DEPARTMENT of HEALTH & HUMAN SERVICES

Fiscal Year

2012

Office of Inspector General

Online Performance Appendix

Introduction

The Fiscal Year (FY) 2012 Online Performance Appendix is one of several documents that fulfill the Department of Health & Human Services (HHS) performance planning and reporting requirements. HHS achieves full compliance with the Government Performance and Results Act of 1993 and Office of Management and Budget Circulars A-11 and A-136 through the HHS agencies' FY 2012 Congressional Justifications and Online Performance Appendices, the Agency Financial Report, and the HHS Summary of Performance and Financial Information (SPFI). These documents are available at http://www.hhs.gov/budget/.

The FY 2012 Congressional Justifications and accompanying Online Performance Appendices contain the updated FY 2010 Annual Performance Report and FY 2012 Annual Performance Plan. The Agency Financial Report provides fiscal and high-level performance results. The SPFI summarizes key past and planned performance and financial information.

Message from the Office of Inspector General

Since its establishment in 1976, this office has consistently achieved commendable results in fulfilling its mission to protect the integrity of HHS programs and the health and welfare of the American public.

OIG's staff of more than 1,600 professionals carries out this mission through a nationwide network of audits, evaluations, investigations, and enforcement and compliance activities focused on HHS programs and participants. Our mission encompasses the more than 300 programs administered by HHS at agencies such as the Centers for Medicare & Medicaid Services, National Institutes of Health, Food and Drug Administration, Centers for Disease Control and Prevention, and Administration for Children and Families. As required by statute, the majority of this office's resources are directed toward safeguarding the integrity of the Medicare and Medicaid programs and the health and welfare of their beneficiaries. Consistent with our responsibility to oversee all departmental programs, we also focus considerable effort on HHS's other programs and management processes, including key issues, such as food and drug safety, child support enforcement, conflict-of-interest and financial disclosure policies governing HHS staff, and the integrity of departmental contracts and grants management processes and transactions.

As HHS programs and operations continue to grow in size, scope, and complexity, it is essential that they be simultaneously protected against threats of fraud, waste, and abuse. In FY 2010, OIG's contributions to safeguarding HHS programs from threats of fraud, waste, and abuse and to promoting economy, efficiency, and effectiveness in HHS programs included:

- $3.8 billion in expected investigative receivables that were court ordered or agreed to be paid through civil settlements that resulted from cases developed by OIG investigators;

- $1.1 billion in audit receivables that were agreed to be pursued by HHS program managers as a result of OIG audit disallowance recommendations;

- a ratio of $16.7 to $1 expected return on investment measuring the efficiency of OIG's health care oversight efforts; and

- 120 of OIG's quality and management improvement recommendations that HHS program managers accepted and agreed to implement.

This report describes OIG's accomplishments in several key aspects. At the time of this writing, there were no known weaknesses in the completeness or reliability of the information in this appendix.

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Summary of Performance Targets and Results

Fiscal Year	Total Targets	Targets With Results Reported	Percentage of Targets With Results Reported	Total Targets Met	Percentage of Targets Met
2007	3	3	100%	3	100%
2008	3	3	100%	3	100%
2009	3	3	100%	3	100%
2010	3	3	100%	3	100%
2011	3	TBD	TBD	TBD	TBD
2012	3	TBD	TBD	TBD	TBD

Note: The table provides an overview of OIG outcome measure targets established for each corresponding fiscal year (FY).

Performance Detail

The Department of Health & Human Services (HHS), Office of Inspector General (OIG), Fiscal Year (FY) 2012 Online Performance Appendix uses three key 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 return on investment (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 reflect the culmination of investigation, audit, and evaluation efforts initiated in prior years. Moreover, these measures express OIG's joint success and collaboration with a network of program integrity partners at all levels of government. For example, OIG investigators and attorneys work closely with the Department of Justice (DOJ), State Medicaid Fraud Control Units, 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 and improve programs. While OIG does not have the authority to implement these corrective actions, OIG recommendations inform Congress and HHS program officials of potential cost disallowances and corrective actions that may be taken to address the vulnerabilities OIG identifies.

Performance Measure Tables and Performance Narrative

Performance Measure Summary and Reporting for "Expected Recoveries" and ROI

"Expected recoveries" resulting from OIG's health care oversight quantify the potential financial benefit to the Government that results directly from OIG's work. The difference between expected and actual recoveries is attributable to the ability to recover funds. Expected recoveries are composed of financial receivables to the Federal Government from:

- successful prosecutions, court-ordered restitution, and out-of-court settlements;
- audit disallowances that HHS program management has agreed to recoup; and
- administrative enforcement actions during a given reporting period.

Once OIG calculates expected recoveries for a reporting period, an ROI estimate is calculated. ROI is the ratio of expected recoveries to OIG's annual operating budget; the result expresses the potential financial benefit to the Federal Government for funding OIG oversight activities. For example, an ROI of $10:$1 would indicate that for every $1 spent by OIG, the Federal Government may receive $10 in financial recoveries.

For both measures, expected recoveries and ROI, performance is reported using a 3-year moving average. This methodology takes into account the time necessary to complete complex audits and investigations and to recover misspent funds identified during those inquiries. The 3-year moving average also accounts for year-to-year variability and provides a more accurate depiction of results over time.

Measure	FY	Target	Result[1]
1.1.1: Expected recoveries resulting from OIG involvement in health care fraud and abuse oversight activities (dollars in millions)	2012	$3,400	TBD, October 2012
	2011	$3,300	TBD, October 2011
	2010	$3,400	$3,782 (Target exceeded)
	2009	$3,470	$3,719 (Target exceeded)
	2008	$2,623	$3,268 (Target exceeded)
	2007	$2,460	$2,836 (Target exceeded)

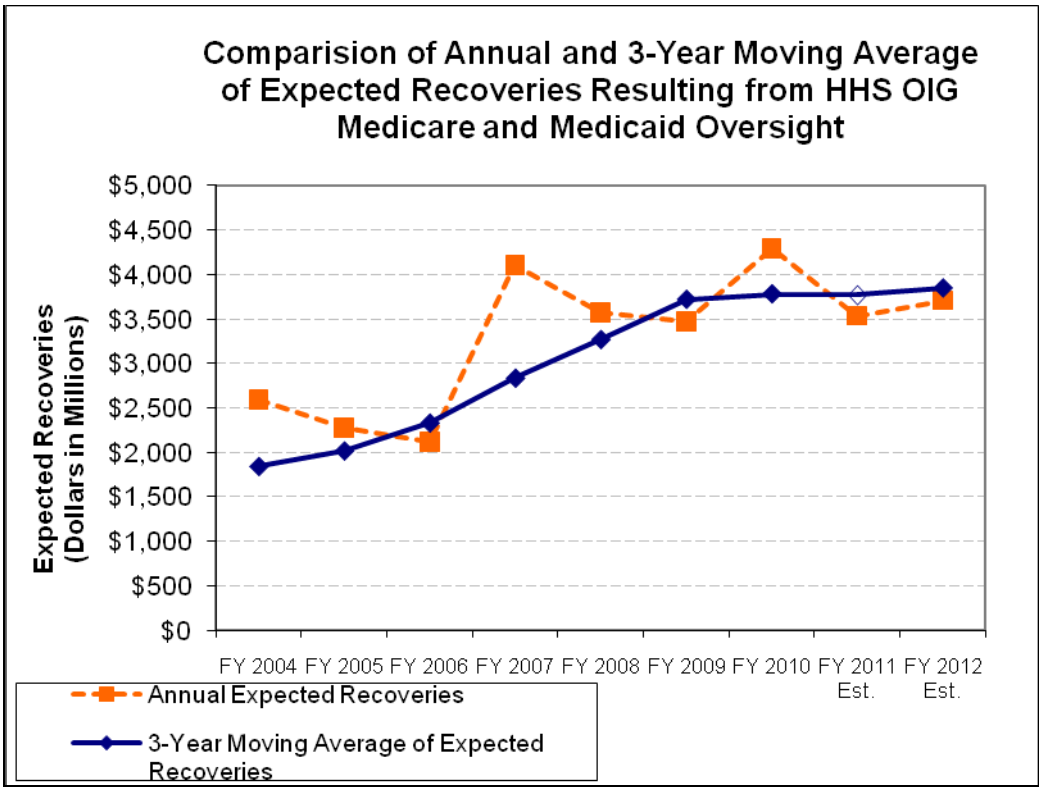
[1] OIG has updated previously reported expected recoveries and ROI results to fully reflect previously excluded investigative receivables. The revised results are within 1% of previously reported results and do not change OIG's target-achieving status.

Measure	FY	Target	Result[2]
1.1.2: ROI resulting from OIG involvement in health care fraud and abuse oversight activities	2012	$12.3	TBD, October 2012
	2011	$13.0	TBD, October 2011
	2010	$15.0	$16.7 (Target exceeded)
	2009	$16.8	$17.6 (Target exceeded)
	2008	$13.5	$16.9 (Target exceeded)
	2007	$11.4	$16.5 (Target exceeded)

The expected recoveries resulting from OIG investigative and audit oversight of Medicare and Medicaid[3] averaged $3.8 billion per year for the 3-year period from FY 2008 through FY 2010 and exceeded expected recoveries from all previous reporting periods. These results include an average of approximately $2.9 billion in investigative receivables and $0.9 billion in audit disallowances per year. The corresponding ROI for OIG oversight of Medicare and Medicaid for the same 3-year reporting period was $16.7:$1. The line graph on the following page shows the relationship between the annual and 3-year moving averages of OIG expected recoveries from health care activities from FY 2004 through FY 2010 and estimates for FYs 2011 and 2012.

[2] OIG has updated previously reported expected recoveries and ROI results to fully reflect previously excluded investigative receivables. The revised results are within 1% of previously reported results and do not change OIG's target-achieving status.

[3] OIG investigative and audit oversight of Medicare and Medicaid is also referred to as health care fraud and abuse oversight activities.



Out-year targets for expected recoveries and ROI are set on a year-by-year basis, considering recent-year averages, estimates of current workload, and the effect of recent settlements—large or small—which may skew the averages. This process sometimes results in conservative out-year targets which at times are lower than the annual expected recoveries determined purely by trend data.

For FY 2010, OIG reported expected recoveries of approximately $4.9 billion: $1.1 billion in audit receivables and $3.8 billion in investigative receivables, which includes $577 million in non-HHS investigative receivables resulting from OIG work (e.g., the States' share of Medicaid restitution).[4] Also for this FY, OIG reported exclusions of 3,340 individuals and entities from participation in Federal health care programs; 647 criminal actions against individuals or entities that engaged in crimes against departmental programs; and 378 civil actions, which included False Claims Act (FCA) and unjust enrichment settlements and lawsuits filed in Federal district court, Civil Monetary Penalties Law settlements, and administrative recoveries related to provider self-disclosure matters.

[4] The figures reported in this section include all OIG FY 2010 expected recoveries. Only HHS health care investigative receivables and health care audit disallowances are included in the expected recoveries and ROI performance measures discussed in this Performance Appendix.

Specific examples of OIG's recent Centers for Medicare and Medicaid Services (CMS) oversight work in FY 2010 include:

- Medicare Fraud Strike Force Activities: The Health Care Fraud Prevention and Enforcement Action Team (HEAT), which is made up of top-level law enforcement and professional staff from DOJ and HHS, builds on existing partnerships to prevent fraud and enforce current anti-fraud laws around the country. The initiative is enhancing efforts like the Medicare Fraud Strike Force teams, which coordinate law enforcement operations among Federal, State, and local law enforcement entities in specified localities identified as vulnerable to fraud. Strike Forces began in March 2007 and are operating in seven major cities—Miami, Florida; Los Angeles, California; Detroit, Michigan; Houston, Texas; Brooklyn, New York; Baton Rouge, Louisiana; and Tampa, Florida. During FY 2010, Strike Force efforts in 7 cities resulted in: 140 indictments involving charges filed against 284 defendants, who collectively had billed the Medicare program more than $590 million; 217 guilty pleas negotiated, 19 jury trials litigated, and guilty verdicts against 23 defendants; and imprisonment for 146 defendants sentenced to an average of more than 40 months.

- CMS Contractors: Independent Review of Claims From the Comprehensive Error Rate Testing Program (CERT): OIG determined that CMS independent medical reviews of a subsample of Medicare claims from the FY 2008 CERT samples may not have provided assurance that the FY 2008 error rate was accurate. CMS's independent medical review found 116 erroneous claims that CMS's CERT contractor had not initially determined to be in error. Although OIG was unable to quantify the statistical effect of these results on the error rate, the results indicated the need for further CMS improvements in the Medicare error rate process. OIG recommended that CMS clarify documentation policies to reduce the number of differences in professional judgment, require the CERT contractor to obtain physician orders to support the medical necessity for diagnostic tests, and require the CERT contractor to develop a corrective action plan to reduce the number of incorrect determinations. CMS concurred with the recommendations.

- Medicare and Medicaid Prescription Drugs: AstraZeneca Pays $520 million To Resolve FCA Violations: AstraZeneca, LP, and AstraZeneca Pharmaceuticals, LP (collectively, AstraZeneca), agreed to pay $520 million plus interest and enter into a 5-year corporate integrity agreement to resolve their civil FCA liability in connection with the promotion of the atypical antipsychotic drug Seroquel. AstraZeneca was alleged to have promoted Seroquel between January 2001 and December 2006 for uses that were not approved by the Food and Drug Administration (FDA) as safe and effective. AstraZeneca also was alleged to have violated the Federal anti-kickback statute by offering and paying illegal remuneration to doctors in connection with services rendered by the doctors relating to the unapproved uses of Seroquel.

Performance Measure Summary and Reporting for "Number of Accepted Quality and Management Improvement Recommendations"

OIG also reports the "number of accepted quality and management improvement recommendations" generated by OIG audits and evaluations during a reporting period. This measure captures an important aspect of OIG's efforts to identify and recommend corrections to systemic weaknesses in HHS program administration and policy implementation.

When OIG completes a report that includes recommendations to disallow costs or pursue administrative or policy improvements, HHS program managers have a fixed period of time to concur or nonconcur with each recommendation. While some recommendations may not be implemented because of the lack of available resources or other factors, OIG considers the number of accepted recommendations one appropriate measure of OIG's contribution to improving the efficiency and effectiveness of HHS programs and operations.

During FY 2010, HHS operating and staff divisions accepted 120 of OIG's recommendations. This result exceeded the annual target of 110. OIG's FY 2011 and FY 2012 workloads are likely to result in similar numbers of recommendations and the performance targets for accepted recommendations reflect this.

Measure	FY	Target	Result
1.1.3: Number of quality and management improvement recommendations accepted	2012	123	TBD, October 2012
	2011	120	TBD, October 2011
	2010	110	120 (Target exceeded)
	2009	73	112 (Target exceeded)
	2008	75	85 (Target exceeded)
	2007	75	88 (Target exceeded)

Summaries of the audits and evaluations that contributed to this performance measure are included in the OIG *Semiannual Reports to Congress*, which are located in the "Publications" section of the OIG Web site.

Some examples of high impact reviews and investigations completed during FY 2010 include:

- Challenges to FDA's Ability to Monitor and Inspect Foreign Clinical Trials: In FY 2010, OIG released a report that found that in FY 2008, sponsors relied heavily on data from foreign clinical trials to support their marketing applications for drugs and biologics. The Food, Drug, and Cosmetic Act requires all new investigational drugs and biologics to undergo clinical trials on human subjects to demonstrate the safety and efficacy of these products prior to approval for sale in the United States. Sponsors may submit data from foreign and domestic clinical trials to support marketing applications. OIG found that 80 percent of approved marketing applications for drugs and biologics contained data from

foreign clinical trials. Further, over half of clinical trial subjects and sites were located outside the United States. OIG found that FDA inspected less than 1 percent of foreign clinical trial sites. Challenges in conducting foreign inspections and data limitations inhibit FDA's ability to monitor foreign clinical trials.

- Failure to Comply With Appropriations and Acquisition Requirements: OIG found that the Centers for Disease Control and Prevention (CDC) did not comply with appropriations and acquisitions requirements when administering a contract and task orders awarded to a small business. CDC violated acquisition regulations and circumvented civil service laws by using contractor personnel for personal services and violated the bona fide needs statute by expending annual appropriations outside their 1-year period of availability. OIG recommended that CDC correct the administration of contracts used for personal services, determine whether funds expended outside the period of availability violated the Anti-Deficiency Act and correct any such violations, and ensure compliance with requirements for the obligation and expenditure of funds.

Agency Support for HHS Strategic Plan

OIG contributes to the HHS Strategic Plan directly through enforcement and compliance activities and indirectly through its reviews and recommendations for making program improvements that align with specific HHS strategic goals. The following table highlights the strategic goals and objectives to which OIG's program integrity and fraud prevention activities correspond most directly.

	OIG Goal 1: Make a positive impact on HHS programs
1. Transform Health Care	
1.A: Make coverage more secure for those who have insurance, and extend affordable coverage to the uninsured	
1.B: Improve health care quality and patient safety	
1.C: Emphasize primary and preventive care linked with community prevention services	
1.D: Reduce the growth of health care costs while promoting high-value, effective care	
1.E: Ensure access to quality, culturally competent care for vulnerable populations	
1:F: Promote the adoption of health information technology	
2. Advance Scientific Knowledge and Innovation	
2.A: Accelerate the process of scientific discovery to improve patient care	
2.B: Foster innovation at HHS to create shared solutions	
2.C: Invest in the regulatory sciences to improve food and medical product safety	
2.D: Increase our understanding of what works in public health and human service practice	
3. Advance the Health, Safety and Well-Being of the American People	
3.A: Ensure the safety, well-being, and healthy development of children and youth	
3.B: Promote economic and social well-being for individuals, families, and communities	
3.C: Improve the accessibility and quality of supportive services for people with disabilities and older adults	
3.D: Promote prevention and wellness	
3.E: Reduce the occurrence of infectious diseases	
3.F: Protect Americans' health and safety during emergencies, and foster resilience in response to emergencies	
4. Increase Efficiency, Transparency, and Accountability of HHS Programs	
4.A: Ensure program integrity and responsible stewardship of resources	X
4.B: Fight fraud and work to eliminate improper payments	X
4.C: Use HHS data to improve the health and well-being of the American people	
4.D: Improve HHS environmental, energy, and economic performance to promote sustainability	
5. Strengthen the Nation's Health and Human Services Infrastructure and Workforce	
5.A: Invest in the HHS workforce to help meet America's health and human service needs today and tomorrow	
5.B: Ensure that the Nation's health care workforce can meet increased demands	
5.C: Enhance the ability of the public health workforce to improve public health at home and abroad	
5.D: Strengthen the Nation's human services workforce	
5.E: Improve national, state, local, and tribal surveillance and epidemiology capacity	

OIG's Contributions to the HHS Strategic Plan, FY 2010 Through FY 2015

The HHS Strategic Plan outlines how HHS will advance its mission of enhancing the health and well-being of Americans. The strategic goals and objectives in the Strategic Plan correspond to specific HHS operating divisions and the programs and initiatives they operate. Objective A under Goal 4 of the plan—"Increase Efficiency, Transparency, and Accountability of HHS Programs"—outlines HHS's dedication to ensuring program integrity and responsible stewardship of HHS resources by improving the efficiency and effectiveness of HHS programs and by strengthening the integrity and accountability of payments to program beneficiaries. Objective B under the same goal highlights HHS's commitment to fighting fraud and eliminating improper payments through provider education, data analysis, audits, investigations, and enforcement.

OIG's program integrity activities support the Department's responsible stewardship of taxpayer money, which includes combating fraud, waste, and abuse in all HHS programs. In particular, OIG is directed by law to conduct independent and objective audits, evaluations, analyses, and investigations to assess the effectiveness and efficiency of policy and program implementation and to identify wrongdoers. These independent inquiries and associated recommendations strengthen the integrity of HHS's programs.

The following table shows that OIG assigns approximately 20 percent of its program costs to Objective 4.A because this objective aligns most closely with OIG's Public Health, Human Services, and Departmentwide Issues Oversight efforts, which represent approximately 20 percent of OIG's budget authority. Following a similar rationale, OIG assigns approximately 80 percent of its program costs to Objective 4.B because of the objective's close link to OIG's CMS Oversight program, which represents approximately 80 percent of OIG's budget authority. While OIG has distributed its full program costs between two objectives for the purpose of conveying commitment to specific HSS strategic goals, the results of OIG's discrete oversight activities often encompass more than any single HHS strategic objective by addressing threats to the financial integrity of all HHS programs and the well-being of beneficiaries.

Full Cost Table

(Dollars in Millions)

	Office of Inspector General		
HHS Strategic Goals and Objectives	**FY 2010**	**FY 2011**	**FY 2012**
1. Transform Health Care			
1.A: Make coverage more secure for those who have insurance, and extend affordable coverage to the uninsured			
1.B: Improve health care quality and patient safety			
1.C: Emphasize primary and preventive care linked with community prevention services			
1.D: Reduce the growth of health care costs while promoting high-value, effective care			
1.E: Ensure access to quality, culturally competent care for vulnerable populations			
1:F: Promote the adoption of health information technology			
2. Advance Scientific Knowledge and Innovation			
2.A: Accelerate the process of scientific discovery to improve patient care			
2.B: Foster innovation at HHS to create shared solutions			
2.C: Invest in the regulatory sciences to improve food and medical product safety			
2.D: Increase our understanding of what works in public health and human service practice			
3. Advance the Health, Safety, and Well-Being of the American People			
3.A: Ensure the safety, well-being, and healthy development of children and youth			
3.B: Promote economic and social well-being for individuals, families, and communities			
3.C: Improve the accessibility and quality of supportive services for people with disabilities and older adults			
3.D: Promote prevention and wellness			
3.E: Reduce the occurrence of infectious diseases			
3.F: Protect Americans' health and safety during emergencies, and foster resilience in response to emergencies			
4. Increase Efficiency, Transparency, and Accountability of HHS Programs	**$290**	**$290**	**$366**
4.A: Ensure program integrity and responsible stewardship of resources	**$58**	**$58**	**$73**
4.B: Fight fraud and work to eliminate improper payments	**$232**	**$232**	**$293**
4.C: Use HHS data to improve the health and well-being of the American people			
4.D: Improve HHS environmental, energy, and economic performance to promote sustainability			

5. Strengthen the Nation's Health and Human Services Infrastructure and Workforce			
5.A: Invest in the HHS workforce to help meet America's health and human service needs today and tomorrow			
5.B: Ensure that the Nation's health care workforce can meet increased demands			
5.C: Enhance the ability of the public health workforce to improve public health at home and abroad			
5.D: Strengthen the Nation's human service workforce			
5.E: Improve national, state, local, and tribal surveillance and epidemiology capacity			
Total	**$290**	**$290**	**$366**

Data Sources and Validation

Unique Identifier	Data Source	Data Validation
1.1.1	OIG data systems that track audit disallowances, judicial and administrative adjudications, and out-of-court settlements	Estimates of expected recoveries are recorded in OIG data systems when (1) program managers agree to disallow and pursue recovery of questioned costs, (2) judicial and administrative adjudications are established, or (3) out-of-court settlements are agreed upon.
1.1.2	OIG data systems that track audit disallowances, judicial and administrative adjudications, out-of-court settlements, and the OIG operating budget in a given year	See "Data Validation" for measure 1.1.1.
1.1.3	OIG data systems that track reports and recommendations	OIG follows a process for reporting, tracking, and validating accepted recommendations.