellate Division met its timeliness standard of 45% in FY 2007 (Long-term Performance Objective 1, hereafter "Objective" 1). This objective measures the percentage of total Board decisions issued in cases with a net age of six months or less. Meeting this goal was challenging, given the prolonged vacancy in the Chair position, previous staff attorney reductions, and recent increases in case receipts that created a backlog of cases ready for decision. The Board generally decides the oldest appeals first, which in turn increases the age of newer appeals ready for decision. To meet its FY 2007 timeliness target, the Division focused on cases with a net case age of six months or less; DAB has set new timeliness targets of 50% for FY 2008 and 55% for FY 2009. Objective 2 for the Appellate Division measures the number of Board decisions reversed or remanded in Federal court, as a percentage of all Board decisions. The Appellate Division met its target of 2% for FY 2007, and will maintain this extraordinary low reversal rate in FY 2008 and FY 2009.

Administrative Law Judges – Civil Remedies Division (CRD)

DAB ALJs are supported by staff in CRD. These ALJs conduct adversarial hearings in proceedings that are critical to HHS healthcare program integrity efforts, 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. For example, appeals of enforcement cases brought under the Health Insurance Portability and Accountability Act (HIPAA) are likely to raise new issues.

DAB ALJs hear cases brought by CMS or OIG to exclude providers, suppliers, or other healthcare practitioners from participating in Medicare, Medicaid and other federal healthcare programs or to impose civil money penalties for fraud and abuse in such programs. CRD's jurisdiction also includes appeals from Medicare providers or suppliers, including cases under CLIA and provider/supplier enrollment cases. Expedited hearings are now required by statute, when requested, in some proceedings, such as provider terminations and certain nursing home penalty cases. These cases typically involve important quality of care issues. DAB ALJs also hear cases which may require challenging testimony from independent medical/scientific experts, for example, in appeals regarding Medicare Local Coverage Determinations or issues of research misconduct.

CRD nursing home case receipts are increasing due to renewed enforcement efforts and enhanced oversight by CMS of the timeliness of survey actions. Appeals from clinical laboratories, appeals in provider/supplier enrollment cases, and appeals in OIG cases based on corporate integrity agreements are also generating more cases. In addition, HIPAA and OIG cases are likely to increase in FY 2008 and FY 2009, and research misconduct cases and OIG false claims cases are very resource-intensive. DAB is addressing this increased workload through new efficiencies. For example, DAB will implement a no-cost e-filing initiative for

CRD cases in FY 2008, resulting in more efficient docket management, case processing and other activities.

Performance Analysis: CRD closed 660 cases in FY 2007 (130 by decision) and exceeded its two timeliness goals (Objectives 3 and 4). Objective 3 relates to OIG actions to impose civil money penalties or to exclude individuals from participating in Federal programs. The measure for this goal is the percentage of OIG cases in which DAB ALJs issue decisions within 60 days of the close of the record. The FY 2007 target was increased from 90% in FY 2007 to 97% for FY 2008 and 99% for FY 2009. (Although the actual was 100% for FY 2007, the targets were adjusted downward slightly to reflect a shift in staff to the Medicare Operations Division in FY 2008.) Objective 4 ensures that increases in case receipts do not result in a greater number of aged cases. The measure is the number of cases open at the end of the year that had been received in prior years. CRD exceeded the target of having no more than 100 cases from FY 2006 or earlier still pending at the end of FY 2007. CRD expects improved efficiencies and productivity increases that should enable it to reduce this target in FY 2008 and FY 2009 (to fewer than the FY 2007 actual of 85 cases), despite increased workloads and vacant ALJ positions.

Medicare Appeals Council – Medicare Operations Division (MOD)

With support from MOD attorneys and staff, Administrative Appeals Judges (AAJs) on the Medicare Appeals Council review decisions involving Medicare coverage or entitlement issued primarily by ALJs in OMHA. Medicare Appeals Council review strengthens Medicare management by:

- Improving patient access to health services by ensuring that Medicare requirements are applied correctly nationwide;
- Protecting parties' due process rights;
- Ensuring that interpretations applied to individual claims conform to the statute, regulations, and policy guidance; and
- Avoiding costly court review by ensuring that the administrative record is complete and that the administrative decision is sound and is clearly communicated.

MOD previously increased both the quality and rate of its case dispositions. However, productivity gains did not substantially reduce the number of pending cases, since MOD receives an ever-larger number of cases each year (increasing about ten-fold in the last ten years). MOD receipts increased to 2,384 in FY 2007 (12,300 claims), compared to 1,238 in FY 2006 (10,090 claims). This trend will continue through FY 2008 and FY 2009, since there are now more older and disabled Medicare beneficiaries. Statutory changes for Medicare Part A and B appeals resulted in 90-day timeframes, lower thresholds for amounts to be appealed, and a right to *de novo* review by the Council – all of which resulted in increases in both the number of cases and the amount of work required on each case.

Performance Analysis: In the second half of FY 2007, MOD filled some vacant positions, although hires were delayed because of the long-term Continuing Resolution. MOD did not meet the target for Objective 6, constraining the growth in case age by reducing to 125 days (as

measured from the date MOD received the case folder) the average time to complete action on Medicare Part B cases. The FY 2007 result, 169 days, is directly attributable to the fact that MOD had to divert all resources away from deciding older cases (more older cases drives up average case age) to deciding newer cases, since those newer cases have a mandatory statutory deadline of 90-days for resolution. MOD should meet the revised targets of 160 days for FY 2008 and 155 days for FY 2009. MOD exceeded its FY 2007 target for Objective 7, to increase the number of decisions to 1,150, by closing 1511 cases (disposing of 10,583 claims). Management achieved this by implementing a new case management system which focuses on a balanced approach to case assignment and increased individual accountability. With the shift of two attorneys from other Divisions to MOD and further management attention to individual productivity, MOD will meet its new targets of 1800 cases for FY 2008 and 1900 cases for FY 2009. However, DAB cannot shift more resources to MOD without compromising productivity in other Divisions.

Alternative Dispute Resolution (ADR) 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. Using ADR techniques saves 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 DAB Chair is the Dispute Resolution Specialist for HHS and oversees ADR activities under the HHS policy issued under the Act. ADR Division staff provide mediation services in DAB cases, provide or arrange for mediation services in other HHS cases (including workplace disputes and claims of employment discrimination filed under the HHS Equal Employment Opportunity program), and provide training and information on ADR techniques (including negotiated rulemaking – a process for public dialogue in developing regulations).

DAB has only a small ADR staff, and leverages its reach through a variety of innovative programs. For example, DAB's Sharing Neutrals Program won an award from the Office of Personnel Management for the innovative use of collateral duty mediators to resolve workplace disputes. (The Shared Neutrals Program is designed so that Federal employees who are trained and experienced mediators can occasionally mediate disputes for Federal agencies other than their home agency, in exchange for similar services to their home agency from mediators employed by other Federal agencies.) DAB also partners with the ADR office at the Department of Transportation (DOT) to provide conflict management seminars to HHS and DOT staff. DAB staff encourages parties to mediate DAB cases, and many staff members are trained mediators who serve in that capacity when their other duties permit.

Performance Analysis: In FY 2007, the ADR Division exceeded its goal of providing 8 conflict resolution seminars to HHS employees and providing ADR services in 50 DAB cases. This new goal, Objective 5, is a consolidation of previous ADR performance goals. It measures the new core ADR objective of enhancing ADR capacity, such that ADR is used whenever appropriate in disputes involving HHS. The new objective measures capacity as a function of training

opportunities (which assure sufficient ADR information and skills in the HHS population) and ADR interventions in DAB cases (which measures actual use in a significant subset of HHS conflicts). ADR resources and targets for the number of trainings and interventions will increase only slightly for FY 2008 and FY 2009, since ADR resources are projected to remain relatively constant.

Funding History

FY 2004	\$8,747,000
FY 2005	\$8,853,000
FY 2006	\$8,691,000
FY 2007	\$9,600,000
FY 2008	\$9,363,000

Budget Request

DAB's FY 2009 request is \$9,445,000, an increase of \$82,000 over the FY 2008 enacted level. At this level, DAB should be able to retain most of its FY 2008 staff, since the likely retirement of some senior personnel should offset increases for pay and inflation. Although new staff should be fully trained and more productive by FY 2009, case receipts will exceed case closings (as shown on the following charts), and the overall age of pending cases will increase.

The funding request for DAB is fully justified by the increasing Medicare and other workloads, workload statistics for each Division (see below), increased personnel and other costs (such as IT costs and rent), DAB e-Government needs, and the potential fiscal and legal consequences of not meeting statutory and regulatory deadlines for hearings and appeals.

<u>Board Members – Appellate Division</u>

Chart A shows total caseload data for this Division. FY 2007 data is based on actual case receipts, and FY 2008 and 2009 data is based on certain assumptions, including:

- Nationwide Federal pay raise of 3.0% in January 2009 and non-pay inflation factor of 2% for FY 2009;
- Continued increases in Medicaid disallowance appeals due to stepped-up enforcement;
- Relatively high levels of non-CMS public assistance program appeals from disallowances or penalties resulting from program reviews;
- Some measurable efficiencies from DAB's no cost e-filing project for these cases beginning in the third quarter of FY 2008;
- Increased productivity in FY 2008 from new staff hired in the third quarter of FY 2007;
- Filling a newly vacated Board Member position in the second quarter of FY 2008.

Chart A APPELLATE DIVISION CASES

	FY 2007	FY 2008	FY 2009
Open/start of FY	126	146	166
Received	150	160	165
Decisions	77	90	95
Total Closed	130	140	145
Open/end of FY	146	166	186

<u>Administrative Law Judges – Civil Remedies Division</u>

Caseload data for CRD is shown in Chart B. The caseload data and projections for FY 2007 were modified from prior budget charts to reflect more recent data, as well as updated information from HHS agencies. Assumptions include the following:

- Nationwide Federal pay raise of 3.0 % in January 2009 and non-pay inflation factor of 2% for FY 2009;
- No new resources for this division during FY 2008 or FY 2009;
- A continued upward trend in nursing home enforcement cases; and
- Some measurable efficiency from DAB's e-filing initiative and other management initiatives.

Chart B CIVIL REMEDIES DIVISION CASES

	FY 2007	FY 2008	FY 2009
Open/start of FY	378	458	488
Received	740	750	760
Decisions	130	135	140
Total Closed	660	720	730
Open/end of FY	458	488	518

Medicare Appeals Council – Medicare Operations Division

By strategic management of human capital and improved management generally, MOD has dramatically improved staff productivity and achieved greater control over a caseload that has increased significantly. With some new staff at the end of FY 2007, MOD increased dispositions to 1,511 (10,583 claims).

However, the efficiencies which MOD achieved are insufficient to significantly decrease the number of cases filed prior to January 1, 2006, because MOD has had to divert all resources away from deciding older cases to deciding newer cases, since the newer cases have a mandatory statutory deadline of 90-days for resolution. Cases are also taking more time to complete because the Medicare Appeals Council must now perform *de novo* review and, in general, cases under the current regulations are raising more complex issues than in the past. Under the prior

standard, the Council reviewed appeals based on a substantial evidence standard, under which not all appeals required full decisions. Under current regulations, the Council must conduct a review of the complete evidentiary record for all requests for review, and issue an order within a 90-day statutory timeframe for appeals arising from ALJ decisions in Part A and Part B cases. In order to address MOD's growing caseload, DAB will shift two attorneys from other Divisions to MOD. DAB cannot afford to shift more attorney resources to MOD without adversely affecting workload in other Divisions.

Chart C contains case data for this Division, based on actual numbers for FY 2007 and trends in case receipts at lower levels of appeals. DAB is reporting data about those cases requiring individual determinations, while noting the associated individual claims. (A single case may represent hundreds of Medicare claims and more than one Medicare contractor denial. For example, the 2,384 cases docketed in FY 2007 represent over 12,300 claims.) Assumptions on which the data are based include:

- Nationwide Federal pay raise of 3.0 % in January 2009 and non-pay inflation factor of 2% for FY 2009, and
- Increased receipts of appealed and referred cases in FY 2008 and FY 2009, as OMHA's disposition rate increases.

Chart C
MEDICARE OPERATIONS DIVISION CASES

	FY 2007	FY 2008	FY 2009
Open/start of FY	850	1,723	2,423
Received	2,384	2,500	2,700
Cases Closed	1,511	1,800	1,900
(claims closed)	(10,583 claims)	(12,000 claims)	(12,660 claims)
Open/end of FY	1723	2,423	3,223

Alternative Dispute Resolution Division

In FY 2008 and FY 2009, ADR will strive to meet the following goals:

- Continue working to enhance ADR capacity at HHS, such that ADR is used whenever appropriate in disputes involving HHS;
- Continue using ADR in HHS cases so as to increase efficiency and decrease contentiousness in case resolution:
- Continue OPM award winning Sharing Neutrals Program as a way to leverage limited resources for HHS cases and advance interagency ADR goals; and
- Continue working with staff in other HHS offices and the federal ADR community to advance joint ADR goals.

ADR's ability to meet these goals will be affected if DAB needs to devote resources from this Division to meet other management and workload demands.

Outputs / Outcomes Table

#		FY	FY	FY	2006	FY	2007	FY	FY	Out-
_	Key Outcomes	2004 Actual	2005 Actual	Target	Actual	Target	Actual	2008 Target	2009 Target	Year Target
	Long-Term Objective 1: Strengthen program management by maintaining the efficiency of Appellate Division case processing. (outcome and efficiency measure)									
1	Percentage of Board decisions with net case age of six months or less.	60%	35%	35%	36%	45%	45%	50%	55%	57%
	ng-Term Objective 2: Maintain rality of decisions. (outcome measu		d remand	rate of Bo	ard decisio	ons appeal	ed to Fede	ral courts	as a meası	ire of
1	Number of decisions reversed or remanded on appeals to Federal court as a percentage of all Board decisions issued.	2%	2%	2%	2%	2%	2%	2%	2%	2%
exc	ng-Term Objective 3: Assure ma lusion cases by increasing Civil R asure)									
1	Percentage of decisions issued within 60 days of the close of the record.	100%	95%	90%	90%	90%	100%	97%	99%	100%
	ng-Term Objective 4: Constrain asure)	growth in	number of	aged Civi	l Remedie	s Division	cases. (out	come and	efficiency	
1	Number of case open at end of Fiscal Year that were opened in previous Fiscal Years.	157	100	≥FY05	100	≥100	85	≥2007	≥2008	≥2009
	ng-Term Objective 5: Enhance A olution and promote efficiency in					ntentiousn	ess and as	sociated co	osts in disp	oute
1	Number of conflict resolution seminars conducted for HHS employees.	managen	practi	ces. (oute		8 sessions	9 sessions	8 sessions	8 sessions	8 sessions
2	Number of DAB cases (those logged into ADR Division database) requesting facilitative ADR interventions prior to more directive adjudicative processes.					50	59	55	57	60
	ng-Term Objective 6: Constrain	growth in	average ti	me to com	plete actio	n on Medi	care Appe	als cases. (outcome a	nd
effi	Average time to complete action on Part B Requests for Review measured from receipt of case folder. (FY 2001 and following Fiscal Years) Note: Results for FY 05 determined after excluding outlier cases in which delays related to court proceedings beyond DAB's control.	12 months	80 days	90 days	101 days	125 days	169 days	160 days	155 days	150 days

"		FY	FY FY 2004 Actual Actual	FY 2006		FY 2007		FY 2008	FY 2009	Out-Year Target	
#	Key Outputs			Target / Est.	Actual	Target / Est.	Actual	Target / Est.	Target / Est.	/ Est.	
Lo	Long-Term Objective 7: Increase number of Medicare Appeals dispositions to resolve and respond to Medicare claims										
bro	ought by program providers and	beneficia	ries. (out	put and effi	iciency)						
1	Number of dispositions. Counting method changed in FY 05 (see narrative below); FY 04 comparable results are 2183 cases.	16,000	1,619	1,200	1,140	1,150	1,511	1,800	1,900	1,950	
	Appropriated Amount (\$ Million)	\$8.7	\$8.9		\$8.7		\$9.6	\$9.4	\$9.4		

For further details, see the DAB section in the GDM Online Performance Appendix.

OFFICE ON DISABILITY

	FY 2007	FY 2008	FY 2009	FY 2009
	<u>Actual</u>	Enacted	<u>PB</u>	<u>+/- FY 2008</u>
Budget Authority	\$739,000	\$721,000	\$728,000	+\$7,000
FTE	4	4	4	0
FY 2009 Authorization.			•••••	Indefinite
Allocation Method			• • • • • • • • • • • • • • • • • • • •	Direct federal

Program Description and Accomplishments

The mission of the Office on Disability (OD) is to respond to the President's New Freedom Initiative by helping to break down barriers to support the full integration of people with disabilities in all aspects of everyday life, including employment, education, transportation, health care and the use of adaptive technologies. Promoting the abilities of all persons with disabilities dovetails with the Secretary's broader vision and goals for the Department, emphasizing accountability, effectiveness and quality of service delivery, research, and policy on behalf of the 54 million Americans with disabilities.

OD's mission is guided by three core strategic goals:

- Healthcare
- Public Health Promotion, Disease Prevention, and Health Promotion
- Human Services

OD's long-term goal is to promote the abilities of all persons with disabilities, leading to the vision of an inclusive America.

The following OD objectives and supporting programs are funded by this budget:

- Promote Integrated Health and Wellness Services: Ensure service capacity and affordability; encourage health education initiatives inclusion of persons with disabilities; promote prevention and wellness for persons with disabilities; ensure that research routinely includes persons with disabilities; promote healthcare provider knowledge of best practices to meet the full range of health needs of persons with disabilities of all ages.
- **Promote Effective Access:** Ensure that persons with disabilities across the lifespan have access to the full range of health, social support, education, employment, technology, transportation and income services needed to live with dignity in the community; Ensure that service providers (health care, education, employers) have the tools and knowledge needed to serve the whole person with a disability; Build on the Americans with Disabilities Act (ADA) to promote accessibility of all services and facilities to serve persons with disabilities.
- **Individual Self-Determination:** Promote the value of "ownership" for persons with disabilities, emphasizing self determination and self reliance; Foster Federal, State and local policies that promote and award self reliance and engagement in work, family and

- community over chronic entitlement and dependency; Provide and promote the knowledge and skills that enable individuals with disabilities to coordinate and manage their lives in the community.
- Efficient Community Integration of Services: Promote seamless integrated services to meet the individual, community-based needs of persons with disabilities across the lifespan; Promote development and use of evidence based/ best practices in service delivery and support in communities nationwide to promote independence for persons with disabilities which enhance collaborations across service orientations to correct current "stove pipe" services and funding.

Examples of OD activities under each of these objectives include the following:

Promote Integrated Health and Wellness Services

- Promote the Surgeon General's Call to Action (CTA) to Improve the Health and Wellness of Persons with Disabilities including monitoring of the National Action Plan to operationalize CTA recommendations and strategies.
- Ensure the understanding of Medicaid programs and services for persons with disabilities through collaboration with CMS.
- Promote physical fitness for youth with disabilities in conjunction with the President's Healthier US Initiative and the President's Council on Physical Fitness and Sports, through the OD's "I Can Do It, You Can Do It" program promoting physical fitness among children and youth with disabilities.
- Develop, publish and promote the Guide on "Closing the Gaps in Services for Infants and Young Children with Hearing Loss" to support the Surgeon General's Call to Action to Promote the Health and Wellness of Persons with Disabilities.
- Advance the action plan in collaboration with the Office of on Women's Health to address health screening and access barriers for women with disabilities.
- Partner with the Office of Minority Health to publish a White Paper on programs to meet the health disparities of women of color with disabilities and supporting recommendations.
- Ensure disability attention to all Departmental initiatives including emergency response, eliminating health disparities, health promotion/disease prevention, Healthy People 2010 objectives, and Healthy People 2020 planning.
- Address with the Administration on Aging and other HHS partners the caregiver/workforce challenges for persons with disabilities, including promotion of interagency funding collaborations.

Promote Effective Access / Transportation

• Continue collaboration with the Federal Transit Administration (FTA) to implement the President's Coordinated Transportation Executive Order, United We Ride, to work with States to provide best transportation options for persons with disabilities and ensure disability-related action steps acted on.

Promote Effective Access / Employment Opportunities

• Work with Federal and private sector employers to address employment of persons with disabilities as an important factor in health care access and health status. Help employers

- to overcome barriers to hiring persons with disabilities as well as ensure accessibility and disability relevance of employer-sponsored health services.
- Address the resettlement of refugees who have a disability and the development of employment opportunities for this population.
- Promote information on tax incentives and individual investment plans for employers and tax credits for persons with disabilities.

Efficient Community Integration of Services

- In partnership with the HHS Assistant Secretary for Preparedness and Response, the Federal Emergency Management Agency, and the Department of Homeland Security develop and help promote disability-based emergency preparedness templates, evidence-based and best practices, and toolkits to support the special needs of persons with disabilities, first responders and other emergency response providers at the Federal, State and local levels during all emergency situations.
- With the HHS Assistant Secretary for Preparedness and Response, monitor the inclusion of at-risk populations, including persons with disabilities, in infectious disease prevention planning as per the Pandemic and All Hazards Preparedness Act requirements.
- Increase the number of HHS Public Health Service Corps personnel, Federal, State, Local and Tribal Emergency Managers trained in addressing the needs of persons with disabilities during emergency planning and response.
- Help enhance medical and general shelters accessibility for persons with disabilities by including access to accommodating mobility devices, personal care support, and other accommodations.
- Implement and manage the OD interdepartmental program, Needs of Youth with Co-Occurring Developmental Disabilities and Emotional/Substance Abuse Disorders.
- Promote education and information on disability-based topics by facilitating the HHS New Freedom Initiative interagency workgroup and supporting subcommittees.
- Convene regularly scheduled NFI-based interagency meetings to share, inform and
 education agencies on all aspects of disability and related matters especially regarding
 integration of all age groups on the Medical Home Systems initiative with the Health
 Resources Services Administration, American Academy of Pediatrics, and other HHS
 agency programs.
- Foster collaboration with constituent advocacy organizations on the Surgeon General's
 Call to Action while increasing opportunities to reach people with disabilities, disability
 advocates, healthcare providers, and diverse other audiences, including the general
 public.
- In conjunction with Federal agencies and Departments identify current gaps and corrective actions to help address current limited state and local Traumatic Brain Injury (TBI) rehabilitation services coordination.
- Create national attention on the successes of Americans with disabilities in professional and personal endeavors.

Individual Self-Determination / Assistive Technology

 Manage and ensure Department-wide adherence including accessible electronic documents required by Section 508 of the Rehabilitation Act through on-going technical assistance and training of 508 officials and managers responsible for procurement across

- all HHS Operating Divisions.
- Manage and enhance the OD website, a focal point and clearinghouse on HHS-related and other government disability information.
- Expand on Federal-State interactive website communication processes for persons with disabilities to ensure a one-stop information based on entitlements and other health and human service supports to heighten the interaction of HHS programs and disability-based State partners.

Funding History

FY 2004	\$536,000
FY 2005	\$655,000
FY 2006	\$643,000
FY 2007	\$739,000
FY 2008	\$721,000

Budget Request

OD's FY 2009 request is \$728,000, and increase of +\$7,000 over the FY 2008 enacted level. This amount will cover the annualization of the January 2008 pay raise and the anticipated January 2009 pay raise for OD's staff.

Outputs / Outcomes Table

#		FY	FY	FY	FY 2006		FY 2007		FY	Out-	
"	Key Outcomes	2004 Actual	2005 Actual	Target	Actual	Target	Actual	2008 Target	2009 Target	Year Target	
	Long-Term Objective 1: Promote the coordination, development and implementation of programs and special initiatives to help increase the service capacity and affordability for integrated health and wellness services for persons with disabilities.*										
1.1	Increase the number of states (from a total 6) that establish collaborative agreements across respective state agencies to provide integrated services across all six life domains (housing, employment, education, health, assistive technology, and transportation) on behalf of young adults (14 to 30 years) with disabilities as part of the Office on Disability Young Adult Program initiative.			2 States	2 States	4 States	4 States	6 States	N/A		
1.2	Increase the number of states (from a total 6) that establish supporting infrastructures to sustain cross-agency collaborations to provide integrated services across respective state agencies			2 States	2 States	4 States	4 States	6 States	N/A		

	to provide integrated services across all six life domains (housing,								
	employment, education, health, assistive								
	technology, transportation)								
	on behalf of young adults								
	(14 to 30 years) with								
	disabilities as part of the Office on Disability								
	Young Adult Program								
	initiative.								
	Increase the number of								
	states (from a total 6) that								
	demonstrate utilization of								
	evidence-based practices								
	to sustain integrated								
	services across all six life								
	domains (housing, employment, education,		2	2	4	4	6		
1.3	health, assistive		States	States	States	States	States	N/A	
	technology, and		States	States	States	States	States		
	transportation) on behalf								
	of young adults (14 to 30								
	years) with disabilities as								
	part of the Office on								
	Disability Young Adult								
	Program initiative.								

^{*}This program concludes in FY 2008, due to a reprioritization of OD activities and goals.

#		FY	FY 2005 Actual	FY 2006		FY 2007		FY	FY	Out-
"	Key Outcomes	2004 Actual		Target	Actual	Target	Actual	2008 Target	2009 Target	Year Target
	Long-Term Objective 2: Promote the coordination, development and implementation of programs and special initiatives to help increase the service capacity and affordability for integrated health and wellness services for persons with disabilities.									
2.	Increase the number of youth participating in the "I Can Do It, You Can Do It" Program.			600	600	800	800	1000*	1000	

^{*}OD is enhancing this program's evaluation to become both output and outcome-based, and will pursue OMB clearance of this impact evaluation during FY 2008, with the goal of beginning the evaluation in May/June of 2008.

#		FY		FY	FY 2006		FY 2007		FY	Out-	
_	Key Outcomes	2004 Actual	2005 Actual	Target	Actual	Target	Actual	2008 Target	2009 Target	Year Target	
	Long-Term Objective 3: Increase the number of State and territories that train emergency managers in addressing the needs of										
pers	sons with disabilities during eme	ergency pla	anning and	response.							
3.	In partnership with HHS Office of the Assistant Secretary for Preparedness and Response (ASPR), implement and monitor the use of the disability-based tool kit and future use of			6	6	20	*	30	40	50 (2010) 55 (2011)	
	public health staff education modules.										

^{*}Target was not reached due to delay in contracting of the Emergency Preparedness Toolkit; data will not be available until late 2008.

OFFICE OF GLOBAL HEALTH AFFAIRS Summary of Request

Brief Overview

The Office of Global Health Affairs (OGHA) represents the Department of Health and Human Services (HHS) to other governments, Federal Departments and agencies, international organizations, and the private sector on global health, welfare and family issues. OGHA requests \$16.723 million for the following: the U.S.-Mexico Border Health Commission (USMBHC); the Secretary's Afghanistan Health Initiative; the Health Diplomacy Initiative; and continuation of critical international policy development and coordination.

- \$3.552 million for the USMBHC (level to FY 2008), including the Commission's work in developing a border health research forum, hosting U.S.-Mexico community venues for Border Binational Health Week, and engaging the U.S. and Mexican border States and local health departments to better align programmatic strategies at the federal levels and in such areas as influenza preparedness, early warning surveillance and response, and import safety issues to improve the health of the border populations.
- \$5.789 million for the Afghanistan Health Initiative (level to FY 2008) to improve maternal and neonatal health at Rabia Balkhi Hospital (RBH) in Kabul, Afghanistan. HHS' efforts focus on training health personnel and developing logistics and management capacity at RBH.
- \$3.545 million for the Health Diplomacy Initiative; FY 2008 funding at zero. Under the President's Initiative to Advance the Cause of Social Justice in the Western Hemisphere, the Health-Diplomacy Initiative channels U.S. Government and private-sector resources to touch people's lives by delivering direct patient care and training local health workers, starting in Central America, and thereby improve the image of the United States in the Hemisphere. The FY 2009 funding will be used towards strengthening the existing Latin American Health Initiative.
- \$3.7 million to continue funding crucial OGHA activities that have expanded significantly while reimbursement agreements with the U.S. Department of State, U.S. Agency for International Development (USAID) and others have simultaneously decreased. Despite reduced or loss of revenue streams, programmatic needs remain or even increase. Such activities include: continued support for African public health activities (i.e. infectious disease control, material and child health) and workforce strengthening that were funded under a USAID Participating Agency Service Agreement (PASA); support of biotechnology engagement with Russian and surrounding States due to former bioweapon scientists remaining a public health security for HHS and the U.S. Government; and increasing global health engagement on policy and programmatic levels is expected for the African and the Americas Region.

Authorization

OGHA's activities are authorized under the Afghanistan Freedom Support Act of 2002, which authorizes U.S. Government to develop programs to improve maternal and child health and reduce maternal and child mortality, and the United States-Mexico Border Health Commission Act (Public Law 103-400), which authorizes USMBHC activities.

OFFICE OF GLOBAL HEALTH AFFAIRS

FUNDING SUMMARY

Activity	FY 2007 Actual	FY 2008 Enacted	FY 2009 P.B.
GDM Appropriation:			
U.SMexico Border Health Commission	\$3,464,580	\$3,522,580	\$3,552,580
Afghanistan Health Initiative	5,892,000	5,789,000	5,789,000
Other GDM	375,420	375,420	3,836,420
Health Diplomacy Initiative	0	0	3,545,000
Subtotal, OGHA Budget Authority	\$9,732,000	\$9,687,000	\$16,723,000
Biotechnology Engagement Program (funds transferred from State Dept)	2,250,000	0	0
Reimbursables (estimated)	13,250,000	10,050,000	8,425,000
Subtotal, OGHA Other	\$15,500,000	\$12,300,000	\$8,425,000
TOTAL, OGHA Program Level	\$25,232,000	\$21,987,000	\$25,148,000

Afghanistan Health Initiative

	FY 2007	FY 2008	FY 2009	FY 2009
	<u>Actual</u>	Enacted	<u>PB</u>	<u>+/- FY 2008</u>
BA	\$5,892,000	\$5,789,000	\$5,789,000	
FTE	1	1	1	

Program Description and Accomplishments

Funding for the Afghanistan Health Initiative was established through the Afghanistan Freedom Support Act of 2002. Starting in Fiscal Year (FY) 2003, The Department of Health and Human Services (HHS) received funding for the initiative, aimed at supporting the reconstruction of that country by improving maternal and child health, and reducing maternal and child mortality. Specifically, the activities of the HHS Afghanistan Health Initiative have focused on Rabia Balkhi Hospital (RBH), in Kabul, Afghanistan, as RBH is a Ministry of Public Health supported hospital which delivers care to high-risk women at a rate of 13,000-14,000 deliveries a year. Accomplishments have focused on the following:

- Increase the core knowledge and clinical skills of the physicians and other health-care professionals at RBH;
- Improve the leadership and management skills of the hospital administrators;
- Implement a quality-assurance collaborative for Caesarian-Section to reduce such rates as the overall intrapartum and postpartum maternal mortality rate;
- Improve the case-specific maternal mortality rate associated with Caesariansection (C-section), the perinatal intrapartum mortality rate, and newborn predischarge mortality rate, as well as improvement in anesthesia outcomes that affect infants and mothers.

By strengthening hospital management and leadership, and clinical capacity for physicians, midwives and other health providers at RBH, we are working to improve the quality of maternal and infant health-care delivery and birth outcomes. As part of the Afghanistan Health Initiative, HHS has also worked with the Afghanistan Ministry of Public Health (MoPH) to help the MoPH implement its national health strategy, which focuses on implementing a basic package of care for all Afghans and a comprehensive health-care delivery system from the community-health worker, to comprehensive health center, to district- and tertiary-level hospitals, and to support the MoPH as it builds capacity to sustain these public-health and medical investments in RBH.

Funding History

FY 2004 \$4,970,000 FY 2005 \$5,850,000 FY 2006 \$5,890,000 FY 2007 \$5,892,000 FY 2008 \$5,789,000

Budget Request

The funding request for the Afghanistan Health Initiative supports improving maternal and newborn health outcomes at Rabia Balkhi Hospital (RBH) in Kabul, Afghanistan. The initiative focuses on improving the clinical capacity and developing logistics and management capacity of staff at RBH. Approximately 99 percent of hospital staff including physicians, nurses and midwives participated in these training activities to improve the quality of care provided in 2007. This continues to align well with the work of the Afghan Government's Urban Health Task Force (UHTF) in its development of a comprehensive maternal and newborn referral system within Kabul as a potential model for maternal care throughout Afghanistan. Recent Kabul surveillance data from hospitals reported a deterioration of important maternal and newborn health indicators that required urgent attention. The indicators also reflected an inability to properly implement on a population basis (Kabul) the high-risk intervention associated with emergency obstetrical care (Cesarean Section) so urgently needed in a low-resource setting like Kabul.

Beginning in Fiscal Year 2008, and working closely with U.S. Embassy colleagues, HHS has increased its expertise in-country to engage directly with RBH and the Ministry of Public Health in the implementation of a QA collaborative program. HHS engages through teams of two to four experts for an in-country period ranging from two to six weeks. Time in the country is focused on training and capacity building in such areas as obstetrics, pediatrics, pharmacology, health informatics, anesthesia, and systems surveillance. HHS continues to dedicate some of its appropriated dollars to support the activities of the Afghanistan Ministry of Public Health (MoPH), and non-governmental organizations.

The Office of Global Health Affairs requests \$5.789 million for Afghanistan Health Initiative to cover the following activities:

- Focus on RBH and a quality-assurance collaborative on C-sections program by:
 - The "quality assurance collaborative on C-section" is an improvement collaborative for rapidly improving the quality and efficiency of implementing C-section as a means to reduce maternal and newborn mortality and morbidity. This collaborative will focus on the technical area and logistical aspects of performing a c-section and seeks to rapidly spread existing knowledge or best practices related to performing a C-section at RBH and the other maternity services in Kabul through systematic improvement efforts, usually lasting from 12 to 24 months.
 - Increasing engagement by HHS experts in areas such as, obstetrics, pediatrics, clinical pharmacology, anesthesia, health informatics, hospital personnel staffing, and health systems (community-based to tertiary-level care settings

- Assist the MoPH in its capacity to further reduce maternal and newborn mortality in Afghanistan by:
 - o bolstering provision of health care among underserved high-risk populations,
 - o improving its responsible governance and stewardship role in public health and the delivery of health care to its citizens.
 - o improving the implementation of MoPH programs in maternal and newborn health, and
 - o Enhancing public knowledge and the knowledge of MoPH/MNH providers through strengthening of clinical decisionmaking, public health surveillance, use of medical records within RBH and working toward consistent use of a medical record at any point of entry into the Afghan health system. As the Department focal point of coordination, OGHA coordinates with senior Afghan public health leadership and the donor community in Kabul, as well as across HHS and with U.S. DOD and USAID colleagues to align respective contributions and maximize efforts in country, e.g., improve the various elements within the Afghan health-care delivery system in Kabul.
- Continue efforts to enable more strategic collaboration with other U.S.
 Government partners (U.S. Department of Defense and the U.S. Agency for
 International Development), other international donors, and the MoPH to scale-up
 needed interventions in a sustainable way, to minimize risks to mothers, infants
 and the larger community.

Outputs and Outcomes

#		FY	FY 2005	FY 20	006	FY	2007	FY 2008	FY	Out-	
<i>"</i>	Key Outcomes	2004 Actual	Actual	Target	Actual	Target	Actual	Target	2009 Target	Year Target	
Long	Long-Term Objective 1: By 2007, reduce by 20% the number of maternal and neonatal deaths in Afghanistan. The overall purpose of the program is to achieve the long term goal by improving the skills and training of the hospital staff.										
1.1	The mortality rate at Rabia Balkhi Hospital (RBH) in Kabul, Afghanistan.	189	146	170	136.5	130	129.5	120	110	<u>105</u>	
1.2	The percent of trainees enrolled in courses.	N/A	50%	75%	70%	80%	99%	85%	90%	95%	
1.3	The time to hire and deploy essential staff trainers.	N/A	3 mos	2.5 mos	4.2 mos	3 mos	4.5 mos	2.5 mos	2 mos	1.5 mos	
1.4	The percent of staff trainers who fulfill the agreed upon incountry contract.	N/A	80%	89%	85%	89%	87.5%	92%	95%	95%	
1.5	The intrapartum mortality rate among neonates with a birth specific rate of 2500 grams	7	5.2	5.8	8.7	6.3	7.8	6	5.8	5.2	

	at RBH in Kabul, Afghanistan.									
1.6	The predischarge neonatal mortality rate among neonates with a birth specific weight of 2500 grams at RBH in Kabul, Afghanistan.	2.7	2.2	2.2	2.54	2.2	2.50	2.0	1.9	1.8
1.7	The percent of nurse midwifery's who meet competency measures on the 37 Afghanistan Standards of Practice.	N/A	40%	50%	75%	85%	71%	88%	92%	95%
1.8	The post-operative infection rate among maternity patients at RBH in Kabul, Afghanistan.	3.7	3.75	3.0	6.3	3.0	1.8	2.7	2.5	2.3

United States-México Border Health Commission

	FY 2007	FY 2008	FY 2009	FY 2009
	<u>Actual</u>	Enacted	<u>PB</u>	+/- FY 2008
BA	\$3,464,580	\$3,552,580	\$3,552,580	
FTE	8	8	8	

Program Description and Accomplishments

The United States México Border Health Commission (USMBHC), established binationally in 2000, provides international leadership to optimize health and quality of life along the United States–México border. Its primary goals are to institutionalize a U.S. domestic focus on border health, and create an effective binational venue to address the public health challenges that impact border populations in sustainable and measurable ways. The USMBHC facilitates identification of public health issues of mutual significance; supports studies and research on border health; and, brings together effective federal, state and local public/private resources by forming dynamic partnerships and alliances to improve the health of the border populations through creative, multi-sectoral approaches. The Office of Global Health Affairs is the Secretary's focal point of coordination for the USMBHC; and the HHS Secretary is the Commissioner for the U.S. Section.

The USMBHC promotes (1) sustainable partnerships which engage international, federal, state and local public health entities in support of annual initiatives of *Border Binational Health Week* and *National Infant Immunization Week/Vaccination Week of the Americas*; (2) leads the development of a comprehensive border health research agenda that will inform policy makers, researchers and entities which fund research where research gaps, needs and opportunities lay; and (3) hosts the Border Binational Health Week events along the entire U.S.-México border, which bring together local communities for health screenings and health education interventions. In FY 2007 for Border Binational Health Week, the USMBHC helped to host 258 events along both sides of the border, engaging 378 partners, and providing 153,644 free health screenings to U.S. and México border communities (U.S. side 11,124 and México side 142,520), reflecting a composite of various resources (including financial and in-kind support) from federal, State, local and community stakeholders.

Funding History

FY 2004	\$3,503,444
FY 2005	\$3,503,444
FY 2006	\$3,493,451
FY 2007	\$3,464,580

FY 2008 \$3,552,580

Budget Request

The FY 2008 and FY 2009 request for the U.S. Mexico Border Health Commission to remain level at \$3.552 million. The Commission will continue to serve as a catalyst for border health issues, identify measurable and sustainable binational solutions through the engagement of public and private stakeholders at the international, federal, state, and local levels; and provide international leadership to optimize health and quality of life along the United States–México border. For example, in Fiscal Year 2008, the Commission, in its leadership role will host a binational import safety forum engaging federal, State and local organizations engaged in food/feed imports that cross the border. In its catalytic role, the Commission has hosted a forum with the State of Arizona to explore the legal barriers with the border context to effectively address increasing incidence of extensively drug-resistant tuberculosis. Funding in Fiscal Year 2009 will support important activities including:

- Border Binational Health Week
- Studies that provide the necessary evidence-base to inform federal, state and local policymakers
- Continued binational engagement to institutionalize a U.S. domestic focus on border health, and create an effective binational venue to address the public health challenges that impact border populations in sustainable and measurable ways.
 Areas of focus include influenza preparedness, early warning surveillance and response, and import safety issues to improve the health of the border populations.

Outputs and Outcomes Table

#		FY	FY 2005	FY	2006	F	Y 2007	FY	FY	Out-	
TT .	Key Outcomes	2004 Actual	Actual	al Target Actual Target Actua		Actual	2008 Target	2009 Target	Year Target		
Long	Long-Term Objective 1: To improve access to primary health care via the Healthy Border 2010										
1.1	Reduce the percent of indirect spending on border health activities	16%	24.6%	11%	4%	10%	4/08	9%	8%		
1.2	The number of health cards distributed to health care providers.	29,343	Not Determined, closure of program	N/A	Not Determined	N/A	Not Determined	N/A	N/A	N/A	
1.3	The incidence of tuberculosis cases per 100,000 inhabitants on the U.S. side of border.	10	N/A	N/A	N/A	N/A	N/A	N/A	N/A	5	
1.4	The incidence of HIV cases per 100,000 inhabitants on the U.S. side of	8.4	N/A	N/A	N/A	N/A	N/A	N/A	N/A	4.2	

	border.									
1.5	The diabetes death rate on the United States side of the border (number of deaths per 100,000 inhabitants).	26.9	N/A	24.2						
1.6	United States- Mexico Border Health Commission (BHC): Border Binational Health Week (BBHW) celebrated on both sides of the U.S. Mexico Border	19,566	15,836	25,000	10,688	25,000	10,774	25,000	25,000	25,000
1.7	Increase the number of patients at the U.S. Mexico border using the TB Card.	470	1281	600	97	600	27	N/A	N/A	N/A

Health Diplomacy Initiative

	FY 2007	FY 2008	FY 2009	FY 2009
	<u>Actual</u>	Enacted	<u>PB</u>	+/- FY 2008
BA	0	0	\$3,545,000	+\$3,545,000
FTE	N/A	0	0	
Authorizing Legi	islation			Unauthorized

Program Description and Accomplishments

The Secretary's Health-Diplomacy Initiative channels U.S. Government and private-sector resources to touch people's lives by delivering direct patient care and training local health workers in Central America, and thereby improve the image of the United States in the Hemisphere, which in recent years has deteriorated given the weakening of strong democratic governments, with three main objectives:

- Train Central American health-care workers through a Regional Health-Care Training Center located in Panamá City. Students return to their homes and apply the skills learned, thereby contributing to the improvement of health care provided at the community-level.
- Train U.S. Government medical personnel through forward-deployment missions, focusing first on Central American and Caribbean countries, as part of U.S. military medical and humanitarian missions to provide health care, including oral health care, for poor populations in the region; and
- Establish a strategic approach to engage with U.S. Government-funded, non-governmental organizations (NGOs) that provide health care in Central America and Caribbean countries to "re-brand" their assistance and coordinate it with direct U.S. Government efforts in health.

Funding History

A new health initiative, funding request for FY 2008 was not granted.

Budget Request

The President's budget request for FY 2008 was denied. In FY 2009, \$3.545 million will support the continued strengthening and expansion of the Presidential Western Hemisphere Initiative for Social Justice and Secretarial Health-Diplomacy Initiative in Latin America. In FY 2009, the following will be targeted:

- Provide additional health care services in Latin American through deployment of USPHS Officers on humanitarian and medical training missions.
- Increase collaboration with non-governmental organizations to ensure sustainability and positive impact.
- The continued strengthening of the RHCTC as a viable training center for Central America, aimed at increasing skill sets and expertise for students from

communities at highest-risk and needs in a range of public health areas, including influenza preparedness, oral health, and maternal/child health.

In FY 2009, with the increase in funding, HHS presence and engagement would be expanded to collaborate with these Central American Governments to enable a well-functioning Board of Directors to guide the Center strategically. Training and provision of medical care through military and humanitarian assistance missions would continue. The funding support would provide expansion of types of training offered, longer training periods, course materials and increase in number of trainers with varying expertise.

Outputs and Outcomes Table

Program funding was not allocated for FY 2008. Performance measures are currently being developed for FY 2009.

OFFICE OF PUBLIC HEALTH AND SCIENCE Summary of Request

Statement of Agency Mission

The Office of Public Health and Science (OPHS) provides leadership to the Nation on public health and science, and communicates on these subjects to the American people. OPHS is a unique Staff Division in the Department of Health and Human Services (HHS) in that it performs both policy and program roles. OPHS is led by the Assistant Secretary for Health (ASH) whose chief interest is promoting, protecting, and improving the Nation's health. This role encompasses responsibilities as senior advisor for public health and science to the Secretary thereby providing senior professional leadership on population-based public health and clinical preventive services, directing a variety of program offices housing essential public health activities, providing senior professional leadership across HHS on White House and special Secretarial initiatives involving public health and science, and guiding and providing technical assistance to the ten Regional Health Administrators.

Discussion of Strategic Plan

The FY 2009 Performance Plan takes a focused look at the core contributions of OPHS to the Department and the Nation in the areas of prevention, health disparities, and public health infrastructure. The goals are drawn from the HHS Strategic Plan, *Healthy People 2010*, and the Secretary's priorities. The FY 2009 Plan sets ambitious goals and challenges for OPHS to demonstrate the impact of its programs.

OPHS programs support all four goals of the HHS strategic plan:

Goal 1: Improve the safety, quality, affordability and accessibility of health care, including behavioral health care and long-term care

The Adolescent Family Life Program supports this goal by providing comprehensive care and prevention services to pregnant and parenting adolescents.

Goal 2 – Prevent and control disease, injury, illness, and disability across the lifespan, and protect the public from infectious, occupational, environmental, and terrorist threats

All OPHS offices contribute to this goal through their programs which primarily focus on prevention. In particular, the Office of Disease Prevention and Health Promotion *Healthy People 2010* goals for the Nation provide a framework for promoting and encouraging preventive health care and lifelong healthy behaviors.

The Office of the Surgeon General is responsible for ensuring the deployability of Commissioned Officers to respond to national and man-made disasters.

Goal 3: Promote the economic and social well-being of individuals, families and communities

The activities of the Office of Minority Health are directed to this objective by addressing health disparities. Other offices, including the Office on Women's Health, the Office of Disease Prevention and Health Promotion, the Office of HIV/AIDS Policy, the President's Council on Physical Fitness and Sports, and the Office of Population Affairs also contribute.

Goal 4: Advance scientific and biomedical research and development related to health and human services

The activities of the Office for Human Research Protections are directed to enforcing the Federal Regulations protecting human research subjects. The Office of Research Integrity enforces regulations requiring all research institutions to have policies for responding to allegations of scientific misconduct and reviewing them for compliance.

Discussion of OPHS Performance Plan

The OPHS Performance Plan has three over-arching strategic goals:

- Strengthen Prevention,
- Close the Health Gap, and
- Strengthen the Public Health Infrastructure.

They are complex national challenges and reach beyond the control and responsibility of the Federal government. Achievement is dependent on various health programs and providers, all levels of government, and the efforts of the private sector as well as individual contributions. In some instances, OPHS's contributions act as a catalyst for action; in other instances OPHS provides the leadership and "glue" that makes the difference in collective efforts.

Within each strategic goal area, OPHS reports its performance in the following five broad areas.

Shaping Policy at the Local, State, National, and International Level

• **OPHS influences policies, programs, and practices** through review, analysis, and advice on existing policy-related efforts as well as the development, coordination, and implementation of new initiatives and activities. OPHS produces a variety of reports which translate state-of-the-art science into documents that are extensively read by legislators, the media, professionals and the public.

Within this area, OPHS program offices report performance as the number of
communities, state and local agencies, Federal entities, NGOs or research
organizations that adopt (or incorporate into programs) recommendations,
policies, laws or regulations that are generated or promoted by OPHS thorough
reports, committees, etc.

Communicating Strategically

- OPHS increases awareness, understanding, and action on the major public health concerns and health systems through strategic communications to decision makers, health professionals, and those serving racial/ethnic minority communities to spur responsive policy and programmatic action. OPHS produces key reports, background papers, and journal articles. Several measures go into the reporting by OPHS offices. One is the number of targeted print and educational materials and campaigns, another is the number of regional national workshops and conferences and consultations with professional and institutional organizations. OPHS facilitates the sharing of information from the field on best practices related to the public health improvement.
- OPHS provides leading Internet portals which ensure that the general public and specific populations have high quality, reliable information for managing health and wellness. Through internationally-recognized Websites, such as 4Women.gov and healthfinder.gov, OPHS offers selected resources to empower people to make sound decisions for themselves and their loved ones. OPHS offices measure performance based on the number of unique visitors to these websites.

Promoting Effective Partnerships

• OPHS establishes and strengthens effective networks, coalitions, and partnerships to identify public health concerns and to stimulate and undertake innovative projects that solve them. OPHS reaches out to professional groups, advocacy groups, international partners, non-governmental organizations, and colleagues in Federal, State, tribal and local governments, engaging in collaborative work to assist in the identification of health concerns and problems and development of creative solutions. Within this context, OPHS offices report the number of formal IAAs, MOUs, contracts, cooperative agreements and community implementation grants with governmental and non-governmental organizations that lead to changes in their agendas/efforts related to the public health or research infrastructure.

Building a Stronger Science Base

• OPHS promotes the collection of health data and the strengthening of data infrastructures to monitor the health of all Americans, especially specific populations for whom data sources have been weakest, to measure the effects of

initiatives and interventions aimed at improving health, and ultimately to provide a sound basis for decision-making.

- OPHS fosters service demonstration projects, evaluations, and other studies of interventions aimed at improving health and the health care system to strengthen and expand the science base for decision-making, determine best practices, identify and overcome barriers to health, and assess program and intervention effectiveness. OPHS program offices measure the number of research, demonstration, or evaluation studies completed and findings disseminated and the number of promising practices identified by research, demonstrations, evaluation or other studies.
- OPHS strengthens the health sciences research enterprise by protecting the integrity of the research underlying public health policy and clinical treatments, by ensuring that all institutions that conduct research supported by the Public Health Service agencies have an understanding and commitment to research integrity and an administrative process for responding to allegations of scientific misconduct. To promote the responsible conduct of research, ORI conducts oversight review of institutional investigations into alleged misconduct in science, and monitors institutional efforts. OPHS helps to instill confidence by the public and others in research involving human subjects by working to ensure the protection of human research participants in accordance with U.S. laws and regulations.

Leading and Coordinating Key Initiatives Within or on Behalf of the Department

• OPHS provides the coordination needed for agencies to work as "One HHS" on key Departmental priorities. Healthy People 2010, the nation's third decade-long prevention initiative, harnesses the energies of all HHS public health agencies in pursuing and monitoring progress toward national goals and objectives. The development of the 2010 national health goals involved Federal, tribal, State, local and non-governmental organizations. The initiative drives health policy-making in many States, communities and businesses, and provides the basis for curricula in many health professional schools. In FY 2007, OPHS published a Midcourse assessment of the Healthy People 2010 28 focus areas.

Other significant leadership includes the Department-wide effort to register Institutional Review Boards and to coordinate pandemic influenza planning. During FY 2007, OPHS continued to identify agency activities for the elimination of racial and ethnic health disparities that could be replicated would build partnerships in HHS, and will show tangible results in the near future. OPHS will continue to coordinate focused and intensified Departmental strategies aimed at closing the gaps that exist by race and ethnicity for all groups in the 6 priority health issue areas (infant mortality, cancer screening and management, cardiovascular disease, diabetes, HIV/AIDS, and child and adult immunization).

- **OPHS coordinates Federal efforts that bridge Departments**, such as development of the statutorily mandated *Dietary Guidelines for Americans*, which were released in January 2005. The Guidelines provide the policy basis for all Federal nutrition education activities and are published jointly with U.S. Department of Agriculture. OPHS coordinates President Bush's *Healthier US* initiative that encourages Americans to live healthier lives by improving nutrition, increasing physical activity and reducing youth risk-taking behaviors, such as tobacco and illegal drug use. *Healthier US* is supported by the Departments of Agriculture, Defense, Education, Housing and Urban Development, Labor, Transportation, and Veterans Affairs; the Environmental Protection Agency; and the General Services Administration.
- OPHS coordinates nationwide efforts in strategic areas, such as the Minority AIDS Initiative.

OPHS Overview of Performance

Strengthening Prevention Efforts

Activities in this OPHS priority area include coordination of the President's prevention initiative, *HealthierUS*, which uses all of the available resources of the Federal government to alert Americans to the vital health benefits of simple and modest improvements in physical activity, nutrition, and healthy lifestyle choices such as eliminating tobacco and illegal drug use, and preventive screenings. OPHS manages *Healthy People 2010*, which sets out the science and the data to support national health improvement efforts. OPHS supports the Secretary's prevention priority area with development of Physical Activity Guidelines for Americans.

Closing Health Gaps

OPHS plays a leading role in many efforts to eliminate disparities, including the Mobilization Campaign on AIDS, Minority AIDS Initiative, Centers of Excellence in Women's Health and National Community Centers of Excellence in Women's Health.

OPHS communication efforts for special populations include the Office of Minority Health Resource Center, the National Women's Health Information Center, and population-specific sections on 4Women.gov and healthfinder® (including healthfinder® "espanol") and special resources for racial and ethnic minority populations.

Strengthening the Public Health Infrastructure

OPHS plays a vital role in building the data systems for understanding the health problems of our growing racial and ethnic minority populations; in promoting the integrity of the scientific research enterprise; and in promoting the development of a balanced national health information infrastructure that serves the public as well as

professionals and supports prevention and chronic disease management as well as treatment and administration.

OPHS helps build capacity in State and local agencies and private organizations to support prevention. Some examples include the Leadership Campaign on AIDS to increase the capacity of minority community-based organizations to develop effective and innovative partnerships at the local level to enhance HIV/AIDS services and education and the National American Indian/Alaska Native Health Forum to identify strategies through which State, tribal, and Federal governments can complement and supplement their respective health systems.

OPHS contribution to the scientific research infrastructure includes the Federal Research Misconduct Officials Network with representatives from 27 agencies. OPHS enforces the Federal Regulations which protect human subjects participating in biomedical research.

OPHS has had a lead role in the development of key documents and activities related to the national health information infrastructure (NHII), which includes standards, applications, research with emphasis on linkages among consumers/patients, providers, and public health.

OPHS values collaboration and works in partnership with other HHS components, as well as a variety of other Federal agencies (including the Departments of Education, Justice, Labor, Agriculture, Defense, State, Transportation, Commerce, Energy, Housing and Urban Development, and Veterans Affairs; the Environmental Protection Agency; the Federal Emergency Management Agency; and the U.S. Consumer Product Safety Commission), tribal, State and local governments, health departments and agencies, the academic community, health providers, national professional associations, tribal, national and international health-related organizations, community-based organizations, minority community-based organizations, faith-based institutions, the media, advocacy groups, the business community, foundations, the public, Congress, and others. Through its program offices, OPHS has established close ties with stakeholders who are critical to addressing significant public health and science issues in the Nation and around the world.

Detail of Performance Measures

			FY	FY 2	006	F	Y 2007			Out-
#	Key Outcomes	FY 2004 Actual	2005 Actual	Target	Actual	Target	Actual	FY 2008 Target	FY 2009 Target	Year Target
Long	-Term Objective: 1. Strei	ngthen Prevent	tion Effor	ts						
1.a.	Shape policy at the local, State, national and international levels	30,358	32,052	42,000	32,409	50,000	32,578	50,000	50,000	50,000
1.b.	Communicate strategically	22,929,822	43,976 ,880	46,000,0 00	47,831 ,042	49,000 ,000	67,314,114	51,000,00 0	52,000,0 00	53,000 ,000
1.c	Promote effective partnerships	208	300	314	354	334	499	160	175	200
1.d.	Strengthen the science base	352	205	200	205	200	447	200	225	250
1.e.	Lead and coordinate key initiatives within and on behalf of the Department	3,542	1,291	1,200	1,433	1,300	1,337	1,500	1,600	1,700
Long	-Term Objective: 2. Clos	e Health Gaps	•							
2.a.	Shape policy at the local, State, national and international levels	117	45	133	88	96	190	92	97	100
2.b.	Communicate strategically	1,462,837	1,576, 355	1,640,00 0	1,943, 511	1,900, 000	2,146,111	1,900,000	2,305,00 0	2,400, 000
2.c.	Promote Effective Partnerships	224	170	131	142	72	336	110	126	140
2.d.	Strengthen the science base	80	50	38	47	47	275	42	45	50
2.e.	Lead and coordinate key initiatives within and on behalf of the Department	47	18	58	31	86	24	23	23	25
Long	-Term Objective: 3. Strei	ngthen the Pub	lic Healt	h Infrastru	cture					
3.a.	Shape policy at the local, State, national and international levels	430	1,875	2,500	1,978	2,400	2,416	1,700	1,800	1,900
3.b.	Communicate strategically	144,762	237,27 9	450,000	670,94 0	651,82 5	1,173,866	1,000,000	1,178,84 0	1,200, 000
3.c.	Promote Effective Partnerships	76	93	11	117	6	116	30	30	50
3.d.	Strengthen the science base	22	1,196	61	3,738	67	4,205	125	189	200
3.e.	Lead and coordinate key initiatives within and on behalf of the Department	4,163	5,610	6,324	3,454	6,800	3,135	7,300	7,300	7,500

OFFICE OF PUBLIC HEALTH AND SCIENCE SUMMARY TABLE

	FY 2007			FY 2008		FY 2009
		Actual		Enacted	P	res. Budget
	<u>FTE</u>	Amount	FTE	<u>Amount</u>	FTE	Amount
GDM Direct:						
Immediate Office	39	\$8,165,000	38	\$7,927,000	38	\$7,998,000
Office of HIV/AIDS Policy	4	930,000	4	904,000	4	912,000
Adolescent Family Life	11	30,229,000	11	29,778,000	11	30,307,000
Office of Disease Prevention and						
Health Promotion	21	7,305,000	20	7,097,000	20	7,159,000
President's Council on Physical						
Fitness and Sports	7	1,230,000		1,195,000	7	1,205,000
Office of Minority Health	58	53,455,000	57	48,738,000	57	42,686,000
Office on Women's Health	42	28,219,000	41	31,033,000	41	28,458,000
Office for Human Research						
Protections	33	6,897,000		6,701,000	32	6,671,000
Commissioned Corps Initiatives	23	9,926,000		4,119,000	140	30,159,000
National Vaccine Program Office	10	6,980,000		6,781,000	10	6,841,000
Public Health Reports	2	455,000		443,000	2	446,000
Subtotal, Direct	250	\$153,791,000	245	\$144,716,000	362	\$162,932,000
GDM Reimbursables:						
Office of Research Integrity ¹	23	[8,172,000]	23	[8,571,000]	23	[8,909,000]
Other	32	[0,172,000]	32	[0,571,000]	32	[0,707,000]
Subtotal, Reimbursables	55		55		55	
,						
Subtotal, Direct + Reimbursables	305		300		417	
Service and Supply Fund	_64		<u>71</u>		<u>71</u>	
Total, GDM	369	\$153,791,000	371	\$144,716,000	488	\$162,932,000
PHSSEF:						
Medical Reserve Corps	3	\$9,748,000	6	\$9,578,000	6	\$15,110,000
1					_	
TOTAL, OPHS	372	\$163,539,000	377	\$154,294,000	494	\$178,042,000
[PHS Evaluation Set-Aside; non-add]		[\$4,552,000]		[\$4,510,000]		[\$4,510,000]

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ORI is funded by NIH dollars, which are reflected as non-add.

OPHS IMMEDIATE OFFICE

	FY 2007	FY 2008	FY 2009	FY 2009
	<u>Actual</u>	Enacted	<u>PB</u>	<u>+/- FY 2008</u>
BA	\$8,165,000	\$7,927,000	\$7,998,000	+\$71,000
FTE	39	38	38	
0 0	gislation			Health Service Act
1 1 2007 Hamon	ILMIIOII			·····

Allocation Method.......Direct federal

Program Description and Accomplishments

This request provides funding to support the Immediate Office of the Office of Public Health and Science (OPHS) and the Office of the Surgeon General (OSG). OPHS is under the direction of the Assistant Secretary for Health (ASH), who serves as the senior advisor to the Secretary on issues of public health and science. The Immediate Office of the ASH serves as the focal point for leadership and coordination across the Department in public health and science, provides advice and counsel to the Secretary on these issues, and provides direction to policy offices within OPHS.

The role of the Surgeon General (SG) is to protect and advance the health of the Nation. The SG, who reports to the ASH, provides a highly recognized symbol of national commitment to protecting and improving the public's health, communicates with the American people on issues related to health and advises on health related behaviors and interventions.

The Immediate Office and OSG directly support several of the Secretary's priorities, such as Obesity Prevention, Pandemic Preparedness, and Emergency Response and Commissioned Corps Renewal. In its leadership role, the Immediate Office ensures a public health perspective on all other Secretarial and Presidential priorities. The Immediate Office provides leadership to and oversight of the OPHS policy/program offices as they implement their programs and other HHS and Presidential priorities.

OPHS strives to establish and strengthen effective networks, coalitions, and partnerships to identify public health concerns and to stimulate and undertake innovative projects that solve them. OPHS reaches out to professional groups, advocacy groups, international partners, non-governmental organizations, and colleagues in Federal, State, tribal and local governments, engaging in collaborative work to assist in the identification of health concerns and problems and development of creative solutions. The OPHS goal is to increase by at least ten percent annually, commitments to prevention on the part of public and private entities, as measured by the number of these entities that change or strengthen their prevention efforts as a result of partnerships with OPHS. Each year, OPHS has met

this goal. In FY 2007, the goal was to increase the reach and impact of prevention efforts through partnerships and assist in building capacity at the State and local levels by measuring formal agreements and grants with governmental and non-governmental organizations that lead to prevention oriented-changes. The actual outcome was 499, and increase of 50 percent above the target of 334.

Support for Presidential and Secretarial initiatives was a priority across all of the OPHS program offices. The Secretarial Prevention Initiative, led by OPHS, has received over \$327 million in donated media support, a quantifiable index for measuring a campaign's success. Ad Council tracking research has also revealed a significant increase in the number of adults reporting healthier habits (16 percent to 23 percent) and that levels of reported physical activity have risen dramatically (45 percent to 56 percent). OPHS also supported the Medicare Prevention tour by sending many senior staff to participate in events and engaging local OPHS partners.

In response to both Presidential and Secretarial initiatives, the Commissioned Corps deployed officers on two separate health diplomacy missions. The USNS COMFORT undertook a four month mission to 12 countries in Latin America and the Caribbean during which four successive teams, totaling 71 officers, participated. The USS PELELIU undertook a three month mission to six Pacific Island countries during which four successive teams, totaling 16 officers, participated. In addition to the valuable training environment afforded to the embarked personnel, the skills and expertise of the officers enabled the delivery of medical, surgical, dental, veterinarian, engineering and public health services to thousands of indigenous patients and improved the living conditions of populations in all the countries visited. OPHS, as part of its responsibility to help employ the HHS Pandemic Influenza Implementation Plan, leads interagency groups focused on antiviral drug use strategies, vaccine prioritization strategies, and surveillance of Influenza A/H5N1.

Collaboration is a cornerstone of the work of OPHS. Highlights of significant FY 2007 collaborations include:

- Office on Women's Health partnership with the Administration on Children and Families to increase national participation in the "Rescue and Restore" trafficking program;
- Office of Disease Prevention and Health Promotion partnership with the National Institutes of Health, the Centers for Disease Control and Prevention, the Indian Health Service, the Food and Drug Administration, and the Administration on Aging to complete 30 Dietary Guidance Reviews;
- Office of Minority Health leadership to the HHS Health Disparities Council and co-leadership with the Centers for Disease Control and Prevention to the Federal Collaborative on Health Disparities Research, thus resulting in the release of two new disparity-focused research opportunities;
- The Office of Minority Health, National Institutes of Health and Substance Abuse and Mental Health Services Administration partnership to launch a new program to address a Methamphetamine crisis among tribes;

• Office on Women's Health partnership with the Centers for Disease Control and Prevention to expand the capacity of the National Intimate Partner and Sexual Violence survey.

Funding History

FY 2004	\$7,993,000
FY 2005	\$8,042,000
FY 2006	\$8,131,000
FY 2007	\$8,165,000
FY 2008	\$7,927,000

Budget Request

The FY 2009 Request for the OPHS Immediate Office is \$7,998,000, an increase of \$71,000 above the FY 2008 Enacted Level. This level will allow the Immediate Office of the ASH and the OSG to maintain its cadre of senior public health staff. Funds support salaries and benefits, rent, and other overhead costs.

In FY 2009, OPHS will continue to build upon its solid foundation of providing leadership and focus for HHS and the nation on health and science initiatives. OPHS will lead and coordinate Presidential and Secretarial priorities and initiatives on public health and science issues. Through the Surgeon General, the OSG will issue Reports or Call to Actions as necessary, and will continue to lead the Childhood Obesity Initiative.

OFFICE OF HIV/AIDS POLICY

	FY 2007	FY 2008	FY 2009	FY 2009
	<u>Actual</u>	Enacted	<u>PB</u>	<u>+/- FY 2008</u>
BA	\$930,000	\$904,000	\$912,000	+\$8,000
FTE	4	4	4	
0 0	ationTitle			
FY 2009 Authorizat	tion			Indefinite
Allocation Method				Direct federal

Program Description and Accomplishments

The Department of Health and Human Services (HHS) Secretary has delegated the Assistant Secretary for Health (ASH) responsibility for coordinating, integrating, and directing the Department's policies, programs, and activities related to HIV/AIDS. The Office of HIV/AIDS Policy (OHAP) works with the ASH to meet HHS' needs by supporting its mission and goals in the following areas:

- Providing strong, responsive, and accountable administrative structure to HIV/AIDS related issues for OPHS and OS to ensure the success of the Department's HIV/AIDS programs, policies, and activities, while maintaining fiscal accountability and engaging in outcome evaluation.
- Serving as the senior advisory agency on HIV/AIDS issues to the Secretary, the Deputy Secretary and the ASH. The Office also provides policy information and analysis to the Department's OPDIVs and STAFFDIVs. OHAP ensures that senior Department officials are fully briefed on HIV/AIDS-related matters and that they are able to provide information on HIV/AIDS policies, programs, and activities to the White House or to members of Congress in an expeditious manner. With both internal and external partners, OHAP promotes awareness of, understanding of, and implementation of HHS policies on HIV/AIDS.
- OHAP coordinates department-wide internal assessments and evaluation activities
 covering such areas as HIV testing, technical assistance and prevention strategies.
 In working with all OPDIVs and STAFFDIVs with an HIV/AIDS portfolio,
 OHAP seeks areas for future collaboration, elimination of redundancy, filling of
 vital gaps, and recommendations on best practices.
- Serving as the Department's central coordinating office for the following agencies
 and activities: OHAP is leading a two year National HIV/AIDS Community
 Mobilization Campaign to promote the President's domestic agenda, to increase
 HIV testing opportunities and to support the use of rapid HIV testing technology
 application in non traditional venues to reach hard to serve populations and
 individuals. Rapid HIV tests can be administered from the truck of a car, in a
 church basement, at a community recreation center and other non-clinical settings

to reach hard to serve populations and individuals. Using a coordinated approach OHAP is expanding public knowledge about the availability of HIV testing sites using the internet and cell phone technologies, developing population specific literature about HIV testing, creating public service announcements, and providing technical assistance to churches, mosques, and synagogues that are hosting HIV testing and education community forums and workshops.

OHAP is the lead for all Minority AIDS Initiative program and budget activities, including monitoring, reporting and evaluating. OHAP directs and provides administrative support to the Minority AIDS Initiative Steering Committee for Evaluation and Implementation. OHAP also provides a leadership role as the Co-Chair of the Department's HIV/AIDS Management Coordination Team (HMCT), which is comprised of principals from all of the HHS agencies with key HIV/AIDS portfolios. With the HMCT, OHAP and the Assistant Secretary for Planning and Evaluation (ASPE) are developing and implementing strategies and policies to address priority areas that HMCT has identified.

OHAP coordinates the Department's participation in a wide variety of HIV/AIDS-related conferences to ensure cost-effective and outcome-driven participation and successes. OHAP organizes information and activities around numerous National HIV Awareness Days, and coordinated both inter-agency and intra-agency HIV/AIDS activities. OHAP works to keep front-line and senior-level staff informed about the Department's HIV goals and objectives and how they affect communities, as well as to demonstrate effective ways to disseminate information about those policies inside and outside the Department.

In addition, OHAP is improving HHS' usage of the Internet, Federal web sites, and email to support the Department's strategic plan for prevention and the treatment of HIV/AIDS. Secretary Mike Leavitt uses a 500-Day Plan as a management tool to guide his energies in fulfilling the President's vision of a healthier and more hopeful America. The Secretary's 500 Day Plan can be viewed at: www.hhs.gov/500DayPlan/500dayplan.html.

Accomplishments for FY 2007:

- HHS officials presented information on the broad range of existing Federal HIV/AIDS programs to African American clergy members at the National Conclave on HIV/AIDS Policy for Black Clergy in New York City on October 8-9. The Conclave was a national conference devoted to educating clergy about the continuing impact of HIV/AIDS upon the African American community and discussing how to address the disease within their respective congregations. This event was sponsored by the National Black Leadership Commission on AIDS (NBLCA) with technical assistance provided by OHAP.
- HHS announced the launch of the National HIV Testing Mobilization Campaign (NHTMC) at the Presidential Advisory Council on HIV/AIDS (PACHA) meeting on October 15, 2007. The NHTMC is a nationwide endeavor sponsored by the
- (OHAP), in partnership with the Centers for Disease Control and Prevention (CDC) and other HHS agencies and offices to encourage all sexually active

Americans to take control of their health by getting tested for HIV. Through Campaign Coordinators in each of the ten HHS regional offices and partnerships with national and regional groups and organizations, OHAP is reaching out to and educating individuals and communities about the importance and ease of getting an HIV test.

- Launched AIDS.gov this model Internet portal provides access to all Federal information on domestic HIV/AIDS issues. The website contains useful, reliable, and government-wide information and resources about HIV/AIDS. It is highly visible and drives traffic to existing Federal programs, polices, and resources.
- Created and chaired the DHHS Podcast Work Group OHAP chairs the DHHS
 Web Council's first-ever subcommittee and will lead the development of a
 clearance process for podcasts and standards for using podcasts at DHHS.
- Hosted the first National HIV Testing Day Webinar this event with senior Federal leaders was pitched to blog writers who address HIV/AIDS and other health topics. The event became the standard for reaching today's leading communicators about HIV/AIDS. Estimated reach: 269,000

OHAP's performance goals have been to advise Department officials on all HIV/AIDS-related issues and to coordinate the Department's internal and external HIV/AIDS programs, policies, and activities. Those goals have been met, as evidenced by the increasing reliance of the Secretary's office, the White House, the Department's OPDIVs and STAFFDIVs, and other Federal agencies on the information and services that OHAP provides. In the last year, OHAP has increased the number of projects and events it manages by 45 percent.

Funding History

FY 2004	\$953,000
FY 2005	\$992,000
FY 2006	\$932,000
FY 2007	\$930,000
FY 2008	\$904,000

Budget Request

The FY 2009 Request for OHAP is \$912,000, an increase of \$8,000 above the FY 2008 Enacted level. This activity funds solely the salaries of OHAP staff, and will allow OHAP to maintain its staffing at the FY 2008 level.

In FY 2009, OHAP will continue to serve as the senior advisory agency on HIV/AIDS issues to the Secretary, the Deputy Secretary and the ASH, including serving as the Department's central coordinating office for the Minority HIV/AIDS Initiative and as the Co-Chair of the Department's HIV/AIDS Management Coordination Team. OHAP will continue to coordinate the Department's participation in a wide variety of HIV/AIDS-related conferences and meetings, such as activities around National HIV Awareness Days and World AIDS Day.

ADOLESCENT FAMILY LIFE

	FY 2007	FY 2008	FY 2009	FY 2009 +/-
	<u>Actual</u>	<u>Enacted</u>	Pres. Budget	<u>FY 2008</u>
BA	\$30,229,000	\$29,778,000	\$30,307,000	+\$529,000
FTE	11	11	11	
Authorizing Legislation				.
FY 2009 Authorization				Expired
Allocation Method		Compe	titive Grant; Contra	act; Direct Federal

Program Description and Accomplishments

The purpose of the Adolescent Family Life (AFL) program is to evaluate innovative and integrated approaches to the delivery of comprehensive services to pregnant and parenting adolescents, and provide and evaluate services promoting abstinence from sexual activity for adolescents. The AFL program targets pre-adolescents, adolescents, families, infants of pregnant and parenting teens, as well as teen fathers. The AFL program supports two types of demonstration programs:

- Prevention demonstration programs to develop and test curricula, educational materials, youth development or developmental assets approaches designed to encourage adolescents to postpone sexual activity until marriage; and
- *Care* demonstration programs to develop and test interventions with pregnant and parenting teens, in an effort to ameliorate the negative effects of childbearing on teen parents, their infants and their families.

AFL demonstration projects assist in preventing disease, particularly STDs and HIV/AIDS; promoting early childhood and youth development; reducing child abuse and neglect; and reducing health disparities by ensuring that pregnant and parenting adolescents have access to adequate prenatal and postnatal care as well as pediatric care. In addition, AFL also teaches adolescents about good health habits and preventing diseases, promoting healthy life styles, and reducing disparities in health services for young people.

Community-based, community supported, faith-based, and school-based applicants are encouraged to apply for these grants. AFL demonstration grants are awarded for a five year budget period; all grantees are required to reapply each year of their continuing grant.

The annual appropriation directs that \$13.2 million be used for prevention demonstration grants that provide "abstinence education" as defined in section 510(b) (2) (A-H) of Title V of the Social Security Act. In FY 2007, there were 36 prevention demonstration grants and 31 care demonstration grants. The AFL program is also authorized to provide support for basic and

applied research as to the causes and consequences of adolescent premarital sexual relations, adolescent pregnancy and parenting. In FY 2007, the program supported seven research projects.

Since 2004, the AFL program has substantially increased evaluation funding and intensified evaluation efforts. Grantees are required to include a rigorous evaluation design. The AFL program provides evaluation technical assistance to grantees by providing individual, workshop, and AFL staff training. This assistance may be provided by telephone, during a session the annual conference, or during site visits. All grantee evaluation reports for the end of the year are reviewed and scored based on the merits of the grantee's evaluation plan. The scoring of these reports ties directly into the Performance Assessment Rating Tool (PART) evaluation performance measures approved by OMB. The field of adolescent family life will greatly benefit from these improved efforts in evaluation, dissemination and publication of findings.

In spring 2004, the AFL program was reviewed through the PART process and rated, "Results Not Demonstrated (RND)." AFL was recognized for its efforts in creating core data instruments; however, no performance measures or measurement data were being used at that time. The PART score reflected this weakness. To address this weakness, six performance measures and one efficiency measure were established and approved in 2006 for both prevention and care demonstration programs. Two performance measures (1.1 and 1.2) are associated with encouraging adolescents to postpone sexual activity by developing and testing interventions. Three performance measures (2.1-2.3) are associated with ameliorating the effects of too-early childbearing by developing and testing interventions. The sixth performance measure (3.1) is directly associated with identifying interventions that have already been proven to produce results.

Baseline data was gathered in the spring 2007 for measures 1.1, 1.2, and 3.1; targets will be set for these measures in the spring of 2008. Measures 2.1, 2.2, and 2.3 specifically reference annual follow-up data, so baseline data will be gathered in the spring of 2008 as well. Using this data, the AFL program will prepare for a reassessment.

To prepare the program for reassessment, an improvement plan has been established for the program which will be completed by May 2008. Three new items were recently added to the improvement plan to continue strengthening the program. Additional information about the AFL PART may be found on www.ExpectMore.gov.

The AFL program supports the HHS Strategic Plan, Goal 3: Promote the economic and social well-being of individuals, families and communities; Objective 3.2 Protect the safety and foster the well-being of children and youth. In addition, AFL supports the OPHS/HHS strategic goals by contributing to the following measures:

- Increase number of local, state and national health policies that incorporate prevention elements
- Increase the reach of OPHS prevention communications
- Increase the number of substantive commitments to prevention on the part of governmental and non-governmental organizations

- Increase knowledge about disease prevention and health promotion
- Increase impact of selected departmental, Federal and public-private collaborative efforts through effective OPHS leadership and coordination
- Support programs that seek to eliminate health disparities

Funding History

FY 2004	\$30,720,000
FY 2005	\$30,742,000
FY 2006	\$30,256,000
FY 2007	\$30,229,000
FY 2008	\$29,778,000

Budget Request

The FY 2009 request is \$30,307,000, an increase of \$529,000 above the FY 2008 enacted level. The increase provides funds for staff pay increases and enables the program to continue to support demonstration projects and quality evaluation efforts.

Based on the performance measures established in response to the PART process, the AFL program has significantly increased efforts to strengthen the independent evaluations of AFL grant programs, as well as evaluate the entire AFL program. Since 2006, the program has developed a phased cross-site evaluation plan. In the fall of 2008, a cross-site evaluation of grants funded across the country will provide a comprehensive assessment of the AFL program and demonstrate whether it is benefiting its targeted population. Long term outcome objectives 1 and 2, with associated measures, will be assessed through this process (see "AFL Outcome Table"). In addition, a descriptive process evaluation will detail what programs are providing services across the country and what models they are using.

To prepare for the cross-site evaluation, AFL demonstration grantees have been required to strengthen their evaluation designs as measured by outcome objective 3 by completing a detailed evaluation report each year. An independent evaluation contractor reviews each report and scores them using a standardized assessment tool. The AFL program is confident that with stronger program evaluation designs, comprehensive evaluation technical assistance and training for grantees, and a standardized way of assessing evaluation reports, that the quality of program evaluations will improve.

The AFL program is striving to ensure efficiency by AFL grantees. An efficiency measure, referenced in the below table, tracks the cost per service hour in each program. AFL is committed to ensuring the costs are maintained in each AFL program over the next five years.

ADOLESCENT FAMILY LIFE Outcome Data

		FY	FY	FY 2	006	FY	2007			Out-
#	Key Outcomes	2004 Actual	2005 Actual	Target	Actual	Target	Actual	FY 2008 Target	FY 2009 Target	Year Target
1. Lo	1. Long-Term Objective: Encourage adolescents to postpone sexual activity by developing and testing abstinence interventions.									
1.1	Increase the involvement of parents in the lives of their adolescent children measured by the change in the proportion of AFL Prevention demonstration project clients who communicate with their parents about puberty, pregnancy, abstinence, alcohol, and/or drugs.			Baseline	44.4%	46.6%	March 31, 2008	48.8%	48.8%	51%
1.2	Increase adolescents' understanding of the positive health and emotional benefits of abstaining from premarital sexual activity as measured by the change in the proportion of AFL Prevention demonstration project clients who indicate that it is important to them to remain abstinent until marriage.			Baseline	80%	83%	March 31, 2008	83%	83%	84%
	ong-Term Objective: Ameliorate nting teens.	the effects o	of too-early	y-childbeari	ng by dev	eloping an	d testing into	erventions w	ith pregnan	t and
2.1	Reduce the incidence of repeat pregnancies among clients in AFL Care demonstration projects as measured by the proportion of project clients with a repeat pregnancy at annual follow-up.					Baseline	March 31, 2008	TBD	TBD	TBD
2.2	Increase AFL Care demonstration project client conformance with recommended infant immunization schedules as measured by the proportion of project clients whose infant has received all recommended immunizations at annual follow-up.					Baseline	March 31, 2008	TBD	TBD	TBD
2.3	Increase the educational attainment of AFL Care demonstration project clients as measured by the proportion that have enrolled in or completed a high school or GED program at annual follow-up.					Baseline	March 31, 2008	TBD	TBD	TBD
	ng-Term Objective: Identify inte						, .	te premarita	l abstinence	for
3.1	Improve the quality of the independent evaluations, required by statute, of Title XX prevention and care demonstration projects as	Sinosquono		Baseline (Prev / Care)	11% /42%	19.25% / 46.2%	March 31, 2008	27.5% / 50.4%	35.75% / 54.6%	44%/ 58.8%

	measured annually by an independent review of grantee end of year evaluation reports.									
4. Lo	ng-Term Objective: Improve the	efficiency of the	he AFL pro	ogram.						
4.1	Sustain the cost to encounter ratio in Title XX prevention and care demonstration projects.			Baseline (Prev/ Care)	\$37/ \$125	\$37/ \$125	March 31, 2008	\$37/\$125	\$37/\$125	\$37/ \$125
	Appropriated Amount (\$ Million)	\$30.7	\$30.7	\$30	.3	\$30	.2	\$29.8	\$30.3	

Notes: With performance measures established and approved in 2006, baseline data was gathered in the spring 2007 for measures 1.1, 1.2, and 3.1. Targets will be set for these measures in the spring 2008. Since measures 2.1, 2.2, and 2.3 specifically reference annual follow-up data, baseline data will be gathered on these measures at that time.

ADOLESCENT FAMILY LIFE Program Data

	FY 2007		FY 2008		FY 2009	
Activity	Actual		Enacted		Pro	es. Budget
PROGRAM FUNDING	No,	<u>Amount</u>	<u>No.</u>	<u>Amount</u>	No.	<u>Amount</u>
Care Demonstration Grants						
Continuations	24	\$8,376,682	31	\$10,999,022	17	\$6,186,264
New	<u>7</u>	2,622,340	<u>0</u>	<u>0</u>	<u>12</u>	<u>5,147,069</u>
Subtotal, Care	31	\$10,999,022	31	\$10,999,022	29	\$11,333,333
Prevention Demonstration Grants						
Continuations	19	\$4,968,966	31	\$10,562,916	24	\$9,334,553
New	<u>17</u>	8,151,034	6	\$2,557,084	<u>13</u>	3,785,447
Subtotal, Care	36	\$13,120,000	37	\$13,120,000	37	\$13,120,000
Total, Demonstration Grants	67	\$24,119,022	68	\$24,119,022	66	\$24,453,333
Research						
Continuations	4	\$888,199	6	\$997,243	0	\$0
New	<u>3</u>	<u>496,660</u>	<u>1</u>	100,000	<u>6</u>	1,097,243
Subtotal, Research	7	\$1,384,859	7	\$1,097,243	6	\$1,097,243
Demonstration related technical						
assistance and support activities		1,315,830		1,499,446		1,644,135
Research IAAs & Related Activities		771,289		640,418		640,418
Support Costs		2,638,000		<u>2,421,871</u>		2,471,871
TOTAL		\$30,229,000		\$29,778,000		\$30,307,000
CLIENTS SERVED*						
Title XX Care Demonstrations	31	9,300	31	9,500	29	9,000
Title XX Prevention Demonstrations	<u>36</u>	<u>18,000</u>	<u>37</u>	18,500	<u>37</u>	18,700
TOTAL	67	27,300	68	27,900	66	27,700

^{*}Number of clients estimated by average 300 clients per year per prevention and 200 per year per care program. In 07 efforts have been made to help programs increase client hours. This should result in an increase per grant in 08 and 09.

OFFICE OF DISEASE PREVENTION AND HEALTH PROMOTION

	FY 2007 Actual	FY 2008 Enacted	FY 2009 Pres. Budget	FY 2009 +/- FY 2008
BA	\$7,305,000	\$7,097,000	\$7,159,000	+\$62,000
FTE	21	20	20	
Authorizing Legislation FY 2009 Authorization Allocation Method	•••••			Expired

Program Description and Accomplishments

ODPHP provides leadership, coordination, and policy development in disease prevention and health promotion activities within OPHS for the Department. ODPHP's central mandates are to assist the Assistant Secretary for Health and the Office of the Secretary in:

- coordinating health promotion and disease prevention activities, especially those related to the President's HealthierUS initiative (e.g., the National Prevention Summit), Healthy People 2010, Healthy People 2020, Dietary Guidelines for Americans, and Physical Activity Guidelines for Americans;
- developing, evaluating, and promoting innovative approaches to communicating health information and operating the National Health Information Center; and
- addressing cross-cutting and gap-filling issues in public health, prevention, and science.

ODPHP is actively engaged in the Secretary's Prevention Priority and commitment to creating a culture of wellness derived from the President's HealthierUS initiative. Together, these activities focus on promoting health and preventing obesity and related chronic diseases by addressing major risk factors (physical inactivity, poor nutrition, tobacco use, and youth risk-taking behaviors) and reducing the burden of disease through appropriate health screenings and prevention of secondary conditions.

The National Prevention and Health Promotion Summit: Creating a Culture of Wellness held November 27-29 in Washington, D.C. focused on these areas. The keynote address highlighted Health Promotion Programs advancing President Bush's HealthierUS initiative, plenary sessions highlighted disease prevention and health promotion topics in various age, ethnic, community, school, work, and other demographic groups and featured partnerships, communications, and health education methods that work, and also offered a town hall meeting during which experts from various sectors (business, academia, government, etc.) discussed the opportunity and costs of prevention. More than 1180 health professionals from non-profit organizations, academia, businesses, and government attended. The Secretary's Innovation in Prevention Awards were presented to select organizations that have implemented innovative and creative chronic disease prevention and health promotion programs. In FY 2007, ODPHP partnered with CDC to combine four annual meetings on the common theme of disease prevention and health promotion into the 2007 National Prevention and Health Promotion Summit. ODPHP contributed partial funding for the Summit through the Direct federal allocation method.

ODPHP coordinates the implementation of *Healthy People 2010*. Healthy People supports the President's HealthierUS initiative by offering 10-year health objectives for the Nation with two main goals: first, to increase the quality and years of healthy life, and second, to eliminate health disparities. The objectives are designed to drive action and represent an opportunity for individuals to make healthy lifestyle choices, for clinicians to put prevention into practice, for communities and businesses to support health-promoting policies in schools, worksites, and other settings and for scientists to pursue new research. Example objectives include "reduce the proportion of adults with high blood pressure" (12-9) or "reduce hospital-acquired infections in intensive care unit patients" (14-20). Through evidence-based objectives with measurable targets, Healthy People provides a framework for programs necessary to achieve the vision of these initiatives. The objectives were reassessed through a mid-decade review that culminated in the publication of the Healthy People 2010 Midcourse Review in FY 2007. In FY 2007, ODPHP continued the final round of progress reviews to review the most current data, to look for opportunities and challenges, and to assess the status of objectives in the 28 focus areas of Healthy People 2010. The results of these progress reviews are posted on the healthy people.gov website.

Development of the next decade's 10-year health objectives began in FY 2007 and will continue in FY 2008 and FY 2009. ODPHP does not directly fund *Healthy People 2010*, except through staff time. ODPHP measures the percentage of states that use the national objectives in their health planning processes (this activity was stimulated in FY 2007 by an annual meeting and periodic calls with the *Healthy People* State coordinators) and the percentage of *Healthy People 2010* focus area progress review summaries that have been written, cleared, and posted on the internet within 16 weeks of the progress review date through the PART. To date, ODPHP has met its target for the former measure but has not met its target for the latter. ODPHP works closely with OMB to revise targets, measures, and/or processes to align results and demonstrate improved performance as needed. Tracking the 467 disease prevention and health promotion objectives for the Nation and monitoring progress toward meeting the established targets is ODPHP's second core activity. ODPHP has established a long-term outcome measure through PART to increase the percentage of *HP 2010* objectives that have met the target or are moving in the right direction.

In FY 2007, ODPHP and the Regional Health Administrators (RHAs), who are senior Federal public health officials and scientists in the ten regional offices across the country, collaborated to assess benefits of translating disease prevention and health promotion science shared at the National Prevention Summits and similar HHS-sponsored events into practice at the community level. In October 2006, ODPHP and the RHAs held a workshop to garner input from state public health professionals. The resulting project titled, Take Action: Healthy People, Places and Practices in Communities, will provide one year seed funding to about 27 community groups to carry out projects in each of the HHS regions, such as walking programs for a neighborhood or workplace, development of school lunch programs that include locally grown, seasonal fruits and vegetables, and implementation of skin cancer detection programs and smoking prevention programs. The projects are required to support the four pillars of the President's HealthierUS

initiative: eat a nutritious diet, be physically active, get preventive screenings, and make healthy lifestyle choices. An evaluation of project outcomes is planned for FY 2008.

ODPHP plays a leadership role in co-coordinating the development and review and also promoting the recommendations from the Dietary Guidelines for Americans (Dietary Guidelines), the cornerstone of Federal nutrition policy launched every five years by the HHS and the US Department of Agriculture (USDA). In FY 2007, ODPHP targeted materials to health professionals with a robust toolkit that included an older adult module developed in collaboration with the Administration on Aging. ODPHP also compiled and packaged research findings on the Dietary Guidelines qualitative work (eg. focus groups) and separately, the quantitative data gleaned from the Health and Diet Survey: Dietary Guidelines Supplement. The survey, done collaboratively with the Food and Drug Administration (FDA), tracks national change of Americans' attitudes, awareness, knowledge, and behavior regarding various elements of nutrition and physical activity. HHS initiated the baseline survey just prior to the launch of the Sixth Edition, Dietary Guidelines for Americans in January 2005, and repeated the survey a year later. The next wave of the survey will be fielded and reported in FY 2008. The FY 2006 survey showed that 48 percent of Americans were aware of the Dietary Guidelines, exceeding the target of 37 percent, and the FY 2004 baseline of 33 percent.

Also in FY 2008, ODPHP plans to release the Hispanic over-sampling survey data along with a new Spanish language consumer brochure and community guide developed in collaboration with the Office of Minority Health. ODPHP is spearheading the development of a compilation CD-ROM featuring Federal Nutrition materials in Spanish developed by HHS agencies and USDA. To reach out to another important audience, ODPHP is supporting the Indian Health Service in the development of nutrition materials targeted to the American Indian/Native Alaskan population. ODPHP does not provide direct federal funding towards the Dietary Guidelines, except through staff time. ODPHP does provide support through evaluation set-aside funds for survey and related work. As referenced above, ODPHP measures awareness of Dietary Guidelines for Americans for the general population as one of its PART measures.

ODPHP coordinates the process for developing and disseminating the Physical Activity Guidelines for Americans, which is part of the Secretary's Prevention Priority. This initiative addresses the growing number of overweight and obese Americans. The Guidelines will provide science-based recommendations on the latest knowledge about activity and health, with depth and flexibility to target specific population subgroups, such as seniors, children, and persons with disabilities. Consumer materials are one component of the communication and outreach plan to inform the public about the Guidelines. The Physical Activity Guidelines are on track to be released in the Fall of 2008.

ODPHP has developed opportunities for professional growth and development in both prevention policy and medical education through the Luther Terry Fellowship, as well as education and training of Preventive Medicine Residents, medical students, emerging leaders, and public health interns as part of the Disease Prevention and Health Promotion Scholarship Program. ODPHP funds a competitive cooperative agreement to support this activity.

A key component of ODPHP's mission is to provide leadership and innovative research in

consumer health information. These activities support the Secretary's value-driven health care, health information technology, and personalized health care priorities. ODPHP manages the National Health Information Center which, in addition to traditional information and referral services, supports websites for Healthy People 2010 and healthfinder.gov®, the Federal government's award-winning health information portal. In FY 2007, ODPHP continued its multi-year effort to design the next generation healthfinder.gov based upon audience research and health literacy principles. A prevention information service, based upon this research and in collaboration with HRSA and the community health centers, is being designed to be integrated into patient record systems and health care delivery processes. The goal of the Putting Prevention into Practice project is to develop and implement a cost-effective way to integrate prevention information from healthfinder.gov into the electronic medical record and into daily interactions with patients in a community health center environment. Patients' use of preventive services and satisfaction with the health center visit will be evaluated as outcomes of this project. The intersection between the community health center setting, clinical preventive service guidelines and health information technology make this project a collaborative effort among several agencies in HHS including the Health Resources and Services Administration, the Agency for Healthcare Research and Quality, and the Office of the National Coordinator for Health Information Technology.

Additionally, the National Health Information Center is developing a collection of evidence based e-health tools and templates for professionals to personalize health information for their diverse audiences. ODPHP measures customer satisfaction with healthfinder® and visits to ODPHP-supported websites through PART performance measures. In FY 2006, ODPHP exceeded the target set for visits to ODPHP-supported websites. A survey to measure consumer satisfaction with healthfinder.gov was also fielded and results indicate 75 percent of those who use healthfinder.gov are satisfied with the health information they find on the site. ODPHP's health communication work is funded by two (competitive) contracts.

ODPHP supported the development of the proceedings of the Surgeon General's Workshop on Health Literacy. In FY 2008, ODPHP anticipates organizing multiple town hall meetings across the country on behalf of the HHS-wide working group on Health Literacy for the purpose of advancing the science and implementation of promising practices. As the departmental lead for *Healthy People 2010* Focus Area 11 - health communication, ODPHP has coordinated efforts to identify data systems to measure all of the objectives for Focus Area 11 by FY 2007.

ODPHP was reviewed through the Performance Assessment Rating Tool (PART) in 2005 and received a score of Results Not Demonstrated. Through that process developed a long term measure and five annual performance measures which have been incorporated into the performance analysis. ODPHP's long term measure and annual measures relate to its mission and core activities: the *Healthy People 2010* national health objectives, the Dietary Guidelines for Americans, and the National Health Information Center and related communications efforts. Additional information about the ODPHP PART may be found on www.ExpectMore.gov.

Funding History:

FY 2004 \$7,306,000

FY 2005	\$7,533,000
FY 2006	\$7,330,000
FY 2007	\$7,305,000
FY 2008	\$7,097,000

Budget Request

The FY 2009 Request for ODPHP is \$7,159,000, an increase of \$62,000 above the FY 2008 enacted level. The increase provides funds to partially support pay increases.

Healthy People 2020 is under development and implementation process of the national objectives will begin in FY 2009. The Healthy People 2020 objectives will underpin the President's HealthierUS initiative, as well as the Secretary's priorities of Prevention, Health IT and Preparedness. Extensive Federal and public participation will be critical to the development of a set of objectives that are based on science, driven by data, and address the major health needs and priorities of the Nation. In FY 2009, the development process will include meetings of the Secretary's Advisory Committee on Health Promotion and Disease Prevention Objectives for 2020, regional public meetings, and the building of a public comment database. Ultimately, the implementation process calls for awards to be made to States which support the development of their own disease prevention and health promotion action plans that will be modeled after the national Healthy People 2020 objectives. This activity supports one of ODPHP's PART measure, "The percentage of States that use the national objectives in their health planning process."

The FY 2009 Request for ODPHP also includes \$455,800 to support development, coordination, and outreach for Dietary Guidelines for Americans, Physical Activity Guidelines for Americans, and ongoing work of Healthy People 2010, all of which, as described above support the Secretary's Prevention Priority and commitment to creating a culture of wellness derived from the President's HealthierUS initiative by focusing on promoting health and preventing obesity and related chronic diseases by addressing major risk factors (physical inactivity, poor nutrition, tobacco use, and youth risk-taking behaviors) and reducing the burden of disease through appropriate health screenings and prevention of secondary conditions. ODPHP supports the development of science-based reviews for nutrition, physical activity, and development of national health objectives. The science documents need to be developed into materials that can be used by public health professionals, communities, policy makers, individuals, etc. so that the scientific information is communicated to and can be implemented by a variety of target audiences. As noted previously, many of ODPHP's performance measures in PART are directly related to the outcomes of these initiatives. In addition, the Request includes \$1,658,000 for the National Health Information Center Communication Support which, as described above supports healthfinder® (one of ODPHP's PART measures) and ODPHP-supported websites (another PART measure).

OFFICE OF DISEASE PREVENTION AND HEALTH PROMOTION Outcome Data

#		FY	FY	FY 2	006	FY 2007		FY	FY	Out-
#	Key Outcomes	2004 Actual	2005 Actual	Target	Actual	Target	Actual	2008 Target	2009 Target	Year Target
	-Term Objective: Communica		lly by inc	reasing the	reach of	ODPHP	disease preve	ention and h	ealth prom	otion
info	rmation and communications	S								
I.a	Awareness of Dietary Guidelines for Americans (will be measured at least two times between 2005 and 2010)	33%	NA	37%	48%	39%	Feb-08	41%	50%	NA ^a
	Long-Term Objective: Shape prevention policy at the local, State and national level by establishing and monitoring National disease prevention and health promotion objectives									
II.a	Percentage of States that use the national disease prevention and health promotion objectives in their health planning process	65%	96%	94%	survey not fielded	98%	Fall 2008	98% ^b	98%	NA
II.b	Increase the percentage of Healthy People 2010 objectives that have met the target or are moving in the right direction	NA	42.2%	NA	NA	NA	NA	NA	NA	FY 2010 60%

				FY 2	2006	FY	2007	FY 2008	FY 2009 Target/ Est.	Out-
#	Key Outputs	FY 2004 Actual	FY 2005 Actual	Target/ Est.	Actual	Target/ Est.	Actual	Target/ Est.		Year Target/ Est.
_	Term Objective: Communication and communication	_	lly by incre	easing the re	each of OD	PHP disea	ase preven	tion and he	ealth prom	otion
I.b	Visits to ODPHP- supported websites	10.41M	14.16M	11.92 M	16.17 M	12.76 M	19.42 M	13.65 M	14.60 M ^e	NA
I.c	Consumer Satisfaction with healthfinder.gov, measured every three years at a minimum	FY 2003 72%	NA	75%	75%	NA	NA	78%	NA	FY2010 80%
Effici	ency Measure									
I.d	Increase the percentage of Healthy People 2010 focus area progress review summaries that have been written, cleared, and posted on the internet within 16 weeks of the progress review date	NA	NA	25%	100% (2/2)	50%	40%	75%	75%°	NA
	Appropriated Amount (\$ Million)	\$7.3	\$7.5	\$7	.3	\$7	7.3	\$7.1	\$7.2	

OFFICE OF DISEASE PREVENTION AND HEALTH PROMOTION Program Data

PREVENTION FRAMEWORK:	FY 2007 Actual	FY 2008 Enacted	FY 2009 <u>Request</u>
Healthy People 2010, HealthierUS, Dietary Guidelines for Americans, Physical Guidelines for Americans outreach and coordination PREVENTION COMMUNICATI	\$555,800 ON:	\$455,800	\$455,800
National Health Information Center	1,758,200	1,658,000	1,658,000
Communication Support SCIENCE:	750,000	700,000	700,000
Disease Prevention and Health Promotion Scholarship Program OPERATING EXPENSES:	400,000	400,000	400,000
Operating Costs	3,841,000	3,883,200	3,945,200
TOTAL	\$7,305,000	\$7,097,000	\$7,159,000

PRESIDENT'S COUNCIL ON PHYSICAL FITNESS AND SPORTS

	FY 2007 <u>Actual</u>	FY 2008 Enacted	FY 2009 <u>Pres. Budget</u>	FY 2009 +/- FY 2008
BA	\$1,230,000	\$1,195,000	\$1,205,000	+\$10,000
FTE	7	7	7	
Authorizing Legislation FY 2009 Authorization			,	
Allocation Method				

Program Description and Accomplishments

Physical activity and fitness have made great strides in the last several decades. However, there is still evidence that despite the increased awareness and knowledge of the benefits of a fit and active lifestyle, the U.S. continues to be a basically sedentary population. With enhanced national and State-level partnerships and collaborations, the President's Council on Physical Fitness and Sports (PCPFS) plans to develop and implement creative, grassroots/community initiatives and collaborations to advance both the Departmental and administration's goals and policy recommendations for improving the health, physical activity/ fitness of all Americans, able and disabled. PCPFS is a federal advisory committee and does not distribute grants.

PCPFS creates and cultivates grassroots partnerships and collaborations to raise the public's awareness about the benefits of a physically active and fit lifestyle and provides motivational, easy-to-use, adaptable tools and resources. The PCPFS' longstanding, landmark presidential physical activity and fitness recognition programs for ages 6 and above, lends itself to be modified so organizations, schools, companies, hospitals, etc. can address specific populations: i.e. youth, seniors, minorities, persons with disabilities – virtually Americans of all ages and abilities – with a motivational, individual or group, physical activity and fitness tracker. In addition, PCPFS creates, develops, disseminates and provides technical assistance on diverse implementation strategies for a wide range of physical activity/fitness and health programs and information/education materials. This increase would allow the PCPFS to target those most vulnerable where they live, learn, work, and play – a priority when considering the growing diversity of the American public and its changing demographics.

In 2007, PCPFS partnered with OPM to launch the HealthierFeds Physical Activity Challenge. Close to 30,000 Federal employees from 30 different agencies joined the Challenge from all three branches of government. Federal employees, family members, retirees and contractors were eligible to participate. The Challenge required participants to engage in 30 minutes of physical activity, five days per week for a six week period and served as a stepping stone to regular, ongoing lifetime activity. A six-month follow-up survey was made available to all participants who completed the Challenge. Questions asked pertain to frequency and duration of continued physical activity, and a 12-month follow-up survey will also be made available in Spring 2008.

This initiative supported the Secretary's prevention initiative and HealthierUS initiative. HealthierFeds will once again be available as part of the National Challenge to be launched in March 2008, a call to action to all Americans to engage in regular physical activity as part of a healthy lifestyle and to prevent chronic disease.

PCPFS presented the inaugural Lifetime Achievement and Community Leadership Awards in 2007 during National Physical Fitness and Sports Month. Luminaries in the health and fitness field were recognized for their major contributions to impacting the health of Americans.

Throughout 2008, PCPFS will serve as a member of the federal steering committee for the first ever National Physical Activity Guidelines (PAGs) to be announced in Fall 2008 by Secretary Leavitt. In addition, PCPFS is chairing the partnership subcommittee for the Communications Team. The purpose of the PAG Partnership Plan is to establish an ongoing, sustainable, interactive relationship between the PAG Communications Team and other public/private organizations concerned with delivering a science-based, clear, consistent message on physical activity following the official release.

PCPFS supports the OPHS/HHS strategic goals by contributing to the following measures:

- Increase number of local, state and national health policies that incorporate prevention elements
- Increase the reach of OPHS prevention communications
- Increase the number of substantive commitments to prevention on the part of governmental and non-governmental organizations
- Increase knowledge about disease prevention and health promotion
- Increase impact of selected departmental, Federal and public/private collaborative efforts through effective OPHS leadership and coordination
- Support programs that seek to eliminate health disparities

Funding History

FY 2004	\$1,179,000
FY 2005	\$1,247,000
FY 2006	\$1,228,000
FY 2007	\$1,230,000
FY 2008	\$1,195,000

Budget Request

The FY 2009 request for PCPFS is \$1,205,000, an increase of \$10,000 above the FY 2008 enacted level. The increase provides funding for pay increases to allow the Council to maintain the same level of activity as in FY 2008. Funds for this activity only provide salaries and benefits, rent, travel, and other overhead costs for staff that support the Council. The PCPFS reports to the President through the HHS Secretary, thus serving both Presidential and Secretarial prevention initiatives.

One of PCPFS' greatest assets is the presidential appointed Council, whose mandate is to meet at

least once a year to generate creative ideas and initiatives to promote and enhance the development and maintenance of physical activity/fitness and sports programs. Council meetings are the best venue to generate ideas and initiatives by this highly knowledgeable and prestigious group of volunteers, leaders in physical activity, sports, medicine, education, business, and organizations. The Council is the main advocacy and educational tool of PCPFS, and enhanced teamwork among the members will increase productivity. A greater number of public speaking appearances by the Council members, the Executive Director and senior staff, as well as representation and participation at major physical activity conferences, which are important national information-exchange venues, will assist PCPFS to increase its effectiveness in promoting and advocating physical activity and raising awareness to diverse audiences on the administration's and Department's initiatives highlighted above.

PCPFS plans to accomplish the following objectives in FY 2009:

- Support/promote the Department's Prevention Priorities and enhance coordination and collaboration within departmental components to ensure effective and efficient incorporation of science-based physical activity/fitness strategies and messages in diverse federal, state, and local government programs and information pieces.
- Work closely with OPM on creating a healthier, more active Federal workforce (Healthier Feds).
- Continue to enhance and support governors, schools, hospitals, industry, and corporations by promoting the enhancement, adoption, and incorporation of the motivational presidential recognition program, the President's Challenge Physical Activity and Fitness Awards Program, into national, state, and local, public and private sector, action plans.
- Develop and disseminate clear, concise synopses of the 2008 science-based Physical Activity Guidelines through the Partnership Subcommittee of the Communications Team, at regional and annual sports medicine, kinesiology and exercise physiology conferences, to our growing President's Challenge advocates who are organizations and groups that represent people of all cultures and ages where they live, work, play, and pray. The PCPFS will provide technical assistance in the development and dissemination of national, state, and local implementation strategies.
- Enhance the visibility and augment options available on the President's Challenge Physical Activity and Fitness Awards Program for persons with special needs. Summarize lessons learned from the I Can Do It! You Can Do It! pilots and present adaptable alternatives to the PCPFS President's Challenge criteria. I Can Do It! You Can Do It! Is the Office on Disability/HHS' National Initiative on Physical fitness for Children and Youth with disabilities.
- Ensure the continuation of the annual Lifetime Achievement Awards and Community
 Leadership Awards to recognize, encourage and motivate individuals and institutions to
 maximize outreach to their communities by disseminating science-based programs and
 messages to their constituents.
- Enhance the use of modern technology to bring the science to the people via monthly webinars which will disseminate timely departmental physical activity/fitness policy and program information to Americans across the nation.

- Create additional opportunities for joint program developments and collaborative implementation strategies on ongoing inter-departmental MOUs e.g., Recreation and Public Health, and Healthier Children.
- As co-lead of the Physical Activity and Fitness objectives of Healthy People 2010, and soon to be developed Healthy People 2020, PCPFS will continue to collaborate with public and private organizations in the development, dissemination, and promotion of 2020 goals and subsequent implementation strategies to increase the health of Americans of all ages and abilities through the adoption and maintenance of regular physical activity.

OFFICE OF MINORITY HEALTH

	FY 2007	FY 2008	FY 2009	FY 2009
	<u>Actual</u>	Enacted	<u>PB</u>	<u>+/- FY 2008</u>
BA	\$53.455.000	\$48.738.000	\$42,686,000	-\$6.052.000
FTE	58	57	57	
~ .	gislationrization			
	nod: Direct federal;			-
	Contract		_	

Program Description and Accomplishments

OMH resides within the Office of Public Health and Science (OPHS), in the Office of the Secretary of the U.S. Department of Health and Human Services (HHS). Its creation in 1986 by then-HHS Secretary Margaret Heckler was one of the most significant outcomes 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), and reauthorized under the Health Professions Education Partnerships Act of 1998 (PL 105-392).

OMH's mission is "to improve the health of racial/ethnic minority populations through the development of policies and programs that help eliminate disparities."

Long-Term Problems Being Addressed by OMH

- Racial/ethnic minority health status. There is significant evidence of poor health status among racial/ethnic minority populations, with respect to preventable disease and disability as well as premature death.
- Racial/ethnic health disparities. The poor health outcomes for racial/ethnic minorities are reflected in the health status and health care disparities that are apparent when comparing health indicators for minorities against those of the rest of the U.S. population.

In many respects, racial/ethnic minority populations continue to be under-served by the U.S. health care system:

• Blacks had 90 percent more lower extremity amputations for diabetes. ¹

¹2006 National Healthcare Disparities Report, page IV. AHRQ, 2007. http://www.ahrq.gov/qual/nhqr06/index.html

- Asian American/Pacific Islander women, and Vietnamese American women especially tend to have much lower rates of cervical cancer screening than other groups.¹
- About 1 in 4 American Indian or Alaska native adults (23.8 percent) were poor compared with 1 in 5 Black adults (20.9 percent), 1 in 8 Asian adults (12.7 percent) and 1 in 11 White adults (9.0 percent).
- Hispanics had 63 percent more pediatric asthma hospitalizations.²
- About one-third of poor and near poor Hispanic or Latino women experienced an unmet medical need due to cost.³
- Black children have a 260% higher emergency department visit rate, a 250% higher hospitalization rate, and a 500% higher death rate from asthma, as compared with White children.⁴

OMH Activities

Thus, improving racial/ethnic minority health status and ending persistent racial/ethnic health disparities remains an important priority. OMH addresses its mandate in a manner appropriate to its role and capacity and through a number of disease prevention, risk reduction, health promotion, and service delivery strategies and activities, many of which are supported through competitive grants, cooperative agreements, contracts, technical assistance, and partnerships. The strategies and activities are categorized as follows:

- <u>Leadership</u>. OMH helps establish, strengthen, and support partnerships among HHS offices/agencies, other Federal agencies, state and local agencies, tribes/tribal organizations, public and private sector interests, minority-serving organizations, and others involved in addressing the health of racial/ethnic minorities. The goal of these partnerships is to leverage different stakeholders' resources and activities in a concerted fashion to mount a multi-pronged approach toward eliminating health disparities.
- <u>Policy development and implementation</u>. OMH develops, disseminates, and coordinates the implementation of policies, including data policy, related to racial/ethnic minority health and health disparities. For example, OMH may issue

¹Freeman G, Lethbridge-Cejku M. Access to health care among Hispanic or Latino women: United States, 2000-2002. Advance data from vital and health statistics; no 368. Hyattsville, MD: National Center for Health Statistics. 2005

² Barnes PM, Adams PF, Powell-Griner E. Health characteristics of the American Indian and Alaska native adult population: Unites States, 1999-2003. Advance Data from vital and health statistics; no 356. Hyattsville, Maryland: National Center for Health Statistics. 2005

³ CDC, 2006. Access to Health Care Among Hispanic or Latino Women: United States, 2000–2002, page 6. http://www.cdc.gov/nchs/data/ad/ad368.pdf

⁴ CDC 2006. The State of Childhood Asthma, United States, 1980–2005. Table B. http://www.cdc.gov/nchs/data/ad/ad381.pdf

practice guidelines, policy statements, service standards, and other similar products.

- <u>Education and awareness</u>. OMH disseminates information about disease prevention, risk reduction, health promotion, and service delivery strategies and practices that have demonstrated effectiveness, and promotes the translation of research into practice aimed at improving racial/ethnic minority health and eliminating health disparities.
- <u>Research, demonstration, and evaluation</u>. OMH supports demonstration and evaluation projects at the community, regional, tribal and national levels. These projects explore and document the effectiveness of various strategies and practices to improve racial/ethnic minority health, including efforts to increase access to and appropriate use of health care. Such projects also examine how to fill data gaps to inform planning; develop population-specific knowledge about health risks, prevention, and screening, as well as culturally and linguistically appropriate health delivery systems; promote workforce diversity and collaborations in service delivery.

In the spring of 2005, OMH underwent an Office of Management and Budget (OMB) Program Assessment Rating Tool (PART) review and received a "Results Not Demonstrated" score. Findings from the review were that: (1) initiatives appeared duplicative of other entities; (2) measures to demonstrate impact of programs were not developed; (3) documentation of how grantees and other contractors contribute to outcome and efficiency goals is needed. As a result, OMH has worked to effect a more "results-oriented" approach to its mission, grantees, and other partners. A strategic framework, preliminary set of long- and short-term performance measures, and evaluation planning guidelines and protocols to strengthen health disparities-related evaluations have been developed. Specific information about the OMH PART may be found on www.ExpectMore.gov.

Important contributions to improved OMH efforts came from the second National Leadership Summit on Eliminating Racial and Ethnic Health Disparities (Summit) held in January 2006. The Summit included nearly 2,000 participants representing federal, state, tribal, and local governments; communities; institutions of higher education; health care providers; health plans; national medical and healthcare organizations; foundations; and the business sector. In direct response to feedback from OMB, as well as input from Summit participants, OMH has undertaken a number of actions to effect greater results. In addition to the strategic framework, performance measures, and evaluation planning guidelines and protocols, OMH implemented the *National Partnership for Action to End Health Disparities* (NPA) to guide and strengthen future actions at the community, state, tribal, regional, and national levels.

The NPA comprises a set of strategic actions that are intended to address factors at the individual, community, and/or systems level(s) that influence the health of racial/ethnic minorities, disparities that disproportionately impact such populations, or systems issues that inhibit or promote effective and efficient approaches to such problems. Actions under the NPA are organized around five related objectives:

- 1. Increasing awareness of health disparities.
- 2. Strengthening leadership at all levels for addressing health disparities.
- 3. Improving patient-provider interactions.
- 4. Improving cultural and linguistic competency.
- 5. Improving coordination and utilization of research and outcome evaluations.

All OMH grant program-related efforts and other key OMH-funded initiatives are expected to contribute to achievement of the NPA objectives. The objectives, in turn, must contribute to outcome and efficiency measures established by OMH, in concert with OMB, as well as the broader *Healthy People 2010* objectives and goals for the Nation.

OMH's programs directly support the President's *HealthierUS* Initiative and the Secretary's focus on prevention (e.g., culture of wellness, healthy choices, and medical screenings). OMH programs address disease prevention, health promotion, risk reduction, healthier lifestyle choices, utilization of health care services, and barriers to health care for racial/ethnic minorities. They also facilitate development, implementation, and/or improvement of state/tribal government policies and programs to improve collaboration and reduce redundancy; increase availability and utilization of all forms of data and information; and improve access to, and availability of, quality health care for racial/ethnic minorities.

Recent Accomplishments

<u>Improved Individual and Public Knowledge and Understanding about Minority Health</u> and Health Disparities Problems and Solutions

OMH has moved to increase awareness and understanding of the major health problems and needs of racial and ethnic minorities, and the nature and extent of health disparities between racial/ethnic groups in the U.S. through a wide range of informational and educational efforts aimed at decision-makers, health professionals, those serving racial/ethnic minority communities, and the general public. OMH developed an annual measure on public awareness of health disparities in FY 2006 and funded a study related to this measure in FY 2007. Study instruments are in the final stages of completion and preliminary results are anticipated in Fall of 2008. Other targeted activities that address awareness are as follows:

Through a toll-free service staffed by English and Spanish speaking information staff and an active outreach program to national minority and public health organizations, the OMH Resource Center (OMHRC) supports HHS health campaigns, the NPA, and public-private partnerships for health education. In FY 2006, OMHRC distributed 88,702 documents to meet the cultural and health information needs of health professionals and consumers for utilization in community and faith based health education programs and outreach efforts. It also distributed over 25,000 pieces of Spanish language health literature at 12 Celebra la

Vida Con Salud Health Fairs which also provided health screening and referrals for over 10,000 Hispanics.

- OMH's website and electronic newsletter reach thousands of users with information about HHS programs to eliminate health disparities, stories about what minority community organizations are accomplishing, and news about the expertise, educational materials and resources HHS makes available to health departments, academic institutions, community-based agencies, public health professionals, and faculty and students working on minority health. Unique visitors to OMH's website seeking health information are projected to increase from 345,000 in FY 2007 to 440,000 in FY 2009.
- o In FY 2007, OMH launched its first infant mortality awareness campaign in cooperation with the District of Columbia Department of Health. *A Healthy Baby Begins with You* provides information and assistance to women of childbearing age, women who are pregnant and young fathers in the African American community. The campaign is the first of several that are intended to reach out to racial and ethnic minority groups in communities affected by high rates of infant deaths, premature birth, and low birth weight across the U.S. to promote life-saving information.

OMH also supports HIV/AIDS programs, some of which are funded by the Minority HIV/AIDS Initiative (MAI). These programs include the *Technical Assistance/Capacity Development (TA/CD) Demonstration Program for HIV/AIDS-Related Services in Highly Impacted Minority Communities*. The TA/CD Program assists minority-serving community based organizations in communities where there are needs or gaps in providing HIV/AIDS-related prevention and care services, as well as develops financial and programmatic capacity to compete for funds and effectively manage needed services. In FY 2007, continuation support was provided to 24 TA/CD projects. In FY 2006, the organizations funded under this program provided training to more than 400 organizations/individuals. It is anticipated that MAI funds will be available in FY 2008 to provide continued support to TA/CD projects.

In FY 2007, OMHRC's HIV capacity development team conducted direct technical assistance to 30 organizations, 17 regional training sessions, and 11 educational projects aimed at assisting minority-serving community-based in improving health education, health service delivery, management and sustainability. OMHRC also received funds to plan and support the opening of a Pacific Regional Resource Center in Guam (Pacific Center) that is intended to provide assistance to community-based organizations and health departments to increase local capacity to conduct outreach and education on HIV/AIDS, tuberculosis, and sexually transmitted diseases in the U.S.-associated jurisdictions. The Pacific Center works in coordination with several HHS agencies, institutions of higher education, national governments, and international organizations throughout the region. Community based organizations on the Marshall Islands, FSM (Chuuck State, Pohnpei), Saipan, Palau and Guam also have received direct support through the Pacific Center. The Pacific Center established a goal of reaching 1,000

individuals during its first year, and between October 1, 2006 and December 31, 2006, 633 individuals were served.

Funding History

FY 2004	\$54,851,000
FY 2005	\$50,269,000
FY 2006	\$56,338,000
FY 2007	\$53,455,000
FY 2008	\$48,738,000

Budget Request

The FY 2009 request for the Office of Minority Health is \$42,686,000, a net decrease of \$6,052,000 below the FY 2008 enacted level.

The FY 2009 budget request continues some programs at prior budget levels, reflects some increases, and includes reductions. Increases support legislated salary increases, required enhancements to our website (OMHRC), and health disparities initiatives. OMH's programs and initiatives are intended to yield outcomes that inform health policies and improve practices that prevent disease, reduce risk, promote health, and improve service delivery strategies for racial/ethnic minorities. These activities are supported through grants, cooperative agreements, and contracts.

Strengthened Community Capacity and Assets

The FY 2009 request includes \$6,000,000 for continuation of *Community Partnership to Eliminate Health Disparities Demonstration grants* at the FY 2008 funding level. This program was competed in FY 2007 and was shaped by outcomes of robust interventions carried out by prior OMH grantees. The intent of these grants is to improve the health status of racial/ethnic minority populations through the development of evidence-based models that address health promotion and disease risk reduction for racial/ethnic minority communities and improve access and utilization of preventive health care services through community-level partnerships. In FY 2006, projects funded under this program provided health education and outreach services to more than 60,000 individuals.

The FY 2009 request includes \$2,300,000 for continuation of *Bilingual/Bicultural Demonstration grants* at the FY 2008 funding level. This program was competed in FY 2007 and is intended to address the health status of limited English proficient minority populations (LEP) by reducing barriers and increasing access to quality health care, increasing the diversity of the healthcare workforce, and supporting demonstrations, and dissemination of outcomes related to research and demonstrations, on improvement in patient outcomes through implementation of culturally and linguistically appropriate services and training. Projects funded under this program in FY 2006 provided training in cultural competency to approximately 1,200 health care providers and interpretation services to more than 6,000 individuals.

The FY 2009 request includes \$800,000 for continuation of *HIV/AIDS Health Promotion* and Education Program grants at the FY 2008 funding level. This program was competed in FY 2007 and grants were awarded to national minority serving organizations that partnered with institutions of higher education to implement HIV/AIDS prevention, education and health promotion programs targeting young adults on college campuses and in the surrounding community.

<u>Strengthened Infrastructure and Capacity to Address Racial/Ethnic Minority Health and Health Disparities</u>

The FY 2009 request includes \$6,000,000 for continuation of *State Partnership Program grants* which represents an increase of \$100,000 above the FY 2008 funding level. Grants under this program were competitively awarded and are designed to assist states in strengthening their existing infrastructure; develop or adopt state-wide collaborative plans for eliminating health disparities; ensure use of best practices in providing services for all populations; and facilitate implementation of innovative programs that reduce disparities in health. Thirty-nine states are currently funded under this program.

The FY 2009 request includes \$2,000,000 for continuation of *American Indian and Alaska Native (AI/AN) Partnership Program grants* which represents a \$200,000 increase above the FY 2008 funding level. This program was competed for the first time in FY 2007 and is intended to address health disparities in AI/AN communities. Tribal epidemiology centers have been funded to work with their respective tribal leaders to better access data, engage in data development activities, and/or use a broad array of data to facilitate evidence-based health care decision-making and address health disparities planning; develop non-traditional alliances and partnerships to improve coordination/alignment of health and human services and access to quality care for their communities; and improve the diversity of the tribal healthcare, public health, and research workforce.

Effective Leadership to End Health Disparities

In addition to implementing the NPA in FY 2007 as a means for addressing leadership and improving nationwide coordination and collaboration for greater effectiveness, efficiency, and impact on health disparities, OMH established partnerships with the Association of State and Territorial Health Officials and the National Association of State Offices of Minority Health to strengthen and increase state-based strategic planning and partnerships. Additional partnerships are being established in FY 2009 to further improve efficiency of collective efforts at the community, state, tribal, regional, and national levels.

OMH will continue to support the use of evidence-based clinical care guidelines, collaborate with HHS agencies on health disparities projects, and partner with public and private organizations to address public health and emergency preparedness in minority

communities, racial/ethnic minority participation in clinical trials, coordination of federal health disparities research, and coordination of HHS AI/AN research efforts in consultation with tribal leaders.

OFFICE OF MINORITY HEALTH Outcomes Data

		FY	FY EW 2005		006	FY	2007	EX 2000		0.477
#	Key Outcomes	2004 Actual	FY 2005 Actual	Target	Actual	Target	Actual	FY 2008 Target	FY 2009 Target	Out-Year Target
	erm Goal: Increase the percenta res that have met the target or are				minority-s	specific <i>H</i>	ealthy Peop	<i>le 2010</i> obj	ectives and	l sub-
1.	Increased percentage of measurable racial/ethnic minority-specific <i>Healthy People 2010</i> objectives and sub-objectives that have met the target or are moving in the right direction. (2005 Baseline: 62.4%)		62.4%					NA ^a	NA ^a	68.6%
_	erm Objective: Increase individules in Increase individules ies problems and solutions	ual and pul	blic knowl	edge and u	ınderstan	ding abou	ıt racial/eth	nic minori	ty health ai	nd health
2.	Increased knowledge and understanding of the nature and extent of racial and ethnic health disparities in the general population					49.8%	Expected by 12/08	50.8%	51.8%	
	(1999 Baseline: 47.5%)									

	Annual Efficiency Measure: Increase the average number of persons participating in OMH grant programs per \$1 million in OMH grant support									
3.	Increased average number of persons participating in OMH grant programs per \$1 million in OMH grant support (2006 Baseline: 18,960)				18,960	19,529	19,722	20,313	20,922	
	Appropriated Amount (\$ Million)	\$54.9	\$50.3	\$56.	3	\$5.	3.5	\$48.7	\$42.7	

Notes:

a. Long term measure does not require annual, interim targets.

OFFICE OF MINORITY HEALTH Program Data Chart

Activity	FY 2007 Actual	FY 2008 Enacted	FY 2009 Request
CONTRACTS:	Actual	Enacted	Request
OMH Resource Center	\$3,000,000	\$3,000,000	\$3,300,000
Logistical Support Contract	1,100,000	1,000,000	1,100,000
Center for Linguistic and Cultural	-,,	-,000,000	-,,
Competency in Health Care	1,600,000	1,500,000	1,400,000
Stroke Belt Initiative	250,000	0	0
Other Contracts & IAAs	3,029,000	3,029,000	3,629,000
Subtotal, Contracts	8,979,000	8,529,000	9,429,000
COOPERATIVE AGREEMENTS:			
Morehouse Male Health Project	500,000	900,000	0
HIV/AIDS Coop Agreements	2,300,000	800,000	800,000
Umbrella Cooperative Agreements	2,300,000	2,300,000	2,125,000
Subtotal, Coop Agreements	5,100,000	4,000,000	2,925,000
DEMONSTRATION PROJECTS:			
Bilingual/Bicultural Demonstrations	2,300,000	2,300,000	2,300,000
Health Disparities Program:			
State Partnership Grants	5,900,000	5,900,000	6,000,000
American Indian/Alaska Natives			
Partnership Grants	1,200,000	1,800,000	2,000,000
Community Partnership Grants	6,300,000	6,000,000	6,000,000
Youth Empowerment Program	5,971,000	2,735,000	0
Technical Demonstration Program for			
HIV/AIDS	<u>200,000</u>	<u>0</u>	<u>0</u>
Subtotal, Demonstration Projects	21,671,000	18,735,000	17,657,000
Health Disparities in Mississippi	6,900,000	5,000,000	0
Specified Project – St. Francis Hospital	0	565,000	0
Operating Expenses	10,805,000	11,909,000	12,675,000
TOTAL	\$53,455,000	\$48,738,000	\$42,686,000

OFFICE ON WOMEN'S HEALTH

	FY 2007 <u>Actual</u>	FY 2008 Enacted	FY 2009 Pres. Budget	FY 2009 +/- FY 2008
BA	\$28,219,000	\$31,033,000	\$28,458,000	-\$2,575,000
FTE	42	41	41	
Authorizing Legisla FY 2009 Authorizat Allocation Methods	ion		***************************************	Indefinite

Program Description and Accomplishments

OWH was established in 1991 to improve the health of American women and girls by advancing and coordinating a comprehensive women's health agenda throughout HHS. The program has two goals: 1) development and implementation of Model Programs on Women's Health; and 2) leading Education, Collaboration and Coordination on Women's Health. The program fulfills its mission through competitive contracts and grants to an array of community, academic and other organizations at the national and community levels. National educational campaigns provide information about the important steps women can take to improve and maintain their health. OWH provides Departmental leadership on women's health, while developing partnership opportunities across agencies and with the private sector. This approach maximizes efficiency and minimizes costs. OWH has experienced success in both program goals.

In response to the OMB PART findings, OWH undertook a strategic planning process to define its two major goals: Develop and Evaluate Model Programs on Women's Health; and Lead Education/Collaboration efforts to improve Women's Health. OWH seeks to identify gaps and influence changes in healthcare for women and girls. OWH developed annual and long-term outcome measures, which link to the program's mission and make it possible to measure progress in achieving long-term performance goals.

OWH is also reviewing program evaluation plans and conducting independent, outcome-based evaluations of its program areas to assess OWH's impact on improving women's health. Additional information about the OWH PART may be found on www.ExpectMore.gov.

OWH began implementing the Performance Management System (PERMS) in FY 2007. PERMS is a web-based data collection system that OWH contractors and grantees will use to submit their progress reports electronically to a centralized database. PERMS will collect and store quantitative performance information concerning the participants in OWH funded programs for OWH staff to monitor and report findings. The new PERMS system will enable OWH to monitor overall program performance and results. OWH will use the data collected from contractors and grantees to calculate its annual efficiency measures.

Model Programs on Women's Health

Model Programs on Women's Health focus on developing and replicating the best public health programs in women's health. The newest OWH model program, *Advancing System Improvements to Support Targets for Healthy People 2010* (ASIST 2010) will provide three years of funding to support public health systems and/or collaborative partnerships that emphasis gender-specific approaches to 7 of the 28 Focus Areas of *Healthy People 2010*. Implementing evidence-based programs will help grantees meet performance objectives. In FY 2007, OWH awarded 12 grants and will monitor progress toward grantees reaching the *Healthy People 2010* goals throughout the grant periods. Funding from diabetes and some cardiovascular programs was redirected to the ASIST proposals addressing these areas.

In FY 2008, the OWH will begin a national external evaluation of the ASIST 2010 program. This evaluation will assess the effectiveness of the surveillance system in supporting the operations of the public health system/collaborative partnership, its ability to track changes within the system and the sex and gender focus, examine the ability of different public health systems/collaborative partnerships to effectively deliver sex and gender-based care, and the sustainability of the data collection effort.

In FY 2008, OWH will also fund an initiative to examine the sustainability of its former multidisciplinary models program in an effort to define the process involved in sustaining a program, and to determine what a sustained program looks like. The lessons learned from this evaluation will help Federal agencies determine if it is realistic to ask a program to sustain itself, and if so, provide in their announcements and solicitation guidance the program and/or examples of acceptable sustained programs (best practices/lessons learned).

Three OWH HIV/AIDS prevention model programs completed evaluations in FY 2007 - HIV Prevention in the Rural South, HIV Prevention for Incarcerated/Newly Released Women, and the Model Mentorship Program. Between 1985 and 2005, the proportion of AIDS cases among adolescent and adult women reported in the U.S. increased from 7 to 27 percent. Similarly, African American women account for 62 percent of all new AIDS cases. These prevention programs focus on building awareness of primary and secondary HIV/AIDS prevention, providing support and referral services for those living with HIV/AIDS and building capacity for community-based HIV/AIDS programs. Preliminary results verified that program participants have a high level of trust in the community-based organizations, and their ability to provide meaningful information on women's health and the risks for HIV infection. The evaluation further found that both the Rural South and Newly Released Programs were successful in significantly increasing participants' basic knowledge about HIV/AIDS.

In FY 2008, OWH will pilot a violence against women prevention, education and awareness program that will promote safety and nonviolence on college and university campuses. The initiative is based upon recommendations provided in the *Toolkit To End Violence Against Women* developed by the National Advisory Council on Violence Against Women in 2001.

FY 2007, OWH expanded evaluation efforts to include prevention targeting young women

attending minority academic institutions (HBCUs, HSIs, and TCUs). It has been estimated that half of all new HIV infections in the U. S. are among people under the age of 25. In addition, the OWH is working in partnership with the CDC to develop a gender toolkit for capacity building for community based organizations providing HIV/AIDS prevention education and services targeting women and girls. The gender toolkit is a resource guide for community-based organizations that serve women.

Six OWH funded comprehensive women's heart programs completed evaluations in FY 2007. Significant increases have been found in the percent of women over 40 who know to call 911 at the appearance of symptoms, as well as increases in diabetes education, in high blood pressure control, and in counseling for physical activity and diet. Significant decreases have also been observed in triglyceride levels as a result of OWH interventions. In FY 2008, OWH plans to launch a new women and heart disease initiative targeting physicians and nurses. We have learned that primary care physicians seem to be the least aware of women's heart issues, such that OWH plans to launch a new initiative in FY 2008-2010 to encourage medical and nursing organizations to educate and encourage health care professionals to learn about these issues and successful interventions through the dissemination of the *Heart Truth* Provider education CME, case-studies, and slide presentations.

Education/Collaboration/Coordination on Women's Health

The second OWH goal concentrates on leading Women's Health Education, Collaboration, and Coordination with three major constituencies: health organizations, health care professionals, and the public (women). OWH has strengthened HHS prevention efforts by communicating strategically to the public and health care professionals and providing prevention information tailored to women and girls.

OWH maintains the National Women's Health Information Center (NWHIC), which provides health information and referrals to consumers of health care services, health professionals, researchers, educators, and students. NWHIC had a total of 26,083,677 user sessions to the womenshealth.gov website and 1,697,813 user sessions to the girlshealth.gov website from January 1 – December 31, 2007. Additionally, for this same period there were over 30,580 phone calls, an increase of 5,000 calls over those received in 2006. For all of 2006, NWHIC had more than 32 million users to the website and more than 2 million users to the girls' health site, an increase of 62 percent and 61 percent, respectively, over previous year results.

OWH's <u>www.girlshealth.gov</u> website is the #1 Google return when searching on "girls health." The site was recently rated as one of the top ten teen health websites by the "Voice of Youth Advocates" publication. The site motivates girls ages 10-16 to choose healthy behaviors by providing information on fitness, nutrition, stress management, relationships with friends and family, peer pressure, suicide, drugs, and self-esteem.

The *BodyWorks* toolkit for the prevention of obesity focuses on the family as the most important environment to prevent obesity in girls and the rest of the family. The toolkit helps parents and caregivers of young adolescent girls (ages 9-13) improve family eating and activity habits. Evaluation of the program will be completed in FY 2008. Preliminary responses of trainers and

families have been enthusiastic; currently there are over 1600 trainers and 800 families throughout the country who have participated in the program. The Spanish version of the *BodyWorks* toolkit will be released in the Summer of 2008. In addition, OWH awarded a contract to develop culturally appropriate materials for low literacy and economically disadvantaged parents to enhance their communication on important life skills with their teen daughters. OWH will integrate the *Powerful Bones, Powerful Girls* (PBPG) osteoporosis prevention campaign into its adolescent girls' programming to improve efficiency and reduce redundancy. OWH resumed leadership of the PBPG campaign in FY 2007 from CDC, which had been supported by OWH funding. OWH awarded a new contract to continue the PBPG work and address other girl/adolescent health needs.

Quick Health Data Online is a dynamic and comprehensive database containing about 2000 data elements from 1988-2005. National, regional, state, and county data is stratified by gender, race/ethnicity, and age concurrently. Database elements include demographics, mortality, access to care, infectious and chronic disease, reproductive health, maternal health, mental health, violence and abuse. User sessions average 6000 per month. OWH modified and expanded this data warehouse in FY 2007 and updates the data annually. In FY 2008, an update of the Women's Health and Mortality Chartbook will appear on the website, showing states' ranking on 25 key health indicators.

OWH contributes to, and expects to continue, several nationwide women's heart health initiatives. Recent data show that the percentage of women who know that heart disease is the number one killer has doubled in the last 6 years. As a founding sponsor (with the National Institutes of Health's National Heart, Lung, and Blood Institute) of the Heart Truth Campaign, OWH is disseminating health professional educational modules on the science behind the campaign's messages. OWH also supports the Heart Truth Champions program in several cities to deliver the education messages. In addition, OWH supports the *Sister to Sister Everyone Has a Heart* Foundation's annual Women's Heart Day Campaign every February.

Building on the success of the 2006 National Women's Health Week (NWHW), OWH led HHS' planning for the May 2007 event. More than 1,100 events and outreach activities occurred in all 50 states and some territories, and about 100 proclamations were issued. On this day, hundreds of health care providers around the country offered preventive screenings for free or at reduced rates. OWH also conducted the WOMAN (Women and girls Out Moving Across the Nation) Challenge. Over 42,000 women signed up to increase their physical activity to recommended levels, and the Surgeon General's radio interviews generated over 18 million audience impressions.

In FY 2007, OWH contracted with the Advertising Council to develop a National Lupus Awareness Campaign, whose purpose is to increase awareness and understanding of the symptoms and health effects of lupus among young minority women. As this disease is often misdiagnosed, the campaign will educate the community and asset in galvanizing young women to seek medical evaluation. By increasing awareness on the symptoms of lupus, women are more likely to seek medical evaluation that leads to early diagnosis.

In FY 2007, OWH collaborated with HRSA to continue the National Breastfeeding Initiative by

co-funding the National Workplace Lactation Program.

The National Breastfeeding Initiative program will continue through FY 2008 and into FY 2009. The goal of the program is to increase support to sustain breastfeeding for six months by women who return to work. Ten State Breastfeeding Coalitions were selected for training and implementation of the program in FY 2008. The new *Business Case for Breastfeeding Kit* is approved for release in February 2008.

Based on the initial intensive work conducted to develop the OWH Lupus Awareness Campaign, OWH and the Ad Council will continue to provide message testing, development of radio, newspaper and magazine ads, and evaluation of outcomes of the preliminary consumer response to the campaign. In FY 2008, the campaign will be revised accordingly and evaluated through FY 2009.

Funding History

FY 2004	\$28,707,000
FY 2005	\$28,641,000
FY 2006	\$28,205,000
FY 2007	\$28,219,000
FY 2008	\$31,033,000

Budget Request

The FY 2009 Request for the Office on Women's Health (OWH) is \$28,458,000, a decrease of \$2,575,000 below the FY 2008 enacted level. At this level of funding, OWH will support salary increases, and maintain programs at the FY 2008 level. Some of the programs funded in 2008 were targeted for one-year funding only. The program data chart submitted below provides a display of activities to be supported.

Model Programs on Women's Health

In FY 2009, OWH plans to broaden the Women and Mental Health initiative to include depression, trauma, and other challenges to women's mental health. Assessment/evaluation and revision of the anticipated *Mental Health Report*, and consumer companion booklet, *Women's Mental Health: What It Means to You*, will be implemented in FY 2008. Likewise, a release and evaluation project has been established for a Spanish version of the booklet, and a similar booklet targeted for girls and young women.

Education/Collaboration/Coordination on Women's Health

In FY 2009, OWH will convene a State and Territorial Women's Health Conference. The goal is to: 1) examine indicators of state performance on women's health issues to identify priorities and measure success; 2) coordinate women's health policies across state programs; and 3) sustain the focus on women's health issues. States will have an opportunity to examine a number of different measurement tools, draw upon state experiences in implementing collaborative

approaches across agencies and private/public sector organizations to improve women's health; and examine leadership and social marketing strategies that can work to promote the importance of women's health issues from the state perspective.

In FY 2009, OWH is planning a new *Violence Against Women* initiative that will target adolescent relationship violence. This effort will build on a joint HHS-Department of Justice (DOJ) FY 2008 invitational meeting to explore research outcomes and programmatic needs.

The National Breastfeeding Initiative program will continue through FY 2009. The goal of the program is to increase support to sustain breastfeeding for six months by women who return to work. Fifteen State Breastfeeding Coalitions will be selected for FY 2009, and 15 more states will be selected for FY 2010.

Office on Women's Health Outcome Data

		FY	FY	FY 2	006	F	Y 2007	EW 2000	ET 2000	Out-
#	Key Outcomes	2004 Actual	2005 Actual	Target	Actual	Target	Actual	FY 2008 Target	FY 2009 Target	Year Target
Long	-Term Objective: Advance super	ior health out	comes for v	vomen						
1	Increase the percentage of women-specific Healthy People 2010 objectives and sub-objectives that have met their target or are moving in the right direction.		Baseline Interim Measure 64.3% (200/311)	N/A	N/A	67.5% (210/311)	69.5% (235/338)	71.0% (240/338)	72.5% (245/338)	74.0% (250/338)
Long	Long-Term Objective: Increase heart attack awareness in women									
2	Increase the percentage of women who are aware of the early warning symptoms and signs of a heart attack and the importance of accessing rapid emergency care by calling 911.		Baseline 54.5% of women	N/A	N/A	60.0%	65.8%	70.0%	75.0%	80.0%

				FY 2006		FY 2007		FY 2008	FY 2009	Out-
#	Key Outputs	FY 2004 Actual	FY 2005 Actual	Target/ Est.	Actual	Target/ Est.	Actual	Target/ Est.	Target/ Est.	Year Target/ Est.
Long-	Term Objective: Expand the	number of users	of OWH con	nmunication	resources					
3	Number of users of OWH communication resources (e.g., National Women's Health Information Center; womenshealth.gov website; and girlshealth.gov website).			Baseline	21.5m sessions	24.5m sessions	28.4m sessions	31.5m sessions	34.5m sessions	37.5m sessions
Efficie	Efficiency Measure: Increase the number of people that participate in OWH-funded programs per million dollars spent annually									
4	Number of girls ages 9-17 and women ages 18-85+ that participate in OWH- funded programs (e.g., information sessions, web sites, and outreach) per million dollars spent annually.			Baseline	760,658	813,904	1,006,245	1,114,453	1,220,591	1,326,729
	Appropriated Amount (\$ Million)	\$28.7	\$28.6	\$28	3.2	\$2	8.2	\$31.0	\$28.5	

Office on Women's Health Program Data

Activity	FY 2007 Actual	FY 2008 Enacted	FY 2009 Estimate
ASIST 2010	4,000,000	5,134,791	4,650,000
Sustainability of Federal Programs	0	500,000	0
Adolescent Health & Osteoporosis	2,425,000	2,425,000	2,425,000
Cardiovascular Disease Programs	1,300,000	1,050,000	1,300,000
Workplace Breastfeeding	0	300,000	250,000
Quick Health Data	410,000	411,000	410,000
Diabetes and Women	600,000	0	0
Mental Health	400,000	400,000	400,000
Regional Women's Master Contract	0	1,000,000	0
Concept Mapping/Analysis - 2010	0	300,000	0
SG's Conference on Pre-Term Birth	0	125,000	0
HIV/AIDS in Minority Communities	1,340,000	1,872,000	1,340,000
Lupus	855,000	608,711	855,000
Minority Women's Health	175,000	175,000	175,000
Violence Against Women	525,000	625,000	625,000
Nat'l Women's Hlth Info Center	3,200,000	3,200,000	3,200,000
Print Materials (incl mini calendars)	250,000	1,000,000	600,000
Communications Outreach	300,000	300,000	300,000
National Women's Health Week	250,000	250,000	250,000
2008 Woman Challenge	0	116,400	0
IOM Congressional Earmark	0	983,000	0
Co-sponsorships (incls IAAs & others)	500,000	500,000	500,000
Meeting Logistics Contract	0	500,000	0
Operating Expenses	11,689,000	9,257,098	11,178,000
TOTAL	\$28,219,000	\$31,033,000	\$28,458,000

OFFICE FOR HUMAN RESEARCH PROTECTIONS

	FY 2007 Actual	FY 2008 Enacted	FY 2009 Pres. Budget	FY 2009 +/- <u>FY 2008</u>
BA	\$6,897,000	\$6,701,000	\$6,761,000	+\$60,000
FTE	33	32	32	
Authorizing Legislation FY 2009 Authorization			•••••	Indefinite
Allocation Method			Direct federal, Co	ontracts, and Other

Program Description and Accomplishments

The Office for Human Research Protections (OHRP) was created in June 2000 in order to fulfill the Department of Health and Human Services (HHS) responsibilities set forth in the Public Health Service Act. OHRP supports, strengthens and provides leadership to the nation's system for protecting volunteers in research that is conducted or supported by the HHS. OHRP provides clarification and guidance to research institutions, develops educational programs and materials, and promotes innovative approaches to enhancing human subject protections. To carry out their research mission, nearly 10,000 universities, hospitals, and other research institutions in the U.S. and abroad have formal agreements ("assurances") with OHRP to comply with the regulations pertaining to human subject protections. OHRP organized into three functional Divisions and headed by the Office of the Director (OD). Each Division contributes to these responsibilities in numerous ways.

The following narrative provides a brief description of each organizational component and some of OHRP's recent accomplishments and future expectations.

Office of the Director (OD) – The OD supervises and manages the development and promulgation of policies, procedures, and plans for meeting the responsibilities set forth above and the activities of the Divisions as described below. Specific responsibilities and accomplishments include:

- Serve as Executive Secretary of Secretary's Advisory Committee on Human Research Protections (SACHRP) and co-chair of Human Subject Research Subcommittee of the National Science and Technology's Committee on Science. In FY 2007, the OD:
 - o Supported three SACHRP meetings
 - o Organized the start-up of a new subcommittee and five meetings
 - o Led six meetings of the Human Subjects Research Subcommittee, Committee on Science, National Science and Technology Council
- Manage its International Activities Program which provides leadership for HHS in
 the global effort to improve human research protections through developing policies,
 procedures and practices for the monitoring and protection of human research
 participants in studies conducted outside the US, and to enhance the global capacity
 for protecting human research participants. In FY 2007 the OD participated in

- several international meetings designed to expand technical support for human subjects protection programs in developing countries and enhance international capacity for ethical review of human subjects research. This activity is expected to increase significantly in FY 2008.
- Coordinate responses to requests for OHRP documents and information under the Freedom of Information Act.

Division of Policy and Assurances (DPA) – DPA prepares policies and guidance documents and interpretations of requirements for human subject protections and disseminates this information to the research community. The Division also administers the assurances of compliance. Specific responsibilities and accomplishments include:

- Maintains, develops, promulgates, and updates policy and guidance documents regarding regulatory requirements and ethical issues for biomedical and behavioral research involving human subjects. DPA also coordinates appropriate HHS regulations, policies and procedures with other Departments and agencies in the Federal government, organizes and coordinates consultations with panels of experts for certain research involving pregnant women, fetuses, and neonates; prisoners; and, children, when required by HHS regulations for the protection of human subjects at 45 CFR 46.207, 46.306 and 46.407, respectively. DPA coordinates responses to requests for information, technical assistance, and guidance from Congress, other HHS agencies, other Federal agencies, and non-governmental entities.
- Negotiates Assurances of Compliance with research entities; registers Institutional Review Boards (IRBs); provides liaison, guidance, and regulatory interpretation to research entities, investigators, Federal officials, and the public; maintains and modifies, as necessary, existing assurance mechanisms; operates and maintains a registration system for institutional review boards; provides technical support to SACHRP and its subcommittees; reviews and approves certifications for HHSconducted or –supported research involving prisoners; develops Federal Register notices, including notices related to the issuance of OHRP guidance, requests for information, advance notices of proposed rulemaking (ANPRM), notices of proposed rulemaking (NPRM), and final rules; prepares submissions to the Office of Management and Budget (OMB) for forms that need to be approved by OMB under the Paperwork Reduction Act; and develops and implements new procedures to ensure that HHS' human subjects protection regulations are appropriately and effectively applied to the changing needs of the research community. In FY 2007, DPA:
 - - o Issued one Federal Register notice related to issuance of guidance. In FY 2008, DPA plans to issue up to four notices related to issuance of guidance and one ANPRM.
 - o Took action on more than 100 prisoner certification requests and expects this level to be sustained in FY 2008.
 - o Created, renewed or updated 4,604 Assurances of Compliance, and 2,822 IRB registrations. DPA expects to process the same volume of Assurances and IRB registrations in FY 2008.

Division of Compliance Oversight (DCO) – DCO evaluates all written substantive indications of non-compliance with HHS regulations—title 45, Part 46, Code of Federal Regulations (45

CFR part 46). Specific responsibilities and accomplishments include:

- Conducts inquiries and investigations into alleged non-compliance with the HHS regulations for the protection of human subjects. These activities include conducting and preparing investigative reports, and recommending remedial or corrective action as necessary. In FY 2007, DCO opened 15 new compliance oversight investigations and closed 19 compliance oversight investigations. So far in FY 2008, DCO has opened three new compliance oversight investigations and closed two compliance oversight investigations. OHRP has maintained the volume of open compliance oversight investigations to about 20.
- Conducts a program of not-for-cause surveillance evaluations of institutions. This
 program provides an important complement to the performance-based quality
 improvement programs described below. In FY 2007, DCO conducted four not-forcause compliance oversight evaluations. DCO has conducted one not-for-cause
 compliance oversight evaluation so far in FY 2008, and will do three more.
- Receives, reviews, and responds to incident reports from Assured institutions. These
 reports include reports of suspensions or terminations of institutional review board
 (IRB) approval of research, serious or continuing non-compliance, and unanticipated
 problems involving risks to subjects or others. In FY 2007, DCO reviewed and
 closed about 741 incident reports. DCO has so far reviewed and closed about 270
 incident reports in FY 2008.

Division of Education and Development (DED) – Universally, education is recognized as one of the most important elements in improving protections for human research subjects. DED provides guidance to individuals and institutions conducting HHS-supported human subject research; conducts national and regional conferences; participates in professional, academic, and association conferences; and develops and distributes resource materials in an effort to improve protections for human research subjects. OHRP also helps institutions assess and improve their human research protection programs through quality improvement consultations. Specific responsibilities and accomplishments include:

- Develops and conducts education conferences, gives presentations, develops other training tools, and carries out quality improvement activities to help ensure human research subjects protections. In FY07, DED:
 - o Gave approximately 100 presentations
 - o Conducted eight regional one-day QA workshops for institutions with a FWA utilizing an internal IRB, as part of the OHRP quality improvement program,
 - o Initiated half-day regional QA workshops for institutions with a FWA utilizing only an external IRB, and conducted two of these half-day programs
- Provides liaison to Federal officials and guidance and regulatory interpretation to research entities, investigators, and the public regarding ethical issues in biomedical and social/behavioral research involving human subjects.
- Provides technical assistance to institutions engaged in HHS-conducted or sponsored research involving human subjects; maintains, promulgates, and updates educational guidance materials related to protection of human research subjects; and conducts public outreach and education or information programs to promote and enhance public awareness of the activities of OHRP and human subject protections. In FY 2007, OHRP began to produce on-line training modules for posting on the OHRP website and is

working to further develop and refine these modules prior to posting in FY 2008. These modules will provide a free educational resource to all members of the research community. In addition, in FY 2007 OHRP began distribution of its tri-fold public education pamphlet for Hispanic audiences via the OHRP website and in hard copy; requests and distribution of this very popular pamphlet in FY 2008 remain strong. These pamphlets provide potential volunteers in communities under-represented in research with guidelines to aid in their consideration of participation in research. In FY 2008, OHRP will continue with the second phase of the education evaluation project, the collection and analysis of data from a statistically significant number of institutions, and initiate an evaluation project to assess the impact of the public education pamphlet initially distributed in FY 2005.

• DED provides staff support to the Human Subjects Research Subcommittee, Committee on Science, National Science and Technology Council.

The activities of OHRP contribute directly to Goal 4 of the HHS Strategic Plan, which is to *Advance scientific and biomedical research and development related to health and human services.* Scientific and biomedical research will only continue so long as the rights and welfare of human subjects in scientific and biomedical research are protected, so that people continue to trust the research community and agree to participate in research in sufficient numbers. Advancing scientific and biomedical research in turn supports Goals 1, 2, and 3 of the HHS Strategic Plan, since the findings of scientific and biomedical research enable us to improve health care (Goal 1), prevent or control medical conditions and protect public health (Goal 2), and promote the economic and social well-being of individuals, families, and communities (Goal 3).

OHRP supports the OPHS/HHS strategic goals by contributing to the following measures:

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

Funding History

FY 2004	\$7,275,000
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FY 2005	\$7,380,000
FY 2006	\$6,921,000
FY 2007	\$6,897,000
FY 2008	\$6,701,000

Budget Request

The FY 2009 Request for OHRP is \$6,761,000; an increase of \$60,000 above the FY 2008 enacted level. A large majority of these funds are used to pay the salary and benefits of the office personnel, and to support the operations of the office. OHRP expects the number of personnel to remain constant through FY 2009. A small part of the budget is used to support program activities, including the maintenance of an electronic database system for assurances and IRB registration, costs associated with its advisory committee meetings, seed money for collaboration with other institutions co-sponsoring regional fora, and travel costs associated with educational events, public outreach and leadership activities, and compliance oversight evaluations. At this level, OHRP expects to maintain its current level of policy and assurance activities, compliance oversight activities, and educational activities. OHRP expects to realize increased efficiencies that will result from an enhanced electronic submission system for FWAs and IRB registrations. OHRP will not increase the level of activity with respect to SACHRP and HSRS in FY 2009, but does expect a significant increase in the International Activities Program related to making determinations of equivalent protections for institutions in foreign countries that conduct HHS-funded human subjects research.

Office of the Director (OD): In FY 2009, the OD will support two SACHRP meetings and approximately four SACHRP subcommittee meetings. The OD will also lead six HSRS meetings. In FY 2009, the OD expects a significant increase in the International Activities Program related to making determinations of equivalent protections for institutions in foreign countries that conduct HHS-funded human subjects research.

Division of Policy and Assurances (DPA): In FY 2009, DPA plans to develop up to four guidance documents, as well as issue up to four *Federal Register* notices related to guidance. DPA expects that the attained level of 100 prisoner certification requests will continue into FY 2009, as will the same volume of Assurances of Compliance (4,604) and IRB registrations (2,822).

Division of Compliance Oversight (DCO): In FY 2009 DCO anticipates maintaining the number of not-for-cause compliance oversight evaluations as performed in prior years, including the international area, at four per year.

Division of Education and Development (DED): In FY 2009, OHRP will strive to continue its education and quality improvement program. DED plans to give approximately 100 presentations at various meetings; conduct three regional fora; and conduct eight QA workshops. These QA workshops provide attendees with the necessary information to assess their institution's human subjects protection program and offer tools to facilitate improvement.

COMMISSIONED CORPS TRANSFORMATION, READINESS AND TRAINING

	FY 2007	FY 2008	FY 2009	FY 2009
	<u>Actual</u>	Enacted	<u>PB</u>	<u>+/- FY 2008</u>
BA	\$9,926,000	\$4,119,000	\$30,159,000	+\$26,040,000
FTE	23	23	140	+117

Program Description and Accomplishments

This item supports the transformation the Commissioned Corps, and Readiness and Response activities.

Transformation: To protect the health and safety of the American people, the Secretary has decided to transform the US Public Health Service Commissioned Corps into a force that is ready to respond rapidly to the most dramatic public health challenges and health care crises that can result from natural disasters (including infectious disease epidemics), technological catastrophes, terrorist attacks, and other extraordinary needs. In its day-to-day role, the Corps will remain an essential national resource within HHS to meet critical mission requirements and to address health care needs in isolated, hardship, hazardous, and other hard-to-fill positions. This funding request identifies and describes the necessary force management and operational activities required to assure that the Corps can meet the Department's critical clinical and public health missions for the nation.

To be successful, transformation must create and maintain systems whereby the Commissioned Corps can readily support the critical missions of the Department. One of the key Corps missions is to provide public health and clinical services to underserved populations. Positions that have been established to fill that mission are historically difficult to fill, involve significant hardship for the incumbent and his/her family, are in remote/isolated locations and/or are those that subject the officers to hazardous working conditions.

The new recruitment, assignment, classification, training and career development systems are beginning to enable the Corps to rapidly identify specific position needs, target recruitment accordingly, rapidly assign officers for 2-4 year tours to address these needs, develop the functional skills of the officers, provide personal and professional support to them while in those positions and rotate them out to new assignments through the continued targeted recruitment of replacement officers. In addition, to encourage officers to accept assignments in historically hard-to-fill duty stations and isolated/ hardship areas, the Transformation Team has created incentive packages that will help offset the

difficulties encountered with these assignments. Assignment Incentive Pay may be provided to officers who accept multi-year assignments at a hard-to-fill duty station. Additionally, through Transformation, the Corps is examining programs that will provide assistance to dependents for childcare, employment and relocation.

A robust, flexible and efficient IT system is key to supporting the broad range of Transformation activities. Throughout FY 2007 and FY 2008, the Corps has worked closely with the US Coast Guard to form a partnership that will result in the consolidation of three Uniformed Services personnel systems into a single system maintained by the Coast Guard. The personnel system, Direct Access, is PeopleSoft based and has been operational for more than seven years, processing Coast Guard personnel actions for more than 50,000 service members. The advantages of moving to the Direct Access system are: 1) consolidation of multiple Department's personnel management systems, 2) annual cost savings to the Corps, 3) retirement of archaic and inefficient IT systems currently used by the Corps and 4) migration to a PeopleSoft-based system that has a proven track record of effective and efficient personnel management in the Uniformed Services environment.

An effective IT support system will enhance the Corps' ability to develop a consistent and equitable billet (position description) system in support of the Corps workforce. Each professional category has established standard billet templates that describe the duties and responsibilities of each of the ~6000 billets encumbered by Corps officers. Eventually, each position that could be filled by a Corps officer will have a unique billet associated with it. These billets will be included in the Direct Access system and will be used to effectively manage the force. In FY 2008, the standard billets are being converted to a web-based system that allows each officer on extended active duty to complete his/her billet description for inclusion in the Direct Access system.

Training activities are also critical in order to foster career identity and growth for Corps officers as well as improve retention in the Corps workforce. In FY 2007, the Corps launched the mandatory 2-week PHS Officer Basic Course. It is required of all officers who are newly called to active duty and stresses the characteristics of Uniformed Services personnel, the culture of our Corps and the mission of the Service and the agencies in which officers serve. Over 150 newly commissioned officers have successfully taken the course as of December 2007, and it has received a very positive assessment by an independent evaluation panel. Planning has begun for the PHS Officer Intermediate Course (the second in the training continuum) that will be offered in FY 2008 to 25-50 officers who are rising to positions of greater responsibility and assuming supervisory roles. This course will stress leadership within both the agency and deployment settings.

Readiness and Response: The Department is required to mount robust responses to public health emergencies. The Office of Force Readiness and Deployment (OFRD), a division in the Office of the Surgeon General that manages the Commissioned Corps Readiness and Response Program, was established to improve HHS' ability to respond to urgent public health needs. All Commissioned Corps officers are considered deployable assets and must meet requirements for physical fitness, height and weight standards, immunizations, basic life support certification, and the completion of training related to emergency response and humanitarian assistance.

The mission of the Commissioned Corps Readiness and Response Program is to provide a timely, appropriate, and effective response by U.S. Public Health Service officers to:

- public health and medical emergencies,
- urgent public health needs and challenges, and
- National Special Security Events.

To carry out this mission, OFRD functions to ensure that 1) individual Corps officers are appropriately trained and ready to deploy, and 2) the Corps deploys the appropriate team or individual(s) in a timely, appropriate, and effective manner.

As a result of the Katrina Lessons Learned report, the revitalized Corps will consist of an organized, tiered response structure. The teams and the magnitude of the response will be tailored to the severity of the event and the specialties required.

	Arrival On	
Team	Scene	Deployment Duration
Health and Medical Response (HAMR)	<12 Hours	Duration of Response
Rapid Deployment Force (RDF) (Corps Tier 1)	<24 Hours	14-30 days
Applied Public Health Teams (APHT) (Corps Tier 2)	<48 hours	14 days
Mental Health Team (MHT) (Corps Tier 2)	<48 Hours	14 days
Corps Augmentation Staff (Corps Tier 3)	<72 hours	14 days

The first Corps responders will be members of the Health and Medical Response (HAMR) teams. They can remain on site for the duration of the Federal public health and medical response. These officers are not assigned to any of the OPDIVs or STAFFDIVs of the Department; consequently, their deployment will not draw down on agency resources. They will be highly trained and prepared to respond to a wide array of public health emergencies from routine staff enhancement requests to weapons of mass destruction events. The HAMR teams will be responsible for the majority of Corps responses; as a result, the burden on OPDIVs and STAFFDIVs caused by the depletion of resources due to deployments will be significantly lessened.

In larger responses that will require officers from the Department's OPDIVs, the Corps has organized and trained five Rapid Deployment Force (RDF) teams that can respond within 24 hours of an event. The officers on each of these teams train and deploy together as a cohesive unit. Additionally, five specialized teams of Applied Public

Health professionals will deploy to affected communities to provide basic public health functions such as infrastructure assessments, vector control, food and water sanitation and environmental health in the wake of a complex disaster. When the situation on the ground warrants, teams of mental health professionals will be deployed to provide clinical services to the affected populations and to responders. Each of these Tier 1 and Tier 2 teams will be augmented by officers from the remainder of the Corps who all meet readiness standards and comprise Tier 3. A limited number of officers whose duties are deemed by the Agency Head to be critical to achieving the agency's mission will be exempt from deployment.

Performance: A PART review of the Commissioned Corps Readiness and Response was conducted, and received a score of adequate. Prior PART analysis acknowledged that each deployment should be to a relevant, clearly defined, and address an unmet need, and performance measures must be developed to reflect the Corps transformation from an individual-centric deployment to a team-focused deployment. This year, team evaluation tools were developed to more accurately measure the timeliness, appropriateness, and effectiveness of individual and team responses. Additional information about the Corps Readiness and Response PART may be found on www.ExpectMore.gov.

Performance goals, measures and targets have been established within the Corps to also assure that progress is made in achieving the sizing and operational goals established by the Secretary. These goals define the staffing requirements for the Corps for its readiness, public health, isolated/ hardship and other clinical requirements, as well as its management, research, and other functions. The established performance goals have already facilitated the following:

- The development of training curricula and the conducting of Tier 1 and Tier 2 Response Team Field Training during five separate week-long sessions at Camp Bullis, in San Antonio, TX.
- Collaborative arrangements with a broad variety of federal and private partners to obtain readiness training at no-cost or low-cost.
- As communicated by Federal, state, and local entities, increased effectiveness of Corps officers in meeting the public health needs of populations impacted by disasters and other urgent public health challenges.
- For the past three years, OFRD has successfully and dramatically increased the readiness numbers and standards of Corps officers to match performance. In FY 2007, the percent of officers meeting readiness standards exceeded the target.
- The establishment, following the issuance of the White House Katrina Lessons Learned Report and the Report from the Office of the Inspector General of response teams that are pre-identified, rostered, trained, and equipped. These performance measures are based on team responses rather than the readiness and deployment of individuals.

As a result of this shift in focus, active duty Commissioned Corps officers can be deployed within hours either as individuals or as purpose-specific strike teams. In the event of a national or international health emergency, the OFRD response can be

delivered by pre-identified, trained, and equipped response teams; or it can be "customtailored" in that officers who have a wide variety of professional training and experience (e.g., clinical, environmental, regulatory, research) are selected and aggregated as needed. Officers can respond to large scale emergencies and incidents of national significance such as the over 2600 officers deployed to Hurricanes Katrina, Rita and Wilma serving on over 50 separate missions. Officers are also utilized in the context of pre-positioned teams for high-profile mass gatherings, such as the Ford State Funeral, National Political Conventions, Group of Eight Summits, International Monetary Fund meetings, or Presidential Inaugurations; special population needs, such as investigating lead in the blood of small children in Washington, DC; humanitarian assistance, such as for Indonesia after the December 2004 tsunami and the March 2005 earthquake; Presidential or Secretarial health diplomacy missions such as those taking place aboard US Navy ships in the Caribbean and the Pacific during the summer of 2007 and planned for 2008; support for urgent public health needs, such as augmenting the Indian Health Service in remote, isolated sites; and supporting DoD in time of conflict, such as providing officers to rapidly provide readiness support, including dental care and medical clearance for deploying Marines during the Iraq war.

Funding History

FY 2004	\$4,216,000
FY 2005	\$4,177,000
FY 2006	\$4,155,000
FY 2007	\$9,926,000
FY 2008	\$4,119,000

Budget Request

The FY 2009 request is \$30,159,000, an increase of \$26,040,000 above the FY 2008 enacted level. This budget provides funds to support a number of Commissioned Corps initiatives.

Transformation: The FY 2009 request of \$7,690,000, an increase of \$4,764,000 above the FY 2008 enacted level, continues the implementation of the Commissioned Corps transformation. Recruitment must be strengthened to attract those with the best clinical and public health skills; appointment practices must be modernized; selection, assignment and deployment systems need to be made more efficient; training and career development must be strengthened in order to promote officer retention; and the Corps' IT systems need to be modernized. At this funding level, contracts that support transformation efforts will be awarded and funds will support mandatory pay increases for staff supporting transformation activities. Specific activities include:

• The first system(s) will begin migrating to the Coast Guard in the spring 2008 with the majority of the migrations taking place throughout FY 2009. Prior to the migration of the systems and data, the data must be formatted properly to be interpreted by the Direct Access system. Furthermore, the secure transfer of data

- must be ensured. Additionally, once the data have been migrated, the functionality of the system(s) must be independently verified and validated.
- All relevant personnel data will be warehoused on Coast Guard servers or secure interfaces between HHS data warehouses and the Direct Access system will have to be established. The Corps will be required to contribute to the maintenance fees for the Direct Access system and to the Coast Guard's System Development Life Cycle (SDLC). Additionally, in order to coordinate the management of the Corps' personnel data and activities at the Coast Guard, two Corps officers will be detailed to the Coast Guard Headquarters.
- The functional requirements and content of the various personnel systems are being determined. Throughout FY 2008 and FY 2009, IT systems we will be developed systems that will support the following personnel management activities:
 - a. Billets
 - b. Officer Profiles
 - c. Assignments
 - d. Training and Career Development
 - e. Recruitment and Officer Selection
 - f. Position Classification

Those systems not developed in FY 2008 will be developed throughout FY 2009. Inherent in the development process is the requirement that existing data be formatted in order to be properly interpreted by the Direct Access system.

- Ongoing support of the Corps' recruitment activities will be provided through a contractor. This same contractor will be required to maintain the content and functionality of the Corps' website.
- On the continuum of leadership training expected of officers, the Officer Advanced Course (OAC) and Office Executive Course (OEC) are the Corpssponsored classes focused at officers who will assume senior leadership positions, including those encumbered by Flag-grade officers. Funds will support the development of course materials, training of instructors, contracting for instructional space and initial offering of the course to 25 senior officers with demonstrated ability to serve as senior leaders in the Corps and the Department. In addition, each year members of the Inactive Reserve Corps are called to active duty for short tours in order to participate in the Basic Officer Training Course (BOTC). In the event of a national emergency or to backfill for officers who are deployed from their duty station, Inactive Reserve Officers are called upon to fill critical roles. Training is essential to their seamless integration into the deployment teams and working in the uniformed service environment.

Readiness and Response: The growth in the Office of Force Readiness and Deployment (OFRD) staffing and the creation of Health and Medical Response (HAMR) Teams were the result Recommendation 60 from the White House's Katrina Lessons Learned Report, which recommended that HHS create a dedicated, full-time response team of Commissioned Corps officers. Further, Section 206 of the Pandemic and All-Hazards

Preparedness Act (PAHPA) directs the Secretary to train, equip and organize members of the Corps into units for rapid deployment to respond to urgent or emergency public health care needs.

- The FY 2009 request for OFRD is \$1,935,000, an increase of \$742,000 above the FY 2008 enacted level, supports the salary and benefits of the current eight positions that are involved in program management and oversight; training development and coordination; response coordination; information technology development and maintenance, and the contracted support for the learning management system (necessary to provide ongoing web-based readiness training for all 6,000 Commissioned Officers). Furthermore, funding will support two additional staff in FY 2009, as well as other increased overhead and pay costs.
 - These additional personnel are essential for enabling OFRD to coordinate and support the Secretary's Priority for Health Diplomacy and specifically to support the Secretary's Initiative for Health Diplomacy in Latin America. In FY 2008 alone, OFRD has been asked to support humanitarian assistance activities including missions aboard USS Boxer (Western Central America), USS Kearsarge (Eastern Central America/Caribbean), USNS Mercy (Pacific Partnership), and 40+ Medical Readiness Training Exercises (MEDRETEs). These missions will increase in number and duration in FY 2009.
 - o These staff will include a senior International Response Coordinator and Program Staff Officer. These staff will also take the lead in supporting the Deputy Secretary's International Concept of Operations Developmental Task Force.
- The FY 2009 request also includes \$20,534,000 for the establishment of two HAMR teams. Each team consists of 105 officers, for a total of 210 members. The HAMR teams are a direct result of recommendations from the White House Katrina Lessons Learned Report (KLL) and PAHPA. The HAMR Teams will have four primary duties:
 - deploy to domestic and international responses as required by the Secretary;
 - o train to deploy;
 - train other Corps officers and Medical Reserve Corps members to deploy;
 and
 - o maintain their clinical and public health skills by working in underserved and/or hard-to-fill assignments.

Both the KLL and the PAHPA legislation emphasized the requirement of properly equipping the Commissioned Corps response teams. This request will provide funding for the response team equipment, including HAMR team caches, response team go-bags, APHT team cache updates, and communications support.

In addition, the KLL report and the PAHPA legislation emphasized the requirement of appropriate training for the Commissioned Corps response teams.

Funds are requested for necessary and essential training for both the HAMR teams as well as integrated training for the tiered response teams. These training activities are designed specifically to address the National Planning Scenarios as directed by the Assistant Secretary for Preparedness and Response. This training will include, leadership training; Medical Management of Chemical and Biological Casualties and Medical Effects of Ionizing Radiation training; field training (including international field training); and quarantine Station TSE/HHS training and exercise.

Outcome Data

		FY	TT. 2005	FY 2	006	FY	FY 2007	EW 2000	FY	Out-
#	Key Outcomes	2004 Actual	FY 2005 Actual	Target	Actual	Target	Actual	FY 2008 Target	2009 Target	Year Target
Lor	Long-Term Objective: Increase the size and operational capability of the Commissioned Corps.									
3	Increase the percent of individual responses that meet timeliness, appropriateness, and effectiveness requirements. (Baseline - 2007: 77%)	NA	NA	NA	NA	NA	77%	a	a	a
4	Increase the percent of team responses that meet timeliness, appropriateness, and effectiveness requirements. (Baseline - 2007: 89%)	NA	NA	NA	NA	NA	89%	a	a	a
#		FY	EX 2005	FY	2006	FY	2007	EX. 2000	FY	O-4 V
_	Key Outputs	2004 Actual	FY 2005 Actual	Target	Actual	Target	Actual	FY 2008 Target	2009 Target	Out-Year Target
Lor	ng-Term Objective: Increase the	e size and op	erational caj	pability of t	he Comm	issioned Co	orps.			
1	Increase the percentage of Officers that meet Corps readiness requirements, thus expanding the capability of the individual Officer.	50%	71%	75%	73%	80%	82.3%	82.5%	85%	87.5%
2	Increase the percentage of Officers that are deployable in the field, thus expanding the capability of the Corps. (Baseline - 2005: 40%)	NA	40%	50%	54%	55%	61.6%	60%	65%	70%
5	Increase the number of response teams formed, thus enhancing the Department's capability to rapidly and appropriately respond to medical emergencies and urgent public health needs. (Baseline - 2005: 0)	NA	0	10	10	26	26	26	36	36 ^b
6	Increase the number of response teams which have met all requirements, including training, equipment, and logistical support, and can deploy in the field when needed as fully functional teams, thus enhancing the Department's capability to appropriately respond to medical emergencies and urgent public health care needs. (Baseline - 2006: 0)	NA	NA	NA	0	10	20	20°	26	26
Eff	Cost and Office to the cost of the cost		1	1	1					
7	Cost per Officer to attain or maintain readiness requirements.	\$164.20	\$115.56	\$110.00	\$77.74	\$105.00	\$119.68	\$100.00	\$100.00	\$100.00
	Appropriated Amount (\$ million)	\$4.2	\$4.2	\$	4.2	9	\$9.9	\$4.1	\$30.2	

Notes:

- a. Baselines established in 2007, long-term targets to be established in 2008.
- b. Not yet established in PART; maintain the same number of teams as in FY 2009
- c. Originally, this target was 26. However, with the lack of funding in FY 2008 the targets had to be pushed back. Thus, the FY 2008 target must remain at the FY 2007 level, the original FY 2008 target is now the FY 2009 target, an

so on.

COMMISSIONED CORPS TRANSFORMATION, READINESS AND TRAINING Program Data

	FY 2007	FY 2008	FY 2009
	Enacted	Pres Budget	Request
Transformation	\$7,526,000	\$2,926,000	\$7,690,000
OFRD	1,200,000	1,193,000	1,935,000
HAMR Teams / Training	1,200,000	0	20,534,000
Total	\$9,926,000	\$4,119,000	\$30,159,000

NATIONAL VACCINE PROGRAM OFFICE

	FY 2007	FY 2008	FY 2009	FY 2009
	<u>Actual</u>	Enacted	<u>PB</u>	+/- FY 2008
BA	\$6.980.000	\$6.781.000	\$6.841.000	+\$60.000
FTE	10	10	10	
FY 2009 Auth	egislation norizationthod			Expired

Program Description and Accomplishments

The National Vaccine Program Office (NVPO) was created by Congress in 1987, to provide leadership and coordination among Federal agencies as they work together to carry out the goals of the National Vaccine Plan. The development of this plan was mandated in P.L. 99-660. The Plan includes values, goals, objectives, and strategies for pursuing the prevention of infectious diseases through immunization. The four goals of the National Vaccine Plan are to:

- Develop new and improved vaccines;
- Ensure the optimal safety and effectiveness of vaccines and immunization;
- Better educate the public and health professionals about the benefits and risks of immunizations; and
- Achieve better use of existing vaccines to prevent disease, disability, and death.

NVPO coordinates interaction between the Department of Health and Human Services agencies and interacts with stakeholders in these areas through regular communication on issues including vaccine safety, vaccine supply, vaccine coverage, vaccine adverse events, vaccine financing, and international vaccine and immunization issues. NVPO also advances the Secretary's priority on prevention from the work done to promote safe and effective vaccines, and enhance delivery of these preventive medical services, as well as being deeply involved in pandemic influenza preparedness, and thereby contributes to the Secretary's priority on preparedness. Highlights include:

Updating the National Vaccine Plan. The National Vaccine Plan identifies
priority activities to improve the safety and effectiveness of disease prevention
through immunization. The initial Plan, published in 1994, is being evaluated and
revised to redefine the current actions that can be taken to improve the vaccine
enterprise and set a vision for the future. NVPO is coordinating the revision with
all relevant agencies and offices in HHS, and with the Departments of Defense
and Veterans Affairs, and the U.S. Agency for International Development. Input

- also is being obtained from the Institute of Medicine, interested stakeholders, and the general public.
- Overview of the National Vaccine Safety. The safety of vaccines is an issue that affects all children and families in the United States. The National Vaccine Program Office coordinates an interagency group that reviews the Federal system to anticipate, detect, understand, and improve the safety of vaccines that are used in the United States. As a result of this review, the NVPO has completed a Vaccine Safety Inventory report that catalogues and describes the Federal vaccine safety system. The report includes surveillance; communication, education and risk management; regulation, research and development. This report will serve as the basis for communications with healthcare providers and the public to maintain and enhance confidence in the safety of the nation's vaccine program.
- Pandemic Influenza Preparedness. NVPO provides direction to achieve optimal
 prevention of adverse reactions to vaccines including consideration of the
 developing science of genomic information to both predict which persons may be
 at higher risk of adverse reactions, and develop vaccines that are less likely to
 cause such reactions. These activities contribute to the Secretary's Priority of
 Personalized Health Care.
- Strategic Issues in Vaccine Research (SIVR) Program. Through a competitive process, with input from NVAC, NVPO's Strategic Issues in Vaccine Research (SIVR) program allocates "seed" monies to meet needs that emerge outside of traditional budget cycles and to initiate and stimulate priority vaccine and immunization-related projects. The Strategic Issues in Vaccine Research program has led to significant advances in vaccine safety, development and use while building capacity within HHS and leveraging agency resources to support followon activities. Examples of SIVR key program accomplishments include:
 - Improving the safety of new vaccines by developing methods to detect potential contaminants of vaccine substrates;
 - Developing improved methods to produce and evaluate candidate pandemic influenza vaccines; and
 - Evaluating the impacts of influenza vaccination in children leading to expansion of vaccination recommendations.
- National Vaccine Advisory Committee. NVPO serves as executive secretariat for
 the National Vaccine Advisory Committee (NVAC) advises and makes vaccinerelated recommendations to the Assistant Secretary for Health. NVAC meets
 three times a year and is funded through the NVPO budget. In 2007, NVAC
 focused on a number of areas relevant to the National Vaccine Plan:
 - Improving immunization information systems ("vaccination registries");
 - NVAC's recommendations of the immunization information system report include steps to ensure privacy protections and information security, improve provider participation, appropriate functionality, and secure funding;
 - Adolescent immunization programs;
 - NVAC's report on adolescent vaccination highlights the new opportunities presented by licensure and recommendation of new adolescent vaccines

and the challenges posed in achieving high levels of disease prevention in this age group. Recommendations focus on strategies to improve vaccination coverage, surveillance, and program financing;

- Vaccine Financing;
- NVAC's Vaccine Financing Working Groups' efforts are currently
 focused on reviewing Section 317 funding and the Vaccines for Children
 program to ensure persons, especially non-insured or underinsured
 children, receive all ACIP recommended vaccines without financial
 barriers; and are examining financial incentives for the public to seek
 vaccination, and payers to support vaccination, as a cost-effective health
 care service.

Funding History

FY 2004	\$7,179,000
FY 2005	\$7,133,000
FY 2006	\$7,004,000
FY 2007	\$6,980,000
FY 2008	\$6,781,000

Budget Request

The FY 2009 Request for NVPO is \$6,841,000, an increase of \$60,000 above the FY 2008 Enacted level. This level will provide mandatory pay increases, off-set costs of new projects to engage stakeholders and the public on vaccine issues, but will reduce the previous funding level for the *Strategic Issues in Vaccine Research* initiatives.

In FY 2009, NVPO will continue to:

- Coordinate and integrate activities of all Federal agencies involved in vaccine and immunization efforts. NVPO hosts a biweekly interagency teleconference to coordinate current vaccine-related activities;
- Assess, evaluate, and fund Strategic Issues in Vaccine Research (SIVR) projects.
 SIVR will continue to calculate its impact on vaccine and immunization activities that address defined HHS and national priorities;
- Enhance interagency collaboration, so that vaccine and immunization-related activities are carried out in an efficient, consistent, and timely manner. NVPO uses the monthly Flu Risk Management Meeting (FRMM) and weekly Departmental Influenza Conference Call to specifically coordinate influenza information across the Federal government;
- Complete the Revised National Vaccine Plan;
- Work with Agencies to develop and implement strategies for achieving the highest possible level of prevention of human diseases through immunization and the highest possible level of prevention of adverse reactions to vaccines; and
- Work to minimize gaps that may exist in Federal planning of vaccine and immunization activities.

PUBLIC HEALTH REPORTS

	FY 2007	FY 2008	FY 2009	FY 2009 +/-
	<u>Actual</u>	Enacted	Pres. Budget	FY 2008
BA	\$455,000	\$443,000	\$446,000	+\$3,000
FTE	2	2	2	
Authorizing Legislation. FY 2009 Authorization				
Allocation Method		Direct federa	al; Contract, Coop	erative agreement

Program Description and Accomplishments

Public Health Reports (PHR) is the oldest journal of public health in the U.S. and has been published continuously since 1878. PHR is the public health journal of the U.S. Public Health Service (USPHS) and the Surgeon General, and is produced in collaboration with the Association of Schools of Public Health. For 129 years this bi-monthly peer-reviewed journal has been a highly respected vehicle for public health academicians, practitioners, planners, legislators, and students. It is the venue of choice for many to publish their original work and acquire much of their knowledge and skills on innovative public health theory, research, and practice activities.

Each issue of PHR includes research, viewpoint, and practice articles and columns titled *International Observer, Law and the Public's Health, Public Health Chronicles*, and *From the Schools of Public Health* that address important international public health issues. In addition to six regular issues per year, two or more supplemental and/or special issues on important topics are published annually. Many years of useful public health premiums are provided to subscribers. Topics such as tobacco control, teenage, violence, occupational injury and disease, housing immunization, drug treatment and policy, lead screening, Native American health, minority population health, infectious disease response and control, domestic violence, human research protection, women's health, fitness, homeland security and preparedness, medical care delivery and all other public health topics are covered. These papers are written by the leaders in the public health research and practice. The Journal also has a special interest in emphasizing public health history.

Funds are used to support two staff positions and overhead costs. In addition, to accomplish the work of the *Public Health Reports* contracts are awarded for professional services to provide technical editors for editing services and project management of supplemental issues and special projects. Since 1999, PHR has been published in partnership with the Association of Schools of Public Health. ASPH publishes the journal and collects all revenues from subscriptions.

The PHR has had tremendous growth over the last five years. Manuscript submissions have continued to increase with a notable ~30 percent increase from 2006 to 2007. In 2007, the

number of annual special supplements has also increased, with three special supplements plus a public health calendar, in addition to the standard six, bi-monthly issues. Another accomplishment was PHR's production and presentation of three webcasts on selected PHR topics that were broadcast to schools of public health and the interested public health community. For FY 2008 PHR is planning on producing a total of four webcasts.

Also in FY 2007, PHR began discussions to partner with the USPHS Commissioned Officers Association (COA) to provide the PHR Journal as a premium for all COA members. It is hoped that a final agreement with COA will be completed in FY 2008. If successful, this partnership has the potential to increase our total number of PHR subscribers from about 6,000 to ~12,000 to 13,000.

Lastly, the Office of the Surgeon General will produce a Surgeon General's column for each regular issue of PHR. The first Surgeon General's column is scheduled for release in the third issue of PHR in 2008.

End-of-year	# of Manuscript Submissions
2001	177
2002	227
2003	257
2004	253
2005	320
2006	323
2007	416

PHR supports the OPHS strategic goals by contributing to the measures that strive to increase the reach of OPHS prevention communications. In addition, PHR supports the Secretary goals to prevent and control disease, injury, illness and disability across the lifespan, and protect the public from information, occupational, environmental and terrorist threats by publishing articles and targeted columns that provide information to guide scientific and programmatic research in these areas.

Funding History

FY 2004	formerly part of National Library of Medicine, NIH
FY 2005	\$463,000
FY 2006	\$463,000
FY 2007	\$455,000
FY 2008	\$443,000

Budget Request

The FY 2009 request for the Public Health Reports is \$446,000, an increase of \$3,000 above the FY 2008 enacted level. Funds will be used to support the operation of the Reports. The PHR have been very successful in producing a robust and scientifically respected journal.

The goal of the PHR is to provide research and discuss key public health issues. Each issue examines subject matter needed to understand health promotion and disease prevention issues of the Nation's population. This goal is achieved through a regularly published a scholarly journal as well as offering supplements, webcasts and special project products.

OFFICE OF RESEARCH INTEGRITY

	FY 2007	FY 2008	FY 2009	FY 2009
	<u>Actual</u>	Enacted	<u>PB</u>	<u>+/- FY 2008</u>
BA*	[\$8,172,000]	[\$8,571,000]	[\$8,909,000]	[+\$338,000]
FTE	23	23	23	

^{*} ORI is funded by NIH dollars, which are reflected as non-add

Program Description and Accomplishments

The overall mission of the Office of Research Integrity (ORI) is to promote integrity in the research programs of the Public Health Service (PHS), both intramural and extramural, including responding to allegations of research misconduct. To accomplish this mission, ORI engages in research and evaluation, education, oversight of institutional and HHS investigations, collaboration with external partners, including scientific societies and associations, and research institutions, and other activities intended to promote integrity, reduce misconduct, and maintain the public confidence in science-based medicine.

Since 1999, ORI has placed greater emphasis on educational activities, research, evaluation, and prevention activities. In response to these changes, ORI adopted an action plan, approved by the Assistant Secretary for Health, to increase resources in these areas. A key part of this plan was the establishment of a research program to study the factors influencing research integrity, an education program on the responsible conduct of research, and ongoing collaborations with ORI's research partners, including the Association of American Medical Colleges, the Council of Graduate Schools, other research associations, academic and scientific societies, numerous individual institutions, and others.

ORI's budget, resources, and programs are directly relevant to the Department's interest in the prevention of disease and promotion of health. ORI's overall mission supports the integrity of PHS research and the public confidence in such research. Since clinical trials, human studies, animal studies, and basic research lead to new drugs, devices, and medical interventions, confidence in the science base which leads to such improvements in health is closely intertwined with the beneficial products of the research. ORI is also emphasizing prevention in its programs by developing educational resources to support best practices and by supporting extramural studies through its research program on the indicators of research integrity and the causes of misconduct. Only through the development of this science base can PHS identify effective and cost efficient means of

promoting integrity and preventing misconduct. ORI's mission to identify and take action in response to research misconduct also provides primary and secondary prevention by removing from research those who commit misconduct and reinforcing the scientific norms of honest scientists who conduct research responsibly.

ORI responds to research misconduct and promotes research integrity, thereby directly supporting HHS and OPHS objectives to advance science and medical research, improve the quality of health care (through science-based medicine), and strengthen prevention. ORI efforts to prevent misconduct and promote integrity and responsible research practices strengthen the integrity of the science base, which supports the progress in new health care products and treatments which can prevent disease and illness. ORI also supports the public health infrastructure by helping ensure a trustworthy science database, upon which decisions are made and which support public confidence in utilizing science-based medical discoveries.

Over the past three years, ORI has accomplished the following:³

- Reviewed 800 allegations of misconduct, opened over 80 formal inquiries and investigations, and made 31 findings of research misconduct.
- Reviewed over 100 institutional policies and procedures for regulatory compliance and responded to over 15 incidents of possible retaliation against good faith whistleblowers or non-compliance with regulatory requirements.
- Sponsored over 21 workshops and conferences with research institutions, scientific societies, and others on research misconduct, the responsible conduct of research, and the promotion of research integrity.
- Provided funds for development of 22 educational products in Responsible Conduct in Research (RCR).
- Funded 17 grants to support research on misconduct, education in research integrity, conflicts of interest, and institutional practices that affect the integrity of the research environment.
- Provided on-site or telephonic technical assistance to 150 research institutions in handling allegations of misconduct.
- Adopted a sample policy in 2007 to assist institutions in implementing the new PHS misconduct regulation, 42 CFR Part 93, Subpart E, that requires the accused scientist to provide specific factual evidence to demonstrate his/her innocence.
- Funded 39 awards to 33 societies through a cooperative agreement with Association of American Medical Colleges (AAMC). This resulted in 20 products related to research integrity and the responsible conduct of research.

In FY 2008, ORI plans to:

• Support demonstration projects at five research intensive universities to institutionalize Responsible Conduct in Research (RCR) training in graduate

³ All ORI data are reported on a calendar year, rather than fiscal year, basis.

education.

- Continue a major new initiative to train institutional research integrity officers (RIOs) in handling and managing allegations for research misconduct. Two trainings are planned in 2008 for University of Washington and Duke University. Ultimately, ORI plans to train all RIOs at the top 100 research institutions and to expand to the next 100 as resources permit.
- Continue a collaboration with the National Postdoctoral Association to provide responsible research training to 40,000 postdocs at 135 institutions
- Contract with the Laboratory Management Institute at the University of California-Davis to provide live or on-line training in laboratory management to graduate students, postdocs, and faculty.
- Collaborate with the Office of Human Research Protections (OHRP) to share
 resources and speakers at workshops and conferences on human subjects, research
 misconduct, and research integrity. This will facilitate the communication of a
 common message by two Federal offices that have responsibility for research
 integrity issues, thus benefiting both the Federal government and OHRP's
 extramural partners.
- Collaborate with the NIH regional seminars by making presentations related to research misconduct, the responsible conduct of research, and the promotion of research integrity.

ORI supports the following OPHS performance measures:

- Increase the number of substantive commitments to prevention on the part of governmental and non-governmental organizations
- Increase knowledge about disease prevention and health promotion, including effective interventions and research needs
- Increase the reach and impact of OPHS communications related to strengthening the public health and research infrastructures
- Increase knowledge about the public health and research infrastructure, including research needs, and improve data collection needed to support public health decisions

Funding History

FY 2004	\$7,974,000
FY 2005	\$8,213,000
FY 2006	\$8,172,000
FY 2007	\$8,172,000
FY 2008	\$8,571,000

Budget Request

The FY 2009 request for the Office of Research Integrity (ORI) is \$8,909,000, an increase of \$338,000 above the FY 2008 enacted level. At this level, ORI will support

salary and other inflationary increases; programs will be maintained at essentially the FY 2008 level. Below are some of the activities ORI will accomplish in FY 2009:

- Provide technical assistance to at least 20 institutions which conduct investigations into alleged misconduct and need assistance.
- Assess 300 potential allegations of misconduct.
- Open 50 or more inquiries and investigations into alleged misconduct for ORI oversight.
- Take final actions on 20 or more findings of research misconduct involving PHS funding.
- Cause ten or more articles that misrepresent research results to be corrected or retracted.
- Issue charge letters and defend ORI authorities and actions in specific cases before the Departmental Appeals Board and in civil litigation.
- Review 100 or more institutional policies for compliance with program regulations.
- Respond to five or more whistleblower complaints of retaliation and institutional compliance problems.
- Respond to five or more whistleblower complaints of retaliation and institutional
 compliance problems. ORI will contract for a mentoring program with a large
 institutional partner to develop mentoring programs that will address training for
 post docs and students, provide training for potential mentors; mentoring
 programs will be developed at two or more sites and evaluation instruments will
 be used both before and after the trainees and mentors have completed their
 assignments
- Support a new version of the Guide to Animal Welfare which is the gold standard for using animals in research. ORI will also provide copies of the new version to the top100 research institutions.

OFFICE OF RESEARCH INTEGRITY Program Data

Activity	FY 2007 Actual	FY 2008 Enacted	FY 2009 Request
Oversight and Case	\$1,889,369	\$1,920,000	\$1,920,000
Resolution			
Assurance and Compliance	885,040	900,000	900,000
Program			
Education and Integrity	2,912,026	3,151,000	3,151,000
Program			
Management of Allegations	400,000	400,000	400,000
of Research Misconduct			
Support Costs	2,085,565	2,200,000	2,538,000
TOTAL	\$8,172,000	\$8,571,000	\$8,909,000

Workload Data

Calendar Year	Misconduct Cases	Whistleblower Compliance/ Cases	Policy Reviews	Judicial Litigation
2005	Queries 265 Cases opened 30 Cases closed 22 Assessments underway 16	Carried into 2005 4 Opened	Closed 185	Opened
2006	Current cases59Queries266Cases opened29Cases closed35Assessments underway32	Carried into 2006	Opened 127 Closed 127 Current 0	Opened 4 Closed 1 Current 4
2007 (through Dec 31, 2007)	Current cases53Queries217Cases opened9Cases closed11Assessments underway34Current cases51	Current	Opened79 Closed79 Current26	5 pending civil cases and 2 pending criminal cases

EMBRYO ADOPTION AWARENESS CAMPAIGN

	FY 2007 Actual	FY 2008 Enacted	FY 2009 Pres. Budget	FY 2009 +/- FY 2008
BA	\$1,980,000	\$3,930,000	\$1,980,000	-\$1,950,000
FTE	N/A	N/A	N/A	
Authorizing Legislation. FY 2009 Authorization Allocation Method				Indefinite

Program Description and Accomplishments

The purpose of the campaign is to educate Americans about the existence of frozen embryos (resulting from in-vitro fertilization) which may be available for donation/adoption for family building. There are an estimated 400,000 frozen embryos in fertility clinics in the United States and increasing public awareness of embryo donation and adoption remains an important goal. Approximately 88 percent are estimated to be used by the creating couple for their own future family building efforts. The remaining 12 percent might be available for embryo donation and adoption if the creating couple were educated about the alternative to release the embryos for adoption by another infertile couple. At the beginning of the awareness campaign, very few people had any idea what embryo donation and adoption was about. As a result of the public awareness campaign, increasingly more professionals and infertile couples are becoming aware of embryo donation and adoption as an alternative for frozen embryos.

This is a relatively new endeavor and funded projects focus on educating couples who have frozen embryos and who may wish to choose to donate them, as well as to inform infertile couples about their availability for adoption. Information and educational activities are specifically directed at potential donors and recipients, as well as professionals (e.g., physicians, IVF clinic personnel, attorneys, and/or social workers) involved with the process of embryo donation and/or adoption.

With the passage of P.L. 107-116, the fiscal year 2002 Departments of Labor, Health and Human Services, Education and Related Agencies Appropriations Act, the Congress authorized the Department to conduct a public awareness campaign to education American about the existence of frozen embryos available for adoption. The Congress directed the Department to launch an embryo adoption public awareness campaign and provided \$1,000,000 for this purpose. Congress appropriated a similar amount in FY 2004 and 2005. In FY 2006 and 2007, the appropriation increased to \$1.98 million. In FY 2008, Congress increased funding for the program to \$3,930,000 and included permissive authority to expend funds for medical and administrative services related to embryo adoption, stating, "That funds provided in this Act for embryo adoption activities may be used to provide to individuals adoption embryos, through grants and other mechanisms, medical and administrative services deemed necessary for such adoption: Provided further, That such services shall be provided consistent with 42 CFR 59.5

(a) (4)."

Each year, the program issues a notice announcing the availability of funds and requests applications for competitive grants/cooperative agreements for three or four new projects, each in the range of \$200,000 to \$350,000. Public agencies, non-profit organizations and for profit organizations that can demonstrate previous experience with embryo donation and/or adoption and are knowledge about all elements of the process are eligible to apply. Funded agencies have included national infertility membership organizations, an embryo donation clinic, a hospital, and adoption agencies. These organizations work with professionals, IVF clinics, patients, prospective adoptive parents, and couples experiencing infertility to provide information and education about how the embryo donation and adoption process works. One of the key challenges is educating couples about the process and the decision-making that is necessary to result in the release frozen embryos for donation to and adoption by another couple.

The core focus of the program is information and education activities that contribute to increasing public awareness and understanding of embryo donation and adoption. Grant funded projects have developed and distributed educational videos and brochures for various target audiences, supported community events and resource materials, public service announcements, informational advertisements, and outreach to IVF clinics. In addition to information and education awareness activities focused on the target population of potential donor and adoptive couple, the program has also supported educational activities targeted toward professional audiences with the goal of increasing public awareness. Some of these projects have trained professionals to equip them with the knowledge, skills and abilities necessary to effectively provide information and education regarding embryo donation and/or adoption to the public. Another project supports a national conference to examine the technical, medical, legal, ethical and social issue of major importance in the field. With grants support, one project developed a web-based resource center to assist in advancing public understanding of the embryo donation and/or adoption.

Because the operating authority was dependent on annual appropriations language, the project periods for grants funded in FY 2002 and 2004 were limited to one year. In FY 2006, the President's budget included a request to continue funding the program. Based on the request for continued funding, the notice soliciting grant applications for FY 2005 was modified to incorporate a two-year project period for new awards. Currently, grant projects awards continue to be for a two-year project period. The program benefits include greater awareness of this option in order to equip professionals with the skills necessary to provides program information and education to their patients who have frozen embryos, as well as potential adoption couples. The program seeks to increase the awareness of couples who have frozen embryos about the embryo donation and adoption as a workable alternative for those embryos, and to create an opportunity for family building for infertile couples.

By educating Americans about this family building option, the program supports the Department's Strategic Goal 3, which seeks to protect life, family, and human dignity by promoting the economic and social well-being of individuals, families, and communities; enhancing the safety and well-being of children, youth, and other vulnerable populations; and strengthening communities.

Funding History

FY 2004	\$ 994,000
FY 2005	\$ 992,000
FY 2006	\$1,979,000
FY 2007	\$1,980,000
FY 2008	\$3,930,000

Budget Request

The FY 2009 budget request is \$1,980,000, a decrease of \$1,950,000 from the enacted FY 2008 appropriation level. The FY 2009 request provides continued funding only for embryo adoption public awareness information and education activities, which have been the core of the program since its inception.

Embryo Adoption Awareness	FY 2007	FY 2008	FY 2009
Total Number of Grants	6	6	6
New Grants	3	3	3
Continuation Grants	3	3	3

HIV/AIDS IN MINORITY COMMUNITIES

	FY 2007 <u>Actual</u>	FY 2008 Enacted	FY 2009 Pres. Budget	FY 2009 +/- FY 2008
BA	\$51,891,000	\$50,984,000	\$51,891,000	+\$907,000
FTE				
FY 2009 Authoriza	ation itions		•••••	Indefinite

Program Description and Accomplishments

In 1999, the Congressional Black Caucus initiated a partnership with the Department of Health and Human Services (HHS) to significantly increase the national response to the HIV/AIDS epidemic in racial and ethnic minority communities since they are disproportionately impacted by this epidemic. The partnership identified the following issues as priorities:

- developing more effective prevention education interventions;
- increasing access to HIV counseling and testing services; and
- ensuring that comprehensive and quality health care and drug abuse treatment services are available in these communities.

Since FY 1999, Congress has appropriated \$50 million or more each year to support the Minority AIDS Initiative. Utilizing these funds, significant steps have been taken to respond to this unfolding crisis through capacity enhancements to mount a community-based response, delivering prevention and treatment services, and providing guided and informed technical assistance and research. A sustained commitment to these goals will ensure a durable response – with a flexible resource pool that can be quickly targeted to respond to newly emerging problems – and to capitalize on lessons learned. Since most minority communities have disproportionately high rates of HIV/AIDS infection, these targeted investments have been successful in identifying and addressing key barriers to allowing the Department's programs to effectively reach and serve minority communities.

Funds received by the Office of the Secretary for the MAI are disbursed to the Public Health Service agencies in HHS on a competitive basis. Project proposals are subject to three levels of review, including peer review by fellow agency representatives who comprise the MAI Steering Committee; secondary review committee of senior OPHS staff lead by the Director of OHAP; and final review team comprised of the Assistant Secretary for Health (ASH) and a few of his key advisors. Following approval from the ASH, agencies then award the funds through grants and/or contracts to support hundreds of organizations across the country.

Following are the four categories of programs that have been funded in the past few years.

Capacity Development in Rural and Moderate Incidence Areas. This initiative represents a commitment by the Department to address the need for capacity development and technical assistance in communities affected by HIV/AIDS outside of the highest incidence urban areas. There are significant pockets of HIV disease in second-tier cities with populations between 100,000 and 250,000, as well as in more rural areas in the southeastern and mid-western US.

The Department has expanded efforts to provide technical assistance to highly depressed rural communities. There is a need to increase the number of health officials and to open additional primary health care centers in rural communities. Planning is underway to develop an infrastructure in these communities. The HIV/AIDS epidemic in minority populations in rural areas is particularly acute in settings that are often under served and resource poor, this intervention can help before the HIV/AIDS incidence increases to the first tier levels. Grants for these rural areas are awarded to not for profit community-based and faith-based organizations, local health departments and clinics, health care providers, and universities and colleges, including historically black colleges and universities, Hispanic serving colleges and universities, and Tribal colleges and universities, research institutions, local government agencies, tribal government and for profit organizations and companies.

Technical Assistance and Training Activities. MAI funds are being used to expand technical assistance and capacity building activities for organizations serving racial and ethnic minorities disproportionately impacted by HIV/AIDS. Grants are awarded to not-for-profit community-based and faith-based organizations, local health departments and clinics, health care providers, and universities and colleges, including historically black colleges and universities, Hispanic serving colleges and universities, and Tribal colleges and universities, research institutions, local government agencies, tribal government and for-profit organizations and companies.

Recently, training centers from the Health Resources and Services Administration (HRSA), Substance Abuse and Mental Health Services Administration (SAMHSA), Centers for Disease Control and Prevention (CDC), and Office of Population Affairs (OPA) have formed a formal partnership to collaborate among these providers. These collaborative efforts have significantly reduced duplication of efforts, and have fostered more rigorous and comprehensive training both across and within the areas of HIV/AIDS prevention, care and treatment. Currently, training centers in the HHS regions are developing curricular and training modules that reflect the many advances in treating HIV, as well as aiding HHS in activities which promote and support the Department's policy, "Advancing HIV Prevention (AHP)." This policy has a four-part focus:

• incorporation of routine HIV prevention interventions in all clinical settings;

- integration of prevention intervention supporting HIV-positive individuals as a routine part of care;
- promotion of voluntary HIV testing of all pregnant women; and
- promotion of aggressive use of rapid HIV testing technology in both clinical and non-traditional settings.

At the heart of AHP is the promotion of routine testing and rapid HIV testing technology. We encourage or require clinical settings, community-based organizations, and other providing HIV testing and funded by the MAI to integrate AHP in their service delivery plan. These MAI projects and activities complement larger CDC efforts to encourage all clinical settings to adopt such measures. Some OPDIVs have chosen to tie the awarding of funds to entities that demonstrate an understanding of AHP and have provided a plan of integration.

Prevention. Since the inception of the HIV/AIDS epidemic, CDC has been the sole purveyor of HIV testing services. However, over the past five years there has been a move to expand HIV testing services beyond the clinical and laboratory settings. Satellite service sites and mobile health vans have provided new access into difficult to reach communities and population groups. Unfortunately, these strategies often lack the clinical structure to adequately meet the HIV testing needs of many communities. These strategies impose challenges related to confidentiality and privacy. In 2002, OraSure introduced the OraQuick® Rapid HIV-1 Antibody Test – the first FDA-approved and CLIA-waived rapid point-of-care test – to aid in the diagnosis of infection with HIV-1, using a finger stick and venipuncture whole blood specimen. In 2004, OraSure launched the OraQuick® ADVANCETM HIV-1/2 Antibody Test – the first oral fluid rapid HIV test and the only FDA-approved test which can be used on oral fluid, plasma, finger stick and venipuncture whole blood specimens. This technology has allowed public health officials to conduct HIV testing in both clinical and non-traditional settings.

OPA, through its Title X-funded Family Planning Clinics, is now providing rapid HIV testing as part of its HIV prevention services which includes funding for the HIV test, as well as counseling and referral services. The Family Planning Clinics provide comprehensive family planning, counseling and prevention services. Rapid HIV testing is also now being provided in many SAMHSA-funded/ State-run and private-sector facilities and institutions that provide substance abuse prevention treatment. In both cases the funding provided by the MAI has made rapid testing a reality in these expanded opportunities to conduct critical HIV testing. In general, grants to fuel prevention work are awarded to not- for-profit community-based and faith-based organizations, local health departments and clinics, health care providers, and universities and colleges, including historically black colleges and universities, Hispanic serving colleges and universities, and Tribal colleges and universities, research institutions, local government agencies, tribal government and for-profit organizations and companies.

Outreach and Partnership Building. An integral part of OPHS' national prevention strategy is to educate, motivate and mobilize local and national minority leaders in the fight against HIV/AIDS. The goal is to leverage the credibility and influence of

community leaders, and to place resources (information and technical) in the hands of those who know and can reach vulnerable racial and ethnic communities. This strategy also hopes to improve health outcomes in general for these populations, while promoting HIV testing and early medical treatment for those who are HIV-infected. Towards this end, several efforts are underway which have facilitated the creation of new partnerships and initiatives. At the national level, dialogues with the Salvation Army and the US Congress of Catholic Bishops have resulted in these faith-based organizations adopting HIV awareness, education and/or prevention activities which target their employees, clients and members.

Concurrently, the HHS Regional Offices have reached hundreds of leaders, faith and community-based groups in first-time engagements with HHS on HIV/AIDS awareness and education. Some of these groups have now become advocates of HIV prevention education, while others have stepped forward to become providers of HIV/AIDS services. Grants for outreach and partnership activities are awarded to not-for-profit community-based and faith-based organizations, local health departments and clinics, health care providers, and universities and colleges, including historically black colleges and universities, Hispanic serving colleges and universities, and Tribal colleges and universities, research institutions, local government agencies, tribal government and for-profit organizations and companies. With the awarding of these grants, many influential and well-positioned entities educate and mobilize local communities through a variety of venues and mediums to engage the HIV epidemic. From sponsoring health fairs to town hall meetings and prayer breakfasts, local leaders become federal partners. Similarly, through the use of their own internal publications, training, listserves and e-mail blasts, community leaders provide additional mediums for outreach.

In 2007, the MAI Fund participated in a Program Assessment Rating Tool (PART). OHAP coordinated the data and responses to the PART and was responsible for its completion. The MAI Fund was assessed a rating of "Results Not Demonstrated (RND)". As a result of this rating, OHAP has developed a PART Improvement Plan for the MAI Fund. The plan consists of improving four performance objectives and one management objective. Specifically, the Improvement Plans consists of: (1) establishment of baselines and ambitious targets for long-term performance measures; (2) development of a comprehensive evaluation plan for MAI Fund activities; (3) development of a formal process to document the use of performance information in managing the MAI Fund and making funding allocation decisions; (4) establishment of procedures that get grantees to commit to measures and report on performance related to the program's goals; and (5) arrangement for the inventory of programs with related missions or activities and document their complimentary relationship to the activities of the MAI Fund. Additional information about the MAI PART may be found on www.ExpectMore.gov.

By working with the MAI Steering Committee, OHAP has integrated or will soon integrate all of the improvement objectives outline in the Improvement Plan. All process or procedural fixes are now in place and the establishment of baselines and ambitious targets are complete. Steps have been taken to evaluate the MAI Fund beginning in 2008

and concluding in 2009. Performance measures have been included as one of the variables to consider when assessing the merit of new proposals and most agencies have quickly aligned their proposals to our efforts to increase testing and knowledge of HIV status; decrease new HIV infections; delay the onset of an AIDS diagnosis; decrease AIDS mortality; and improve the cost efficiency of both HIV testing and the training of clinical staff.

Funding History

FY 2004	\$ 49,544,000
FY 2005	\$ 52,415,000
FY 2006	\$ 51,855,000
FY 2007	\$ 51,891,000
FY 2008	\$ 50.984.000

Budget Request

The FY 2009 Request is \$51,891,000, an increase of \$907,000 above the FY 2008 Enacted Level. At this funding level, the amount available to be disbursed to agencies will be slightly higher than last year. Funds will be used to strengthen efforts in the following areas:

Capacity Development in Rural and Moderate Incidence Areas

One of the keys to having an impact on this epidemic is to provide sustainable capacity development in rural and moderate incidence areas where an HIV/AIDS infrastructure may be weak or non-existent. But given these infrastructure challenges, its incumbent upon federal agencies to think creatively about what will work and how best to move these areas forward. The MAI Fund in FY 2009 represents an important opportunity to provide indigenous organizations within these communities the capacity development around service delivery and the management of HIV/AIDS. During times of tightened resources but and unwavering epidemic, our sustainable and proactive efforts are desperately needed. From the rural South to tribal country to some small cities in the Midwest and southwest, there are places where carefully targeted resources from the MAI Fund could have significant impact on the local epidemic.

Technical Assistance and Training Activities

Innovations in technology and new media or new perspectives on the use of old media, has broadened our understanding of how the federal government can provide invaluable technical assistance and training to organizations and other entities. From podcasts to text messaging to PSAs, there's a new and exciting way the MAI Fund can provide the tools to our local partners to assist them to carry awareness and prevention messages to their constituents, encourage HIV testing or refer for treatment and care. With our recognized challenges to reach youth and other populations detached from trasditional public health campaigns and messages, its' important we use every tool we have in our

arsenal to make a dent in this epidemic. Creative use of the MAI Fund in FY 2009 and beyond can be the vanguard of such efforts.

Prevention

In 2009, these funds will be used to continue our expansion of HIV testing opportunities as the cornerstone of prevention and our efforts to find the more than 250,000 individuals who are positive but don't know their status. Part of our prevention efforts must also involve getting those who test positive in care and returning to care those that have left. There remains strong evidence that those individuals who know their positive status and in care are more likely to take steps to modify unsafe behaviors. Finally, prevention can't lose sight of the majority of Americans who are negative and the segment of those who are at great risk. Whether its high risk youth, women, or minorities, our prevention efforts must continue to evolve and stay relevant and appropriate. The MAI Fund provides the funding vehicle for agencies to be innovative and to test new approaches on a short-term basis.

Outreach and Partnership Building

In FY 2009, these funds will be used to continue our outreach and partnerships with non-traditional and under-served community-based and faith-based entities. While certain focus will be on those communities and populations that are disproportionately impacted by HIV/AIDS, we will continue to try to stay ahead of the epidemic and target resources to those emerging communities that have lower incidence levels but are ripe for a much larger problem. Outreach to youth and those individuals over 50 will play an increasingly important role as the rates of infection rise among both segments. Within our partnerships we will explore new ways to communicate and forge relationships through the use of innovative technology and new media.

HIV/AIDS IN MINORITY COMMUNITIES Outcome Data

#	Key Outcomes	FY 2006 Actual	FY 2007 Target	FY 2007 Actual	FY 2008 Target	FY 2008 Actual	FY 2009 Target	FY 2009 Actual
1.	By 2010 increase the number of ethnic and racial minority individuals surviving 3 years after a diagnosis of AIDS	83.5%	84.25%	March 2008	85%	TBD	86.25%	TBD
2.	Reduce percentage of AIDS diagnosis within 12 months within 12 months of HIV diagnosis among racial and ethnic minority communities.	40.25%	39.25%	March 2008	38.25%	TBD	37.25%	TBD
3.	Reduce the rate of new HIV infection among racial and ethnic minorities in the U.S.	TBD March 2008	TBD	February 2009	TBD	TBD 2010	TBD	TBD 2011
4.	Increase the number of African American individuals surviving 3 years after a diagnosis of AIDS	82%	83%	March 2008	85%	TBD	87%	TBD
5.	Increase the number of Latino/Hispanic individuals surviving 3 tears after a diagnosis of AIDS	88%	89%	March 2008	89%	TBD	90%	TBD
6.	Increase the number of Native American / Alaska Native individuals surviving 3 tears after a diagnosis of AIDS	89%	88%	March 2008	88%	TBD	89%	TBD
7.	Increase the number of Asian/Pacific Islander individuals surviving 3 tears after a diagnosis of AIDS	87%	77%	March 2008	78%	TBD	79%	TBD

#	Key Outcomes	FY 2006 Actual	FY 2007 Target	FY 2007 Actual	FY 2008 Target	FY 2009 Actual	FY 2010 Target	Out-Year Target
8.	Reduce percentage of AIDS diagnosis within 12 months of HIV diagnosis among African American communities.	38%	37%	March 2008	36%	TBD	35%	TBD
9.	Reduce percentage of AIDS diagnosis within 12 months of HIV diagnosis among Latino/Hispanic communities.	42%	41%	March 2008	40%	TBD	39%	TBD
10.	Reduce percentage of AIDS diagnosis within 12 months of HIV diagnosis among Native American /Alaska native communities.	41%	40%	March 2008	39%	TBD	38%	TBD
11.	Reduce percentage of AIDS diagnosis within 12 months of HIV diagnosis among Asian/Pacific Islander communities.	40%	39%	March 2008	38%	TBD	37%	TBD
12.	Increase the number of individuals who learn their HIV status for the first time through MAI Fund programs.	128,975	132,805	March 2008	140,773	TBD	149,219	TBD
13.	Maintain the actual cost of MAI Fund HIV testing clients below the medical care inflation rate.	February 2008	\$91.46	February 2009	\$94.88	TBD	\$98.29	TBD

General Departmental Management

14.	Maintain the actual cost per MAI Fund physician and other clinical staff trained below the medical care inflation rate.	February 2008	\$1,050.15	February 2009	\$1,089.36	TBD	\$1280.57	TBD
	Appropriated Amount (\$ Million)	\$51.6	\$52	2.4	\$51.0	\$2.0		

HIV/AIDS IN MINORITY COMMUNITIES

FUNDING ALLOCATION (Dollars in thousands)

Agency	FY 2002	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007	FY08 1/	FY09 1/
CDC	\$15,641	\$15,641	\$10,500	\$9,850	\$8,500	\$8,745		
SAMHSA	12,000	12,000	11,000	11,345	9,500	\$10,235		
HRSA	6,200	5,600	6,900	8,205	8,637	\$8,641		
NIH	_	_	_	_	_	_		
IHS	1,450	1,450	1,500	2,096	1,963	1,913		
OS	14,700	13,363	18,554	19,661	22,090	21,192		
OPHS:								
ОНАР	3,200	1,863	2,914	2,956	6,335	3,932		
ОМН	7,900	7,900	8,000	7,650	7,000	6,760		
OPA	3,000	3,000	6,000	6,000	6,100	6,500		
OWH	600	600	1,640	3,055	2,655	4,000		
ASPE	_	_	_	_	_	_		
Eval Set-aside		1,021	1,090	1,258	1,165	1,165		
TOTAL	\$49,991	\$49,075	\$49,544	\$52,415	\$51,855	\$51,891	\$50,984	\$51,891

^{1/} Allocation to be determined.

RENT AND COMMON EXPENSES

	FY 2007 <u>Actuals</u>	FY 2008 Enacted	FY 2009 Pres. Budget	Increase or Decrease
Rent:			_	
GDM	\$9,350,000	\$10,385,000	\$10,385,000	-
OGC	3,932,000	4,011,000	4,091,000	+80,000
OPHS	7,221,000	7,438,000	7,661,000	+223,000
IGA	602,000	640,000	565,000	-75,000
DAB	420,000	440,000	440,000	
Total	21,525,000	\$22,914,000	23,142,000	+228,000
Operations and				
Maintenance:				
GDM	3,025,000	3,375,000	3,375,000	-
Related Services:				
GDM	2,874,000	3,122,000	3,090,000	-32,000
OGC	<u>295,000</u>	<u>301,000</u>	307,000	+6,000
Total	3,169,000	3,423,000	3,397,000	-26,000
Subtotal, GDM only	\$15,249,000	\$16,882,000	\$16,850,000	-32,000
Common Expenses:				
GDM	2,566,000	2,670,000	3,090,000	+420,000
OGC	1,135,000	1,158,000	1,181,000	+23,000
OPHS	<u>2,089,000</u>	2,152,000	<u>2,216,000</u>	+64,000
Total	5,790,000	5,980,000	6,487,000	+507,000
Service and Supply Fund:				
GDM	14,174,000	16,191,000	19,321,000	+3,130,000
OGC	2,255,000	2,301,000	2,347,000	+46,000
OPHS	9,897,000	8,938,000	<u>9,995,000</u>	+1,057,000
Total	26,326,000	27,430,000	31,663,000	+4,233,000
Subtotal, GDM only	\$16,740,000	\$18,861,000	\$22,411,000	+3,550,000
<u>Totals</u> :				
GDM	31,989,000	35,743,000	39,261,000	+3,518,000
OGC	7,617,000	7,771,000	7,926,000	+155,000
OPHS	19,207,000	18,528,000	19,872,000	+1,344,000
IGA	602,000	640,000	565,000	-75,000
DAB	<u>420,000</u>	<u>440,000</u>	440,000	
Total	\$59,835,000	\$63,122,000	\$68,064,000	+4,942,000
FY 2009 Authorization			Ir	definite
Allocation Method			Direc	t federal

Program Description and Accomplishments

Rent/O&M and Related Services

The Office of Facilities Management and Policy (OFMP) in the Office of the Assistant Secretary for Administration and Management, administers both Rent/O&M and Related Services funds for all headquarters facilities occupied by the Office of the Secretary. OFMP provides stewardship, fiscal responsibility in managing the Department's real property assets, monitors the amount and type of space occupied by each STAFFDIV, and coordinates efforts to achieve the most efficient use of space, while maintaining a quality work environment.

Descriptions of each area follow:

- Rental payments (Rent) to the General Services Administration (GSA) include funds to cover the rental costs of office space, non-office space, and parking facilities in GSA-controlled buildings.
- o *O&M* (formerly known as Delegated Authority) includes funds to cover the operation, maintenance and repair of buildings for which management authority has been delegated to HHS by GSA; this includes the HHS headquarters, the Hubert H. Humphrey Building (HHH) (Note: All Rent amounts are shown in object class 23.1, Rental Payments to GSA; however, O&M amounts are spread across other object classes.)
- o *Related Services* include funds to cover all non-Rent activities in GSA-controlled buildings (e.g., housekeeping, guard services, other security, and building repairs and renovations).
 - Provides mission-enabling facilities and a safe, secure and healthy work environment for Southwest Complex and HHH Building.
 - Creation of a security-oriented guard's desk in HHH Building.
- o *Building Management* OFMP is committed to a high level of performance in the management of the HHH Building.
 - Traffic and security changes to the Third Street and Independence Avenue entrances to the building.
 - Installation of glass fragmentation film on all the windows.

Over the past several years, HHS has completed a number of Humphrey Building improvement projects. In FY 2001 through FY 2007, all performance targets in this area were achieved. OFMP's current practices and procedures adhere to GSA guidelines that building services complaints are responded to within 72 hours of receipt.

To verify performance, an independent analysis of computer-generated data from the contractor's service call system is regularly performed. In order to ensure accuracy, individual work orders (issued as a result of estimates for service) are manually pulled on a random and periodic basis, and performance verified. These reviews have consistently supported the automated reports.

Common Expenses/ SSF Payment

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

- o Telecommunications (e.g., FTS and commercial telephone expenses),
- o Worker's Compensation,
- o Postage and Printing,
- o Unemployment Insurance,
- o Records storage at the National Archives,
- o Radio Spectrum Management Services,
- o Federal Employment Information and Services, and
- o Federal Laboratory Consortium.

Payments to the Service and Supply Fund (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:

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

Funding History

FY 2004	\$25,135,000
FY 2005	\$27,278,000
FY 2006	\$27,912,000
FY 2007	\$31,989,000
FY 2008	\$35,743,000

Budget Request

The FY 2009 request increases the funding level by \$3,518,000 from the FY 2008 President's Budget. These funds are to cover centralized payments for Rent/Operations and Maintenance (O&M), Related Services, Common Expenses, and the Service and Supply Fund. These payments are made from centrally-managed accounts on behalf of all GDM accounts except the Office of Public Health and Science (OPHS), the Office of the General Counsel (OGC), the Office of Intergovernmental Affairs (IGA – ten Regional Directors offices only), and the Departmental Appeals Board (DAB); the costs for these accounts are included in their individual sections of the budget. The SSF payment, which now includes UFMS, accounts for nearly the entire increase.

PHS EVALUATION SET-ASIDE

	FY 2007	FY 2008	FY 2009	FY 2009 +/-
	<u>Actual</u>	Enacted	<u>PB</u>	FY 2008
Reimb. Authority	\$39,552,000	\$46,756,000	\$46,756,000	
ASPE	34,500,000	41,243,000	41,243,000	
OPHS	4,552,000	4,510,000	4,510,000	
ASRT	500,000	1,003,000	1,003,000	
FTE	49	114	114	
FY 2009 Authorization				Indefinite
Allocation Method	• • • • • • • • • • • • • • • • • • • •			Direct federal

Program Description and Accomplishments

HHS's Public Health Service (PHS) Evaluation Set-Aside program is authorized by section 241 of the US Public Health Service Act. Through the systematic collection of information on program performance, this program has a significant impact on the improvement of activities and services provided by the Department. Projects supported by PHS Evaluation funds traditionally serve decision-makers in both the public and private sectors of public health research, education and practice communities, by providing valuable information regarding how well HHS programs and services are working.

The FY 2009 request for the PHS Evaluation Set-Aside in GDM includes funding for programs in three offices: the Assistant Secretary for Planning and Evaluation (ASPE); the Office of Public Health and Science (OPHS); and the Assistant Secretary for Resources and Technology (ASRT). Descriptions of each of these office's PHS Evaluation programs follows.

Assistant Secretary for Planning and Evaluation (ASPE)

ASPE serves as the principal advisor to the Secretary on policy development in health, disability, aging, human services, and science, and provides advice and analysis on economic policy.

ASPE leads special initiatives on behalf of the Secretary, and provides direction for HHS-wide strategic, evaluation, legislative and policy planning. ASPE conducts research and evaluation studies; provides critical policy analysis, development, and advice; provides policy planning, coordination, and management; conducts research, evaluation, and data collection; and estimates the costs and benefits of policies and programs under consideration by HHS or the Congress.

ASPE develops and reviews issues with a perspective that is broader in scope than the specific focus of any one Operating Division or Staff Division. ASPE assists Operating Divisions in developing policies and planning policy research, evaluation, and data collection, within broad HHS and administration initiatives. ASPE coordinates and manages data and information policy within HHS. ASPE also coordinates crosscutting policy-related activities within, and sometimes outside, HHS.

ASPE's accomplishments are numerous. Analytical, evaluation, and policy development efforts in the health, science and data, and human services policy areas have led to major improvements in information for decision-making in policy formation in health and human services, science policy and program management and evaluation across HHS. ASPE continues to build a strong analytical capacity. Policy support services provided simulation modeling, statistical analysis, and other technical and analytic services needed in order to carry out policy research. ASPE seeks to ensure efficient, reliable, and timely analytic support, while offsetting increases in costs through the introduction of cost-saving technologies. These services supported internal Department-wide data policy and coordination in data policy, including interagency data collection and data standards, and collaborative efforts between HHS and the health industry.

Four policy offices within ASPE (described further below) perform the functions listed above, with either a focus on their primary population or issue of interest, or cooperatively, to work through more complex concerns. When appropriate, ASPE offices collaborate with HHS Operating Divisions and Staff Divisions, as well as other Federal agencies, State and local partners, and non-governmental groups, in performing these functions. Working with these partners enables ASPE to leverage available resources more effectively, achieve efficiencies, and assist the translation of research to practice.

- Health Policy Health Policy research and analysis includes health care financing and public health service delivery issues. In 2009, the Office of Health Policy will dedicate its research efforts to supporting priorities identified by the Secretary. This includes continuing to support implementation of the Medicare Prescription Drug benefit, and evaluating the provisions of the Medicare Modernization Act of 2003 (MMA) that have been put in place. The Office of Health Policy will also provide support for value-based purchasing initiatives, modernizing Medicare and efforts to address the long-term financial viability of the program. Working closely with States, the Office of Health Policy will continue to encourage the development of new options for providing health insurance for the uninsured, examine effective methods of preventing disease and promoting health by identifying and evaluating strategies for reducing health disparities domestically and internationally, preventing and treating mental illness and substance abuse, as well as other issues related to health services delivery and outcomes. In addition, ASPE will continue ongoing research and policy development activities specifically requested by the Secretary.
- Human Services Policy Human Services Policy research and analysis focuses on low-income and other vulnerable populations, including families, children, youth and homeless individuals. In FY 2009, the Office of Human Services Policy will focus its research efforts on priorities articulated in the HHS FY2007-2012 Strategic Plan. This includes promoting economic self-sufficiency among families receiving welfare through enhanced work requirements and supports, healthy marriage education, and fatherhood initiatives. The Office will also concentrate on issues related to homeless families and individuals, promoting children's safety and stability such as by streamlining the foster care system and removing barriers to foster care services and placements,, helping parents and families understand the importance of a stimulating environment and cognitive development in the earliest years of life and strengthening Head Start and child

care. The Office is supporting on-line resources to help communities achieve outcomes for youth through the Helping America's Youth Initiative and expanding choices for individuals receiving benefits from federal programs by increasing participation of faith-based and community groups. The Office of Human Services Policy also will emphasize healthy living and prevention of risky behaviors, through research focused on the incidences and consequences of unintended pregnancies, especially among unmarried adolescents.

- Disability, Aging, and Long-Term Care Policy (DALTCP) DALTCP research and analysis will continue to address the health care and long-term support needs of individuals with chronic illness and disability in both institutional and community-based settings. DALTCP will continue to produce information which can be used by policymakers at the federal, state, and community level, as well as providers and consumers, to increase the availability and affordability of an array of high-quality long-term care services and reduce barriers to consumer choice and independence. This portfolio addresses active aging, system design, service delivery, quality, staffing and coverage issues.
- Science and Data Policy Science and Data Policy research and analysis is designed to ensure support of a wide range of science policy, public health preparedness and data policy issues within HHS. Research activities promote the availability of high quality policy analysis, data, information and analytical resources for policy formulation and decision making, address critical information gaps in science policy and data policy in a coordinated fashion, support departmental and interagency policy development, and enhance HHS research and analytical capabilities. This portfolio addresses health research and technology policy, food and drug technology and safety policy, prevention issues, the impact of biomedical research and development investments, economic analysis, evaluation of the health and economic impact of Health IT policy, and an array of data policy, data development and statistical policy and resource issues for program management, accountability and decision making.

In addition to the activities of the four policy offices, ASPE also performs the following primary activities:

- Data Collection Coordination ASPE leads the coordination of data collection and statistical policy across HHS. To promote HHS-wide data planning and coordination for data collection investments, ASPE co-chairs the HHS Data Council which is comprised of senior executives and managers from all HHS Operating Divisions and Staff Divisions. The Council promotes HHS wide communication and planning for data collection from a collective, department-wide perspective, assures coordination and cost efficiencies in addressing interagency data needs and issues, stresses efficient and effective approaches to data collection, and serves as a forum to address priority interagency, departmental and national data needs in a coordinated fashion.
- Research Coordination ASPE also has the lead role in ensuring that the Department's investment in health and human services research supports the Secretary's priorities in

the most efficient and effective manner. ASPE works with other OS components to develop the basic framework of the Department's research priorities and themes that serve to organize agency research budget submissions for FY 2009. ASPE continues to work to achieve efficient leveraging of the Department's health and health services research portfolio by identifying areas where efficiencies could be achieved through collaboration, and by identifying better ways to translate the findings of Department-sponsored research into practice.

• Research and Evaluation – ASPE's research and evaluation program has a significant impact on the improvement of policies, programs and services of the Department, through the systematic collection of information on program performance: gauging program effectiveness, improving performance measurement, performing environmental assessments, and providing program management.

ASPE supports the Department's mission and works to implement the Strategic Goals from the FY 2007-2012 HHS Strategic Plan, as described in the GDM Online Performance Appendix.

Office of Public Health and Science (OPHS)

OPHS has had a fundamental role in the PHS Evaluation Set-Aside since the program's inception at HHS. Within OPHS, the Office of Disease Prevention and Health Promotion (in conjunction with the OPHS Budget Office) coordinates the Evaluation Set-Aside program for the Assistant Secretary for Health. Each fiscal year, the OPHS program offices submit proposals to utilize these funds to support comprehensive, far-reaching evaluation projects to further the mission of HHS. Proposals for FY 2008 are still under review; final decisions will be completed by Spring 2008. Projects supported in FY 2007 included:

Reduce the major threats to the health and well-being of Americans

- Body Works Adolescent Evaluation and Dissemination
- Healthfinder.gov Evaluation
- National Women's Health Week 2007 Evaluation
- Evaluation of Food Label Education
- Evaluation of HIV Prevention Programs: HIV/AIDS Prevention for Young Women Attending Minority Institutions
- Evaluation of "Steps to Healthier Girls", a joint project with the Girl Scouts
- Evaluate the effectiveness of a media campaign "Healthy Heart Philadelphia"

Improve the Stability and Healthy Development of our Nation's Children and Youth

- An Assessment of Strategies for Providing Culturally Competent Care in Title X-Supported Family Planning Clinics
- Dissemination of Findings of Adolescent Family Life Demonstration Projects

Reduce the major threats to the health and well-being of Americans

- Evaluating Healthy People, Places and Practices in the Community, Phase 2
- Moving Forward on Development of Health Indicators for the Nation

- Evaluation of the National Action Agenda
- Trends in US Public Awareness of Racial and Ethnic Disparities in Health: An assessment of the public's perceptions and experiences about race, ethnicity, and health care system.
- Development of the first federal guidelines to focus on physical activity

Improve the Stability and Healthy Development of our Nation's Children and Youth

• Developing a Theoretical Framework for Abstinence Education Programs to strengthen the understanding and improve the scientific foundation and theoretical grounding of these programs.

Enhance the capacity and productivity of the Nation's health science research enterprise

• Evaluating the Impact on Whistleblowers who Report Research Misconduct

Enhance the ability of the Nation's health care system to effectively respond to bioterrorism and other public health challenges

 Evaluation of the Rostering, Training, Exercising and Deployment Activities of the Commissioned Corps Response TEAMS as Recommended in the White House Katrina After Action Report

Reduce the major threats to the health and well-being of Americans

- Specific Population Analysis Research Report from the HHS Health and Diet survey: Dietary Guidelines Supplement
- *Healthy People 2010* Focus Area 11: Action Plan Evaluation: Next Steps in Health Communication
- An evaluation of the 2006 CDC/Behavioral Risk Surveillance System Asthma Call-Back Survey

Assistant Secretary for Resources and Technology (ASRT)

In FY 2009, \$1,003,000 is requested to fund program evaluation activities within the Office of the Assistant Secretary for Resources and Technology – the same as the FY 2008 Enacted level. The request will be used to fund program evaluation activities within ASRT's Office of Budget and Office of Finance, including:

- salaries of staff focused on program evaluation activities in the PHS agencies, particularly PART and preparation of the Performance and Accountability Report; and
- development and operation of an electronic performance tracking system for HHS programs, similar to systems used by a number of other Federal agencies.

Funding History

Fiscal Year	<u>Amount</u>	<u>FTE</u>
2004	\$41,019,000	53
2005	\$39,202,000	52
2006	\$39,552,000	53
2007	\$39,552,000	49
2008	\$46,756,000	114

Budget Request

The total FY 2009 request for GDM's PHS Evaluation program is \$46,756,000, the same as the FY 2008 enacted level. Beginning in FY 2008, these PHS Evaluation amounts reflect the transfer of funding for ASPE from the GDM appropriation; all funding for ASPE operations is now centralized in PHS Evaluation funds.

The FY 2009 request for **ASPE** is \$41,243,000, the same as the FY 2008 enacted level. This funding level will allow ASPE to continue a variety of independent policy research and evaluation activities across the spectrum of the Department's programs, with particular attention to specific crosscutting initiatives, the breadth and depth of which are described in this submission. Along with the extensive agenda outlined above, ASPE will ensure that both the President's goal of accelerating the use of electronic health records (EHR) and the Secretary's initiative to transform health care through health information technology (HIT) are addressed in the FY 2009 research agenda. Another key area of ASPE emphasis will be to conduct research and analysis in support of the Secretary's initiative to promote a more Value-driven Health Care (VHC) system, which is based on four cornerstones: health information technology, measurement and publication of health care prices, measurement and publication of health care quality, and creation of positive incentives for participation in a VHC system.

The FY 2009 request for **OPHS** is \$4,510,000, the same as the FY 2008 Enacted level. This level will allow OPHS to allocate the same level of funds to its program offices to continue conducting evaluation projects.

The FY 2009 request for **ASRT** is \$1,003,000, the same as the FY 2008 Enacted level.

Outputs / Outcomes Table ASPE

#	Key	FY 2004	FY	FY	2006	FY	2007	FY	FY	Out-
	Outcomes	Actual	2005	Target	Actual	Target	Actual	2008	2009	Year
			Actual					Target	Target	Target
Long	g-Term Objective	1								
All	Provide analysis (policy research and evaluation studies) and	Demonstrate impact of policy analysis and leadership on	Same as FY 2004	Same as FY 2005	Target Met	Same as FY 2006	Target Met	Same as FY 2007	Same as FY 2008	Same as FY 2009
	leadership that contributes to the development of sound Department and public policy	formulation of public policy.								
			Lo	ng-Term	Objective	e 2				
All	Maintain human and technological capacity to respond to planning and analytical needs of the Secretary	Analytic support contributes to the development of analyses for the Secretary. Hire and train staff.	Same as FY 2004	Same as FY 2005	Target Met	Same as FY 2006	Target Met	Same as FY 2007	Same as FY 2008	Same as FY 2009

OS SERVICE AND SUPPLY FUND

	FY 2007	FY 2008	FY 2009	FY 2009 +/-
	<u>Actual</u>	Enacted	President's Budget	FY 2008
	651 404 000	¢ 40, 4 70 , 000	Φ . 0. 2. 2. 0. 0. 0. 0. 0. 0. 0. 0. 0. 0. 0. 0. 0.	# 000 000
Budget Authority	\$71,484,000	\$49,473,000	\$50,363,000	+\$890,000
FTE	109	127	128	+1
Authorizing Legislation	n: 42 II S.C. 231			
0 0				T 1 C' '4
2009 Authorization	• • • • • • • • • • • • • • • • • • • •	• • • • • • • • • • • • • • • • • • • •		Indefinite
Allocation Method			C	ontract, Other

Statement of the Budget

The FY 2009 budget for the Office of the Secretary (OS) Service and Supply Fund (SSF) is \$50,363,000, an increase of \$890,000 above the FY 2008 SSF Board-approved level of \$49,473,000 (approved July 26, 2007). The FY 2009 increases over the FY 2008 level are modest compared to the overall OS SSF budget. The majority of the net increase can be attributed to Commission Corps Force Management (CCFM) and the Web Communications Division (WCD). The FY 2009 CCFM increase (from \$22,643,000 to \$23,214,000) is primarily related to increased pay, growth in the Commissioned Corps related to the force transformation, contract costs, and intra-service costs. The FY 2009 increase in the budget for WCD (from \$6,127,000 to \$6,423,000) is primarily for pay (including 1 additional FTE), and contract increases in support of the Secretary's priorities.

Two changes that have taken place since the SSF Board approved the FY 2007 budget have impacted the SSF Board-approved budgets for FY 2008 and FY 2009. First, the Information Technology Service Center (ITSC) has been reorganized and placed under the auspices of the Program Support Center (PSC) for FY 2008 and FY 2009. The FTE adjustments related to this change are reflected in FY 2008 and FY 2009 numbers above. Budget and program information for ITSC can be found in the FY 2009 PSC budget justifications and will no longer appear in any OS Service and Supply Fund justification document. Additionally, while ITSC is now in the PSC and is being incorporated into that organization, the Enterprise Email activity which was previously a component of ITSC business is now independent of ITSC and will remain an OS SSF activity. Therefore, the methodology for calculating the OS SSF budget for FY 2008 and FY 2009 has changed and is reflected in the budget tables in this document.

This budget provides funding to support the provision of common services to Federal customers within HHS. Services provided include Acquisition Integration and Modernization (AIM), Audit Resolution, Claims, the Commissioned Corps Force Management (CCFM), Competitive Sourcing, Departmental Contracts Information System (DCIS), Enterprise Email (HHS Mail), the Small Business Office (OSDBU), Tracking Accountability of Government Grants System (TAGGS), and the Web Communications Division (WCD).

Program Description and Accomplishments

This section describes the OS components funded through the Department=s Service and Supply Fund (SSF), which is a revolving fund authorized under 42 U.S.C. 231. The SSF provides consolidated financing and accounting for business-type operations which involve the provision of common services to customers. The SSF is governed by a Board of Directors, consisting of representatives from each of the Department=s ten (10) Operating Divisions (OPDIVs) and the Office of the Secretary. A representative from the Office of Inspector General (OIG) serves as an "Ex Officio," non-voting member of the SSF Board.

The SSF does not have its own appropriation, but is funded entirely through charges to its customers (HHS=s OPDIVs and STAFFDIVs, plus other Federal agencies) for their usage of goods and services. Each activity financed through the SSF is billed to the Fund=s customers, based on either fee-for-service billing based upon actual usage of service or an allocated methodology. Each of these activities is described in detail below.

Acquisition Integration and Modernization (AIM): AIM creates a seamless integration of HHS-wide acquisition process standardization, internal controls and oversight, and performance measurement inputs to serve employees, customers and vendors. AIM leverages HHS spending opportunities, captures knowledge within the acquisition workforce, and seizes opportunities to adopt best practices. The AIM activity was added to the SSF effective October 1, 2004 and contractor support to sustain the AIM website was included from FY 2005 through FY 2007.

In addition, for FY 2007 and FY 2008, contractor support has been and will be used to achieve the following milestones: (a) developing process standardizations in the areas of purchase cards, acquisition plans, interagency contracting, and earned value management; (b) establishing emergency contracting procedures, developing an emergency contracting website, identifying emergency contracting training opportunities; and (c) issuing the BuyLines newsletter which fosters communication within the acquisition community and promotes sharing lessons-learned and best practices across the Department. For the remainder of FY 2008 and FY 2009, HHS will continue these efforts, as many are long term in nature. For example, the Office of Federal Procurement Policy (OFPP) is expected to issue new interagency contracting guidance in 2008. HHS will need to coordinate that implementing guidance, as well as HHS Acquisition Regulation changes implementing Earned Value Management.

Consistent with the President's Management Agenda (PMA) and in line with departmental objectives, HHS is committed to measuring success and assessing progress. To that end, an HHS Acquisition Dashboard was developed to measure HHS acquisition performance for critical functions such as the AIM standardization and modernization of acquisition systems, and Acquisition Balanced Scorecard. The balanced scorecard is a tool to measure and improve performance in terms of efficient business processes, innovative leadership, empowered employees and satisfied customers. In FY 2007, the semi-annual Acquisition Dashboard assessments of HHS OPDIVs were conducted across four categories, including strategic sourcing, balanced scorecard, small business participation and process improvement. OPDIVs achieved 15 "Green" ratings, 18 "Yellow" ratings and four "Red" ratings. This formed the performance baseline and alerted the OPDIVs as to the criticality of future improvement efforts.

Additional FY 2008 performance measures were developed to emphasize the use of performance-based acquisitions, increase the use of competition and support workforce training and development. The measures are performance based acquisition, competition and workforce training and development. For each of these measures, the performance standards, performance indicators, assessment criteria, and the basis for measurement have been established to measure the effectiveness of the HHS acquisition function.

In FY 2009 we will continue to pursue opportunities to standardize and modernize acquisition processes. An ongoing objective is to focus on performance measurement, including additional purchase card oversight and management reviews to measure how well HHS manages its procurement function. We will continue to make further refinements.

Audit Resolution: Audit Resolution, as mandated by P.L. 96-304 and P.L. 98-502, resolves grantee audit findings within a statutorily mandated six month period. Audit Resolution reviews and resolves audit reports containing monetary and/or systemic findings of grantee and contractor organizations affecting the programs of more than one OPDIV or Federal agency. These reviews can be initiated in response to findings identified by auditors in a grantee's A-133 audit. Audit Resolution makes recommendations and ensures that corrective action is taken on deficiencies in grantee/contractor accounting systems, internal controls, or other management systems.

Under the authority of OMB Circular A-50, paragraph 7.c., the audit follow-up official has responsibility for ensuring that timely responses are made to all audit reports, disagreements are resolved, and corrective actions are actually taken. The Federal Register (Volume 72, Number 131, Page 38886), dated July 10, 2006, empowers Audit Resolution to provide leadership in cross-cutting audit findings as well as make recommendations to the Secretary, the ASRT, and other officials on safeguards or other actions against a grantee or contractor, where the organization is unwilling or unable to correct serious deficiencies in a timely manner.

This activity also assists OPDIVs on the PMA scorecard initiative to reduce improper payments which includes completing program risk assessments, developing appropriate methodologies for estimating improper payments, and engaging in contract recovery auditing activities. Additionally, Audit Resolution provides functional leadership for completing and coordinating with OIG the Annual Management Report on Final Action to Congress on audit findings and with OMB on the annual update to the A-133 Compliance Supplement. This division also works closely with the OPDIVs to measure, identify, and implement corrective actions to prevent improper payments from a programmatic perspective; coordinates required program risk assessments; and engages in recovery auditing activities.

Claims: The Federal Tort Claims Act (FTCA) requires claimants to file administrative claims with the responsible agency before filing suit against the United States in Federal court. Each agency is given six months to settle or deny administrative claims. If no action is taken within six months, the claimant may then file suit in Federal court. As such, administrative claim processing is mission critical work that is required by Federal statute.

The HHS Office of General Counsel (OGC) receives and adjudicates all administrative tort claims (e.g., medical malpractice, vehicle accidents, acts or omissions that cause damages) on behalf of the Department. OGC staff logs in the matters, creates the files, researches the issues, coordinates with claimants and their representatives and with agency officials for background facts, and prepares a recommendation for the agency settlement authority, which has also been delegated to OGC. OGC settles claims where appropriate, and denies claims where not. For claims that are not settled which result in litigation, OGC works with the Department of Justice to defend the agency.

In FY 2005, OGC received 407 new claims. In FY 2006, 475 claims were received, about two-thirds of which reflected claims from nearly 900 community health centers deemed eligible for FTCA coverage with more than 3,000 delivery sites throughout the nation. The number of claims filed continued to increase in FY 2007, when 537 were filed, demanding approximately \$1.5 billion in damages. Thus, the number of claims has increased by more than 30% since FY 2005. If workload trends from the past continue, OGC can expect to receive 618 cases in FY 2008 and 710 in FY 2009. As of December 2007, OGC is tracking 827 pending matters.

Commissioned Corps Force Management: CCFM provides both personnel support to active-duty and retired PHS Commissioned Officers, and force management activities for the Corps as a whole. Force management of the Corps is administered by two offices within the Office of Public Health and Science (OPHS) – the Office of Commissioned Corps Force Management (OCCFM) that reports to the Assistant Secretary for Health (ASH) and the Office of Commissioned Corps Operations (OCCO) within the Office of the Surgeon General (OSG). OCCFM develops policies and proposed regulations in order to carry out a comprehensive force management program for the Corps. The office establishes timelines, performance standards, and measurements of the evaluation of the operations and management of the Corps, and works closely with the OSG to facilitate operations and the implementation of policies and programs. OCCO provides advice on matters related to the day-to-day management of the Corps, and also provides for the delivery of training and career development. The OCCO manages the personnel administration systems for the assignment, appointment, promotion, assimilation, and awarding of Corps members.

The following CCFM initiatives are planned and the dates of completion are dependent upon available funding:

<u>Automating the Medical records of active duty officers</u>: This plan will extend through FY 2008 and FY 2009. The expected completion date is the end of calendar year 2009.

Currently, the medical records of most active-duty officers consist solely of paper records. The information contained in these records is critical in determining the disability retirement pay and benefit entitlements of certain officers as well as Veteran's disability entitlements of individuals who have served on active duty. However, these paper documents are vulnerable to loss or destruction. The Commissioned Corps will be converting all of the paper medical files into an electronic format that will be easily retrievable and less vulnerable to loss or destruction, with the expected date of completion at the end of calendar year 2009. Also, the electronic Commissioned Corps Issuance System (eCCIS) replaced the Commissioned Corps Personnel

Manual and continues to be updated and modified. The target date for completion of this work is September 30, 2008, and it serves as a performance measure for FY 2008.

<u>Completion of the development of the new Commissioned Corps Effectiveness Report Tool</u>: This is expected to be completed by the end of calendar year 2009.

Activities continue on the revision of the Commissioned Officers' Effectiveness Report (COER), which is the annual evaluation process for Commissioned Corps officers. A prototype of the proposed new tool was shared with senior leadership and the Chief Professional Officers. Pilot testing of the tool will begin in the Fall of 2008 as a performance measure for FY 2009. A revised timeline with final product delivery by October 1, 2009 for the 2009 COER cycle is on target.

<u>Development of an online Officer Basic Course (OBC)</u>: This version of the present OBC is for officers who are well into their PHS careers but who did not have the opportunity to complete either a residential OBC or its predecessor Basic Officer Training Course. The online course is expected to be available by the end of calendar year 2008.

The two-week residential Officer Basic Course was successfully launched during the summer of 2007. Monthly OBC classes are scheduled through the remainder of FY 2008. Research is continuing on the development of the content and presentation of an introductory on-line course.

Other CCFM Activities: The Department successfully launched a major recruitment initiative, including the development of targeted recruitment materials, presence at major recruitment and professional events, through advertising in a variety of media, including professional journals and on line, and through the establishment of a call center. The major recruitment initiatives were targeted for April 2007 meeting their respective goal dates. The response to this campaign has been promising and will assist in the goal of increasing the size of the Corps by 10 percent to 6.600 officers.

The development of the Electronic Call to Active Duty (eCAD) system is designed to fully automate the application and applicant processing system. Phase one of this three-phased project has been completed. Launch of the product is anticipated by February 2008. Delays in the launch during 2007 were due to technical difficulties with aligning the newly designed system with existing systems, other unanticipated technical issues, and changes in call to active duty procedures that mandated system redesign.

The new Commissioned Corps Personnel and Payroll System (CCPayroll System), in effect for the past two years for retired officers and annuitants, continues to be used with a high level of success. The anticipated go-live date for active duty officers is in January 2008. Parallel testing of the new system along with the existing payroll system continued during the month of January. Several inconsistencies were noted and are being addressed. The revised go-live date is February 2008.

High Performing Organizations and Competitive Sourcing Reporting Support:

Competitive Sourcing provides support for activities related to the President's Management Agenda (PMA) for the Department. This activity was added to the SSF effective on October 1, 2005, with the purpose of maintaining a database to gather Federal Activities Inventory Reform (FAIR) Act inventory data at all levels of the Department. During FY 2006, the Office of Management and Budget developed an Oracle-based database, called the FAIR Act Automated Data Collection System. The FAIR Act Automated Data Collection System permits collection of FAIR Act inventory data at all levels throughout the Department. In compliance with P.L. 105-270, Competitive Sourcing populates the database with the Department's competitive sourcing data, providing accurate, accessible reporting capabilities and linkage of data to the Department's competitive sourcing plans 100 percent of the time.

Competitive Sourcing has established two annual performance measures. The first measure aims to provide information that is current and accessible to OPDIV competitive sourcing managers at least 95% of the time. This is computed by comparing the rate of access per the database to total OPDIV competitive sourcing managers. In FY 2007, the result was 100%, exceeding the target. The targets for FY 2008 and FY 2009 for this measure remain 95%. The second measure aims to submit complete information to the OMB by its deadline for the competitive sourcing database. The deadline for FY 2007 was December 31, 2007, and this goal was met. The goal for this second measure for FY 2008 and FY 2009 remains the same. Of note, Competitive Sourcing has earned Green Status and Progress scores from the Office of Management and Budget for 16 consecutive fiscal quarters.

Departmental Contracts Information System (DCIS): DCIS provides a central repository for Department-wide procurement data, and is the primary system used by HHS to fulfill procurement reporting requirements to the Federal Procurement Data System Next Generation/OMB (FPDS-NG), which is mandated by Public Law 93-400. This system compiles contract information to produce geographically based reports to the Office of Management and Budget (OMB) and Congress under P.L. 93-400. It also provides procurement information for Freedom of Information Act (FOIA), requests from OMB, the Congress, State governments, and HHS management.

Prior to FY 2007, HHS data on open contracts and orders awaiting closeout were collected either manually or resided within each Operating Division. As a result, there was no uniform, automated method to record and assess contract closeout activity, including backlog, on a department-wide basis. For FY 2007 and FY 2008, contractor support was obtained to provide IT support services to DCIS. The contractor provides services that include: application software enhancements to make for a smooth delivery of HHS procurement data to the FPDS-NG; application software maintenance; systems environment and database maintenance; training support for system users; systems operation support; and, system security. Utilizing DCIS to capture order and contract closeout transactions provided the Department with a robust, automated method to maintain and report this important activity. In FY 2008 and FY 2009, the DCIS contractor will deploy and disseminate additional standard reports and an ad hoc reporting system.

Since FY 2007, the Office of Federal Procurement Policy (OFPP) has required each Executive agency to establish agency-wide requirements for statistically valid verification and validation of

data submitted to FPDS-NG. Each Executive agency must provide certification of data accuracy and completeness to the OFPP/General Services Administration (GSA) each year no later than December 15. To ensure objectivity, HHS retained the services of an independent consultant to gauge the accuracy of HHS FY 2007 contract data. The verification and validation captured two types of errors: (1) incorrect entry in any field, and (2) missing entries in required fields.

In light of the significant data input errors that the consultant identified, it is imperative that financial resources be mobilized and aggressive steps be taken to improve DCIS/FPDS-NG data accuracy and support compliance with the Federal Funding Accountability and Transparency Act in FY 2008, 2009 and beyond. HHS has embarked on a systematic approach to improve its contract data, including the following strategies: providing its contracting offices with lessons learned from the verification and validation study; developing and applying appropriate performance metrics; establishing and implementing an active Department-wide oversight program under which HHS' Office of Acquisition Management and Policy would centrally manage and monitor the program, while holding HHS' Operating Divisions accountable for improvements in data accuracy; identifying the most appropriate officials to input the data; emphasizing the need for pre-award review of data input; enhancing data input guidelines to address the most critical errors (e.g., those relating to FFATA); developing Department-wide standardized training materials, as needed; and updating the HHS' Acquisition Regulation and HHS' supplement to the FPDS-NG Manual, as appropriate, to reinforce the importance of the data quality control.

Enterprise Email (HHS Mail): HHS Mail provides an enterprise-wide electronic mail service for the Department. The service is outsourced to a contractor which established the infrastructure and currently maintains and operates the system. The contract was originally awarded in January 2004 with one base year and four optional years. The system is deployed at two primary locations, with a third separate security enclave supporting FDA. The multiple locations provide for the continuity of operations and disaster recovery services. The total mailbox count exceeds 70,000.

The mail system provides access for users located at the major locations as well as regional offices across the country. The system operates on a fee-for-service basis consisting of the standard mailbox and includes archival services. Additional storage and support for mobile devices is billed separately. The scope of the consolidation includes OS, PSC, CMS, FDA, IHS, CDC (including ATSDR), SAMHSA, AoA, ACF, and AHRQ. The consolidation reduced the number of legacy servers from 194 to 16 and the number of physical sites from 109 to 3. The migrations have been substantially completed with a small number of field sites remaining.

Efforts are ongoing to continuously enhance the services provided with a number of planned initiatives to be analyzed during FY 2008 to include technology refreshment for the anti-SPAM and archival solutions as well as a review of the strategy for enhanced disaster recovery services. The program will be transferred to the PSC for operations and maintenance by October 1, 2008. The acquisition planning is underway to provide a follow-on contract as the current contract approaches completion on January, 19, 2009. (The HHS CIO Council has voted in support of extending this contract through September, 2009.) Contractual performance measures have been exceeded for calendar year 2007 and include performance measures for basic services,

mobile communications devices, Network, and remote web access. These four performance measures will continue to be measured on a monthly basis with a minimal acceptable level of 99.9%. Conformance to these performance goals is measured through system monitoring tools that continuously collect operational statistics. The HHS Mail office receives and analyzes monthly systems performance reports that provide a summary of round-the-clock monitoring of the HHS Mail system. Performance statistics from these reports are presented at a monthly meeting of OPDIV representatives for their review.

Office of Small and Disadvantaged Business Utilization (OSDBU): OSDBU was established in 1979 under P.L. 95-507, the Small Business Act (SBA). The Small Business Office was added as an activity of the Service and Supply Fund, effective on May 18, 2005. The Small Business Office provides leadership, guidance and recommendations to insure that small businesses are given an equitable opportunity to participate in the provision of goods and services to HHS. The activities and performance goals for Small Business can be grouped into three broad categories.

Training

This element measures the level of effort to target and provide meaningful training to contract and program office staff on small business goals and objectives. This training raises the level of awareness and value in using small businesses for HHS procurement needs. The Small Business Program at HHS targeted this training as a key objective for FY 2007, building on the outcomes of the Climate Assessment performed in FY 2006. The goal for FY 2007 was to train 10% of HHS procurement and program staff and this goal was met within the calendar year. The goal for FY 2008 is to train at least 20% of the remaining staff and to continue this effort until all eligible staff have been trained.

Vendor Outreach

This element measures a critical spectrum of the OSDBU mission which is to reach out and educate small business owners on marketing strategies and contracting opportunities at HHS. This effort demonstrates top level Department commitment and strategy to increase opportunities and awarded contracts to small businesses. Providing access and one on one counseling to small business owners is key to creating greater awareness and understanding of what HHS buys and how to successfully market to HHS.

The target goals for FY 2007 were to conduct eleven (11) monthly Vendor Outreach Sessions in the Washington, D.C. area and to support ten (10) national/regional conference workshops, and these goals were met. The goals for FY 2008 are to continue to provide eleven (11) Vendor Outreach Sessions in the Washington, D.C. area, while also supporting fifteen (15) national/regional conferences workshops.

Meet or Exceed Small Business Contracting Goals

This element measures the percentage of HHS contracts awarded to small businesses. This goal is a key element upon which HHS is measured by the Small Business Administration and Congress. In FY 2007 HHS achieved its negotiated goal of 20% in awards to small businesses. For FY 2008, the Department's goal has been set at 19% which reflects the addition of several billion dollars to the Department's operational budget for Medicare and Flu/Vaccine contracts –

work which generally cannot be performed by small businesses due to their specialized nature. At this time, the Department's goal for FY 2009 has not yet been determined.

Tracking Accountability in Government Grants System (TAGGS): TAGGS is the HHS central repository of grant award data. The publicly searchable database houses HHS discretionary and mandatory grant funding data awarded from 1995 to the present. As the largest grant-making agency in the Federal government, awarding approximately 60% of the Federal government's grant dollars and annually providing over \$273 billion in grants to domestic and foreign grantees for U.S. health assistance and social service programs, the system is an essential tool for monitoring and reporting on HHS grant spending.

TAGGS supports HHS grants consolidation efforts. The system primarily receives OPDIV and STAFFDIV data via ACF's GrantsSolutions.gov or NIH's IMPAC II, effectively decreasing costs and resources attributed to maintaining multiple interfaces with multiple grants management systems, while improving the oversight, quality, and integrity of grant data HHS reports. By consolidating OPDIV and STAFFDIV grant data into a central system, TAGGS allows internal users, Congress, government agencies, interest groups, and the general public the ready ability to query the system for information on HHS domestic and international grants. Although basic grants award data has been submitted to TAGGS since 1995, the increased number of grants abstracts enables users to review the specific objectives and activities of a greater percentage of awards, providing the following advantages:

<u>Transparency</u> - Users can learn more about the funded projects, thereby improving funding transparency. The information also assists HHS management with grant administration oversight.

<u>Consolidation</u> - Supports the Department's strategic objective to consolidate grants systems, with all project abstracts being extracted from the ACF GATES and NIH IMPAC II systems.

<u>Cross-referencing and Supporting Data</u> - Provides supporting data for key HHS financial management systems, such as the Unified Financial Management System (UFMS) to track grant expenditures in accordance with specific budget and appropriation guidelines. Data from TAGGS may be cross-referenced with UFMS to monitor grants management controls.

TAGGS plays a key role in facilitating HHS compliance with Public Law 109-282, The Federal Funding Accountability and Transparency Act of 2006. The Act sought to develop a publicly searchable OMB database by January 2008, which would house all Federal grants, contracts, loans, and other forms of financial assistance. The January 2008 target was met and this database can now be accessed by the public (http://www.usaspending.gov). This FY 2006 law also established the goal that sub-grant and sub-contract data under the Act are due on or after January 1, 2009. Additionally, all award data must be submitted to OMB's database within 30 days of award. To support these challenging requirements the Office of Grants, ASRT has convened a TAGGS Advisory Workgroup to gather input from all HHS grant-making OPDIVs and STAFFDIVs on the necessary business and technical modifications to support FFATA and ensure appropriate implementation. TAGGS has tested and deployed a web service that will permit searching of the TAGGS database by the OMB FFATA website search engine.

The long term goal for TAGGS is to increase the transparency of HHS Grant Funding Activities to the public and other Federal Agencies. TAGGS exceeded this FY 2007 Service and Supply Fund (SSF) performance metric and met its target ahead of schedule. The system surpassed the 65% metric, showing 70% of the grants having abstracts loaded by the end of FY 2007 and 79% loaded by December 2007. The FY 2008 SSF performance metric is set at 75%, and HHS does not anticipate difficulty in achieving this milestone. Goals for FY 2009 will be established in FY 2008 and will be based on degree of success in meeting or surpassing the prior year's goals.

Web Communications and New Media Division (WCD): The WCD is responsible for redesigning and refocusing the HHS Departmental Web sites to be topics-based and citizencentric. The over-arching goal is to ensure that users can locate information easily across the entire Department. Specific projects of the WCD include: the establishment and application of Web standards and guidance; the promulgation of Department-wide Web governance; the creation and management of cross-government Web sites (such as PandemicFlu.gov and AIDS.gov); the management, consulting on, and approval of HHS-wide sites, including the establishment of a protocol for interlinking related content across HHS Web sites. WCD is charged with improving Department-wide Web site Section 508 compliance. Web site quality and utility will be increased by providing page and link context and gradual reorganization by topic. This work will be guided by usability testing.

WCD is directly responsible for managing content on the HHS/OS Web sites, both external and internal. WCD supports this through: the implementation of a Content Management System; the application of a search engine (including specialized configurations); the management of enterprise-wide Frequently Asked Questions; the operation of a portal collaborative application; the provision of multiple language translation on specified sites; and the application of Web 2.0 concepts and technologies.

The WCD is establishing a User Survey and will use this as a tool to improve content feedback scores submitted by site visitors. Use of this survey will be ongoing. During FY 2007, the Web Communications Division successfully handled a 39 percent increase in the number of requests for Web-related services (content updates, redesigns, refreshes, usability testing) over FY 2006 requests. Below is a sample of some of the accomplishments and activities of the WCD in FY 2007:

- Web usage measurement tool implemented:
 WCD acquired a new metrics tool that allows our team to track usage of www.hhs.gov
 and www.pandemicflu.gov.
- O Implemented various technical improvements to pandemicflu.gov and hhs.gov: PandemicFlu.gov and HHS.gov have both been given the ability to stream video to the web, giving HHS the ability to do live streaming of news or alerts in case of emergency. The video on demand capability allows HHS to communicate with a wider audience in a new and effective way.
- Established Web Governance:
 - Working with representatives across the department, WCD wrote and obtained approval of Web Governance. The Secretary officially adopted the governance structure in April

2007.

- WCD hosted the HHS Web Council meetings.
- Created HHS Web sites for Secretarial Priorities:
 The WCD established several Web sites to support Secretarial and Departmental priority topics, including topics such as Health Information Technology, Value-Driven Health Care, Import Safety, and Health Diplomacy.
- Launched a re-engineered and rebuilt HHS Enterprise Portal:
 The HHS Portal went from dormancy, with no active communities to hosting 25 new communities by the end of 2007.

During FY 2008 and FY 2009, WCD is anticipating increased costs for server consolidations and server load balancing. There are a number of newly realized technology projects needed to run the HHS Web successfully. These consist of the HHS Portal expansion to integrate more HHS customers and the addition of an HHS "Newsroom" database that will feature Department-wide news releases. They will also enable the Department to keep the public abreast of pertinent health information. WCD will continue to conduct usability testing of the HHS Homepage and other sites, and will remain committed to strengthening Section 508 compliance Department-wide, and issuing PDF guidance. Updated web security standards are also an area of focus for WCD.

The development of FY 2009 performance measures is not completed. However, performance goals for FY 2008 include:

- o Establishing guidance and training for Section 508 compliance
- o Promulgating acquisition language to ensure that products delivered for the Web are Section 508-compliant
- o Increasing Section 508 compliance on HHS/OS Web sites by 25 percent over 2007 levels
- o Establishing 12 new Web standards
- o Establishing an HHS/OS Web (governance) Board
- o Establishing a dynamic FAQ database
- o Establishing a Department-wide Web-based newsroom
- o Establishing a dynamic news release database
- o Establishing a dynamic database for Web standards and policies
- o Establishing a plan and timeline for reorganization of the HHS/OS intranet
- o Increasing Portal utilization by 20 percent over FY 2007 levels

OFFICE OF THE SECRETARY SERVICE AND SUPPLY FUND FY 2007 REVENUE DISTRIBUTION 1 (\$000)

ACTIVITY	ACF	AHRQ	AoA	CDC	CMS	FDA	HRSA	IHS	NIH	os	SAMHSA	Other	Total
AIM	\$11	\$11	\$2	\$210	\$44	\$121	\$44	\$254	\$298	\$0	\$22	\$0	\$1,018
Audit Resolution	520	0	58	103	257	1	52	68	285	0	77	0	1,421
Claims	5	0	0	36	14	38	547	297	14	28	0	0	980
CCFM	2	41	1	2,367	245	2,049	1,439	6,363	1,165	465	151	3,068	17,355
Competitive Sourcing	4	1	0	23	13	27	5	40	47	0	1	0	162
DCIS	8	8	2	152	32	88	32	184	216	0	16	0	737
ITSC	6,998	3,051	633	525	300	1,169	1,160	1,002	773	21,119	3,372	0	40,101
Small Business	0	39	0	335	256	210	89	176	1,192	0	81	0	2,380
TAGGS	23	10	8	96	103	27	190	89	364	1	111	0	1,021
Web Comm.	117	27	11	809	440	912	178	1,447	1,562	218	50	0	5,771
TOTAL OS SSF	\$8,066	\$3,311	\$751	\$4,658	\$1,704	\$4,642	\$3,737	\$9,919	\$5,916	\$42,950	\$3,881	\$3,068	\$71,484

¹ The above table represents actual FY 2007 revenue billed by OS-SSF cost centers to customers (horizontal axis) as captured by the PRICES billing system. The revenue amounts collected from customers for ITSC shown above also include revenue from the Enterprise Email cost center (HHS Mail). However, due to a reorganization within the SSF, the exhibits on subsequent pages showing the SSF Board-Approved budgets for FY 2008 and FY 2009 are slightly different, for two reasons. First, the Information Technology Service Center (ITSC, above) has been reorganized and placed under the auspices of the Program Support Center (PSC) for FY 2008 and FY 2009. Budget and program information for ITSC (since renamed Information Technology Operations, or ITO) can be found in the FY 2009 PSC budget justification for FY 2009 and will no longer appear in any OS Service and Supply Fund justification document. Additionally, while ITSC is now in the PSC and is being incorporated into that organization, the Enterprise Email service (HHS Mail) which was previously a component of ITSC business is now independent of ITSC and is being reported with OS SSF activities and cost centers. Therefore, the methodology for calculating the OS SSF budget for FY 2008 and FY 2009 has changed and is reflected in the budget tables in this document.

OFFICE OF THE SECRETARY SERVICE AND SUPPLY FUND FY 2008 REVENUE DISTRIBUTION (\$000)

ACTIVITY	ACF	AHRQ	AoA	CDC	CMS	FDA	HRSA	IHS	NIH	os	SAMHSA	Other	Total
AIM	\$11	\$11	\$2	\$214	\$45	\$124	\$45	\$259	\$304	\$32	\$23	\$0	\$1,069
Audit Resolution	519	0	58	83	255	1	44	54	271	0	65	0	1,350
Claims	2	0	0	8	23	33	622	299	22	37	0	0	1,046
CCFM	0	49	0	3,122	356	2,733	1,810	8,220	1,571	559	180	4,045	22,643
Competitive Sourcing	4	1	0	23	13	26	5	39	46	11	1	0	169
DCIS	8	8	2	155	33	90	33	188	221	23	16	0	777
Enterprise Email	549	174	46	3,825	1,372	2,591	-	2,646	-	1,443	218	-	12,864
Small Business	26	40	5	341	246	212	90	177	1,172	0	82	0	2,390
TAGGS	23	10	8	97	104	27	191	89	366	10	112	0	1,037
Web Comm.	123	28	11	868	428	934	184	1,447	1,631	423	50	0	6,127
TOTAL OS SSF	\$ 1,265	\$321	\$132	\$8,736	\$2,874	\$6,771	\$3,023	\$13,419	\$5,604	\$2,537	\$747	\$4,045	\$49,473

OFFICE OF THE SECRETARY SERVICE AND SUPPLY FUND FY 2009 REVENUE DISTRIBUTION (\$000)

ACTIVITY	ACF	AHRQ	AoA	CDC	CMS	FDA	HRSA	IHS	NIH	os	SAMHSA	Other	Total
AIM	\$12	\$12	\$2	\$219	\$46	\$127	\$46	\$265	\$311	\$32	\$23	\$0	\$1,094
Audit Resolution	534	. 0	60	86	262	1	45	55	279	0	67	0	1,389
Claims	2	0	0	8	23	33	636	319	22	38	0	0	1,080
CCFM	0	50	0	3,201	365	2,801	1,856	8,427	1,610	573	185	4,146	23,214
Competitive Sourcing	4	. 1	0	23	13	26	5	39	46	11	1	0	169
DCIS	8	8	2	159	33	92	33	192	226	23	17	0	793
Enterprise Email	549	174	44	3,825	1,372	2,591	0	2,646	0	1,443	218	0	12,862
Small Business	26	40	5	351	249	217	92	181	1,186	0	84	0	2,431
TAGGS	171	5	14	40	10	1	117	14	488	8	40	0	908
Web Comm.	128	29	12	911	448	980	193	1,517	1,709	443	53	0	6,423
TOTAL OS SSF	\$1,434	\$319	\$139	\$8,823	\$2,821	\$6,869	\$3,023	\$13,655	\$5,877	\$2,570	\$688	\$4,146	\$50,363

DEPARTMENT OF HEALTH AND HUMAN SERVICES OFFICE OF THE SECRETARY – SERVICE & SUPPLY FUND (OS-SSF)							
Detail of Full-time Equivalent (FTE)							
	FY 2007 Actual	FY 2008 Targets	FY 2009 Targets				
OS-SSF Activities							
ASAM Activities: AIM Competitive Sourcing DCIS OSDBU Total ASAM	0 2 1 10 13	0 2 1 12 15	0 2 1 12 15				
ASRT Activities: Audit Resolution TAGGS SSF Fund Mgr Total ASRT	7 1 2 10	8 2 <u>4</u> 14	8 2 4 14				
OPHS Activity: CCFM	64	71	71				
OGC Activity: Claims	6	7	7				
ASPA Activity: Web Communications Division	16	19	20				
OS-SSF Activities – TOTAL	109	126	127				
FY 2009 +/- FY 2008	+1						

There is an estimated increase of one (+1) FTE for the OS-SSF in FY 2009. This increase of one FTE in the Web Communications Division is needed due to several factors. There has been a steady increase in the number of requests for web related services. In FY 2007 alone, the WCD handled a 39 percent increase in the number of these requests over the preceding fiscal year. The WCD is engaging in a number of new initiatives, implementing new technology projects, and working to develop new guidance and training for Section 508 compliance during FY 2008 and FY 2009. Additional human resources will be needed to meet these demands.

SPECIAL REQUIREMENTS

Unified Financial Management System Operations and Maintenance (UFMS O & M)

UFMS has now been fully deployed. The Program Support Center, through the Service and Supply Fund, manages the ongoing Operations and Maintenance (O & M) activities for UFMS. The scope of O & M services includes post deployment support and ongoing business and technical operations services, as well as an upgrade of Oracle software from version 11.5.9 to version 12.0. The Office of the Secretary Service and Supply Fund will use \$174,903 for these O&M costs in FY 2009.

Questions should be directed to David Tillette, Office of Finance, at (202) 260-7123.

HHS Consolidated Acquisition System (HCAS)

The HHS Consolidated Acquisition System (HCAS) initiative is a Department-wide contract management system that will integrate with the Unified Financial Management System (UFMS). The applications within the HCAS are Compusearch PRISM and a portion of the Oracle Compusearch Interface (OCI). PRISM is a federal contract management system that streamlines the procurement process. PRISM automates contract writing, simplified acquisitions, electronic approvals and routing, pre-award tracking, contract monitoring, post award tracking, contract closeout and reporting. The Office of the Secretary Service and Supply Fund will use \$9,461 to support the completion of HCAS implementation in FY 2009.

Questions should be directed to Mike Fullem, at (301) 443-6774

DETAIL OF FULL TIME EQUIVALENT (FTE) EMPLOYMENT (excluding Service and Supply Fund)

	FY 2007	FY 2008	FY 2009
	<u>Actual</u>	<u>Enacted</u>	<u>Estimate</u>
Immediate Office of the Secretary	68	66	66
Public Affairs	28	27	27
Legislation	28	24	24
Planning and Evaluation	97	97	97
Resources and Technology	141	140	140
Administration and Management	114	113	113
Intergovernmental Affairs	33	32	32
General Counsel	376	365	357
Departmental Appeals Board	60	59	59
Office on Disability	4	4	4
Global Health Affairs	43	38	37
Public Health and Science 1/	305	300	417
President's Council on Bioethics	10	9	90
Center for Faith-Based Initiatives	<u>6</u>	<u>6</u>	<u>6</u>
Total, GDM (excluding SSF)	1,313	1,280	1,469

1/ OPHS: Increase in FY 2009 due to transformation of the Commissioned Corps

Average GS Grade

2004	GS-12/3
2005	GS-12/2
2006	GS-12/2
2007	GS-12/2
2008	GS-12/3

DETAIL OF POSITIONS

	FY 2007 Actual	FY 2008 Enacted	FY 2009 Estimate
Executive Level I	1	1	1
Executive Level II	1	1	1
Executive Level III	-	_	_
Executive Level IV	9	9	9
Executive Level V	<u>–</u>	<u>=</u>	
Subtotal	11	11	11
Total – Executive Level Salaries	\$1,663,000	\$1,704,000	\$1,756,000
SES Subtotal	96	102	102
Total – ES Salaries	\$13,424,000	\$14,620,000	\$15,059,000
GS-15	160	149	150
GS-14	240	223	223
GS-13	302	276	277
GS-12	253	230	231
GS-11	109	97	97
GS-10	5	5	5
GS-09	103	95	95
GS-08	41	35	35
GS-07	52	45	45
GS-06	11	9	9
GS-05	7	6	6
GS-04	1	1	1
GS-03	_	_	_
GS-02	_	_	_
GS-01			
Subtotal	1,284	1,172	1,175

	FY 2007 <u>Actual</u>	FY 2008 Enacted	FY 2009 Estimate
Commissioned Corps	50	50	167
Ungraded	<u>86</u>	84	84
Total positions	1,526	1,419	1,539
Total FTE usage, end of year	1,313	1,280	1,388
Average ES salary	\$139,838	\$154,955	\$155,419
Average GS grade	GS-12/2	GS-12/3	GS-12/3
Average GS salary	\$68,993	\$74,416	\$76,648
Average Special Pay (Commissioned Corps)	\$86,764	\$89,447	\$92,578

SIGNIFICANT ITEMS FOR INCLUSION IN THE FY 2009 CONGRESSIONAL JUSTIFICATION

FY 2008 House Appropriations Committee Report Language (H. Rpt 110-231)

Item

Preterm birth -- The Committee encourages the Surgeon General to convene a conference on preterm birth and produce a report establishing a public-private agenda to expedite the identification of and treatments for the causes and risk factors for preterm labor and delivery as authorized by the PREEMIE Act (P.L. 109B450). (p. 210)

Action taken or to be taken

The Office of the Surgeon General is actively planning the Surgeon General's Conference on the Prevention of Preterm Birth, scheduled for June 2008 in Washington, D.C. The goals of the conference are to:

- increase public, policymakers and scientists awareness of the seriousness and rising incidence of preterm births;
- review the scientific findings from several recent reports regarding preterm birth and establish research priorities for identifying the causes of / risk factors for preterm birth and translating this knowledge into effective treatments; and
- review communication/outreach efforts and establish an action plan for activities in both the public and private sectors.

NICHD will be the lead agency on facilitating this conference and other entities within the DHHS as well as major professional organizations are participating in the planning of the conference.

Item

Sodium -- The Committee encourages the Secretary to explore funding a study by the Institute of Medicine of the National Academy of Sciences that will examine and make recommendations regarding various means that could be employed to reduce dietary sodium intake to levels recommended by the Dietary Guidelines for Americans. These should include, but not be limited to, actions by food manufacturers, such as new product development and food reformulation, and governmental approaches, such as regulatory, legislative approaches, and public and professional information and education. In addition, the Committee encourages the Secretary to request a report from the Surgeon General on ways in which the department could strengthen its activities pertaining to health issues related to salt. (p. 210)

Action taken or to be taken

The Office of the Surgeon General actively participates in the Secretary's Prevention Initiative. There are several Department activities and programs that address the public health concerns related to inappropriate consumption of sodium. The Department of Health and Human Services (HHS) and the Department of Agriculture (USDA) have published the Dietary Guidelines for Americans (2005) jointly every 5 years since 1980. The Guidelines provide science-based advice to promote health and to reduce risk for major chronic diseases through diet and physical activity. Key recommendations for sodium consumption per day as well as guidance for food

choices are outlined in this publication. They serve as the basis for federal food and nutrition education programs. The 2005 Dietary Guidelines for Americans are currently being revised by HHS and USDA with the updated document anticipated to be completed for 2010.

The Food and Drug Administration (FDA), in response to a citizen's petition, had a public hearing for stakeholders to explore approaches for reducing sodium content in foods and sodium consumption at the end of November 2007. The comment period is currently open. It is anticipated that the information gathered will inform the 2010 Dietary Guidelines for Americans and current policies related to the regulation of sodium. Additionally, FDA provides Nutrition Facts Label information on the food package and has public educations that highlight different nutrition areas. It is anticipated that a sodium education module will be released in 2008.

Item

Steroid use -- The Committee supports education efforts to demonstrate the consequences of using performance-enhancing drugs. The Department of Health and Human Services should undertake a comprehensive campaign to educate youth on the dangers of steroid use for 5th through 8th graders, an education campaign authorized in the Anabolic Steroid Control Act of 2004.

Action taken or to be taken

National Institute on Drug Abuse (NIDA) has supported and will continue to support research that increases our understanding of the impact of steroid abuse and improves our ability to prevent abuse of these drugs. For example, NIDA funding of researchers at the Oregon Health and Science University led to the development of two highly effective programs that not only prevent anabolic steroid abuse among male and female high school athletes, but also promote other healthy behaviors and attitudes. Both the Athletes Training and Learning to Avoid Steroids (ATLAS) program targeting teenage male athletes and the Athletes Targeting Healthy Exercise and Nutrition Alternatives (ATHENA) program targeting teenage female athletes demonstrate that sports teams can be effective vehicles to promote healthy lifestyles and deter drug abuse and other harmful behaviors. Their format uses influential coaches and existing, single-gender bonded peer groups to deliver immediately relevant messages about the harmful effects of anabolic steroids and other illicit drugs and risky behaviors on immediate sports performance, and provide nutrition and weight-training alternatives to steroid use. These programs have been adopted by 130 schools in 35 states and Puerto Rico. The Anabolic Steroid Control Act of 2004, which amended the Controlled Substances Act to focus on steroid abuse, specifically mentioned ATLAS and ATHENA as model programs. SAMHSA has established the National Registry of Evidence-based Programs and Practices (NREPP) to assist State, local, and non-profit organizations identify the effective programs that will help those organizations maximize the impact of their activities. Three are currently identified, including the two specifically mentioned in the ASCA of 2004. The final General Departmental Management appropriation did not include funds for an education campaign grant program.

Item

Obesity awareness and prevention -- The Committee encourages the OMH to continue its effort to partner with organizations that are focused on collaborative efforts to eliminate health disparities by, among other things, raising awareness of obesity as a public health epidemic and removing barriers to obesity prevention through culturally competent community education and helping to create community environments that facilitate equal access to healthy lifestyles. (p. 211)

Action taken or to be taken

The Office of Minority Health (OMH) shares the Committee's concern regarding the impact of obesity on increased risks for disease and the need to raise awareness through enhanced prevention efforts. This issue is particularly important among racial and ethnic minorities, some of whom have significantly higher rates of obesity and overweight. In response, OMH is partnering with the National Hispanic Medical Association (NHMA) to develop culturally competency strategies to combat the growing obesity epidemic among the Hispanic community. Specifically, through the NHMA project OMH is supporting three (3) regional summits to develop consensus on strategies to increase health care access; increase obesity and diabetes programs; increase opportunities for Hispanics to enter the health professions; and to increase public awareness of health disparities for Hispanics. OMH will use the findings of this project to leverage other partnerships to reduce the burden of health disparities among racial and ethnic minority communities.

In FY 2007 OMH funded a number of projects under its Community Partnerships to Eliminate Health Disparities Demonstration Grants Program that address obesity prevention through culturally competent community education and healthier lifestyles. An example includes the *Diabetes Prevention Youth Program* of the Gila River Health Care Corporation which seeks to prevent or delay the onset of diabetes among 5-19 year-olds in the Gila River Indian Community. The objectives of this demonstration project include increasing physical activity and healthy eating habits of participating youth by 70 percent. Another example is the *Grassroots Partnership to Promote Healthy Living, Eliminate Health Disparities and Prevent Childhood Obesity* in the District of Columbia demonstration project. The Summit Health Institute for Research and Education, Inc. will focus on obesity and overweight among children and adolescents aged 1-9 through implementation of: a culturally appropriate, community-based awareness effort; health education and promotion strategies; peer education; healthcare professional outreach program; and connecting children to regular health care. These and other OMH-funded projects/partnerships reduce barriers to obesity prevention and help to develop culturally competent programs for healthier lifestyles.

Item

Centers of excellence -- Multidisciplinary centers of excellence in women's health were established in 1996 to develop standards of excellence in women's health care, research, leadership, training and education. The 48 institutions from 40 States and Puerto Rico that have been designated as centers of excellence participate in one of five model programs developed by the OWH to provide comprehensive, integrated, interdisciplinary and coordinated women's health care: national centers of excellence in women's health, national community centers of

excellence in women's health, ambassadors for change, region VIII demonstration projects, and rural frontier women's health coordinating centers. This network has successfully leveraged significant public and private funding across all 48 sites. The Committee urges OWH to maintain the center of excellence designation and the existing structure of this innovative initiative, and to reconsider its decision to discontinue funding for these centers of excellence. (p. 211/212)

Action taken or to be taken

The Office on Women's Health (OWH) developed a new model program in September 2007, Advancing System Improvements to Support Targets For Healthy People 2010 (ASIST 2010). The intent of the ASIST 2010 Program is to use a public health systems approach and evidence-based strategies to improve performance on two or more of the seven Healthy People 2010 Focus Areas. The new program provides three years of funding to support public health systems and/or collaborative partnerships with baseline data available that puts a gender focus on the Healthy People 2010 Focus Areas: 3--Cancer, 5—Diabetes, and /or 12—Heart Disease and Stroke, the leading causes of death among women and men. The focus area objectives also crosscut with Healthy People 2010 Focus Areas: 1—Access to Quality Health Services, 7—Educational and Community-Based Programs, 19—Nutrition and Overweight, and 20—Physical Activity and Fitness, and their objectives.

The three-year grant awards were made to 12 organizations - three academic medical centers, three community-based organizations, two hospitals, two State health departments, one county health department, and one foundation. Many of the former OWH Centers of Excellence grantees competed for the new ASIST 2010 program, and several successfully became ASIST 2010 grantees including, the University of Utah (Center of Excellence - CoE) partnering with Utah and Navajo Health System, Inc. (Rural/Frontier Women's Health Coordinating Center), Brigham and Women's Hospital, Women's Wellness and Maternity Center (Rural/Frontier Women's Health Coordinating Center), University of Illinois at Chicago (CoE), and Drexel University (CoE). In addition, the University of Minnesota (CoE) partnering with the Minnesota Community Center of Excellence, though not a OWH grantee, is participating fully in the program [Due to University error, the University of Minnesota application was received late and deemed unacceptable. The University made the decision to fully fund the project].

In addition, the former centers of excellence sites may continue using their name and logo so long as they reference (whether in writing or speaking) their DHHS affiliation in former terms. Many of the sites have sustained one or more components of the model through leveraged dollars and the OWH is exploring options for examining the sustainability of the program to inform a global definition of sustainability for Federal programs that can be used in future grant/contract announcements.

FY 2008 Senate Appropriations Committee Report Language (S. Rpt 110-107)

Item

[Health care delivery in Louisiana] -- The Committee recognizes the importance of rebuilding the health care delivery system in Louisiana following hurricanes Katrina and Rita in 2005 and encourages the Department of Health and Human Services to work with the State of Louisiana to rebuild a redesigned, properly funded health care system for its citizens. Barriers to expanded access and choice to the medically uninsured low-income population should be eliminated. Recognizing the failings and poor health outcomes of the State's two-tier delivery system, the Committee encourages HHS to continue working with Louisiana on the development of a waiver for more flexible use of Federal match DSH dollars to ensure more expanded access to community and private providers to the state's low-income population.

Action taken or to be taken

Currently, Louisiana has no waiver application pending before the Centers for Medicare & Medicaid Services (CMS) to permit the State to use its Federal DSH dollars more flexibly to ensure expanded access for low-income populations to community and private providers. However, CMS is available to provide technical assistance to the State should it decide to develop a waiver application for such a purpose.

Item

Chronic Fatigue Syndrome -- The Committee appreciates the work of the Department's Chronic Fatigue Syndrome Advisory Committee [CFSAC], especially the August 30, 2006 renewal of its charter and the personal participation of the Assistant Secretary for Health in recent meetings. The Committee encourages the CFSAC to prioritize strategies to address the low rate of diagnosis of CFS and lack of defined standards of medical care for CFS patients and the stagnation in research funding by CDC and NIH in spite of progress being demonstrated in the field. (p. 206)

Action taken or to be taken

The Chronic Fatigue Syndrome Advisory Committee (CFSAC) is addressing the low rate of diagnosis of Chronic Fatigue Syndrome (CFS) and the lack of defined standards of medical care for CFS by actively supporting the Center for Disease Control and Prevention's (CDC) CFS Awareness campaign. This campaign provides CFS information for patients and caregivers as well as for health professionals. Through public service announcements, brochures, photo exhibits, and CME (continuing medical education) courses for health professionals, CDC continues to address the lack of awareness and keeps CFSAC up to date with progress. CFSAC has also recommended that the Secretary request the Surgeon General send a letter to state health departments, health professional education programs, national organizations for physicians, physician assistants, nurses, and other allied health professional groups informing them about the CDC and National Institute of Health (NIH)CFS resources, including the CDC toolkit, CME course and other resources.

CFSAC is addressing the stagnation in research funding by CDC and NIH by having continued dialogue with these HHS operating agencies about their ongoing research agenda and progress. CFSAC members recently took part in NIH's CFS Grantsmanship Workshop to assist prospective CFS researchers in the field with applying for grants. CFSAC has also recommended to the Secretary that CDC's research effort be restructured to develop a lab-based component that maintains the current search for biomarkers and pathophysiology and to support existing and new longitudinal studies.

<u>Item</u>

[Institute of Medicine study of women's health] -- The Committee has included \$1,000,000 for a study by the Institute of Medicine which would comprehensively review the status of women's health research, summarize what we have learned about the how diseases specifically effect woman, and report back to Congress suggestions for the direction of future research. (p. 208)

Action taken or to be taken

The Office on Women's Health (OWH) will work with the Departmental Coordinating on Women's Health (CCWH) and the Institute of Medicine to develop a comprehensive research study to review the status of women's health research. The CCWH is comprised of senior-level women's health leaders from the agencies/offices in DHHS, including the National Institutes of Health, Agency for Healthcare Research and Quality, Centers for Disease Control and Prevention, Health Resources and Services Administration, Food and Drug Administration, and the Substance Abuse and Mental Health Services Administration. This partnership will ensure that all recommendations to Congress reflect women's health research needs, challenges and opportunities.

Item

[Media awareness] -- The Committee strongly encourages HHS and CDC to support public and professional education, media awareness and outreach programs, and pandemic influenza risk communication. These activities would increase seasonal vaccination rates, thereby lowering influenza-related deaths and hospitalizations. The Committee strongly encourages CDC and HHS to aggressively implement initiatives for increasing influenza vaccine demand to match the increased domestic vaccine production and supply resulting from pandemic preparedness funding. Developing a sustainable business model for vaccine production will go a long way toward making vaccine available when needed.

Action taken or to be taken

Each year, CDC conducts a media campaign to educate the public about and promote influenza vaccination. Our campaign messages flow directly from Advisory Committee on Immunization Practices recommendations and the scientific studies on which those recommendations are based. Before they are released, many CDC messages and materials are tested with target audience members and all messages and materials are reviewed and approved by CDC influenza and immunization program subject matter experts to ensure that in attempts to tailor them to public audiences CDC has not created any inaccuracies.

Communication vehicles include: press releases and briefings, CDC website, print materials (posters and flyers), radio and television public service announcements and advertisements. A great deal of work goes into outreach to stations to play the ads. CDC met with three major TV networks in NYC this past season and got CBS to agree to air the ads during NIVW and beyond), matte articles, audio and video bite packages, satellite media tours, e-newsletters to partners, webinars (including CDC's first webinar for health blog writers), technical assistance calls with immunization coalition members and other partners (like the National Business Group on Health). We also rely on partners as a way to more effectively get our messages to target audiences. In the past we collaborated with the American Association for Respiratory Care to send a direct mail piece to their 30,000 members, the Association of Black Cardiologists to develop and send a letter to its more than 500 members encouraging them to get vaccinated and to urge their patients to do the same. Special Olympics International put our information on their "Healthy Athletes" webpage, the National Alliance for Hispanic Health distributed our Spanish language posters to several clinics, and we developed an article for the American Association for People with Disabilities to place on its website.

The most effective vehicle is a recommendation from a health care provider. In terms of media outreach, different channels are more or less effective for reaching different audiences. Messages are most effective when they are tailored to the specific audience we are trying to reach. For instance, in our messages for asthmatics and parents of asthmatics we try to address barriers specific to that audience (e.g., they don't consider themselves to have a "chronic condition" if their asthma is "under control" and thus do not think they are included in recommendations that people with chronic conditions be vaccinated).

CENTRALLY-MANAGED PROJECTS

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

Project	Description	FY 2008 Funding
President's Council on Bioethics	The Council was created by President Bush in 2001 to advise him on bioethical issues related to advances in biomedical science and technology. The President has extended the Council's charter through September 30, 2007. Funding for the Council (including 18 members and 13 staff) comes entirely from HHS.	\$2,500,000
HSPD-12 Implementation	These funds will be used to fund the HHS Program Management Office for Homeland Security Presidential Directive 12 (HSPD-12), which requires Federal agencies to issue PIV-2 compliant ID cards to all HHS contractors and employees by October 2008.	\$2,088,300
Electronic and IT Access for Persons with Disabilities	These funds ensure that HHS complies with the requirements of Section 508 of the Rehabilitation Act Amendments, and that a comprehensive program is implemented which becomes a part of the HHS infrastructure – in the same manner that EEO requirements and programs have.	\$199,200
HHS Health and Wellness Center	These funds are used to provide a portion of the ongoing operating costs of a health facility which promotes physical fitness for all HHS employees located in the Southwest DC complex.	\$154,100
Media Outreach	These funds are used to expand the production and distribution of public service announcements and video news reports for air time on TV and radio (including in Spanish), and media fact books and health care kits directed to disadvantaged and minority audiences.	\$75,000
Safety, Health and Environmental Programs	These funds enable HHS to conduct the safety and occupational health program evaluations and environmental compliance assessments necessary to ensure that all employees have a safe and healthful working environment, as required by statute.	\$75,000

Energy Program Review	These monies fund a private contractor to evaluate the status of Operating Division energy conservation programs, and to update existing policies to ensure Departmental compliance with Federal energy laws and regulations.	\$70,000
Human Capital Initiative	These funds support the activities of the HHS Labor-Management Cooperation Council, as well as Department-wide Human Resource Initiatives such as recruitment materials, mentoring programs and exitinterview surveys.	\$60,000
Safety Management Information System (SMIS)	SMIS is a Department-wide accident and injury reporting and analysis system which enables HHS to verify the accuracy of Worker's Compensation claims charged by the Department of Labor (DOL); it also assists ion the accidental prevention efforts required by DOL and Executive Order 12196, and identifies deficiencies in HHS's accident prevention program.	\$12,000
TOTAL		\$5,233,600

SPECIAL REQUIREMENTS

Unified Financial Management System (UFMS) Operations and Maintenance

UFMS has now been fully deployed. The Program Support Center, through the Service and Supply Fund, now manages the ongoing Operations and Maintenance (O&M) activities for UFMS. The scope of O&M services includes post-deployment support and ongoing business and technical operations services, as well as an upgrade of Oracle software from version 11.5.9 to version 12.0. GDM will be assessed a total of \$2,254,123 for its portion of the O&M costs in FY 2009. The HHS Program Manager for this initiative is David Tillette, Office of Finance, (202) 2607123.

HHS Consolidated Acquisition System (HCAS)

The HCAS initiative is a Department-wide contract management system that will integrate with UFMS. The applications within HCAS are Compusearch PRISM and a portion of the Oracle Compusearch Interface (OCI). PRISM is a Federal contract management system that streamlines the procurement process; PRISM automates contract writing, simplified acquisitions, electronic approvals and routing, pre-award tracking, contract monitoring, post-award tracking, contract closeout and report. GDM will be assessed a total of \$121,932 to support the completion of HCAS implementation in FY 2009. The HHS Program Manager for this initiative is Mike Fullem, ASAM, (301) 443-6774.

Grants.Gov

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

The Assistant Secretary for Resources and Technology (ASRT) manages the Grants.gov program. Grants.gov is the Federal government's "one-stop-shop" for grants information, providing information on over 1,000 grant programs and \$450 billion awarded by the 26 grant-making agencies and other Federal grant-making organizations. The initiative enables Federal agencies to publish grant funding opportunities and application packages online, while allowing the grant community of over one million organizations (State, local, and tribal governments, education and research organizations, non-profit organizations, public housing agencies, and individuals) to search for opportunities and download, complete, and electronically submit applications.

Through the use of Grants.gov, agencies are able to reduce operating costs associated with online posting and application of grants. Additionally, agencies are able to improve their operational effectiveness through the use of Grants.gov, by increasing data accuracy and reducing processing cycle times.

The initiative provides benefits to the following agencies:

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

From its inception, Grants.gov has transformed the Federal grants environment by streamlining and standardizing public-facing grant processes, thus facilitating an easier application submission process for our applicants. The Grants.gov Program Management Office (PMO) works with agencies on system adoption, utilization, and customer satisfaction. Grants.gov's development status is Mixed Life cycle.

RISK MANAGEMENT OVERVIEW: Risks are categorized and prioritized to facilitate and focus risk management activities. Risk categories are aligned with OMB risk management guidance, ensuring comprehensive consideration of possible risks and simplifying program reporting. Risk prioritization is based on the probability of occurrence and potential impact, and focuses project resources where they are most needed.

All risks are tracked in the Grants.gov Risk Management Database, from identification through resolution. This online database is accessible to all Grants.gov team members and is updated regularly, in keeping with a continuous risk management process. Although physically separate, the Risk Management Database is considered an integral part of the Grants.gov Risk Management Plan.

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

<u>Risk 1</u>: Grants.gov may not receive sufficient funding to complete project milestones. The Grants.gov PMO operations are funded entirely by agency contributions, including salaries and expenses for full-time staff, and support contracts for system integration, Independent Verification and Validation, outreach and liaison, contact center, performance metrics monitoring, credentialed service provision, and office support. If the PMO does not receive sufficient funding, or if the agency contributions are not provided in a timely manner, the PMO would have to limit or stop providing the services it offers to its stakeholders.

Risk mitigation response: Grants.gov risk mitigation is a multifaceted approach that includes internal actions as well as external entities. Internally, the PMO incrementally funds contract requirements when adequate funds are not available, and when funds becomes available it will fully fund requirements. The PMO closely monitors contract expenditures and PMO activities such as training and travel expenditures to ensure the available budget will cover the actual expense. Externally at the beginning of the fiscal year the PMO develops and sends documentation to each funding agency to initiate funding transfers and then reports the status of agency contribution to the Grants Executive Board (GEB) and OMB. Another mitigation activity is that the GEB is currently working on a long term funding strategy for Grants.gov.

<u>Risk 2</u>: Grants.gov requires e-authentication policies and procedures to ensure proprietary information is not compromised.

Risk mitigation response: Grants.gov mitigates this risk through the use of policy /procedure and by physical means. Grants.gov has specific policy on the creation of system super user accounts and provides these users recommended authentication procedures. Grants.gov uses encrypted channels and limits the time that application data is retained on the Grants.gov system.

<u>Risk 3</u>: A fundamental concept of electronic commerce is the standardization of a common set of terms to be used by trading partners during business communications. Grants.gov requires common data processes in order to function. The inability to define common data and processes could delay system adoption or impede program goals.

Risk mitigation response: The Grants.gov system was developed in accordance with the electronic standards for core grants data, Transaction Set 194, which were developed by the Inter-Agency Electronic Grants Committee (IAEGC). The Grants.gov PMO worked with the PL 106/107 workgroup and IAEGC to build consensus, and continues to work to minimize the required changes to agency and applicant processes, to minimize agency-specific forms, and to publish existing forms and encourage agencies to use them.

Risk 4: The Grants.gov system's centralized architecture increases the impact of system failure

and performance issues.

Risk mitigation response: The PMO has incorporated off-line forms that can be submitted through alternate paths (e.g., e-mail, mail, or fax) and that distribute the computational load. The PMO also ran pilot electronic applications in parallel with paper submissions during it initial operational phases. The Grants.gov system uses a high-availability configuration for central system and has implemented effective monitoring & restoration procedures. The PMO routinely measures system performance and forecasts application loads and recommends that agencies spread opportunity closing dates to spread system loads. In times of heavy system loads the PMO gives a higher priority to application receipt processing and defers back-end processing to after peak capacity periods. In FY 2007 the PMO deployed system changes and enhancements to reduce application processing load and will continue to enhance the system to increase efficiency.

FUNDING: The total development cost of the Grants.gov initiative by fiscal year -- including costs to date, estimated costs to complete development to full operational capability, and estimated annual operations and maintenance costs -- are included in the table below. Also included are the sources and distribution of funding by agency, showing contributions to date and estimated future contributions through FY 2009:

	2007	TDCTD*	2008 (ECTCD*)	2009 (O&MC*)	GRAND TOTAL
HHS	1,900,000	6,139,000	1,957,000	1,889,755	9,985,755
DOT	1,073,700	5,312,700	1,105,885	1,067,885	7,486,470
ED	1,073,700	5,312,700	1,105,885	1,067,885	7,486,470
HUD	1,073,700	5,312,700	1,105,885	1,067,885	7,486,470
NSF	520,600	3,246,000	536,187	517,763	4,299,950
DOJ	520,600	3,246,000	536,187	517,763	4,299,950
DOL	520,600	3,849,600	536,187	517,763	4,903,550
USDA	1,073,700	3,482,700	1,105,885	1,067,885	5,656,470
DOC	520,600	2,326,000	536,187	517,763	3,379,950
DOD	520,600	1,873,300	536,187	517,763	2,927,250
DHS	520,600	2,326,000	536,187	517,763	3,379,950
AID	520,600	1,426,000	536,187	517,763	2,479,950
EPA	520,600	1,426,000	536,187	517,763	2,479,950
DOE	520,600	1,426,000	536,187	517,763	2,479,950
NASA	520,600	1,426,000	536,187	517,763	2,479,950
DOI	520,600	1,426,000	536,187	517,763	2,479,950
CNCS	130,000	582,600	133,900	129,299	845,799
VA	130,000	582,600	133,900	129,299	845,799
IMLS	130,000	582,600	133,900	129,299	845,799
State	130,000	582,600	133,900	129,299	845,799
SBA	130,000	582,600	133,900	129,299	845,799
NEH	130,000	695,800	133,900	129,299	958,999
NEA	130,000	695,800	133,900	129,299	958,999
SSA	75,000	527,600	77,250	74,596	679,446
Treasury	75,000	527,600	77,250	74,596	679,446
NARA	75,000	527,600	77,250	74,596	679,446
TOTAL	13,056,400	55,444,100	13,447,647	12,985,569	81,877,316

Enterprise Information Technology

The Departmental Management account will contribute a total of \$394,762 in FY 2009 to support HHS Enterprise Information Technology (EIT) initiatives, as well as the President's Management Agenda (PMA) Expanding E-Government initiatives. Operating Division contributions are combined to create an EIT Fund which finances both the PMA initiatives and specific IT initiatives identified through the HHS Information Technology Capital Planning and Investment Control process. These HHS enterprise initiatives must meet cross-functional criteria and be approved by the HHS IT Investment Review Board, based on funding availability and business case benefits. Development is collaborative in nature and achieves HHS enterprise-wide goals that produce common technology, promote common standards, and enable data and system interoperability. The HHS initiatives also position the Department to have a consolidated approach, ready to join in PMA initiatives.

Of the amount specified above, \$175,053 is allocated specifically to support the PMA Expanding E-Government initiatives in FY 2009, as follows:

PMA e-Gov Initiative	FY 2009 GDM	FY 2009 PHSSEF
	Allocation	Allocation
Business Gateway	\$3,105	
E-Authentication	\$0	
E-Rulemaking	\$0	
E-Travel	\$0	
Grants.Gov	\$69,581	
Integrated Acquisition	\$0	
Geospatial LOB	\$502	
Federal Health Architecture LoB	\$45,338	\$2,466
Human Resources LoB	\$2,878	\$267
Grants Management LoB	\$7,288	\$96
Financial Management LoB	\$1,767	
Budget Formulation & Execution LoB	\$1,361	
IT Infrastructure LoB	\$0	
Integrated Acquisition – Loans and		
Grants	\$10,403	
Disaster Assistance Improvement Plan	\$15,000	\$15,000
TOTAL	\$157,223	\$17,830

Prospective benefits from these initiatives are:

Business Gateway: Provides cross-agency access to government information including: forms; compliance assistance resources; and, tools, in a single access point. The site offers businesses various capabilities including: "issues based" search and organized agency links to answer business questions; links to help resources regarding which regulations businesses need to comply with and how to comply; online single access to government forms; and, streamlined submission processes that reduce the regulatory paperwork burdens. HHS' participation in this

initiative provides HHS with an effective communication means to provide its regulations, policies, and forms applicable to the business community in a business-facing, single access point.

Grants.gov: Allows HHS to publish grant funding opportunities and application packages online while allowing the grant community (state, local and tribal governments, education and research organizations, non-profit organization, public housing agencies and individuals) to search for opportunities, download application forms, complete applications locally, and electronically submit applications using common forms, processes and systems. In FY 2007, HHS posted over 1,000 packages and received 108,436 application submissions – more than doubling the 52,088 received in FY 2007, with NIH substantially increasing its applications submissions to 89,439 submissions from 47,254.

Lines of Business-Federal Health Architecture: Creates a consistent Federal framework that improves coordination and collaboration on national Health Information Technology (HIT) Solutions; improves efficiency, standardization, reliability and availability to improve the exchange of comprehensive health information solutions, including health care delivery; and, to provide appropriate patient access to improved health data. HHS works closely with federal partners, state, local and tribal governments, including clients, consultants, collaborators and stakeholders who benefit directly from common vocabularies and technology standards through increased information sharing, increased efficiency, decreased technical support burdens and decreased costs.

Lines of Business-Human Resources Management: Provides standardized and interoperable HR solutions utilizing common core functionality to support the strategic management of Human Capital. HHS has been selected as a Center of Excellence and will be leveraging its HR investments to provide services to other Federal agencies.

Lines of Business-Geospatial One-Stop: Promotes coordination and alignment of geospatial data collection and maintenance among all levels of government: provides one-stop web access to geospatial information through development of a portal; encourages collaborative planning for future investments in geospatial data; expands partnerships that help leverage investments and reduce duplication; and, facilitates partnerships and collaborative approaches in the sharing and stewardship of data. Up-to-date accessible information helps leverage resources and support programs: economic development, environmental quality and homeland security. HHS registers its geospatial data, making it available from the single access point.

Lines of Business-Grants Management: Supports end-to-end grants management activities promoting improved customer service; decision making; financial management processes; efficiency of reporting procedure; and, post-award closeout actions. An HHS agency, Administration for Children and Families (ACF), is a GMLOB consortia lead, which has allowed ACF to take on customers external to HHS. These additional agency users have allowed HHS to reduce overhead costs for internal HHS users. Additionally,

NIH is an internally HHS-designated Center of Excellence and has applied to be a GMLOB consortia lead. This effort has allowed HHS agencies using the NIH system to reduce grants

management costs. Both efforts have allowed HHS to achieve economies of scale and efficiencies, as well as streamlining and standardization of grants processes, thus reducing overall HHS costs for grants management systems and processes.

Lines of Business–Financial Management: Supports efficient and improved business performance while ensuring integrity in accountability, financial controls and mission effectiveness by enhancing process improvements; achieving cost savings; standardizing business processes and data models; promoting seamless data exchanges between Federal agencies; and, strengthening internal controls.

Lines of Business-Budget Formulation and Execution: Allows sharing across the Federal government of common budget formulation and execution practices and processes resulting in improved practices within HHS.

Integrated Acquisition Environment for Loans and Grants: Managed by GSA, all agencies participating in the posting and/or awarding of Loans and Grants are required by the Federal Funding Accountability and Transparency Act (FFATA) to disclose award information on a publicly accessible website. Cross-government cooperation with the Office of Management and Budget's Integrated Acquisition Environment initiative in determining unique identifiers for Loans & Grants transactions furthers the agency in complying with the Transparency Act, which enhances transparency of federal program performance information, funding, and Loans & Grants solicitation.

Disaster Assistance Improvement Plan (DAIP): The DAIP, managed by Department of Homeland Security, assists agencies with active disaster assistance programs such as HHS to reduce the burden on other federal agencies which routinely provide logistical help and other critical management or organizational support during disasters. The DAIP program office, during its first year of operation, will quantify and report on the benefits and cost savings or cost reductions for each member agency.

Office of Medicare Hearings and Appeals

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APPROPRIATIONS LANGUAGE

For expenses necessary for administrative law judges responsible for hearing cases under title XVIII of the Social Security Act (and related provisions of title XI of such Act), [\$65,000,000] \$65,344,000, to be transferred in appropriate part from the Federal Hospital Insurance *Trust Fund* and the Federal Supplementary Medical Insurance Trust [Funds] *Fund*. (*Department of Health and Human Services Appropriations Act*, 2008.)

LANGUAGE ANALYSIS

Language Provision

"from the Federal Hospital Insurance *Trust Fund* and the Federal Supplementary Medical Insurance Trust [Funds] *Fund*"

Explanation

These changes are necessary in order to correct and standardize all HHS appropriations language which references the HI and SMI Trust Fund

AMOUNTS AVAILABLE FOR OBLIGATION

	FY 2007	FY 2008	FY 2009
	<u>Actual</u>	Enacted	Estimate
<u>Trust funds</u> :			
Annual appropriation	\$59,727,000	\$65,000,000	\$65,344,000
Rescission pursuant to P. L.110-161	0	-1,136,000	0
Subtotal, adjusted budget authority.	59,727,000	63,864,000	65,344,000
Unobligated balance lapsing	-134,000		
Total obligations	\$59,593,000	63,864,000	\$65,344,000

SUMMARY OF CHANGES

2008	General funds appropriation				<u>63,864,000</u>
2009	Request – General funds				<u>65,344,000</u> 65,344,000
		200	8 Enacted	Chang	e from Base
		(FTE)	Budget Authority	(FTE)	Budget <u>Authority</u>
1. A (1. 2. E	ases: uilt-in: Annualization of January 2008 pay raise 3.5%) Effect of January 2009 pay raise (3.0%)	(374) (374)	\$39,100,000 39,100,000	() ()	+\$894,000 +348,000 +1,242,000
·	rogram:				
	Rental Payments to GSA		6,525,000		+318,000
	Contract Funding		15,264,000		<u>+143,000</u>
Decre	tal increaseseases: uilt-in:				+1,703,000
1. 0	One day less pay	(374)	39,100,000	()	-153,000
B. <u>P</u> 1	rogram:				
1. S	Supplies and Materials		746,000		-70,000
То	tal decreases				-223,000
Net	change				+\$1,480,000

BUDGET AUTHORITY BY ACTIVITY (Dollars in thousands)

	FY 2007 <u>Actual</u>		FY 2008 Enacted		FY 2009 <u>Estimate</u>	
	<u>FTE</u>	Amount	<u>FTE</u>	Amount	<u>FTE</u>	Amount
Total budget authority	356	\$59,727	374	\$63,864	374	\$65,344

BUDGET AUTHORITY BY OBJECT

	FY 2008	FY 2009	Increase or
	<u>Enacted</u>	<u>Estimate</u>	<u>Decrease</u>
Full-time Equivalent Employment	374	374	
Average SES salary	\$140,724	\$144,242	+\$3,518
Average GS grade	12.5	12.7	+0.2
Average GS salary	\$80,623	\$81,145	+\$522
Personnel compensation:			
Full-time permanent	\$30,333,000	\$31,072,000	+\$739,000
Other than full-time permanent	0	0	0
Other personnel compensation	630,000	632,000	+2,000
Subtotal, personnel compensation	30,963,000	31,704,000	\$741,000
Civilian personnel benefits	8,137,000	8,485,000	+348,000
Benefits to former personnel	0	0	0
Subtotal, Pay costs	39,100,000	40,189,000	+1,089,000
Travel	250,000	250,000	0
Transportation of things	297,000	297,000	0
Rental payments to GSA	6,525,000	6,843,000	+318,000
Rental payments to others	0	0	0
Communications, misc charges	1,656,000	1,656,000	0
Printing and reproduction	26	26	0
Other contractual services:			
Advisory and assistance services	6,556,000	6,556,000	0
Other services	2,308,000	2,308,000	0
Purchases of goods and services from			
Government accounts	5,707,000	5,850,000	+143,000
Operation and maintenance of facilities	635,000	635,000	0
Research and development contracts	0	0	0
Medical care	0	0	0
Operation and maintenance of equipment	58	58	0
Subsistence and support of persons	0	0	0
Subtotal, Other contractual services	15,264,000	15,407,000	+143,000
Supplies and materials	538,000	551,000	+13,000
Equipment	208,000	125,000	-83,000
Grants, subsidies and contributions	0	0	0
Subtotal, Non-pay costs	24,764,000	25,155,000	+391,000
Total, Budget Authority	\$63,864,000	\$65,344,000	+\$1,480,000

SALARIES AND EXPENSES (Budget Authority)

	FY 2008 Enacted	FY 2009 Estimate	Increase or Decrease
Personnel compensation:			
Full-time permanent (11.1)	\$30,333,000	\$31,072,000	+\$739,000
Other than full-time permanent (11.3)	0	0	0
Other personnel compensation (11.5/11.8)	630,000	632,000	+2,000
Subtotal, personnel compensation (11.9)	30,963,000	31,704,000	+741,000
Civilian personnel benefits (12.1)	8,137,000	8,485,000	+339,000
Benefits to former personnel (13.0)	0	0	0
Subtotal, Pay costs	39,100,000	40,189,000	+1,089,000
Travel (21.0)	250,000	250,000	0
Transportation of things (22.0)	297,000	297,000	0
Rental payments to others (23.2)	0	0	0
Communications, misc charges (23.3)	1,656,000	1,656,000	0
Printing and reproduction (24.0)	26	26	0
Other contractual services:			
Advisory and assistance services (25.1)	6,556,000	6,556,000	0
Other services (25.2)	2,308,000	2,308,000	0
Purchases of goods and services from			
Government accounts (25.3)	5,707,000	5,850,000	+143,000
Operation and maintenance of facilities (25.4)	635,000	635,000	0
Research and development contracts (25.5)	0	0	0
Medical care (25.6)	0	0	0
Operation and maintenance of equipment (25.7)	58	58	0
Subsistence and support of persons (25.8)	0	0	0
Subtotal, other contractual services	15,264,000	15,407,000	+143,000
Supplies and materials (26.0)	538,000	551,000	+13,000
Subtotal, Non-pay costs	18,031,000	18,187,000	+156,000
Total Salaries and Expenses	\$57,131,000	\$58,376,000	+\$1,245,000

AUTHORIZING LEGISLATION

	2008 Amount <u>Authorized</u>	2008 Enacted	2009 Amount <u>Authorized</u>	2009 <u>Request</u>
Medicare Prescription				
Drug, Improvement, and				
Modernization Act of				
2003	Indefinite	\$63,864,000	Indefinite	\$65,344,000

APPROPRIATIONS HISTORY TABLE (Non-Comparable)

	Budget Estimate to Congress	House <u>Allowance</u>	Senate <u>Allowance</u>	<u>Appropriation</u>
FY 2006 Appropriation Rescission	\$80,000,000	\$60,000,000	\$75,000,000 -	\$60,000,000 -600,000
FY 2007 Appropriation	\$74,250,000	\$70,000,000	\$75,000,000	\$59,727,000
FY 2008 Appropriation Rescission	\$74,250,000 -	\$70,000,000 -	\$70,000,000 -	\$65,000,000 -1,136,000
FY 2009 Appropriation	\$65,344,000			

AGENCY MISSION

The Office of Medicare Hearings and Appeals (OMHA), an agency of the U.S. Department of Health and Human Service (HHS), administers hearings and appeals nationwide for the Medicare program, and ensures that the American people have equal access and opportunity to make such appeals and can exercise their rights for health care quality and access. On behalf of the Secretary of HHS, the Administrative Law Judges within OMHA conduct impartial hearings and issue decisions on claims determination appeals involving Medicare Parts A, B, C and D, as well as Medicare entitlement and eligibility appeals.

Vision

OMHA will continue to be a model Federal adjudicative agency for serving the American public by:

- developing and maintaining a highly-qualified, professional staff to adjudicate Medicare appeals;
- utilizing state-of-the-art technology;
- maintaining a quality assurance program that ensures the integrity of decisions and data, while maintaining decisional independence; and
- serving appellants and other customers in such a way as to reflect a seamless Medicare appeals process.

Mission

OMHA provides an independent forum for the fair and efficient adjudication of Medicare appeals for beneficiaries and other parties. This mission is carried out by a cadre of knowledgeable Administrative Law Judges, exercising judicial and decisional independence under the Administrative Procedures Act, with the support of a professional legal and administrative staff. In fulfilling this mission, OMHA strives for the equitable treatment of all who appear before it, and recognizes its responsibility to be an efficient and effective agency within the U.S. Department of Health and Human Services.

Overview of Budget Request

The FY 2009 President's Budget request for OMHA is \$65,344,000 – an increase of \$1,480,000 above the FY 2008 enacted level. This budget supports HHS Strategic Goal 3, "Promote the economic independence and social well-being of individuals and families across their lifespan," by supporting the Medicare program -- providing the basic mechanisms through which individuals and organizations who are dissatisfied with Medicare determinations affecting their right to, or their participation in, the Medicare program may administratively appeal these determinations.

OFFICE OF MEDICARE HEARINGS AND APPEALS

	FY 2007	FY 2008	FY 2009	FY 2009
	<u>Actual</u>	Enacted	Estimate	<u>+/- FY 2008</u>
Budget Authority	\$59,727,000	\$63,864,000	\$65,344,000	+\$1,480,000
FTE	356	374	374	0

Authorizing Legislation: Titles XVIII and XI of the Social Security Act

Allocation Method: Direct Federal

Program Description and Accomplishments

The Office of Medicare Hearings and Appeals (OMHA) was established by Section 931 of Public Law 108-173, the Medicare Prescription Drug, Improvement, and Modernization Act (MMA), enacted on December 8, 2003. MMA transferred the responsibility for hearing Medicare appeals at the Administrative Law Judge (ALJ) level – the third level of Medicare claims appeals – from the Social Security Administration (SSA) to the Office of the Secretary at the Department of Health and Human Services (HHS). The Medicare Benefits Improvement and Protection Act of 2000 (BIPA) also mandated that ALJ appeals be heard within 90 days after receipt of a request from a Medicare appellant. OMHA began processing cases on July 1, 2005 and to date has received almost 65,000 appeals from across the United States containing approximately 280,000 claims.

Approximately 44 million Americans currently receive Medicare benefits. On an annual basis, carriers and intermediaries process approximately 1.2 billion claims for payment, with carriers processing Medicare Part B claims (84%) and intermediaries generally processing Medicare Part A claims (16%). Of the 1 billion total claims, carriers and intermediaries approve payment for approximately 900 million (90%), and deny payment for approximately 10 million (10%).

Claims submitted for Medicare items and services are denied for a variety of reasons. The most common reasons for denying a claim are:

- The services provided were determined to not have been medically necessary for the beneficiary;
- Medicare did not cover the services; or
- The beneficiary was not eligible for the services.

OMHA administers its program in four field offices, including the Southern Field Office in Miami, Florida; the Midwestern Field Office in Cleveland, Ohio; the Western Field Office in Irvine, California; and the Atlantic Field Office in Arlington, Virginia. OMHA extensively utilizes video-teleconferencing (VTC) and telephone hearings, in order to provide appellants with hearings which are timely, close to their homes, and have a broad array of access points. VTC technology, which is now commonly used throughout the

country in courtrooms and for telemedicine, plays a critical role in OMHA's ability to both meet the BIPA timeframes and provide expanded access for appellants to ALJ hearings.

In January 2006, OMHA began hearing appeals arising from the new Medicare Part D Prescription Drug Plan. In January 2007, OMHA began hearing Medicare Part B Income-Related Medicare Adjustment Amount (IRMAA) appeals.

In August 2007, OMHA began receiving new cases as a result of the Centers for Medicare & Medicaid Services (CMS) pilot Recovery Audit Contractor (RAC) program. This program includes RACs for Medicare Secondary Payer (MSP) claims, as well as non-MSP claims. The demonstration project was designed to determine whether the use of RACs would be a cost-effective means of adding resources to ensure that correct payments are made to providers and suppliers, thereby protecting the Medicare Trust Funds. CMS selected California, New York and Florida as the three pilot States. Under Title III, Section 302, of the Tax Relief and Health Care Act of 2006, the RAC program will become permanent and be expanded to all 50 States by no later than January 1, 2010. By October 2008, the RAC program will cover 21 States, and by January 2009 or later, the remaining 29 States will be included. Over the past nine months, OMHA has received approximately 750 RAC cases from the three pilot States. OMHA anticipates that the number of cases will increase proportionately as the program expands to additional States in fiscal years 2009 and 2010.

In FY 2006, OMHA received 14,000 appeals, representing approximately 100,000 claims. In FY 2007, the total number of appeals increased to more than 31,000 and the total number of claims increased to 125,000. With workload increases of this magnitude, OMHA is challenged in its efforts to project future funding needs. Although OMHA's workload increased by 116% in its second year of operation, its FTE levels increased by only 11% (to 356 FTE). OMHA also increased its contractor staffing by 17% (140 to 164 positions) to process the additional workload at the established performance levels. The proposed FY 2009 increase of \$1,480,000 will be used primarily to fund cost-of-living increases for Federal staff and increased logistics costs.

OMHA will continue to monitor the caseloads across its 72 ALJ teams and will adjust resources as necessary, in order to continue meeting the statutory 90-day case processing timeframe. OMHA tracks its caseload by utilizing the Medicare Appeals System (MAS) that was developed and operated by CMS.

In FY 2006, OMHA participated in its first OMB PART assessment. Although OMHA was rated Results Not Demonstrated, due to insufficient historical data at that time, OMHA used the PART process to assist in the development of its Strategic Plan and performance and efficiency measures.

In accordance with its FY 2006 PART Improvement Plan, OMHA completed development and implementation of its FY 2007 – 2011 Strategic Plan and integrated it into the program management system and everyday business processes. Through this

process, OMHA also completed the development of long-term and annual measures, and submitted baseline and target information to the Office of Management and Budget. Moreover, OMHA completed development of the organization's intranet and internet sites. Furthermore, OMHA conducted a detailed Best Practices review of its four field offices. Best practices supporting reduced case processing timeframes were identified and will be implemented nationwide in fiscal years 2008 and 2009. OMHA has completed all of the 2006 PART Improvement Plan action items and is prepared to participate in the FY 2008 PART reassessment.

Funding History

\underline{FY}	<u>Amount</u>	\underline{FTE}
2006	\$59,359,000	274
2007	\$59,727,000	356
2008	\$63,864,000	374

Budget Request

The FY 2009 budget request for OMHA of \$65,344,000 is an increase of \$1,480,000 over the FY 2008 enacted level. At the requested level, OMHA will be able to adequately maintain appeals processing operations. The requested funding is required to support:

- 374 FTE to adjudicate all Medicare appeals, including Medicare Parts A, B, C, D, Medicare entitlement and eligibility appeals, IRMAA cases, and RAC cases.
- Continued legal and administrative support provided by contractors working across the four offices nationwide, to adjudicate appeals and ensure strict adherence to all financial and administrative management internal controls.
- Operations and maintenance plus licensing fees to maintain all information technology support systems.
- GSA lease agreements for the central office and four field offices, and related utilities, telecommunications, security and other facility support costs.
- Maintenance of 59 on-site adjudication hearing rooms and the associated VTC equipment and telecommunications infrastructure, along with access to external hearing room facilities via commercial vendors.

Outputs / Outcomes Table

#		FY		FY 2006		FY 2007		FY	FY	Out-
_	Key Outcomes	2004 Actual		Target	Actual	Target	Actual	2008 Target	Z009 Target	Year Target
Loi	ng-Term Objective 1: Consistent	tly process	BIPA and	l non-BIP	A cases wit	thin 90-da	y timefran	ıe.		
	Increase the number of BIPA cases closed within 90 days	N/A	N/A	85%	74%	85%	84%	86%	87%	88%
	Increase the number of non-BIPA cases closed within 90 days	N/A	N/A	47%	47%	49%	43%	51%	53%	55%

	Key Outputs	FY FY		FY	FY 2006 FY 20		2007 FY 2008		FY 2009	Out- Year
#		2004 Actual	2005 Actual	Target / Est.	Actual	Target/ Est.	Actual	Target/ Est.	Target/ Est.	Target/ Est.
	For cases that go to hearing, increase the percentage of decisions rendered in 30 days	N/A	N/A	80%	80%	81%	80%	82%	83%	84%
	Reduce the percentage of decisions reversed or remanded on appeals to the Medicare Appeals Council	N/A	N/A	4%	1%	4%	1%	1%	1%	1%
	Increase number of claims processed per ALJ team	N/A	N/A	Baseline	1,851	1,925	1,814	1,868	1,905	1,924
	Appropriated Amount (\$ Million)	N/A	N/A	\$80M	\$59M	\$74	\$59M	\$63M	\$65M	

DETAIL OF FULL-TIME EQUIVALENT (FTE) EMPLOYMENT

	FY 2007 Actual	FY 2008 Enacted	FY 2009 Estimate
	<u> 71ctuar</u>	Enacted	<u>L'attitute</u>
Medicare Hearings and Appeals	356	374	374
Average GS Grade			
2007GS-12/7			
2008GS-12/5			
2009GS-12/7			

DETAIL OF POSITIONS

	FY 2007 Actual	FY 2008 Enacted	FY 2009 Estimate
AL-1	1	1	1
AL-1	4	4	4
AL-3	4 <u>67</u>	67	67
Subtotal, ALJs	<u>07</u> 72	72	72
Suoioiai, ALJS	12	12	12
SES	3	3	3
GS-15	8	8	8
GS-14	21	21	21
GS-13	11	11	11
GS-12	76	85	85
GS-11	75	84	84
GS-10	0	0	0
GS-09	24	24	24
GS-08	44	44	44
GS-07	18	18	18
GS-06	5	5	5
GS-05	2	2	2
GS-04	0	0	0
GS-03	0	0	0
GS-02	0	0	0
GS-01	<u>0</u>	<u>0</u>	<u>0</u>
Subtotal	284	302	302
Ungraded Positions	<u>0</u>	<u>0</u>	<u>0</u>
Total Positions	360	374	374
Total FTE usage, end of year	356	374	374
Average SES salary	\$136,653	\$140,724	\$144,242
Average GS grade	GS-12/7	GS-12/5	GS-12/7
Average GS salary	\$77,456	\$80,263	\$81,545

SPECIAL REQUIREMENTS

Unified Financial Management System (UFMS) Operations and Maintenance

UFMS has now been fully deployed. The Program Support Center, through the Service and Supply Fund, now manages the ongoing Operations and Maintenance (O&M) activities for UFMS. The scope of O&M services includes post-deployment support and ongoing business and technical operations services, as well as an upgrade of Oracle software from version 11.5.9 to version 12.0. OMHA will be assessed \$417,836 for their portion of the O&M costs in FY 2009. The HHS Program Manager for this initiative is David Tillette, Office of Finance, (202) 2607123.

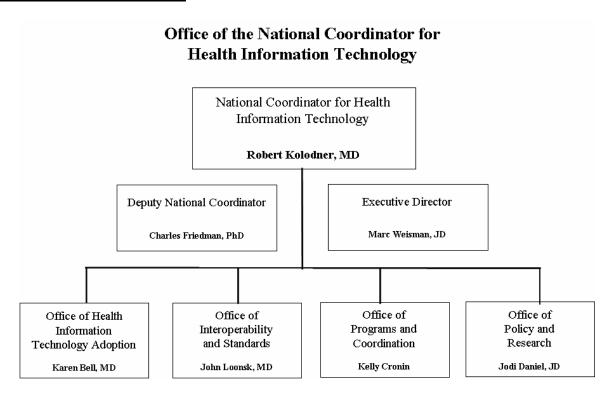
HHS Consolidated Acquisition System (HCAS)

The HCAS initiative is a Department-wide contract management system that will integrate with UFMS. The applications within HCAS are Compusearch PRISM and a portion of the Oracle Compusearch Interface (OCI). PRISM is a Federal contract management system that streamlines the procurement process; PRISM automates contract writing, simplified acquisitions, electronic approvals and routing, pre-award tracking, contract monitoring, post-award tracking, contract closeout and report. OMHA will be assessed \$22,602 to support the completion of HCAS implementation in FY 2009. The HHS Program Manager for this initiative is Mike Fullem, ASAM, (301) 443-6774.

Office of the National Coordinator for Health Information

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ORGANIZATION CHART



EXECUTIVE SUMMARY

The Office of the National Coordinator for Health Information Technology (ONC), in the Office of the Secretary for the U.S. Department of Health and Human Services (HHS), is the principal Federal organization charged with coordination of national efforts related to the implementation and use of electronic health information exchange. Although computer technology has changed the way that Americans communicate and share information, for the most part medical data are still available to health care providers and patients only through paper and film records; millions of care providers and patients still face barriers to quality health care because of the lack of readily available health information. Coordinating the public and private-sector efforts to improve the quality of health and care through information technology is a key ONC role.

Vision

A Nation in which the health and well-being of individuals and communities are enabled by health information technology.

Mission

ONC leads, coordinates, and stimulates public and private sector activities that promote the development, adoption, and use of health information technologies to achieve a healthier Nation.

As the coordinating office for national health information technology (health IT) activities, ONC provides leadership, program resources and services needed to guide nationwide implementation of interoperable health IT. ONC organizes its activities in four program areas:

- Standards Software applications must 'speak the same language' to be able to work together. This involves creating, testing, and adopting interoperability standards that will allow systems across the health care market to move health information seamlessly. A technology certification process gives assurance that these accepted standards are appropriately incorporated in health IT products and systems. Multi-stakeholder collaboration that prioritizes standards development and advises the HHS Secretary on how to accelerate the development and adoption of health IT is currently accomplished through the American Health Information Community (AHIC). HHS is in the process of establishing a successor to AHIC as an independent public-private partnership organization by 2009 that will enable continuation of this highly collaborative process.
- **Privacy and Security** —Careful attention to privacy and security policies to guide evolving technology will help to build the high degree of public confidence and trust needed to achieve nationwide interoperable health IT. Ongoing work identifies disparate state policies and business practices to resolve variations that are barriers to health information exchange.
- Architecture and Adoption The implementation of a Nationwide Health Information Network will provide the foundation for interoperable, secure and standards-based health information exchange. Demonstrating the value of electronic and personal health record systems and identifying enablers and barriers to their use and implementation will also advance adoption of health IT. Regularly assessing the adoption rate through surveys and studies will monitor progress toward the President's goal that most Americans will have electronic health records by 2014.
- **Operations** Required support for all activities and infrastructure necessary to sustain ONC including workforce, finance, administration, performance measurement, and strategic planning activities

Overview of Budget Request

The FY 2009 President's Budget request for ONC is \$66,151,000 including \$48,000,000 in Public Health Evaluation Funds – an increase of \$5,590,000 over FY 2008. This budget supports the President's goal of most Americans having access to electronic health records by 2014, as well as the Secretary's Priorities to provide value-driven health care, information technology, and national preparedness in emergencies and disasters. If the Nation is to realize the benefits of a connected system and achieve the President's goal, the adoption of interoperable health IT systems must remain at the forefront and health IT must remain a national priority.

Program Increases:

Standards (+\$7,721,000).

This increase will maintain standards harmonization development and assurance necessary for IT systems to "speak the same language" to exchange data across different health care settings and will include specialty and special areas of health care delivery, as well as the additional review of previously established standards for any necessary updates. It will also expand the scope of technology certification processes for specialty areas (such as cardiovascular or child health) and special areas (such as emergency department or long term care) of health care. The goal of this program is to build on the successes of the current work to ensure that standards are quickly harmonized and deployed into health information technology products and mechanisms for health information exchange. This increase will provide support for a consolidated resource for Federal agencies as they transition to harmonized standards. Included is critical funding needed to support the American Health Information Community and a public-private successor in the private sector.

Architecture and Adoption (+\$6,848,000).

An increase for architecture and adoption will build on progress already achieved with the demonstrations of the trial implementations of a Nationwide Health Information Network begun in 2007, funding nine health information exchanges across the country. Additionally, these funds will support work needed to identify the best way to structure consumer-directed access to electronic medical data in a health information exchange.

Program Decreases:

Privacy and Security (-\$7,579,000).

The FY 2009 request continues to support projects to address barriers to exchanging health information electronically across states, territories and regions while maintaining and improving important privacy and security protections nationwide. Less funding is requested because during 2008, ONC plans to evaluate all ongoing work and determine which projects will be supported during FY 2009. ONC will continue to focus on these critical aspects of health information exchange.

Operations (-\$1,400,000)

Funding for Operations declines in FY 2009 as ONC anticipates economies through greater use of onboard Federal staff in lieu of contractor support.

Discretionary All-Purpose Table Office of the National Coordinator for Health Information Technology

(Dollars in Thousands)

	FY 2007 Actual		FY 2008 Enacted			FY 2009 Estimate	Change from FY 2008 Enacted	
Budget Authority	\$	42,402	\$	41,661	\$	18,151	\$	(23,510)
PHS Evaluation Funds		18,900		18,900		48,000		29,100
Total, Program Level	\$	61,302	\$	60,561	\$	66,151	\$	5,590
FTE		23		28		28		-
HCFAC Account		[\$490]		0		0		-

Funding for the Health Care Fraud and Abuse Control (HCFAC) program is appropriated separately and is a non-add to ONC.

APPROPRIATION LANGUAGE

For expenses necessary for the Office of the National Coordinator for Health Information Technology, including grants, contracts and cooperative agreements for the development and advancement of an interoperable national health information technology infrastructure, \$42,800,000\$18,151,000: Provided, That in addition to amounts provided herein, \$18,900,000\$48,000,000 shall be available from amounts available under section 241 of the Public Health Service Act to carry out health information technology network development. (Department of Health and Human Services Appropriations Act, 2009.)

Office of the National Coordinator for Health Information Technology Amounts Available for Obligation

	FY 2007	FY 2008	FY 2009
General Fund Discretionary Appropriation:			
Annual appropriation	\$ 42,402,000	\$ 42,402,000	\$ 18,151,000
Rescission (PL 110-161)		\$ (741,000)	
Subtotal, adjusted appropriation	\$ 42,402,000	\$ 41,661,000	\$ 18,151,000
Total obligations	\$ 42,398,000	\$ 41,661,000	\$ 18,151,000

Office of the National Coordinator for Health Information Technology Summary of Changes

2008						
Total budget authority					\$	41,661,000
(Obligations)			•••••		\$	(60,561,000)
2009						
Total estimated budget authority					\$	18,151,000
(Obligations)					\$	(66,151,000)
Net Change		•••••			\$	(23,510,000)
	20	009 1	Estimate	Cha	ınge	from Base
	FTE	Pro	ogram Level	FTE	Pro	gram Level
Increases:						
A. Built-in:	28			0		
1. Cost of January 2009 Civilian Pay Raise of						
2.9 percent		\$	3,342,000		+\$	96,000
Cost of January 2009 Commission Officer Pay Raise of 3.4 percent			112 000			4.000
•		\$	112,000		+\$	4,000
Subtotal, Built-in Increases		\$	3,454,000		+\$	100,000
Increases:						
A. Program:						
1. Standards		\$	21,500,000		+\$	7,721,000
2. Architecture and Adoption		\$	26,033,000		+\$	6,848,000
Subtotal, Program Increases		\$	47,533,000		+\$	14,569,000
Total Increases		\$	50,987,000		+\$	14,669,000
Decreases:						
A. Program:						
1. Privacy and Security		\$	10,568,000		\$	(7,579,000)
2. Operations		\$	4,596,000		\$	(1,500,000)
Total, Program Decreases		\$	15,164,000		\$	(9,079,000)
Net Change		\$	66,151,000	0	+\$	5,590,000

Office of the National Coordinator for Health Information Technology Program Level by Activity

(Dollars in thousands)

	2007	2008	2009
Health Information Technology			
Standards	\$ 10,963	\$ 13,779	\$ 21,500
Privacy and Security	10,568	18,147	10,568
Architecture and Adoption	29,465	19,185	26,033
Operations	10,306	 9,450	 8,050
	\$ 61,302	\$ 60,561	\$ 66,151
Total, Budget Authority	\$ 42,402	\$ 41,661	\$ 18,151
Evaluation Funds	\$ 18,900	\$ 18,900	\$ 48,000
Total Program Level	\$ 61,302	\$ 60,561	\$ 66,151
FTE	23	28	28

Office of the National Coordinator for Health Information Technology Authorizing Legislation

	2008 Amount Authorized	2008 Budget Estimate	2009 Amount Authorized	2009 Budget Request
Health Information Technology PHS Evaluation Funds (non-add)		\$ 41,661,000 [\$18,900,000]		\$ 18,151,000 [\$48,000,000]

Office of the National Coordinator for Health Information Technology Appropriations History Table

		Budget Estimate to Congress	House Allowance		Senate Allowance		Appropriation	
EV 2006								
FY 2006 Budget Authority	\$	75,000,000	\$	58,100,000	\$	32,800,000	\$	42,800,000
PHS Evaluation Funds		2,750,000	э \$	16,900,000	\$	12,350,000		18,900,000
	Ф	2,730,000	Ф	10,900,000	Ф	12,550,000	\$	
Rescission (PL 109-148)							\$	(428,000)
Transfer to CMS	ф	77 750 000	Ф	77 000 000	Ф	45 150 000	\$	(29,107)
Total	\$	77,750,000	\$	75,000,000	\$	45,150,000	\$	61,242,893
FY 2007								
Budget Authority	\$	89,872,000	\$	86,118,000	\$	51,313,000	\$	42,402,000
PHS Evaluation Funds	\$	28,000,000	\$	11,930,000	\$	11,930,000	\$	18,900,000
Total	\$	117,872,000	\$	98,048,000	\$	63,243,000	\$	61,302,000
FY 2008								
Budget Authority	\$	89,872,000	\$	13,302,000	\$	43,000,000	\$	42,402,000
PHS Evaluation Funds	\$	28,000,000	\$	48,000,000	\$	28,000,000	\$	18,900,000
Rescission (PL 110-161)							\$	(741,000)
Total	\$	117,872,000	\$	61,302,000	\$	71,000,000	\$	60,561,000
FY 2009								
Budget Authority	\$	18,151,000						
PHS Evaluation Funds	\$	48,000,000						
Total	\$	66,151,000						

STANDARDS

	2	007 Actual	20	2008 Enacted		009 Estimate	FY 2009 + / - FY 2008		
BA	\$	10,963,000	\$	12,279,000	\$	4,500,000	\$	(7,779,000)	
PHS Evaluation		-		1,500,000		17,000,000		15,500,000	
TOTAL Program	\$	10,963,000	\$	13,779,000	\$	21,500,000	\$	7,721,000	

Authorizing Legislation:

Allocation Method:

None

Contract, Cooperative Agreement

Program Description and Accomplishments

The Standards program gathers the priorities from all stakeholders, including the government, and incorporates them into two related activities that will enable different health information technology systems to exchange data: 1) harmonization of data and technical standards and 2) certification of systems technologies and products that have incorporated these standards. These processes are key to the advancement of interoperability among systems engaged in health information exchange and the advancement of the widespread adoption of interoperable health information technologies.

Secure and reliable exchange of electronic health data and information is a complex challenge of huge magnitude. For each piece of information that needs to be exchanged, there needs to be standards for the type of data element, the transport of that element, the technical connection between software systems, and security of that data. At times, additional standards are necessary for the units of measure for the data, for what represents a high and low normal value, and more. Given the vast amount of data involved, the first step is one of prioritization, which has been accomplished through the American Health Information Community (AHIC) processes. Since it was established in 2005, the AHIC has made priority recommendations to the HHS Secretary by annually identifying the health-related activities where standardized data is needed. These priorities have then been used by ONC in an open, iterative process to develop Use Cases, which are detailed, real-life scenarios for each of these health-related activities that can be used to identify the necessary standards needs. This function of prioritizing health-related activities and needs will be transitioned by December 2008 from the AHIC to the AHIC Successor Organization. In FY 2009, ONC will continue to develop Use Cases for the priority recommendations made to HHS by the AHIC during FY 2008.

To assess the effectiveness of this program, ONC is developing ambitious targets with which to measure progress toward the goal of developing a unified set of standards to support requirements for broad health information exchange.

Standards Harmonization

The Healthcare Information Technology Standards Panel (HITSP) was established to be a multi-stakeholder, consensus-based body designed to provide the process where representatives from all aspects of health care select and harmonize standards to support the Use Cases. At the close of 2007, the HITSP process successfully reviewed over 950 possible standards, harmonized them into 75 interoperability standards, including over 1,100 pages of specifications on exactly how those standards need to be used. In January 2008, harmonized standards from HITSP were approved by AHIC and accepted by the HHS Secretary for the second round of AHIC priorities: Emergency Responder Electronic Health Records, Consumer Access to Clinical Information, and Quality Reporting. The harmonized standards for Medication Management will soon be advanced by HITSP for similar approval and Secretarial acceptance.

Technology Certification

Providers and consumers must be able to have confidence that the electronic health information products and systems they use are secure, can maintain data confidentiality as directed by patients and consumers, can work with other systems to share information, and can perform a set of well-defined functions. ONC established the Certification Commission for Healthcare Information Technology (CCHIT) in 2005 to accomplish these goals. The CCHIT certifies provider-based ambulatory care electronic health records (EHRs) and inpatient EHRs through a public-private process that develops specific criteria for health IT systems and then rigorously evaluates them to determine that they truly meet the criteria for:

- Functionality ensuring that the systems can support the activities and perform the functions for which they are intended
- Security ensuring that systems can protect and maintain the confidentiality of data entrusted to them; and
- Interoperability ensuring that system can exchange information with other systems.

The CCHIT is now exploring how to certify health information networks, EHRs in specialty settings, and specific components of longitudinal personal health records.

The CCHIT assures that the products and services it certifies have incorporated the tested interoperability standards. This process will allow different certified EHRs used by physicians and other health care providers to freely exchange information as directed by their patients. In 2006, the first year, the total of number of certified ambulatory medical record products was 89. By the end of CY 2007, 98 ambulatory EHR products were certified representing more than 40 percent of the estimated ambulatory EHR product vendors.

These products offer health care providers more certainty about viability and components of their health IT investments, thus advancing adoption of EHRs and moving toward interoperability. Likewise, inpatient EHR products are quickly adapting to the certification process. In November 2007, CCHIT announced 6 inpatient EHR vendors received certification representing 25 percent of the vendors in that market space. While the certifying body itself is creating a self-sustaining business model for existing certification criteria, continued ONC support will be needed to expand the certification

process in other areas such as long-term care, behavioral health care and special populations.

CCHIT closely coordinates its work with HITSP and the Nationwide Health Information Network to integrate all standards and specifications necessary for secure, reliable, patient-controlled exchange of health information.

To ensure that software developers have adequate time to implement recognized standards in their software, which is a key component of the interoperability certification criteria, the HHS Secretary has established a two step process for recognition of interoperability standards. First, the Secretary publicly "accepts" standards recommended to him by the AHIC and then, one year after "acceptance," the Secretary commits to formal "recognition" of these standards. The intervening year between "acceptance" and "recognition" of interoperability standards allows software developers time to test the standards within their systems and allows the HITSP to refine the guidance for how the standards need to be implemented based on feedback from these tests.

Forty-eight (48) interoperability standards for medical history, laboratory result reporting, and biosurveillance were publicly recognized by the Secretary in January, 2008. Four (4) additional interoperability standards are expected to be recognized in June, 2008. These standards will be included in ambulatory and inpatient EHR product certifications beginning in mid-2008. Additionally, it is anticipated that the Federal Government will require all federal health care delivery systems that support direct patient care to use these standards in their new and upgraded health-related software systems for exchanging information with external systems. Federal agency adoption plans are being developed for incorporating interoperability capabilities into their software systems using these standards.

American Health Information Community

The American Health Information Community (AHIC) is an advisory body to the HHS Secretary. This Federal Advisory Committee Act (FACA)-governed body and its workgroups have been instrumental in developing recommendations to HHS in all areas of health IT that are necessary for moving the health IT agenda forward. AHIC is made up of representatives from across the Nation and includes leaders from the federal government, employers concerned with the high cost of health care, members of the health care sector and consumer advocates. AHIC meets eight times each year. In addition, there are seven workgroups that meet monthly to engage all interested stakeholders in making recommendations to the Secretary about all aspects of the health IT agenda. These workgroups focus on population health, chronic care, consumer empowerment, and electronic health records, privacy and security, quality measurement and improvement, and personalized health care. In 2007, there were 163 volunteers that worked approximately 9,340 hours, including 54 participants from federal entities outside of ONC. This amount of effort demonstrates the program's momentum.

HHS is in the process of transitioning the collaborative functions related to all non-policy areas of interoperability – to a successor organization (AHIC 2.0), which will be an independent, sustainable public-private partnership focused on achieving health information interoperability. The existing AHIC will continue to function until December 2008, when the transition of the collaborative functions will be complete. To ensure a smooth transition without slowing down, AHIC is continuing as a FACA body until its charter is dissolved in December 2008. The mandated activities of a FACA body require support for the remaining meetings, reports, transcriptions and other public disclosures and announcements required by this Act.

The AHIC Successor Organization

The AHIC successor organization cooperative agreement was awarded in January 2008 and, as noted above, will be an independent, sustainable public-private partnership that brings together the best attributes of public and private entities and involves representation from all health- and health care-related sectors, including the federal government. With the specific organizational details being determined in FY 2008 by a broad spectrum of health care stakeholders, the new entity will develop a unified approach among all sectors for achieving health information interoperability nationwide to enable improved quality, safety, and efficiency of health care in the U.S. Given the competitive nature of the health care industry, widespread exchange of health care information requires a level of trust among the participants that has never been achieved previously (in addition to issues related to privacy policies and to security of the systems and networks). A governance body is needed, comprised of multiple stakeholders representing the competing interests and organized in a manner that ensures that all are represented and that equitable decisions are made that are perceived by all to be trustworthy and fair, such that no special interest or group of special interests dominates or can force its will on the other sectors. AHIC 2.0 will recruit broad-based membership from all stakeholder communities to ensure balanced representation while having stronger private-sector leadership.

Funding will ensure the new entity is given the time needed to firmly establish its organization and infrastructure, including a sustainable business plan. In addition to Federal funding for the initial start-up, the entity is expected to obtain financial contributions from the private sector to support the operations of the organization.

AHIC 2.0 is expected to become self-sustaining after FY 2009. ONC staff will continue to actively coordinate across the relevant Federal departments and agencies to ensure that the federal representatives to AHIC 2.0 are fully engaged and informed to be able to speak on behalf of the broad federal interests.

Other Federal Efforts

The Federal government is actively involved as a major stakeholder in the health care industry and there are many Federal efforts utilizing the results of ONC-sponsored work as the government moves to implementing adopted standards and certified products within federal health care systems. Executive Order 13410, issued on August 22, 2006,

requires that HHS and all federal agencies ensure that internal programs and external contracts implement relevant HHS-recognized interoperability standards. This requirement applies to the implementation, acquisition and upgrade of health information technology systems consistent with the Executive Order. The Federal Health Architecture, an e-Gov initiative that involves all federal entities with a health care practice, provides federal expertise and experience as a coordinated voice, reviewing standards recommendations produced through the HITSP process and then works with and across agencies toward implementation of these standards. These activities include coordination of federal participation in health care-related Standard Development Organization activities, communication, and collaboration on National Health IT Standards.

Other Federal entities are collaborating with ONC to further the goal of incorporating standards and certified EHR systems and services. Some examples include:

- CMS: EHR Adoption Demonstration On October 30, 2007, CMS announced a new demonstration project which will provide financial incentives for physician practices to improve the quality and efficiency of services through adoption of certified EHR systems.
- In 2005, CMS published a final rule setting three "foundation" eRx standards. These standards cover transactions between prescribers and dispensers, eligibility and benefit queries and responses, and eligibility queries between dispensers and Part D Plans. The rule became effective January 1, 2006. In 2006, CMS initiated pilot projects to test six expanded eRx standards including formulary history, medication history, fill status notification, structured and codified patient instructions, clinical drug terminology, and prior authorization messages.
- The National Library of Medicine (NLM) is leading an effort with a broad constituency of health care stakeholders to target clinical vocabularies for use in the U.S., and make them generally available at low or no cost through the NLM Unified Medical Language System Metathesaurus. NLM also coordinates feedback on how to improve standard clinical vocabularies to promote their use as a critical tool to improve health care quality, optimize public health surveillance, and facilitate clinical research. NLM coordinates their data standards activities, which are related to terminologies and vocabularies, with ONC.

Funding History

FY 2004	NA
FY 2005	NA
FY 2006	\$ 9,480,000
FY 2007	\$ 10,963,000
FY 2008	\$ 13,779,000

Budget Request

The FY 2009 Budget Request is \$21,500,000, an increase of +\$7,721,000 from FY 2008. The development and implementation of standards in health information technology is critical to enabling an interoperable, secure capability for health information exchange. This request includes:

- Funding for Standards Harmonization to continue the contracted work of the Healthcare Information Technology Standards Panel (HITSP). In FY 2009, HITSP will provide the harmonized standards to address the areas prioritized by the AHIC and recommended to the HHS Secretary in 2008. HITSP will also fill the gaps identified in prior rounds of standards harmonization and maintain and update existing standards as technology continues to evolve. Additional emphasis will be placed on solidifying the processes required to transfer the standards-setting process to the private sector.
- Continued funding for Certification to support the next phase of a technology certification contract that will (1) update the existing criteria to incorporate the standards (just accepted in January 2008) that will be recognized by the HHS Secretary in early FY 2009 and (2) build upon FY 2008 efforts and advance them in several critical areas. The increased scope for certification efforts will meet the accelerated timeline for certification of specialty area products as well as aspects of personal health records. Other areas to be advanced include: long-term care, additional specialty areas, and a variety of different network certification needs. Progress has been made in developing a self-sustaining business model for the certification of ambulatory and inpatient provider-based EHRs. It is anticipated that a similar self-sustaining business model will be developed after the certification criteria are developed for these expanded certification processes.
- Funding through a memorandum of understanding with the National Institute of Standards and Technology, to provide technical program expertise for conformance testing infrastructure as well as provide advice to the testing activities implemented by CCHIT. These activities include engaging these technologies to support the secure exchange of interoperable information among the private sector and regional, state, and Federal entities.
- A Memorandum of Understanding with the National Library of Medicine to support the increasingly important effort both to make federal standards work related to terminologies and vocabularies available across the government and to coordinate and map between and among existing standards during 2009. This initiative is critical to ensuring that federal terminologies and vocabularies work is readily available for national needs. There is a need for resources to support collaborative activities across the National Library of Medicine, the Food and Drug Administration, and the Department of Veterans Affairs in the development, testing, and dissemination of well-maintained terminologies and vocabularies and to fill similar standards gaps where there is a unique federal role. Funding is needed in support of these federal efforts to advance the implementation of the national health IT agenda, including

achievement of commensurate quality and efficiency outcomes, all of which will move the federal government toward interoperability of health care information.

- Funds to continue support for the FACA requirements of the AHIC as its charter sunsets.
- This request also funds the second year of a cooperative agreement with the AHIC 2.0 successor organization an independent, sustainable public-private partnership focused on achieving health information interoperability. Because health information technology adoption is an incredibly complex undertaking, input from both the public and private sectors must be obtained and considered. These funds will support start-up operations to transition the collaborative functions of the current AHIC interoperability initiatives except for privacy and security policies and to coordinate the federal government's participation.

The FY 2009 Request for Standards will fund critical efforts building on the extensive progress already made in the areas of standards harmonization and certification of EHR products and continue to provide a critical advisory function through the public/private partnership of the AHIC and AHIC successor organization.

ONC received a PART review in 2006, and received a Results Not Demonstrated rating. This was not unexpected with the office having been established just eight months earlier in August 2005. As a result of the PART review, ONC is taking actions to continue to develop milestones and targets for the annual measures, which will produce tangible outcomes and results. ONC has initiated development of a Health IT Strategic Plan and is identifying program/office priorities to achieve over the shorter-term (two years). These priorities will have outcome-oriented results and show clear links to the program's resources and overall mission.

Outcomes Table

#	# Key Outcomes		FY 2005	FY 2006	FY 2007	FY 2008	FY 2009	Out-Year
			Actual	Target Actual	Target Actua	Target	Target	Target
Long-	Term Objective 1: Increas	se adoptio	n of Elect	ronic Health Rec	ords (EHRs)			
1.3.5	Develop a unified set of standards to support requirements for broad health information exchange	N/A	N/A	Under Development				

PRIVACY AND SECURITY

	2	007 Actual	20	008 Enacted	20	009 Estimate	F	Y 2009 + / - FY 2008	
BA	\$	8,343,000	\$	3,897,000	\$	2,568,000	\$	(1,329,000)	
PHS Evaluation		2,225,000		14,250,000		8,000,000		(6,250,000)	
TOTAL Program	\$	10,568,000	\$	18,147,000	\$	10,568,000	\$	(7,579,000)	
Authorizing Legislate Allocation Method:	ion:							Non Contrac	

Program Description and Accomplishments

The Privacy and Security Program provides leadership to federal, state and local governments and the private sector to ensure that health information is exchanged in a manner that is appropriately confidential, private and secure. These basic assurances are important components to the success of health IT adoption. As a foundational document and a supplement to existing laws that protect health information, a Nationwide Health Information Technology Confidentiality, Privacy and Security Framework, begun in 2007, will be the result of a federal-led effort involving stakeholders community-wide and will serve to increase trust among consumers and users of electronic individual health information and to govern all efforts to advance electronic health information exchange. HHS reviewed various international, national and private-sector confidentiality, privacy and security principles that focused on individual health information in an electronic environment, although not all principles were specific to electronic health information exchange. While there was some variation, many of the same confidentiality, privacy, and security concepts appeared in most of these principles. Common themes and salient concepts were extracted and are being used as the basis for developing a nationwide health information confidentiality privacy and security framework. In 2009, the Framework will be reviewed and updated.

State and Regional Policies for Electronic Health Information Exchange

Reaching the President's goal and Secretary's priority for health IT adoption requires addressing the privacy and security concerns related to health information exchange. Under ONC leadership, significant progress has been made both through the Health Information Security and Privacy Collaboration (HISPC) and the State Alliance for e-Health (State Alliance), which provide the Federal government the ability to communicate and coordinate with multiple state governments. These collaborative initiatives address issues that have direct benefit to U.S. citizens, and cannot be resolved at the Federal level alone. It is important that HHS engage the States to recommend and develop solutions for:

- variability in state privacy and security laws, which pose challenges to the transmission of electronic health information across state borders;
- variances in state licensure laws and processes that directly impede telemedicine, which is particularly essential to providing treatment to underserved areas;

• processes for involving state Medicaid and public health programs in electronic exchange of health information that will promote more comprehensive information for public health and emergency preparedness; and consumer and provider education.

With representatives from 45 states and territories and approximately 4,000 people engaged in privacy and security discussions at the state level, the work of the HISPC brings collaborative, replicable solutions to critical issues and has expanded the base of informed stakeholders who will promote interstate interoperability for health information exchange. These efforts are expected to inform the Nationwide Health Information Network trial implementations, as well as the State Alliance work in 2009 to garner state government support. These multi-state collaboratives are currently working to:

- develop model inter-organizational agreements, such as data sharing agreements, that will facilitate electronic health information exchange (8 jurisdictions);
- identify, analyze and recommend possible solutions for variations in consent data elements required for electronic health information exchange (12 jurisdictions);
- recommend approaches for obtaining patient consent for the release of information (4 jurisdictions);
- advance recommendations for business and operational security policies and practices that can be tied to already proposed technology standards (10 jurisdictions);
- increase consumer engagement in electronic health information exchange through the development of a toolkit to educate consumers in the privacy and security of their health records (8 jurisdictions);
- develop tools and techniques to enhance provider awareness and adoption of health IT and involvement in electronic health information exchange (8 jurisdictions); and
- develop a legislative template, with a common taxonomy, which will allow states to analyze their privacy and security laws and promote consensus to advance electronic health information exchange (8 jurisdictions).

The State Alliance for e-Health is a state legislative/executive-level advisory body that is identifying and assessing consensus-based approaches to resolve state-level health IT issues that pose challenges to interoperable exchange of electronic health information. After conducting an analysis of major issues that all states should consider as they engage in electronic health information exchange activities within their states and across states, they made recommendations:

- 1. relative to States' recognition of certified EHRs and network components;
- 2. encouraging States to facilitate the alignment of interstate privacy protections;
- 3. regarding harmonizing licensure applications and facilitating the use of electronic licensure applications and a common credentials verification organization;
- 4. relative to the coordination and finance mechanisms of state government-based electronic exchange of health information implementation activities and electronic health information exchange; and
- 5. regarding state Medicaid agencies and health IT and health information exchange.

The State Alliance is accepting additional recommendations from its taskforces in January 2008 and will publish a report that will include its recommendations in spring 2008. It is anticipated that these recommendations will strategically influence state change-agents furthering the progress being made toward interoperable health information exchange.

By FY 2009, the State Alliance will have disseminated two reports. The first, *Report to the Nation – Critical Pathways for States*, will include recommendations regarding privacy and security of electronic health information, health care practice and integration of state programs into health information exchange. The follow-up report, the *State Leadership Guide*, will address some of the issues that are relevant and essential but for which there are no 'best practices' and will offer additional tools and content related to possible mechanisms states might explore.

A major goal for the State Alliance is to work toward self-sustainment. This project is critical to meeting the President's goal of most Americans having access to EHRs by 2014 with the developed interrelationship of federal and state laws and programs.

Other Federal Efforts:

All privacy and security efforts must support the development and implementation of appropriate policies, practices, and standards for electronic health information exchange. In addition to the activities described above, ONC provides support to the Confidentiality, Privacy, and Security Workgroup of the AHIC. This workgroup makes policy recommendations to the AHIC regarding health IT and health information exchange.

In addition, since 2006, ONC has been leading the Interagency Health Information Technology Policy Council, which involves representation from across the federal government. Through this group, representatives from more than 20 Federal departments and agencies regularly interact and exchange information about Federal health IT activities and examine collaborative approaches to implementing health IT policy.

Funding History

FY 2004	NA
FY 2005	NA
FY 2006	\$ 13,921,000
FY 2007	\$ 10,568,000
FY 2008	\$ 18,147,000

Budget Request

The FY 2009 Request is \$10,568,000, a decrease of -\$7,579,000 from FY 2008. These funds are critical to continue the contracted support of the implementation of regional, State and multi-State solutions to identified barriers to exchange of electronic health

information and, where appropriate, align State and health information exchange efforts with the work of the Nationwide Health Information Network. The increased effort during FY 2008 will complete some collaborative projects described above. In FY 2008, activities that, in previous years had been funded with shared resources, were fully funded by ONC. Less funding is requested in FY 2009 because during 2008, ONC plans to evaluate all continuing work and determine which projects will be supported during FY 2009. ONC will continue to focus on these critical aspects for exchange of health information.

ARCHITECTURE AND ADOPTION

	2	2007 Actual		2008 Enacted		2009 Estimate		FY 2009 + / -	
	2007 Actual		2006 Effacted		20	009 Estillate		FY 2008	
BA	\$	12,790,000	\$	16,035,000	\$	3,033,000	\$	(13,002,000)	
PHS Evaluation		16,675,000		3,150,000		23,000,000		19,850,000	
TOTAL Program	\$	29,465,000	\$	19,185,000	\$	26,033,000	\$	6,848,000	

Authorizing Legislation:
Allocation Method:
None
Contract

Program Description and Accomplishments

Architecture and Adoption provides coordination and leadership for activities that are moving the Nation toward adoption of a nationwide solution that supports the creation, use, and exchange of reliable and secure electronic health information to better coordinate care among providers, engage individuals in their own health maintenance and management, and meet the needs of research, public health, biomedical research, quality improvement, and emergency preparedness and other related community and population health efforts. ONC is working toward the President's goal of most Americans having access to EHRs by 2014 by focusing on a number of non-technical barriers and enablers while developing and demonstrating an information technology architecture that will allow interoperable exchange of electronic health information.

Architecture

Today's health information environment is fragmented with different systems unable to communicate with each other to transmit data in a consistent, safe and secure way. Development of a technological roadmap – or architecture – that can support true interoperability across state and organizational lines is critical to achieving the goal of a safer, more effective, efficient and coordinated person-centric health care system. In addition, successful adoption of health information technologies, which can generate and use electronic health information, is inextricably linked to success in meeting this goal.

One of the goals of ONC is to interconnect health care providers so that they can better coordinate care through secure and reliable exchange of health information. Building on the work of the Standards Program, ONC is leading activities to establish a minimum set of information exchange standards that can be adopted by any entity engaged in exchanging electronic health information. This minimal set of standards and services is the architectural basis of the Nationwide Health Information Network (NHIN). Entities that use this architecture of standards and services will be able to exchange health information with other entities that also use them. In order to be able to scale beyond a small number of entities, the networking activities will need governance and oversight functions in the future. Discussion will be occurring in FY 2008 and early FY 2009, in conjunction with the establishment of AHIC 2.0, to establish these functions to be

provided by AHIC 2.0 as multiple entities begin using the NHIN architecture of standards and services for daily operations.

ONC has awarded contracts over the past three years that have developed and demonstrated how existing technologies can be leveraged to allow interoperability among organizations that had previously created distinct and separate ways of exchanging data within each organization.

Nationwide Health Information Network Trial Implementations

Based on public input through a request for information published in June 2005, ONC received more than 500 comments expressing options, recommendations and issues regarding the creation and operation of a nationwide health information network. The resulting report (http://www.hhs.gov/healthit/rfisummaryreport.pdf) informed the basic approach to developing this capability and the subsequent request for proposals that was issued in June 2005. This evolution has progressed through the following activities:

- 1. Developing pilots to connect health information exchanges in different parts of the country the Nationwide Health Information Network prototype architectures.
 - a. Four contracts were awarded in FY 2006 to develop prototype IT 'blueprints' or architectures with functional requirements, as well as security and business models for health information exchange.
 - b. Through three subsequent public forums, the information gained from the resulting four prototypes was shared and commented on by participants. Through these meetings: a list of functional requirements that framed the development of the NHIN was developed; the need to ensure security and protect confidentiality of data was discussed, including policy and practicality implications developed clarity on architecture approaches; demonstrations of health information exchanges were given; and experiences from state and regional health information exchanges as they implement and test them were shared. Two additional forums are planned for 2008.
 - 2. Advancing the prototype architectures work in FY 2007, nine contracts were awarded to form the NHIN Cooperative for NHIN Trial Implementations. Subsequently, a tenth health information exchange participant group made up of the Indian Health Service, Department of Defense and Department of Veterans Affairs was formed to bring a Federal presence to the Cooperative.
 - a. The Cooperative involves public and private health information exchange organizations across the country that can move health-related data among entities within a state, a region or a non-geographic participant group.
 - b. The goal of the Cooperative is to demonstrate on-site, interoperable and secure health information exchange based on common specifications. There are four core services that are included: 1) delivery of data across the involved health information exchanges that include a summary patient record; 2) the ability to look up and retrieve data across the exchanges from EHRs and personal health records; 3) the ability for consumers to decide whether they want to participate in electronic exchange of their data and to whom they want

to give access; and 4) supporting the delivery of data for population health uses, such as emergency response.

- 3. Adding specific scenarios to the existing successful demonstrations, including one coordinated with and supported by contracts issued by the Centers for Disease Control and Prevention (CDC).
 - a. Sites will demonstrate information exchange in specific areas (based on the priorities recommended by the AHIC to the HHS Secretary), such as reporting laboratory test result data to the clinician who ordered the test through secure data delivery, while limiting access to only the appropriate health care provider and notifying the recipient of the information's availability.
 - b. Other priority areas to demonstrate information exchange include: medication management, emergency responder EHRs, biosurveillance (with CDC funding), consumer registration and medication history, consumer access to clinical information, and quality information data exchange.

Consumer Permissions and Access to Information

One important aspect of privacy and security that needs to be addressed is identifying the best way to structure consumer permissions in health information – that is, the manner and degree to which consumers can elect to share their health information – which is one important aspect of ensuring the privacy and security of their health information. Based on recommendations from the National Committee on Vital and Health Statistics (NCVHS), this project is critical to gain consumer trust in electronic health information exchange.

This study will focus on how health information exchanges (geographical or non-jurisdictional) have implemented a health information technology that allows individual choice for participation in an exchange, as well as how much information will be accessed through the health information exchange. Once that base-line is established, the study will involve collaboration with numerous stakeholders to develop consensus on how best to obtain consumer trust while not overburdening the industry. The expected results will be published in 2009 and describe the current and upcoming landscape regarding the manner in which consumer permissions are being handled, marketed, or developed within health information exchanges and highlight best practices.

With an interoperable network, the need to limit and compartmentalize access is critical. This will ensure that the correct permissions are available to only those individuals that the patient wants to have access and then only to information related to the request. However, there could be emergency situations requiring that the context allow for other, qualified health care professionals have access to a record. ONC will propose a draft and facilitate a process to reach widespread agreement on the concept of different contexts that would protect the privacy of individuals by preventing unnecessary information from being disclosed while allowing for appropriate access in the event of an emergency. For example, it would allow for an employer to request only information that they should, by law, be able to view while the Emergency Room doctor would be able to view everything related to the current urgent care of the patient.

ONC work will examine and propose appropriate role classifications for access to EHRs and networks (e.g., who would have access to which part of a patient's health information) as well as the application of contextual access criteria to EHRs that will enable limiting disclosures beyond the health care setting to be relevant to the request.

Adoption

ONC is also focusing on the non-technical issues related to adoption of interoperable EHRs. A number of activities have been undertaken to achieve the President's goal of most Americans having access to EHRs by 2014.

- 1. A standardized methodology has been established for measuring the rate of EHR adoption in both the ambulatory and inpatient care settings.
- 2. Annual surveys to measure EHR adoption in outpatient care settings are in place. Additional survey instruments are being developed to measure the rate of adoption in inpatient or hospital settings and will be deployed in 2008.
- 3. The vendor community has embraced a highly visible and rigorous certification process for ambulatory and outpatient EHRs, currently overseen by the Commission for Certification of Healthcare Information Technology and described in the Standards Program narrative. The ambulatory EHR certification process, which certified its first products in 2006, now enables physician practices to invest in health IT products with confidence, knowing that they have been tested and shown to perform a core set of functions, have incorporated specific criteria for security, and are interoperable with respect to key clinical information. The first hospital or inpatient EHR systems were certified in 2007. The Commission is now focusing on developing certification criteria for specialty EHRs, personal health records and network systems.
- 4. A methodology to measure the value of specific types of health information exchange was developed.
- 5. A number of secure messaging pilots are being implemented, which will assess the effect of different forms of reimbursement for clinician time and expertise on patient care and outcomes.
- 6. A consensus process was established to develop a consistent ontology or precise utilization of words as descriptors of entities with respect to health information terminologies and contexts. Payers, legislators, vendors, policy-makers, providers all use health information terms indiscriminately, confusing the public and increasing the risk of unsuccessful investments.

ONC also engages the private sector to encourage innovative practices related to health information technology adoption. Examples include: working with malpractice insurers to offer credits toward malpractice premiums for use of certified EHRs; collaborating with local medical societies and others in their efforts to purchase and implement EHRs; engaging local commercial health insurers when developing secure messaging pilots; and working with the community of the disabled in developing a personal health record focused on the unique needs of this population.

Through three performance measures (1.3.1, 1.3.2 and 1.3.4 in the Outcomes Table), ONC monitors its progress toward the ultimate goal of most American having access to interoperable EHRs by 2014. These measures were established through the FY 2006 Program Assessment Rating Tool (PART) process with reported baselines and goals set in 2007. The key performance measure for ONC is to increase physician adoption of EHRs with a long-term goal of more than 50 percent in 2014. The most recent survey results are reporting lower adoption rates than anticipated and analyses of possible adoption barriers are currently underway.

The results of the 2007 outpatient adoption survey indicate that 14 percent of physicians have adopted minimally functional EHRs. While this is lower than the anticipated rate of 18 percent in 2007, it does represent a significant increase. The new availability of EHRs that are certified for specific functionalities and security addresses one of the key concerns that physicians have had when making their investments. The Centers for Disease Control and Prevention (CDC), is measuring the adoption rate of EHRs in physician offices and inpatient hospitals through established surveys. CDC has expanded the sample size of its National Ambulatory Medical Care Survey (NAMC) to measure the adoption rate of EHRs by physicians. CDC will increase the sampling framework to measure the adoption rate among small and rural physician practices by adding mailed survey questionnaires to an additional 10,000 physicians.

Current surveys for measuring health IT adoption in the hospital setting have published adoption rates ranging from 10 percent to 70 percent, as the result of differing definitions of "adoption" and varying survey designs. A standardized survey methodology to assess health IT adoption among hospitals has been developed and field tested in for deployment in FY 2008. Analysis and reporting of the data generated from this survey instrument, which will be the "gold standard" against which the effectiveness of programs developed to improve adoption can be evaluated, will be conducted during FY 2009. The collection of this data will enable ONC to begin reporting a national rate of hospital adoption of EHRs.

An additional measure (1.3.7 in the Outcomes Table) will provide information about the cost of adopting certified EHRs. This efficiency measure was established in FY 2008 and targets are currently being developed. This measure will indicate the per physician cost by dividing the costs of certification by the number of physicians who are adopting certified EHRs as reported through the annual adoption survey. The information could inform the adoption rate results as the cost of adoption has been identified as one of the barriers that need to be addressed.

The demonstration projects that ONC initiated during 2008 to demonstrate and measure the value of secure messaging in four geographically distributed areas will yield at least one year's worth of data resulting in methodologically sound information with respect to outcome assessment and to demonstrate value. Data generated will be analyzed with a report published in 2009. This report will inform areas in policy and aspects of the

Nationwide Health Information Network that would require modification to increase the potential for physician adoption of EHRs.

Other Federal Efforts:

Other Federal entities are collaborating with ONC to further the goal of advancing and adopting interoperable EHRs and health information exchange. Some examples include:

- CDC is awarding contracts to include interoperable biosurveillance information in health information exchange.
- CDC will incorporate the standardized methodology for measuring EHRs to its annual National Center for Health Statistics' National Ambulatory Medical Care Survey questions that were collaboratively added to the FY 2008 survey.
- Leading the work of the Federal Health Architecture Program, an eGov initiative that
 involves representation from across the federal government of all organizations that
 engage in health care activities. Through this group, a collaborative Federal voice
 informs the development of the Nationwide Health Information Network from the
 government's perspective and provides a venue for implementing and deploying a
 federal version of the architecture that will allow data exchange with all entities
 across the Nation.
- To further the adoption of health IT, the CMS budget includes funding for a demonstration project providing financial incentives for physician practices to adopt certified EHR systems to improve the quality and efficiency of services.
- The Internal Revenue Service, after working closely with ONC, provided guidance to non-profit hospitals and other institutions that their non-profit status would not be threatened when exercising Stark Amendment and Anti-Kickback relief.
- Coordinating closely with the AHRQ to leverage contracts that support the establishment of health information exchange organizations and to document the benefits of EHRs on health care quality and efficiency.
- Coordinating closely with the Office of Personnel Management to implement Executive Order 13410, issued August 22, 2006, to advance quality and efficient health care in federal government. ONC worked with OPM to develop contract language for inclusion in their federal health care contracts to advance the use of the HITSP standards and to advance quality and efficiency in care.
- As a result of a recommendation made by the AHIC in 2006, ONC has been working
 with the Federal Communications Commission to fund a Rural Health Care Pilot
 Program that would expand access to health care to America's rural and underserved
 communities through the creation of broadband telehealth networks in 42 states and 3
 U.S. territories. This will bring added value to physicians interested in adopting
 EHRs.

Funding History

FY 2004	NA
FY 2005	NA
FY 2006	\$ 29,500,000
FY 2007	\$ 29,465,000
FY 2008	\$ 19,185,000

Budget Request:

The FY 2009 Request for Architecture and Adoption is \$26,033,000; an increase of +\$6,848,000 over FY 2008. This request includes:

- Funding to broaden and sustain the existing capabilities of the Nationwide Health Information Network Cooperative and particularly increase capabilities across integrated delivery systems and specialty networks. Included is the continuation of core services work for nine sites funded in 2007 and 2008. Continuing the work of all nine sites is essential to assure that the standards for information exchange that are developed through these implementations meet the full and broadest set of needs and are applicable across the Nation. Because each of these sites brings a different set of challenges to testing these implementations due to the differences in regional, state or organizational business processes, this continuation work will further align the required standards that allow interoperability. This would allow other entities to access a network to exchange health data. This is critical to ensure that proven implementations will spur the private sector to increase market activity, advancing value in others connecting to the NHIN without support, and making available certified network products, thus expanding the potential coverage of the NHIN.
- Funds to support the identification of the best way to structure consumer permissions and prevent unauthorized access to electronic health information. This includes the identification of the best way to structure consumer permissions and a study to determine the appropriate role classifications for access to electronic health data.
- Continuation of the Memorandum of Understanding with the Centers for Disease Control and Prevention (CDC), to continue measuring the adoption rate of EHRs in physician offices and inpatient hospitals through established surveys.

ONC received a PART review in 2006, and received a Results Not Demonstrated rating. This was not unexpected with the office having been established just eight months earlier in August 2005. As a result of the PART review, ONC is taking actions to continue to develop milestones and targets for the annual measures, which will produce tangible outcomes and results. ONC has initiated development of a Health IT Strategic Plan and is identifying program/office priorities to achieve over the shorter-term (two years).

These priorities will have outcome-oriented results and show clear links to the program's resources and overall mission.

Outcomes Table

#	Key Outcomes		FY 2005		FY 2	FY 2006		FY 2007		FY 2009	Out-Year
	·	Actual	Actual	Target	Actual	Target	Actual	Target	Target	Target	
Long-Term Objective 1: Increase adoption of Electronic Health Records (EHRs)											
1.3.2	Increase physician adoption of EHRs	N/A	10%	14%	N/A*	18%	14%	24%	30%	51% (2014)	
1.3.3	Increase the percentage of small practices with EHRs	N/A	N/A	Baseline	4%	5%	Feb 08	8%	11%	16% (2014)	
1.3.4	Percent of physician offices adopting ambulatory EHRs in the past 12 months that meet certification criteria	N/A	N/A	N/A		Baseline	Feb 08	25%	50%	55% (2010)	
1.3.6	Develop a mature Nationwide Health Information Network (NHIN) architecture that will support broad health information exchange	N/A	N/A	Under Development							
1.3.7	Cost per physician for adopting certified EHRs	N/A	N/A	Un Develo							

^{*} The initial data reported in 2006 was based on 2005 surveys; no survey was conducted in 2006

OPERATIONS

	2	007 Actual	20	08 Enacted	20	09 Estimate	Y 2009 + / - FY 2008
BA	\$	10,306,000	\$	9,450,000	\$	8,050,000	\$ (1,400,000)
PHS Evaluation		-		-		-	-
TOTAL Program	\$	10,306,000	\$	9,450,000	\$	8,050,000	\$ (1,400,000)

Authorizing Legislation:

Allocation Method:

None

Contract

Program Description and Accomplishments

The amount of work generated by the AHIC, as well as the self-directed work in ONC, could not have been anticipated when the office was established in late 2005. In order to immediately react and lead national initiatives without permanent staff in place, a number of large contracts were awarded to provide needed program support to the office. Through concentrated hiring efforts since its inception, the addition of staff has allowed the office to reduce the amount of funding needed for the contracted program support. ONC anticipates increasing the staffing level from 23 FTE at the beginning of FY 2008 to a total of 28 in order to fully meet ONC's responsibilities as the nationwide health IT leader, including the new tasks associated with coordinating the federal involvement and participation in AHIC 2.0 beginning in FY 2009.

Funds in this request will support the ongoing ONC operations as a functioning office within the Office of the Secretary and allow ONC to provide continuing leadership for the development and nationwide implementation of an interoperable health IT infrastructure to improve the quality and efficiency of health care. In addition, it will provide the funding necessary to cover the costs of our facilities, including rental increases, communications, acquisition of assets, and a small number of Memoranda of Understanding, Inter-Agency Agreements and contracts supporting ONC administrative, financial, logistical and planning activities.

Funding History

FY 2004	NA
FY 2005	NA
FY 2006	\$ 8,799,000
FY 2007	\$ 10,306,000
FY 2008	\$ 9,450,000

Budget Request

The FY 2009 Budget Request is \$8,050,000, a decrease of -\$1,400,000 below FY 2008. Funding for Operations is reduced as ONC anticipates economies through greater use of onboard Federal staff in lieu of contractor support. This level of funding will allow ONC

to support and manage its programs toward achievement of the President's health IT agenda and the Secretary's priority related to advancing health IT while maintaining basic office operations, at a minimal level, and will allow ONC to prudently oversee and coordinate ongoing programs.

Public Health Service Act Evaluation Funds

ONC will use \$48,000,000 (+\$29,100,000 increase over FY 2008) of Public Health Service (PHS) Act Evaluation Funds to support the demonstration and evaluation activities described in the budget narrative discussions. These programs include Standards, Privacy and Security, and Architecture and Adoption.

Office of the National Coordinator for Health Information Technology Program Level by Object

- 1 · · · · · · · · · · · · · · · · · ·	2008 Enacted	2009 Estimate	Increase or Decrease
Personnel compensation:	Litacted	Listimate	Decreuse
Full-time permanent (11.1)	\$ 3,310,000	\$ 3,425,000	\$ 115,000
Other than full-time permanent (11.3)	-	-	Ψ 112,000
Other personnel compensation (11.5)	_	_	
Military personnel (11.7)	108,000	112,000	4,000
Special personnel services payments (11.8)	,	,	,
Subtotal personnel compenstion	3,418,000	3,537,000	119,000
Civilian benefits (12.1)	1,029,000	1,065,000	36,000
Military benefits (12.2)	30,000	31,000	1,000
Benefits to former personnel (13.0)			
Total Pay Costs	4,477,000	4,633,000	156,000
Travel and transportation of persons (21.0)	160,000	120,000	(40,000)
Transportation of things (22.0)	-	-	-
Rental payments to GSA (23.1)	1,665,000	1,765,000	100,000
Communication, utilities, and misc. charges (23.3)			
Printing and reproduction (24.0)	245,000	-	(245,000)
Other Contractual Services:			
Advisory and assistance services (25.1)	2,000,000	1,750,000	(250,000)
Other services (25.2)	38,848,000	49,691,000	10,843,000
Purchase of goods and services from			
government accounts (25.3)	13,018,000	8,072,000	(4,946,000)
Operation and maintenance of facilities (25.4)	50,000	50,000	-
Research and Development Contracts (25.5)			
Medical care (25.6)			
Operation and maintenance of equipment (25.7)	8,000	-	(8,000)
Subsistence and support of persons (25.8)			
Subtotal Other Contractual Services	53,924,000	59,563,000	5,639,000
Supplies and materials (26.0)	50,000	50,000	-
Equipment (31.0)	40,000	20,000	(20,000)
Total Non-Pay Costs	56,084,000	61,518,000	5,434,000
Total Budget Authority by Object Class	\$ 60,561,000	\$ 66,151,000	\$ 5,590,000

Office of the National Coordinator for Health Information Technology Salaries and Expenses

	2008 Estimate	2009 Estimate	Increase or (Decrease)	
Personnel compensation:				
Full-time permanent (11.1)	\$ 3,310,000	\$ 3,425,000	\$ 115,000	
Other than full-time permanent (11.3)				
Other personnel compensation (11.5)				
Military personnel (11.7)	108,000	112,000	4,000	
Special personnel services payments (11.8)				
Subtotal personnel compenstion	3,418,000	3,537,000	119,000	
Civilian benefits (12.1)	1,029,000	1,065,000	36,000	
Military benefits (12.2)	30,000	31,000	1,000	
Benefits to former personnel (13.0)				
Total Pay Costs	4,477,000	4,633,000	156,000	
Travel and transportation of persons (21.0)	160,000	120,000	(40,000)	
Transportation of things (22.0)				
Rental payments to Others GSA (23.2)				
Communication, utilities, and misc. charges (23.3)				
Printing and reproduction (24.0)	245,000	0	(245,000)	
Other Contractual Services:				
Advisory and assistance services (25.1)	2,000,000	1,750,000	(250,000)	
Other services (25.2)	38,848,000	49,691,000	10,843,000	
Purchase of goods and services from				
government accounts (25.3)	13,018,000	8,072,000	(4,946,000)	
Operation and maintenance of facilities (25.4)	50,000	50,000	0	
Research and Development Contracts (25.5)				
Medical care (25.6)				
Operation and maintenance of equipment (25.7)	8,000		(8,000)	
Subsistence and support of persons (25.8)				
Subtotal Other Contractual Services	53,924,000	59,563,000	5,639,000	
Supplies and materials (26.0)		50,000	0	
Total Non-Pay Costs	54,379,000	59,733,000	5,354,000	
Total Salary and Expense	\$ 58,856,000	\$ 64,366,000	\$ 5,510,000	
Direct FTE	28	28	0	

Office of the National Coordinator for Health Information Technology Detail of Full Time Equivalents (FTE)

	2007	2008	2009
-	Actual	Enacted	Estimate
Health Information Technology			
ONC FTE Total	23	28	28
Average GS Grade			
2006	12.9		
2007	12.8		
2008	13.2		
2009	13.4		

Office of the National Coordinator for Health Information Technology Detail of Positions

(Dollars in thousands)

		2007 Actual	2008 Enacted		2009 Estimate
SES	\$	795,556	\$ 876,340	\$	919,240
Total - SES Salary	\$	795,556	\$ 876,340	\$	919,240
GS-15	\$	1,279,053	\$ 1,319,771	\$	1,277,589
GS-14		704,669	420,312		644,645
GS-13		503,439	528,764		452,755
GS-12			68,315		70,542
GS-11		66,849			
GS-10					
GS-9		265,500	204,516		172,229
Total - GS Salary	\$:	2,819,510	\$ 2,541,678	\$	2,617,760
Average SES salary	\$	159,111	\$ 175,268	\$	183,848
Average GS grade		13.1	13.2		13.4
Average GS salary	\$	104,426	\$ 84,723	\$	113,816
Average CO salary	\$	95,888	\$ 108,132	\$	111,268

SIGNIFICANT ITEMS IN APPROPRIATION COMMITTEE REPORTS

FY 2009 CONGRESSIONAL JUSTIFICATION CONFERENCE REPORT NO. 110-424

Item

Medical Device Information Sharing – The conference agreement includes \$66,151,000 for this activity, of which \$27,651,000 is provided in budget authority and \$38,500,000 is made available through the Public Health Service program evaluation tap. The House provided a combined total of \$61,302,000 for this activity; the Senate provided a combined total of \$71,000,000. The conferees encourage the Department to develop an interoperability standard, tool set, and validation protocol that facilitates seamless medical device information sharing and device connectivity. (p. 163)

Action taken or to be taken

ONC staff have participated in public and private-sector activities related to medical device information sharing. For example, staff presented information at a conference, *Improving Patient Safety through Medical Device Interoperability and High Confidence Software*, a Joint Workshop On High Confidence Medical Devices, Software, and Systems (HCMDSS) and Medical Device Plug-and-Play (MD PnP) Interoperability, June 25-27, 2007 in Boston, MA. http://rtg.cis.upenn.edu/hcmdss07/index.php3. The Federal Health Architecture Program will work with Federal partners to inform the standards process related to interoperability for medical device information sharing and device connectivity.

SPECIAL REPORTS REQUIRED BY THE APPROPRIATIONS COMMITTEE HOUSE REPORT NO. 110-231

Item

Health information technology strategic plan – The Committee has not provided the full budget request for health information technology due to concerns that this office has yet to develop a detailed and integrated implementation plan for achieving the health information technology program's strategic goals, as recommended by the General Accounting Office. The Committee requests that, no later than **March 1, 2008**, the Secretary submit a report to the House and Senate Committees on Appropriations that provides an implementation plan for health information technology (including related activities funded through the Agency for Healthcare Research and Quality and the Centers for Disease Control), which includes performance benchmarks, milestones, and timelines for achieving program objectives. This report should also identify the resource requirements for achieving specific performance benchmarks. (p. 213)

Action taken or to be taken

ONC has prepared a draft Health IT Strategic Plan and plans to release it in the second quarter of 2008.

Item

Framework for Health Information Exchange – In addition, the Committee requests that the Secretary develop and make available for public comment, not later than March 1, 2008, a privacy and security framework that will establish trust among consumers and users of electronic personal health information and will govern all efforts to advance electronic health information exchange. The framework shall address generally accepted fair information practices, including transparency; specifying the purposes of any data collection; collecting only what is necessary for that purpose; adhering to the uses agreed to by the individual; allowing individuals to know and have a say in who and how their information is used; maintaining the integrity of the data; security; audit; strong oversight; and appropriate remedies in the event of breach or misuse. The development of this framework should include participation by affected stakeholders and be conducted with adequate opportunity for public comment and review. The Committee requests that the Secretary report to the House and Senate Committees on Appropriations on the development and implementation of this framework by no later than **June 30, 2008**. This report shall describe the appropriate enforcement mechanisms to assure general conformity with the privacy and security framework, including how various enforcement tools, such as federal and state statutes, government procurement policy, third-party certification, self-attestation, business contracts, and FTC enforcement of public claims, may assist in achieving general adoption of the privacy framework. The Secretary's report should also include any appropriate recommendations for Congressional or executive action. The Committee requests that the Secretary issue, after an appropriate public comment and review period, such rules, regulations, and technical requirements as may be needed to assure implementation of the privacy and security framework, consistent with the report to Congress. The Committee further requests that the Secretary ensure that any Federally endorsed or funded standards development and harmonization or product certification products be developed consistent with all elements of the privacy and security framework. (pp. 213 – 214)

Action taken or to be taken

As a foundational document and a supplement to existing laws that protect health information, a Nationwide Health Information Technology Confidentiality, Privacy and Security Framework, begun in 2007, will be the result of a federal-led effort involving stakeholders community-wide and will serve to increase trust among consumers and users of electronic individual health information and to govern all efforts to advance electronic health information exchange. ONC is developing a draft document and will obtain input from affected stakeholders. This document will address generally accepted fair information practices, such as transparency; specifying the purposes of any data collection; collecting only what is necessary for that purpose; adhering to the uses agreed to by the individual; allowing individuals to know and have a say in who and how their information is used; maintaining the integrity of the data; security; audit; oversight; and appropriate remedies in the event of breach or misuse. Both internal departmental and external HHS and private-sector involvement in the development of the framework are seen as critical to its acceptance and adoption. It is anticipated that the document will be completed in 2008.

SPECIAL REQUIREMENTS

Unified Financial Management System Operations and Maintenance (UFMS O & M)

Unified Financial Management System Operations and Maintenance (UFMS) has now been fully deployed. The Program Support Center, through the Service and Supply Fund, manages the ongoing Operations and Maintenance activities for UFMS. The scope of Operations and Maintenance services includes post-deployment support and ongoing business and technical operations services, as well as an upgrade of Oracle software from version 11.5.9 to version 12.0. ONC will use \$41,565 for these Operations and Maintenance costs in FY 2009.

HHS Consolidated Acquisition System (HCAS)

The HHS Consolidated Acquisition System (HCAS) initiative is a Department-wide contract management system that will integrate with the Unified Financial Management System (UFMS). The applications within the HCAS are Compusearch PRISM and a portion of the Oracle Compusearch Interface (OCI). PRISM is a federal contract management system that streamlines the procurement process. PRISM automates contract writing, simplified acquisitions, electronic approvals and routing, pre-award tracking, contract monitoring, post award tracking, contract closeout and reporting. ONC will use \$2,248 to support the completion of HCAS implementation in FY 2009.

Federal Health Architecture (FHA)

The Federal Health Architecture (FHA) is a partnership among federal agencies, the Office of the National Coordinator for Health IT (ONC), and the Office of Management Budget (OMB). The Department of Health and Human Services (HHS) is the Managing Partner; together with the Department of Defense (DoD) and the Department of Veterans Affairs (VA); all Lead Partners provide program funding. In addition, approximately 20 agencies, all with health-related responsibilities, contribute time and expertise to participate in specific FHA activities. These agencies collaborate to advance health information interoperability between Federal agencies and tribal, state, and local governments and the private sector.

FHA was initiated in July 2003 and is governed by principles that focus on achieving the vision of interoperable health information in support of the agency priorities, Federal mandates and the national Health IT agenda to enable better care, increase efficiency and improve population health. FHA's priorities are driven by value, where FHA will demonstrate the value of each task or activity and ensure that every undertaking is Stakeholder-driven. This ensures alignment of FHA objectives, deliverables and timeframes to agency priorities and mandates.

In FY 2007, FHA developed its strategy and goals to include development of four main initiatives:

- 1) Federal Adoption of Standards for Health IT (FAST) to provide support and guidance for implementation of Health IT Standards
- 2) Federal Health IT Planning and Reporting (FHIPR) to provide health IT specific guidance to agencies for the purposes of planning health IT investments and reporting
- 3) Federal Health Interoperability Architecture (FHIA) to provide support and guide program managers and enterprise architects in implementing products created by the national health IT agenda
- 4) Nationwide Health Information Network Connect (NHIN-C) to enhance federal sector participation in the nationwide health information exchange initiative

The first three initiatives provide for information dissemination and guidance across federal agencies. NHIN-C will facilitate the standardization of federal nationwide health information connection solution architecture design and identified services with the help of other federal partners. Ultimately, this will enable stakeholders to connect and exchange health information between federal agencies and with private organizations. Each of the initiatives has been designed to support the President's health information technology plan.

Schedule risk will be managed throughout the entire lifecycle of the program. FHA has a risk mitigation plan that is available upon request. In addition, FHA has developed a

strategic plan, which outlines the following years' deliverables as well as adjusting the direction of the program as a whole when needed. The identified tasks have been prioritized by the Leadership Council and project charters, project plans and project cost estimates are developed for tracking purposes. Changes in scope are assessed for cost and appropriateness by the Leadership Council prior to moving forward.

The cost of establishing the FHA is based on a number of assumptions. To address this risk, the FHA program will update its cost estimates for the program incorporating the new mission/vision/goals. For the out-years through FY 2014, FHA is in the process of defining the specific workload for the program by conducting strategic planning sessions involving various federal agencies having health IT interoperability issues. Agency partners will contribute to and review FTE estimates each year. By using an iterative approach, estimates will improve over time. A dedicated project manager will closely monitor schedule and expenditures. EVM will also be used to monitor progress.

Changes to FHA activities will be prioritized and managed by the partners throughout the life cycle. FHA is incrementally funded, which allows for discussions to occur with existing funding partners, as well as opportunity to seek out additional partners to secure future funding if required and approved. Since FHA is not building a system but rather architecture, the operations and maintenance costs should be minimal. FHA partners reevaluate the lifecycle costs yearly during strategy planning to identify the next year's work plan.

FUNDING

FEDERAL HEALTH ARCHITECTURE PROGRAM

	Fur	nding to Date	200	8 Enacted	200	9 Estimate
Health & Human Services	\$	11,769,568	\$	3,522,000	\$	3,662,000
Veterans Affairs	\$	5,164,907	\$	1,861,000	\$	1,936,000
Defense	\$	4,164,927	\$	1,861,000	\$	1,936,000
Total Funding Contributed	\$	21,099,402	\$	7,244,000	\$	7,534,000

Public Health and Social Services Emergency Fund

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FY 2009 PROPOSED APPROPRIATION LANGUAGE

For expenses necessary to support activities related to countering potential biological, disease, nuclear, radiological and chemical threats to civilian populations, and for other public health emergencies, \$810,740,000, of which not to exceed \$22,360,000, to remain available until September 30, 2010, is to pay the costs described in section 319F-2(c)(7)(B) of the Public Health Service Act, and of which \$275,000,000, shall be used to remain available until September 30, 2010, is to support advanced research and development of medical countermeasures and ancillary products, consistent with section 319L of the Public Health Service Act.

For expenses necessary to prepare for and respond to an influenza pandemic, \$585,091,000, of which \$507,000,000 shall be available until expended, for activities including the development and purchase of vaccine, antivirals, necessary medical supplies, diagnostics, and other surveillance tools: Provided, That products purchased with these funds may, at the discretion of the Secretary, be deposited in the Strategic National Stockpile: Provided further, That notwithstanding section 496(b) of the Public Health Service Act, funds may be used for the construction or renovation of privately owned facilities for the production of pandemic influenza vaccines and other biologics, where the Secretary finds such a contract necessary to secure sufficient supplies of such vaccines or biologics: Provided further, That funds appropriated herein may be transferred to other appropriation accounts of the Department of Health and Human Services, as determined by the Secretary to be appropriate, to be used for the purposes specified in this sentence.

LANGUAGE ANALYSIS

Language Provision

"of which not to exceed \$22,360,000, to remain available until September 30, 2010, is to pay the costs described in section 319F-2(c)(7)(B) of the Public Health Service Act."

"of which \$275,000,000, to remain available until September 30, 2010, is to support advanced research and development of medical countermeasures and ancillary products, consistent with section 319L of the Public Health Service Act."

"For expenses necessary to prepare for and respond to an influenza pandemic, \$585,091,000, of which \$507,000,000 shall be available until expended, for activities including the development and purchase of vaccine, antivirals, necessary medical supplies, diagnostics, and other surveillance tools: Provided, That products purchased with these funds may, at the discretion of the Secretary, be deposited in the Strategic National Stockpile: Provided further, That notwithstanding section 496(b) of the Public Health Service Act, funds may be used for the construction or renovation of privately owned facilities for the production of pandemic vaccine and other biologicals, where the Secretary finds such a contract necessary to secure sufficient supplies of such vaccines or biologicals: Provided further, That funds appropriated herein may be transferred to other appropriation accounts of the Department of Health and Human Services, as determined by the Secretary to be appropriate, to be used for the purposes specified in this sentence."

Explanation

This language provides two-year funding for management of Project Bioshield. Funding will support oversight and implementation infrastructure for medical countermeasure procurement.

This language provides two-year funding for advanced research and development activities within the Office of the Assistant Secretary for Preparedness and Response.

This language provides funding for pandemic influenza activities, of which \$870,000,000 is requested as no-year funds.

AMOUNTS AVAILABLE FOR OBLIGATION¹

	FY 2007 <u>Actual</u>	FY 2008 Enacted	FY 2009 Estimate
Annual Appropriation	\$602,200,000	\$708,016,000	\$591,471,000
Supplemental (P.L. 110-28)	\$99,000,000	\$700 01 <i>C</i> 000	¢501 471 000
Subtotal Annual Appropriations	\$701,200,000	\$708,016,000	\$591,471,000
Comparable transfer from			
FY 2002, no-year carryover	\$8,005,000		
GDM, for Office of Security and Strategic Information	\$474,000		
CDC, for BioShield Management	\$15,820,000		
Comparable transfer to			
GDM, for Commissioned Corps Transformation	-\$8,726,000		
Multi-Year Appropriation		\$21,243,000	\$297,360,000
No-Year Appropriation			\$507,000,000
Total, adjusted budget authority	\$716,773,000	\$729,259,000	\$1,395,831,000
Unobligated balance, start of year	\$3,278,778,048	\$2,087,777,416	\$10,000,000
Unobligated balance, end of year	\$2,087,777,416	\$10,000,000	\$10,000,000
Unobligated balance lapsing	\$2,533,845		
Total obligations	\$2,002,887,717	\$2,807,036,416	\$1,395,831,000

¹ Excludes reimbursable activities carried out by this account and evaluation fund transfers.

SUMMARY OF CHANGES

2008 Comparable Enacted Level	\$729,259,000
Total estimated budget authority	\$729,259,000
2009 Budget	\$1,395,831,000
Total estimated budget authority	\$1,395,831,000
Net change	+\$666,572,000

	2008 Enacted			
	Budget Base Chan		ge from Base	
	Budget			Budget
	(FTE)	Authority	(FTE)	<u>Authority</u>
<u>Increases:</u>				
Assistant Secretary for Preparedness and Response		\$632,703,000)	+\$142,884,000
Cyber-Security		\$8,906,000)	+\$3,074,000
Medical Reserve Corps		\$9,578,000)	+\$5,532,000
Office of Security and Strategic Information (OSSI)		\$3,263,000)	+\$1,500,000
Healthcare Provider Credentialing				+\$3,300,000
Pandemic Influenza		\$74,809,000	<u>) </u>	+\$510,282,000
Total Increases	440	\$729,259,000	+76	+\$666,572,000
Decreases:				
Total Decreases				
Net Change			+76	+\$666,572,000

BUDGET AUTHORITY BY ACTIVITY (Dollars in thousands)

	FY 2007		FY 2008		FY 2009	
	<u>Actual</u>		Enacted		Estimate	
	<u>FTE</u>	<u>Amount</u>	<u>FTE</u>	<u>Amount</u>	<u>FTE</u>	<u>Amount</u>
Bioterrorism	287	\$716,773,000	404	\$654,450	469	\$810,740
Pandemic Influenza	<u>10</u>		<u>36</u>	<u>74,809</u>	<u>47</u>	<u>585,091</u>
TOTAL	297	\$716,773,000	440	\$729,259	516	\$1,395,831

BUDGET AUTHORITY BY OBJECT (Dollars in thousands)

	FY 2008	FY 2009	FY 2009 +/-
	Enacted	Estimate	FY 2008
Full-time equivalent employment	440	516	+76
Average SES salary	\$160,399	\$153,837	\$154,298
Average GS grade	GS-13/6	GS-13/6	GS-13/7
Average GS salary	\$90,640	\$93,694	\$96,130

	FY 2008	FY 2009	FY 2009 +/-
Demonstration.	Enacted	<u>Estimate</u>	<u>FY 2008</u>
Personnel compensation:	¢27.020	¢52.707	¢15.076
Full-time permanent	\$37,920	\$53,796	\$15,876
Other than full-time permanent	4,820	4,820	
Other personnel compensation	10.201	24.006	 5.515
Military Personnel	19,391	24,906	5,515
Special Personnel Services			21 200
Subtotal, personnel compensation	62,132	83,522	21,390
Civilian personnel benefits	8,408	8,697	289
Military Benefits			
Benefits to former personnel			
Subtotal, pay costs	70,540	92,219	21,679
Travel	4,801	6,172	1,372
Transportation of things	117	150	33
Rental payments to GSA	7,872	10,145	2,273
Rental payments to others	1,940	2,499	560
Communications, misc charges	1,903	2,452	549
Printing and reproduction	9	12	3
Other contractual services:			
Advisory and assistance services	53	65	12
Other services	17,095	28,562	11,467
Purchases of goods and services from Govt accounts	114,351	115,020	669
Operation and maintenance of facilities	63	83	20
Research and development contracts	1,276,871	249,997	-1,026,874
Medical care			
Operation and maintenance of equipment	309	359	50
Subsistence and support of persons			
Subtotal, other contractual services	1,408,742	394,086	-1,014,656
Supplies and materials	516,278	512,754	-3,524
Equipment	2,691	3,460	769
Grants, subsidies and contributions	802,367	371,882	-430,485
Subtotal, non-pay costs	2,746,719	1,303,612	-1,443,107

SALARIES AND EXPENSES (Budget Authority)

(Suugov i Iulion	FY 2008 Enacted	FY 2009 Estimate	FY 2009 +/- FY 2008
Personnel compensation:			
Full-time permanent	\$37,920	\$53,796	\$15,876
Other than full-time permanent	4,820	4,820	
Other personnel compensation			
Military Personnel	19,391	24,906	5,515
Special Personnel Services			
Subtotal, personnel compensation	62,132	83,522	21,390
Civilian personnel benefits	8,408	8,697	289
Military Benefits			
Benefits to former personnel			
Subtotal, pay costs	70,540	92,219	21,679
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Communications, misc charges	1,903	2,452	549
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Other contractual services:			
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Research and development contracts	1,276,871	249,997	-1,026,874
Medical care			
Operation and maintenance of equipment	309	359	50
Subsistence and support of persons			
Subtotal, other contractual services	1,408,742	394,086	-1,014,656
Supplies and materials	516,278	512,754	-3,524
Total budget authority	\$2,012,201	\$1,020,489	-\$991,712

AUTHORIZING LEGISLATION

	2008	2008	2009	2009
	Amount		Amount	
	<u>Authorized</u>	Enacted	<u>Authorized</u>	<u>Estimate</u>
Pandemic and All-Hazards Preparedness Act, 2006 and the Public Health Security and Bioterrorism Preparedness and Response Act, 2002		\$729,259,000		\$1,395,831,000

APPROPRIATIONS HISTORY TABLE (Non-Comparable)

	Budget			
	Estimate	House	Senate	
	to Congress	<u>Allowance</u>	<u>Allowance</u>	<u>Appropriation</u>
<u>FY 1998</u>				
Appropriation	_	_	_	_
FY 1999				
Appropriation	_	_	_	\$216,922,000
Y2K Appropriation	_	_	_	\$189,053,000
FY 2000	204.022.000	201 000 000	477 000 000	702
Appropriation	386,022,000	391,800,000	475,000,000	583,600,000
Rescission				-437,000
EV 2001				
FY 2001	264 600 000	207 700 000	264 600 000	241 221 000
Appropriation	264,600,000	286,600,000	264,600,000	241,231,000
Rescission Supplement	itai			-282,000
Appropriation	_	_	_	126,150,000
FY 2002				
Appropriation	250,619,000	300,619,000	250,619,000	2,429,490,000
Defense Approp	230,019,000	300,019,000	230,019,000	2,429,490,000
Rescission				-1,396,000
Reseission				-1,570,000
FY 2003				
Appropriation	1,806,180,000	2,507,184,000	2,306,580,000	2,246,680,000
Rescission	1,000,100,000	2,507,101,000	2,500,500,000	-14,604,000
Transfer to Dept				1 1,00 1,000
of Homeland				
Security (DHS)				-427,638,000
Supplemental				, ,
Appropriation				142,000,000
FY 2004				
Appropriation	1,896,149,000	1,776,846,000	1,856,040,000	1,776,846,000
Rescission				-10,483,000
Transfer from DHS				397,640,000
114110101 110111 1111				277,010,000

	Budget			
	Estimate	House	Senate	
	to Congress	<u>Allowance</u>	<u>Allowance</u>	<u>Appropriation</u>
FY 2005				
Appropriation Rescissions	\$61,456,000	\$61,456,000	\$61,456,000	\$161,456,000 -1,389,984
Supplemental Appropriation				60,000,000
FY 2006				
Appropriation	203,589,000	60,633,000	60,633,000	63,589,000
Rescissions				-635,890
Transfer to CMS				-43,245
Supplemental Appropriation				5,570,000,000
FY 2007				
Appropriation	218,413,000	160,475,000	166,907,000	602,200,000
Supplemental Appropriation				99,000,000
FY 2008				
Appropriation	1,729,211,000	\$1,705,382,000	\$1,674,556,000	\$729,295,000
FY 2009				
Estimate	\$1,395,831,000			

PUBLIC HEALTH AND SOCIAL SERVICES EMERGENCY FUND

OFFICE OF THE SECRETARY - FUNDING SUMMARY

(Dollars in thousands)

	FY 2007	FY 2008	FY 2009
A	<u>Actual</u>	<u>Enacted</u>	<u>Estimate</u>
Assistant Secretary for Preparedness and Response		***	.
Operations	\$7,626	\$10,261	\$14,290
Preparedness and Emergency Operations	13,564	17,275	34,917
National Disaster Medical System	46,605	45,999	53,000
Hospital Preparedness	474,030	423,399	361,660
Training Curriculum and Development	20,790		
Advanced Research and Development	103,921	101,544	250,000
Advanced Development of Ventilators			25,000
BioShield Management	15,820	21,243	22,360
International Early Warning Surviellence	8,808	8,690	9,030
Policy, Strategic Planning, and Communications	3,116	4,292	5,330
Subtotal, ASPR	694,280	632,703	775,587
Assistant Secretary for Resources and Technology			
Cyber-Security	9,482	8,906	11,980
Office of Public Health and Science			
Medical Reserve Corps	9,748	9,578	15,110
Office of the Secretary			
Office of Security and Strategic Information (OSSI)	3,263	3,263	4,763
Healthcare Provider Credentialing			3,300
Pandemic Influenza		74,809	585,091
Total, PHSSEF	\$ 716,773	\$ 729,259	\$ 1,395,831

PUBLIC HEALTH AND SOCIAL SERVICES EMERGENCY FUND

(Office of the Secretary)

	FY 2007	FY 2008	FY 2009	FY 2009 +/-
	<u>Actual</u>	Enacted	Estimate	FY 2008
Budget Authority	\$716,773,000	\$729,259,000	\$1,395,831,000	+\$666,572,000
FTE	297	440	516	+76

NOTE: FY 2007 amounts have been revised to reflect the reallocation of carryover funds to maintain funding at FY 2006 levels. Also, comparable adjustments have been made for the funding of the Office of Policy and Strategic Planning, which was establish

OVERVIEW

The FY 2009 request for the Public Health and Social Services Emergency Fund (PHSSEF) is \$1,395,831,000, and increase of \$666,572,000 and 76 FTE above the FY 2008 enacted level. These funds will provide the necessary resources to:

- support a more comprehensive program to prepare for the health and medical consequences of bioterrorism and other public health emergencies;
- continue the Department's cyber-security efforts; and
- support the Department's pandemic influenza activities.

The budget justification which follows represents funds requested within the Office of the Secretary (OS) for the Office of the Assistant Secretary for Preparedness and Response (ASPR), the Office of the Assistant Secretary for Resources and Technology (ASRT), and the Office of Public Health and Science (OPHS). This justification also requests funding for the Department's Pandemic Influenza Initiative, the Office of Security and Strategic Information (OSSI), and healthcare provider credentialing.

OFFICE OF THE ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE SUMMARY OF REQUEST

	FY 2007	FY 2008	FY 2009	FY 2009 +/-
	<u>Actual</u>	Enacted	Estimate	FY 2008
Budget Authority	\$694,280,000	\$632,703,000	\$775,587,000	+\$142,884,000
FTE	266	377	434	+57

NOTE: Project BioShield program management is funded through direct appropriations beginning in FY 2008. In addition, the request assumes funding for Pandemic Influenza program management is included within the consolidated request for the Office of the Secretary. FY 2007 amounts have been revised to reflect the reallocation of carryover funds to maintain funding at FY 2006 levels. One-time funding for Katrina Lessons Learned and COOP relocation is not included. Also, comparable adjustments have been made for the funding of the Office of Policy and Strategic Planning, which was established in FY 2007, and for the transfer of funding for the Office of Security and Strategic Information. FTE estimates do not include FTE supported by Pandemic Influenza program management.

ASPR's mission – to lead the Nation in preventing, preparing for, and responding to the adverse health effects of public health emergencies and disasters – and its vision – a Nation prepared to prevent, respond to and reduce the adverse health effects of public health emergencies and disasters – reflect the essential role ASPR plays within the Nation's public health preparedness and emergency response arena. ASPR focuses its efforts on promoting community preparedness and prevention; building public health partnerships with federal departments and agencies, academic institutions and private sector partners; and coordinating federal public health and medical response capability.

The FY 2009 request for the Office of the Assistant Secretary for Preparedness and Response to direct the Department's efforts to prepare for, protect against, respond to, and recover from public health emergencies, including acts of bioterrorism that affect the civilian population, is \$775,587,000, an increase of +\$142,884,000 above the FY 2008 Enacted level. The staff to support the programmatic responsibilities of ASPR in FY 2008 and FY 2009 will be 510 positions; this does not include positions supported by funding for Pandemic Influenza program management. The request includes:

- \$14,290,000, an increase of +\$4,029,000, for Operations to support salaries, rent and service changes, equipment costs, travel, telecommunications, training and continued implementation of revised OMB Circular A-123
- \$34,917,000, an increase of +\$17,642,000, for Preparedness and Emergency Operations to strengthen HHS' capabilities to deploy, coordinate, and communicate effectively during a response. Funding will support improved regional response coordination, including the development of scenario-based response plans tailored to individual geographic regions; systems upgrades and infrastructure enhancements in the Secretary's Operations Center; and the development of emergency response capabilities, including training and exercises.
- \$53,000,000, an increase of +\$7,001,000, for the National Disaster Medical System to support headquarters operations as well as medical response assets including teams, supplies, and equipment.

- \$361,660,000, a decrease of -\$61,739,000, for Hospital Preparedness. The formula grant level for awards to states, cities, and territories will be reduced due to a shortening of the grant cycle to nine months three weeks. This is a technical adjustment, not a reduction in grant awards.
- \$250,000,000, an increase of +\$148,456,000, for Advanced Research and Development to support efforts to evaluate, assess and develop candidate medical countermeasures with the long-term potential to qualify for acquisition as medical countermeasures for the Strategic National Stockpile. These funds are requested with two years of fiscal availability.
- \$25,000,000 is requested to support advanced development of next generation ventilators. Ventilators would have a significant impact during an influenza pandemic, and gap analysis of domestic manufacturing surge capacity for ventilators demonstrated that pandemic preparedness could not be accommodated by present capacities for existing types of ventilators.
- \$22,360,000, an increase of +\$1,117,000, is requested for BioShield Management for oversight and implementation for medical countermeasure procurement under Project BioShield.
- \$9,030,000 is requested, an increase of \$340,000, for International Early Warning Surveillance to coordinate and facilitate development of international preparedness and response capabilities.
- \$5,330,000, an increase of +\$1,038,000, is requested for Policy, Strategic Planning, and Communication to maintain on-going efforts to support policy formulation, analysis, coordination, and evaluation of preparedness and response efforts across ASPR and to support the development of the National Health Security Strategy.

OFFICE OF THE ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE OPERATIONS

	FY 2007	FY 2008	FY 2009	FY 2009 +/-
	<u>Actual</u>	Enacted	Estimate	FY 2008
Budget	\$7,626,000	\$10,261,000	\$14,290,000	+\$4,029,000
FTE	22	27	32	+5

Allocation Method: Direct federal/intramural; contracts

<u>Program Description and Accomplishments:</u>

The Pandemic and All-Hazards Preparedness Act of 2006 created the Office of the Assistant Secretary for Preparedness and Response (ASPR). ASPR directs and coordinates HHS-wide capabilities of preparing for and responding to bioterrorism and other public health and medical emergencies. ASPR also coordinates activities with other Departments and Agencies as the leader of Emergency Support Function #8 of the National Response Framework ASPR's mission – to lead the Nation in preventing, preparing for, and responding to the adverse health effects of public health emergencies and disasters – and its vision – a Nation prepared to prevent, respond to and reduce the adverse health effects of public health emergencies and disasters – reflect the essential role ASPR plays within the Nation's public health preparedness and emergency response arena.

Carrying out HHS' responsibility as the primary agency for medical and public health preparedness requires the diverse and unique skills of scientists, public health experts and health care providers at the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), the Health Resources and Services Administration (HRSA), the Agency for Healthcare Research and Quality (AHRQ), the Substance Abuse and Mental Health Services Administration (SAMHSA), and the Administration for Children and Families (ACF). Through its program offices, ASPR coordinates the activities of these agencies, develops and coordinates national policies and plans, provides program oversight, and is the Secretary's public health emergency representative to other federal, state and local organizations. The Public Health Emergency Medical Countermeasures Enterprise (PHEMC Enterprise), consisting of ASPR, CDC, FDA and NIH with non-voting members from the Department of Defense, Department of Homeland Security and Department of Veterans Affairs, serves as the overarching coordination focus for the research, development, procurement, storage, maintenance, deployment and use of medical countermeasures for public health emergencies.

The Pandemic and All-Hazards Preparedness Act of 2006 provides ASPR with "authority over and responsibility for" National Disaster Medical System (NDMS) (as of January 1, 2007) and the Hospital Preparedness Program. Additionally, the Act states that ASPR shall "exercise the responsibilities and authorities of the Secretary with respect to the coordination of" the Medical Reserve Corps, the Emergency Systems for the Advance Registration of Volunteer Health Professionals (ESAR-VHP), the Strategic National

Stockpile, the Cities Readiness Initiative (CRI) and other duties as the Secretary determines appropriate. The Act also established the Biomedical Advanced Research and Development Authority (BARDA) to facilitate collaboration between HHS and other federal agencies, relevant industries, academia, and other persons, with respect to advanced research and development of medical countermeasures for chemical, biological, radiological and nuclear (CBRN) threats and pandemic or epidemic threats. BARDA also promotes countermeasure and product advanced research and development, facilitates contacts between interested persons and the offices or employees authorized by the Secretary to advise such persons regarding requirements under the Federal Food, Drug, and Cosmetic Act and under PAHPA, and promotes innovation to reduce the time and cost of countermeasure and product advanced research and development.

Funding History:

\$12,645,000
\$9,404,000
\$9,147,000
\$7,626,000
\$10,261,000

Budget Request:

\$14,290,000, an increase of +\$4,029,000, is requested to support ASPR's leadership for all HHS bioterrorism and emergency preparedness activities. Funding will be used for staff salaries, rent and service changes, equipment costs, travel, telecommunications, training and continued implementation of revised OMB Circular A-123. Funding requested in Operations also will support continued development and implementation of the ASPR Strategic Management System (SMS) initiative. Through FY 2009, this effort will help ensure that ASPR's resources are aligned with performance priorities. Primary components of the initiative will improve strategic planning and communications, transparency and accountability of business operations, and overall organizational and employee development. The SMS initiative will give ASPR the capacity to provide feedback around critical program activities and internal business processes as well as track external outcomes in order to continuously improve strategic performance and results.

OFFICE OF THE ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE PREPAREDNESS AND EMERGENCY OPERATIONS

	FY 2007	FY 2008	FY 2009	FY 2009 +/-
	<u>Actual</u>	Enacted	Estimate	FY 2008
Budget	\$13,564,000	\$17,275,000	\$34,917,000	+\$17,642,000
FTE	62	100	120	+20

Allocation Method: Direct federal/intramural; contracts

<u>Program Description and Accomplishments:</u>

HHS serves as the primary agency for Emergency Support Function (ESF) #8 – preparedness for and response to the public health and medical consequences of disasters, including terrorist incidents involving weapons of mass destruction – under the National Response Framework (NRF). ASPR is the action agent for all activations of ESF #8 and independent authorities under which HHS is responsible such as the Public Health Service Act, Sections 311 and 319. Through the Secretary's Operations Center (SOC), the Incident Response Coordination Team (IRCT), the National Disaster Medical System (NDMS), and the office's regional emergency coordinators, ASPR directs and coordinates all public health and medical assets associated with ESF #8 response. In addition, ASPR has lead responsibility for ensuring that HHS complies with all Continuity of Operations (COOP) and Continuity of Government (COG) requirements. This includes planning and implementing the Department's essential functions during emergencies. ASPR has the lead representing HHS for the Critical Infrastructure Protection program for the Healthcare and Public Health Sector as outlined in Homeland Security Presidential Directive (HSPD) - 7.

ASPR leads planning activities required to fulfill HHS mass casualty care responsibilities under ESF #8 of the NRP and HSPD-10. This includes the continuing development of Federal Medical Stations (FMS). The FMS project supports HHS in fulfilling the responsibility under mandates as set forward above to develop a federal asset to provide over 30,000 patient beds. The HHS mass casualty care initiative also works to mobilize emergency medical personnel by developing protocols for coordinating with the Emergency Systems for the Advance Registration of Volunteer Health Professionals (ESAR-VHP) and the Medical Reserve Corps. Other mass casualty preparedness planning activities include initiatives to promote development of subject matter expertise and decision support tools for chemical, biological, radiological and nuclear (CBRN) incidents.

ASPR has successfully responded to tropical storms, food safety concerns, national special security events, threats and exercises throughout the past year. These responses have provided ASPR and HHS the opportunity to strengthen their situational awareness, analysis and decision support capabilities, and mature their response management. ASPR is building its ability to manage information by outlining the existing information management processes between its internal and external stakeholders and by improving the definition of the Department's core capabilities to ensure essential elements of

information are collected. ASPR is building a regional response capability by consolidating warehousing and equipment/supply caches within the regions. ASPR is establishing a readiness system to further develop mechanisms to improve their readiness program. Many Departmental and national plans have been exercised and lessons learned applied which allows the Department to make necessary revisions in order to expand the capabilities of the Department to respond. ASPR also successfully executed a COOP exercise in conjunction with "Pinnacle 2007" as well as classified COG exercises, demonstrating the ability to carry out essential functions at remote locations.

ASPR is building mass casualty care capability by developing threat-based operational plans, building surge bed capabilities, establishing logistics mechanisms for rapidly deploying federal and civilian medical personnel and medical materiel, and developing subject matter expertise both within HHS and in the community. ASPR has continued to develop operational playbooks for the national planning scenarios. ASPR is also building a cadre of surge personnel with specialized skills anticipated to be in short supply during disasters.

In its role of coordinating efforts to address mental health and needs of "at-risk individuals," ASPR has undertaken several significant initiatives. In 2007, ASPR conducted a thorough assessment of the Department's emergency behavioral/mental health capabilities. This assessment inventoried assets including personnel, technical assistance, materials, and grants, also identifying current gaps and potential solutions. To address needs of "at-risk individuals," ASPR surveyed all the Operating and Staff Divisions to identify current efforts aimed at special needs, at-risk, and vulnerable populations.

Funding History:

FY 2004	\$9,742,000
FY 2005	\$12,769,000
FY 2006	\$14,942,000
FY 2007	\$13,564,000
FY 2008	\$17,275,000

Budget Request:

\$34,917,000, an increase of +\$17,642,000 above the FY 2008 Enacted level is requested. Funding will support training and exercises including the Secretary's Quarterly Readiness Exercises. Funding will also support the Emergency Management Group (EMG)/SOC activities and operations, such as responses to national special security events (e.g. the State of the Union). The request also includes funding for deployment support and cache management which will enhance the development of regional readiness capability. Funding will also support preparedness planning activities such as regional readiness exercises and playbooks and the development of web-based training modules addressing multiple scenarios and disciplines. Additional funds will be used to strengthen preparedness and response based on the findings of the White House report, *Federal Response to Hurricane Katrina: Lessons Learned* and the requirements outlined in the

Pandemic and All-Hazards Preparedness Act and Homeland Security Presidential Directive - 21.

Increased funding will be directed to preparedness planning and response operations, which will identify requirements for the public health and medical needs of the national planning scenarios and will help quantify the assets and other capabilities needed to meet ASPR's preparedness and response mission as the lead for ESF #8. Increased funding will also support information technology and communication systems upgrades and infrastructure enhancements in the SOC, which are necessary to maintain situational awareness and the ability to share information with federal, state, and local partners during an incident. The requested increase will also support improved regional response coordination, including through the development of scenario-based response plans tailored to individual geographic regions; and the development of emergency response capabilities, including through training and table top exercises. Also, the increase will also continue efforts to coordinate and provide services specifically aimed at assisting atrisk individuals, including developing training for responders. Together, these investments will enhance HHS' capabilities to deploy, coordinate, and communicate effectively during a response.

Outcomes and Outputs:

#	Key Outcomes	FY 2004	FY 2005	FY 2	2006	FY 20	FY 2007		FY 2009 Target
	Outcomes	Actual	Actual	Target	Actual	Target	Actual	Target	Target
Long-	 Term Goal: 1	 Improve D	HHS resp	onse asset	s to suppo	rt municipalities and	d States.		
2.4.1	Improve ESF #8 prepared- ness planning and response capability.	n/a	n/a	n/a	n/a	Develop threat-based response plans; continue to assess the Department's ability to respond to scenarios and actual events; respond to public health and medical threats and emergencies; participate in exercises (e.g. TOPOFF). Develop capacity for, interoperable communications between field elements and headquarters. Coordinate expansion of FMS. Build cadre of surge personnel with specialized skills. Sustain and enhance monitoring and medical management of a radiological/ nuclear public health emergency. Continue development of operational playbooks for each of the National Planning Scenarios. Transfer NDMS to HHS.	operational playbooks written. Responded to Hurricane Dean. Executed COOP exercise in conjunction with "Pinnacle 2007". Provided ICS training to IRCT. Implementing a national surge bed reporting system (HAVBED). Identified 159 respiratory therapists who could deploy. Launched the Radiation Event Medical Management (REMM) website NDMS was transferred successfully teams have been successfully deployed.	Continue to develop and revise existing threat-based response plans. Continue to train personnel to lead ESF #8 planning and response. Conduct regional site-specific surveys to determine availability of assets to be utilized in a response. Develop capacity for interoperable communications between field elements and headquarters. Develop web-based training modules. Train human services assessment teams. Coordinate expansion of FMS. Sustain and expand the cadre of surge personnel with specialized skills.	Fully define public health and medical capability areas. Begin to develop interagency response framework guidelines by capability area. Enhance situational awareness within SOC. Provide materiel readiness to ASPR domestic deployable medical capability. Enhance development of regional readiness capability. Exercise ability to deploy HHS command and control, medical shelter and initial triage/emergency capabilities. Exercise COOP far and near site functionality.

OFFICE OF THE ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE NATIONAL DISASTER MEDICAL SYSTEM

	FY 2007	FY 2008	FY 2009	FY 2009 +/-
	<u>Actual</u>	Enacted	Estimate	FY 2008
Budget	\$46,605,000	\$45,999,000	\$53,000,000	+\$7,001,000
FTE	86	90	96	+6

Allocation Method: Direct federal/intramural; contracts

Program Description and Accomplishments:

The National Disaster Medical System (NDMS) is a cooperative, asset-sharing partnership that leverages federal and non-federal resources to care for large numbers of casualties generated in a domestic disaster or an overseas conventional war. NDMS consists of three key functions:

- Medical response, which includes assessments of health/medical needs, primary
 and emergency medical care, health/medical equipment and supplies, victim
 identification/mortuary services, veterinary services, and other auxiliary services
 at the site of an emergency through NDMS response teams.
- Patient evacuation, which consists of establishing and maintaining a
 communication, transportation, and medical regulating system to evacuate
 patients from a mobilization center near the disaster site to reception facilities
 where they may receive definitive medical care and communicating evacuation
 information to federal, state, and local authorities, as needed.
- Definitive medical care, which consists of medical treatment or services beyond
 emergency medical care, initiated upon inpatient admission to an NDMS partner
 hospital and provided for injuries or illnesses resulting directly from a specified
 public health emergency, or for injuries, illnesses and conditions requiring nondeferrable medical treatment or services to maintain health when such medical
 treatment and services are temporarily not available as a result of the public health
 emergency.

Definitive care is rendered by a nationwide network of voluntarily participating, preidentified, non-federal and federal hospital services. The network includes an ability to track available beds by medical specialty. In a public health emergency, these services provide definitive medical care for victims. In a military health emergency, NDMS nonfederal hospitals provide backup to the available military and VA medical services for military beneficiaries.

In FY 2007, NDMS was transferred successfully to ASPR from the Department of Homeland Security, Federal Emergency Management Agency. The transfer included over 9,000 intermittent federal employees within NDMS. Teams have been successfully deployed to a variety of missions, including the Ford State Funeral. The NDMS Training Summit was held in Nashville, TN in March 2007. Equipment caches have been inventoried. An electronic health record has been developed and was pilot tested and

deployed during to the California Wild Fires of 2007. Patient information data was successfully transmitted to the NDMS central repository in Washington. A demographic report was generated within minutes and transmitted back to the Incident Response Coordination Team (IRCT) and the Secretary's Operations Center (SOC) Emergency Management Group (EMG) for up to the minute situational awareness. This effort represents a 90% reduction in time for data availability based on the traditional paper-based record with 10-14 day collection, analysis, and reporting process.

Funding History:

FY 2004	approx. \$46,605,000
FY 2005	approx. \$46,605,000
FY 2006	approx. \$46,605,000
FY 2007	\$46,605,000
FY 2008	\$45,999,000

Budget Request:

\$53,000,000 is requested, an increase of +\$7,001,000 above the FY 2008 Enacted, to support central headquarters operations as well as medical response assets including teams, supplies, and equipment. In FY 2009, activities will include training, exercises and supply for over 100 Disaster Medical Assistance Teams, Disaster Mortuary Operational Response Teams, and other NDMS Teams located across the country. Funding will support operational needs to support teams and ensure they are ready to deploy. This includes logistics support and cache maintenance such medical and pharmaceutical supplies, IT and communications capabilities, and preventive maintenance of equipment. Funding will also support preparation, equipping and response for national special security events, such as the State of the Union. Funding will also continue support for the annual training summit and the electronic patient health record.

Outcomes and Outputs:

See information provided under Preparedness and Emergency Operations.

OFFICE OF THE ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE HOSPITAL PREPAREDNESS

	FY 2007	FY 2008	FY 2009	FY 2009 +/-
	<u>Actual</u>	Enacted	Estimate	FY 2008
Budget	\$474,030,000	\$423,399,000	\$361,660,000	-\$61,739,000
Hospital Preparedness (non-add)	\$470,070,000	\$419,508,000	\$355,660,000	-\$63,848,000
ESAR-VHP (non-add)	\$3,960,000	\$3,891,000	\$6,000,000	+\$2,109,000
FTE	28	29	31	+2

<u>Allocation Method</u>: Formula grant/cooperative agreement; direct federal/intramural; contracts

Program Description and Accomplishments:

The Pandemic and All-Hazards Preparedness Act of 2006 (PAHPA) transferred responsibility for the Hospital Preparedness Program from the Health Resources and Services Administration (HRSA) to ASPR. Consistent with the legislation, the program is working to develop stronger state and regional partnerships to improve overall surge capacity and capability and enhance hospital preparedness. The program's focus is on strengthening the capability of hospitals and healthcare systems to plan, respond to, and recover from all hazard events. These capabilities include but are not limited to interoperable communications, bed and resource tracking systems, development and operation of ESAR-VHP systems, fatality management planning, evacuation planning, and supporting training and exercises to promote seamless preparedness integration across the local, state, regional and federal tiers of health care asset management. The program also supports the activities of the Critical Infrastructure Protection program for the Healthcare and Public Health Sector in meeting the requirements of the National Infrastructure Protection Program (NIPP) in building partnerships with local, state, and regional stakeholders under the NIPP framework.

A Program Assessment Rating Tool (PART) review of the program was conducted for the FY 2005 budget. The program received a rating of "Results Not Demonstrated." The assessment indicated that the program had not yet demonstrated results due to its relative newness and the inherent difficulty in measuring preparedness for events that do not regularly occur. Performance measures focusing on the implementation of various aspects of awardees' plans to address surge capacity were initially developed during the FY 2005 PART review, but they no longer reflect the evolution of the program and the elements identified in the National Preparedness Goal that involve increasing medical surge capacity. The program is currently in the process of developing new evidence-based measures that reflect the requirements of PAHPA, which will provide a more accurate picture of the direction and focus of current and future proposed preparedness efforts.

In FY 2007, ASPR competitively awarded \$18.1 million to Healthcare Facilities Partnerships for the purposes of improving surge capacity and enhancing community and hospital preparedness for public health emergencies in defined geographic areas. The

projects focused on innovative processes that could be replicated across the country in the areas of:

- enhanced situational awareness of capabilities and assets that partnership entities possess and can bring to bear during a response;
- advanced planning and exercising of plans that address common risks and vulnerabilities and consequences in a defined geographic area;
- fostering the development of Medical Mutual Aid agreements among partnership entities insuring the inclusion of public health, emergency management and private sector partners; and
- developing and strengthening relationships between and among partnership entities, traditional first response agencies, public health and other response partners prior to disasters and emergencies so that during these kinds of events response and recovery activities happen in an expedited coordinated manner.

In FY 2007, ASPR also competitively awarded \$25 million to Healthcare Facilities Emergency Care Partnerships. The projects focused on:

- helping integrate public and private emergency care system capabilities with public health and other first responder systems through periodic preparedness and response capabilities evaluation via drills and exercises; and integrating public and private sector public health and medical donations and volunteers;
- improving the efficiency, effectiveness and expandability of emergency care systems and overall preparedness and response capabilities in hospitals, other health care facilities (including mental health and long-term care facilities), and trauma care and emergency medical service systems, with respect to public health emergencies; or
- developing plans for strengthening public health emergency medical management, and the provision of emergency care and treatment capabilities.

PAHPA also transferred responsibility for the Emergency System for Advance Registration of Volunteer Health Professionals (ESAR-VHP) program from HRSA to ASPR. The ESAR-VHP program is a companion to the Hospital Preparedness Program. The purpose of the program is to facilitate the use of volunteers at all tiers of response (local, regional, state, interstate, and federal). The ESAR-VHP program has been working to establish a national network of state-based programs that manage the information needed to effectively use health professional volunteers in an emergency. It provides states with standardized guidance for volunteer recruitment, registration, credential verification, classification according to verified professional credentials, legal and regulatory issues, and policies for the use of volunteers. The program also provides technical assistance to the States in all of these areas.

In FY 2007, the ESAR-VHP revised its national compliance requirements and provided significant assistance to continue to increase the number of operational state systems and enhance the capability of those state systems already in place. Currently thirty seven (37) jurisdictions have operational ESAR-VHP systems, including 80% of the top ten

population states. These jurisdictions are continuing to develop fully operational and compliant ESAR-VHP programs. Other high population states and localities have developed registered volunteer capacity, while they continue to develop their electronic systems. The remaining states and territories have plans to become fully operational. ASPR/ESAR-VHP and four states exercised the states' ability to roster their volunteers to participate as part of a federal Emergency Support Function (ESF) #8 response. The exercise was successful in that states were able to provide greater than 70% of the requested resources, except activities listed for physicians. Lessons learned are being developed into corrective action plans and incorporated into planning for the 2008 hurricane season.

In FY 2008, the program will finalize its national compliance requirements and issue the 3rd version of the ESAR-VHP Technical and Policy Guidelines, Standards, and Definitions: System Development Tools (Guidelines). The Guidelines will provide the technical information that states need to develop systems capable of registering a wide range of health volunteers, verify their credentials and qualifications, and assign volunteers to one of four credential levels. Included are new and interim standards for 20 healthcare profession occupations. ASPR/ESAR-VHP and additional states will exercise the states' ability to roster their volunteers to participate as part of a federal ESF #8 response.

Funding History:

FY 2004	\$514,943,000
FY 2005	\$487,098,000
FY 2006	\$473,882,000
FY 2007	\$474,030,000
FY 2008	\$423,399,000

Budget Request:

\$361,660,000, a decrease of -\$61,739,000 below the FY 2008 Enacted level is requested. As recommended by stakeholders as a strategy to fully implement PAHPA, grant cycles will shift during FY 2009 to better align with state funding cycles. The formula grant awards to States, cities, and territories will be reduced by shortening the grant cycle to nine months three weeks. With the shortened grant cycle, States' monthly funding levels will be maintained. Consistent with directions identified in PAHPA, the program will focus on aspects of medical surge planning to include fatality management planning, evacuation planning, incorporating the needs of at risk individuals, maximizing the interactions of public private partnerships and utilizing exercises as a major component of the evaluation of the program. To the extent practical exercises will be integrated with the other preparedness grant programs (e.g. CDC and DHS) and will test the target capabilities that are identified as part of the National Preparedness Goal. There will be ongoing requirements for the states and health care facilities to report available assets in support of seamless preparedness and response across the tiers of health care asset management. Funding also supports evaluation activities such as reviewing current performance measures and implementing a management information system to improve

and simplify the process of data collection for grantees. In FY 2009, funding will support progress towards the performance goal, Improve surge capacity and enhance community and hospital preparedness for public health emergencies. The FY 2009 targets for the goal include that 80 percent of States will be able to demonstrate the ability to report hospital bed data using HAvBED System in at least one drill, exercise, or real life event and 80 percent of States will be able to demonstrate through reporting and/or exercises the use of interoperable communications systems with multiple communications technologies that would ensure connectivity and operability in a public health emergency.

No funding is requested for Healthcare Facility Partnerships. Within the total, \$1,500,000 will support the activities of the Critical Infrastructure Protection program for the Healthcare and Public Health Sector. This includes collaboration with federal, state, local, tribal and private sector stakeholders on a range of activities from information sharing to threat risk assessments, to participation in exercises to enhance the resiliency of the sector.

Also within the total, \$6,000,000 will support the ESAR-VHP program to create operational and compliant state ESAR-VHP systems. Funding will be used to provide supplemental grants targeted to support and maintain state and territorial ESAR-VHP programs. Additionally, funding will be used to update the ESAR-VHP Technical and Policy Guidelines, Standards, and Definitions and provide state access to national databases, such as the American Board of Medical Specialties (ABMS), Drug Enforcement Agency (DEA) and American Osteopathic Association (AOA) as well as other databases. Funding will also be used to evaluate the ESAR-VHP program and conduct a national meeting with the state and territorial ESAR-VHP programs.

Outcomes and Outputs:

#	Key Outcomes	FY	FY	FY 2	FY 2006 FY 2007		FY	FY 2009	
		2004 Actual	2005 Actual	Target	Actual	Target	Actual	2008 Target	Target
		Actual	Actual	Target	Actual	Target	Actual	Target	
Long-	Term Goal: Enhand	ce State an	d Local Pr	reparednes	SS			<u> </u>	
2.4.2	Improve surge capacity and enhance community and hospital preparedness for public health emergencies through:								
a.	% of States demonstrating ability to report hospital bed data	n/a	n/a	n/a	n/a	50%	04/2009	60%	80%
b.	% of States demonstrating use of Interoperable Communications Systems	n/a	n/a	n/a	n/a	50%	04/2009	60%	80%
c.	% of States demonstrating development of Fatality Management Plans	n/a	n/a	n/a	n/a	50%	04/2009	60%	80%
d.	% of States demonstrating development of Hospital Evacuation Plans	n/a	n/a	n/a	n/a	50%	04/2009	60%	80%
e.	% of States will demonstrating development of fully operational and compliant ESAR-VHP programs	n/a	n/a	n/a	n/a	50%	Sixty percent (60%) of States and U.S. Territories have operational ESAR- VHP systems, including 80% of the top ten population states.	60%	80%

#	Key	FY	FY 2005	FY	2006 FY 2007		FY	FY 2009	
	Outcomes	2004 Actual	Actual	Target	Actual	Target	Actual	2008 Target	Target
Long-	Term Goal: En	hance Stat	e and Local Pr	eparedness	S				
2.4.3	Increase the ratio of preparedness exercises and drills per total program (Coop. Agreement) dollar by 50% each year. (Approved by OMB.)	n/a	.000004482 (baseline) or 4.48 per million dollars	6.72 per million dollars	14.4 per million dollars	10.08 per million dollars	04/2009	15.13 per million dollars	22.69 per million dollars

DISCRETIONARY STATE/FORMULA GRANTS

CFDA NUMBER/PROGRAM NAME: 93.889 -

Hospital Preparedness Program

nospital Frepareuriess Frog	FY 2007				
STATE/TERRITORY		Actual			
Alabama	\$	6,330,289			
Alaska		1,349,441			
Arizona		8,317,173			
Arkansas		4,063,403			
California		47,218,015			
Colorado		6,525,958			
Connecticut		4,943,121			
Delaware		1,581,970			
District of Columbia		1,737,218			
Florida		23,432,938			
Georgia		12,370,869			
Hawaii		2,129,653			
Idaho		2,359,069			
Illinois		17,267,363			
Indiana		8,503,785			
Iowa		4,280,453			
Kansas		4,004,077			
Kentucky		5,832,130			
Louisiana		5,935,695			
Maine		2,175,388			
Maryland		7,619,177			
Massachusetts		8,660,567			
Michigan		13,298,463			
Minnesota		7,050,445			
Mississippi		4,189,754			
Missouri		7,906,932			
Montana		1,697,530			
Nebraska		2,741,751			
Nevada		3,663,636			
New Hampshire		2,166,921			
New Jersey		11,560,312			
New Mexico		2,977,887			
New York		25,474,862			
North Carolina		11,727,581			
North Dakota		1,306,102			

	FY 2007			
STATE/TERRITORY	Actual			
Ohio	15,050,914			
Oklahoma	5,037,444			
Oregon	5,191,530			
Pennsylvania	16,271,242			
Rhode Island	1,853,432			
South Carolina	5,978,140			
South Dakota	1,491,255			
Tennessee	8,155,520			
Texas	30,301,320			
Utah	3,732,769			
Vermont	1,290,942			
Virginia	10,189,048			
Washington	8,608,090			
West Virginia	2,805,313			
Wisconsin	7,544,102			
Wyoming	1,152,882			
Subtotal	407,053,871			
Indian Tribes	0			
Migrant Program	0			
American Samoa	323,330			
Guam	457,390			
Marshall Islands	321,536			
Micronesia	387,095			
Northern Mariana Islands	346,510			
Palau	274,996			
Puerto Rico	5,479,326			
Virgin Islands	387,946			
Subtotal Total States/Territories	7,978,129 415,032,000			
Total States/Territories	415,032,000			
Technical Assistance	0			
State Penalties	0			
Contingency Fund	0			
Other Adjustments (specify)	0			
Subtotal Adjustments	0			
TOTAL RESOURCES	415,032,000			

OFFICE OF THE ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE TRAINING AND CURRICULUM DEVELOPMENT

	FY 2007	FY 2008	FY 2009	FY 2009 +/-
	<u>Actual</u>	Enacted	Estimate	FY 2008
Budget	\$20,790,000			
FTE	4			

<u>Allocation Method</u>: Competitive grants/cooperative agreements; direct federal/intramural; contracts

Program Description and Accomplishments:

The purpose of the Bioterrorism Training and Curriculum Development Program was to improve the capability of the Nation's healthcare workforce to respond to bioterrorism and other public health emergencies. The goal of this program was the development of a healthcare workforce capable of demonstrating the ability to: (1) recognize indications of a terrorist event and other public health emergencies; (2) treat patients and communities in a safe and appropriate manner; (3) participate in a coordinated response; and (4) rapidly and effectively alert the public health system of such an event at the community, state, and national level. In response to concerns raised in the FY 2006 Senate Appropriations Report, the program eliminated funding for the 13 curriculum development awards and initiated contracts with interested accreditation bodies. By working to change the accreditation standards, the program was more rapidly able to affect the incorporation of preparedness elements into the curriculum of a larger number of academic institutions.

Funding History:

FY 2004	\$27,706,000
FY 2005	\$27,520,000
FY 2006	\$20,776,000
FY 2007	\$20,790,000
FY 2008	

Budget Request:

No funding was requested or provided in FY 2008 and no funding is requested for this program in FY 2009. There has been a proliferation of training opportunities, courses, and materials at the federal, state and local levels since 2001.

Outcomes and Outputs:

The program has discontinued its performance measures since the program has been eliminated.

OFFICE OF THE ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE ADVANCED RESEARCH AND DEVELOPMENT

	FY 2007	FY 2008	FY 2009	FY 2009 +/-
	<u>Actual</u>	Enacted	Estimate	FY 2008
Budget	\$103,921,000	\$101,544,000	\$250,000,000	+\$148,456,000
FTE	8	23	27	+4

Allocation Method: Direct federal/intramural; contracts

Program Description and Accomplishments:

The Office of Biomedical Advanced Research and Development Authority (BARDA) within ASPR was established in April 2007. BARDA incorporates the responsibilities and functions of the Office of Public Health Emergency Medical Countermeasures. BARDA has assumed all applicable responsibilities for implementation of new authorities provided in the Pandemic and All-Hazards Preparedness Act of 2006 (PAHPA), as well as all of the previous responsibilities for the development and acquisition of medical countermeasures, including those activities related to Pandemic Influenza preparedness and the implementation of Project BioShield. Under new authorities provided in PAHPA, BARDA intends to expand advanced development efforts initiated in FY 2006 within the Pandemic Influenza preparedness program and enhance direction and support of the advanced development of promising medical countermeasure candidates for CBRN threats. BARDA will balance investments across the medical countermeasure development pipeline to mitigate risks in the acquisition phase.

Title IV of PAHPA, "Pandemic and Biodefense Vaccine and Drug Development," established that BARDA will facilitate collaboration among the United States Government (USG), industry, and academia, support the advanced research and development of medical countermeasures, and promote innovation to reduce time and cost of medical countermeasures. Consistent with the requirements established by PAHPA and the roles and responsibilities identified in Homeland Security Presidential Directive (HSPD) -18, the National Strategy for Medical Countermeasures against Weapons of Mass Destruction, BARDA leads HHS efforts to manage the PHEMC Enterprise, under the direction of the Enterprise Governance Board, composed of the leadership of ASPR, CDC, FDA and NIH with non-voting members from the Department of Homeland Security, Department of Defense and Department of Veterans Affairs. BARDA is responsible for coordinating medical countermeasure research and development and acquisition programs across HHS and with interagency partners. BARDA's efforts include the advanced development and acquisition of medical countermeasures to improve efforts to prevent, prepare for and respond to the adverse public health consequences of public health emergencies resulting from chemical, biological, radiological or nuclear (CBRN) threats, including emerging infectious diseases.

In March 2007, BARDA released the Public Health Emergency Medical Countermeasures Enterprise Strategy for CBRN Threats (*PHEMCE Strategy*). It defined the goals for HHS development and acquisition programs and provided a framework for priority-setting to establish top priority medical countermeasures.

In April 2007, the *PHEMC Enterprise* (led by ASPR) identified top priorities for the advanced development and acquisition of medical countermeasures for CBRN threats. Determinations were based on principles established in the *National Strategy for Medical Countermeasures against Weapons of Mass Destruction* (HSPD-18) and the goals and framework for priority-setting detailed in the *PHEMCE Strategy*. HHS published the *Public Health Emergency Medical Countermeasures Enterprise Implementation Plan* (*PHEMCE Implementation Plan*) which describes top priority medical countermeasure development and acquisition programs for CBRN threats. The investments in both advanced research and development and in Project BioShield acquisitions are aligned with these priorities.

Medical countermeasure requirements for CBRN threats are established under the PHEMC Enterprise Governance Board, chaired by ASPR. The highest priority requirements are reflected in the *PHEMCE Implementation Plan* and are based on population threat assessments developed by the Department of Homeland Security and medical and public health consequences of the threat as determined through HHS-coordinated modeling efforts.

Broad agency announcements have been issued in partnership with NIAID in the following areas: vaccine enhancement initiative; advanced development of pan-filovirus vaccines; development of broad spectrum antibiotics and antivirals. Awards are expected in September 2008. Additionally, BARDA is supporting several existing NIAID contracts that could be considered advanced development and that are consistent with the *PHEMCE Implementation Plan* and Draft BARDA Strategic Plan.

Funding History:

FY 2004	\$4,971,000
FY 2005	\$4,923,000
FY 2006	\$54,421,000
FY 2007	\$103,921,000
FY 2008	\$101,544,000

Budget Request:

\$250,000,000, an increase of +\$148,456,000 above the FY 2008 enacted level to support efforts to evaluate, assess and develop candidate medical countermeasures with the long-term potential to qualify for acquisition as medical countermeasures for the Strategic National Stockpile (SNS). These funds are requested with two years of fiscal availability to maximize flexibility to direct resources to multiple development efforts over time, improve the U. S. Government's negotiating position, and allow increased timeframe required for broad-agency announcements for responses and technical evaluations. DHS

has identified threats to the American public that can be mitigated by the development and acquisition of medical countermeasures. It is the responsibility of HHS, specifically ASPR, to develop and obtain such countermeasures. Funds will support the advancement of medical countermeasures for twelve biological threat agents, a class of chemical threats (volatile nerve agents) and radiological/nuclear threats identified in the *PHEMCE Implementation Plan*.

BARDA will manage advanced research and development allowing for improved coordination of all necessary requirements and steps to address FDA regulatory issues, from the late research phase of a product to its procurement for the SNS. The funds requested for FY 2009 will support the advanced research and development of medical countermeasures for viral hemorrhagic fever, a next generation anthrax vaccine and antitoxins, broad spectrum antibiotics, smallpox antivirals, biological diagnostics and platforms, radiological and nuclear agent medical countermeasures, and volatile nerve agent antidotes. Investing in the research and development of these specific medical countermeasures supports future successful acquisitions of medical countermeasures under Project BioShield. Research and development efforts will focus on demonstrating the feasibility of improvements in medical countermeasures for exposure to chemical nerve agents, obtaining sufficient data on smallpox antiviral drugs, demonstrating proof of principle for a filovirus antiviral drug, evaluating the usefulness of new anthrax therapeutic antibodies, and demonstrating potential usefulness of new or existing drugs or biologics for treatment of acute radiation syndrome. Funds will support public health consequence modeling, development and testing of medical countermeasures in late stage advanced development that are critical to provide the maximum benefit to the public in the event of an emergency.

Outcomes and Outputs:

#	Key Outcomes	FY 2004	FY 2005	FY 2	2006	FY 2	2007	FY 2008 Target	FY 2009 Target
		Actual	Actual	Target	Actual	Target	Actual		2 m. gov
threat	Term Goal: Define s (biological, chemicacing with industry Obtain sufficient evidence for the safety, efficacy and product	ical, radia	ation and	nuclear) t	to the SN			Issue BAAs, RFPs or other FAR-sanctioned notices for advanced	Demonstrate feasibility of improvements in medical countermeasures
	and product characteristics of candidate medical countermeasures for priority chemical, biological, radiological and nuclear agents to accelerate their potential for procurement under Project BioShield.							advanced development of top priority MCM for CBRN threats in accordance with the PHEMCE Implementation Plan. Award contracts with product developers responsive to USG requirements. Obtain data on usefulness of broad spectrum antibiotics against bacterial threat agents identified by DHS Material Threat Determinations. Demonstrate technology for increased stability of protein-based vaccines. Accomplish stability studies and consistency lot manufacturing of a candidate rPA vaccine. Identify potential novel	countermeasures for exposure to chemical nerve agent. Provide sufficient data on smallpox antiviral drug to support potential Project BioShield acquisition. Demonstrate proof of principle for a filovirus antiviral drug. Evaluate usefulness of new anthrax therapeutic antibodies. Demonstrate potential for usefulness of new or existing drugs or biologics for treatment of acute radiation syndrome.
								candidate medical countermeasures for acute radiation syndrome.	

OFFICE OF THE ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE ADVANCED DEVELOPMENT OF NEXT GENERATION VENTILATORS

	FY 2007	FY 2008	FY 2009	FY 2009 +/-
	<u>Actual</u>	Enacted	Estimate	FY 2008
Budget			\$25,000,000	+\$25,000,000
FTE				

Allocation Method: Direct federal/intramural; contracts

Program Description and Accomplishments:

Modeling of public health non-pharmaceutical countermeasures needs showed that ventilators would have a significant impact during an influenza pandemic. An analysis indicated that there was limited manufacturing capacity in the U.S. and the cost of full-line present ventilator models was too expensive (\$8,000-\$10,000/unit) and presented a challenge to acquire 70,000 ventilators. Ventilators currently purchased for stockpile require trained teams of specialists to run them effectively, creating a workforce barrier to preparedness. They are also bulky and expensive. Devices that could perform the same function as ventilators, but with a shorter production time, lower price, and greater portability, are needed. HHS determined that the development of a next generation ventilator that was portable, inexpensive, and equipped with universal parts which would progress towards FDA clearance over a two to three year span would be the most effective means to bridge the shortfall of adequate numbers of ventilators.

An initiative in FY 2009 is envisioned to award multiple contracts with incremental and performance-based funding to develop next generation ventilators for usage in an influenza pandemic and other threats (e.g. anthrax). Towards this objective, a Blue Ribbon Panel was convened in November 2007 to deliberate on the requirements for a next generation ventilator. A request for proposals (RFP) is expected to be issued in 2008. Contracts are expected to develop next generation ventilators that meet the aforementioned requirements towards U.S.-regulatory clearance within 2 to 3 years post-award with an expectation that stockpile purchases may ensue. The need for domestic manufacturing of these ventilators with a manufacturing surge capacity of at least 2,000 units/month post-pandemic onset would be required.

Funding History:

FY 2004	
FY 2005	
FY 2006	
FY 2007	
FY 2008	

Budget Request:

\$25,000,000 is requested to support advanced development of ventilators. A Blue Ribbon Panel developed a set of requirements for a next generation ventilator that

included low cost (\$1,000-\$2,000/unit), wide patient usage, user-friendliness, closed-loop circuitry, portability, easy storage, universal interchangeable parts, internal oxygen source, and remote interface. If funded, the program plans to award multiple contracts with incremental and performance-based funding for advanced development of next generation ventilators for pandemic and all-hazards purposes.

Outcomes and Outputs:

ASPR will develop performance measures for this program.

OFFICE OF THE ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE BIOSHIELD MANAGEMENT

	FY 2007	FY 2008	FY 2009	FY 2009 +/-
	<u>Actual</u>	Enacted	Estimate	FY 2008
Budget	\$15,820,000	\$21,243,000	\$22,360,000	+\$1,117,000
FTE	41	83	97	+14

Allocation Method: Direct federal/intramural; contracts

Program Description and Accomplishments:

On July 21, 2004, President George W. Bush signed the Project BioShield Act of 2004 (Project BioShield) into law as part of a broader strategy to defend America against the threat of weapons of mass destruction. The purpose of Project BioShield is to accelerate the research, development, purchase, and availability of effective medical countermeasures against chemical, biological, radiological, and nuclear (CBRN) agents.

Contracts for the currently licensed anthrax vaccine (AVA) and pediatric potassium iodide (KI) were awarded in 2005 and the products have been delivered to the SNS (5 million AVA doses and 1.7 million bottles of pediatric KI). Also in FY 2005, a contract was awarded for a next generation anthrax vaccine (rPA) with an original delivery target in FY 2007. This contract was terminated in December 2006 because a critical milestone could not be met by the company. Despite the decision to terminate the contract, HHS remains committed to developing a next-generation rPA anthrax vaccine for the SNS and has continued to vigorously pursue an anthrax vaccine acquisition strategy under the BioShield program as demonstrated by the Sources Sought Notice released in May 2007 (SS-DHHS-BARDA-07-01). In FY 2006 a contract was awarded for calcium and zinc DTPA, chelating agents that remove radioactive particulates from the body, and over 474,000 doses have been delivered to the SNS. Existing contracts were also modified in FY 2006 to purchase an additional 5 million doses of AVA and 3.1 million bottles of the pediatric formulation of KI; delivery of these products has been completed. The following contracts were also awarded under Project BioShield in FY 2006:

- Anthrax therapeutic 10,000 treatment courses of Anthrax Immune Globulin
- Anthrax therapeutic 20,000 treatment course of a monoclonal antibody, ABthrax
- Botulism antitoxin -200,000 treatment courses of an equine plasma-derived heptavalent botulism antitoxin.

These three acquisition contracts all involve late-stage development, and it is anticipated that they will be delivered to the SNS in advance of licensure/approval upon demonstration of sufficient evidence of utility to enable their use in a public health emergency. In FY 2006, HHS also issued a Request for Proposals (RFP) for medical countermeasures to treat the neutropenia associated with Acute Radiation Syndrome (ARS). Although this RFP was cancelled in FY 2007 due to the determination that no competing offeror possessed a product that met USG requirements that was mature enough for a BioShield acquisition, HHS remains committed to purchasing products to respond to radiological and nuclear threats.

In June 2007, a Project BioShield contract was awarded for 20 million doses of a smallpox Modified Vaccinia Ankara (MVA) vaccine to protect 10 million immunocompromised persons. This contract uses the original Project BioShield 10% advance payment provision as well as the milestone payment authorities provided by PAHPA. In September 2007, a contract was awarded for 18.75 million doses of AVA anthrax vaccine.

<u>Funding History</u>:

FY 2004	\$1,226,000
FY 2005	\$8,167,000
FY 2006	\$12,313,000
FY 2007	\$15,820,000
FY 2008	\$21,243,000

Budget Request:

\$22,360,000, an increase of +\$1,117,000, is requested for oversight and implementation infrastructure for medical countermeasure procurement under Project BioShield. The goal of the program is to deliver licensed, licensable and approvable medical countermeasures for priority chemicals, biological, radiation and nuclear agents.

Funding will support program management, regulatory affairs, and quality assurance staff to oversee both product development and implementation of internal controls and quality assurance programs including on-site oversight of contract manufacturers, pre-award audits, and legal and subject matter experts. Staff will be responsible for monitoring previous acquisitions as well as well as for new efforts planned in FY 2009 including initiation of pivotal clinical trials for licensure of the Modified Vaccinia Ankara smallpox vaccine; licensure of botulinum antitoxin, and submission of data to FDA in support of licensure for anthrax therapeutics. These investments in internal capacity will improve results. For example, support for "man-in-plant" will decrease delays in delivery of product to the Strategic National Stockpile for targeted Project BioShield contracts through intense on-site oversight of manufacturers.

In addition, funds will support modeling efforts for determining MCM requirements and assessing response capacities as well as to maintain the web-based stakeholder portal for information management and sharing, professional staff training in medical countermeasure research, development and acquisition, document management, and program management. In FY 2009, ASPR will continue to support policy and strategic planning to set requirements and acquisition strategies for needed public health emergency medical countermeasures including a stakeholder outreach to solicit input from industry, academia, and other interested parties of the planning process. In FY 2009, BARDA will hold the 3rd annual Industry Day to facilitate collaboration with all stakeholders.

Outcomes and Outputs:

#	omes and Outp Key Outcomes	FY	FY	FV '	2006	FY 2007		FY 2008	FY 2009
#	Key Outcomes	2004	2005	FY 2006		F 1 2007		Target	Target
		Actual	Actual	Target	Actual	Target	Actual	2412800	I III get
	Long-Term Goal: Define requirements for and deliver safe and effective medical countermeasures to identified threats (biological,								
	chemical, radiation and nuclear) to the SNS through coordination of interagency activities, interfacing with industry and acquisition								
2.4.5	gement. Deliver	n/a	n/a	Complete	Targets met	Complete	Delivery	Issue RFPs	Initiate
2.4.3	licensed,	11/α	11/α	delivery of	for AVA,	delivery	of the 2 nd	for needed	pivotal
	licensable and			the 1 st 5M	pediatric KI	of 2 nd 5M	acquisition	products in	clinical
	approvable top			doses of	and DTPA.	doses of	of 5M	accordance	trials for
	priority medical			Anthrax	Target not	AVA;	doses of	with the	licensure
	countermeasures			(AVA)	met for rPA	complete	AVA to	РНЕМСЕ	of the
	for chemical,			vaccine to	anthrax	delivery	the SNS	Strategy	Modified
	biological,			the SNS,	vaccine due	of 2 nd	and 3.1M	and	Vaccinia
	radiological and			begin	to	2.3M	bottles of	РНЕМСЕ	Ankara
	nuclear threats.			delivery of	development	bottles of	pediatric	Implemen-	smallpox
				the 2 nd 5M	delays.	pediatric	KI were	tation	vaccine.
				doses of AVA;		KI to SNS;	completed. Contract	<i>Plan</i> . Modified	Support licensure
				complete		initiate	was	Vaccinia	of
				delivery of		begin	awarded	Ankara	botulinum
				the 1 st 1.3M		delivery	for 20M	(MVA)	antitoxin,
				bottles of		of anthrax	doses of a	smallpox	a MCM
				pediatric KI		immune	next-	vaccine -	for
				delivered to		globulin	generation	begin	botulism.
				the SNS;		to the	smallpox	delivery to	Submit
				begin		SNS;	vaccine	the SNS.	data to
				delivery of		delivery	Modified	Botulism	FDA in
				2 nd 2.3M bottles of		of additional	Vaccinia	antitoxin:	support of
				Pediatric KI		botulinum	Ankara (MVA)	continue	licensure for
				to the SNS;		antitoxin	smallpox	delivery to the SNS.	anthrax
				complete		to the	vaccine	Anthrax	thera-
				delivery of		SNS.	and 18.75	Thera-	peutics.
				Ca- and Zn-			million	peutics:	F
				DTPA to			doses of	AIG:	
				SNS.			AVA.	continue	
				Modify rPA			Deliveries	delivery to	
				anthrax			of AIG	the SNS.	
				vaccine			and H-	ABthrax:	
				contract to			BAT to	begin	
				acknowledge			SNS were initiated.	delivery to the SNS.	
				delay in delivery of			illitiated.	rPA:	
				vaccine to				Award	
				SNS.				contract	
								for	
								acquisition	
								ARS:	
								Award	
								contract	
								for	
								acquisition	

OFFICE OF THE ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE INTERNATIONAL EARLY WARNING SURVEILLANCE

	FY 2007	FY 2008	FY 2009	FY 2009 +/-
	<u>Actual</u>	Enacted	Estimate	FY 2008
Budget	\$8,808,000	\$8,690,000	\$9,030,000	+\$340,000
FTE	7	12	15	+3

<u>Allocation Method</u>: Formula grant/cooperative agreement; direct federal/intramural; contracts

Program Description and Accomplishments:

HHS' primary international responsibilities are those actions required to protect the health of all Americans, in cooperation with the Secretariat of the World Health Organization (WHO) and other technical partners, including leading U.S. Government efforts in the surveillance and detection of influenza outbreaks overseas. ASPR, in coordination with the Office of Global Health Affairs (OGHA), continues to work to enhance activities for pandemic influenza preparedness and response. This includes strengthening the pandemic influenza preparedness and response capacity in a number of other developing countries. ASPR supports several projects to enhance the surveillance, epidemiological investigation, and laboratory diagnostic capabilities in Asia, Africa and Latin America that are or could be at risk for the H5N1 influenza strain of pandemic influenza. ASPR also will continue to build the capacity of public health systems of all 20 U.S. Border States (including Alaska), to provide cross-border early warning of infectious diseases by enhancing the infectious disease surveillance capabilities and prompt sharing of information among U.S. states, Mexican states, and Canadian provinces along the borders.

Progress has been made toward the FY 2007 performance target for expanding worldwide surveillance through agreements with the WHO, with Ministries of Health and other international entities, and by leveraging global partnerships to increase preparedness and response capabilities around the world. ASPR's activities last year included regional activities that provided technical assistance, training and capacity enhancing activities of Asian and Latin American health care, public health, and laboratory workers as well as building influenza vaccine production capacity in key developing countries through a global initiative with the WHO. Efforts have also been directed toward improving influenza surveillance and pandemic preparedness for H5N1 avian influenza in Asia, Africa and Latin America thereby strengthening global health security. Additionally, the U.S. and members of the Global Health Security Initiative (GHSI) continue to undertake collaborative efforts to plan and share their experiences and lessons learned in preparing for CBRN threats, and pandemic threats to these countries' public health. ASPR also continued developing and implementing a collaborative program with U.S. and Mexican states, and Canadian provinces immediately across from the U.S. international border, to enhance disease detection capabilities.

Progress has been made on the FY 2008 target for the measure, Provide medical, scientific, and public health subject matter expertise. The inaugural meeting of the National Biodefense Science Board (NBSB) occurred on December 17th and 18th at the Ronald Reagan Building and International Trade Center in Washington, DC. The Board, established as part of the Pandemic and All-Hazards Preparedness Act of 2006, is comprised of 13 individuals selected from among the Nation's preeminent scientific, public health, and medical experts. The Board will provide independent advice and guidance on scientific, technical and other matters regarding naturally occurring, accidental, or deliberate incidents involving chemical, biological, radiological, and nuclear (CBRN) agents. In addition to the 13 voting members, 21 ex officio representatives from across the federal government were appointed to the Board. At the close of the meeting, the Board voted to establish four working groups. The working groups will examine the current state of pandemic influenza research efforts; conduct an overview of the U.S. government's research portfolio of medical countermeasure and biosurveillance efforts; consider efforts to address and strengthen the medical countermeasure marketplace; and explore the development of an integrated disaster medicine framework.

Funding History:

FY 2004	\$9,444,000
FY 2005	\$9,354,000
FY 2006	\$8,988,000
FY 2007	\$8,808,000
FY 2008	\$8,690,000

Budget Request:

\$9,030,000 is requested, an increase of \$340,000, to continue development of public health infrastructure in the Western Pacific, Southeast Asia, the Americas and other regions to further enhance epidemiological and laboratory capabilities and capacities and associated information technology to foster accurate and prompt reporting of and response to naturally occurring and intentional infectious disease outbreaks. In the Western Pacific and Southeast Asia, funds will be used for programs with a specific emphasis on increasing capacity for influenza detection, surveillance and response. Funds will also be used to continue the HHS partnership to enhance the capacity of public health systems along the U.S. border to rapidly detect infectious disease outbreaks; this will continue to improve cross-border public health early warning and situational awareness capability by decreasing the time needed to identify health events that could result from terrorism or naturally-occurring events. ASPR will also continue to continue to increase preparedness and response capabilities around the world with international entities such as the WHO and/or by leveraging global partnerships.

Outcomes and Outputs:

#	Key	FY 2004	FY 2005	FY 2	FY 2006		FY 2007		FY 2007		FY 2009
	Outcomes	Actual	Actual	Target	Actual	Target	Actual	Target	Target		
Long	Term Goal: Mit	igata tha	odvorco r	uhlia haa	lth offoct	e of a torroriet a	ttack				
2.4.6	Coordinate	n/a	n/a	n/a	n/a		Progress	Continue	Continue to		
2.4.0	coordinate and facilitate development of international preparedness and response capabilities.	n/a	n/a	n/a	n/a	Leverage global partnerships to increase preparedness and response capabilities around the world with the intent of stopping, slowing or otherwise limiting the spread of a pandemic to the United States.	made through agreements with the WHO, Ministries of Health and other international entities, and by leveraging global partnerships. Also, U.S. and members of the GHSI continue to undertake collaborative efforts in preparing for CBRN threats and pandemic influenza. Continued developing and implementing disease detection capabilities through a collaborative program with U.S. border states.	continue support of global partnerships. Assess progress of countries/ regions in early detection reporting surveillance and response. Continue support of the WHO early warning and response activity; continue the U.S. Mexico and Canada border activities. Continue to decrease the time needed to identify causes, risk factors, and appropriate interventions needed.	continue to improve cross-border public health early warning and situational awareness capability by decreasing the time needed to identify health events that could result from terrorism or naturally-occurring events, in partnership with other federal, state, regional, local and tribal health agencies along the U.S. northern and southern borders and across the international border with neighboring jurisdictions in Canada and México.		

#	Key Outcomes	FY 2004	FY 2005	FY 2	2006	FY 2007		FY 2008 Target	FY 2009 Target
		Actual	Actual	Target	Actual	Target	Actual		
Long-	Long-Term Goal: Mitigate the adverse public health effects of a terrorist attack.								
2.4.7	Provide medical, scientific, and public health subject matter expertise.	n/a	n/a	n/a	n/a	n/a	n/a	Conduct two annual meetings of the National Biodefense Science Board. Participate on working groups. Identify and engage with subject matter experts. Draft policy options papers and reports.	Conduct two annual meetings of the National Biodefense Science Board. Participate on working groups. Identify and engage with subject matter experts. Draft policy options papers and reports.

OFFICE OF THE ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE POLICY, STRATEGIC PLANNING, AND COMMUNICATIONS

	FY 2007	FY 2008	FY 2009	FY 2009 +/-
	<u>Actual</u>	Enacted	Estimate	FY 2008
Budget	\$3,116,000	\$4,292,000	\$5,330,000	+\$1,038,000
FTE	8	13	16	+3

Allocation Method: Direct federal/intramural; contracts

Program Description and Accomplishments:

The enactment of PAHPA has elevated the profile of the Department's emergency preparedness and response activities, now coordinated by ASPR. As a result of the new authorities and program requirements there are additional expectations for the office to enhance its strategic communications both within and outside the HHS. Internally, ASPR continues to initiate knowledge management tools to enable our stakeholders and partners to learn from the programs, projects and lessons learned. Externally, and in coordination with the Office of the Assistant Secretary for Public Affairs (ASPA), ASPR will continue to enhance public health risk communication. Through paid and free media, and training and education of journalists and public spokespersons, HHS will develop and deliver messages and strategies that can enhance communications with the public during a public health emergency, including a pandemic influenza outbreak or a terrorist attack.

Work on implementing the Emergency Public Information and Communications (EPIC) committee's recommendations is ongoing. Planning and development of emergency crisis risk communications necessary as part of the response to a pandemic influenza outbreak is well underway. Public health communications strategies and messages have been identified, used and shared during both major disasters such as Hurricanes Katrina and Rita and training sessions such as the series of pandemic influenza outbreak response tabletop exercises. Ongoing collaboration on crisis and emergency risk communications related to public health emergencies, including a pandemic influenza outbreak or terrorism, has expanded to include not only federal partners via the Incident Communications Public Affairs Coordination Committee but also the National Public Health Information Coalition of state and local public health communicators, our North American partners Canada and Mexico, and the entire international health community via the World Health Organization. Production activities to provide emergency preparedness information via satellite are underway.

<u>Funding History</u>:

FY 2004	\$4,772,000
FY 2005	\$4,726,000
FY 2006	\$2,756,000
FY 2007	\$3,116,000
FY 2008	\$4,292,000

Budget Request:

\$5,330,000, an increase of +\$1,038,000, is requested to maintain on-going efforts to support policy formulation, analysis, coordination, and evaluation of preparedness and response efforts across ASPR. This includes coordination of analyses of proposed policies, Presidential directives (such as Homeland Security Presidential Directives) and regulations. Activities also include the development of short and long-term policy and strategic objectives and strategic communication including programming support for the HHS-TV studio which provides 24-hour emergency health preparedness information to the public. The increase in funding will support the development of the National Health Security Strategy, which is required by the Pandemic and All-Hazards Preparedness Act to be published beginning in 2009 and every four years thereafter. ASPR will conduct regularly scheduled communications meetings internally and externally with key stakeholders and will communicate strategy via web, video, and presentations at major meetings of stakeholders. ASPR will also publish the ASPR annual plan and refine the "balanced scorecard" used as part of the strategic management system.

Outcomes and Outputs:

Long-Term Goal: Improve DHHS response assets to support municipalities and States.	# Key Outcomes
2.4.8 Improve strategic communications effective- ness. Na	
2.4.8 Improve strategic communications effective-ness. Na	Long-Term Coal:
strategic communications effectiveness. Interpretation of emergency and crisis risk communications packages. Publish and begin distribution of reporter's field guide on terrorism and other public health emergencies. Complete Public Health Emergency and crisis risk and developing employees. cations and developing employees. cations meetings awareness of internall and communications. Expanding collaboration on crisis and stakeholders. Increase participation and presentation at key comferences. Complete Incident Increase and strengthen Emergency Public Affairs emergency and Coordination crisis risk communications and presentation and presentati	
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Responders Health the international	
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create public state and local community.	
health public health Continue	
emergency- communicators, outreach efforts	
related radio North American to other key	
public service partners Canada stakeholders of	
announcements. and Mexico, and informational	
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outreach efforts international exercises and	
to inform news health training	
media and community via opportunities.	
public health the WHO. Expand short	
community of form	
all the above programming to	
initiatives. programming to priority projects	
Create new that reach larger	
programming. audiences.	

#	Key Outcomes	FY 2004	FY 2005	FY	2006	FY 2	2007	FY 2008	FY 2009
	Outcomes	Actual	Actual	Target	Actual	Target	Actual	Target	Target
Long	Long-Term Goal: Improve DHHS response assets to support municipalities and States.								
2.4.9	Establish and improve awareness of the ASPR strategy for preparedness and response.							Ensure ASPR initiatives are aligned with ASPR strategy. Develop ASPR annual plan that supports the ASPR Strategic Plan. Finalize Balanced Scorecard for full implementation of ASPR Strategic Management System. Complete development of framework for the National Health Security Strategy.	Publish National Health Security Strategy and execute an effective awareness and outreach campaign to internal and external stakeholders. Communicate strategy via web, video, and presentations at major meetings of stakeholders. Publish ASPR annual plan (web and video) and refine Balanced Scorecard as appropriate. Increase awareness of ASPR strategy internally and externally through regular outreach and publication of effective communications.

OFFICE OF THE ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE Significant Items for Inclusion in FY 2009 Congressional Justification

HOUSE REPORT NO. 110-258:

Anthrax --The Committee is concerned about significant biological threats facing the nation, particularly anthrax. The Committee is further concerned that the Department of Health and Human Services (HHS) seems to be far away from filling the Strategic National Stockpile as authorized by Project BioShield. The Committee recognizes HHS' efforts to develop a next generation anthrax vaccine. However, given the recent failure to add doses of an experimental anthrax vaccine to the Strategic National Stockpile, the Committee urges HHS to continue to give FDA-approved projects priority in procurement. Furthermore, the Committee recognizes the importance of maintaining a domestic supply of vaccine and building a diversified manufacturing base and encourages HHS to continue to support the development of a domestic biodefense infrastructure and urges ASPR to accelerate the issuance of anthrax therapy and vaccine requests for proposals under project BioShield (p.216).

Action taken or to be taken

The events of October 2001 made it very clear that bioterrorism is a serious threat to our Nation and the world. HHS has made substantial progress in the development and acquisition of Medical Countermeasures for known biological threats such as anthrax while recognizing that public health threats and emergencies can ensue from multiple other causes, both naturally-occurring and man-made, and that many of the preparedness activities HHS is pursuing will have cross-cutting value. Bioterrorism preparedness is not an insular activity for HHS but rather a critical component integrated within an all-hazards preparedness program.

Although much remains to be done, we have made substantive progress in building our Strategic National Stockpile from where it was pre-9/11 to what we have available today. In the near term, antibiotics remain a cornerstone of our response strategy to anthrax and demonstrate the dramatic improvements to our readiness. In December 2000, we only had enough 60-day regimens to provide post-exposure prophylaxis for approximately 137,000 people. Today we could provide this antibiotic regimen to over 40 million individuals. HHS has also built upon its efforts to maintain and improve preparedness for anthrax including obligating over \$1.1 billion for anthrax vaccines. Since 2005 HHS has signed contracts to acquire nearly 30 million doses of Anthrax Vaccine Adsorbed (AVA, BioThrax), the only currently available anthrax vaccine, manufactured by Emergent Biodefense Operations of Lansing, Michigan. In addition, HHS has issued two contracts for development and delivery of a total of 30,000 treatment courses of anthrax antitoxin therapeutics.

HHS is pursuing a comprehensive anthrax medical countermeasures strategy to maximize our near-term preparedness by procuring available antibiotics, antitoxins and vaccines while also supporting the research and development of next-generation products for the mid- and long-term. Both of these activities are necessary in parallel for us to maintain

and improve our anthrax medical countermeasures stockpile. A comprehensive advanced development program is essential for supporting the scientific and technological advances that will lead to the next generation products with improved storage conditions, more rapid production and mechanisms for delivery.

In the mid-term HHS is committed to supporting the research, development, and acquisition of next-generation anthrax vaccines and enhanced antitoxin products. The requirement for a next-generation vaccine serves these important goals: (a) to maintain the most effective stockpile possible in light of scientific, medical, and technological developments, as feasible under budgetary considerations; and (b) to broaden the manufacturing base for an essential medical countermeasure. Multiple sources can expedite fulfillment of requirements and mitigate the risk associated with only having a single supplier.

HHS is striving to establish a diversified manufacturing base for anthrax vaccines and to address shortcomings of the AVA vaccine identified in the 2002 Institute of Medicine report. To achieve this goal, HHS is pursuing the development and acquisition of a recombinant protective antigen (rPA) anthrax vaccine, and will be seeking proposals from any industry partner that has the ability to develop, produce, and deliver such a vaccine safely, securely, and reliably. Because government acquisitions are performed through full and open competition, HHS cannot predetermine if an rPA vaccine manufacturer will be based in the United States. If a non-domestic source proves to be the most appropriate, HHS will pursue every opportunity to meet our anthrax vaccine requirement for protecting 25 million people. A comprehensive advanced development program is essential for supporting the scientific and technological advances that will lead to the next generation of vaccines with improved storage conditions, more rapid production and mechanisms for delivery.

The timing of the next generation anthrax vaccine and antitoxin RFPs will depend on the maturation of candidate products that are currently in development and that we are closely monitoring. HHS recently released an rPA draft RFP and anticipates releasing the actual RFP in 2008. In September 2007, HHS made three advanced development contract awards for next generation anthrax antitoxins totaling over \$55 million which was supported jointly by ASPR/BARDA and NIH/NIAID.

Preparedness data -- Ensuring national preparedness requires regular review of the preparedness efforts of each State. The Committee urges ASPR to collect and review State-by-State data on benchmarks and performance measures developed pursuant to the provisions of the Pandemic and All-Hazards Preparedness Act and to make these data available to Congress, State and local public health departments and governments, and the public. The Committee further urges that as ASPR collects and evaluates State pandemic response plans that results of these evaluations be made available to the Congress and to the public (p. 216).

Action taken or to be taken

The Hospital Preparedness Program routinely collects data from grantees on a semi annual basis. The most recent data are for the FY 2006 grant year, which ended August 31, 2007. Measures through FY 2007 were established prior to the implementation of the PAHPA legislation. State by State and grantee by grantee analysis of these data is currently underway, and will be reported by August 2008.

As directed by PAHPA, ASPR is currently undertaking several projects to improve the timeliness and quality of the data, and make reports available to Congress, State and local public health departments and governments, and the public. In particular, a project with the University of Pittsburgh Medical Center's Center for Biosecurity is defining preparedness and the data elements needed to measure it, to ensure that ASPR asks grantees questions that truly measure healthcare preparedness. A project with the Agency for Healthcare Research and Quality is reviewing current performance measures, validating them where possible, and reviewing literature to ensure that the measures are evidence-based. Monthly meetings with CDC's Coordinating Office for Terrorism Preparedness and Emergency Response (COTPER) are also being held to improve integration with CDC, and develop common measures, where possible. Finally, ASPR is also developing the capacity to improve and simplify the process of data collection for grantees, capture the data in a format suitable for analysis, and make both standardized and customizable report available to Congress and other stakeholders in a transparent and timely way.

In 2007 and in coordination with multiple Federal agencies, ASPR conducted its first State-by-State review of State, DC and Territory pandemic response plans. ASPR and its Federal partners are currently preparing the final assessments of the 2007 review and they will be distributed to State, DC and Territorial officials.

ASPR has launched a second State-by-State review of State, DC and Territory pandemic response plans and is currently working with Federal partners and external stakeholders to develop the guidance, benchmarks and performance measures for the second review. ASPR will send out the guidance and solicit submissions on behalf of the USG Departments in February 2008 with the aim of disseminating completed assessments to the States, DC and Territories by the end of September 2008.

Surge capacity -- The Committee is concerned that not enough is being done at the State or Federal level to build up medical surge capacity for use during a pandemic or other public health emergency. The Committee urges ASPR, in consultation with medical and public health experts, to develop benchmarks of State readiness for medical surge capacity (p. 217).

Action taken or to be taken

During FY 2007 the Hospital Preparedness Program awarded \$75 million to all States, directly funded cities and Pacific jurisdictions to further preparedness in support of Pandemic Influenza planning. To be consistent with funds previously awarded through the Centers for Disease Control and Prevention (CDC) the funds were awarded via a

formula and ranged from \$136,000 to \$5,482,954. Activities that States were asked to focus on included Alternate Care Site (ACS) selection, set up, staffing and operation; personal protective equipment and infectious disease supplies; medical supplies and equipment including ventilators and associated equipment; fatality management planning and associated supplies and exercising of medical surge plans related to Pandemic Influenza.

In 2007 and in coordination with multiple Federal agencies, ASPR conducted its first State-by-State review of State, DC and Territory pandemic response plans. ASPR and its Federal partners are currently preparing the final assessments of the 2007 review and they will be distributed to State, DC and Territorial officials.

ASPR has launched a second State-by-State review of State, DC and Territory pandemic response plans and is currently working with Federal partners and external stakeholders to develop the guidance, benchmarks and performance measures for the second review. ASPR will send out the guidance and solicit submissions on behalf of the USG Departments in February 2008 with the aim of disseminating completed assessments to the States, DC and Territories by the end of September 2008.

Trauma centers -- In its CDC-funded September 2006 report, "U.S. Trauma Center Preparedness for a Terrorist Attack," a panel of experts assessed 175 trauma centers and made a number of recommendations with regard to planning and preparedness, communication and information sharing, resource allocation, and surge and decontamination capacities, among others. The report also noted the need to create sources of sustainable prospective funding for these purposes. The Committee strongly urges ASPR to review these recommendations and to incorporate them into the hospital preparedness cooperative agreement grants program (p. 217).

Action taken or to be taken

The ASPR Hospital Preparedness Program's (HPP) mission is to improve the capacity and capability of hospitals (including trauma centers) and emergency departments nationally to respond to biological, chemical and radiological terrorist attacks, infectious disease epidemics and mass casualty events. Activities aimed at increasing hospital/trauma center surge capacity and capability have included, but are not limited to, acquiring communication and decontamination equipment, upgrading isolation capabilities, training hospital/trauma center personnel, and developing plans and mutual aid agreements for the sharing of staff and resources in defined geographic areas.

One of the program's critical benchmarks from FY 2002 to FY 2006 focused on Trauma and Burn Care. That benchmark specifically instructed States to "enhance the statewide trauma and burn care capacity to respond to a mass casualty incident due to terrorism. This plan should ensure the capability of providing trauma care to at least 50 severely injured adult and pediatric patients per million of population."

Consistent with the Pandemic and All-Hazards Preparedness Act, HPP awarded 11 Healthcare Facility Partnership grants of which trauma centers were a mandatory

participating entity. The mission of the Healthcare Facilities Partnership Program is to improve surge capacity and enhance community and hospital preparedness for public health emergencies in defined geographic areas. This will be accomplished through innovative and creative projects that can be replicated across the country that further the concepts surrounding:

- Enhanced situational awareness of capabilities and assets that partnership entities possess and can bring to bear during a response.
- Advanced planning and exercising of plans that address common risks and vulnerabilities and consequences in a defined geographic area.
- Fostering the development of Medical Mutual Aid agreements among partnership entities insuring the inclusion of public health, emergency management and private sector partners.
- Developing and strengthening relationships between and among partnership
 entities, traditional first response agencies, public health and other response
 partners prior to disasters and emergencies so that during and after these kinds of
 events, response and recovery activities happen in an expedited coordinated
 manner.

SENATE REPORT NO. 110-258:

Terrorism preparedness -- According to a September 2006, report entitled "U.S. Trauma Center Preparedness for a Terrorist Attack" (funded by the Centers for Disease Control), an assessment of 175 trauma centers found an overall preparedness level of 74 percent. The report found that Level I trauma centers were more likely to score above average in preparedness than Level II centers, that preparedness (and supporting funding) correlated well with proximity to large numbers of hazardous sites (especially sites that could trigger mass decontamination requirements), and that funding through the National Bioterrorism Hospital Preparedness Program had resulted in high levels of emergency planning preparedness. However, the report also found significant variations in decontamination and surge capacity, often inadequate planning and preparation for prolonged operations in a "siege" environment, the absence of health care resource capacity monitoring, the absence of adequate preparedness for special needs populations, and the need for broader implementation of mutual aid agreements (MAAs) to include cross credentialing. The Committee strongly urges the Secretary to review these recommendations and to incorporate them into the Hospital Preparedness Cooperative Agreement Grants Program, including through providing support for local partnerships (p. 211).

Action taken or to be taken

The ASPR Hospital Preparedness Program's mission is to improve the capacity and capability of hospitals (including trauma centers) and emergency departments nationally to respond to biological, chemical and radiological terrorist attacks, infectious disease epidemics and mass casualty events. Activities aimed at increasing hospital/trauma center surge capacity and capability have included, but are not limited to, acquiring communication and decontamination equipment, upgrading isolation capabilities, training hospital/trauma center personnel, and developing plans and mutual aid agreements for the sharing of staff and resources in defined geographic areas.

During FY 2006 and FY 2007, HPP asked cooperative agreement awardees to conduct and/or use State/local Hazard and Vulnerability Assessments or HVAs to logically and systematically target HPP program funding. This was done in an effort to develop hospital/healthcare preparedness capability based on need.

New technologies for rapid in vitro response assessment -- The Committee has not specified how these no-year funds are to be used, and is broadly supportive of plans for vaccine development and purchase, antiviral procurement, and research and development of diagnostics. However, the Committee encourages HHS to identify new technologies that might have the potential to greatly enhance our response to a pandemic, and to be open to using the provided flexibility to make strategic investments in these potentially paradigm shifting technologies. Examples made known to the Committee include universal vaccines and passive immunotherapy. The Committee continues to support progress being made in influenza and pandemic viral vaccine selection and development. The Committee is aware of new technologies for rapid in vitro high throughput immune

response assessment that could accelerate vaccine protection against influenza and pandemic viruses and monitoring of vaccine efficacy, storage and distribution. The Committee encourages the Department and CDC to consider supporting the development of such technology (p. 212).

Action taken or to be taken

HHS supports new vaccine and antiviral therapeutic technologies for seasonal and pandemic influenza through the awarding of ten (10) advanced development contracts thus far totaling \$1.5 B since 2005. Adjuvants developed in these contracts are showing not only 10-20 fold antigen-sparing effects for influenza vaccines but broader subtype and cross-clade protective immunity for egg- and cell-based inactivated H5N1 vaccines. Licensure applications for these adjuvanted influenza vaccine products from at least two vaccine manufacturers are expected in 2008, which represent the advent of new adjuvants into U.S. commercial vaccine products for the first time in 40 years. The FY 2008 President's Budget requested funding to support next generation recombinant influenza vaccines. Next generation recombinant vaccine may provide influenza vaccine in nearly half the production time than egg- and cell-based influenza vaccines during an influenza pandemic.

Universal influenza vaccines, which focus primarily on the M2 and NP viral polypeptides as immune targets, are in the early product developmental stage (pre-clinical and Phase 1), which are supported by the National Institutes of Health primarily. As more of these products make their way into Phase 2 development, BARDA keeps a keen eye on these vaccine products and will be pleased to consider supporting the advanced development of these products towards U.S.-licensure upon demonstration of significant cross-subtype immunogenicity and availability of funds. Similarly, development of prophylactic and therapeutic polyclonal and monoclonal antibody products is in early stage product development. BARDA supports several NIH and NIH-sponsored investigators with H5N1 vaccine antigens to immunize persons for determination of production feasibility and antiviral effects of antibodies to H5 antigens. As these antibody products progress further in development, BARDA will consider supporting them upon availability of funds.

CDC and BARDA work jointly in the advanced development of rapid diagnostics for influenza. Contracts, which were awarded previously for the development of clinical point-of-care diagnostics to detect influenza viruses in clinical respiratory samples, are yielding prototype devices that are under independent government evaluation prior to clinical evaluation. Proposals are under review presently for development of laboratory-based rapid high throughput diagnostic devices of clinical samples to detect influenza viruses and their products, and contracts awards are expected in FY08. Contract solicitation for proposals to develop rapid virus immunity tests is slated for issuance in FY08 also.

OFFICE OF THE ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE SPECIAL REQUIREMENTS

Unified Financial Management System Operations and Maintenance (UFMS O & M) UFMS has now been fully deployed. The Program Support Center, through the Service and Supply Fund, manages the ongoing Operations and Maintenance (O & M) activities for UFMS. The scope of O & M services includes post deployment support and ongoing business and technical operations services, as well as an upgrade of Oracle software from version 11.5.9 to version 12.0. ASPR will use \$241,887 for these O&M costs in FY 2009.

Questions should be directed to David Tillette, Office of Finance, at (202) 260-7123.

OFFICE OF THE ASSISTANT SECRETARY FOR RESOURCES AND TECHNOLOGY CYBER SECURITY

	FY 2007	FY 2008	FY 2009	FY 2009 +/-
	<u>Actual</u>	Enacted	Estimate	FY 2008
Budget Authority	\$9,482,000	\$8,906,000	\$11,980,000	+\$3,074,000
FTE				

Allocation method: Contracts

Program Description and Accomplishments

The Office of the Chief Information Officer (OCIO), under the Assistant Secretary for Resources and Technology (ASRT), is responsible for ensuring the security of the Department's systems and assets and information that are used to disburse billions of dollars through Medicare and Medicaid; provide critical social services such as Head Start, childcare and child support enforcement; support a life-giving organ transplant system; maintain food and pharmaceutical quality; develop groundbreaking biomedical research; report accurate and timely disease treatment information; and detect disease outbreaks and bioterrorism. IT security and critical infrastructure protection (CIP) are essential components underlying HHS' mission – namely, the stewardship of our information resources and preservation of our trust and credibility.

The HHS IT Security Program focuses on the protection of critical assets – information systems data – so that the people using the systems can depend on the electronic environment being reliable, available, accurate, and authorized. The IT Cyber-Security projects aim to prevent, detect, and respond to security events. Critical Infrastructure Protection ensures that those IT assets, systems, and services that are essential to the conduct of critical business functions are safeguarded from disruption, failures, and compromise. The OCIO staff that oversee the HHS IT Security Program are funded in the ASRT budget.

In FY 2007, OCIO was able to:

- Identified new IT Critical Infrastructure activities and associated assets in accordance with HSPD-7 requirements. Update HHS inventory to include critical functions and assets in the Secretary's Command Center and vaccine stockpile, identified as a result of HHS efforts to defend against bioterrorism.
- Perform continuous Critical Infrastructure risk assessment and analysis for all
 existing functions and assets, to determine weaknesses, risks, and vulnerabilities
 resulting from interfacing with public and private sector systems.
- Provide continuous risk assessment, analytic and consulting assistance to OPDIVs, including dependencies between organizations, in order to improve Federal Information Systems Management Act compliance and implement corrective actions for HHS critical IT assets.

- Implement improved and continuous security monitoring for all HHS system, assets, and services.
- Ensure minimum security standards enterprise-wide, consistent with Federal guidelines and best practices.

Funding History

FY 2004	\$9,941,000
FY 2005	\$9,846,000
FY 2006	\$9,586,000
FY 2007	\$9,482,000
FY 2008	\$8,906,000

Budget Request

The FY 2009 request for Cyber-Security is \$11,980,000 an increase of +\$3,074,000 over the FY 2008 enacted level. Requested funds for Cyber-Security in FY 2009 will implement and maintain a vigorous and consistent Cyber-Security program and policy across HHS, as required by National Institute of Standards and Technology (NIST) standards and the Federal Information Security Management Act (FISMA). This request is part of the overall effort by ASRT to increase resources dedicated to the IT Security program.

Through the additional funding, the IT Security Program will strive to meet OMB Memorandums 06-15, Safeguarding Personally Identifiable Information, 06-16, Protection of Sensitive Agency Information, 06-19, Reporting Incidents Involving Personally Identifiable Information Incorporating the Cost for Security in Agency Information Technology Investments, 07-11, Implementation of Commonly Accepted Security Configurations for Windows Operating Systems, & 07-16, Safeguarding Against and Responding to the Breach of Personally Identifiable Information, which establish processes for protecting personally identifiable information (PII). The IT Security Program will also strive to keep pace with ever emerging threats and increasing risks such as:

- Increasing complexity multiple attack vectors are combined together in new ways that are difficult to detect and respond to.
- Increased organization and coordination attacks are being coordinated to launch large scale attacks against US government and private interests.
- Online crime for profit online crimes are being carried out for monetary gain and are sponsored at times by organized crime and states.
- Increased skill and cooperation tools, techniques, and resources are all part of a black market trade in data exploits.

Additional funding will also allow the HHS IT Security program to perform the following functions:

• Address recommendations made by the Government Accountability Office (GAO) in GAO-06-267, Information Security: Department of Health and Human Services Needs to Fully Implement its Program, as well as annual IG evaluations including

financial and FISMA. Specifically,

- O Develop a programmatic vulnerability scanning and penetration testing capability at both enterprise and OPDIV levels;
- Develop and implement standard security configuration and develop processes by which compliance may be evaluated;
- o Detect and remediate issues involving patching and virus updates;
- o Reinforce programmatic requirements for certification and accreditation (C&A), contingency planning and annual security control testing activities;
- Address gaps in security policy based on existing and emerging federal requirements and NIST guidance;
- Mitigate issues detected in reviews of Plan of Action and Milestones (POA&M) processes;
- o Facilitate more effective contractor oversight and management; and
- Develop and implement Information System Security (ISS) Lines of Business (LOB) compliant general security awareness training and provide role-based training for individuals with significant security responsibilities.
- Adjust existing policies and procedures and corresponding implementation in response to suggestions made in connection with the audits and evaluations including the Department's FY 2006 financial statement audit.
- Provide more effective perimeter defense and vulnerability scanning to proactively identify vulnerabilities before they are exploited for access to the critical infrastructure and Departmental assets;
- Strengthen the overall HHS IT security posture to protect confidentiality, integrity, and availability of IT resources; and
- Develop and manage a continuous monitoring capability to determine OPDIV compliance with Department policy and standards to include quarterly evaluation of:
 - o Plans of Action and Milestones (POA&M);
 - o Privacy impact assessments (PIA) and system of records notice (SORN) compliance; and
 - o Performance metrics.
- Expand incident management capabilities integrating new technologies to improve incident reporting and tracking and increase support to and oversight of OPDIV incident response
- Support the establishment and activities of the HHS personally identifiable information (PII) Breach Response Team including the development of the *Breach Response Team Policy*, the *Breach Response Team Charter*, and *Breach Response Team Standard Operating Procedures* to:
 - Evaluate OPDIV breach response assessments to determine the appropriate audience to respond to breaches of PII;
 - o Approve or recommend breach notification activities;
 - o Decide what actions should be taken by which stakeholders and determine the proper notification of individuals affected by a breach of PII;
 - o Work closely with the OPDIV Breach Response POC to coordinate breach response activities and after-action monitoring of breach response.
- Formalize and expand an enterprise-wide vulnerability management capability to include vulnerability and policy compliance scanning of all HHS networks Promote

an environment where all employees' actions reflect the importance of IT security

While the Department has begun addressing these areas, the requested funding level is necessary to ensure these endeavors are implemented fully and consistently at all levels of HHS. Implementing an effective Cyber-Security program will decrease the number and severity of exploits of sensitive HHS information systems, including compromise of mission critical data. Maintenance and updating of infrastructure will be required Department-wide in order to proactively identify and address vulnerabilities before they are successfully exploited.

Performance Table

#		FY 2004	FY 2005	FY	2006	FY	2007	FY 2008	FY 2009	Out- Year
#	Key Outcomes	Actua l	Actua l	Targe t	Actua l	Targe t	Actua l	Targe t	Targe t	Year Targe t
Lo	ng-Term Objective 1: Prov	ide a se	cure an	d truste	ed Infor	mation	Techno	ology (I'	<u>T)</u>	
	1.1. Enhance confidentiality, integrity, and availability of IT resources. 1.1.1. Improve reliability of critical IT infrastructure.	99.4%	99.9%	99.5%	99.8%	99.5%	99.8%	99.5%	99.5%	99.5%
	1.2. Ensure the availability and dissemination of information in preparation of or in response to local and national emergencies or other significant business disruptions. 1.2.1. Maintain the reliability of HHS IT systems.	99.9%	99.4%	99.8%	99.9%	99.8%	99.8%	99.8%	99.8%	99.8%

OFFICE OF PUBLIC HEALTH AND SCIENCE MEDICAL RESERVE CORPS

	FY 2007	FY 2008	FY 2009	FY 2009 +/-
	<u>Actual</u>	Enacted	Estimate	FY 2008
Budget Authority	\$9,748,000	\$9,578,000	\$15,110,000	+\$5,532,000
FTE	3	6	6	<u></u>

Authorizing Legislation: Public Health Service Act, section 2813

Allocation Methods: Direct Federal; Contract; and Cooperative Agreement

Program Description and Accomplishments

In March 2002, the Office of the Surgeon General was assigned responsibility for carrying forward, on behalf of the Department, the development of the Medical Reserve Corps (MRC) as part of the White House's USA Freedom Corps initiative. The MRC originated as a Demonstration Project (started in FY 2002 and continued in FY 2003) that provided start-up grants to 166 communities across the US. Many other communities have realized the importance of the MRC concept and established MRC units without receiving the Demonstration Project funding support. As of January 2008, there are over 720 MRC units in all 50 states, Washington, DC, Guam, Palau, Puerto Rico and the US Virgin Islands, with almost 150,000 volunteers.

The MRC has changed how many jurisdictions improve public health and prepare for emergencies in their communities. MRC members are identified, credentialed, trained and organized in advance of an emergency, and can be utilized throughout the year to improve the public health system. While the MRC provides volunteers with an opportunity to make a difference in the health and safety of those nearest to them, it also fills gaps in both public health initiatives and preparedness. This has enabled local communities to achieve a higher degree of resiliency and independence.

Medical Reserve Corps units are organized locally to meet the needs in their community. They are encouraged to contribute to local public health initiatives, such as those meeting the Surgeon General's priorities for public health. As this is a community-based program, each MRC is responsible for determining its own structure and developing its own policies and procedures. MRC units may be established and implemented by local governmental agencies or non-governmental organizations, but strong partnerships with local medical, public health and emergency management entities are necessary.

Much national attention has been focused on the MRC program in light of its astounding growth and its response following the 2005 Hurricanes. Public Law No.109-417, the "Pandemic and All-Hazards Preparedness Act" (PAHPA), was signed into law in December 2006. Of particular significance for the MRC was Section 303 of the Act, which codified the MRC program, called for its expanded functioning, and authorized a

Federal deployment capacity. Action items regarding the MRC that were included in the PAHPA Implementation Plan have been successfully completed.

Furthermore, Homeland Security Presidential Directive 21, with its requirement to increase community resiliency, also has significance for the MRC. Therefore, in support of the President's national strategies, in keeping with the National Response Plan and consistent with PAHPA, the MRC program office has undertaken efforts to expand the capacity of MRC units throughout the nation. This work is closely coordinated with the Office of the Surgeon General, the Assistant Secretary for Preparedness and Response, state coordinators, MRC regional coordinators, Regional Health Administrators and other Federal officials. The vital, ongoing work of MRC program continues, but additional efforts are being made to establish the necessary mechanisms and processes to involve MRC members who are willing, able and approved to deploy with HHS on national-level responses.

The Office of the Civilian Volunteer Medical Reserve Corps is housed within the Office of the Surgeon General, and has a mission to support local efforts to establish, implement, and sustain MRC units nationwide. Office activities include strategic planning, coordination, policy development, program operations, and a new function - deployment operations. These activities are carried out by OSG/OCVMRC staff, as well as onsite and regional contract staff.

In order to accomplish its mission, the Office leverages a number of different resources, including:

- Cooperative agreement with the National Association of County and City Health Officials (NACCHO). This three-year cooperative agreement (CA) was initiated in FY 2006 (FY06 \$8M; FY07 \$6M). Activities included in this CA include providing "Capacity-building Awards" directly to MRC units (FY06 491 awards; FY07 511 awards), providing logistical and other support for regional and national MRC conferences, supporting several national-level MRC work groups, and assisting with MRC communications, outreach and marketing efforts. The capacity-building awards (\$5-10,000 per eligible/selected MRC unit) are used by MRC units to offset a variety of administrative costs, including personnel, training, travel, supplies and equipment.
- Contract with ICF/Z-tech Corporation for MRC program support. This five-year contract was awarded in FY 2006. This contract provides direct onsite and off-site program staffing National Technical Assistance Coordinator, Public Information Officer, Junior Communications Specialist, and Regional Coordinators situated in the HHS regional offices. The Regional Coordinators provide day-to-day connection with the MRC units and conduct annual technical assistance assessments. Z-tech hosts and maintains the MRC website (www.medicalreservecorps.gov), as well as the database of MRC units. Other activities supported by this contract include the MRC National Leadership and Training Conference, technical assistance materials and resources, MRC promotional materials (i.e. brochures, exhibit booth, information packets), and MRC outreach.

• Interagency Agreement with Centers for Disease Control and Prevention which provides funding supplements to CDC Cooperative Agreements with the National Association of Local Boards of Health (NALBOH) and the Public Health Foundation (PHF). The funding to NALBOH supports efforts to improve awareness and understanding of the MRC with local boards of health. The funding to PHF supports MRC-Train, a learning management resource offered to all MRC units.

Though still a young program, the MRC has seen tremendous growth, both in the number of units and in the number of volunteers:

	New MRC Units	Total Number of MRC Units	Total Number of Volunteers
FY02	42	42	Inception)
FY03	124	166	10,116
FY04	66	232	34,164
FY05	118	350	62,982
FY06	247	597	112,089
FY07	116	713	146,414

The rapidly increasing number of MRC units (especially those outside of the MRC Demonstration Project that did not receive any funding support) indicates the level of acceptance of the MRC concept, mission and purpose within communities and States throughout the nation. While there was a tremendous growth rate in 2006 (due to increased awareness following Hurricane Katrina and a funding opportunity through our cooperative agreement with the National Association of County and City Health Officials), a decline in the rate of growth is expected. Furthermore, with the implementation of annual Technical Assistance Assessments in 2007, we expect to see an increase in the number of de-registrations of inactive MRC units.

While we do hope to see continued growth in the number of registered MRC units, our focus is shifting to ensuring that all MRC units are strong and active in both their community as well as to serve as unpaid Federal employees during a national disaster. This will be achieved through enhancement and adherence to the unit registration criteria, improved data collection and the implementation of the annual technical assistance assessments. It is our expectation all MRC units will work towards having an impact on the health and safety in their communities.

The MRC program is engaged in the broader HHS and OPHS Priorities. Specifically the MRC program supports the OPHS strategic goals by contributing to the following measures:

- Increase the number of local, state, and national health policies, programs, and services that strengthen the public health infrastructure (OPHS measure 3.a.)
- Increase the reach and impact of OPHS communications related to strengthening the public health and research infrastructures. (OPHS measure 3.b.)

Funding History

FY 2004	\$9,941,000
FY 2005	\$9,846,000
FY 2006	\$9,748,000
FY 2007	\$9,748,000
FY 2008	\$9,578,000

Budget Request

The FY 2009 request for the Office of the Civilian Volunteer Medical Reserve Corps is \$15,110,000, an increase of \$5,532,000 over the enacted FY 2008 budget. Funds for this Presidential Initiative (as part of USA Freedom Corps) will support salaries, travel, cooperative agreements, contracts, grants and contract management, technical assistance, outreach, and other programmatic activities. The budget increase will allow work to advance on the development of the MRC deployment capability. The following are some of the tasks that will need to be undertaken to accomplish the enhanced mission:

- Develop and implement MRC Deployment concept
- Develop and submit any necessary Paperwork Reduction Act and Privacy Act documents
- Draft policies and procedures
- Develop operational guidance and member manuals
- Maintain member roster
- Develop member screening plan (credentials verification, background checks)
- Establish ID card system
- Develop training requirements
- Identify/procure equipment/supplies (i.e. go-kits, uniforms)
- Develop deployment mechanisms
- Integrate with PHS response teams
- Develop evaluation plan

In addition, the MRC support the following HHS Priorities:

- Prevention: Local Medical Reserve Corps units are encouraged to conduct and support activities that address ongoing public health priorities and improve prevention efforts, such as diabetes detection, hypertension screening, and backto-school immunizations
- Emergency Response: Local Medical Reserve Corps units are encouraged to conduct and support activities that enable their community to prepare and respond to emergencies.
- Pandemic Preparedness: Local Medical Reserve Corps units are encouraged to be involved in pandemic preparedness activities in their local communities.

OFFICE OF SECURITY AND STRATEGIC INFORMATION

	FY 2007	FY 2008	FY 2009	FY 2009 +/-
	<u>Actual</u>	Enacted	Estimate	FY 2008
Budget Authority	\$3,263,000	\$3,263,000	\$4,763,000	+\$1,500,000
FTE	18	21	29	+8

Allocation Method: Direct Federal

Program Description and Accomplishments

OSSI was established in May of 2007 to consolidate functions related to physical security, personnel/classified information security, and strategic information, working across all HHS operating and staff divisions. The OSSI Director represents the Department on several Homeland Security Council and national security committees and workgroups, with OSSI staff providing representation on several others. HHS has taken the lead role in the development of plans and approaches for collaborations and cooperative ventures among science-based departments and agencies. OSSI assists and supports the Secretary in his responsibilities to manage national security, classified information, and strategic information programs and to provide representational leadership across the Federal Government, as well as to HHS programs as they apply to State and local authorities. A central OSSI responsibility is to assist and promote the access to and sharing of classified information to be used to improve HHS operating and staff division mission performance.

OSSI has been assigned a broad portfolio of responsibilities in support of the variegated social welfare, scientific, and public health missions of HHS. The exercise of these responsibilities is overseen by the Director and a leadership team that is organized into the three functional divisions as described above functionally. As a newly organized unit, OSSI's performance goals are still in development.

Program Division Descriptions

The Division of Strategic Information (DSI) within OSSI has a leadership role to ensure that the Department has the ability to access, share, and protect strategic and classified information. DSI will coordinate internal sharing and analysis of sensitive information among the OPDIVS/STAFFDIVS and external relationships with the Intelligence Community (IC). To accomplish this, DSI has initiated short and long term efforts to establish a network of scientific, public health, and security professionals within the Department, and to identify points of contact in other non-title 50 agencies, in the IC and the Information Sharing Environment Council.

DSI provides policy direction to facilitate the identification of potential vulnerabilities or threats to security; conduct analyses of potential or identified risks to security and safety; and work with agencies to develop methods to address them. DSI also oversees the development of an infrastructure of sensitive and classified communications among HHS

components. The infrastructure will be developed to include Secret Internet Protocol Router Network (SIPRNET), Joint Worldwide Intelligence Communications System (JWICS) and sensitive but unclassified systems of communication.

The Division will support the HHS goal to "Enhance the ability of the Nation's health care system to effectively respond to bioterrorism and other public health challenges" by:

- Providing HHS OPDIVS/STAFFDIVS with the necessary information and analysis to prevent or respond to public health threats in a timelier and effective manner, especially bioterrorism threats, to include naturally occurring threats such as contagious diseases [e.g. influenza, tuberculosis, smallpox, etc.].
- Coordinating the acquisition of strategic information and passage to appropriate Departmental elements by developing and maintaining a communications infrastructure to share sensitive or classified information related to public health threats as well as opportunities to prevent events and anticipate issues.
- Coordinating with other non-title 50 agencies and members of the Intelligence Community to identify common threats and develop shared strategies to address the threats.

<u>The Division of Personnel and Classified Information Security (DPCIS)</u> has the Departmental responsibility for policy and oversight for the following:

- Overseeing and managing personnel security and suitability background investigations and adjudications and national security clearances.
- Ensuring and enhancing communications security, including secure telecommunications equipment and classified information systems with direct management of these functions within the OS.
- Improving information security, to include receipt and categorization of classified and sensitive but unclassified materials, security awareness programs and management of the document classification and declassification program.
- Operating and managing the international traveler/foreign visitor awareness program and the drug-free workplace program, including HHS employee drug testing.

DPCIS provides Departmental guidance and oversight for these security functions and provides centralized adjudication of background investigations for all the Department's high public trust and national security positions. DPCIS is responsible for managing the national security clearance adjudication program and granting or denying security clearances, to include coordinating the reinvestigations of cleared employees.

DPCIS will conduct site visits, assessments, audits and inspections as part of its Department-wide leadership, management and oversight for the following directives and programs:

- EO 10450, Security Requirements for Government Employment
- EO 12958, as amended, Classified National Security Information
- EO 12968, Access to Classified Information
- Intelligence Reform and Terrorism Protection Act of 2004
- EO 13381, Strengthening Processes Relating to Determining Eligibility for Access to Classified National Security Information
- HSPD-12, Policy for a Common Identification Standard for Federal Employees and Contractors
- EO 12564, Drug-Free Federal Workplace
- Secure Communications Program
- Foreign Visitor and International Travel Awareness Program

DPCIS prepares annual reports for the Information Security Oversight Office (ISOO) of the National Archives and Records Administration (NARA) to track document classification and declassification decisions, numbers of oversight actions, and costs to protect classified information. DPCIS conducts an annual audit of all classified documents in the Department and assess control and safeguarding effectiveness. DPCIS will track timeliness and accuracy of the security clearance processes, including background investigation submissions to U.S. OPM and adjudication actions.

These responsibilities and associated activities directly support the 2007 Departmental Objective – Improve the Service of Management Functions and Administrative Operations for the support of the Department's Mission. This includes implementing the Department-wide HSPD-12 plan in accordance with the established schedule, and participating in Departmental initiatives to transform and improve business operations, including consolidation initiatives, implementing best practices, and leveraging the capabilities and resources for the benefit of the Department and meeting objective measures established for such initiatives.

<u>The Division of Physical Security (DPS)</u> consolidates previously divided and fractionated security functions within HHS and brings key subject matter expertise together to better address policy and critical security issues, while reducing funding requirements for identified previously redundant program initiatives across the Department.

Via audits and integrated physical security assessments, the Division of Physical Security provides Department-wide leadership, coordination, policy and oversight for the following directives and core programs:

- HSPD-7 Critical Infrastructure Identification, Prioritization, and Protection
- HSPD-12 Policy for a Common Identification Standard for Federal Employees and Contractors
- HSPD-19 Combating Terrorist Use of Explosives in the United States

- Bioterrorism
- National Select Agent Program
- Strategic National Stockpile Program
- Critical Infrastructure Protection (CIP) Program
- Continuity of Operations Plan (COOP)
- Cyber security Program
- Physical Security Program (guns, gates, and guards)
- Department Security Council leadership

The Division of Physical Security will adopt a comprehensive and repeatable integrated physical security assessment methodology, which will foster the ability to assess compliance with the above directives and provide appropriate corrective action support across the Department. These assessments will provide information to identify key physical security risks, threats and vulnerabilities and the Department's ability to provide the appropriate response. The assessment results will also assist the Division in developing the appropriate Departmental strategies to build and refine the various programs outlined above.

The Division of Physical Security will also establish and maintain the HSPD-12 Program Office, previously a part of the Assistant Secretary for Administration and Management (ASAM) organization. HSPD-12 establishes a requirement for all Federal agencies to create and use a government-wide secure and reliable form of identification for their Federal employees and contractors (a Personal Identity Verification (PIV) credential). The HSPD-12 Program Office's primary purpose is to oversee and coordinate HSPD-12 efforts across all OPDIVs to assure the Department complies with the directive and associated Federal standards. This includes addressing card issuance schedules mandated by OMB M-05-24 and recurring Certification and Accreditation processes.

The Division of Physical Security is responsible for policy, oversight and monitoring compliance with several Homeland Security Presidential Directives and other HHS mission critical infrastructure programs. These responsibilities and associated activities directly support the following HHS Strategic Goals and Departmental Objectives. HHS Strategic Plan Goal - Enhance the ability of the Nation's health care system to effectively respond to bioterrorism and other public health challenges:

- Build the capacity of the health care system to respond all to public health threats in a more timely and effective manner.
- Establish "continuity of operations" plans to ensure that personnel and analytical capability will still be operational in the event of a terrorist attack.
- Ensure the safety and security of personnel, physical assets, and sensitive information.
- Cooperate with other countries and with international organizations to enhance preparedness and response.
- Ensure the security of food and medical products.

Funding History

FY 2004 --FY 2005 --FY 2006 --

FY 2007 \$3,263,000 FY 2008 \$3,263,000

Budget Request

The FY 2009 request for OSSI is \$4,763,000, an increase of \$1,500,000 above FY 2008. This will cover increased personnel costs and will fulfill the anticipated January 2009 pay raise, an increase of (8 FTE), and increased costs in other services. This requested increase will support infrastructure improvement and will result in OSSI fulfilling the numerous presidential directives, and national security organizations and will result in attaining many of the scientific and public health Secretarial objectives/goals for this new organization.

This budget is requested for the continued support of HHS responses and compliance with Homeland Security Presidential Directives, physical security, personnel security, and strategic information initiatives and functions. The Director of OSSI represents the Department on several Steering Committees that are responsible for the implementation of the national strategies, and HHS will be taking a lead role in the development of national security plans and approaches for science-based departments and agencies. OSSI assists the Secretary in discharging his responsibilities to implement and manage mandated programs and to provide leadership across the government, as well as to develop and implement these essential programs within HHS. The budget request will support OSSI's responsibilities and programs in obtaining access to and sharing and protecting strategic and classified information that, in turn, supports HHS public health and science programs, protection of HHS employees, and HHS critical infrastructure security. This work will entail coordination of analytical activity with senior HHS officials and their staffs throughout the Department and will include building relations with Federal officials in other non-title 50 agencies who conduct similar programs, as well as maintaining customer relationships with the intelligence community and with the Department of Homeland Security.

New Secure Compartmented Information Facility (SCIF): A new SCIF will be constructed as a collaborative effort between OSSI and at least two other users of such facilities. The total construction and outfitting cost will be shared among the partners. The new SCIF will be constructed within the Southwest Complex, but will be separate from existing SCIF facilities; electronic interconnections will be operated independently of the existing facilities to assure continuity of availability of a secure facility in the event the current facilities are compromised.

<u>Update and Improve Electronic Resources</u>: The Department requires new technologies to routinely "sweep" critical areas. With the increasing number of visitors to Secretarial, Deputy Secretarial, and senior officials' offices, the potential for the nefarious placement of electronic monitoring equipment has increased. Current equipment to assure that any

such placement can be detected is inadequate. There is also a need to increase the numbers of computers, printers, and associated peripherals within secure facilities to handle the increasing volume and types of classified information traffic. New telephonic and cellular equipment is needed, as well as equipment to assure that the Department's appointed leadership have access to mobile secure communications at all times and that this equipment is survivable and available under the direct of circumstances.

Programmatic Improvements: The number of high level background investigations is projected to increase by a minimum of 20% as new employees are hired to replace numerous anticipated retirees. Security clearance requests are expected to increase as more employees and supervisors require access to classified strategic health information and need to attend classified meetings as part of their mandatory program work. The change of administration will add to the turnover of employees needing extensive background investigations in FY 09. All new investigations require personnel security specialists to initiate the process and review and adjudicate the completed reports, and to assure that OPM and EO mandated renewals of checks occur in a timely manner. Additional drug testing will be required as numerous new positions will be added to applicant and random drug testing pooling. Alcohol testing will be added to the testing requirements for many DOT-mandated driving positions.

HHS has responsibility in the implementation of Homeland Security Presidential Directive-7, Critical Infrastructure Identification, Prioritization and Protection. HSPD-7 requires all Federal departments and agencies to implement plans for protecting the physical and cyber critical infrastructure that they own or operate and this position will be used to oversee and coordinate the plans developed and implemented by OPDIV and HHS headquarters activities to meet the HSPD-7 mandates. Much of this effort is applicable to classified level information and/or facilities, adding an increased level of complexity.

Additional major duties that were initiated in FY 2008 pertaining to the physical security of key emergency response facilities, the Strategic National Stockpile, deployed personnel, and other potentially vulnerable assets, and will be in implementation phases through FY 2008, thus requiring added resources, attention, and oversight in FY 2009.

OSSI's program in obtaining access to and sharing and protecting strategic and classified information will support HHS public health and science programs, protection of HHS employees, and HHS critical infrastructure. This work will entail coordination of analytical activity of HHS officials throughout the Department's organizational units and will include building relations with Federal officials in other non-title 50 agencies who conduct similar programs, as well as maintaining customer relationships with the intelligence community.

The mandate of Executive Order 13434, National Security Professional Development, set forth a framework that will provide to designated national security professionals in HHS, and other departments and agencies, required access to education, training and professional experience opportunities. The Director of OSSI represents the Department

on the steering committee that is responsible for implementation of the national strategy, and HHS will be taking the lead role in the development of plans and approaches for science-based departments and agencies. In addition to activities needed to meet the requirements of the EO within HHS, support will be needed to assist the OSSI Director in his responsibilities to manage the work of the committee and to provide science-based leadership across the government, as well as support the development and implementation of this program specifically within HHS. A specialized curriculum that incorporates national security and intelligence knowledge with scientific knowledge will be developed and implemented within HHS, which is expected to be the used as the basic model for other science-based departments and agencies.

HEALTHCARE PROVIDER CREDENTIALING

	FY 2007	FY 2008	FY 2009	FY 2009 +/-
	<u>Actual</u>	Enacted	Estimate	FY 2008
Budget Authority			\$3,300,000	+\$3,300,000
FTE				

Allocation Method: Direct Federal

Program Description

Healthcare provider credentialing, both before and after a mass casualty event, is essential to protect the health and safety of victims, to match expertise with need, and to satisfy liability-related requirements. Funds will be used to create a national credentialing system that will link existing state-based systems that verify health care professionals' credentials from relevant Federal, State and non-governmental sources. The information will be accessed through a single electronic portal available to parties who have received prior permission for such a query from the practitioner. The National network of primary source data will be sufficiently inclusive to permit credentialing determinations of spontaneous volunteers. The system will link state-based systems that are required by the ASPR-based Emergency System for Advanced Registration of Volunteer Healthcare Professionals (ESAR VHP). The portal will also assist ASPR in meeting the credentialing requirements of the Pandemic and All Hazards Preparedness Act.

Funding History

FY 2004	
FY 2005	
FY 2006	
FY 2007	
FY 2008	

Budget Request

The FY 2009 request includes \$3,300,000 for healthcare provider credentialing, which is a vital part of the Department's ESF #8 Preparedness and Response Initiative. The Healthcare Credentialing Portal will accomplish the following objectives:

- Assist States in managing spontaneous volunteers who respond to assist during large-scale emergencies.
- Provide a national system of credentialed civilian health care professionals who have volunteered to participate in a disaster response.

- Collaborate with Federal, State, local and private partners for a seamless integration and sharing of currently available data.
- Provide a national system to credential civilian health care professionals.

PANDEMIC INFLUENZA

	FY 2007	FY 2008	FY 2009	FY 2009 +/-
	<u>Actual</u>	Enacted	Estimate	FY 2008
Budget Authority		\$74,809,000	\$585,091,000	+\$510,282,000
FTE	10	36	47	+11

Authorizing Legislation: Pandemic and All-Hazards Preparedness Act (PAHPA) of 2006.

Allocation Methods: Federal/Intramural/International, Competitive Grants, Cooperative Agreements, Contracts; and Other

The FY 2009 request for pandemic preparedness in the Public Health and Social Services Emergency Fund is \$585,091,000. This request includes \$507,000,000 to enhance the Nation's preparedness by providing funds for the procurement of pre-pandemic vaccine and for increased vaccine production capacity. It also reflects the principle of shared responsibility by protecting HHS staff, clinicians, and patient populations through the purchase of antiviral drugs and other medical supplies. The request also provides \$78,091,000 for ongoing activities within the Office of the Secretary to prepare the Nation against an influenza pandemic.

In addition, the FY 2009 President's Budget includes \$235,000,000 to fund ongoing annual activities at FDA, CDC, and NIH.

Program Description and Accomplishments:

On November 1, 2005, the President requested a total of \$7.1 billion in emergency funding for pandemic influenza preparedness activities, of which \$6.7 billion was for implementation of the *HHS Pandemic Influenza Plan*. This funding was requested in FY 2006 to fund a staged preparedness effort to ensure the Nation could effectively respond in the event of a pandemic. In December 2005, Congress appropriated \$3.3 billion in emergency funding for HHS in a FY 2006 supplemental, for the first year of the *HHS Pandemic Influenza Plan*. In June 2006, Congress appropriated \$2.3 billion for HHS in emergency funding in a second FY 2006 supplemental for the second year of the HHS Plan. In addition, HHS requested \$870 million in the FY 2008 President's Budget in one-time funding to continue these efforts.

Since December 2005, HHS has been funding the first stage of pandemic preparedness activities, which include: expanding and diversifying domestic vaccine production and surge capacity; enlarging H5N1 pre-pandemic vaccine and antiviral drug stockpiles; supporting advanced development of cell culture and antigen sparing influenza vaccines, and new antiviral drugs; advanced development of point-of care clinical diagnostics; stockpiling of medical supplies and ventilators; improving State and local preparedness; expanding risk communication efforts; enhancing FDA's regulatory science base; and expanding surveillance, research, and international collaboration efforts of CDC, NIH, and the HHS Offices of the Assistant Secretary for Public Health Preparedness and Response and of Global Health Affairs.

Recent Accomplishments include:

- ♦ Over the past three years, HHS has established a pre-pandemic influenza vaccine stockpile of H5N1 vaccine. As of January 2008, HHS has procured approximately 13 million courses of pre-pandemic vaccine. Recognizing the continuous evolution of the H5N1 virus, stockpile purchases include both clade 1 and clade 2 vaccines.
- ◆ HHS has supported the development of cell-based influenza vaccines that are currently in Phase II and III clinical development. Construction of the first North American cell-based manufacturing facility began in 2007 with HHS support.
- ♦ HHS has completed the purchase of 50 million courses of antiviral drugs for the Federal portion of its antiviral drug stockpile goal. HHS continues to subsidize the State purchase of influenza vaccine. States have purchased 21.7 million courses since June 2006. HHS also continues to support the advanced development of new antiviral drugs.
- HHS has purchased the following medical supplies for the SNS:
 - o 104 million N95 Respirators
 - o 52 million Surgical Masks
- ◆ HHS has completed clinical evaluation of a new 5-target PCR rapid diagnostic test for avian and seasonal influenza. This high-throughput assay test will be used in all U.S. public health laboratories and internationally at WHO reference laboratories.
- ♦ HHS has awarded a total of \$576 million for State and local preparedness, including medical surge capacity.
- ◆ HHS has deployed teams of experts to help investigate suspected cases of human transmission of infection with influenza A in 12 countries in Asia, Africa, and Europe. It also supports pandemic influenza preparedness activities in approximately 40 countries around the world.

Funding History:

FY 2004	\$49,705,000
FY 2005	\$500,198,000
FY 2006	\$5,590,000,000
FY 2007	
FY 2008	\$74,809,000

Budget Request:

\$585,091,000 is requested in FY 2009 for Pandemic Influenza preparedness activities in the Public Health and Social Services Emergency Fund. The FY 2009 request supports the following activities:

\$467,000,000 is requested to continue to build vaccine production capacity. Funding will be used to allow HHS to continue to work toward its goal to acquire 20 million egg-based courses of pre-pandemic vaccine for the national stockpile. Currently, HHS has approximately 13 million courses of H5N1 clade 1 and 2 vaccine on hand and on order. The FY 2009 request includes funds to procure additional courses of pre-pandemic vaccine, which will bring HHS closer to meeting the national goal. Within the total for vaccine capacity, \$42 million will be used for the contractual purchase of five years' worth of eggs and other vaccine supplies that will be used to produce pre-pandemic and pandemic vaccine. The eggs may also be used for seasonal influenza vaccine manufacturing if a vaccine shortage occurs. In this instance, the manufacturer would reimburse the HHS contract. The egg supply, a critical infrastructure component, provides the materials needed to maintain a secure, year-round readiness state to manufacture pre-pandemic and pandemic influenza vaccine. Over the past three years, HHS has entered into contracts to develop the production capacity to vaccinate every American within six months of the first sign of a pandemic through its investments in cell-based and antigen sparing technologies. However, it is also critical that investments are maintained for egg-based vaccine, the current technology for developing influenza vaccine.

\$40,000,000 is requested to protect HHS employee and patient populations and to uphold HHS' commitment to the policy of shared responsibility in the event of a pandemic. Pandemic preparedness is a shared responsibility between Federal, State and local governments, the private sector, families, and individuals. Consistent with this principle, the FY 2009 request includes funds to purchase antiviral courses, personal protective equipment, and other medical supplies for HHS employees and contractors, and the IHS patient population. These investments will prevent morbidity and mortality, and to increase the workforce available to respond effectively to a pandemic. Through these procurements, HHS is setting an example of the steps that all stakeholders must take to ensure pandemic preparedness.

\$78,091,000 is requested in FY 2009 request for ongoing OS Pandemic Influenza preparedness activities through the Public Health and Social Services Emergency Fund. The FY 2009 request supports the following activities:

\$4,000,000 is requested for the Office of the Assistant Secretary for Public Affairs (ASPA) to ensure effective communications for pandemic preparedness and response activities. Through APSA, HHS has undertaken a number of steps to educate the public, including the creation and maintenance of the website www.PandemicFlu.gov, development and distribution of the *Individuals and Families Pandemic Planning Guide*; the release of television and radio public

service announcements; and the launch of a stakeholder campaign. HHS also held pandemic planning summits with public health and emergency management and response leaders in 56 States and localities which receive pandemic preparedness funding. The FY 2009 request will allow ASPA to continue educational efforts and maintain a communications operation to respond to a pandemic.

\$35,000,000 is requested for the Office of Global Health Affairs (OGHA) and the Office of the Assistant Secretary for Preparedness and Response (ASPR) for pandemic preparedness and response planning. Preparedness and response is key to effective containment of an outbreak of influenza with pandemic potential in the US or abroad. To prepare for a global epidemic, OGHA and ASPR will continue to work with other agencies of the Federal government and international partners to ensure that the global community has the capacity and the commitment to contain an outbreak at its site of origin, and to limit its spread. HHS will lead global, multi-lateral, bi-lateral, and inter- and intra-governmental initiatives that will include global training efforts and international preparedness exercises to ensure the United States, other countries, and international organizations use the most effective approaches to better prepare for an influenza pandemic. ASPR will continue working towards the facilitation of country-specific pandemic preparedness plans that are coordinated with international strategies. The targeted programs will expand medical, veterinary, and laboratory expertise and capacity abroad; enhance laboratory diagnostic capacity and technical capabilities; and improve surveillance.

\$15,000,000 is requested for international in-country advanced development and industrialization of human pandemic influenza vaccine. In FY 2009, ASPR will continue the accelerated international development of an in-country H5N1 vaccine for humans to prevent avian H5N1 influenza globally. The funding will address global and specific country needs for further pilot lot and commercial scale manufacturing of H5N1 vaccines for clinical trials and pandemic usage, scale-up development for vaccine manufacturing, vaccine production equipment, and development and validation of product release assay methods and clinical sample analysis.

\$15,000,000 is requested for the advanced development of rapid tests/detection. The prevention and containment of a pandemic influenza epidemic requires the ability to produce vaccine that targets the current virus strain in circulation. HHS will continue to accelerate the development of modular, high throughput diagnostic kits, equipments, reagents, and methods (antigen and genetic-based tests) for rapid bedside detection of human, avian and pandemic influenza viruses at the subtype and virus variant level on a national scale. This will be accomplished by advancing current technology through assay development and validation processes; engaging in stringent proficiency testing and validation studies for rapid tests; and implementing quality systems that insure compliance in the total development process as well as through the Public Health Information

Network-compliant electronic reporting of laboratory results and other critical communications from local jurisdictions to State public health laboratories and to HHS.

\$9,000,000 is requested for management and administration of pandemic influenza preparedness activities. Funds will be used for: salaries of scientists, project managers, contracting officers and other program staff; travel, including site visits to facilities and for convening technical evaluation panels; rent and utilities; intermittent subject matter experts, and contractor support.

DETAIL OF FULL-TIME EQUIVALENT (FTE) EMPLOYMENT

	FY 2007	FY 2008	FY 2009		
	<u>Actual</u>	Enacted	Estimate		
Assistant Secretary for Preparedness and Response	266	377	434		
Pandemic Influenza	7	32	43		
Total	273	409	477		
Average GS Grade					
2007	GS-13/6				
2008	GS-13/6				
2009	GS-13/7				

Increased FTE will be used to support the new programs and increases within PHSSEF request. Details will be found within the individual sections of the request.

DETAIL OF POSITIONS

	FY 2007	FY 2008	FY 2009
FG (<u>Actual</u>	Enacted 4	<u>Estimate</u>
ES-6	4	4	4
ES-5	2	2	2
ES-4	2	2	2
ES-3	2	3	3
ES-2			
ES-1			
Subtotal	10	11	11
Total – ES Salaries	\$1,603,987	\$1,692,206	\$1,697,282
GS-15	54	83	102
GS-14	51	83	99
GS-13	55	89	107
GS-12	35	55	66
GS-11	12	21	23
GS-10	4	6	7
GS-09	12	19	23
GS-08	3	5	6
GS-07	5	9	12
GS-06	2	2	2
GS-05	2	2	2
GS-04	2	2	2
GS-03	2	2	2
GS-02	1	1	1
GS-01			
Subtotal	240	379	454
Commissioned Corps	83	83	83
Ungraded	6	6	6
Total Positions	339	479	554
Total FTE usage, end of year	273	409	477
Average ES level	5	5	5
Average ES salary	\$160,398	\$168,417	\$173,957
Average GS grade	GS-13/6	GS-13/6	GS-13/7
Average GS salary	\$90,640	\$93,694	\$96,130
Average Special Pay (Commissioned Corps)	\$93,554	\$96,706	\$99,221
Average Ungraded	\$60,965	\$62,989	\$63,153
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

PROPOSED GENERAL PROVISIONS FOR FISCAL YEAR 2009

The President's Budget recommends that a number of general provisions be included in the FY 2009 Departments of Labor, Health and Human Services and Education Appropriations Act. These provisions follow appendix schedules for the Department of Health and Human Services (Title II General Provisions) and the Departments of Labor, Health and Human Services and Education (Title V General Provisions). Following is a summary of the proposed provisions:

Title II

- Sec. 201. This provision provides authority for up to \$50,000 in appropriated funds to be used for official reception and representation expenses which are specifically approved by the Secretary.
- Sec. 202. This provision enables the Secretary to assign not more than 60 Public Health Service employees to assist in child survival activities and to work in AIDS programs through and with funds provided by the Agency for International Development, the United Nation's International Children's Emergency Fund or the World Health Organization.
- Sec. 203. This provision provides that no funds appropriated in this Act 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.
- Sec. 204. This provision limits the rate at which the Head Start Program may pay an individual when using a grant or extramural funding appropriated under this title, to a maximum of Executive Level II.
- Sec. 205. This provision allows the Secretary to use not more than 2.4 percent of any appropriations authorized under the Public Health Service Act for the evaluation of the implementation and effectiveness of the Public Health Service Act programs.
- Sec. 206. This provision proposes that the Secretary may transfer up to 1 percent of discretionary funds, appropriated for the current fiscal year, between appropriations for the Department of Health and Human Services in this, or any other Act (e.g., Agriculture and Rural Development Act, Interior Act, and Labor, Health and Human Services, Education, and Related Agencies Act), with a limitation that no such appropriation may be increased by more than 3 percent, and that an appropriation may be increased by up to an additional 2 percent after notification of the Appropriations Committees in both Houses of Congress. The Appropriations Committees in both Houses of Congress are to be notified at least 15 days in advance of any transfer.
- Sec. 207. This provision provides that the Director of the National Institutes of Health, 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 House and Senate Appropriations Committees are promptly notified of the transfer.

- Sec. 208. This provision provides that the amount for research related to the human immunodeficiency virus at the National Institutes of Health, as jointly determined by the Director of the National Institutes of Health and the Director of the Office of AIDS Research, shall be available to the Office of AIDS Research account as necessary to carry out section 2353(d)(3) of the Public Health Service Act.
- Sec. 209. This provision provides that none of the funds appropriated in this Act may be available to any entity under title X of the Public Health Service Act unless the award applicant certifies to the Secretary that it encourages family participation in family planning services for minors and provides counseling to minors on how to resist coercion into engaging in sexual activities.
- Sec. 210. This provision provides that no provider of services under title X of the Public Health Service Act be exempt from State laws requiring notification or reporting of child abuse, child molestation, sexual abuse, rape or incest.
- Sec. 211. This provision provides that none of the funds appropriated by this Act, including trust funds, may be used to carry out the Medicare Advantage program if the Secretary of Health and Human Services denies an otherwise eligible entity participation in the program based on the information that the entity will not provide, pay for, or provide referrals for abortions.
- Sec. 212. This provision provides that none of the funds appropriated by this Act can be used to withhold substance abuse funding from a State, if the State certifies to the Secretary of Health and Human Services by May 1, 2009, that it will commit additional State funds to ensure compliance with State laws prohibiting the sale of tobacco products to individuals under 18 years of age. The State is to submit a report to the Secretary on all fiscal year 2008 State expenditures and all fiscal year 2009 obligations for tobacco prevention and compliance activities, by program activity, by July 31, 2009. Expenditures in FY 2008 must be greater than or equal to FY 2008expenditures.
- Sec. 213. This provision provides authority to support HHS in carrying out international HIV/AIDS and other infectious, chronic and environmental disease and other health activities abroad during fiscal year 2009.
- Sec. 214. This provision provides authority for the Office of the Director of the National Institutes of Health (NIH) to enter directly into transactions in order to implement the NIH Common Fund, in lieu of the peer review and advisory council review procedures that would otherwise be required. The Director of NIH may utilize such peer review procedures as determined appropriate to obtain assessments of scientific and technical merit.
- Sec. 215. This provision limits to \$35,000,000 the amount of funds appropriated by this Act to the Institutes and Centers of the National Institutes of Health that may be used for alteration, repair, or improvement of facilities, as necessary for the proper and efficient conduct of the activities authorized herein, at not to exceed \$2,500,000 per project.
- Sec. 216. This provision provides that 1 percent of the funds available for the National Institutes of Health National Research Service Awards (NRSA) will be available to the Administrator of the Health Resources and Services Administration for NRSA awards for research in primary medical care; 1 percent of the amount available for NRSA is to be available to the Director of the Agency for Healthcare Research and Quality to make NRSA awards for health service research.

- Sec. 217. This <u>proposed</u> provision would cancel unobligated balances available to the Health Resources and Services Administration for the Health Centers Loan Guarantee Program, authorized under section 330 (d) of the Public Health Service Act and Title II of P.L. 104-208.
- Sec 218. This provision <u>proposes</u> that an institution of higher education with a student loan revolving fund established under certain authorities of the Public Health Service Act, shall, no later than September 30, 2009, pay to the Secretary of Health and Human Services the Federal portion of all the liquid assets of such fund, as determined by the Secretary on June 30, 2009 and not make new loans under these authorities until the amount equal to that Federal portion determined no June 30, 2009, has been paid to the Secretary.
- Sec. 219. NONRECURRING EXPENSES FUND This provision <u>proposes</u> to amend Sec. 223 of the Department of Health and Human Services Appropriations Act, 2008, by inserting ", with respect to this and any succeeding fiscal year," after "by this or any other Act."

Title V

- Sec. 501. This provision authorizes the Secretaries of Labor, Health and Human Services, and Education to transfer unexpended balances of prior appropriations to accounts corresponding to those included in this Act as long as the balances are used for the same purpose and the same period of time they were originally appropriated.
- Sec. 502. This provision provides that no appropriation contained in this Act shall remain available for obligation for a period beyond the current fiscal year, unless it is expressly stated in this Act.
- Sec. 503. This provision provides that:
- (a) Except for normal and recognized executive-legislative relationships, no part of any appropriation in this Act shall be used for publicity or propaganda, preparation, distribution, publication, radio or TV broadcast or film presentation designed to support or defeat legislation pending before Congress, except as a presentation to Congress itself.
- (b) No part of any appropriation in this Act be used to pay the salary or expenses of any grant or contract recipient (or their agent) related to activities designed to influence legislation or appropriations pending before the Congress or any State legislature.
- Sec. 504. This provision provides the amounts available to the Secretaries of Labor and Education, the Director of the Federal Mediation and Conciliation Service, and the Chair of the National Mediation Board, from their respective Salaries and Expenses accounts, for official reception and representation expenses.
- Sec. 505. This provision provides that no funds appropriated under this Act may be used to carry out a program of distributing sterile needles for the hypodermic injection of any illegal drug.
- Sec. 506. This provision provides that all Federal grantees (including State and local governments and recipients of Federal research grants) issuing press releases, requests for proposals and other documents describing projects or proposals supplied with Federal funds clearly state the following: (1) the percentage of total costs of the program or project financed

- with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) the percentage and dollar amount of the total cost to be financed by non-governmental sources.
- Sec. 507. This provision provides that none of the funds appropriated in this Act, and none of the funds in any trust fund to which funds are appropriated under this Act, may be expended for abortion or for health benefits coverage that includes coverage of abortion. The term 'health benefits coverage' means the package of services covered by a managed care provider or organization pursuant to a contract or other arrangement.
- Sec. 508. The limitations established in the preceding section shall not apply to an abortion:
- (a) If the pregnancy is the result of an act of rape or incest; or in the case where a woman suffers from a physical disorder, physical injury, or physical illness, including a life-endangering physical condition caused by or arising from the pregnancy itself, that would, as certified by a physician, place the woman in danger of death unless the abortion is performed.
- (b) Nothing in the preceding section shall be construed as prohibiting the expenditure by a State, locality, entity, or private person of State, local, or private funds (other than a State's or locality's Medicaid matching funds).
- (c) Nothing in the preceding section shall be construed as restricting the ability of any managed care provider from offering abortion coverage or the ability of a State or locality to contract separately with such a provider for such coverage with State funds (other than a State's or locality's contribution of Medicaid matching funds).
- (d) None of the funds may be available to any Federal program, agency or State and local government, if said institution subjects the individual or health care entity to discrimination on the basis that the health care entity does not provide coverage of, or referrals for abortions.
- Sec. 509. This provision provides that none of the funds made available in this Act may be used for creation of a human embryo, embryos for research, or research in which a human embryo or embryos is destroyed. For the purposes of this section, human embryos include any organism derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.
- Sec. 510. This provision provides that none of the funds made available in this Act may be used for any activity that promotes the legalization of any drug or controlled substance except when there is significant medical evidence of therapeutic advantage to the use of such drug or other substance, or Federally-sponsored clinical trials are being conducted to determine therapeutic advantage.
- Sec. 511. This provision provides that 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. 512. This provision provides that none of the funds made available in this Act may be used to enter into or renew a contract with a contractor with the U.S. Government who is subject to section 4212(d) of title 38, United States Code, but has not submitted the most recent annual report required by that section to the Secretary of Labor, detailing the employment of certain veterans.

- Sec. 513. This provision affects the Department of Education and pertains to a library's eligibility for funding under the Library Services and Technology Act, as amended by the Children's Internet Protections Act.
- Sec. 515. This provision prescribes that Iraqi and Afghan aliens with special immigrant status under section 101(a)(27) of the Immigration and Nationality Act shall be eligible for benefits available to refugees admitted under section 207 of the Act for a period not to exceed 6 months.