



**DEPARTMENT
of HEALTH
and HUMAN
SERVICES**

**Fiscal Year
2016**

Office of Inspector General

*Justification of
Estimates for
Appropriations Committees*

Mission, Vision, and Values

The Department of Health and Human Services (HHS) touches the lives of all Americans through programs that provide health insurance, promote public health, protect the safety of food and drugs, and fund medical research, among other activities.

Mission

The Office of Inspector General's (OIG) mission is to protect the integrity of HHS programs and the health and welfare of the people they serve. As established by the [Inspector General Act of 1978](#), OIG is an independent and objective organization that fights fraud, waste, and abuse and promotes efficiency, economy, and effectiveness in HHS programs and operations. We work to ensure that Federal dollars are used appropriately and that HHS programs well serve the people who use them.

Vision

Our vision is to drive positive change in HHS programs and in the lives of the people served by these programs. We pursue this vision through independent oversight of HHS programs and operations and by providing HHS and Congress with objective and reliable information for use in policymaking. We assess the Department's performance, administrative operations, and financial stewardship. We evaluate risks to HHS programs and the people they serve and recommend improvements. The law enforcement component of OIG investigates fraud and abuse against HHS programs and holds wrongdoers accountable for their actions.

Values

OIG strives to be relevant, impactful, customer focused, and innovative. We apply these values to our work in order to persuade others to take action by changing rules, policies, and behaviors to improve HHS programs and operations. OIG strives to serve as a model for good government. Of key importance is engagement with our stakeholders—Congress, HHS, health and human services professionals, and consumers—to understand their needs, challenges, and interests in order to identify areas for closer scrutiny and offer recommendations for improvement. We do this throughout the year, but most visibly through the development of our [Work Plan](#) and HHS's [Top Management and Performance Challenges](#). The goals, priorities, and strategies in these documents reflect our ongoing stakeholder engagement and our assessment of the input we receive.



DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201



I am pleased to present the U.S. Department of Health and Human Services (HHS), Office of Inspector General (OIG), fiscal year (FY) 2016 Performance Budget Submission. This submission is in accordance with the Inspector General Act, as amended (5 U.S.C. App. 3). It presents OIG's budgetary requirements for meeting its responsibility to protect the integrity of hundreds of HHS programs, as well as the health and welfare of the beneficiaries whom they serve.

The FY 2016 request includes \$417 million to further OIG's commitment to protecting the integrity of HHS programs by conducting work that is relevant, innovative, customer focused, and high impact. The request will support OIG's efforts to oversee the administration of HHS's public health and human services programs and Health Insurance Marketplaces, while continuing to support and expand the joint HHS and Department of Justice Medicare and Medicaid program integrity efforts.

This budget is presented during a dynamic time for HHS programs and their oversight. The 2016 request will further OIG's work examining core risk areas and issues identified as top management challenges facing HHS. Priority areas of oversight will include the following: Health Insurance Marketplaces, focusing on proper expenditure of taxpayer funds and the efficient and effective operation of the Marketplaces; management and administration of HHS's grants and contracts; abuse of prescription drugs and other Medicare Part D fraud; payment accuracy and value in health care delivery; safety of food, drugs, and medical devices; emergency preparedness and public health; and meaningful and secure exchange of electronic health information. In addition, OIG will continue to promote voluntary compliance in the health care industry by providing guidance to health care providers and pursuing affirmative administrative enforcement actions against those who commit fraud.

OIG continues to protect HHS programs and the well-being of beneficiaries by detecting and preventing fraud, waste, and abuse; identifying opportunities to improve program economy, efficiency, and effectiveness; and holding accountable those who do not meet program requirements or who violate Federal laws. Since its establishment in 1976, this office has consistently achieved commendable results and significant returns on investment.

I am confident that the funding requested will improve programs that protect the health and welfare of all Americans.

Daniel R. Levinson
Inspector General

<http://oig.hhs.gov/>

The FY 2016 Justification of Estimates for Appropriations Committees

U.S. Department of Health and Human Services
Office of Inspector General

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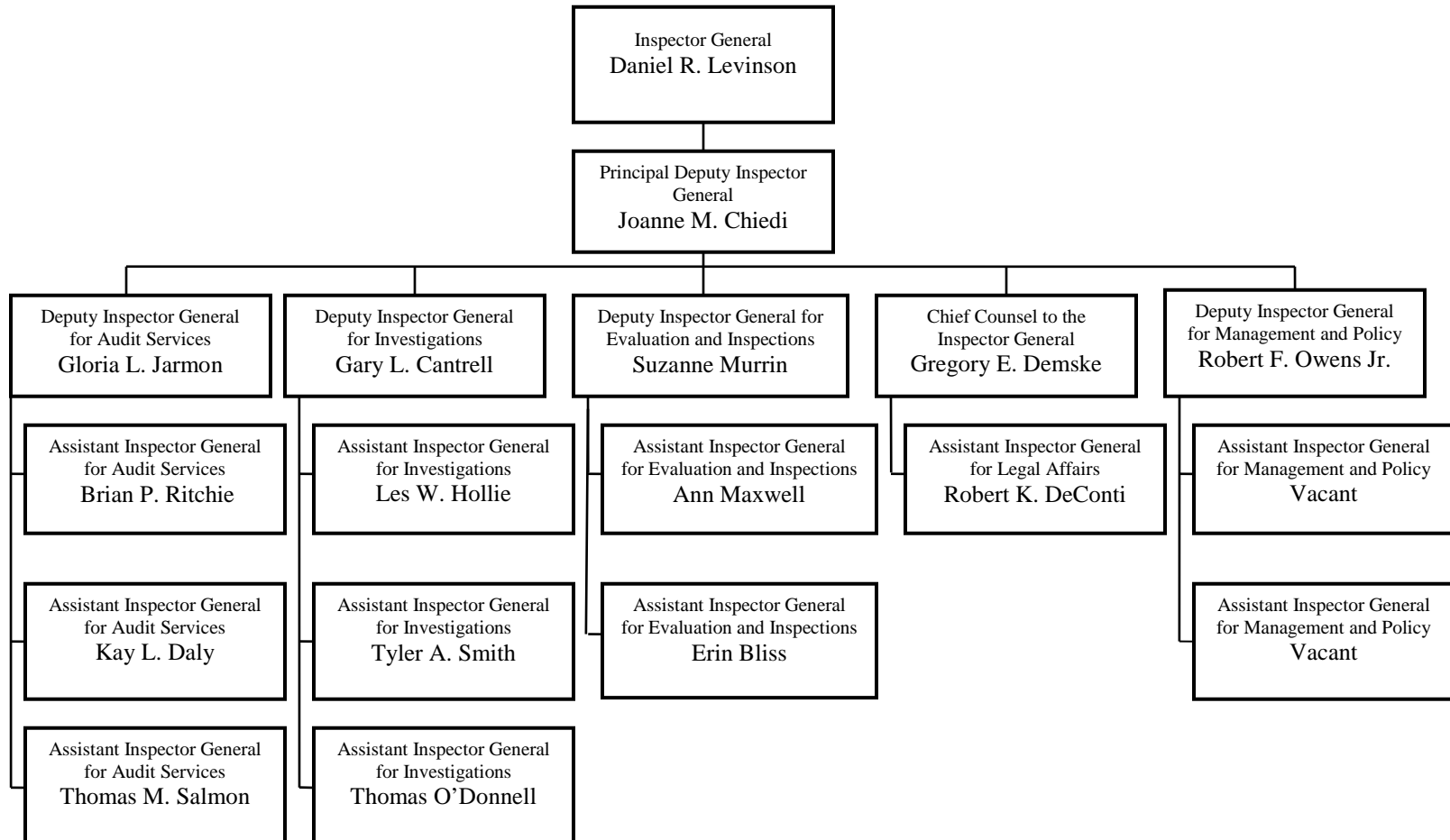
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**Department of Health and Human Services
Office of Inspector General**

Organizational Chart



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Introduction

The Office of Inspector General's (OIG) fiscal year (FY) 2016 budget requests \$417 million to support OIG's efforts to oversee the administration of the Department of Health and Human Services (HHS) public health and human services (PHHS) programs and Health Insurance Marketplaces, while continuing to support and expand the joint HHS and Department of Justice (DOJ) Health Care Fraud Prevention and Enforcement Action Team (HEAT) initiative and other Medicare and Medicaid program integrity efforts.

With the requested FY 2016 resources, OIG will continue its fraud-fighting efforts and heighten its focus on reducing waste in HHS programs. Waste includes fraud, but also unnecessary services, inefficient delivery of care or service, poor quality of care or services, inflated prices, excess administrative costs, or mismanagement of grant or contract funds. The Institute of Medicine (IOM) estimated that 30 percent of U.S. health spending (public and private) in 2009—roughly \$750 billion—was wasted. Other estimates suggest similar levels of waste.

To secure the continued financial viability of its programs, HHS must be vigilant in reducing waste and increasing the cost-effectiveness and value of its programs. Addressing waste requires a robust and multifaceted program integrity approach. The FY 2016 budget will support OIG efforts to address this challenge by providing oversight, identifying vulnerabilities, and making recommendations for program improvements.

OIG at a Glance: FY 2014

Oversight

- OIG was responsible for overseeing approximately 27 cents of every Federal dollar spent.
- On average, each OIG full-time equivalent (FTE) was responsible for overseeing over \$594 million.
- Seventy-six percent of efforts were dedicated to oversight of Medicare and Medicaid.

Accomplishments

- **Expected Recoveries:** A total of \$4.9 billion in total investigative and audit receivables were reported.
- **Program Exclusions:** A total of 4,017 individuals and organizations were excluded from participation in Federal health care programs.
- **Return on Investment (ROI):** A return on investment of approximately \$8 to \$1 was reported for the Health Care Fraud and Abuse Control (HCFAC) program in 2013, in which OIG is a key partner.
- **Quality and Management Improvement Recommendations:** A total of 160 quality and management improvement recommendations were accepted by HHS program managers.

Staffing

- A total of 1,574 FTE were located in 78 cities.

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Overview of Budget Request

The FY 2016 request for OIG includes \$417 million and 1,821 FTE, an increase of +\$80 million and +230 FTE above the FY 2015 Enacted Level. Program increases include:

- PHHS Oversight¹ (+\$11 million, +38 FTE): To assess and ensure the effectiveness of HHS's administrative, financial, and program management; beneficiary protections; and oversight and use of grant and contract funds. The goals are to reduce waste, fight fraud, promote effectiveness, and protect beneficiaries across PHHS programs. Specific programmatic focus areas include the Health Insurance Marketplaces, emergency preparedness and disaster relief, food and drug safety, information technology, and child support enforcement.

Additional funding will support OIG's efforts to increase its level of grant and procurement oversight, at a time when HHS's business purchases are increasing significantly; expand its capacity to analyze data, identify fraud trends, and determine the best approach for oversight for the PHHS programs; and follow through on plans to expand its efforts to assess whether HHS's public health and safety programs are effectively protecting beneficiaries, promoting public health, overseeing compliance with safety and quality standards, and ensuring appropriate access to services and benefits.

- Medicare and Medicaid Oversight (+\$70 million, +192 FTE): To support and strengthen OIG's efforts to protect Medicare and Medicaid from fraud, waste, and abuse; enhance OIG's fraud detection, prevention, and enforcement efforts, including the Medicare Strike Force teams and affirmative litigation of civil monetary penalty (CMP) cases; and deter future fraud.

OIG's oversight work in FY 2016 will target wasteful spending, including improper payments, unreasonable payment methodologies, and unsafe or low quality health care. Oversight of specific programmatic areas includes Medicaid expansion, including beneficiary enrollment, managed care, and the sufficiency of data used for oversight; prescription drug fraud and abuse; promoting industry compliance; contracting and contractor oversight; Medicare Advantage payment accuracy; home health agency compliance and payments; and new payment and delivery models in Medicare and Medicaid.

OIG's [Strategic Plan](#) and annual assessment of the *Top Management and Performance Challenges* facing HHS will continue to guide OIG work in FY 2016.

¹ PHHS oversight includes oversight of programs authorized in Title I of the Affordable Care Act (ACA) and administered by the Centers for Medicare & Medicaid Services (CMS).

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Overview of Performance

OIG's [Strategic Plan](#) outlines the vision and priorities that guide OIG in carrying out its mission to protect the integrity of HHS programs and operations and the health and welfare of the people they serve. The Strategic Plan articulates four goals that drive OIG's work:

- fight fraud, waste, and abuse;
- promote quality, safety, and value;
- secure the future; and
- advance excellence and innovation.

OIG ensures an efficient and effective use of its resources through integrated planning, monitoring, and reporting processes. Together these processes are used to set organizational priorities that best further our strategic goals, measure and analyze the impact of our work, and inform strategic and operational change.

Planning: OIG plans its work and allocates its resources using a number of factors. These include the purpose limitations in OIG's various funding sources, authorizing statutes and mandates, stakeholder input, and risk assessments of HHS programs. OIG plans work on an ongoing basis and publishes a [Work Plan](#). Priorities identified in the work-planning process correspond with issues outlined in the HHS [Top Management and Performance Challenges](#) as well as the goals and objectives expressed in the [OIG Strategic Plan](#). Throughout the year, OIG responds to emerging issues and adjusts its work priorities.

Monitoring: OIG monitors its efforts through qualitative and quantitative metrics, capturing both outputs and outcomes, which are integrated into executive performance plans of OIG's senior leadership.

Reporting: OIG produces, or is a significant contributor to, several comprehensive annual or semiannual reports that communicate the impact of our work to Congress and the public. These reports include the OIG [Semiannual Report to Congress](#), the HCFAC [Annual Report](#), and the [Compendium of Priority OIG Recommendations](#).

Significant Accomplishments

As reported in OIG's Fall 2014 [Semiannual Report to Congress](#), OIG reported expected recoveries of approximately \$4.9 billion for FY 2014. This includes \$4.1 billion in investigative receivables (which includes \$1.1 billion in non-HHS investigative receivables resulting from OIG's work in areas such as States' share of Medicaid restitution) and \$835 million in audit receivables. OIG also identified about \$15.7 billion in savings estimated for FY 2014 as a result of legislative, regulatory, or administrative actions that were supported by its recommendations.

Additionally, in FY 2014, OIG excluded 4,017 individuals and organizations from participation in Federal health care programs. OIG reported 971 criminal actions against individuals or

organizations that engaged in crimes against HHS programs and 533 civil and administrative enforcement actions, including False Claims Act and unjust enrichment suits filed in Federal district court, CMP law settlements, and administrative recoveries related to provider self-disclosure matters. OIG work also prevents fraud and abuse through industry outreach and guidance and recommendations to remedy program vulnerabilities.

For a more complete discussion of OIG's outcome and output measures and recent performance results, refer to the sections of this document describing OIG's PHHS (beginning on page 31) and Medicare and Medicaid (beginning on page 41) oversight work.

All-Purpose Table¹

(Dollars in Thousands)

	FY 2014 Final	FY 2015 Enacted	FY 2016 Pres. Bud.	FY 2016 +/- FY 2015
PHHS Oversight:²				
Discretionary Budget Authority (BA) ³	\$71,000	\$72,500	\$83,000	+\$10,500
Subtotal, PHHS Oversight BA	71,000	72,500	83,000	+10,500
Medicare and Medicaid Oversight:				
HCFAC Mandatory BA	184,979	186,066	203,262	+17,196
HCFAC Discretionary BA	28,122	67,200	118,631	+51,431
Subtotal, Medicare and Medicaid Oversight BA⁴	213,101	253,266	321,893	+68,627
HCFAC Estimated Collections ⁵	10,765	11,124	12,000	+876
Subtotal, Medicare and Medicaid Oversight Program Level (PL)	223,866	264,390	333,893	+69,503
Total BA	284,101	325,766	404,893	+79,127
Total PL	\$294,866	\$336,890	\$416,893	+\$80,003
FTE	1,574	1,591	1,821	+230

¹ Table excludes non-HCFAC reimbursable funding. In FY 2014, OIG obligated \$15 million in non-HCFAC reimbursable funding. The estimate for FYs 2015 and 2016 is \$21 million. This estimate includes funds from section 6201 of the ACA for OIG to evaluate a nationwide program for national and State background checks on direct patient access employees of long-term-care facilities and providers. OIG obligated \$56,000 for this effort in FY 2014.

² PHHS oversight includes oversight of programs authorized in Title I of the ACA and administered by the Center for Consumer Information and Insurance Oversight (CCIIO), a component of CMS.

³ In FY 2015, OIG's Discretionary BA includes \$1.5 million, transferred from the Food and Drug Administration (FDA), consistent with the Consolidated and Further Continuing Appropriations Act, 2015.

⁴ OIG's HCFAC funding is drawn from the Medicare Hospital Insurance Trust Fund (sec. 1817(k)(3) of the Social Security Act) and is requested and provided through the CMS budget.

⁵ In FY 2014, OIG collected \$11.6 million under authority of 42 U.S.C. 1320a-7c (section 1128C of the Social Security Act), and the actual amount sequestered is \$0.9 million. The table includes estimates for HCFAC collections for FYs 2015 and 2016, and the amounts available will depend on the amounts actually collected.

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Appropriations Language**Office of Inspector General**

For expenses necessary for the Office of Inspector General, including the hire of passenger motor vehicles for investigations, in carrying out the provisions of the Inspector General Act of 1978, [\$71,000,000]\$83,000,000: Provided, That of such amount, necessary sums shall be available for providing protective services to the Secretary and investigating non-payment of child support cases for which non-payment is a Federal offense under 18 U.S.C. Section 228.

Amounts Available for Obligation ¹

(Dollars in Thousands)

	FY 2014 Final	FY 2015 Enacted	FY 2016 Pres. Bud.
Discretionary			
<u>General Fund Discretionary Appropriation:</u>			
Appropriation (Labor/HHS).....	\$71,000	\$71,000	\$83,000
Rescission/Increase (Labor/HHS)	--	--	--
Subtotal, Appropriation (Labor/HHS)	71,000	71,000	83,000
Amount sequestered	--	--	--
Total, Discretionary Appropriation	71,000	71,000	83,000
<u>Transfers</u>			
Transfer of funds from FDA	--	1,500	--
Amount sequestered	--	--	--
Total, Disaster Relief Appropriations Act	--	1,500	--
<u>Offsetting collections from:</u>			
Trust Fund HCFAC Discretionary	28,122	67,200	118,631
Rescission/Increase (Labor/HHS).....	--	--	--
Subtotal, HCFAC Discretionary.....	28,122	67,200	118,631
Amount sequestered.....	--	--	--
Total, Discretionary Offsetting Collections	28,122	67,200	118,631
<u>Offsetting collections from:</u>			
Trust Fund HCFAC Mandatory	199,331	200,718	203,262
Amount sequestered.....	-14,352	-14,652	--
Trust Fund HCFAC Mandatory Additional Amounts.....	--	--	--
HCFAC Mandatory Recoveries.....	7,229	--	--
Estimated HCFAC Collections ²	10,125	12,000	12,000
Amount sequestered ²	-835	-876	--
Amounts previously sequestered, but available	516	835	876
Total, Mandatory Offsetting Collections	203,808	198,066	215,262
Total Discretionary and Mandatory			
Unobligated balance, lapsing	290	--	--
Unobligated balance, start of year	19,774	22,400	36,115
Unobligated balance, end of year.....	22,400	36,115	68,849
Total, Obligations	\$300,014	\$324,051	\$384,159

¹ Table excludes non-HCFAC reimbursable funding. In FY 2014, OIG obligated \$15 million in non-HCFAC reimbursable funding. The estimate for both FYs 2015 and 2016 is \$21 million.

² The table includes the estimated amounts for FY 2015 and FY 2016.

Summary of Changes
(Dollars in Thousands)

2015		
Total, BA		\$72,500
Obligations.....		72,500
2016		
Total, Estimated BA		83,000
Estimated Obligations.....		83,000
Net Change in BA.....		+\$10,500

	FY 2016 Estimate <u>FTE</u>	FY 2016 Estimate <u>BA</u>	Change From Base <u>FTE</u>	Change From Base <u>BA</u>
Increases:				
A. Built in:				
1. Provide for salary of FTE	414	\$64,621	+51	+\$8,749
<i>a. Pay to support additional FTE (non-add).....</i>	<i>51</i>	<i>7,850</i>	<i>+51</i>	<i>+7,850</i>
<i>b. Increase due to 1- percent pay</i>				
<i>raise (non-add)</i>	<i>--</i>	<i>899</i>	<i>--</i>	<i>+899</i>
2. Increased costs related to General Services				
Administration (GSA) rent	<u>--</u>	<u>3,978</u>	<u>--</u>	<u>-153</u>
Subtotal, Built-in Increases.....	414	\$68,599	+51	+\$8,596
B. Program:				
1. Costs related to general operating expenses	<u>--</u>	<u>14,401</u>	<u>--</u>	<u>+1,904</u>
Subtotal, Program Increases.....	--	14,401	--	+1,904
Total, Increases	414	\$83,000	+51	+\$10,500

Note: Table displays OIG's Direct Discretionary funding only. OIG's HCFAC Discretionary BA is appropriated to the CMS HCFAC account.

Budget Authority by Activity

(Dollars in Thousands)

	FY 2014 Final	FY 2015 Enacted	FY 2016 Pres. Bud.
PHHS Oversight			
Discretionary BA ¹	\$71,000	\$72,500	\$83,000
Subtotal, PHHS Oversight BA	71,000	72,500	83,000
[Subtotal, PHHS Oversight PL	[71,000]	[72,500]	[83,000]
Medicare and Medicaid Oversight			
HCFAC Mandatory BA	184,979	186,066	203,262
HCFAC Discretionary BA	28,122	67,200	118,631
Subtotal, Medicare and Medicaid Oversight BA²	213,101	253,266	321,893
[HCFAC Collections ³	[10,765]	[11,124]	[12,000]
[Subtotal, Medicare and Medicaid Oversight PL ...]	[223,866]	[264,390]	[333,893]
Total, BA.....	284,101	325,766	404,893
[Total PL.....]	[\$294,866]	[\$336,890]	[\$416,893]
FTE	1,574	1,591	1,821

Note: Table excludes non-HCFAC reimbursable funding. In FY 2014, OIG obligated \$15 million in non-HCFAC reimbursable funding. The estimate for both FYs 2015 and 2016 is \$21 million. This estimate includes funds made available in section 6201 of the ACA for OIG to evaluate a nationwide program for national and State background checks on direct patient access employees of long-term-care facilities and providers. OIG obligated \$56,000 for this effort in FY 2014.

Note: Bracketed information is not BA, but rather is PL information. The PL information is included for purposes of comparability.

¹ In FY 2015, OIG's Discretionary BA includes \$1.5 million, transferred from FDA, consistent with the Consolidated and Further Continuing Appropriations Act, 2015

² OIG's HCFAC BA is appropriated to the CMS HCFAC account.

³ In FY 2014, OIG collected \$11.6 million and the actual amount sequestered is \$0.9 million. The table includes estimates for HCFAC collections for FYs 2015 and 2016, and the amounts available will depend on the amounts actually collected.

Authorizing Legislation

(Dollars in Thousands)

	FY 2015 Amount Authorized	FY 2015 Actual	FY 2016 Amount Authorized	FY 2016 Pres. Bud.
<u>OIG:</u>				
Inspector General Act of 1978 (P.L. No. 95-452, as amended)	Indefinite	\$71,000	Indefinite	\$83,000
Health Insurance Portability and Accountability Act of 1996 (HIPAA) (P.L. No.104-191, as amended), HCFAC Mandatory	\$200,718	\$186,066	\$203,262	\$203,262
HIPAA, as amended, HCFAC Discretionary	Indefinite	\$67,200	Indefinite	\$118,631
HIPAA, as amended, HCFAC Collections	Indefinite	\$11,124 ¹	Indefinite	\$12,000 ¹
<u>Unfunded Authorizations</u>				
Supplemental Appropriations Act of 2008 (P.L. No. 110- 252, as amended)	\$25,000	--	\$25,000	--

¹ The table includes estimates for HCFAC collections for FYs 2015 and 2016, and the amounts available will depend on the amounts actually collected.

Appropriations History

	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
<u>FY 2007</u>				
Discretionary Direct	\$43,760,000	\$41,415,000	\$43,760,000	\$39,808,000
HCFAC Discretionary Allocation Adjustment	11,336,000	--	--	--
HCFAC Mandatory	160,000,000	160,000,000	160,000,000	165,920,000
Medicaid Oversight ¹	25,000,000	--	--	25,000,000
Never Events ²	--	--	--	3,000,000
<u>FY 2008</u>				
Discretionary Direct	44,687,000	44,687,000	45,687,000	44,000,000
Rescission	--	--	--	-769,000
HCFAC Discretionary Allocation Adjustment	17,530,000	36,690,000	36,690,000	--
HCFAC Mandatory	169,238,000	--	--	169,736,000
Medicaid Oversight ¹	25,000,000	--	--	25,000,000
<u>FY 2009</u>				
Discretionary Direct	46,058,000	44,500,000	46,058,000	45,279,000
HCFAC Discretionary Allocation Adjustment	18,967,000	18,967,000	18,967,000	18,967,000
HCFAC Mandatory	174,998,000	--	--	177,205,000
Medicaid Oversight ¹	25,000,000	--	--	25,000,000
Medicaid Oversight ³ (Supplemental)	--	--	--	25,000,000
Recovery Act: Medicaid Oversight	--	--	--	31,250,000
Recovery Act: General Oversight	--	--	--	17,000,000
<u>FY 2010</u>				
Discretionary Direct	50,279,000	50,279,000	50,279,000	50,279,000
HCFAC Discretionary Allocation Adjustment	29,790,000	29,790,000	29,790,000	29,790,000
HCFAC Mandatory ⁴	177,205,000	--	--	177,205,000
Medicaid Oversight	25,000,000	--	--	25,000,000
<u>FY 2011</u>				
Discretionary Direct	51,754,000	--	54,754,000	50,278,000
Rescission	--	--	--	-100,000
HCFAC Discretionary Allocation Adjustment	94,830,000	--	94,830,000	29,730,000
Rescission	--	--	--	-59,000
HCFAC Mandatory	177,205,000	--	--	197,998,000

¹ Funds appropriated for Medicaid Oversight in the Deficit Reduction Act of 2005 (DRA) (P.L. No. 109-171).

² The Tax Relief and Health Care Act of 2006 (P.L. No. 109-432) included \$3 million for OIG to study Medicare "never events."

³ Funds appropriated for Medicaid Oversight in the Supplemental Appropriations Act of 2008 (P.L. No. 110-252).

⁴ The HCFAC Mandatory amount for FY 2010 does not include \$1.5 million allocated to OIG by HHS.

Budget Exhibits

Department of Health and Human Services

Office of Inspector General

	<u>Budget Estimate to Congress</u>	<u>House Allowance</u>	<u>Senate Allowance</u>	<u>Appropriation</u>
<u>FY 2012</u>				
Discretionary Direct	\$53,329,000	--	\$50,178,000	\$50,178,000
Rescission	--	--	--	-95,000
Public Health Services Evaluation Set-Aside	10,000,000	--	--	--
HCFAC Discretionary Allocation Adjustment	97,556,000	--	97,556,000	29,730,000
Rescission	--	--	--	-56,000
HCFAC Mandatory	193,387,000	--	--	196,090,000
<u>FY 2013</u>				
Discretionary Direct	58,579,000	--	55,483,000	50,083,000
Rescission	--	--	--	-100,000
Sequestration	--	--	--	-2,518,000
HCFAC Discretionary Allocation Adjustment	102,500,000	--	102,500,000	29,855,000
Rescission	--	--	--	-59,348
Sequestration	--	--	--	-1,492,771
HCFAC Mandatory ¹	196,669,000	--	--	196,299,000
Sequestration	--	--	--	-10,011,228
Disaster Relief Appropriations Act of 2013	--	--	--	5,000,000
Sequestration	--	--	--	-251,849
<u>FY 2014</u>				
Discretionary Direct	68,879,000	--	59,879,000	71,000,000
HCFAC Discretionary Allocation Adjustment	29,790,000	--	107,541,000	28,122,000
HCFAC Mandatory	278,030,000	--	--	199,331,000
Sequestration	--	--	--	-14,351,831
<u>FY 2015</u>				
Discretionary Direct ²	75,000,000	--	72,500,000	72,500,000
HCFAC Discretionary Allocation Adjustment	28,122,000	--	112,918,000	67,200,000
HCFAC Mandatory	\$285,129,000	--	--	200,718,000
Sequestration	--	--	--	-14,652,449
<u>FY 2016</u>				
Discretionary Direct	83,000,000	--	--	--
HCFAC Discretionary Allocation Adjustment	118,631,000	--	--	--
HCFAC Mandatory	\$203,262,000	--	--	--
Sequestration	--	--	--	--

¹ The HCFAC Mandatory amount for FY 2013 does not include \$7.1 million that was allocated to OIG by HHS.

² The Discretionary Direct amount for FY 2015 includes \$1.5 million transferred from FDA, consistent with the Consolidated and Further Continuing Appropriations Act, 2015.

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OIG Summary of Request

(Dollars in Thousands)

	FY 2014 Final	FY 2015 Enacted	FY 2016 Pres. Bud.	FY 2016 +/- FY 2015
PHHS Oversight ^{1, 2}	\$71,000	\$72,500	\$83,000	+\$10,500
Medicare and Medicaid Oversight ³	223,866	264,390	333,893	+69,503
Total Request	\$294,866	\$336,890	\$416,893	+80,003
FTE	1,574	1,591	1,821	+230

Authorizing Legislation Inspector General Act of 1978, as amended
 FY 2016 Authorization Indefinite
 Allocation Method Direct Federal

Program Description

For over 35 years, OIG has safeguarded HHS expenditures and beneficiary well-being and has promoted the economy, efficiency, and effectiveness of HHS programs. Legislative and budgetary requirements shape OIG activities. These activities are carried out in accordance with professional standards established by the Government Accountability Office (GAO), DOJ, and the IG community.

OIG's areas of oversight fall into two broad categories: (1) PHHS and (2) Medicare and Medicaid. In a given year, the amount of work conducted in each category is set by the purpose limitations in OIG's appropriations. OIG's funding that is directed toward oversight of the Medicare and Medicaid programs constitutes a significant portion of its total funding (about 76 percent in 2014). The remaining share of OIG's efforts and resources addresses HHS's other programs and management processes, including food and drug safety, disaster relief, child

¹ PHHS oversight includes oversight of programs authorized in Title I of the ACA and administered by CCHIO.

² In FY 2015, PHHS oversight includes \$1.5 million transferred from FDA, consistent with the Consolidated and Further Continuing Appropriations Act, 2015.

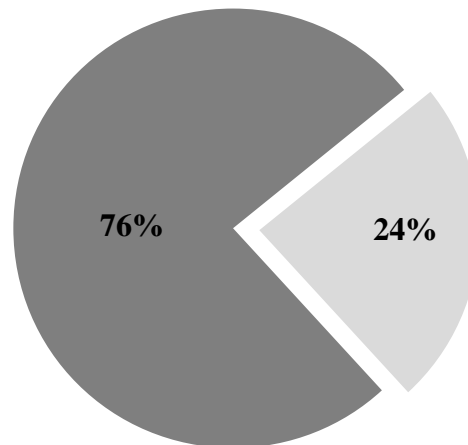
³ The request for Medicare and Medicaid oversight includes HCFAC funding, which is drawn from the Medicare Hospital Insurance Trust Fund (sec. 1817(k)(3) of the Social Security Act) and is requested and provided through the CMS budget. Additionally, this total includes an estimate for HCFAC collections.

support enforcement, the integrity of departmental contracts and grants management processes and transactions, and oversight of the ACA-established Health Insurance Marketplaces.

OIG's Areas of Oversight

Medicare and Medicaid Oversight Areas Include:

- Medicare Part A
- Medicare Part B
- Medicare Parts C and D
- Medicaid
- Children's Health Insurance Program (CHIP)



PHS Oversight Areas Include:

- Health Insurance Marketplaces and related programs management
- Financial program management
- Food and drug safety
- Child support enforcement
- Emergency preparedness

OIG accomplishes its mission through the complementary efforts of five components, which are:

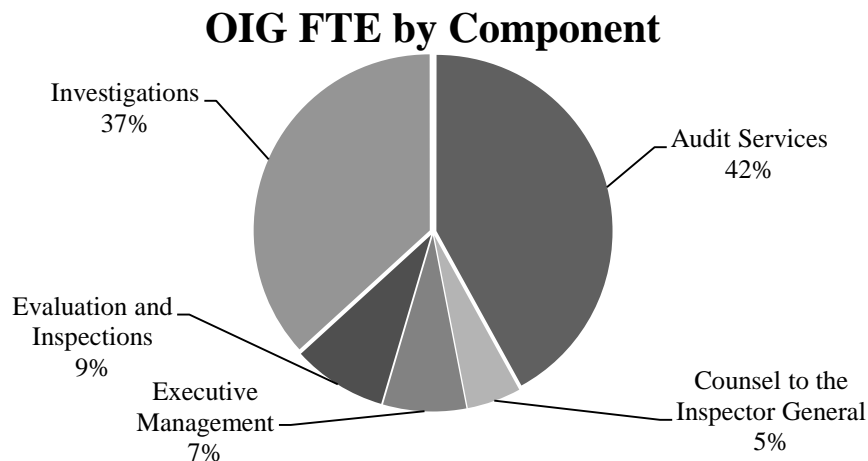
- Office of Audit Services (OAS): OAS provides auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work performed by others. Audits examine the performance of HHS programs and its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations. These assessments help reduce waste, abuse, and mismanagement and promote economy and efficiency throughout HHS.
- Office of Investigations (OI): OI conducts criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs, operations, and beneficiaries. OI actively coordinates with DOJ and other Federal, State, and local law enforcement authorities. OI's investigations often lead to criminal convictions, civil recoveries, CMPs, exclusions from participation in Federal health care programs, and administrative sanctions.
- Office of Evaluation and Inspections (OEI): OEI conducts national evaluations to provide HHS, Congress, and the public with useful and reliable information on significant issues. These evaluations focus on preventing fraud, waste, and abuse and promoting economy, efficiency, and effectiveness in departmental programs. To promote impact, OEI reports also present practical recommendations for improving program operations.

- Office of Counsel to the Inspector General (OCIG):** OCIG provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support for OIG’s internal operations. OCIG represents OIG in all civil and administrative fraud and abuse cases involving HHS programs, including False Claims Act, program exclusion, and CMP cases. In connection with these cases, OCIG also negotiates and monitors corporate integrity agreements (CIAs). OCIG renders advisory opinions, issues compliance program guidance, publishes fraud alerts and special bulletins, develops provider education resources and promotes compliance, and provides other guidance to the health care industry concerning the anti-kickback statute and other OIG enforcement authorities.
- Executive Management (EM):** EM is composed of the Immediate Office of the Inspector General and the Office of Management and Policy. EM is responsible for generally supervising and coordinating the activities of OIG’s components; setting vision and direction, in collaboration with the components, for OIG’s priorities and strategic planning; ensuring effective management of budget, finance, information technology (IT), human resource management, and other operations; and serving as a liaison with HHS, Congress, and other stakeholders. EM plans, conducts, and participates in a variety of cooperative projects within HHS and with other Government agencies.

The specialties and technical skills of OIG’s multidisciplinary professionals enable OIG to implement a multifaceted program integrity approach. OIG assesses HHS programs at a systemic level to promote economy, efficiency, and effectiveness, while also identifying and addressing specific instances of suspected fraud, waste, and abuse.

OIG maintains a Washington, DC, office and a nationwide network of regional and field offices; over 70 percent of employees work outside the Washington metropolitan area. At all levels, OIG staff work closely with HHS and its operating divisions (OPDIVs) and staff divisions (STAFFDIVs); DOJ, other IG offices, and other Federal agencies in the executive branch; Congress; and States to bring about systemic changes, successful prosecutions, negotiated settlements, and recovery of funds to protect the integrity of HHS programs and expenditures and the well-being of beneficiaries.

In FY 2014, the OIG staff was composed of 1,574 FTE, who were distributed among the five components as follows:

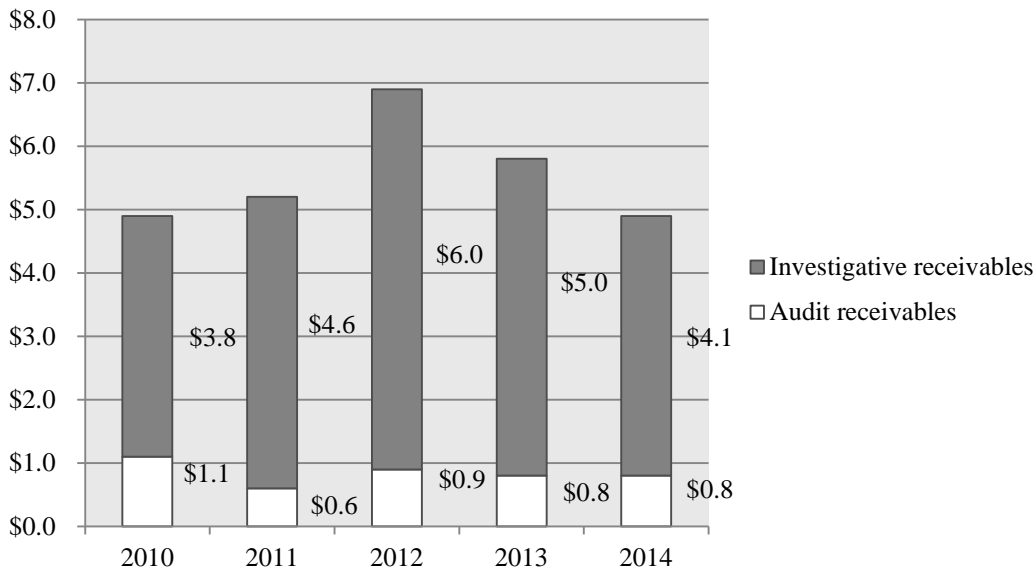


Accomplishments

In OIG’s Fall 2014 *Semiannual Report to Congress*, OIG reported expected recoveries¹ of approximately \$4.9 billion for FY 2014. This includes \$4.1 billion in investigative receivables (which includes approximately \$1.1 billion in non-HHS investigative receivables resulting from OIG’s work, such as States’ shares of Medicaid restitution) and \$0.8 billion in audit receivables. OIG also identified approximately \$15.7 billion in cost savings estimated for FY 2014 as a result of legislative, regulatory, or administrative actions that were supported by its recommendations.

- **Expected Recoveries:** As reflected in the following graph, over the last 5 years, OIG’s expected recoveries have averaged over \$5 billion annually. Changes in the amount of expected recoveries from year to year are due to the particular mix of cases resolved in a given year, as well as continued efforts to work with OPDIVs to implement OIG recommendations.

OIG Expected Recoveries, FYs 2010 - 2014
(Dollars in Billions)



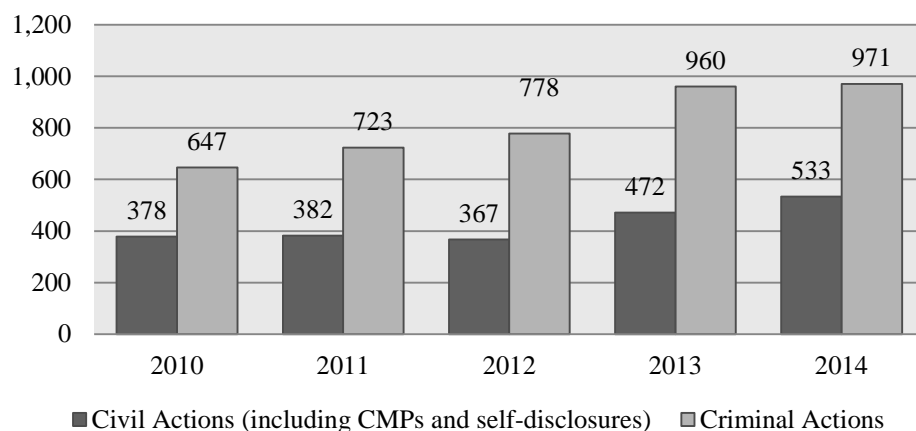
- **Cost savings:** OIG identified approximately \$15.7 billion in estimated savings for FY 2014. This estimate reflects prior-period legislative, regulatory, or administrative actions that were supported with OIG recommendations. Such estimates generally reflect third-party projections (such as those by Congressional Budget Office (CBO) or HHS actuaries) made at the time the action was taken. Actual savings may be higher or lower.

¹ Expected Recoveries are the amount the Government expects to recover or receive as a result of OIG’s oversight efforts. These amounts are typically post-adjudicated amounts and CMPs on the investigative side and, in case of audits, recommendations that HHS management has agreed to and taken action on. Additional details are available in OIG’s *Semiannual Report to Congress*.

Savings of this kind generally reflect not only OIG work, but also the contributions of others, including those in HHS program agencies, the Congress, and GAO. At all levels, OIG works closely with its Federal partners to bring about successful systemic improvements through modifications to administrative policies, processes, and procedures or changes to existing regulations and law.

- Criminal and Civil Actions¹ and Program Exclusions:** In FY 2014, OIG reported 971 criminal actions, a 50-percent increase above the percentage for FY 2010, against individuals or organizations that engaged in crimes against HHS programs. The increased actions in recent years can be attributed to increased Strike Force efforts, efficiencies gained through better targeting efforts through use of data, and an increase in cases focused on the quality of care for the beneficiary². Additionally, OIG reported 533 civil and administrative actions. Among other things, civil and administrative actions include False Claims Act suits filed in Federal district court and CMP cases, some of which resolve matters self-disclosed by providers. The number of civil and administrative actions has increased approximately 40 percent since FY 2010. During FY 2014, OIG concluded CMP settlements involving more than \$33.1 million in penalties and assessments.

**Civil and Criminal Actions
FYs 2010 - 2014**

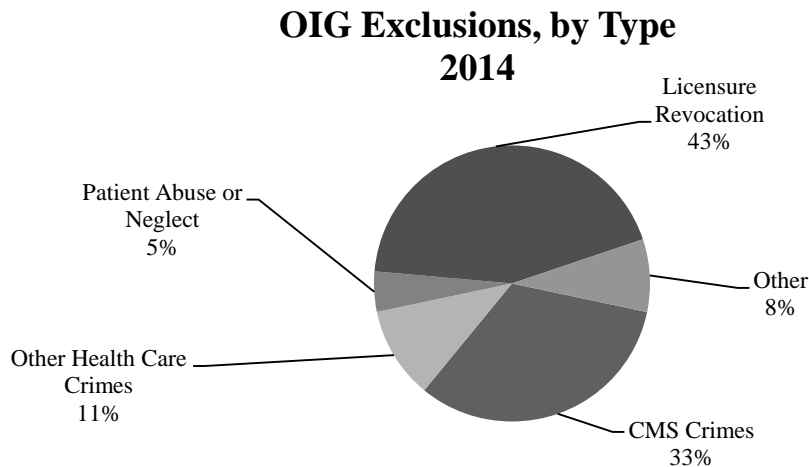


Also in FY 2014, OIG excluded 4,017 individuals and organizations from participating in Federal health care programs, approximately 25 percent above the number excluded in FY 2013. OIG achieved these results by enhancing processes and boosting productivity, while improving outreach to State and Federal partners in an effort to improve the quantity and quality of referrals. Included in the FY 2014 exclusions were those based on convictions for crimes related to Medicare and Medicaid (1,310) or to other health-care-

¹ OIG defines “criminal action” as a conviction or pretrial or precharging diversion agreement. A “civil action” is a civil settlement or judgment or a CMP law action.

² For more information on Strike Forces, please see page 44.

related matters (432), patient abuse or neglect (189), or licensure revocations (1,744). Approximately 49 percent were permissive exclusions, in which OIG had discretion to exclude certain individuals or entities on any of a number of grounds. The remaining 51 percent of OIG's FY 2014 exclusions were mandatory—OIG is required by law to exclude the individuals and entities from participating in all Federal health care programs because of the nature of their improper conduct. Additional information may be found at <http://oig.hhs.gov/fraud/exclusions.asp>.



- **CIA**s: OIG often negotiates compliance obligations with persons (e.g., corporations, individuals) as part of the settlement of allegations arising under civil and administrative false claims and fraud statutes. A person consents to these obligations as part of the civil settlement and in exchange for OIG's agreement not to seek exclusion from participation in Federal health care programs. CIAs typically last for 5 years. OIG monitors entities' compliance with CIAs and holds accountable those who violate them. CIAs generally include penalties for failure to meet certain terms, and OIG may exclude a person that has breached the CIA. During FY 2014, OIG entered into 39 new CIAs and, at the close of the year, was monitoring compliance with 205 CIAs.
- **Advisory Opinions, Education, and Other Guidance**: As authorized in statute and as part of continuing efforts to promote the highest level of health care industry ethics and lawful conduct, OIG issues advisory opinions and other guidance to educate industry and other stakeholders on how to avoid fraud and abuse. This enables OIG to help industry navigate the anti-kickback statute safe harbor regulations and other OIG health care fraud and abuse authorities. During FY 2014, OIG received 55 advisory opinion requests and, in consultation with DOJ, issued 15 advisory opinions.¹ During the 18 years of the HCFAC program, over 314 advisory opinions have been issued.

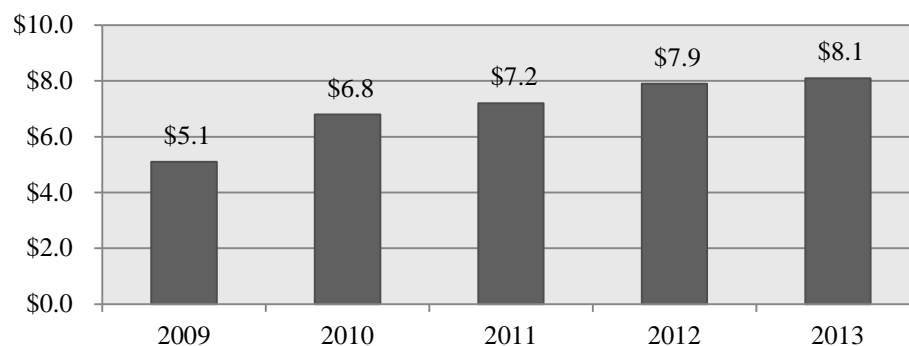
¹ OIG closes many advisory opinion requests without issuing opinions, frequently because the requests are withdrawn. In FY 2014, OIG closed 39 advisory opinion requests without issuing opinions.

OIG also develops outreach materials and conducts training about the Federal laws designed to protect HHS funds, programs, and beneficiaries from fraud and abuse. For example, OIG makes available on its web site a video series on grant and contract vulnerabilities using Hurricane Sandy funding as an example. OIG also posts podcasts that include compliance material, such as its 2014 podcast on Compliance With Federal Regulations for Reporting Allegations of Abuse and Neglect.

Additionally, OIG continues to look for ways to improve the effectiveness of its publications and expand on its work in key areas. This involves developing new work products to provide more timely information for policymakers; synthesizing related OIG work to provide additional perspective; and providing access to our work in more convenient and accessible formats, such as social media. An example of this approach is OIG's "Spotlight" articles summarizing our work in a specific area. In June 2013, OIG published a "Spotlight" on [drug diversion](#) and an accompanying podcast on its web site, highlighting OIG's work to address this fast growing public health problem. In addition, OIG published an OIG Alert directed, for the first time, at tribes and tribal organizations, reminding them of their obligation to protect from misuse IHS funds awarded under the Indian Self-Determination and Education Assistance Act and to ensure that Medicare and Medicaid reimbursements are expended in accordance with Federal law.

- HCFAC Program ROI:** Under the joint direction of the Attorney General and the Secretary of HHS acting through the IG, the HCFAC Program coordinates Federal, State, and local law enforcement activities with respect to health care fraud and abuse. The most recent ROI for the HCFAC program is approximately \$8 to \$1. This is a ratio of actual monetary returns to the Government to total HCFAC program appropriations. From the HCFAC Program's inception in 1997, program activities have returned more than \$25 billion to the Medicare Trust Funds. HCFAC's continued success confirms the soundness of a collaborative approach to identify and prosecute the most egregious instances of health care fraud, to prevent future fraud, and to protect program beneficiaries. The chart below shows the ROIs reported each year from FY 2009 through 2013.

**HCFAC Program Return on Investment
FYs 2009 - 2013**



Budget Request

The FY 2016 budget request for OIG includes \$417 million and 1,821 FTE, an increase of +\$80 million and +230 FTE above the FY 2015 Enacted Level. This request supports pressing oversight needs driven by current demographic trends, recent program changes, and the breadth of HHS programs. Examples include:

- An estimated 10,000 individuals become newly eligible for Medicare each day, and Medicaid enrollment is increasing significantly as a result of expanded eligibility in some States and increased awareness and outreach to uninsured populations nationally.
- HHS spending is approaching a trillion dollars annually, including over 76,000 PHHS grant awards.
- Implementation of new models of health care creating new vulnerabilities, challenges, and opportunities.
- Health care accounts for approximately 17 percent of Gross Domestic Product, yet the IOM estimates that up to 30 percent of health care dollars (public and private) are wasted.
- FDA regulates products that account for 20 to 25 percent of all U.S. consumer spending, and food, drug, and medical device safety affect the lives of nearly all Americans.
- Natural disasters (e.g., Hurricane Sandy) and infectious disease outbreaks (e.g., the recent Ebola outbreak) illustrate the critical need for oversight of the public health infrastructure and response.
- Threats to the security of personal and health information (e.g., recent hacking incidents involving hospitals), as well as the opportunities for health improvement and cost savings through information technology, warrant dedicated oversight, where appropriate, and enforcement efforts.
- Significant investments in electronic health IT and use warrant continued oversight to ensure that program goals are being achieved.

FY 2015 Funding

The Consolidated and Further Continuing Appropriations Act, 2015, included an additional \$40 million for OIG's oversight activities. This additional funding allows OIG to lift the hiring freeze that began in FY 2012 and provides an opportunity to acquire new skills in areas such as data analytics and technology.

The additional funding also supports significant nonpersonnel investments in FY 2015, including long-needed IT investments to address an aging infrastructure and medical record review services to function as a force multiplier for OIG activities.

The hiring and nonpersonnel investments in FY 2015 will position OIG to have significant impact on HHS programs moving forward.

- Serious emerging issues and events, such as the surge of unaccompanied children arriving in the United States, the meningitis outbreak linked to contaminated compounded drugs, or the increase in prescription drug fraud, affect health and human services and require a rapid assessment and effective oversight.

Consistent with its funding, OIG's spending falls into two broad categories: PHHS, including ACA Title I programs, and Medicare and Medicaid oversight. This submission includes:

- **PHHS Oversight**: To assess and ensure the effectiveness of HHS's administrative, financial, and program management; beneficiary protections; and oversight and use of grant and contract funds. The goals are to reduce waste, fight fraud, promote efficiency and effectiveness, and protect beneficiaries across PHHS programs. Specific programmatic focus areas include the Health Insurance Marketplaces, emergency preparedness and disaster relief, food and drug safety, IT, and child support enforcement.

Additional funding will support OIG's efforts to:

- increase its level of grant and contract oversight, at a time when HHS's business purchases are increasing significantly;
- provide additional oversight of HHS's financial and administrative management;
- follow through on plans to expand its efforts to assess whether HHS's emergency preparedness and public safety programs are effectively protecting beneficiaries, promoting public health, overseeing compliance with safety and quality standards, responding to emerging diseases and novel threats, and ensuring appropriate access to services and benefits;
- continue its efforts to protect consumers of food, drugs, and medical devices; and
- expand its capacity to analyze data, identify fraud trends, respond to cybersecurity threats, and determine the best approach for oversight for the PHHS programs.

Additional detail about OIG's PHHS oversight request can be found in the PHHS subsection beginning on page 31.

- **Medicare and Medicaid Oversight**: To support and strengthen OIG's efforts to protect Medicare and Medicaid from fraud, waste, and abuse; improve the quality and safety of care; enhance OIG's fraud detection, prevention, and enforcement efforts, including the Medicare Strike Force teams and affirmative litigation of CMP cases; and increase recoveries and deter future fraud.

OIG's oversight work in FY 2016 will target wasteful spending, including improper payments, unreasonable payment methodologies, and unsafe or low quality health care. Oversight of specific programmatic areas includes Medicaid expansion—including beneficiary enrollment, managed care, and the sufficiency of data used for oversight; prescription drug fraud and abuse; home- and community-based services (HCBS) fraud; promoting industry compliance; contracting and contractor oversight; Medicare Advantage payment accuracy; home health agency compliance and payments; and new payment and delivery models in Medicare and Medicaid.

The FY 2016 President's Budget will expand OIG's oversight of Medicare and Medicaid, at a time when these programs are changing and growing. Activities that will be supported with additional funds include:

- addressing prescription drug vulnerabilities on a national scale;
- overseeing changes in Medicaid, including managed care, access to services, and eligibility;
- promoting a culture of compliance among health care providers and businesses;
- ensuring quality of care in nursing home, hospice, or HCBS programs;
- assessing payment accuracy and value in Medicare and Medicaid;
- ensuring the meaningful and secure exchange and use of electronic health information; and
- enhancing OIG's prevention and enforcement efforts through the use of advanced data analysis, education, and training, among other tools.

Additional information about this request and the success of the HCFAC program and OIG's Medicare and Medicaid oversight efforts can be found in the "Medicare and Medicaid Oversight" subsection beginning on page 41.

OIG-Wide Performance Table

Key Outcomes¹	Most Recent Result (FY 2014)	FY 2015 Target	FY 2016 Target	FY 2016 +/- FY 2015
Expected recoveries resulting from OIG involvement in health care fraud and abuse oversight activities (dollars in millions)	\$4,4582 (Target exceeded)	\$4,000	\$4,000	--
ROI resulting from OIG involvement in health care fraud and abuse oversight activities	\$18.6:\$1 (Target exceeded)	\$15:\$1	\$15:\$1	--
Number of quality and management improvement recommendations accepted	160 (Target exceeded)	175	200	+25
PL funding (dollars in millions)	\$295	\$337	\$417	+\$80
Key Outputs	Most Recent Result (FY 2014)	FY 2015 Target	FY 2016 Target	FY 2016 +/- FY 2015
Audits:				
Audit reports started	334 (Target met)	313	338	+25
Audit reports issued	292 (Target met)	292	321	+29
Audit reports issued within 1 year of start (percentage)	44% (Target not met)	55%	55%	--
Evaluations:				
Evaluation reports started	55	61	66	+5
Evaluation reports issued	79 (Target exceeded)	55	60	+5
Evaluation reports issued within 1 year of start (percentage)	59% (Target exceeded)	55%	55%	--
Investigations:				
Complaints received for investigation	3,829 (Target not met)	4,000	4,000	--
Investigative cases started	2,102 (Target not met)	2,260	2,476	+216
Investigative cases closed	2,023 (Target met)	2,023	2,387	+364
PL funding (dollars in millions)	\$295	\$337	\$417	+\$80

¹ The “expected recoveries” and ROI performance measures are calculated using 3-year moving averages.

Performance Measures

Among other indicators, OIG uses three key outcome measures to express progress in accomplishing OIG's mission of combating fraud, waste, and abuse and promoting economy, efficiency, and effectiveness in HHS programs and operations:

- the 3-year moving average of expected recoveries from OIG's health care oversight activities that resulted in investigative receivables and audit disallowances,
- the 3-year moving average of the expected ROI from OIG's health care oversight activities that resulted in investigative receivables and audit disallowances, and
- the number of accepted quality and management improvement recommendations.

These measures (also shown on the table on the previous page) generally reflect the culmination of investigation, audit, and evaluation efforts initiated in prior years. Moreover, these measures are expressions of OIG's joint success and joint efforts with a network of program integrity partners at all levels of government. For example, OIG investigators and attorneys work closely with DOJ; Medicaid Fraud Control Units; and other Federal, State, and local law enforcement organizations to develop cases and pursue appropriate enforcement actions, which often include criminal or administrative sanctions and restitution to the Federal and State governments and other affected parties. Similarly, OIG audits and evaluations generate findings and recommendations intended to save money or improve programs. While OIG is not authorized to implement its recommendations, it informs Congress and HHS program officials of potential cost disallowances and corrective actions that may be taken to address the vulnerabilities OIG identifies.

As shown in the table on the previous page, several outputs contribute to OIG's success in meeting its goals. Many factors are considered when identifying OIG's output targets. An increase in resources in one fiscal year may not necessarily yield results in the same fiscal year, as some actions are multiyear matters. Performance targets reflect the time required to hire and train new staff. Similarly, a lack of resources can negatively impact performance results in future years.

A breakdown of OIG's output measures by PHHS and Medicare and Medicaid oversight can be found on pages 31 and 41, respectively.

**Subsection: Public Health, Human Services, and Departmentwide Issues
Oversight**
(Dollars in Thousands)

	FY 2014 Final	FY 2015 Enacted	FY 2016 Pres. Bud.	FY 2016 +/- FY 2015
Direct BA ¹	\$71,000	\$72,500	\$83,000	+\$10,500
Total PL	\$71,000	\$72,500	\$83,000	+\$10,500
FTE ²	376	376	414	+38

Program Description

HHS is the Government’s principal agency for protecting the health of all Americans and providing essential human services, especially for the most vulnerable. HHS’s eight U.S. Public Health Service agencies and two human services agencies operate hundreds of programs, with diverse missions, ranging from ensuring food safety to operating community health centers. OIG’s work in this area also includes the non-Medicare and non-Medicaid programs operated by CMS, such as the Marketplaces and related programs. During FY 2014, OIG’s oversight effort for PHHS was allocated across HHS OPDIVs and STAFFDIVs as follows:

HHS OPDIVs and STAFFDIVs	Percentage
ACA – Marketplaces/Title I Programs	27%
Administration for Children and Families (ACF).....	21%
Administration for Community Living (ACL)	<1%
Agency for Health Care Research and Quality (AHRQ).....	<1%
Centers for Disease Control and Prevention (CDC) / Agency for Toxic Substances and Disease Registry (ATSDR).....	3%
FDA	2%
Health Resources and Services Administration (HRSA).....	4%
Indian Health Service (IHS)	4%
National Institutes of Health (NIH)	6%
Substance Abuse and Mental Health Services Administration (SAMHSA).....	1%
Office of the Secretary (OS) ³	14%
Other PHHS Programs ⁴	17%

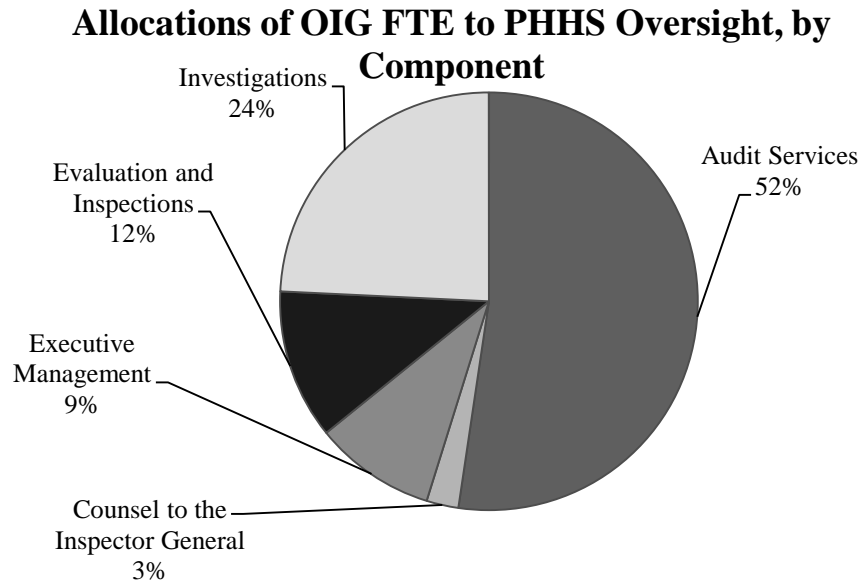
¹ Discretionary Direct BA for FY 2015 includes \$1.5 million transferred from FDA, consistent with the Consolidated and Further Continuing Appropriations Act, 2015.

² FTE reflects those supported by the OIG Direct Discretionary appropriation and funding from the Disaster Relief Appropriations Act of 2013.

³ OS includes oversight efforts related to OS STAFFDIVs, such as the Assistant Secretary for Preparedness and Response, as well as protective services for the Secretary, and the Chief Financial Officer Audit.

⁴ Examples of these efforts include grant and contract oversight that cross multiple OPDIVs.

In FY 2014, OIG's direct discretionary funding for PHHS Oversight supported 363 FTE, who were assigned across OIG's five components as follows:



Accomplishments

In FY 2014, OIG issued 56 audits and 11 evaluations related to PHHS oversight. In addition, OIG continued to participate in the child support enforcement collaborative effort with the Office of Child Support Enforcement in ACF, contributing to over 60 criminal actions and nearly \$5 million in restitution, fines, penalties, settlements, and recoveries. These efforts result in payments of vital child support to custodial parents. The following accomplishments are recent examples of the impact of OIG recommendations on PHHS programs.

- **The Indian Country Grant Fraud Initiative:** OIG's Indian Country Grant Fraud Initiative has resulted in 31 Federal criminal indictments, 20 convictions, and court-ordered restitutions ranging from \$10,000 to \$1.7 million. The project involves the review of various HHS grant programs—primarily the Low Income Home Energy Assistance program (LIHEAP), Temporary Assistance for Needy Families program, and Head Start program—overseen by HHS OPDIVs, such as ACF, IHS, and HRSA. Several Federal law enforcement agencies are assisting in the initiative, including other OIGs and the Federal Bureau of Investigation (FBI).

The project has exposed a number of fraudulent schemes, including theft and embezzlement; bribery of tribal officials and grantees; provision of false information on applications by recipients; unauthorized or inflated salaries (paid to staff, family, and friends); wages paid even though work was not performed or completed; and use of grant funds for personal travel.

- Improving the Effectiveness of Eligibility Verification Safeguards in Marketplaces: Two recent OIG reports address vulnerabilities in the verification procedures for Marketplace enrollment data. Our work found that not all internal controls at reviewed Marketplaces were effective and that Marketplaces were unable to resolve most inconsistencies between applicants' self-reported information and data obtained from other sources. CMS and reviewed State Marketplaces concurred with OIG's recommendations to strengthen eligibility verification internal controls. CMS also concurred with our recommendations to address resolution of inconsistencies.
- Vulnerabilities in the HHS Small Business Innovation Research Program: Although it was not required to do so, HHS did not consistently collect information on, or assess the commercial success of, Small Business Innovation Research Program awards and therefore cannot determine whether the program is meeting one of its primary goals. We found that 31 percent of awardees had questionable or unverified eligibility for at least one requirement, and none of the awarding OPDIVs completed a required check for duplicative awards across other Federal agencies.
- Creating Accountability for Scientific Disagreements Regarding Medical Device Regulatory Decisions: In response to recommendations in an OIG report, FDA's Center for Devices and Radiological Health (CDRH) revised its standard operating procedures for resolving internal differences of opinion in regulatory decisionmaking. The procedures now require all disputes, whether resolved formally or informally, to be fully documented. CDRH has also trained 75 percent of its reviewers and managers on these new procedures, tracking which employees have been trained. CDRH's regulatory decisions have significant implications for the public's health.
- Improving Vaccine Management in the Vaccines for Children Program (VFC): In response to recommendations in an OIG report, CDC issued interim guidance for vaccine storage and handling to emphasize the importance of weekly review of vaccine expiration dates and rotation of stock. Additionally, CDC

Priority Unimplemented Recommendations—PHHS

OIG presents opportunities for cost savings and/or improvements in program efficiency and effectiveness in its *Compendium of Unimplemented Recommendations*.

- FDA: Expand market surveillance of dietary supplements to enforce the use of disclaimers for structure/function claims and detect disease claims.
- ACF: Require that any prospective or current employee be disqualified for or terminated from employment with a Head Start grantee if the individual has been convicted of sexual abuse of a child, other forms of child abuse and neglect, or a violent felony.
- NIH: Promulgate regulations that address institutional financial conflicts of interest.

reissued its *VFC Operations Guide* to reinforce VFC providers' responsibility to properly manage their vaccine inventory. CDC also republished its reference manual titled *Storage and Handling Toolkit* to emphasize the importance of weekly review of expiration dates and rotation of vaccine stock, as well as immediate removal of expired vaccine.

- Strengthened Accountability Over the President's Emergency Plan for AIDS Relief (PEPFAR): As a result of our audits of PEPFAR, CDC indicates that it has implemented a range of corrective actions and program improvements, among them a comprehensive review of cooperative agreements, updated standard operating procedures, project officer refresher training, quality control checks, development of annual monitoring plans for each grantee, detailed documentation of site visits, and rigorous progress report oversight. PEPFAR allocates billions of dollars annually to foreign countries for combating HIV/AIDS, tuberculosis, and malaria. CDC awards funds to governments of these countries and other recipients to achieve the objectives of the program. To date, OIG has conducted 14 audits in 5 nations on 2 continents, Asia and Africa.
- Improving FDA's Foreign Clinical Trial Guidance: In FY 2012, as a result of an OIG report that highlighted the increased globalization of foreign clinical trials and the challenges faced as a result, FDA issued guidance for industry and staff on conducting foreign clinical trials. The guidance addresses the importance of standardized data, which will contribute to improved economy and efficiency.

Funding History

The funding history in the table below includes the BA provided to OIG for PHHS oversight. The funds displayed are provided to OIG through an annual Discretionary Direct appropriation included within the Labor, Health and Human Services, Education and Related Agencies appropriations bill. In FY 2015, \$1,500,000 was included in the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies appropriations bill for oversight of FDA.

FY	PHHS Oversight
2012	\$50,083,000
2013	47,465,000
2014	71,000,000
2015	72,500,000
2016	83,000,000

Budget Request

With funding from its annual Discretionary Direct appropriation, OIG conducts program integrity and enforcement activities with regard to PHHS programs and operations, including oversight of the Marketplaces and related programs created by Title I of the ACA. These programs represent over \$100 billion in spending each year, and are carried out by approximately 70,000 HHS employees spread across the globe.

OIG prioritizes the allocation of these resources to comply with the requirements in appropriations language and other directives established in law. These include requirements that OIG conduct or oversee reviews under the Federal Information Security Management Act (P.L. No. 107-347) and the Single Audit Act (P.L. No. 98-502), other IT audits, and investigations of interstate nonpayment of child support obligations. In addition, OIG provides protective services for the HHS Secretary using its discretionary appropriation.

The Consolidated Appropriations Act of 2014 (P.L. 113-76) provided an additional \$24 million for oversight of PHHS programs and operations. With the additional funding, OIG prioritized oversight of the Marketplaces and related programs created by Title I of the ACA. Much of this work is ongoing and is focused on payments, eligibility systems, CMS management and administration, data security, and consumer protection. While oversight of the ACA remains a priority, additional funds are needed to maximize the positive impact of OIG's overall PHHS oversight activities.

OIG's FY 2016 request is \$83,000,000, which is an increase of +\$10,500,000 and +38 FTE above the FY 2015 Enacted Level. The additional funds will be invested in the following areas:

- ***Grant and Contract Oversight.*** The FY 2016 request will allow OIG to place a greater emphasis on grant and contract oversight and will support OIG's oversight of HHS's efforts to foster sound stewardship and coordination across all HHS funds and programs. OIG will also build its contract expertise and increase focus on grant and contract fraud investigations, which would lead to a corresponding increase in enforcement or administrative actions, such as suspensions and debarments of HHS grantees and contractors. Examples of OIG's increased emphasis on grant and contract oversight include new or expanded work related to the growth in contract costs and values, HHS contracting qualifications, and the safety of Head Start facilities.

Implementing, Operating, and Overseeing the Marketplaces

The Marketplaces add a substantial new dimension to the Department's landscape. The Marketplaces must implement and successfully operate complex program requirements. Individuals use the Marketplaces to get information about their health insurance options; be assessed for eligibility (for, among other things, qualified health plans, premium tax credits, and cost sharing reductions); and enroll in the health plan of their choice.

OIG's oversight of the Marketplaces focuses on payments, eligibility, management and administration, and security. By focusing on these key areas, OIG hopes to ensure that taxpayer dollars are spent for their intended purposes in a system that operates efficiently and is secure.

HHS is the largest grant-making organization in the Federal Government; over 79,000 grants totaling \$389 billion were awarded in FY 2014. That amount comprised \$47 billion in discretionary awards and the remaining amount in formula/block grant and entitlement awards.

HHS is also the third largest contracting agency in the Federal Government. OIG has identified weaknesses in HHS contracting processes and contract management throughout the Department, and oversight is a particular concern. OIG work has revealed poor execution of required contractor performance assessments by HHS. Under the ACA, contractors have a vital role in building, maintaining, and fixing the systems that underpin the Federal Marketplace. HHS faces a challenge to ensure proper management and oversight of these and other contracts.

Furthermore, many HHS grant programs are operating in a public health care service environment that is undergoing significant changes. Recent CBO estimates indicate that millions of additional people will have insurance coverage as a result of the ACA, either through the Marketplaces or through expanded Medicaid coverage.

The size and scope of departmental awards make vigilant oversight by the Department crucial to the success of programs designed to improve the health and well-being of the public. Yet OIG has noted weaknesses in the oversight of grantees, as demonstrated by late or absent financial and related reports, insufficient documentation on progress toward meeting program goals, and failure to ensure that grantees obtain required annual financial audits.

A common problem uncovered by OIG reviews at the grantee level is that grantees lacked robust financial management systems, creating the need for program integrity efforts and compliance programs. Many grantees still do not account for specific costs on a grant-by-grant basis, making it difficult to reliably monitor and account for costs associated with specific grant awards. When combined with frequent findings of significant unallowable expenses, these conditions support the need for more purposeful and consistent oversight.

- *Financial and Administrative Management.* The FY 2016 request supports the expansion of programmatic and management reviews to identify opportunities to reduce waste from inefficiencies or duplication, as well as to improve compliance, effectiveness, and service delivery through more effective program management. OIG's increased emphasis on HHS's financial and administrative management will include new or expanded reviews of PHHS agencies to assess gaps and overlaps across agencies, the structure of leadership and staffing, goals and prioritization, alignment with agency missions, and use of resources. OIG will also review systems that interact with the public to provide outgoing information (e.g., NIH's clinicaltrials.gov) or to receive information from the public (e.g., FDA's adverse event reporting systems) to assess how OPDIVs ensure the reliability of the information provided and received, update the data systems, and evaluate the utility of these systems.

The Department manages health care insurance, public health, social services, and research programs designed to enhance the health, safety, and well-being of all Americans. Responsible stewardship of these programs is vital. Underpinning such stewardship should be a financial management and administrative infrastructure that employs appropriate internal controls to minimize risk to the programs and safeguard resources.

Financial statement audit results provide an important assessment of financial management challenges HHS faces. Independent auditors have identified material weaknesses in HHS's financial management systems related to IT security and a significant deficiency in its financial reporting systems, analyses, and oversight. HHS also faces continued challenges in addressing certain provisions of the Anti-Deficiency Act.

Further, careful coordination of Departmental staff, contract staff, grantees, and other partners is essential to achieve mission objectives in accordance with Federal, departmental, and agency requirements. Many grantees receive multiple awards from HHS, which does not currently have a central infrastructure to find information on all grants and contract awards. OIG is working to assist and assess what is necessary to reach a level of grant and contract management in which there is Departmentwide accountability.

While HHS has been taking steps to address outstanding financial and administrative management challenges, the need to increase oversight in these areas is significant.

- *Emergency Preparedness and Public Health.* HHS leads medical and public health responses to naturally occurring and man-made disasters that threaten Americans' health, safety, and well-being. Protecting public health requires international cooperation on a host of issues, including combating global outbreaks of disease and illness. OIG needs to acquire and develop additional expertise to effectively oversee these activities and to build on the related work done on the PEPFAR program.

With the requested funding, OIG will expand its oversight of HHS's preparedness for and response to disasters and emergencies, including the ability to exchange health information in such situations and communication and coordination with its partners at the Federal, State, and local levels. Additionally, the request will further efforts to ensure that program participants and beneficiaries have access to public health and emergency services and that they are being delivered appropriately. We will also increase oversight of OPDIVs and STAFFDIVs to ensure that they have the capacity and the ability to perform effective contract and grant administration. For instance, they must be able to quickly and effectively get grant funds out to grantees and contractors during a health- or weather-related emergency.

OIG's increased emphasis on emergency preparedness and public health will include new or expanded work to examine the integration and effectiveness of emergency

preparedness and infection control operations to combat public health risks, as well as the ways in which agencies are using information derived from electronic health records for public health surveillance purposes, such as identifying and monitoring outbreaks and targeting public health interventions.

- *Protecting Consumers of Food, Drugs, and Medical Devices.* HHS is responsible for protecting public health by ensuring the safety, efficacy, and security of drugs, medical devices, biologicals, and much of our Nation's food supply. Additionally, HHS must ensure that once a drug, biologic, or device has been approved for use, it is marketed appropriately. Furthermore, during a food emergency, HHS must find the contamination source and oversee the removal by manufacturers of these products from the market. In FY 2016, OIG will continue to evaluate the Department's management of food, drug, and device safety issues. Furthermore, OIG continues to work closely with FDA and DOJ to investigate illegal marketing practices by drug and device manufacturers.
- *Data and Technology.* To keep pace with the expanded role of technology in the delivery, monitoring, and evaluation of HHS services, OIG plans to increase its oversight of data and technology exchanged among and used by providers of HHS services, including contractors, grantees, and others, to ensure that data and technology are being used effectively to achieve program goals.

Performance Table for PHHS Oversight

Key Outputs	Most Recent Result (FY 2014)	FY 2015 Target	FY 2016 Target	FY 2016 +/- FY 2015
Audits:				
Audit reports started	111	80	89	+9
Audit reports issued	56	56	62	+6
Evaluations:				
Evaluation reports started	18	17	19	+2
Evaluation reports issued	11	11	13	+2
Investigations:				
Complaints received for investigation	670	700	700	--
Investigative cases started	446	455	522	+67
Investigative cases closed	301	301	343	+54
PL funding (dollars in millions)	\$71	\$73	\$83	+\$10

Additional PHS Performance Information

OIG oversight efforts take multiple forms and include reports and recommendations, as well as compliance and enforcement actions.

FY 2014 Reports and Cases by OPDIV

Category	Audit Starts	Audit Issued	Audit Recommendations	Evaluation Starts	Evaluations Issued	Evaluation Recommendations	Cases Opened	Cases Closed
ACA - Marketplaces	39	3	34	7	2	5	8	2
ACF	24	21	53	1	1	5	227	155
ACL	--	--	--	1	1	--	5	2
AHRQ	--	--	--	1	--	--	*	*
CDC	7	5	22	--	--	--	9	8
FDA	1	1	31	4	--	--	17	14
HRSA	5	--	--	2	--	3	4	6
IHS	6	4	6	--	--	--	30	21
NIH	6	9	14	--	1	--	*	*
SAMHSA	4	2	--	--	--	--	*	*
Grants and Contracts*	--	--	--	--	--	--	70	32
OS	19	11	54	2	2	9	21	14
Other	--	--	--	0	2	--	55	47
Total	111	56	214	18	11	22	446	301

* Grants and contracts cases include the include work from multiple OPDIVS.

Subsection: Medicare and Medicaid Oversight

(Dollars in Thousands)

	FY 2014 Final	FY 2015 Enacted	2016 Pres. Bud	FY 2016 +/- FY 2015
HCFAC Mandatory BA ¹	\$184,979	\$186,066	\$203,262	+\$17,196
HCFAC Discretionary BA	28,122	67,200	118,631	+51,431
HCFAC Estimated Collections	10,765	11,124	12,000	+876
Total PL	\$223,866	\$264,390	\$333,893	+\$69,503
FTE	1,186	1,203	1,395	+192

Program Description

Through its oversight work, OIG saves taxpayer dollars and works to ensure that patients receive medically appropriate care in the Nation's largest health care programs—Medicare and Medicaid. For FY 2014, potential savings from legislative and administrative actions that were supported by OIG recommendations were estimated by third parties, such as the Congressional Budget Office and HHS actuaries, to be \$14.4 to \$15.7 billion in Medicare savings and \$1.3 billion in savings to the Federal share of Medicaid. The size and scope of the Medicare and Medicaid programs create challenges to and heighten the importance of effective program administration; therefore, OIG's oversight role and program recommendations are crucial. Together, these programs, administered by CMS, serve approximately one in four Americans. In 2013, these programs accounted for over \$860 billion in Federal Government spending. Medicare, the single largest health insurance program in the Nation, processes more than 1 billion claims per year. Medicaid and CHIP are operated by States, but they are funded jointly with the Federal Government. They offer medical coverage to low-income individuals and families with dependent children; pregnant women; children; and aged and blind individuals and persons with disabilities. The ACA created the option for states to provide Medicaid coverage for low-income adults without children, effective January 1, 2014.

OIG protects these programs and their beneficiaries using a multidisciplinary approach, including an important partnership with DOJ. HIPAA established HCFAC under the direction of the Attorney General and the Secretary of HHS acting through the IG to combat fraud, waste, and abuse in health care. The funds OIG received under HIPAA are dedicated exclusively to activities relating to the Medicare and Medicaid programs. The ACA added significant new requirements and authorities intended to protect Medicare and Medicaid. Overall, HCFAC funding constitutes the major portion of OIG's annual operating budget.

¹ HCFAC funding is drawn from the Medicare Hospital Insurance Trust Fund (sec. 1817(k)(3) of the Social Security Act) and is requested and provided through the CMS budget. Information in this section provides an overview of OIG's Medicare and Medicaid oversight activities.

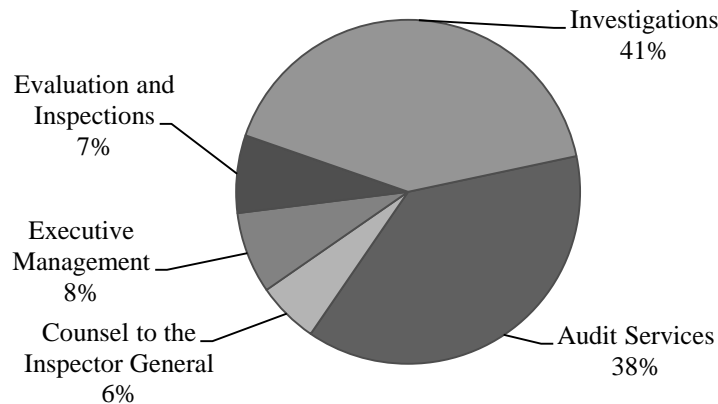
HEAT

Fighting health care fraud is a top priority for the Administration. Through the Health Care Fraud Prevention and Enforcement Action Team (HEAT), a Cabinet-level commitment to combat health care fraud, waste, and abuse, CMS, HHS-OIG, and DOJ carry out a coordinated program to reduce fraud and recover taxpayer dollars. Each HEAT partner plays a critical role in this effort to reduce Medicare and Medicaid fraud, waste, and abuse, including CMS’s enhanced provider screening and fraud prevention endeavors; OIG’s investigative, audit, evaluation, and data analytic work; and DOJ’s investigative and prosecutorial activities and tougher sentencing guidelines. Together, these efforts root out existing fraud and abuse and act as a deterrent for potential future bad actors. This collaboration continues to demonstrate positive results, yielding an \$8.1 to \$1 return on investment for law enforcement and detection efforts in FY 2013.

The HCFAC cap adjustment provided in the Consolidated and Further Continuing Appropriations Act, 2015, allows HHS and DOJ to enhance existing, successful health care fraud prevention and law enforcement efforts by investing more in proven anti-fraud and abuse strategies. Continuing to fund these efforts in FY 2016 up to the cap adjustment, as requested in this budget, will support enhancements in interagency HEAT efforts, strike a proper balance between prevention and enforcement, and return billions of dollars to the Federal Government.

In FY 2014, funding for Medicare and Medicaid oversight supported 1,186 FTE, who were assigned across OIG’s five components as follows:

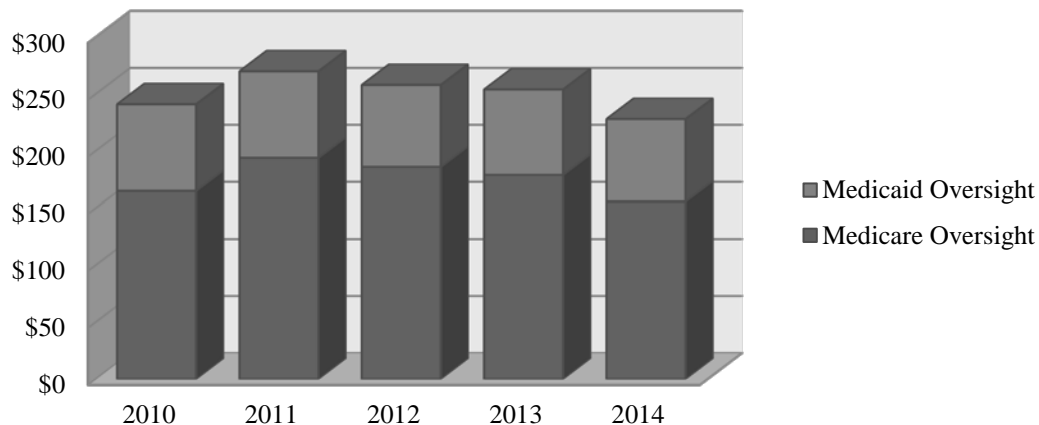
Allocation of OIG FTE to Medicare and Medicaid Oversight, by Component



In FY 2014, approximately 68 percent of OIG's appropriated resources for activities with respect to Medicare and Medicaid were allocated to Medicare oversight and approximately 32 percent were allocated to Medicaid. Many OIG activities benefit both programs. For example, excluding a provider who committed Medicare fraud also protects the Medicaid program from potential fraudulent billing by that provider and protects Medicare and Medicaid beneficiaries from being harmed or rendered substandard care by that provider.

OIG Obligations for CMS Oversight

(Dollars in Millions)



Accomplishments

As reported in other sections of the document, during FY 2014, OIG's oversight of Medicare and Medicaid resulted in significant expected health care monetary recoveries (which include non-HHS investigative receivables resulting from OIG's work, such as the States' shares of Medicaid restitution). Specific examples of OIG's recent Medicare and Medicaid oversight work include:

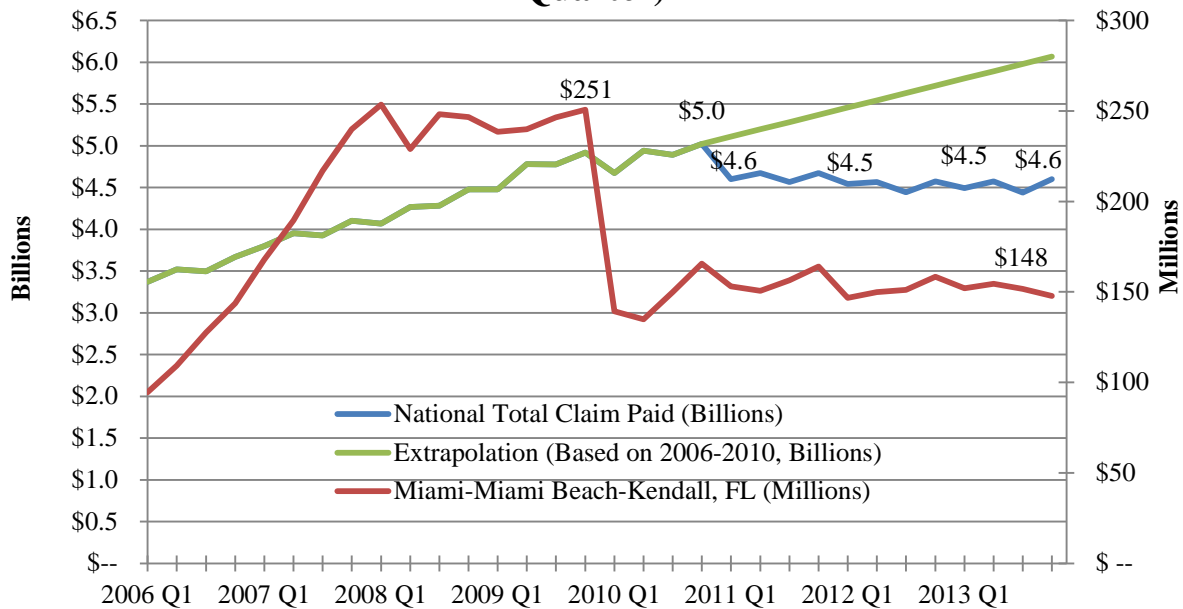
- Strike Forces—Targeting and Investigating Health Care Fraud in High-Risk Locales: Strike Forces have proven to be an effective means of identifying fraud and enforcing anti-fraud laws since inception in 2007. The Strike Forces work in nine locations: Miami, Florida; Los Angeles, California; Detroit, Michigan; Houston, Texas; Brooklyn, New York; southern Louisiana;¹ Tampa, Florida; Chicago, Illinois; and Dallas, Texas. In FY 2014 alone, OIG's Strike Force efforts resulted in:
 - charges filed against more than 228 individuals or entities and
 - more than 232 criminal actions and expected receivables of over \$441 million.

In addition, Medicare billing trends demonstrate the positive impact of Strike Force enforcement and prevention efforts. For example, Medicare payments for home health care

¹ While the Strike Force in southern Louisiana started in Baton Rouge, it now operates in New Orleans as well.

increased from 2006 until 2010. In 2009, Federal enforcement actions (initiated by the HEAT Strike Force case *U.S. v. Zambrana* in Miami), followed by OIG reports regarding home health outlier payments, influenced CMS to change Medicare’s HHA outlier coverage policy. As reflected on the chart below, since 2010, Medicare payments for home health care nationally decreased by more than \$300 million per quarter (e.g., more than \$1 billion annually). In Miami, payments for HHAs decreased by \$100 million per quarter since the peak in 2009; in Dallas and McAllen, Texas, payments for HHAs are down by \$30 million per quarter; while in Detroit, payments for HHAs decreased by \$25 million per quarter since peaking in 2009. This may suggest that the home health fraud convictions not only eliminated some of the “bad actors” but also deterred “would be” fraudsters. We have seen similar patterns of decreased billing for durable medical equipment (DME) and community mental health services following concentrated law enforcement initiatives and administrative fraud prevention efforts.

**Medicare Payments for Home Health Care, 2006-2013
U.S National and Miami Area, (Calendar Year per
Quarter)**



- Hospital Compliance Review—Inpatient and Outpatient Payments to Acute Care Hospitals: Using prior audits, investigations, and evaluations, along with computer and data-matching techniques, OIG identified multiple areas of risk to be reviewed in a single audit at each facility. The goals of these audits are to identify overpayments for recovery, assist the hospitals in improving their internal controls and compliance with Medicare rules, and increase provider awareness of common billing errors and the importance of compliance.
- Improving Billing Practices and Overall Spending in Skilled Nursing Facilities: OIG reports on payments to skilled nursing facilities (SNFs) contributed to policy changes that resulted in a forecast of lower than projected spending for SNF services. As noted in a recent Medicare Board of Trustees report, the decreased spending is one of the factors that positively impacted the solvency of the Hospital Insurance Trust Fund; the Fund is now estimated to remain solvent 9 years longer than previously estimated. In addition, CMS addressed a key recommendation made in the report series by developing and implementing a SNF model in its Fraud Prevention System to identify SNFs with aberrant billing practices.
- Recouping Payments to Ineligible Beneficiaries—Unlawfully Present and Incarcerated: As a result of OIG reviews, potentially \$190 million in overpayments was identified for care rendered to unlawfully present and incarcerated beneficiaries. OIG found that a beneficiary’s unlawful presence or incarceration dates overlapped with the dates of service on paid Medicare claims. OIG made several recommendations to CMS to improve its processes for recovering some of the improper payments and ensuring that Medicare no longer pays for services provided to unlawfully present and incarcerated beneficiaries.
- Excessive Rates Found at New York State-Operated Intermediate Care Facilities: New York’s Medicaid daily rate for 15 selected State-operated intermediate care facilities (ICFs or development centers) for individuals with intellectual and developmental disabilities did not meet Federal requirements that payments be consistent with economy and efficiency. The daily rate for Medicaid beneficiaries to

Priority Unimplemented Recommendations—Medicare and Medicaid Oversight

OIG presents opportunities for cost savings and/or improvements in program efficiency and effectiveness in its [Compendium of Unimplemented Recommendations](#).

- Improve monitoring and reporting of adverse events (incidents of patient harm resulting from care) in hospitals.
- Ensure that States report complete, accurate, and timely information to the national Medicaid database (known as T-MSIS) to support effective oversight.
- Limit enhanced payments to public providers to cost and require that Medicaid payments returned by public providers be used to offset the Federal share.
- Establish and enforce strong controls over claims for Medicare services with known program integrity vulnerabilities, including home health care, community mental health services, and skilled nursing services.

reside in the selected developmental centers grew from \$195 per day in State fiscal year (SFY) 1985 to \$4,116 per day in SFY 2009 (a rate more than nine times the average of all other State- and privately operated ICFs). The growth occurred because the State's rate-setting methodology significantly inflated the Medicaid daily rate for the developmental centers. Following issuance of the report, OIG testified before Congress on the developmental center rates, which led to a New York State plan amendment (effective April 1, 2013) that changed the rate to better reflect the actual costs of providing care. As a result of this change, the Federal Government saved approximately \$1.2 billion from April 2013 through September 2014. In addition, CMS issued a disallowance letter to New York for \$1.25 billion for 2010-2011 and plans to review 2 subsequent FYs.

- Johnson & Johnson Pays \$2.2 Billion To Resolve Violations of the False Claims Act and the Federal Food, Drug, and Cosmetic Act: In one of the largest health care fraud settlements in U.S. history, Johnson & Johnson (J&J) and its subsidiaries agreed to pay more than \$2.2 billion to resolve criminal and civil allegations relating to the prescription drugs Risperdal, Invega, and Natrecor. The allegations included promoting the drugs for uses not approved as safe and effective by FDA and paying kickbacks to physicians and to the Nation's largest long-term care pharmacy provider, Omnicare, Inc. According to court documents, sales representatives for J&J subsidiary Janssen Pharmaceuticals, Inc. (Janssen), allegedly urged physicians and other prescribers who treated elderly dementia patients to prescribe the drug Risperdal to treat symptoms of anxiety, agitation, depression, hostility, and confusion. Janssen allegedly created written sales aids for use by its ElderCare sales force that emphasized symptoms and minimized any mention of the FDA-approved use, which was for the treatment of schizophrenia. The company also provided incentives for off-label promotion and intended use by basing sales representatives' bonuses on total sales of Risperdal in their respective sales areas, not just the sales for FDA-approved uses. J&J agreed to pay a criminal fine, a forfeiture amount, and a civil settlement amount based on the False Claims Act. Also, Janssen pleaded guilty to one misdemeanor count of introduction of a misbranded drug (Risperdal) into interstate commerce. Finally, J&J entered into a CIA with OIG that includes provisions designed to promote accountability and transparency.
- Nationwide Review of Medicare Outpatient Services Results in Recoveries and Future Savings: In a nationwide series of audits of Medicare outpatient services in which payments exceeded charges, an OIG audit team achieved high-impact results through an innovative risk-based approach, which included the use of data mining and analysis that significantly reduced the resources required on the front end of each audit. The team completed a series of reviews whose objectives and scopes required auditing 15 Medicare contractors and approximately 2,600 hospitals. Pooling their resources for a more efficient approach, the team issued a total of 26 final reports to the Medicare contractors, resulting in expected recoveries totaling \$106 million. In addition, CMS implemented a verification policy edit as a result of these OIG audits, which is projected to save about \$30.3 million in future Medicare payments each year.

Funding History

The funding history in the table below includes the BA provided to OIG for Medicare and Medicaid oversight. The funds displayed are provided to OIG through a number of sources, including HCFAC Mandatory, HCFAC Discretionary Allocation Adjustment, and HCFAC Collections.

FY	Medicare and Medicaid Oversight
2012	\$238,164,000
2013	224,017,000
2014	223,866,000
2015	264,390,000
2016	333,893,000

Budget Request¹

As indicated in the “Accomplishments” sections of this document, OIG audits and evaluations provide HHS policymakers, program officials, and the Congress with recommendations for improving the health care system, ensure that providers are complying with the appropriate rules, and recommend the recovery of improper payments, while OIG investigations and administrative enforcement actions hold individuals and entities accountable through criminal, civil, and administrative enforcement actions (including exclusions from participation in Federal health care programs).

OIG’s FY 2016 budget for Medicare and Medicaid oversight is \$333,893,000, which is an increase of +\$69,503,000, and +192 FTE above the FY 2015 Enacted Level. The OIG estimate includes:

- \$203,262,000 in HCFAC Mandatory funding, an increase of +\$18,761,000 above the FY 2015 President’s Budget. This includes the projection of increases based on the Consumer Price Index-Urban, as specified in current law, and does not assume sequestration.
- \$118,631,000 in HCFAC Discretionary funding. Of this funding, \$88,841,000 million is not subject to discretionary budget caps, consistent with section 251(b)(2)(C) of the Balanced Budget and Emergency Deficit Control Act of 1985.

¹ This section includes funding estimates for all OIG Medicare and Medicaid oversight activities. All of OIG’s Medicare and Medicaid oversight funding is mandatory, except for the HCFAC Discretionary Allocation Adjustment.

- \$12,000,000 in HCFAC Collections, which, to a limited extent, reimburse OIG for its costs of conducting investigations, audits, and compliance monitoring. This amount is an estimate, and the amounts available will depend on the amount actually collected.

The FY 2016 request continues the Administration's priority of aggressively addressing fraud, waste, and abuse in Federal health care programs. The request invests additional resources in proposed HCFAC funding above current levels. This approach would provide a dedicated source of funding to perform program integrity activities. Additional details concerning this approach are included in the HCFAC section of the CMS Budget Justification, and OIG's portion is discussed below.

OIG's budget request will support and expand its work in preventing fraud, waste, and abuse and promote program integrity across a rapidly changing and increasingly complex health care environment. These changes are fueled by increased Medicare and Medicaid enrollment, innovations in science and IT, the rate of health care spending, the movement toward value-based payment, reforms in the delivery of care, advances in quality measurement, and the increase in complexity and technical sophistication of fraud schemes. There is also a heightened emphasis on coordinated care and an increased use of technology, including electronic health records. OIG will need to adapt existing and adopt new oversight approaches that are tailored for new models and take into account changes in technology usage.

While overseeing this rapidly changing health care system, OIG will focus on the following key efforts and risk areas:

- *Addressing Prescription Drug Vulnerabilities on a National Scale:* Throughout the Medicare and Medicaid programs, OIG has uncovered improper and potentially harmful prescribing practices, pharmacies billing for drugs not dispensed, and diversion of prescription drugs. OIG has also identified waste related to payments for prescription drugs under HHS programs, increasing costs to taxpayers and beneficiaries. The need to invest additional resources in this area is clear, and additional FY 2016 funding would support the integrity of these two programs and ensure patient safety.

For example, on the topic of HIV drugs, criminals are illegally obtaining and selling prescription drugs, pharmacies are billing Medicare for drugs that beneficiaries never received, and beneficiaries' Medicare identification numbers were stolen. Medicare paid \$32 million for HIV drugs for beneficiaries with questionable utilization patterns in 2012.

OIG has also identified the diversion and abuse of prescription drugs as an ongoing problem. Drug diversion is the transfer of legitimate prescription drugs for unlawful purposes. Controlled substances, such as opiate pain relievers, are potentially so dangerous that they require restrictions on their manufacture, possession, or use. CDC characterizes prescription drug abuse as an epidemic, reaching virtually all demographics and geographic locations. In one noteworthy example, an OIG investigation found that a health care worker infected with Hepatitis C diverted a controlled prescription drug from a hospital for his own personal use. The worker took syringes filled with a controlled prescription drug, injected the drug into his arm, and refilled the same syringe with

saline. Because the worker used his contaminated syringes to switch the fluids, several patients treated from these vials contracted the infectious disease.

In addition to increased investigative efforts, additional investments in addressing prescription drug vulnerabilities will include new or expanded work to (1) identify drug-related hospitalizations of Medicare beneficiaries and analyze the prescribers and pharmacies associated with those beneficiaries to identify patterns that merit more specific review or investigation; (2) evaluate early implementation of drug traceability requirements under the Drug Supply Chain Security Act, including conducting a drug traceability test to determine whether the new requirements work as intended; (3) evaluate States' Medicaid drug utilization review programs to examine clinical misuse of prescription drugs as well as potential fraud; and (4) examine Medicare and Medicaid payment policies and pricing trends for specialty drugs, many of which are extremely high cost for the programs and for Medicare beneficiaries (through copayments), raising risks regarding beneficiary access and adherence to treatment regimens.

- *Overseeing Changes in Medicaid:* OIG's FY 2016 request supports targeted Medicaid program integrity efforts and the expansion of ongoing work involving Medicaid managed care, such as reviewing payment rates, effectiveness of current models, access to services, eligibility determinations, State oversight, and investigative and enforcement efforts. OIG's work in this area will focus on ensuring that the Federal Government pays the appropriate share of costs; improper payments are identified and collected; eligibility is correctly determined; managed care programs, in which approximately a third of all Medicaid beneficiaries are enrolled, maintain sufficient program integrity efforts; and payment rates to health care providers are economical.

OIG's additional investments to oversee changes in Medicaid will include new or expanded work addressing Medicaid eligibility; preventing waste and fraud in Medicaid managed care programs; the availability, completeness, and reliability of national Medicaid data, which are essential to effective program oversight and program integrity; and Medicaid provider screening and enrollment safeguards to help prevent fraud and abuse.

The number of individuals covered by Medicaid continues to grow. The Congressional Budget Office projects the number of individuals covered by Medicaid to grow significantly. As enrollment and spending increase, there is heightened urgency to address the program integrity challenges that Medicaid already faces.

The expansion of the program also poses new challenges related to eligibility and enrollment determinations and ensuring appropriate Federal Medical Assistance Percentages calculations and associated Federal payments. Further, managed care models are increasingly prevalent in the Medicaid program. OIG has found that fraud or abuse by managed care plans can increase Medicaid costs. The predominant concerns are provider fraud—billing for services that were not provided, were medically unnecessary, or were upcoded—health plan fraud; and beneficiary fraud, including prescription drug abuse.

- *Culture of Compliance:* OIG promotes voluntary compliance in the health care industry by providing guidance to health care providers on compliance and pursuing enforcement where appropriate against those who commit fraud, which helps level the playing field for honest providers.

OIG has a long history of giving the majority of providers, who want to play by the rules, guidance to help navigate the complex regulatory environment of Federal health care programs. For example, the Anti-Kickback Statute broadly applies to many business arrangements in the health care field, and OIG publishes safe harbor regulations and issues advisory opinions to help define the scope of permissible conduct under the statute. More broadly, over the past 20 years, OIG has been instrumental in catalyzing and supporting the health care industry's extensive voluntary compliance efforts. Among other guidance efforts, OIG has published compliance program guidance to help those setting up compliance programs, issued special fraud alerts and bulletins to notify health care providers of risk areas and problematic conduct, conducted in-person compliance training programs, and produced a series of compliance videos available on its web site. Together, these efforts help honest providers understand the rules that apply to them and operate effective compliance programs for their organizations.

OIG takes administrative enforcement action against those providers that choose not to comply with the rules and instead defraud Federal health care programs. OIG uses its administrative tools to complement, not duplicate, DOJ criminal and civil enforcement efforts. For example, unscrupulous providers can steer patients by paying kickbacks. Strategic CMP enforcement helps level the playing field for honest providers complying with the law. OIG also pursues individuals and entities for a wide range of other conduct, including false claims and the provision of medically unnecessary services. Administrative enforcement also helps support OIG's highly successful self-disclosure protocol by initiating actions against, and collecting more money from, wrongdoers who fail to disclose their conduct.

The FY 2016 request will expand OIG's ability to provide more guidance to health care providers and initiate more administrative enforcement actions. With these requested funds, OIG could more frequently update safe harbor regulations, issue additional guidance bulletins and alerts, and provide more compliance education resources. Additional administrative enforcement actions will further support OIG compliance guidance and help level the playing field for honest providers. These actions would also protect the Federal health care programs and their beneficiaries from fraudulent providers and provide greater deterrence. Finally, this additional investment will yield a substantial positive ROI and have an unquantifiable deterrent effect.

- *Ensuring Patient Safety and Quality of Care:* The FY 2016 request supports critical oversight for nursing home, hospice, or HCBS programs. As the median age of Americans continues to rise and as more Americans live with chronic medical conditions, HHS faces challenges in ensuring that beneficiaries who require HCBS receive high quality care. High quality nursing home and HCBS programs are important for the

continued well-being of people who need ongoing assistance with daily living, as well as those who need additional help recuperating from hospital stays or other acute care. Hospice care provides comfort for terminally ill beneficiaries by reducing pain and addressing physical and other needs. High quality nursing home, hospice, and HCBS personal care services can often prevent the need for disruptive and costly hospitalizations.

OIG continues to identify various problems with nursing home and hospice care. For example, in reports on nursing homes, OIG raised concerns about the frequency of preventable adverse events due to substandard care, the extent to which nursing homes comply with Federal regulations for reporting abuse and neglect, and the lack of monitoring of nursing homes' resident hospitalization rates. With respect to hospice care, OIG has raised concerns about insufficient monitoring of hospice service use, as well as inadequate oversight of hospice certification surveys and hospice-worker licensure requirements.

It is critical to ensure effective oversight of HCBS programs and Medicaid-paid personal care services. HCBS programs are important, in part, because they enable beneficiaries whose needs and preferences are better served by remaining in their own homes or other community-based settings to avoid or delay institutionalization. These programs offer many advantages for promoting beneficiary choice and preferences, but OIG efforts have revealed persistent payment, compliance, and quality vulnerabilities.

OIG's additional emphasis on ensuring high quality care for HHS beneficiaries will include new or expanded work to identify frequency of and patterns in unnecessary testing and procedures, a comprehensive management review of the survey and certification process, a review of quality of care provided in ambulatory care settings, and an assessment of infection control practices in nursing homes and other settings.

- *Payment Accuracy and Value in Care Delivery:* OIG continues to conduct targeted reviews to determine the scope of improper payments, identify areas of questionable billing for specific service types, and recommend actions to improve program safeguards. By reviewing billing data, medical records, and other documentation associated with claims, OIG identifies services that are questionable, undocumented, not medically necessary, or incorrectly coded, as well as duplicate payments and payments for services that were not provided. In doing so, OIG uncovers systemic payment vulnerabilities and makes recommendations to prevent and recover improper payments and fraud.

OIG's additional emphasis on ensuring payment accuracy for HHS beneficiaries will include new or expanded work to (1) assess the accuracy of Medicare payments to Medicare Advantage plans; (2) evaluate whether program measures are valid, data are accurate, reporting systems are efficient and not unduly burdensome, and payment models protect against incentives or opportunities to abuse the payment system; and (3) assess the evidence accepted by Medicare Administrative Contractors in determining whether claims comply with national and local coverage policies.

Medical record review is a powerful tool to establish whether an improper payment was made or to render a judgment on the quality of care provided. Such reviews are costly, but can significantly increase the impact of OIG findings and recommendations. The FY 2016 request will allow increased investment in medical record review that will be strategically performed to address high-risk and high-dollar services provided or paid for by HHS through Medicare, Medicaid, and IHS, and even care provided at health centers. Medical record review could also be used to assess quality of care and compare outcomes across different health care delivery and coordination models. In addition, the FY 2016 request will support OIG's efforts to use and assess quality-based data analytics and to perform analysis of quality metrics.

A key part of OIG's effort is to assess payment policies for potential waste and abuse. In some cases, payment rates and policies are not aligned with market prices or medical practices. This can inflate Medicare and Medicaid costs to both the programs and beneficiaries. Evidence from price and competitive bidding studies suggests that Medicare and Medicaid fees for some services and products may be too high, including those for DME and prescription drugs. Recent OIG work found that as much as \$15 billion could be saved if outpatient surgical procedures that do not pose significant risk to patients were performed in an ambulatory surgical center instead of a hospital outpatient department.

The FY 2016 request will support continued efforts to assess Medicare and Medicaid payment policies and will support new work examining the effectiveness and efficiency of new payment and delivery models, including, for example, accountable care organizations, bundled payments, and value-based purchasing programs.

- *The Meaningful and Secure Exchange and Use of Electronic Health Information:* Health IT and the use of electronic health records (EHRs) is a cross-cutting program area that affects not only the Medicare and Medicaid programs, but also multiple PHHS OPDIVs, including the Office of the National Coordinator for Health Information Technology and the Office for Civil Rights. A large portion of OIG's work in this area to date has been related to Medicare and Medicaid, given the size of their EHR Incentive Programs. As such, it is included under Medicare and Medicaid Oversight in this budget request. OIG has conducted some related work under PHHS Oversight, and may conduct additional work in the future.

The American health care system increasingly relies on health IT and the electronic exchange and use of health information. Health IT, including EHRs, offers opportunities for improved patient care, more efficient practice management, and improved overall public health.

The Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH) provided for Medicare and Medicaid incentive payments to eligible professionals, eligible hospitals, and critical access hospitals for adopting, implementing, upgrading, or demonstrating meaningful use of EHRs and established a variety of grant

programs to encourage widespread adoption of EHRs. HITECH also included requirements for public reporting of breaches of unsecured protected health information.

Although participation in the Medicare and Medicaid EHR Incentive Programs is high and has led to widespread adoption among eligible providers, significant challenges exist with respect to overseeing the EHR Incentive Programs, achieving interoperability of EHRs and keeping sensitive health information secure. Additionally, as HHS works to link payments with care quality, health outcomes, or performance as part of health care delivery system reforms, it will need to ensure that EHR and other health information data are accurate and reliable and are protected from misuse.

OIG's increased emphasis in this area will include new or expanded work to review the goals, use, and effectiveness of HHS's investments in creating a national interoperable infrastructure for health information exchange; evaluate the use of EHRs by hospitals, the use of hospitals' EHRs by post-acute care facilities (e.g., skilled nursing facilities), and the use of EHRs by accountable care organizations to coordinate care; and review the implementation of meaningful use requirements for the EHR incentive programs and the viability of the program objectives of interoperability and improved access to health information.

- *Enhanced Prevention and Enforcement*: The FY 2016 request will increase capacity to leverage technology in addressing emerging trends and support efforts to deter misconduct through litigation.

The FY 2016 request will expand OIG's Strike Force efforts and continue to build on the successes of the Strike Force model, which has been extremely effective in targeting emerging patterns of fraud and holding wrongdoers accountable. The Strike Force model succeeds through a combination of intelligence gathered by agents, proactive data analysis, and availability of attorneys dedicated to prosecuting Medicare fraud. Analysts use near-real-time data to examine Medicare claims to identify potentially fraudulent providers and patterns of suspected fraud, such as disproportionate payment levels for various services and ratios of services as compared with national averages. These and other assessments enable OIG to identify enforcement efforts and adapt them to emerging and evolving trends. For example, since the inception of the Strike Force model in 2007, OIG has identified and pursued health care fraud schemes in a variety of sectors, for example, DME supplier and infusion clinic services, home health care, community mental health, and other types of fraud.

Advances in data analysis have changed the way OIG detects and investigates health care fraud and significantly reduced the average time from investigation to indictment for Strike Force model cases. However, health care fraud itself has become more sophisticated as criminals use technology, including EHRs, to their advantage. Since the enactment of the HITECH Act, requirements for the implementation of EHR systems, and the ACA, the use of EHRs has grown significantly. Accordingly, evidence collection is moving increasingly away from paper files to an unprecedented amount of electronic evidence. For example, the amount of data collected by the Digital Investigations Branch

of OIG's Office of Investigations grew tenfold since 2009. Moreover, there is an increasing demand for forensic enhancements to more effectively analyze large amounts of investigative data. Additionally, such advances have the potential to provide OIG, and its law enforcement partners, with more leads to investigate than ever before. OIG's efforts in this area, along with those of CMS, through its Fraud Prevention System, increase the urgency that OIG have the resources needed to analyze data in near real time to investigate suspected fraud that the data flag.

Performance Table for Medicare and Medicaid Oversight

Key Outputs	Most Recent Result (FY 2014)	FY 2015 Target	FY 2016 Target	FY 2016 +/- FY 2015
Audits:				
Audit reports started	201	211	223	+12
Audit reports issued	213	213	236	+23
Evaluations:				
Evaluation reports started	37	44	47	+3
Evaluation reports issued	68	44	47	+3
Investigations:				
Complaints received for investigation	3,159	3,300	3,300	--
Investigative cases started	1,656	1,805	1,954	+149
Investigative cases closed	1,722	1,722	2,032	+310
PL funding (dollars in millions)	\$224	\$264	\$334	+\$70

<http://oig.hhs.gov/>

Total Object Class

(Dollars in Thousands)

	FY 2014	FY 2015	FY 2016	FY 2016
	<u>Final</u>	<u>Enacted</u>	<u>Pres. Bud.</u>	<u>+/-</u>
				<u>FY 2015</u>
<u>Obligations</u>				
Personnel compensation:				
Full-time permanent (11.1).....	\$163,227	\$169,463	\$196,784	+\$27,321
Other than full-time permanent (11.3).....	2,880	2,991	3,503	+512
Other personnel compensation (11.5).....	1,700	1,763	2,046	+283
Military personnel (11.7).....	--	--	--	--
Special personnel services payments (11.8).....	81	85	99	+15
Subtotal, Personnel.....	167,889	174,302	202,432	+28,131
Civilian benefits (12.1).....	57,977	60,191	69,959	+9,767
Military benefits (12.2).....	--	--	--	--
Benefits to former personnel (13.0).....	--	--	--	--
Subtotal, Pay Costs.....	225,866	234,493	272,391	+37,898
Travel and transportation of persons (21.0).....	5,317	8,958	10,804	+1,846
Transportation of things (22.0).....	2,330	2,401	2,190	-211
Rental payments to GSA (23.1).....	20,947	20,872	19,843	-1,029
Rental payments to others (23.2).....	0	--	--	--
Communication, utilities, and misc. charges	3,352	3,343	3,864	+520
Printing and reproduction (24.0).....	38	85	98	+13
Other contractual services:				
Advisory and assistance services (25.1).....	2	2	2	--
Other services (25.2).....	1,794	1,938	2,154	+216
Purchases of goods and services from				
Government accounts (25.3).....	40,009	54,774	71,144	+16,370
Operation and maintenance of facilities (25.4)....	3,996	4,121	4,864	+743
Research and development contracts (25.5).....	--	--	--	--
Medical care (25.6).....	--	--	--	--
Operation and maintenance of equipment	2,349	3,423	4,544	+1,121
Subsistence and support of persons (25.8).....	--	--	--	--
Subtotal, Other Contractual Services.....	48,149	64,258	82,707	+18,449
Supplies and materials (26.0).....	1,542	1,587	1,870	+283
Equipment (31.0).....	7,809	9,055	11,392	+2,337
Land and structures (32.0).....	--	--	--	--
Investments and loans (33.0).....	--	--	--	--
Grants, subsidies, and contributions (41.0).....	23	6	7	+1
Insurance claims and indemnities (42.0).....	63	--	--	--
Refunds (44.0).....	--	--	--	--
Subtotal, Nonpay Costs.....	89,571	110,559	132,768	+22,209
Total, Obligations¹.....	\$315,436	\$345,051	\$405,159	+\$60,107

¹ Figures in Object Class and Salaries and Expenses tables may not sum to totals because of rounding.

PHHS Oversight Object Class

(Dollars in Thousands)

	FY 2014	FY 2015	FY 2016	FY 2016
	<u>Final</u>	<u>Enacted</u>	<u>Pres. Bud.</u>	+/-
				<u>FY 2015</u>
<u>Obligations</u>				
Personnel compensation:				
Full-time permanent (11.1).....	\$39,196	\$40,230	\$46,529	+\$6,299
Other than full-time permanent (11.3).....	651	668	772	+105
Other personnel compensation (11.5).....	560	574	664	+90
Military personnel (11.7).....	--	--	--	--
Special personnel services payments (11.8).....	18	18	21	+3
Subtotal, Personnel.....	40,424	41,490	47,987	+6,497
Civilian benefits (12.1).....	14,013	14,382	16,634	+2,252
Military benefits (12.2).....	--	--	--	--
Benefits to former personnel (13.0).....	--	--	--	--
Subtotal, Pay Costs.....	54,437	55,873	64,621	+8,749
Travel and transportation of persons (21.0).....	1,381	2,182	2,436	+254
Transportation of things (22.0).....	572	582	37	-545
Rental payments to GSA (23.1).....	4,127	4,130	3,977	-153
Rental payments to others (23.2).....	0	--	--	--
Communication, utilities, and misc. charges	1,697	786	898	+112
Printing and reproduction (24.0).....	18	20	23	+3
Other contractual services:				
Advisory and assistance services (25.1).....	0	0	1	--
Other services (25.2).....	506	515	587	+72
Purchases of goods and services from				
Government accounts (25.3).....	4,967	5,388	6,701	+1,313
Operation and maintenance of facilities (25.4)....	726	738	858	+121
Research and development contracts (25.5).....	--	--	--	--
Medical care (25.6).....	--	--	--	--
Operation and maintenance of equipment	428	435	506	+71
Subsistence and support of persons (25.8).....	--	--	--	--
Subtotal, Other Contractual Services.....	6,627	7,076	8,652	+1,577
Supplies and materials (26.0).....	439	447	520	+73
Equipment (31.0).....	1,382	1,405	1,835	+430
Land and structures (32.0).....	--	--	--	--
Investments and loans (33.0).....	--	--	--	--
Grants, subsidies, and contributions (41.0).....	6	6	7	--
Insurance claims and indemnities (42.0).....	22	--	--	--
Refunds (44.0).....	--	--	--	--
Subtotal, Nonpay Costs.....	16,272	16,627	18,378	+1,751
Total, Obligations¹.....	\$70,710	\$72,500	\$83,000	+\$10,500

Note: The amounts in this table include only direct discretionary appropriations to OIG for PHHS oversight through the annual appropriations process.

¹ Figures in Object Class and Salaries and Expenses tables may not sum to totals because of rounding.

Medicare and Medicaid Oversight Object Class

(Dollars in Thousands)

	FY 2014	FY 2015	FY 2016	FY 2016
	<u>Final</u>	<u>Enacted</u>	<u>Pres. Bud.</u>	<u>+/-</u>
				<u>FY 2015</u>
<u>Obligations</u>				
Personnel compensation:				
Full-time permanent (11.1).....	\$121,620	\$126,756	\$149,059	+\$22,303
Other than full-time permanent (11.3).....	2,219	2,313	2,720	+407
Other personnel compensation (11.5).....	1,121	1,169	1,374	+206
Military personnel (11.7).....	--	--	--	--
Special personnel services payments (11.8).....	64	66	78	+12
Subtotal, Personnel.....	125,024	130,304	153,231	+22,928
Civilian benefits (12.1).....	43,192	45,016	52,937	+7,921
Military benefits (12.2).....	--	--	--	--
Benefits to former personnel (13.0).....	--	--	--	--
Subtotal, Pay Costs.....	168,216	175,320	206,168	+30,848
Travel and transportation of persons (21.0).....	3,877	5,801	7,868	+2,067
Transportation of things (22.0).....	1,755	1,816	2,150	+334
Rental payments to GSA (23.1).....	16,820	16,742	15,866	-876
Rental payments to others (23.2).....	0	--	--	--
Communication, utilities, and misc. charges	1,655	2,558	2,966	+408
Printing and reproduction (24.0).....	20	65	75	+10
Other contractual services:				
Advisory and assistance services (25.1).....	1	1	1	--
Other services (25.2).....	1,279	1,323	1,567	+243
Purchases of goods and services from				
Government accounts (25.3).....	21,258	29,468	45,548	+16,080
Operation and maintenance of facilities (25.4)....	3,270	3,383	4,005	+622
Research and development contracts (25.5).....	--	--	--	--
Medical care (25.6).....	--	--	--	--
Operation and maintenance of equipment	1,922	2,988	4,038	+1,050
Subsistence and support of persons (25.8).....	--	--	--	--
Subtotal, Other Contractual Services.....	27,730	37,164	55,159	+17,995
Supplies and materials (26.0).....	1,102	1,140	1,350	+210
Equipment (31.0).....	6,427	7,650	9,557	+1,907
Land and structures (32.0).....	--	--	--	--
Investments and loans (33.0).....	--	--	--	--
Grants, subsidies, and contributions (41.0).....	16	--	--	--
Insurance claims and indemnities (42.0).....	41	--	--	--
Refunds (44.0).....	--	--	--	--
Subtotal, Nonpay Costs.....	59,443	72,935	94,991	+22,056
Total, Obligations¹.....	\$227,660	\$248,255	\$301,159	+\$52,904

Note: The amounts in this table include the funding available to OIG for Medicare and Medicaid oversight.

¹ Figures in Object Class and Salaries and Expenses tables may not sum to totals because of rounding.

Reimbursables Object Class

(Dollars in Thousands)

	FY 2014	FY 2015	FY 2016	FY 2016
	<u>Final</u>	<u>Enacted</u>	<u>Pres. Bud.</u>	<u>+/-</u>
				<u>FY 2015</u>
<u>Obligations</u>				
Personnel compensation:				
Full-time permanent (11.1).....	\$1,148	\$1,179	\$1,196	+\$17
Other than full-time permanent (11.3).....	10	11	11	--
Other personnel compensation (11.5).....	7	7	7	--
Military personnel (11.7).....	--	--	--	--
Special personnel services payments (11.8).....	--	--	--	--
Subtotal, Personnel.....	1,165	1,197	1,214	+17
Civilian benefits (12.1).....	371	382	387	+5
Military benefits (12.2).....	--	--	--	--
Benefits to former personnel (13.0).....	--	--	--	--
Subtotal, Pay Costs.....	1,537	1,579	1,601	+22
Travel and transportation of persons (21.0).....	51	500	500	--
Transportation of things (22.0).....	4	4	4	--
Rental payments to GSA (23.1).....	--	--	--	--
Rental payments to others (23.2).....	--	--	--	--
Communication, utilities, and misc. charges	--	--	--	--
Printing and reproduction (24.0).....	--	--	--	--
Other contractual services:				
Advisory and assistance services (25.1).....	--	--	--	--
Other services (25.2).....	--	--	--	--
Purchases of goods and services from				
Government accounts (25.3).....	13,774	18,917	18,895	-22
Operation and maintenance of facilities (25.4)....	--	--	--	--
Research and development contracts (25.5).....	--	--	--	--
Medical care (25.6).....	--	--	--	--
Operation and maintenance of equipment	--	--	--	--
Subsistence and support of persons (25.8).....	--	--	--	--
Subtotal, Other Contractual Services.....	13,774	18,917	18,895	-22
Supplies and materials (26.0).....	0	--	--	--
Equipment (31.0).....	--	--	--	--
Land and structures (32.0).....	--	--	--	--
Investments and loans (33.0).....	--	--	--	--
Grants, subsidies, and contributions (41.0).....	--	--	--	--
Insurance claims and indemnities (42.0).....	--	--	--	--
Refunds (44.0).....	--	--	--	--
Subtotal, Nonpay Costs.....	13,829	19,421	19,399	-22
Total, Obligations¹.....	\$15,366	\$21,000	\$21,000	+\$5,634

¹ Figures in Object Class and Salaries and Expenses tables may not sum to totals because of rounding.

Disaster Relief Oversight Object Class

(Dollars in Thousands)

	<u>FY 2014</u>	<u>FY 2015</u>	<u>FY 2016</u>	<u>FY 2016</u>
	<u>Final</u>	<u>Enacted</u>	<u>Pres. Bud.</u>	<u>+/-</u>
				<u>FY 2015</u>
<u>Obligations</u>				
Personnel compensation:				
Full-time permanent (11.1).....	\$1,263	\$1,298	--	--
Other than full-time permanent (11.3).....	--	--	--	--
Other personnel compensation (11.5).....	12	12	--	--
Military personnel (11.7).....	--	--	--	--
Special personnel services payments (11.8).....	--	--	--	--
Subtotal, Personnel.....	1,275	1,310	--	--
Civilian benefits (12.1).....	400	411	--	--
Military benefits (12.2).....	--	--	--	--
Benefits to former personnel (13.0).....	--	--	--	--
Subtotal, Pay Costs.....	1,675	1,721	--	--
Travel and transportation of persons (21.0).....	8	475	--	--
Transportation of things (22.0).....	--	--	--	--
Rental payments to GSA (23.1).....	--	--	--	--
Rental payments to others (23.2).....	--	--	--	--
Communication, utilities, and misc. charges	--	--	--	--
Printing and reproduction (24.0).....	--	--	--	--
Other contractual services:				
Advisory and assistance services (25.1).....	--	--	--	--
Other services (25.2).....	9	100	--	--
Purchases of goods and services from				
Government accounts (25.3).....	9	1,001	--	--
Operation and maintenance of facilities (25.4)....	--	--	--	--
Research and development contracts (25.5).....	--	--	--	--
Medical care (25.6).....	--	--	--	--
Operation and maintenance of equipment	--	--	--	--
Subsistence and support of persons (25.8).....	--	--	--	--
Subtotal, Other Contractual Services.....	18	1,101	--	--
Supplies and materials (26.0).....	--	--	--	--
Equipment (31.0).....	--	--	--	--
Land and structures (32.0).....	--	--	--	--
Investments and loans (33.0).....	--	--	--	--
Grants, subsidies, and contributions (41.0).....	--	--	--	--
Insurance claims and indemnities (42.0).....	--	--	--	--
Refunds (44.0).....	--	--	--	--
Subtotal, Nonpay Costs.....	26	1,576	--	--
Total, Obligations¹.....	\$1,701	\$3,297	--	--

Note: The amounts in this table include the funding available to OIG through the Disaster Relief Appropriations Act of 2013.

¹ Figures in Object Class and Salaries and Expenses tables may not sum to totals because of rounding.

Total Salary and Expenses

(Dollars in Thousands)

	FY 2014	FY 2015	FY 2016	FY 2016
	<u>Final</u>	<u>Enacted</u>	<u>Pres. Bud.</u>	<u>+/-</u>
				<u>FY 2015</u>
<u>Obligations</u>				
Personnel compensation:				
Full-time permanent (11.1).....	\$163,227	\$169,463	\$196,784	+\$27,321
Other than full-time permanent (11.3).....	\$2,880	\$2,991	\$3,503	+\$512
Other personnel compensation (11.5).....	\$1,700	\$1,763	\$2,046	+\$283
Military personnel (11.7).....	--	--	--	--
Special personnel services payments (11.8).....	81	85	99	+15
Subtotal, Personnel.....	167,889	174,302	202,432	+28,131
Civilian benefits (12.1).....	57,977	60,191	69,959	+9,767
Military benefits (12.2).....	--	--	--	--
Benefits to former personnel (13.0).....	--	--	--	--
Subtotal, Pay Costs.....	225,866	234,493	272,391	+37,898
Travel and transportation of persons (21.0).....	5,317	8,958	10,804	+1,846
Transportation of things (22.0).....	2,330	2,401	2,190	-211
Communication, utilities, and misc. charges (23.3)...	3,352	3,343	3,864	+520
Printing and reproduction (24.0).....	38	85	98	+13
Other contractual services:				
Advisory and assistance services (25.1).....	2	2	2	--
Other services (25.2).....	1,794	1,938	2,154	+216
Purchases of goods and services from				
Government accounts (25.3).....	40,009	54,774	71,144	+16,370
Operation and maintenance of facilities (25.4).....	3,996	4,121	4,864	+743
Research and development contracts (25.5).....	--	--	--	--
Medical care (25.6).....	--	--	--	--
Operation and maintenance of equipment (25.7)...	2,349	3,423	4,544	+1,121
Subsistence and support of persons (25.8).....	--	--	--	--
Subtotal, Other Contractual Services.....	48,149	64,258	82,707	+18,449
Supplies and materials (26.0).....	1,542	1,587	1,870	+283
Subtotal, Nonpay Costs.....	60,729	80,631	101,533	+20,901
Total Salary and Expenses.....	286,594	315,124	373,924	+58,799
Rental payments to GSA.....	20,947	20,872	19,843	-1,029
Rental payments to others.....	--	--	--	--
Grand Total, Salary and Expenses and Rent.....	\$307,541	\$335,996	\$393,767	+\$57,770
FTE.....	1,574	1,591	1,821	+230

PHHS Oversight Salary and Expenses
(Dollars in Thousands)

	FY 2014	FY 2015	FY 2016	FY 2016
	<u>Final</u>	<u>Enacted</u>	<u>Pres. Bud.</u>	+/-
				<u>FY 2015</u>
<u>Obligations</u>				
Personnel compensation:				
Full-time permanent (11.1).....	\$39,196	\$40,230	\$46,529	+\$6,299
Other than full-time permanent (11.3).....	651	668	772	+105
Other personnel compensation (11.5).....	560	574	664	+90
Military personnel (11.7).....	--	--	--	--
Special personnel services payments (11.8).....	18	18	21	+3
Subtotal, Personnel.....	40,424	41,490	47,987	+6,497
Civilian benefits (12.1).....	14,013	14,382	16,634	+2,252
Military benefits (12.2).....	--	--	--	--
Benefits to former personnel (13.0).....	--	--	--	--
Subtotal, Pay Costs.....	54,437	55,873	64,621	+8,749
Travel and transportation of persons (21.0).....	1,381	2,182	2,436	+254
Transportation of things (22.0).....	572	582	37	-545
Communication, utilities, and misc. charges (23.3)...	1,697	786	898	+112
Printing and reproduction (24.0).....	18	20	23	+3
Other contractual services:	--	--	--	--
Advisory and assistance services (25.1).....	0	0	1	--
Other services (25.2).....	506	515	587	+72
Purchases of goods and services from	--	--	--	--
Government accounts (25.3).....	4,967	5,388	6,701	+1,313
Operation and maintenance of facilities (25.4).....	726	738	858	+121
Research and development contracts (25.5).....	--	--	--	--
Medical care (25.6).....	--	--	--	--
Operation and maintenance of equipment (25.7)...	428	435	506	+71
Subsistence and support of persons (25.8).....	--	--	--	--
Subtotal, Other Contractual Services.....	6,627	7,076	8,652	+1,577
Supplies and materials (26.0).....	439	447	520	+73
Subtotal, Nonpay Costs.....	10,735	11,091	12,566	+1,474
Total Salary and Expenses.....	65,172	66,964	77,187	+10,223
Rental payments to GSA.....	4,127	4,130	3,977	-153
Rental payments to others.....	0	--	--	--
Grand Total, Salary and Expenses and Rent.....	\$69,299	\$71,094	\$81,165	+\$10,070
FTE.....	363	363	414	+51

Note: The amounts in this table include only direct Discretionary appropriations to OIG for PHHS oversight through the annual appropriations process.

Medicare and Medicaid Oversight Salary and Expenses

(Dollars in Thousands)

	FY 2014	FY 2015	FY 2016	FY 2016
	<u>Final</u>	<u>Enacted</u>	<u>Pres. Bud.</u>	<u>+/-</u>
				<u>FY 2015</u>
<u>Obligations</u>				
Personnel compensation:				
Full-time permanent (11.1).....	\$121,620	\$126,756	\$149,059	+\$22,303
Other than full-time permanent (11.3).....	\$2,219	\$2,313	\$2,720	+407
Other personnel compensation (11.5).....	\$1,121	\$1,169	\$1,374	+206
Military personnel (11.7).....	--	--	--	--
Special personnel services payments (11.8).....	64	66	78	+12
Subtotal, Personnel.....	125,024	130,304	153,231	+22,928
Civilian benefits (12.1).....	43,192	45,016	52,937	+7,921
Military benefits (12.2).....	--	--	--	--
Benefits to former personnel (13.0).....	--	--	--	--
Subtotal, Pay Costs.....	168,216	175,320	206,168	+30,848
Travel and transportation of persons (21.0).....	3,877	5,801	7,868	+2,067
Transportation of things (22.0).....	1,755	1,816	2,150	+334
Communication, utilities, and misc. charges (23.3)...	1,655	2,558	2,966	+408
Printing and reproduction (24.0).....	20	65	75	+10
Other contractual services:				
Advisory and assistance services (25.1).....	1	1	1	--
Other services (25.2).....	1,279	1,323	1,567	+243
Purchases of goods and services from				
Government accounts (25.3).....	21,258	29,468	45,548	+16,080
Operation and maintenance of facilities (25.4).....	3,270	3,383	4,005	+622
Research and development contracts (25.5).....	--	--	--	--
Medical care (25.6).....	--	--	--	--
Operation and maintenance of equipment (25.7)...	1,922	2,988	4,038	+1,050
Subsistence and support of persons (25.8).....	--	--	--	--
Subtotal, Other Contractual Services.....	27,730	37,164	55,159	+17,995
Supplies and materials (26.0).....	1,102	1,140	1,350	+210
Subtotal, Nonpay Costs.....	36,139	48,543	69,568	+21,025
Total Salary and Expenses.....	204,355	223,863	275,736	+51,873
Rental payments to GSA.....	16,820	16,742	15,866	-876
Rental payments to others.....	0	--	--	--
Grand Total, Salary and Expenses and Rent.....	\$221,176	\$240,605	\$291,602	+\$50,997
FTE.....	1,186	1,203	1,395	+192

Note: The amounts in this table include the funding available to OIG for Medicare and Medicaid oversight

Reimbursables Salary and Expenses

(Dollars in Thousands)

	FY 2014	FY 2015	FY 2016	FY 2016
	<u>Final</u>	<u>Enacted</u>	<u>Pres. Bud.</u>	<u>+/-</u>
				<u>FY 2015</u>
<u>Obligations</u>				
Personnel compensation:				
Full-time permanent (11.1).....	\$1,148	\$1,179	\$1,196	+\$17
Other than full-time permanent (11.3).....	10	11	11	--
Other personnel compensation (11.5).....	7	7	7	--
Military personnel (11.7).....	--	--	--	--
Special personnel services payments (11.8).....	--	--	--	--
Subtotal, Personnel.....	1,165	1,197	1,214	+17
Civilian benefits (12.1).....	371	382	387	+5
Military benefits (12.2).....	--	--	--	--
Benefits to former personnel (13.0).....	--	--	--	--
Subtotal, Pay Costs.....	1,537	1,579	1,601	+22
Travel and transportation of persons (21.0).....	51	500	500	--
Transportation of things (22.0).....	4	4	4	--
Communication, utilities, and misc. charges (23.3)...	--	--	--	--
Printing and reproduction (24.0).....	--	--	--	--
Other contractual services:				
Advisory and assistance services (25.1).....	--	--	--	--
Other services (25.2).....	--	--	--	--
Purchases of goods and services from				
Government accounts (25.3).....	13,774	18,917	18,895	-22
Operation and maintenance of facilities (25.4).....	--	--	--	--
Research and development contracts (25.5).....	--	--	--	--
Medical care (25.6).....	--	--	--	--
Operation and maintenance of equipment (25.7)...	--	--	--	--
Subsistence and support of persons (25.8).....	--	--	--	--
Subtotal, Other Contractual Services.....	13,774	18,917	18,895	-22
Supplies and materials (26.0).....	--	--	--	--
Subtotal, Nonpay Costs.....	13,829	19,421	19,399	-22
Total Salary and Expenses.....	15,366	21,000	21,000	--
Rental payments to GSA.....	--	--	--	--
Rental payments to others.....	--	--	--	--
Grand Total, Salary and Expenses and Rent.....	\$15,366	\$21,000	\$21,000	--
FTE.....	12	12	12	--

Note: The amounts in this table do not include HCFAC funding. HCFAC funding is displayed in the Medicare and Medicaid oversight tables.

Disaster Relief Oversight Salary and Expenses

(Dollars in Thousands)

	FY 2014	FY 2015	FY 2016	FY 2016
	<u>Final</u>	<u>Enacted</u>	<u>Pres. Bud.</u>	<u>+/-</u>
				<u>FY 2015</u>
<u>Obligations</u>				
Personnel compensation:				
Full-time permanent (11.1).....	\$1,263	\$1,298	--	--
Other than full-time permanent (11.3).....	--	--	--	--
Other personnel compensation (11.5).....	12	12	--	--
Military personnel (11.7).....	--	--	--	--
Special personnel services payments (11.8).....	--	--	--	--
Subtotal, Personnel.....	1,275	1,310	--	--
Civilian benefits (12.1).....	400	411	--	--
Military benefits (12.2).....	--	--	--	--
Benefits to former personnel (13.0).....	--	--	--	--
Subtotal, Pay Costs.....	1,675	1,721	--	--
Travel and transportation of persons (21.0).....	8	475	--	--
Transportation of things (22.0).....	--	--	--	--
Communication, utilities, and misc. charges (23.3)...	--	--	--	--
Printing and reproduction (24.0).....	--	--	--	--
Other contractual services:				
Advisory and assistance services (25.1).....	--	--	--	--
Other services (25.2).....	9	100	--	--
Purchases of goods and services from				
Government accounts (25.3).....	9	1,001	--	--
Operation and maintenance of facilities (25.4).....	--	--	--	--
Research and development contracts (25.5).....	--	--	--	--
Medical care (25.6).....	--	--	--	--
Operation and maintenance of equipment (25.7)...	--	--	--	--
Subsistence and support of persons (25.8).....	--	--	--	--
Subtotal, Other Contractual Services.....	18	1,101	--	--
Supplies and materials (26.0).....	--	--	--	--
Subtotal, Nonpay Costs.....	26	1,576	--	--
Total Salary and Expenses.....	1,701	3,297	--	--
Rental payments to GSA.....	--	--	--	--
Rental payments to others.....	--	--	--	--
Grand Total, Salary and Expenses and Rent.....	\$1,701	\$3,297	--	--
FTE.....	13	13	--	--

Note: The amounts in this table include the funding available to OIG through the Disaster Relief Appropriations Act of 2013.

Detail of FTE

	2014 Actual <u>Civilian</u>	2014 Actual <u>Military</u>	2014 Actual <u>Total</u>	2015 Est. <u>Civilian</u>	2015 Est. <u>Military</u>	2015 Est. <u>Total</u>	2016 Est. <u>Civilian</u>	2016 Est. <u>Military</u>	2016 Est. <u>Total</u>
<u>PHHS Oversight FTE:</u>									
Discretionary:									
Direct	363	--	363	363	--	363	414	--	414
Reimbursable	12	--	12	12	--	12	12	--	12
Disaster Relief Appropriations Act of 2013:									
Direct	13	--	13	13	--	13	--	--	--
PHHS Oversight Subtotal.....	388	--	388	388	--	388	426	--	426
<u>Medicare and Medicaid Oversight FTE:</u>									
HCFAC Mandatory / Collections									
Reimbursable	1,027	--	1,027	941	--	941	936	--	936
HCFAC Discretionary:									
Reimbursable	159	--	159	262	--	262	459	--	459
Medicare and Medicaid Oversight Subtotal.....	1,186	--	1,186	1,203	--	1,203	1,395	--	1,395
Total, OIG FTE.....	1,574	--	1,574	1,591	--	1,591	1,821	--	1,821

Detail of Positions

	2014 Final	2015 Estimate	2016 Pres. Bud.
Executive Schedule (ES) Positions:			
Executive level X	1	1	1
ES-00.....	<u>14</u>	<u>17</u>	<u>17</u>
Subtotal, ES Positions	15	18	18
Senior Leader (SL) Positions:			
SL	2	4	4
General Schedule (GS) Positions:			
GS-15	100	107	107
GS-14	210	210	215
GS-13	712	712	700
GS-12	431	431	487
GS-11	49	22	50
GS-10	--	--	--
GS-9	22	91	190
GS-8	4	4	4
GS-7	9	30	64
GS-6	1	1	1
GS-5	<u>5</u>	<u>20</u>	<u>20</u>
Subtotal, GS Positions.....	1,543	1,628	1,838
Total, OIG Positions	1,560	1,650	1,860
Average GS Grade ¹	12.8	12.5	12.2
Average GS Salary	\$105,979	\$107,731	\$108,875

Average GS Grade ¹

2012	12.5
2013	12.7
2014	12.8
2015	12.5
2016	12.2

¹ The average GS grade reflects a mathematical average of the number of positions at each grade level in the agency.

Physicians' Comparability Allowance Worksheet

(Dollars in Thousands)

	FY 2014 Final	FY 2015 Estimate	FY 2016 Estimate¹
Physicians receiving physicians' comparability allowances (PCAs)	1	1	1
Physicians with 1-year PCA agreements	--	--	--
Average annual PCA physician pay (without PCA payment)	\$150	\$159	\$159
Average annual PCA payment	\$27	\$28	\$28
Physicians receiving PCA, category IV-B Health and Medical Administration	1	1	1

Provide the maximum annual PCA amount paid to each category of physician in your agency and explain the reasoning for these amounts by category.

OIG sets its annual PCA amount consistent with HHS policy. In 2014, \$27,000 was provided to the physician in Category IV-B.

Explain the recruitment and retention problem for each category of physician in your agency.

The position in question is the OIG Chief Medical Officer (CMO), and the incumbent serves as OIG's internal medical consultant to all OIG offices on a wide array of OIG activities. The CMO is in a unique role in that the incumbent provides technical expertise on a variety of medical and clinical issues relating to investigations, litigation, and compliance involving potential fraud, quality-of-care violations, and other significant health-care-related issues. As this position is critical to the success of many OIG efforts, the PCA helps to ensure that the CMO position is competitive to qualified candidates and that, once selected, quality individuals are retained.

Explain the degree to which recruitment and retention problems were alleviated in your agency through the use of PCAs in the prior FY.

See above response for detail. The position was not vacant in the prior FY, which is attributable, in part, to the PCA.

¹ FY 2016 data will be approved during the FY 2017 budget cycle.

<http://oig.hhs.gov/>

Significant Items

The Joint Explanatory Statement accompanying the Consolidated and Further Continuing Appropriations Act, 2015 (P.L. 113-235), included seven Significant Items to report on in the FY 2016 budget request, quoted verbatim below.

Item: *ACA Activities in FY 2015 Work Plan.* The agreement expects the OIG to ensure full oversight of ACA activities are included and described in the fiscal year 2015 Work Plan. The work plan should provide substantive activity for all HHS operating divisions including the Food and Drug Administration.

Response: The [FY 2015 OIG Work Plan](#) was released in November 2014. OIG is planning a mid-year update to the FY 2015 Work Plan and will keep the Committees informed about its status.

Appendix A of the *Work Plan*, which begins on page 66, details ACA reviews underway or planned for FY 2015. OIG is prioritizing work in three main areas: the Health Insurance Marketplaces, including financial assistance payments; Medicare and Medicaid reforms; and grant expenditures for public health programs. In addition to initiating the reviews detailed in the *Work Plan*, OIG is committed to initiating in FY 2015 at least 5 to 10 additional reviews addressing ACA programs. These reviews could focus on emerging Marketplace issues, including, for example, vulnerabilities that may arise in connection with the second open enrollment period; implementation of additional Marketplace functionality, such as the redetermination process; or the premium stabilization programs. They could also focus on other ACA areas, including Medicaid expansion, new Medicare payment and delivery models, or new grant programs.

In any given year, OIG conducts a wide array of PHHS and other HHS-related reviews. Parts IV, V, and VI of the *Work Plan* include the details of these reviews. Part IV includes five FDA reviews underway or planned for FY 2015. The *Work Plan* includes at least one review for each major PHHS OPDIV. Certain financial, performance, and investigative issues cut across multiple HHS programs. Examples include financial statement audits; financial accounting; information systems management; and other departmental issues, including discounted airfares and protections for people in residential settings who have disabilities.

Item: *Lobbying.* The agreement requests an update on how the OIG is working with the HHS agencies to improve monitoring of grantee activities to ensure that no taxpayer resources are used for lobbying.

Response: In July 2014, OIG issued a report, entitled *Laws Prohibit the Use of HHS Grant Funds for Lobbying, but Limited Methods Exist To Identify Noncompliance* (OEI-07-12-00620), related to the use of HHS funds for lobbying. A summary of the findings and recommendations is below.

Findings: All awarding agencies reported using Federal and departmental sources of guidance regarding the prohibitions on the use of grant funds for lobbying. Through grant applications, notices of award, and/or training, all awarding agencies informed grantees of the prohibitions. For all sampled grant awards, grantees reported being aware of the lobbying prohibitions. However, limited methods exist to identify noncompliance. HHS awarding agencies found two instances of noncompliance in FYs 2011 and 2012

Recommendations: We recommended that the Assistant Secretary for Financial Resources (ASFR) facilitate Departmentwide information sharing among awarding agencies about methods to identify the use of grant funds for prohibited lobbying activities. We also recommended that ASFR centralize on its Web site the guidance pertaining to the prohibitions on the use of grant funds for lobbying.

ASFR concurred with both recommendations, and expects to complete implementation of the recommendations by July 2, 2015. OIG will keep the Committees informed as additional information on the implementation of these recommendations is available.

Item: *Top-25 Unimplemented Recommendations.* The agreement again requests that within 90 days of enactment the OIG provide a revised top-25 unimplemented recommendations report under the same terms and conditions as described in the explanatory statement accompanying the Consolidated Appropriations Act of 2014.

Response: OIG is preparing a report to the Secretary, as well as the House and Senate Appropriations Committees and appropriate authorizing committees, containing the top 25 unimplemented recommendations that, on the basis of the professional opinion of OIG, should be prioritized for implementation to better protect the integrity of departmental programs. OIG is working to make this report more targeted than the prior year submission and will submit the report not later than 90 days after enactment.

Item: *Office for Human Research Protections (OHRP).* Recent reviews by the OIG raise questions about the independence of the OHRP during the process to make determinations. The agreement requests the OIG conduct a formal review of OHRP procedures and make appropriate recommendations to ensure and strengthen human subjects protections in future research and ensure the independence of OHRP.

Response: In September 2014, OIG published a report (OIG-12-14-04) providing the results of our review of allegations that officials of the National Institutes of Health (NIH), the Immediate Office of the Secretary, the Office of the General Counsel, and others improperly intervened in the compliance oversight deliberations of OHRP with respect to the NIH-funded study entitled Surfactant Positive Airway Pressure and Pulse Oximetry Trial (also called SUPPORT). OIG research disclosed that no law, regulation, or written policy prohibits or restricts the kind of consultation that occurred here or would make such consultations improper. That is, no law establishes OHRP's organizational independence or prohibits the HHS Secretary from seeking input from other HHS components on OHRP determinations. Accordingly, we found no basis for action against the individuals involved. OIG also published a related report (OEI-01-14-

00560), which found that OHRP followed its procedures and exercised discretion throughout its evaluation of SUPPORT.

In response to this request, OIG plans to conduct a review of OHRP procedures and make appropriate recommendations. This work is in the preliminary planning stages, and we welcome and appreciate input from the Committees to inform our planning.

Item: *Health Reform Oversight.* The agreement provides support for oversight activities related to health reform. The OIG is expected to provide a plan of how it will conduct these oversight activities within 60 days after enactment to the appropriate House of Representatives and Senate Committees.

Response: OIG is preparing a plan that describes how it will conduct its Health Reform Oversight activities. An advisory team has convened and is on schedule to submit the plan not later than 60 days after enactment to the appropriate House and Senate Appropriations Committees.

Item: *Effectiveness of Subsidy Data.* No later than June 1, 2015, the HHS OIG, in consultation with the Treasury Inspector General, shall submit a report to Congress that assesses Internal Revenue Service procedures to reconcile Advance Premium Tax Credit (APTC) amounts paid to individual taxpayers for health care coverage in Federal and State Health Insurance Exchanges and how HHS uses IRS information to reduce fraud and overpayments.

Response: OIG is working closely with the Treasury Inspector General for Tax Administration (TIGTA) on oversight of the APTC program; jointly, OIG and TIGTA have work underway that examines the issues raised in the item above. The offices anticipate issuing, between them, a series of products in FY 2015 about a range of APTC issues.

Item: *Oversight of FDA.* Over the past five years FDA's responsibilities have grown significantly and resources available to the agency have increased more than 60 percent. There is concern that oversight of FDA has not kept pace with the growth in the agency's regulatory authority or funding. Therefore, the agreement includes \$1,500,000 for the HHS Office of Inspector General specifically for oversight activities supported within the Inspector General's regular appropriation. The Inspector General is instructed to submit a plan to the Committees on the additional oversight activities planned with this funding and base funding for FDA oversight.

Response: Part IV of OIG's FY 2015 *Work Plan*, includes five FDA reviews underway or planned for FY 2015. These reviews focus primarily on consumer protections, specifically, inspection of generic drug manufacturers, oversight of postmarketing studies of approved drugs, FDA inspections of high-risk food facilities, review of information exchange in the drug supply chain, and drug sponsors' compliance with clinical trial reporting requirements.

With the additional \$1.5 million provided in the Consolidated and Further Continuing Appropriations Act, 2015, OIG is committed to initiating additional reviews of key risk areas. OIG is assessing what additional work will have significant impact and how best to position the

organization to provide effective FDA oversight in FY 2015 and beyond. OIG will keep Congress advised as these plans develop.

Requirements of the Inspector General Act

Section 6 of the Inspector General Act (IG Act) was amended in 2008 by the Inspector General Reform Act (P.L. No. 110-409). Revised section 6 now reads:

“(f)(1) For each fiscal year, an Inspector General shall transmit a budget estimate and request to the head of the establishment or designated Federal entity to which the Inspector General reports. The budget request shall specify the aggregate amount of funds requested for such fiscal year for the operations of that Inspector General and shall specify the amount requested for all training needs, including a certification from the Inspector General that the amount requested satisfies all training requirements for the Inspector General’s office for that fiscal year, and any resources necessary to support the Council of the Inspectors General for Integrity and Efficiency. Resources necessary to support the Council of the Inspectors General on Integrity and Efficiency shall be specifically identified and justified in the budget request.

“(2) In transmitting a proposed budget to the President for approval, the head of each establishment or designated Federal entity shall include –

- (A) an aggregate request for the Inspector General;
- (B) amounts for Inspector General training;
- (C) amounts for support of the Council of the Inspectors General on Integrity and Efficiency; and
- (D) any comments of the affected Inspector General with respect to the proposal.

“(3) The President shall include in each budget of the United States Government submitted to Congress –

- (A) a separate budget statement of the budget estimate prepared in accordance with paragraph (1);
- (B) the amount requested by the President for each Inspector General;
- (C) the amount requested by the President for training of Inspectors General;
- (D) the amount requested by the President in support for the Council of the Inspectors General on Integrity and Efficiency; and
- (E) any comments of the affected Inspector General with respect to the proposal if the Inspector General concludes that the budget submitted by the President would substantially inhibit the Inspector General from performing the duties of the office.”

OIG meets the above requirement by providing the following information:

- OIG's aggregate budget estimate and request to HHS at the beginning of the FY 2016 process was \$456 million.
- OIG's aggregate budget request to Congress for FY 2016 is \$418 million.
- Funding requested for training is approximately \$8 million.
- Funding will be necessary to support the Council of the Inspectors General on Integrity and Efficiency (CIGIE).
- The OIG comments on this budget request are contained within this document.

OIG Training Requirements

In accordance with section 6(f)(3)(C) of the IG Act, this budget requests approximately \$8 million in FY 2016 for training expenses, of which a portion will be funded from the Discretionary budget. This amount is composed of OIG's baseline training budget for its entire staff, which, with the FY 2016 request, includes approximately 1,860 criminal investigators, auditors, program evaluators, attorneys, and administrative and management staff.

OIG Financial Support for CIGIE

In support of the Governmentwide IG community, OIG contributes funds for the operation of CIGIE. In accordance with the reporting requirements of section 6(f)(3)(D) of the IG Act, this budget requests necessary funding for OIG's support of CIGIE, of which a portion will be funded from the OIG's Discretionary budget.