

## Section III: Other Accompanying Information

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## Section III: Other Accompanying Information

This section contains other financial information, HHS' detailed *Improper Payments Information Act of 2002 Report*, summary of financial statement audit and management assurance findings, the HHS Inspector General's summary of the most significant management and performance challenges facing the Department, and the Department's response to the Inspector General's assessment.

## OTHER FINANCIAL INFORMATION

**CONSOLIDATING BALANCE SHEET BY BUDGET FUNCTION**  
**As of September 30, 2010**  
**(in Millions)**

	Education, Training & Social Services	Health	Medicare	Income Security	Agency Combined Totals	Intra-HHS Eliminations	HHS Consolidated Totals
<b>Assets (Note 2)</b>							
Intragovernmental							
Fund Balance with Treasury (Note 3)	\$ 10,024	\$ 154,917	\$ 1,996	\$ 15,298	\$ 182,235	\$ -	\$ 182,235
Investments, Net (Note 4)	-	5,379	354,503	-	359,882	-	359,882
Accounts Receivable, Net (Note 5)	57	1,309	50,015	7	51,388	(50,251)	1,137
Other (Note 8)	-	299	4	-	303	(204)	99
Total Intragovernmental	10,081	161,904	406,518	15,305	593,808	(50,455)	543,353
Accounts Receivable, Net (Note 5)	-	3,017	4,377	-	7,394	-	7,394
Inventory and Related Property, Net (Note 6)	-	6,077	-	-	6,077	-	6,077
General Property, Plant & Equipment, Net (Note 7)	-	4,891	372	-	5,263	-	5,263
Other (Note 8)	-	489	1,163	-	1,652	-	1,652
<b>Total Assets</b>	<b>\$ 10,081</b>	<b>\$ 176,378</b>	<b>\$ 412,430</b>	<b>\$ 15,305</b>	<b>\$ 614,194</b>	<b>\$ (50,455)</b>	<b>\$ 563,739</b>
<b>Stewardship PP&amp;E (Note 1)</b>							
<b>Liabilities</b>							
Intragovernmental							
Accounts Payable	\$ 5	\$ 107	\$ 50,810	\$ -	\$ 50,922	\$ (50,016)	\$ 906
Other (Note 13)	35	1,181	777	18	2,011	(439)	1,572
Total Intragovernmental	40	1,288	51,587	18	52,933	(50,455)	2,478
Accounts Payable	15	657	-	1	673	-	673
Entitlement Benefits Due and Payable (Note 10)	-	27,705	45,007	-	72,712	-	72,712
Accrued Grant Liability (Note 12)	898	2,514	-	792	4,204	-	4,204
Federal Employee and Veterans Benefits (Note 11)	5	9,968	12	-	9,985	-	9,985
Other	26	8,517	601	17	9,161	-	9,161
Total Liabilities	984	50,649	97,207	828	149,668	(50,455)	99,213
<b>Net Position</b>							
Unexpended Appropriations - Earmarked funds	-	(101)	1,776	-	1,675	-	1,675
Unexpended Appropriations - Other funds	9,074	116,908	-	14,486	140,468	-	140,468
Unexpended Appropriations, Total	9,074	116,807	1,776	14,486	142,143	-	142,143
Cumulative Results of Operations - Earmarked funds	-	3,887	313,447	-	317,334	-	317,334
Cumulative Results of Operations - Other funds	23	5,035	-	(9)	5,049	-	5,049
Cumulative Results of Operations, Total	23	8,922	313,447	(9)	322,383	-	322,383
<b>Total Net Position</b>	<b>9,097</b>	<b>125,729</b>	<b>315,223</b>	<b>14,477</b>	<b>464,526</b>	<b>-</b>	<b>464,526</b>
<b>Total Liabilities and Net Position</b>	<b>\$ 10,081</b>	<b>\$ 176,378</b>	<b>\$ 412,430</b>	<b>\$ 15,305</b>	<b>\$ 614,194</b>	<b>\$ (50,455)</b>	<b>\$ 563,739</b>

**CONSOLIDATED BALANCE SHEET BY OPERATING DIVISION**  
**As of September 30, 2010**  
**(in Millions)**

	ACF	AoA	AHRQ	CDC	CMS	FDA	HRSA	IHS	NIH	OS	PSC	SAMHSA	Agency Consolidated Totals	Intra-HHS Eliminations	HHS Consolidated Totals
<b>Assets (Note 2)</b>															
<b>Intragovernmental</b>															
Fund Balance with Treasury (Note 3)	\$ 24,620	\$ 702	\$ 724	\$ 7,371	\$ 64,841	\$ 1,986	\$ 7,332	\$ 2,185	\$ 39,326	\$ 30,178	\$ 207	\$ 2,763	\$ 182,235	\$ -	\$ 182,235
Investments, Net (Note 4)	-	-	-	-	356,621	-	3,222	-	39	-	-	-	359,882	-	359,882
Accounts Receivable, Net (Note 5)	21	43	22	91	493	7	39	39	1	296	362	100	1,514	(377)	1,137
Other (Note 8)	-	-	-	-	5	-	-	-	1	-	1	94	101	(2)	99
<b>Total Intragovernmental</b>	<b>24,641</b>	<b>745</b>	<b>746</b>	<b>7,462</b>	<b>421,960</b>	<b>1,993</b>	<b>10,593</b>	<b>2,224</b>	<b>39,367</b>	<b>30,474</b>	<b>570</b>	<b>2,957</b>	<b>543,732</b>	<b>(379)</b>	<b>543,353</b>
Accounts Receivable, Net (Note 5)	-	-	1	6	7,046	160	4	158	3	8	8	-	7,394	-	7,394
Inventory and Related Property, Net (Note 6)	-	-	-	1,795	-	1	2	11	30	4,233	5	-	6,077	-	6,077
General Property, Plant & Equipment, Net (Note 7)	-	-	-	1,420	398	385	-	875	1,920	262	3	-	5,263	-	5,263
Other (Note 8)	-	-	-	-	1,309	10	330	1	2	-	-	-	1,652	-	1,652
<b>Total Assets</b>	<b>\$ 24,641</b>	<b>\$ 745</b>	<b>\$ 747</b>	<b>\$ 10,683</b>	<b>\$ 430,713</b>	<b>\$ 2,549</b>	<b>\$ 10,929</b>	<b>\$ 3,269</b>	<b>\$ 41,322</b>	<b>\$ 34,977</b>	<b>\$ 586</b>	<b>\$ 2,957</b>	<b>\$ 564,118</b>	<b>\$ (379)</b>	<b>\$ 563,739</b>
<b>Stewardship PP&amp;E (Note 1)</b>															
<b>Liabilities (Note 9)</b>															
<b>Intragovernmental</b>															
Accounts Payable	\$ 5	\$ -	\$ 2	\$ -	\$ 959	\$ 13	\$ 25	\$ 3	\$ 18	\$ 21	\$ -	\$ 2	\$ 1,048	\$ (142)	\$ 906
Other (Note 13)	52	1	49	128	811	33	86	332	84	48	4	181	1,809	(237)	1,572
<b>Total Intragovernmental</b>	<b>57</b>	<b>1</b>	<b>51</b>	<b>128</b>	<b>1,770</b>	<b>46</b>	<b>111</b>	<b>335</b>	<b>102</b>	<b>69</b>	<b>4</b>	<b>183</b>	<b>2,857</b>	<b>(379)</b>	<b>2,478</b>
Accounts Payable	15	1	10	-	-	5	45	36	376	147	28	10	673	-	673
Entitlement Benefits Due and Payable (Note 10)	-	-	-	-	72,712	-	-	-	-	-	-	-	72,712	-	72,712
Accrued Grant Liability (Note 12)	1,594	96	11	360	-	9	397	23	1,667	79	-	(32)	4,204	-	4,204
Federal Employee and Veterans Benefits (Note 11)	5	-	-	34	13	22	20	77	56	17	9,729	12	9,985	-	9,985
Other (Note 13)	41	2	13	192	6,009	263	769	594	423	796	54	5	9,161	-	9,161
<b>Total Liabilities</b>	<b>1,712</b>	<b>100</b>	<b>85</b>	<b>714</b>	<b>80,504</b>	<b>345</b>	<b>1,342</b>	<b>1,065</b>	<b>2,624</b>	<b>1,108</b>	<b>9,815</b>	<b>178</b>	<b>99,592</b>	<b>(379)</b>	<b>99,213</b>
<b>Net Position</b>															
Unexpended Appropriations - Earmarked funds	-	-	-	-	1,776	(97)	(4)	-	-	-	-	-	1,675	-	1,675
Unexpended Appropriations - Other funds	22,954	606	659	6,924	34,377	(1,572)	6,646	1,425	36,330	29,367	49	2,703	140,468	-	140,468
Unexpended Appropriations, Total	22,954	606	659	6,924	36,153	(1,669)	6,642	1,425	36,330	29,367	49	2,703	142,143	-	142,143
Cumulative Results of Operations - Earmarked funds	-	-	2	36	313,447	925	2,531	11	375	-	-	7	317,334	-	317,334
Cumulative Results of Operations - Other funds	(25)	39	1	3,009	609	2,948	414	768	1,993	4,502	(9,278)	69	5,049	-	5,049
Cumulative Results of Operations, Total	(25)	39	3	3,045	314,056	3,873	2,945	779	2,368	4,502	(9,278)	76	322,383	-	322,383
<b>Total Net Position</b>	<b>22,929</b>	<b>645</b>	<b>662</b>	<b>9,969</b>	<b>350,209</b>	<b>2,204</b>	<b>9,587</b>	<b>2,204</b>	<b>38,698</b>	<b>33,869</b>	<b>(9,229)</b>	<b>2,779</b>	<b>464,526</b>	<b>-</b>	<b>464,526</b>
<b>Total Liabilities and Net Position</b>	<b>\$ 24,641</b>	<b>\$ 745</b>	<b>\$ 747</b>	<b>\$ 10,683</b>	<b>\$ 430,713</b>	<b>\$ 2,549</b>	<b>\$ 10,929</b>	<b>\$ 3,269</b>	<b>\$ 41,322</b>	<b>\$ 34,977</b>	<b>\$ 586</b>	<b>\$ 2,957</b>	<b>\$ 564,118</b>	<b>\$ (379)</b>	<b>\$ 563,739</b>

**NET COST OF TOP 20 PROGRAMS**  
**For The Year Ended September 30, 2010 and 2009**  
(in Millions)

HHS Program	HHS Net Cost (\$)		Rank by (\$)		Budget Function	HHS Component Responsible for Program
	FY 2010	FY 2009	FY 2010	FY 2009		
Medicare	\$447,162	\$ 430,025	1	1	Medicare	CMS
Medicaid	272,995	253,352	2	2	Health	CMS
Research	33,476	29,985	3	3	Health	NIH
Temporary Assistance to Needy Families	20,307	19,058	4	4	Education, Training & Social Services / Income Security	ACF
Head Start	8,262	7,074	5	7	Education, Training & Social Services / Income Security	ACF
Children's Health Insurance Program (CHIP)	7,968	7,610	6	6	Health	CMS
Child Welfare	7,883	7,915	7	5	Education, Training & Social Services / Income Security	ACF
Child Care	5,972	5,262	8	8	Education, Training & Social Services / Income Security	ACF
Infectious Diseases	5,970	5,153	9	9	Health	CDC
Public Health and Social Services	5,057	1,355	10	18	Health	OS
Low-Income Home Energy Assistance	4,599	4,537	11	10	Education, Training & Social Services / Income Security	ACF
Child Support Enforcement	4,408	4,430	12	11	Education, Training & Social Services / Income Security	ACF
Primary Care	3,103	2,358	13	12	Health	HRSA
HIV/AIDS Programs	2,448	2,353	14	13	Health	HRSA
Clinical Services	2,188	2,148	15	14	Health	IHS
Social Services Block Grant	1,991	1,840	16	15	Education, Training & Social Services / Income Security	ACF
Substance Abuse Prevention and Treatment Block Grant	1,727	1,749	17	16	Education, Training & Social Services / Income Security	SAMHSA
Community Services	1,500	834	18	23	Education, Training & Social Services / Income Security	ACF
State and Community Based Services	1,395	1,331	19	19	Education, Training & Social Services	AOA
Health Promotion	1,193	994	20	21	Health	CDC
<b>Total, Top 20 Programs</b>	<b>839,604</b>	<b>789,363</b>				
All Other HHS Programs	17,124	14,542			Various Functions	Various Components
<b>Total Net Costs</b>	<b>\$856,728</b>	<b>\$ 803,905</b>				

**SUPPLEMENTAL STATEMENT OF NET COST**  
**For The Years Ended September 30, 2010 and 2009**  
**(in Millions)**

Responsibility Segments	2010			
	Agency Consolidated Totals	Inter-Agency Eliminations		Consolidated Totals
		Costs (-)	Earned/Exchange Revenues (+) <sup>1</sup>	
ACF	\$ 56,331	\$ (13)	\$ 51	\$ 56,369
AoA	1,529	(2)	5	1,532
AHRQ	57	(361)	13	(291)
CDC	10,356	(378)	200	10,178
CMS	728,704	(6)	298	728,996
FDA	2,153	(26)	140	2,267
HRSA	9,158	(24)	151	9,285
IHS	4,390	(33)	55	4,412
NIH	33,476	(188)	921	34,209
OS	6,513	(342)	191	6,362
PSC	738	(631)	30	137
SAMHSA	3,399	(157)	30	3,272
<b>Net Cost of Operations</b>	<b>\$ 856,804</b>	<b>\$ (2,161)</b>	<b>\$ 2,085</b>	<b>\$ 856,728</b>

Responsibility Segments	2009			
	Agency Consolidated Totals	Inter-Agency Eliminations		Consolidated Totals
		Costs (-)	Earned/Exchange Revenues (+) <sup>1</sup>	
ACF	\$ 52,318	\$ (18)	\$ 48	\$ 52,348
AoA	1,440	(4)	5	1,441
AHRQ	(6)	(393)	11	(388)
CDC	9,124	(351)	170	8,943
CMS	691,452	(2)	260	691,710
FDA	1,939	(28)	127	2,038
HRSA	7,311	(56)	173	7,428
IHS	3,952	(29)	56	3,979
NIH	29,985	(127)	753	30,611
OS	1,913	(428)	182	1,667
PSC	1,406	(607)	22	821
SAMHSA	3,301	(34)	40	3,307
<b>Net Cost of Operations</b>	<b>\$ 804,135</b>	<b>\$ (2,077)</b>	<b>\$ 1,847</b>	<b>\$ 803,905</b>

<sup>1</sup>Eliminations for non-exchange revenue are reported in the Statement of Changes in Net Position

**CONSOLIDATING STATEMENT OF NET COST BY BUDGET FUNCTION**  
**For The Year Ended September 30, 2010**  
**(in Millions)**

Responsibility Segments	Education, Training, & Social Services	Health	Medicare	Income Security	Agency Combined Totals	Intra-HHS Eliminations		Consolidated Totals
						Cost (-)	Revenue	
ACF	\$ 13,864	\$ -	\$ -	\$ 42,467	\$ 56,331	\$ (13)	\$ 51	\$ 56,369
AoA	1,529	-	-	-	1,529	(2)	5	1,532
AHRQ	-	57	-	-	57	(361)	13	(291)
CDC	-	10,356	-	-	10,356	(378)	200	10,178
CMS	-	281,542	447,162	-	728,704	(6)	298	728,996
FDA	-	2,153	-	-	2,153	(26)	140	2,267
HRSA	-	9,158	-	-	9,158	(24)	151	9,285
IHS	-	4,390	-	-	4,390	(33)	55	4,412
NIH	-	33,476	-	-	33,476	(188)	921	34,209
OS	-	6,513	-	-	6,513	(342)	191	6,362
PSC	-	738	-	-	738	(631)	30	137
SAMHSA	-	3,399	-	-	3,399	(157)	30	3,272
<b>Net Cost of Operations</b>	<b>\$ 15,393</b>	<b>\$ 351,782</b>	<b>\$ 447,162</b>	<b>\$ 42,467</b>	<b>\$ 856,804</b>	<b>\$(2,161)</b>	<b>\$ 2,085</b>	<b>\$ 856,728</b>

**GROSS COST AND EXCHANGE REVENUE**  
**For The Year Ended September 30, 2010**  
**(in Millions)**

Responsibility Segments	Intragovernmental						With the Public		Consolidated Net Cost of Operations
	Gross Cost			Less: Exchange Revenue			Gross Cost	Less: Exchange Revenue	
	Combined	Eliminations	Consolidated	Combined	Eliminations	Consolidated			
ACF	\$ 179	\$ (23)	\$ 156	\$ 53	\$ (61)	\$ (8)	\$ 56,213	\$ 8	\$ 56,369
AoA	11	(2)	9	3	(5)	(2)	1,521	-	1,532
AHRQ	38	(361)	(323)	394	(13)	381	409	(4)	(291)
CDC	949	(418)	531	535	(240)	295	9,951	9	10,178
CMS	942	(6)	936	17	(298)	(281)	788,777	60,998	728,996
FDA	917	(26)	891	41	(140)	(99)	2,239	962	2,267
HRSA	296	(35)	261	59	(162)	(103)	8,961	40	9,285
IHS	601	(33)	568	330	(55)	275	4,694	575	4,412
NIH	4,478	(2,960)	1,518	3,147	(3,693)	(546)	32,258	113	34,209
OS	657	(357)	300	573	(206)	367	6,420	(9)	6,362
PSC	126	(631)	(505)	871	(30)	841	1,491	8	137
SAMHSA	132	(164)	(32)	134	(37)	97	3,394	(7)	3,272
<b>Totals</b>	<b>\$ 9,326</b>	<b>\$ (5,016)</b>	<b>\$ 4,310</b>	<b>\$ 6,157</b>	<b>\$ (4,940)</b>	<b>\$ 1,217</b>	<b>\$ 916,328</b>	<b>\$ 62,693</b>	<b>\$ 856,728</b>



## **IMPROPER PAYMENTS INFORMATION ACT REPORT**

### **1.0 Overview**

Our FY 2010 *Improper Payments Information Act* Report includes a discussion of the following information, as required by the *Improper Payments Information Act of 2002 (IPIA)*, OMB Circular A-136 and OMB Circular A-123, Appendix C.

- Program Descriptions (Section 1.10)
- Risk Assessments (Section 2.0)
- Statistical Sampling Process (Section 3.0)
- Corrective Action Plans (Section 4.0)
- Recovery Auditing Reporting (Section 5.0)
- Accountability in Reducing and Recovering Improper Payments (Section 6.0)
- Information Systems and Other Infrastructure (Section 7.0)
- Mitigation Efforts Related to Statutory or Regulatory Barriers (Section 8.0)
- Progress and Achievements (Section 9.0)
- Improper Payment Reduction Outlook (Section 10.0)
- Program Specific Reporting Information (Section 11.0)
  - Medicare Fee-for-Service (FFS) Program (Section 11.10)
  - Medicare Advantage (Section 11.20)
  - Medicare Prescription Drug Benefit (Section 11.30)
  - Medicaid (Section 11.40)
  - Children's Health Insurance Program (Section 11.50)
  - Temporary Assistance for Needy Families (Section 11.60)
  - Foster Care (Section 11.70)
  - Head Start (Section 11.80)
  - Child Care (Section 11.90)

- 4) Medicaid - A joint Federal/State program, administered by the States that provides health insurance to certain low income individuals.
- 5) Children's Health Insurance Program (CHIP) - A joint Federal/State program, administered by the States that provides health insurance for qualifying children.
- 6) Temporary Assistance for Needy Families (TANF) - A joint Federal/State program, administered by the States that provides time-limited assistance to needy families with children to promote work, responsibility and self-sufficiency.
- 7) Foster Care - A joint Federal/State program, administered by the States for children who need placement outside their homes in a foster family home or a child care facility.
- 8) Head Start - A Federal program that provides comprehensive developmental services for America's low-income, preschool children ages three to five and their families.
- 9) The Child Care Development Fund (CCDF) - A joint Federal/State program, administered by the States that provides child care financial assistance to low-income working families.

### **2.0 Risk Assessments**

In addition to the nine programs deemed by OMB to be susceptible to significant improper payments, HHS conducts risk assessments on 23 additional high-dollar programs. OMB Circular A-123, Appendix C requires HHS to perform risk assessments once every three years on these programs. In the most recent review cycle, all 23 of these programs were deemed non-high-risk programs.

### **3.0 Statistical Sampling Process**

The statistical sampling process conducted to estimate the improper payment rate for each program identified in our program description section is discussed in the Program-Specific Reporting Information section. Eight of our programs that report error rates use a statistical contractor. Unless otherwise stated in the Program-Specific Reporting Information section, all programs also comply with *IPIA* guidance that requires that all estimates be based on the equivalent of a statistically valid random sample of sufficient size to yield an estimate with a 90-percent confidence interval of plus or minus 2.5 percentage points around the estimate of the percentage of erroneous payments.

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#### **1.10 Program Descriptions**

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The following is a brief description of the nine programs that will be discussed in this report.

- 1) Medicare Fee-for-Service (Medicare Parts A and B) - A Federal health insurance program for: people age 65 or older, people younger than age 65 with certain disabilities, and people of all ages with End-Stage Renal Disease.
- 2) Medicare Advantage (Medicare Part C) - A Federal health insurance program that allows beneficiaries to receive their Medicare benefits through a private health plan.
- 3) Medicare Prescription Drug Benefit (Medicare Part D) - A Federal prescription drug benefit program for Medicare beneficiaries.

#### 4.0 Corrective Action Plans

Corrective Action Plans for reducing the estimated rate of improper payments for each program are included in the Program-Specific Reporting Information section. There are two important aspects to the corrective action plans: (1) setting aggressive, but realistic, goals and targets and (2) achieving the targets according to the timetable in the plan. Corrective Action Plans are reviewed each year to ensure that they are focused on the root causes of the errors and that the targets are being met. If targets are not being met, remediation will take place that can include employing new strategies, adjusting staffing and other resources, and possibly revising targets.

#### 5.0 Recovery Auditing Reporting

In July 2004, HHS awarded a contingency fee contract to a recovery auditing firm to review FY 2002 and FY 2003 contract payments. During FY 2006, HHS exercised an option under the contract for review of FY 2004 and FY 2005 contract payments. As previously reported, our recovery auditors have found the HHS payment systems to be without major program integrity issues. HHS has recovered \$74,401 out of more than \$24 billion of contracts reviewed. We have not sought a contractor to attempt to recover funds beyond FY 2005 because our efforts to date have produced such small recoveries.

The table below displays full results for FY 2002-FY 2005.

AGENCY COMPONENT	HHS
Amount Subject to Review for CY + PY Reporting	\$24.2 billion
Actual Amount Reviewed and Reported CY + PY	\$24.2 billion
Amounts Identified for Recovery CY	0
Amounts Recovered CY	0
Amounts Identified for Recovery PYs	\$1,586,643
Amounts Recovered PYs	\$74,401
Cumulative Amounts Identified for Recovery (CY + PYs)	\$1,586,643
Cumulative Amounts Recovered (CY + PYs)	\$74,401

NOTE: PY= Prior Year, CY= Current Year

#### 6.0 Accountability in Reducing and Recovering Improper Payments

HHS has shown tremendous leadership in the improper payments arena. We have been publishing an error rate for Medicare Fee-for-Service (FFS) since FY 1996, which was one of the first error rates published across government.

HHS has also been reporting Foster Care and Head Start error rates since FY 2004. Last year, we reported at least one error component for seven of our high risk programs. HHS continues to implement corrective action plans to reduce future error rates.

In addition, HHS management performance plan objectives hold agency managers, beginning with leadership and cascading down through HHS Senior Executives (including component heads) to the lowest accountable program official, responsible for achieving progress on this initiative. As part of the semiannual and annual performance evaluation, HHS Senior Executives and program officials are evaluated on the progress the agency achieves toward this and other goals.

#### 7.0 Information Systems and Other Infrastructure

Reporting requirements related to information systems and other infrastructure is discussed by program within the Program-Specific Reporting Information section.

#### 8.0 Mitigation Efforts Related to Statutory or Regulatory Barriers

Reporting requirements related to whether there are any statutory or regulatory barriers to reducing improper payments are discussed by program within the Program-Specific Reporting Information section.

#### 9.0 Progress and Achievements

##### 9.10 FY 2010 Progress

HHS currently has nine programs that have been deemed risk susceptible: Medicare Fee-for-Service, Medicare Advantage, Medicare Prescription Drug Benefit, Medicaid, Children's Health Insurance Program (CHIP), Temporary Assistance for Needy Families (TANF), Head Start, Child Care, and Foster Care. HHS expects to report a comprehensive error rate for the Medicare Prescription Drug Benefit program next year.

HHS works with OMB to put approved measurement plans in place for all risk-susceptible programs as well as a corrective action plan with OMB-approved targets for all programs that have established baseline measurements.

## 9.20 Achievements

### 9.21 Improving Program Integrity in Medicare and Medicaid

- Medicare:

Section 302 of the *Tax Relief and Health Care Act of 2006* required HHS to implement a Recovery Audit Contractor (RAC) program in all 50 States no later than January 1, 2010. In February 2009, HHS awarded contracts to four RACs. Each RAC is responsible for identifying and correcting improper payments in approximately 25 percent of the country. HHS completed the nationwide implementation effort in October 2009.

FY 2010 was the first year for the national RAC program. During FY 2010 HHS focused on education and outreach, and establishing an infrastructure for managing and overseeing the RACs. As of September 30, 2010, the RAC program has demanded approximately \$135 million and recovered \$75.4 million. HHS expects collections to continue to increase as the RACs expand their reviews.

- Medicaid:

Section 6411 of the *Affordable Care Act* requires States to establish Medicaid RAC programs. HHS has required States to submit State plan amendments by December 31, 2010, on how they will establish their RAC program. Medicaid RACs will be paid by the States on a contingency basis. They will review Medicaid provider claims to identify and recover overpayments and identify underpayments made for services provided under Medicaid State plans and Medicaid waivers. HHS is in the process of developing a proposed rule that outlines requirements States must meet for this program.

### 9.22 Head Start Signed Statement Template Form

HHS has developed a standard signed statement template form for Head Start, which was made available to all grantees in FY 2009. Since OMB clearance (OMB 0907-0374) was obtained in FY 2010, the use of the form is optional, but grantees are strongly encouraged to use it. The standard signed statement form helps guide grantees on the type of information they need to collect from prospective families during the enrollment process and provides them with a structure for recording this information.

### 9.23 Public Assistance Reporting Information System

The Public Assistance Reporting Information System (PARIS) is a voluntary project that

enables participating States' public assistance data to be matched against several databases to help maintain program integrity and detect and deter improper payments in several programs (TANF, Medicaid and the Supplemental Nutritional Assistance Program). The August 2010 data match was the largest to date in terms of number of agencies (50) participating.

HHS engaged in a number of activities to improve data-match capabilities and usefulness to increase State utilization of PARIS. These activities included engaging in outreach activities to encourage States to participate in the PARIS match process; providing HHS training to States in utilizing the PARIS to its fullest capability; conducting an evaluation of the PARIS; formulating recommendations for improving and enhancing its usefulness; and developing a uniform reporting format.

On October 10, 2008, the *QI Program Supplemental Funding Act of 2008* was signed. The *Act* stated that in order to receive Medicaid Federal matching funds for automated data systems to administer the Medicaid State plan, the provision requires States to have an operational Medicaid eligibility determination system that provides for data matching through PARIS (or any successor system), including matching with medical assistance programs operated by other States. HHS issued a State Medicaid Directors Letter dated June 21, 2010 to promulgate this information to the States

## 10.0 Improper Payment Reduction Outlook FY 2009 through 2013

The chart on the following page shows our *IPIA* results for the current year (CY) 2010, the prior year (PY) 2009, as well as the targets for the years 2011 through 2013. For each year we show, for each program, outlays for that fiscal year (FY), an error rate or target (IP%), and the dollars paid improperly (IP\$). Table notes are defined in Section 10.1, after the table.

### IMPROPER PAYMENT REDUCTION OUTLOOK FY 2009 - FY 2013 (in Millions)

Program	PY Outlay \$	PY %	PY \$	CY Outlay \$	CY IP %	CY IP \$	CY+1 Est Outlay \$	CY+1 IP %	CY+1 IP \$	CY+2 Est Outlay \$	CY+2 IP %	CY+2 IP \$	CY+3 Est Outlay \$	CY+3 IP %	CY+3 IP \$
Medicare FFS	308,418 Note (a)	12.4 Note (1)	\$35,400	326,400 Note (b)	10.5	34,300	355,956 Note (c)	8.5	30,300	372,303	6.2	23,100	399,112	5.8	23,100
Medicare MC	77,985 Note (d)	15.4	12,010	96,437 Note (e)	14.1	13,600	129,213 Note (f)	13.7	17,700	111,802	13.2	14,800	120,581	12.9	15,600
Medicare Drug	54,869 Note (g)	N/A	N/A	58,822	N/A Note (2)	N/A	68,458	N/A	N/A	66,065	N/A	N/A	77,333	N/A	N/A
Medicaid	188,286 Note (h)	9.6	18,075	239,012 Note (i)	9.4 Note (3)	22,500	258,706 Note (j)	8.4	21,700	261,284	7.4	19,300	282,831	6.4	18,100
CHIP	7,855 Note (k)	N/A Note (4)	N/A	8,909	N/A	N/A	10,292	N/A	N/A	11,605	N/A	N/A	12,885	N/A	N/A
TANF	20,727	N/A	N/A	17,320	N/A Note (5)	N/A	17,191	N/A	NA	17,061	NA	NA	17,148	NA	N/A
Head Start	7,113	3.0	213.4	7,234	1.7	123	8,234	1.7 Note (6)	140	8,646	1.7	147	9,077	1.7	154.3
Foster Care	1,610	4.7	75.7	1,483	4.9	72.7	1,306	4.7	61.4	1,224	4.5	55.1	1,190	4.3	51.2
Child Care	5,245	11.9	624	6,091	13.3 Note (7)	810	6,239	13.1	817.3	5,722	12.8	732.4	5,583	12.4	692.3

Note: The CY+1, CY+2 and CY+3 estimated dollars paid improperly (IP\$) is calculated based on the target error rate and estimated outlays for each year, respectively. However, it is important to note that the measurement periods for each program vary. Therefore, the future outlay estimates presented are not the actual amounts against which the target error rates will be applied to compute the dollars paid improperly in future years. To illustrate, the CY outlays for Medicaid, \$239,012 million, is actually based on FY 2009 claims data, as explained in note (i), whereas the CY+1 outlays of \$258,706 million reflects FY 2011 estimated outlays. When determining the amount of dollars paid improperly next year, the target error rate of 8.4% will be applied to the FY 2010 claims data.

### 10.10 Improper Payment Reduction Outlook Notes

(a) – PY benefit outlays for Medicare FFS are from the November 2009 Improper Medicare FFS Payments Report (based on claims from April 2008 – March 2009).

(b) – CY benefit outlays for Medicare FFS are from the November 2010 Improper Medicare FFS Payments Report (based on claims from April 2009 – March 2010).

(c) – Medicare FFS CY+1, CY+2, CY+3 benefit outlay numbers are based on the FY 2011 Midsession Review (Medicare Benefit Outlays current law (CL)).

(d) – Medicare Advantage PY benefit outlays are from the Medicare Part C Payment Error Final Report 2009 (based on CY 2007 data).

(e) – Medicare Advantage CY benefit outlays are from the Medicare Part C Payment Error Final Report 2010 (based on CY 2008 data).

(f) – Medicare Advantage CY+1, CY+2, CY+3 benefit outlay numbers are based on the FY 2011 Midsession Review (Medicare Benefit Outlays (CL)).

(g) – Medicare Prescription Drug Benefit PY, CY, CY+1, CY+2, CY+3 outlay numbers are based on the FY 2011 Midsession Review (Medicare Benefit Outlays (CL)).

(h) – PY benefit outlays for Medicaid are from the 2009 Medicaid Annual Error Rate Report (based on FY 2008 claims).

(i) – CY benefit outlays for Medicaid are from the 2010 Medicaid Annual Error Rate Report (based on FY 2009 claims).

(j) – Medicaid CY+1, CY+2, CY+3 benefit outlay numbers are based on the FY 2011 Midsession Review (Medicaid Net Benefit Outlays (CL), excluding CDC Program Vaccine for Children obligations).

(k) – CHIP PY, CY, CY+1, CY+2, CY+3 benefit outlays are based on the FY 2011 Midsession Review (CHIP Total Benefit Outlays with CHIPRA Bonus and Health Care Quality Provisions (CL)).

(1) – The FY 2009 Agency Financial Report (AFR) reported the Medicare FFS error rate as 7.8 percent with \$24.1 billion in improper payments. HHS changed its error rate measurement methodology during the FY 2009 review year. Thus, the 7.8 percent represents a combination of review results using two different methodologies. The

original methodology, under which most of the claims were reviewed, was less stringent than the new methodology. The error rate based on the subsample of claims using the new stricter methodology was 12.4 percent with \$35.4 billion in error (the amount of \$35.4 billion in improper payments was derived from statistical calculations based on the subsample reviewed). Given the change in methodology, and that HHS is now using the new methodology, HHS is reporting the prior year error rate as 12.4 percent rather than 7.8 percent.

(2) – For FY 2010 *IPIA* reporting for the Medicare Prescription Drug Benefit, HHS calculated four components of payment error: (1) the Medicare Advantage and Prescription Drug System (MARx) Payment Error (MPE): the measurement reflects errors in Part D payments caused by errors in the transfer/interpretation of source data and errors in payment calculations in the MARx payment system; (2) payment error relating to Low Income Subsidy status (PELS): the measurement reflects errors in Low Income Cost sharing Subsidy (LICS) payments; (3) Payment Error Related to Incorrect Medicaid Status (PEMS): the measurement reflects errors in LICS and two other Low Income Subsidy-related payments: the Low Income Premium Subsidy and Direct Subsidy amounts; where the FY 2009 Payment Error Rate Measurement (PERM) national Medicaid eligibility case error rate is applied to Part D payments to calculate a PEMS error rate for *IPIA* reporting; and (4) Payment Error Related to Prescription Drug Event Data Validation (PEPV): the measurement reflects errors due to invalid and/or inaccurate Prescription Drug Event (PDE) records that impact Part D LICS and reinsurance payments. The MPE, PELS, and PEMS measures are based on CY 2008 payments, and the PEPV measure is based on CY 2007 payments. Note that the four Part D estimates of gross dollars in error reported for FY 2010 are not mutually exclusive, and therefore, cannot be summed. HHS calculated a Part D MPE rate of 0.1 percent for payments made from January 1, 2008 through December 31, 2008, and estimated a gross amount of payment error totaling \$45.0 million. Estimated Part D MPE underpayments were \$20.0 million and estimated overpayments were \$25.0 million. HHS calculated a Part D PELS error rate of 0.1 percent for payments made from January 1, 2008 through December 31, 2008, and estimated a gross amount of payment error totaling \$54.0 million. Estimated Part D PELS underpayments were \$33.0 million and estimated overpayments were \$21.0 million. HHS calculated a

Part D PEMS error rate of 1.7 percent for payments made from January 1, 2008 through December 31, 2008, and estimated a gross amount of payment error totaling \$785.0 million (all errors are overpayments). HHS calculated a Part D PEPV error rate of 12.7 percent for payments from January 1, 2007 through December 31, 2007, and estimated a gross amount of payment error totaling \$5.4 billion. Estimated Part D PEPV underpayments were \$3.0 million and estimated overpayments were \$5.4 billion.

(3) – HHS calculated and is reporting the three-year weighted average national error rate that includes data reported in the *AFR* for FYs 2008, 2009, 2010. The weighted national error components rates are as follows: Medicaid FFS: 4.4 percent; Medicaid managed care: 1.0 percent; and Medicaid eligibility: 5.9 percent. However, as required under Section 601 of the *Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA P.L. 111-3)*, HHS published a final rule on August 11, 2010, which required the eligibility reviews to be consistent with the State's eligibility verification policy rather than reviewing eligibility against a uniform methodology, which was done in the past. Based on current regulations, certain cases from FYs 2008-2010 would no longer be considered as errors.

(4) – The Payment Error Rate Measurement final rule (75 FR 48816), the methodology used to measure the Medicaid and Children's Health Insurance Program, was published on August 11, 2010, and became effective September 10, 2010. This final rule implements provisions from the *Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA)* with regard to the PERM program. Section 601 of *CHIPRA* prohibits HHS from calculating or publishing any national or state-specific error rates for CHIP until six months after the new PERM final rule is effective. HHS did not report a national error rate for CHIP in the FY 2009 *AFR* and due to timing of the published PERM final rule, will not be reporting a national error rate for CHIP in the FY 2010 *AFR*. However, HHS will begin conducting the CHIP error rate measurement in FY 2011, with the results being published in the FY 2012 *AFR*. Due to the recent publication of the PERM final rule, setting out-year target rates for CHIP is not applicable at this time.

(5) – The TANF program is not reporting an error rate for FY 2010. Statutory limitations prohibit HHS from requiring States to participate in a TANF improper payment measurement. Despite statutory limitations, HHS continues to explore options that will allow for a future error rate measurement.

(6) – HHS is engaged in a number of efforts to reduce erroneous determinations in the Head Start eligibility process and to improve our detection and measurement of errors. Until HHS determines how these efforts will impact error rates, HHS will be maintaining our FY 2010 rates as our out-year targets.

(7) – Since States measure once every three years, this is the first year that HHS is reporting a baseline error rate for Child Care. The error rate is based on a three year weighted average of error rates.

## 11.0 Program-Specific Reporting Information

Within this section we discuss each program's methodology for complying with *IPIA*, the results and future plans. For each program we discuss:

- How they performed their sampling, including sample sizes and methodology;
- Plans for corrective action, including a breakdown of most common error types;
- Recovery Actions taken as a result of identifying improper payments;
- Whether there are statutory, regulatory, or information systems barriers that limit potential corrective actions and;
- Best practices that have been incorporated in each error rate process.

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### 11.10 Medicare Fee-for-Service Program - A Federal health insurance program for: people age 65 or older, people under age 65 with certain disabilities, and people of all ages with End-Stage Renal Disease.

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#### 11.11 Statistical Sampling Process

The Medicare Fee-for-Service (FFS) improper payment estimate is calculated under the Comprehensive Error Rate Testing (CERT) Program.

The Medicare FFS improper payment methodology begins with a random sample of claims. This year approximately 82,000 claims were sampled. Next, for each sampled claim, HHS obtains medical records from providers and additional claim detail from its shared systems. This information is

reviewed for compliance with Medicare coverage, coding and billing rules. When a provider does not provide the requested medical record documentation or the information submitted does not meet the Medicare requirements, the claim is counted as an error.

The Medicare FFS error rate for FY 2010 is 10.5 percent, or \$34.3 billion.

During the analysis of improper payments identified in 2010, CMS found that the improper payments error rate for inpatient hospital claims had increased significantly from last year. A large number of the payment errors were due to clinical care and procedures provided in an acute inpatient hospital that should have been provided in an outpatient hospital or other less intensive setting, meaning the clinical service was medically necessary but the place of service was incorrect. Under current Medicare statute, these claims must be denied in full. These inappropriate "place of service" errors accounted for projected improper payments of \$5.1 billion.

#### **11.12 Medicare FFS Corrective Action Plans**

The primary causes of improper payments, as identified in the FY 2010 Medicare FFS Improper Payments report, were insufficient documentation errors (Administrative and Documentation), medically unnecessary services (Authentication and Medical Necessity), and to a lesser extent, coding errors (Administrative and Documentation). When the errors are analyzed based on the setting in which the service took place, the data shows that the most improper payments are due to medically unnecessary errors for durable medical equipment (DME) and inpatient hospitals services. Physicians and inpatient hospitals contribute substantially to the amount of improper payments due to insufficient documentation and incorrect coding errors.

HHS developed an Error Rate Reduction Plan (ERRP) that outlines actions the agency will implement in an effort to prevent/reduce improper payments for all categories of error.

#### **Administrative and Documentation Errors - Corrective Actions:**

HHS has implemented safeguards to better ensure that only legitimate providers and suppliers receive Medicare payments:

- HHS undertook numerous aggressive actions to strengthen the provider enrollment process; provided more rigorous oversight and monitoring once a provider/supplier enrolled in the program; and strengthened the provider revocation process. HHS implemented a durable medical equipment accreditation program to

ensure the legitimacy of the DME suppliers that bill Medicare and to ensure those suppliers meet all the requirements for participation in the Medicare program.

- HHS implemented surety bond requirements for most suppliers of durable medical equipment, prosthetics and orthotics.
- HHS published an Interim Final Rule with Comment (IFC) regulation titled, "Medicare and Medicaid Programs; Changes in Provider and Supplier Enrollment, Ordering and Referring, and Documentation Requirements; and Changes in Provider Agreements" in the Federal Register on May 5, 2010. This IFC implemented several provider enrollment enhancements as required by the *Patient Protection and Affordable Care Act (Affordable Care Act) (P. L. 111-148)* designed to support the Administration's efforts to prevent and detect fraud, waste, and abuse in the Medicare and Medicaid programs, and to ensure quality care for beneficiaries.
- HHS published a final rule titled, "Medicare Program; Establishing Additional Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Supplier Enrollment Safeguards" (CMS-6036-F) in the Federal Register on August 27, 2010. This final rule clarified and expanded on the existing enrollment requirements that DMEPOS suppliers must meet to establish and maintain billing privileges in the Medicare program.
- HHS initiated the realignment of the Program Safeguard Contractors (PSC) with the Medicare Administrative Contractors (MACs). When the realignment is completed, there will be seven zones to address fraud "hot spots" in the United States, thereby concentrating on areas of high fraud occurrence. The name for this entity is being changed from PSCs to Zone Program Integrity Contractor (ZPIC). Four ZPIC awards have already been made.
- HHS took steps to fight durable medical equipment, prosthetics and orthotics (DMEPOS) fraud in the "high risk" states of Florida, California, Texas, Illinois, Michigan, North Carolina and New York. These efforts include more stringent reviews of new suppliers' applications; unannounced site visits; extensive pre- and post-payment review of claims; interviews with high volume ordering/referring physicians; and visits to high risk beneficiaries to ensure they are appropriately receiving items and services for which Medicare is being billed.
- HHS implemented the DME competitive bidding program which will have a gradual impact on the DME error rate.

HHS implemented improvements and continues to improve upon the Medicare FFS error rate measurement program to ensure that providers and suppliers submit the required documentation, as follows:

- HHS commenced DME and MAC task forces. These task forces consist of contractor medical review professionals that meet regularly to develop strategies for provider education in error prone areas. One potential strategy involves the task forces writing informational articles that will be distributed on an as-needed basis to promote education among providers. The articles would be maintained on the Medical Learning Network (MLN).
- When a supplier is contacted for documentation, HHS contacts the ordering provider and advises them that they may be contacted by the supplier.
- HHS conducted calls with contractors and sent notices to providers to advise them of the special studies, measures, the associated documentation requests they may receive, and what they are required to provide.
- HHS continuously revises the medical record request letters to clarify the components of the medical record that are required for a CERT review.
- HHS contacts third party providers to request documentation when the billing provider indicated that a portion of the medical record is possessed by a third party.
- HHS conducts ongoing education to inform providers about the importance of submitting thorough and complete documentation. This involves national training sessions, individual meetings with providers with high error rates, presentations at industry association meetings, and the dissemination of educational materials.

**Authentication and Medical Necessity Errors - Corrective Actions:**

- HHS continually updates its review manuals to clarify requirements for reviewing documentation to promote uniform interpretation of our policies across all medical reviews performed by Medicare contractors.
- The HHS implementation of the Electronic Submission of Medical Documentation (ESMD) into the CERT review process will create greater program efficiencies, allow a quicker response time to documentation requests, and provide better communication between the provider, the CERT contractors, and HHS.

- HHS developed Comparative Billing Reports (CBRs) to help Medicare non-hospital providers analyze administrative claims data. CBRs compare a provider's billing pattern for various procedures or services to their peers on a state and national level. HHS also developed the Program for Evaluating Payment Patterns Electronic Report (PEPPER). The PEPPER allows Medicare inpatient hospital providers to also analyze their billing patterns through a comparison to other providers in their state and in the nation.
- HHS is developing a Vulnerability Tracking System (VTS) which will track and analyze vulnerabilities identified by internal and external sources.
- HHS is conducting a competition to procure private sector edits to implement within the Medicare program. As part of this effort HHS will evaluate the accuracy of commercial products and determine whether these products are feasible in the Medicare FFS environment and whether they can reduce improper payments in the Medicare FFS program. HHS posted two requests for proposals (RFPs) during FY 2010. The first RFP, for the automated edit integration contractor, was awarded in September 2010. The second RFP, for the automated edit module contractor, was posted August 2010 and will be awarded late second quarter FY 2011.
- HHS will explore conducting probe samples on providers to identify potential problem areas. Based on the probe results, additional corrective actions will be taken.
- HHS is increasing medical review. The findings shall be used to target additional medical review in those areas with high rates of error.
- HHS will allow RACs to review additional provider types and will closely monitor the decisions made by the RACs.
- HHS tasked each Carrier, FI, and MAC with developing an Error Rate Reduction Plan (ERRP) that targets medical necessity errors in their jurisdiction.
- HHS requires the Carriers, FIs, and MACs to review and validate the CERT results for their jurisdiction to determine the education needed to reduce medical necessity and incorrect coding errors.
- HHS developed medically unlikely auto-deny edits to catch services where the level billed falls beyond a specified limit. These edits are updated quarterly.



- HHS increased and refined educational contacts with providers who are billing in error.
- HHS developed and installed new correct coding edits.

### **11.13 Medicare FFS Improper Payment Recovery**

The actual overpayments identified in the FY 2010 Medicare FFS Improper Payments Report were \$5,057,759. The identified overpayments are to be recovered by the Medicare contractors via the standard payment recovery methods. As of the report publication date, Medicare contractors reported collecting \$3,297,479 of the actual overpayment dollars identified in the report.

HHS traditionally has been able to recover 85 percent of identified Medicare overpayments over the last five years. Specifically, in FY 2009, HHS recovered 89 percent or \$4,202,977 of the total actual identified Medicare overpayments of \$4,729,993.

### **11.14 Medicare FFS Information Systems and Other Infrastructure**

HHS has the information systems and other infrastructure it needs to reduce improper Medicare FFS payments to the levels that we have targeted. HHS' systems have the ability to identify developing and continuing aberrant billing patterns based upon a comparison of local payment rates with national rates. The systems at both the Medicare contractor level and the central office level are tied together by a high-speed secure network that allows rapid transmission of large data sets between systems. No other systems or infrastructure are needed at this time.

### **11.15 Medicare FFS Statutory or Regulatory Barriers that could limit Corrective Actions**

No statutory or regulatory barriers that could limit corrective actions have been identified at this time.

### **11.16 Medicare FFS Best Practices**

The following best practices have been incorporated into the overall CERT process to ensure the highest degree of efficiency for the program:

- CERT offers many educational forums for providers to gain additional knowledge about the CERT program, and to give providers the latest up-to-date information. Such educational resources include several CERT-related websites, a toll-free CERT contractor customer service line, CERT provider calls, and on-line manuals.

- HHS holds weekly calls with all CERT contractors in order to facilitate communication and problem solving and to improve the CERT process.

### *11.20 Medicare Advantage or Medicare Part C - A Medicare health insurance program that allows beneficiaries to receive their Medicare benefits through a private health plan.*

### **11.21 Part C Medicare Advantage Statistical Sampling Process**

For FY 2010, HHS is reporting a composite error estimate for the Medicare Advantage Program (Part C), based on CY 2008 payments. The CY 2008 Part C Composite Payment Error Rate combines two component payment error measures: the Medicare Advantage Prescription Drug (MARx) Payment Error (MPE) estimate and the Risk Adjustment Error (RAE) estimate.

The Part C MPE estimate captures errors in prospective Part C payments caused by errors in the transfer of data, interpretation of data, and payment calculations in the MARx system. The methodology consists of:

- Selection of a random three percent sample of beneficiaries for whom HHS made payments to plans, for each month of CY 2008.
- Computation of the prospective payment error amount for sampled beneficiaries.
- Extrapolation of the sample payment error to the population, resulting in a Part C gross payment error amount.

The RAE estimate captures payment errors due to the application of incorrect beneficiary risk scores. The primary component of a beneficiary's risk score is based on clinical diagnoses submitted by plans. If diagnoses submitted to HHS by the plans are not supported by medical records, the risk scores will be inaccurate and result in payment errors. The RAE estimate is based on medical record reviews conducted under HHS' annual Risk Adjustment Data Validation (RADV) process, where unsupported diagnoses are identified and corrected risk scores are calculated.

The CY 2008 RAE methodology consists of:

- Selection of a stratified random sample of 600 beneficiaries for whom a risk adjusted payment was made in CY 2008, where the strata are high, medium, and low risk scores.
- Medical record review of the diagnoses submitted by plans for the 600 sampled beneficiaries.

- Calculation of beneficiary-level payment error for the sample.
- Extrapolation of the sample payment error to the population subject to risk adjustment, resulting in a Part C gross payment error amount.

The CY 2008 Part C composite payment error amount is the sum of the MPE and RAE gross payment error amounts described above. The Part C composite payment error rate is this sum divided by the CY 2008 total final Part C payments.

The Part C composite error rate for CY 2008 is 14.1 percent.

### **11.22 Medicare Advantage Corrective Action Plans**

The root cause of improper payments in the Part C program for CY 2008 is Administrative and Documentation errors. The majority of the payment error estimate results from insufficient documentation to support the diagnoses submitted by plans for payment, measured by the RAE. The remainder of the payment error in the program is related to transfer of data, interpretation of data, and payment calculations within the MARx payment system, reflected in the MPE estimate. HHS is taking steps to address the error measured by both the MPE and RAE.

For the MPE error estimate, HHS will continue to routinely implement payment controls in the MARx payment system to ensure accurate and timely payments, including monthly payment validation and authorization processes. MARx payment errors are corrected and payment adjustments are made on a flow basis, including payment adjustments applied as part of the final Part C risk score reconciliation. These steps have been successful, as the MPE rate has declined from that reported in the *FY 2009 Agency Financial Report*.

For the RAE error estimate, HHS has implemented a corrective action plan. HHS is proceeding with the RADV process to estimate payment error at the contract level for the purposes of recovering overpayments. HHS has also conducted national training sessions for Medicare Advantage plans that provided comprehensive information on the processes for submitting accurate risk adjustment data. This training reviewed RADV procedures based on medical record review and payment error associated with inaccurate risk adjustment data. Additionally, outreach to plans is conducted regularly through a monthly user group call, during which any questions pertaining to risk adjustment may be addressed. Finally, HHS is developing a method for identifying risk adjustment diagnoses that are more likely to be associated with payment error. This study will examine the reasons these

diagnoses are problematic. HHS will use these findings to conduct outreach and education to plans.

### **11.23 Medicare Advantage Program Improper Payment Recovery**

The MARx payment system error rate is based on analysis of prospective payments. MARx payment system errors are fixed continuously throughout the payment year. The resulting payment adjustments are regularly corrected in the MARx system, including payment adjustments due to the final Part C risk score reconciliation. Therefore, recovery of MPE errors occurs as part of the routine operation of the MARx payment system.

Regarding the risk adjustment error, the CY 2008 Medical Record Review was based on a national sample of beneficiaries, and no payment recovery has been conducted at this point. However, HHS is proceeding with the RADV process to estimate CY 2007 payment error at the contract level for the purposes of recovering overpayments.

### **11.24 Medicare Advantage Information Systems and Other Infrastructure**

HHS has the information systems and other infrastructure needed to reduce improper Part C Medicare Advantage payments. HHS uses the following internal Medicare systems to make and validate the Part C payments: the Medicare Beneficiary Database, the Risk Adjustment System, the Health Plan Management System, and the MARx payment system. No other systems or infrastructure are needed at this time.

### **11.25 Medicare Advantage Statutory or Regulatory Barriers that could limit Corrective Actions**

No statutory or regulatory barriers that could limit corrective actions have been identified at this time.

### **11.26 Medicare Advantage Program Best Practices**

HHS has taken several steps to ensure payment accuracy in the Medicare Advantage program. HHS performs a monthly evaluation of the MARx payment system, as represented in the MPE estimate, which has led to system refinement and more accurate prospective payment to plans.

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### *11.30 Medicare Prescription Drug Benefit or Part D - A Federal prescription drug benefit program for Medicare beneficiaries.*

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### **11.31 Part D Statistical Sampling Process**

In FY 2009, HHS implemented two methodologies developed in prior years to estimate improper payments for two components of Part D payment:

the Medicare Advantage Prescription Drug (MARx) Payment Error (MPE) and the Payment Error related to Low Income Subsidy (LIS) status (PELS). HHS also reported for the first time the Part D Payment Error related to incorrect Medicaid Status (PEMS). In FY 2010, in addition to reporting the MPE, PELS, and PEMS estimates, HHS is reporting for the first time the Part D Payment Error related to Prescription Drug Event Data Validation (PEPV).

The Part D MPE estimate captures errors in prospective Part D payments caused by errors in the transfer of data, interpretation of data, and payment calculations in the MARx system. The MPE methodology consists of:

- Selection of a random three percent sample of beneficiaries for whom HHS made payments to plans, for each month of CY 2008.
- Computation of the prospective payment error amount for sampled beneficiaries.
- Extrapolation of the sample payment error to the population, resulting in a Part D MPE gross payment error amount and an MPE rate.

For FY 2010, the MPE rate is 0.10 percent.

The Part D PELS estimate captures payment errors due to inconsistent HHS data on beneficiary LIS status and the related low income cost sharing subsidy (LICS) payments. The payment error may occur when a State Medicaid agency or the SSA submit to HHS' systems an update on a beneficiary's level of LIS after a Prescription Drug Event (PDE) record has been accepted. The PELS methodology consists of:

- Identification of the population subject to PELS.
- For this population, identification of discrepancies between LIS status in HHS' systems at the time of reconciliation and LIS status in the PDE record generated on the date of service, and computation of the LICS payment amount based on the corrected LIS status.
- Computation of: (1) the gross payment amount in error (the absolute difference between actual and corrected LICS payments for accepted PDE records), and (2) the PELS rate.

For FY 2010, the PELS rate is 0.12 percent.

The Part D PEMS estimate captures payment errors due to incorrect assignment of Medicaid status, which results in incorrect LIS-related payments. Full benefit dually-eligible beneficiaries (eligible for Medicare and Title XIX benefits -- comprehensive health benefits and/or the Medicare Savings

Program) are also eligible for the Part D full LIS. If a beneficiary were incorrectly assigned Medicaid eligibility, all or part of HHS' LIS-related payment to the Part D sponsor would be in error. The CY 2008 PEMS estimate is based on the 2008 national Medicaid eligibility case error rate determined by another of HHS' *IPIA* error rate measurement programs, the Payment Error Rate Measurement (PERM) program. For the PEMS estimate, this PERM rate (representing incorrect status for the entire Medicaid population) is assumed to be a proxy for the eligibility error rate for a subset of Medicaid beneficiaries, those also eligible for Medicare. The PEMS rate reflects overpayments only. The PEMS methodology consists of:

- Application of the PERM eligibility active case error rate to 100 percent of dual-eligible beneficiaries, by dividing them into three groups: (1) those who would remain eligible for the Part D full LIS even without dual eligible status; (2) those who would become eligible for the Part D partial LIS; and (3) those who would no longer be LIS-eligible.
- Computation of: (1) the PEMS gross payment error amount as the sum of the LIS payment amounts in error for the three groups, and (2) the PEMS rate.

For FY 2010, the PEMS error rate is 1.76 percent.

The Payment Error related to PEPV captures errors in payment due to invalid and/or inaccurate PDE records that result in adjustments to the benefit phase assignment of beneficiaries' PDE records, thus changing Part D LICS and reinsurance payments. The PEPV methodology consists of:

- Validation of the accuracy of 2,000 sampled PDE records using hard copy prescriptions and other claims documentation submitted by plan sponsors, and the creation of a corrected PDE record for all sampled records with discrepancies.
- Imputation of PDE sample validation findings onto the PDE records for a random five percent sample of the Part D population.
- Calculation of a payment error estimate for the sample of beneficiaries. The simulation measures the change in LICS and reinsurance payments as they relate to the changes in gross drug costs.
- Extrapolation of the sample payment error to the entire Part D population resulting in a PEPV gross payment error amount and PEPV rate.

For FY 2010, the PEPV error rate is 12.74 percent.

### 11.32 Corrective Action Plan

The root cause of improper payments in the Part D program is Administrative and Documentation errors. For the MPE component, HHS will continue to routinely implement payment controls in the MARx payment system to ensure accurate and timely payments, including monthly payment validation and authorization processes. MARx payment errors are corrected and future payments adjustments are made on a flow basis, including the payment adjustments applied to the final Part D risk score reconciliation.

The corrective action steps identified in Medicaid Section 11.42 will also assist in addressing the PEMS error estimate, which is driven by the PERM findings. HHS will conduct more in depth analyses on the PELS error estimate to further describe the PELS population and assist in identifying the subsequent steps that could be taken to address improper payment issues.

A significant portion of the FY 2010 PEPV payment error was driven by missing prescription documentation. For FY 2011 *IPIA* reporting, HHS will conduct validation of CY 2009 PDE records, thus shortening the gap between the date of service and the collection period and likely reducing the volume of missing prescription documentation.

### 11.33 Medicare Prescription Drug Benefit Improper Payment Recovery

The MARx payment system error rate is based on analysis of prospective payments. MARx payment system errors are fixed on a flow basis throughout the payment year. The resulting payment adjustments are also implemented on a flow basis in the MARx system, including the round of payment adjustments due to the final Part D risk score reconciliation. Therefore, recovery of MPE errors occurs on a flow basis as part of the routine operation of the MARx payment system.

Regarding the PELS estimate, further investigation must be done to better understand the inconsistencies identified by this analysis in order to determine how to conduct payment recovery.

Regarding the PEMS estimate, application of the aggregate national active case eligibility error rate from another program (PERM) to Part D payments in order to estimate PEMS does not allow HHS to identify which dual eligible beneficiaries actually had incorrect Medicaid status. Thus, it is not possible to identify any beneficiary-level payments for which HHS should pursue recovery.

Regarding the PEPV error, the CY 2007 PDE validation was based on a national sample of PDEs and the imputation of these results onto the Part D

population, therefore payment errors cannot be linked to specific beneficiaries for payment recovery purposes.

### 11.34 Medicare Prescription Drug Benefit Information Systems and Other Infrastructure

The information systems and other infrastructure that would be valuable to HHS in reducing errors in the Part D program cannot be identified with certainty until this measurement is fully implemented. However, for the four components that we have measured, HHS has the information systems and other infrastructure needed to reduce improper Medicare Prescription Drug Benefit payments. HHS uses the following internal Medicare systems to make and validate the Part D payments: the Medicare Beneficiary Database, the Risk Adjustment System, the Health Plan Management System, the MARx payment system, and the Integrated Data Repository. No other systems or infrastructure are needed at this time.

### 11.35 Medicare Prescription Drug Benefit Statutory or Regulatory Barriers that could limit Corrective Actions

No statutory or regulatory barriers that could limit corrective actions have been identified at this time. Statutory or regulatory barriers for limiting corrective actions will not be known until full implementation is complete and results are available.

### 11.36 Medicare Prescription Drug Benefit Program Best Practices

HHS has taken several steps to ensure payment accuracy in the Medicare Prescription Drug program. Monthly validation of the MARx generated prospective payments, as represented in the MPE estimate, has led to system refinement and robust monitoring of prospective payments to plans. Outreach to plans before and during the PEPV data collection and validation process provides an open forum for improving instructions for data submission, and extending the collection period will allow for increased response rates and decreased improper payment estimates over time.

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*11.40 Medicaid - A joint Federal/State program, administered by the States that provides health insurance to certain low income individuals.*

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### 11.41 Medicaid Statistical Sampling Process

The Payment Error Rate Measurement (PERM) program uses a 17 State three-year rotation for measuring Medicaid improper payments. To select the 17 States for the three-year cycle, States were ranked by size based on their past Federal FFS

expenditures and grouped into three major strata with 17 States in each stratum. The expenditure data showed that nine States represent the major portion (approximately 50 percent) of total Federal Fee-for-Service (FFS) expenditures. To get a precise estimate for the national rate, it was important to make these nine high-expenditure States their own stratum. Therefore, the 17 States in Strata - 1 were further divided into two substrata – Strata - 1A (consisting of the nine States with the highest Federal FFS expenditures) and Strata - 1B (consisting of the eight remaining high-expenditure States). The States were sampled such that three States were selected from Strata - 1A each year. Given the criterion that each State be sampled exactly once over a three-year cycle, each stratum will have one year in which only five States are sampled. That is, the pattern will resemble the sample distribution shown in Table 1.

**Table 1: Number of States to be Selected from Each Stratum in Each Year**

Strata	Year 1	Year 2	Year 3
1A	3	3	3
1B	3	3	2
2	6	5	6
3	5	6	6

Medicaid improper payments are estimated on a Federal fiscal year basis and measure three component error rates: FFS, managed care, and eligibility. HHS, through its use of Federal contractors, measures the FFS and managed care components and States perform the eligibility component measurement.

**FFS and Managed Care Component:**

States submit quarterly adjudicated claims data from which a randomly selected sample of FFS claims and managed care claims are drawn each quarter. Each selected FFS claim is subjected to a medical and data processing review. Managed care claims are subject only to a data processing review. For States reporting in FY 2010, the average FFS sample size was 500 claims and the average managed care sample size was 250 claims per State.

**Eligibility Component:**

For FY 2010, States conducted an eligibility review on a randomly selected sample of 504 active and 204 negative Medicaid cases over a 12-month period.

- Active cases contain information on a beneficiary who is enrolled in the Medicaid program in the month that eligibility is reviewed.

- Negative cases contain information on a beneficiary who applied for benefits and was denied, or whose program benefits were terminated based on the State agency’s eligibility determination in the month eligibility was reviewed.

Each State calculated two error rates for active cases, a payment error rate and a case error rate.

- The payment error rate is calculated using the dollar value of payments made for services provided to beneficiaries who were ineligible, divided by the dollar value of claims for the sample of beneficiaries, i.e., dollars in error over total dollars in the sample. HHS combines the State reported eligibility component payment error rates to develop a national eligibility error rate for Medicaid.
- The case error rate is calculated by dividing the number of ineligible beneficiaries by the total number of beneficiaries in the sample. States calculate only a case error rate for negative cases because no payments were made. For the active and negative case error rates, the errors are not dollar weighted.

Since there was no historical eligibility error rate data, the initial sample size was calculated under the assumption that the error rate would be five percent. This means that the desired precision requirements will be achieved with a high probability if the actual error rate is five percent or less. For this reason, an annual sample of 504 active cases should meet the desired State-level precision with a high probability. In subsequent years, if the State’s actual error rate is lower, the State may demonstrate that a smaller sample size based on the documented lower error rate is sufficient. Conversely, if a State’s actual error rate is higher, the State may need to select a larger sample.

**Calculations and Findings:**

All payment error rate calculations for the Medicaid program (the FFS component, managed care component, eligibility component, and national Medicaid error rate) are based on the ratio of estimated dollars of improper payments to the estimated dollars of total payments. Individual State error rate components are combined to calculate the national component error rates. The national Medicaid program error rate is calculated by combining the individual State error rates. National component error rates and the Medicaid program error rate are weighted by State size, so that a State with a \$10 billion program “counts” 10 times more toward the national rate than a State with a one billion dollar program. The national program error rate represents the combination of

Medicaid FFS, Medicaid managed care, and Medicaid eligibility error rates. A small correction factor ensures that Medicaid eligibility errors do not get "double-counted."

HHS calculated and is reporting the three-year weighted average national error rate that includes data from FYs 2008, 2009, and 2010. The three-year rolling error rate is 9.4 percent or \$22.5 billion. The weighted national error components rates are as follows: Medicaid FFS: 4.4 percent; Medicaid managed care: 1.0 percent; and Medicaid eligibility: 5.9 percent. However, as required under Section 601 of the *Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA P.L. 111-3)*, HHS published a final rule on August 11, 2010, which requires the eligibility reviews to be consistent with the State's eligibility verification policy rather than reviewing eligibility against a uniform methodology, which was done in the past. Based on current regulations, certain cases from FYs 2008-2010 would no longer be considered as errors.

The active case error rate for Medicaid is 8.9 percent; the negative case error rate is 8.1 percent.

#### 11.42 Medicaid Corrective Action Plans

Overall, the majority of the FY 2010 errors were a result of cases reviewed for eligibility that were either not eligible or their eligibility status could not be determined, thus they were considered errors (Verification errors). The most common cause of cases in error for the Medicaid FFS medical review was insufficient documentation (Administrative and Documentation errors).

For FY 2010, the most common causes of improper payments were:

- Administrative and Documentation:
  - Insufficient documentation
  - No documentation
  - Administrative/other
- Authentication and Medical Necessity:
  - Diagnosis coding error
  - Number of units error
  - Medically unnecessary services
  - Policy violation
  - Procedure coding error
  - Unbundling
- Verification:
  - Eligibility Errors

- Duplicate item
- FFS claim for a managed care service
- Pricing error
- Logic edit
- Third party liability
- Non-covered service
- Data entry error
- Rate cell error (wrong managed care payment amount)
- Managed care payment error

HHS works closely with States to develop State-specific Corrective Action Plans (CAPs). States are responsible for implementing, monitoring, and evaluating the effectiveness of their CAPs. HHS received CAPs from all States whose Medicaid programs were measured and reported in FY 2009. States continue to take steps to reduce errors identified during the measurement.

Because much of the error rate in the past was due to missing or insufficient documentation, the majority of States focused on provider education and communication methods to improve the responsiveness and timeliness of submission of requested documentation. These methods included provider training sessions; meetings with provider associations; notices, bulletins and provider alerts; provider surveys; improvements and clarifications to written State policies emphasizing documentation requirements; and performing more provider audits.

States focus their efforts on major causes of error where HHS and the State can identify clear patterns. For example, States have found that particular provider types, such as pharmacies or long-term care facilities, repeatedly fail to comply with documentation requirements and may find that a targeted corrective action for these providers is cost-effective and likely to reduce future improper payments. When States have pricing and logic errors occur in their processing system, they work to ensure that those systems are fixed to avoid improper payments.

For eligibility errors, specific corrective action strategies implemented by the States to reduce eligibility errors have included leveraging technology and available databases to obtain eligibility verification information without client contact; providing additional caseworker training, particularly in areas determined by the PERM review to be error-prone; and providing additional eligibility policy resources through a consolidated manual and web-based training.

The States reviewed for the FY 2010 AFR will also be reviewed and have error rates reported again in the FY 2013 AFR. The re-measurement audit will document effectiveness of prior years' corrective actions and HHS expects to see improvement in the State and national component payment error rates. HHS is also developing an error rate reduction plan at the Federal level based on its analysis of the FY 2010 improper payments.

In addition to the development, execution, and evaluation of the State-specific CAPS, HHS has also made significant efforts to lower error rates:

- A significant portion of medical review errors in previous measurements resulted from providers failing to submit necessary documentation. It is possible that some of these claims were accurate, but HHS could not verify their validity in the absence of sufficient documentation. The claims were therefore considered to be fully in error. HHS increased its efforts to reach out to providers and to obtain medical records to help resolve this problem. This activity had a significant impact on reducing the no documentation errors. HHS also advanced a pilot program to give States more information on the potential impact of these documentation errors and more time for the States to work with providers to resolve them.
- HHS sponsored a series of provider open forum calls from May 2010 through August 2010 for all States in the next PERM review cycle. HHS also enhanced the CMS PERM website with up-to-date information, included a separate web page for providers, and an email account for providers to communicate directly with HHS.
- HHS is working to reduce the State burden and align PERM data collection more closely with other HHS program integrity data collection processes. Over the past two years, HHS developed and pilot tested a new, streamlined methodology (referred to as "PERM Plus") to collect data required for PERM. When implemented, this approach will position HHS to integrate PERM data collection with other emerging HHS program integrity initiatives.
- HHS is exploring the development of an eligibility measurement methodology that would combine the requirements of section 1903(u) of the Medicaid statute for Medicaid Eligibility Quality Control (MEQC) with the requirement of *IPIA*. The *CHIPRA* regulation requires HHS to review the requirements of the MEQC and PERM programs and coordinate the implementation of the requirements to reduce redundancies between the measurements. The eventual goal is to allow one measurement to meet the quality control requirements of MEQC and the

improper payment requirements of PERM. Harmonization would benefit States by reducing workload for conducting eligibility reviews, providing meaningful results for corrective actions, and allowing HHS to recover identified erroneous payments based on Medicaid eligibility determinations.

- States have historically struggled to include "aggregate payments" (ie., payments that cannot be identified by an individual claim transaction) in the PERM review. HHS has developed a theoretical framework to address this issue and has pilot tested the approach with three States. HHS is applying the aggregate payment framework to all States in the next year's review.

As an additional program corrective action, HHS formed a State systems workgroup to address individual State system problems that may cause payment errors. The workgroup includes representatives from HHS and State staff.

#### **11.43 Medicaid Program Improper Payment Recovery**

For FY 2008, the actual improper payments identified for the Medicaid program in the sample were \$1,258,525.

For FY 2009, the actual improper payments identified for the Medicaid program in the sample were \$1,095,473.

For FY 2010, the actual Medicaid improper payments identified for the Medicaid program in the sample were \$784,877.

The recoveries of Medicaid improper payments are governed by Section 1903(d)(2) of the *Social Security Act* and related regulations at Part 433, Subpart F under which States must return the Federal share of overpayments. States reimburse the Federal share on the CMS-64 expenditure report for Medicaid which contains a line item for program collections.

As of January 2010, PERM Recoveries are reported on Form CMS 64.90 PERM, which will automatically transfer to the CMS-64 Summary Form on Line 10D, specifically created for PERM. HHS continues to work with the States to collect recoveries. Our efforts are ongoing. Due to our continued efforts, HHS will be able to report on Medicaid recoveries in the future.

#### **11.44 Medicaid Information Systems and Other Infrastructure**

Since Medicaid payments occur at the State level, information systems and other infrastructure needed to reduce Medicaid improper payments would need to be implemented at the State level.

PERM faced many challenges with State payment systems that had paper only and aggregate claims; changes in information systems at the State level during the course of the measurement cycle; and a wide variation of systems designs and capabilities from State to State. HHS has been active in encouraging and supporting States in their efforts to modernize and improve State Medicaid Management Information Systems (MMIS). Such improvements will produce greater efficiencies in the PERM measurement and strengthen program integrity. Recently, HHS formed a State systems workgroup consisting of State and HHS representatives. This group meets regularly to identify and discuss State system vulnerabilities and the impact on the measurement of improper payments. In addition, HHS developed a methodology to measure aggregate claims that will be incorporated into future PERM processes.

Also, HHS is developing a comprehensive plan to modernize Children's Health Insurance Program (CHIP) and Medicaid data systems. The primary goal of this plan is to leverage technologies to create an authoritative and comprehensive Medicaid and CHIP data structure so that HHS can provide effective oversight of its programs. The plan will also result in a reduction in State burden and more robust data available for the PERM measurement.

#### **11.45 Medicaid Statutory or Regulatory Barriers that could limit Corrective Actions**

No statutory or regulatory barriers that could limit corrective actions have been identified at this time.

#### **11.46 Medicaid Program Best Practices**

Based on lessons learned through previous PERM cycles and in an effort to address challenges faced by the States, HHS implemented a pre-cycle aspect of the PERM measurement starting with FY 2009. The pre-cycle phase occurs prior to the first submission of data, and allows HHS to disseminate information on changes in the program and conduct individual orientation and education sessions with the States. The following additional measures have been incorporated into the overall process:

- States receive further education on the PERM process through HHS-initiated cycle calls and website activity.
- HHS has designated a cycle manager as the lead for a fiscal year measurement and the main point of contact at HHS for that year.
- HHS utilizes dashboards, a compilation of the contractors' and States' work, to monitor the progress of the measurement. The dashboards enable HHS to monitor problems in the measurement earlier and provide assistance to

resolve issues delaying the measurement progress.

- The use of biweekly all-contractor meetings has been employed to facilitate communication and problem solving between HHS and its contractors to improve the PERM process.
- For States having difficulty providing complete data, HHS has provided on-site technical assistance.

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#### **11.50 Children's Health Insurance Program (CHIP) - A Joint Federal/State program administered by the States that provides health insurance for qualifying children.**

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#### **11.51 CHIP Statistical Sampling Process**

On August 11, 2010, as part of enhanced efforts to reduce improper payments in Federal programs, HHS issued the final regulations (PERM final rule) that will fully implement improvements to the Payment Error Rate Measurement (PERM) program for Medicaid and the Children's Health Insurance Program (CHIP). Section 601 of the *Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA P.L. 111-3)* prohibited HHS from calculating or publishing any national or State-specific error rates for CHIP until six months after a new PERM final rule is in effect. HHS did not report a national error rate for CHIP in the FY 2009 AFR and, due to timing of the published PERM final rule, will not be reporting a national error rate for CHIP in the FY 2010 AFR. However, HHS will begin conducting the CHIP error rate measurement in FY 2011, with the results being published in the FY 2012 AFR.

Prior to the passage of *CHIPRA* and the statutory requirement prohibiting the calculation or publication of a CHIP error rate, Medicaid and CHIP employed the same State sampling process. HHS determined that CHIP can be measured in the same States selected for Medicaid review each fiscal year with a high probability that the CHIP error rate will meet the *IPIA* required confidence and precision levels. Since CHIP and Medicaid will be measured in the selected States at the same time, each State will be measured for CHIP once and only once every three years. For detailed information on the State sampling process implemented prior to passage of *CHIPRA*, please read Section 11.41, Medicaid Statistical Sampling Process.

CHIP improper payments are estimated on a Federal fiscal year basis and measure three component error rates: FFS, managed care, and eligibility. HHS, through its use of Federal contractors, measures the FFS and managed care components and States perform the eligibility component measurement.



### 11.52 CHIP Corrective Action Plans

Since HHS is not reporting a national CHIP FY 2010 error rate, the affected States were not required to submit a corrective action plan.

States will submit and implement corrective action plans in FY 2012 when we report a CHIP error rate. That corrective action plan will include the following:

- Data analysis - an analysis of the findings to identify where and why errors are occurring.
- Program analysis - an analysis of the findings to determine the causes of errors in program operations.
- Corrective action planning - steps taken to determine cost-effective actions that can be implemented to correct error causes.
- Implementation - plans to operationalize the corrective actions, including milestones and a timeframe for achieving error reduction.
- Monitoring and evaluation – assessment of whether the corrective actions are in place and are effective at reducing or eliminating error causes.

HHS will monitor States' implemented corrective actions to determine whether the actions are effective and whether milestones are being reached.

### 11.53 CHIP Program Improper Payment Recovery

Improper payments identified in FY 2009, prior to the passage of *CHIPRA*, are subject to recovery, as detailed at 42 Code of Federal Regulations (CFR) §§ 431.1002 and 457.232. For FY 2009, the actual improper payments identified for the CHIP program in the sample, prior to the passage of *CHIPRA*, was \$4,570.

For FY 2010, no improper payments were identified for the CHIP program due to the reasons stated above.

The recoveries of CHIP improper payments are governed by Section 1903(d)(2) of the *Social Security Act* and related regulations at Part 433, Subpart F under which States must return the Federal share of overpayments. States reimburse the Federal share on the CMS-21 form for CHIP which contains a line item for program collections. Historically, the CMS-21 expenditure report did not include space for States to separately report PERM recoveries. In January 2010, CMS added a new section in the CMS-21 financial report where States separately reported PERM recoveries for the first time. Due to our continued efforts, HHS will be able to report on CHIP recoveries in the future.

### 11.54 CHIP Information Systems and Other Infrastructure

Since CHIP payments occur at the State level, information systems and other infrastructure needed to reduce CHIP improper payments would need to be implemented at the State level. PERM faced many challenges with State payment systems that had paper only and aggregate claims; changes in information systems at the State level during the course of the measurement cycle; and a wide variation of systems designs and capabilities from State to State. HHS has been active in encouraging and supporting States in their efforts to modernize and improve State Medicaid Management Information Systems (MMIS). Such improvements will produce greater efficiencies in the PERM measurement and strengthen program integrity. Recently, HHS formed a State systems workgroup consisting of State and HHS representatives. This group meets regularly to identify and discuss State system vulnerabilities and the impact on the measurement of improper payments. In addition, HHS developed a methodology to measure aggregate claims that will be incorporated into future PERM processes.

Also, HHS is developing a comprehensive plan to modernize CHIP and Medicaid data systems. The primary goal of this plan is to leverage technologies to create an authoritative and comprehensive Medicaid and CHIP data structure so that HHS can provide effective oversight of its programs. The plan will also result in a reduction in State burden and more robust data available for the PERM measurement.

### 11.55 CHIP Statutory or Regulatory Barriers that could limit Corrective Actions

Section 601 of the *Children's Health Insurance Program Reauthorization Act (CHIPRA) of 2009 (P.L. 111-3)* prohibited HHS from calculating or publishing any national or State-specific error rates for CHIP until six months after a new PERM final rule is in effect. The new final rule for PERM became effective September 10, 2010; therefore, for FY 2009 and FY 2010, HHS did not report a national CHIP error rate. However, HHS will begin the CHIP measurement in FY 2011 and report an error rate in the FY 2012 AFR.

### 11.56 CHIP Best Practices

This section is not currently applicable to the program as the CHIP error rate has only been calculated and measured once, and HHS is not reporting a CHIP error rate for FY 2010.

*11.60 Temporary Assistance for Needy Families (TANF) - A joint Federal/State program administered by the States that provides time-limited assistance to needy families with children to promote work, responsibility and self-sufficiency.*

### **11.61 TANF Statistical Sampling Process**

Statutory limitations prohibit HHS from requiring States to participate in a TANF improper payment measurement. As a result, the TANF program is not reporting an error rate for FY 2010.

Despite statutory limitations, HHS continues to explore options that will allow for a future error rate measurement.

### **11.62 TANF Corrective Action Plans**

Since TANF is a state administered program, corrective actions that could help reduce improper payments would have to be implemented at the State level. The TANF statute prohibits HHS from requiring State TANF agencies to implement and report on corrective actions. Despite the limitations, HHS annually submits a letter to all TANF States with recommendations for potential corrective actions based on the past reviews done by OIG. The reviews show that the primary causes of error are ineligible recipients, incorrect payment amounts and insufficient documentation. States may employ these recommendations voluntarily in their corrective action efforts to reduce future improper payments.

### **11.63 TANF Improper Payments Recovery**

Statutory limitations prohibit HHS from requiring States to participate in a TANF improper payment measurement. As a result, the TANF program is not reporting an error rate for FY 2010.

Despite statutory limitations, HHS continues to explore options that will allow for a future error rate measurement and improper payment recoveries.

### **11.64 TANF Information Systems and Other Infrastructure**

Since TANF payments occur at the State level, information systems and other infrastructure needed to reduce TANF improper payments would need to be implemented at the State level. States utilize the Public Assistance Reporting Information System (PARIS), the National Directory of New Hires (NDNH), and the Income Eligibility Verification System (IEVS), to help ensure that improper payments are minimized. No other systems or infrastructure are needed at this time.

### **11.65 TANF Statutory or Regulatory Barriers**

Statutory limitations prohibit HHS from requiring States to participate in a TANF improper payment measurement. As a result, the TANF program is not reporting an error rate for FY 2010.

Despite statutory limitations, HHS continues to explore options that will allow for a future error rate measurement.

### **11.66 TANF Program Best Practices**

We encourage States to stress the importance of payment accuracy for TANF cases and seriously consider measures that will reduce the incidence of erroneous payments in their States. Actions that may prove beneficial in this area include but are not limited to, the following:

- Conduct local office quality control reviews at both the initial intake and redetermination stages of case development for basic assistance eligibility and payment processes.
- Consider payment accuracy as proper case documentation measures or elements of staff performance.
- Develop and maintain a reminder system for critical follow-up actions on cases such as responding to reports of non-cooperation with child support, IEVS "hits", redeterminations of eligibility, or failure to fulfill work requirements.
- Establish a process for the collection of TANF overpayments from the applicable recipients.
- Periodically remind TANF recipients of their responsibility to accurately report income, resources, and other family circumstances to the local TANF agency on a timely basis.
- Conduct training on investigative interviewing techniques for intake workers and case managers.
- Perform periodic "checks" of case records, paying particular attention to documentation that includes a current application and facts supporting income, household composition, participation in work activities, and cooperation with child support enforcement.
- Establish and monitor internal procedures to ensure that TANF payments are adjusted on a timely basis when family circumstances change and affect case eligibility or the amount of payment.

States may also improve the integrity of their programs by participating in the Public Assistance

Reporting Information System (PARIS) and/or by using information available through the National Directory of New Hires (NDNH). PARIS is a federal-state partnership which provides all fifty States, D.C., and Puerto Rico detailed information and data to assist them in maintaining program integrity and detecting duplicate or other improper payments by public assistance programs such as TANF, Medicaid, Supplemental Nutritional Assistance Program, and Child Care.

State TANF agencies can use NDNH information to verify the eligibility of adult TANF recipients residing in the State and, once the information is verified, it can be used to modify benefits or close the case if the individual is not eligible for assistance. States using NDNH information have reported that it has been a valuable tool in improving payment accuracy. By using NDNH information, States have uncovered previously unknown employment, improved TANF program integrity by evaluating benefit accuracy, and even uncovered identity theft.

HHS will issue a TANF Information Memorandum providing technical assistance to States in the form of recommendations gleaned from OIG reports and other activities undertaken by HHS that can reduce improper payments. The TANF Information Memorandum will be posted on the HHS TANF website and distributed via our listserv to all States and to the other TANF stakeholders on our listserv.

HHS Regional Offices will follow-up with the States regarding the TANF Information Memorandum on strategies to reduce improper payments to respond to questions and to provide further information and/or technical assistance.

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*11.70 Foster Care - A joint Federal/State program administered by the States for children who need placement outside their homes in a foster family home or a child care facility.*

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### **11.71 Foster Care Statistical Sampling Process**

There have been no changes to the statistical sampling process for Title IV-E Foster Care during the current year. Under the regulatory review promulgated at 45 CFR 1356.71, Foster Care Eligibility Reviews are conducted systematically in each State (the 50 States, the District of Columbia and Puerto Rico) every three years. During these reviews, a team comprised of Federal and State staff review 80 cases selected from the State's Title IV-E Foster Care population to determine a State's level of compliance in meeting the Federal eligibility requirements for the Foster Care program and to validate the accuracy of a State's claim for Federal reimbursement of Foster Care payments. Each regulatory review identifies the number of error cases and amount of payment errors

determined from the review of a sample drawn from the State's overall Title IV-E caseload for its six-month Period Under Review (PUR). The sample is a random sample drawn from the universe of cases having at least one Title IV-E Foster Care maintenance payment during the PUR. An error case is defined as a case in which a Title IV-E Foster Care maintenance payment is made on behalf of an ineligible child during the PUR. Payment errors may include payments for error cases, payments made for non-error cases which failed to meet an eligibility criterion outside the PUR, and payments for services not covered by Title IV-E or its regulatory provisions (e.g. therapy). If any payment errors are identified during a primary review, HHS imposes a disallowance in the total amount of all identified payment errors.

HHS employs a 10 percent error threshold to determine the level of State compliance in meeting the Federal requirements in the Foster Care program. If during a primary review a State exceeds the error threshold, (a) HHS takes a disallowance as described above, (b) the State is required to develop and implement a Program Improvement Plan (PIP) and, (c) following PIP implementation (which generally is completed within a year), the State is subjected to a secondary review where 150 cases are selected for review. If a State exceeds the error threshold for the case and dollar error rates in a secondary review, the State is assessed an additional extrapolated disallowance, which is equal to the lower limit of a 90 percent confidence interval for the State Foster Care population's total dollars in error during the six-month PUR. The extrapolation increases geometrically the resulting disallowance. Since FY 2000, HHS has systematically conducted more than 155 regulatory Foster Care reviews, with over 14,500 Foster Care cases reviewed.

The Foster Care error rate and national estimates of improper payments are calculated each year using data collected in the most recent eligibility review for each of 50 States, the District of Columbia, and Puerto Rico. Since each State is reviewed every three years, each year's "composite sample" of data from 52 State reviews incorporates new review data for about one-third of the States. While each State sample represents a distinct six-month PUR, the national "composite" sample reflects a composite PUR. Consequently, the resulting error rate is referred to as a "rolling" estimate, since about one-third of the review data are replaced with new data each year. To arrive at the national estimates of improper payments and payment error rate, data from each State review sample are used to develop an estimate of State improper payments for the PUR. This estimate considers both under- and overpayments in accordance with the *IPIA*. State

estimates are then aggregated to estimate national improper payments for the composite PUR. The national estimate is divided by the sum of payments received during respective PURs to determine the national payment error rate for the program. The FY 2008 and FY 2009 estimates reflected a transition from case-based estimation to a refined dollar-based methodology for estimating State improper payments. Continued application of the new, refined methodology to eligibility review data for this year indicates that, for FY 2010, the Foster Care estimated national payment error rate is 4.9 percent. This represents a slight increase compared to the FY 2009 error rate of 4.7 percent; however, current performance still represents a decrease of over 50 percent from the baseline rate of 10.33 percent. The slight increase in the error rate does not represent a regular pattern across States reviewed but appears to be more of an artifact of mixed individual State review performance relative to the size of the States. Specifically, those States that demonstrated substantively improved performances, as indicated by lower error rates, were relatively small, so the improvements had minimal impact on the national rate. Only one large State demonstrated a substantial drop in its payment error rate. Additionally, a few relatively large States reported slightly higher payment error rates than in their previous review. Due to these circumstances, the net national result was a slightly higher overall program error rate.

### 11.72 Foster Care Corrective Action Plans

All payment errors in the Title IV-E Foster Care Program are “Administrative and Documentation” errors because they all reflect incorrect classifying or processing of payments by State agencies or third parties who are not the beneficiaries. Thus, all corrective action plans are targeted to improving processing of IV-E claims by State and local agencies. Corrective action plans instituted by HHS to address improper payments in the Foster Care program have been designed to help States address those payment errors (e.g., underpayments) that have contributed most to improper payments made by the IV-E program to State agencies. In FY 2010, the most common payment errors made by States involving IV-E Foster Care funds included the following:

- Underpayments (19 percent of errors)
- Provider not licensed or approved (16 percent of errors)
- Ineligible payment (e.g., therapy) (14 percent of errors)
- Not AFDC eligible at time of removal (11 percent of errors)
- Criminal records check not completed (9 percent of errors)
- Judicial determination regarding reasonable efforts to finalize permanency plan not timely (6 percent of errors)
- Duplicate or excessive maintenance payments to providers (6 percent of errors)
- No judicial determination of reasonable efforts to prevent removal (4 percent of errors)

Together these eight items account for nearly 85 percent of payment errors for Foster Care. The overall frequency of all types of payment errors in the composite Foster Care sample (i.e., across all States) decreased by about 19 percent from FY 2009 to 2010. This decrease may have been fueled in part due to the drop in underpayments. While underpayments are the most frequent payment error occurring in the composite sample, the total frequency dropped considerably from FY 2009 (down from 176 or 28 percent of all errors last year to 96 or 19 percent of all errors this year). This occurred because several States with high numbers of underpayments in earlier reviews were reviewed again this year and were found to have fewer or no underpayment errors.

It is of interest to note that over the course of efforts to reduce improper payments, the overall number of payment errors has dropped substantially and the composition of error types identified has changed as well. When reporting commenced in FY 2004, the most prevalent errors were errors associated with the requirement for a judicial determination in finalizing the permanency plan. However, these errors have been reduced from a frequency of 286 in FY 2004 to only 30 in FY 2010. Currently, underpayments, rather than overpayments are the largest component of a much smaller universe of payment errors in the program. While the overall impact of payment errors has been reduced between FY 2009 and FY 2010, this reduction highlights the importance of maintaining diligence in corrective action efforts. Key features of HHS’s corrective action strategies include the following:

- HHS conducts on-site and post-site review activities to effectively validate the accuracy of a State’s claim for reimbursement of payments made on behalf of children and their Foster Care providers. Specific feedback is provided on-site to the State agency to directly impact the

proper and efficient administration and implementation of the State's Title IV-E Foster Care programs. Further, a comprehensive report is issued to the State agency to confirm the final findings of the on-site review. The final report serves as the basis for the development of a Program Improvement Plan (PIP) for States that exceed the error threshold.

- States are required to develop and execute State-specific PIPs that target corrective action to the root cause of payment errors in the State. The PIP is developed by State staff in consultation with Federal staff and is required to include: (1) Specific goals or outcomes for program improvement; (2) Measurable action steps required to correct each identified weakness or deficiency; (3) Target date for completing each action step; (4) Description of how progress will be evaluated by the State and reported to HHS, including the frequency and format of the evaluation procedures; and (5) Description of how the State will report to HHS when an action step has been achieved.
- The PIP is designed to lead to measurable changes in State program operations and is required to identify the specific action steps developed to attain the desired outcomes and correct program deficiencies. Each action strategy has a projected completion date that will not extend more than one year from the date the PIP is approved by HHS. This assures that proper attention is given to correcting deficiencies in a timely manner. HHS believes that the development and implementation of the PIP is the key to identifying the reasons why cases are in error and motivating States to correct the identified problems. Requiring States to implement PIPs has proven to be an effective solution in addressing eligibility errors as reflected in the decrease in the national error rate since FY 2004.
- HHS provides onsite training and technical assistance to States to develop and implement program improvement strategies.
- HHS works toward heightening judicial awareness and monitoring of reviews. In past years, three of the six most frequently occurring errors have involved the judiciary. In FY 2010, none of the five most frequent payment errors involved the judiciary. HHS continues to share the results of the Foster Care reviews with judicial organizations and offers training and technical assistance to educate and inform the judiciary in areas pertaining to their role directly impacting the State agency's performance on the eligibility factors.

- HHS works closely with the Court Improvement Program in States where judges require training and court orders warrant modification to maintain the gains in reducing improper payments related to the judiciary.
- HHS conducts secondary reviews (as applicable) and takes appropriate disallowances consistent with the review findings. HHS's expectation is that these disallowances, in conjunction with the development and implementation of the PIP, will serve as strong encouragement to the States to improve their programs to the extent that when a secondary review is conducted they will be determined to be in substantial compliance.
- HHS provides technical guidance to ensure reliable identification of underpayments by (1) discussing any underpayments identified during a Title IV-E eligibility review at the exit conference with State agency senior management; (2) identifying underpayments in final reports issued to States following Title IV-E eligibility reviews; and (3) including language in the *Title IV-E Foster Care Eligibility Review Guide* clarifying what constitutes an "underpayment" to ensure that Federal and State agency staff accurately identify underpayments.
- Also, HHS provides training and technical assistance tailored to assist States and Tribes in improving their child welfare systems and to conform to outcomes and systemic factors identified in the results of the regulatory Foster Care monitoring reviews. The aim is to refine their management and operations, expand organizational capacity, and foster effective and consistent practice while improving outcomes for children, youth, and families.

Through implementation of its comprehensive corrective action plan, HHS reduced the national Foster Care error rate below target levels and demonstrated steady progress in reducing the error rate in FY 2005, FY 2006, and FY 2007. The error rate decreased from 10.33 percent in FY 2004 (baseline) to 8.60 percent (FY 2005) to 7.68 percent (FY 2006) to 3.30 percent (FY 2007). Although the rate increased in FY 2008 to 6.42 percent, that change still represented a reduction of the rate by over one-third since establishing the baseline for FY 2004. In addition, the FY 2008 error rate estimate reflected a transition from a case-based estimation to a refined dollar-based methodology for estimating State improper payments. Subsequent rulings by the Departmental Appeals Board reversed some errors for one of three States contributing to the increase in FY 2008. In 2009, the error rate decreased to

4.7 percent, and in 2010, the error rate remained low at 4.9 percent; thus, the IV-E Foster Care program continues to maintain a payment error rate that is less than half the baseline rate.

**11.73 Foster Care Improper Payment Recovery**

As a result of its conducting Foster Care eligibility reviews in 18 States during the 12-month period of August 2009 – July 2010, HHS has recovered over \$1.7 million in Title IV-E improper payments. The funds recovered are comprised of \$966,556 disallowed maintenance payments and \$798,076 disallowed administrative payments. The following table shows over \$12.2 million improper payments recovered through IV-E Foster Care Eligibility Reviews from FY 2004 through FY 2010.

**Recovery of Improper Payments Table  
(in Millions)**

FY	Reporting Period	# Reviews	Amount Identified = Amount Recovered		
			Maintenance Disallowances	Administrative Disallowances	Total Disallowances
2004	10/2003-9/2004	20	\$ .949	\$ .652	\$ 1.601
2005	10/2004-9/2005	13	.611	.405	1.017
2006	10/2005-7/2006	9	.371	.333	.704
2007	8/2006-7/2007	24	2.104	1.587	3.691
2008	8/2007-7/2008	14	1.420	.729	2.150
2009	8/2008-7/2009	17	.535	.751	1.287
2010	8/2009-7/2010	18	.967	.798	1.765

**Recovery of Improper Payments through Title IV-E Foster Care Eligibility Reviews**

The recovery of improper payments through eligibility reviews is most aptly classified as occurring through *post-payment reviews*. HHS does not systematically track cost recovery through the Office of Inspector General reviews and Single Audit Reports; however, such information has been obtained from HHS reports generated as part of the audit clearance process. Specifically, audit findings where the audit has been closed and a recommended cost recovery has been sustained for the Title IV-E Foster Care program were identified and tabulated.

These amounts are in addition to amounts identified through the eligibility reviews and are presumed as recovered in the fiscal year, when the audit is closed.

Recoveries of improper payments through audits can include Title IV-E Foster Care maintenance assistance payments, administration, and training and automated systems development costs. Thus, the following table summarizes the recovery of improper payments – as monitored by HHS – for Title IV-E Foster Care:

**Title IV-E Foster Care:  
Costs Identified and Recovered  
(in Millions)**

Source	2004	2005	2006	2007	2008	2009	2010**	TOTAL
Eligibility Reviews	\$ 1.6	\$ 1.0	\$ 0.7	\$ 3.7	\$ 2.1	\$ 1.3	\$ 12.2	\$ 10.4
OIG Reviews	40.0	3.0	11.7	32.0	12.4	0.0	2.8	102.0
Single Audits	5.5	1.7	5.2	1.6	6.4	5.3	0.3	26.1

\*\* FY 2010 amount contains data through 07/31/2010

**11.74 Foster Care Information Systems and Other Infrastructure**

HHS uses the Adoption and Foster Care Analysis and Reporting System for the regulatory reviews. Utilizing this existing source of data reduces the burden on States to draw their own samples, promotes uniformity in sample selection, and employs the database in a practical and beneficial manner.

Since Foster Care payments occur at the State level, information systems and other infrastructure needed to reduce Foster Care improper payments would need to be implemented at the State level. No other systems or infrastructure are needed at this time.

**11.75 Foster Care Statutory or Regulatory Barriers that could limit Corrective Actions**

No statutory or regulatory barriers that could limit corrective actions have been identified at this time.

**11.76 Foster Care Best Practices**

Since the inception of its improper payment reporting, HHS has maintained a diligent focus on improper payment identification and reduction efforts in the Foster Care program. Over the past five years, HHS has consistently received positive feedback from OMB for its original, sound methodology for estimating improper payments from existing data sources as well as for continued

refinements of the methodology to accurately identify improper payments and maximize adherence to *IPIA* requirements. These refinements have included steps to ensure systematic examination and consideration of underpayments in eligibility reviews and modifying data retention practices to permit shifting from case-based extrapolation to dollar-based extrapolation.

Concurrent with these efforts to continually refine its identification and reporting on improper payments, HHS has worked successfully to reduce improper payments across the Foster Care program. Working on dual fronts with States to improve administrative procedures for tracking and documenting eligibility and with the judiciary to support adherence to requirements for timely and thoroughly documented case hearings and court orders has yielded reductions in eligibility errors and resulting improper payments nearly each year since baseline reporting in FY 2004. The payment error rate has been reduced from a baseline rate of 10.33 percent of payments in FY 2004 to a rate of 4.9 percent in FY 2010. Furthermore, in the years since baseline reporting commenced, the Title IV-E Foster Care Program has recovered a total of \$12.2 million in improper payments.

In addition to the ongoing efforts to address improper payments outlined above, in FY 2010 the Foster Care program has continued to lay the groundwork for and move towards future implementation of a new methodology to review administrative payments for Title IV-E Foster Care (i.e., Administrative Cost Review, or ACR). The methodology has been recognized by OMB for its innovative approach to examining and testing the allocation and assignment of administrative costs to Title IV-E Foster Care. In FYs 2009 and 2010, HHS conducted two additional pilot tests of the ACR methodology, and shared the findings with the participating States for their consideration and implementation in improving the administrative cost allocation and the assignment to Title IV-E Foster Care.

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*11.80 Head Start - A Federal program that provides comprehensive developmental services for America's low-income, preschool children ages three to five and their families.*

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### **11.81 Head Start Statistical Sampling Process**

HHS is legislatively required to perform reviews of each Head Start program every three years. The design of the sample for the Erroneous Payments Study of Head Start programs is a three-stage element sample. Since each program is reviewed once every three years, the first stage of the sample is to identify the programs up for review. The second stage of the sample is to select the

programs to be reviewed. As was done in the previous Erroneous Payments studies, the FY 2010 study selected 50 programs and several alternates. Programs were selected through a stratified random sample, where programs were divided into five strata by size of enrollment. The number of programs sampled within each stratum is roughly proportional to the number of children represented in each stratum, based on the most recent Program Information Report funded enrollment data. The third stage of the sample is to select the records to be reviewed in each selected program, using a systematic sampling scheme.

For the FY 2010 Erroneous Payments Study, 50 Head Start programs from 21 States and Puerto Rico were reviewed. Approximately 10,748 records were examined. The objective of the reviews is to produce a national error rate of enrolled children who are ineligible for Head Start or Early Head Start services according to Head Start's income eligibility guidelines.

A payment error in the Head Start program is defined as a payment for an enrolled child from a family whose income exceeds the allowable limit (in excess of the 10.0 percent program allowance for families above the income limit). To make this determination, reviewers were required to look at each sample child's folder and determine if the child was ineligible. A child was deemed ineligible if (1) there was not, as required by 45 CFR Part 1305.4(e), a signed statement by a Head Start employee stating the child was eligible to participate or (2) there was income documentation in the child's folder that, in the reviewer's judgment, suggested the child was not Head Start eligible. Reviewers are also asked to review income documentation regardless of whether there was a signed statement in the file.

The FY 2010 error rate is 1.7 percent, a decrease from the FY 2009 rate which was 3.0 percent. Included this year was a formal examination of the 2007 *Head Start Act* requirement regarding the eligibility of children whose families fall between 100 and 130 percent poverty. On-site examination shows that programs are beginning to include children in that category, and no programs exceeded the allowed 35 percent enrollment threshold for that group of children.

### **11.82 Head Start Corrective Action Plans**

The statistical analysis indicates that approximately 99 percent of the FY 2010 Head Start Erroneous Payments error rate is due to Administrative and Documentation errors and Verification errors.

In May 2010, HHS issued a Program Instruction (ACF-PI-HS-10-02) reminding programs that they are required to verify family income before

determining a child is eligible to participate in the program. The Program Instruction also encouraged programs to maintain copies of the eligibility documents with the eligibility verification form in the child's official record and to provide annual training to employees responsible for determining and verifying income eligibility.

To further reduce Administrative and Documentation errors, HHS has developed a standard signed statement template form for Head Start. Since OMB clearance (OMB 0907-0374) was obtained in FY 2010, the use of the form is optional, but grantees are strongly encouraged to use it. The standard signed statement form helps guide grantees on the type of information they need to collect from prospective families during the enrollment process and provides them with a structure for recording this information.

In FY 2011, HHS will expand the Erroneous Payments study to review more child files while onsite. In addition, during monitoring reviews for all programs, additional files will be sampled to verify age/income eligibility requirements and information will be collected on how many programs maintain source documentation with the child's record. If available, a review of source documentation will be used to better understand whether the program is accurately determining eligibility status. Maintaining source documentation is currently not a requirement.

### **11.83 Head Start Improper Payments Recovery**

HHS has determined that no program reviewed as part of the FY 2010 Erroneous Payment study will be subject to a disallowance. Since 99 percent of the error rate is due to Administrative and Documentation errors and Verification errors, HHS is concentrating its efforts on instructing and training their employees to reduce these correctable errors. In addition, HHS will continue to concentrate on improper payment recovery wherever necessary.

### **11.84 Head Start Information Systems and Other Infrastructure**

HHS has the information systems and infrastructure needed to reduce improper Head Start payments to the levels that HHS has targeted. HHS has two systems in place that identify grantees that are not complying with Head Start's income eligibility requirements. First, all review reports are processed centrally by HHS as part of Head Start monitoring. Secondly, Head Start is using the Risk Management System, implemented in each region, to help identify and manage grantee compliance with eligibility requirements. Both systems allow HHS to identify grantees that fail to comply with income

eligibility requirements. No other systems or infrastructure are needed at this time.

### **11.85 Head Start Statutory or Regulatory Barriers**

Currently, HHS cannot require programs to maintain source documentation that supports the determination of income eligibility.

### **11.86 Head Start Program Best Practices**

HHS continues to explore ways as to how to improve the Head Start error rate process and address the Administrative and Documentation errors.

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*11.90 Child Care - A Joint Federal/State program, administered by the States that provides child care financial assistance to low-income working families.*

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### **11.91 Child Care Statistical Sampling Process.**

The Child Care and Development Fund (CCDF) Error Rate methodology is conducted on a three-year cycle, beginning with Year One and Year Two States whose baseline data was reported in the FY 2008 and FY 2009 *Agency Financial Report (AFR)*. For the FY 2010 *AFR*, Year One, Year Two, and Year Three States' data have been combined to generate the complete baseline payment error rate and related findings reported below.

The CCDF program baseline payment error rate or percentage of improper authorizations for payment is 13.3 percent. The national over-authorization error rate, or the percentage of authorizations in excess of the amounts for which cases are eligible, is 12.6 percent. The percentage of under-authorizations is equal to 0.7 percent.

HHS uses a three-year rotation for measuring CCDF improper authorizations for payments. A stratified random sampling method was used for selecting States. One third of the total of 52 States (50 States plus the District of Columbia and Puerto Rico) was selected to participate each year of a three-year cycle in the error rate measurement methodology. The sample of States was stratified by region (10 total), with the regions randomly ordered. States were sorted within each region by caseload, from the most to the least. Every third State on the list was then selected, using a random start number for the first and second years. The third year included those States not selected in year one or year two. Each year this sample yields a mix of county-administered and State-administered programs and States serving small and large numbers of children.

The CCDF error rate methodology employs a case record review process to determine whether child



care subsidies were properly authorized to eligible families. The methodology focuses on administrative errors and improper authorizations for payment made during the client eligibility determination process. It is important to note that the CCDF methodology distinguishes between authorizations for payment and actual payments made to providers for child care services rendered. Because States were estimating improper *authorizations* for payment, the authorization amounts do not represent what was actually paid. In general, the amount of actual payments is lower, computed to be about 17 percent lower. Reporting the amount of improper authorizations for payment in the CCDF program is more stringent than the *IPIA* requirements.

CCDF improper authorizations for payment are estimated on a fiscal year basis. States select a random statewide sample of cases for each month of the fiscal year. States may choose to sample either 271 or 276 cases for the 12-month review period which provides a representative estimate of the annualized amount of improper authorizations for payments. This sample size is projected to allow the CCDF program at the national level to achieve a precision level of 5 percent at the 90 percent confidence interval. CCDF was granted an exception by OMB allowing CCDF to meet the 5 percent precision rather than the required 2.5 percent. States generate a list of all active cases authorized to receive a child care payment during the review month. The list is subsequently sorted by county and caseload size, listing counties with the largest caseload first to counties with the smallest caseload. States utilize a random number generator of their choice to calculate a sampling interval based on the size of the sampling frame and the sample cases that are selected. This process is repeated to allow States to select the monthly sample cases and replacement cases.

States conduct reviews of sampled cases using the ACF-400 *Record Review Worksheet* template. As a block grant, CCDF devolves a great deal of flexibility to States to determine administrative rules and eligibility requirements within broad Federal guidelines. Therefore, States have the option to customize the *Record Review Worksheet* to incorporate State eligibility policies in effect at the time of the case record review. The template consists of four sections designed for review of the following areas:

- Section I: State Child Care Program Forms – Review the presence and completeness of application/ re-determination forms.
- Section II: Priority Group Placement – Review if the child met the criteria of State-designated priority groups.

- Section III: General Program Requirements – Review if the client met the State's definition of parent, residency requirements, and if the client was working or attending job training or educational program or other eligible activity. Review the child's eligibility for a subsidy, the number of hours of care authorized, and if the child care provider regulatory requirements were met.
- Section IV: Income and Authorizations – Review if the household income met State requirements and if the computation of the amount authorized was accurate based on income and family size the State's payment rate schedule, and the sliding fee schedule (parent co-pay requirement).

The Year Three States conducted case record reviews and calculated State-specific error measures for reporting to HHS. The payment error rate, which is the improper authorizations for payment rate for purposes of CCDF, is estimated by applying the percentage of improper authorizations for payment derived from the sampled cases to the annual amount of authorizations for payment. HHS combines the State-reported payment authorization error rates to develop a weighted national improper authorization for payment error rate for the CCDF program for the three year cycle.

#### 11.92 Child Care Corrective Action Plans

*Administrative and Documentation Errors* accounted for 55 percent of the improper authorization for payment errors primarily due to missing or insufficient documentation. The most frequently cited reasons for errors due to missing or insufficient documentation included: (1) insufficient documentation of earned income, unearned income and income deductions; (2) inability to locate the case record, missing or incomplete application or recertification forms, missing pages or forms without signatures; (3) missing or incomplete documentation about the work/educational/training activity of the head of household; (4) insufficient documentation of the hours of care needed; and (5) while less common, States also cited lack of documentation for the child's immigration status; correct household size/composition; and provider materials.

The next highest error rate category consisted of *Verification Errors* caused by the failure or inability to verify recipient information including: (1) income calculation errors: inability to determine income calculation method, failure to include all income, and use of an incorrect monthly conversion factor; (2) co-pay calculations, including incorrect use of the fee schedule; (3) parents' work/training/educational hours did not meet the minimum

requirement; and (4) incorrect inclusion or exclusion of household members.

Corrective actions targeting *Administrative and Documentation Errors* include efforts by both the States administering the program as well as HHS.

States' efforts include:

- Conducting ongoing case record reviews.
- Increasing program monitoring to incorporate performance improvement plans, increased awareness through review of results, and targeted corrective actions to managers.
- Evaluating and revising program policies and procedures.
- Additional training, policy clarification, calculation tools and checklists for workers to ensure accuracy in the application process.
- Modifying contracts with local agencies to include measures on payment accuracy rates, annual management reviews, and corrective action plans.

HHS corrective actions include:

- Providing technical assistance by HHS, specifically designed to help States focus on staff training, eligibility determination procedures, documentation requirements, and routine case reviews.
- Conducting on-site visits to assist States in the implementation of the Error Rate Review methodology.
- Providing guidance as States explore technological avenues to reduce Administrative and Documentation errors.
- Initiating a series of conference calls on accountability topics which include addressing fraud, using assessments to monitor risk and error, developing an inter-disciplinary team that addresses fraud, waste, and abuse.
- Sharing information regarding errors identified and the major causes of those errors with participants attending the annual State and Territories Administrators' Meeting.
- Revising the CCDF Plan Pre-Print to require specific information regarding reducing administrative errors, fraud, waste, and abuse. State Plan summaries are made available to the public in the spring following the year of submission. The next summary will be available in FY 2012.

- Designing a comprehensive Accountability Framework for CCDF which includes the Error Rate Review process, monitoring audit processes, addressing potential fraud, waste, and abuse in administration of CCDF.
- Delivering targeted technical assistance to States to meet their individual needs within a block grant format.
- Providing States with an opportunity for peer-to-peer sharing of both error causes and program improvements to reduce and/or eliminate errors and improper payments.
- Providing technical assistance through Regional training opportunities with States in conjunction with efforts that address overall program administration with the benefit of reducing errors and improper payments.
- Convening conference calls with all stakeholders regarding promising practices, sharing of tools and information, and concerns around fraud, waste, and abuse.
- Assigning contracted technical assistance specialists to work with individual States on implementing the Error Rate Review process. This added support was in addition to the technical assistance provided through the HHS Regional and Central Offices.
- Planning technical assistance and training opportunities to encourage States to begin their next review early, through examining current policies and procedures and automating their case review tool.
- Streamlining the review tool for ease of implementation, avoiding duplications, and eliminating errata.
- Determining additional means to ascertain data on the scope of administrative errors, fraud, waste, and abuse.

Corrective actions that target *Verification Errors* include both State and HHS efforts.

States' efforts include:

- Developing an aggressive training plan to provide one-on-one training for eligibility workers.
- Additional monitoring for verification accuracy.
- Including income, co-payment and rate calculators used by caseworkers as part of the automated eligibility system.

HHS efforts include:

- Providing technical assistance to the States including individualized webinar training, site visits, conference calls, peer-to-peer sharing.
- Developing the technical assistance tool *State Internal Control Self-Assessment Instrument*, which is under revision and will be implemented with targeted programs early next year. States will assess their internal control system, identify areas of risk, develop a program improvement plan based on the results, and receive technical assistance as they implement the plan. The tool will also be available on the Child Care Bureau website for any program to use.
- Developing targeted technical assistance to aid States specifically with concerns over potential fraud in the CCDF program. This includes sharing documents and other best practices, as well as, sharing tools and information to reduce fraud, waste, and abuse.
- Providing an Information Technology Guide, currently under revision, that will provide up-to-date information to assist States in their plans to upgrade and enhance IT needs.
- Planning information briefs to outline promising practices regarding reducing Administrative and Documentation errors as well as Verification errors. Many programs have offered to share tools developed for program monitoring, designing corrective actions, IT enhancements, and training tools.

**11.93 Child Care Program Improper Payment Recovery**

As reported in FY 2010, the actual CCDF improper authorizations for payment identified in the sample baseline review cycle was \$774,833, consisting of \$175,610 for Year One, \$214,475 for Year Two States, and \$384,748 for Year Three States.

The CCDF methodology distinguishes between authorizations for payment and actual payments made to providers. Therefore, the amount of improper authorizations for payment identified during the review process does not represent actual improper payments. In general, the amount of payments is lower, computed to be on average about 17 percent lower. Any actual improper payments related to a specific case that was included in the sample during the case review process will be recovered from States by HHS through the disallowance process as set forth at 45 CFR 98.86 of CCDF regulations.

States also may take their own action to pursue recovery from the appropriate party (e.g., client or child care provider), however pursuant to CCDF

regulations at 45 CFR 98.60 (i), States are required to recover child care payments that are the result of fraud. States have discretion as to whether to recover misspent funds that were not the result of fraud, such as in cases of administrative error. Improperly spent funds are subject to disallowance by HHS regardless of whether the State pursues recovery.

Guidance is under development that will provide information to Lead Agencies regarding those sampled cases found to be in error. Programs will have an opportunity to verify if identified cases with improper authorizations were in fact improperly paid. In the event that improper payments are identified it is expected that they will be recovered in accordance with 45 CFR 98.60 (g) which provides that such payments shall 1) if received by the Lead Agency during the applicable obligation period be used for activities specified in the Lead Agency's approved plan and must be obligated by the end of the obligation period or 2) if received after the end of the applicable obligation period, be returned to the Treasury.

Single State Audits reported the following information regarding closed audit findings that resulted in a sustained amount of disallowance (dollars in thousands).

**Closed Audit Findings**

FY	Number of Sustained Audits	Total Dollars from Sustained Audits
2005	8	747,040
2006	5	65,610
2007	3	59,948
2008	4	201,207
2009	8	3,894,640
2010	3 (to date)	173,563

**11.94. Child Care Program Information Systems and Other Infrastructure**

Since CCDF program payments occur at the State level, information systems and other infrastructure needed to reduce CCDF improper payments would need to be implemented at the State level. State investments in information systems for administering the CCDF program vary widely and there are large disparities in the capacity and capabilities of State systems. The majority of States report having sufficient infrastructure to meet designated targets. Eighteen States report actively working toward updating their computer data systems and ten States plan to have new systems in place before their next review cycle.

While the majority of States have statewide automated systems and the necessary infrastructure to meet targets to reduce improper

authorizations in their next reporting cycle, States reported a variety of areas in which improvements to information systems are still needed:

- Integrating systems to enhance the application for child care benefits and to build the child care authorization spreadsheet into the application system.
- Incorporating alerts into the child care application system to remind eligibility workers to check completeness and accuracy of case files.
- Enhancing child care information systems to include capacity for automated calculation of authorization amounts given family income, hours of care needed, provider payment rate and co-pay requirements.

In addition, HHS has been active in encouraging and supporting States in their efforts to modernize and improve Information Systems. Such improvements would produce greater efficiencies in the CCDF measurement and strengthen program integrity. Recently, HHS formed a State systems workgroup consisting of State and HHS representatives. This group meets regularly to identify and discuss State system vulnerabilities and the impact on the measurement of improper payments.

#### **11.95 Child Care Program Statutory or Regulatory Barriers.**

No statutory or regulatory barriers that would limit corrective actions have been identified at this time.

#### **11.96 Child Care Program Best Practices**

Many Lead Agencies have shown reductions in errors by implementing strategic measures determined from review results. Additional highlights from the implementation of the Error Rate Review include:

- Several States that participated in pilots as part of the development of the Error Rate methodology had lower error rates when conducting their first cycle *IPIA* reviews. Reductions in errors were noted after implementing corrective actions based on the pilot review results. Similar reductions are anticipated as all States conduct the next cycle of reviews.
- During the first cycle of reviews, States with existing monitoring processes in place tended to have lower initial error rates.
- Implementation of a new tool for caseworkers resulted in a 30 percent reduction in errors in one State.

Reports have included rich information as well. We have included the following quotes from several reports as highlights of key lessons learned from the reviews:

*"...learning from peers by arranging visits to neighboring States to learn about their information system..."*

*"...implement an Error Reduction Conference to discuss root causes of errors and potential options for reductions..."*

*"...revisions to policies and procedures were recommended as a result of common errors found on reviews..."*

*"...most important thing we do to reduce errors is implementation of an ongoing monitoring program..."*

*"...developing an aggressive training plan to provide regional or one-on-one training for all eligibility workers..."*

## MANAGEMENT REPORT ON FINAL ACTION

### October 1, 2009 - September 30, 2010

#### Background

*The Inspector General Act Amendments of 1988 (P.L. 100-504)* require Departments and Agencies to report to Congress on the actions they have taken and the amount of funds recovered or saved in response to the Office of Inspector General's (OIG) audit recommendations. This annual management report provides the status of OIG A-133 audit reports in the Department and summarizes the results of actions taken to implement OIG audit recommendations during the reporting period. As part of the U.S. Chief Financial Officer Council's Streamlining Effort of FY 1996, the Management Report on Final Action has been incorporated in the Agency Financial Report.

#### Status of Audits in the Department

In general, HHS Agencies follow-up on OIG recommendations effectively and within regulatory time limits. The HHS Agencies usually reach a management decision within the 6-month period that is prescribed by P.L. 100-504 and OMB Circular A-50, *Audit Follow-up*. For the most part, they also complete their final actions on OIG reports, including collecting disallowed costs and carrying out corrective action plans, within a reasonable amount of time. However, the Department continues to monitor this area to improve procedures and ensure compliance with corrective action plans.

#### Departmental Conflict Resolution

In the event that HHS agencies and OIG staff cannot resolve differences on specific report recommendations, a conflict resolution mechanism is available. During FY 2010, there were no disagreements requiring the convening of the Conflict Resolution Council.

#### Final Action Tables and Departmental Findings

Table I – Management Action on Costs Disallowed in OIG Reports. Disallowed costs are those costs that are challenged by HHS because a grantee has violated a law, regulation, grant term, or condition.

#### The HHS Process

#### Four Key Elements to the HHS Audit Resolution and Follow-up Process

- The HHS Agencies have a lead responsibility for implementation and follow-up on OIG and independent auditor recommendations;
  - The Assistant Secretary for Resources and Technology establishes policy and monitors HHS Agencies' compliance with audit follow-up requirements;
  - The audit resolution process includes the ability to appeal disallowances administratively under such programs as Head Start, Foster Care and Medicaid pursuant to the Departmental Grant Appeals Board's regulations in 45 C.F.R. Part 16; and
  - If necessary, the Conflict Resolution Council resolves conflicts between the HHS Agencies and the OIG.
- In FY 2010, HHS initiated Recovery Action, through collection, offset or other means, on 308 cases for a total of \$1,105,989,201.
  - In FY 2010, HHS completed Recovery Action, through collection, offset or other means, on 328 cases for a total of \$726,476,325.
  - As of September 30, 2010, HHS reports 170 outstanding balances over one year old totaling \$1,741,756,232. Forty-one percent of these accounts receivable are currently being pursued for collection. These accounts receivable are owed by State and local governments (72), hospital and medical related organizations (52), nonprofit organizations (18), Indian tribes (18), and educational institutions (10). A detailed list of reports over one year old with outstanding balances to be collected can be found at: <http://www.hhs.gov/asfr/of/finpollibrary/financialpolicies/outstandingbalances2010.html>.

**TABLE I**  
**MANAGEMENT ACTION ON COSTS DISALLOWED IN OIG REPORTS**  
 As of September 30, 2010  
 (in Thousands)

	Number	Disallowed Costs
A. Reports for which final action had not been taken by the commencement of the reporting period. See Note 1.	269	\$2,242,413
B. Reports on which management decisions were made during the reporting period. See Note 2.	308	1,105,989
Subtotal (A+B)	577	3,348,402
C. Reports for which final action was taken during the reporting period:		
i. The dollar value of disallowed costs were recovered through collection, offset, property in lieu of cash, or otherwise.	328	726,476
ii. The dollar value of disallowed costs that were written off by management.	15	1,615
Subtotal (i+ii)	343	728,091
D. Reports for which no final action has been taken by the end of the reporting period. See Note 3.	234	\$2,620,311

Notes:

1. Includes adjustments of amended disallowance and disallowance excluded from the previous reporting period.
2. Represents the amount of management concurrence with the OIG's recommendations. For this fiscal year, the OIG's reconciliation with the HHS Agencies showed a variance that represents the three organizations having different cut-off dates.
3. In addition to current unresolved cases, this figure includes audits over 1 year old with outstanding balances totaling \$1,741,756,232 (e.g., audits under current collection schedule, or audits under administrative or judicial appeal).

**TABLE II**  
**MANAGEMENT ACTION ON OIG REPORTS**  
**with Recommendations That Funds Be Put to Better Use**  
**As of September 30, 2010**  
*(in Thousands)*

	Number	Disallowed Costs
A. Reports for which final action had not been taken by the commencement of the reporting period. See Note 1.	12	\$14,880
B. Reports on which management decisions were made during the reporting period.	8	412,567
Subtotal (A+B)	20	427,447
C. Reports for which final action was taken during the reporting period:		
i. The dollar value of recommendations that were actually completed based on management action or legislative action.	9	414,377
ii. The dollar value of recommendations that management has subsequently concluded should not or could not be implemented or completed.	0	-
Subtotal (i+ii)	9	414,377
D. Reports for which no final action has been taken by the end of the reporting period.	11	\$13,069
Notes:		
1. Includes adjustments of amended disallowance and disallowance excluded from the previous reporting period.		

Table II – Management Action on OIG Reports with Recommendations that Funds Be Put to Better Use. “Funds to be put to better use” relates to those costs associated with cost avoidances, budget savings, etc.

- In FY 2010, HHS initiated action on \$412,566,811 in OIG recommendations to put funds to better use.
- In FY 2010, HHS completed action on \$414,377,233 in OIG recommendations to put funds to better use.

## SUMMARY OF FINANCIAL STATEMENT AUDIT AND MANAGEMENT ASSURANCES

TABLE 1 SUMMARY OF FINANCIAL STATEMENT AUDIT					
Audit Opinion			Unqualified for Four Financial Statements. No Opinion Expressed on Statement of Social Insurance		
Restatement			No		
Material Weaknesses	Beginning Balance	New	Resolved	Consolidated	Ending Balance
Financial Reporting, Systems, Analyses & Oversight	<input checked="" type="checkbox"/>				<input checked="" type="checkbox"/>
Financial Management Information Systems	<input checked="" type="checkbox"/>				<input checked="" type="checkbox"/>
Total Material Weaknesses	<i>2</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>2</i>

### Definition of Terms – Tables 1 and 2

**Beginning Balance:** The beginning balance shall agree with the ending balance of material weaknesses from the prior year.

**Resolved:** The total number of material weaknesses that have dropped below the level of materiality in the current year.

**Consolidated:** The combining of two or more findings.

**Reassessed:** The removal of any finding not attributable to corrective actions (e.g., management has re-evaluated and determined a material weakness does not meet the criteria for materiality or is redefined as more correctly classified under another heading (e.g., Section 2 to a Section 4 and vice versa).

**Ending:** The agency's year-end balance.



**TABLE 2  
SUMMARY OF MANAGEMENT ASSURANCES**

**Effectiveness of Internal Control over Financial Reporting (FMFIA #2)**

Statement of Assurance	Qualified					
<b>Material Weaknesses</b>	<b>Beginning Balance</b>	<b>New</b>	<b>Resolved</b>	<b>Consolidated</b>	<b>Reassessed</b>	<b>Ending Balance</b>
Financial Reporting Systems & Processes	<input checked="" type="checkbox"/>					<input checked="" type="checkbox"/>
<i>Total Material Weaknesses</i>	<i>1</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>1</i>

**Effectiveness of Internal Control over Operations (FMFIA #2)**

Statement of Assurance	Qualified					
<b>Material Weaknesses</b>	<b>Beginning Balance</b>	<b>New</b>	<b>Resolved</b>	<b>Consolidated</b>	<b>Reassessed</b>	<b>Ending Balance</b>
Information System Controls and Security	<input checked="" type="checkbox"/>					<input checked="" type="checkbox"/>
<i>Total Material Weaknesses</i>	<i>1</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>1</i>

**Conformance with Financial Management System Requirements (FMFIA #4)**

Statement of Assurance	Non-conformance					
<b>Non-Conformances</b>	<b>Beginning Balance</b>	<b>New</b>	<b>Resolved</b>	<b>Consolidated</b>	<b>Reassessed</b>	<b>Ending Balance</b>
Financial Reporting Systems & Processes	<input checked="" type="checkbox"/>					<input checked="" type="checkbox"/>
Information System Controls and Security	<input checked="" type="checkbox"/>					<input checked="" type="checkbox"/>
<i>Total Non-Conformances</i>	<i>2</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>2</i>

**Compliance with Federal Financial Management Improvement Act (FFMIA)**

	<b>Agency</b>	<b>Auditor</b>
Overall Substantial Compliance	No	No
1. System Requirements	No	
2. Accounting Standards	Yes	
2. USSGL at Transaction Level	No	

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**OIG TRANSMITTAL OF  
FY 2010 TOP MANAGEMENT AND PERFORMANCE CHALLENGES**

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## DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Office of the Secretary

Washington, D.C. 20201

NOV 12 2010

TO: The Secretary  
 Through: DS \_\_\_\_\_  
           COS \_\_\_\_\_  
           ES \_\_\_\_\_

FROM: Inspector General

SUBJECT: Top Management and Performance Challenges facing the Department of Health and Human Services in Fiscal Year 2011

This memorandum transmits the Office of Inspector General's (OIG) list of top management and performance challenges facing the Department of Health and Human Services (Department) in fiscal year (FY) 2011. The Reports Consolidation Act of 2000, Public Law 106-531, requires OIG to identify these management challenges, assess the Department's progress in addressing each challenge, and submit this statement to the Department annually.

OIG's list of top management and performance challenges for FY 2011 includes the following:

- Part I: Health Care Reform
  - Incorporating Integrity into Health Care Reform Implementation
- Part II : Integrity of Medicare, Medicaid, and the Children's Health Insurance Program
  - Integrity of Provider and Supplier Enrollment
  - Integrity of Federal Health Care Program Payment Methodologies
  - Promoting Compliance With Federal Health Care Program Requirements
  - Oversight and Monitoring of Federal Health Care Programs
  - Response to Fraud and Vulnerabilities in Federal Health Care Programs
  - Quality of Care
- Part III: Integrity of the Department's Public Health and Human Services Programs
  - Oversight of Food, Drugs, and Medical Devices
  - Public Health Emergency Preparedness and Response
  - Grants and Contracts Management
- Part IV: Cross-Cutting Issues
  - American Recovery and Reinvestment Act Accountability and Transparency
  - Health Information Technology and Integrity of Information Systems
  - Ethics Program Oversight and Enforcement

Page 2 - The Secretary

OIG looks forward to continuing to work with the Department to identify and implement strategies to protect the integrity of the Department's programs and the well-being of the beneficiaries of these programs. If you have any questions or comments, please contact me, or your staff may contact Erin Lemire, Director of External Affairs, at (202) 205-9523 or [Erin.Lemire@oig.hhs.gov](mailto:Erin.Lemire@oig.hhs.gov).

/Daniel R. Levinson/

Daniel R. Levinson

Attachment

## FY 2010 TOP MANAGEMENT AND PERFORMANCE CHALLENGES IDENTIFIED BY OFFICE OF THE INSPECTOR GENERAL

Pursuant to the *Reports Consolidation Act of 2000* (P.L. No. 106-531), each year the Office of Inspector General (OIG) summarizes what the Office considers to be the most significant management and performance challenges facing the Department of Health & Human Services (the Department or HHS) and the Department's progress in addressing those challenges. In 2010, the Office identified the following top management challenges for fiscal year (FY) 2011. This document is divided into four parts: (1) health care reform; integrity of the Medicare, Medicaid and the Children's Health Insurance Program (CHIP); (2) integrity of the Department's public health and human services programs; and (3) cross-cutting issues that span the Department.

### PART I: Health Care Reform

The *Patient Protection and Affordable Care Act*, as amended by the *Health Care and Education Reconciliation Act of 2010* (collectively, the *Affordable Care Act* or the *Act*) sets forth the most comprehensive changes to Federal health care programs and the national health insurance system since the inception of the Medicare program in 1965.

#### Management Issue 1: Incorporating Integrity into Health Care Reform Implementation

#### MANAGEMENT CHALLENGE AND ASSESSMENT OF PROGRESS IN ADDRESSING THE CHALLENGE:

The *Act's* 10 titles include private insurance market reforms, Medicare and Medicaid amendments, quality and efficiency of care, public health, the health care workforce, and *Community Living Assistance Services and Support (CLASS)*. The Congressional Budget Office (CBO) has estimated the costs of the new programs to be \$940 billion over the next 10 years. The magnitude of expenditures and impact on providers, insurers, employers, and beneficiaries from financial and health perspectives make it critical that *Affordable Care Act* programs operate efficiently and effectively and are protected from fraud and abuse.

Under the *Affordable Care Act*, the Department has broad new responsibilities. It will manage the significant modification and expansion of many existing programs, develop and implement new programs, promulgate regulations, issue and oversee billions of dollars in grants and loans,

develop strategic plans, conduct a variety of studies, prepare reports for Congress, and enforce program rules. Much of this has occurred and will continue to occur with short implementation timelines.

Many components within the Department are responsible for implementing the *Affordable Care Act*, including the new Office of Consumer Information and Insurance Oversight (OCIO), Centers for Medicare & Medicaid Services (CMS), Food and Drug Administration (FDA), National Institutes of Health (NIH), Indian Health Service (IHS), Centers for Disease Control and Prevention (CDC), Administration on Aging (AoA), Agency for Healthcare Research and Quality (AHRQ), and the Office of Inspector General. In addition, implementing the *Act* requires that the Department work closely with other Federal agencies, including the Department of Labor and the Department of the Treasury. Successful implementation depends on extensive intra-agency and inter-agency collaboration and coordination.

Successful implementation of the *Affordable Care Act* also requires clear and effective communication with program beneficiaries, private citizens, and health care industry stakeholders. For example, the Department has substantial new involvement with the private insurance markets, requiring subject-matter expertise, new oversight strategies, and new technologies and approaches in generating and disseminating consumer information.

Implementation of the law merits thoroughness, scrutiny, and oversight. A significant challenge for the Department will be identifying key vulnerabilities and prioritizing oversight resources. Based on the Office's experience in auditing, evaluating, and investigating fraud, waste, and abuse, areas that warrant vigilant HHS oversight include:

- Programs implemented under expedited timeframes. The Department can draw upon experience gained in two recent programs that were implemented with short timeframes - the Medicare Prescription Drug Benefit and the *American Recovery and Reinvestment Act (Recovery Act) of 2009* (P.L. No. 111-5).
- Programs involving data collection to ensure accuracy and completeness of data.

- Grant programs.
- Ensuring accuracy of payments involving risk corridors, reconciliation payments, or similar payment structures.
- Changes to Part D and other Medicare and Medicaid payments.
- Activities, such as insurance scams, that may put beneficiaries at risk. Already, OIG has received reports that criminals, preying on the fears and confusion that surround the new program, are offering fake insurance policies.

The Department has taken many steps to address the challenges posed by implementation of the *Act*. For example, to address internal coordination challenges, the Department has established a structure of cross-component subject matter working groups to promote effective collaboration. To ensure timely and complete implementation, the Department has engaged dedicated staff to maintain a database with a dashboard feature to track implementation milestones and deliverables. Representatives from HHS components confer regularly to monitor progress in meeting the implementation goals. In addition, the management of individual components meets regularly to discuss and track policy development and implementation of the *Act* as it pertains to their components.

The Department is also building infrastructure to support implementation of the *Act*. For example, the Department created and is staffing up OCIO to focus on private insurance issues (including enforcement), CMS created the new Center for Medicare and Medicaid Innovation to focus on innovative delivery models and established the Center for Program Integrity to strengthen its oversight of the Medicare and Medicaid programs. The Department is also devoting additional resources and effort to enhance the use of information technology to foster effective implementation of the *Act*, including the use of sophisticated performance tracking tools.

Finally, the Department has provided guidance about new requirements to affected stakeholders by issuing many proposed and final regulations implementing *Affordable Care Act* provisions and a variety of subregulatory guidance documents. More remains to be done as implementation proceeds.

The Department, including OIG, must work with its partners to respond to vulnerabilities in current Federal health care programs and in the expanded and new programs established through the

*Affordable Care Act*. The Department, including OIG, must identify new risks posed by the changing dynamics of Federal health care programs and the evolving nature of fraud and abuse schemes and respond effectively to those risks.

## **PART II: INTEGRITY OF MEDICARE, MEDICAID, AND THE CHILDREN'S HEALTH INSURANCE PROGRAM**

For Federal health care programs to best serve beneficiaries and remain solvent for future generations, the Government must pursue a comprehensive strategy to prevent, detect, and correct fraud, waste, and abuse. Based on its experience in combating health care fraud, waste, and abuse, OIG has identified five principles that it believes should guide the Department's integrity strategy for Medicare, Medicaid, and CHIP. These principles offer a framework for implementing programs, as well as designing integrity safeguards and putting them into practice.

- **Enrollment** – Scrutinize individuals and entities that seek to participate as providers and suppliers before they enroll in health care programs.
- **Payment** – Establish payment methodologies that are reasonable and responsive to changes in the marketplace.
- **Compliance** – Assist health care providers and suppliers in adopting practices that promote compliance with program requirements, including quality and safety standards.
- **Oversight** – Vigilantly monitor programs for evidence of fraud, waste, and abuse.
- **Response** – Respond swiftly to fraud, impose appropriate punishment to deter others, and promptly eliminate program vulnerabilities.

Consistent with these principles, OIG has applied this framework to identify the top management challenges that the Department faces in protecting the integrity of its health care programs, meeting the needs of beneficiaries, and keeping Federal health care programs solvent.

Ensuring that the beneficiaries receive quality health care has many dimensions, including overseeing providers' compliance with quality-of-care standards, ensuring patient safety, and identifying opportunities for improvements in quality of care.



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## *Management Issue 2: Integrity of Provider and Supplier Enrollment*

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### **Management Challenge and Assessment of Progress in Addressing the Challenge:**

Large Federal Government expenditures on the Medicare and Medicaid programs attract certain individuals and entities that may seek to exploit the health care system for financial gain. Although the vast majority of health care providers and suppliers are honest and well intentioned, the Department faces challenges in ensuring the integrity of the programs' provider and supplier enrollment processes. A small percentage of providers and suppliers intent on defrauding these programs has exploited weaknesses in the enrollment process, causing significant harm. These providers and suppliers drain resources that should be spent on providing care to beneficiaries. OIG's oversight and enforcement work identified weaknesses in provider and supplier enrollment that enable unqualified, dishonest, and unethical individuals and entities to access a system they can easily exploit. OIG also identified weaknesses in the oversight of provider and supplier eligibility to receive payments under Medicare and Medicaid.

A number of OIG's concerns have been addressed in the *Affordable Care Act*. Provisions of the *Act* require the Secretary, in consultation with OIG, to establish more rigorous enrollment and screening processes and to provide for enhanced oversight measures, disclosure requirements, enrollment moratoriums, and requirements for developing compliance programs. The *Act* also requires that any home health or durable medical equipment (DME) prescription or referral covered by Medicare Parts A or B be written by a Medicare-enrolled physician or nonphysician practitioner and authorizes the Secretary to extend this requirement to other Medicare-covered items and services. The *Act* also requires any agents, clearinghouses, or other alternate payees that submit claims on behalf of Medicaid health care providers to register with the State and the Secretary in a form and manner specified by the Secretary.

In the area of enforcement, the *Affordable Care Act* introduces new civil monetary penalties (CMP) for certain types of infractions, including falsifying information on provider enrollment applications. The *Act* also expands the Inspector General's discretionary authority to exclude individuals and entities from participation in Medicare, Medicaid, and all other Federal health care programs to include situations in which an individual or entity makes a false statement or misrepresentation on an enrollment application.

All these provisions, when implemented, will help the Government to better know and control with whom it is doing business. Protecting programs and beneficiaries from unqualified, fraudulent, or abusive providers and suppliers upfront is more effective than trying to recover payments or redress fraud or abuse after it occurs.

### ***Enrollment Process and Oversight Activities***

Ensuring adequate and appropriate provider and supplier enrollment standards and screening is an essential first step to strengthening the integrity of the Medicare and Medicaid programs. OIG identified certain characteristics that may indicate a provider's increased potential for fraud, including interest in or ownership of other health services providers and related businesses with Medicare or Medicaid debt; other evidence of financial instability; no evidence of a physical business facility; previous criminal history, suspension, or exclusion from participation in Federal health care programs; or sanctions by State Medicaid agencies or other health care organizations. The *Affordable Care Act* requires the Secretary to implement screening procedures for different categories of providers and suppliers based on the risk of fraud, waste, and abuse. The screening must be applied to all new enrollments starting March 23, 2011, and all providers and suppliers must be subject to the same process by March 23, 2013.

The *Affordable Care Act* has several additional provisions aimed at reducing vulnerabilities in provider and supplier enrollment, including subjecting new providers and suppliers to enhanced oversight, such as prepayment review for 30 days to 1 year after enrollment. Providers or suppliers applying for enrollment on or after March 23, 2011, must disclose any direct or indirect, current, or previous affiliation with a provider or supplier that has uncollected debt or that has been subject to a payment suspension, program exclusion, or revocation or denial of its billing privileges under a Federal health care program. The Secretary may also impose a temporary moratorium on enrollment of providers and suppliers or on enrollment of certain categories of providers and suppliers, if necessary, to prevent or combat fraud, waste, and abuse. The Secretary's authority was expanded to impose surety bond requirements on DME and home health providers by allowing the imposition of a larger requirement based on the suppliers' or providers' volume of billing, as well as by allowing the extension of the surety bond requirements to other types of providers. Finally, the Secretary has the authority to require that providers and suppliers maintain compliance programs as a condition of

enrollment. Effective use of these new tools and authorities will be critical to addressing fraud, waste, and abuse in the future.

The Department has responded to vulnerabilities in provider and supplier enrollment with measures to enhance enrollment standards for DME suppliers. The response includes a final rule published August 2010 (CMS-6036-F) which clarifies and expands the existing enrollment requirements for DME suppliers. The Department also initiated a demonstration project requiring reenrollment of DME suppliers in south Florida and southern California as a condition for remaining enrolled in the Medicare program. OIG recognizes the Department's progress and continues to recommend further improvements to oversight and enforcement of provider enrollment standards. OIG will also monitor progress under the competitive bidding program for DME suppliers once it is fully implemented in 2011 to determine whether the application and enrollment process is sufficiently rigorous to prevent suppliers prone to fraud, waste, and abuse from receiving contracts.

In other work, OIG investigations identified a fraud scheme involving foreign nationals who obtained Medicare provider numbers that they used to submit fraudulent claims. Unknown individuals recruit foreign nationals who are in the United States on student visas to obtain Medicare provider numbers. These provider numbers are used to fraudulently bill Medicare while the foreign nationals return to their home countries. OIG alerted CMS to this fraud scheme and recommended that CMS adopt guidelines with regard to foreign nationals' obtaining Medicare provider numbers. CMS responded that it was unclear whether it had the authority to implement the recommended actions and noted that when conducting reviews, surveyors examine the Employment Eligibility Verification document (Form I-9) for facility owners and key employees as part of the accreditation process. While surveyor reviews may identify some schemes, until the vulnerabilities brought to light by this fraud scheme are addressed, Medicare continues to risk exposure to fraudulent claims by ineligible providers.

The Department also faced challenges stemming from the variation in Medicaid provider and supplier enrollment standards, which can differ across States and for providers within a State. For example, an OIG evaluation of State Medicaid enrollment requirements for personal care attendants found that State Medicaid programs established multiple sets of provider requirements that often vary among programs and by delivery models within programs, resulting in 300 sets of provider requirements nationwide for personal care

attendants. OIG is examining whether States enforce their requirements for personal care attendants. The *Affordable Care Act* requirements, when implemented, should create a more consistent approach to the enrollment and screening process.

OIG has identified challenges related to nursing home ownership transparency. (See Management Issue 7 for more information on this topic.) Greater transparency in the enrollment process for nursing homes would help the Government know with whom it is doing business and whom to hold accountable in cases of noncompliance, fraud, or abuse. Congress recognized this in enacting the *Affordable Care Act*, which requires nursing homes to disclose information about the identity of parties with an ownership or management interest. This information will be made public. OIG will monitor implementation of this provision to ensure that it addresses vulnerabilities in nursing home enrollment.

### **Provider and Supplier Eligibility for Certain Payments**

The *Affordable Care Act* includes provisions that address program vulnerabilities to prevent ineligible providers from enrolling in the Medicare and Medicaid programs. The *Act* also includes provisions to enhance OIG's authority to obtain any information necessary from any individual or entity to validate claims for payment under Titles XVIII or XIX for evaluation of the economy, efficiency, or effectiveness of these programs. Together, these provisions should help the Department oversee the programs and prevent providers that are improperly enrolled from participating in the programs or receiving payments for which they are not eligible.

OIG identified instances in which Medicare and Medicaid made payments to providers that were improperly enrolled or were not eligible to receive payments. For example, OIG found that between FYs 2000 and 2006, 397 hospitals received \$21.9 million in capital disproportionate share hospital (DSH) payments for which they were not eligible. Further, OIG reviewed States' compliance with Medicaid DSH payment requirements and found that from July 2000 through June 2003, one State paid \$142.3 million (\$88.2 million Federal share) to three State-owned psychiatric hospitals that were not eligible for such payments.

OIG also determined that from July 1, 1996, through June 30, 2007, one State paid \$26.2 million (\$16.3 million Federal share) to a hospital that was not eligible to receive Medicaid payments for inpatient psychiatric services because it did not show compliance with certain Medicare Conditions of Participation requirements. OIG audits at

numerous Medicare fiscal intermediaries (FI) found that unallowable payments of about \$4.9 million were made to providers that were not eligible for payment because the services were provided on or after the dates that the providers were terminated from the Medicare program.

The Department responded to these vulnerabilities by directing the Medicare administrative contractors (MAC) and FIs to assess capital DSH eligibility as part of their review processes. CMS will also include an edit to the hospital cost report software to prevent ineligible hospitals from claiming capital DSH payments on their cost reports.

OIG continues to encourage the Department to implement payment safeguards to ensure that payments are made only to eligible providers and suppliers. As described above, the *Affordable Care Act* authorizes the Department to establish procedures to strengthen provider and supplier enrollment standards. Fully implementing the new procedures should lessen the risk of improper enrollments or payments for which providers are not eligible.

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### *Management Issue 3: Integrity of Federal Health Care Program Payment Methodologies*

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#### **Management Challenge and Assessment of Progress in Addressing the Challenge:**

The Federal Government must act as a prudent purchaser of health care. Medicare and Medicaid payment methodologies must ensure access to quality care without wasteful spending. Achieving this objective is critical to maintaining an effective and efficient health care delivery system. The challenges associated with meeting this objective are complex and are evolving, especially in the context of implementing health care reform. Initial payment methodologies must be set to reimburse providers and suppliers fairly for appropriate care. Payment methodologies must also be responsive to ensure that they remain reasonable and appropriate as the health care marketplace and medical practice evolve. Finally, CMS must be nimble enough to safeguard against the financial incentives and fraud and abuse risks associated with each payment methodology that is established.

#### ***Setting Initial Payment Methodologies***

As Federal health care programs are created, expanded, or revised under the *Affordable Care Act*, which creates new payment methods and updates existing payment methods, it is critical to establish initial payment rates based on the most accurate data available and on reasonable assumptions and projections. OIG has identified instances in which issues with the data used in the development of initial payment methodologies have resulted in

increased expenditures by Medicare and its beneficiaries. For example, because of earlier work, OIG is concerned that the Part A prospective payment systems (PPS) for home health services, Skilled Nursing Facility (SNF) services, and Part B PPS for hospital outpatient department services were based on data known to be problematic, which may have resulted in inaccurate payment rates. CMS will need to address this challenge when it rebases the home health PPS, as required by the *Affordable Care Act*. With the new and expanded programs enacted under health care reform, it is important to strengthen oversight of these programs.

Setting proper payment rates for Medicare Part B services has also proved challenging. OIG reviews have determined that Medicare payments for certain categories of DME do not accurately reflect the costs of these products because the payment rates are based on historical average prices and do not reflect current market prices. For example, in 2006, OIG found that Medicare allowed more than \$7,000 for 36 months of rental payments for oxygen concentrators that cost \$587, on average, to purchase. OIG also found that Medicare allowed an average of \$4,018 to purchase standard power wheelchairs and \$11,507 for complex rehabilitation power wheelchair packages, compared with supplier acquisition costs of \$1,048 and \$5,880, respectively. OIG has recommended that CMS determine whether these amounts should be adjusted using its inherent reasonableness authority, using information from the Competitive Bidding Acquisition Program, or seeking legislation to ensure that fee schedule amounts are reasonable and responsive to market changes. OIG's 2009 findings that more than half of power wheelchair claims submitted by suppliers do not meet the requirements for payments underscores the need to closely align the amount Medicare pays for power wheelchairs with the costs to suppliers.

The Competitive Bidding Acquisition Program is CMS's main initiative to reduce beneficiary costs and improve the accuracy of Medicare payments for certain categories of DME. Legislation delayed its implementation, and contracts under the program's first round of bidding are to become effective on January 1, 2011, and CMS plans to expand the program.

Payments to Medicare Advantage (MA) organizations under Part C may also be higher than necessary. Based on numerous reviews of the Medicare + Choice program (MA's predecessor), OIG concluded that the data and estimates used to calculate monthly capitation payments were flawed, resulting in higher payments. The inflated base-year data continue to affect MA payments, which have not been adjusted to take into account problems

with Medicare + Choice data that OIG had identified. OIG plans to further examine the accuracy of the data used to adjust capitation payments to MA organizations. In addition, the *Affordable Care Act* will reduce payments to MA organizations in 2012.

Appropriate payment rates for Medicare Part D continue to be a challenge. OIG is examining the extent to which Part D Plans report all rebates and direct and indirect remuneration they receive. In earlier work, OIG found that estimated costs in sponsors' bids were higher than their actual costs, which resulted in higher Medicare payments and premiums. In response, CMS agreed to ensure that sponsors' bids accurately reflect the cost of providing benefits and noted that it incorporates data submitted to CMS for reconciliation of prior years into its bid review process.

### **Responding to Changes in the Marketplace and Health Care Practices**

The Department faces a substantial challenge in reacting swiftly and appropriately to changes in health care delivery systems and standards of care so that the programs continue to effectively reimburse for quality care. OIG has conducted reviews of Medicare and Medicaid payment methodologies and found that when reimbursement methodologies do not respond to such changes, the programs and their beneficiaries bear the cost.

Medicare Part B payments for new wound therapy pumps provide one example of the costs of failing to update payments in response to market changes. When Medicare first covered wound pumps, it covered only one model and Medicare based the payment on that model's purchase price. As new models became eligible for coverage, Medicare continued to reimburse suppliers based on the original model's purchase price, which OIG found is more than four times the average price currently paid by suppliers for new pumps.

Another example is demonstrated in OIG work, which found that Medicare has paid physicians for evaluation and management (E&M) services that were included in global fees for eye surgery but were not provided during the global surgery periods. The misalignments in global eye surgery payments are attributable, in part, to CMS's not updating payments to reflect changes in medical practice. Over time, the average number of E&M services provided during the global period has decreased, but payments continue to be based on estimates that a higher number of E&M services are provided.

Other examples include Medicare Part B payments for laboratory tests and for certain drugs. OIG

found that Medicare Part B payments for laboratory tests, which were established over 20 years ago, vary within and between Medicare contractors. The variances did not appear to reflect geographic differences in costs. OIG recommended that CMS seek legislation to establish a new process for setting accurate and reasonable payment rates. CMS stated that it would consider OIG's recommendation as the agency continues to monitor the effects of its current payment policies. OIG work has also shown that Medicare payments for certain Part B drugs are higher than actual costs in the marketplace when newly available generic versions first enter the market.

Payment methodologies for other benefits also present challenges in responding to marketplace changes. The average manufacturer price (AMP), which is used in calculations of both Medicaid drug rebates and the Federal Upper Limit (FUL), has been redefined in the *Affordable Care Act*. This change may resolve the disparity between what Medicaid pays for drugs and the prices available in the marketplace.

### **Payment Incentives and Risks of Fraud and Abuse**

Payment methodologies inherently create incentives and risks for fraud. Fee-for-service (FFS) payments create financial incentives to provide excessive, complex, or unnecessary services. Conversely, under capitated or bundled payment systems, financial incentives may encourage providers to stint on needed care. The *Affordable Care Act* introduces several new payment models, such as accountable care organizations, medical homes, and shared savings programs. A key challenge for the Department will be ensuring that it strikes the right balance between protecting the integrity of the health care programs and fostering innovation that increases quality, efficiency, and cost effectiveness. Because fraud schemes develop and multiply quickly, it is crucial that the Department rapidly identify and address the risks inherent in new payment models.

OIG's work on Medicare and Medicaid outlier payments highlights the importance of addressing the integrity of payment methodologies. Recent investigations have identified abuses of CMS's home health outlier payment methodology, which has resulted in providers' receiving significant outlier payments to which they were not entitled. In response to evidence of abuse in this area, CMS caps outlier payments to individual home health agencies. Continuing OIG work is examining vulnerabilities linked to this payment methodology.

Similarly, OIG found in previous work that Medicare payment methodologies for inpatient outlier payments had loopholes whereby inflated charges submitted by hospitals and delays in FI financial analysis of hospital data resulted in hundreds of millions of dollars of wasteful spending. Policy changes were made, and financial settlements with several hospital groups were reached. OIG work in several States has shown that if the State Medicaid programs modified their outlier payment policies to mirror changes made in the Medicare program, they could save tens of millions of dollars.

OIG has also found other instances in which payment methodologies have created incentives for providers to alter their practices to maximize reimbursement. For example, ongoing OIG work has found that the current SNF payment methodology gives SNFs an incentive to fraudulently increase the level of services and therapy needed by each beneficiary to qualify for higher per diem rates. This has resulted in severe overutilization of SNF therapy services, including therapy for patients for whom any therapy is inappropriate.

Certain types of services may be vulnerable to abuses such as upcoding, or billing a higher complexity code than the one appropriate for the service performed. OIG has observed that Medicare payments for E&M services increased by over \$9 billion between 2000 and 2009, in part because of a trend of increased billing for high-complexity E&M codes. E&M services may be particularly vulnerable to abuse because the differences among complexity levels are less distinct than the differences in other services and because monitoring by CMS and contractors is lacking.

Medicaid's reliance on published prices as the basis for drug reimbursement also creates fraud vulnerabilities. OIG investigations of allegations that pharmaceutical manufacturers have manipulated prices to decrease Medicaid rebate payments and increase Medicaid drug reimbursement have resulted in significant *False Claims Act* (FCA) settlements. In late 2009, Mylan Pharmaceuticals, Inc., paid \$118 million to resolve allegations that it misclassified drugs in informational filings to the Government to reduce the amounts it paid under the Medicaid Rebate Program. AstraZeneca Pharmaceuticals LP and Ortho MacNeil Pharmaceuticals, Inc., each settled similar allegations in 2007. In 2007, Aventis Pharmaceuticals, Inc., paid \$182.8 million to resolve allegations that it inflated its prices for products paid for by Federal health care programs. Because of the alleged illegal pricing, programs, including Medicaid, overpaid for Aventis's drug, Anzemet.

The Department's challenge to react to payment methodology vulnerabilities is not limited to abuses by providers and suppliers. OIG has found problems with States' implementation of financing mechanisms involving certain intergovernmental transfer of funds, which resulted in an inappropriate inflation of the Federal share of Medicaid payments. Through these arrangements, States often retained funds that were intended to reimburse Medicaid providers. Another way in which States have inappropriately increased the Federal share of Medicaid payments is requiring hospitals to return larger portions of their disproportionate share payments to the States. This practice is contrary to the program's purpose, which is to compensate hospitals that care for large percentages of Medicaid beneficiaries and uninsured patients.

As the Medicare and Medicaid populations grow, the importance of establishing and maintaining the integrity of payment methodologies becomes more critical so that scarce resources are not lost to fraud, waste, and abuse, and beneficiary care is not diminished.

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#### *Management Issue 4: Promoting Compliance with Federal Health Care Program Requirements*

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#### **MANAGEMENT CHALLENGE AND ASSESSMENT OF PROGRESS IN ADDRESSING THE CHALLENGE:**

Provider compliance with Federal health care program requirements is essential to the integrity of the Medicare and Medicaid programs. Compliance prevents fraud, waste, and abuse and promotes efficiency and economy. To ensure compliance, the Department must partner with health care providers. The Medicare program pays for health care services for about 47 million beneficiaries rendered by 1.2 million participating providers and suppliers, including hospitals, nursing homes, physicians and other practitioners, DME companies, and others. An estimated 1.2 billion Medicare FFS claims are processed by CMS annually, amounting to an average 4.6 million claims processed each working day. In FY 2009, Medicare FFS payments totaled \$327.8 billion. Medicare is required to process and pay electronically submitted claims within 30 days of receipt. The Medicaid Federal Medical Assistance Percentage (FMAP) payment totaled \$252.9 billion in FY 2009, helping to address the care needs for about 51 million Medicaid recipients.

The Medicare and Medicaid programs rely on the premise that providers and suppliers submit legitimate and accurate claims by providers and suppliers. Although most providers and suppliers are honest and well intentioned, even honest providers and suppliers can make mistakes or fail to

comply with the rules. Though small in number, dishonest providers and suppliers attempt to game the system by exploiting or circumventing payment and coverage rules. The challenge facing the programs is illustrated by a December 2009 OIG study, which found that 60 percent of claims for standard and complex rehabilitation power wheelchairs did not meet Medicare documentation requirements and that error rates varied by power wheelchair type and supplier volume during the first half of 2007, with greater documentation error rates accompanying claims for complex rehabilitation wheelchairs than for standard models. CMS concurred with all of OIG's recommendations for improving documentation processes to reduce improper payments in this area and noted multiple efforts underway to improve compliance. For example, a contract was recently awarded to a Program Safeguard Contractor (PSC) to conduct medical review on power mobility claims submitted by certain providers. In addition, CMS will instruct MACs to examine whether beneficiaries were receiving the correct wheelchairs for their conditions and whether correct documentation was present.

A June 2010 OIG report reveals how noncompliance with even the most basic documentation safeguards challenges Federal health care programs. Medicare Part D sponsors and beneficiaries paid pharmacies \$1.2 billion in 2007 for claims in which the listed prescriber identifiers did not correspond to practicing physicians. Without a valid prescriber identifier, CMS and its contractors cannot determine whether a physician actually prescribed the drug or whether the physician was validly licensed and had not been excluded from the Medicare program. Furthermore, invalid prescriber identifiers inhibit OIG investigations by making it more difficult to identify questionable prescribing patterns and the parties responsible for potential fraud.

Effectively combating fraud, waste, and abuse includes ensuring that a provider and supplier community is well informed about program rules and is actively engaged in compliance efforts.

### ***The Costs of Noncompliance***

Assisting health care providers and suppliers in adopting practices that promote compliance with program coverage, payment, and quality requirements must be an integral part of the Department's program integrity strategy. The benefits of industry compliance include reduced risk of fraud and abuse, as well as fewer billing and payment errors; better quality of care; and the fostering of an ethical culture that enhances public confidence in the system.

The risks associated with failing to create a culture of compliance and the costs of noncompliance are

significant. CMS estimated that in FY 2009, improper FFS payments cost Medicare \$24.1 billion (7.8-percent error rate). Changes were implemented during FY 2009 review year and, as a result, the 7.8 percent was a combined error rate using two different methodologies. The revised methodology is more stringent. The national paid claims error rate for those claims reviewed under the strictest criteria, when applied to the entire year, is 12.4% or \$35.4 billion. CMS estimated that in FY 2008, improper Medicaid State and Federal payments cost \$28.7 billion (8.71-percent error rate). OIG has identified inappropriate Medicare payments for specific services and products. (See also management issues 2, 3, 5, and 6.) OIG recently found that certain DME claims did not meet Medicare program requirements, resulting in potentially more than \$200 million in improper payments. OIG found that New York's Medicaid program paid more than \$414.5 million (\$207.6 million Federal share) to providers in New York City for rehabilitation services claims that did not meet program requirements. Error rates and improper payment estimates include paid claims that do not meet program rules, whether because of error, fraud, or other factors.

OIG has also identified fraud and abuse that have resulted in substantial costs to Federal health care programs: expected OIG recoveries for the 6 months that ended March 2010 include about \$667 million in audit receivables and \$2.5 billion in investigative receivables. In addition, noncompliance with standards of care can be so egregious as to constitute a failure of care and jeopardize patient health and safety. (See Management Issue 7.) When settling allegations of fraud and abuse, OIG often requires health care providers to enter into Corporate Integrity Agreements (CIA) in exchange for OIG's agreement not to exclude the provider from participation in Federal health programs. OIG tailors CIAs according to the conduct and circumstances of each case. However, CIAs generally require providers to implement compliance programs that include a compliance officer or committee, written standards and policies, employee training programs, confidential disclosure mechanisms, reviews by an independent reviewer, and various reporting requirements.

### ***Education and Guidance Efforts***

Provider education and guidance are important tools for fostering compliance. However, several factors create challenges in promoting industry compliance with program rules through education. Federal health care programs are governed by complex statutes, regulations, and subregulatory guidance.

There are national rules, such as statutes, regulations, and national coverage determinations, and local rules, including local medical review policies. These rules and regulations are frequently updated or changed by law or by administrative action. In a complex programmatic environment, it is a challenge to ensure that guidance is clear, informed, complete, and audience appropriate.

The audience for compliance education is diverse in terms of sophistication, size, and resources. Medicare providers range from health care corporations that hire top legal and management advisors to small operations with minimal legal or regulatory expertise. Some are integrated delivery systems that need to master the rules and regulations for multiple benefit categories, while others are purveyors of only one item or a few items and services. Some providers may have limited resources to devote to compliance, which competes with other priorities, such as providing care, managing business operations, and earning a profit. Others are affiliated with well-established, large, multi-facility organizations with a widely dispersed workforce and significant resources to devote to compliance.

To address these challenges, the Department must work to ensure that it is providing guidance that assists providers and suppliers in understanding and complying with program requirements, educating providers and suppliers effectively about program requirements, and promoting industry adoption of effective internal controls and other compliance measures. The Department must also ensure that its claims-processing contractors are knowledgeable about program requirements, that the contractors provide useful guidance on their policies, and that they offer adequate education for the providers and suppliers whose claims they process.

The Department has a variety of tools and approaches available for this effort. These include regulatory and subregulatory issuances (including manuals, frequently asked questions, advisory opinions, and other materials), provider listservs, Web sites (such as the Medicare Learning Network), and live educational opportunities (such as open-door forums and sponsored education programs on requirements of the *Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 (P.L. No. 108-173)*). CMS is also exploring the use of new media, such as podcasts and RSS feeds, to reach provider and supplier audiences. It recently launched a series of national listening sessions related to OIG reports in an effort to educate provider and suppliers on specific vulnerabilities that exist in DME, Part A, Part B, and home health and hospice settings.

A National Health Care Fraud Summit was held in Washington, DC, in January 2010. The Department is working with the Department of Justice (DOJ) on additional live educational opportunities, such as Regional Fraud Prevention Summits; summits have been held in Miami and Los Angeles. At this point, additional summits have been planned for New York, Detroit, Boston, and Philadelphia. The summits bring together representatives from Federal, State, and local law enforcement agencies and representatives from the private sector, including health care providers, hospitals, and doctors for a day of panels and training sessions that facilitate the sharing of information about trends in health care fraud that will ensure effective referral mechanisms and procedures.

The Department also works with the private sector to promote compliance. For example, CMS has a Provider Partnership Program through which it shares Medicare FFS information with national organizations that are Medicare billers or serve as intermediaries for Medicare billers. Through the Medicaid Integrity Program, CMS funds contracts for educating health care providers and suppliers, managed care entities, and beneficiaries to promote payment integrity and quality of care.

OIG also collaborates with health care providers to promote compliance. As discussed more fully in Management Issue 7, OIG has worked with nursing home providers through roundtables that focus on how boards of directors can better monitor and ensure quality of care. Another collaborative live educational opportunity will be represented by the OIG's Provider Compliance Training initiative, to begin in 2011. The Provider Compliance Training Initiative will bring together representatives from a variety of government agencies to provide compliance training at no cost to local provider, legal, and compliance communities in Medicare Strike Force cities and other locations across the country. Strike Forces are multiagency teams of prosecutors and investigators that use real-time analysis of Medicare billing data to assist in the identification, investigation, and prosecution of individuals and entities that have committed fraud.

The continuing challenge is determining which tools and approaches are most cost effective, which are best suited to a diverse and rapidly evolving health care industry, and which produce the greatest benefit for increasing compliance.

### ***Provider and Supplier Adoption of Compliance Programs***

Implementation of effective compliance programs is another method of fostering an industry culture of compliance and a continuing commitment to

delivering quality health care. Successful compliance programs should establish internal controls to decrease providers' and suppliers' risk of practices that result in billing errors, fraud, and abuse. Quality assurance and improvement programs should ensure compliance with Federal health care program requirements and result in tangible benefits to the organization and the beneficiaries it serves.

One challenge, historically, is that the implementation of compliance programs has been largely voluntary. Before enactment of the *Affordable Care Act*, most Medicare and Medicaid providers were not required to adopt compliance programs. Compliance programs have been required only among certain categories of providers and suppliers, including Medicare Part D drug plan sponsors and MA organizations, which are required by statute to implement compliance plans and individuals and entities that have entered into CIAs with OIG. In addition, Medicaid providers in New York have been required by the State to implement effective compliance plans as a condition of Medicaid participation. Several other States besides New York have imposed compliance plan requirements on certain types of health care providers or entities. In some sectors of the health care industry, such as hospitals, voluntary compliance programs have been widespread and sophisticated; other sectors were slower to adopt internal compliance practices and may have had fewer resources to devote to compliance. As discussed below, the *Affordable Care Act* promises improvements because it contains provisions that effectively mandate compliance programs across provider categories.

Voluntary compliance program efforts are supported through OIG's compliance program guidance (CPG). CPGs give health care providers, suppliers, and organizations comprehensive frameworks, standards, and principles by which to establish and maintain effective internal compliance programs. CPGs also strongly encourage providers to identify and focus compliance efforts on those areas of potential concern or risk that are most relevant to their organizations.

OIG has recommended that all Medicare and Medicaid providers and suppliers be required to adopt compliance programs as a condition of participating in the Medicare and Medicaid programs. Passage of the *Affordable Care Act* entails major changes in the role of provider and supplier compliance plans in Federal health care programs. Section 6102 of the *Act* requires, among other things, that nursing homes develop effective

compliance and ethics programs to be in place by March 2013. More broadly, section 6401 of the *Act* sets out provider screening and enrollment requirements for Medicare, Medicaid, and CHIP, which include compliance program mandates for providers and suppliers. The compliance programs for providers and suppliers within a "particular industry or category" will need to meet certain core elements to be developed by the Department in consultation with OIG. Implementation timelines for the compliance program requirements are to be determined by the Secretary.

Even where compliance programs have been required, however, the Department has faced challenges in implementing a comprehensive safeguard strategy. OIG's reviews of the Part D program indicate that CMS's program integrity efforts have been limited in scope and may not sufficiently protect the program. While some of CMS's safeguards are functional, other critical safeguards have been implemented to a limited extent or have not been put in place. OIG found, for example, that CMS relied largely on complaints to identify potential fraud in Part D and that not all complaints were investigated in a timely manner.

OIG recently completed an indepth audit of one plan sponsor's internal controls for the Part D program during 2007 and 2008 and found that although most of the sponsor's internal controls were adequate, they had several weaknesses that compromised the sponsor's ability to detect, correct, and prevent fraud, waste, and abuse. In another report, issued in 2008, OIG found that plan sponsors vary widely in the identification of potential fraud. Although sponsors are the initial gatekeepers for protecting the Part D program, OIG found that not all of them identified potential fraud and abuse, conducted inquiries, initiated corrective actions, or made referrals for further investigation.

Failure to implement effective compliance programs can be a contributing factor that enables fraud and abuse to go unaddressed. CMS's task is to determine what Part D sponsors can do to improve program safeguards based on the information collected in audits of individual sponsors. After Medicare Drug Integrity Contractors (MEDIC) conducted 16 desk-review compliance plan audits, however, CMS found that these audits were of only limited value in monitoring and oversight efforts. As a result, in 2009, CMS revised its approach to compliance audits, changing from reliance on desk review, to on-site review.

CMS also found that it needed to develop more comprehensive, meaningful, and robust compliance plan audit protocols focused on evaluating and



validating the effectiveness of compliance programs, including measures to prevent, detect, and correct fraud, waste, and abuse. The new audit protocols were piloted in 2009 and early 2010, and changes were made based on lessons learned.

The benefits of promoting compliance, and highlighting the costs of noncompliance, will grow as beneficiary populations and health care costs increase. The Department must assist an ever larger and more diverse population of Medicare and Medicaid providers and suppliers in complying with program requirements.

The new mandates in the *Affordable Care Act* should ensure an expanded and redefined role for compliance programs. The Department is implementing several provider compliance education efforts and exploring many others. OIG will continue to provide compliance tools and resources to the provider and supplier community and work closely with the Department to meet this essential but difficult challenge.

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#### *Management Issue 5: Oversight and Monitoring of Federal Health Care Programs*

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### **MANAGEMENT CHALLENGE AND ASSESSMENT OF PROGRESS IN ADDRESSING THE CHALLENGE:**

The Department's health care programs have been founded largely on a system of trust. Although most providers are honest and well intentioned, a system based on trust is vulnerable to exploitation by a minority of providers intent on gaming or defrauding the system. Thus, oversight and monitoring to detect potential fraud, waste, and abuse are critical. However, tension exists between the dual goals of implementing measures preventing and detecting fraud, waste, and abuse, and making timely payments to legitimate providers.

The Department is further challenged to provide effective oversight and monitoring of Federal health care programs because the programs are large and complex, with increasing expenditures and growing numbers of beneficiaries. The size of the programs means that fraud, waste, and abuse in claim submission and payments can result in substantial financial losses. Schemes have become increasingly sophisticated, and criminals adapt to oversight efforts.

Analysis of claims data is a key method of identifying fraud, waste, and abuse. Each program compiles an enormous amount of data on beneficiaries, providers, and the delivery of services. Processing, managing, and analyzing these vast and varied types of data is challenging. These challenges will grow with the additional data

collection and reporting required under the *Affordable Care Act*. The Department often fails to use these data effectively for oversight and monitoring, resulting in the loss of Federal health care dollars. Claims-processing and payment systems have traditionally relied on claim-by-claim review. However, in many cases, fraud or abuse can be detected only by reviewing aggregated claims and billing patterns because each claim may appear on its face to be legitimate. OIG has identified opportunities for the Department to improve its collection, analysis, and monitoring of data to better fight fraud, waste, and abuse. As will be discussed in more detail later, CMS plans to enhance the data available to monitor payment accuracy and integrity across the Medicare and Medicaid programs.

#### **Measuring Error Rates**

Measuring error rates is key to monitoring program integrity and the scope of inappropriate payments. In its reviews of CMS's annual Comprehensive Error Rate Testing (CERT) program, OIG has raised concerns that the Medicare error rates for certain provider types may be understated. To address these problems, CMS in 2009 made substantial changes in the CERT medical record review process, including revising the *Program Integrity Manual* to clarify requirements and promote uniform interpretation of its policies. As a result of the changes and a more complete accounting of improper payments, the FY 2009 national paid claim error rate was 7.8 percent, compared with the FY 2008 error rate of 3.6 percent. The changes were implemented during the FY 2009 review year, and as a result, the 7.8 percent was a combined error rate using two different methodologies. The revised methodology is more stringent. If the results from the revised methodology were annualized, the error rate would have been 12.4 percent. The Department has reported the 12.4 percent error rate and has set out-year targets based on that rate.

Measuring payment errors and their causes in the Medicaid and CHIP programs is particularly challenging because of the diversity of State programs and the variation in their administrative and control systems. CMS's Payment Error Rate Measurement (PERM) program was designed to measure error rates for three components of Medicaid and CHIP: FFS, managed care, and eligibility. OIG is performing audit work to determine whether problems similar to those discovered in the CERT program exist in the PERM program.

Improper payments are also a significant problem across Federal programs. In November 2009, the President signed *Executive Order 13520, Reducing Improper Payments*, and in July 2010, the *Improper*

*Payments Elimination and Recovery Act (IPERA)* was enacted. The purpose of the Executive Order and *IPERA* is to reduce improper payments by intensifying efforts to eliminate payment error, waste, fraud, and abuse in the major programs administered by the Federal Government, including the Department's health care programs, while continuing to ensure that Federal programs serve and provide access to their intended beneficiaries. The requirements of the Executive Order and *IPERA* will further help to reduce improper payments by boosting transparency, holding agencies accountable for reducing improper payments, and creating incentives for States and other entities to reduce improper payments and increasing penalties for contractors who fail to disclose improper payments in a timely manner. The Department and OIG are working together to implement requirements of both the Executive Order and *IPERA*.

### ***Oversight through Effective Analysis of Data***

The health care system compiles an enormous amount of data on patients, providers, and the delivery of health care items and services. However, OIG has found numerous examples in which Federal health care programs have failed to use claims-processing edits and other information technology effectively to prevent improper claims. The following are examples of how vigilant claims analysis could assist the Department in monitoring programs for fraud, waste, and abuse.

Claims analysis can reveal instances in which providers bill for medically unnecessary services to defraud programs. In December 2008, a Miami physician was sentenced to 30 years in prison and ordered to pay more than \$8.2 million in joint and several restitution in connection with her role in an HIV infusion fraud scheme. In another example, at the Saint Jude Rehabilitation Center, Inc., HIV-positive Medicare patients were paid cash kickbacks in exchange for allowing the physician and her co-conspirators to prescribe medically unnecessary infusion treatments; the case was brought by the Medicare Strike Force (see Management Issue 6).

Claims analysis can also reveal instances in which providers bill for more services than are physically possible. In one of the largest civil fraud recoveries ever against a single U.S. hospital, Staten Island University Hospital agreed to pay \$88.9 million in a global settlement resolving allegations that it defrauded Medicare and Medicaid. OIG identified potentially fraudulent billing, among other allegations, for inpatient alcohol and substance abuse detoxification treatment for more beds than the facility was authorized by the State of New York.

Claims analysis can also identify service areas in which providers submit questionable claims. OIG found that providers in a south Florida county accounted for more home health outlier payments in 2008 than the rest of the counties in the Nation combined. Twenty-three more counties nationwide also exhibited aberrant home health payment patterns similar to that of the Florida county but to a lesser extent. CMS has taken steps to address widespread abuse of Medicare outlier payments to home health providers.

### ***Challenges in Using Data Effectively***

In some cases, program data are insufficient to support effective oversight and monitoring. OIG found that Medicare data are insufficient to determine consistently whether Medicare Part B chemotherapy administration payments are appropriate. Part B data do not identify drugs that are not billed to the program even when their administration is billed to Part B. In these cases, when there is no matching drug claim, the data alone cannot be used to determine whether the administration fee has been appropriately billed for administering a qualifying drug.

In other cases, CMS does not effectively use the safeguards available to monitor claims. Unique provider identifiers are a primary tool for ensuring that Medicare services and products are ordered by qualified, legitimate providers. However, OIG work has uncovered vulnerabilities related to the misuse of physician identifiers. OIG found that more than 18 million Medicare Part D prescription drug claims accounting for \$1.2 billion contained invalid prescriber identifiers in 2007. These identifiers either were not listed as valid identifiers in the National Provider Identification (NPI), Drug Enforcement Administration (DEA) number, or Unique Physician Identification Number (UPIN) registry databases or had been deactivated or retired before January 1, 2006. In another review, OIG found that Medicare Part B allowed almost \$28 million for claims with inactive referring physician UPINs, including \$5 million for claims with dates of services after the dates of death of the referring physicians. In 2008, CMS completed its transition from UPINs to a new NPI system for Medicare claims processing. However, OIG has concerns that the vulnerabilities associated with the UPIN system may also affect the integrity of the NPI system.

The Medicaid program has unique data challenges because key program operations occur in States, rather than on a national level. The Medicaid Statistical Information System (MSIS) is the only source of nationwide Medicaid claims information, and weaknesses in MSIS data limit its usefulness for

oversight and monitoring of the program. OIG determined that during FYs 2004 through 2006, MSIS data were an average of 1.5 years old when CMS released the data to users for data analysis purposes. And MSIS did not capture many of the data elements that can assist in fraud, waste, and abuse detection. CMS did not fully disclose or document information about the accuracy of MSIS data; however, CMS maintains a Data Anomalies/State Issues document, which identifies State-specific data issues by file type and year.

The effective use of data is critical to the Department's oversight and monitoring activities and in turn will support the overall success of the Department's anti-fraud efforts.

### **Recent and Planned Oversight Enhancements**

The Department is making progress in improving the oversight and monitoring of Federal health care programs. CMS is augmenting its oversight capabilities by contracting with outside entities to perform many oversight and monitoring functions for Medicare and Medicaid. CMS is also acting to enhance data systems available for use by these contractors. The *Affordable Care Act* creates new implementation challenges in directives requiring the Department to collect, use, and share data. The *Act* requires the Department to expand CMS's Integrated Data Repository to include claims and payment data from Medicaid, the Department of Veterans Affairs (VA), the Department of Defense (DOD), the Social Security Administration (SSA), and IHS. The *Act* also contemplates real-time access by law enforcement to Medicare claims data. To facilitate oversight, the *Act* exempts OIG from prohibitions against matching data across programs. The *Act* also provides OIG with more streamlined access to data and will improve its ability to oversee the integrity of Federal health care programs.

For Medicare, CMS is transitioning program safeguard functions from PSCs and MEDICs to Zone Program Integrity Contractors (ZPIC). These new contractors will be responsible for ensuring the integrity of all Medicare-related claims under Parts A and B (e.g., hospital, skilled nursing, home health, physician, and DME claims); Part C (MA health plans); and Part D (prescription drug data) and for coordinating Medicare-Medicaid data matches (Medi-Medi). As of November 2010, CMS had awarded four ZPIC contracts, with three more contracts planned. With the transition to ZPICs, determining whether the change in contractors has brought about improvement in the use of proactive methods in analyzing claims data will be important. OIG is examining ZPICs' efforts to identify program vulnerabilities and detect and investigate fraud and abuse.

In 2003, Congress authorized the Department to establish a demonstration program for Recovery Audit Contractors (RAC) to identify underpayments and overpayments and to recoup overpayments under Part A or B of the Medicare program. Under this authority, Congress provided for payments to RACs on a contingent basis for detecting and correcting overpayments and underpayments. In 2006, Congress mandated that the Department implement RACs on a nationwide and permanent basis. As of October 2009, CMS completed implementation of the national RAC program in all 50 States. CMS reported that the RAC demonstration project successfully returned almost a billion dollars to Medicare, which represented a new mechanism for detecting improper payments, and provided CMS with a tool for preventing and reducing future improper payments. CMS will require RACs to help develop plans designed to address vulnerabilities found during their reviews. RACs are also responsible for referring to CMS any cases of potential fraud that are found during their reviews. However, OIG noted that over the 3-year demonstration period, RACs referred only two cases of potential fraud to CMS. OIG and CMS are working together to ensure appropriate referrals of suspected fraud under the national RAC program. CMS has agreed to implement a system to track fraud referrals and to require RACs to receive mandatory training on the identification and referral of fraud. Section 6411 of the *Affordable Care Act* expands the RAC program, giving it additional responsibilities to address improper payments in Medicaid and Medicare Parts D and C.

As part of the Medicaid Integrity Program, CMS has hired contractors to perform data analysis to detect aberrant billing patterns and to audit claims to identify improper payments. OIG is examining the contractors' work. The Medicaid Integrity Group developed a data engine, a central component of its data strategy and information technology infrastructure. The data engine combines State Medicaid claims data to facilitate detection of fraud, waste, and abuse. The need for an accurate and comprehensive Medicaid claims database that can be used at the national level for data mining and fraud detection is important.

In 2009, OIG formed a cross-disciplinary, interdepartmental Advanced Data Intelligence and Analytics Team (Data Team) to support the work of the Health Care Fraud Prevention and Enforcement Action Team (HEAT) initiative and the Medicare Fraud Strike Forces. (See Management Issue 6 for further discussion of this issue.) The Data Team consists of investigators, auditors, and evaluators from OIG as well as DOJ personnel; the team combines sophisticated data analysis with criminal intelligence gathered through traditional law

enforcement techniques to identify fraud trends. Using Data Team analysis, in December 2009 the HEAT Operations Committee announced several metropolitan “hot spots” for new Strike Force operations. In April 2010, the Data Team provided additional national-level analysis in support of the planned expansion of HEAT operations.

Despite the progress described and plans for enhancements, the Department needs to make continued improvements in oversight and monitoring to meet the challenges that have been outlined. As fraud schemes become more sophisticated and migratory, the use of advanced data analysis to monitor claims and provider characteristics becomes even more important. (See Management Issue 6 for further discussion of this issue.) Needed improvements in using data analysis to support program oversight include sufficient access to data for investigations and analysis; uniform, comprehensive data elements; more timely collection and validation of data; robust reporting of program data by States and others; interoperability of systems; consistent data extraction methods; and the ability to select and analyze claims and provider data across Medicare Parts A, B, C, and D and Medicaid.

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*Management Issue 6: Response to Fraud and Vulnerabilities in Federal Health Care Programs*

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**MANAGEMENT CHALLENGE AND ASSESSMENT OF PROGRESS IN ADDRESSING THE CHALLENGE:**

Responding to fraud and program vulnerabilities requires a high degree of coordination and collaboration between multiple Federal and State agencies and contractors. Federal health care programs are built on a range of regulations, program requirements, and payment methodologies that are often the result of detailed rulemaking and programmatic balancing of competing stakeholder interests. The size and complexity of Federal health care programs also make implementing a comprehensive and swift response to fraud and vulnerabilities difficult. Adding to this complexity, the Medicare administration and program integrity responsibilities are divided among a variety of contractors, and Medicaid and CHIP have their own systems and contractors. The programs compile an enormous amount of data on patients, providers, and the delivery of health care items and services, which are often housed in many locations with different data infrastructures. Operating within this complex framework, it is often difficult for the programs to respond nimbly in the face of a vulnerability, which can result in a significant monetary loss before a remedy or sanction is applied.

OIG work has identified fraud and vulnerabilities across the Department’s health care programs. (See also Management Issues 2-5 and 7.) It is a challenge for the Department to prioritize and respond to the most serious vulnerabilities in the face of limited resources to implement the response. Further, once perfected, many fraudulent schemes are easily replicated and move quickly through communities and across the country. Law enforcement may respond with criminal prosecutions in one jurisdiction only to see the scheme replicated in another part of the country. Fraud schemes are also becoming increasingly sophisticated and often evolve in response to Government’s detection and enforcement efforts. An effective response must be swift; too often, program funds are lost and unrecoverable by the time data are analyzed and the fraud scheme is detected.

These and other factors create conditions that are ripe for those who would take advantage of Federal health care programs. In the face of this significant challenge, the Department brings to bear a law enforcement response through OIG and a programmatic response through CMS.

**Law Enforcement Response**

The law enforcement response to fraud and program vulnerabilities falls into three categories: criminal prosecution, civil litigation, and administrative remedies. Challenges in these three areas are described below.

While most health care providers submit legitimate claims, a minority abuse the system. Adding to this are an increasing number of criminals whose sole purpose is to defraud the program. These are often career criminals running sophisticated and organized criminal enterprises, and the most appropriate response is criminal prosecution. Of particular concern has been the increase in medical identity theft in a broad range of cases. Medical identity thieves often sell and resell beneficiary information. It is not unusual for physicians or beneficiaries to have their identities compromised multiple times.

In response, HHS and DOJ took strong and decisive enforcement action through the creation of Medicare Fraud Strike Forces as part of the HEAT initiative to combat health care waste, fraud, and abuse. HEAT built on the successful Medicare Fraud Strike Force (Strike Force) initiated in south Florida by expanding Strike Forces to other metropolitan areas across the country. These Strike Forces use advanced data analysis techniques (see Management Issue 5) to identify criminals operating as health care providers and detect emerging or

migrating fraud schemes. Strike Force teams operate in Miami, Los Angeles, Detroit, Houston, Brooklyn, Baton Rouge, and Tampa, and 13 more teams are to be established in other cities as resources permit. As of September 30, 2010, Strike Force efforts have resulted in charges against approximately 625 individuals or entities, more than 300 convictions, and approximately \$315 million in investigative receivables. Strike Forces have been successful, but the teams require sufficient staffing and resources to respond effectively to health care fraud schemes.

The *Affordable Care Act* increases criminal penalties for health care offenses under the Federal Sentencing Guidelines, and it expands the types of conduct that constitute Federal health care fraud offenses under Title 18 of the United States Code. As a result, those who commit health care fraud will serve longer prison terms and face larger criminal fines, and the government will have a broader range of tools to address criminal health care fraud schemes.

In addition to criminal prosecution, civil litigation continues to be an important response to fraud and program vulnerabilities. Complex corporate fraud and other matters can be resolved through civil litigation in addition to or as an alternative to criminal enforcement. Despite multimillion-dollar, and even billion-dollar civil settlements, corporations often write checks and continue their abuse of the system. Large corporations that engage in health care fraud often resolve a criminal case through a guilty plea of a nonoperating subsidiary. In those cases, which involve admitted criminal conduct, OIG may have no basis to exclude the parent-company defendant or any other operating company from future participation in the Federal health care programs based on the criminal conviction. Even when there may be a basis for a permissive exclusion of the parent company or when a company has engaged in multiple schemes and its subsidiary has been convicted in more than one criminal case, OIG must carefully consider how beneficiary access to vital medical products and services could be affected by any such exclusion of the parent company.

A comprehensive law enforcement response to fraud must use all tools available to the Government. In addition to criminal and civil actions, the appropriate response in a particular case may include alternate remedies, such as OIG's use of targeted CMPs and program exclusions. For example, where DOJ might pursue civil litigation against a large corporate defendant that paid health care kickbacks, OIG might bring a parallel case under the CMP Law against the individual recipients of the kickbacks. Where a health care fraud case involves potential harm to program beneficiaries,

the most appropriate response will often include OIG's exclusion of the defendant from future participation in the programs. Wherever possible, OIG works with its law enforcement partners to tailor the response to a given scheme in a way that maximizes the use of resources and effectively utilizes administrative tools, in addition to criminal and civil remedies.

### **Federal Health Care Program Responses**

Law enforcement actions alone will not eliminate fraud and abuse; and yet where vulnerabilities are accurately identified, it can be a significant challenge for the Department to respond effectively and ensure that the problems are corrected. During a series of unannounced site visits to DME suppliers in south Florida in 2007, OIG found that 491 of 1,581 suppliers failed to meet Medicare standards; CMS revoked their billing privileges. Nearly half of these suppliers appealed the revocations and received hearings, and 91 percent had their billing privileges reinstated. Two-thirds of those suppliers who were reinstated have since had their privileges revoked again, and some individuals connected with reinstated suppliers have been indicted. In a report on DME supplier appeals, OIG found that because there are no criteria for the types of evidence necessary to reinstate providers' billing privileges, hearing officers made decisions based on a variety of evidence, which resulted in inconsistencies. CMS agreed that it should consider establishing consistent guidelines on the evaluation of evidence that a hearing officer will review during the appeal process. Establishing consistent guidelines will continue to be a challenge for the Department.

OIG is assessing other Medicare contractors' use of enrollment-screening mechanisms and post-enrollment monitoring to identify DME and home health agency applicants that pose a risk of fraud to Medicare and will determine the extent to which applicants omitted ownership information on enrollment applications, potentially circumventing the program's safeguards. (See Management Issue 2.)

Despite CMS's and its contractors attempts to address billing problems in high-risk areas, aberrant billing problems persist. In a 2009 review, OIG's analysis of Medicare billing patterns in south Florida for inhalation drugs used with DME uncovered evidence of abusive billing. Medicare paid almost \$143 million for inhalation drugs in Miami-Dade County alone, an amount 20 times greater than was paid in Cook County, Illinois, the jurisdiction (outside south Florida) with the next-highest total payments. However, according to Medicare enrollment data, Cook County is home to almost twice as many Medicare beneficiaries as Miami-Dade County.

In response to this scheme, CMS reported that its contractor had implemented a “medically unlikely” edit for the inhalation drug, budesonide, and after the edit there was an immediate 50-percent decrease in allowed and billed amounts for budesonide in Miami-Dade and Broward Counties in October 2008. Although CMS response was an important first step, experience tells us that this alone will not solve the problem. The same criminals who were exploiting the system with respect to budesonide will attempt to circumvent this response by billing for other items or services.

Therefore, it is important to use analytic tools such as data mining to monitor whether and how criminals are adapting their fraud schemes in response to the Government’s program integrity efforts. CMS is developing such tools through its Integrated Data Repository (see also Management Issue 5). OIG’s experience tells us that such approaches can be effective in identifying and responding to fraud. For example, in the coming months, OIG will issue a report analyzing how use of certain inhalation drugs may have changed in the wake of Medicare program integrity efforts relating to budesonide. OIG is also using a combination of claims and sales data to determine whether the amount of a different inhalation drug billed by south Florida suppliers and paid for by Medicare exceeded the total amount of the drug distributed for sale in the area. By using innovative data analysis to detect unusual patterns, OIG is able to target high-risk services and geographic regions and make recommendations for a more comprehensive approach to address systemic vulnerabilities.

As described above, the programs rely on contractors to pay claims and to administer the response to fraud and vulnerabilities. This dual reliance on contractors presents a unique challenge for CMS. In February 2010, OIG evaluated the results of CMS’s 3-year RAC demonstration project. Three RACs participated in the project. Although they were not responsible for reviewing claims for fraudulent activity, they were responsible for referring to CMS any instances of suspected fraud found during their reviews. However, the RACs have a disincentive for referring instances of suspected fraud because they are paid through contingency fees based on overpayments collected. In case of suspected fraud, overpayments are generally not collected while the fraud is being investigated. Despite their identification of more than \$1.03 billion in Medicare improper payments, between 2005 and 2008, the RACs referred only two cases of potential fraud to CMS. As the RAC demonstration shows, it will continue to be a challenge for the Department to ensure that its response to program vulnerabilities captures not

only improper payments but also fraud and that the contractors on which it relies have the tools, training, resources, and incentive to appropriately address improper payments and make appropriate fraud referrals.

In addition, CMS contracts with MEDICs to perform integrity functions, such as identifying and investigating potential fraud, waste, and abuse in the Part D program. OIG found that CMS’s program integrity efforts have been limited in scope and that major challenges remain to sufficiently protect the Part D program. One of the key aspects of CMS’s strategy to combat fraud in Part D was the MEDICs’ use of innovative techniques for proactive data analysis. While proactive data analysis is a key element of MEDICs’ responsibility, OIG found in a 2009 review that MEDICs identified most incidents of potential fraud through external sources, such as beneficiary complaints, rather than proactive data analysis. MEDICs may not have been aware of some potential fraud and abuse incidents because Part D plan sponsors are not required to refer them. Finally, CMS did not give MEDICs approval to conduct audits of sponsors’ compliance plans in FY 2008. In November, 2009, after the issuance of this report, CMS restructured the MEDIC program. However, CMS indicated that it does not have the regulatory authority to require sponsors to report these incidents.

Given the significant expenditures at issue, responding quickly and comprehensively to identified weaknesses in the Part D program is imperative. Ensuring that Part D and its beneficiaries are paying appropriately for the benefit will remain a significant challenge for the Department. OIG is performing reviews on questionable billing patterns, sponsors’ anti-fraud training, the status and results of all audits of sponsors, Part D electronic-prescribing initiatives, invalid prescriber identifiers on prescription drug data, payments made to excluded providers, reconciliation calculations, and Part D rebates and pharmacy discounts.

OIG has also found that challenges remain in the programs’ efforts to respond to fraud, waste, and abuse vulnerabilities in home health and personal care services similar to those described above for DME. OIG analyzed all Medicare home health claims that were submitted and fully paid in 2008 to identify geographic areas that exhibited aberrant Medicare home health outlier payment patterns. OIG’s review found that Miami-Dade County, Florida, accounted for more home health outlier payments in 2008 than the rest of the Nation combined. OIG also found that 23 other counties nationwide exhibited aberrant home health outlier

payment patterns similar to that of Miami-Dade County. Despite the programs' focus in this area, these findings demonstrate that home health services in Miami-Dade County, as well as in other counties nationwide, warrant additional attention as part of continuing anti-fraud activities, such as HEAT.

Another challenge for the Department is to respond to detected vulnerabilities by suspending payments to providers upon credible evidence of fraud. This is critical in an environment in which claims are submitted and paid electronically, with potentially large sums of money being paid by the Government in a very short period if the payment suspension is not implemented in a timely manner. The *Affordable Care Act* expressly authorizes the Secretary to suspend payments to providers if the Secretary determines, in consultation with OIG, that there is a credible allegation of fraud. To mount a comprehensive response to fraud and program vulnerabilities, the Department must use the payment-suspension authority wherever it is warranted to protect the programs while also protecting the rights of providers.

As discussed in other sections, the *Affordable Care Act* strengthens the Government's ability to detect fraud and abuse and to respond rapidly to health care fraud. The law also requires the Department to expand CMS's integrated data repository to include claims and payment data from Medicaid, VA, DOD, SSA, and IHS and fosters data-matching agreements among Federal agencies. These agreements will make it easier for the Federal Government to identify fraud, waste, and abuse. It will then be a challenge for the Department to integrate all of this data into its systems for analysis and response. The challenge remains to obtain real-time information across all areas of the programs, which will enable the government to respond to fraud more quickly, bring criminals to justice, and recoup stolen funds. Timely data are also essential to responding with agility as criminals shift their schemes and locations to avoid detection.

By using the new tools described above to meet these challenges, the Department, including OIG, must continue to work with its many partners to respond to vulnerabilities in Federal health care programs. The Department must work to reduce improper Medicare and Medicaid payments resulting from fraud, waste, and abuse across all service areas by addressing vulnerabilities and weaknesses with all available tools.

OIG's *Compendium of Unimplemented Recommendations* identifies many significant vulnerabilities and provides recommended responses requiring action by the Department or Congress. The Department, including OIG, must

also identify new risks posed by the changing dynamics of Federal health care programs and the resulting evolving nature of fraud and abuse schemes and act promptly and effectively.

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### *Management Issue 7: Quality of Care*

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#### **MANAGEMENT CHALLENGE AND ASSESSMENT OF PROGRESS IN ADDRESSING THE CHALLENGE:**

Ensuring quality of care for beneficiaries of Federal health care programs continues to be a significant challenge for the Department. This challenge has many facets, such as ensuring that the Department adequately oversees health care providers' compliance with quality-of-care standards and ensuring that beneficiaries do not receive substandard care and are not abused or neglected. The Department also faces challenges in adopting tenets of the patient-safety movement, which focuses on improving care through quality improvement initiatives, measurement, and reporting.

#### ***Oversight of Compliance with Existing Quality Standards***

Overseeing compliance with quality standards represents a challenge for the Department. The growing number of beneficiaries receiving care in hospitals, in nursing facilities, and from home health agencies underscores the need to ensure beneficiaries receive quality care and to enforce quality standards.

Ensuring quality care for nursing home residents remains a significant challenge. OIG is examining whether atypical antipsychotic drugs provided to residents are in compliance with CMS standards for unnecessary drugs. OIG is also examining SNFs' compliance with Federal requirements for quality of care by reviewing their plans of care and discharge planning. In addition, OIG is updating its 2006 review of SNF compliance with emergency preparedness planning standards. In future work, OIG will review poorly performing nursing homes. (See Management Issue 9 for further discussion of emergency preparedness in nursing homes.)

OIG will also examine quality of care in Medicaid home- and community-based settings, such as assisted-living facilities and adult day health centers. This work will determine whether the care provided follows the plans of care and will assess the extent of CMS's oversight of quality of care in these settings.

The Department has made progress on its oversight of quality standards. For example, CMS expanded its oversight of accreditation organizations and effective mid-2010, it approved the Joint Commission's deeming authority for hospitals. The

Joint Commission previously held a unique statutory status that allowed it permanent deeming authority, but now this authority must be periodically reapproved by CMS. CMS also proposed rules that would require unannounced and extended surveys of home health agencies and the imposition of sanctions when they are found to be out of compliance with Federal standards.

### **Protecting Beneficiaries from Substandard Care and from Abuse and Neglect**

Protecting beneficiaries is an ever-present challenge for the Department. Identifying and addressing instances of substandard care are central to this challenge.

OIG investigations and enforcement cases demonstrate that some beneficiaries receive substandard care or are abused or neglected by providers. In January 2010, five Cathedral Rock Corporation nursing homes pleaded guilty to felony health care fraud, and Cathedral Rock Corporation's chief executive officer (CEO) entered into a 2-year deferred prosecution agreement for submitting claims for worthless care resulting in serious harm and patient death. The five homes and the CEO were jointly assessed a \$1 million criminal penalty. Cathedral Rock Corporation paid \$628,000 to resolve its civil FCA liability and entered into a 5-year CIA requiring Cathedral Rock to retain an independent quality monitor selected by OIG.

As cases resolved in 2010 indicate, these problems exist across provider types. In January 2010, FORBA holdings paid \$24 million to resolve allegations that it provided substandard and medically unnecessary dental services to Medicaid patients at its pediatric dental clinics. In April 2010, Harbor Senior Concepts, an assisted-living facility chain, paid \$258,000 to resolve allegations that it provided substandard care to Medicaid beneficiaries resulting in patient harm.

Other OIG work has also identified instances of patient abuse and neglect. For example, OIG found serious quality-of-care issues in the delivery of Medicaid personal care services, which are delivered in beneficiaries' homes. Beneficiaries alleged that they were abused, neglected, and mistreated, and that personal care attendants stole their property. OIG recommended that States improve monitoring. In future work, OIG will examine hospital reports of restraint-related deaths and subsequent investigations by State agencies.

Complex ownership arrangements that include multiple entities present a particular challenge for holding nursing home owners accountable for substandard care. Pursuant to the *Affordable Care*

*Act*, the Department must promulgate regulations within 2 years requiring nursing homes to report their ownership in a standard format and, within 3 years, to make it public. Promulgating these regulations promptly and making effective use of the new authority provided by the *Affordable Care Act* poses a continuing challenge for the Department. Collection and publication of this information should facilitate more effective oversight and response to quality-of-care problems.

Medicare's primary program for addressing substandard care is the Quality Improvement Organization (QIO) program, which was established to promote the effective, efficient, and economical delivery of Medicare health care services and ensure the quality of those services. However, in 2007, OIG found that only 11 percent of cases reviewed by QIOs were for quality-of-care concerns and that sanction referrals were rare. Moreover, QIOs routinely failed to respond to OIG referrals on beneficiary care. CMS has improved the QIO program, adding the use of management information tools, such as milestone and project tracking. The use of these tools is intended to ensure that QIOs' services improve beneficiary care.

The Department also relies, in part, on the State Medicaid Fraud Control Units to investigate and address abuse and neglect in State-regulated Medicaid facilities. In addition, as part of the *Affordable Care Act*, the *Elder Justice Act* will improve reporting and investigation of allegations of abuse, neglect, and misappropriation of funds of residents in nursing homes. It requires nursing facility owners, operators, employees, managers, and contractors to report a reasonable suspicion of a crime against residents in nursing facilities to the Department and to law enforcement officers. Failure to report may result in significant penalties and, in cases where further harm occurred after the failure to report, exclusion from participation in the Federal health care programs. In addition, the Federal Elder Justice Interagency Working Group provides a forum for the exchange of current agency activities, emerging trends in policy and research, promising practices, and legislative developments related to elder justice.

### **The Patient Safety Movement and Incentives for Quality Improvement**

The Department, which represents a major purchaser of health care, faces challenges in adopting tenets of the expanding patient-safety movement, which focuses on quality improvement, measurement, root-cause analysis, transparency, and public reporting.



The OIG's recent work on adverse events underscores the significance of this challenge. OIG reported that 13.5 percent of hospitalized Medicare beneficiaries experienced serious adverse medical events that prolonged a hospitalization, required life-sustaining intervention, or contributed to permanent harm or death and that another 13.5 percent of beneficiaries experienced temporary-harm events requiring medical intervention. These events, nearly half of which (44 percent) were preventable, cost the Medicare program \$324 million in additional costs in a single month. OIG is reviewing the extent to which internal hospital incident-reporting systems capture adverse events, report the information to external patient-safety entities, and use the information to improve practices. OIG also is assessing CMS's response to adverse events in hospitals.

The Department faces a challenge in working with health care providers to ensure that they are knowledgeable about and consistently implement quality-improvement processes. OIG has sponsored roundtables with hospital and nursing home representatives to explore involving boards of directors and trustees in quality-improvement matters. In 2010, OIG began incorporating requirements for board and trustee members' increased involvement in quality-of-care CIAs.

The Department has implemented a number of programs as part of the challenge to ensure patient safety and become a more prudent purchaser of health care. It established the Office of Healthcare Quality, which is leading and coordinating an initiative on preventing health-care-associated infections. Also, CMS continues to fund demonstrations on value-based purchasing and gain-sharing to provide payments to improve quality and efficiency. And it continues to have its QIOs work with providers to improve their performance on clinical measures related to patient safety and disease prevention.

The Department continues to make hospital, nursing home, and dialysis facility ratings available to consumers. AHRQ has also made considerable progress in implementing Patient Safety Organizations (PSO), which encourage clinicians and health care organizations to voluntarily report and share quality and patient safety information without fear of legal discovery. PSOs play an important role in collecting and studying data regarding adverse events.

OIG will examine hospitals' controls regarding the accuracy of quality-related data reported to CMS. OIG will also determine whether States have sufficient controls in place to ensure appropriate incentive payments in Medicaid programs aimed at rewarding high-quality care.

### **Related Challenge of Health Care Reform**

The *Affordable Care Act* further underscores the importance of the challenges associated with ensuring quality of care. It creates an interagency workgroup on quality and calls for developing a national strategy to improve health care delivery. It calls for new models for patient care while focusing on greater transparency and accountability. In addition, it links payment to health care outcomes. It also requires background checks for those who will be working directly with patients in long-term care facilities. The successful implementation of these and other quality mandates in the *Act* will ensure enhanced quality of care in the health care delivery system, but the magnitude, complexity, and timely implementation of these changes present a challenge for the Department.

### **PART III: INTEGRITY OF THE DEPARTMENT'S PUBLIC HEALTH AND HUMAN SERVICES PROGRAMS**

The Department faces challenges in ensuring the integrity of its public health and human services programs. These include oversight systems to ensure the safety of food, drugs, biologics, and medical devices; efforts to effectively prepare for and respond to a public health emergency; and oversight of the awarding, appropriate use, and effectiveness of departmental grants.

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#### *Management Issue 8: Oversight of Food, Drugs, and Medical Devices*

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### **MANAGEMENT CHALLENGE AND ASSESSMENT OF PROGRESS IN ADDRESSING THE CHALLENGE:**

Recent outbreaks of foodborne illness and increased drug and medical device recalls underscore the importance of ensuring the safety and security of the Nation's food supply, human and veterinary drugs, biologics, and medical devices. However, the Department's oversight responsibilities for these products are vast, creating a number of management challenges. For instance, responding to food safety emergencies often involves multiple State and Federal public health agencies, which makes coordination difficult. Likewise, ensuring that medical products, once proven to be safe and effective, are labeled and advertised appropriately is more demanding than ever given technological advances in the media used to promote such products. In the increasingly globalized market for food, drugs, biologics, and medical devices, these challenges -- combined with new statutory authorities that expand the Department's oversight role to include new products, such as tobacco -- elevate the significance of the Department's oversight function.

Despite these difficulties, the Department has made progress in addressing challenges in the oversight of food, drugs, biologics, and medical devices. FDA opened field offices in China, India, and Costa Rica to conduct more inspections and work with local officials to improve the safety of foods exported to the United States. In September 2009, FDA also required food facilities to report in a new registry all instances in which an article of food might cause serious health consequences and to investigate the causes of any adulteration reported. The Department has also made efforts to improve the safety of drugs and biologics through initiatives such as a new Risk Evaluation and Mitigation Strategy, which is designed to ensure that the benefits of a drug or biologic outweigh its risk. Although these efforts highlight the strides the Department has made, OIG work in the areas of food, drugs, biologics, and medical devices illustrates that more effort needs to be made to ensure quality and safety.

### **Oversight of Food Safety**

More than 300,000 Americans are hospitalized and 5,000 die annually after consuming contaminated food and beverages. FDA is responsible for finding the contamination source during a food emergency and overseeing the voluntary removal by manufacturers of these products from the market. Yet recent OIG reports found that recordkeeping issues, inspection coverage, and recall problems impair FDA's ability to effectively resolve food emergencies.

Food facilities' failure to comply with FDA's recordkeeping requirements is a vulnerability that impedes the Department's ability to ensure the safety of the Nation's food supply. FDA requires some food facilities to maintain information about their product sources, recipients, and transporters. However, in a food traceability study, OIG found that only 5 of the 40 products purchased could be traced through each stage of the food supply chain back to a farm or a border. Fifty-nine percent of selected food facilities did not comply with FDA's recordkeeping requirements. Twenty-five percent of the facilities were not aware of such requirements. In another report, OIG found that 5 percent of selected facilities failed to register with FDA as required. Of those that did register, almost half failed to provide accurate and complete information.

The absence of guidelines establishing a minimum frequency with which FDA should conduct food facility inspections is problematic. OIG found that FDA inspects less than a quarter of food facilities each year and that more than half of food facilities have gone 5 or more years without an FDA

inspection. Furthermore, because FDA lacks adequate internal inspection procedures, the agency took actions against less than half of the food facilities where inspectors found objectionable conditions that warranted FDA's most severe inspection classification.

OIG also identified vulnerabilities in FDA's oversight of pet food recalls. OIG found that FDA lacks the statutory authority to require manufacturers to initiate pet food recalls and did not always follow its own procedures in overseeing the recall of pet food tainted with melamine. Nor were FDA's procedures always adequate for monitoring recalls as large as those required in the pet food incident of 2007.

OIG will continue to oversee the Department's management of food safety issues. As part of that oversight, OIG is reviewing FDA's monitoring of State agencies that contract with FDA to conduct food facility inspections; food facilities' compliance with requirements of FDA's Reportable Food Registry; FDA oversight and operations related to imported pet food and feed products; and the extent to which it tested human food for contamination from melamine and other contaminants.

### **Oversight of Drugs, Biologics, and Medical Devices**

The Department is responsible for ensuring that all drugs, biologics, and medical devices are safe and effective. The Department must also ensure that once a drug, biologic, or device has been approved for use, it is marketed appropriately. However, OIG work in this area has exposed weaknesses in FDA's ability to adequately oversee the safety of drugs, biologics, and medical devices. In particular, OIG work found vulnerabilities in FDA's ability to ensure the timeliness of drug application reviews, the adequate monitoring of adverse-event reporting, and the prevention of off-label marketing of drugs, biologics, and medical devices.

FDA faces challenges in approving generic drug applications in a timely manner. In its June 2008 report, OIG found that FDA exceeded the 180-day review for nearly half of the original generic drug applications. FDA has implemented some changes that are consistent with OIG's recommendations to improve the generic drug approval process. In July 2008, FDA published a final rule that required it to review generic drug applications and describe all deficiencies to the applicant within 180 days. FDA also issued additional guidance on what information to include in generic drug applications. The *Affordable Care Act* expanded FDA's authority to include approval of biosimilars (generic biologics). Because of the unique nature of biologics research

and production, FDA faces additional challenges in implementing this new responsibility.

Providing adequate oversight of adverse events associated with the use of medical devices is a challenge for FDA. The agency receives about 200,000 adverse-event reports each year about medical devices. However, OIG found that FDA did not use the reports in a systematic manner to detect and address safety concerns. In a 2009 report, OIG found that FDA did not document followup on adverse events nor did it consistently read adverse-event reports in a timely manner. FDA has since developed a new database that will enable it to more effectively review adverse-event reports and conduct followup.

Although this is a step in the right direction, the Department still faces a number of obstacles in its oversight of medical device safety. For example, preventing the use of unapproved medical devices and the illegal marketing of potentially harmful devices continues to be a challenge. In December 2009, Spectranetics Corporation agreed to pay \$4.9 million in civil damages plus a \$100,000 forfeiture to resolve allegations that the company illegally imported unapproved medical devices and provided them to physicians for use in patients, conducted a clinical study in a manner that failed to comply with Federal regulations, and promoted certain products for procedures for which the company had not received FDA approval or clearance.

Among the Department's challenges is ensuring that drugs, once they have been determined to be safe and effective, are marketed appropriately. OIG has investigated a number of cases involving the illegal promotion of drugs by pharmaceutical manufacturers. In September 2009, Pfizer, Inc., and its subsidiary Pharmacia & Upjohn, Inc., agreed to pay \$2.3 billion to resolve criminal and civil liability arising from alleged illegal promotion of Bextra, an anti-inflammatory drug pulled from the market in 2005, and three other drugs. In April 2010, AstraZeneca LP and AstraZeneca Pharmaceuticals LP entered into a \$520 million civil and administrative settlement to resolve allegations that it illegally marketed the antipsychotic drug Seroquel. In January 2009, Eli Lilly and Company entered a \$1.4 billion global criminal, civil, and administrative settlement to resolve allegations that it illegally marketed its antipsychotic drug Zyprexa.

OIG is investigating many more allegations of fraudulent marketing and promotional practices in the pharmaceutical and medical device industries and is reviewing over 100 sealed *qui tam* complaints involving pharmaceutical and medical device fraud and abuse. Also, OIG is increasingly using its administrative authorities to sanction

individuals and entities engaged in fraudulent and abusive practices in the pharmaceutical and medical device industries. Even as cases are investigated and enforcement remedies are pursued, the Department faces the task of identifying systemic responses that can reduce illegal off-label marketing.

### ***Oversight of Human Subject Protections in Clinical Trials***

The Department's ability to protect human subjects enrolled in clinical trials and to ensure the identity and security of data collected in those trials remains a challenge that OIG continues to monitor. In 2007, OIG found that the lack of a clinical trial registry and inconsistencies in inspection classifications inhibited FDA's ability to manage its oversight of clinical trials. OIG also found that FDA inspected only about 1 percent of clinical trial sites during fiscal years 2000-2005. A recent OIG report found that sponsors relied heavily on foreign clinical trial data to support their marketing applications for drugs and biologics. OIG found that FDA inspected clinical investigator facilities at less than 1 percent of foreign sites. Logistical and jurisdictional challenges in conducting foreign inspections and data limitations also inhibited FDA's ability to monitor foreign clinical trials. FDA has taken steps to improve its oversight of foreign clinical trials. To leverage its inspection resources, FDA reached an agreement with the European Medicines Agency to share inspection-related data and other information. FDA is also piloting a data analysis tool to identify foreign and clinical investigator sites for inspection.

As the agency tasked with ensuring the safety and efficacy of food, cosmetics, drugs, biological products, medical devices, and products that emit radiation, the Department faces important challenges with respect to increasingly globalized markets. These challenges will only be exacerbated with new legislative mandates increasing the Department's oversight responsibilities, such as new authority to regulate the content, marketing, and sale of tobacco products. Despite making progress and plans for improvement, the Department must make strides in its oversight efforts to meet those challenges.

### ***Management Issue 9: Public Health Emergency Preparedness and Response***

#### **MANAGEMENT CHALLENGE AND ASSESSMENT OF PROGRESS IN ADDRESSING THE CHALLENGE:**

Recent natural disasters, such as hurricanes, wildfires, floods, and the outbreak of the H1N1 virus, highlight the importance of a comprehensive national public health infrastructure that is prepared to respond rapidly and capably to emergencies. The

ability to effectively prepare for and respond to a public health emergency requires planning, coordination, and communication across a range of entities, including Federal agencies; States, localities, and tribal organizations; the private sector; individuals and families; and international partners. This combination of organizations with significantly different roles and structures poses unique and unprecedented demands on the Department.

In its FY 2010 budget, the Department requested over \$5.1 billion to fund programs to enhance the Nation's emergency preparedness activities to better respond to large-scale public health emergencies, such as natural disasters, infectious disease outbreaks, or acts of bioterrorism. (See Management Issue 8 for discussions of preparedness for and response to foodborne illness and related emergencies.)

The Department has continued to work with States and selected localities to improve their public health emergency preparedness and response capacity. However, OIG work assessing preparedness as recently as June 2010 shows both progress and the need for significant improvements in the public and private sectors' preparedness and response capabilities during public health emergencies.

#### ***State and Local Public Health Emergency Preparedness Planning***

Documented emergency preparedness plans that are current and cohesive and contain sufficient detail are critical for ensuring that States and localities are prepared for a public health emergency. The Department provides guidance to States and localities on the development of emergency preparedness plans. However, variations in State and local health department structures and the size of the populations they serve make it challenging to provide Federal guidance that is tailored to an individual jurisdiction's needs.

In its evaluation of the Nation's pandemic influenza preparedness, OIG found that most selected States and localities had begun emergency preparedness planning but had not addressed in planning documents most of the items in departmental guidance. States and localities also varied in the extent to which they exercised their emergency response plans and addressed lessons learned. OIG recommended that the Department (1) work with States to help localities improve preparedness and (2) ensure that States and localities consistently document their exercises and lessons learned. In response to these recommendations, the Office of the Assistant Secretary for Preparedness and

Response (ASPR) and CDC have developed guidance for States and localities that addresses the gaps found by OIG. ASPR implemented a new standardized reporting template to improve documentation of emergency preparedness exercises in health care systems and data collection. CDC now requires that grantees develop and submit mass vaccination after-action reports and improvement plans as a part of the Public Health Emergency Response grant application and the Public Health Emergency Preparedness cooperative agreement.

In its audit of State agencies' pandemic influenza funding expenditures in three States, OIG found that the States spent 51 percent (about \$13.6 million) of their total funding as of June 2008. States cited delays in CDC guidance, funding, and timing problems with the State's fiscal year as reasons that they spent only about half of their total funds. States that OIG reviewed generally complied with most, but not all, Federal cost requirements. The three States spent about \$1.2 million in unallowable or unsupported costs.

OIG is reviewing State and local preparedness for radiological and nuclear incidents. In its review, OIG will determine the extent to which selected States and localities are prepared to respond to the public health challenges of a radiological and nuclear incident and how they have used Department guidance in their preparedness efforts.

#### ***Federal and State Drug Storage and Laboratory Capability and Security***

Early and accurate detection and reporting of biological and chemical agents are critical components of a national public health response. These threats include anthrax, influenza, nerve agents, and foodborne pathogens that cause outbreaks such as E. coli and salmonella. It is also important that the drugs used to treat these agents be available and effective during a public health emergency. However, OIG's findings reveal vulnerabilities in the Nation's preparedness to respond to potential biological and chemical threats.

For example, weaknesses exist in the Nation's laboratory system capability and security. CDC provides funds to States, in part, to improve public health laboratory preparedness. State public health laboratories rely on private clinical laboratories, which are not under the authority of the State, to perform diagnostic tests ordered by physicians. Yet in its review of laboratory capacity, OIG found that not all clinical laboratories have the ability to conduct initial screenings and refer suspicious specimens to a State laboratory, which could confirm the presence of public health threats. OIG

recommended that CDC continue to assist States in meeting the requirement to decrease the time needed to detect and report biological public health threats, and CDC concurred with that overall recommendation.

OIG reviewed Department and external laboratories to determine their compliance with the regulations governing select agents (i.e., pathogens or biological toxins that pose a severe threat to public health and safety) and found that some laboratories did not adequately safeguard the agents against theft or loss. In its recent audits at six departmental laboratories, OIG found problems with access controls, training, and/or recordkeeping, among other findings. These problems mirrored those found during earlier work at universities and public and private laboratories. Through its authority to impose CMPs against persons or entities who violate select agent regulations, including universities and nonpublic laboratories, OIG has collected over \$2 million for such violations as conducting unauthorized research with select agents, conducting unauthorized select agent transfers, failing to secure select agents against unauthorized access, and allowing unauthorized individuals access to select agents.

OIG also reviewed CDC's CHEMPACK project, which places nerve agent antidotes in monitored storage containers in multiple State locations for immediate use in the event of a nerve agent release. In its review, OIG determined the extent to which nerve agent antidotes were stored at the temperatures required by FDA. OIG also reviewed the extent to which CDC implemented procedures to ensure the quality of nerve agent antidotes and the extent to which antidotes appropriately received extended expiration dates under the Shelf Life Extension Program (SLEP). OIG found that CDC's policies for CHEMPACK drug storage did not meet FDA's temperature and quality requirements and that CDC did not monitor and store containers appropriately. Also, CDC allowed CHEMPACK drugs to inappropriately receive extended expiration dates under SLEP. OIG recommended that CDC revise its policies and procedures regarding CHEMPACK drug storage and SLEP to comply with FDA requirements. CDC concurred with all OIG's recommendations.

### ***Lessons Learned From Real-Life Public Health Emergency Responses***

It is important that the public and private sectors prepare for large-scale public health emergencies, and it is equally important that they effectively execute their plans in response to an emergency. Therefore, it is essential that Federal, State, and local entities identify vulnerabilities in, and determine the lessons learned from, responses to real-life public health emergencies.

For example, during the 2009 H1N1 influenza pandemic, OIG conducted onsite evaluations of selected localities' administration of H1N1 vaccine at School-Located Vaccination (SLV) sites. OIG found that SLV programs can be a viable strategy for vaccinating a large number of students in a short time. However, SLV programs require significant planning and resources, and selected localities had difficulty implementing SLV programs. OIG's report identified challenges and lessons learned and provided Federal, State, and local planning considerations for future SLV programs.

After the 2005 Gulf Coast hurricanes, OIG examined selected public health disaster responses to these events to highlight potential vulnerabilities and lessons learned. OIG reviewed the emergency plans of nursing homes in five Gulf Coast States and found that all had problems in implementing their emergency plans or with impromptu decisionmaking. OIG recommended that CMS consider strengthening Federal certification standards for nursing home emergency plans and encourage communication and collaboration between States and localities and nursing homes. CMS concurred with OIG's recommendations and issued Federal guidance and requirements as a result. OIG is conducting a followup evaluation that reexamines nursing home emergency preparedness and evacuation during recent hurricanes, wildfires, and floods. OIG will assess the use of the new tools that CMS developed and now requires as a result of the first OIG report. OIG will also describe the experiences of selected nursing homes, including challenges, successes, and lessons learned when they implemented their plans during natural disasters. (See Management Issue 7 for discussion of preparedness within nursing homes as it relates to quality of care.)

Overall, the Department has made progress in implementing some of OIG's recommendations for improvements to the Nation's preparedness for and response to public health emergencies. However, to mitigate the vulnerabilities noted in this management issue, the Department should continue to focus on providing additional guidance to States and localities to improve their public health emergency preparedness capability.

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### ***Management Issue 10: Grants and Contracts Management***

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#### **MANAGEMENT CHALLENGE AND ASSESSMENT OF PROGRESS IN ADDRESSING THE CHALLENGE:**

In FY 2009, the Department awarded over \$364 billion in grants, making it the largest grant-awarding Department in the Federal Government. Almost 71 percent of the money was for health care

coverage under Medicaid and CHIP. The remaining 29 percent funded health and social service programs administered by the Administration for Children & Families (ACF), the Health Resources and Services Administration, (HRSA) NIH, CDC, and other Department agencies. The *Recovery Act* provided \$27 billion for the temporary expansion of these health and social service programs for FYs 2009 and 2010.

The size and scope of the Department's grant expenditures make grants management a significant challenge for the Department. New legislative mandates, such as the *Recovery Act* and the *Affordable Care Act*, that increase the Department's portfolio of grants and oversight responsibilities exacerbate this challenge. For instance, the *Affordable Care Act* establishes an \$11 billion Community Health Center Fund to be administered through the Department. (See also Management Issue 11 for a discussion of broader departmental challenges related to the oversight and implementation of the *Recovery Act* and OIG reviews specifically focused on grants management issues related to *Recovery Act* funding. Broad challenges related to implementation of the *Affordable Care Act* are discussed in Management Issue 1. Challenges related to the Medicaid and CHIP programs are discussed in Management Issues 2 through 7.)

Adding to this challenge is that the primary responsibility for performance and management of a grant rests with the grantee, with limited Federal involvement in the funded activity. However, the grant-awarding agency retains oversight responsibility for ensuring that funds are awarded and used appropriately and that grantees comply with grant requirements. Recent statutory changes, most notably through the *Recovery Act*, have increased Federal agencies' responsibilities for grantee oversight. OIG's work in reviewing grant programs administered by ACF, CDC, HRSA, and NIH has highlighted grants management vulnerabilities and opportunities for improvements in the Department's oversight of grant funds and grantee compliance.

In addition to awarding grants, the Department awarded over \$20 billion in contracts in FY 2009. The top five products or services purchased with these contracts were drugs and biologics, professional services, information technology and telecommunications, operations of Government facilities, and research. The scope and size of these contracts are significant and pose a challenge to effective oversight. OIG's work in reviewing the award and management of contracts at NIH and

CDC found problems with compliance with appropriations and acquisition laws and regulations.

### **Grant Oversight**

OIG has identified risks related to grantee noncompliance in departmental grants programs at ACF and NIH. Funding from both the *Recovery Act* and the *Affordable Care Act* for community health centers increases the challenge HRSA faces in ensuring that Federal grant awards to health centers are used in accordance with Federal regulations. OIG performed a series of audits to assess the financial capability of community health centers receiving *Recovery Act* funds to account for and manage Federal funds. The assessments identified problems with inventory, cash management, and financial systems controls. In response, HRSA has increased its efforts in monitoring, assisting grantees, and ensuring program integrity.

OIG performed a series of reviews in one State to determine whether the State agency claimed foster care costs to ACF in accordance with Federal regulations. Title IV-E of the *Social Security Act*, as amended, authorizes Federal funds for States to provide foster care for children under an approved State plan. For children who meet Title IV-E Foster Care requirements, Federal funds are available to States for maintenance, administrative, and training costs. HHS must ensure that costs claimed by a State are in accordance with Federal regulations. In 2008, OIG found that one State agency claimed costs for children in unlicensed facilities and for ineligible services. As of November 2010, ACF had not responded to more than \$56 million in questioned costs in this report. In a 2009 review of the same State, OIG found that the State agency inappropriately claimed costs of over \$1.6 million for children after they turned 19.

In another example, OIG found that although NIH's National Cancer Institute had implemented processes to ensure the completeness and accuracy of grantees' progress reports, 41 percent of progress reports were received late. OIG also identified deficiencies in NIH's financial oversight of grants, including delays in closing out some grants. NIH agreed with OIG's recommendations to initiate earlier and more frequent followup with grantees to obtain required documents and to improve its grants monitoring, including conducting a pilot study to verify grantees' self-reported fund balances by contacting external sources. OIG is evaluating the NIH National Center for Research Resources' management of the Clinical and Translational Science Awards, which are expected to award 60 grantees with annual funding of \$500 million by 2012.

Without proper controls to ensure the appropriate use of Federal funds and to oversee grantees, the Department's grant programs are at risk of fraud, waste, abuse, and ineffectiveness. Expansions in the number and size of grants awarded by the Department magnify grant oversight vulnerabilities facing the programs. OIG will continue to monitor grants management challenges and recommend improvements to the Department's grants oversight, as warranted.

### **Contract Oversight**

OIG conducted a series of contracting audits at NIH and CDC, which found that both improperly funded contracts. CDC administered one contract improperly. An HHS "Tiger Team" initially identified Departmentwide concerns about potential improper contracting, including at NIH. A key concern was the improper partial funding of long-term high-dollar-value research contracts. Federal appropriations statutes require that agency fiscal year funds may be obligated or used only for legitimate needs (including through contracts) of that fiscal year; fiscal year funds cannot generally be used for agency needs of prior or future years. Failure to comply with this statute may result in agencies' not being able to fund or pay outstanding contracts.

OIG is reviewing 21 NIH contracts identified by the Tiger Team to determine whether the contracts were awarded in compliance with Federal appropriations laws. While some of these audits are still in process, OIG's work thus far indicates that at least some of the contracts were improperly funded.

OIG also performed a series of contract audits at CDC. One contract was improperly administered as a personal services contract. In this same contract, CDC was using fiscal year funds after their periods of availability. OIG recommended that CDC determine whether these contract actions violated the *Anti-Deficiency Act* and take action to correct such violations. OIG plans to continue its contract audit work at CDC, NIH, and throughout the Department.

NIH and CDC stated that they have taken action to correct problems identified in the audit reports. NIH and CDC provided appropriations law training to their acquisition workforce. HHS is developing a training course that specifically addresses the issues identified in the OIG audits. CDC stated that they reviewed all FY 2010 contracts for adherence to contract funding regulations.

HHS acknowledged the appropriations-related acquisition challenges identified by OIG and has informed OIG that it is taking the necessary steps to address those challenges. The Department noted that while achieving full compliance with

appropriation law will involve adjustments to its budgetary, program planning, financial, and contracting processes, it is confident that its business process improvement effort will succeed.

### **PART IV: CROSS-CUTTING ISSUES**

OIG has identified three more Departmentwide issues as top management challenges: assessing whether the Department is using *Recovery Act* funds in accordance with legal and administrative requirements and is meeting the accountability objectives defined by the Office of Management and Budget (OMB); developing and maintaining adequate internal controls over its information systems to protect the security and privacy of health data; and effectively overseeing its ethics program.

#### *Management Issue 11: American Recovery and Reinvestment Act Accountability and Transparency*

### **MANAGEMENT CHALLENGE AND ASSESSMENT OF PROGRESS IN ADDRESSING THE CHALLENGE:**

As the nation faced what is generally reported to be the most serious economic crisis since the Great Depression, the *Recovery Act* was enacted in 2009 to promote economic recovery and minimize the impact of the recession. The Congressional Budget Office (CBO) originally projected that the *Recovery Act's* combined spending and tax provisions would cost \$787 billion over 10 years, including more than \$499 billion in additional Federal spending and \$288 billion in tax relief. The objectives of the *Recovery Act* include preserving and creating jobs, assisting those most affected by the recession; increasing economic efficiency by investing in technological advances in science and health; investing in transportation, environmental protection, and other infrastructure that will provide long-term economic benefits; and stabilizing State and local budgets.

The *Recovery Act* provides \$141.4 billion to the Department to provide additional Federal assistance for health care, public health and human services programs, and to invest in research and health information technology (health IT), as estimated in the 2011 President's Budget. This amount includes \$4.3 billion in the form of reduced contributions for prescription drug costs for additional fiscal relief to the States in addition to the funding in direct provisions from the *Recovery Act*. The magnitude of expenditures and the potential impact of this funding on the economy, Federal and State budgets, program beneficiaries, and taxpayers make it critical that *Recovery Act* funds be used efficiently and effectively and be protected from fraud, waste, and abuse.

The Department's *Recovery Act* funding spans a range of agencies and programs. Some of the more significant funding is for:

- **Medicaid** – improving and preserving health care by providing an estimated \$84.5 billion temporary increase in the FMAP.
- **Health IT** – accelerating the adoption of health IT by (1) providing the Office of the National Coordinator with \$2 billion for Health Information Technology to coordinate Federal health IT policy and programs and foster the electronic use and exchange of health information, and (2) by providing CMS with an estimated \$25 billion to make incentive payments to encourage physicians and hospitals to adopt “meaningful use” of certified electronic health records starting in 2011. (“Meaningful use” of health IT is the standard established in the *Recovery Act*, and defined by CMS, that must be met for a hospital or eligible professional to receive incentive payments.)
- **Children and Families** – improving services to children and communities by providing ACF with more than \$13.2 billion to temporarily expand the Temporary Assistance for Needy Families Program (TANF), Child Support Enforcement, Foster Care FMAP, Head Start and Early Head Start, Child Care Development, and community services programs.
- **Research** – strengthening scientific research and facilities by providing \$10.4 billion to NIH.
- **Health Care** – strengthening community health care services by providing HRSA with \$2.5 billion to renovate and construct new centers, to expand health care services, and to train health care professionals.

Most of the Department's *Recovery Act* funds are increases in Federal funding for existing programs. OIG has conducted extensive work and identified management challenges specific to these programs. (Challenges related to Medicaid are discussed in Management Issues 2 through 7. Challenges related to programs and grants administered by ACF, CDC, NIH, and HRSA are discussed in detail in Management Issue 10. Finally, challenges related to health IT are discussed in Management Issue 12.)

Implementation and oversight to ensure accountability and transparency of *Recovery Act* funding present significant challenges. *Recovery Act* funds are to be awarded and distributed within short timeframes to stimulate economic growth and minimize the impact of the recession. Expediting

the awards process, however, also creates challenges for the Department in ensuring that funds are distributed to qualified recipients and used appropriately and effectively. Further, creating or expanding programs may increase the number of new recipients that lack experience with Federal requirements for grantees and contractors.

The *Recovery Act* also established new reporting requirements for the awarding and use of funds to promote transparency and accountability. Challenges associated with the new reporting requirements include developing systems and infrastructure for collecting and reporting the required information, educating recipients about the reporting requirements, validating the reported information, and using the collected information effectively to monitor and oversee *Recovery Act* programs and performance. The new reporting requirements for *Recovery Act* funds are in addition to reporting requirements that some grantees must also provide for similar activities funded outside the *Recovery Act*; this can create multiple and inconsistent reporting rules.

Overseeing and protecting the integrity of *Recovery Act* funds requires coordination among agencies within the Department and with States and other entities. The Department has established the Office of Recovery Act Coordination, headed by the Deputy Assistant Secretary for Recovery Act Coordination. Department agencies administering programs and activities funded by the *Recovery Act* are responsible for ensuring the appropriate awarding, distribution, use, and reporting of *Recovery Act* funds. OIG is charged with overseeing the Department's execution of these responsibilities and with preventing and detecting fraud, waste, and abuse. The *Recovery Act* also established the Recovery Accountability and Transparency Board (RATB), consisting of 12 Inspectors General, including the HHS Inspector General, to coordinate and conduct oversight of *Recovery Act* funds; prevent fraud, waste, and abuse; and promote accountability and transparency.

State agencies also have roles in overseeing *Recovery Act* funds, particularly those that increase Federal contributions to State-administered programs, such as Medicaid, TANF, and Community Services programs. Some States have raised concerns about having adequate funds for the administrative costs associated with meeting *Recovery Act* oversight and reporting requirements.

At the request of RATB, OIG completed a series of reviews to assess the Department's process, oversight, and effectiveness in performing data-quality reviews of information reported by recipients



of *Recovery Act* funds. OIG found that the Department has designed an adequate process for performing limited data-quality reviews that identify material omissions and significant errors in recipient-reported *Recovery Act* information. In another RATB-requested review, OIG reviewed the staffing, training, and qualifications of Department personnel responsible for overseeing *Recovery Act* funds; the overall results of the review based on our findings and those reported by other OIGs concluded that staffing qualifications at the largest Federal agencies, including HHS, were inadequate.

In addition, a series of OIG risk assessments was conducted that covered \$72.7 billion of the \$76.4 billion allocated to health IT and non-Medicaid programs to determine which *Recovery Act* programs to review. As a result, OIG performed 127 reviews of grant applicants and new or existing grantees to determine whether the entities were financially viable and had financial management systems in place to adequately manage and account for the additional *Recovery Act* funds in accordance with Federal regulations. Consequently, OIG identified entities that were not capable of handling *Recovery Act* grant funds or required increased HHS oversight and guidance. For example, OIG conducted limited-scope audits on 83 Early Head Start applicants for grant funds and based on those audits, ACF decided not to award 15 applicants \$31 million in *Recovery Act* funds. In addition, 60 Early Head Start applicants received funds with increased HHS oversight.

The *Recovery Act* provided an additional \$2.1 billion for the Head Start and Early Head Start programs during FYs 2009 and 2010. OIG has identified risks related to grantee compliance with health and safety requirements at Head Start facilities. OIG initiated a series of reviews to determine whether grantees could provide a safe environment for children. In the multiple reviews performed, OIG found instances of noncompliance with regulations that jeopardized the health and safety of children. OIG has made recommendations to the grantees to address the deficiencies.

As for *Recovery Act* oversight of Medicaid programs, OIG conducted two reviews to determine whether the Department and CMS had correctly calculated the temporary increase in the FMAP awarded under the *Recovery Act*, in accordance with the applicable provisions. OIG also conducted 17 reviews of various States and determined that States were generally in compliance with the requirements for Medicaid funding under Section 5001 of the *Recovery Act*.

OIG has also increased investigative efforts related to programs affected by the *Recovery Act*. A

screening process has been developed to identify applicants for *Recovery Act* funds that are under investigation by OIG. OIG has developed and implemented processes for addressing allegations related to the fraudulent use of *Recovery Act* funds and allegations of retaliation against whistleblowers who disclosed instances of the improper use of *Recovery Act* funds. OIG has also provided training to OIG agents on the *Recovery Act* and its whistleblower protection provisions.

The *Recovery Act* provides explicit protections for certain individuals who make specified disclosures relating to these funds. OIG receives allegations of fraud, waste, and mismanagement of *Recovery Act* funds from various sources, including the RATB and OIG hotline. OIG has received 50 complaints alleging inappropriate use of *Recovery Act* funds. These complaints have resulted in several investigations and some cases have entered the judicial process. To date, OIG has received one whistleblower-retaliation complaint related to HHS *Recovery Act* funds.

In addition to steps taken to oversee and protect the integrity of *Recovery Act* funds, examples of OIG's efforts include reviewing *Recovery Act* grantees' compliance with the recipient reporting requirements under section 1512 of the *Recovery Act*; reviewing agencies' progress toward implementing *Recovery Act* incentive payments for electronic health records and other funded health IT initiatives; reviewing CMS policies and procedures for protecting against IT breaches and medical identity theft involving Medicare identification numbers and determining whether responses to any breaches complied with notification requirements; reconciling the CMS-64, the standard form States use to claim FMAP, to claims-level data and identifying high-risk areas and providers for increased audit scrutiny; and performing audits of *Recovery Act* spending for recipients receiving HHS *Recovery Act* funding to ensure that awards are being used for authorized purposes and program goals are achieved.

OIG and the Department will continue to work to ensure that the Department meets its *Recovery Act* responsibilities. The Department continues to face challenges to ensuring the accountability and transparency of *Recovery Act* funds and ensuring that the funds are used for designated purposes and for the benefit of the beneficiaries served under the programs receiving enhanced resources. Continuing activities include minimizing risk; assessing controls for preventing fraud, waste, and abuse; and ensuring program goals are achieved and *Recovery Act* funds are accurately tracked and reported. The Department's and OIG's efforts in

overseeing the awarding and effective use of funds will have long-term benefits for Department programs beyond the expenditure of *Recovery Act* funding.

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*Management Issue 12: Health Information Technology and Integrity of Information Systems*

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**MANAGEMENT CHALLENGE AND ASSESSMENT OF PROGRESS IN ADDRESSING THE CHALLENGE:**

The *Health Information Technology for Economic and Clinical Health Act (HITECH Act)* established the Office of the National Coordinator for Health Information Technology (ONC) within the Department and tasked it with leading the development of an interoperable national health information network that allows for the electronic exchange of health information while, among other things, protecting the security and privacy of health data. OIG has divided health IT management challenges into two categories: (1) ensuring the integrity of information systems through which health information is transmitted and stored to prevent fraud, waste, and abuse and (2) ensuring the integrity of the Department's programs to promote health IT. Protecting sensitive health data is a challenge because a patchwork of authorities establishes, and agencies oversee, such data.

Within the Department, CMS, ONC, and the Office for Civil Rights (OCR) are responsible for ensuring the privacy and security of health information. One challenge is coordinating among HHS agencies to ensure the privacy and security of health information by enforcing standards and monitoring security controls for health IT at the provider level. Ineffective or inadequate management processes, controls, or IT security put data and systems at risk. With the enactment of the *HITECH Act*, HHS initiatives promoting the use of health IT include:

- The adoption of interoperability standards by the Secretary;
- Payment of Medicare and Medicaid incentives for providers engaged in the "meaningful use" of health IT;
- HRSA grants for the acquisition of health IT;
- ONC programs to facilitate the adoption of health IT through extension center programs; and
- State grants for health information exchange and development of a health IT workforce.

As electronic medical records become more prevalent and the exchange of personal health data

over expanding networks becomes more pervasive – and as Federal and State health and human services programs implement the requirement in section 1561 of the *Affordable Care Act* to facilitate electronic enrollment of beneficiaries - we identify the risk for a rise in medical identity theft. The Department must quickly identify and address vulnerabilities in each of its health IT initiatives. It is also imperative that *Recovery Act* funds to support the widespread adoption of health IT be used efficiently and effectively. The Department's challenge is to balance the need to meet its health IT development goals with its obligation to oversee the expenditure of *Recovery Act* funds; an estimated \$30 billion over the next several years in pursuit of health IT objectives. Comprehensive guidance to all health care providers is needed to ensure robust IT security that supports health information systems and the underlying network infrastructures to protect health information as it is created, transmitted, and stored.

***Integrity of Information Systems***

The Department administers its programs through a mix of grants, contracts, and cooperative agreements and as a payer of health benefits through Medicare, Medicaid, CHIP, and IHS. To accomplish its mission, the Department relies on a network environment that includes Federal agencies, State and local governments, grantees and contractors, health care providers, and colleges and universities. A significant challenge for the Department is to establish an information security program that protects critical infrastructure and assets and creates, monitors, and maintains an enterprisewide baseline of core security requirements.

OIG has monitored the ability to meet this challenge by determining whether the Department's information system security controls are adequate. OIG has also examined departmental oversight of health care providers' compliance with the *Health Insurance Portability and Accountability Act (HIPAA) Security Rule* (the applicability of which the *HITECH Act* has expanded and enforcement of which has been transferred from CMS to OCR).

OIG has performed dozens of independent audits of departmental agencies, as well as audits of State and local governments, contractors, and hospitals. The audits have identified vulnerabilities in the areas of:

- Network access and management;
- Security program infrastructure, which includes security program documentation, contingency plan documentation, accuracy

of system inventory, and acknowledgment of management responsibilities;

- Security training;
- Personnel security, such as background checks and user account management;
- Contractor oversight; and
- Integration of security into major applications, which includes certification and accreditation, contingency plan testing, privacy impact statements, and annual self-assessments.

With the push for increased adoption of health IT, there is heightened public concern about the security of personal health information. Accordingly, OIG has increasingly focused on combating medical identity theft. OIG investigations have uncovered a growing number of fraud schemes involving stolen provider and beneficiary identification numbers. In response, OIG issued a consumer education brochure that provides tips and resources to help beneficiaries protect themselves and Medicare from medical identity theft and fraud. OIG is also reviewing CMS's policies and procedures regarding information security breaches and medical identity theft involving Medicare identification numbers. OIG will continue its work in this area and make recommendations to the Department, as appropriate, about safeguards for personally identifiable information.

### ***Integrity of Health Information Technology Programs***

Like all grants and contracts, Federal health IT initiatives are susceptible to fraud, noncompliance, and inefficiency. Even before the enactment of the *HITECH Act*, OIG monitored Federal health IT initiatives. In 2009, OIG assessed Medicare Part D plan sponsors' implementation of CMS-mandated e-prescribing standards. OIG found that most sponsors had implemented some of the standards but that few had implemented all of them. Another study in 2008 examined the State Medicaid agencies' health IT initiatives. OIG recommended that States work with other Federal agencies and offices in developing policies to protect patient privacy and data security and coordinate State Medicaid initiatives with Federal health IT activities to ensure consistency with national goals.

OIG has developed a work plan to ensure that the estimated \$49 billion in incentive payments and health IT program funds are used in ways consistent with the requirements in the *HITECH Act* and the Department's implementing regulations and policies. (See Management Issue 11 for further

discussion of challenges associated with the *Recovery Act*.)

Looking forward, OIG is considering ways in which the design and function of electronic health records and health IT systems can help prevent and detect fraud, waste, and abuse and ways in which these tools can be misused to facilitate fraud, waste, and abuse and impede their detection.

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### ***Management Issue 13: Ethics Program Oversight and Enforcement***

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#### **MANAGEMENT CHALLENGE AND ASSESSMENT OF PROGRESS IN ADDRESSING THE CHALLENGE:**

During the past year, conflicts of interest in the health care system generally, and specifically in the Department, have been the subject of scrutiny, raising the issue of which stakeholders should be responsible for monitoring and managing conflicts of interest: individuals, government, or institutions.

#### ***Government Ethics Programs and Conflicts of Interest of Department Employees***

Pursuant to Office of Government Ethics (OGE) regulations, the head of each Department and agency appoints a Designated Agency Ethics Official (DAEO) to oversee its ethics program. At HHS, the OIG assists the DAEO, with oversight and enforcement of the Department's ethics program. A key focus is ensuring that employees do not participate in official matters in which they have a conflict of interest or in which there may be impartiality concerns.

Monitoring for conflicts of interest continues to be a challenge for the Department. In December 2009, OIG determined the extent to which CDC and its Special Government Employees (SGE) on Federal Advisory Committees complied with ethics requirements. SGEs on Federal Advisory Committees provide expert advice to the Federal Government on important public health topics, such as breast and cervical cancer, immunization, smoking, tuberculosis, and clinical laboratory improvement. SGEs are temporary Federal employees who are typically involved in work outside the Government in the same areas as their committees' work. SGEs must comply with essentially the same OGE financial disclosure and conflict-of-interest regulations issued by OGE as Federal employees while performing their temporary work. OIG determined that CDC did not require SGEs to disclose their interests completely before participating in meetings, and CDC did not identify or resolve all SGE potential conflicts of interest, even when adequate information identifying a conflict was provided. CDC concurred with all seven of OIG's recommendations. Since the

OIG report was issued, CDC has worked with the General Services Administration and the OGC Ethics Division to provide specialized training for all staff with advisory committee responsibilities to address conflict-of-interest issues identified by OIG.

OIG is reviewing HHS waivers and analyzing the extent to which the waivers are being created and used across the Department. Most HHS waivers are limited in nature and contain certain recusal requirements. OIG is examining the HHS waiver process to ensure that recusals within waivers are clear to the employees receiving the waivers and to ensure that higher level managers inform employees not to engage in matters from which they are recused. Another challenge for the Department is monitoring for conflicts of interest in a workforce that has become increasingly reliant on contract workers. For example, a recent audit of a CDC service contract found CDC managers "maintained relatively continuous supervision and control of contractor personnel who worked onsite at CDC," effectively treating these contractors as if they were operating under personal services contracts, which is a prohibited practice. (See also Management Issue 10, for further discussion of this issue as it relates to service contracts.)

In a July 2009 memorandum, the OMB director recognized the formidable task agencies face in appropriately and effectively managing a multi-sector workforce of both Federal employees and contractors to deliver important services. Since December 2007, OIG has maintained hotline posters on its Web site for use by departmental contractors and their employees to encourage reporting fraud to OIG. The OGE is releasing guidance on conflict-of-interest considerations of contractor employees in the workplace and OIG is developing internal training to prepare supervisors to address emerging issues involving contractors.

OIG continues to consult with the Department about the number and quality of conflict-of-interest referrals from divisions in the Department. Since OIG created a form for referrals of conflict-of-interest cases, OIG has seen a significant improvement in the quality of information received on such cases, resulting in reduced evaluation time. OIG's relations with the Office of General Counsel (OGC) Ethics Division, as well as regular interactions by OIG staff with the operating and staff divisions, continue to yield positive results. Departmental management appears to have a greater understanding of what constitutes potential ethics and conflict-of-interest violations as evidenced by an increase in reporting potential violations, in the quality of the referrals, and in the number of contacts by departmental officials

seeking input and guidance on conflict-of-interest matters.

OIG's enforcement efforts are often measured in convictions. In 2009, an employee of the National Library of Medicine at NIH failed to receive required prior approval for outside activities and to report income from them. The employee admitted receiving as much as \$500,000 in unauthorized income after testifying as an expert witness on toxicology issues in legal proceedings. As a result, he was sentenced to 1 year of probation and 160 hours of community service and was ordered to pay a \$200,000 fine.

As important as convictions are for redressing serious violations, it is more important to prevent employees from violating criminal conflict-of-interest statutes and to protect the integrity of departmental programs. In 2010, in cooperation with the OGC Ethics Division, OIG examined allegations of conflict of interest involving high-level Department officials and determined that no conflict-of-interest violations had occurred. OIG confirmed that the OGC Ethics Division's efforts to work with HHS employees, focusing on incoming high-level officials to reduce and prevent conflict-of-interest violations from occurring, were successful. New employees were encouraged to seek counsel to get advice, and avoid actions that could violate criminal conflict-of-interest statutes.

### ***Oversight of Department Grantee, Researcher and Contractor Conflicts of Interest***

In addition to departmental employees and contractors, Federal grantees and non-Federal researchers play important roles in departmental programs, and their conflicts of interest could also bias these programs and ultimately affect the public's health and safety. Eighty percent of NIH research funding goes to extramural grantees, primarily to research universities that undertake grant and contract work. Conflicts of interest among extramural grantees could compromise the integrity of the research that the Department funds. Therefore, in addition to performing work focused on departmental employees, OIG also examined potential conflicts of interest of Federal grantees and non-Federal researchers.

In 2008, OIG identified vulnerabilities associated with NIH's monitoring of conflict-of-interest reports submitted by external grantees for FYs 2004 through 2006. OIG found that NIH's Institutes and the Office of Extramural Research (OER) were unable to provide all the conflict-of-interest reports they received from grantee institutions and did not follow up with grantee institutions about reported conflicts of interest. OIG recommended that NIH

increase oversight of grantee institutions and require them to provide details about the nature of financial conflicts of interest and the ways in which they are managed, reduced, or eliminated and ensure that OER's conflict-of-interest database contains information on all conflict-of-interest reports provided by grantee institutions. In July 2009, NIH began requiring that all financial conflict-of-interest reports from grantees be submitted electronically to NIH's system, using a uniform format.

In its followup work, OIG examined the nature of financial conflicts of interest reported by grantee institutions to NIH and the ways in which grantee institutions managed, reduced, or eliminated these conflicts. OIG identified vulnerabilities, including grantee institutions' reliance on researchers' discretion in reporting conflicts, failure to require researchers to report amounts of compensation in financial disclosures, and failure to routinely verify information submitted by researchers. OIG continues to recommend that NIH ask grantee institutions to provide it with details on the nature of all reported financial conflicts of interest and ways in which they are managed, reduced, or eliminated. OIG also recommended that NIH (1) require grantee institutions to collect all information on significant financial interests held by researchers, (2) require grantee institutions to collect from researchers information on specific amounts of equity and compensation, (3) increase oversight of grantee institutions to ensure that financial conflicts of interest are reported and managed appropriately, and (4) develop regulations that address institutional financial conflicts of interest. OIG is undertaking a review to determine what policies and procedures NIH grantee institutions have in place to address researchers' conflicts of interest.

In response to concerns about these vulnerabilities, NIH sought input from the public and from the research community on modifying Federal regulations by publishing an Advance Notice of Proposed Rulemaking (NPRM) on Promoting Objectivity in Research in May 2009. NIH invited public comments on all aspects of potential regulation in this area, particularly on the following issues: (1) expanding the scope of the regulation and the disclosure of conflicts of interest, (2) the definition of "significant financial interest," (3) identification and management of conflicts by grantee institutions, (4) assuring grantee institution compliance, (5) requiring grantee institutions to

provide additional information to NIH, and (6) broadening the regulations to address institutional conflicts of interest. The NPRM was published in May 2010 and the comment period closed on August 19, 2010. The NPRM also proposed regulations for revising conflict-of-interest policies for contractors in 45 CFR Part 94.

OIG has also identified departmental conflict-of-interest vulnerabilities affecting other agencies. In 2009, OIG reported on vulnerabilities in FDA oversight of clinical investigators' financial interests. Clinical investigators lead clinical trials, recruit subjects, supervise trials, and analyze and report clinical trial results that are submitted to FDA in new drug applications. OIG identified vulnerabilities in the disclosure process and in FDA's review of the disclosed financial interests. OIG recommended that FDA ensure that new drug sponsors submit complete financial information for all clinical investigators and that FDA consistently review and take action in response to disclosed financial interests. OIG also recommended that sponsors submit financial information for their clinical investigators earlier in the process. In its response to the report, FDA agreed with most of our recommendations. FDA is currently in the process of revising its *Guidance for Industry: Financial Disclosure by Clinical Investigators*. It also updated its *Compliance Program Guidance Manual* chapter on Clinical Investigator Inspections to ensure that clinical investigators submit required financial information to sponsors.

Recent decisions by the Government Accountability Office (GAO) have highlighted the issue of organizational conflicts of interest of Government contractors. GAO sustained two bid protests under the CMS ZPIC program, agreeing that CMS had failed to reasonably consider the awardee's plan to mitigate its impaired objectivity. OIG is also evaluating how CMS oversees potential ZPIC organizational conflicts of interest. In addition, OIG is evaluating the oversight of potential conflicts of interest within the pharmacy and therapeutics committees within Part D plans.

Congress passed conflict-of-interest statutes, and OGE and the Department have promulgated ethics regulations to ensure that Department missions and programs are not compromised by conflicts of interest. Maintaining a heightened focus on ethics in the Department will require continued vigilance by all HHS employees, grantees, contractors, and researchers working with HHS.

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## DEPARTMENT'S RESPONSE TO THE OIG TOP MANAGEMENT AND PERFORMANCE CHALLENGES



DEPARTMENT OF HEALTH & HUMAN SERVICES

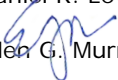
Office of the Secretary

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Washington, D.C. 20201

November 15, 2010

To: Daniel R. Levinson, Inspector General

From:  Ellen G. Murray, Assistant Secretary for Financial Resources and Chief Financial Officer

Subject: FY 2010 Top Management and Performance Challenges Identified by the Office of the Inspector General

This memorandum is in response to OIG's *FY 2010 Top Management and Performance Challenges*, which summarized the top management and performance challenges that the Department has faced over recent years.

We concur with OIG's findings concerning the HHS top management and performance challenges. In response to OIG's report, we are providing the attached table which includes a brief summary of the top management challenges, management's response, and future plans to address these challenges during FY 2011.

Our management is committed to working toward resolving these challenges, and looks forward to continued collaboration with OIG to improve the health and well-being of the American people through our efforts.

## FY 2010 Top Management and Performance Challenges Summary

### Part I: Health Care Reform

Management Challenge Identified by the OIG	OIG Progress Assessment	Management Response	Future Plans to Address the Challenge
1. Incorporating Integrity into Health Care Reform Implementation	HHS is working to successfully implement the numerous provisions of the <i>Affordable Care Act</i> . This will continue to require clear and effective communication with program beneficiaries, private citizens, and health care industry leaders. The Department will need to identify key vulnerabilities and prioritize oversight resources to address the new risks posed by the changing dynamics of evolving Federal health care programs. Effective collaboration is necessary to monitor progress in meeting implementation goals, while building infrastructure to support implementation of the <i>Affordable Care Act</i> .	HHS is building infrastructure to address the challenges posed by the implementation of the <i>Affordable Care Act</i> , and engaged a staff to maintain a database with a dashboard feature to track implementation. In addition, the Department created the Office of Consumer Information and Insurance Oversight (OCIIO) to focus on private insurance issues. Also, the Centers for Medicare and Medicaid (CMS) created the new Center of Medicare and Medicaid Innovation to focus on innovative delivery models and the Center for Program Integrity to strengthen its oversight of the Medicare and Medicaid programs.	The OIG and the Department will work together to ensure we meet our <i>Affordable Care Act</i> responsibilities. In addition, we will continue to work with our partners to respond to vulnerabilities in current Federal health care programs. We will strive to work with the OIG and identify new risks posed by the changing dynamics of Federal health care programs and the evolving nature of fraud.

### Part II: Integrity of Medicare, Medicaid, Children’s Health Insurance Program

Management Challenge Identified by the OIG	OIG Progress Assessment	Management Response	Future Plans to Address the Challenge
2. Integrity of Provider and Supplier Enrollment	CMS has made continued progress in responding to enrollment vulnerabilities, including implementing some measures aimed at enhancing enrollment standards for durable medical equipment suppliers. The <i>Affordable Care Act</i> contains several provisions, including subjecting new providers and suppliers to enhanced oversight, such as prepayment review for 30 days to 1 year after enrollment, aimed at reducing vulnerabilities in provider and supplier enrollment.	We agree with the OIG and have made significant progress responding to vulnerabilities to strengthen the integrity of the Medicare program. CMS has taken steps to tighten the provider enrollment process, provide more oversight and monitoring once a provider/supplier enrolls in the program, and strengthen the provider revocation process. These steps include claims specialty editing to ensure suppliers are only paid for items they are properly licensed to provide, and increasing the number of random site visits.	CMS will continue to clarify and expand on existing enrollment requirements that durable medical equipment, orthotics, prosthetics, and supplies (DMEPOS) suppliers must meet to establish and maintain billing privileges in the Medicare program. CMS will also look at future ways to improve the Medicare enrollment process, including enhanced monitoring of a provider or supplier once it has entered the program.



**Part II: Integrity of Medicare, Medicaid, Children’s Health Insurance Program (Continued)**

Management Challenge Identified by the OIG	OIG Progress Assessment	Management Response	Future Plans to Address the Challenge
<p>3. Integrity of Federal Health Care Program Payment Methodologies</p>	<p>CMS continues efforts to ensure payments are based on accurate data, responds to changes in the marketplace and medical practice, and limit the risk of fraud. While many of the payment issues identified by the OIG have not been resolved, the Department faces the challenge of developing new payment models under <i>the Affordable Care Act</i>, to bring balance between protecting the integrity of health care programs and fostering innovation that increases quality, efficiency, and cost effectiveness.</p>	<p>CMS continues making progress to aggressively identify those payment methodologies that create fraudulent incentives in Medicare and Medicaid, as well as address vulnerabilities, which includes steps to address widespread abuse of outlier payments to Medicare-certified Home Health Agencies (HHAs).</p>	<p>The Department is reacting to ongoing changes in the marketplace and medical practices. In this regard, CMS is escalating its recent efforts to review and adjust the relative values upon which payments for physicians’ services rely to reflect contemporary medical practice.</p>
<p>4. Promoting Compliance With Federal Health Care Program Requirements</p>	<p>CMS program and contract efforts, such as the Medicaid Integrity Program, provide education for health care providers and suppliers, managed care entities, and beneficiaries to promote payment integrity and quality of care. The Department faces the challenge of implementing a comprehensive safeguard strategy for Medicare and Medicaid as new mandates in the <i>Affordable Care Act</i> expand and redefine roles for compliance programs.</p>	<p>CMS recognizes the importance of clear guidance and the need for broad access to that guidance. Because of the diversity of Medicare providers, CMS has an extensive inventory of Medicare Learning Network educational products. Efforts are ongoing to continually evaluate provider outreach, education, and inquiry support.</p>	<p>CMS will continue its efforts to create a robust education, training, and outreach campaign, which is designed to improve the plan sponsor’s compliance with Medicare program requirement. Recognizing the importance of program integrity, CMS will devote additional resources to the Medicare Drug Integrity Contractors (MEDICs) to address new complexities, including routine compliance and enforcement tracking.</p>
<p>5. Oversight and Monitoring of Federal Health Care Programs</p>	<p>CMS is making progress in developing oversight tools and monitoring of Federal Health Programs. The <i>Affordable Care Act</i> will challenge the Department by requiring CMS to expand its Integrated Data Repository to include claims from Medicaid and other Federal entities, including the Social Security Administration.</p>	<p>CMS continues to strive and eliminate improper payments in the Medicare program to maintain the Medicare trust funds and protect beneficiaries. CMS altered the Comprehensive Error Rate Testing (CERT) program and called for a more strict enforcement of its policies.</p>	<p>CMS understands the importance of having complete and timely data for use in oversight and monitoring of its programs. CMS remains committed to leveraging innovative technology and techniques to better identify excessive payments early.</p>

**Part II: Integrity of Medicare, Medicaid, Children’s Health Insurance Program (Continued)**

Management Challenge Identified by the OIG	OIG Progress Assessment	Management Response	Future Plans to Address the Challenge
<p>6. Respond to Fraud and Vulnerabilities in Federal Health Care Programs</p>	<p>Progress continues in the Department’s efforts to respond to fraud through law enforcement (through OIG, in partnership with the Department of Justice) and by addressing program vulnerabilities (through CMS). Under the <i>Affordable Care Act</i>, the Department is further challenged with its efforts to work and reduce improper Medicare and Medicaid payments resulting from fraud, waste, and abuse across all service areas.</p>	<p>CMS agrees that responding to fraud and program vulnerabilities requires a high degree of coordination and collaboration between multiple Federal and State agencies. CMS agrees that access to real-time information across all areas is critical towards meeting the challenges and demands of its programs. A proven industry best practice, Master Data Management (MDM), will be put in place at CMS to focus on eliminating redundancy, inconsistency, and fragmentation of information.</p>	<p>CMS will continue to work with its partners to respond to health care waste, fraud, and abuse. CMS will also strive to implement additional tools to provide access to real-time information, which is critical to the Department’s data analytical environment.</p>
<p>7. Quality of Care</p>	<p>HHS continues making progress in ensuring that providers comply with quality standards, developing initiative to protect beneficiaries from abuse or neglect, and implementing payment incentives linked to quality. The Department is challenged by the <i>Affordable Care Act</i> to provide enhanced quality of care in the health care delivery system.</p>	<p>CMS continues to improve its oversight of accrediting organizations (AOs) through increased use of validation surveys and analysis of AO data. AHRQ has made considerable progress expanding its influence on health care provider practices to improve health care quality and patient safety. It collaborated within HHS to develop <i>Common Formats</i> for reporting patient safety events to Patient Safety Organizations.</p>	<p>The Department will continue to implement programs, and work with providers to enhance the quality of care in the health care delivery system.</p>

**Part III: Integrity of the Department’s Public Health and Human Services Programs**

Management Challenge Identified by the OIG	OIG Progress Assessment	Management Response	Future Plans to Address the Challenge
8. Oversight of Food, Drugs, and Medical Devices	FDA continues making progress in ensuring the timely approval and oversight of drugs and medical devices. The Department; however, faces challenges with respect to increasingly globalized markets and new legislative mandates increasing oversight responsibilities, such as new authority to regulate tobacco product.	FDA remains committed to the work of the Food Safety Working Group, and it focus on a new public health-focused approach to food safety, which includes prioritizing prevention. FDA expanded the availability of high-quality generic drug products and provided consumers and health care providers with information on both safety and effectiveness.	FDA will continue to collaborate with sponsors and contract research organizations as part of its on-going improvement of the generic drug process. It will also strive to expand its training of employees in foreign posts as part of its multifaceted and collaborative approach to the oversight of clinical trials..
9. Emergency Preparedness and Response	The Department continues working with State and local health officials to make progress in preparing for and responding to public health emergencies, and in the development of emergency preparedness and detention plans for pandemic influenza, bioterrorist attacks, and natural disasters.	HHS continues its work with experts to develop guidance on developing emergency preparedness plans for States, local and territorial public health departments. Progress also is being made to improve the Nation's preparedness for and response to public health emergencies.	On-going progress is being made to provide additional guidance to States and localities to improve their public health emergency preparedness capability. This includes specifically targeting high-risk populations, minority and hard-to reach populations, and underserved and vulnerable populations.
10. Grants and Contract Management	HHS continues its progress in developing consistent policies and procedures to oversee Federal grantees and has maintained its key leadership role in the temporary expansion of health and social programs under the <i>Recovery Act</i> , due to the Department's significant grant expenditures as the largest grant-awarding agency in the Federal Government. HHS is challenged with increasing its contracting training and clarifying guidance on the use of annual appropriated funds throughout the Department.	The Department continued its oversight responsibility for ensuring that grant funds are awarded and used appropriately by grantees. HHS resolved concerns regarding whether one State agency claimed foster care costs under the Title IV-E Foster Care program in accordance with Federal regulations. HHS is developing on-line and instructor –led acquisition appropriation law courses to further educate appropriate parties on acquisition policy.	The Department will continue coordinating the expeditious financial closeout of ended projects. HHS is establishing internal policy workgroups to foster greater consistency and accountability in the application of its grant and management policies. In addition, HHS plans to institute greater management oversight of the use of contractor support and the related acquisition practices.

**Part IV: Cross-Cutting Issues that Span the Department**

<b>Management Challenge Identified by the OIG</b>	<b>OIG Progress Assessment</b>	<b>Management Response</b>	<b>Future Plans to Address the Challenge</b>
<p>11. <i>American Recovery and Reinvestment Act.</i></p>	<p>The <i>Recovery Act</i> provided an estimated \$141.4 billion over 11 years to the Department to provide Federal assistance for health care, public health, and human services programs, as well as to invest in research and health information technology (health IT). In addition to the funding in direct provisions, the <i>Recovery Act</i> provides for additional fiscal relief to the States, in the form of reduced contributions for prescription drug costs, in the amount of \$4.3 billion. It is critical that <i>Recovery Act</i> funds are used efficiently and effectively and are protected from fraud, waste, and abuse.</p>	<p>The Office of Recovery Act Coordination continues to ensure the appropriate awarding, distributing, use, and reporting of <i>Recovery Act</i> funds. In addition, the <i>Recovery Act</i>, established by the Recovery Accountability and Transparency Board (RATB), consisting of 12 Inspectors General, including the HHS Inspector General, coordinates and conducts oversight of <i>Recovery Act</i> funds; prevent fraud, waste, and abuse; and promote accountability and transparency.</p>	<p>The OIG and the Department will continue to work together to ensure HHS meets its <i>Recovery Act</i> responsibilities. This includes ensuring the accountability and transparency of <i>Recovery Act</i> funds. In addition, activities will continue to focus on minimizing risk, assessing controls for preventing fraud, waste and abuse; and ensuring program goals are achieved and <i>Recovery Act</i> funds are tracked and reported.</p>
<p>12. Health Information Technology and Integrity of Information Systems</p>	<p>The Department continues to make progress in ensuring the integrity of the Department's programs to promote health information technology, in addition to ensuring the integrity of information systems through which health information is transmitted and stored.</p>	<p>The Office of the National Coordinator for Health IT (ONC) continues to provide national leadership in health IT adoption and electronic health information exchange. Under the ONC, we identified potential approaches for addressing medical identity theft in a comprehensive manner through research and stakeholder "town hall" meetings.</p>	<p>ONC and the Department are well aware of privacy and security challenges as we transition to wide adoption and use of electronic health records and secure electronic health information exchange. We will be seeking recommendations on additional security capabilities from our Federal advisory committees that may be incorporated into future phases of the transition processes.</p>

**Part IV: Cross-Cutting Issues that Span the Department (Continued)**

<b>Management Challenge Identified by the OIG</b>	<b>OIG Progress Assessment</b>	<b>Management Response</b>	<b>Future Plans to Address the Challenge</b>
<p>13. Ethics Program Oversight and Enforcement</p>	<p>NIH and FDA continue implementing additional measures to strengthen their processes for reviewing and approving outside activities. The OGC Ethics Division continued its ethics program oversight.</p>	<p>The OGC Ethics Division has responsibility for administering the Department's ethics program as it pertains to HHS employees (including special Government employees). It continued to conduct internal reviews of OPDIV and STAFFDIV ethics programs to ensure that these programs function effectively and that conflicts of interest on the part of HHS employees are identified and resolved.</p>	<p>The DAEO and the OGC Ethics Division will continue to work closely with the OIG in identifying and addressing areas of improvement within HHS' ethics program and the handling of referrals of conflict of interest violations.</p>

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