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, 2009
(in Millions)

	Education, Training & Social Services	Health	Medicare	Income Security	Agency Combined Totals	Intra-HHS Eliminations	HHS Consolidated Totals
Assets (Note 2)							
Intragovernmental							
Fund Balance with Treasury (Note 3)	$ 11,710	$ 127,866	$ 3,265	$ 19,121	$ 161,962	$ -	$ 161,962
Investments, Net (Note 5)	-	5,281	375,835	-	381,116	-	381,116
Accounts Receivable, Net (Note 6)	28	954	52,047	14	53,043	(52,130)	913
Anticipated Congressional Appropriation (Note 7)	-	-	-	-	-	-	-
Other (Note 10)	-	326	17	-	343	(251)	92
Total Intragovernmental	$ 11,738	$ 134,427	$431,164	$ 19,135	$ 596,464	$ (52,381)	$ 544,083
Accounts Receivable, Net (Note 6)	-	2,497	3,007	-	5,504	-	5,504
Cash and Other Monetary Assets (Note 4)	-	-	357	-	357	-	357
Inventory and Related Property, Net (Note 8)	-	5,604	-	-	5,604	-	5,604
General Property, Plant & Equipment, Net (Note 9)	-	4,694	353	-	5,047	-	5,047
Other (Note 10)	-	492	1,693	-	2,185	-	2,185
Total Assets	**$ 11,738**	**$ 147,714**	**$436,574**	**$ 19,135**	**$ 615,161**	**$ (52,381)**	**$ 562,780**
Stewardship PP&E (Note 32)							
Liabilities (Note 11)							
Intragovernmental							
Accounts Payable	$ 14	$ 95	$ 52,379	$ -	$ 52,488	$ (51,922)	$ 566
Accrued Payroll and Benefits	2	103	7	-	112	(1)	111
Other (Note 15)	30	998	484	17	1,529	(458)	1,071
Total Intragovernmental	$ 46	$ 1,196	$ 52,870	$ 17	$ 54,129	$ (52,381)	$ 1,748
Accounts Payable	20	533	-	1	554	-	554
Entitlement Benefits Due and Payable (Note 12)	-	25,446	46,772	-	72,218	-	72,218
Accrued Grant Liability (Note 14)	715	2,336	-	989	4,040	-	4,040
Federal Employee and Veterans Benefits (Note 13)	5	9,671	14	-	9,690	-	9,690
Accrued Payroll and Benefits	13	781	57	-	851	-	851
Other (Note 15)	17	4,697	519	33	5,266	-	5,266
Total Liabilities	**$ 816**	**$ 44,660**	**$100,232**	**$ 1,040**	**$ 146,748**	**$ (52,381)**	**$ 94,367**
Net Position							
Unexpended Appropriations - earmarked funds	-	(98)	3,590	-	3,492	-	3,492
Unexpended Appropriations - other funds	10,932	94,999	-	18,106	124,037	-	124,037
Unexpended Appropriations, Total	10,932	94,901	3,590	18,106	127,529	-	127,529
Cumulative Results of Operations - earmarked funds	-	4,059	332,752	-	336,811	-	336,811
Cumulative Results of Operations - other funds	(10)	4,094	-	(11)	4,073	-	4,073
Cumulative Results of Operations, Total	(10)	8,153	332,752	(11)	340,884	-	340,884
Total Net Position	$ 10,922	$ 103,054	$336,342	$ 18,095	$ 468,413	$ -	$ 468,413
Total Liabilities and Net Position	**$ 11,738**	**$ 147,714**	**$436,574**	**$ 19,135**	**$ 615,161**	**$ (52,381)**	**$ 562,780**

CONSOLIDATED BALANCE SHEET BY OPERATING DIVISION
As of September 30, 2009
(in Millions)

	ACF	AoA	AHRQ	CDC	CMS	FDA	HRSA	IHS	NIH	OS	PSC	SAMHSA	Agency Consolidated Totals	Intra-HHS Eliminations	HHS Consolidated Totals
Assets (Note 2)															
Intragovernmental															
Fund Balance with Treasury (Note 3)	$30,135	$ 696	$ 803	$ 6,993	$ 49,340	$ 1,675	$ 7,661	$2,328	$ 41,584	$ 17,917	$ 159	$ 2,671	$ 161,962	$ -	$ 161,962
Investments, Net (Note 4)	-	-	-	-	377,948	-	3,122	-	46	-	-	-	381,116	-	381,116
Accounts Receivable, Net (Note 5)	20	22	-	105	492	8	21	35	15	153	325	45	1,241	(328)	913
Other (Note 8)	-	-	-	1	17	-	-	-	1	-	3	71	93	(1)	92
Total Intragovernmental	30,155	718	803	7,099	427,797	1,683	10,804	2,363	41,646	18,070	487	2,787	544,412	(329)	544,083
Accounts Receivable, Net (Note 5)	-	-	-	20	5,165	89	3	208	6	4	9	-	5,504	-	5,504
Cash and Other Monetary Assets (Note 1)	-	-	-	-	357	-	-	-	-	-	-	-	357	-	357
Inventory and Related Property, Net (Note 6)	-	-	-	1,258	-	2	2	9	8	4,320	5	-	5,604	-	5,604
General Property, Plant & Equipment, Net (Note 7)	-	-	-	1,327	384	318	-	848	1,990	178	2	-	5,047	-	5,047
Other (Note 8)	-	-	-	-	1,821	1	357	-	6	-	-	-	2,185	-	2,185
Total Assets	**$30,155**	**$ 718**	**$ 803**	**$ 9,704**	**$ 435,524**	**$ 2,093**	**$11,166**	**$3,428**	**$ 43,656**	**$ 22,572**	**$ 503**	**$ 2,787**	**$ 563,109**	**$ (329)**	**$ 562,780**
Stewardship PP&E (Note 1)															
Liabilities (Note 9)															
Intragovernmental															
Accounts Payable	$ 14	$ -	$ -	$ -	$ 602	$ 9	$ 9	$ 7	$ 18	$ 27	$ -	$ -	$ 686	$ (120)	$ 566
Accrued Payroll and Benefits	2	-	-	18	7	14	5	26	27	8	2	3	112	(1)	111
Other (Note 13)	45	2	71	141	513	5	56	299	59	26	-	62	1,279	(208)	1,071
Total Intragovernmental	$ 61	$ 2	$ 71	$ 159	$ 1,122	$ 28	$ 70	$ 332	$ 104	$ 61	$ 2	$ 65	$ 2,077	$ (329)	$ 1,748
Accounts Payable	21	-	-	-	-	3	-	42	480	1	6	1	554	-	554
Entitlement Benefits Due and Payable (Note 11)	-	-	-	-	72,218	-	-	-	-	-	-	-	72,218	-	72,218
Accrued Grant Liability (Note 12)	1,617	87	5	199	-	6	417	23	1,468	196	-	22	4,040	-	4,040
Federal Employee and Veterans Benefits (Note 11)	5	-	-	42	15	19	20	75	45	17	9,439	13	9,690	-	9,690
Accrued Payroll and Benefits	12	1	3	138	62	114	13	71	391	30	11	5	851	-	851
Other (Note 13)	49	1	14	51	4,322	58	333	291	18	55	53	21	5,266	-	5,266
Total Liabilities	**$ 1,765**	**$ 91**	**$ 93**	**$ 589**	**$ 77,739**	**$ 228**	**$ 853**	**$ 834**	**$ 2,506**	**$ 360**	**$ 9,511**	**$ 127**	**$ 94,696**	**$ (329)**	**$ 94,367**
Net Position															
Unexpended Appropriations - earmarked funds	-	-	-	-	3,590	(98)	-	-	-	-	-	-	3,492	-	3,492
Unexpended Appropriations - other funds	28,427	611	703	6,706	20,936	(986)	6,660	2,017	38,680	17,655	27	2,601	124,037	-	124,037
Unexpended Appropriations, Total	28,427	611	703	6,706	24,526	(1,084)	6,660	2,017	38,680	17,655	27	2,601	127,529	-	127,529
Cumulative Results of Operations - earmarked funds	-	-	2	29	332,752	750	2,898	18	362	-	-	-	336,811	-	336,811
Cumulative Results of Operations - other funds	(37)	16	5	2,380	507	2,199	755	559	2,108	4,557	(9,035)	59	4,073	-	4,073
Cumulative Results of Operations, Total	(37)	16	7	2,409	333,259	2,949	3,653	577	2,470	4,557	(9,035)	59	340,884	-	340,884
Total Net Position	$28,390	$ 627	$ 710	$ 9,115	$ 357,785	$ 1,865	$10,313	$2,594	$ 41,150	$ 22,212	$ (9,008)	$ 2,660	$ 468,413	$ -	$ 468,413
Total Liabilities and Net Position	**$30,155**	**$ 718**	**$ 803**	**$ 9,704**	**$ 435,524**	**$ 2,093**	**$11,166**	**$3,428**	**$ 43,656**	**$ 22,572**	**$ 503**	**$ 2,787**	**$ 563,109**	**$ (329)**	**$ 562,780**

NET COST OF TOP 20 PROGRAMS
For the Years Ended September 30, 2009 and 2008
(Dollars in Millions)

	HHS Net Cost ($)		Rank by ($)			HHS Component Responsible for
HHS Program	**FY 2009**	**FY 2008**	**FY 2009**	**FY 2008**	**Budget Function**	**Program**
Medicare	$430,025	$ 395,055	1	1	Medicare	CMS
Medicaid	253,352	201,094	2	2	Health	CMS
Research	29,985	29,477	3	3	Health	NIH
Temporary Assistance to Needy Families	19,058	18,147	4	4	Education, Training & Social Services / Income Security	ACF
Child Welfare	7,915	7,667	5	5	Education, Training & Social Services / Income Security	ACF
Children's Health Insurance Program	7,610	6,978	6	6	Health	CMS
Head Start	7,074	6,968	7	7	Education, Training & Social Services / Income Security	ACF
Child Care	5,262	5,045	8	8	Education, Training & Social Services / Income Security	ACF
Infectious Diseases	5,153	4,692	9	9	Health	CDC
Low-Income Home Energy Assistance	4,537	2,666	10	11	Education, Training & Social Services / Income Security	ACF
Child Support Enforcement	4,430	4,204	11	10	Education, Training & Social Services / Income Security	ACF
Primary Care	2,358	2,139	12	13	Health	HRSA
HIV/AIDS Programs	2,353	2,229	13	12	Health	HRSA
Clinical Services	2,148	1,828	14	14	Health	I H S
Social Services Block Grant	1,840	1,823	15	15	Education, Training & Social Services	ACF
Substance Abuse Prevention & Treatment Block Grant	1,749	1,718	16	16	Health	SAMHSA
PHS Commissioned Corps	1,451	804	17	22	Health	PSC
Public Health and Social Services	1,355	1,484	18	17	Health	OS
Community Based Services	1,331	1,291	19	18	Education, Training & Social Services	AOA
Terrorism	1,135	1,150	20	19	Health	CDC
Total, Top 20 Programs	**$790,121**	**$ 696,459**				
All Other HHS Programs	13,784	12,687			Various Functions	Various Components
Total Net Costs	**$803,905**	**$ 709,146**				

SUPPLEMENTAL STATEMENT OF NET COST

For the Years Ended September 30, 2009 and 2008
(In Millions)

Responsibility Segments	Agency Consolidated Totals	Inter-Agency Eliminations Costs (-)	Inter-Agency Eliminations Earned/Exchange Revenues (+) [1]	HHS Consolidated Totals
2009				
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
Net Cost of Operations	**$ 804,135**	**$ (2,077)**	**$ 1,847**	**$ 803,905**
2008				
ACF	$ 48,544	$ (21)	$ 51	$ 48,574
AoA	1,398	(6)	3	1,395
AHRQ	5	(394)	11	(378)
CDC	8,487	(342)	164	8,309
CMS	603,557	(2)	284	603,839
FDA	1,210	(35)	104	1,279
HRSA	7,003	(33)	174	7,144
IHS	3,532	(24)	54	3,562
NIH	29,477	(127)	892	30,242
OS	2,149	(401)	183	1,931
PSC	775	(471)	19	323
SAMHSA	3,102	(213)	37	2,926
Net Cost of Operations	**$ 709,239**	**$ (2,069)**	**$ 1,976**	**$ 709,146**

[1]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, 2009
(In Millions)

Responsibility Segments:	Education, Training, & Social Services	Health	Medicare	Income Security	Agency Combined Totals	Intra-HHS Eliminations: Cost (-)	Intra-HHS Eliminations: Revenue	HHS Consolidated Totals
ACF	$ 11,787	$ -	$ -	$ 40,531	$ 52,318	$ (18)	$ 48	$ 52,348
AoA	1,440	-	-	-	1,440	(4)	5	1,441
AHRQ	-	(6)	-	-	(6)	(393)	11	(388)
CDC	-	9,124	-	-	9,124	(351)	170	8,943
CMS	-	261,427	430,025	-	691,452	(2)	260	691,710
FDA	-	1,939	-	-	1,939	(28)	127	2,038
HRSA	-	7,311	-	-	7,311	(56)	173	7,428
IHS	-	3,952	-	-	3,952	(29)	56	3,979
NIH	-	29,985	-	-	29,985	(127)	753	30,611
OS	-	1,913	-	-	1,913	(428)	182	1,667
PSC	-	1,406	-	-	1,406	(607)	22	821
SAMHSA	-	3,301	-	-	3,301	(34)	40	3,307
Net Cost of Operations	**$ 13,227**	**$320,352**	**$430,025**	**$ 40,531**	**$ 804,135**	**$(2,077)**	**$ 1,847**	**$ 803,905**

GROSS COST AND EXCHANGE REVENUE

For the Year Ended September 30, 2009
(In Millions)

Responsibility Segments	Intragovernmental: Gross Cost: Combined	Intragovernmental: Gross Cost: Eliminations	Intragovernmental: Gross Cost: Consolidated	Intragovernmental: Less: Exchange Revenue: Combined	Intragovernmental: Less: Exchange Revenue: Eliminations	Intragovernmental: Less: Exchange Revenue: Consolidated	With the Public: Gross Cost	With the Public: Less: Exchange Revenue	HHS Consolidated Net Cost of Operations
ACF	$ 197	$ (33)	$ 164	$ 39	$ (63)	$ (24)	$ 52,162	$ 2	$ 52,348
AoA	11	(4)	7	5	(5)	-	1,434	-	1,441
AHRQ	37	(393)	(356)	345	(11)	334	301	(1)	(388)
CDC	887	(351)	536	496	(170)	326	8,738	5	8,943
CMS	847	(2)	845	11	(260)	(249)	748,159	57,543	691,710
FDA	737	(28)	709	38	(127)	(89)	1,920	680	2,038
HRSA	257	(63)	194	44	(180)	(136)	7,120	22	7,428
IHS	544	(29)	515	187	(56)	131	4,710	1,115	3,979
NIH	4,320	(2,809)	1,511	3,077	(3,435)	(358)	28,858	116	30,611
OS	832	(544)	288	962	(298)	664	2,053	10	1,667
PSC	105	(607)	(502)	840	(22)	818	2,152	11	821
SAMHSA	189	(38)	151	238	(44)	194	3,350	-	3,307
Totals	**$8,963**	**$ (4,901)**	**$ 4,062**	**$ 6,282**	**$ (4,671)**	**$ 1,611**	**$ 860,957**	**$ 59,503**	**$ 803,905**

IMPROPER PAYMENTS INFORMATION ACT REPORT

1.0 Overview

Our FY 2009 *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)
  - State 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)

1.10 Program Descriptions

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 Medicare health insurance program that allows beneficiaries to receive their Medicare benefits through a private heath plan.
3) Medicare Prescription Drug Benefit (Medicare Part D) - A Federal prescription drug benefit program for Medicare beneficiaries.
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 age's three to five and their families. Head Start provides diverse services consistent with its goals for success in education, health, parent involvement and social services.
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 that HHS measures and that are described in this report, we conduct risk assessments on 23 additional high-dollar programs. OMB Circular A-123, Appendix C requires HHS to perform risk assessments once every 3 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, whereas one has used the HHS Office of Inspector General to ensure that all statistical methodologies, sampling, calculations, and validation are performed according to accepted statistical practices.

Unless otherwise stated in the Program-Specific Reporting Information section, all programs also comply with IPIA guidance that requires that all estimates shall 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.

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 because 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 all nine 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 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 2009 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. All of these programs have reported comprehensive error rates with the exception of the new Medicare Prescription Drug Benefit program.

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 measurement baselines.

9.20 Achievements

9.21 Improving Program Integrity in Medicare

Section 302 of the *Tax Relief and Health Care Act of 2006* made the Recovery Audit Contractor (RAC) program permanent and requires HHS to implement the program in all 50 States no later than January 1, 2010. HHS completed the procurement effort in October 2008 and awarded contracts to four RACs. A protest delayed the implementation until February 2009. Each RAC is responsible for identifying and correcting improper payments in approximately 25 percent of the country. HHS has initiated a gradual implementation and it will be completed nation-wide by January 2010. HHS and the RACs will continue to provide extensive outreach to the provider community after implementation.

HHS has been proceeding with implementation since February 2009. Extensive provider outreach in all 50 States has occurred, as well as coordination and implementation activities with the Medicare claim-processing contractors. HHS developed a new issue review process to ensure that topics proposed for review by the RAC are approved by HHS. Because of the extensive implementation startup activities with providers and States across the nation and the establishment of enhanced oversight protocols, the identification and collection of overpayments by the four RACs did not begin until late in the 4th quarter of FY 2009. The initial FY 2009 adjustment and collection files for the national RAC program totaled $63,825. In addition to the initial collections from the national RAC program, residual collections from the demonstration program occurred (those overpayments that were identified before the demonstration end date but were collected after the demonstration end date). These residual RAC demonstration collections in FY 2009 totaled $14.8 million. HHS is on target to complete implementation by January 1, 2010, and HHS expects collections to increase as the implementation process is completed.

9.22 Contracting Actions

HHS for the first time included a "pilot" Comprehensive Error Rate Testing (CERT) program award fee metric into the award fee plan for the Jurisdiction 3 (J3) Medicare Administrative Contractor (MAC). The purpose of this pilot was to utilize contract actions, specifically award fee plans, to create incentives for MAC's to further reduce improper payments. Under this award fee pilot, the J3 contractor could earn some, all or none of the award fee pool for the CERT program metric based on its FY 2008 error rate.

HHS evaluated this metric in spring 2009. The CMS Award Fee Performance Evaluation Board determined that the J3 MAC was eligible for 88 percent of the award fee pool assigned to the CERT metric based on achieving a 2008 CERT score of 3.1 percent, which was below the 3.8 percent *Government Performance Results Act* goal for 2008. From the results of the J3 pilot, HHS will implement the strategy for including a CERT metric into future MAC award fee plans pending availability of contractor-specific error rates and baselines.

9.23 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. Grantees will be encouraged to use the template until OMB clearance for the form can be obtained, at which point the use of the form will be mandatory. 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.

9.24 Public Assistance Reporting Information System

The Public Assistance Reporting Information System (PARIS) is a voluntary Federal-State partnership that provides the participating State Public Assistance Agencies detailed information and data to assist them in maintaining program integrity and detecting/deterring improper payments.

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 reimbursement of State costs for automated data systems to administer the Medicaid State plan, the provision would require States to have in operation a 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 will be issuing a State Medicaid Directors Letter to promulgate this information to the States.

In FY 2009, the newest match with Child Care continued to expand. In the latest August 2009 PARIS match, nine States sent Child Care data as part of the quarterly match, almost double what had been previously sent. This match is in addition to the Federal, State, and Veteran program matches already available to States. One other change in the August match was providing additional data as part of the Veterans match with respect to dependent children that will assist States in determining additional eligibility issues. The August 2009 data match was the largest to date in terms of number of agencies (47) participating and the amount of SSNs submitted. Since last year, seven additional States joined PARIS - Alabama, New Hampshire, Vermont, Texas, North Dakota, Iowa, and Hawaii which translates to PARIS now including all 50 States, DC and Puerto Rico.

10.0 Improper Payment Reduction Outlook FY 2008 – 2012

The chart on the next page shows our IPIA results for the current year (CY) 2009, the prior year (PY) 2008, along with targets for the years 2010-2012.

For each year we show, for each program, outlays for that fiscal year, an error rate or target (IP%), and the dollars paid improperly (IP$).

Improper Payment Reduction Outlook FY 2008 – FY 2012

(Dollars in Millions)

Program	PY Outlays	PY %	PY$	CY Outlays	CY IP%	CY IP$	CY+1 Est Outlays	CY+1 IP%	CY+1 IP$	CY+2 Est Outlays	CY+2 IP%	CY+2 IP$	CY+3 Est Outlays	CY+3 IP%	CY+3 IP$
Medicare FFS	$288,200 Note (a)	3.6	$10.4B	308,418 Note (b)	7.8 Note (1)	$24,100	$335,445 Note (c)	N/A Note (2)	N/A	$348,295	N/A	N/A	$373,651	N/A	N/A
Medicare MC	64,600 Note (d)	10.6	6,848	77,985 Note (e)	15.4 Note (3)	12,010	116,256 Note (f)	14.3 Note (4)	16,625	134,440	13.7	18,420	123,176	13.2	16,300
Medicare Drug	43,740 Note (g)	N/A	N/A	54,869	N/A Note (5)	N/A	64,131	N/A	N/A	71,869	N/A	N/A	68,579	N/A	N/A
Medicaid	177,547 Note (h)	10.5	18,642	188,286 Note (i)	9.6 Note (6)	18,075	281,185 Note (j)	N/A Note (7)	N/A	269,421	N/A	N/A	280,046	N/A	N/A
CHIP	5,676 Note (k)	14.7	834.4	7,855 Note (l)	N/A Note (8)	N/A	9,410	N/A Note (9)	N/A	10,885	N/A	N/A	12,105	N/A	N/A
TANF	17,880	9.3	1,663	20,727	Note (10)	N/A	20,937	N/A	N/A	19,700	N/A	N/A	17,774	N/A	N/A
Head Start	6,878	3.0	206.3	7,113	3.0	213.4	7,235	2.8	202.6	7,235	2.6	188.1	7,235	2.4	173.6
Foster Care	1,551	6.42	99.6	1,610	4.7	75.7	1,546	4.5	69.6	1,385	4.3	58.9	1,317	4.0	52.7
Child Care	4,983	11.5	573	5,245	11.9 Note (11)	624	6,342	11.7	742	6,453	11.2	723	6,181	10.7	661

Improper Payment Reduction Outlook Notes:

(a)
PY Outlays for Medicare FFS are from the November 2008 Improper Medicare FFS Payments Report (based on claims from April 2007-March 2008).

(b)
CY Outlays for Medicare FFS are from the November 2009 Improper Medicare FFS Payments Report (based on claims from April 2008-March 2009).

(c)
Medicare FFS CY+1, CY+2, CY+3 - CY outlay numbers based on FY 2010 Mid-session Review (Medicare Outlays current law (CL)).

(d)
Medicare Advantage PY Outlays are from the Medicare Part C Payment Error Final Report 2008 (based on CY 2006 data).

(e)
Medicare Advantage CY Outlays are from the Medicare Part C Payment Error Final Report 2009 (based on CY 2007 data).

(f)
Medicare Advantage CY+1, CY+2, CY+3 outlay numbers based on FY 2010 Mid-session Review (Medicare Outlays (CL)).

(g)
Medicare Prescription Drug Benefit PY, CY, CY+1, CY+2, CY+3 outlay numbers based on FY 2010 Mid-session Review (Medicare Outlays (CL)).

(h)
PY Outlays for Medicaid are from the 2008 Medicaid Annual Error Rate Report (based on FY 2007 claims).

(i)
CY Outlays for Medicaid are from the 2009 Medicaid Annual Error Rate Report (based on FY 2008 data).

(j)
Medicaid CY+1, CY+2, CY+3 outlay numbers based on FY 2010 Mid-session Review (Medicaid Net Outlays (CL), excluding CDC Program Vaccine for Children obligations).

(k)
CHIP PY outlays are from the 2008 CHIP Annual Error Rate Report (based on FY 2007 data).

(l)
CHIP CY, CY+1, CY+2, CY+3 outlays are based on FY 2010 Mid-session Review (CHIP Total Outlays with CHIPRA Bonus and Health Care Quality Provisions (CL).

1) This report shows that 7.8 percent of the dollars paid nationally did not comply with one or more Medicare coverage, coding, billing, and payment rules. The improper payment amount for the Medicare FFS program for fiscal year 2009 is projected as $24.1 B. Based on both the recommendations contained in recent OIG audit reports and those of CMS' advisory medical staff, HHS modified the medical review process for the November 2009 improper payments report. HHS implemented three separate revisions to the CERT review criteria based on these recommendations. Due to these modifications, the CERT contractor was not able to meet the original goal of 120,000 reviewed claims. Approximately 99,500 claims completed the review process. Of that number, approximately 19,000 claims were reviewed using the most stringent criteria. The national paid claims error rate for those claims reviewed under the strictest criteria, when applied to the entire year, is 12.4 percent or $35.4 billion (this amount was derived from statistical calculations based on the sub-sample reviewed). However, HHS consulted with the OIG concerning the limited time period covered by these claims, and determined that reporting the error rate for this subset of claims only, would not be in compliance with *Improper Payment Information Act* requirements.

2) Given the change in the Medicare FFS methodology (explained in footnote 1), HHS will use 12.4 percent as an estimated baseline, implement corrective actions to reduce improper payments, and set targets not greater than 9.5 percent, 8.5 percent, and 8.0 percent, respectively, for FY 2010 through FY 2012.

3) HHS has taken initial steps and continues to evaluate the benefits of including a dual eligible (a term used to describe beneficiaries eligible for benefits under both Medicare and Medicaid) component in future Medicare Part C error measurements. Of the total Medicare Part C payments of $78 billion for Calendar Year 2007, approximately 3 percent of payments are attributable to dual eligible beneficiaries. While the actual error rate for dual eligibles has not been determined the impact of dual eligibles on the overall Medicare Part C error rate would range from as little as approximately 0.04 percent or $33 million (based on the Medicaid eligible errors for dual eligibles in 5 states) up to approximately 0.07 percent or $55 million (assuming that dual eligibles have the same level of Medicaid eligibility error as the entire Medicaid population).

4) HHS is setting an FY 2009 Part C outyear target rate for CY+1, based on CY 2008 payments, of 14.3 percent, and an estimated gross amount of payment error of $16.6 billion for CY 2008. Additionally, the CY+2 target rate (for CY 2009 payments) is 13.7 percent and the CY+3 target rate (for CY 2010 payments) is 13.2 percent, with estimated gross amounts of payment error of $18.4 billion and $16.3 billion for CY 2009 and CY 2010, respectively. The CY+1 (CY 2008) target rate of 14.3 percent is set using three assumptions about the RAE portion of the Part C composite error: (1) the proportion of beneficiaries with diagnoses is the same in CY 2008 as in CY 2007; (2) the number of diagnoses per beneficiary for CY 2008 is the same as CY 2007; and (3) the proportion between underpayments and overpayments remains constant.

5) For FY 2009 IPIA reporting for the Medicare Prescription Drug Benefit, HHS calculated three components of payment error, based on CY 2007 payments, as described in section 11.31: (1) the Medicare Advantage and Prescription Drug System (MARx) Payment Error (MPE); (2) a payment error relating to Low Income Subsidy status (PELS); and (3) Payment Error Related to Incorrect Medicaid Status (PEMS), where the FY 2007 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. Both the PELS and PEMS measurements reflect errors in the three types of Low Income Subsidy-related payments: Low Income Cost Sharing Subsidy, Low Income Premium Subsidy, and the Direct Subsidy amounts. HHS calculated a Part D MPE rate of 0.59 percent for prospective payments made from January 1, 2007 through December 31, 2007, and estimated a gross amount of payment error totaling $250 million. Estimated Part D MPE underpayments were $233 million and estimated overpayments were $17 million. HHS calculated a Part D PELS error rate of .25 percent for prospective payments made from January 1, 2007 through December 31, 2007, and estimated a gross amount of payment error totaling $106.5 million (all errors are underpayments). HHS calculated a Part D PEMS error rate of 1.06 percent for final reconciled payments made from January 1, 2007 through December 31, 2007, and estimated a gross amount of payment error totaling $449 million (all errors are overpayments).

6) HHS calculated and is reporting the 2-year weighted average national error rate, that includes data from the FY 2007 and FY 2008 cycles. This 2-year average national Medicaid error rate is 9.6 percent. The weighted national error component rates are: Medicaid Fee-for-Service: 5.7 percent; Medicaid managed care: 1.5 percent; and Medicaid eligibility 4.9 percent. The error rate for the States that participated in the FY 2008 cycle is 8.7 percent. The FY 2008 cycle annual component error rate for Medicaid Fee-for-Service is 2.6 percent; Medicaid managed care is 0.1 percent; and Medicaid eligibility is 6.7 percent.

7) The baseline measurement for Medicaid, based on the measurement of 50 States and the District of Columbia (DC) over a three year period (FY 2007 – FY 2009) will be published in the *FY 2010 Agency Financial Report (AFR).* Therefore, setting out-year target rates is not applicable at this time.

8) Section 601 of the *Children's Health Insurance Program Reauthorization Act* (CHIPRA) of 2009 (P.L. 111-3) prohibits HHS from calculating or publishing any national or State-specific error rates for CHIP until six months after a new PERM final rule is effective. HHS issued a proposed rule on July 15, 2009. HHS is currently developing a final regulation as required by CHIPRA. Therefore, HHS is not reporting a national CHIP error rate in the FY 2009 Agency Financial Report.

9) Section 601 of the *Children's Health Insurance Program Reauthorization Act* (CHIPRA) of 2009 *(P.L. 111-3)* prohibits 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 issued a proposed rule on July 15, 2009. HHS is currently developing a final regulation as required by CHIPRA. Following publication of the final regulation and establishment of a baseline, HHS will set out-year reduction targets.

10) The TANF program is not reporting an error rate for FY 2009. HHS is limited in its ability to require State participation in the IPIA process for TANF, per the relevant statutes. HHS is working with all relevant parties to re-formulate the IPIA measurement for TANF so that we can report error rates in future years.

11) The Child Care Development Fund (CCDF) program measures on a three year reporting cycle. The first error rate was reported in the FY 2008 *AFR* and we are reporting the second year error rate in the *FY 2009 AFR*. We will report our first comprehensive baseline measurement in the *FY 2010 AFR* since all grantees will have completed the measurement.

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;
- Actions taken as a result of potential overpayments; and
- Whether there are statutory, regulatory, or information systems barriers that limit potential corrective actions.

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.

11.11 Medicare Fee-for-Service Statistical Sampling Process

The Medicare Fee-for-Service (FFS) improper payment estimate is calculated under the Comprehensive Error Rate Testing (CERT) Program. For the 2009 report period, the Medicare FFS error rate was 7.8 percent.

The Medicare FFS improper payment methodology begins with a random sample of claims. This year approximately 99,500 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.

Changes to the Medicare FFS improper payment measurement program:

In the past, the Medicare FFS improper payment estimate was derived from two programs: the CERT Program and the Hospital Payment Monitoring Program (HPMP). The CERT Program calculated the error rate for Medicare Administrative Contractors (MAC), Carriers, and non-Prospective Payment System (PPS) in-patient Hospital claims submitted to Fiscal Intermediaries (FIs). The HPMP calculated the error rate for PPS in-patient hospital claims submitted to the FIs. Beginning with claims sampled for the FY 2009 report, the CERT program will sample and review the in-patient hospital claims previously reviewed by the HPMP.

Based on both the recommendations contained in recent OIG audit reports and those of CMS' advisory medical staff, HHS modified the medical review process for the November 2009 improper payments report. HHS implemented three separate revisions to the CERT review criteria based on these recommendations. Due to these modifications, the CERT contractor was not able to meet the original goal of 120,000 reviewed claims. Approximately 99,500 claims completed the review process. Of that number, approximately 19,000 claims were reviewed using the most stringent criteria. The national paid claims error rate for those claims reviewed under the strictest criteria, when applied to the entire year, is 12.4 percent or $35.4 billion. However, HHS consulted with the OIG concerning the limited time period covered by these claims and determined that reporting the error rate for this subset of claims only would not be in compliance with IPIA requirements.

11.12 Medicare FFS Corrective Action Plans

The primary causes of improper payments, as identified in the FY 2009 Medicare FFS Improper Payments report, were medically unnecessary services and insufficient documentation errors. Changes in the review approach accounted for the majority of the increases in these error rates. No documentation and insufficient documentation errors have been significantly reduced since the inception of the measurement program. Aggressive actions to better ensure that only legitimate providers and suppliers receive Medicare payments have nearly eliminated no documentation errors caused by potentially fraudulent providers and suppliers that bill Medicare but cannot be located to request medical records. HHS developed an Error Rate Reduction Plan 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 has undertaken numerous aggressive actions to tighten the provider enrollment process, provide more rigorous oversight and monitoring once a provider/supplier enrolls in the program, and strengthen the provider revocation process. HHS implemented a Durable Medical Equipment Accreditation (DME) 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 has established a surety bond requirement for most suppliers of durable medical equipment, prosthetics and orthotics.
- HHS is in the process of publishing the Home Health Prospective Payment System (PPS) Rate Update for

Calendar Year 2010, which includes several payment safeguard provisions designed to: (1) improve our ability to verify that Home Health Agencies (HHAs) meet minimum enrollment criteria and (2) ensure that HHAs that are changing ownership meet and continue to meet Medicare regulations.

- HHS has 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 has taken 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 improvements to the Medicare FFS error rate measurement program to ensure that providers and suppliers submit the required documentation, as follows:

- HHS revised 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.

Authentication and Medical Necessity Errors - Corrective Actions:

- HHS is revising its review manuals to clarify requirements for reviewing documentation to promote uniform interpretation of our policies across all medical reviews performed by Medicare contractors.
- HHS is developing comparative billing reports to help Medicare contractors and providers analyze administrative claims data.
- HHS is undertaking an automated edit demonstration to evaluate the accuracy of several commercial products that purport to deny health care claims that contain Medicare improper payments. The demonstration will determine whether these products are feasible in the Medicare FFS environment and would result in added value to the Medicare FFS program. HHS plans to release a request for proposal for an automated edit contractor during the first quarter of FY 2010, with an award anticipated in September 2010.
- 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 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 over payments identified in the FY 2009 Medicare FFS Improper Payments Report were $4,729,993. 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 $2,626,477 of the actual overpayment dollars identified in the report.

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 State and 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.

11.20 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

In FY 2009, HHS implemented the methodology developed in FY 2008 to estimate improper payments in the Medicare Advantage Program (Part C). The CY 2007 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 2007.
- 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 process, where unsupported diagnoses are identified and corrected risk scores are calculated.

The CY 2007 RAE methodology consists of:

- Selection of a stratified random sample of 651 beneficiaries for whom a risk adjusted payment was made in CY 2007, where the strata are high, medium, and low risk scores. Note that application of strata is an improvement made over the FY 2008 RAE methodology, which was based on a simple random sample.
- Medical record review of the diagnoses submitted by plans for the 651 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 2007 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 2007 total final Part C payments.

FY 2009 is the baseline year for reporting the Part C composite error estimates because, by law, CY 2007 was the first year in which payments to MA plans were 100 percent risk-adjusted. In prior years, MA payments were a blend of risk-adjusted and demographic-only payments.

The Part C composite error rate for CY 2007 is 15.4 percent.

11.22 Medicare Advantage Corrective Action Plans

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 2008 Agency Financial Report.*

For the RAE error estimate, HHS has implemented a corrective action plan. HHS is proceeding with the Risk Adjustment Data Validation (RADV) process to estimate CY 2007 payment error at the contract level for the purposes of conducting payment recovery. Additionally, in CY 2008 HHS conducted national training sessions for Medicare Advantage plans that provided comprehensive information on the processes for submitting accurate risk adjustment data. This training also reviewed RADV procedures based on medical record review and payment error associated with inaccurate risk adjustment data. Finally, outreach to plans is conducted regularly through a monthly user group call, during which any questions pertaining to risk adjustment may be addressed.

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

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.

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

11.31 Part D Statistical Sampling Process

In FY 2008, HHS developed a methodology to estimate improper payments for two components of the Medicare Prescription Drug Benefit (Part D) error rate: the Medicare Advantage Prescription Drug (MARx) Payment Error (MPE), and Payment Error related to Low Income Subsidy (LIS) status (PELS). In FY 2009, in addition to reporting the MPE and PELS estimates, HHS is reporting for the first time the Part D Payment Error related to incorrect Medicaid Status (PEMS).

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 2007.
- Computation of the prospective payment error amount for sampled beneficiaries.
- Extrapolation of the sample payment error to the population, resulting in a Part D gross payment error amount.

For FY 2009, the MPE error rate is 0.59 percent.

The Part D PELS estimate captures errors in three types of Medicare payments to Part D plan sponsors that are affected by beneficiary LIS status: the Low Income Cost Sharing Subsidy (LICS) amount; the Low Income Premium Subsidy (LIPS) amount; and the Direct Subsidy amount, due to the application of the incorrect low-income multiplier to the beneficiary risk score. The methodology consists of:

- For 100 percent of Part D beneficiaries with LIS status in HHS records and/or plan records, identification of those beneficiaries for whom the Part D sponsor records have a more favorable LIS status than HHS' records. (This can occur due to time lags in transfer of LIS status data from other agencies to HHS).
- Computation of the LICS, LIPS, and Direct Subsidy payment error amounts based on the corrected LIS status.
- Computation of the PELS gross payment error amount as the sum of the LICS, LIPS, and Direct Subsidy gross payment error amounts.

For FY 2009, the PELS error rate is .25 percent.

The Part D PEMS estimate captures payment errors due to incorrect assignment of Medicaid status, which result incorrect Low-Income Status-related payments. Full benefit dually-eligible beneficiaries (eligible for Medicare and Title XIX comprehensive health benefits and/or the Medicare Savings Program) are also eligible for the Part D full low-income subsidy. If beneficiaries were incorrectly assigned Medicaid eligibility, the LIS-related payments would be in error. The CY 2007 PEMS estimate is based on the FY 2007 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 is assumed to be a proxy for the rate of incorrect Medicaid status for Part D beneficiaries. The PEMS methodology consists of:

- Application of the PERM eligibility 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 the PEMS gross payment error amount as the sum of the LIS payment amounts in error for the three groups.

For FY 2009, the PEMS error rate is 1.06 percent.

11.32 Corrective Action Plan

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. For the PELS and PEMS components, HHS will continue to resolve LICS, LIPS, and Direct Subsidy payment-related errors through Part D payment reconciliation process.

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.

The LIS payment errors are addressed in separate reconciliation processes. Specifically, Low-Income Cost Sharing payments are reconciled through a cost settlement process. Low Income Premium Subsidy payments are reconciled during the Part D reconciliation process. Errors in the LIS multiplier are reconciled in the Part D Risk Adjustment reconciliation process. Payment adjustments are conducted as a result of these reconciliations.

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 three 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 (IDR). 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.

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

11.41 Medicaid Statistical Sampling Process

The Payment Error Rate Measurement program (PERM) uses a 17-State 3-year rotation for measuring Medicaid improper payments. To select the 17 States for the 3-year cycle, States were ranked by size based on their past Federal Fee-for-Service (FFS) expenditures and grouped into 3 major strata with 17 States in each stratum. The expenditure data showed that 9 States represent the major portion (approximately 50 percent) of total Federal FFS expenditures. To get a precise estimate for the national rate, it was important to make these 9 high-expenditure States their own stratum. Therefore, the 17 States in Strata 1 were further divided into 2 substrata – Stratum 1A (consisting of the 9 States with highest Federal FFS expenditures) and Strata 1B (consisting of the 8 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 3-year cycle, each stratum will have 1 year in which only 5 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 in the FY 2006 cycle, the average FFS sample size was 1,000 claims (managed care was not measured in the FY 2006 cycle). For States in the FY 2007 cycle, the average FFS sample size was 500 claims and the average managed care sample size was 250 claims per State. Since FY 2007 was the first year of the composite measurement, measuring 3 components, HHS reduced the

sample size to ensure timely completion. Experience with the FY 2007 cycle results enabled HHS to keep the sample sizes approximately the same size for the FY 2008 cycle. The FY 2008 cycle results are being published in the *FY 2009 Agency Financial Report.*

Eligibility Component

For FY 2008, 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 and individual State Medicaid program error rates are combined to calculate the national Medicaid program error rate. National component error rates and the Medicaid program error rate are weighted by State size, so that a State with a ten billion dollar program "counts" ten 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."

Beginning next year, HHS will be reporting a baseline error rate for Medicaid and going forward the reported rate will be a "rolling average" of the most recent three years. Since the FY 2008 cycle is the second year that HHS calculated error rates for all components (the FFS component, managed care component, eligibility component) of the Medicaid program, HHS calculated and is reporting the 2-year weighted average national error rate, that includes data from the FY 2007 and FY 2008 cycles. This 2-year average national Medicaid error rate is 9.6 percent. The weighted national error component rates are: Medicaid FFS: 5.7 percent; Medicaid managed care: 1.5 percent; and Medicaid eligibility 4.9 percent.

The error rate for the states that participated in the FY 2008 cycle is 8.7 percent. The FY 2008 cycle annual component error rate for Medicaid is 2.6 percent; Medicaid managed care is 0. Fee-for-Service 1 percent; and Medicaid eligibility is 6.7 percent. HHS also calculated a national case error rate. The active case error rate for Medicaid is 8.9 percent and the negative case error rate is 7.4 percent.

11.42 Medicaid Corrective Action Plans

Overall, the majority of the FY 2008 cycle errors were a result of cases reviewed for eligibility that were either not eligible or undetermined, followed by insufficient documentation and no documentation errors in the Fee-for-Service medical review.

For the FY 2008 cycle, the most common causes of improper payments were:

Medical review:

- Insufficient documentation, and
- No documentation

Data processing review:

- Pricing errors,
- Non-covered services,
- Administrative/other, and

- Managed care payment error

Eligibility review:

- Specific causes of eligibility errors are not reported because States conducted the eligibility reviews. HHS conducted an informal survey of large, medium, and small States to ascertain the causes of eligibility errors. The reasons provided by the surveyed States were: caseworker errors, misapplication of income and resources policies and lack of internal controls

HHS received corrective action plans from all States whose Medicaid programs were measured during the FY 2006 and FY 2007 PERM cycles. Many States are taking steps to reduce errors identified during the measurement, including enhanced provider education to ensure proper documentation is submitted timely and in accordance with PERM requirements. For the FY 2008 measurement, each State is expected to take corrective actions to reduce the most common causes of improper payments within the State. States will submit and implement corrective action plans that 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. HHS is also developing an error rate reduction plan at the Federal level based on its analysis of the FY 2008 measurement.

11.43 Medicaid Program Improper Payment Recovery

For the FY 2006 cycle, the actual Medicaid FFS improper payments identified in the sample were $ 693,319.

For the FY 2007 cycle, the actual improper payments identified for the Medicaid program in the sample were $1,258,525.

For the FY 2008 cycle, the actual improper payments identified for the Medicaid program in the sample were $1,095,473.

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 form for Medicaid which contains a line item for program collections.

Currently the CMS-64 expenditure report does not include space for States to separately report PERM recoveries. Starting in January 2010, the CMS-64 financial report will include a new section where States can separately report PERM recoveries.

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 based on those claims that were only on paper 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 would 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 continues to investigate possible collaborations with States and providers with regard to shared databases, data repositories, and other technology innovations that may benefit the PERM measurement.

Specifically, one of the initiatives HHS is exploring is the development of a common set of data to support a number of Federal and State data needs. HHS is reviewing the data requirements to support the PERM program and comparing these data fields to data requirements to support, among others, the Medi-Medi and Medicaid Integrity programs. The goal through this cross comparison is to develop a common set of data fields that would support HHS needs, thereby reducing the States' burden. An essential benefit of such standardization is to allow the States to collect the needed data in real time in order to meet the requirements with minimal workload impact.

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- Additional Information

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 the FY 2008 cycle. 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.

11.50 CHIP - A joint Federal/State program administered by the States that provides health insurance for qualifying children.

11.51 CHIP Statistical Sampling Process

Section 601 of the *Children's Health Insurance Program Reauthorization Act* (CHIPRA) of 2009 *(P.L. 111-3)* prohibits 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 is currently developing a final regulation as required by CHIPRA. Therefore, for the FY 2008 cycle, HHS is not reporting a national CHIP error rate.

Prior to the passage of CHIPRA and the statutory requirement to prohibit the calculation or publishing of an FY 2008 CHIP error rate, Medicaid and the Children's Health Insurance Program (CHIP) employed the same State sampling process. For detailed information on the State sampling process implemented prior to passage of CHIPRA, please see section 11.41. 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 requirements for IPIA approved 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.

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

HHS received corrective action plans from all States whose CHIP programs were measured during the FY 2007 PERM cycle. Many States are taking steps to reduce errors identified during that measurement, including enhanced provider education to ensure proper documentation is submitted timely and in accordance with PERM requirements. Since HHS is not reporting a national CHIP FY 2008 cycle error rate, the FY 2008 States will not submit a corrective action plan at this time.

States will submit and implement corrective action plans during the next measurement cycle that 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

For the FY 2007 cycle, the actual improper payments identified for the CHIP program in the sample were $539,436.

Improper payments already identified during the FY 2008 cycle, 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 the FY 2008 cycle, the actual improper payments identified for the CHIP program in the sample were $4,570.

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. Currently the CMS-21 expenditure report does not include space for States to separately report PERM recoveries. Starting in January 2010, the CMS-21 financial report will include a new section where States can separately report PERM recoveries.

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 based those claims that were only on paper 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 would 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 continues to investigate possible collaborations with States and providers with regard to shared databases, data repositories, and other technology innovations that may benefit the PERM measurement.

Specifically, one of the initiatives HHS is exploring is the development of a common set of data to support a number of Federal and State data needs. HHS is reviewing the data requirements to support the PERM program and comparing these data fields to data requirements to support, among others, the Medi-Medi and Medicaid Integrity programs. The goal through this cross comparison is to develop a common set of data fields that would support HHS needs, thereby reducing the States' burden. An essential benefit of such standardization is to allow the States to collect the needed data in real time in order to meet the requirements with minimal workload impact. All of these initiatives could impact future CHIP error rate measurements.

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)* prohibits 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 issued a proposed rule on July 15, 2009. HHS is currently developing a final regulation as required by CHIPRA. Therefore, for the FY 2008 cycle, HHS is not reporting a national CHIP error rate. Since HHS is prohibited from calculating or publishing a CHIP error rate during this period, HHS cannot require FY 2008 cycle States to implement corrective actions.

11.56 CHIP- Additional Information

Based on lessons learned through previous Payment Error Rate Mechanism (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 2008. 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. 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.

11.60 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

The TANF program is not reporting an error rate for FY 2009 and had no sampling activity in that year. HHS is limited in its ability to require State participation in the IPIA process for TANF, per the statute. HHS is working with all relevant parties at the State and Federal levels to re-formulate the IPIA measurement for TANF so that we can report error rates in future years.

HHS' Office of Inspector General (OIG) conducted the reviews of the TANF program in prior years. The objective was to determine whether the State agency made TANF basic assistance payments to recipient families in accordance with Federal and State requirements, as demonstrated by adequate documentation of eligibility and payment determinations.

The sampling universe for each State consisted of all TANF basic assistance payments made for a 12-month audit period. The sample unit was a monthly TANF basic assistance payment to a recipient family for the audit period. The payment includes all basic assistance payments made to the family for the month. OIG used a simple random sample and sequentially numbered the payments in the sampling frame and selected the sequential numbers that correlated to the random numbers generated.

The OIG determined whether each sampled payment was improper based on Federal and State laws, regulations, and other requirements. Specifically, if at least one of the following characteristics was met, OIG considers the payment under review improper:

- The recipient family did not meet one or more eligibility requirements.
- The recipient family was eligible for assistance but received an improper payment amount (overpayment or underpayment).
- The case file did not contain sufficient documentation to support eligibility and payment determinations as required by Federal and State regulations.

11.62 TANF Corrective Action Plans

HHS does not have new corrective action plans for FY 2009, given that no measurements were performed this year. However, we have taken the following corrective actions in previous years. HHS annually submitted a letter to all TANF States with recommendations for potential corrective actions based on the reviews done by OIG. The reviews show that the primary causes of error are ineligible recipients, incorrect payment amounts and insufficient documentation. State may employ these recommendations in their corrective action efforts to reduce future improper payments.

11.63 TANF Improper Payment Recovery

Due to legislative restrictions, HHS is not able to recover improper payments in the TANF program, nor do we have the authority to require States to recover improper payments.

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) matching program, 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 that could limit Corrective Actions

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.

11.66 TANF- Additional Information

Here are some of the best practices developed by program managers over the years:

- 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 and 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, "hits" from the Income Eligibility Verification System , redeterminations of eligibility, or failure to fulfill work requirements;
- Establish a process for the collection of TANF overpayments from the applicable recipients;
- Periodically remind 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; and
- 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.

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.

11.71 Foster Care Statistical Sampling Process

There have been no changes to the statistical sampling process for title IV-E Foster Care since the FY 2008 report. 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 receiving at least one IV-E Foster Care maintenance payment during the PUR. An error case is defined as a case in which a 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, "ineligible" payments made to non-error cases which failed to meet an eligibility criterion outside the PUR, and "unallowable" payments for services not covered by title IV-E or its regulatory provisions (e.g. therapy).

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) Foster Care takes a disallowance, (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 cases 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 140 regulatory Foster Care reviews, with over 13,000 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. Last year's FY 2008 error rate estimate reflected a transition from a 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 2009, the Foster Care estimated national payment error rate is 4.70 percent. This represents a decrease compared to the FY 2008 error rate of 6.42 percent.

11.72 Foster Care Corrective Action Plans

As first reported in FY 2008, all payment errors in IV-E Foster Care fall under the rubric of "Verification and Local Administration" errors (i.e., root cause of errors). Thus, all corrective action plans are targeted to improving verification and processing of eligibility information in State and local agencies as well as courts. Corrective action plans instituted by the Children's Bureau to address improper payments in the Foster Care program have been designed to address those eligibility errors and other payment errors (e.g., underpayments) that have contributed most to improper payments. In 2009, the major contributors to payment errors for the Foster Care program included the following:

- Underpayments (28 percent of errors)
- Provider not licensed or approved (13 percent of errors)
- Ineligible payment (e.g., therapy) 12 percent of errors)
- Not AFDC eligible under "Aid to Families with Dependent Children" standards at time of removal (9 percent of errors)
- Criminal records check not completed (7 percent of errors)

- Judicial determination regarding reasonable efforts to finalize permanency plan not timely (6 percent of errors)
- No judicial determination of reasonable efforts to prevent removal (5 percent of errors)

Together these seven items account for about 80 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) increased by about eight percent from FY 2008 to FY 2009. However, total payment errors for the program for FY 2009 remain far below the initial level of eligibility errors reported in the program's FY 2005 Corrective Action Plan. Thus, since the inception of these improper payment reduction efforts solid progress has been made in reducing payment errors across the program. In FY 2009, the most frequently identified payment error across Foster Care reviews is underpayments which account for 28 percent of all errors).

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 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.

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. Subsequent rulings by the Departmental Appeals Board reversed some errors for one of three States contributing to the increase in FY 2008. These changes are incorporated in the FY 2009 update. In 2009, the error rate decreased to 4.70 percent.

11.73 Foster Care Improper Payment Recovery

As a result of its conducting Foster Care eligibility reviews in 17 States during the 12-month period of August 2008 - July 2009, HHS has recovered over $1 million in title IV-E improper payments. The funds recovered are comprised of $535,000 in disallowed maintenance payments and $751,000 in disallowed administrative payments. The following table shows improper payments recovered through IV-E Foster Care reviews from FY 2004 through FY 2009 (dollars in millions).

FY	Reporting Period	# Reviews	Maintenance Disallowance	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

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- Additional Information

Since the inception of its improper payment reporting, HHS has maintained diligent focus on improper payments identification and reduction efforts. 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 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 4.70 percent in FY 2009. Furthermore, in the years since baseline reporting commenced, the IV-E Foster Care Program has recovered a total of $10.4 million in improper payments.

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. Head Start provides diverse services consistent with its goals for success in education, health, parent involvement and social services.

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 FY 2008 Erroneous Payments study, the FY 2009 study selected 50 programs and alternates. Programs were selected through a stratified random sample, where programs were divided into five stratum by 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 2009 Erroneous Payments Study, 50 Head Start programs from 23 states and Puerto Rico were reviewed. Approximately 11,200 records were examined. 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 ten 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 from the staff in the file.

The FY 2009 error rate is 3.0 percent, the same as FY 2008. The factor that contributed most to the rate is a single, large grantee that had flawed signed statements in a significant majority of its children's files.

Also included this year was a formal examination of the *2007 Head Start Act* requirement regarding the eligibility of children whose families fall between 100 percent 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 primary error in the Head Start review is the absence of a complete and accurate signed income verification statement, meeting regulatory requirements, in the grantees' files. The grantee develops a corrective action plan based on its findings.

In addition, HHS has taken the following actions:

- Issued a memorandum reminding all grantees of documentation requirements.
- Developed a standard signed statement template form, which was made available to all grantees in FY 2009. Grantees are encouraged to use the form until OMB clearance for the form can be obtained, at which point the use of the form will be mandatory.
- HHS regional offices are providing increased oversight regarding documentation.
- Increased grantee emphasis for on-going monitoring through training and development of a monitoring protocol to review management systems.

11.83 Head Start Improper Payment Recovery

Given the recent legislative changes to Head Start, HHS is reviewing the potential for seeking recoveries in Head Start. Currently there is no recovery activity for this program.

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 that could limit Corrective Actions

The *Head Start Act* does not require grantees to maintain documentation supporting eligibility in a case file. Grantees are only required to maintain a signed statement verifying eligibility. Monitoring of grantees' compliance with eligibility requirements is therefore limited to whether the case file contains a signed eligibility statement.

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

11.91 Child Care Statistical Sampling Process

The Child Care Development Fund (CCDF) Error Rate methodology is conducted on a 3-year cycle, beginning with Year One States whose baseline FY 2007 data were reported in last year's *FY 2008 AFR.* For the *FY 2009 AFR*, Year One and Year Two States data have been combined to generate the payment error rate and related findings reported below.

For FY 2008 and FY 2009, Year One and Year Two 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 the error rate calculation, 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 authorizations for payment rate for the CCDF program.

For FY 2008, reported in the *FY 2009 AFR*, the Child Care and Development Fund (CCDF) program payment error rate or percentage of improper authorizations for payment is 11.9 percent. The national over-authorization error rate, or the percentage of authorizations in excess of the amounts for which cases are eligible, is 11.5 percent. The percentage of under-authorizations is equal to .4 percent.

HHS uses a 3-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 3-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 number of cases. Every third State on the list was then selected, using a random start number 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 15 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 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 presences 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 a 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).

Further, there are inherent challenges in establishing a national error measure for a block grant program like CCDF. Under CCDF, each State is given maximum flexibility in developing child care programs and policies that best suit the needs of children and parents within the State. As a result, there is significant variation in how CCDF is implemented across the country. Since CCDF eligibility and documentation requirements vary greatly across States, individual State error rates cannot easily be aggregated or compared to one another.

11.92 Child Care Corrective Action Plans

Fifty-four percent of the improper authorization for payment errors were 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 while less common, (5) States also cited lack of documentation for the child's citizenship, correct household size/composition, and provider materials.

Most frequently cited reasons for errors due to a cause other than missing or insufficient documentation were: (1)income calculation errors including: 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; and (4) incorrect inclusion or exclusion of household members.

Year One and Year Two States described a range of corrective actions they had taken or planned to take based on the findings of the case record review to reduce the amount of improper authorizations for payment. The primary strategy reported by States was to conduct ongoing case record reviews. Several States plan to use the results from reviews to monitor additional corrective initiatives including: training, policy clarification, performance improvement plans, increased awareness through review of results, and targeted corrective actions to managers. States reported action steps to hold staff accountable at the both the agency and staff level. Agency accountability steps included performance improvement plans, decisions on whether or not to contract with local agencies based on payment accuracy performance, and annual management reviews with corrective action plans if case reviews fail to meet targets.

HHS corrective actions for payment errors associated with missing and insufficient documentation include:

- HHS provides technical assistance specifically designed to meet the individual needs of the States. Training helped States focus on effective and proper administration of the CCDF program through increased awareness on staff training, improving knowledge of State policies, eligibility determination procedures, documentation requirements, and the quality of routine case reviews.
- HHS works with States to explore technological avenues that can help reduce errors associated with missing and/or insufficient documentation. An Information Memorandum drafted by the Child Care Bureau (CCB) Central Office and disseminated to CCDF grantees regarding *American Recovery and Reinvestment Act* funds highlighted the flexibility of programs to build enhancements to their Information Technology systems.
- The annual State and Territories Administrators' Meeting in July 2009 highlighted training and peer sharing. Information was shared regarding errors identified during the Error Rate Review process and the major causes of those errors. States shared their experiences with the Review process, lessons learned, and promising practices they have implemented in their child care programs as a result of the Error Rate Review process. Some of these practices include: calculation tools and checklists for workers to ensure accuracy in the application process, additional case record reviews and corrective action plans based on errors found.

HHS corrective actions for other types of payment errors include:

- HHS revised the CCDF Plan Pre-Print to require States to submit information on strategies implemented to prevent, measure, identify, reduce and/or collect improper payments. Information from the FY 2010 Plans will be summarized and made available to States and the general public in spring 2010.
- HHS continues to work with State Child Care Administrators to promote participation in the Public Assistance Reporting Information System (PARIS) program which is a data matching process that can help States identify duplicate receipt of benefits and reduce fraud and improper payments.
- Technical Assistance continues to provide value to the States, including the use of individualized webinar training, site visits, conference calls, and peer-to-peer sharing of review documents and other tools.
- HHS continues to make available to States:
  - *State Internal Control Self-Assessment Instrument,* as a systematic method for reviewing and documenting the adequacy of a State's internal control system, identifying internal control weaknesses, and providing documentation of findings and possible corrective actions. This tool was developed in FY 2006 and is posted on the CCB Website: www.acf.hhs.gov/programs/ccb.
  - *State Survey Analysis Report* which summarizes survey responses from 24 States about the design and scope of their CCDF systems used for administering the child care program and managing improper payments. Available on the web-site, HHS has utilized responses to this survey to promote sharing of best practices among States.

11.93 Child Care Program Improper Payment Recovery

For FY 2009, the actual CCDF improper authorizations for payment identified in the sample review was $220,314 for Year Two States.

Recoveries for Year One States were $175,610, as reported in the *FY 2008 AFR*.

As stated earlier, the CCDF methodology distinguishes between authorizations for payment and actual payments made to providers. Therefore, the amount of improper authorizations for payment identified by Year One and Year Two States during the review process does not represent actual improper payments. In general, the amount of payments is lower, computed to be on average about 15 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. In the event that improper payments identified through the case review process are recovered, 45 CFR 98.60 (g) 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.

11.94 Child Care Program Information Systems and Other Infrastructure.

Since child care 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 Year One and Year Two States report having sufficient infrastructure to meet designated targets. Eight States report actively working toward updating their computer data systems and three States plan to have new systems in place before their next review cycle.

While the majority of Year One and Year Two 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.

11.95 Child Care Program 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.

11.96 Child Care Program- Additional Comments

The following are promising practices regarding the CCDF Error Rate Review and Improper Payments utilized by HHS staff this year:

- Provided 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.
- Provided 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.
- Convened conference calls with all stakeholders regarding promising practices, findings, training opportunities, and sharing of tools and information.
- Conducted sessions on improper payments and lessons learned from the Error Rate Review process at the National State Child Care Administrators' Conference.
- Assigned 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 ACF Regional and Central Offices.
- Planned 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.

MANAGEMENT REPORT ON FINAL ACTION
October 1, 2008 – September 30, 2009

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 2009, there were no disagreements requiring the convening of the Conflict Resolution Council.

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.

Final Action Tables and Departmental Findings

Table 1 – 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 or grant term or condition.

- In FY 2009, HHS initiated recovery action, through collection, offset or other means, on 331 cases for a total of $492,516,000.
- In FY 2009, HHS completed recovery action, through collection, offset or other means, on 331 cases for a total of $573,937,000.
- As of September 30, 2009, HHS reports 183 outstanding balances over one year old totaling $2,462,220,401. Sixty-two percent of these account receivable balances are currently being pursued for collection. The account receivables balances are owed by State and local governments (77), hospital and medical related organizations (47), nonprofit organizations (26), Indian tribes (23), 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/asrt/of/finpollilibrary/financialpolicies/outstandingbalances2009.html.

TABLE 1

MANAGEMENT ACTION ON COSTS DISALLOWED IN OIG REPORTS
As of September 30, 2009
(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.	278	$2,831,247
B. Reports on which management decisions were made during the reporting period. See Note 2.	331	$492,516
Subtotal (A+B)	609	$3,323,763
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.	331	$573,937
ii. The dollar value of disallowed costs that were written off by management.	10	$621
Subtotal (i+ii)	341	$574,558
D. Reports for which no final action has been taken by the end of the reporting period. See Note 3.	268	$2,749,205

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 $2,462,220,401 (e.g., audits under current collection schedule or audit under administrative or judicial appeal).

Table 2 – 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 2009, HHS initiated action on $1,784,313,000 in OIG recommendations to put funds to better use.
- In FY 2009, HHS completed action on $1,807,537,000 in OIG recommendations to put funds to better use.

TABLE 2

MANAGEMENT ACTION ON OIG REPORTS
with Recommendations That Funds Be Put to Better Use
As of September 30, 2009
(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.	14	$47,693
B. Reports on which management decisions were made during the reporting period.	24	$1,784,313
Subtotal (A+B)	38	$1,832,006
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.	23	$1,807,537
ii. The dollar value of recommendations that management has subsequently concluded should not or could not be implemented or completed.	0	$0
Subtotal (i+ii)	23	$1,807,537
D. Reports for which no final action has been taken by the end of the reporting period.	15	$24,469

Notes:

1. Includes adjustments of amended disallowance and disallowance excluded from the previous reporting period.

SUMMARY OF FINANCIAL STATEMENT AUDIT AND MANAGEMENT ASSURANCES

TABLE 1 SUMMARY OF FINANCIAL STATEMENT AUDITAL STATEMENT AUDIT					
Audit Opinion			Unqualified		
Restatement			No		
Material Weaknesses	**Beginning Balance**	**New**	**Resolved**	**Consolidated**	**Ending Balance**
Financial Reporting, Systems, Analyses & Oversight	☑				☑
Financial Management Information Systems	☑				☑
Total Material Weaknesses	***2***	***0***	***0***	***0***	***2***

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					
Material Weaknesses	**Beginning Balance**	**New**	**Resolved**	**Consolidated**	**Reassessed**	**Ending Balance**
Financial Reporting Systems & Processes	☑					☑
Total Material Weaknesses	***1***	***0***	***0***	***0***	***0***	***1***

Effectiveness of Internal Control over Operations (FMFIA #2)

Statement of Assurance	Qualified					
Material Weaknesses	**Beginning Balance**	**New**	**Resolved**	**Consolidated**	**Reassessed**	**Ending Balance**
Information System Controls and Security	☑					☑
Total Material Weaknesses	***1***	***0***	***0***	***0***	***0***	***1***

Conformance with financial management system requirements (FMFIA #4)

Statement of Assurance	Non-conformance					
Non-Conformances	Beginning Balance	New	Resolved	Consolidated	Reassessed	Ending Balance
Financial Reporting Systems & Processes	☑					☑
Information System Controls and Security	☑					☑
Total Non-Conformances	***2***	***0***	***0***	***0***	***0***	***2***

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

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Washington, D.C. 20201

TO: The Secretary
Through: DS _____
COS _____
ES _____

FROM: Inspector General

SUBJECT: Top Management and Performance Challenges in the Department of Health and Human Services for Fiscal Year 2009

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) 2009. 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 2009 includes the following:

Part I: Integrity of Medicare, Medicaid, and 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 II: Integrity of the Department's Public Health and Human Services Programs
- Emergency Preparedness and Response
- Oversight of Food, Drugs, and Medical Devices
- Grants Management

Part II: Cross-Cutting Issues That Span the Department
- American Recovery and Reinvestment Act
- Health Information Technology and Integrity of Information Systems
- Ethics Program Oversight and Enforcement

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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, Acting Director of External Affairs, at (202) 205-9523 or Erin.Lemire@oig.hhs.gov.

Daniel R. Levinson

Daniel R. Levinson

Attachment

FY 2009 TOP MANAGEMENT AND PERFORMANCE CHALLENGES IDENTIFIED BY THE OFFICE OF THE INSPECTOR GENERAL

Pursuant to the *Reports Consolidation Act of 2000* (P.L. 106-531), each year the Office of Inspector General (OIG) summarizes what OIG considers to be the most significant management and performance challenges facing the Department of Health and Human Services (Department) and the Department's progress in addressing those challenges. The top management challenges for fiscal year (FY) 2009 are organized according to three broad categories: (1) integrity of 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 1: 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 remediate fraud, waste, and abuse. Based on its extensive experience in combating health care fraud, waste, and abuse, OIG has identified the following five principles that OIG believes should guide the Department's integrity strategy for Medicare, Medicaid, and CHIP. These principles offer a useful framework for implementing programs, as well as designing and implementing integrity safeguards.

- **Enrollment** – Scrutinize individuals and entities that seek to participate as providers and suppliers prior to their enrollment 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 detected fraud, impose appropriate punishment to deter others, and promptly remedy 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 for future generations.

In addition, a sixth management challenge is ensuring that the beneficiaries of Federal health care program receive quality health care. This challenge has many dimensions, including overseeing providers' compliance with quality-of-care standards, ensuring patient safety, and identifying opportunities for improvements in quality of care.

Management Issue 1: Integrity of Provider and Supplier Enrollment

MANAGEMENT CHALLENGE AND ASSESSMENT OF PROGRESS IN ADDRESSING THE CHALLENGE:

The large Federal Government expenditures on the Medicare and Medicaid programs attract certain individuals and entities that seek to exploit the health care system for their own financial gain. Although the vast majority of health care providers and suppliers are honest and well intentioned, the Department faces challenges ensuring the integrity of the programs' provider and supplier enrollment processes. A small percentage of providers and suppliers intent on defrauding these programs have exploited weaknesses in the enrollment process, causing significant harm. These providers and suppliers drain resources that should be spent on providing needed and appropriate care to beneficiaries. Therefore, it is imperative that Medicare and Medicaid provider and supplier enrollment standards and screening processes be strengthened to clarify that participation as a provider or supplier is a privilege, not a right.

OIG's extensive oversight and enforcement work has identified weaknesses in provider and supplier enrollment that enable unqualified, dishonest, and unethical individuals and entities to access a system they can easily exploit. In addition, OIG identified weaknesses in the oversight of provider and supplier eligibility to receive certain payments under Medicare and Medicaid. More rigorous enrollment, screening, and transparency standards would help the Government better know with whom it is doing business. Protecting these programs and their beneficiaries from unqualified, fraudulent, or abusive providers and suppliers up front is more efficient and 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 strengthen the integrity of the Medicare and Medicaid programs. OIG identified certain characteristics that may indicate a provider's increased potential for fraud. Examples of potential fraud or risk indicators include interest or ownership in other health services 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 other sanctions by State Medicaid agencies or other health care organizations. Current provider enrollment standards and screenings do not use all these fraud indicators to determine a provider's level of risk for fraudulent conduct.

OIG has identified significant vulnerabilities in the enrollment screening of durable medical equipment (DME) suppliers and high rates of noncompliance with enrollment standards. In 2006, OIG conducted unannounced site visits of 1,581 DME suppliers in three south Florida counties and found that 31 percent did not maintain physical facilities or were not open and staffed, contrary to Medicare requirements. Similarly, in 2008, OIG inspected 905 suppliers in Los Angeles County and found that 13 percent did not have physical facilities or were not open during repeated unannounced site visits. In 2008, OIG examined a small random sample of DME suppliers with uncollectible Medicare debt and found that these suppliers were associated with other DME suppliers and home health agencies (primarily through shared ownership, management, or family relationships) that had received approximately $58 million in Medicare payments. The associations are of interest because Federal investigators suspect, and have found in some cases, that individuals associated with the Medicare debt may omit ownership or management information on enrollment applications and inappropriately receive Medicare payments through businesses publicly fronted by associates or family members.

To address these DME enrollment vulnerabilities, OIG recommended more rigorous screening of provider and supplier applicants. Heightened screening measures for high-risk items and services could include requiring providers to meet accreditation standards; requiring proof of identity and licensure (e.g., fingerprinting, database checks, and in-person interviews); requiring proof of business integrity or surety bonds; periodic recertification and onsite verification that conditions of participation have been met; and full disclosure of ownership and control interests, including disclosure of affiliations with other providers or suppliers with uncollected Medicare or Medicaid debt. As this additional screening would be costly for CMS to conduct, OIG suggested that CMS consider charging application fees to cover the increased costs. In addition, OIG has suggested that establishing a provisional enrollment period during which new Medicare and Medicaid providers and suppliers would be subject to enhanced oversight, such as prepayment review and payment caps could reduce fraud vulnerabilities.

The Department has made progress in responding to these vulnerabilities with measures aimed at enhancing enrollment standards for DME suppliers. On November 1, 2007, the Centers for Medicare & Medicaid Services (CMS) began a demonstration project requiring DME suppliers in south Florida and southern California to reapply for participation to maintain their privileges. On January 25, 2008, CMS published regulations to clarify and enhance supplier standards. CMS also stated that it would consider seeking legislative authority to impose temporary moratoriums on supplier enrollment. On January 1, 2009, CMS published regulations requiring certain DME suppliers to obtain surety bonds as a prerequisite for enrolling and maintaining enrollment in the Medicare program. OIG recognizes this progress and continues to recommend further improvements to oversight and enforcement of provider enrollment standards.

In other work, OIG investigations identified a fraud scheme involving foreign nationals who obtained Medicare provider numbers that they subsequently 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 subsequently 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 surveyors examine the Employment Eligibility Verification document (Form I-9) for the owner and key employees as part of the accreditation process. Until the vulnerabilities demonstrated by this fraud scheme are addressed, Medicare continues to risk exposure to fraudulent claims by ineligible providers.

The Department also faces challenges stemming from the variation in Medicaid provider and supplier enrollment standards, which can vary both across States and for providers within a State. An OIG evaluation of State Medicaid enrollment requirements for personal care attendants found that State Medicaid programs established multiple sets of provider requirements for personal care attendants that often vary among programs and by delivery models within programs, resulting in 300 sets of provider requirements nation-wide. An OIG audit of Medicaid

personal care services in New York City underscores the importance of enrollment standards and oversight of personal care service attendants to ensure beneficiary safety and quality of care. As part of the audit, OIG interviewed 65 beneficiaries, of whom 40 reported problems with their personal care services attendant or agency or other problems. The reported problems ranged from personal care attendants' engaging in activities unrelated to beneficiary care while on duty to beneficiary abandonment to physical abuse.

In addition, OIG identified challenges related to nursing home ownership transparency. (See also Management Issue 6.) 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. OIG has ongoing work determining whether nursing homes conduct criminal records background checks for employees and whether nursing homes are protecting residents from unqualified or excluded individuals.

Provider and Supplier Eligibility for Certain Payments

Eligibility requirements for certain types of payments help ensure that the providers furnishing items and services to beneficiaries can be relied on to deliver the needed care and meet program criteria. OIG identified instances in which Medicare and Medicaid made payments to providers who were improperly enrolled or were not eligible to receive those payments. These conditions raise concerns about enrollment oversight.

For example, in a review of Medicare capital disproportionate share hospital (DSH) payments made between FYs 2000 and 2006, OIG found that 397 hospitals received $21.9 million in 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 to receive DSH 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 in-patient psychiatric services because it did not demonstrate compliance with two special Medicare conditions of participation requirements.

OIG audits at two Medicare fiscal intermediaries found that unallowable payments totaling $890,000 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 and fiscal intermediaries to assess capital DSH eligibility as part of their review process. 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.

Management Issue 2: Integrity of Federal Health Care Program Payment Methodologies

MANAGEMENT CHALLENGE AND ASSESSMENT OF PROGRESS IN ADDRESSING THE CHALLENGE:

The Federal Government should act as a prudent purchaser of health care. Medicare and Medicaid payment methodologies should ensure access to quality care without wasteful spending. This objective is of paramount importance in maintaining an effective and efficient health care delivery system. The challenges associated with meeting this objective are complex and evolving. Initial payment methodologies must be set to reimburse 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 should anticipate financial incentives and safeguard against fraud risks associated with each payment methodology established.

Setting Initial Payment Methodologies

As Federal health care programs are created, expanded, or revised, it is critical to establish initial payment rates based on the most accurate data available, as well as reasonable assumptions and projections. OIG has identified instances in which issues with the initial data used in payment methodologies have resulted in increased expenditures by both Medicare and its beneficiaries.

For example, aligning Part D payments by Medicare and beneficiaries with plan sponsors' actual costs has been a challenge. Currently, Medicare payments and beneficiary premiums are determined based on bids submitted by plan sponsors and approved by CMS before to the start of the plan year. Ongoing OIG work has found that plans excluded some anticipated rebates from their bids, resulting in a higher net bid amount and therefore higher Medicare payments and beneficiary premiums than if the anticipated rebates had been included. In another review, OIG found that 25 percent of CMS's bid audits of Part D plans for 2006 and 2007 identified at least one material error. Although these audits may influence future bids, they are completed after the bids have been approved for the current plan year. CMS does not adjust a plan's payment amount or beneficiary premiums based on errors

or omissions identified after a bid has been approved. OIG has recommended that CMS hold plans accountable for the accuracy of their bids, and CMS stated that it would consider OIG's recommendation.

In 2006 and 2007, estimated costs in sponsors' bids were higher, in the aggregate, than their actual costs, which resulted in higher Medicare payments and premiums. Medicare recoups a percentage of these higher payments through the reconciliation process following the plan year. Beneficiaries do not recoup any money paid in higher premiums. In 2006, Part D sponsors owed Medicare a net total of $4.4 billion. In 2007, 154 sponsors owed Medicare a total of $1.81 billion and 97 sponsors were owed $1.79 billion from Medicare, resulting in a net total of $18 million owed to Medicare. Seventy-one percent of sponsors earned unexpected profits in 2007 large enough to trigger risk-sharing payments of $795 million due to Medicare. Statutory changes to risk sharing that begin with the 2008 reconciliation will decrease the Federal Government's share of sponsors' unexpected profits and losses. Therefore, if sponsors continue to make large unexpected profits in 2008 and beyond, they will return a smaller percentage to the Federal Government. To mitigate this risk, OIG recommended that CMS determine whether changes to the risk sharing are appropriate, and if so, to seek a statutory change.

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. CMS noted, however, that it does not believe that changes to risk sharing are appropriate because plans now have sufficient data on Part D costs to develop bids that are more accurate.

Concerns about the accuracy of Medicare's prospective payments to hospitals also demonstrate the importance of setting appropriate initial reimbursement methodologies. For example, the *Balanced Budget Act of 1997* required CMS to develop a prospective payment system for hospital out-patient department services based on prior claims and cost report data. However, previous OIG work had identified unallowable costs in hospitals' Medicare cost reports and several areas of payment improprieties in Medicare reimbursement for hospital out-patient departments. Because the hospital out-patient prospective payment system is based on data known to be problematic, OIG is concerned that the resulting payments are inaccurate.

OIG reviews have also determined that Medicare payments for certain DME do not accurately reflect the costs of these products. Before 1986, Medicare paid DME suppliers the amounts that the suppliers billed. In 1986, a DME fee schedule was created, which was based on the average prices that Medicare had paid (i.e., the billed amounts) for each type of equipment. This system has resulted in Medicare payments that do not reflect market prices. For example, OIG found that Medicare allows more than $7,000 for 36 months of rental payments for oxygen concentrators that cost $587, on average, to purchase. OIG has recommended that CMS consider working with Congress to reduce the rental period so that Medicare payments more accurately reflect market prices.

CMS's main initiative to reduce beneficiary costs and improve the accuracy of Medicare payments for certain categories of DME is the Competitive Bidding Acquisition Program. Although CMS started to implement the program in 2008, legislation delayed its implementation. CMS plans to restart the program in 2009 in 10 areas, which CMS expects to result in an average 26-percent decrease in the prices of medical equipment in these areas.

Payments to Medicare Advantage organizations may also be higher than necessary. Based on numerous reviews of the Medicare + Choice program (the predecessor to Medicare Advantage), OIG concluded that the data and estimates used as the basis to calculate monthly capitation payments were flawed, resulting in higher payments. This inflated base year data continue to affect the current payments to Medicare Advantage plans, which have not been adjusted to take into account these problems with the underlying data. OIG plans to further examine payments to Medicare Advantage organizations.

Responding to Changes in the Marketplace and Health Care Practices

The Department also faces a substantial challenge to react swiftly and appropriately to changes in the marketplace and medical practices so that the programs continue to effectively reimburse for quality care. OIG has conducted extensive 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 payments for new wound therapy pumps provide one example of the costs of failing to update payments in response to market changes. OIG found that in 2007, Medicare reimbursed suppliers for negative pressure wound therapy pumps based on a purchase price of more than $17,000, but that suppliers paid, on average, approximately $3,600 for new models. When Medicare first covered wound pumps, it covered only one model, manufactured and supplied by one company, and Medicare based the payment on that company's purchase price. When Medicare expanded its coverage to several new pump models, it continued to reimburse suppliers for these new pumps based on the original pump's purchase price,

which is more than four times the average price paid by suppliers for new pumps.

OIG has also raised concerns regarding Medicaid and Medicare Part B prescription drug reimbursement. OIG studies have revealed that published prices used to set Medicaid Federal upper limit (FUL) amounts for multiple source (generic) drugs often exceeded prices available in the marketplace. A new FUL reimbursement methodology using average manufacturer price, a sales-based price used in the Medicaid drug rebate program, has been established but not implemented because of a court injunction. Therefore, FUL amounts continue to exceed marketplace prices. In addition, OIG work has demonstrated that Medicare payment rates for some Part B drugs are higher than other prices in the marketplace. Further, the Part B drug reimbursement methodology can result in temporarily inflated payment amounts when newly available generic versions enter the market. To date, no changes have been made to Part B reimbursement as a result of OIG's work.

Payment methodologies for other Medicare benefits also present challenges in responding to marketplace changes. For example, OIG found that Medicare Part B payments for laboratory tests, which were established over 20 years ago, vary within and between Medicare contractors. These variances did not appear to reflect geographic differences in costs. To align payment methodologies, OIG recommended that CMS seek legislation to establish a new process for setting accurate and reasonable payment rates. CMS did not concur with this recommendation. However, CMS stated that it would consider OIG's recommendation as the agency continues to monitor the effects of its current payment policies.

OIG also 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. These misalignments in global eye surgery payments are attributable, in part, to CMS 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.

Payment Incentives and Risks of Fraud and Abuse

Payment methodologies inherently create incentives and risks for fraud. For example, Fee-for-Service (FFS) payments create financial incentives to maximize the number and complexity of services provided, even when such services are not medically necessary. Conversely, under a fixed, prospective payment system, financial incentives encourage fewer services and patients may not receive all of the care that they need and for which the program is paying. For any payment methodology, it is imperative to identify the incentives and associated risks that it creates and to implement necessary safeguards to remediate the negative incentives and reduce fraud risks. This challenge is compounded by the need to react swiftly to new and unanticipated fraud and abuse schemes that exploit vulnerabilities in established payment methodologies.

OIG's work on Medicare and Medicaid outlier payment highlights the importance of this challenge. Recent investigations have identified abuses of CMS's home health outlier payment methodology, which has resulted in providers' receipt of significant outlier payments to which they are not entitled. Ongoing OIG work is further examining vulnerabilities related to this payment methodology. In response to evidence of abuse of home health outlier payments, CMS proposed a rule in July 2009 that would lower the total amount of home health outlier payments available and would cap outlier payments to individual home health agencies. Implementation of this rule could provide an important safeguard to prevent abuse of the home health outlier payment system.

Similarly, OIG found in prior work that Medicare payment methodologies for in-patient outlier payments had loopholes whereby inflated charges submitted by hospitals and delays in fiscal intermediary financial analysis of hospital data resulted in hundreds of millions of dollars of wasteful spending. Policy changes were subsequently made and financial settlements with selected hospital groups were reached. OIG has also completed work in several States that has shown that if the 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 instance, Medicare had a policy of not paying for pre-admission diagnostic tests within 24 hours of the patient's admission to a hospital. OIG found that in response to this rule, hospitals were performing the tests shortly in advance of the 24-hour period. Although the timeframe was extended based on OIG recommendations to within 72 hours of admittance, subsequent OIG work showed that hospitals responded to this change in payment policy by performing the tests up to 2 weeks before the admittance date so that they could bill separately for those tests.

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 increase Medicaid drug reimbursement have resulted in significant

False Claims Act settlements. For example, in 2007, Aventis Pharmaceuticals, Inc., entered into a $182.82 million civil settlement to resolve allegations that it falsified price reports and inflated its prices for products that it submitted to 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 involved States' requirements that hospitals return large portions of their disproportionate share payments to the States. This practice is contrary to the program's purpose 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.

Management Issue 3: Promoting Compliance With Federal Health Care Program Requirements

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 with program requirements prevents fraud, waste, and abuse in the programs and promotes program efficiency and economy. To ensure compliance, the Department must partner with health care providers. The Medicare program pays for care for 45 million beneficiaries rendered by 1.2 million participating providers and suppliers, including hospitals, physicians, nursing homes, practitioners, DME companies, and others. CMS processes 1.2 billion Medicare FFS claims annually, averaging 4.4 million claims each working day. In 2007, Medicare FFS payments totaled $431.2 billion. Medicare is required to pay submitted claims within 30 days of receipt, and while all claims are processed electronically, Medicare contractors review fewer than 3 percent of claims before payment is made.

As a result, the Medicare and Medicaid programs rely on providers and suppliers to submit legitimate and accurate claims. 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. Further, a small number of dishonest providers and suppliers attempt to game the system by exploiting or circumventing payment and coverage rules. Effectively combating fraud, waste, and abuse includes ensuring a provider and supplier community that is well informed about the rules and actively engaged in compliance efforts.

The Costs of Noncompliance

Assisting health care providers and suppliers to adopt 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 billing and payment errors; higher quality of care; and 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 2009, improper FFS payments cost Medicare $24.1 billion (7.8 percent error rate). OIG has identified inappropriate Medicare payments for specific services and products. (See also Management Issues 1, 2, 4, and 5.) For example, OIG found that 63 percent of Medicare-allowed claims for facet joint injections (used to diagnose or treat back pain) did not meet program requirements, resulting in $129 million in improper payments. In the Medicaid program, OIG found that New York's Medicaid program paid more than $545.4 million ($275.3 million Federal share) to providers in New York City for personal care 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 schemes that have resulted in substantial costs to Federal health care programs. For example, investigations of alleged illegal marketing tactics by drug manufacturers have resulted in *False Claims Act* settlements of up to $2.3 billion. (See Management Issue 8.) Further, 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 6.) 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 these CIAs based on the conduct and circumstances of the 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 preventing noncompliance. However, several factors create challenges to promoting industry compliance with program rules through education efforts. The 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. The 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.

Further, the audience for compliance education is diverse in terms of sophistication, size, and resources. Medicare providers range from sophisticated 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. In addition, 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 multifacility 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 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 CMS-sponsored education programs on requirements of the *Medicare Prescription Drug Improvement and Modernization Act of 2003*). CMS is also exploring the use of new media, such as podcasts and RSS feeds, to reach provider and supplier audiences.

The Department also partners, and should continue to partner, 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. For example, as noted in Management Issue 6, OIG has worked with nursing home providers through roundtables that focus on how boards of directors can better monitor and ensure quality of care.

A challenge going forward is to determine which tools and approaches are the 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 are another method of fostering an industry culture of compliance and an ongoing 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 program beneficiaries that it serves.

One challenge, however, is that implementation of compliance programs is largely voluntary. Most Medicare and Medicaid providers are not required to adopt compliance programs. Three notable exceptions are Medicaid providers in New York, which are required by the State to implement effective compliance plans as a condition of Medicaid participation; Medicare Part D drug plan sponsors, which are required by statute to implement compliance plans; and individuals and entities that have entered into CIAs with OIG. In addition, several State laws impose 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 are widespread and can be very sophisticated; other sectors have been slower to adopt internal compliance practices and may have fewer resources to devote to compliance.

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

Where compliance programs are required, the Department faces challenges with overseeing adherence to and implementation of program requirements. For example, OIG has found that CMS has not provided sufficient oversight to ensure that Part D sponsors have implemented sufficient compliance plans. Specifically, OIG found that as of January 2006, all prescription drug plan sponsors had compliance plans in place but that only 7 of 79 plan sponsors met all CMS requirements for compliance plans. Sponsors' compliance plans contained only broad outlines of fraud and abuse plans and did not include details or describe specific processes. In its response to OIG's reports on drug plan sponsors' compliance plans, CMS indicated that it planned to conduct routine audits of Part D sponsors' compliance plans beginning in 2007. However, as of July 2009, CMS had conducted only a limited number of compliance plan audits.

Failure to implement effective compliance programs can be a contributing factor that enables fraud and abuse to go unaddressed. In follow-up to its Part D compliance plan review, OIG found evidence suggesting that plan sponsors need to improve the effectiveness of compliance programs in detecting and responding to potential fraud and abuse. Specifically, OIG found that in the first 6 months of 2007, 24 of 86 plan sponsors did not identify any potential fraud and abuse incidents, while a small number of sponsors identified hundreds of incidents. Seven plan sponsors accounted for 90 percent of the incidents identified. Further, OIG found that not all plan sponsors that identified potential fraud and abuse incidents conducted inquiries, initiated corrective actions, or made referrals for further investigation.

Looking forward, the benefits of promoting compliance—and the costs of noncompliance—will grow as beneficiary populations and health care costs increase. The Department faces challenges to effectively assist a large and diverse population of Medicare and Medicaid providers and suppliers in complying with program requirements. However, CMS is implementing several provider education efforts and exploring others. OIG will also continue to provide compliance tools and resources to the provider community and work with the Department to meet this challenge.

Management Issue 4: Oversight and Monitoring of Federal Health Care Programs

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 trust-based system 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 critically important. However, a tension exists between 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 the Federal health care programs because they are large and complex, with increasing expenditures and growing beneficiary populations. The large size of the programs means that fraud, waste, and abuse in payments can result in substantial financial losses. Additionally, fraud, waste, and abuse schemes have become increasingly sophisticated, and criminals constantly adapt to the latest oversight efforts to avoid detection.

A key method to effectively identify fraud, waste, and abuse is the analysis of claims data. Although each program compiles an enormous amount of data on beneficiaries, providers, and the delivery of services, failing to effectively use these data for oversight and monitoring can result in the loss of scarce Federal health care dollars. Claims-processing and payment systems have traditionally relied upon claim-by-claim review. However, in many cases, fraud or abuse can be detected only by reviewing aggregated claims and billing patterns because each individual 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 prevent, detect, and respond to fraud, waste, and abuse. As discussed in more detail later in this Management Issue, 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 Comprehensive Error Rate Testing (CERT) program, OIG has raised concerns that the Medicare error rates for certain provider types may be

understated. For example, in FY 2006, CMS's CERT contractor estimated the Medicare error rate for DME to be 7.5 percent. However, in our review of the CERT program, we estimated the error rate in the CERT DME sample at 17.3 percent using the same methodology as CMS's CERT contractor. Further, using a different methodology, which entailed reviewing additional documentation, OIG found additional errors and estimated a 28.9-percent error rate of the sample. OIG attributed these review discrepancies to the CERT contractor's inadequate review of available documentation and reliance on clinical inference, CMS's inconsistent policies regarding proof-of-delivery documentation, and the agency's lack of procedures for obtaining information on high-risk DME items from beneficiaries. Similar problems affected the FY 2008 DME error rate. An independent contractor identified 142 additional errors that the CERT contractor had not counted as errors in a sample of 250 claims from the FY 2008 DME CERT sample. CMS reported that to address these problems, it will revise its manuals to clarify requirements and promote uniform interpretation of its policies by Medicare contractors, it has provided direction to the CERT contractor regarding the use of clinical judgment, and it plans to incorporate this clarification into the "Program Integrity Manual."

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.

Error rate reviews can identify important oversight vulnerabilities that result in improper payments. For example, OIG found that for the 6-month period ending June 30, 2006, approximately $363 million (Federal share) in Medicaid payments and $67.2 million (Federal share) in CHIP payments were made on behalf of beneficiaries who did not meet Federal and State eligibility requirements in three States. OIG has also identified CHIP eligibility errors outside the PERM process. Children eligible for Medicaid are not eligible for CHIP. OIG estimated that in 2006, at least 4 percent of children enrolled in separate CHIP programs in 36 States were eligible for Medicaid. The Federal matching rate for CHIP is higher than that for Medicaid. Enrollment errors can result in the inappropriate use of Federal matching funds and the expenditure of limited CHIP resources on Medicaid-eligible children.

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 identified numerous examples in which the 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 with monitoring programs for fraud, waste, and abuse.

Claims analysis can reveal providers' improper use of service and diagnostic codes to defraud programs. For example, OIG found that Regenerations, Inc., purportedly a mental-health-counseling agency employing high- and mid-level psychologists and counselors, billed for 84,000 psychotherapy services that were never rendered. Varnador K. Sutton, the sole owner and operator, used the identities of 2,500 Medicaid beneficiaries to defraud the Medicaid program. Sutton usually billed the same service code with the same diagnostic code for all the Medicaid beneficiaries. Once the fraud was detected, the investigation led to Sutton's conviction and sentencing to 10 years in prison and an order to pay $3.3 million in restitution.

Claims analysis can also reveal instances when providers bill for more services than are physically possible. For example, in one of the largest civil fraud recoveries ever against a single U.S. hospital, Staten Island University Hospital agreed to pay $88,916,448 in a global settlement resolving allegations that it defrauded Medicare and Medicaid. The OIG investigation identified potential fraudulent billing, among other allegations, of in-patient alcohol and substance abuse detoxification treatment for more beds than the facility was authorized by the State of New York.

Additionally, claims analysis can detect erroneous place-of-service or discharge codes, and implementing claims edits can reduce inappropriate payments resulting from such miscoding. In 2003, OIG identified over $100 million in improper payments made to hospitals for erroneously coded claims that indicated patients were discharged to home when they actually were transferred to post-acute care. Medicare makes higher payments to hospitals on behalf of patients who are discharged to home compared to those on behalf of patients discharged to other settings, such as skilled nursing facilities. Consistent with OIG's recommendation, CMS implemented an edit to detect transfers improperly coded as discharges. In follow-up work, OIG determined that such overpayments were substantially lower following CMS's implementation of this edit.

Further, claims analysis can identify particular service areas in which providers submit questionable claims. For example, OIG found that in 2007, 20 counties that had only 6 percent of Medicare beneficiaries accounted for 16 percent of Medicare Part B spending on ultrasound services, suggesting possible fraudulent billing by

providers in these counties. Further, nearly one in five ultrasound claims nation-wide had characteristics, such as the lack of a prior office visit or other service claim from the physician who ordered the ultrasound service, that raise concern about whether the claims for $403 million in Part B charges were appropriate. CMS concurred with OIG's recommendations to increase its monitoring of ultrasound claims and to further review questionable claims.

Through use of historical program data, OIG has identified improper Medicare and Medicaid payments and associated program vulnerabilities and recommended corrective actions. For instance, OIG found that five State Medicaid programs had claims from providers for more than 24 hours of personal care services in a day. Other recent findings include personal care services inappropriately billed during institutional stays, duplicate Medicare and Medicaid home health payments for medical supplies and therapeutic services, and improper FFS payments for services covered by capitated Medicaid managed care.

Challenges To Using Data Effectively

In some cases, program data are insufficient to support effective oversight and monitoring. For example, OIG found that Medicare data are insufficient to determine consistently whether Medicare Part B chemotherapy administration payments are appropriate. Specifically, 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. Additionally, OIG found that hospice claims do not collect information needed to determine whether hospice agencies comply with the requirement that they not be reimbursed for more than 5 consecutive days of respite care at a time. In another example, CMS and States do not maintain a primary level-of-care designation for nursing homes that could facilitate accurate claim submission by suppliers and proper claim adjudication by payment contractors.

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 with respect to DME, and OIG is looking into potential vulnerabilities in prescriber identifiers in Medicare Part D records. An OIG study found that Medicare allowed over $6 million for DME claims with invalid Unique Physician Identification Numbers (UPIN) in 2007 of referring physicians. OIG also found that Medicare 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 National Provider Identification (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 new NPI system. In ongoing work, OIG is also examining whether prescription drug event records representing Medicare Part D claims include valid prescriber identifiers.

The Medicaid program has unique data challenges because key functions of program operations occur in States, rather than on a national level. The Medicaid Statistical Information System (MSIS) is currently the only source of nation-wide Medicaid claims information, and weaknesses in MSIS data limit its usefulness for oversight and monitoring of the program. For example, OIG found that CMS accepted submissions to MSIS from 15 State Medicaid agencies that lacked required managed care encounter data. Encounter data are the primary record of Medicaid services provided to beneficiaries enrolled in capitated Medicaid managed care. Further, 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. Moreover, 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.

OIG has also identified opportunities for State Medicaid agencies to improve their monitoring and oversight of claims. For example, in 2006 OIG found that providers in 8 of 10 audited States received an estimated total of $27.3 million in Medicaid overpayments, which the States never recovered, for services claimed to have been provided after beneficiaries' deaths. Prepayment screening by some States did not successfully identify the overpayments because the States did not use all available information sources to identify deceased beneficiaries and their payment systems had data entry, matching, and processing problems.

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 both Medicare and Medicaid. Additionally, CMS has plans to enhance data systems available for use by these contractors.

For Medicare, CMS is transitioning program safeguard functions from its current Program Safeguard Contractors

and Medicare Drug Integrity Contractors 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 (Medicare Advantage health plans); and Part D (prescription drug data) and for coordinating Medicare-Medicaid data matches (Medi-Medi). As of October 2009, CMS had awarded four ZPIC contracts, with three additional contracts planned. While CMS expects that the new ZPIC model will have advantages over the previous model, transitioning from one model to another presents implementation challenges in contracting and in transferring data and responsibilities from one contractor to another.

In 2003, Congress authorized the Department to establish a demonstration program for Recovery Audit Contractors (RACs) for the purpose of identifying underpayments and overpayments and recouping 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 nation-wide and permanent basis. These RACs will cover all 50 States by 2010. CMS reported that the RAC demonstration project successfully returned almost a billion dollars to Medicare, represented a new mechanism for detecting improper payments, and provided CMS with a tool for preventing future improper payments. CMS will require RACs to help develop plans designed to address vulnerabilities identified during their reviews. OIG is determining whether the demonstration RACs have referred cases to law enforcement. OIG and CMS are working together to ensure appropriate referrals of suspected fraud under the permanent RAC program.

As part of the Medicaid Integrity Program, CMS has recently hired contractors to perform data analysis to detect aberrant billing patterns and to audit claims to identify improper payments. In addition, the Medicaid Integrity Group is working to develop a Medicaid data engine to combine State Medicaid claims data to facilitate detection of fraud, waste, and abuse. Further, CMS plans to enhance the data available to monitor payment accuracy and integrity across the Medicare and Medicaid programs. To this end, CMS is working to develop an Integrated Data Repository (IDR), which would warehouse data on Medicare Parts A, B, and D and DME, as well as Medicaid. To this end, in 2007 CMS began developing an Integrated Data Repository (IDR), which CMS indicates will eventually contain all Part A, Part B, DME, HHA, and key Part D data, as well as Medicaid. The prospect of such a comprehensive data warehouse holds considerable promise for detecting and preventing fraud, waste, and abuse; however, the system is still under development.

Despite the progress described and plans for future enhancements, the Department needs to make continued improvements in oversight and monitoring to meet the challenges identified. 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 5 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 draw and analyze claims and provider data across Medicare Parts A, B, C, and D and Medicaid.

Management Issue 5: Response to Fraud and Vulnerabilities in Federal Health Care Programs

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 upon an extensive range of regulations, program requirements, and payment methodologies, which 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. Similarly, Medicaid and CHIP have their own unique systems and contractors. Further, the programs collectively 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 an identified vulnerability, which can result in significant monetary losses before an appropriate remedy or sanction is applied.

OIG's work has identified fraud and vulnerabilities across many areas of the Department's health care programs. See also Management Issues 1-4. 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 moved virally through communities and across the country. Law enforcement may respond with criminal prosecutions in one jurisdiction only to see the scheme transplanted and 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 the Federal health care programs. In the face of this significant management challenge, the Department brings to bear a law enforcement response through OIG and a programmatic response through CMS.

Law Enforcement Response

On May 20, 2009, the Secretary and the Attorney General for the United States Department of Justice announced the creation of the Health Care Fraud Prevention and Enforcement Action Team (HEAT) joint task force to combat health care waste, fraud, and abuse. Among other activities, HEAT is building on the successful Medicare Fraud 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 to identify criminals operating as health care providers and detect emerging or migrating fraud schemes.

One goal of the Strike Forces is to decrease the time between the Government's detection of a fraudulent scheme and the arrest and prosecution of the offenders. The Strike Force model is designed specifically to address the challenges to quick response and has proven to be particularly effective against schemes that have been spread quickly and virally in local communities, where criminals have discovered how to circumvent program controls and then quickly replicate the schemes. By creating organized teams of prosecutors and Federal, State, and local, the Strike Force brings a high level of coordination among law enforcement authorities. This increased coordination, combined with rapid Medicare billing analysis and close relations with financial institutions, is intended specifically to accelerate the Government's response to fraud schemes. Equally important, the Strike Force attempts to identify program weaknesses and lessons drawn from these cases and to communicate rapidly those program vulnerabilities, along with recommendations for improvement, to CMS. Strike Force teams are operating in Miami, Los Angeles, Detroit, and Houston. As of September 30, 2009, Strike Force efforts have resulted in the filing of charges against 423 individuals or entities, 187 convictions, and $226 million in investigative receivables.

The Strike Force model provides significant benefits and has produced substantial results and return on investment; yet, even this model continues to face challenges in responding quickly and effectively to fraud. For example, the success of a Strike Force depends upon having timely access to claims data, which enables law enforcement to respond quickly to stop fraudulent billing and recover stolen funds before the perpetrators have fled. However, in some cases, timely access to data has been impeded by variations between how quickly contractors can respond, contract limitations, competing data requests, and other operational challenges. In some cases, data may not exist in a usable form across different service areas, making it harder to identify fraud schemes. Although efficient, the Strike Forces depend upon having prosecutors and agents available to pursue the cases and resources are limited.

In addition, not all types of fraud may lend themselves to a Strike Force model of enforcement. The model appears most effective when fraud is concentrated geographically and among particular services and provider types. This tends to occur among providers/services with low barriers to entry, such as DME, home health, physical/occupational therapy, and infusion therapy, and often includes fraudulent schemes, such as billing for services not rendered and kickbacks to providers or beneficiaries. Yet law enforcement responds to many other types of health care fraud and vulnerabilities, including complex corporate frauds; document-intensive cases against pharmaceutical manufacturers for false claims arising from off-label drug marketing and other violations; serious quality-of-care violations; cases involving difficult issues of medical necessity; and cases arising in rural, as well as urban, areas across the country.

Federal Health Care Program Responses

Law enforcement alone will not eliminate fraud and abuse; yet even where vulnerabilities are accurately identified, it can be a significant challenge for the Department to respond effectively and ensure that the problems are corrected. For example, during the 2007 unannounced site visits to DME suppliers in south Florida (described in Management Issue 1), OIG found that 491 of the suppliers failed to meet Medicare standards; CMS revoked these suppliers' 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 have subsequently had their privileges revoked, and some individuals connected to reinstated suppliers have been indicted. OIG found that because there are no criteria regarding the types of evidence necessary to reinstate providers' billing privileges, hearing officers made their decisions based on a variety of evidence. CMS agreed that it should consider establishing consistent guidelines regarding the evaluation

of evidence that a hearing officer will review during the appeal process, and this will be a challenge for the Department going forward. OIG intends to assess other Medicare contractors' use of enrollment screening mechanisms and post-enrollment monitoring activities 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 in this area.

In a 2007 review, OIG found that CMS had limited success in controlling the aberrant billing practices of south Florida infusion therapy providers. CMS and its contractors have used multiple approaches, but none has proven effective over time. CMS may take action against a particular provider billing number, such as a payment suspension, billing number revocation, or requirement for prepayment review. Each of these tools has limitations with respect to its administrative burden and its ability to prevent payment for fraudulent claims. One limitation of all these tools is that they apply to specific provider billing numbers; however, fraudulent providers often bill using multiple billing numbers, sometimes steal billing numbers from legitimate providers, and may reapply for new billing numbers using false information (see related discussions in Management Issues 1 and 4). Further, claims-processing edits have been effective in responding to aberrant billing in the short term but have not had lasting effects. Although edits have reduced payments for particular codes, aberrant billers tend to switch to new codes, undermining the edits' overall effectiveness.

Another challenge for the Department is to respond to detected vulnerabilities by suspending payments to providers upon credible evidence of fraud. Payment suspension must be used judiciously with safeguards to protect the rights of providers while also protecting the programs. This is critical in an environment where claims are submitted electronically and paid electronically and large sums of money may be paid by the Government in a very short period of time if the payment suspension is not implemented in a timely manner. This challenge is heightened because when defendants challenge CMS's legal authority to suspend payments, the Government often cannot reveal the source of its investigative information to the target in the midst of the fraud investigation.

The Department, including OIG, must continue to work with its many partners to respond to vulnerabilities in the current 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 known vulnerabilities and weaknesses. OIG's "Compendium of Unimplemented Recommendations" includes many significant vulnerabilities and recommended responses requiring action by the Department or Congress. The Department, including OIG, must also continually identify new risks posed by the changing dynamics of Federal health care programs and the evolving nature of fraud and abuse schemes as well as effective responses to remediate those risks.

Management Issue 6: Quality of Care

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 of the Federal health care programs do not receive substandard care and are not subject to abuse and neglect. The Department also faces challenges in adopting tenets of the patient safety movement, which focuses on improving care delivery systems through quality improvement initiatives, measurement, and reporting.

Oversight of Compliance with Existing Quality Standards

Overseeing compliance with existing quality standards through certification and accreditation processes represents a challenge for the Department. Ensuring that hospitals, skilled nursing facilities, and home health agencies, among other provider types, meet those standards is an enormous undertaking, but necessary to afford the public some external assurances about the adequacy of care practices, systems, and physical facilities.

Ensuring quality care for nursing home residents continues to be a significant challenge. For example, in 2008, OIG determined that over 90 percent of nursing homes surveyed for compliance with Federal regulations were cited for deficiencies, most commonly for quality of care, resident assessment, and quality of life. OIG is currently conducting a related study looking at skilled nursing facilities' compliance with regulations regarding resident assessment, care planning, and discharge planning. In other ongoing work, OIG is examining atypical antipsychotic drugs that are prescribed for nursing home residents.

In addition, OIG is examining quality of care issues in home and community-based settings. In 2008, OIG reviewed home health agencies with patterns of noncompliance. Fifteen percent of home health agencies were cited for the same deficiency on three consecutive surveys. OIG also found that CMS oversight could be improved by using historical information about

deficiencies to identify at-risk home health agencies. OIG is currently reviewing whether Medicaid-funded home- and community-based waiver programs and assisted living facilities comply with State and Federal requirements to ensure the health and welfare of service recipients.

The Department has made some progress in ensuring that providers comply with existing quality standards. For example, CMS continues to expand its Special Focus Facility (SFF) program and plans to increase the number of SFF nursing homes beginning in FY 2010. Under the SFF program, nursing homes with the worst survey performance undergo enhanced monitoring. OIG plans to review CMS oversight of poorly performing nursing homes, including SFFs. CMS has also tasked its Quality Improvement Organizations (QIO) to work with providers on improving their performance on specific clinical measures related to patient safety and disease prevention. The agency is rolling out a revised nursing home survey process, called the Quality Indicator Survey. CMS reports that 16 States are using this enhanced, data-driven survey process. CMS also reports that it has drafted a proposed rule that will establish requirements for unannounced, standard, and extended surveys of home health agencies and provide for various intermediate sanctions

Protecting Beneficiaries From Substandard Care and From Abuse and Neglect

Protecting beneficiaries of Federal health care programs from substandard care and from abuse and neglect by providers is an ever-present challenge for the Department. Identifying and addressing instances of substandard care is a central part of this challenge.

OIG investigations and enforcement cases demonstrate that some beneficiaries receive substandard care or are abused and neglected by providers. To illustrate, in August 2008, Grant Park Care Center, a skilled nursing facility in the District of Columbia, agreed to pay $2 million to resolve OIG allegations that it failed to provide basic nursing care to many residents, resulting in serious patient harm. In June 2008, OIG alleged that Ivy Ridge Personal Care Center in Pennsylvania physically abused residents and denied them necessary food and medicine. As a result of OIG's investigation, the home was closed and OIG excluded the owner from participating in Federal health care programs.

Complex ownership arrangements that include multiple layers of entities present a particular challenge for holding nursing home owners accountable for substandard care. OIG investigations have found instances in which nursing home owners have used such arrangements to avoid accountability for failing to provide necessary and required care. Through these complex corporate structures, owners divert funds from resident care. While investigating nursing homes for substandard care, OIG found 1 facility with as many as 17 limited liability companies that played a role in the facility's operations and ownership.

The Department's primary program for addressing substandard care is Medicare's QIO program. The QIO program includes, among other things, medical review of beneficiary complaints and quality improvement activities. However, in a 2007 report, OIG found that only 11 percent of cases reviewed by QIOs were for quality-of-care concerns and that QIOs rarely initiated sanction activity after confirming a quality-of-care concern. Moreover, in OIG's experience, QIOs routinely fail to respond to OIG referrals regarding beneficiary care.

The Department has several other programs and initiatives to help ensure that beneficiaries are free from abuse and neglect. The Department relies, in part, on the State Medicaid Fraud Control Units, which are funded on a 75-percent matching basis by the Department, to investigate and address abuse and neglect in State-regulated Medicaid facilities. In addition, Congress recently renewed and expanded CMS's seven-State Background Check Pilot Program, which is intended to identify efficient, effective, and economical procedures for checking the backgrounds of employees with direct access to patients. OIG is currently evaluating whether and to what extent nursing facilities employ individuals with criminal convictions.

The Patient Safety Movement and Incentives for Quality Improvement

The Department faces challenges in adopting tenets of the patient safety movement, which focuses on quality improvement, measurement, root cause analysis, and public reporting, in a manner consistent with its own mission and responsibilities as a purchaser of health care.

OIG's recent work underscores the significance of this challenge. For example, OIG reported on the extent to which States have established adverse event reporting systems, finding that only half the States have adopted systems. Further, States collect different types of events and lack consistent definitions, which create substantial challenges to compiling State data to develop benchmarks. In a case study of two counties, OIG found that about 15 percent of hospitalized Medicare beneficiaries experienced adverse events that resulted in harm. OIG is currently expanding this work to calculate a national incidence rate of adverse events for the Medicare population and will examine the incidence of adverse events for Medicaid recipients. OIG is also assessing issues associated with public disclosure of adverse event information and reviewing the early implementation of CMS's nonpayment policy for select hospital-acquired conditions.

The Department also faces a challenge in working with various types of health care providers to ensure that they are knowledgeable about and consistently implement quality improvement processes. Recent OIG efforts promoted providers' incorporation of quality assurance and improvement into voluntary compliance programs. For example, OIG sponsored two roundtables, one with the long-term care industry and one with the hospital industry, to explore how best to involve boards of directors and trustees in quality matters. For providers with multiple locations, OIG's work has stressed the importance of company-wide and corporately driven quality assurance and improvement systems, as opposed to relying solely on facility-based programs.

The Department has implemented a number of programs as part of the ongoing challenge to become a more prudent purchaser of quality health care. For example, CMS's value-based purchasing initiative links enhanced payments to reporting quality measures. To report these measures publicly and move toward rewarding providers based on performance, however, CMS must ensure that reported data are complete and accurate. Looking forward, OIG will examine hospitals' controls regarding the accuracy of data reported to CMS. OIG will also begin to review CMS's pay-for-performance initiatives, which are unfolding in varied settings. As an increasing number of States implement pay-for-performance systems in Medicaid, OIG will also determine whether States have sufficient controls to ensure appropriate incentive payments in Medicaid programs aimed at rewarding high-quality care.

CMS is also conducting demonstrations to improve care for individuals with chronic diseases, to improve the quality of transitional care, and to prevent unnecessary hospital readmissions. Looking forward, OIG will analyze hospital readmissions.

The Department continues to play a leadership role in making quality-related data, such as hospital, nursing home, and dialysis ratings, available to consumers. In 2009, CMS began posting its Five-Star Quality Rating System on the Nursing Home Compare Web site, which rates nursing homes on a variety of quality measures. In addition, QIOs provide technical assistance concerning quality improvement processes and best practices to different providers. The Agency for Healthcare Research and Quality (AHRQ) has also made considerable progress in implementing Patient Safety Organizations, which will play an important role in collecting and studying data regarding adverse events. CMS reports that in Medicaid and CHIP, CMS is are working with AHRQ to increase the quality and transparency of information available regarding children's health care and identifying children's measures that can be reported from a hospital setting.

Future Challenges

The population is aging and the delivery of health care is evolving because of new technologies and evolving payment methodologies. As a result, ensuring that beneficiaries receive quality care in all settings will become even more complex in the years ahead. The increased use of health information technology and electronic health records also holds promise to improve the quality of care within and across settings. CMS reports that health information technology and electronic health records are a focus for Medicare, Medicaid and CHIP. However, these developments may also present their own unique challenges that have yet to be identified. For more information on issues associated with health information technology, see Management Issue 11.

PART 2: INTEGRITY OF THE DEPARTMENT'S PUBLIC HEALTH AND HUMAN SERVICES PROGRAMS

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

Management Issue 7: Emergency Preparedness and Response

MANAGEMENT CHALLENGE AND ASSESSMENT OF PROGRESS IN ADDRESSING THE CHALLENGE:

Events like Hurricanes Katrina and Rita, and more recently 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 public health emergencies. The ability to effectively prepare for and respond to a public health emergency requires planning, coordination, and communication across a wide 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 organizational structures poses unique and unprecedented demands on the Department.

Since 2002, the Department has provided over $8 billion to States and localities through various programs to enhance their emergency preparedness activities and to better enable them to respond to large-scale, natural or man-made public health emergencies, such as acts of bioterrorism or

infectious disease outbreaks. (See Management Issue 8 for discussions of preparedness for and response to food-borne illness and related emergencies.) In its January 2009 Pandemic Influenza Preparedness Spending Report to Congress, the Department cited its progress in enhancing the Nation's pandemic preparedness by making strides in the development and production of vaccine antigen and new adjuvants for avian influenza (H5N1), which was the focus of pandemic influenza planning prior to the April 2009 outbreak of the H1N1 virus. The Department has also continued to work with States to improve their preparedness. However, OIG work assessing preparedness as recently as summer of 2008 shows both progress and the need for significant improvements to the public and private sectors' preparedness and response to public health emergencies.

State and Local Emergency Preparedness Planning

The Department provides guidance to States and localities on the development of emergency preparedness plans. Documented emergency preparedness plans that are cohesive and contain sufficient detail are critical for ensuring that States and localities are prepared for a public health emergency. However, variations in State and local health department structures and the size of populations they serve make it difficult to provide Federal guidance to prepare for an event, such as an influenza pandemic.

In its evaluation of the Nation's pandemic influenza preparedness, OIG found that the majority of States and localities OIG reviewed had begun emergency preparedness planning efforts; however, more planning is needed. For example, in its evaluation of the States' and localities' medical surge preparedness, OIG found that most of the selected localities had not identified guidelines for altering triage, admission, and patient care during a pandemic, as recommended. In its evaluation of preparedness to distribute and dispense vaccines and antiviral drugs during a pandemic, OIG found that selected localities had not addressed in their planning documents most of the items identified in Department guidance. Based on the findings from its pandemic influenza preparedness work, OIG recommended that the Department work with States to help localities improve their preparedness. In response to these recommendations, the Office of the Assistant Secretary for Preparedness and Response (ASPR) stated that it has undertaken a number of activities to improve States' and localities preparedness including updating its Medical Surge Capacity and Capability Handbook to further assist State health care system planning efforts in the event of a pandemic.

Some States and localities have established adequate planning documents; however, they vary in the extent to which they exercise their emergency plans and address lessons learned. For instance, in its review of States' and localities' medical surge readiness, OIG found that all of the selected localities conducted medical surge exercises; however, none consistently documented the lessons learned from these exercises. OIG had similar findings in its review of vaccine and antiviral drug distribution and dispensing. As a result, OIG recommended that the Department ensure that States and localities consistently document their exercises and lessons learned from the exercises to improve their preparedness. ASPR stated in FY 2009 that it implemented a new standardized reporting template to improve health care system exercise documentation and data collection.

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

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 response. These threats include anthrax, influenza, nerve agents, and food-borne 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, findings from OIG's work reveal potential vulnerabilities in the Nation's preparedness to respond to these biological and chemical threats.

For example, weaknesses exist in our 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.

Additionally, OIG reviewed Department and external laboratories for 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 many laboratories did not adequately safeguard the agents against theft or loss. Further, in its audits at universities, as well as public, private, and Department laboratories, OIG found problems with recordkeeping, access controls, or training, among other findings. Moreover, through its authority to impose civil monetary penalties against entities that violate select agent regulations, OIG has collected approximately $1.8 million in civil monetary penalties for violations, such as conducting unauthorized research with select agents, taking inadequate precautions in shipping select agents, storing toxins in an unsecured area before transfer, and allowing unauthorized individuals access to select agents.

OIG is currently reviewing CDC's CHEMPACK project, which places nerve agent antidotes in monitored storage containers in cities and States for immediate use in the event of a chemical emergency. In its review, OIG will determine the extent to which nerve agent antidotes were stored at the temperatures required by the Food and Drug Administration (FDA). OIG will also review the extent to which the CDC implemented procedures to ensure the quality of nerve agent antidotes in the CHEMPACK project.

Lessons Learned From Real-Life Events

It is important that both the public and private sectors prepare for large-scale public health emergencies, and it is equally important that they 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 events.

For example, as efforts continue in restoring the health care infrastructure in and around New Orleans after the Gulf Coast hurricanes, OIG continues to examine the Department's disaster response to these events to highlight potential vulnerabilities and lessons learned. OIG reviews of the response to the Gulf Coast hurricanes revealed weaknesses in certain health care entities' ability to respond to a public health emergency. For instance, OIG's review of nursing homes in five Gulf Coast States found that all the nursing homes reviewed experienced problems with implementing emergency plans or impromptu decision making. Specifically, problems in the nursing homes arose because of ineffective emergency planning or failure to execute the emergency plans properly. Administrators and staff from selected nursing homes did not always follow emergency plans during hurricanes during our period of review because plans were not up-to-date or did not include instructions for particular circumstances. Further, plans often lacked components suggested by Department guidance. 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. OIG is currently conducting a follow-up evaluation of this study.

Similarly, in its review of the United States Public Health Service Commissioned Corp's response to Hurricanes Katrina and Rita, OIG found that the Corps provided valuable support to the States but that it could improve its response to public health emergencies. Particularly, OIG found that many deployed officers met Corps readiness standards but lacked experience, effective training, and familiarity with response plans. OIG recommended that the Corps stagger deployments to ensure that experienced officers were in the field. OIG also recommended that the Corps implement more training for Corps officers. As of March 2009, the Corps had implemented all the recommendations noted in this evaluation, including developing more effective officer training programs and staggering deployments to ensure continuity of operations.

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 regarding this management issue, the Department should provide additional guidance to States and localities to improve their public health emergency preparedness.

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

MANAGEMENT CHALLENGE AND ASSESSMENT OF PROGRESS IN ADDRESSING THE CHALLENGE:

Ensuring the safety and security of the Nation's food supply, human and veterinary drugs, and medical devices represents a significant challenge for the Department. That challenge includes responding to emergencies related to food safety, which often involves multiple State and Federal public health agencies. It also includes protecting the rights, safety, and well-being of human subjects who participate in clinical trials conducted here and abroad for the products the Department regulates. It also includes ensuring that medical products, once proven to be safe and effective, and foods that are safe and lawful, are labeled and advertised appropriately. The increasingly globalized market for food, drugs, and medical devices elevates the significance of these challenges.

Oversight of Food Safety

OIG reports have underscored the challenges that FDA faces in tracing food through the distribution chain during a food emergency and in monitoring food recalls. For

example, OIG conducted a food traceability exercise and found that only 5 of the 40 products that OIG purchased could be traced through each stage of the food supply chain back to the farm or border. In addition, 59 percent of selected food facilities did not comply with FDA's recordkeeping requirements, and those requirements were insufficient to ensure the traceability of the food supply. In another review, OIG found that FDA lacks the statutory authority to require manufacturers to initiate pet food recalls and did not always follow its procedures in overseeing the recall of pet food tainted with melamine. Furthermore, FDA's procedures were not always adequate for monitoring recalls as large as those required in the pet food incident. These challenges related to recordkeeping, traceability, and recalls are significant because more than 300,000 Americans are hospitalized and 5,000 die yearly after consuming contaminated foods and beverages. In a food emergency, FDA is responsible for finding the contamination source and overseeing the voluntary removal by the manufacturers of the food products from the supply chain.

Looking forward, OIG is reviewing FDA's inspections of food facilities, its oversight of contractors that conduct those inspections, its oversight and operations related to imported food and feed products, its recall procedures for human food, and the extent to which it tested human food for contamination from melamine and other contaminants.

The Department has made progress toward ensuring the safety of our Nation's food supply, and toward that end, in March 2009, the President created the Food Safety Working Group. The group, chaired by the Secretaries of this Department and the Department of Agriculture, will foster coordination throughout the Government and work toward modernization of food safety laws for the 21st century by building collaborative partnerships with consumers, industry, and regulatory agencies. Among its priorities is establishing an incident command system to link relevant agencies in emergencies. In addition, 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.

Oversight of Drugs and Medical Devices

OIG's recent work highlighted the challenges FDA faces in reviewing generic drug applications in a timely manner. Generic drug applications increased at more than double the rate of FDA's review resources in the last 5 years. In a 2008 report, OIG found that FDA disapproved 96 percent of original generic drug applications under review in 2006 because they did not meet FDA review standards. Furthermore, FDA exceeded the 180-day review for nearly half of the original generic applications. FDA has implemented some changes that are consistent with OIG recommendations to improve the generic drug approval process. Specifically, FDA recently published a final rule that required all its review divisions to review generic drug applications and describe all deficiencies to the applicant within 180 days and issued additional guidance on what information to include in their applications.

Other OIG work relates to the Department's challenge in ensuring that drugs, once determined to be safe and effective, are marketed appropriately. For example, in September 2009, Pfizer, Inc. and its subsidiary Pharmacia & Upjohn, Inc. (Pfizer), agreed to pay $2.3 billion to resolve criminal and civil liability arising from alleged illegal promotion of certain drugs. Pharmacia & Upjohn, Inc. agreed to plead guilty to a felony violation of the *Food, Drug, and Cosmetic Act* for misbranding Bextra, an anti-inflammatory drug pulled from the market in 2005, with the intent to defraud or mislead. The criminal fine and related forfeiture total $1.3 billion. Pfizer agreed to pay $1 billion in a civil settlement to resolve allegations of illegal promotion of Bextra and three additional drugs. As part of the settlement, Pfizer also has agreed to enter into an expansive CIA with OIG. That agreement requires the implementation of procedures and reviews to avoid and promptly detect similar conduct.

In another example, in January 2009, Eli Lilly and Company (Lilly) entered a $1.4 billion global criminal, civil, and administrative settlement to resolve allegations that it illegally marketed its antipsychotic drug Zyprexa. In its plea agreement, Lilly admitted that from September 1999 to March 31, 2001, it promoted Zyprexa for unapproved uses in elderly populations as treatment for dementia, including Alzheimer's dementia. Lilly entered into a 5-year CIA with OIG.

The scope of potential off-label marketing violations is vast. OIG is currently 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. In addition, 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 mitigate against off-label marketing.

OIG's work has also increasingly focused attention on how the Department oversees the safety of medical devices. FDA receives about 200,000 adverse event reports each year regarding medical devices. In a 2009 report, OIG found that FDA does not use these reports in a systematic manner to detect and address safety concerns about medical devices. In future work, OIG will review FDA's

oversight of medical device post-marketing surveillance studies.

Oversight of Human Subject Protections in Clinical Trials

The Department's ability to protect human subjects enrolled in clinical trials remains a challenge that OIG continues to monitor. OIG is determining the extent to which drugs marketed in the United States are approved based on data from foreign clinical trials. That work is also determining the extent to which FDA oversees those trials. 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 the FY 2000-2005 period. FDA has taken steps to improve its oversight of clinical trials by recently finalizing rules to establish a registry for institutional review boards.

As the agency tasked with ensuring the safety and efficacy of food, cosmetics, drugs, biological products, medical devices, and products that emit radiation, FDA faces important challenges with respect to these increasingly globalized markets. Despite the progress described, and plans for future enhancements, FDA needs to make continued improvements in oversight and monitoring with respect to food safety, medical devices, and clinical trials to meet the challenges identified. Looking forward, the Department will be further challenged by its new authority to regulate the content, marketing, and sale of tobacco products. FDA will need to collaborate with public health leaders to develop and implement an effective public health strategy that reduces the burden of illness caused by tobacco products.

Management Issue 9: Grants Management

MANAGEMENT CHALLENGE AND ASSESSMENT OF PROGRESS IN ADDRESSING THE CHALLENGE:

The Department is the largest grant-awarding agency in the Federal Government. In FY 2008, the Department awarded $264 billion in grants. Almost 70 percent of the money was for health care coverage under Medicaid and CHIP. The remaining 30 percent funded health and social service programs administered by the Administration for Children and Families (ACF), the Health Resources and Services Administration (HRSA), the National Institutes of Health (NIH), and other Department agencies. Moreover, the *American Recovery and Reinvestment Act of 2009* (*Recovery Act*) provided a total of $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. (See also Management Issue 10 for a discussion of broader departmental challenges related to the oversight and implementation of the *Recovery Act*. Challenges related to the Medicaid and CHIP programs are discussed in Management Issues 1 through 6.)

Adding to this challenge is the fact that unlike other Government expenditures, the responsibility for performance and management of a grant rests primarily with the grantee, with limited Federal Government 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, HRSA, and NIH has highlighted grants management vulnerabilities and opportunities for improvements in the Department's oversight of grant funds and grantee compliance.

Improper Payments

Ensuring the appropriate use of grant funds is a challenge for the Department. OIG has identified improper payments made under ACF's Temporary Assistance for Needy Families (TANF) and foster care programs, as well as HRSA's Ryan White *Comprehensive AIDS Resources Emergency (CARE) Act* program.

The Office of Management and Budget (OMB) lists TANF as one of the programs that may be susceptible to significant erroneous payments. To assist ACF and the Department in establishing an improper payment rate as required by the *Improper Payments Information Act of 2002 (IPIA)*, OIG statistically selected eight States to review in FY 2008. The improper payment rates for seven of these States ranged from 6 to 29 percent of the Federal dollars expended for the 1-year audit period, and OIG estimated that improper payments totaled $190 million. The eighth State did not cooperate with OIG, and negotiations between that State, OMB, and the Department to conduct the improper payment review in 2009 failed. As a result, the Department will not be able to report an improper payment rate in the *FY 2009 Agency Financial Report* or comply with *IPIA* requirements for the TANF program.

Similarly, OIG has identified improper payments within the foster care program. At the beginning of FY 2009, for example, OIG and ACF officials recommended that the Department disallow $409.1 million in foster care payments to one State. This amount included:

- $78.4 million in unallowable maintenance payments claimed for unlicensed facilities or ineligible children that OIG identified for the period October 1997 through September 2002;
- $111.9 million related to issues with the per diem rates used to charge the Federal Government for providing foster care services. The time period for this disallowance was October 1997 through September 2002; and
- $218.8 million in a projection made by ACF for the period October 2002 through June 2008, based on disallowed amounts between October 1997 and September 2002.

The Department agreed that the State should repay the $409.1 million in disallowed costs. However, as of August 2009, the disallowance letter to the State has not been sent.

OIG has also identified improper payments made under HRSA's *Ryan White CARE Act* program. During a 2008 pilot review of a single territory, OIG determined that over $24 million in services paid for with Ryan White grant funds should have been covered by other health insurance. OIG extended this review to eight more States, and the combined draft and final results from 2009 have uncovered an additional $10.2 million in overpayments for a 2-year period.

Other Grants Oversight Challenges

In addition to ensuring the appropriate use of grant funds, the Department is responsible for ensuring the integrity of the grants award processes and grantee compliance with program requirements. However, OIG has identified vulnerabilities in these areas.

For example, OIG conducted risk assessments as part of its work with the Department to ensure that agencies meet their *Recovery Act* responsibilities. OIG's risk assessment of ACF highlighted the need for greater internal controls for TANF. OIG's interim results indicate that the program may be vulnerable to States manipulating caseloads to qualify for additional assistance. Furthermore, the recent breakdown in controls in New York State's release of TANF emergency funds for school supplies indicates that administrators may not have a full understanding of *Recovery Act* requirements, nor have they implemented suitably designed processes to ensure that clear guidance is provided to recipients and *Recovery Act* funds are appropriately used.

OIG has also identified risks related to grantee noncompliance. For 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 and delays in closing out some grants. NIH agreed with OIG's recommendations to initiate earlier and more frequent follow-up with grantees to obtain required documents and to improve its grants monitoring, including by annually verifying grantees' self-reported fund balances with external sources. In another example, OIG is concerned about whether Head Start and Early Head Start program grantees can provide safe environments, as required, as the number of enrolled children increases through the *Recovery Act* expansions of these programs. OIG is initiating reviews in eight States to assess this issue.

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 will only magnify grant oversight vulnerabilities. OIG will continue to monitor grants management challenges and recommend improvements to the Department's grants oversight, as warranted.

PART 3: CROSS-CUTTING ISSUES

OIG has also identified three other Department-wide issues that are top management challenges. These include assessing whether the Department is using *Recovery Act* funds in accordance with legal and administrative requirements and is meeting the accountability objectives defined by OMB; developing and maintaining adequate internal controls over its information systems; and effectively overseeing its ethics program.

Management Issue 10: 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 to promote economic recovery and ameliorate the impacts of the recession. The *Recovery Act's* combined spending and tax provisions are expected to 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 maintaining jobs, assisting those most affected by the recession, increasing economic efficiency by investing in technological advances in science and health, and stabilizing State and local budgets.

The *Recovery Act* provides $166.6 billion to the Department to provide additional Federal assistance for health care, public health, and human services programs, as

well as to invest in research and health information technology (health IT). 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 are used efficiently and effectively and are protected from fraud, waste, and abuse.

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

- improving and preserving health care by providing an $87.5 billion temporary increase in the Medicaid Federal Medical Assistance Percentage (FMAP);

- accelerating the adoption of health IT through (1) the Office of the National Coordinator for Health Information Technology ($2 billion) to coordinate Federal health IT policy and programs and foster the electronic use and exchange of health information and (2) CMS ($44.7 billion) to make incentive payments to encourage physicians and hospitals to adopt and use certified electronic health records in a meaningful way;

- improving children and community services by providing ACF with over $12.3 billion to temporarily expand the TANF, child support, Head Start, child care development, and community services programs;

- strengthening scientific research and facilities by providing $10.4 billion to NIH; and

- strengthening community health care services by providing HRSA with $2.3 billion to construct and renovate new centers, to expand health care services, and to train health care professionals.

The majority of the Department's *Recovery Act* funding increases 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 detail in Management Issues 1 through 6 of this document. Challenges related to programs and grants administered by ACF, NIH, and HRSA are presented in Management Issue 9. Finally, challenges related to health IT are discussed in Management Issue 11.

Implementation and oversight to ensure accountability and transparency of *Recovery Act* funding present significant management challenges. The *Recovery Act* funds are to be awarded and distributed within short timeframes. Awarding and distributing funds quickly is important to the *Recovery Act's* objectives to stimulate economic growth and ameliorate the impacts of the recession. Expediting the awards process, however, also creates challenges for the Department in ensuring that funds are distributed to qualified recipients and are used appropriately and effectively. Further, creating or expanding programs may increase the number of new recipients that may lack experience with Federal requirements for grantees and contractors.

The *Recovery Act* also established new reporting requirements related to the awarding and use of funds to promote transparency and accountability. Challenges associated with the new reporting requirements include developing the 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. These new reporting requirements are in addition to the information that some recipients of *Recovery Act* funds must also provide for similar activities funded outside the *Recovery Act*, creating multiple and inconsistent reporting requirements.

Overseeing and protecting the integrity of *Recovery Act* funds is a shared responsibility requiring coordination among agencies within the Department and with States and other entities. The Department has established the Office of *Recovery Act* Coordination (ORAC), headed by a 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. In addition, the *Recovery Act* established the Recovery Accountability and Transparency Board (RATB), consisting of 12 Inspectors General, including the HHS Inspector General, to coordinate and conduct oversight of funds distributed pursuant to the *Recovery Act* to prevent fraud, waste, and abuse and promote accountability and transparency. The RATB administers the Government's Recovery.gov Web site. State agencies also have essential 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.

Together, OIG and the Department are working to ensure that the Department meets its *Recovery Act* responsibilities. Ongoing activities include minimizing risk; assessing controls for preventing fraud, waste, and abuse; and ensuring program goals are achieved and stimulus funds

are accurately tracked and reported. Initial steps, for example, include:

- outlining the process for obtaining meaningful coverage by single audits (the financial and compliance audits required of all recipients of $500,000 or more in Federal funding) to assist in determining whether the accountability objectives are met (i.e., that the recipients, uses, and benefits of all funds are transparent to the public; funds are used for authorized purposes; and instances of fraud, waste, error and abuse are mitigated);

- reviewing the spending plans for each *Recovery Act* initiative with a focus on the purpose of funding, means of execution, method of selection, intended recipients, and accountability measures;

- conducting a risk assessment covering $72.7 billion of the $76.4 billion allocated to Health IT and non-Medicaid programs;

- reviewing the Department and State controls to ensure that the temporary increase in the FMAP is implemented as intended by the *Recovery Act*;

- reviewing training and qualifications of Departmental personnel responsible for overseeing *Recovery Act* funds;

- reviewing the implementation plans for *Recovery Act* initiatives or programs with a focus on objectives, performance measures, monitoring and evaluation, transparency, accountability, and barriers to effective implementation; and

- developing a screening process to identify applicants for *Recovery Act* funds that are under investigation by OIG.

In addition, the *Recovery Act* requires OIG to investigate alleged instances of retaliation against whistleblowers who disclose the potential misuse of *Recovery Act* funds. OIG is preparing for a possible influx of complaints by updating its hotline and tracking systems and training agents on the evaluation and investigation of such whistleblower complaints.

Although the Department faces challenges in ensuring the accountability and transparency of *Recovery Act* funds, the Department's and OIG's efforts underway, including the use of risk assessments, may have long-term benefits for Department programs even beyond the expenditure of *Recovery Act* funding.

Management Issue 11: Health Information Technology and Integrity of Information Systems

MANAGEMENT CHALLENGE AND ASSESSMENT OF PROGRESS IN ADDRESSING THE CHALLENGE:

Over the past decade, the development and implementation of interoperable health IT has become a national priority. The Federal Government has recognized the potential for health IT to revolutionize the delivery of medical care by both improving quality and lowering costs. In 2004, the President issued Executive Order 13335 to create the Office of the National Coordinator for Health IT (ONC) within the Department of Health and Human Services. ONC was tasked with the goal of achieving access to an interoperable electronic medical record for most Americans by 2014. Since then, the public and private sectors have worked together to advance the vision of the nation-wide adoption of interoperable health IT, which includes the use of electronic health records (EHR) and electronic prescribing (e-prescribing).

The Department must balance the need to meet these goals with its obligations to oversee the expenditure of Federal funds in pursuit of health IT objectives. For example, the *Health Information Technology for Economic and Clinical Health (HITECH) Act*, as part of the *Recovery Act*, includes a wide array of mandates, contracts, grants, loans, incentives, and penalties aimed at promoting the widespread and secure use of interoperable health IT. The *HITECH Act* also tasks the Department, with ONC as the lead, with adopting standards and establishing a governance mechanism for the nation-wide health information network (NHIN), through which health data, such as EHR and e-prescriptions, will be exchanged. The goals of these provisions are also supported by unprecedented funding to encourage the adoption of health IT—an estimated $49 billion in spending over the next several years.

Achieving the widespread use of electronic medical records is an ambitious target, and it is imperative that *Recovery Act* funds to support this goal be used efficiently and effectively. The success of this massive undertaking, like that of any Government initiative, can be threatened by vulnerabilities created or overlooked during planning, funding, and implementation. In addition, with the push for increased adoption of health IT, there is also heightened concern among the public regarding the privacy and security of their personal health information. Therefore, the Department must identify and address to the fullest extent possible, and as early as possible, such vulnerabilities with respect to each of its health IT initiatives.

The Department's health IT management challenges identified by OIG can be divided into two broad

categories: ensuring the integrity of the Department's programs to promote health information technology and ensuring the integrity of information systems through which health information is transmitted and stored.

Integrity of Health Information Technology Programs

Like any of the Department's grants programs or contracts, Federal health IT initiatives are susceptible to potential fraud, noncompliance, and inefficiency. Even before the enactment of the *HITECH Act*, OIG was engaged in monitoring Federal health IT initiatives. For example, in 2009 OIG initiated an assessment of Medicare Part D plan sponsors' implementation of CMS-mandated e-prescribing standards. OIG found that most plan sponsors had implemented some of the mandated standards but that few had completely implemented all required standards. Another study, completed 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.

With the enactment of the *HITECH Act*, Federal initiatives to promote the use of health IT now 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; and ONC programs to facilitate the adoption of health IT through health IT extension programs, State grants for health information exchange, and development of an HIT workforce. OIG has developed a work plan to provide oversight to these areas 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 10 for further discussion of challenges associated with the *Recovery Act*.

Integrity of Information Systems

The Department administers its wide array of programs through a mix of grants, contracts, and cooperative agreements and as a payor of health benefits. As such, to accomplish its mission, the Department relies on a distributed network environment that includes Federal agencies, State and local governments, grantees and contractors, health care providers, and colleges and universities. This environment presents a significant challenge for the Department to establish an information security program that protects critical infrastructure and assets and creates, monitors, and maintains an enterprise-wide baseline of core security requirements.

OIG has monitored the Department's ability to meet this challenge by determining whether the Department's information system security controls are robust, as well as examining its oversight over health care providers' compliance with the Health *Insurance Portability and Accountability Act of 1996* Security Rule (the applicability of which the HITECH Act has expanded and whose enforcement been transferred from CMS to the Department's Office for Civil Rights). OIG has performed dozens of independent audits of key departmental agencies, as well as audits of State and local governments, contractors, and hospitals. These 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 the integration of security into major applications, which includes certification and accreditation, contingency plan testing, privacy impact statements, and annual self-assessments.

The *HITECH Act* will present a challenge to the Department's processes for ensuring the confidentiality, integrity, and availability of critical systems and data. In response, OIG will use the results of its risk assessments to target its oversight and monitoring of the security controls of the Department's networks, as well as those of its contractors and grantees.

Because of increasing recognition of the scope and detrimental consequences of identity theft, OIG is increasing its focus on medical identity theft, which can result from breaches in information security. OIG investigations have uncovered an increasing number of fraud schemes involving stolen provider and beneficiary identification numbers. In response, OIG issued a consumer education brochure providing tips and resources to help beneficiaries protect themselves and Medicare from medical identity theft and fraud. OIG will continue its work in this area and make recommendations to the Department, as appropriate, regarding safeguards for personally identifiable information.

Management Issue 12: Ethics Program Oversight and Enforcement

MANAGEMENT CHALLENGE AND ASSESSMENT OF PROGRESS IN ADDRESSING THE CHALLENGE:

The year 2008 marked the 30th anniversary of both the *Inspector General Act of 1978* and the *Ethics in Government Act of 1978*, which established the Office of Government Ethics (OGE). Both statutes set the stage for a more robust framework and mechanism for ensuring the integrity of the Federal workforce and Federal programs.

Government Ethics Programs and Conflicts of Interest of Department Employees

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

Monitoring for conflicts of interest continues to be a challenge for the Department. For example, OIG currently has a study underway that will determine the extent to which the CDC and its Special Government Employees (SGE) on Federal advisory committees complied with ethics requirements. OIG is also planning to conduct similar reviews of other Departmental agencies.

The Department has recently implemented some model practices, such as expanding oversight by monitoring the financial disclosure systems and the ethics training program department wide, providing instructor-led initial ethics orientation to departmental employees, and providing instructor-led annual ethics training to political employees. The Department also provides face-to-face initial ethics orientation for incoming scholars and SGE advisory committee members.

Another challenge for the Department is monitoring for conflicts of interest of a workforce that has become increasingly reliant on contract workers. A recent revision under the Federal Acquisition Regulation requires contractors to have a written code of ethical conduct and to post information on how to report fraud. In response, OIG created an OIG hotline poster for use by Department contractors. Also, as OGE releases guidance on conflict-of-interest considerations of contractor employees in the workplace, OIG is developing internal training on this topic to prepare for emerging issues involving contractors working in the Department. To examine the scope of this challenge, OIG has plans to assess CMS's process for oversight and monitoring of contractors' conflicts of interest.

OIG has also identified the lack of uniform procedures for resolving allegations of improper conduct as a management challenge within the Department. In 2008, OIG issued a report on how NIH handles allegations about employee activities that might be criminal or improper. OIG's evaluation found a lack of uniform procedures for handling allegations and recommended that NIH develop a formal written policy for handling allegations. OIG also recommended that NIH maintain documentation detailing how allegations are ultimately resolved. NIH concurred with the recommendations and has since implemented them in a new chapter of the "NIH Policy Manual."

OIG also consulted with the Department regarding the number and quality of conflict-of-interest referrals that it was receiving from across the various divisions in the Department. To improve the quality of referrals, OIG created a comprehensive form for the DAEO and other departmental ethics officials to use when referring conflict-of-interest cases. OIG's ongoing relations with the Office of General Counsel (OGC) Ethics Division, as well as regular interactions by OIG staff with the operating and staff divisions, have yielded positive results with an increase in the quality of the referrals, an increase in the number of referrals from various departmental components, and an increase in departmental officials seeking input and guidance on conflict-of-interest matters. For example, OIG's enforcement efforts in 2009 included the conviction of an employee of the National Library of Medicine, NIH, who was sentenced to 1 year probation and 160 hours of community service and ordered to pay a $200,000 fine as punishment for a felony violation relating to conflict-of-interest regulations by failing to receive approval and failing to report finances from his outside activities. The employee admitted to receiving as much as $500,000 in unauthorized income from testifying as an expert witness on toxicology issues in legal proceedings.

Oversight of Department Grantee and Researcher 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 bias these programs and ultimately affect the public's health and safety. For example, 80 percent of NIH research funding goes to extramural grantees, primarily to research universities that undertake work pursuant to grants and contracts. Conflicts of interest among extramural grantees could compromise the integrity of the research that the Department funds. Therefore, in addition to performing our work focused on departmental employees, OIG has also examined potential

conflicts of interest relating to Federal grantees and non-Federal researchers.

In a January 2008 report, OIG identified vulnerabilities associated with NIH's monitoring of conflict-of-interest reports submitted by external grantees in FYs 2004 through 2006. OIG found that NIH's Institutes and the Office of Extramural Research (OER) were unable to provide all the actual conflict-of-interest reports they received from grantee institutions and did not follow up with grantee institutions regarding reported conflicts of interest. OIG recommended that NIH increase oversight of grantee institutions and require grantee institutions to provide details regarding 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. Beginning in July 2009, NIH began requiring all financial conflict-of-interest reports from grantees to be submitted electronically using a uniform format in their systems.

In its follow-up, 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 request grantee institutions to provide it with details regarding the nature of all reported financial conflicts of interest and the ways in which they are managed, reduced, or eliminated. OIG offered additional recommendations, including that NIH (1) require grantee institutions to collect all information on significant financial interests held by researchers and not just those deemed by researchers to be reasonably affected by the research; (2) require grantee institutions to collect information on specific amounts of equity and compensation from researchers; (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.
With regard to the last recommendation, OIG is currently undertaking a review to determine what policies and procedures NIH grantee institutions have in place to address institutional conflicts of interest.

In considering potential changes to the Federal regulations that would address some of the current vulnerabilities, NIH sought to gain input from the public and research community on whether modifications are needed to Federal regulations addressing grantee conflicts of interest. In May 2009, NIH published an Advanced Note of Proposed Rulemaking on Promoting Objectivity in Research. 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.

OIG has also identified research conflict-of-interest vulnerabilities in other Department agencies. For example, in 2009, OIG reported on vulnerabilities in FDA's 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. The OIG report highlighted 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. Finally, OIG recommended that sponsors submit financial information for their clinical investigators earlier in the process. In its response to the report, FDA stated that it will consider making changes to 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. However, FDA did not agree that sponsors should submit financial information for their clinical investigators earlier as part of the pretrial application process.

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

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

Date: November 16, 2009

To: Daniel R. Levinson, Inspector General

From: Richard J. Turman, Acting Assistant Secretary for Financial Resources and Chief Financial Officer

Subject: FY 2009 Top Management and Performance Challenges Identified by the Office of the Inspector General

This memorandum is in response to OIG's *FY 2009 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 2010.

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 2009 Top Management and Performance Challenges Summary

Part I: 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
1. Integrity of Provider and Supplier Enrollment	CMS has made progress in responding to enrollment vulnerabilities, including implementing some measures aimed at enhancing enrollment standards for durable medical equipment (DME) suppliers; additional measures would further improve integrity of provider and supplier enrollment.	We agree with OIG's assessment and are making progress to respond to enrollment vulnerabilities. CMS implemented new durable medical equipment, orthotics, prosthetics, and supplies (DMEPOS) suppliers Accreditation Standards and has also established a surety bond requirement for all DMEPOS suppliers.	Medicare administrative contractors and fiscal intermediaries are being directed to review capital disproportionate share hospital (DSH) payments in support of provider and supplier eligibility. CMS is confident it has the necessary tools to ensure that future DSH payments comply with all applicable Federal provider and supplier requirements.
2. Integrity of Federal Health Care Program Payment Methodologies	CMS is working to ensure that payments are based on accurate data, respond to changes in the marketplace and medical practice, and limit the risk of fraud and abuse; however, many the payment issues identified by OIG have not yet been resolved.	CMS is making progress on issues with data used in payment methodologies that have affected both Medicare and its beneficiaries. CMS agrees it must be a prudent purchaser of health care and must work to ensure that the Medicare and Medicaid payment methodologies allow access to quality care without wasteful overspending.	The Department is reacting to changes in the marketplace and medical practices so that the programs continue to effectively reimburse for quality care, while ensuring payment incentives limit the risks of fraud and abuse.
3. Promoting Compliance with Federal Health Care Program Requirements	CMS is partnering with providers and suppliers in adopting practices and promoting compliance with program coverage, payment, and quality requirements. This includes education and guidance efforts, including continued participation in the Provider Partnership Program.	CMS continues to participate in the Provider Partnership Program, and is partnering with providers and suppliers in education and guidance efforts.	Medicare and Medicaid providers are being encouraged to implement compliance programs. CMS is creating an education, training, and outreach campaign, which is designed to improve the plan sponsor's compliance with Medicare program requirements.

Part I: 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
4. Oversight and Monitoring of Federal Health Care Programs	CMS has efforts underway, including developing oversight tools such as the Integrated Data Repository, to make needed improvements to oversight and monitoring of Federal health care programs.	Progress continues as CMS contracts with outside entities to perform oversight and monitoring functions for both Medicare and Medicaid. Improving the integrity of Medicare fee for service payments is a top priority at CMS.	CMS has plans to enhance data systems available for use by the contractors. CMS is committed to continuously improving the Payment Error Rate Measurement (PERM) program.
5. Response to Fraud and Vulnerabilities in Federal Health Care Programs	HHS is making progress in responding to fraud through law enforcement (through OIG, in partnership with the Department of Justice) and by addressing program vulnerabilities (through CMS). The Heath Care Fraud Prevention and Enforcement Action Team (HEAT) is a collaborative initiative focused on fraud prevention and response.	In conjunction with accurately identified vulnerabilities, CMS revoked suppliers' billing privileges that failed to meet Medicare standards. CMS agrees that responding to fraud and program vulnerabilities requires a high degree of coordination and collaboration between Federal and State agencies.	CMS will continue to work with its partners to respond to health care waste, fraud, and abuse.
6. Quality of Care	CMS has made some 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.	CMS continues to operate its Special Focus Facility (SFF) program, monitoring nursing homes with the worst survey performances. CMS agrees that there are significant opportunities for improvement in the Beneficiary Protection Program and has launched a redesign of the program.	Quality Improvement Organizations (QIO) will work with providers on improving their performance on specific clinical measures related to patient safety in all States.

Part II: 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
7. Emergency Preparedness and Response	The Department working with State and local health officials has made progress in preparing for and responding to public health emergencies. They continue to work together in the development of emergency preparedness and detection plans for pandemic influenza, bioterrorist attacks, and natural disasters.	The Department provided guidance to States and localities on the development of a tiered health care response structure, and seamless emergency preparedness plan development and integration for all-hazards health care system preparedness. In addition, an update to the Medical Surge Capacity and Capability Handbook was completed.	Progress continues toward health care system preparedness, which requires exercise and evaluation strategies, including evaluations of all tiers within the health care system.
8. Oversight of Food, Drugs, and Medical Devices	FDA has made progress in ensuring the timely approval and oversight of drugs and medical devices. In FY 2009, the Food Safety Working Group was created to help ensure the safety of our Nation's food supply however; FDA continues to face challenges in tracing food during food emergencies.	FDA opened field offices in China, India, and Costa Rice to conduct more inspections and work with local officials to improve the safety of foods exported to the United States.	FDA will continue to improve its generic drug approval process in addition to its oversight of clinical trials.
9. Grants Management	HHS made progress in developing consistent policies and procedures to oversee Federal grantees and has taken a key leadership role in the temporary expansion of health and social service programs under the Recovery Act, due to the Department's significant grant expenditures as the largest grant-awarding agency in the Federal Government.	The Department continued to establish practices regarding the integrity of grant data and its use, including grantee reporting and closeout procedures. NIH created a new centralized processing center for the receipt of closeout documents, and reminds grantees of their ability to submit closeout reports in the electronic research administration (eRA) Commons Closeout Module.	Focus will continue on the timely financial closeout of ended projects.

Part III: Cross-Cutting Issues that Span the Department

Management Challenge Identified by the OIG	OIG Progress Assessment	Management Response	Future Plans to Address the Challenge
10. *American Recovery and Reinvestment Act.*	The *Recovery Act* provided an estimated $167 billion over 10 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). It is critical that *Recovery Act* funds are used efficiently and effectively and are protected from fraud, waste, and abuse.	HHS established the Office of Recovery Act Coordination (ORAC) for ensuring the appropriate awarding, distributing, use, and reporting of *Recovery Act* funds. In addition the *Recovery Act* established the Recovery Accountability and Transparency Board (RATB), including the HHS Inspector, to prevent fraud, waste, and abuse, while promoting accountability and transparency.	The OIG and the Department will work together to ensure we meet our *Recovery Act* responsibilities. In addition, we will continue to prepare for a potential influx of complaints by updating our OIG hotline and tracking systems, and training agents on the evaluation and investigation of such whistleblower complaints.
11. Health Information Technology and Integrity of Information Systems	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.	The Office of the National Coordinator for Health IT (ONC) provided national leadership in health IT adoption and electronic health information exchange. The *Health Information Technology for Economic and Clinical Health (HITECH) Act* highlighted ONC's leadership by providing significant funding and authority for the Department to promote the use of health IT.	Under the guidance of ONC, the Department will continue to improve health care quality, safety, and efficiency by establishing new policies, and fostering the nation-wide health information network (NHIN). The Department will continue to collaborate with partners with regards to privacy, security, and data stewardship for electronic individually identifiable health information.
12. Ethics Program Oversight and Enforcement	NIH and FDA have implemented additional measures to strengthen their processes for reviewing and approving outside activities. The OGC Ethics Division continues its ethics program oversight.	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.	HHS will adopt a number of model practices to ensure the continued efficacy of the agency's ethics programs, and will continue to work closely with the OIG in the handling of referrals of conflict of interest violations.

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GLOSSARY

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ACRONYM	DESCRIPTION
ACF	Administration for Children and Families
ADD	Administration for Developmental Disabilities
ADRC	Aging and Disability Resource Center
AFR	Agency Financial Report
AHIC	American Health Information Community
AHRQ	Agency for Healthcare Research and Quality
AIDS	Acquired Immunodeficiency Syndrome
AoA	Administration on Aging
ASAM	Assistant Secretary for Administration and Management
ASL	Assistant Secretary for Legislation
ASPA	Assistant Secretary for Public Affairs
ASRT	Assistant Secretary for Resources and Technology
ASPE	Assistant Secretary for Planning and Evaluation
ASPR	Assistant Secretary for Preparedness and Response
ATSDR	Agency for Toxic Substances and Disease Registry
BBA	Balanced Budget Act of 1997
CARE	Comprehensive AIDS Resources Emergency
CCB	Child Care Bureau
CCDF	Child Care Development Fund
CDC	Centers for Disease Control and Prevention
CERT	Comprehensive Error Rate Testing
CFBCI	Center for Faith-Based and Community Initiatives
CFO	Chief Financial Officer
CFR	Code of Federal Regulations
CHIP	Children's Health Insurance Program
CHIPRA	Children's Health Insurance Reauthorization Act of 2009
CIA	Corporate Integrity Agreement
CIT	Center for Information Technology
CL	Current Law
CMS	Centers for Medicare & Medicaid Services
CMSO	Center for Medicare and State Operations
COLA	Cost of Living Adjustment

ACRONYM	DESCRIPTION
COTS	Commericial-off-the shelf
CPG	Compliance Program Guidance
CPI	Consumer Price Index
CSRS	Civil Service Retirement System
CY	Calendar Year (or Current Year in IPIA Tables)
DAB	Departmental Appeals Board
DAEO	Designated Agency Ethics Officer
DC	District of Columbia
DME	Durable Medical Equipment
DMEPOS	Durable Medical Equipment, Prosthetics, Orthotics, and Supplies
DOJ	Department of Justice
DOL	Department of Labor
DSH	Disproportionate Share Hospital
E&M	Evaluation and Management
EHR	Electronic Health Records
ERRP	Error Rate Reduction Plan
EY	Ernst & Young, LLP
FASAB	Federal Accounting Standards Advisory Board
FBWT	Fund Balance with Treasury
FCRA	Federal Credit Reform Act
FDA	Food and Drug Administration
FECA	Federal Employees' Compensation Act
FERS	Federal Employees Retirement System
FFDCA	Federal Food, Drug and Cosmetic Act of 1938
FFMIA	Federal Financial Management Improvement Act of 1996
FFS	Fee-for-Service
FHA	Federal Health Architecture
FICA	Federal Insurance Contributions Act
FISMA	Federal Information Security Management Act of 2002
FMFIA	Federal Managers' Financial Integrity Act of 1982
FFS	fee-for-service
FUL	Federal Upper Limit
FY	Fiscal Year

ACRONYM	DESCRIPTION
GAAP	Generally Accepted Accounting Principles
GDP	Gross Domestic Product
GSA	General Services Administration
HEAT	Health Care Fraud Prevention and Enforcement Action Team
HEW	Department of Health, Education and Welfare (now HHS)
HHAs	Home Health Agencies
HHS	Department of Health and Human Services
HI	Hospital Insurance
HIGLAS	Healthcare Integrated General Ledger Accounting System
HIPAA	Health Insurance Portability and Accountability Act of 1996
HIT	Health Information Technology
HITECH	Health Information Technology for Economic and Clinical Health
HIV	Human Immunodeficiency Virus
HPMP	Hospital Payment Monitoring Program
HPP	Hospital Preparedness Program
HRSA	Health Resources and Services Administration
IBNR	Incurred But Not Reported
IDR	Integrated Data Repository
IEVS	Income Eligibility Verification System
IGA	Intergovernmental Affairs and Regional Representatives
IHS	Indian Health Service
INMEGEN	National Institute of Genomic Medicine of Mexico
IP	Improper Payment
IPIA	Improper Payments Information Act of 2002
IT	Information Technology
J3	Jurisdiction 3
LICS	Low Income Cost Sharing Subsidy
LIPS	Low Income Premium Subsidy
LIS	Low-Income Subsidy
LLP	Limited Liability Partnership
MACs	Medicare Administrative Contractors
MARx	Medicare Advantage Prescription Drug
MC	Managed Care

ACRONYM	DESCRIPTION
MK	Non-Marketable Market Based
MMA	Medicare Prescription Drug, Improvement and Modernization Act 0f 2003
MPE	MARx Payment Error
MSIS	Medicaid Statistical Information Systems
N/A	Not Applicable
NCI	National Cancer Institute
NDNH	National Directory of New Hires
NHIN	Nationwide Health Information Network
NIH	National Institutes of Health
NPI	National Provider Identification
OACT	Office of the Actuary
OCR	Office for Civil Rights
OER	Office of Extramural Research
OGC	Office of the General Counsel
OGE	Office of Government Ethics
OGHA	Office of Global Health Affairs
OIG	Office of Inspector General
OMB	Office of Management and Budget
OMHA	Office of Medicare Hearings and Appeals
ONC	Office of the National Coordinator (for Health Information Technology)
OPDIV	Operating Division
OS	Office of the Secretary
PAHPA	Pandemic and All-Hazards Preparedness Act
PARIS	Public Assistance Reporting Information System
PELS	Payment Error related to Low-Income Subsidy
PEMS	Payment Error related to incorrect Medicaid Status
PERM	Payment Error Rate Measurement
PHS	Public Health Service
PIP	Program Improvement Plan
P.L.	Public Law
PNS	Projects of National Significance
PP&E	Property, Plant and Equipment
PPS	Prospective Payment System

ACRONYM	DESCRIPTION
PRRB	Provider Reimbursement Review Board
PSA	Public Service Advertisements
PSC	Program Support Center
PUR	Period Under Review
PY	Prior Year
QI	Qualifying Individual
QIO	Quality Improvement Organization
RAC	Recovery Audit Contractor
RADV	Risk Adjustment Data Validation
RAE	Risk Adjustment Error
RDS	Retiree Drug Subsidy
RSI	Required Supplementary Information
RSSI	Required Supplementary Stewardship Information
SAMHSA	Substance Abuse and Mental Health Services Administration
SAS	Statement of Auditing Standards
SBR	Statement of Budgetary Resources
SECA	Self-Employment Contribution Act of 1954
SFF	Special Focus Facility
SFFAS	Statement of Federal Financial Accounting Standards
SGE	Special Government Employees
SMI	Supplementary Medical Insurance
SNS	Strategic National Stockpile
SOSI	Statement of Social Insurance
SSA	Social Security Administration
SSN	Social Security Number
STAFFDIV	Staff Division
TAGGS	Tracking Accountability in Government Grants System
TANF	Temporary Assistance for Needy Families
Treasury	Department of the Treasury
UFMS	Unified Financial Management System
U.S.	United States
VICP	Vaccine Injury Compensation Program
ZPIC	Zone Program Integrity Contractor

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