OTHER INFORMATION

SECTION 3

IN THIS SECTION

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Other Financial Information

Consolidating Balance Sheet by Budget Function

As of September 30, 2019

(in Millions)

	Education, Training & Social Services	Health	Medicare	Income Security	Agency Combined Totals	Intra HHS Eliminations	HHS Consolidated Totals
Assets (Note 2)							
Intragovernmental Assets							
Fund Balance with Treasury (Note 3)	$ 13,563	$ 194,781	$ 63,442	$ 24,471	$ 296,257	$ -	$ 296,257
Investments, Net (Note 4)	-	3,971	305,378	-	309,349	-	309,349
Accounts Receivable, Net (Note 5)	129	10,227	78,180	-	88,536	(87,724)	812
Advances (Note 8)	32	308	-	52	392	(212)	180
Total Intragovernmental Assets	**13,724**	**209,287**	**447,000**	**24,523**	**694,534**	**(87,936)**	**606,598**
Accounts Receivable, Net (Note 5)	1	9,019	15,008	128	24,156	-	24,156
Inventory and Related Property, Net (Note 6)	-	10,781	-	-	10,781	-	10,781
General Property, Plant and Equipment, Net (Note 7)	-	6,408	136	-	6,544	-	6,544
Advances (Note 8)	252	728	3	1,469	2,452	-	2,452
Other Assets	-	197	-	-	197	-	197
Total Assets	**$ 13,977**	**$ 236,420**	**$ 462,147**	**$ 26,120**	**$ 738,664**	**$ (87,936)**	**$ 650,728**
Stewardship Land (Notes 19)							
Liabilities (Note 9)							
Intragovernmental Liabilities							
Accounts Payable	$ 27	$ 326	$ 88,520	$ 4	$ 88,877	$ (87,724)	$ 1,153
Other Liabilities (Note 13)	27	2,484	3,154	120	5,785	(212)	5,573
Total Intragovernmental Liabilities	**54**	**2,810**	**91,674**	**124**	**94,662**	**(87,936)**	**6,726**
Accounts Payable	25	1,162	28	6	1,221	-	1,221
Entitlement Benefits Due and Payable (Note 10)	-	38,509	71,591	-	110,100	-	110,100
Accrued Liabilities (Note 12)	1,056	12,242	-	2,245	15,543	-	15,543
Federal Employee and Veterans' Benefits (Note 11)	4	14,822	-	-	14,826	-	14,826
Contingencies and Commitments (Note 14)	-	16,910	173	-	17,083	-	17,083
Other Liabilities (Note 13)	19	2,864	801	11	3,695	-	3,695
Total Liabilities	**1,158**	**89,319**	**164,267**	**2,386**	**257,130**	**(87,936)**	**169,194**
Net Position							
Unexpended Appropriations - Funds from Dedicated Collections (Note 18)	-	73	57,895	-	57,968	-	57,968
Unexpended Appropriations - Other funds	12,727	133,842	-	23,869	170,438	-	170,438
Cumulative Results of Operations - Funds from Dedicated Collections (Note 18)	-	18,407	239,985	-	258,392	-	258,392
Cumulative Results of Operations - Other funds	92	(5,221)	-	(135)	(5,264)	-	(5,264)
Total Net Position - Funds from Dedicated Collections	**-**	**18,480**	**297,880**	**-**	**316,360**	**-**	**316,360**
Total Net Position - Other Funds	**12,819**	**128,621**	**-**	**23,734**	**165,174**	**-**	**165,174**
Total Net Position	**12,819**	**147,101**	**297,880**	**23,734**	**481,534**	**-**	**481,534**
Total Liabilities and Net Position	**$ 13,977**	**$ 236,420**	**$ 462,147**	**$ 26,120**	**$ 738,664**	**$ (87,936)**	**$ 650,728**

Consolidating Statement of Net Cost by Budget Function

For the Year Ended September 30, 2019

(in Millions)

Responsibility Segments	Education, Training, & Social Services	Health	Medicare	Income Security	Agency Combined Totals	Intra HHS Eliminations Cost ( )	Intra HHS Eliminations Revenue	Consolidated Totals
ACF	$ 13,724	$ -	$ -	$ 42,465	$ 56,189	$ (122)	$ (5)	$ 56,062
ACL	2,184	-	-	-	2,184	(10)	1	2,175
AHRQ	-	328	-	-	328	(20)	18	326
CDC	-	12,296	-	-	12,296	(286)	98	12,108
CMS	-	434,128	653,143	-	1,087,271	(380)	16	1,086,907
FDA	-	3,017	-	-	3,017	(293)	22	2,746
HRSA	-	11,843	-	-	11,843	(248)	11	11,606
IHS	-	5,916	-	-	5,916	(182)	238	5,972
NIH	-	35,340	-	-	35,340	(256)	376	35,460
OS	-	3,280	-	-	3,280	(485)	424	3,219
PSC	-	1,082	-	-	1,082	(74)	762	1,770
SAMHSA	-	4,424	-	-	4,424	(51)	125	4,498
Totals	**$ 15,908**	**$ 511,654**	**$ 653,143**	**$ 42,465**	**$ 1,223,170**	**$ (2,407)**	**$ 2,086**	**$ 1,222,849**

Gross Cost and Exchange Revenue

For the Year Ended September 30, 2019

(in Millions)

Responsibility Segments	Intragovernmental Gross Cost Combined	Gross Cost Eliminations	Gross Cost Consolidated	Less: Exchange Revenue Combined	Less: Exchange Revenue Eliminations	Less: Exchange Revenue Consolidated	With the Public Gross Cost	With the Public Less: Exchange Revenue	Consolidated Net Cost of Operations
ACF	$ 289	$ (122)	$ 167	$ (2)	$ (5)	$ (7)	$ 55,920	$ (18)	$ 56,062
ACL	21	(10)	11	(2)	1	(1)	2,165	-	2,175
AHRQ	48	(20)	28	(19)	18	(1)	307	(8)	326
CDC	909	(286)	623	(218)	98	(120)	11,662	(57)	12,108
CMS	1,016	(380)	636	(25)	16	(9)	1,200,994	(114,714)	1,086,907
FDA	1,301	(293)	1,008	(38)	22	(16)	4,331	(2,577)	2,746
HRSA	365	(248)	117	(11)	11	-	11,538	(49)	11,606
IHS	727	(182)	545	(286)	238	(48)	7,005	(1,530)	5,972
NIH	1,496	(256)	1,240	(593)	376	(217)	34,582	(145)	35,460
OS	991	(485)	506	(609)	424	(185)	2,933	(35)	3,219
PSC	357	(74)	283	(1,736)	762	(974)	2,461	-	1,770
SAMHSA	95	(51)	44	(156)	125	(31)	4,481	4	4,498
Totals	**$ 7,615**	**$ (2,407)**	**$ 5,208**	**$ (3,695)**	**$ 2,086**	**$ (1,609)**	**$ 1,338,379**	**$ (119,129)**	**$ 1,222,849**

Reduce the Footprint

Reduce the Footprint Baseline Comparison (in Square Footage)

	2015 Baseline	2018 Year End	Change
Total Leased	13,014,210	13,757,629	743,419
Total Owned	6,273,290	5,282,841	(990,449)
Total	**19,287,500**	**19,040,470**	**(247,030)**

Reporting of O&M Costs - Owned and Direct Lease Buildings (in Millions)

	2015 Baseline	2018 Year End	Change
Operation and Maintenance Costs	$ 92.2	$ 90.0	$ (2.2)

OMB Memorandum 12-12, *Promoting Efficient Spending to Support Agency Operations*, and OMB Management Procedures Memorandum 2015-01, *Implementation of OMB Memorandum M-12-12 Section 3: Reduce the Footprint*, require CFO Act Departments to set annual targets for reducing the total square footage (sq.) of their domestic office and warehouse space compared to the FY 2015 baseline.

In FY 2018, HHS office and warehouse space decreased by 247,030 sq.; as compared to the Reduce the Footprint baseline of 19,287,500 sq. established for FY 2015. HHS will continue the efforts to reduce the inventory of office and warehouse space through reconfiguration of office spaces, Regional Office consolidations, and warehouse consolidations, and will continue to review its warehouse inventory to identify future reduction opportunities.

Summary of Financial Statement Audit and Management Assurances

As described in the "Management's Discussion and Analysis" section, management annually presents an assurance statement on the effectiveness of internal control. The following two tables present summary information related to any material weakness identified during the audit, as well as conformance with FMFIA and compliance with FFMIA.

Table 1: Summary of Financial Statement Audit

Audit Opinion			Unmodified for Four Financial Statements Disclaimed Opinion on Statement of Social Insurance and Statement of Changes in Social Insurance Amounts		
Restatement			No		
Material Weaknesses	Beginning Balance	New	Resolved	Consolidated	Ending Balance
No Material Weaknesses Noted	0	-	-	-	0
Total Material Weaknesses	***0***	***-***	***-***	***-***	***0***

Definition of Terms – Tables 1 and 2
(Reference: OMB Circular A-136, *Financial Reporting Requirements*, June 28, 2019, page 105)

Beginning Balance: The beginning balance must agree with the ending balance from the prior year.

New: The total number of material weaknesses / non-conformances identified during the current year.

Resolved: The total number of material weaknesses / non-conformances that 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 finding does not meet the criteria for materiality or is redefined as more correctly classified under another heading).

Ending Balance: The year-end balance that will be the beginning balance next year.

Table 2: Summary of Management Assurances

Effectiveness of Internal Control over Reporting (FMFIA Section 2)

Statement of Assurance	Unmodified					
Material Weaknesses	Beginning Balance	New	Resolved	Consolidated	Reassessed	Ending Balance
No Material Weaknesses Noted	0	-	0	-	-	0
Total Material Weaknesses	*0*	*-*	*0*	*-*	*-*	*0*

Effectiveness of Internal Control over Operations and Compliance with Laws and Regulations (FMFIA Section 2)

Statement of Assurance	Modified					
Material Weaknesses/ Noncompliances	Beginning Balance	New	Resolved	Consolidated	Reassessed	Ending Balance
Error Rate Measurement	1	1	-	-	-	2
Medicare Appeals Process	1	-	-	-	-	1
Contracting	0	1	-	-	-	1
Total Material Weaknesses/ Noncompliances	*2*	*2*	*0*	*-*	*-*	*4*

Conformance with Federal Financial Management System Requirements (FMFIA Section 4)

Statement of Assurance	Federal Systems conform to financial management system requirements					
Noncompliance	Beginning Balance	New	Resolved	Consolidated	Reassessed	Ending Balance
No Noncompliances Noted	0	-	0	-		0
Total Noncompliance	*0*	*-*	*0*	*-*		*0*

Compliance with Section 803(a) of the *Federal Financial Management Improvement Act* (FFMIA)

	Agency	Auditor
1. Federal Financial Management System Requirements	No lack of compliance noted	No lack of compliance noted
2. Applicable Federal Accounting Standards	No lack of compliance noted	No lack of compliance noted
3. U.S. Standard General Ledger at Transaction Level	No lack of compliance noted	No lack of compliance noted

Civil Monetary Penalty Adjustment for Inflation

The Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (the 2015 Act), as amended, requires agencies to make regular and consistent inflationary adjustments of civil monetary penalties and to maintain their deterrent effect. To improve compliance with the 2015 Act, agencies are required to publish annual inflation adjustments in the Federal Register and should report annually in their agency financial report.

The 2015 Act applies to eight Operating Divisions (OpDivs) and Staff Divisions (StaffDivs): ACF, AHRQ, HRSA, FDA, CMS, Office for Civil Rights, Office of the General Counsel, and Office of Inspector General. The tables below illustrates HHS's civil monetary penalties by OpDivs and StaffDivs. Refer to the Federal Register for the Annual Civil Monetary Penalties Inflation Adjustment.

Administration for Children and Families

Penalty	Statutory Authority	Date of Previous Adjustment	Date of Current Adjustment	Current Penalty Level ($ Amount)
Penalty for Misuse of Information in the National Directory of New Hires.	42 U.S.C. 653(l)(2)	2018	2019	$ 1,542

Agency for Healthcare Research and Quality

Penalty	Statutory Authority	Date of Previous Adjustment	Date of Current Adjustment	Current Penalty Level ($ Amount)
Penalty for an establishment or person supplying information obtained in the course of activities for any purpose other than the purpose for which it was supplied.	42 U.S.C. 299c—(3)(d)	2018	2019	$ 15,034

Health Resources and Services Administration

Penalty	Statutory Authority	Date of Previous Adjustment	Date of Current Adjustment	Current Penalty Level ($ Amount)
Penalty for each instance of overcharging a 340B covered entity.	42 U.S.C. 256b(d)(1)(B)(vi)	2018	2019	$ 5,781

Office for Civil Rights

Penalty	Statutory Authority	Date of Previous Adjustment	Date of Current Adjustment	Current Penalty Level ($ Amount)
Penalty for violation of confidentiality provision of the *Patient Safety and Quality Improvement Act*.	42 U.S.C. 299b-22(f)(1)	2018	2019	$ 12,695
Penalty for each pre-February 18, 2009 violation of the HIPAA administrative simplification provisions.	42 U.S.C. 299b-22(f)(1)	2018	2019	159
Calendar Year Cap	42 U.S.C. 299b-22(f)(1)	2018	2019	39,936
Penalty for each February 18, 2009 or later violation of a HIPAA administrative simplification provision in which it is established that the covered entity or business associate did not know and by exercising reasonable diligence, would not have known that the covered entity or business associate violated such a provision.	42 U.S.C. 1320(d)-5(a)			
Minimum	42 U.S.C. 1320(d)-5(a)	2018	2019	117
Maximum	42 U.S.C. 1320(d)-5(a)	2018	2019	58,490
Calendar Year Cap	42 U.S.C. 1320(d)-5(a)	2018	2019	1,754,698

Penalty	Statutory Authority	Date of Previous Adjustment	Date of Current Adjustment	Current Penalty Level ($ Amount)
Penalty for each February 18, 2009 or later violation of a HIPAA administrative simplification provision in which it is established that the violation was due to reasonable cause and not to willful neglect.	42 U.S.C. 1320(d)-5(a)			
Minimum	42 U.S.C. 1320(d)-5(a)	2018	2019	1,170
Maximum	42 U.S.C. 1320(d)-5(a)	2018	2019	58,490
Calendar Year Cap	42 U.S.C. 1320(d)-5(a)	2018	2019	1,754,698
Penalty for each February 18, 2009 or later violation of a HIPAA administrative simplification provision in which it is established that the violation was due to willful neglect and was corrected during the 30-day period beginning on the first date the covered entity or business associate knew, or, by exercising reasonable diligence, would have known that the violation occurred.	42 U.S.C. 1320(d)-5(a)			
Minimum	42 U.S.C. 1320(d)-5(a)	2018	2019	11,698
Maximum	42 U.S.C. 1320(d)-5(a)	2018	2019	58,490
Calendar Year Cap	42 U.S.C. 1320(d)-5(a)	2018	2019	1,754,698
Penalty for each February 18, 2009 or later violation of a HIPAA administrative simplification provision in which it is established that the violation was due to willful neglect and was not corrected during the 30-day period beginning on the first date the covered entity or business associate knew, or by exercising reasonable diligence, would have known that the violation occurred.	42 U.S.C. 1320(d)-5(a)			
Minimum	42 U.S.C. 1320(d)-5(a)	2018	2019	58,490
Maximum	42 U.S.C. 1320(d)-5(a)	2018	2019	1,754,698
Calendar Year Cap	42 U.S.C. 1320(d)-5(a)	2018	2019	1,754,698

Office of the General Counsel

Penalty	Statutory Authority	Date of Previous Adjustment	Date of Current Adjustment	Current Penalty Level ($ Amount)
Penalty for the first time an individual makes an expenditure prohibited by regulations regarding lobbying disclosure, absent aggravating circumstances.	31 U.S.C. 1352	2018	2019	$ 20,134
Penalty for second and subsequent offenses by individuals who make an expenditure prohibited by regulations regarding lobbying disclosure.	31 U.S.C. 1352			
Minimum	31 U.S.C. 1352	2018	2019	20,134
Maximum	31 U.S.C. 1352	2018	2019	201,340
Penalty for the first time an individual fails to file or amend a lobbying disclosure form, absent aggravating circumstances.	31 U.S.C. 1352	2018	2019	20,134
Penalty for second and subsequent offenses by individuals who fail to file or amend a lobbying disclosure form, absent aggravating circumstances.	31 U.S.C. 1352			
Minimum	31 U.S.C. 1352	2018	2019	20,134
Maximum	31 U.S.C. 1352	2018	2019	201,340
Penalty for failure to provide certification regarding lobbying in the award documents for all sub-awards of all tiers.	31 U.S.C. 1352			
Minimum	31 U.S.C. 1352	2018	2019	20,134
Maximum	31 U.S.C. 1352	2018	2019	201,340

Penalty	Statutory Authority	Date of Previous Adjustment	Date of Current Adjustment	Current Penalty Level ($ Amount)
Penalty for failure to provide statement regarding lobbying for loan guarantee and loan insurance transactions.	31 U.S.C. 1352			
Minimum	31 U.S.C. 1352	2018	2019	20,134
Maximum	31 U.S.C. 1352	2018	2019	201,340
Penalty against any individual who - with knowledge or reason to know - makes, presents or submits a false, fictitious or fraudulent claim to the Department.	31 U.S.C. 3801-3812	2018	2019	10,520
Penalty against any individual who - with knowledge or reason to know - makes, presents or submits a false, fictitious or fraudulent claim to the Department.	31 U.S.C. 3801-3812	2018	2019	10,520

Office of Inspector General

Penalty	Statutory Authority	Date of Previous Adjustment	Date of Current Adjustment	Current Penalty Level ($ Amount)
Penalty for each individual who violates safety and security procedures related to handling dangerous biological agents and toxins.	42 U.S.C. 262a(i)(1)	2018	2019	$ 348,708
Penalty for any other person who violates safety and security procedures related to handling dangerous biological agents and toxins.	42 U.S.C. 262a(i)(1)	2018	2019	697,418
Penalty per violation for committing information blocking.	42 U.S.C. 300jj-51	2018	2019	1,063,260
Penalty for knowingly presenting or causing to be presented to an officer, employee, or agent of the United States a false claim.	42 U.S.C. 1320a-7a(a)	2018	2019	20,504
Penalty for knowingly presenting or causing to be presented a request for payment which violates the terms of an assignment, agreement, or PPS agreement.	42 U.S.C. 1320a-7a(a)	2018	2019	20,504
Penalty for knowingly giving or causing to be presented to a participating provider or supplier false or misleading information that could reasonably be expected to influence a discharge decision.	42 U.S.C. 1320a-7a(a)	2018	2019	30,757
Penalty for an excluded party retaining ownership or control interest in a participating entity.	42 U.S.C. 1320a-7a(a)	2018	2019	20,504
Penalty for remuneration offered to induce program beneficiaries to use particular providers, practitioners, or suppliers.	42 U.S.C. 1320a-7a(a)	2018	2019	20,504
Penalty for employing or contracting with an excluded individual.	42 U.S.C. 1320a-7a(a)	2018	2019	20,504
Penalty for knowing and willful solicitation, receipt, offer, or payment of remuneration for referring an individual for a service or for purchasing, leasing, or ordering an item to be paid for by a Federal health care program.	42 U.S.C. 1320a-7a(a)	2018	2019	102,522
Penalty for ordering or prescribing medical or other item or service during a period in which the person was excluded.	42 U.S.C. 1320a-7a(a)	2018	2019	20,504
Penalty for knowingly making or causing to be made a false statement, omission or misrepresentation of a material fact in any application, bid, or contract to participate or enroll as a provider or supplier.	42 U.S.C. 1320a-7a(a)	2018	2019	102,522
Penalty for knowing of an overpayment and failing to report and return.	42 U.S.C. 1320a-7a(a)	2018	2019	20,504
Penalty for making or using a false record or statement that is material to a false or fraudulent claim	42 U.S.C. 1320a-7a(a)	2018	2019	102,522
Penalty for failure to grant timely access to HHS OIG for audits, investigations, evaluations, and other statutory functions of HHS OIG.	42 U.S.C. 1320a-7a(a)	2018	2019	30,757
Penalty for payments by a hospital or critical access hospital to induce a physician to reduce or limit services to individuals under direct care of physician or who are entitled to certain medical assistance benefits.	42 U.S.C. 1320a-7a(b)	2018	2019	5,126
Penalty for physicians who knowingly receive payments from a hospital or critical access hospital to induce such physician to reduce or limit services to individuals under direct care of physician or who are entitled to certain medical assistance benefits.	42 U.S.C. 1320a-7a(b)	2018	2019	5,126

Penalty	Statutory Authority	Date of Previous Adjustment	Date of Current Adjustment	Current Penalty Level ($ Amount)
Penalty for a physician who executes a document that falsely certifies home health needs for Medicare beneficiaries.	42 U.S.C. 1320a-7a(b)	2018	2019	10,252
Penalty for knowingly presenting or causing to be presented a false or fraudulent specified claim under a grant, contract, or other agreement for which the Secretary provides funding.	42 U.S.C. 1320a-7a(o)	2016	2019	10,461
Knowingly makes, uses, or causes to be made or used any false statement, omission, or misrepresentation of a material fact in any application, proposal, bid, progress report, or other document required to directly or indirectly receive or retain funds provided pursuant to grant, contract, or other agreement.	42 U.S.C. 1320a-7a(o)	2016	2019	52,308
Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent specified claim under grant, contract, or other agreement.	42 U.S.C. 1320a-7a(o)	2016	2019	52,308
Knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit funds or property with respect to grant, contract, or other agreement, or knowingly conceals or improperly avoids or decreases any such obligation.	42 U.S.C. 1320a-7a(o)	2016	2019	52,308
Fails to grant timely access, upon reasonable request, to the I.G. for purposes of audits, investigations, evaluations, or other statutory functions of I.G. in matters involving grants, contracts, or other agreements.	42 U.S.C. 1320a-7a(o)	2016	2019	15,692
Penalty for failure to report any final adverse action taken against a health care provider, supplier, or practitioner.	42 U.S.C. 1320a-7e(b)(6)(A)	2018	2019	39,121
Penalty for the misuse of words, symbols, or emblems in communications in a manner in which a person could falsely construe that such item is approved, endorsed, or authorized by HHS.	42 U.S.C. 1320b-10(b)(1)	2018	2019	10,519
Penalty for the misuse of words, symbols, or emblems in a broadcast or telecast in a manner in which a person could falsely construe that such item is approved, endorsed, or authorized by HHS.	42 U.S.C. 1320b-10(b)(2)	2018	2019	52,596
Penalty for certification of a false statement in assessment of functional capacity of a Skilled Nursing Facility resident assessment.	42 U.S.C. 1395i-3(b)(3)(B)(ii)(1)	2018	2019	2,194
Penalty for causing another to certify or make a false statement in assessment of functional capacity of a Skilled Nursing Facility resident assessment.	42 U.S.C. 1395i-3(b)(3)(B)(ii)(2)	2018	2019	10,967
Penalty for any individual who notifies or causes to be notified a Skilled Nursing Facility of the time or date on which a survey is to be conducted.	42 U.S.C. 1395i-3(g)(2)(A)	2018	2019	4,388
Penalty for a Medicare Advantage organization that substantially fails to provide medically necessary, required items and services.	42 U.S.C. 1395w-27(g)(2)(A)	2018	2019	39,936
Penalty for a Medicare Advantage organization that charges excessive premiums.	42 U.S.C. 1395w-27(g)(2)(A)	2018	2019	39,121
Penalty for a Medicare Advantage organization that improperly expels or refuses to reenroll a beneficiary.	42 U.S.C. 1395w-27(g)(2)(A)	2018	2019	39,121
Penalty for a Medicare Advantage organization that engages in practice that would reasonably be expected to have the effect of denying or discouraging enrollment.	42 U.S.C. 1395w-27(g)(2)(A)	2018	2019	156,488
Penalty per individual who does not enroll as a result of a Medicare Advantage organization's practice that would reasonably be expected to have the effect of denying or discouraging enrollment.	42 U.S.C. 1395w-27(g)(2)(A)	2018	2019	23,473
Penalty for a Medicare Advantage organization misrepresenting or falsifying information to Secretary.	42 U.S.C. 1395w-27(g)(2)(A)	2018	2019	156,488
Penalty for a Medicare Advantage organization misrepresenting or falsifying information to individual or other entity.	42 U.S.C. 1395w-27(g)(2)(A)	2018	2019	39,121
Penalty for Medicare Advantage organization interfering with provider's advice to enrollee and non-MCO affiliated providers that balance bill enrollees.	42 U.S.C. 1395w-27(g)(2)(A)	2018	2019	39,121
Penalty for a Medicare Advantage organization that employs or contracts with excluded individual or entity.	42 U.S.C. 1395w-27(g)(2)(A)	2018	2019	39,121
Penalty for a Medicare Advantage organization enrolling an individual in without prior written consent.	42 U.S.C. 1395w-27(g)(2)(A)	2018	2019	39,121

Penalty	Statutory Authority	Date of Previous Adjustment	Date of Current Adjustment	Current Penalty Level ($ Amount)
Penalty for a Medicare Advantage organization transferring an enrollee to another plan without consent or solely for the purpose of earning a commission.	42 U.S.C. 1395w-27(g)(2)(A)	2018	2019	39,121
Penalty for a Medicare Advantage organization failing to comply with marketing restrictions or applicable implementing regulations or guidance.	42 U.S.C. 1395w-27(g)(2)(A)	2018	2019	39,121
Penalty for a Medicare Advantage organization employing or contracting with an individual or entity who violates 1395w-27(g)(1)(A)-(J).	42 U.S.C. 1395w-27(g)(2)(A)	2018	2019	39,121
Penalty for a prescription drug card sponsor that falsifies or misrepresents marketing materials, overcharges program enrollees, or misuse transitional assistance funds.	42 U.S.C. 1395w-141(i)(3)	2018	2019	13,669
Penalty for improper billing by Hospitals, Critical Access Hospitals, or Skilled Nursing Facilities.	42 U.S.C. 1395cc(g)	2018	2019	5,317
Penalty for a hospital or responsible physician dumping patients needing emergency medical care, if the hospital has 100 beds or more.	42 U.S.C. 1395dd(d)(1)	2018	2019	109,663
Penalty for a hospital or responsible physician dumping patients needing emergency care, if the hospital has less than 100 beds.	42 U.S.C. 1395dd(d)(1)	2018	2019	54,833
Penalty for a HMO or competitive plan is such plan substantially fails to provide medically necessary, required items or services	42 U.S.C. 1395mm(i)(6)(B)(i)	2018	2019	54,833
Penalty for HMOs/competitive medical plans that charge premiums in excess of permitted amounts	42 U.S.C. 1395mm(i)(6)(B)(i)	2018	2019	54,833
Penalty for a HMO or competitive medical plan that expels or refuses to reenroll an individual per prescribed conditions	42 U.S.C. 1395mm(i)(6)(B)(i)	2018	2019	54,833
Penalty for a HMO or competitive medical plan that implements practices to discourage enrollment of individuals needing services in future.	42 U.S.C. 1395mm(i)(6)(B)(i)	2018	2019	219,327
Penalty per individual not enrolled in a plan as a result of a HMO or competitive medical plan that implements practices to discourage enrollment of individuals needing services in the future.	42 U.S.C. 1395mm(i)(6)(B)(i)	2018	2019	31,558
Penalty for a HMO or competitive medical plan that misrepresents or falsifies information to the Secretary.	42 U.S.C. 1395mm(i)(6)(B)(i)	2018	2019	219,327
Penalty for a HMO or competitive medical plan that misrepresents or falsifies information to an individual or any other entity.	42 U.S.C. 1395mm(i)(6)(B)(i)	2018	2019	54,833
Penalty for failure by HMO or competitive medical plan to assure prompt payment of Medicare risk sharing contracts or incentive plan provisions.	42 U.S.C. 1395mm(i)(6)(B)(i)	2018	2019	54,833
Penalty for HMO that employs or contracts with excluded individual or entity.	42 U.S.C. 1395mm(i)(6)(B)(i)	2018	2019	50,334
Penalty for submitting or causing to be submitted claims in violation of the Stark Law's restrictions on physician self-referrals.	42 U.S.C. 1395nn(g)(3)	2018	2019	25,372
Penalty for circumventing Stark Law's restrictions on physician self-referrals.	42 U.S.C. 1395nn(g)(4)	2018	2019	169,153
Penalty for a material misrepresentation regarding Medigap compliance policies.	42 U.S.C. 1395ss(d)(1)	2018	2019	10,519
Penalty for selling Medigap policy under false pretense.	42 U.S.C. 1395ss(d)(2)	2018	2019	10,519
Penalty for an issuer that sells health insurance policy that duplicates benefits.	42 U.S.C. 1395ss(d)(3)(A)(ii)	2018	2019	47,357
Penalty for someone other than issuer that sells health insurance that duplicates benefits.	42 U.S.C. 1395ss(d)(3)(A)(ii)	2018	2019	28,413
Penalty for using mail to sell a non-approved Medigap insurance policy.	42 U.S.C. 1395ss(d)(4)(A)	2018	2019	10,519
Penalty for a Medicaid MCO that substantially fails to provide medically necessary, required items or services.	42 U.S.C. 1396b(m)(5)(B)(i)	2018	2019	52,596
Penalty for a Medicaid MCO that charges excessive premiums.	42 U.S.C. 1395mm(i)(5)(B)(i)	2018	2019	52,596
Penalty for a Medicaid MCO that improperly expels or refuses to reenroll a beneficiary.	42 U.S.C. 1395mm(i)(5)(B)(i)	2018	2019	210,386

Penalty	Statutory Authority	Date of Previous Adjustment	Date of Current Adjustment	Current Penalty Level ($ Amount)
Penalty per individual who does not enroll as a result of a Medicaid MCO's practice that would reasonably be expected to have the effect of denying or discouraging enrollment.	42 U.S.C. 1396b(m)(5)(B)(i)	2018	2019	31,558
Penalty for a Medicaid MCO misrepresenting or falsifying information to the Secretary.	42 U.S.C. 1396b(m)(5)(B)(i)	2018	2019	210,386
Penalty for a Medicaid MCO misrepresenting or falsifying information to an individual or another entity.	42 U.S.C. 1396b(m)(5)(B)(i)	2018	2019	52,596
Penalty for a Medicaid MCO that fails to comply with contract requirements with respect to physician incentive plans.	42 U.S.C. 1396b(m)(5)(B)(i)	2018	2019	47,357
Penalty for willfully and knowingly certifying a material and false statement in a Skilled Nursing Facility resident assessment.	42 U.S.C. 1396r(b)(3)(B)(ii)(I)	2018	2019	2,194
Penalty for willfully and knowingly causing another individual to certify a material and false statement in a Skilled Nursing Facility resident assessment.	42 U.S.C. 1396r(b)(3)(B)(ii)(II)	2018	2019	10,967
Penalty for notifying or causing to be notified a Skilled Nursing Facility of the time or date on which a survey is to be conducted.	42 U.S.C. 1396r(g)(2)(A)(i)	2018	2019	4,388
Penalty for the knowing provision of false information or refusing to provide information about charges or prices of a covered outpatient drug.	42 U.S.C. 1396r-8(b)(3)(B)	2018	2019	189,427
Penalty per day for failure to timely provide information by drug manufacturer with rebate agreement.	42 U.S.C. 1396r-8(b)(3)(C)(i)	2018	2019	18,943
Penalty for knowing provision of false information by drug manufacturer with rebate agreement.	42 U.S.C. 1396r-8(b)(3)(C)(ii)	2018	2019	189,427
Penalty for notifying home and community-based providers or settings of survey.	42 U.S.C. 1396t(i)(3)(A)	2018	2019	3,788
Penalty for failing to report a medical malpractice claim to National Practitioner Data Bank.	42 U.S.C. 11131(c)	2018	2019	22,927
Penalty for breaching confidentiality of information reported to National Practitioner Data Bank.	42 U.S.C. 11137(b)(2)	2018	2019	22,927

Food and Drug Administration

Penalty	Statutory Authority	Date of Previous Adjustment	Date of Current Adjustment	Current Penalty Level ($ Amount)
Penalty for violations related to drug samples resulting in a conviction of any representative of manufacturer or distributor in any 10-year period.	21 U.S.C. 333 (b)(2)(A)	2018	2019	$ 105,194
Penalty for violation related to drug samples resulting in a conviction of any representative of manufacturer or distributor after the second conviction in any 10-yr period.	21 U.S.C. 333 (b)(2)(B)	2018	2019	2,103,861
Penalty for failure to make a report required by 21 U.S.C. 353(d)(3)(E) relating to drug samples.	21 U.S.C. 333 (b)(3)	2018	2019	210,386
Penalty for any person who violates a requirement related to devices for each such violation.	21 U.S.C. 333 (f)(1)(A)	2018	2019	28,413
Penalty for aggregate of all violations related to devices in a single proceeding.	21 U.S.C. 333 (f)(1)(A)	2018	2019	1,894,261
Penalty for any individual who introduces or delivers for introduction into interstate commerce food that is adulterated per 21 U.S.C. 342(a)(2)(B) or any individual who does not comply with a recall order under 21 U.S.C. 350l.	21 U.S.C. 333 (f)(2)(A)	2018	2019	79,875
Penalty in the case of any other person other than an individual) for such introduction or delivery of adulterated food.	21 U.S.C. 333 (f)(2)(A)	2018	2019	399,374
Penalty for aggregate of all such violations related to adulterated food adjudicated in a single proceeding.	21 U.S.C. 333 (f)(2)(A)	2018	2019	798,747
Penalty for all violations adjudicated in a single proceeding for any person who violates 21 U.S.C. 331(jj) by failing to submit the certification required by 42 U.S.C. 282(j)(5)(B) or knowingly submitting a false certification; by failing to submit clinical trial information under 42 U.S.C. 282(j); or by submitting clinical trial information under 42 U.S.C. 282(j) that is false or misleading in any particular under 42 U.S.C. 282(j)(5)(D).	21 U.S.C. 333 (f)(3)(A)	2018	2019	12,103

Penalty	Statutory Authority	Date of Previous Adjustment	Date of Current Adjustment	Current Penalty Level ($ Amount)
Penalty for each day any above violation is not corrected after a 30-day period following notification until the violation is corrected.	21 U.S.C. 333 (f)(3)(B)	2018	2019	12,103
Penalty for any responsible person that violates a requirement of 21 U.S.C. 355(o) (post-marketing studies, clinical trials, labeling), 21 U.S.C. 355(p) (risk evaluation and mitigation (REMS)), or 21 U.S.C. 355–1 (REMS).	21 U.S.C. 333 (f)(4)(A)(i)	2018	2019	302,585
Penalty for aggregate of all such above violations in a single proceeding.	21 U.S.C. 333 (f)(4)(A)(i)	2018	2019	1,210,340
Penalty for REMS violation that continues after written notice to the responsible person for the first 30-day period (or any portion thereof) the responsible person continues to be in violation.	21 U.S.C. 333 (f)(4)(A)(ii)	2018	2019	302,585
Penalty for REMS violation that continues after written notice to responsible person doubles for every 30-day period thereafter the violation continues, but may not exceed penalty amount for any 30-day period.	21 U.S.C. 333 (f)(4)(A)(ii)	2018	2019	1,210,340
Penalty for aggregate of all such above violations adjudicated in a single proceeding.	21 U.S.C. 333 (f)(4)(A)(ii)	2018	2018	12,103,404
Penalty for any person who violates a requirement which relates to tobacco products for each such violation.	21 U.S.C. 333 (f)(9)(A)	2018	2019	17,547
Penalty for aggregate of all such violations of tobacco product requirement adjudicated in a single proceeding.	21 U.S.C. 333 (f)(9)(A)	2018	2019	1,169,798
Penalty per violation related to violations of tobacco requirements.	21 U.S.C. 333 (f)(9)(B)(i)(I)	2018	2019	292,450
Penalty for aggregate of all such violations of tobacco product requirements adjudicated in a single proceeding.	21 U.S.C. 333 (f)(9)(B)(i)(I)	2018	2019	1,169,798
Penalty in the case of a violation of tobacco product requirements that continues after written notice to such person, for the first 30-day period (or any portion thereof) the person continues to be in violation.	21 U.S.C. 333 (f)(9)(B)(i)(II)	2018	2019	292,450
Penalty for violation of tobacco product requirements that continues after written notice to such person shall double for every 30-day period thereafter the violation continues, but may not exceed penalty amount for any 30-day period.	21 U.S.C. 333 (f)(9)(B)(i)(II)	2018	2019	1,169,798
Penalty for aggregate of all such violations related to tobacco product requirements adjudicated in a single proceeding.	21 U.S.C. 333 (f)(9)(B)(i)(II)	2018	2019	11,697,983
Penalty for any person who either does not conduct post-market surveillance and studies to determine impact of a modified risk tobacco product for which the HHS Secretary has provided them an order to sell, or who does not submit a protocol to the HHS Secretary after being notified of a requirement to conduct post-market surveillance of such tobacco products.	21 U.S.C. 333 (f)(9)(B)(ii)(I)	2018	2019	292,450
Penalty for aggregate of for all such above violations adjudicated in a single proceeding.	21 U.S.C. 333 (f)(9)(B)(ii)(I)	2018	2019	1,169,798
Penalty for violation of modified risk tobacco product post-market surveillance that continues after written notice to such person for the first 30-day period (or any portion thereof) that the person continues to be in violation.	21 U.S.C. 333 (f)(9)(B)(ii)(II)	2018	2019	292,450
Penalty for post-notice violation of modified risk tobacco product post-market surveillance shall double for every 30-day period thereafter that the tobacco product requirement violation continues for any 30-day period, but may not exceed penalty amount for any 30-day period.	21 U.S.C. 333 (f)(9)(B)(ii)(II)	2018	2019	1,169,798
Penalty for aggregate above tobacco product requirement violations adjudicated in a single proceeding.	21 U.S.C. 333 (f)(9)(B)(ii)(II)	2018	2019	11,697,983
Penalty for any person who disseminates or causes another party to disseminate a direct-to-consumer advertisement that is false or misleading for the first such violation in any 3-year period.	21 U.S.C. 333 (g)(1)	2018	2019	302,585
Penalty for each subsequent above violation in any 3-year period.	21 U.S.C. 333 (g)(1)	2018	2019	605,171
Penalty to be applied for violations of restrictions on the sale or distribution of tobacco products promulgated under 21 U.S.C. 387f(d) (*e.g.,* violations of regulations in 21 CFR part 1140) with respect to a retailer with an approved training program in the case of a second regulation violation within a 12-month period.	21 U.S.C. 333 note	2018	2019	292

Penalty	Statutory Authority	Date of Previous Adjustment	Date of Current Adjustment	Current Penalty Level ($ Amount)
Penalty in the case of a third tobacco product regulation violation within a 24-month period.	21 U.S.C. 333 note	2018	2019	584
Penalty in the case of a fourth tobacco product regulation violation within a 24- month period.	21 U.S.C. 333 note	2018	2019	2,340
Penalty in the case of a fifth tobacco product regulation violation within a 36-month period.	21 U.S.C. 333 note	2018	2019	5,849
Penalty in the case of a sixth or subsequent tobacco product regulation violation within a 48-month period as determined on a case-by-case basis.	21 U.S.C. 333 note	2018	2019	11,698
Penalty to be applied for violations of restrictions on the sale or distribution of tobacco products promulgated under 21 U.S.C. 387f(d) (*e.g.,* violations of regulations in 21 CFR part 1140) with respect to a retailer that does not have an approved training program in the case of the first regulation violation.	21 U.S.C. 333 note	2018	2019	292
Penalty in the case of a second tobacco product regulation violation within a 12-month period.	21 U.S.C. 333 note	2018	2019	584
Penalty in the case of a third tobacco product regulation violation within a 24–month period.	21 U.S.C. 333 note	2018	2019	1,170
Penalty in the case of a fourth tobacco product regulation violation within a 24–month period.	21 U.S.C. 333 note	2018	2019	2,340
Penalty in the case of a fifth tobacco product regulation violation within a 36–month period.	21 U.S.C. 333 note	2018	2019	5,849
Penalty in the case of a fifth tobacco product regulation violation within a 36–month period.	21 U.S.C. 333 note	2018	2019	5,849
Penalty in the case of a sixth or subsequent tobacco product regulation violation within a 48–month period as determined on a case-by-case basis.	21 U.S.C. 333 note	2018	2019	11,698
Penalty for each violation for any individual who made a false statement or misrepresentation of a material fact, bribed, destroyed, altered, removed, or secreted, or procured the destruction, alteration, removal, or secretion of, any material document, failed to disclose a material fact, obstructed an investigation, employed a consultant who was debarred, debarred individual provided consultant services.	21 U.S.C. 335b(a)	2018	2019	445,846
Penalty in the case of any other person (other than an individual) per above violation.	21 U.S.C. 335b(a)	2018	2019	1,783,384
Penalty for any person who violates any such requirements for electronic products, with each unlawful act or omission constituting a separate violation.	21 U.S.C. 360pp(b)(1)	2018	2019	2,924
Penalty imposed for any related series of violations of requirements relating to electronic products.	21 U.S.C. 360pp(b)(1)	2018	2019	996,806
Penalty per day for violation of order of recall of biological product presenting imminent or substantial hazard.	42 U.S.C. 262(d)	2018	2019	229,269
Penalty for failure to obtain a mammography certificate as required.	42 U.S.C. 263b(h)(3)	2018	2019	17,834
Penalty per occurrence for any vaccine manufacturer that intentionally destroys, alters, falsifies, or conceals any record or report required.	42 U.S.C. 300aa-28(b)(1)	2018	2019	229,269

Centers for Medicare & Medicaid Services

Penalty	Statutory Authority	Date of Previous Adjustment	Date of Current Adjustment	Current Penalty Level ($ Amount)
Penalty for a clinical laboratory's failure to meet participation and certification requirements and poses immediate jeopardy.	42 U.S.C. 263a(h)(2)(B) & 42 U.S.C. 1395w-2(b)(2)(A)(ii)			
Minimum	42 U.S.C. 263a(h)(2)(B) & 42 U.S.C. 1395w-2(b)(2)(A)(ii)	2018	2019	6,417
Maximum	42 U.S.C. 263a(h)(2)(B) & 42 U.S.C. 1395w-2(b)(2)(A)(ii)	2018	2019	21,039
Penalty for a clinical laboratory's failure to meet participation and certification requirements and the failure does not pose immediate jeopardy.	42 U.S.C. 263a(h)(2)(B) & 42 U.S.C. 1395w-2(b)(2)(A)(ii)			
Minimum	42 U.S.C. 263a(h)(2)(B) & 42 U.S.C. 1395w-2(b)(2)(A)(ii)	2018	2019	106
Maximum	42 U.S.C. 263a(h)(2)(B) & 42 U.S.C. 1395w-2(b)(2)(A)(ii)	2018	2019	6,311
Failure to provide the Summary of Benefits and Coverage (SBC).	42 U.S.C. 300gg-15(f)	2018	2019	1,156
Penalty for violations of regulations related to the medical loss ratio reporting and rebating.	42 U.S.C. 300gg-18	2018	2019	116
Penalty for manufacturer or group purchasing organization failing to report information required under 42 USC 1320a-7h(a), relating to physician ownership or investment interests.	42 U.S.C. 1320a-7h(b)(1)			
Minimum	42 U.S.C. 1320a-7h(b)(1)	2018	2019	1,156
Maximum	42 U.S.C. 1320a-7h(b)(1)	2018	2019	11,562
Calendar Year Cap	42 U.S.C. 1320a-7h(b)(1)	2018	2019	173,436
Penalty for manufacturer or group purchasing organization knowingly failing to report information required under 42 USC 1320a-7h(a), relating to physician ownership or investment interests.	42 U.S.C. 1320a-7h(b)(2)			
Minimum	42 U.S.C. 1320a-7h(b)(2)	2018	2019	11,562
Maximum	42 U.S.C. 1320a-7h(b)(2)	2018	2019	115,624
Calendar Year Cap	42 U.S.C. 1320a-7h(b)(2)	2018	2019	1,156,242
Penalty for an administrator of a facility that fails to comply with notice requirements for the closure of a facility.	42 U.S.C. 1320a-7h(b)(2)	2018	2019	115,624
Minimum penalty for the first offense of an administrator who fails to provide notice of facility closure.	42 U.S.C. 1320a-7j(h)(3)(A)	2018	2019	578
Minimum penalty for the second offense of an administrator who fails to provide notice of facility closure.	42 U.S.C. 1320a-7j(h)(3)(A)	2018	2019	1,735
Minimum penalty for the third and subsequent offenses of an administrator who fails to provide notice of facility closure.	42 U.S.C. 1320a-7j(h)(3)(A)	2018	2019	3,468
Penalty for an entity knowingly making a false statement or representation of material fact in the determination of the amount of benefits or payments related to old-age, survivors, and disability insurance benefits, special benefits for certain World War II veterans, or supplemental security income for the aged, blind, and disabled.	42 U.S.C. 1320a-8(a)(1)	2018	2019	8,457

Penalty	Statutory Authority	Date of Previous Adjustment	Date of Current Adjustment	Current Penalty Level ($ Amount)
Penalty for the violation of 42 USC 1320a-8a(1) if the violator is a person who receives a fee or other income for services performed in connection with determination of the benefit amount or the person is a physician or other health care provider who submits evidence in connection with such a determination.	42 U.S.C. 1320a-8(a)(1)	2018	2019	7,975
Penalty for a representative payee (under 42 USC 405(j), 1007, or 1383(a)(2)) converting any part of a received payment from the benefit programs described in the previous civil monetary penalty to a use other than for the benefit of the beneficiary.	42 U.S.C. 1320a-8(a)(3)	2018	2019	6,623
Penalty for failure of covered individuals to report to the Secretary and 1 or more law enforcement officials any reasonable suspicion of a crime against a resident, or individual receiving care, from a long-term care facility.	42 U.S.C. 1320b-25(c)(1)(A)	2018	2019	231,249
Penalty for failure of covered individuals to report to the Secretary and 1 or more law enforcement officials any reasonable suspicion of a crime against a resident, or individual receiving care, from a long-term care facility if such failure exacerbates the harm to the victim of the crime or results in the harm to another individual.	42 U.S.C. 1320b-25(c)(2)(A)	2018	2019	346,872
Penalty for a long-term care facility that retaliates against any employee because of lawful acts done by the employee, or files a complaint or report with the State professional disciplinary agency against an employee or nurse for lawful acts done by the employee or nurse.	42 U.S.C. 1320b-25(d)(2)	2018	2019	231,249
Penalty for any person who knowingly and willfully fails to furnish a beneficiary with an itemized statement of items or services within 30 days of the beneficiary's request.	42 U.S.C. 1395b-7(b)(2)(B)	2018	2019	156
Penalty per day for a Skilled Nursing Facility that has a Category 2 violation of certification requirements.	42 U.S.C. 1395i-3(h)(2)(B)(ii)(I)	2018	2019	
Minimum	42 U.S.C. 1395i-3(h)(2)(B)(ii)(I)	2018	2019	110
Maximum	42 U.S.C. 1395i-3(h)(2)(B)(ii)(I)	2018	2019	6,579
Penalty per instance of Category 2 noncompliance by a Skilled Nursing Facility.	42 U.S.C. 1395i-3(h)(2)(B)(ii)(I)			
Minimum	42 U.S.C. 1395i-3(h)(2)(B)(ii)(I)	2018	2019	2,194
Maximum	42 U.S.C. 1395i-3(h)(2)(B)(ii)(I)	2018	2019	21,933
Penalty per day for a Skilled Nursing Facility that has a Category 3 violation of certification requirements.	42 U.S.C. 1395i-3(h)(2)(B)(ii)(I)			
Minimum	42 U.S.C. 1395i-3(h)(2)(B)(ii)(I)	2018	2019	6,690
Maximum	42 U.S.C. 1395i-3(h)(2)(B)(ii)(I)	2018	2019	21,933
Penalty per instance of Category 3 noncompliance by a Skilled Nursing Facility.	42 U.S.C. 1395i-3(h)(2)(B)(ii)(I)			
Minimum	42 U.S.C. 1395i-3(h)(2)(B)(ii)(I)	2018	2019	2,194
Maximum	42 U.S.C. 1395i-3(h)(2)(B)(ii)(I)	2018	2019	21,933
Penalty per day and per instance for a Skilled Nursing Facility that has Category 3 noncompliance with Immediate Jeopardy.	42 U.S.C. 1395i-3(h)(2)(B)(ii)(I)			
Per Day (Minimum)	42 U.S.C. 1395i-3(h)(2)(B)(ii)(I)	2018	2019	6,690
Per Day (Maximum)	42 U.S.C. 1395i-3(h)(2)(B)(ii)(I)	2018	2019	21,933
Per Instance (Minimum)	42 U.S.C. 1395i-3(h)(2)(B)(ii)(I)	2018	2019	2,194
Per Instance (Maximum)	42 U.S.C. 1395i-3(h)(2)(B)(ii)(I)	2018	2019	21,933

Penalty	Statutory Authority	Date of Previous Adjustment	Date of Current Adjustment	Current Penalty Level ($ Amount)
Penalty per day of a Skilled Nursing Facility that fails to meet certification requirements. These amounts represent the upper range per day.	42 U.S.C. 1395i-3(h)(2)(B)(ii)(I)			
Minimum	42 U.S.C. 1395i-3(h)(2)(B)(ii)(I)	2018	2019	6,690
Maximum	42 U.S.C. 1395i-3(h)(2)(B)(ii)(I)	2018	2019	21,933
Penalty per day of a Skilled Nursing Facility that fails to meet certification requirements. These amounts represent the lower range per day.	42 U.S.C. 1395i-3(h)(2)(B)(ii)(I)			
Minimum	42 U.S.C. 1395i-3(h)(2)(B)(ii)(I)	2018	2019	110
Maximum	42 U.S.C. 1395i-3(h)(2)(B)(ii)(I)	2018	2019	6,579
Penalty per instance of a Skilled Nursing Facility that fails to meet certification requirements.	42 U.S.C. 1395i-3(h)(2)(B)(ii)(I)			
Minimum	42 U.S.C. 1395i-3(h)(2)(B)(ii)(I)	2018	2019	2,194
Maximum	42 U.S.C. 1395i-3(h)(2)(B)(ii)(I)	2018	2019	21,933
Penalty for knowingly, willfully, and repeatedly billing for a clinical diagnostic laboratory test other than on an assignment-related basis. (Penalties are assessed in the same manner as 42 USC 1395u(j)(2)(B), which is assessed according to 1320a-7a(a)).	42 U.S.C. 1395l(h)(5)(D)	2018	2019	15,975
Penalty for knowingly and willfully presenting or causing to be presented a bill or request for payment for an intraocular lens inserted during or after cataract surgery for which the Medicare payment rate includes the cost of acquiring the class of lens involved.	42 U.S.C. 1395l(i)(6)	2018	2019	4,208
Penalty for knowingly and willfully failing to provide information about a referring physician when seeking payment on an unassigned basis.	42 U.S.C. 1395l(q)(2)(B)(i)	2018	2019	4,027
Penalty for any durable medical equipment supplier that knowingly and willfully charges for a covered service that is furnished on a rental basis after the rental payments may no longer be made. (Penalties are assessed in the same manner as 42 USC 1395u(j)(2)(B), which is assessed according to 1320a-7a(a)).	42 U.S.C. 1395m(a)(11)(A)	2018	2019	15,975
Penalty for any nonparticipating durable medical equipment supplier that knowingly and willfully fails to make a refund to Medicare beneficiaries for a covered service for which payment is precluded due to an unsolicited telephone contact from the supplier. (Penalties are assessed in the same manner as 42 USC 1395u(j)(2)(B), which is assessed according to 1320a-7a(a)).	42 U.S.C. 1395m(a)(18)(B)	2018	2019	15,975
Penalty for any nonparticipating physician or supplier that knowingly and willfully charges a Medicare beneficiary more than the limiting charge for radiologist services. (Penalties are assessed in the same manner as 42 USC 1395u(j)(2)(B), which is assessed according to 1320a-7a(a)).	42 U.S.C. 1395m(b)(5)(C)	2018	2019	15,975
Penalty for any supplier of prosthetic devices, orthotics, and prosthetics that knowing and willfully charges for a covered prosthetic device, orthotic, or prosthetic that is furnished on a rental basis after the rental payment may no longer be made. (Penalties are assessed in the same manner as 42 USC 1395m(a)(11)(A), that is in the same manner as 1395u(j)(2)(B), which is assessed according to 1320a-7a(a)).	42 U.S.C. 1395m(h)(3)	2018	2019	15,975
Penalty for any supplier of durable medical equipment including a supplier of prosthetic devices, prosthetics, orthotics, or supplies that knowingly and willfully distributes a certificate of medical necessity in violation of Section 1834(j)(2)(A)(i) of the Act or fails to provide the information required under Section 1834(j)(2)(A)(ii) of the Act.	42 U.S.C. 1395m(j)(2)(A)(iii)	2018	2019	1,692
Penalty for any supplier of durable medical equipment, including a supplier of prosthetic devices, prosthetics, orthotics, or supplies that knowingly and willfully fails to make refunds in a timely manner to Medicare beneficiaries for series billed other than on as assignment-related basis under certain conditions. (Penalties are assessed in the same manner as 42 USC 1395m(j)(4) and 1395u(j)(2)(B), which is assessed according to 1320a-7a(a)).	42 U.S.C. 1395m(j)(4)	2018	2019	15,975

Penalty	Statutory Authority	Date of Previous Adjustment	Date of Current Adjustment	Current Penalty Level ($ Amount)
Penalty for any person or entity who knowingly and willfully bills or collects for any outpatient therapy services or comprehensive outpatient rehabilitation services on other than an assignment-related basis. (Penalties are assessed in the same manner as 42 USC 1395m(k)(6) and 1395u(j)(2)(B), which is assessed according to 1320a-7a(a)).	42 U.S.C. 1395m(k)(6)	2018	2019	15,975
Penalty for any supplier of ambulance services who knowingly and willfully fills or collects for any services on other than an assignment-related basis. (Penalties are assessed in the same manner as 42 USC 1395u(b)(18)(B), which is assessed according to 1320a-7a(a)).	42 U.S.C. 1395m(l)(6)	2018	2019	15,975
Penalty for any practitioner specified in Section 1842(b)(18)(C) of the Act or other person that knowingly and willfully bills or collects for any services by the practitioners on other than an assignment-related basis. (Penalties are assessed in the same manner as 42 USC 1395u(j)(2)(B), which is assessed according to 1320a-7a(a)).	42 U.S.C. 1395u(b)(18)(B)	2018	2019	15,975
Penalty for any physician who charges more than 125% for a non-participating referral. (Penalties are assessed in the same manner as 42 USC 1320a-7a(a)).	42 U.S.C. 1395u(j)(2)(B)	2018	2019	15,975
Penalty for any physician who knowingly and willfully presents or causes to be presented a claim for bill for an assistant at a cataract surgery performed on or after March 1, 1987, for which payment may not be made because of section 1862(a)(15). (Penalties are assessed in the same manner as 42 USC 1395u(j)(2)(B), which is assessed according to 1320a-7a(a)).	42 U.S.C. 1395u(k)	2018	2019	15,975
Penalty for any nonparticipating physician who does not accept payment on an assignment-related basis and who knowingly and willfully fails to refund on a timely basis any amounts collected for services that are not reasonable or medically necessary or are of poor quality under 1842(l)(1)(A). (Penalties are assessed in the same manner as 42 USC 1395u(j)(2)(B), which is assessed according to 1320a-7a(a)).	42 U.S.C. 1395u(l)(3)	2018	2019	15,975
Penalty for any nonparticipating physician charging more than $500 who does not accept payment for an elective surgical procedure on an assignment related basis and who knowingly and willfully fails to disclose the required information regarding charges and coinsurance amounts and fails to refund on a timely basis any amount collected for the procedure in excess of the charges recognized and approved by the Medicare program. (Penalties are assessed in the same manner as 42 USC 1395u(j)(2)(B), which is assessed according to 1320a-7a(a)).	42 U.S.C. 1395u(m)(3)	2018	2019	15,975
Penalty for any physician who knowingly, willfully, and repeatedly bills one or more beneficiaries for purchased diagnostic tests any amount other than the payment amount specified by the Act. (Penalties are assessed in the same manner as 42 USC 1395u(j)(2)(B), which is assessed according to 1320a-7a(a)).	42 U.S.C. 1395u(n)(3)	2018	2019	15,975
Penalty for any practitioner specified in Section 1842(b)(18)(C) of the Act or other person that knowingly and willfully bills or collects for any services pertaining to drugs or biologics by the practitioners on other than an assignment-related basis. (Penalties are assessed in the same manner as 42 USC 1395u(b)(18)(B) and 1395u(j)(2)(B), which is assessed according to 1320a-7a(a)).	42 U.S.C. 1395u(o)(3)(B)	2018	2019	15,975
Penalty for any physician or practitioner who knowingly and willfully fails promptly to provide the appropriate diagnosis codes upon CMS or Medicare administrative contractor request for payment or bill not submitted on an assignment-related basis.	42 U.S.C. 1395u(p)(3)(A)	2018	2019	4,208
Penalty for a pharmaceutical manufacturer's misrepresentation of average sales price of a drug, or biologic.	42 U.S.C. 1395w-3a(d)(4)(A)	2018	2019	13,669
Penalty for any nonparticipating physician, supplier, or other person that furnishes physician services not on an assignment-related basis who either knowingly and willfully bills or collects in excess of the statutorily-defined limiting charge or fails to make a timely refund or adjustment. (Penalties are assessed in the same manner as 42 USC 1395u(j)(2)(B), which is assessed according to 1320a-7a(a)).	42 U.S.C. 1395w-4(g)(1)(B)	2018	2019	15,975
Penalty for any person that knowingly and willfully bills for statutorily defined State-plan approved physicians' services on any other basis than an assignment-related basis for a Medicare/Medicaid dual eligible beneficiary. (Penalties are assessed in the same manner as 42 USC 1395u(j)(2)(B), which is assessed according to 1320a-7a(a)).	42 U.S.C. 1395w-4(g)(3)(B)	2018	2019	15,975

Penalty	Statutory Authority	Date of Previous Adjustment	Date of Current Adjustment	Current Penalty Level ($ Amount)
Penalty for each termination determination the Secretary makes that is the result of actions by a Medicare Advantage organization or Part D sponsor that has adversely affected an individual covered under the organization's contract.	42 U.S.C. 1395w-27(g)(3)(A); 42 U.S.C. 1857(g)(3)(A)	2018	2019	39,121
Penalty for each week beginning after the initiation of civil money penalty procedures by the Secretary because a Medicare Advantage organization or Part D sponsor has failed to carry out a contract, or has carried out a contract inconsistently with regulations.	42 U.S.C. 1395w-27(g)(3)(B); 42 U.S.C. 1857(g)(3)(B)	2018	2019	15,649
Penalty for a Medicare Advantage organization's or Part D sponsor's early termination of its contract.	42 U.S.C. 1395w-27(g)(3)(D); 42 U.S.C. 1857(g)(3)(D)	2018	2019	145,335
Penalty for an employer or other entity to offer any financial or other incentive for an individual entitled to benefits not to enroll under a group health plan or large group health plan which would be a primary plan.	42 U.S.C. 1395y(b)(3)(C)	2018	2019	9,472
Penalty for any non-governmental employer that, before October 1, 1998, willfully or repeatedly failed to provide timely and accurate information requested relating to an employee's group health insurance coverage.	42 U.S.C. 1395y(b)(5)(C)(ii)	2018	2019	1,542
Penalty for any entity that knowingly, willfully, and repeatedly fails to complete a claim form relating to the availability of other health benefits in accordance with statute or provides inaccurate information relating to such on the claim form.	42 U.S.C. 1395y(b)(6)(B)	2018	2019	3,383
Penalty for any entity serving as insurer, third party administrator, or fiduciary for a group health plan that fails to provide information that identifies situations where the group health plan is or was a primary plan to Medicare to the HHS Secretary.	42 U.S.C. 1395y(b)(7)(B)(i)	2018	2019	1,211
Penalty for any non-group health plan that fails to identify claimants who are Medicare beneficiaries and provide information to the HHS Secretary to coordinate benefits and pursue any applicable recovery claim.	42 U.S.C. 1395y(b)(8)(E)	2018	2019	1,211
Penalty for any person that fails to report information required by HHS under Section 1877(f) concerning ownership, investment, and compensation arrangements.	42 U.S.C. 1395nn(g)(5)	2018	2019	20,134
Penalty for any durable medical equipment supplier, including a supplier of prosthetic devices, prosthetics, orthotics, or supplies, that knowingly and willfully fails to make refunds in a timely manner to Medicare beneficiaries under certain conditions. (42 U.S.C. 1395(m)(18) sanctions apply here in the same manner, which is under 1395u(j)(2) and 1320a–7a(a)).	42 U.S.C. 1395pp(h)	2018	2019	15,975
Penalty for any person that issues a Medicare supplemental policy that has not been approved by the State regulatory program or does not meet Federal standards after a statutorily defined effective date.	42 U.S.C. 1395ss(a)(2)	2018	2019	54,832
Penalty for someone other than issuer that sells or issues a Medicare supplemental policy to beneficiary without a disclosure Statement.	42 U.S.C. 1395ss(d)(3)(A) (vi)(II)	2018	2019	28,413
Penalty for an issuer that sells or issues a Medicare supplemental policy without disclosure statement.	42 U.S.C. 1395ss(d)(3)(A) (vi)(II)	2018	2019	47,357
Penalty for someone other than issuer that sells or issues a Medicare supplemental policy without acknowledgement form.	42 U.S.C. 1395ss(d)(3)(B)(iv)	2018	2019	28,413
Penalty for issuer that sells or issues a Medicare supplemental policy without an acknowledgement form.	42 U.S.C. 1395ss(d)(3)(B)(iv)	2018	2019	47,357
Penalty for any person that sells or issues Medicare supplemental polices after a given date that fail to conform to the NAIC or Federal standards established by statute.	42 U.S.C. 1395ss(p)(8)	2018	2019	28,413
Penalty for any person that sells or issues Medicare supplemental polices after a given date that fail to conform to the NAIC or Federal standards established by statute.	42 U.S.C. 1395ss(p)(8)	2018	2019	47,357
Penalty for any person that sells a Medicare supplemental policy and fails to make available for sale the core group of basic benefits when selling other Medicare supplemental policies with additional benefits or fails to provide the individual, before selling the policy, an outline of coverage describing benefits.	42 U.S.C. 1395ss(p)(9)(C)	2018	2019	28,413

Penalty	Statutory Authority	Date of Previous Adjustment	Date of Current Adjustment	Current Penalty Level ($ Amount)
Penalty for any person that sells a Medicare supplemental policy and fails to make available for sale the core group of basic benefits when selling other Medicare supplemental policies with additional benefits or fails to provide the individual, before selling the policy, an outline of coverage describing benefits.	42 U.S.C. 1395ss(p)(9)(C)	2018	2019	47,357
Penalty for any person that fails to suspend the policy of a policyholder made eligible for medical assistance or automatically reinstates the policy of a policyholder who has lost eligibility for medical assistance, under certain circumstances.	42 U.S.C. 1395ss(q)(5)(C)	2018	2019	47,357
Penalty for any person that fails to provide refunds or credits as required by section 1882(r)(1)(B).	42 U.S.C. 1395ss(r)(6)(A)	2018	2019	47,357
Penalty for any issuer of a Medicare supplemental policy that does not waive listed time periods if they were already satisfied under a proceeding Medicare supplemental policy, or denies a policy, or conditions the issuances or effectiveness of the policy, or discriminates in the pricing of the policy base on health status or other specified criteria.	42 U.S.C. 1395ss(s)(4)	2018	2019	20,104
Penalty for any issuer of a Medicare supplemental policy that fails to fulfill listed responsibilities.	42 U.S.C. 1395ss(t)(2)	2018	2019	47,357
Penalty someone other than issuer who sells, issues, or renews a Medigap Rx policy to an individual who is a Part D enrollee	42 U.S.C. 1395ss(v)(4)(A)	2018	2019	20,503
Penalty for an issuer who sells, issues, or renews a Medigap Rx policy who is a Part D enrollee.	42 U.S.C. 1395ss(v)(4)(A)	2018	2019	34,174
Penalty for any individual who notifies or causes to be notified a home health agency of the time or date on which a survey of such agency is to be conducted	42 U.S.C. 1395bbb(c)(1)	2018	2019	4,388
Maximum daily penalty amount for each day a home health agency is not in compliance with statutory requirements.	42 U.S.C. 1395bbb(f)(2)(A)(i)	2018	2019	21,039
Penalty per day for home health agency's noncompliance (Upper Range).	42 U.S.C. 1395bbb(f)(2)(A)(i)			
Minimum	42 U.S.C. 1395bbb(f)(2)(A)(i)	2018	2019	17,883
Maximum	42 U.S.C. 1395bbb(f)(2)(A)(i)	2018	2019	21,039
Penalty for a home health agency's deficiency or deficiencies that cause immediate jeopardy and result in actual harm.	42 U.S.C. 1395bbb(f)(2)(A)(i)	2018	2019	21,039
Penalty for a home health agency's deficiency or deficiencies that cause immediate jeopardy and result in potential for harm.	42 U.S.C. 1395bbb(f)(2)(A)(i)	2018	2019	18,934
Penalty for an isolated incident of noncompliance in violation of established HHA policy.	42 U.S.C. 1395bbb(f)(2)(A)(i)	2018	2019	17,883
Penalty for a repeat and/or condition-level deficiency that does not constitute immediate jeopardy, but is directly related to poor quality patient care outcomes (Lower Range).	42 U.S.C. 1395bbb(f)(2)(A)(i)			
Minimum	42 U.S.C. 1395bbb(f)(2)(A)(i)	2018	2019	3,157
Maximum	42 U.S.C. 1395bbb(f)(2)(A)(i)	2018	2019	17,883
Penalty for a repeat and/or condition- level deficiency that does not constitute immediate jeopardy and that is related predominately to structure or process-oriented conditions (Lower Range).	42 U.S.C. 1395bbb(f)(2)(A)(i)			
Minimum	42 U.S.C. 1395bbb(f)(2)(A)(i)	2018	2019	1,052
Maximum	42 U.S.C. 1395bbb(f)(2)(A)(i)	2018	2019	8,415
Penalty imposed for instance of noncompliance that may be assessed for one or more singular events of condition-level noncompliance that are identified and where the noncompliance was corrected during the onsite survey.	42 U.S.C. 1395bbb(f)(2)(A)(i)			
Minimum	42 U.S.C. 1395bbb(f)(2)(A)(i)	2018	2019	2,104

Penalty	Statutory Authority	Date of Previous Adjustment	Date of Current Adjustment	Current Penalty Level ($ Amount)
Maximum	42 U.S.C. 1395bbb(f)(2)(A)(i)	2018	2019	21,039
Penalty for each day of noncompliance (Maximum).	42 U.S.C. 1395bbb(f)(2)(A)(i)	2018	2019	21,039
Penalty for discriminating or discouraging enrollment or disenrollment of participants on the basis of an individual's health status or need for health care services.	42 U.S.C. 1396b(m)(5)(B)			
Minimum	42 U.S.C. 1396b(m)(5)(B)	2018	2019	23,473
Maximum	42 U.S.C. 1396b(m)(5)(B)	2018	2019	156,488
Penalty for a PACE organization that charges excessive premiums.	42 U.S.C. 1396b(m)(5)(B)	2018	2019	39,121
Penalty for a PACE organization misrepresenting or falsifying information to CMS, the State, or an individual or other entity.	42 U.S.C. 1396b(m)(5)(B)	2018	2019	156,488
Penalty for each determination the CMS makes that the PACE organization has failed to provide medically necessary items and services of the failure has adversely affected (or has the substantial likelihood of adversely affecting) a PACE participant.	42 U.S.C. 1396b(m)(5)(B)	2018	2019	39,121
Penalty for involuntarily disenrolling a participant.	42 U.S.C. 1396b(m)(5)(B)	2018	2019	39,121
Penalty for PACE organization's practice that would reasonably be expected to have the effect of denying or discouraging enrollment.	42 U.S.C. 1396b(m)(5)(B)	2018	2019	39,121
Penalty per day for a nursing facility's failure to meet a Category 2 Certification.	42 U.S.C. 1396r(h)(3)(C)(ii)(I)			
Minimum	42 U.S.C. 1396r(h)(3)(C)(ii)(I)	2018	2019	110
Maximum	42 U.S.C. 1396r(h)(3)(C)(ii)(I)	2018	2019	6,579
Penalty per instance for a nursing facility's failure to meet Category 2 certification	42 U.S.C. 1396r(h)(3)(C)(ii)(I)			
Minimum	42 U.S.C. 1396r(h)(3)(C)(ii)(I)	2018	2019	2,194
Maximum	42 U.S.C. 1396r(h)(3)(C)(ii)(I)	2018	2019	21,933
Penalty per day for a nursing facility's failure to meet Category 3 certification.	42 U.S.C. 1396r(h)(3)(C)(ii)(I)			
Minimum	42 U.S.C. 1396r(h)(3)(C)(ii)(I)	2018	2019	6,690
Maximum	42 U.S.C. 1396r(h)(3)(C)(ii)(I)	2018	2019	21,933
Penalty per instance for a nursing facility's failure to meet Category 3 certification, which results in immediate jeopardy.	42 U.S.C. 1396r(h)(3)(C)(ii)(I)			
Minimum	42 U.S.C. 1396r(h)(3)(C)(ii)(I)	2018	2019	2,194
Maximum	42 U.S.C. 1396r(h)(3)(C)(ii)(I)	2018	2019	21,933
Penalty per instance for a nursing facility's failure to meet Category 3 certification, which results in immediate jeopardy.	42 U.S.C. 1396r(h)(3)(C)(ii)(I)			
Minimum	42 U.S.C. 1396r(h)(3)(C)(ii)(I)	2018	2019	2,194
Maximum	42 U.S.C. 1396r(h)(3)(C)(ii)(I)	2018	2019	21,933
Penalty per day for nursing facility's failure to meet certification (Upper Range).	42 U.S.C. 1396r(h)(3)(C)(ii)(I)			

Penalty	Statutory Authority	Date of Previous Adjustment	Date of Current Adjustment	Current Penalty Level ($ Amount)
Minimum	42 U.S.C. 1396r(h)(3)(C)(ii)(I)	2018	2019	6,690
Maximum	42 U.S.C. 1396r(h)(3)(C)(ii)(I)	2018	2019	21,933
Penalty per day for nursing facility's failure to meet certification (Lower Range).	42 U.S.C. 1396r(h)(3)(C)(ii)(I)			
Minimum	42 U.S.C. 1396r(h)(3)(C)(ii)(I)	2018	2019	110
Maximum	42 U.S.C. 1396r(h)(3)(C)(ii)(I)	2018	2019	6,579
Penalty per instance for nursing facility's failure to meet certification.	42 U.S.C. 1396r(h)(3)(C)(ii)(I)			
Minimum	42 U.S.C. 1396r(h)(3)(C)(ii)(I)	2018	2019	2,194
Maximum	42 U.S.C. 1396r(h)(3)(C)(ii)(I)	2018	2019	21,933
Grounds to prohibit approval of Nurse Aide Training Program—if assessed a penalty in 1819(h)(2)(B)(i) or 1919(h)(2)(A)(ii) of "not less than $5,000" [Not CMP authority, but a specific CMP amount (CMP at this level) that is the triggering condition for disapproval].	42 U.S.C. 1396r(f)(2)(B)(iii)(I)(c)	2018	2019	10,967
Grounds to waive disapproval of nurse aide training program—reference to disapproval based on imposition of CMP "not less than $5,000" [Not CMP authority but CMP imposition at this level determines eligibility to seek waiver of disapproval of nurse aide training program].	42 U.S.C. 1396r(h)(3)(C)(ii)(I)	2018	2019	10,967
Penalty for each day of noncompliance for a home or community care provider that no longer meets the minimum requirements for home and community care.	42 U.S.C. 1396t(j)(2)(C)			
Minimum	42 U.S.C. 1396t(j)(2)(C)	2018	2019	2
Maximum	42 U.S.C. 1396t(j)(2)(C)	2018	2019	18,943
Penalty for a Medicaid managed care organization that fails substantially to provide medically necessary items and services.	42 U.S.C. 1396u–2(e)(2)(A)(i)	2018	2019	39,121
Penalty for Medicaid managed care organization that imposes premiums or charges on enrollees in excess of the premiums or charges permitted.	42 U.S.C. 1396u–2(e)(2)(A)(i)	2018	2019	39,121
Penalty for a Medicaid managed care organization that misrepresents or falsifies information to another individual or entity.	42 U.S.C. 1396u–2(e)(2)(A)(i)	2018	2019	39,121
Penalty for a Medicaid managed care organization that fails to comply with the applicable statutory requirements for such organizations.	42 U.S.C. 1396u–2(e)(2)(A)(i)	2018	2019	39,121
Penalty for a Medicaid managed care organization that misrepresents or falsifies information to the HHS Secretary.	42 U.S.C. 1396u–2(e)(2)(A)(ii)	2018	2019	156,488
Penalty for Medicaid managed care organization that acts to discriminate among enrollees on the basis of their health status.	42 U.S.C. 1396u–2(e)(2)(A)(ii)	2018	2019	156,488
Penalty for each individual that does not enroll as a result of a Medicaid managed care organization that acts to discriminate among enrollees on the basis of their health status.	42 U.S.C. 1396u–2(e)(2)(A)(iv)	2018	2019	23,473
Penalty for a provider not meeting one of the requirements relating to the protection of the health, safety, and welfare of individuals receiving community supported living arrangements services.	42 U.S.C. 1396u(h)(2)	2018	2019	21,933
Penalty for disclosing information related to eligibility determinations for medical assistance programs.	42 U.S.C. 1396w–2(c)(1)	2018	2019	11,698
Failure to comply with requirements of the *Public Health Services Act*; Penalty for violations of rules or standards of behavior associated with issuer participation in the Federally-facilitated Exchange. (42 U.S.C. 300gg–22(b)(2)(C))	42 U.S.C. 18041(c)(2)	2018	2019	159
Penalty for providing false information on Exchange application.	42 U.S.C. 18081(h)(1)(A)(i)(II)	2018	2019	28,906
Penalty for knowingly or willfully providing false information on Exchange application.	42 U.S.C. 18081(h)(1)(B)	2018	2019	289,060
Penalty for knowingly or willfully disclosing protected information from Exchange.	42 U.S.C. 18081(h)(2)	2018	2019	28,906

Payment Integrity Report

OVERVIEW

HHS is committed to advancing a transparent, accountable, and collaborative financial management environment to fulfill its federal requirements, as well as to provide stakeholders with accessible and actionable financial information. An important part of this commitment is the continuous improvement of payment accuracy in all HHS programs. The Department has implemented various innovative solutions to prevent, detect, and reduce improper payments, while reducing unnecessary administrative burden on its stakeholders and protecting beneficiaries' access to important programs.

As required by the *Improper Payments Information Act of 2002* (IPIA), as amended by the *Improper Payments Elimination and Recovery Act of 2010* (IPERA) and the *Improper Payments Elimination and Recovery Improvement Act of 2012* (IPERIA); Office of Management and Budget (OMB) Circular A-136; and Appendix C of OMB Circular A-123, HHS's Fiscal Year (FY) 2019 Payment Integrity Report includes a discussion of the following topics:

Section	Topic
1.0	Program Description
2.0	Risk Assessments
3.0	Statistical Sampling Process:
3.1	• Improper Payment Measurement Estimates
3.2	• Improper Payment Root Causes and Drivers
4.0	Corrective Action Plans
5.0	Accountability in Reducing and Recovering Improper Payments
6.0	Information Systems and Other Infrastructure
7.0	Mitigation Efforts Related to Statutory or Regulatory Barriers
8.0	FY 2019 Achievements
9.0	Improper Payment Performance FY 2018 through FY 2020
9.1	• Accompanying Notes for Table 1
10.0	Improper Payment Root Cause Categories
11.0	Program-Specific Reporting Information:
11.1	• Medicare Fee-for-Service (FFS) (Parts A and B)
11.2	• Medicare Advantage (Part C)
11.3	• Medicare Prescription Drug Benefit (Part D)
11.4	• Medicaid
11.5	• Children's Health Insurance Program (CHIP)
11.6	• Temporary Assistance for Needy Families (TANF)
11.7	• Foster Care
11.8	• Child Care and Development Fund (CCDF)
12.0	Recovery Auditing Reporting

Refer to PaymentAccuracy.gov for additional detailed information on HHS's improper payment efforts.

1.0 PROGRAM DESCRIPTIONS

HHS utilizes annual improper payment risk assessments to identify new risk-susceptible programs, which are required to estimate improper payments and report other information, such as reduction targets and corrective actions. Figure 1 provides a brief description of the programs that HHS or OMB identified as risk-susceptible, and that are discussed in this report.

Figure 1: Risk-Susceptible Programs

Medicare FFS	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 (ESRD).
Medicare Part C	A federal health insurance program that allows beneficiaries to receive their Medicare benefits through a private health plan.
Medicare Part D	A federal prescription drug benefit program for Medicare beneficiaries.
Medicaid	A joint federal/state program, administered by the states, that provides health insurance to qualifying low-income individuals.
CHIP	A joint federal/state program, administered by the states, that provides health insurance for qualifying children.
Advance Premium Tax Credit (APTC)	A federal insurance affordability program, administered by HHS and/or the states, to support enrollees in purchasing Qualified Health Plan (QHP) coverage from state and federal insurance exchanges.
TANF	A joint federal/state program, administered by the states, that provides time-limited cash assistance as well as job preparation, work support, and other services to needy families with children to promote work, responsibility, and self-sufficiency.
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.
CCDF	A joint federal/state program, administered by the states, that provides child care financial assistance to low-income working families.

Program-specific information on each risk-susceptible program is located throughout the Payment Integrity Report. However, since HHS is not reporting an Advance Premium Tax Credit (APTC) improper payment estimate for FY 2019, the program is not included in Section 11.0: *Program-Specific Reporting Information*. See Note 6 of Section 9.1*: Accompanying Notes for Table 1* for more detailed information on the Department's efforts to develop an APTC improper payment measurement program. In addition, under the *Bipartisan Budget Act of 2018* and the *Additional Supplemental Appropriations for Disaster Relief Requirements Act of 2017,* HHS received approximately $1 billion to respond to and recover from hurricanes, wildfires, and other disasters. Department programs that received funding and expended more than $10 million during an annual reporting period will begin reporting improper payment estimates in the FY 2020 Payment Integrity Report, as appropriate. HHS anticipates that three programs will establish methodologies and report improper payment estimates for disaster funding in FY 2020.

2.0 RISK ASSESSMENTS

As required by the amended IPIA and OMB implementation guidance, HHS reviews its non-risk-susceptible programs (including payment streams and activities) using the HHS IPERIA Risk Assessment Tool to determine susceptibility to significant improper payments. The HHS IPERIA Risk Assessment Tool contains:

- The seven risk factors contained in Appendix C of OMB Circular A-123, Part I.C.Step2.b (specific risk factors are listed on page 187 of HHS's FY 2018 AFR);
- Specific program-identified risks that may lead to improper payments; and
- Controls that may mitigate those risks.

By examining these areas, the HHS IPERIA Risk Assessment Tool provides for a comprehensive review and analysis of selected program operations to determine potential payment risks and risk severity. HHS follows guidance contained in OMB Circular A-123, Appendix C, when determining how to group programs or activities for risk assessments, if applicable. In FY 2019, HHS made no changes to the grouping of programs for improper payment risk assessments. However, HHS strengthened its risk assessment and reporting activities in FY 2019 by enhancing policies and procedures and improving the HHS risk assessment by applying lessons learned from the previous year. In addition, in FY 2019, HHS began efforts to update its program inventory and explore options to automate this process. For example, HHS applied the *Digital Accountability and Transparency Act of 2014* (DATA Act) information to the universe of programs to improve the process of identifying and selecting programs for review. HHS also created and leveraged an online tool to provide guidance to the Operating Divisions (OpDivs), collect information for the program risk assessments, and maintain supporting documentation. HHS will provide an additional update in the FY 2020 Payment Integrity Report.

3.0 STATISTICAL SAMPLING PROCESS

All programs that reported improper payment estimates complied with OMB-approved statistical sampling plans and confidence intervals per OMB's previously issued guidance[26] on sampling and estimation plans. OMB updated its guidance in June 2018,[27] and, effective for FY 2019 reporting, three programs (Medicare FFS, Medicare Part C, and Medicare Part D) complied with the new OMB requirements for statistical sampling plans and confidence intervals. OMB approved four other programs' (Medicaid, CHIP, Foster Care, and CCDF) use of non-statistical plans due to the rolling nature of the improper payment methodologies. Generally, these programs' improper payment estimates are based on a system of reviews, wherein each state is reviewed triennially and each year's improper payment estimate incorporates new review data for approximately one-third of states. As a result, the improper payment estimate is based not on a statistical sample drawn from the full population of payments for any one time period, but, rather, on a combination of statistical samples drawn from several different time periods. HHS will continue to work with its risk-susceptible programs and OMB to modify, to the extent possible, its sampling and estimation plans to comply with OMB's prescribed statistical requirements.

The statistical sampling and estimation process is detailed in Section 11.0: *Program-Specific Reporting Information*.

[26] On October 20, 2014, OMB issued M-15-02, "Appendix C to Circular No. A-123, *Requirements for Effective Estimation and Remediation of Improper Payments*".

[27] On June 26, 2018, OMB issued M-18-20, "Transmittal of Appendix C to OMB Circular A-123, *Requirements for Payment Integrity Improvement*", which replaces M-15-02.

3.1 IMPROPER PAYMENT MEASUREMENT ESTIMATES

As discussed in Section 1.0: *Program Descriptions* and throughout the Payment Integrity Report, HHS prioritizes protecting taxpayer resources, and strives to prevent and reduce future improper payments. While the vast majority of the Department's payments are proper, unfortunately, some payments are improper.

Most improper payments are either unintentional payment errors or instances where the reviewer cannot determine if a payment is proper due to insufficient payment documentation. While fraud and abuse are improper payments, it is important to note that not all improper payments constitute fraud, and improper payment estimates are not fraud rate estimates.

Finally, HHS leverages improper payment methodologies to identify estimates of monetary loss (a subset of improper payments where the wrong recipient was paid or the correct recipient was paid the wrong amount). Not all improper payments are expenses that should not have occurred; they do not all represent funds the federal government should not have spent. For example, a significant amount of HHS's improper payments are due to documentation errors; that is, either lack of documentation or errors in the documentation that limited HHS's ability to verify information. Some improper payment estimation methodologies are able to discern if the insufficient documentation payment error would have resulted in the government making the payment in the assigned amount, therefore representing a non-monetary loss to the federal government. Lastly, a smaller proportion of improper payments are payments that either should not have been made or should have been made in a different amount and represent monetary losses to the government.

3.2 IMPROPER PAYMENT ROOT CAUSES AND DRIVERS

A key component of the improper payment sampling and reporting process is the identification of improper payment root causes. Once a program identifies improper payment root causes, the program staff works with stakeholders to implement corrective actions to address those root causes. Table 2: *Improper Payment Root Cause Category Matrix for HHS's Risk-Susceptible Programs* and Section 11.0: *Program-Specific Reporting Information* include program-specific root cause information and corrective actions that align with OMB A-123 Appendix C's root cause categories. In addition, some HHS risk-susceptible programs have also identified improper payment drivers that are more detailed or program-specific than OMB's root cause categories. Section 11.0 provides more information on these improper payment drivers and the related corrective actions.

4.0 CORRECTIVE ACTION PLANS

Generally, each program develops a multi-faceted corrective action plan with various remediation efforts taking place concurrently. Corrective actions vary by stage — from development, to piloting, to steady-state implementation, to completion. Corrective action plans help set aggressive but realistic targets for reducing improper payments with a timetable to achieve scheduled targets. Under OMB's implementing guidance, OMB approves all corrective action plans and reduction targets published in the Agency Financial Report (AFR). The Department reviews corrective action plans annually to confirm remediation plans focus on the root causes of the improper payments, thus increasing the likelihood that targets are successfully met. If targets are not met, HHS develops new strategies, adjusts staffing and other resources, and/or revises targets.

See Section 11.0: *Program-Specific Reporting Information* for each program's corrective action plan for reducing the estimated rate of improper payments.

5.0 ACCOUNTABILITY IN REDUCING AND RECOVERING IMPROPER PAYMENTS

Strengthening program integrity throughout the organization is a top departmental priority, extending to all HHS senior executives and program officials. As evidence of this focus, beginning with senior leadership and cascading down, performance plans contain strategic goals related to enhancing program integrity, protecting taxpayer resources, and reducing improper payments. As part of the semi-annual and annual performance evaluations, senior executives and program officials are evaluated on progress toward achieving these goals.

6.0 INFORMATION SYSTEMS AND OTHER INFRASTRUCTURE

Section 11.0: *Program-Specific Reporting Information* details each program's information system(s) and other infrastructure. Unless otherwise stated in Section 11.0, HHS has the appropriate information systems and other necessary infrastructure to reduce improper payments to the targeted levels in applicable risk-susceptible programs.

7.0 MITIGATION EFFORTS RELATED TO STATUTORY OR REGULATORY BARRIERS

Section 11.0: *Program-Specific Reporting Information* details each program's statutory or regulatory barriers to reducing improper payments. Unless otherwise stated in Section 11.0, HHS has no current statutory or regulatory barriers to reducing improper payments.

8.0 FY 2019 ACHIEVEMENTS

In FY 2019, HHS strengthened its efforts to reduce and recover improper payments in its programs. Results of the efforts are outlined here and in Section 11.0: *Program-Specific Reporting Information*. Four of the seven risk-susceptible programs that report improper payment estimates reported lower estimated improper payment rates in FY 2019 than in FY 2018. The more notable efforts are highlighted below and detailed information on program performance and corrective actions can be found in Section 11.0.

President's Management Agenda and Cross-Agency Priority Goal

In March 2018, the Administration announced the President's Management Agenda (PMA), which is designed to improve how the federal government operates, provides customer service, and oversees taxpayer resources. As part of the PMA, the Administration also announced a series of Cross-Agency Priority (CAP) Goals, where multiple agencies must collaborate to achieve success and meet the PMA's vision. CAP Goal 9, "Getting Payments Right," focuses on improving and streamlining improper payment regulations and reducing monetary loss.

In FY 2018, HHS assumed a key role in supporting the implementation of the "Getting Payments Right" CAP Goal – serving as an agency lead and contributor on multiple workgroups created under the CAP Goal. HHS's key role carried into the CAP Goal's efforts in FY 2019. HHS led and supported workgroups that focused on addressing the challenges that federal agencies face in effectively identifying monetary loss root causes and the existing limitations on prepayment checks due to the availability of data sources. These efforts produced findings and recommendations that will be used in future work groups to link the agencies' data sources to root causes and will help the government identify effective mitigation strategies to prevent monetary loss. HHS will continue to support this CAP Goal and other efforts to reduce improper payments in FY 2020.

Head Start

As of FY 2013, the Head Start program no longer reports annual improper payment estimates due to the strong internal controls, monitoring systems, and low reported error rates from FYs 2009 through 2012. In lieu of an annual error rate measurement, HHS monitors Head Start's existing internal controls and monitoring systems and annually reports to OMB on the status and results of the internal controls and monitoring systems. HHS also performs

periodic risk assessments of the Head Start program. An improper payment risk assessment of the program in FY 2018 indicated that Head Start continues not to be susceptible to significant improper payments.

For FY 2019, HHS conducted an assessment of eligibility practices as part of the review process, focusing on grantee compliance with Eligibility, Recruitment, Selection, Enrollment, and Attendance Head Start Performance Standards. In FY 2019, HHS assessed 190 grantees, which exceeds the number of grantees (50) that were assessed each year as part of the previously required improper payment rate reporting efforts. Of the grantees assessed, only seven were identified as having erroneous payments related to eligibility, providing reasonable assurance that the Department's control and monitoring systems are still working as intended.

Vulnerability Collaboration Council (VCC)

To detect and combat fraud, waste, and abuse, the Centers for Medicare & Medicaid Services (CMS) utilizes a centralized, vulnerability management process to identify, prioritize, track, and mitigate vulnerabilities that affect the integrity of federal health programs. The centralized component of this process, known as the VCC, is comprised of CMS leadership and subject matter experts that work collaboratively to identify vulnerabilities that lead to fraud, waste, and abuse, and develop comprehensive risk strategies to mitigate these vulnerabilities. HHS has aligned the VCC's risk-based approach with the Government Accountability Office's (GAO) "A Framework for Managing Fraud Risk in Federal Programs" (GAO-15-593SP). By aligning with the GAO framework, HHS has standardized the vulnerability management process by focusing on the identification and mitigation of key risk factors through the development of measurable, verifiable, and time-bound action plans.

Fraud Prevention System (FPS)

The FPS analyzes Medicare FFS claims using sophisticated algorithms to:

- Target investigative resources;
- Generate alerts for suspect claims or providers and suppliers; and
- Provide information to facilitate and support investigations of the most egregious, suspect, or aberrant activity.

HHS uses the FPS information to prevent and address improper payments using a variety of administrative tools and actions, including claim denials, payment suspensions, Medicare billing privilege revocations, and law enforcement referrals. In FY 2019, HHS continued to add and refine models in FPS.

During FY 2019, the FPS generated leads that resulted in 766 new investigations and augmented information for 575 existing investigations. The Unified Program Integrity Contractors reported initiating FPS-attributable actions against 509 providers in FY 2019.

National Benefit Integrity (NBI) Medicare Drug Integrity Contractor (MEDIC) and Investigations MEDIC (I-MEDIC)

In FY 2019, HHS split the Medicare Part C and Part D program integrity initiatives between two contractors, the NBI MEDIC and the I-MEDIC. The NBI MEDIC has a national focus related to plan oversight pertaining to the following Medicare Part C and Part D program integrity initiatives: identification of program vulnerabilities, data analysis, health plan audits, outreach and education, and law enforcement support which includes requests for information. As a result of the NBI MEDIC's data analysis projects, including Part D plan sponsor self-audits, HHS recovered $3.80 million from Part D sponsors during the first three quarters of FY 2019. The primary purpose of the I-MEDIC is to detect, prevent, and proactively deter fraud, waste, and abuse for high-risk prescribers or pharmacies in Medicare Part C and Part D by focusing primarily on complaint intake and response, data analysis, investigative activities, referrals to law enforcement partners, and law enforcement support.

Medicaid Integrity Program

Under Section 1936 of the *Social Security Act*, as amended by the *Deficit Reduction Act of 2005* (DRA), HHS's Medicaid Integrity Program is responsible for:

- Hiring contractors to review Medicaid provider activities, audit claims, identify overpayments, and educate providers and others on Medicaid program integrity issues; and
- Supporting and assisting state efforts to combat Medicaid provider fraud, waste, and abuse.

Increased Medicaid recoveries demonstrate the increased focus on Medicaid program integrity. For example, the Medicaid Integrity Program provided federal staff specializing in program integrity and contractor support to states to bolster program integrity activities and collections. Since enactment of the DRA, total state Medicaid program integrity collections (federal and state shares) have grown from $265 million in FY 2006 to $486.87 million in FY 2019.[28] The Medicaid Integrity Program works in coordination with the Medicaid program integrity activities funded by the Health Care Fraud and Abuse Control program. Such program integrity activities improve HHS's financial oversight of Medicaid and CHIP by supporting reviews of proposed Medicaid state plan amendments, financial management, and other activities.

The DRA also requires HHS to establish a 5-year Comprehensive Medicaid Integrity Plan (CMIP) to guide the Medicaid Integrity Program's development and operations. HHS has established CMIPs since 2006. The last 5-year CMIP covered FYs 2014 through 2018. Noteworthy outcomes from FYs 2014 through 2018 have been referenced in the Medicaid section of the HHS AFR Payment Integrity Report for recent years, as well as in Section 11.4: *Medicaid* of this year's Payment Integrity Report.

In June 2018, HHS issued a Medicaid Program Integrity strategy with new and enhanced initiatives to improve state oversight and accountability. These initiatives – including conducting new audits of state beneficiary eligibility determinations and audits of Medicaid managed care plans' Medical Loss Ratio calculations – will form the foundation for a new 5-year CMIP to be published in FY 2020. In June 2019, HHS celebrated the 1-year anniversary of the Medicaid Program Integrity Strategy by publishing a blog post describing HHS's successes to date.

Public Assistance Reporting Information System (PARIS)

PARIS provides state public assistance agencies in all 50 states, the District of Columbia, and Puerto Rico, with matching data to verify an individual's eligibility and to detect and deter improper payments in TANF, Medicaid, Workers' Compensation, child care related programs, and the Supplemental Nutrition Assistance Program. Provided to states at no cost, PARIS data helps states strengthen program administration. For example, New York used PARIS to close or remove active clients from 8,593 public assistance cases for projected cost savings of $49.35 million during the most recent full state FY (April 2018 to March 2019). For more information, refer to PARIS.

Results of the Do Not Pay (DNP) Initiative in Preventing Improper Payments

In June 2010, the President issued a Memorandum on Enhancing Payment Accuracy Through a "Do Not Pay List" where agencies can access and analyze relevant information before determining eligibility for funding. Since 2010, HHS has worked diligently to implement the DNP initiative. Several of HHS's OpDivs are using DNP to check for recipients' or potential recipients' eligibility for payment and to prevent improper payments. Further, Treasury-disbursed payments are matched against the Social Security Administration's (SSA) Death Master File (DMF) in the DNP portal on a daily basis to identify improper payments. In FY 2019, the Department screened 1.2 million payments against IPERIA-listed databases, representing $493.4 billion. While the Department identified 66 potential

[28] This amount may differ from that which is reported in the Annual Report to Congress on the Medicare and Medicaid Integrity Programs because the Agency Financial Report is prepared prior to the finalization of state reporting.

improper payments over the past year through these daily matches, there was 1 confirmed match in FY 2019. Lastly, CMS also checks certain payments against IPERIA-listed databases outside of the DNP portal. In FY 2019, CMS screened 1.2 billion payments against IPERIA-listed databases, representing $415 billion. Through these checks, CMS stopped 402,871 payments representing $1.7 billion.

9.0 IMPROPER PAYMENT PERFORMANCE FY 2018 THROUGH FY 2020

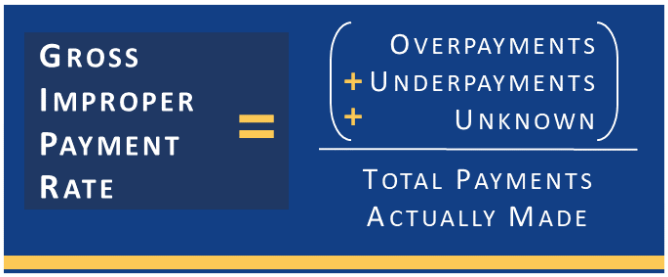
Each year, HHS reports updated improper payment estimates in the Payment Integrity Report. Table 1 displays HHS's proper and improper payment estimates for current year (CY) (FY 2019), improper payment estimates for the prior year (PY) (FY 2018), and improper payment targets for FY 2020 (CY+1). The table includes the following information by year and program, as applicable:

- FY outlays;
- Estimated improper payment rate or future target rate (IP%); and
- Estimated amount and percent paid or projected to be paid properly (PP) and improperly (IP).

In addition, for the CY, Table 1 includes:

- Estimated dollar amount of overpayments (CY Over Payments);
- Estimated dollar amount of underpayments (CY Under Payments); and
- Estimated dollar amount of unknown payments (CY Unknown), when available.

HHS utilizes statistical sampling to calculate each program's estimated gross improper payment rate and a projected dollar amount of improper payments.



The gross improper payment rate is the official program improper payment rate and is included in Table 1.

Table 1
Estimated Proper and Improper Payments for HHS's Risk-Susceptible Programs
FY 2018 – FY 2020 (in Millions)

Program or Activity	PY Outlays $	PY IP %	PY IP $	CY Outlays $	CY PP %	CY PP $	CY IP %	CY IP $	CY Over Payment $	CY Under Payment $	CY Unknown $	CY+1 Est. Outlays $	CY+1 IP %	CY+1 IP $
Medicare FFS	$389,300.05 [a]	8.12	$31,617.94	$398,623.97 [b]	92.75	$369,715.14	7.25 [1]	$28,908.83	$11,016.06	$1,343.75	$16,549.02	$450,403.00 [c]	7.15	$32,203.81
Medicare Part C	$191,923.92 [d]	8.10	$15,554.31	$212,444.68 [e]	92.13	$195,716.10	7.87	$16,728.58	$9,402.18	$6,948.36	$378.04	$295,157.00 [f]	7.77	$22,933.70
Medicare Part D	$79,559.54 [g]	1.66	$1,318.92	$80,787.84 [h]	99.25	$80,179.90	0.75	$607.94	$101.12	$272.47	$234.35	$102,231.00 [i]	0.74	$756.51
Medicaid	$370,391.00 [j]	9.79 [5]	$36,249.70	$384,996.67 [k]	85.10	$327,638.54	14.90 [2 and 5]	$57,358.13	$12,462.32	$377.82	$44,518.00	$401,681.38 [k]	N/A [4]	N/A [4]
CHIP	$16,223.92 [l]	8.57 [5]	$1,389.63	$17,280.95 [m]	84.17	$14,544.57	15.83 [3 and 5]	$2,736.38	$999.00	$12.35	$1,725.02	$17,826.03 [m]	N/A [4]	N/A [4]
APTC	$33,755.55 [n]	N/A	N/A	$47,520.58 [o]	N/A	N/A	N/A [6]	N/A	N/A	N/A	N/A	$50,869.84 [o]	N/A	N/A
TANF	$16,330.95 [p]	N/A	N/A	$16,536.29 [q]	N/A	N/A	N/A [7]	N/A	N/A	N/A	N/A	$16,218.87 [q]	N/A	N/A
Foster Care	$394.00 [r]	7.56	$29.79	$147.00 [s]	95.15	$139.87	4.85	$7.13	$6.82	$0.31	$0.00	$1,387.00 [s]	6.00 [8]	$83.22
CCDF	$7,549.78 [t]	4.00	$301.99	$7,166.95 [u]	95.47	$6,842.29	4.53	$324.66	$106.08	$19.81	$198.77	$9,697.81 [u]	N/A [9]	N/A

Note: Totals do not necessarily equal the sum of the rounded components.

9.1 Accompanying Notes for Table 1: Estimated Proper and Improper Payments for HHS's Risk-Susceptible Programs

a) Medicare FFS PY outlays are from the FY 2018 Medicare FFS Improper Payments Report (based on claims from July 2016 – June 2017).
b) Medicare FFS CY outlays are from the FY 2019 Medicare FFS Improper Payments Report (based on claims from July 2017 – June 2018).
c) Medicare FFS CY+1 outlays are based on the FY 2020 Midsession Review (Medicare Benefit Outlays current law [CL]).
d) Medicare Part C PY outlays reflect 2016 Part C payments, as reported in the FY 2018 Medicare Part C Payment Error Final Report.
e) Medicare Part C CY outlays reflect 2017 Part C payments, as reported in the FY 2019 Medicare Part C Payment Error Final Report.
f) Medicare Part C CY+1 outlays are based on the FY 2020 Midsession Review (Medicare Benefit Outlays [CL]).
g) Medicare Part D PY outlays reflect 2016 Part D payments, as reported in the FY 2018 Medicare Part D Payment Error Final Report.
h) Medicare Part D CY outlays reflect 2017 Part D payments, as reported in the FY 2019 Medicare Part D Payment Error Final Report.
i) Medicare Part D CY+1 outlays are based on the FY 2020 Midsession Review (Medicare Benefit Outlays [CL]).
j) Medicaid PY outlays (based on FY 2017 expenditures) are based on the FY 2019 Midsession Review and exclude CDC Vaccine for Children program funding.
k) Medicaid CY (based on FY 2018 expenditures) and CY+1 outlays (Medicaid - Outlays CL exclude CDC Vaccine for Children program funding), are based on the FY 2020 Midsession Review.
l) CHIP PY outlays (based on FY 2017 expenditures) are based on the FY 2019 Midsession Review.
m) CHIP CY (based on FY 2018 expenditures) and CY+1 outlays (total outlays from the Children's Health Insurance Fund [CL]), are based on the FY 2020 Midsession Review.
n) APTC PY outlays are comprised of FY 2017 estimated expenditures; and are based on the FY 2019 Midsession Review.
o) APTC CY outlays are comprised of FY 2018 estimated expenditures and are based on the FY 2020 Midsession Review. CY+1 outlays are based on the FY 2020 Midsession Review.
p) TANF PY outlays are based on the FY 2019 President's Budget baseline, as reported in the FY 2018 AFR.
q) TANF CY and CY+1 outlays are based on the FY 2020 President's Budget baseline (TANF total outlays including the Healthy Marriage Promotion and Responsible Fatherhood Grants programs and excluding the TANF Contingency Fund).
r) Foster Care PY outlays are based on the FY 2019 President's Budget baseline and reflect the federal share of maintenance payments for states not operating under a demonstration waiver, as reported in the FY 2018 AFR.
s) Foster Care CY and CY+1 outlays are based on the FY 2020 President's Budget baseline, and reflect the federal share of maintenance payments. Foster Care CY+1 outlays' increase reflects an increase in the number of states reporting this data due to the expiration of the waiver authority under Section 1130 of the *Social Security Act*.
t) CCDF PY outlays are based on the FY 2019 President's Budget baseline, as reported in the FY 2018 AFR.
u) CCDF CY and CY+1 outlays are based on the FY 2020 President's Budget baseline.

1. Beginning in FY 2012, HHS consulted with OMB and refined the improper payment methodology to account for the impact of rebilling denied Part A inpatient hospital claims for allowable Part B services when a Part A inpatient hospital claim is denied because the services should have been provided as outpatient services (i.e., improper payments due to inpatient status reviews). HHS used this methodology from FY 2013 through FY 2019. This approach is consistent with: (1) Administrative Law Judge and Departmental Appeals Board decisions that directed HHS to pay hospitals under Part B for all services provided if the Part A inpatient claim was denied and (2) recent Medicare policy changes that allow rebilling of denied Part A claims under Part B.

   HHS calculated an adjustment factor based on a statistical subset of inpatient claims that were in error because the services provided should have been outpatient services. This adjustment factor reflects the difference between the inpatient hospital claims paid under Medicare Part A and what the payment would have been had the hospital claim been properly submitted as a Medicare Part B outpatient claim. Application of the adjustment factor decreased the overall improper payment rate by 0.20 percentage points to 7.25 percent or $28.91 billion in projected improper payments. Additional adjustment factor information is on pages 166-167 of HHS's FY 2012 AFR.
2. HHS calculated and is reporting the national Medicaid improper payment rate based on measurements conducted in FYs 2017, 2018, and 2019. The national Medicaid component improper payment rates are: Medicaid FFS: 16.30 percent, Medicaid managed care: 0.12 percent, and Medicaid eligibility: 8.36 percent.
3. HHS calculated and is reporting the national CHIP improper payment rate based on measurements conducted in FYs 2017, 2018, and 2019. The national CHIP component improper payment rates are: CHIP FFS: 13.25 percent, CHIP managed care: 1.25 percent, and CHIP eligibility: 11.78 percent.
4. Medicaid and CHIP are not reporting CY+1 improper payment targets. As described in Sections 11.4: *Medicaid* and 11.5: *CHIP*, HHS resumed the Medicaid and CHIP eligibility component measurements and is reporting the first updated national eligibility improper payment estimates in FY 2019. Since HHS uses a 17-state, 3-year rotation for measuring Medicaid and CHIP improper payments, the publication of reduction targets will occur in FY 2021 once HHS establishes and reports a full baseline, including eligibility.
5. In FY 2018, HHS identified some concerns with the FY 2018 estimate due to issues with a portion of the Medicaid and CHIP reviews for PERM Cycle 3 states. Prior to reporting in the AFR, HHS calculated scenarios for what the national improper payment rate would be if all reviews in question were considered errors or all were considered proper. In these extreme scenarios, the FY 2018 national rate would be adjusted by +/- 0.33 percent, well within the estimate's confidence interval. Due to the PERM methodology, which utilizes three cycles to combine to the overall Medicaid and CHIP rates, these concerns also have an impact on the FY 2019 and FY 2020 rates, until the same cycle of states is measured again and reported in FY 2021. The FY 2019 rate would adjust by up to +/- 0.27 percent based on these concerns, again well within the estimate's confidence interval. This impact on the national improper payment rate may vary again in FY 2020 depending on the results of the final cycle.
6. While a FY 2016 risk assessment concluded that the APTC program is susceptible to significant improper payments, the program is not yet reporting improper payment estimates for FY 2019. The Department is committed to implementing an improper payment measurement program as required by the IPIA, as amended. As with similar HHS programs, developing an effective and efficient improper payment measurement program requires multiple, time-intensive steps including contractor procurement timelines, developing measurement policies, procedures, and tools, and extensive pilot testing to ensure an accurate improper payment estimate. HHS will continue to monitor and assess the program for changes and adapt accordingly. In FYs 2017, 2018, and 2019, HHS conducted development and piloting activities for the APTC improper payment measurement program and will continue these activities in FY 2020. The Department will continue to update its annual AFRs with the measurement program development status until the reporting of the improper payment estimate.
7. The TANF program is not reporting an error rate for FY 2019. As discussed in Section 11.6: *TANF*, statutory limitations preclude HHS from requiring states to participate in a TANF improper payment measurement.
8. Foster Care is reporting a higher CY+1 improper payment target than the CY improper payment rate due to the anticipated impact of the *Family First Prevention Services Act*. As discussed in Section 11.7: *Foster Care*, HHS expects that the new Title IV-E Foster Care eligibility requirements, which went into effect October 1, 2018, may contribute to an increase in improper payments as states make the necessary adjustments to comply with the law. The FY 2020 improper payment estimate for the Foster Care program will be the first year subject to the new requirements. As a result, HHS increased the Foster Care program's improper payment target for FY 2020.
9. CCDF is not reporting a CY+1 improper payment target. Rolling implementation of the new requirements will continue to affect the error rate in the FY 2020 measurement, making it challenging to determine a target rate. CCDF state grantees are implementing large-scale changes to their child care programs. The *Child Care and Development Block Grant Act of 2014* (CCDBG) and CCDF regulations (2016) require states to create and put in place new policies and procedures. For this reason, a full baseline has yet to be established. HHS anticipates that the error rate may continue to rise as states work to meet the new requirements and anticipates the publication of a reduction target in FY 2022.

10.0 IMPROPER PAYMENT ROOT CAUSE CATEGORIES

OMB guidance requires agencies to report the improper payment root causes for risk-susceptible programs with reported improper payment estimates. Table 2 displays HHS's FY 2019 improper payment root causes and the estimated overpayment, underpayment, or unknown amounts for each risk-susceptible program. For reporting purposes, Administrative or Process Errors Made by Other Party may include health care providers, contractors, or other organization administering federal dollars. Section 11: *Program-Specific Reporting Information* provides additional information on the root causes and corrective actions.

Table 2
Improper Payment Root Cause Category Matrix for HHS's Risk-Susceptible Programs
FY 2019 (in Millions)

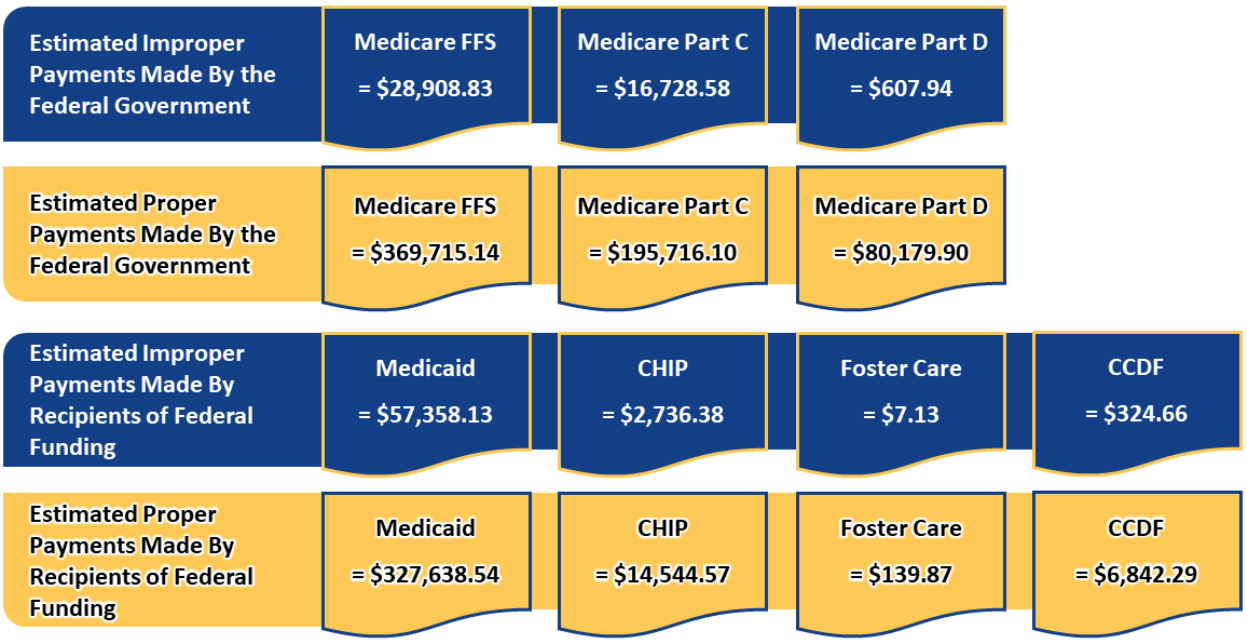
Program or Activity	Payment Type	Inability to Authenticate Eligibility: Inability to access data	Failure to Verify Death Data	Administrative or Process Error Made by: State or Local Agency	Administrative or Process Error Made by: Other Party	Medical Necessity	Insufficient Documentation to Determine	Total [2]
Medicare FFS	Overpayments				$5,620.37	$5,395.69		$11,016.06
	Underpayments				$1,343.23	$0.52		$1,343.75
	Unknown						$16,549.02	$16,549.02
Medicare Part C	Overpayments				$9,402.18			$9,402.18
	Underpayments				$6,948.36			$6,948.36
	Unknown						$378.04	$378.04
Medicare Part D	Overpayments				$101.12			$101.12
	Underpayments				$272.47			$272.47
	Unknown						$234.35	$234.35
Medicaid [1]	Overpayments	$7,093.01	$8.80	$5,071.94	$288.56			$12,462.32
	Underpayments	$326.51		$51.31				$377.82
	Unknown						$44,518.00	$44,518.00
CHIP [1]	Overpayments	$578.32		$408.66	$11.66	$0.37		$999.00
	Underpayments	$7.15		$5.21				$12.35
	Unknown						$1,725.02	$1,725.02
Foster Care	Overpayments			$6.82				$6.82
	Underpayments			$0.31				$0.31
	Unknown							
CCDF	Overpayments			$100.21	$5.87			$106.08
	Underpayments			$16.51	$3.30			$19.81
	Unknown						$198.77	$198.77

Notes:

1. As described in Sections 11.4: *Medicaid* and 11.5: *CHIP*, HHS resumed the eligibility component measurement for the first cycle of 17 states and reported an updated national eligibility improper payment estimate for FY 2019. The national eligibility improper payment rate still includes a proxy estimate for the remaining 34 states that have not yet been measured since the reintegration of the PERM eligibility component. Therefore, eligibility improper payments reported under Inability to Authenticate Eligibility: Inability to Access Data represent the proxy eligibility improper payment rates, which include multiple types of historical eligibility improper payments. All eligibility improper payments from the FY 2019 measurement are included in the appropriate category.
2. Totals do not necessarily equal the sum of the rounded components.

OMB Circular A-136 requires agencies to report by program the estimated amount of improper payments made directly by the federal government or by recipients of federal money as shown in Figure 2. At HHS, all Medicare FFS, Medicare Part C, and Medicare Part D estimated improper payments were made by the federal government or its representatives. The estimated improper payments for the remaining programs, Medicaid, CHIP, Foster Care, and CCDF were made by recipients of federal money (e.g., state agencies or grantees).

Figure 2: FY 2019 Estimated Proper and Improper Payments Made by the Federal Government or Recipients of Federal Funding (in Millions)



OMB Circular A-136 also directs agencies to report, by program, the estimated amount of improper payments attributed to monetary loss, non-monetary loss, and unknown monetary loss. Monetary Loss means that the payment should not have occurred or should have been paid in a different, lower amount. The documentation is sufficient to confirm that the payment should not have been made at all or should have been made in a lesser amount. Examples include medical necessity, incorrect coding, and other errors in Medicare FFS.

For the first time, agencies are required to categorize the total monetary loss estimate as either (1) monetary loss within agency control or (2) monetary loss outside agency control. Monetary loss within agency control is an overpayment that resulted in a monetary loss to the government due to errors in the agency's program processing or billing, excluding payments authorized by law; while monetary loss outside agency control is an overpayment that resulted in a monetary loss to the government due to factors beyond the agency's control.

Non-Monetary Loss means that the payment is either an underpayment or a payment to the right recipient for the correct amount, where the payment process fails to follow applicable regulations and/or statutes.

Unknown Monetary Loss describes a payment where more information is needed to determine if the payment should have been issued or if the amount of the payment should have been different. When a payment lacks appropriate supporting documentation, it cannot be determined whether the payment would have been confirmed proper or confirmed improper, and resulted in a monetary loss to the government. These unknown monetary loss

payments are typically the majority of the payments counted as improper, and could be overpayments, underpayments, or proper payments, if more documentation was available.

HHS's FY 2019 estimated improper payments are distributed between monetary loss, non-monetary loss, and unknown monetary loss for each program as displayed in Table 3. In addition, Table 3 identifies the estimated amounts of monetary loss within agency control and outside agency control. See Section 11.0: *Program-Specific Reporting Information* for the factors contributing toward the programs' estimated monetary loss outside agency control and additional information regarding the distribution of improper payments between monetary loss, non-monetary loss, and unknown.

Table 3
Estimated Proper and Improper Payments (across Monetary Loss [ML], Non-Monetary Loss [NML], and Unknown Monetary Loss) by Program
FY 2019 (in Millions)

			Monetary Loss				Non Monetary Loss		Unknown Monetary Loss	
Program or Activity	CY PP Amount	CY IP Amount	ML Amount	Percent of IP	Within Agency Control	Outside Agency Control	NML Amount	Percent of IP	Unknown Amount	Percent of IP
Medicare FFS	$369,715.14	$28,908.83	$9,757.62 [1]	34%	$9,757.62		$2,602.20	9%	$16,549.02	57%
Medicare Part C	$195,716.10	$16,728.58	$9,402.18	56%		$9,402.18	$6,948.36	42%	$378.04	2%
Medicare Part D	$80,179.90	$607.94	$101.12	17%		$101.12	$272.47	45%	$234.35	38%
Medicaid	$327,638.54	$57,358.13	$12,462.32 [2]	22%		$12,462.32 [3]	$377.82	0.7%	$44,518.00	78%
CHIP	$14,544.57	$2,736.38	$999.00 [2]	37%		$999.00 [3]	$12.35	0.5%	$1,725.02	63%
Foster Care	$139.87	$7.13	$6.82	96%		$6.82 [4]	$0.31	4%		
CCDF	$6,842.29	$324.66	$106.08	33%		$106.08 [5]	$19.81	6%	$198.77	61%
Total [6]	**$994,776.41**	**$106,671.65**	**$32,835.15**	**31%**	**$9,757.62**	**$23,077.52**	**$10,233.32**	**10%**	**$63,603.20**	**60%**

Notes:

1. The majority of monetary loss for the Medicare FFS program is due to medical necessity improper payments for home health and Inpatient Rehabilitation Facility (IRF) claims.
2. The majority of monetary loss for the Medicaid program and CHIP is due to errors resulting from noncompliance with provider enrollment requirements and cases where the beneficiary was ineligible for the program or service.
3. The categorization of Monetary Loss Within versus Outside Agency Control corresponds to the distinction in Figure 2 between Improper Payments Made By the Federal Government versus Improper Payments Made By Recipients of Federal Funding (e.g., Medicaid and CHIP improper payments made by states on behalf of the federal government are considered outside the agency's control).
4. Title IV-E Foster Care is a state-administered program and therefore eligibility is determined by staff at the state and local levels.
5. Since CCDF is a block grant, HHS has limited authority to require specific actions of state grantees given that states determine the specifics of their program.
6. Totals do not necessarily equal the sum of the rounded components.

11.0 PROGRAM-SPECIFIC REPORTING INFORMATION

11.1 MEDICARE FFS (PARTS A AND B)

Medicare FFS Statistical Sampling Process

HHS uses the Comprehensive Error Rate Testing (CERT) program to estimate the Medicare FFS improper payments. The CERT program reviews a stratified random sample of Medicare FFS claims to determine if HHS properly paid claims under Medicare coverage, coding, and billing rules. The Medicare FFS improper payment estimate also includes improper payments due to insufficient or no documentation. Figure 3 depicts the CERT process.

The CERT program considers improper payments to be:

- Any claim payment that should have been denied or was made in the wrong amount, including overpayments and underpayments. The claim counts as either a total or partial improper payment, depending on the error;
- Improper payments of all dollar amounts (i.e., there is no dollar threshold under which errors will not be cited); and
- Improper payments caused by policy changes as of the new policy's effective date (i.e., there is no grace period permitted).

Figure 3: CERT Process

The CERT program ensures statistically valid random sampling across four claim types:

- Part A claims excluding hospital Inpatient Prospective Payment System (IPPS) (including but not limited to home health, Inpatient Rehabilitation Facility [IRF], Skilled Nursing Facility [SNF], and hospice);
- Part A hospital IPPS claims;
- Part B claims (e.g., physician, laboratory, and ambulance services); and
- Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS).

HHS sampled approximately 50,000 claims during the FY 2019 report period. The improper payment rate estimated from this sample reflects all claims processed by the Medicare FFS program during the report period. Additional information on Medicare FFS improper payment methodology is on pages 166-167 of HHS's FY 2012 AFR.

Service Areas Driving Improper Payments

The Medicare FFS improper payment estimate for FY 2019 is 7.25 percent of total outlays or $28.91 billion. This year's estimate decreased from the prior year's reported 8.12 percent improper payment estimate due to a reduction in improper payments for home health, Part B, and DMEPOS claims. Although the improper payment rate for these services and the gross Medicare FFS improper payment rate decreased, improper payments for SNF, hospital outpatient, IRF, and home health claims were major contributing factors to the FY 2019 Medicare FFS improper payment rate, comprising 36.01 percent of the overall estimated improper payment rate. While the factors contributing to improper payments are complex and vary by year, the primary causes of improper payments continue to be insufficient documentation and medical necessity errors as described in the following four driver service areas:

- Insufficient documentation continues to be the major error reason for SNF claims. The SNF claims improper payment rate increased from 6.55 percent in FY 2018 to 8.54 percent in FY 2019. The primary reason for the errors was missing or insufficient certification/recertification statements. Medicare coverage of SNF services requires certification and recertification for these services (42 Code of Federal Regulation [CFR] §424.20).
- Insufficient documentation continues to be the major error reason for hospital outpatient claims. The improper payment rate for hospital outpatient claims increased from 3.25 percent in FY 2018 to 4.37 percent in FY 2019. The primary reason for the errors was that the order (or the intent to order for

certain services) or medical necessity documentation was missing or insufficient (42 United States Code [U.S.C.] §1395y, 42 CFR §410.32).

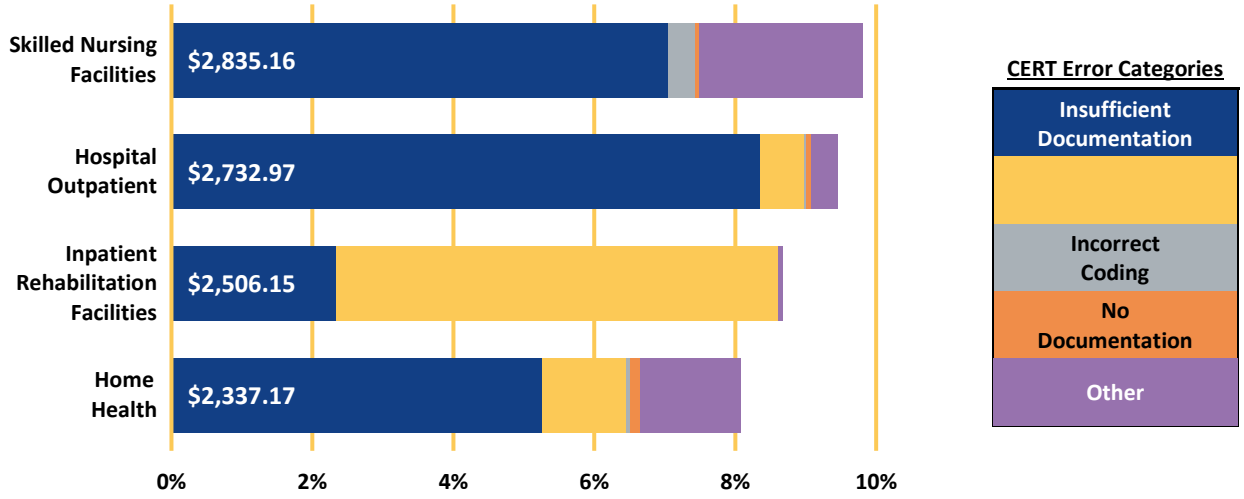
- Medical necessity (i.e., services billed were not medically necessary) continues to be the major error contributor for IRF claims. The IRF claims improper payment rate decreased from 41.55 percent in FY 2018 to 34.87 percent in FY 2019. The primary reason for these errors was that the IRF coverage criteria for medical necessity were not met. Medicare coverage of IRF services requires a reasonable expectation that the patient meets all coverage criteria at the time of IRF admission (42 CFR §412.622(a)(3)).
- Insufficient documentation for home health claims continues to be prevalent, despite the improper payment rate decrease from 17.61 percent in FY 2018 to 12.15 percent in FY 2019. The primary reason for the errors was insufficient or missing documentation to support the certification of home health eligibility requirements. Medicare coverage of home health services requires physician certification of the beneficiary's eligibility for the home health benefit (42 CFR §424.22).

Most CERT error categories are more detailed than OMB root cause categories in an effort to help generate useful root cause information regarding HHS improper payments. Figure 4 describes the CERT error categories, while Figure 5 shows the FY 2019 Medicare FFS drivers for SNF, hospital outpatient, IRF, and home health claims by CERT error category.

Figure 4: CERT Error Categories and Percentage of Improper Payments

CERT Error Category	Error Category Description	Share of Improper Payments
Insufficient Documentation	These errors occur when submitted medical records are inadequate to determine if billed services were provided, provided at the level billed, and/or were medically necessary; or when a specific documentation element required as a condition of payment is missing.	59.54%
Medical Necessity	These errors occur when submitted medical records contain adequate documentation to make an informed decision that services billed were not medically necessary based upon Medicare coverage and payment policies.	18.67%
Incorrect Coding	These errors occur when submitted medical records support a different code than what was billed; the service was performed by someone other than the billing provider or supplier; the billed service was unbundled; or the beneficiary was discharged to a site other than the one coded on the claim.	13.67%
No Documentation	These errors occur when the provider or supplier fails to respond to repeated requests for medical records or responds that they do not have the requested documentation.	6.06%
Other	These errors do not fit into the previous categories (e.g., duplicate payment error, non-covered or unallowable service, ineligible Medicare beneficiary, etc.).	2.05%

Figure 5: FY 2019 Medicare FFS Service Areas with the Largest Estimated Improper Payment Dollar Amounts: Percentage Share of Medicare FFS Improper Payments, by CERT Error Category (Dollar Amounts in Millions)



Unknown versus Monetary Loss Findings

Improper payments do not necessarily represent expenses that should not have occurred. Instances where there is insufficient or no documentation to support the payment as proper is cited as improper payments. The majority of Medicare FFS improper payments are due to documentation errors where HHS could not determine if billed services were provided, provided at the level billed, and/or were medically necessary. In other words, when payments lack the appropriate supporting documentation, validity cannot be determined. These are payments where more documentation is necessary to determine if the claims were payable or if they should be considered monetary losses to the program. In Figure 6, "unknown" represents payments where there was insufficient or no documentation to support the payment as proper or as a known monetary loss.

To provide additional information for unknown payments, HHS reviewed insufficient documentation errors to determine if the errors were "documentation noncompliance errors" which includes services or items:

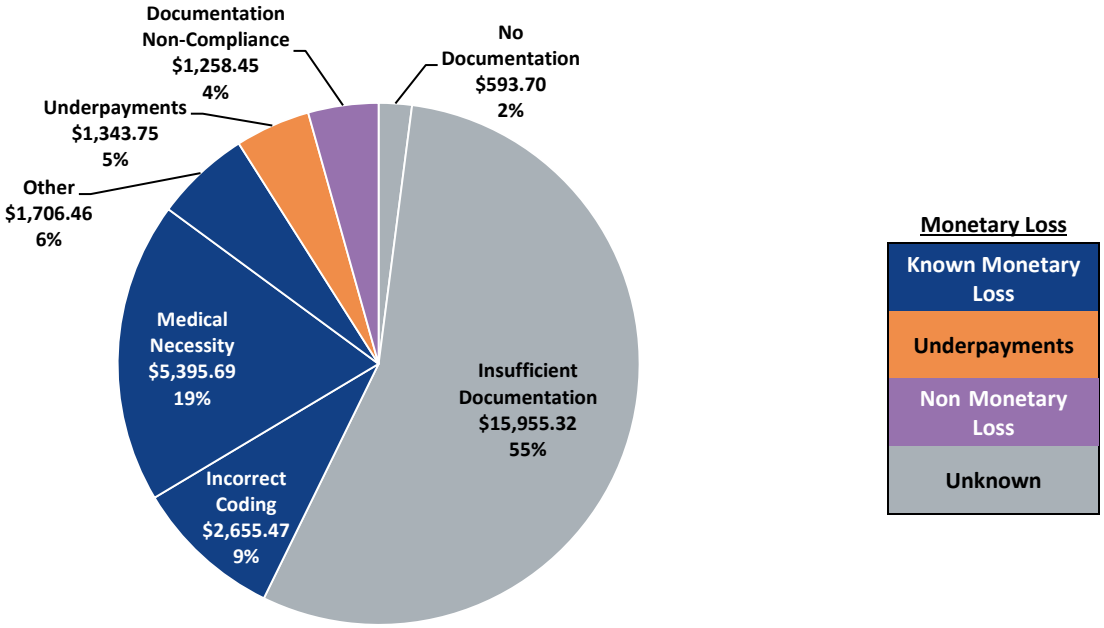
- That were covered and necessary;
- Provided/delivered to an eligible beneficiary;
- Paid in the correct amount; and
- The medical record documentation did not comply with rules and requirements per Medicare policy.

HHS determined that 4.35 percent of the total improper payments were documentation noncompliance errors. If the documentation noncompliance errors were corrected, the government would have made the payment in the assigned amount, and therefore, it represents a "non-monetary loss" to the government. If the documentation noncompliance errors counted as proper payments, the FY 2019 Medicare FFS improper payment rate would have been 6.94 percent, representing $27.65 billion in projected improper payments.

Another proportion of improper payments is claims where HHS determined that the Medicare FFS payment should not have occurred or should have been paid in a different amount. For this reason, medical necessity, incorrect coding, and other errors are improper and known monetary losses to the program.

Figure 6 provides information on Medicare FFS improper payments that are known monetary losses, underpayments, unknown, and non-monetary losses to the program.

Figure 6: FY 2019 Medicare FFS Estimated Improper Payments, by Monetary Loss Category and Type of CERT Error[1] (Dollar Amounts in Millions)



[1] Values in this figure may not add up precisely to other tables in this document due to rounding.

Medicare FFS Corrective Action Plan

HHS uses CERT program data and other sources of information to address improper payments in Medicare FFS through various corrective actions. The following sections discuss key corrective actions to address driver service area errors and OMB root cause categories.

Corrective Actions to Address Driver Service Areas

HHS developed multiple preventive and detective measures for specific service areas with high improper payment rates, such as SNF, hospital outpatient, IRF, and home health claims. HHS believes implementing targeted corrective actions will prevent and reduce improper payments in these areas and reduce the overall improper payment rate.

Service Area: Skilled Nursing Facilities

HHS implemented corrective actions for payment errors related to SNF services resulting from missing or insufficient medical record documentation. Key SNF corrective actions include:

Key SNF Corrective Actions	
Corrective Action	**Description**
Targeted Probe and Educate (TPE) SNF Reviews	During FY 2019, HHS conducted medical review of SNF claims with high error rates under the TPE program. Under the TPE strategy, Medicare Administrative Contractors (MACs) conduct up to three rounds of review of 20-40 claims per round, with one-on-one education provided at the end of each round. In FY 2019, MACs reviewed approximately 1,000 SNF providers under the TPE program.
Supplemental Medical Review	In FY 2019, the SMRC initiated medical review activities related to post-payment review of SNF claims. The SMRC shares the results with the MACs for claim adjustment. The providers

Key SNF Corrective Actions	
Corrective Action	**Description**
Contractor (SMRC) SNF Reviews	receive detailed review result letters from the SMRC and demand letters for overpayment recovery from the MAC. These letters include educational information to providers regarding what was incorrect in the original billing of the claim.
Recovery Audit Contractors (RAC) SNF Reviews	During FY 2019, Medicare FFS RACs continued to conduct rapid post pay reviews of SNF services. Medicare FFS RACs continued to identify and collect improper payments related to SNF claims for several factors, including medical necessity and insufficient documentation. Five percent of Medicare FFS RAC collections were from overpayments identified during SNF claim reviews.

Service Area: Hospital Outpatient

HHS implemented corrective actions for payment errors related to hospital outpatient services resulting from missing or insufficient medical record documentation. Key hospital outpatient corrective actions include:

Key Hospital Outpatient Corrective Actions	
Corrective Action	**Description**
TPE Hospital Outpatient Reviews	During FY 2019, MACs continued performing medical review following the TPE process by conducting up to three rounds of hospital outpatient claims review of 20 to 40 claims per round, with one-on-one education provided at the end of each round. In FY 2019, MACs reviewed approximately 1,400 Hospital Outpatient providers under the TPE program.
SMRC Hospital Outpatient Reviews	In FY 2019, the SMRC performed medical reviews on a post-payment basis for hospital outpatient claims, such as Outpatient Dental services, Electrodiagnostic Testing, Spinal Cord Stimulator, Outpatient Hyperbaric Oxygen services, and Polysomnography services. The SMRC shares the results of its medical review with the MACs for claim adjustments upon the review's completion. The providers receive detailed review result letters from the SMRC and demand letters for overpayment recovery from the MAC. These letters include educational information to providers regarding what was incorrect in the original billing of the claim.
RAC Outpatient Reviews	During FY 2019, Medicare FFS RACs continued to identify and collect improper payments related to outpatient claims for several factors, including insufficient documentation. Thirty-five percent of Medicare FFS RAC collections were from overpayments identified during hospital outpatient claim reviews.

Service Area: Inpatient Rehabilitation Facilities

HHS also continues to focus on addressing IRF payment errors, including errors resulting from medical necessity. Key IRF corrective actions include:

Key IRF Corrective Actions	
Corrective Action	**Description**
TPE IRF Reviews	During FY 2019, HHS conducted medical review of IRF claims with high error rates under the TPE Program. Under the TPE strategy, MACs conduct up to three rounds of review of 20-40 claims per round, with one-on-one education provided at the end of each round. In FY 2019, MACs reviewed approximately 600 IRF providers under the TPE program.

Key IRF Corrective Actions	
Corrective Action	**Description**
SMRC IRF Reviews	In FY 2019, the SMRC initiated medical review activities related to post-payment review of IRF claims. The SMRC shares the results with the MACs for claim adjustment. The providers receive detailed review result letters from the SMRC and demand letters for overpayment recovery from the MAC. These letters include educational information to providers regarding what was incorrect in the original billing of the claim.
RAC IRF Reviews	In FY 2019, HHS approved the Medicare FFS RACs to review IRF claims for several factors, including medical necessity and insufficient documentation.

Service Area: Home Health

HHS continues to implement corrective actions to address program payment vulnerabilities related to home health services, including errors resulting from insufficient or missing documentation to support beneficiary eligibility for home health services and/or for skilled services. Key Home Health corrective actions include:

Key Home Health Corrective Actions	
Corrective Action	**Description**
TPE for Home Health Agencies (HHAs)	During FY 2019, HHS continued reviewing home health agencies with high error rates under the TPE program. Under the TPE strategy, MACs conduct up to three rounds of review of 20-40 claims per round, with one-on-one education provided at the end of each round. HHAs with high error rates at the end of round two of the previous Home Health Probe and Educate program and those identified by MAC data analysis as statistical outliers are included in the TPE process. In FY 2019, MACs reviewed approximately 5,500 HHA providers under the TPE program.
Review Choice Demonstration for Home Health Services	As noted in the September 27, 2018, Federal Register Notice, the Review Choice Demonstration for Home Health Services gives Jurisdiction M (Palmetto) providers operating in Illinois, Ohio, North Carolina, Florida, and Texas an initial choice of 3 options (i.e., pre-claim review, post-payment review, or minimal post-payment review with a 25 percent payment reduction for all home health services). A provider's compliance with Medicare billing, coding, and coverage requirements would determine the provider's next steps under the demonstration. HHS received OMB *Paperwork Reduction Act* (PRA) approval on February 28, 2019. The demonstration began for Illinois providers on June 1, 2019, and for Ohio providers on September 30, 2019.
RAC Home Health Reviews	In FY 2019, the national HHA RAC is currently approved and conducting comprehensive documentation and medical necessity review of home health claims. HHS approved the Medicare FFS Home Health and Hospice RAC to review home health claims for several factors, including lack of documentation to support medical necessity of provided home health services, insufficient documentation to support billed home health claims, and if home health services were rendered as billed.

Other Service Areas

HHS leverages prior corrective action successes in other service areas (such as DMEPOS) and other non-emergent services by working with providers to improve understanding of HHS policies and explore new opportunities for corrective actions. Key Other Service Area corrective actions include:

Key Other Service Area Corrective Actions	
Corrective Action	**Description**
DMEPOS Prior Authorization	In FY 2019, HHS affirmed (approved) over 65,000 items through the prior authorization process. On April 22, 2019, HHS published a Federal Register Notice requiring: • Prior authorization for seven Power Mobility Device codes effective nationwide July 22, 2019; and • Prior authorization for five Pressure Reducing Support Surface codes effective July 22, 2019, in California, Indiana, New Jersey, and North Carolina.
Ambulance Transport Prior Authorization	In FY 2019, HHS continued a prior authorization model for repetitive scheduled non-emergent ambulance transport occurring on or after December 15, 2014, in New Jersey, Pennsylvania, and South Carolina. On January 1, 2016, in accordance with Section 515 of the *Medicare Access and CHIP Reauthorization Act of 2015* (MACRA), HHS added five additional states (North Carolina, Virginia, West Virginia, Maryland, and Delaware) and the District of Columbia to the model. The model is scheduled to end in all states on December 1, 2020. Based on expenditure data, spending decreased in the initial model states from an average of $18.9 million to an average of $6.2 million per month. Based on data from the additional MACRA states, spending decreased from an average of $5.7 million to an average of $2.9 million per month.
RAC Durable Medical Equipment (DME) Reviews	During FY 2019, the national DME RAC continues to conduct complex DME reviews for medical necessity of DME items billed, insufficient documentation to support DME items billed, missing valid orders for DME items billed, and if items/services billed were rendered. The DME RAC is also conducting automated DME reviews for inappropriate unbundling and if the DME items billed were medically necessary.

In addition to these initiatives, HHS has implemented further efforts to reduce improper payments in Medicare FFS, spanning multiple service areas and addressing the OMB root causes of improper payments as outlined below.

Corrective Actions to Address OMB Root Causes:

Root Cause: Administrative or Process Errors Made by Other Party

Administrative or process errors made by other party (24.09 percent) mainly consists of coding errors. Key corrective actions include:

Corrective Actions for Administrative or Process Errors Made by Other Party	
Corrective Action	**Description**
Automated Edits	Due to the high volume of Medicare claims processed by HHS daily and the significant cost associated with conducting medical reviews of an individual claim, HHS relies on automated edits to identify inappropriate claims. HHS designed its systems to detect anomalies on the face of the claims and prevent payment for many erroneous claims through these efforts. HHS uses the National Correct Coding Initiative (NCCI) to stop claims that should never be paid. For example, this program prevents payments for services such as the repair of an organ by two

Corrective Actions for Administrative or Process Errors Made by Other Party	
Corrective Action	**Description**
	different methods. HHS will report FY 2019 savings from the NCCI edits in the forthcoming *Annual Report to Congress on the Medicare and Medicaid Integrity Programs*.
Provider and Supplier Screening	Existing Medicare Providers and Suppliers: HHS revalidates all existing Medicare providers and suppliers on an ongoing basis to ensure that only qualified and legitimate providers and suppliers deliver health care items and services to Medicare beneficiaries. HHS's provider screening and enrollment initiatives have had a significant impact on removing ineligible providers and suppliers from the Medicare program. HHS manages 2.3 million distinct Medicare enrollments through the Provider Enrollment, Chain, and Ownership System (PECOS). In FY 2019, HHS performed approximately 222,740 initial enrollment screenings, completed 199,999 revalidations, deactivated 150,679 enrollments, and revoked 2,556 enrollments.
	New Medicare Providers and Suppliers: HHS established three levels of provider and supplier enrollment risk-based screening: "limited," "moderate," and "high." Providers and suppliers designated in the "limited" risk category undergo verification of licensure and a wide range of database checks to ensure compliance with all provider- or supplier-specific requirements. Providers and suppliers designated in the "moderate" risk category are subject to unannounced site visits in addition to all the requirements in the "limited" screening level. Providers and suppliers in the "high" risk category are subject to fingerprint-based criminal background checks (FCBCs) in addition to all of the requirements in the "limited" and "moderate" screening levels. In FY 2019, the initiative resulted in 30,668 site visits conducted by the National Site Visit Contractor, which conducts site visits for most Medicare FFS providers and suppliers, and 26,438 conducted by the National Supplier Clearinghouse, which conducts site visits for Medicare DME suppliers. This work resulted in 232 revocations due to non-operational site visit determinations for all providers and suppliers. In FY 2019, HHS denied 771 enrollments and revoked 11 enrollments as a result of the FCBCs or a failure to respond.
Healthcare Fraud Prevention Partnership (HFPP)	HHS continues to engage with the HFPP, a public-private partnership to improve detection and prevention of health care fraud, waste, and abuse by exchanging data, information, and anti-fraud practices. During FY 2019, HFPP membership grew from 112 to 142 partner organizations, including federal and state partners, private payers, associations, and law enforcement organizations.
Medical Review Strategies	HHS and its contractors develop medical review strategies using improper payment data to target the areas of highest risk and exposure. HHS requires its Medicare review contractors to identify and prevent improper payments due to documentation errors in certain error-prone claim types, such as SNF, hospital outpatient claims, IRF, and home health.
Overpayment Recoveries Related to Regulatory Provisions	In the final rule titled "Medicare Program: Reporting and Returning of Overpayments" (81 Federal Register 7654, February 12, 2016), HHS codified a rule requiring providers and suppliers to identify, report, and return Medicare Part A or Part B overpayments. This rule implements Section 1128J(d) of the *Social Security Act* and obligates providers and suppliers to report and return self-identified overpayments. This rule incentivizes providers and suppliers to maintain documentation and submit accurate claims, reducing potential improper payments.

Root Cause: Insufficient Documentation to Determine and Medical Necessity

The primary cause of Medicare FFS improper payments is insufficient documentation (59.54 percent). For these claims, the submitted medical records are inadequate to conclude that the billed services were actually provided, provided at the level billed, and/or were medically necessary; or a specific documentation element, required as a condition of payment, is missing. Medicare FFS claims are also included in this category when the provider or supplier fails to respond to repeated requests for medical records or responds that they do not have the documentation. If the provider submitted documentation or the provider had complete and sufficient documentation, then the claim may have been payable.

Another improper payment cause is medical necessity errors (18.67 percent). For these claims, the submitted medical records contain adequate documentation to make an informed decision that services billed were not medically necessary based upon Medicare coverage and payment policies. Key corrective actions include:

Corrective Actions for Insufficient Documentation and Medical Necessity	
Corrective Action	**Description**
SMRC Strategy	HHS contracts with the SMRC to perform medical reviews focused on vulnerabilities identified by HHS data analysis, the CERT program, professional organizations, and federal oversight entities. The SMRC evaluates medical records and related documents to determine if billed claims comply with Medicare coverage, coding, payment, and billing rules. In FY 2019, HHS tasked the SMRC with performing post-payment reviews on multiple areas, such as Replacement Positive Airway Pressure Devices, DME in SNF, Emergency Ambulance Services, Hospice Services, Non-Emergency Ambulance Services, Spinal Cord Stimulator, DME and No Response Providers, and IRF Services. HHS uses the reviewers' results to improve billing accuracy. Results are shared with providers through detailed review results letters and possible overpayment determinations. These letters include educational information regarding what was incorrect in the original claim billing.
Medical Review Strategies	HHS implemented a TPE process, which is a targeted approach where MACs focus on specific providers and suppliers within a service type, rather than all providers and suppliers billing the service. This eliminates the burden to providers and suppliers who, based on data analysis, are already submitting claims that are compliant with Medicare policy. In FY 2019, MACs reviewed 3,647 DME and Hospice providers under the TPE program for several factors, including lack of documentation to support medical necessity of provided items or services. In an attempt to create additional efficiencies to the TPE process, HHS implemented the TPE 10-Claim Preview Pilot for DMEPOS suppliers.
Medical Review Accuracy Award Fee Metric	Beginning in FY 2014, HHS included the Medical Review Accuracy Award Fee Metric in the Award Fee Plan for MACs that process Part A, Part B, and DME claims. The Medical Review Accuracy Award Fee Metric measures the accuracy of the MAC's complex medical review decisions. This project assists with consistent medical review decisions across MACs, leading to uniform education to providers on all improper payments, including medical necessity and the impact of insufficient documentation errors. Additional goals of this project in FY 2020 include identifying unclear and/or burdensome policy requirements that can be clarified or simplified to prevent unnecessary denials. HHS will also work to implement an accuracy review initiative for the MAC redetermination appeal units to ensure consistent medical review decisions are made at that level.

Corrective Actions for Insufficient Documentation and Medical Necessity	
Corrective Action	**Description**
Provider Billing Review Evaluation	In FY 2019, HHS issued Comparative Billing Reports (CBRs) for the following topics: • Intensity-Modulated Radiation Therapy, Office Visits, New and Established Patients, Family Practitioners; • Subsequent Hospital Visit; • Vitamin D Assay Test; • Air Ambulance; • Emergency Department Services; • Modifier 25 Dermatology; • Breast Re-Excision Rate; • Venipuncture; and • Different-Day Elective Upper and Lower Endoscopy Rate, by a Physician. On November 6, 2017, HHS sent CBRs to 7,245 providers with abnormal billing practices for emergency department services. For providers who received the November 2017 and May 2019 CBRs, HHS observed an 11 percent decline in services and a 9 percent ($63.8 million) decline in allowed charges. On September 11, 2017, HHS sent CBRs to 1,536 providers with abnormal billing practices for established office visits with modifier 25 with a dermatology specialty. For providers that received the September 2017 and June 2019 CBRs, HHS observed a decline of 3.5 percent in services, 2 percent ($1.3 million) decline in allowed charges, and 4 percent decline in number of beneficiaries for several billing codes related to office visits for established patients (with modifier 25) combined.

Medicare FFS Information Systems and Other Infrastructure

HHS's systems can identify developing and continuing aberrant billing patterns through comparison of local payment rates to national rates. A secure high-speed network rapidly transmits large data sets between systems at both the Medicare contractor and HHS levels. In addition, to prevent improper payments on a prepayment basis HHS continuously reviews opportunities for centralizing the development and implementation of automated edits based on national coverage determinations, medically unlikely units billed, and other relevant parameters.

Medicare FFS Statutory or Regulatory Barriers that Could Limit Corrective Actions

HHS has not identified statutory or regulatory barriers that limit corrective actions.

11.2 Medicare Advantage (Part C)

Medicare Advantage Statistical Sampling Process

The Part C methodology estimates improper payments due to errors in beneficiary risk scores. The primary component of most beneficiary risk scores is clinical diagnoses submitted by the plan. If medical records do not support the diagnoses submitted to HHS, the risk scores will be inaccurate, ultimately resulting in payment errors. The Part C estimate is based on medical record reviews conducted under HHS's annual National Improper Payment Measurement process, where HHS identifies unsupported diagnoses and calculates corrected risk scores. The National Improper Payment Measurement (see Figure 7) calculates the beneficiary-level payment error for the sample and extrapolates the sample payment error to the population subject to risk adjustment, resulting in a Part C gross payment error amount. In FY 2019, HHS selected a stratified random sample of beneficiaries with a risk adjusted payment in calendar year 2017 (where the strata are high, medium, and low risk scores) and reviewed medical records of the diagnoses submitted by plans for the sample beneficiaries.

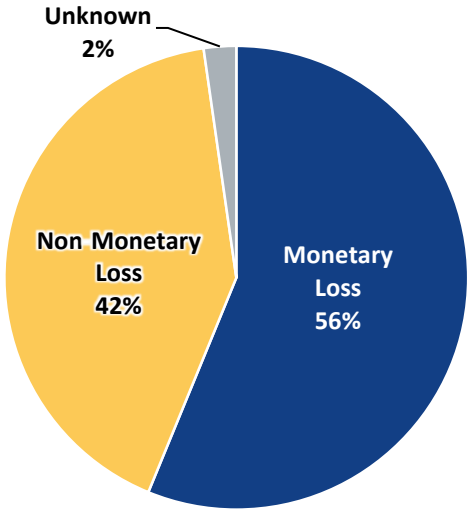
Figure 7: National Improper Payment Process

The Medicare Part C gross improper payment estimate for FY 2019 is 7.87 percent or $16.73 billion. The submission of more accurate diagnoses by Medicare Advantage (MA) organizations for payment primarily drove the decrease from the prior year's estimate of 8.10 percent.

Medicare Advantage Corrective Action Plan

The root causes of FY 2019 Medicare Part C improper payments consist of errors due to administrative or process errors made by another party (56.20 percent in overpayments and 41.54 percent in underpayments), with a smaller portion of overpayments resulting from missing documentation (2.26 percent). Monetary loss results from administrative or process errors by other party, specifically, medical record documentation submitted by the MA organization does not substantiate a condition for which it received payment. The non-monetary loss component is comprised of conditions identified during the medical review process that the MA organization did not submit for payment, while unknown is comprised of situations in which sufficient information was not available to make a determination. Monetary versus non-monetary loss is displayed in Figure 8.

Figure 8: FY 2019 Medicare Part C Estimated Improper Payments, by Monetary, Non-Monetary Loss, and Unknown (i.e., Missing or Insufficient Documentation) Categories[1]



[1] Values in this figure may not add up precisely to other tables in this document due to rounding.

Corrective Actions to Address Root Causes:

Root Causes: Insufficient Documentation to Determine and Administrative or Process Errors Made by Other Party

HHS implemented three key corrective actions to address the Part C improper payment estimate:

Corrective Actions for Insufficient Documentation and Administrative or Process Errors Made by Other Party	
Corrective Action	**Description**
Contract-Level Audits	Contract-level Risk Adjustment Data Validation (RADV) audits are HHS's primary corrective action to recoup overpayments. RADV uses medical record review to verify the accuracy of enrollee diagnoses submitted by MA organizations for risk adjusted payment. HHS expects payment recovery will have a sentinel effect on risk adjustment data quality submitted by plans for payment because contract-level RADV audits increase the incentive for MA organizations to submit valid and accurate diagnosis information. Contract-level RADV audits also encourage MA organizations to self-identify, report, and return overpayments. HHS completed payment recovery for the 2007 pilot audits, totaling $13.7 million recovered, in FYs 2012 through 2014. The Department completed several stages of the contract-level RADV audits for payment years 2011 through 2013. In April 2019, HHS launched the payment year 2014 RADV audit and held a training webinar for MA organizations selected for audits to prepare the audited MA organizations for RADV audits. The payment year 2014 RADV audit is currently underway and is expected to conclude in late FY 2020. HHS launched the payment year 2015 RADV audit in late FY 2019.
Overpayment Recoveries Related to Regulatory Provisions	As required by the *Social Security Act*, HHS regulations require MA organizations to report and return identified overpayments. HHS believes that this requirement will reduce improper payments by encouraging MA organizations to submit accurate payment information. In FY 2019, MA organizations reported and returned approximately $44.55 million in self-reported overpayments.
Training	HHS conducted training sessions for Medicare Part C and Part D sponsors on program integrity initiatives, investigations, data analyses, and potential fraud schemes. In FY 2019, HHS conducted: two small in-person Medicare Parts C and D Fraud, Waste, and Abuse Collaboration Missions (October 2018 and March 2019); a large in-person Fraud, Waste, and Abuse Training (July 2019); and two Opioid Missions (April 2019 and August 2019). The missions included multi-disciplinary teams of experts and decision makers from HHS and its partners, and allowed them to undertake collaborative efforts to protect the Medicare Part C and D programs.

Medicare Advantage Information Systems and Other Infrastructure

HHS uses the following internal Medicare systems to make and validate Medicare Part C payments:

- Medicare Beneficiary Database;
- Risk Adjustment Processing System;
- Encounter Data Processing System;
- Health Plan Management System; and
- Medicare Advantage Prescription Drug (MARx) payment system.

Medicare Advantage Statutory or Regulatory Barriers that Could Limit Corrective Actions

HHS has not identified statutory or regulatory barriers that limit corrective actions.

11.3 MEDICARE PRESCRIPTION DRUG BENEFIT (PART D)

Medicare Prescription Drug Benefit Statistical Sampling Process

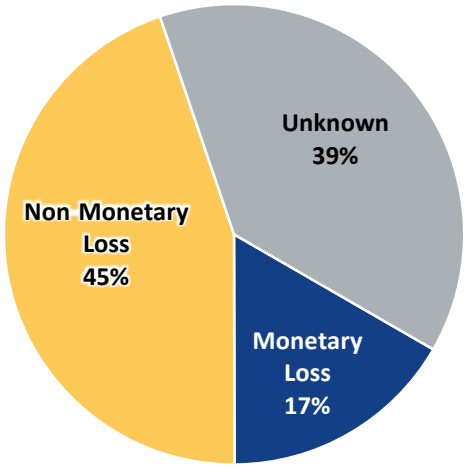
The Part D improper payment estimate measures the payment error related to prescription drug event (PDE) data, where most errors for the program exist. HHS measures inconsistencies between information reported on PDEs and supporting documentation submitted by Part D sponsors: prescription record hardcopies (or medication orders as appropriate) and detailed claims information. Based on these reviews, each PDE in the audit sample is assigned a gross drug cost error. A representative sample of beneficiaries undergoes a simulation to determine the Part D improper payment estimate.

The FY 2019 Medicare Part D gross improper payment estimate is 0.75 percent or $607.94 million. The decrease from the prior year's estimate of 1.66 percent resulted from errors being smaller in magnitude.

Medicare Prescription Drug Benefit Corrective Action Plan

The FY 2019 Medicare Part D improper payments root causes are administrative or process errors made by other party (16.63 percent overpayments and 44.82 percent underpayments) and missing documentation (38.55 percent). Monetary loss results when the prescription documentation submitted indicates that an overpayment occurred. Non-monetary loss results when the documentation submitted indicates that an underpayment occurred, while unknown is comprised of a situation in which insufficient documentation was submitted to make a determination. Monetary versus non-monetary loss is displayed in Figure 9.

Figure 9: FY 2019 Medicare Part D Estimated Improper Payments, by Monetary Loss, Non-Monetary Loss, and Unknown (i.e., Missing or Insufficient Documentation) Categories[1]



[1] Values in this figure may not add up precisely to other tables in this document due to rounding.

Corrective Actions to Address Root Causes:

Root Causes: Insufficient Documentation to Determine and Administrative or Process Errors Made by Other Party

HHS conducted the following corrective actions to address Part D payment errors:

Corrective Actions for Insufficient Documentation and Administrative or Process Errors Made by Other Party	
Corrective Action	**Description**
Outreach	HHS continued formal outreach to plan sponsors for invalid or incomplete documentation. HHS distributed Final Findings Reports to all Part D sponsors participating in the PDE review process. This report provided feedback on their submission and validation results against an aggregate of all participating plan sponsors.
Overpayment Recoveries Related to Regulatory Provisions	As required by the *Social Security Act*, HHS requires Part D sponsors report and return all identified overpayments. HHS believes that overpayment statute and regulation contributed to increased attention to data accuracy by Part D sponsors. In FY 2019, Part D sponsors self-reported and returned approximately $1.54 million in overpayments.
Training	HHS continued national training sessions on payment and data submission with detailed instructions as part of the improper payment estimation process for Part D sponsors. HHS also conducted in-person training sessions for Medicare Part C and Part D sponsors on program integrity initiatives, investigations, data analysis, and potential fraud schemes. In FY 2019: HHS conducted two small in-person Medicare Parts C and D Fraud, Waste, and Abuse Collaboration Missions (October 2018 and March 2019); a large in-person Fraud, Waste, and Abuse Training (July 2019); and two Opioid Missions (April 2019 and August 2019). The missions included multi-disciplinary teams of experts and decision makers from HHS and its partners, and supported collaborative efforts to protect the Medicare Part C and D programs.

Medicare Prescription Drug Benefit Information Systems and Other Infrastructure

HHS uses the following internal Medicare systems to make and validate Medicare Part D payments:

- Medicare Beneficiary Database;
- Risk Adjustment Processing System;
- Health Plan Management System;
- MARx payment system; and
- Integrated Data Repository.

Medicare Prescription Drug Benefit Statutory or Regulatory Barriers that Could Limit Corrective Actions

HHS has not identified statutory or regulatory barriers that limit corrective actions.

11.4 MEDICAID

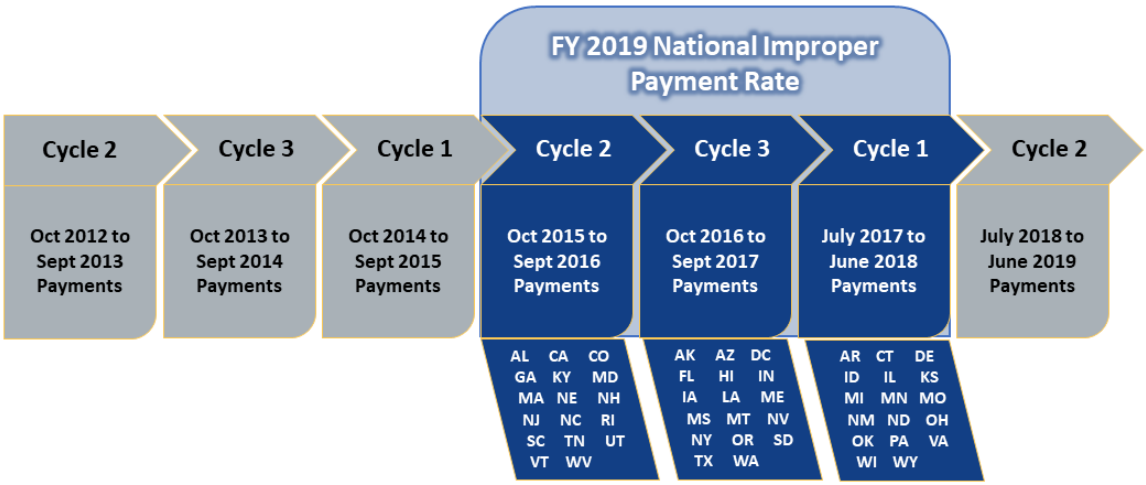
Medicaid Statistical Sampling Process

Through the Payment Error Rate Measurement (PERM) program, HHS estimates Medicaid improper payments on an annual basis, utilizing federal contractors to measure three components: FFS, managed care, and eligibility.

HHS's PERM program uses a 17-states-per-year, 3-year rotation for measuring Medicaid improper payments. All 50 states and the District of Columbia are reflected in the national Medicaid improper payment rate reported here,

as that rate includes findings from the most recent 3 years of measurements. Each time a group of 17 states is measured under the PERM program, HHS removes that group's previous findings from the calculation and includes its newest findings. The national FY 2019 Medicaid improper payment rate is based on FYs 2017, 2018, and 2019 measurements (see Figure 10 below).

Figure 10: FY 2019 Medicaid Cycle Measurements



To learn how HHS grouped states into three cycles, refer to pages 177 – 179 of HHS's FY 2012 AFR.

FFS and Managed Care Components

FFS includes the traditional method of paying for medical services under which a state pays providers for each service rendered to individual beneficiaries, while managed care is a delivery system in which a state makes a monthly payment to a managed care organization, which is responsible for managing beneficiary care. Quarterly, states submit adjudicated claims data and HHS randomly selects a sample of FFS claims and managed care capitated payments. Each FFS claim selected undergoes a medical and data processing review, while managed care payments are subjected to only a data processing review. Reviewing either the medical records associated with historical payments to providers or the medical records associated with payments to providers that occurred during the month sampled does not have a direct link to the established capitated payment sampled and, therefore, is not included in the improper payment review.

Additionally, HHS selects a combination of FFS claims and managed care payments for eligibility review. Based on each state's expenditures and historical FFS and managed care improper payment data, the FFS sample size was between 302 and 1,570 claims per state, the managed care sample size was between 38 and 242 payments per state, the eligibility FFS sample size was between 102 and 298 per state, and the eligibility managed care sample size was between 105 and 380 per state. When a state's FFS or managed care component accounted for less than two percent of the state's total Medicaid expenditures, HHS combined the state's FFS and managed care claims into one component for sampling and measurement purposes.

Eligibility Component

Through the eligibility component, a federal contractor assesses states' application of federal rules and the state's documented policies and procedures related to beneficiary eligibility. Examples of noncompliance with eligibility requirements include a state: enrolling a beneficiary when he or she is ineligible for Medicaid or CHIP; determining a beneficiary to be eligible for the incorrect eligibility category, resulting in an ineligible service being provided; not

conducting a timely beneficiary redetermination; or not performing or completing a required element of the eligibility determination process, such as income verification. As described in the PERM final rule (82 Federal Register 31158, July 5, 2017), HHS resumed the eligibility component measurement for the first cycle of 17 states and reported an updated national eligibility improper payment estimate for FY 2019. Between FY 2015 and FY 2018, HHS did not conduct the eligibility measurement component of PERM; refer to pages 211-214 of HHS's 2018 AFR for more information. Please note that the national eligibility improper payment rate still includes a proxy estimate for the remaining 34 states that have not yet been measured since the reintegration of the PERM eligibility component.

Calculations and Findings

The national Medicaid program's improper payment estimate combines each state's Medicaid FFS, managed care, and eligibility improper payment estimate. In addition, HHS combines individual state component improper payment estimates to calculate the national component improper payment estimates. National component improper payment rates and the Medicaid program improper payment rate are weighted by state size, such that a state with a $10 billion program is weighted more in the national rate than a state with a $1 billion program. A correction factor in the methodology ensures that Medicaid eligibility improper payments are not "double counted."

The national Medicaid improper payment estimate for FY 2019 is 14.90 percent or $57.36 billion.

The FY 2019 national Medicaid improper payment rate for each component is:

- *Medicaid FFS*: 16.30 percent
- *Medicaid managed care*: 0.12 percent
- *Medicaid eligibility*: 8.36 percent

Supplemental information related to the FY 2019 Medicaid improper payment results will be published on HHS's website – www.cms.gov/PERM – in early FY 2020.

Since FY 2014, the Medicaid improper payment estimate has been driven by errors due to state noncompliance with provider screening, enrollment, and National Provider Identifier (NPI) requirements. Most improper payments cited on claims are those where a newly enrolled provider had not been appropriately screened by the state; a provider did not have the required NPI on the claim; or a provider was not enrolled. Although these errors remain a driver of the Medicaid rate, state compliance has improved as the Medicaid FFS improper payment rate for these errors decreased from 7.21 percent in FY 2018 to 6.28 percent in FY 2019.

While the screening errors described above are for newly enrolled providers, states also must revalidate the enrollment and rescreen all providers at least every 5 years. States were required to complete the revalidation process of all existing providers by September 25, 2016. In FY 2019, HHS measured the second cycle of states for compliance with requirements for provider screening at revalidation. Improper payments cited on claims where a provider had not been appropriately screened at revalidation is a new major error source in the Medicaid improper payment rate. HHS will complete the measurement of all states for compliance with provider revalidation requirements in FY 2020.

Another area driving the FY 2019 Medicaid improper payment estimate is the reintegration of the PERM eligibility component, mentioned above. This is the first time in the history of the program that the eligibility component measurement has been conducted by a federal contractor; previously states conducted the measurement and self-reported results to HHS for reporting the national rate. This allows for consistent insight into the accuracy of Medicaid eligibility determinations and increases the oversight of identified vulnerabilities. Based on the measurement of the first cycle of states, eligibility errors are mostly due to insufficient documentation to verify

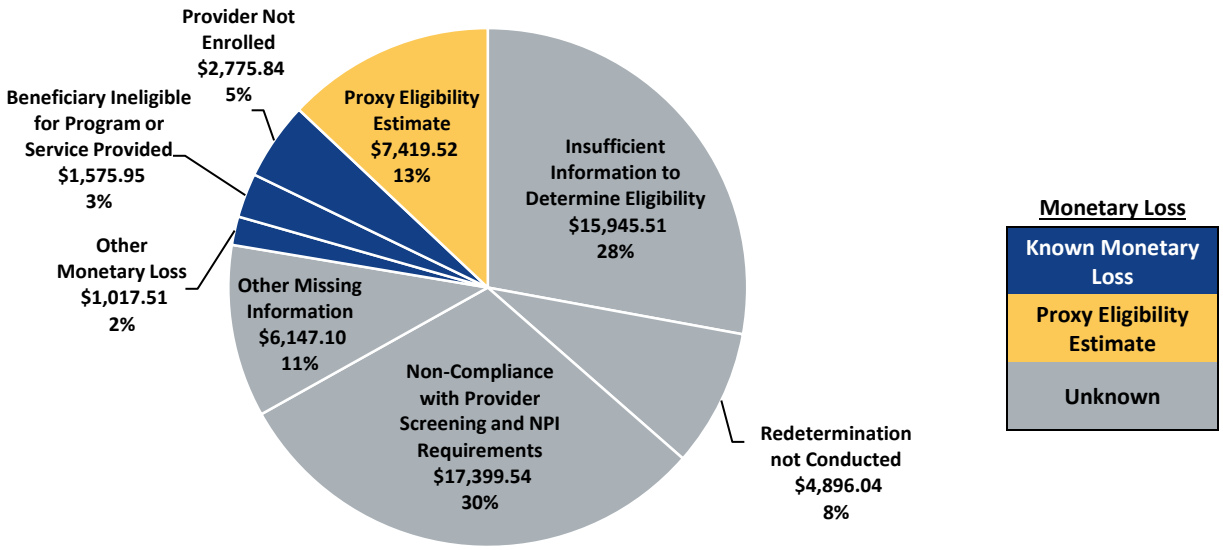
eligibility or noncompliance with eligibility redetermination requirements. The majority of the insufficient documentation errors represent both situations where the required verification was not done at all and where there is indication that the verification was initiated but there was no documentation to validate the verification process was completed. These insufficient documentation situations are related primarily to income or resource verification. HHS will complete the measurement of all states under the new eligibility component and establish a baseline in FY 2021.

Unknown versus Monetary Loss Findings

Improper payments do not necessarily represent expenses that should not have occurred. Improper payments also include instances where there is insufficient or no documentation to support the payment as proper. A majority of Medicaid improper payments were due to instances where information required for payment or eligibility determination was missing from the claim or state systems and/or states did not follow the appropriate process for enrolling providers and/or determining beneficiary eligibility. However, these improper payments do not necessarily represent payments to illegitimate providers or beneficiaries. If the missing information had been on the claim and/or had the state complied with the enrollment or redetermination requirements, then the claims may have been payable. Another proportion of improper payments are considered a known monetary loss to the program, which are claims where HHS determines the Medicaid payment should not have occurred or should have been made in a different amount.

Figure 11 provides information on Medicaid improper payments that are a known monetary loss to the program (i.e., provider not enrolled, beneficiary ineligible for program or service, incorrect coding, and other errors like claims processing errors, duplicate claims, or pricing mistakes). In the figure, "Unknown" represents payments where there was insufficient or no documentation to support the payment as proper or as a known monetary loss (e.g., claims where information was missing or states did not follow appropriate processes).

Figure 11: FY 2019 Medicaid Estimated Improper Payments, by Monetary Loss versus Unknown Categories and Type of PERM Error[1] (Dollar Amounts in Millions)



[1] The Proxy Eligibility Estimate is used to represent the eligibility component for the 34 states not yet measured since the reintegration of the PERM eligibility component. All eligibility improper payments from the FY 2019 measurement are included in the appropriate category (Known Monetary Loss or Unknown). The Proxy Eligibility Estimate includes both overpayments and underpayments, whereas Known Monetary Loss and Unknown only include overpayments. The value of underpayments outside the Proxy Eligibility Estimate ($51.31 million) was too small to report in Figure 11. In addition, due to rounding, amounts in this chart may not add up precisely to other tables in this document.

Medicaid Corrective Action Plan

HHS works closely with all states through enhanced technical assistance (including state-specific liaisons that will be assigned to each state and assist states with identifying and overcoming barriers to corrective action implementation) and guidance to develop state-specific corrective action plans to reduce improper payments. All states are responsible for implementing, monitoring, and evaluating the corrective action plan's effectiveness with assistance and oversight from HHS. When developing corrective action plans, states focus on the major causes of improper payments.

HHS also establishes corrective actions to help reduce improper payments. For example, HHS is actively engaged in:

- Conducting outreach during off-cycle PERM years to address issues identified in corrective action plans;
- Facilitating national best practice calls to share ideas across states;
- Offering ongoing technical assistance;
- Developing a notice of proposed rulemaking to strengthen the integrity of the eligibility determination process and avoid improper payments that will address several of the drivers of eligibility errors such as insufficient recordkeeping, verification of eligibility, redeterminations, and compliance with eligibility requirements when individuals experience a change in circumstances that may impact eligibility; and
- Providing additional guidance as needed.

Additional information on states' and HHS's corrective actions is provided in the following sections.

Corrective Actions to Address OMB Root Causes:

Root Causes: Administrative or Process Errors Made by State or Local Agency and Failure to Verify

Administrative or process errors made by states or local agencies and failure to verify errors mainly consist of errors resulting from noncompliance with the requirement to enroll providers and from cases where the beneficiary was ineligible for the program or service. State corrective action plans focus on system or process changes to reduce these errors. HHS corrective actions include providing additional guidance and oversight to states' enrollment processes for providers and beneficiaries, described below.

Corrective Actions for Administrative or Process Errors Made by State or Local Agency and Failure to Verify	
Corrective Action	**Description**
Enhanced State PERM Corrective Action Plan Process	In FY 2019, HHS worked to establish a more robust state-specific corrective action plan process that provides enhanced technical assistance and guidance to states. Beginning with the FY 2019 state-specific corrective action plans, HHS will work with its components, in conjunction with the states, to coordinate state development of corrective action plans to address each error and deficiency identified during the PERM cycle. After the corrective action plan submissions, HHS will monitor and follow up with all states on their progress in implementing effective corrective actions to address the errors and deficiencies. HHS will also use lessons learned from this process to inform areas to evaluate for future guidance and education.
Enhanced Assistance on State Medicaid Provider Enrollment	HHS provides ongoing guidance, education, and outreach to states on federal requirements to enroll Medicaid providers. In addition, HHS updated the Medicaid Provider Enrollment Compendium in July 2018 to provide additional sub-regulatory guidance to assist states in applying the regulatory requirements, and is planning further updates in FY 2020.

Corrective Actions for Administrative or Process Errors Made by State or Local Agency and Failure to Verify	
Corrective Action	**Description**
	• Technical Assistance for Provider Enrollment: In FY 2016, HHS procured a state assessment contractor to assist with ongoing state technical assistance and process improvements related to provider enrollment. In FY 2019, the state assessment contractor visited Louisiana, Maine, Minnesota, Mississippi, New York, and Oregon to assess compliance with provider enrollment requirements, conduct a gap analysis, and develop strategic blueprints to help states improve processes. HHS discontinued the contract in March 2019 and all future visits will be conducted solely by HHS. • Site Visits: HHS continued state site visits during FY 2019 to assess provider enrollment compliance and provide technical assistance. In addition to the State Assessment contractor visits, HHS internally provided assistance through visits to Illinois and Michigan in FY 2019.
Medicaid Eligibility Quality Control (MEQC) Program	Under the MEQC program, states design and conduct projects, known as pilots, to evaluate the processes that determine an individual's eligibility for Medicaid and CHIP benefits. States have great flexibility in designing pilots to focus on vulnerable or error-prone areas as identified by PERM and by the state. These MEQC pilots are conducted during the two-year intervals ("off-years") that occur between their triennial PERM review years, allowing states to implement prospective improvements in eligibility determination processes prior to their next PERM review.
Audits of State Beneficiary Eligibility Determinations	As part of the Medicaid Program Integrity strategy announced by HHS in June 2018, HHS initiated audits of beneficiary eligibility determinations in states identified as having eligibility errors in previous OIG reports. These audits have included assessments of the impact of state eligibility policies, processes, and systems. For example, HHS is reviewing if beneficiaries were found properly eligible for the correct Medicaid eligibility category. In FY 2019, HHS began eligibility reviews in New York, Kentucky, California, and Louisiana, and potential future audits will focus on states that may be at higher risk of errors, such as those that have higher eligibility improper payment rates under the PERM program.
Medicaid Integrity Institute (MII)	HHS offers training, technical assistance, and support to state Medicaid program integrity officials through the MII. The FY 2019 course schedule included a seminar in May 2019 that focused exclusively on complying with the provider enrollment requirements. The materials from previous MII provider enrollment courses remain available to states on the Regional Information Sharing System. HHS held an additional seminar in September 2019 that focused on managed care issues, including provider enrollment. HHS is finalizing the FY 2020 course schedule but may include similar courses in the future. More information is located at the Medicaid Integrity Institute.
Technical Assistance and Education on Eligibility and Enrollment	In June 2019, HHS released an information bulletin to states reiterating and clarifying existing federal requirements for eligibility and enrollment processes, including information specific to the Medicaid adult expansion group. Specifically, the bulletin provides states technical guidance on requirements related to eligibility and enrollment systems, including systems' requirements to ensure accurate eligibility determinations, distinguish newly eligible adults from non-newly eligible adults, and capacity to conduct trend analysis for eligibility-related

Corrective Actions for Administrative or Process Errors Made by State or Local Agency and Failure to Verify	
Corrective Action	**Description**
	fraud, waste and abuse. In addition, the bulletin describes state responsibilities related to eligibility policies and procedures, included eligibility verification plans, and staff training.

Root Causes: Insufficient Documentation to Determine and Administrative or Process Errors Made by Other Party

Insufficient documentation to determine errors mainly result from noncompliance with provider screening, revalidation, or NPI requirements; insufficient documentation to determine eligibility; noncompliance with eligibility redetermination requirements; insufficient or no medical documentation submitted by providers; or other missing information from the state. Administrative or process errors made by other party mainly consist of other provider errors identified through medical review. State corrective action plans include implementing new claims processing edits, converting to a more sophisticated claims processing system, implementing provider enrollment process improvements, implementing beneficiary enrollment and redetermination process improvements, and conducting provider communication and education to reduce errors related to documentation requirements. HHS corrective actions include additional guidance and technical assistance, as well as greater state oversight, described below.

Corrective Actions for Insufficient Documentation to Determine and Administrative or Process Errors Made by Other Party	
Corrective Action	**Description**
Enhanced State PERM Corrective Action Plan Process	In FY 2019, HHS worked to establish a state-specific corrective action plan process that provides enhanced technical assistance and guidance to states. Beginning with the FY 2019 state-specific corrective action plans, HHS will work with its components, in conjunction with the states, to coordinate state development of corrective action plans to address each error and deficiency identified during the PERM cycle. After the corrective action plan submissions, HHS will monitor and follow up with all states on their progress in implementing effective corrective actions to address the errors and deficiencies. HHS will also use lessons learned from this process to inform areas to evaluate for future guidance and education.
Education	In FY 2019, HHS provided training opportunities to state Medicaid agencies at the MII to address common errors, best practices, and challenges to implementing corrective actions. In addition, historically HHS published a variety of educational toolkits, which include presentations, fact sheets, and booklets made specifically for providers or beneficiaries. These educational resources help educate providers, beneficiaries, and other stakeholders in promoting best practices and raising awareness of Medicaid fraud, waste, and abuse. Lastly, a state technical assistance work group also helps educate states on working with providers to understand the causes of documentation errors and provide recommendations for methods to reduce errors.
State Medicaid Provider Screening and Enrollment Data and Tools	HHS shares Medicare data to assist states with meeting Medicaid screening and enrollment requirements. Specifically, HHS shares the Medicare provider enrollment record via the PECOS administrative interface and via data extracts from the PECOS system and OIG exclusion data. Since May 2016, HHS offered a data compare service that allows a state to rely on Medicare's screening in lieu of conducting a state screening, particularly during revalidation. This allows states to remove dual-enrolled providers from the revalidation workload. Using the data

Corrective Actions for Insufficient Documentation to Determine and Administrative or Process Errors Made by Other Party	
Corrective Action	**Description**
	compare service, a state provides a Medicaid provider enrollment data extract to HHS, and then HHS returns information indicating which of these providers have undergone a Medicare screening on which the state can rely (thus reducing the state's work load). The following states and territories participated in the data compare service in FY 2019: Hawaii, Maine, New Hampshire, New York, Puerto Rico, and Vermont. HHS is working to expand the data compare service to additional states. In addition to the data compare service, HHS will pilot a process to screen Medicaid-only providers on behalf of states. HHS recruited two states, Iowa and Missouri, to participate in this pilot in FY 2019. In FY 2020, HHS will screen these two states' Medicaid-only providers and produce a report of the providers found with licensure issues, criminal activity, and Do Not Pay activity. HHS will evaluate the results and impact of the pilot and assess the value of expanding the service to more states in the future.
Enhanced Technical Assistance and Site Visits Relating to Medicaid Provider Screening and Enrollment	HHS provides ongoing guidance, education, and outreach to states on federal requirements for Medicaid enrollment and screening. In addition, HHS updated the Medicaid Provider Enrollment Compendium in July 2018 to provide additional sub-regulatory guidance to assist states in applying the regulatory requirements, and is planning further updates in FY 2020. • Technical Assistance for Provider Screening and Enrollment: In FY 2016, HHS procured a state assessment contractor to assist with ongoing state technical assistance and process improvements related to provider screening and enrollment. In FY 2019, the state assessment contractor visited Louisiana, Maine, Minnesota, Mississippi, New York, and Oregon to assess compliance with provider screening and enrollment requirements, conduct a gap analysis, and develop strategic blueprints to help states improve processes. HHS discontinued the contract in March 2019 and all future visits will be conducted solely by HHS. • Site Visits: HHS continued state site visits during FY 2019 to assess provider screening and enrollment compliance, provide technical assistance, and offer states the opportunity to leverage Medicare screening and enrollment activities. In addition to the State Assessment contractor visits, HHS internally provided screening and enrollment assistance through visits to Illinois and Michigan in FY 2019.
Death Master File (DMF)	To help alleviate state concerns with the cost of completing the SSA DMF check as part of provider screening, HHS worked with the SSA to provide the DMF to states. In May 2017, HHS made DMF data available to pilot states via the same file server where states currently also access PECOS provider file extracts, Medicare revocations, Medicaid terminations, and OIG exclusions. HHS expanded access to DMF data to additional states via the Data Exchange which is a system for sharing data among HHS and the separate Medicaid programs of every state. As of March 2019, all 50 states, the District of Columbia, and Puerto Rico have access to DMF data through the Data Exchange.
MEQC Program	Under the MEQC program, states design and conduct projects, known as pilots, to evaluate the processes that determine an individual's eligibility for Medicaid and CHIP benefits. States have great flexibility in designing pilots to focus on vulnerable or error-prone areas as identified by PERM and by the state. These MEQC pilots are conducted during the two-year intervals ("off-years") that occur between their triennial PERM review years, allowing states to

Corrective Actions for Insufficient Documentation to Determine and Administrative or Process Errors Made by Other Party	
Corrective Action	**Description**
	implement prospective improvements in eligibility determination processes prior to their next PERM review.
Conduct Audits of State Beneficiary Eligibility Determinations	As part of the Medicaid Program Integrity strategy announced by HHS in June 2018, HHS initiated audits of beneficiary eligibility determinations in states identified as having eligibility errors in previous OIG reports. These audits included assessments of the impact of state eligibility policies, processes, and systems. For example, HHS is reviewing if beneficiaries were found properly eligible for the correct Medicaid eligibility category. In FY 2019, HHS began eligibility reviews in New York, Kentucky, California, and Louisiana, and potential future audits will be focused on states that may be at higher risk of errors, such as those that have higher eligibility improper payment rates under the PERM program.
MII	HHS offers training, technical assistance, and support to state Medicaid program integrity officials through the MII. The FY 2019 course schedule included a seminar in May 2019 that focused exclusively on complying with the provider screening and enrollment requirements. The materials from previous MII provider enrollment courses remain available to states on the Regional Information Sharing System. An additional seminar was held in September 2019 that focused on managed care issues, including provider enrollment. HHS is finalizing the FY 2020 course schedule but may include similar courses in the future. More information is located at the Medicaid Integrity Institute.
Technical Assistance and Education on Eligibility and Enrollment	In June 2019, HHS released an information bulletin to states reiterating and clarifying existing federal requirements for eligibility and enrollment processes, including information specific to the Medicaid adult expansion group. Specifically, the bulletin provides states technical guidance on requirements related to eligibility and enrollment systems, including systems' requirements to ensure accurate eligibility determinations, distinguish newly eligible adults from non-newly eligible adults, and capacity to conduct trend analysis for eligibility-related fraud, waste and abuse. In addition, the bulletin describes state responsibilities related to eligibility policies and procedures, included eligibility verification plans, and staff training.

Medicaid Information Systems and Other Infrastructure

Because Medicaid payments occur at the state level, information systems and other infrastructure need to be implemented at the state level to reduce Medicaid improper payments. HHS encouraged and supported state efforts to modernize and improve state Medicaid Enterprise Systems, which will produce greater efficiencies in areas reflected in the PERM measurement and strengthen program integrity. Lastly, the state systems workgroup (composed of HHS and state staff representatives) meets regularly to identify and discuss system vulnerabilities and the impact on the measurement of improper payments.

HHS developed a comprehensive plan to modernize the federal Medicaid and CHIP data systems. The plan's primary goal is to leverage technologies to create an authoritative and comprehensive Medicaid and CHIP data structure so that HHS can provide more effective oversight of its programs. The plan will also reduce state burden and provide more robust data for the PERM program.

HHS also developed the Transformed Medicaid Statistical Information System (T-MSIS) to facilitate state submission of timely claims data to HHS, expand the MSIS dataset, and allow HHS to review the completeness and quality of state MSIS submissions in real-time. Through the use of T-MSIS, HHS will acquire higher quality data and reduce data requests to the states. As of August 30, 2019, 50 states, the District of Columbia, Puerto Rico, and the US Virgin Islands are submitting T-MSIS data. More information on states' overall data submission progress can be found at T-MSIS. HHS closely monitors monthly T-MSIS data submissions, with a focus on assessing and improving the quality of the data. HHS is also preparing analytics files, tools, and reports aimed at enabling use of the data by various stakeholders. As such, on August 10, 2018, HHS released a State Health Official (SHO) letter 18-008 prioritizing T-MSIS data quality with state leadership. Then, on March 18, 2019, HHS released an Information Bulletin (CIB) providing more specific direction to states on improving their T-MSIS data, followed by individual notices to each State Medicaid Director describing the state's compliance with the CIB requirements. HHS expects states to continue to improve the quality of their T-MSIS data and to ensure changes to state systems or operations will not degrade T-MSIS data submission quality, completeness, and/or timeliness.

Medicaid Statutory or Regulatory Barriers that Could Limit Corrective Actions

HHS is working to address statutory and regulatory barriers that could potentially limit corrective actions. As identified in the Spring 2019 Unified Agenda of Regulatory and Deregulatory Actions, HHS plans to issue new regulations to address barriers that limit corrective actions related to beneficiary eligibility. Regulations will clarify the Medicaid eligibility determination process, including income verification and redetermination processes, and address limitations on HHS's ability to recoup eligibility-related improper payments. In addition, the FY 2020 President's Budget included legislative proposals that would provide HHS with greater flexibility to prevent future improper payments. Specifically, the Budget proposed to modify Section 1903(u) of the *Social Security Act* (42 U.S.C. 1396a) to give HHS broader flexibility in developing actions to address errors associated with ineligible beneficiaries, and sought statutory authority for HHS to conduct centralized screening of Medicaid and CHIP providers.

11.5 CHIP

CHIP Statistical Sampling Process

Through the PERM program, HHS estimates CHIP improper payments on an annual basis, utilizing federal contractors to measure three components: FFS, managed care, and eligibility.

CHIP utilizes the same state sampling process as Medicaid through the PERM program. HHS determined that the same states selected for Medicaid review each year can also measure CHIP, with a high probability that the CHIP improper payment rate estimates will meet the IPIA, as amended, required confidence and precision levels. For information on how HHS grouped states into three cycles for CHIP, refer to page 183 of HHS's FY 2012 AFR.

FFS and Managed Care Components

FFS includes the traditional method of paying for medical services under which a state pays providers for each service rendered to individual beneficiaries, while managed care is a delivery system in which a state makes a monthly payment to a managed care organization, which is responsible for managing beneficiary care. Quarterly, states submit adjudicated claims data, and HHS randomly selects a sample of FFS claims and managed care payments. Each FFS claim selected undergoes a medical and data processing review, while managed care payments are subjected to only a data processing review. Based on each state's expenditures and historical FFS and managed care improper payment data, the FFS sample size was between 172 and 974 claims per state, the managed care sample size was between 22 and 270 payments per state, the eligibility FFS sample size was between 76 and 324 per state, and the eligibility managed care sample size was between 43 and 317 per state. When a state's FFS or managed care

component for a state accounted for less than two percent of the state's total CHIP expenditures, HHS combined the state's FFS and managed care claims into one component for sampling and measurement purposes.

Eligibility Component

Through the eligibility component, a federal contractor assesses states' application of federal rules and the state's documented policies and procedures related to beneficiary eligibility. Examples of noncompliance with eligibility requirements include a state: enrolling a beneficiary when he or she is ineligible for Medicaid or CHIP; determining a beneficiary to be eligible for the incorrect eligibility category, resulting in an ineligible service being provided; not conducting a timely beneficiary redetermination; or not performing or completing a required element of the eligibility determination process, such as income verification. As described in the PERM final rule (82 Federal Register 31158, July 5, 2017), HHS resumed the eligibility component measurement for the first cycle of 17 states and reported an updated national eligibility improper payment estimate for FY 2019. Between FY 2015 and FY 2018, HHS did not conduct the eligibility measurement component of PERM; refer to pages 211-214 of HHS's 2018 AFR for more information. Please note that the national eligibility improper payment rate still includes a proxy estimate for the remaining 34 states that have not yet been measured since the reintegration of the PERM eligibility component.

Calculations and Findings

The national CHIP improper payment estimate combines each state's FFS, managed care, and eligibility improper payment estimate. In addition, HHS combines individual state component improper payment estimates to calculate the national component improper payment estimates. National component improper payment rates and the CHIP improper payment rate are weighted by state size, such that a state with a $1 billion program is appropriately weighted more in the national rate than a state with a $200 million program. A correction factor in the methodology ensures that CHIP eligibility improper payments are not "double counted."

The national CHIP gross improper payment estimate for FY 2019 is 15.83 percent or $2.74 billion.

The FY 2019 national CHIP improper payment rate for each component is:

- *CHIP FFS:* 13.25 percent
- *CHIP managed care:* 1.25 percent
- *CHIP eligibility*: 11.78 percent

Supplemental information related to the FY 2019 CHIP improper payment results will be published on HHS's website – www.cms.gov/PERM – in early FY 2020.

One area driving the FY 2019 CHIP improper payment estimate is the FY 2019 reintegration of the PERM eligibility component, mentioned above. This is the first time in the history of the program that the eligibility component measurement has been conducted by a federal contractor; previously states conducted the measurement and self-reported results to HHS for reporting the national rate. This allows for consistent insight into the accuracy of CHIP eligibility determinations and increases the oversight of identified vulnerabilities. Based on the measurement of the first cycle of states, eligibility errors are mostly due to insufficient documentation to verify eligibility or noncompliance with eligibility redetermination requirements. The majority of the insufficient documentation errors represent both situations where the required verification was not done at all and where there is indication that the verification was initiated but there was no documentation to validate the verification process was completed. These insufficient documentation situations are related primarily to income verification. The CHIP improper payment rate was also driven by claims where the beneficiary was ineligible for CHIP, but was eligible for Medicaid, again, mostly related to beneficiary income. HHS will complete the measurement of all states under the new eligibility component and establish a baseline in FY 2021.

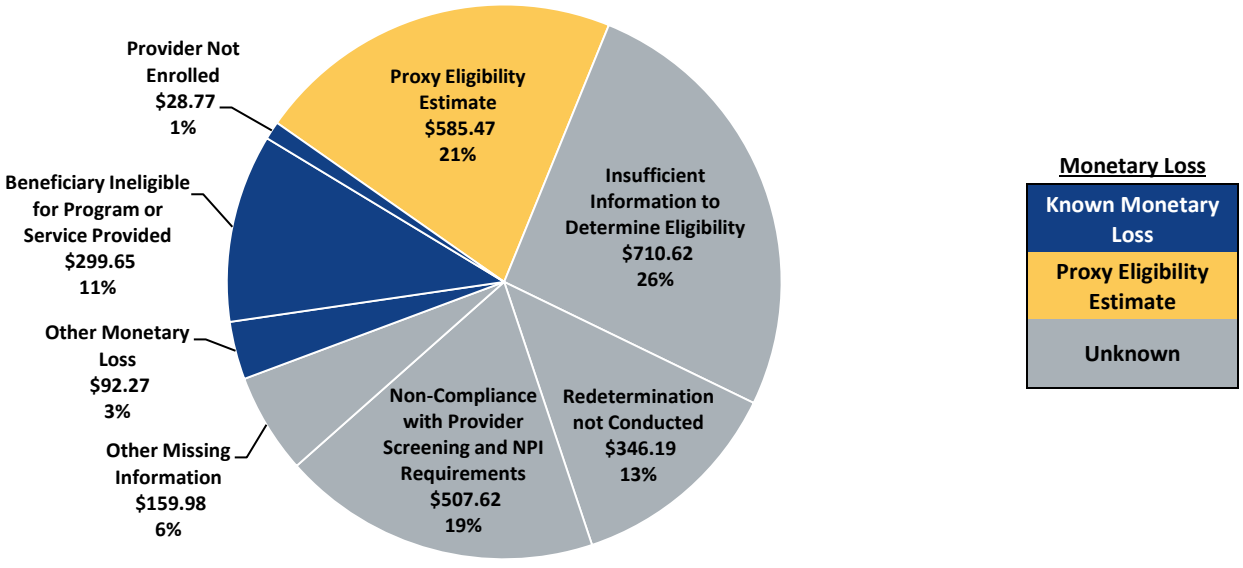
Additionally, since FY 2014, improper payments cited on claims where a newly enrolled provider or a provider due for revalidation had not been appropriately enrolled and screened by the state or a provider did not have the required NPI on the claim have also driven the CHIP rate (see Section 11.4 for further description of HHS's review of these errors). Although these errors remain a driver of the CHIP rate, state compliance with the newly enrolled provider requirements has improved as the CHIP FFS improper payment rate for these errors decreased from 7.73 percent in FY 2018 to 6.02 percent in FY 2019.

Unknown versus Monetary Loss Findings

Improper payments do not necessarily represent expenses that should not have occurred. Instances where there is insufficient or no documentation to support the payment as proper are cited as improper payments. A majority of CHIP improper payments were due to instances where information required for payment or eligibility determination was missing from the claim or state systems and/or states did not follow the appropriate process for enrolling providers and/or determining beneficiary eligibility. However, these improper payments do not necessarily represent payments to illegitimate providers or ineligible beneficiaries. If the missing information had been on the claim and/or had the state complied with the enrollment or redetermination requirements, then the claims may have been payable in whole or in part. A smaller proportion of improper payments are claims where HHS determines that the CHIP payment should not have happened or should have been made in a different amount and are considered a known monetary loss to the program.

Figure 12 provides information on CHIP improper payments that are a known monetary loss to the program (i.e., provider not enrolled, beneficiary ineligible for program or service, incorrect coding, and other errors like claims processing errors, duplicate claims, or pricing mistakes). In the figure, "Unknown" represents payments where there was insufficient or no documentation to support the payment as a proper payment or a known monetary loss (e.g., claims where information was missing or states did not follow appropriate processes).

Figure 12: FY 2019 CHIP Estimated Improper Payments, by Monetary Loss versus Unknown Categories and Type of PERM Error[1] (Dollar Amounts in Millions)



[1] The Proxy Eligibility Estimate is used to represent the eligibility component for the 34 states not yet measured since the reintegration of the PERM eligibility component. All eligibility improper payments from the FY 2019 measurement are included in the appropriate category (Known Monetary Loss or Unknown). The Proxy Eligibility Estimate includes both overpayments and underpayments, whereas Known Monetary Loss and Unknown only include overpayments. The value of underpayments outside the Proxy Eligibility Estimate ($5.21 million) was too small to report in Figure 12. In addition, due to rounding, amounts in this chart may not add up precisely to other tables in this document.

CHIP Corrective Action Plan

HHS works closely with all states through enhanced technical assistance (including state-specific liaisons that will be assigned to each state and assist states with identifying and overcoming barriers to corrective action implementation) and guidance to develop state-specific corrective action plans to reduce improper payments. All states are responsible for implementing, monitoring, and evaluating corrective action plan effectiveness, with assistance and oversight from HHS. When developing corrective action plans, states focus efforts on the major causes of improper payments.

HHS also establishes corrective actions to help reduce improper payments. For example, HHS is actively engaged in:

- Conducting outreach during off-cycle PERM years to address issues identified in corrective action plans;
- Facilitating national best practice calls to share ideas across states;
- Offering ongoing technical assistance;
- Developing a notice of proposed rulemaking to strengthen the integrity of the eligibility determination process and avoid improper payments that will address several of the drivers of eligibility errors such as insufficient recordkeeping, verification of eligibility, redeterminations, and compliance with eligibility requirements when individuals experience a change in circumstances that may impact eligibility; and
- Providing additional guidance as needed.

Additional information on states' and HHS's corrective actions is provided in the following sections.

Corrective Actions to Address Root Causes:

Root Causes: Administrative or Process Errors Made by State or Local Agency

Administrative or process errors made by states or local agencies mainly consist of errors resulting from noncompliance with the requirement to enroll providers and from cases where the beneficiary was ineligible for the program or service.

State corrective action plans focus on system or process changes to reduce these errors. HHS corrective actions include providing additional guidance and oversight of states' enrollment processes for providers and beneficiaries. Section 11.4 provides more detailed information on these activities.

Root Causes: Insufficient Documentation to Determine and Administrative or Process Errors Made by Other Party

Insufficient documentation to determine errors mainly result from noncompliance with provider screening, revalidation, or NPI requirements; insufficient documentation to determine eligibility; noncompliance with eligibility redetermination requirements; insufficient or no medical documentation submitted by providers; or other missing information from the state. Administrative or process errors made by other parties mainly consist of other provider errors identified through medical review. State corrective action plans include implementing new claims processing edits, converting to a more sophisticated claims processing system, implementing provider enrollment process improvements, implementing beneficiary enrollment and redetermination process improvements, and conducting provider communication and education to reduce errors related to documentation requirements. Section 11.4 provides more detailed information on these activities.

Root Cause: Medical Necessity

Although medical necessity has been identified as a minor issue in a few states, HHS works closely with those states to develop state-specific corrective actions to address such errors when they arise. In addition to state-specific corrective action plans, many HHS corrective actions listed in Section 11.4 also address medical necessity errors.

CHIP Information Systems and Other Infrastructure

Since CHIP payments occur at the state level, information systems and other infrastructure need to be implemented at the state level to reduce CHIP improper payments. Refer to Section 11.4 for information on HHS and state-led efforts to modernize information and data systems at the national and state levels.

CHIP Statutory or Regulatory Barriers that Could Limit Corrective Actions

Refer to Section 11.4 for information on statutory or regulatory barriers that could potentially limit corrective actions.

11.6 TANF

TANF Statistical Sampling Process

Statutory limitations preclude HHS from requiring states to participate in a TANF improper payment measurement. As a result, the TANF program is not reporting an improper payment estimate for FY 2019.

TANF Corrective Action Plan

Since TANF is a state-administered program, corrective actions would be implemented at the state level to reduce improper payments. Since HHS cannot require states to participate in a TANF improper payment measurement, the Department is also unable to compel states to collect the required information to implement and report on corrective actions. Despite these limitations, HHS uses a multi-faceted approach to support states in improving TANF program integrity and preventing improper payments:

Corrective Actions for TANF Program Integrity	
Corrective Action	**Description**
Risk Assessment	In FY 2019, HHS performed a detailed risk assessment of the TANF program to determine susceptibility to significant improper payments. HHS identified potential payment risks at the federal level and will continue to work to mitigate these risks.
Promoting and Supporting Innovation in TANF Data	In FY 2017, HHS awarded a 5-year contract for Promoting and Supporting Innovation in TANF Data. A component of the contract includes engaging TANF stakeholders to better understand how states assess improper payments and ensure program integrity in TANF. Through this contract, in FY 2019, HHS conducted a comprehensive needs assessment of all TANF states, territories, and the District of Columbia, including information about payment integrity efforts. This assessment is helping HHS understand existing state approaches and alternative methods for measuring TANF improper payments, including the feasibility and cost-benefit analysis of different approaches.
Final Regulation on Reporting of Electronic Benefit Transfer Policies and Practices	In FY 2016, HHS issued final regulations regarding "State Reporting on Policies and Practices to Prevent the Use of TANF Funds in Electronic Benefit Transfer Transactions in Specified Locations" (81 Federal Register 2092, January 15, 2016). Thus far, HHS has not assessed any penalties for noncompliance with this regulation, and the Department continues to monitor compliance.

TANF Information Systems and Other Infrastructure

Information systems and other infrastructure at the state level are needed to reduce TANF improper payments. States utilize PARIS, the National Directory of New Hires, and the Income and Eligibility Verification System to minimize improper payments.

TANF Statutory or Regulatory Barriers that Could Limit Corrective Actions

Statutory limitations preclude HHS from requiring states to participate in a TANF improper payment measurement. The FY 2020 President's Budget included a proposal that, if enacted, would help address the challenge HHS faces in reporting an improper payment estimate for TANF. The Budget proposes giving HHS authority to collect quantitative and qualitative program integrity information from TANF programs, which will lay the ground work for the data collection efforts needed to provide information on states' improper payments.

11.7 FOSTER CARE

Foster Care Statistical Sampling Process

There were no changes to the statistical sampling process for Title IV-E Foster Care in FY 2019. However, in FY 2018, the program modified the formula used to calculate the state-level standard error as recommended by the OIG. This program uses the review cycle already in place (in compliance with 45 CFR §1356.71, *Foster Care Eligibility Reviews*) and, with OMB approval, leverages the existing review cycle to provide a rolling, 3-year weighted average improper payment estimate. Since each state is reviewed every 3 years, each year's improper payments estimate incorporates new review data for approximately one-third of the states. Each state's triennial review covers a recent 6-month period. For a more detailed description of the Foster Care improper payment methodology, refer to pages 189–190 of HHS's FY 2012 AFR.

As stated in the FY 2015 AFR, an increasing number of time-limited child welfare waiver demonstration projects (which all terminated as of September 30, 2019) have temporarily reduced the number of jurisdictions subject to review and inclusion in the program improper payment estimate during the demonstration projects. More information on these demonstration projects and the impact on the Foster Care improper payment rate calculation can be found on pages 202-203 of HHS's FY 2015 AFR.

The program's improper payment estimate includes data from the most recent review for states with non-statewide waivers, including reviews conducted on the non-waiver populations in those states following waiver implementation. This approach (approved by OMB) maintains continuity while also permitting consistent treatment of states with state-wide and non-state-wide waivers. Following this approach, the FY 2019 estimate is based on review data for 34 states or territories operating traditional Title IV-E programs. The FY 2019 estimate excludes data for 18 states operating statewide waiver demonstrations: 3 states that were due for a review this year (Illinois, Maine, and Tennessee) and 15 states that were due for a review in prior years (Arkansas, Colorado, the District of Columbia, Florida, Hawaii, Indiana, Kentucky, Maryland, Nebraska, Oklahoma Oregon, Utah, Washington, West Virginia, and Wisconsin).

The Foster Care gross improper payment estimate for FY 2019 is 4.85 percent or $7.13 million. The error rate decreased from 7.56 percent in FY 2018 to 4.85 percent in FY 2019 in part because one state with a large program and a high error rate was removed from the national error rate calculations in FY 2019 due to the state's operation of a statewide child welfare waiver demonstration project. During the FY 2019 error rate reporting cycle, one small state had a significant increase in its state-level error rate, 7 of the 12 states reviewed either decreased their error rates or remained about the same, and 4 states had small increases. Overall, 11 of the 12 states had low error rates of less than 3 percent.

Foster Care Corrective Action Plan

All payment errors (100 percent) in the Title IV-E Foster Care program are administrative or process errors due to incorrect case classification and payment processing by state agencies. The Foster Care program designs corrective action plans to help states address the payment errors that contribute most to Title IV-E improper payments.

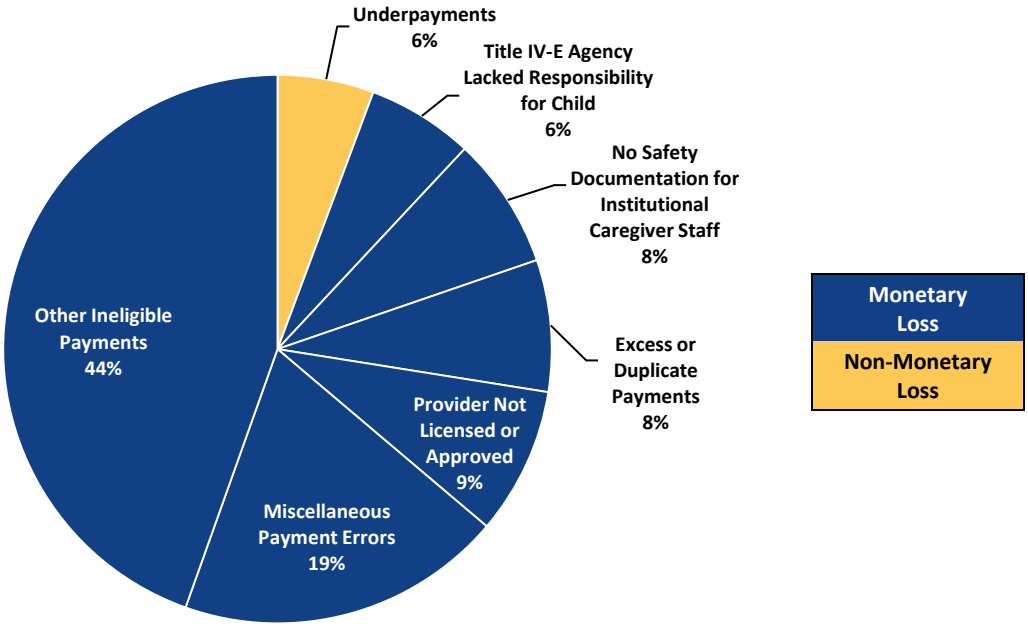
Corrective Actions to Address Root Cause:

Root Cause: Administrative or Process Error Made by State or Local Agency

Foster Care improper payments are caused by administrative or process errors made by state or local agencies. Corrective actions over the years helped reduce the frequency of some error types. For example, following years of work with State Court Improvement Programs and outreach to raise awareness, errors related to judicial determinations (once the most prevalent error type) are now among the least common error types.

Monitoring and Analysis: HHS continues to monitor, review results, and analyze the types of payment errors in the Foster Care program to target corrective action planning. Figure 13 presents the most common administrative or process payment errors in FY 2019.

Figure 13: Root Causes for FY 2019 Title IV-E Foster Care Improper Payments across All States



[1] Values in this figure may not add up precisely to other tables in this document due to rounding.

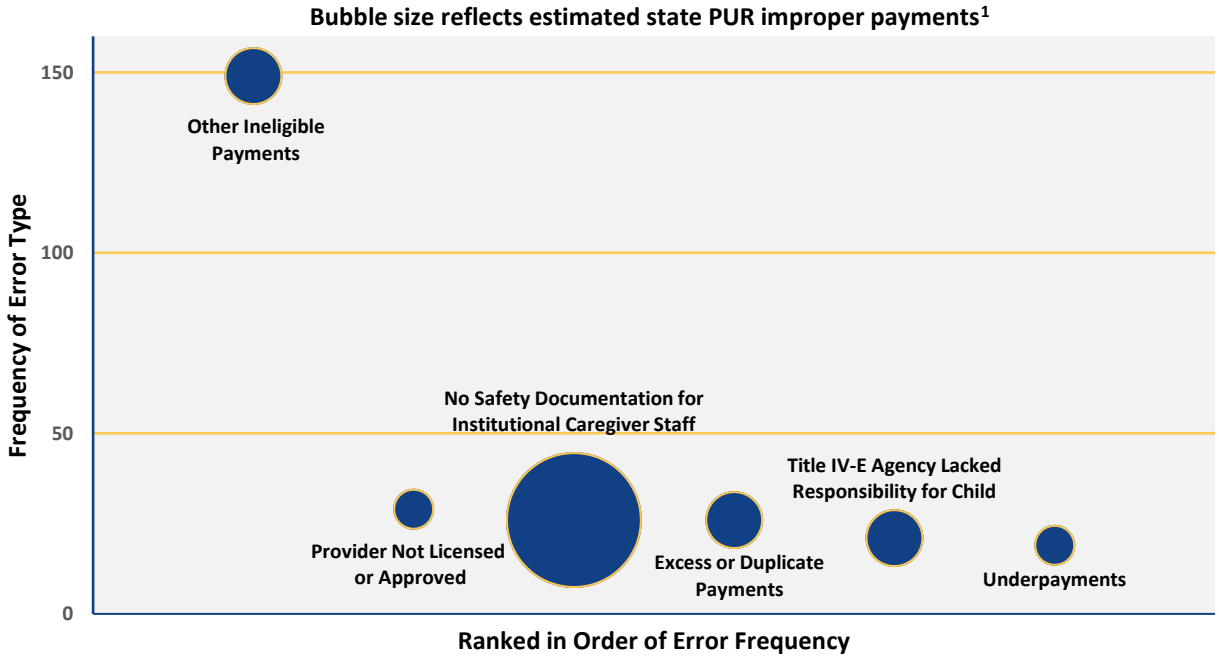
As shown in Figure 13, the six most frequent error types (except for miscellaneous payment errors) account for 80 percent of Foster Care's payment errors.[29] The general pattern of frequency and cost of errors continues from FY 2018 reporting. Of the six most frequent error types, "Other ineligible payments" continues to constitute the largest number of errors, accounting for 44 percent of errors. Two states reviewed in earlier years account for about 80 percent of "Other ineligible payments," which are payments for services such as child health support that are not eligible for Title IV-E funding. Because these states have taken corrective action to address the accounting issues

[29] Because cases may have more than one type of overpayment error, the rate for any specific type of overpayment may involve some duplication and therefore slight overestimation.

that resulted in systemic incorrect claiming of certain costs not allowable as Title IV-E foster care maintenance payments, HHS expects this number of this type of error to decline when the states are next reviewed.

Although cases with "No safety documentation for institutional caregiver staff" were only 8 percent of improper payment errors, they accounted for over half of all improperly paid dollars due to the high cost of institutional care relative to foster care placements. None of the states reviewed in FY 2019 had these types of errors; the majority occurred in two states that were last reviewed in earlier years and are being reviewed again as part of the FY 2020 error rate reporting cycle at which time it is expected they will have completed corrective action and demonstrate improved performance. Figure 14 provides more information on the relative contribution of these top six payment error types.

Figure 14: Reasons for Title IV-E Foster Care Program Improper Payments across All States – FY 2019 Frequency and Dollar Amount across Error Types



[1] Improper payments for cases with more than one error type (N=34) are counted under all applicable error types during the period under review (PUR).

In FY 2019, HHS undertook the following key actions to reduce Foster Care improper payments in the future:

Corrective Actions to Address Administrative or Process Errors Made by State or Local Agency	
Corrective Action	**Description**
Emphasizing Quality Improvement	HHS engaged with Title IV-E Foster Care agencies to enhance the understanding of program compliance requirements and to share successful strategies among states. Based on discussions with individual states on review preparation and compliance results, HHS worked with states to emphasize and develop strategies for continuous program improvement. HHS emphasized viewing the quality assurance process as ongoing and developing sound program improvements that support systemic change and sustain improvement efforts.

Corrective Actions to Address Administrative or Process Errors Made by State or Local Agency	
Corrective Action	**Description**
Enhancing Targeted Outreach Strategies	Pre-Review Engagement of States: Since certain types of improper payments (such as those pertaining to Foster Care provider requirements) occur in a small number of states, HHS implemented pre-review outreach strategies (e.g., calls and site visits) tailored to each state child welfare agency to provide feedback about specific program performance areas needing improvement and to facilitate correction efforts. HHS also reviewed safety documentation of background checks for staff of child care institutions prior to the onsite Title IV-E review to assess and provide feedback on the adequacy of the documentation, given the comparatively high-dollar impact of errors pertaining to institutional care. The pre-review of state documentation focused on the federal requirements to increase state agency staff and Foster Care providers' knowledge of the requirements, help the state identify missing or insufficient documentation, and help the state eliminate payment errors involving inadequate or missing documentation of safety checks.
	Outreach Regarding Changes in Federal Requirements: The *Family First Prevention Services Act*, enacted as Title VII of the *Bipartisan Budget Act of 2018*, changed the federal statutory requirements for staff safety checks at child care institutions. The new requirements became effective October 1, 2018, although some states needing to enact new state legislation are allowed additional time to implement the provisions. In response to this legislation, HHS issued written guidance to federal and state staff and conducted a series of webinars in FY 2018 to instruct all staff on the new federal safety check requirements and other provisions of the new federal law. Additional guidance and instructional tools are planned for early FY 2020 to further federal and state staff knowledge on the federal requirements for state implementation and maintenance of required policies and practices.
	Communications and Monitoring: HHS also worked with states to encourage effective communication between state child welfare agencies and licensing agencies to further promote adequate documentation of safety check compliance. Assisting states with developing and applying techniques to effectively engage Foster Care providers in a partnership to reduce or eliminate improper payments is integral to success. HHS also will encourage states to regularly and systematically monitor Foster Care providers to document and promote compliance with the safety requirements and require non-compliant providers to undergo corrective action.

In addition, HHS continued the following ongoing corrective actions:

Corrective Actions to Address Administrative or Process Errors Made by State or Local Agency	
Corrective Action	**Description**
Conducting Eligibility Reviews and Providing Feedback to State Agencies	HHS conducts onsite and post-site review activities to validate the accuracy of state claims for reimbursement of payments made on behalf of children and their Foster Care providers. Specific feedback is provided onsite to the state agency to bring about proper and efficient program administration and implementation. Furthermore, HHS issues a comprehensive final report that presents review findings to the state agency including if state exceeded the error threshold in a review and must develop a performance improvement plan (PIP).

Corrective Actions to Address Administrative or Process Errors Made by State or Local Agency	
Corrective Action	**Description**
Developing PIPs	HHS requires states that exceed the error threshold in a primary review to develop and execute state-specific PIPs that identify specific action steps to correct error root causes. A PIP is an effective tool with a successful track record at HHS with improper payments reporting; since FY 2004, only one state has not been found in compliance of an eligibility review conducted following PIP completion. States must complete each action strategy within 1 year from the date HHS approved the plan. In FY 2019, one of the 12 states reviewed must complete a PIP.
Providing Training and Technical Assistance	HHS trains and assists states in developing and implementing program improvements, even when states are not required to develop a PIP. This assistance helps states expand organizational capacity and promote more effective program operations. In FY 2019, HHS trained all 12 states reviewed on the federal eligibility and payment requirements and provided technical assistance prior to, during, and after the Foster Care Eligibility Reviews. Furthermore, because they are operating under a capped allocation, states and jurisdictions that are excluded from regulatory Title IV-E reviews while their child welfare waiver demonstration is operational may participate in a Title IV-E Technical Assistance Review. The Technical Assistance Review ensures that as waiver demonstration projects end for all states on September 30, 2019, states are prepared to submit accurate claims and perform successfully on future Title IV-E reviews. At the conclusion of the Technical Assistance Review, HHS reports cases that did not meet Title IV-E eligibility requirements and any other improper payments, discounting the waivers provided in the agency's demonstration terms and conditions. HHS has conducted 17 Technical Assistance Reviews since FY 2017.
Conducting Secondary Reviews and Disallowances	HHS conducts secondary reviews for non-compliant states and establishes appropriate disallowances (e.g., to recover improper payments) consistent with the review findings (HHS establishes disallowances for error findings in both primary and secondary reviews). One state reviewed in the FY 2019 cycle will undergo a secondary review. On a secondary review, if a state is not in substantial compliance, HHS establishes an extrapolated disallowance. Additional disallowances, in conjunction with PIP development and implementation, incentivize states to improve compliance.

Foster Care Information Systems and Other Infrastructure

HHS uses the Adoption and Foster Care Analysis and Reporting System (AFCARS) to draw samples for the regulatory reviews. This reduces the burden on states to draw their own samples, promotes uniformity in sample selection, and employs AFCARS in a practical and beneficial manner. Since Foster Care payments occur at the state level, the state must implement the information systems and other infrastructure needed to reduce Foster Care improper payments. States have the option to receive federal financial participation to develop and implement a Comprehensive Child Welfare Information System in accordance with federal regulations at 45 CFR §1355.50 through §1355.59. Comprehensive Child Welfare Information System project requirements include the performance of automated program eligibility determinations and bi-directional data exchanges with systems generating the financial payments and claims to ensure the availability of needed supporting documentation.

Foster Care Statutory or Regulatory Barriers that Could Limit Corrective Actions

While HHS and states have implemented many corrective actions, the Department recognizes that several factors may contribute to increased improper payments over the next several years. It is likely that changes in Title IV-E

Foster Care eligibility requirements made by the *Family First Prevention Services Act* may contribute to increased improper payments as states adjust to changes in law affecting eligibility, particularly for children placed in child care institutions. Among the changes made in the law are revised safety check requirements applicable to all adults working in child care institutions, which became effective on October 1, 2018. The FY 2020 estimate of improper payments for the Foster Care program will be the first to include review data from states be subject to the new child care institution safety check requirements. Given the historically high level of improper payments under prior safety check eligibility requirements, it is likely that the change in federal requirements may again drive higher error rates in some states. In light of this concern, HHS has set an improper payment target of 6 percent for FY 2020.

New limitations in the availability of Title IV-E Foster Care maintenance payments for children placed in certain non-family based foster care settings will begin to take effect in some states beginning October 1, 2019, and will become applicable in all states by October 1, 2021. These limitations on funding availability may also contribute to increases in improper payment estimates in FY 2021 and beyond. Another factor that may increase the rate of improper payments is that all states previously operating child welfare waiver demonstrations were required to conclude these demonstrations by September 30, 2019, and will be subject to review over the next several years. As previously noted, HHS temporarily suspended conducting Title IV-E eligibility reviews in some states during the operation of their time-limited projects, since the projects allowed the states to use funds more flexibly than under the traditional program. As these states return to operating under traditional program rules, as well as adapting to recent changes in federal law, it is possible that they may experience higher state-level error rates.

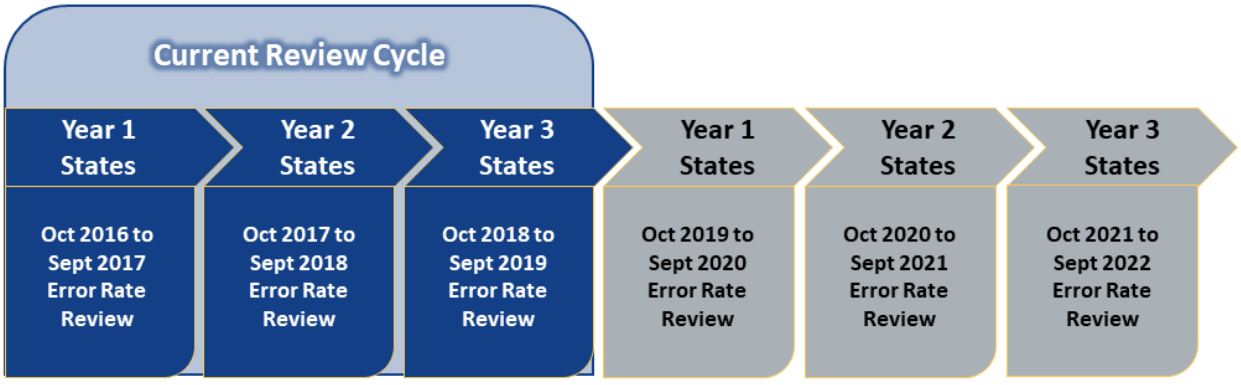
While cognizant of the challenges ahead, HHS remains committed to working with all states to ensure that they have a clear understanding of changes in federal eligibility requirements and are prepared to successfully manage Title IV-E eligibility determinations for their Foster Care programs.

11.8 CCDF

CCDF Statistical Sampling Process

The CCDF improper payments methodology uses a case-record review process to determine if child care subsidies were paid properly for services provided to eligible families. All states, the District of Columbia, and Puerto Rico are divided into three cohorts and conduct the error rate review once every 3 years (as shown in Figure 15).

Figure 15: CCDF Error Rate Review Cycle



In addition to federal rules, states have varying requirements for establishing and verifying eligibility. The methodology enables states to determine types of errors and their sources to reflect policies and procedures unique to each state. For CCDF's improper payments methodology, see Improper Payments Error Rate Review Process.

The current methodology incorporates the following: (1) drawing a statistical sample from a universe of paid cases; (2) measuring improper payments; and (3) requiring states with improper payment estimates exceeding 10 percent to submit a corrective action plan. The improper payment methodology and reporting requirements focus on payment and non-payment errors associated with client eligibility. Effective October 31, 2018, HHS revised the CCDF Data Collection Instructions (DCI) to states regarding implementation of the Error Rate Review. The DCI now instructs states to consider if making additional inquiries might mitigate potential improper payment errors that are due to missing or insufficient documentation. Additional DCI revisions such as clarifying language and requirements to provide more information about error causes and action steps are aimed at increasing accuracy and streamlining data collection. In FY 2019, the Year Three states implemented the revised methodology for review for the first time. Over the next 2 years, HHS will gather data from each of the other state grantee cohorts (Years One and Two) to determine the impact of the revisions.

The CCDF gross improper payment estimate for FY 2019 is 4.53 percent or $324.66 million. HHS attributes the increase in the improper payment estimate, from 4.00 percent in FY 2018 to 4.53 percent in FY 2019, to the challenges that state grantees continue to experience as part of their efforts to comply with the CCDF reauthorization and related regulations. All states had multi-faceted challenges in their attempts to meet the CCDBG and CCDF regulation requirements and many are required to submit corrective action plans for not meeting implementation deadlines. States have had to make information technology (IT) systems changes, including purchasing new IT infrastructure; passing new legislation; promulgating new regulations and policies; drafting new procedures; and adding new staff.

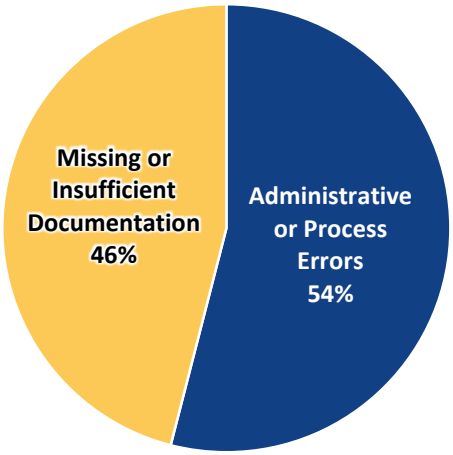
CCDF Corrective Action Plan

As reflected in Figure 16, CCDF program errors can be categorized as (1) non-payment errors and (2) payment errors. An error is any violation or misapplication of law, regulation, or policy governing the administration of CCDF grant funds, regardless of whether such a violation results in an improper payment. A payment error or improper payment is a monetary discrepancy between the subsidy amount as determined by the reviewer and the sample month payment amount, resulting from error. If an error does not result in monetary discrepancy, it is a non-payment error. A non-payment error example may include an incomplete application. The worker may have made an error by not requiring the family to fully complete the form, but if the incomplete application form did not result in a monetary discrepancy, it is considered a non-payment error. A payment error example may include a missing paystub. If non-receipt of a paystub results in a monetary discrepancy, the error is considered a payment error. These errors are further defined as (1) administrative or process errors and (2) errors caused by missing or insufficient documentation. Errors can be a misapplication of policy or procedure and can cause both a payment and a non-payment error. The HHS Payment Integrity Report data only reflects payment errors. States have flexibility in the administration of Child Care programs and state-level policies and procedures reflect this variety.

Figure 16: CCDF Program Error Categories

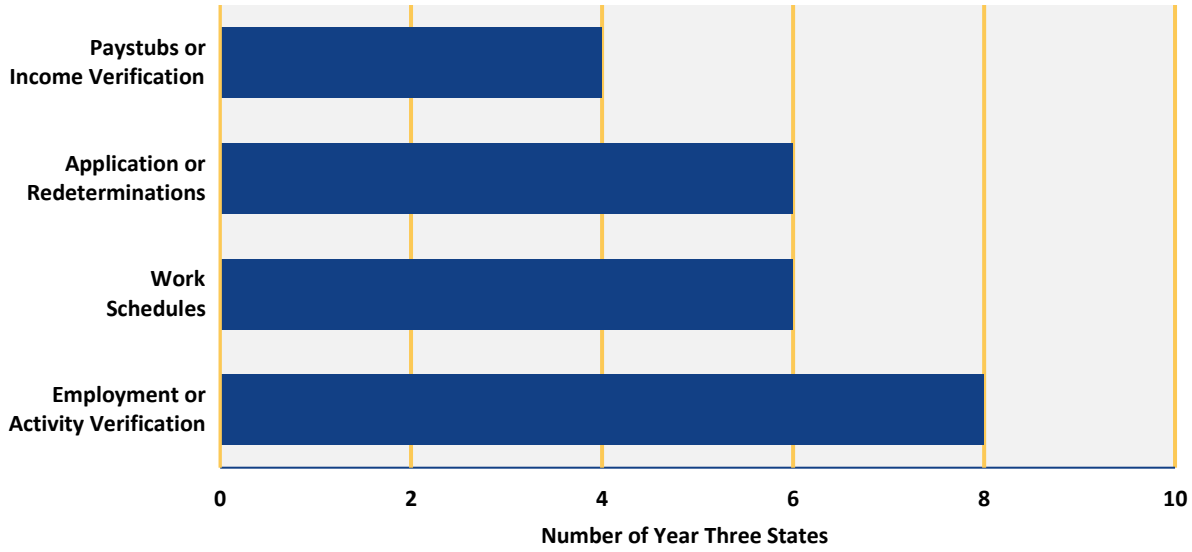
Historically, CCDF improper payments have been divided evenly between administrative or process errors and missing or insufficient documentation. Figure 17 shows there were fewer errors from missing and insufficient documentation (about 45.54 percent) than administrative or process errors (54.46 percent) for Year Three reviews.

Figure 17: Root Causes of FY 2019 CCDF Improper Payments



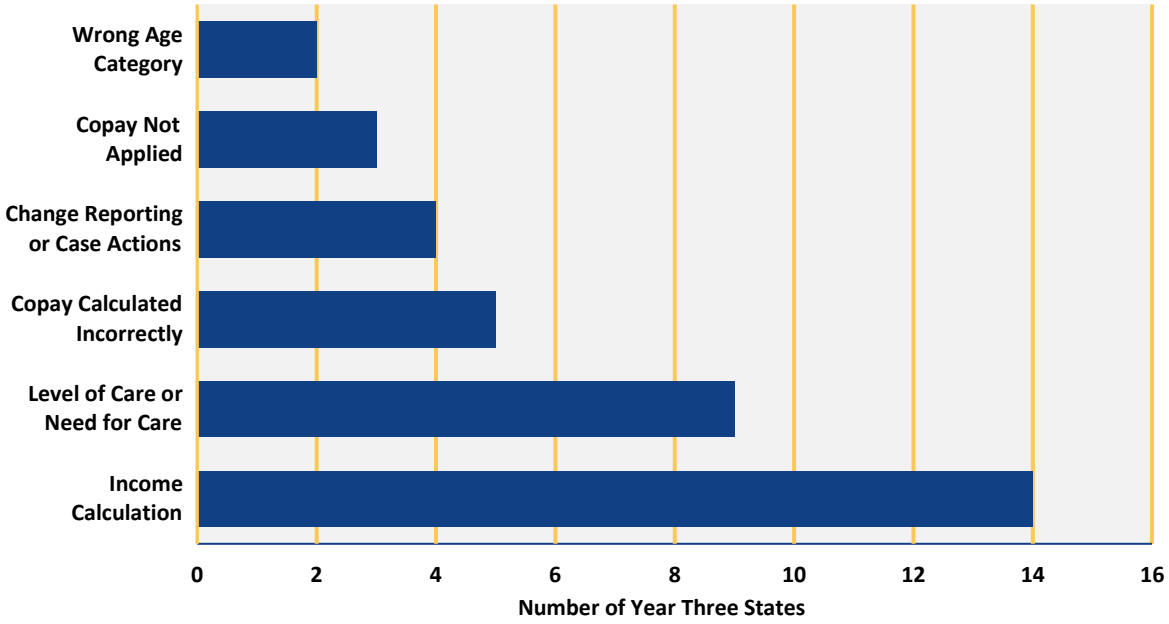
Missing or insufficient documentation errors account for an estimated 45.54 percent of errors identified in the CCDF improper payment review process. Errors were primarily due to missing or insufficient documentation in the case record. Figure 18 presents the most frequently cited errors.

Figure 18: Most Frequently Cited Errors Due to Missing or Insufficient Documentation for CCDF



Administrative or process errors represent approximately 54.46 percent of errors noted in the Year Three reviews. These errors consist of the failure to apply policy correctly, as shown in Figure 19.

Figure 19: Most Frequently Cited Errors Due to Administrative or Process Errors for CCDF



Corrective Actions to Address Root Causes:

Root Causes: Insufficient Documentation to Determine and Administrative or Process Errors Made by State or Local Agency

Insufficient documentation to determine and administrative or process errors made by a state or local agency drive CCDF improper payments. HHS and states establish corrective actions targeting both error types. States must report on the root causes of errors once every 3 years. Each report also allows states to report on actions taken on errors from the prior review. HHS offers targeted technical assistance to specifically support each state's efforts to reduce errors. States reporting in FY 2019 plan the following corrective actions:

State Corrective Actions for Missing or Insufficient Documentation and Administrative or Process Errors Made by State or Local Agency	
Corrective Action	**Description**
Training	Fifteen states plan to conduct training with eligibility staff on CCDF policies and procedures.
Oversight	Reviews: Nine states plan to conduct ongoing case reviews or audits.
State Policies and Procedures	Policy Review: Seven states plan to review and possibly update state eligibility policies.
	Eligibility Procedures: Four states plan to make changes to the eligibility determination procedures.
Information Systems	Six states plan to upgrade or implement new IT systems.
Technical Assistance	Eligibility Agencies: Five states plan to provide technical assistance to eligibility agencies.
	Regulations: Four states plan to issue policy guidance, memoranda, or briefs.

HHS has limited authority to require specific actions of state grantees given that states determine the specifics of their CCDF programs. As resources allow, HHS provides additional onsite and remote oversight of policy and

procedure implementation to assist in lowering the improper payment rate. HHS began monitoring states for compliance with the CCDF regulations in FY 2019. In addition, HHS implemented other corrective actions to assist all states in the review process and error reduction efforts, including:

HHS Corrective Actions for Insufficient Documentation and Administrative or Process Errors Made by State or Local Agency	
Corrective Action	**Description**
Oversight	All reporting states participate in Joint Case Reviews that include state and federal representatives. Through these reviews, HHS gains insight into the error methodology implementation and provides additional technical assistance to states to ensure consistent reviews.
Technical Assistance	Site Visits: HHS visits states needing assistance to address root causes as resources allow.
	Regulations: HHS provides states with technical assistance on policy and procedure changes to meet new CCDBG requirements. HHS funds the Office of Child Care's National Center on Subsidy Innovation and Accountability to provide technical assistance to states and territories on program integrity and accountability, including targeting technical assistance to states to support reauthorization requirements.
	IT: HHS delivers technical assistance to states regarding updating or developing IT systems that will improve practices and reduce errors.
Methodology Training	HHS provides improper payments methodology training on how to conduct error rate reviews, which also allow states to share best practices on conducting the reviews with each other.

CCDF Information Systems and Other Infrastructure

Information systems and other infrastructure needed to reduce CCDF improper payments need implementation at the state level where CCDF payments occur. In addition to the efforts outlined in prior HHS AFRs, states have taken many steps to improve IT systems and infrastructure. Because states were not asked to report on specific information systems or infrastructure, other states may have certain capabilities that were not reported. The following categories include the information systems and infrastructure capabilities some states chose to report for FY 2019:

- Capabilities to improve eligibility determination and authorization;
- Capabilities to improve information on providers or provider payments;
- Capabilities to improve information on active cases to assist in case management; and
- Other capabilities to improve information systems and infrastructure.

Figure 20 identifies the Year Three states and the capabilities applied for FY 2019 to improve information systems and infrastructure.

Figure 20: FY 2019 CCDF Capabilities to Improve Information Systems and Infrastructure

Capabilities and Improvements to:		CCDF Year Three States																	Total
		CT	DC	HI	ID	KY	ME	MD	MI	MN	MO	MT	NE	NJ	NM	NC	SC	WY	
Eligibility Determination and Authorization	Part or All of Eligibility Automated	✓		✓	✓	✓		✓	✓	✓	✓	✓	✓				✓	✓	12
	Flags/Blocks for Avoiding Eligibility Errors	✓		✓	✓						✓	✓			✓		✓		7
	Integrated with Other Agency/State Systems	✓		✓		✓			✓	✓				✓					6
	Data Imaging			✓		✓		✓	✓								✓		5
Information on Providers or Provider Payments	Issues Payments	✓								✓		✓				✓	✓		5
	Flags/Blocks for Avoiding Duplicate/Erroneous Payments									✓	✓						✓	✓	4
	Provider and Licensing Information			✓						✓		✓		✓					4
Information on Active Cases to Assist in Case Management	Reports and Data on Case Accuracy	✓			✓								✓	✓	✓	✓	✓		7
	Integrated with Other Agency/ State Systems	✓		✓		✓			✓	✓				✓					6
	Case Action Alerts			✓			✓		✓										3
	Case Audits						✓						✓						2
Information Systems and Infrastructure	Updates, Enhancements, or New Systems	✓	✓	✓	✓	✓	✓									✓	✓		8
	Planned Updates/System Replacements		✓				✓			✓	✓		✓		✓				6
	Systems Limitations			✓				✓				✓					✓	✓	5

CCDF Statutory or Regulatory Barriers that Could Limit Corrective Actions

The CCDBG Act, signed into law in November 2014, reauthorized CCDF for the first time since 1996. The statute improves the quality and access to care for children across the country by requiring states to:

- Change eligibility to a minimum of 12 months;
- Revise redetermination policies;
- Update provider payment rates and payment practices; and
- Increase health and safety standards for providers.

CCDF regulations (issued in September 2016) also required comprehensive changes for state programs. To enact the law and regulations, states are developing and implementing new policies and procedures, which increased errors as the changes were put in place. Many states needed to pass legislation to enact the requirements under the regulations. Other states needed to update policy and procedure manuals, develop staff training and program oversight methods, and enhance IT resources and infrastructure to monitor and oversee the new requirements. These sweeping changes to the states' child care programs have created many challenges and will likely increase errors in the near future (despite states efforts to implement the requirements). HHS will continue providing support and technical assistance to help reduce errors.

12.0 RECOVERY AUDITING REPORTING

HHS developed a risk-based strategy to implement IPERA's recovery auditing provisions that expanded payment recapture audits to programs or activities that expend $1 million or more annually, if cost effective. Specifically, HHS focuses on implementing recovery audit programs in Medicare, or providing a framework for states to implement recovery audit programs in Medicaid, which accounted for approximately 86 percent of HHS's outlays in FY 2019. HHS is progressing in recovering improper payments in Medicare and Medicaid and, most importantly, implementing corrective actions to prevent improper payments, as described in Section 11.0*: Program-Specific Reporting Information* and below. In addition, in FY 2019 HHS continued reviewing and cataloging potential opportunities to utilize RACs outside of Medicare and Medicaid. HHS will consider lessons learned from these experiences as it implements this requirement.

Medicare FFS RACs

Section 1893(h)(3) of the *Social Security Act* requires HHS to implement the Medicare FFS RAC program in all 50 states by January 1, 2010. RACs can review a variety of claim types, with restrictions on inpatient hospital patient status reviews (limited only to providers referred by the Quality Improvement Organizations for exhibiting persistent noncompliance with Medicare policies). On October 31, 2016, HHS awarded five new Medicare FFS RAC contracts that incorporated several program enhancements developed in response to industry feedback discussed on page 219 of HHS's FY 2017 AFR.

In FY 2019, the Medicare FFS RAC program identified approximately $219.98 million in overpayments and recovered $162.03 million. During FY 2019, the majority of Medicare FFS RAC collections were from Diagnosis Related Group validations and outpatient therapy reviews.

HHS also uses Medicare FFS RAC findings to prevent future improper payments. For example, in FY 2019, HHS released quarterly Provider Compliance Newsletters with detailed information on five findings identified by the Medicare FFS RACs. HHS used these findings to implement local and/or national system edits to prevent improper payments. More information can be found at Medicare FFS RAC program.

Medicare Secondary Payer (MSP) RACs

The MSP RAC, also known as the MSP Commercial Repayment Center (CRC), reviews HHS collected information regarding beneficiaries that had or have primary coverage through an employer-sponsored Group Health Plan (GHP) and situations where a Non-Group Health Plan (NGHP) (e.g., Workers' Compensation entity or No-Fault insurer) has or had primary payment responsibility. When GHP information is incomplete, Medicare FFS may mistakenly pay for services as the primary payer. The CRC recovers these mistaken payments from the entity that had primary payment responsibility (typically the employer or other plan sponsor, insurer, or claims processing administrator). At the end of FY 2016, the CRC workload expanded to include the recovery of certain conditional payments made by Medicare FFS until HHS identifies an NGHP with primary payment responsibility, when the CRC initiates recovery of these conditional payments. In October 2017, HHS awarded the CRC contract to a new RAC. The contract transition completed in February 2018, and the previous contractor entered a wind-down period that ended in February 2019.

In FY 2019, the CRC identified approximately $409.66 million and collected $168.43 million in mistaken payments. More information can be found at CRC.

Medicare Part C and Part D RACs

Section 1893(h) of the *Social Security Act* expanded the RAC program to Medicare Parts C and D.

The primary corrective action on Part C payment error has been the contract-level RADV audits. RADV verifies that diagnoses submitted by MA organizations for risk-adjusted payment corroborate with medical record documentation. The RADV program is currently operational with the support of contractors. To effectively implement a successful Part C RAC program, in 2015, HHS issued a Request for Information on the proposal to place RADV under the purview of a Part C RAC. In response, the MA industry expressed concerns of burden related to the high overturn rate in the early experience of the FFS RAC program. Additionally, potential RAC vendors expressed concerns with the unlimited delay in the contingency payment due to timeframes for appeal decisions in the MA appeal process remaining unestablished (42 CFR §423.2600).

Despite their success in Medicare FFS, RACs have found Medicare Part C to be an unattractive business model because of differing payment structures, a narrow scope of payment error, and unlimited appeal timeframes. To more efficiently use program integrity resources, the FY 2020 budget included a proposal to remove the requirement for HHS to expand the RAC program to Medicare Part C. The proposal also requires plan sponsors to report Part C fraud and abuse incidents and corrective actions. Given that the functions of the Part C RAC program are being performed through other program integrity mechanisms, the proposal creates programmatic and administrative efficiencies while strengthening fraud and abuse reporting.

The functions of the Part C RAC are being performed by the RADV program. The proposed scope of the Part C RAC has been subsumed by an updated RADV methodology that addresses recommendations in the GAO report, "Medicare Advantage: Fundamental Improvements Needed in CMS's Effort to Recover Substantial Amounts of Improper Payments" (GAO-16-76). The new methodology targets payment error using historical payment error data. In January 2019, HHS hosted an industry-wide training providing an overview of the RADV program for MA organizations' representatives, Programs of All-Inclusive Care for the Elderly, Cost Plans, Demonstration Projects, and Third Party Submitters. In April 2019, HHS launched the payment year 2014 RADV audit and held a training webinar for MA organizations selected for audits. The purpose of the training was to prepare the MA industry for the selection of audited MA organizations for RADV audits. The payment year 2014 RADV audit is currently underway and is expected to conclude in late FY 2020. HHS launched the payment year 2015 RADV audit in late FY 2019.

To more efficiently use program integrity resources, the FY 2020 budget included a proposal to remove the requirement for HHS to expand the RAC program to Medicare Part D. The proposal also requires Part D plan sponsors to report Part D fraud and abuse incidents and corrective actions. In a similar circumstance to the Part C RAC, HHS believes that Part D RAC functions are currently being performed by the MEDIC. The MEDIC's primary focus is to conduct program integrity activities aimed to reduce fraud, waste, and abuse in Medicare Part C and Part D. The MEDIC's workload is substantially like that of the Part D RAC, and the MEDIC has a robust program to identify improper payments. After the MEDIC identifies improper payments, HHS requests that plan sponsors delete PDE records that are associated with potential overpayments. Subsequently, HHS validates whether plan sponsors delete the PDEs and do not resubmit such PDEs for payment. In FY 2019, the MEDIC will launch new self-audits and national audits that identify potentially improper payments. Additionally, continued education and outreach will be conducted for Part D plan sponsors.

The Medicare Part D RAC contract has ended, but an administrative and appeals option period allowed the RAC to complete work on outstanding audit issues. Because the Part D RAC program option period does not permit new audit work, there were no new improper payments identified or recovered by the Part D RAC in FY 2019. See Medicare Part C and Part D RAC programs for more information.

State Medicaid RACs

Section 1902(a)(42)(B) of the *Social Security Act* required states to submit by December 31, 2010, assurances that programs meet statutory requirements to establish State Medicaid RAC programs. States were required to implement RAC programs by January 1, 2012. States must implement RAC programs by January 1, 2012. Thus, FY 2019 is the seventh full federal FY of reporting State Medicaid RAC recoveries. In FY 2019, State Medicaid RAC federal-share recoveries totaled $57.72 million and include overpayments collected, adjusted, or refunded to HHS, as reported by states on the Form CMS-64, Medicaid Statement of Expenditures.

Recovery Auditing Reporting Tables

OMB Circular A-136 requires agencies to provide detailed information on agency recovery auditing programs, and other efforts to recapture improper payments. Some Department programs have results to report in this area (see Tables 4, 5A, and 5B). If HHS excluded a program from a table, the program does not have results in that area.

Table 4
Overpayments Recaptured with and without Payment Recapture Audit Programs
FY 2019 (in Millions)

	Overpayments Recaptured through Payment Recapture Audits			Overpayments Recaptured Outside of Payment Recapture Audits		
Program or Activity	Amount Identified	Amount Recaptured [1]	CY Recapture Rate	Amount Identified	Amount Recaptured [1]	CY Recapture Rate
CMS Error Rate Measurements [2]				$22.44	$15.85	71%
Medicare FFS Recovery Auditors	$219.98	$162.03	74%			
Medicare Secondary Payer Recovery Auditor	$409.66	$168.43	41%			
Medicare Contractors [3]				$13,331.39	$11,626.18	87%
Medicare Part C and Part D [4]				$46.09	$46.09	100%
Medicare Part D Recovery Auditors	N/A	$0.00	N/A			
Medicaid Integrity Contractors - Federal Share [5]				$9.66	$9.55	99%
State Medicaid Recovery Auditors - Federal Share [6]	N/A	$57.72	N/A			
ACF Error Rate Measurements and Eligibility Reviews [7]				$0.82	$0.74	90%
ACF OIG Reviews [8]				$6.71	$0.30	4%
ACF Single Audits [9]				$57.69	$35.12	61%
HRSA National Health Service Corps				$10.84	$4.66	43%
TOTAL[10]	**$629.64**	**$388.18**	**62%**	**$13,485.64**	**$11,738.49**	**87%**

Notes:

1. The amount reported in the Amount Recaptured column is the amount recovered in FY 2019, regardless of the year HHS identified the overpayment.
2. The CMS Error Rate Measurements row includes recoveries from Medicare FFS (via the CERT program), as well as Medicaid and CHIP (via the PERM program). The actual overpayments identified by the CERT program during the FY 2019 report period were $18,527,397.95. The MACs recovered the identified overpayments via standard payment recovery methods. As of the report publication date, MACs reported collecting $14,347,495.08 or 77.44 percent of the actual overpayment dollars. For Medicaid and CHIP, HHS works closely with states to recover overpayments identified from the FFS and managed care claims sampled and reviewed. The *Social Security Act* and related regulations governs the recoveries of Medicaid and CHIP improper payments (under which states must return the federal share of overpayments). States reimburse HHS for the federal share of overpayments. Section 1903(d)(d) of the *Social Security Act* allows states up to 1 year from the date of discovery of an overpayment for Medicaid and CHIP services to recover, or to attempt to recover, such overpayment before making an adjustment to refund the federal share of the overpayment. The actual overpayments identified by the PERM program during the FY 2019 report period were $2,390,430.43 for Medicaid and $1,521,584.21 for CHIP. The amounts recovered were $1,136,160.00 for Medicaid and $363,656.00 for CHIP. The amounts recovered were for overpayments identified in prior report periods and, therefore, do not represent a proportion recovered from the identified overpayment amount for this report period.
3. Total reflects amounts reported by Medicare FFS Contractors excluding amounts reported for the Medicare FFS Recovery Auditors program and Medicare FFS Error Rate Measurement program, which HHS reports separately in this table.
4. The values in the Medicare Part C and Medicare Part D row represent overpayments reported and returned by Medicare Advantage organizations and Part D sponsors. The actual overpayments identified and recovered during the FY 2019 report period were $44.55 million for Medicare Part C and $1.54 million for Medicare Part D.
5. For Medicaid, the Medicaid Integrity Contractors identified total overpayments that include both the federal and state shares. However, HHS reports only the actual federal share across audits.
6. For the State Medicaid Recovery Auditor row, the amount of recoveries are the only items states must return, not the amount of improper payments identified or recovery rates. The State Medicaid Recovery Auditors Amount Recaptured cell represents the federal share of the state recoveries as of the publication date of the AFR. The FY 2019 Annual Report to Congress on the Medicare and Medicaid Integrity Programs will report the final amount recaptured for FY 2019 as a result of activities by State Medicaid Recovery Auditors.
7. The ACF Error Rate Measurements and Eligibility Reviews row contains Amount Identified information for the Foster Care and CCDF programs for which the amounts were identified during the current reporting year. As a result of conducting Foster Care eligibility reviews in 12 states between July 2018 and June 2019, HHS recovered $0.71 million in Title IV-E improper payments (comprised of $0.39 million in disallowed maintenance payments and $0.32 million in disallowed administrative payments). For CCDF, states must recover child care payments resulting from fraud and have discretion as to whether to recover misspent funds that were not the result of fraud, such as in cases of administrative error identified in the improper payments review. For the CCDF portion of the Amount Recaptured information, data reported in FY 2019 represent improper payments recovered in FYs 2017 through 2019 by the Year Three states based on improper payments identified in FY 2016. States reported identifying $0.11 million and recovering $0.03 million.

8. The ACF OIG row includes Amount Identified information for all ACF programs for which the amounts from an OIG Report were sustained in FY 2019.
9. The ACF Single Audits row includes Amount Identified information for all ACF programs subject to federal audit requirements for which the audit report amounts were sustained in the FY 2019 reporting period.
10. Totals do not necessarily equal the sum of the rounded components.

Table 5A
Disposition of Funds Recaptured Through Payment Recapture Audit Programs
FY 2019 (in Millions) [1]

Program or Activity	Amount Recaptured	Agency Expenses to Administer the Program	Payment Recapture Auditor Fees	Original Purpose[2]	Returned to Treasury
Medicare FFS Recovery Auditors	$162.03	$34.64	$25.58	$59.67	N/A
Medicare Secondary Payer Recovery Auditor	$168.43	$3.10	$21.06	$144.27	N/A
Medicare Part D Recovery Auditors	$0.00	N/A	$0.00	$0.00	N/A
State Medicaid Recovery Auditors - Federal Share[3]	$57.72	N/A	N/A	$57.72	N/A
Total	**$388.18**	**$37.74**	**$46.64**	**$261.66**	**$0.00**

Notes:

1. HHS did not have any amounts used for financial management improvement activities or the OIG.
2. Funds under the Original Purpose column were returned to the Medicare Trust Funds after taking into consideration agency expenses to administer the program and recovery auditor contingency fees. In addition, the Medicare FFS Recovery Auditors Original Purpose cell also takes into consideration identified and corrected underpayments to providers ($18.3 million) and amounts collected in prior years but overturned on appeal in FY 2019 ($23.8 million).
3. The state Medicaid recovery auditors' row only includes information on the federal share of recoveries returned to the Treasury. States do not report information to HHS on how the recoveries' state portions are used.

Table 5B
Aging of Outstanding Overpayments Identified by Payment Recapture Audit Programs
FY 2019 (in Millions) [1 and 2]

Program or Activity	CY Amount Outstanding (0 to 6 months)	CY % Outstanding (0 to 6 months)	CY Amount Outstanding (6 months to 1 year)	CY % Outstanding (6 months to 1 year)	CY Amount Outstanding (over 1 year)	CY % Outstanding (over 1 year)
Medicare FFS Recovery Auditors[3]	$60.00	3%	$70.71	4%	$1,787.38	96%
Medicare Secondary Payer Recovery Auditor[4 and 5]	$260.94	87%	$38.61	13%	$0.00	0%
Medicare Part D Recovery Auditor[6]	N/A	N/A	N/A	N/A	N/A	N/A
Total	**$320.94**	**14%**	**$109.32**	**5%**	**$1,787.38**	**81%**

Notes:

1. The state Medicaid recovery auditors are omitted in this table since states do not report information to HHS that would allow the Department to calculate the aging of overpayment amounts currently outstanding.
2. HHS had no amount that was determined not to be collectable.
3. Under the Medicare FFS Recovery Auditors Program, recovery of identified overpayments cannot begin until the overpayment is at least 41 days old. Therefore, the CY Amount Outstanding (0-6 months) includes identified overpayments that HHS cannot begin collecting.
4. The MSP recovery auditor maintains debts established under prior MSP recovery programs; consequently, collections exclusively related to mistaken payments identified by the MSP recovery auditor does not directly correlate to the amount outstanding.
5. The MSP recovery auditor amount of outstanding payments included in this table reflects the outstanding balances on debts identified in FY 2019.
6. The Medicare Part D RAC contract ended in December 2015, but an administrative and appeals option period allowed the RAC to complete work on outstanding audit issues until the end of December 2018. Because the option period does not permit new audit work, the Part D RAC identified no new improper payments during FY 2019.

FY 2019 Top Management and Performance Challenges Identified By the Office of Inspector General

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201

DATE: NOV 01 2019

TO: Alex M. Azar II, Secretary

THROUGH: Ann C. Agnew, Executive Secretary

FROM: Joanne M. Chiedi, Acting Inspector General

SUBJECT: Top Management and Performance Challenges Facing the Department of Health and Human Services in Fiscal Year 2019

This memorandum transmits the Office of Inspector General's (OIG's) list of top management and performance challenges facing the Department of Health and Human Services (HHS or the Department). The Reports Consolidation Act of 2000, P.L. No. 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.

HHS's top management and performance challenges for fiscal year 2019 are:

1. Ensuring the Financial Integrity of HHS Programs
2. Delivering Value, Quality, and Improved Outcomes in Medicare and Medicaid
3. Protecting the Health and Safety of HHS Beneficiaries
4. Safeguarding Public Health
5. Harnessing Data To Improve Health and Well-Being of Individuals
6. Working Across Government To Provide Better Service to HHS Beneficiaries

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 Juliet Hodgkins, Deputy Chief of Staff, at (202) 708-9797 or Juliet.Hodgkins@oig.hhs.gov.

U.S. Department of Health and Human Services

Office of Inspector General

2019 TOP MANAGEMENT AND PERFORMANCE CHALLENGES FACING HHS

2019
TOP MANAGEMENT AND PERFORMANCE
CHALLENGES FACING HHS

Introduction

The 2019 Top Management and Performance Challenges Facing HHS is an annual publication of the Department of Health and Human Services (HHS or the Department) Office of Inspector General (OIG). In this edition, OIG has identified six top management and performance challenges (TMCs) facing the Department as it strives to fulfill its mission "to enhance the health and well-being of all Americans, by providing for effective health and human services and by fostering sound, sustained advances in the sciences underlying medicine, public health, and social services." This year, OIG synthesized new and past challenges and reorganized them into six TMCs. These top six challenges reflect overarching issues that affect multiple HHS programs and responsibilities. These are not the only challenges that face HHS, and OIG reports are a key resource that highlight specific opportunities to improve HHS programs and operations.

HHS is responsible for a portfolio of more than $1 trillion, and its programs impact the lives of virtually all Americans. To identify the six TMCs, we integrated OIG's oversight, risk analysis, data analytics, and enforcement work. For each TMC, we describe the dimensions of the challenge, highlight the progress that the Department has made in addressing the challenge, and identify what remains to be done.

Management and performance challenges are inherently cross-cutting and the TMCs reflect how multiple HHS Operating Divisions (OpDivs) may be affected by these pressing issues. For example, the challenge of financial integrity highlighted in TMC 1 has natural intersections with the challenge of delivering value, quality, and improved outcomes in Medicare and Medicaid, the subject of TMC 2. This document identifies those intersections. Given that challenges cross both internal HHS boundaries and sometimes externally across Departments at the Federal and State levels, coordination among HHS agencies and across Government is integral to addressing these challenges.

In addition to this annual publication, OIG maintains a list of significant unimplemented OIG recommendations, including legislative recommendations, to address vulnerabilities. These recommendations are drawn from OIG's audits and evaluations. OIG identifies the top unimplemented recommendations that, in OIG's view, would most positively affect HHS programs in terms of cost savings, program effectiveness and efficiency, and public health and safety.[1]

More information on OIG's work, including the reports mentioned in this publication, is available on our website at https://oig.hhs.gov.

2019
TOP MANAGEMENT AND PERFORMANCE

CHALLENGES FACING HHS

1 Ensuring the Financial Integrity of HHS Programs

2 Delivering Value, Quality, and Improved Outcomes in Medicare and Medicaid

3 Protecting the Health and Safety of HHS Beneficiaries

4 Safeguarding Public Health

5 Harnessing Data To Improve Health and Well-Being of Individuals

6 Working Across Government To Provide Better Service to HHS Beneficiaries

CHALLENGE 1

1: Ensuring the Financial Integrity of HHS Programs

RELEVANT OPDIVS

All HHS

KEY ELEMENTS

- Controlling costs by ensuring proper payment for goods and services
- Reducing improper payments
- Combating fraud, waste, and abuse in HHS programs
- Monitoring and reporting on the integrity of HHS programs

The Department of Health and Human Services (HHS or the Department) is the largest civilian agency in the Federal Government, with a $1.2 trillion budget in fiscal year (FY) 2019, representing more than one-third of the total Federal budget. HHS's Medicare program is the Nation's largest health insurer, handling more than 1 billion claims per year. Medicare and Medicaid, the Department's largest programs, comprise 49 percent of the U.S. health care insurance economy. More than 136 million beneficiaries, or more than 40 percent of Americans, rely on these programs for their health insurance, including senior citizens, individuals with disabilities, low-income families and individuals, and patients with end-stage renal disease.[2] CMS bears the responsibility at HHS for administering these programs. Federal Medicare expenditures totaled $644.8 billion in FY 2019; Federal Medicaid spending totaled $418.7 billion in FY 2019 (with an additional $18.6 billion for the Children's Health Insurance Program (CHIP)).[3]

HHS is also the largest grant-making and fourth-largest contracting agency in the Federal Government. In FY 2018, HHS awarded $109 billion in grants (excluding CMS) and $25 billion in contracts. Responsible stewardship that ensures the transparency and accountability of HHS funds is paramount to making sure that HHS beneficiaries and the American public get the true benefit of this substantial financial investment.

The Department must protect the fiscal integrity of HHS funds and ensure that beneficiaries have access to the services they need, especially in light of looming financial shortfalls in the Medicare program,[4,5] the expansion of Medicaid services to a larger population, and the increased use of grants as funding tools to achieve program results. HHS should take steps to control costs by ensuring proper pricing for goods and services; reducing improper payments; and preventing, detecting, and prosecuting fraud in HHS programs. The Department must not only manage both the efficient and effective use of funds internally but also oversee the thousands of external funding recipients' use of Federal funds to fulfill HHS's mission.

Controlling costs by ensuring proper payment for goods and services

Whether HHS is paying for medical services, prescription drugs, or complex information technology (IT) solutions, managing what the Department pays and recognizing and remedying payment policies that inadvertently incentivize improper billing or inflate prices are critical to controlling costs.

CHALLENGE 1

Medicare

Medicare should act as a prudent payer on behalf of taxpayers and beneficiaries, including instituting payment policies delivering greater value. (See TMC 2 for more information on value-based payment models.) In certain contexts, Medicare payment policies, which are generally set by statute, result in Medicare and beneficiaries paying more for care provided in certain settings than for the same care provided in other settings. For example, Medicare could have potentially saved $4.1 billion over a 6-year period if swing-bed services at critical access hospitals had been paid for at the same rates as at skilled nursing facilities (SNFs).[6] Likewise, Medicare pays hospitals different amounts for the same care depending on whether the hospital admits beneficiaries as inpatients or treats them as outpatients. Some payment policies create financial inequities that actually may drive up Medicare costs without improving care for beneficiaries.[7,8] For example, the OIG found that Medicare payments to SNFs for therapy greatly exceeded SNFs' costs for that therapy, creating an environment that provides incentives to bill for unnecessary therapy.[9]

Prescription drug programs

Vulnerabilities exist in HHS's payment strategies for prescription drugs and biologicals. HHS programs accounted for 40 percent ($136 billion) of the total U.S. prescription drug expenditures in 2017. Increases in prescription drug prices have contributed to the growth in total prescription drug spending. Increases in drug prices may limit patients' access to needed prescription drugs if the out-of-pocket costs become unaffordable. The way that Medicare and Medicaid pay for drugs, in addition to fundamental differences in how the Medicare Part B and Part D programs are structured, can result in additional costs for programs and their beneficiaries. In the Part D program, for example, OIG found that although there was a 17-percent decrease in Medicare Part D prescriptions for brand-name drugs from 2011 to 2015, there was a 77-percent increase in total reimbursement for these drugs, leading to greater overall Part D spending and higher beneficiary out-of-pocket costs.[10] In the Part B program, OIG found that Medicare would have saved millions of dollars if dispensing fees for several drugs had been aligned with the rates that Part D and State Medicaid programs paid.[11] In addition, CMS includes prices for higher-cost versions of drugs that are not covered under Medicare Part B when setting Part B payment amounts. OIG found that, because CMS included noncovered versions when setting payment for two Part B drugs, Medicare and beneficiaries paid an extra $366 million from 2014 through 2016.[12] HHS must endeavor to limit the impact of high prices on programs and beneficiaries while protecting access to medically necessary drugs. Additionally, the Department should be prepared to address coverage and reimbursement challenges of emerging technologies, such as biosimilars and gene therapies like chimeric antigen receptor T-cell therapy.

Contracts

Better controls in HHS's contracting process could strengthen competition and pricing for HHS-purchased goods and services. OIG has identified vulnerabilities in acquisition planning and monitoring of procurement and contracts. For instance, key HHS contracts may not always undergo Contract Review Board oversight before being awarded, and when awarding contracts, CMS has not always performed thorough reviews of contractors' past performance.[13] Similarly, in the past, CMS and other OpDivs have frequently chosen contract types that place the risk of cost increases solely on the Government.[14]

Reducing improper payments

CHALLENGE 1

Due to their size, HHS programs account for some of the largest estimated improper payments in the Federal Government. Medicare, Medicaid, and CHIP accounted for $86.1 billion, or 99.6 percent, of the $86.4 billion in improper payments that HHS reported in its FY 2018 Agency Financial Report.[15] Furthermore, insufficient HHS oversight of grant programs and contracts poses risks of significant improper payments and payments for unallowable costs.

Medicare

Traditional Medicare fee-for-service (FFS) accounted for $31.6 billion, or about 37 percent, of the improper payments that HHS reported. Notably, this improper payment rate decreased from 9.5 percent, or $36.2 billion, in FY 2017 to 8.1 percent in FY 2018.[16] This represents positive momentum upon which the Department and CMS can build. However, some types of providers and suppliers pose heightened risk to the financial security of Medicare.[17] For instance, OIG and CMS have identified especially high rates of improper payments for home health, hospice, and SNF care, durable medical equipment (DME), chiropractic services, and certain hospital services.[18] HHS and CMS have taken corrective actions for the Medicare FFS program focusing on specific service areas with high improper payment rates. Although this year's reduction in the improper payment rate was driven by a reduction in improper payments for home health and SNF claims, CMS should take further action to reduce improper payments among certain provider and supplier types and in geographic locations that present a high risk to the financial security of Medicare. Further, CMS should ensure that it is prepared to detect and prevent improper payments in burgeoning areas, such as telemedicine and genetic testing.

Medicaid

Medicaid is a Federal-State financing partnership with the 50 States, 5 territories, and the District of Columbia, each offering its own program variations reflecting State and local needs and preferences. CMS's Payment Error Rate Measurement (PERM) program measures improper payments in Medicaid and CHIP in all 50 States and the District of Columbia using a 17-State 3-year rotation. In FY 2018, the improper payment rate for the Medicaid program was 9.8 percent.[19] OIG audits have identified substantial improper payments to providers across a variety of Medicaid services, including school-based, non-emergency medical transportation, targeted case management, and personal care services.[20] CMS has engaged with State Medicaid agencies to develop corrective action plans that address State-specific reasons for improper payments identified through the PERM program. OIG work has also identified that States are not always correctly determining eligibility of individuals to receive Medicaid benefits, resulting in potential improper payments. Given that CMS will resume the Medicaid eligibility component measurement and report updated national eligibility estimates for FY 2019, the improper payment rate may significantly increase for this fiscal year.

Grants and contracts

Administering grant programs and contracts requires HHS to implement internal controls to ensure program goals are met and funds are used appropriately. For grant programs, this includes oversight and guidance to award recipients. HHS is responsible for providing up-to-date policies to grant recipients and helping States and other grantees address their own financial management and internal control issues.

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Without proper internal controls, funds may be misspent, duplication of services may occur, and sub-recipients may not be adequately monitored. OIG has identified grantee-level concerns in several HHS programs, including some Office of Refugee Resettlement (ORR) Unaccompanied Alien Children (UAC) Program grantees reporting unallowable costs and lacking effective systems for administering program funds;[21] and States not sufficiently overseeing their Child Care and Development Fund (CCDF) program payments.[22]

As a critical element of ensuring that grant funds are used appropriately, HHS must track and report improper payment rates for its risk-susceptible grant programs, in keeping with the *Improper Payments Information Act of 2002.*[23] However, since the inception of these reporting requirements, HHS has not reported an improper payment estimate for the Temporary Assistance for Needy Families (TANF) program. States receive block grants ($16.5 billion annually) to design and operate TANF programs. HHS has stated that it does not believe it has the statutory authority to collect from States the data necessary for calculating an improper payment rate for the TANF program. The Office of Management and Budget (OMB) has identified TANF as a risk-susceptible program that must report estimated rates and amounts of improper payments. HHS must continue to pursue needed legislative remedies to develop an appropriate methodology for measuring TANF payment accuracy and report an improper payment estimate for TANF.

In terms of the Department's oversight of contracts, HHS has taken steps to enhance its acquisition systems and better monitor contract closeouts and contract payments. Moreover, CMS has increased its efforts in examining workload statistics for benefit integrity contractors and improving performance outcomes. However, OIG has identified problems with the Department's processes for contract closeouts. CMS relies extensively on contractors to carry out its mission and spends billions of dollars each year in contracts. Because improper payments may be identified and recovered during the closeout process, it is imperative that contracts are closed in accordance with Federal Acquisition Regulation (FAR) requirements. The closeout process, generally, is the last chance for improper contract payments to be detected and recovered, and delayed closeout poses a financial risk to agency funds. OIG found that a large backlog of unfinalized indirect cost rates may have contributed to the untimely closeout of CMS contracts totaling $25 billion.[24] Although CMS has taken steps to improve its closeout and contract management processes, the Department needs to take additional actions to ensure that it is meeting FAR requirements.

Combating fraud, waste, and abuse in HHS programs

Fraud, waste, and abuse divert needed program resources to inappropriate, unauthorized, or illegal purposes. Effectively fighting fraud, waste, and abuse requires vigilance and sustained focus on preventing problems from occurring in the first place, detecting problems promptly when they occur, and rapidly remediating detected problems through investigations, enforcement, and corrective actions. To accomplish this, HHS must have controls to ensure the proper use of resources and to detect and prevent fraud. The Department should also apply a robust program integrity strategy to protect current and future HHS programs.

FRAUD SCHEMES

- Billing for Services Not Provided
- Identity Theft
- Kickbacks
- Improper Prescribing
- Deceptive Marketing
- Money Laundering

CHALLENGE 1

Program integrity strategies

HHS programs must be designed with program integrity in mind. These strategies must take into account the various methods that HHS uses to implement its programs, including how public and private partners can help in meeting the Department's mission. Additionally, these strategies must include systems and processes to detect and prevent fraud, as well as plans for addressing fraud when it occurs.

Systems and processes for detecting and preventing fraud

With respect to detecting and preventing fraud and improper payments, CMS's Fraud Prevention System (FPS) serves as an important tool that should be improved to increase its effectiveness. Since 2011, the FPS has continuously run predictive algorithms and other sophisticated analytics nation-wide against Medicare FFS claims prior to payment to identify, prevent, and stop fraudulent claims. However, OIG found that the FPS is not as effective in preventing fraud, waste, and abuse in Medicare as it could be and recommended that CMS should make better use of the performance results within its FPS to refine and enhance its predictive analytic models.[25]

In the Medicare and Medicaid programs, States must keep bad actors intent on committing fraud from participating in the programs. With respect to Medicaid in particular, significant problems remain for ensuring all high-risk Medicaid providers undergo criminal background checks. Further, States are not sharing provider enrollment data with Federal and State partners to streamline the Medicaid enrollment process. Sharing these data would reduce the chance for error within any one of the State and Federal databases and help in identifying fraud schemes and other vulnerabilities that cross State lines.[26] CMS should continue to work directly with States to implement tools such as fingerprint-based criminal background checks for high-risk providers. Further, CMS should develop a central repository or "one-stop shop" with provider information that all States and Medicare can use.

Medicare and Medicaid

Schemes to steal money from Medicare and Medicaid take many forms and vary depending on setting and services provided. These fraud schemes can be as simple as billing for services not provided and identity theft or as complex as kickbacks, improper prescribing, deceptive marketing, and money laundering. The perpetrators of fraud schemes range from highly respected physicians to individuals with no prior experience in the health care industry to organized criminal enterprises.

Managed care continues to play an increasingly important role in Medicare and Medicaid. Unlike in FFS, where CMS (Medicare) or the State (Medicaid) pays providers directly for each covered service received by a beneficiary, under managed care, CMS or the State pays a population-based fee to a managed care plan for each person enrolled in the plan. In turn, the plan pays providers for services a beneficiary may require that are included in the plan's contract with CMS or the State. Managed care is the primary delivery system for Medicaid, covering at least some services for more than 80 percent of all enrollees.[27] In Medicare, one-third of beneficiaries are enrolled in Medicare Advantage organizations (MAOs). HHS faces a significant challenge in protecting managed care programs and other non-traditional models against fraud, waste, and abuse.

CHALLENGE 1

OIG has found weaknesses in MAOs' and Medicaid managed care organizations' (MCOs) efforts to identify and address fraud and abuse by their providers.[28] CMS requires MAOs and Medicaid MCOs to implement compliance plans that include measures to prevent, detect, and correct instances of fraud, waste, and abuse and non-compliance with CMS's program requirements. However, these plans vary widely among the MAOs, as does the detection of suspected fraud. In Medicaid managed care, program integrity responsibilities are even more dispersed, as they are shared among CMS, States, and MCOs. This makes effective oversight by CMS more complex and challenging.

CMS is working to validate the completeness and accuracy of MAO and Medicaid MCO encounter data and recently has released best practices guidance for MAOs to improve encounter data submission. CMS is also working with States to provide technical assistance and education to identify and share best practices for improving Medicaid MCO identification and referral of cases of suspected fraud or abuse. CMS should take further actions to ensure the completeness, validity, and timeliness of Medicaid encounter data. Further, CMS should work with its contractors and with States to make improvements in efforts to identify and address fraud and abuse. Additionally, CMS should work to ensure that appropriate information and referrals are sent to law enforcement.

Grants and contracts

Without adequate oversight and internal controls, grants and contracts are vulnerable to fraud schemes, including embezzlement.[29] HHS has worked to strengthen some of its program integrity efforts focused on grant programs. For instance, it issued guidance to HHS awarding OpDivs about facilitating a review of prospective grantees prior to awarding grants.[30] This information enhances awarding OpDivs' assessment of prospective grant recipients' integrity and potential performance.

Fraud involving prescription opioids

Opioid-related fraud encompasses a broad range of criminal activity, from prescription drug diversion to addiction treatment schemes. OIG investigations show that opioid drug diversion (the redirection of legitimate drugs for illegitimate purposes) is on the rise. Diverted opioid drugs are at high risk to be used inappropriately and create significant harm, including increased risk of overdose. Also at high risk for diversion are potentiator drugs (drugs that exaggerate euphoria and escalate the potential for misuse when combined with opioids) and drugs indicated to treat opioid use disorders (OUDs) (particularly buprenorphine).

OpDivs should improve efforts to identify and investigate potential fraud and abuse in prescription drug programs. For instance, CMS should collect comprehensive data from Medicare Part D plan sponsors. CMS should ensure that national Medicaid data are adequate to detect suspected fraud or abuse. The lack of reliable national Medicaid data hampers enforcement efforts. (See TMC 5.) CMS and States should follow up on prescribers with questionable prescribing patterns to ensure that Medicare Part D and Medicaid are not paying for unnecessary drugs that are being diverted for resale or recreational use. OIG has also recommended that the Indian Health Service (IHS) improve its internal controls against opioid-related fraud, including controls at entry points to sensitive areas of its hospitals to protect its pharmacy inventory from unauthorized access.[31] In addition, the Department must guard against fraud in OUD treatment

programs, including, for example, the submission of fraudulent insurance claims for purported OUD treatment and testing services.[32]

CHALLENGE 1

Monitoring and reporting on the integrity of HHS programs

HHS must ensure the completeness, accuracy, and timeliness of financial and program information provided to other entities, both internal and external to the Federal Government. Responsible stewardship of HHS programs is vital to operating a financial management and administrative infrastructure that employs appropriate safeguards to minimize risk and provide oversight for the protection of resources. Although HHS continues to maintain a clean opinion on their basic financial statements that culminate the results of their programs, addressing weaknesses in financial management systems and meeting the requirements of the *Digital Accountability and Transparency Act (DATA Act) of 2014* remain challenges for HHS.

Addressing weaknesses in financial management systems

Financial management systems help OpDivs ensure operational effectiveness and efficiency, financial reporting reliability, and compliance with applicable laws and regulations. OIG continues to find significant deficiencies in internal controls over segregation of duties, configuration management for approved changes to HHS financial systems, and access to HHS financial systems.[33] HHS must take additional actions to address and resolve these issues, including continuing to work to control user access, ensuring proper approval of and documentation supporting system changes, and ensuring appropriate segregation of duties so that no one employee can both enter and approve information entered into HHS financial management systems.[34]

Meeting the requirements of the DATA Act of 2014

The DATA Act required agencies to use Government-wide data standards to report financial and award information into USAspending.gov. For FYs 2017, 2019, and 2021, the DATA Act also requires the Inspector General of each agency to determine the accuracy, completeness, timeliness, and quality of these data. In FY 2018, OIG performed an additional audit to follow-up on prior issues and monitor and provide feedback on the progress made by the Department. For FY 2018, OIG's audit of compliance with the DATA Act found that HHS complied with data standards but continued to rely on a manual, labor-intensive process.[35] HHS needs to continue to automate the standardization and transmission of data to the Department of Treasury.

2: Delivering Value, Quality, and Improved Outcomes in Medicare and Medicaid

CHALLENGE 2

The transition to innovative, value-based, consumer-empowered care is a top Administration[36] and Departmental priority. HHS continues to enact reforms in Medicare and Medicaid to promote quality, efficiency, and value of care. These reforms come with an array of operational and program integrity challenges, as well as promising opportunities for better health outcomes, lower costs, improved transparency and choices for consumers, and reduced administrative burden on providers.[37]

RELEVANT OPDIVS

CMS, ONC, OS

KEY ELEMENTS

- Aligning program incentives with health outcomes
- Addressing integrity problems across models
- Delivering on the promise of innovative technology to improve health outcomes

Medicare and Medicaid, the two largest programs in the Department, are also among the most complex. Both programs offer benefits in multiple formats (FFS, managed care, and newer payment models); cover a broad array of health conditions, providers, services, and settings; and operate pursuant to intricate statutory directives and regulatory schemes. Increasingly, beneficiaries are enrolling in Medicare and Medicaid managed care options.

The transition to value in the Medicare and Medicaid programs is well underway, with continued growth expected. The Health Care Payment Learning & Action Network, an HHS-sponsored public-private partnership, estimated that for FY 2017, 90 percent of providers in Medicare FFS were paid based, at least in part, on quality and value, with 38 percent being paid under an alternate payment model or a population-based payment; the comparable numbers for Medicaid were 32 percent and 25 percent, respectively.[38] HHS has introduced, and continues to introduce, a range of new models, including accountable care organizations (ACOs), medical homes, bundled payment models, primary care models, and others. Many of these models are designed as all-payer models to align with developments in the private sector. Most recently, HHS announced a major set of initiatives to reform payment and delivery of kidney care, including new payment models, technologies, and care options for patients.

Both Medicare (FFS, Part C, and Part D) and Medicaid have proven susceptible to fraud, waste, and abuse, with estimates of improper payments ranging from 8.1 percent (Medicare FFS) to 9.8 percent (Medicaid) of total expenditures, totaling $86 billion in FY 2018.[39] For the past 16 years, the Government Accountability Office (GAO) has included both programs on its list of high-risk Government programs. OIG work has long demonstrated a range of vulnerabilities in both Medicare and Medicaid:

- Flaws in program design and administration (e.g., improper payments) (see TMC 1),
- Misaligned program incentives and confusing or insufficient program guidance,

- Deficiencies in how providers deliver care to beneficiaries (e.g., poor quality and unsafe care (see TMC 3) or inappropriate utilization),
- Gaps in provider enrollment systems and available data needed for proper oversight (see TMCs 1 and 5), and
- Problems in ensuring that eligible beneficiaries have adequate access to covered services in both FFS and managed care.

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There are three specific elements of this challenge: (1) aligning program incentives with improved health outcomes, (2) strengthening program integrity, and (3) delivering on the promise of innovative technology. Each element is integral to delivering greater value (including savings), quality, and improved outcomes for Medicare and Medicaid, their beneficiaries, and taxpayers.

Aligning program incentives with health outcomes

Developing effective incentives and policies to drive better health outcomes is difficult given the complexities of medicine, the programs themselves, and the populations served by these programs. HHS faces obstacles in correctly measuring the value of care. Designing measures that effectively incentivize high-quality care without being overly prescriptive or burdensome to providers is challenging, and the science of quality measurement continues to evolve.

The Department is undertaking initiatives to streamline, improve, and target quality measures more precisely and to move from process measures to outcome measures. Through its *Meaningful Measures* initiative, CMS reports it rolled back 20 percent of measures because they were topped out, duplicative, or overly burdensome.[40] Where applicable, CMS must clearly define actionable and meaningful quality measures and ensure their reliability, accuracy, and utility. CMS and other OpDivs currently using quality measurements should continue to align efforts to reduce unnecessary provider burden and strengthen quality measurement. Moving forward, HHS will need to ensure that its programs use effective, evidence-based measures for quality improvement. Under the new Executive Order on Health Care Price Transparency and Quality, HHS is producing a health quality roadmap in coordination with the Secretaries of Defense and Veterans Affairs that will include a strategy for developing common quality measures, aligning inpatient and outpatient measures, and eliminating low-value quality measures. The Department is also exploring—via a Regulatory Sprint to Coordinated Care led by the Deputy Secretary—whether better care coordination and value-based care can be fostered through changes to existing regulations that some view as barriers to care coordination, including certain fraud and abuse regulations administered by CMS and OIG, as well as certain Substance Abuse and Mental Health Services Administration (SAMHSA) and Office for Civil Rights (OCR) regulations.

OIG work examining the Medicare Shared Savings Program over the first 3 years of the program revealed that ACOs participating in the Medicare Shared Savings Program reduced Medicare spending and achieved a net spending reduction of nearly $1 billion for 9.7 million beneficiaries. ACOs improved their performance on most (82 percent) of the individual quality measures and outperformed FFS providers on most (81 percent) of the quality measures. ACOs participating in the program longer were more likely to reduce spending and by greater amounts than other ACOs. This suggests that more established ACOs can achieve greater cost savings and quality over time.[41] OIG conducted site visits to successful ACOs and identified strategies used by ACOs to reduce Medicare spending and improve quality of care. Examples of these strategies include engaging beneficiaries in improving their health outcomes, managing beneficiaries with costly or complex care needs, reducing avoidable hospitalizations, controlling costs and improving quality in skilled nursing and home health care, addressing behavioral health needs

and social determinants of health, and using technology to increase information sharing among providers.[42] Based on this work, OIG recommended—and CMS concurred—that CMS take steps to support and share successful ACO strategies. These strategies may be adaptable in other value-based models.[43]

CHALLENGE 2

New payment structures, business arrangements among providers, and incentives all give rise to risk-management challenges. In pursuing innovative models to improve the health care system—whether in FFS or managed care—CMS must take steps to prevent unintended consequences, such as misaligned incentives or abusive practices. Moreover, notwithstanding identified successes, CMS must maintain a steady focus on quality. For example, an OIG review of Medicare Part B dialysis services at a health care group in Puerto Rico found noncompliance with Federal requirements for which the deficiencies could have had a significant impact on the quality of care provided to Medicare beneficiaries and could have resulted in the provision of inadequate or unnecessary dialysis services. OIG provided recommendations for strengthening policies and procedures to meet quality requirements.[44] (See TMC 3 for further discussion of quality-of-care challenges.)

Addressing integrity problems across models

The transition to a value-driven health system could mitigate some of the fraud and abuse vulnerabilities resulting from volume-based incentives and poorly coordinated care. However, familiar risks will continue to exist and new risks will likely emerge. Examples of risks in a value-based system (e.g., one where providers assume financial risk for patients' cost of care) could include providers inappropriately reducing costs by stinting on care, discriminating against expensive patients, or manipulating or falsifying data used to measure performance, outcomes, or acuity. Managed care suffers from similar program integrity problems. More will need to be done across FFS and managed care programs to assess and identify emerging risks so that they can be mitigated.

As health care transitions from paying for procedures to paying for outcomes, the programs will concurrently face risks associated with volume-driven and value-driven payment and care. Indeed, many providers will be paid under models that combine multiple types of incentives, such as a shared savings payment in combination with FFS payments, and some providers will continue to be paid primarily or exclusively on a volume-basis. Managed care programs also are not immune from risks created by mixed incentives. OIG's oversight and enforcement work addressing program integrity in managed care demonstrate the opportunities for "downstream" fraud and abuse, such as by providers paid on an FFS basis, notwithstanding that the Government pays on a population basis (e.g., a capitated payment). (See TMC 1 for further discussion of program integrity in managed care.)

A further, significant program integrity concern arises in connection with services furnished in home- and community-based settings, which patients often prefer and can be less costly. Value-based care models are expected increasingly to promote care in these settings through home visits by practitioners and care managers, remote monitoring, and other technologies. CMS is expanding beneficiaries' access to telehealth. OIG work in areas such as hospice care, home health, and personal care services consistently demonstrates that patients and the programs may be vulnerable to fraud and abuse in home- and community-based settings. Moreover, there is heightened risk that new technologies, when misused, could enable wrongdoers to commit broader and new types of fraud.

Managing and mitigating multifaceted risks to ensure that patients, providers, and taxpayers realize the full benefits of innovative value-based care will require sustained effort, resources, flexibility, and continual prioritization by CMS

CHALLENGE 2

and the Department. In testing and implementing value-based care models, CMS must continue to focus on program integrity risks, incorporate safeguards to reduce them, and promptly correct identified issues. Focusing on these risks is especially important for models that introduce new payment incentives, which might lead to new fraud schemes, and for models for which waivers of payment, coverage, or fraud and abuse laws may have been issued.

Across Medicare and Medicaid, whether in the traditional FFS, managed care, or emerging new models, CMS must remain attentive to tailoring effective program integrity strategies that prevent and detect problems and hold wrongdoers accountable. Attention must be paid to the range of fraud, waste, and abuse risks, including improper payments, compliance with program requirements, provider eligibility and qualifications, data integrity and availability, transparency and accuracy of information available to consumers, patient safety, substandard care, and access to care. These risks are covered in more detail in TMCs 1, 3, and 5.

Delivering on the promise of innovative technology to improve health outcomes

Leveraging digital and health technology to foster efficient, high-quality, safe care is critical to a value-driven health care system, as is ensuring the appropriate flow of complete, accurate, timely, and secure information. For example, recent OIG work examining how Medicare Shared Savings Program ACOs use health IT showed that, although ACOs have used health IT to aid in care coordination in a variety of ways, the full potential of health IT has not been realized.[45]

HHS faces challenges in achieving a connected health care system to support better coordinated and value-based care in which patients' data—including conventional health care data and newer types of data related to social determinants, demographics, and personal trackers—flow freely across provider settings, with appropriate privacy and security protections. As health-related apps and technologies proliferate with the delivery of care, beneficiaries will need access to new and integrated information. This information should enable them to choose reliable apps and technologies to assure themselves that providers they may be engaging with via an app or technology are trustworthy. (See TMC 5.)

Artificial intelligence and machine learning are introducing new paradigms that will likely require fresh thinking about compliance and fraud prevention.

HHS also faces challenges in ensuring that evolving technologies achieve their intended results, enhancing patient access to quality care and providers' ability to furnish such care. The recent billion-dollar law enforcement action known as Operation Brace Yourself illustrated how telehealth technology used for remote physician consultations can make a familiar fraud scheme—charging Medicare for DME that patients do not need—bigger with less effort. HHS must provide appropriate oversight of rapidly evolving technologies, such as telehealth, networked medical devices, robotics, genomic testing, and remote monitoring. In many cases, new technologies and apps are being developed by individuals and entities—often engineers or scientists—unschooled in the complex regulations governing health care and unaware of the range of program integrity risks their inventions may face. These new participants in the health care ecosystem will need education, guidance, and appropriate oversight.

CHALLENGE 2

HHS faces a growing challenge in understanding and, as appropriate, overseeing providers' use of artificial intelligence and machine learning in the delivery of health care, such as in diagnostics, as well as for administrative functions, such as coding and claims submission. Artificial intelligence and machine learning are introducing new paradigms that will likely require fresh thinking about compliance and fraud prevention. Relatedly, HHS will need to assess how it can use artificial intelligence, machine learning, and other technologies to foster program integrity, value, and quality of care in Medicare, Medicaid, and other HHS programs. Finally, HHS will need to ensure that rural beneficiaries and underserved populations are not left out of a technology-enriched, value-driven health system. (See TMC 4 for further information about the Food and Drug Administration's (FDA's) role in emerging technology.)

Realizing the promise of value-based care and payment structures

To achieve better care at lower cost, HHS must maintain a steady focus on developing and refining effective, innovative, evidence-driven models while being proactive in preventing and detecting fraud, waste, and abuse. HHS must pay special attention to effectiveness and program integrity in nascent areas such as the intersection of health care with social determinants of health and new uses of digital technology. This is vitally important given the current and anticipated growth in the cost and number of beneficiaries in Medicare and Medicaid. Meeting this challenge will enable the Department to expand the reach of dollars devoted to these programs, thereby abating some of the anticipated rise in cost of these programs over the next decades and improving the lives and health outcomes of the beneficiaries they serve.

3: Protecting the Health and Safety of HHS Beneficiaries

CHALLENGE 3

HHS programs provide critical services to diverse populations across a broad range of care settings. Some such services are directly provided by HHS personnel, some delivered via HHS grant programs and others rendered by professionals of the beneficiary's choosing, who then claim reimbursement from Federal programs. Services include health care services, educational services, child care services, and even physical custody for select populations. Ensuring that intended beneficiaries receive appropriate services and are not subjected to abuse or neglect represents a major challenge for the Department.

RELEVANT OPDIVS

ACF, CMS, IHS, SAMHSA

KEY ELEMENTS

- Ensuring safety and quality of health care paid for by Federal health insurance programs
- Protecting the health and safety of children served by HHS programs
- Preventing abuse and

Ensuring safety and quality of health care paid for by Federal health insurance programs

HHS operates the Medicare program to insure about 60 million elderly or disabled Americans. In partnership with the States, the Medicaid and CHIP programs insure about 75 million and 7 million beneficiaries, respectively. IHS serves about 2.6 million members of 573 federally recognized Tribes. These programs cover specific health care services, which may include hospital care, physician services, prescription drugs, hospice care, home and community-based care, DME, and skilled nursing care.

Delivering covered services

Ensuring access to care that meets quality and safety standards remains a challenge. Even when Federal health care programs cover care, many beneficiaries do not actually receive the care they need. For example, OIG found that over 500,000 children with attention deficit hyperactivity disorder (ADHD) who were Medicaid-enrolled did not receive timely follow-up care, and that over 50,000 such children did not receive behavioral therapy as recommended by professional guidelines.[46] At the other end of the life cycle, OIG found that more than 80 percent of hospice providers, a growing sector of health care serving beneficiaries and their families at an extremely vulnerable time near end-of-life, had quality-of-care deficiencies.[47] Additionally, fixed daily payment structures may incentivize hospices to enroll beneficiaries for longer time periods but scrimp on care. Oversight work also revealed that patients experience significant rates of adverse events (patient harm as a result of medical care) in health care facilities. Specifically, OIG found that 27 percent of Medicare beneficiaries were harmed during their stays in acute care hospitals, and that harm rates were even higher for post-acute settings: 29 percent in rehabilitation hospitals, 33 percent in skilled nursing facilities, and 46 percent in long-term-care hospitals.[48] In addition

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to the high harm rates, OIG found that hospitals did not identify when harm occurred in their facilities, in part due to confusion over HHS and other Government guidance regarding how to define and report adverse events.[49] OIG is currently conducting a study to update the harm rate for Medicare beneficiaries in hospitals. This review will assess progress made in reducing harm in the decade since the prior study was released in 2010.[50] OIG also has work underway to measure the rate of adverse events for patients at IHS Hospitals. (See TMC 6 for more information on challenges associated with adverse events.)

The Department continues efforts to improve the quality of covered services. The Department has worked to improve information available to beneficiaries and their families when selecting a care provider. One example is CMS's efforts to improve nursing home care. CMS's Five-Star Quality Rating System facilitates informed comparison of nursing homes. CMS has announced plans to revamp its Hospital Quality Star Rating System to enable better informed decision-making for beneficiaries seeking hospital care.

Also, CMS enforcement actions have stopped some poor-performing nursing homes from rendering worthless services. One nursing home chain charged with rendering grossly substandard care to Medicare and Medicaid beneficiaries agreed to repay $18 million and abide by the terms of a Corporate Integrity Agreement to ensure that it delivers appropriate care going forward.[51] Further, after a series of OIG reports about quality of care problems in IHS-operated hospitals,[52] IHS created a new Quality Framework and Office of Quality to provide better guidance and oversight to its facilities and clinical staff.[53]

Although the Department has made progress, more work remains to be done to improve access to and quality of all types of care. Among the top priorities as identified by OIG work are improving hospice care, including strengthening the survey process and better educating beneficiaries and their families and caregivers,[54] and improving the health and safety of nursing home residents by ensuring facility correction of deficiencies.[55] To continue improvements at IHS, OIG has recommended that IHS prioritize developing and implementing a staffing program to ensure sufficient qualified staff, including those at remote facilities; enhance training for staff and hospital leaders; intervene quickly and effectively when quality problems are identified; and establish better procedures, including improved external communication.[56]

Protecting the health and safety of children served by HHS programs

HHS operates or funds many programs providing additional services beyond health care for children, including child care, education, and residential care. The Head Start program promotes school readiness for nearly 1 million children from low-income families and the CCDF provides child care for about 1.3 million children from low-income families. The importance of properly vetting staff for these programs is discussed below.

Operating the UAC Program

Through the UAC Program, ORR assumes custody of children who enter the United States without immigration status and have no parent or guardian in the United States able to provide for their physical and mental well-being. The child may have arrived in the United States alone, or in certain circumstances, may have been separated from their parents or legal guardians at the border. This program merits specific discussion, as it uniquely tasks the Department with assuming physical and legal custody for children, and the comprehensive responsibility for their welfare thus entailed. Through the UAC Program, ORR places

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unaccompanied or separated children in shelters and other facilities operated by grantees or contractors. These facilities provide food and shelter, as well as medical and mental health care and other services. Children remain in these placements until a sponsor (usually a parent or family member) is found to whom the child may be safely released, the child's immigration status is resolved, or the child turns 18 years old and ages out of the program. Since ORR began operating the UAC Program in 2002, it has served more than 175,000 children.

In recent years, ORR has been called upon to care for more children, including children who did not come to the United States alone but were separated from their parent or guardian at or after arrival. HHS reported to a court as part of a lawsuit that 2,737 children had been separated by the Department of Homeland Security (DHS) and remained in ORR care as of June 2018. OIG reported in January 2018 that possibly thousands of children had been separated and released by ORR before the court order and that children had been separated from their parents for longer than had previously been reported. ORR had not been tracking this figure and the exact number of separated children is still not known, although HHS and DHS are now working to identify all of the children separated from their parents since July 2017. OIG also reported that children continue to be separated by DHS from their parents, and ORR does not always receive adequate information.[57] Lack of data about separated children complicates HHS's ability to ensure appropriate placement and reunite children with their families in a timely manner. These factors may cause children to spend more time in HHS custody. Issues related to identifying and vetting appropriate sponsors may also prolong children's time in HHS care facilities. Also, at one influx care facility, OIG found failures in conducting required staff background checks and insufficient clinical staff to serve children's mental health needs.[58]

The Department must work to ensure that UAC Program-funded facilities meet all safety requirements and provide adequate medical and mental health care. As discussed further below, HHS must also enhance efforts to ensure that all staff with access to children have passed required background checks.

Preventing abuse and neglect

HHS funds and oversees many types of services for a broad range of beneficiaries. Countless HHS-funded providers are in a position of trust and in close contact with beneficiaries, often behind closed doors and at especially-vulnerable times in the beneficiary's life. The vast majority of providers seek to serve beneficiaries' best interests. However, some providers may cause beneficiaries harm and HHS must protect its beneficiaries from abuse and neglect. For example, a former IHS pediatrician is currently in prison in one State and standing trial in another State for sexually assaulting boys he treated as patients. That incident commanded extensive attention and the Department has committed to collaborating with a Presidential Task Force on Protecting Native American Children in the IHS system established in March 2019.[59] The Task Force is charged with examining IHS systems that may have failed in the past and recommending improvements to better protect children from abuse. Better attention to protecting vulnerable beneficiaries of all ages in all HHS care settings is also needed.

Vetting providers and staff

Although even the most thorough vetting cannot completely prevent all potential predators from abusing Federal programs to gain access to victims, background checks are a useful tool. OIG identified failure to

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conduct required background checks for UAC facility staff whose jobs entail access to children.[60] Failure to conduct adequate background checks has been a problem in domestic child care programs as well. OIG found that some States have not fully implemented CCDF requirements to conduct comprehensive criminal background checks on current and prospective staff.[61] Implementation of background checks for long-term-care providers remains a challenge as well.[62] Along with demonstrating job-specific competency and qualifications, ensuring that staff pass all required background checks is an important safety measure.

The Department should improve efforts to ensure staff pass required background checks before they have access to patients in various health care settings and to children in the UAC Program, Head Start, and CCDF. The Department is also working to support States' implementation of the CCDF background check requirements. The Department should continue to work with States to ensure that implementation of the *Child Care and Development Block Grant Act of 2014* background check requirements align with the statutorily required effective dates and the allowable timelines described in the CCDF Final Rule.

Identifying and reporting abuse and neglect

Beneficiaries in many care settings are at risk of abuse and neglect. About 1.8 million Medicare beneficiaries receive care in SNFs each year.[63] Home and community-based services allow many Medicaid beneficiaries the opportunity to avoid undesired facility care. However, some beneficiaries have been abused or neglected by individuals, including some family members that Federal health care programs paid to care for the beneficiary at home. Group homes provide care to many especially vulnerable people, including adults with developmental disabilities. OIG work found extensive failures to properly handle critical incidents, including suspected abuse and neglect, of group home residents.[64] OIG has also identified substantial failures to report incidents of potential abuse or neglect of Medicare beneficiaries living in SNFs who require treatment in hospital emergency departments.[65] All States have enacted mandatory reporting laws that require certain individuals, like school teachers or nursing home staff, to report suspected abuse or neglect of vulnerable individuals. However, many instances of abuse and neglect go unreported, making it harder to help victims and hold wrongdoers accountable.[66]

The Department has created several resources to better address abuse and neglect of residents of group homes. These resources include model practices for (1) State incident management and investigation, (2) State incident management audits, (3) State mortality reviews, and (4) State quality assurance.[67]

It is important to prevent ongoing harm by identifying providers and facilities subjecting beneficiaries to abuse or neglect. States and other partners should use claims data to better identify unreported abuse and neglect. OIG created a resource guide to help accomplish this goal.[68] Additional efforts would help to improve reporting. For example, CMS should compile a list of diagnosis codes that indicate potential abuse or neglect, conduct periodic data extracts, and encourage States to better use data to facilitate compliance with mandatory reporting laws.

CMS should also work to ensure that Federal mandatory reporting laws suffice to protect beneficiaries in all care settings and are adequately enforced. Protecting beneficiaries from abuse and neglect is a critical responsibility requiring attention and cooperation from all stakeholders.

4: Safeguarding Public Health

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As HHS pursues its mission of enhancing the health and well-being of all Americans, there are challenges to ensuring public health and safety. These include opioid abuse and misuse, risks associated with public health emergencies caused by communicable diseases and natural disasters, dangers from unsafe food, and medical devices vulnerable to cyberattacks. To best serve the American public, the Department must leverage the skills and tools it has at its disposal to reduce the ill-effects of opioid use disorders (OUDs) through prevention, treatment, and recovery support, prioritize emergency planning and response, and ensure that food, drugs, and devices are safe. Additionally, Americans rely on HHS to recognize and respond to emerging issues such as concerning trends and evidence of detrimental health impacts associated with the use of e-cigarettes and other electronic nicotine delivery systems ("vaping"). Because challenges to public health are often complex, the Department must ensure that operating divisions coordinate with each other, as well as partners within and outside of Government, to effectively promote public health and safety. (See TMC 6 for more information on the Department's challenge of coordinating with internal and external partners.)

RELEVANT OPDIVS

ASPR, CDC, CMS, FDA, HRSA, IHS, SAMHSA

KEY ELEMENTS

- Tackling the opioid epidemic while ensuring access to treatment
- Strengthening emergency preparedness and response capabilities
- Safeguarding the Nation's food supply
- Providing adequate oversight of medical device safety and security

Tackling the opioid epidemic while ensuring access to treatment

The Nation is struggling with an opioid crisis that is, at least partially, fueled by opioids prescribed by licensed medical professionals, dispensed by licensed pharmacies, and paid for by Federal funds. Approximately 2 million people have an OUD,[69] and two out of three overdose deaths involve an opioid.[70] In 2017 alone, there were an estimated 47,600 opioid-related overdose deaths in the United States.[71] Although the opioid epidemic is pervasive nationally, data suggest that the Appalachian region, in particular, has higher opioid prescribing rates and overdose death rates,[72] and that the American Indian/Alaska Native (AI/AN) population is disproportionately harmed by opioid misuse[73, 74] and overdose deaths.[75] Additionally, synthetic opioids such as fentanyl and tramadol present a significant, growing threat and have been associated with more deaths than other types of opioids.[76]

Two out of three overdose deaths involve an opioid.

In 2017, the President directed the Acting HHS Secretary to declare the opioid crisis a national public health emergency, authorizing the Department to use emergency authority to address the opioid epidemic. The

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Department plays a critical role in ensuring that opioids are prescribed and dispensed appropriately and according to program policies.[77] HHS developed a five-point strategy to combat the opioid crisis[78] and must continue working toward addressing the problem, adjusting its approach as appropriate. HHS OpDivs should continue to use the tools available in their programs to address the opioid epidemic while being mindful of patients' needs to access appropriate pain management, which may include the use of opioid analgesics.

Although opioid misuse and abuse remains a problem, OIG found some potential improvements in utilization patterns and access to treatment for substance abuse in Medicare Part D, including a decrease in Medicare beneficiaries receiving opioids, an increase in beneficiaries receiving medication-assisted treatment (MAT) for OUD, and an increase in prescriptions for naloxone—a drug that can prevent overdose deaths.[79] Ensuring access to appropriate pain management therapies and combating opioid abuse remains a high priority. CMS and Part D sponsors should implement effective drug management programs for at-risk beneficiaries.

Further, IHS could improve the quality of care for prescribing and dispensing opioids to the AI/AN population by fully utilizing States' prescription drug monitoring programs. A 2019 OIG report[80] identified that IHS hospitals did not fully use the States' prescription drug monitoring programs when prescribing or dispensing opioids at certain IHS hospitals. In addition, the hospitals did not use available data to identify risks in their prescribing and dispensing practices, such as giving patients (1) opioid doses of as high as 500 daily morphine milligram equivalents; and (2) opioids and benzodiazepines at the same time, which puts patients at greater risk of a potentially fatal overdose. Making data-supported decisions and conducting data analysis will be crucial to identifying risks and reducing the occurrence of adverse events. (See TMC 5.)

Additionally, through the FDA, the Department approves new drugs before they are marketed in the United States and takes into account benefits and risks to assure safety and efficacy.[81] FDA also monitors the safety of marketed drugs as new information becomes available. Through this framework, the FDA can encourage the development of abuse-deterrent formulations of opioids that may be less susceptible to abuse; employ tools, including the Risk Evaluation and Mitigation Strategy program, to mitigate risks associated with approved drugs; and pursue measures that include withdrawal from the market when there are serious safety concerns.[82]

The treatment of OUDs is a priority. Only a fraction of the 2.1 million people with OUDs received specialty treatment in 2018 (19.7 percent).[83] It is important for the public to be able to access effective, quality treatments. Research suggests that MAT medications, in combination with counseling and behavioral therapies, can be an effective treatment for OUDs. Three drugs—methadone, buprenorphine, and naltrexone—are approved to treat OUDs. Access to MAT is a priority as patients suffering from an OUD are at risk for withdrawal and relapse and may seek out illicit opioids, such as heroin. As such, the Department must work diligently to ensure access to these medications.[84]

The Department continues to manage and oversee investments to address OUDs. SAMHSA awarded more than $930 million[85] through the State Opioid Response grants to support a comprehensive response to the opioid epidemic and expand access to treatment and recovery support services; HRSA awarded nearly $400 million for community health centers, rural organizations, and academic institutions to establish and expand access to OUD treatment.[86] Although treatment must be prioritized nationally, the Department should ensure that resources are devoted to areas disproportionately affected by the opioid epidemic, including the AI/AN population and rural

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communities. Recognizing the potential danger of abrupt opioid withdrawal and the patient safety imperative of tapering or discontinuing opioids thoughtfully, the Department released a *Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics*.[87]

The Department can also help save lives through enabling people to access medications that reverse the effects of opioids and illicit drugs. Research shows policies that make it easier to access naloxone may be saving lives.[88] HHS is in the process of implementing the *SUPPORT for Patients and Communities Act of 2018* that proposes several strategies to combat the opioid crisis, including reducing improper opioid prescribing and expanding access to prevention, treatment, and recovery services. For example, it requires CMS to recommend ways to lower consumer prices for opioid overdose-reversal medications such as naloxone and requires HHS to establish a grant program to implement best practices regarding treatment for individuals who experience an overdose, including emergency treatment and the use of recovery coaches. (See TMC 1 for more information on program integrity considerations associated with grants.)

Strengthening emergency preparedness and response capabilities

HHS has a lead role in preventing, preparing for, and responding to the adverse health effects of public health emergencies. (See TMC 6 for more information about HHS's role in the Federal Government's emergency preparedness and response efforts.) Communicable diseases, outbreaks, and natural disasters constitute public health emergencies that can severely strain public health and medical infrastructure and lead to serious illness and loss of life. Prior to and during a public health emergency, it is important to have adequate planning (such as preparing for a medical surge) and mechanisms in place to efficiently and rapidly deploy assets and provide relief to those in need of vital health and human services resources in the aftermath of an emergency. Prior OIG work has identified gaps in emergency preparedness and response planning for health care facilities during disasters and pandemics.[89] The Department's continued efforts to improve preparedness and response are important as it is uniquely positioned with the opportunity to continuously assist communities throughout the United States so that they can respond to and deliver health services in the immediate aftermath of natural disasters, as well as support sustained recovery efforts.

Prior OIG work has identified gaps in emergency preparedness and response planning for healthcare facilities during disasters and pandemics.

Additionally, recent outbreaks of communicable diseases (e.g., measles, hepatitis, and Ebola) are an ongoing challenge and demonstrate the need for the Department to rapidly detect, diagnose, and assess these threats. A 2019 OIG report determined whether HHS's response efforts to the 2014 Ebola outbreak were effective and efficient and found that HHS (1) had no strategic framework in place to coordinate global health security at the international or departmental levels before the Ebola outbreak, (2) was not prepared to deploy the resources needed for such a large-scale international response, and (3) did not have in place internal or external communication channels for responding to an international public health emergency.[90] It is important for HHS to have the ability to readily develop, distribute, and administer medical countermeasures (i.e., vaccines, therapeutics, and diagnostics) to

effectively prevent and treat infectious diseases. States and localities should ensure planning and preparedness in areas including medical surge and vaccine and antiviral drug distribution and dispensing.[91]

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Safeguarding the Nation's food supply

An estimated 1 in 6 Americans get sick from contaminated foods each year, and 3,000 die.[92] Individuals with weakened immune systems, such as older and younger populations, may be particularly susceptible to foodborne illnesses. Foodborne illnesses are largely preventable, and the American public relies on FDA, working with partners including the Centers for Disease Control and Prevention (CDC), to ensure that the food we eat is safe.[93] The passage of the *FDA Food Safety Modernization Act* (FSMA) placed renewed emphasis on the importance of preventing foodborne illnesses and FDA has made progress in implementing that statute. FDA has prioritized creating a more effective and efficient food safety system. One means by which it aims to do this is by increasing the role of the States in improving produce safety.[94] Still, with an increasingly global food supply, keeping food safe presents a constant challenge.

The Department must ensure that FDA continues to modernize the food safety system and responds effectively when issues are identified. FDA should use the array of tools at its disposal to protect the American public. It should conduct risk-based inspections of domestic and foreign food facilities within the timeframes required by FSMA, identify instances of failure to comply with good manufacturing practices, and take necessary steps when health risks are identified, including administrative and enforcement actions when warranted.[95] FDA has made organizational changes with the goal of improving incident response through, for example, instituting its Coordinated Outbreak Response and Evaluation Network, and should continue to optimize its ability to protect the public from outbreaks of foodborne illnesses.

Providing adequate oversight of medical device safety and security

FDA is responsible for approving new medical devices that it determines are safe and effective, and assuring that approved products remain safe and effective.[96] As technology advances, FDA performs this task in an increasingly complex environment. Beneficial aspects of innovative medical devices, such as the ability to communicate widely with other devices, may increase the risk of cybersecurity threats. (See TMC 5 for more information on cybersecurity.) FDA has the difficult task of staying at the forefront of emerging technology, amassing the technical knowledge to understand the science that supports advances in medical device function, and anticipating the potential impacts of new technologies. FDA reports that it has undertaken several initiatives to enhance the Agency's approach to medical device safety, and is working closely with patients, providers, and device developers to make sure that it is appropriately balancing risk and benefit.

The *21st Century Cures Act* (the Cures Act) aims to help accelerate medical product development and bring new innovations and advances to patients.[97] Among the expedited product development programs established by the Cures Act is the Breakthrough Devices program. Under that program, manufacturers of medical devices that meet certain criteria may obtain priority review by FDA. For example, a medical device designed to provide more effective treatment or diagnosis of a life-threatening or irreversibly debilitating disease or condition may be eligible for "Breakthrough Device" designation.[98] Recently, FDA granted breakthrough status to an artificial intelligence-enabled medical device intended to diagnose and improve clinical management of patients with Type 2 diabetes with fast-progressing kidney disease.[99]

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The speed at which science and technology are evolving means that the development and regulation of medical devices presents new safety and effectiveness concerns. For example, artificial intelligence-enabled devices that communicate with other medical devices may be subject to cybersecurity risks[100] or interoperability difficulties, which could adversely affect patient safety and medical device performance. (See TMC 5.) One area of challenge for FDA thus will be to review medical device applications as expeditiously as possible while being mindful of factors that could adversely affect the safety and effectiveness of medical devices. (See TMC 2 for HHS's challenges in overseeing evolving technologies in Medicare and Medicaid.)

Post-market surveillance of medical devices continues to be a management challenge for FDA.[101] Each year, the agency receives several hundred thousand reports of medical devices suspected of being associated with death, injury or malfunction. By regulation, these reports must be submitted in a timely manner to FDA.[102] In 2009, OIG reported that manufacturers and medical device user facilities often submitted tardy and incomplete adverse event reports and that FDA failed to employ adverse event reports in a systematic manner to detect and address safety concerns.[103] FDA reports that it is evolving beyond its current passive post-market surveillance system and moving to an active surveillance system that relies on real-world evidence and timely receipt of robust safety information, which it believes will better protect patients and help enable the Devices Program to act quickly with manufacturers and health care providers to make timelier decisions to keep patients safe. A key element of implementing this strategy will be the multi-stakeholder effort to establish the new national system for gathering real world evidence through the National Evaluation System for health Technology (NEST). Implementing a national surveillance system would also not be possible without the FDA's establishment in recent years of a unique device identification (UDI) system, in which medical devices are marked on their labels with a unique code that can be used to track the device through its distribution and use in patients.

5: Harnessing Data To Improve Health and Well-Being of Individuals

CHALLENGE 5

Improving how the Federal Government manages, shares, and secures its data is a priority for both Congress and the Administration.[104] HHS is prioritizing "Leveraging the Power of Data" as one of its six strategic shifts for its *ReImagine HHS* effort.[105] Collectively, these initiatives recognize the significant value of Federal data and the importance of having a coordinated approach to use "data to deliver on mission, serve the public, and steward resources while respecting privacy and confidentiality."[106] Additionally, HHS's authorities and influence that shape how an individual's data are used and protected by other private and public entities are increasingly important in a technology-enriched health and human service delivery system. Failure to modernize HHS data practices will limit the capability of HHS and its OpDivs to fulfill their missions. HHS and its 11 OpDivs and associated programs have made progress in doing so, but challenges remain in how it manages, shares, and secures data.

RELEVANT OPDIVS

All HHS

KEY ELEMENTS

- Expanding HHS's capacity to use data in policy making, program management, and deployment of emerging technologies
- Providing data to HHS partners and promoting the public data access and sharing
- Protecting data from misuse or unlawful disclosure

Expanding HHS's capacity to use data in policy making, program management, and deployment of emerging technologies

Data play a central role in every HHS program or policy mission.[107] HHS operations depend on the effective collection and use of a large amount of sensitive and important data about individuals, health care providers, key public health assets, and other entities and actors, which are vital to improving the health and welfare of individuals in the Nation. The Department and its programs are increasingly digitally oriented and able to generate, receive, and transmit data in large volumes associated with important programmatic functions.

However, having large amounts of data does not mean that the data can be used efficiently and effectively. HHS faces challenges in how it manages and leverages that data across its programs. Although most OpDivs primarily collect data to administer their own programs, the use of data across programs and OpDivs in remains a challenge. Data are often housed within a single OpDiv ("data silo") and not easily shared with other parts of HHS even though OpDiv missions often overlap.[108] These silos may limit the capability of HHS to use data for evidence-based decision making and better manage its programs and OpDivs. Data silos may also impede deployment of emerging technologies, such as machine learning, that have enormous potential to improve the efficiency and effectiveness of the Department. When OpDivs and programs cannot access data from each other, they miss opportunities to improve the effectiveness of programs. For example, OIG recommended that CMS provide its Medicare Drug

Integrity Contractor with centralized access to Medicare Part C encounter data to enable the contractor to more effectively and proactively identify potential fraud, waste, and abuse.[109] Eliminating or reducing data silos within the Department and increasing appropriate access across programs will be an essential step to improving program management and evidence-based decision-making, as well as seeding the ground for HHS to benefit from emerging technologies.

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Improving data governance to enhance program management

One critical step to improving HHS's capacity to utilize its data is the adoption of a better data governance approach. The need to improve data governance is not unique to the Department and is a priority and a requirement for Federal agencies.[110] It is also part of HHS Strategic Plan and the Digital Strategy at HHS.[111] The Department is taking steps to improve its data governance and more effectively use the data it has. Under the *ReImagine HHS* "Leveraging the Power of Data" initiative and implementation of the Foundations for Evidence-Based Policymaking Act of 2018, the Department is developing an enterprise-wide data sharing strategy to increase combined analysis of disparate data sets to achieve better insights.[112] Although progress has been made, the Department's challenge will be to operationalize its plans notwithstanding the continued effect of data silos, restrictions related to the privacy and use of certain data, and legacy technology and data systems that do not easily support data sharing.

HHS must ensure any progress it makes on improving governance of its internally generated data must also apply to data that are generated by external entities but received and managed by the Department. Without quality data that can provide visibility on how its programs are operating, HHS will have limited capabilities to improve its program management. For example, OIG raised concerns about the national Medicaid data set named the Transformed Medicaid Statistical Information System (T-MSIS).[113] CMS made progress by ensuring that all 50 States, the District of Columbia, Puerto Rico, and the U.S. Virgin Islands report data and work with States to improve the quality of data submissions. However, concerns still exist about the completeness and reliability of the T-MSIS data. Most recently, OIG found a national review of opioid prescribing in Medicaid using T-MSIS is not yet possible because not all at-risk beneficiaries and providers can be identified. Because existing T-MSIS data do not allow identification of all at-risk beneficiaries and potentially inappropriate providers, data enhancements are needed to enable a national review of opioid prescribing in Medicaid.[114] Further, limitations of T-MSIS data impede identification of individual beneficiaries for national opioid analysis.[115] Similar data quality and governance challenges exist across other Departmental programs that collect external data from grantees or other organizations.[116]

Building Advanced Capacity To Use Data

Improving how HHS, its programs, and its employees use data is a critical component of the 2018 HHS's Data Strategy. Better use of data may improve evidence-based policy making, improve internal administrative functions, and support the deployment of emerging technologies, all of which are part of the larger Federal and Departmental strategies to promote efficient and appropriate data use.[117]

In certain areas, the Department made progress. For example, in response to OIG work related to improving Departmental oversight of grantees, HHS established the Audit Tracking and Analysis System, a Department-wide source of adverse information from grantee audits and facilitated Department-wide information sharing about grantees with past performance issues.[118] However, HHS struggles to use and

leverage its own data to improve its program management in several areas, such as financial and payment systems information and reporting operations. (See TMC 1.)

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HHS's ability to use new technologies that can make the Department more effective and efficient is dependent on how well data can be gathered and curated from multiple OpDivs. Technologies such as machine learning and artificial intelligence must function on top of large data sets. To effectively deploy those tools, HHS will have to rely on data from across its programs, which will require complex technical coordination among diverse types of data, some of which have technical limitations.[119] The Department is making progress by exploring solutions through several recent pilots, demonstrations, and other limited scope projects.[120] These use cases can help HHS learn how data can be used in a short-time frame and that can serve as quick feedback loop to inform the next pilot or demonstration.

In December 2017, HHS hosted a "Opioid Code-a-Thon" to develop data-driven solutions to combat the opioid epidemic. The Code-a-Thon involved use and analysis of 10 HHS databases from 5 different OpDivs, and more than 70 data sets in total from other Federal agencies, State and local governments, and publicly available data. The competition resulted in the development of new tools to address the opioid crisis.[121] According to HHS, the Code-A-Thon also provided insights into the data it has and what other steps it should take to improve its data governance that might facilitate development of other solutions to the opioid crisis.[122]

The challenge for HHS will be to go from strategies and pilot tests to fully incorporating lessons learned into the Department's operations. There are significant barriers—legal, cultural, and resource limitations—that strategies and pilots alone will not resolve. To overcome these barriers and fully harness data to improve the health and welfare of the Nation, the Department will need to undertake multiyear efforts and implement sustained change management across its OpDivs.

Increasing Data Access and Sharing with HHS Partners and the Public

There is an increasing recognition that Federal agency stakeholders[123] and the public can also use Federal data assets for the public good.[124] Much of HHS's data are publicly available but may not be easy to use or may have other barriers that limit stakeholders' and the public's access or use. Those barriers present a challenge to providing increased access of HHS data that could lead to innovation and improvement in health and welfare. HHS also has significant authority, incentives, and influence to change the way data are shared in the health care system, public health, emergency preparedness and response, medical research, and other sectors that are vital to the Nation. Despite that significant influence, many of these sectors do not easily and regularly share data to the detriment of patients, individuals, and the public.

Expanding and Improving Access to HHS Data

Many HHS external stakeholders rely on effective dissemination of data collected by Departmental programs. However, most public access to HHS data does not benefit from contemporary approaches, such as the use of application programming interfaces (APIs). Although data might be available, they may not be well understood or in easily accessed formats. OpDivs are attempting to expand access to these important assets, but progress has been slow. In January 2018, FDA announced a pilot to provide more

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access to summary portions of the clinical study report for pivotal drug trials establishing the safety and effectiveness of the drug. However, only one drug sponsor agreed to participate in the FDA pilot program.[125] The CMS *Blue Button 2.0* initiative to improve beneficiaries' access to their Medicare information through apps has made progress by adding more app developers to the program, but widespread use by beneficiaries has yet to take off.[126] (See TMC 2 for more information on the challenge of using technology to improve health outcomes for patients.)

In other areas, the Department sustained progress. Through the National Institutes of Health (NIH) initiative *All of Us*, HHS is leading an effort to collect 1 million or more volunteers' medical history, lifestyle information, and genetic information to support advances in medical research. These data will be shared with research partners to advance breakthroughs in precision medicine.[127] To realize the full potential of these data, NIH utilized modern approaches to collect and then disseminate data to its research partners.[128] At CMS, OIG found that almost all the Open Payments program data reported by CMS met requirements. These data help to promote transparency by making available to the public the financial relationships that providers (physicians and teaching hospitals) have with certain other entities (applicable drug manufacturers and group purchasing organizations).[129] Additionally, OIG created a data toolkit that stakeholders, like State Medicaid programs, can use to identify their beneficiaries at high risk of opioid misuse and facilitate intervention to prevent harm.[130] These successes must be replicated across HHS to remove barriers to other HHS program data and allow HHS partners to more effectively use that data.

Making data sharing between health care providers, patients, and payers commonplace

Several OpDivs have authority or influence to shape how data are shared within the industries they regulate, among HHS partners, and with individuals and patients. Most notable is HHS's potential to improve the availability and interoperability of electronic health information. Yet, the health care system and patients have not realized the benefits of modern approaches to improve the appropriate flow of electronic health information. Promoting interoperability is part of the four Secretarial priorities and HHS will need to continue utilizing its significant leverage to expedite progress.[131]

Routine and robust health information exchange between providers remains a challenge. Less than half of physicians using an electronic health record (EHR) to electronically send or receive patient health information.[132] Only 14 percent of physicians electronically send patient health information to behavioral health and long-term-care providers.[133] The factors limiting increased interoperability and exchange are numerous and complicated. Several Departmental initiatives depend on improving the interoperability of electronic health information, including the transition to value-based care and payment. (See TMC 2.) Making real progress so that the health care system and patients can benefit from the improved flow of data will take sustained engagement within HHS, with HHS partners, and with external stakeholders such as organizations that set data standards.

Recently, HHS has taken significant steps using regulatory authorities and its influence to improve and potentially standardize the way in which health information can be accessed, used, and exchanged. In 2019, the Office of the National Coordinator for Health Information Technology (ONC) proposed rules directly related to improving interoperability and helping cement data standards and data exchange mechanisms.

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For example, ONC is incorporating Fast Health Interoperability Resource (FHIR) standards into its health IT certification program. ONC also proposed standardized use of APIs for certified health IT. In a coordinated effort, CMS proposed rules to improve the interoperability of health information at many entities it regulates through the use standard, open APIs.[134] This was a significant step to improving data exchange. CMS is also piloting novel approaches to provide Medicare claims data to providers through the *Data at the Point of Care* initiative.[135]

Challenges with the flow of electronic health information can also impede patient access to their own data. In 2018, only 51 percent of patients were offered access to their data through online patient portals; of those patients who were offered access, only 30 percent viewed their medical record.[136] These challenges related to improving the flow of electronic health information to providers and patients may also affect other Departmental coordinated care initiatives. (See TMC 2.)Protecting data from misuse or unlawful disclosure Managing, using, and sharing data must be complemented by appropriately securing data. External threats to the confidentiality, integrity, and availability of HHS-held data are persistent and growing. Similar to data governance and sharing challenges, several aspects of cybersecurity within the Department are siloed within its OpDivs and programs. As a result, deployment of effective cybersecurity can be highly variable across the Department's OpDivs. Further increasing the challenge is the vital nature of many of the Department's programs, operations, and data. Interruption of these programs caused by a cyberattack may have significant negative effects on the health and welfare of the Nation. Outside of the Department's systems, many of the HHS's partners, grantees, and the health care system at large are subject to an increasing amount of cyber threats. Any doubts the public may have about HHS's ability to protect sensitive, personal health data may hinder the full potential of Federal initiatives that seek to leverage technology to create medical treatments of the future.

Challenges with the flow of electronic health information can also impede patient access to their own data. In 2018, only 51% of patients were offered access to their data through online patient portals and only 30% of of them viewed their medical record.

Improving HHS's cybersecurity posture

The Department has made progress in improving its overall cybersecurity posture, but certain weaknesses persist and pose challenges. Recent OIG work found that the Department's enterprise-wide information security program was not effective but had improved in some areas.[137] Other OIG work that examined eight Departmental OpDivs identified vulnerabilities in configuration management, access control, data input control, and software patching.[138] This work highlights the challenge the Department faces to simultaneously improve the security across OpDivs while also helping provide resources and support so that OpDivs can take action to improve their own cybersecurity. (See TMC 4 for more information about FDA's role regarding cybersecurity of medical devices.)

HHS also faces other data security challenges outside of cyberthreats. For example, HHS has recognized the threat of foreign government action aimed at unduly influencing and capitalizing on medical research

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programs funded and overseen by the Department. HHS's challenge in responding to these threats is the need to protect these programs while also supporting an open, collaborative research approach that is critical to scientific advances.[139] The Department has made progress recognizing the threats, studying the potential impact on its programs, and exploring recommendations to improve its security posture.[140]

Promoting the security and privacy of the health care system

HHS's responsibilities for ensuring cybersecurity also extend to the health care system. The statistics on the impact and persistence of cyberattacks demonstrate the magnitude of the problem facing HHS and the health care industry. HHS reported that in 2016, $6.2 billion was lost in the U.S. health care system due to data breaches and that 4 in 5 U.S.-based physicians have experienced some form of cyberattack.[141] Despite continued calls for action and additional awareness related to improving the health care system's cybersecurity, health care entities remain prime targets for cyberattacks and health care data are reported to be among the most valuable data for cybercriminals. In addition to data and identity theft, cyberthreats can also pose safety risks by causing system outages needed for patient care or exploiting vulnerabilities in the growing number of connected medical devices and other medical equipment involved in direct patient care. OIG found cybersecurity weakness at Medicaid managed care organizations and several State agencies.[142] Additionally, OIG made recommendations on how FDA could integrate cybersecurity issues into its premarket review process for medical devices.[143]

The Department made some progress to bolster cybersecurity in the health care industry. HHS launched the Health Sector Cybersecurity Coordination Center to increase the amount and frequency of cybersecurity information sharing between the Federal Government and the Healthcare and Public Health (HPH) sector.[144] HHS also worked with industry partners to publish a cybersecurity principles and practices document to educate health care entities on cybersecurity threats and practical steps they could take to mitigate risks.[145] ONC and OCR developed a security risk assessment tool designed to help providers identify where health information might be a risk within their organization.[146] FDA entered into an agreement with DHS to encourage greater coordination between the agencies to identify, address, and mitigate cybersecurity vulnerabilities in medical devices.[147] The Department also proposed rules to protect donations of cybersecurity technology within the health care industry to promote increased adoption of cybersecurity. These developments demonstrate HHS's commitment to working across the health care sector to better prepare for and remediate continuously evolving cyber threats.

The Department also plays a significant role in ensuring the privacy of sensitive individual data, such as personal health information, genetic information, and more. Most notably, OCR established and enforces the *Health Insurance Portability and Accountability Act of 1996* (HIPAA) Privacy Rule's requirements. However, the bulk of the Privacy Rule's requirements were established nearly 20 years ago and may not adequately address modern issues related to individual privacy concerns with health information. For example, an individual's electronic health information that is on the patient's personal electronic device and not in the possession of a HIPAA-covered entity or business associate is not subject to the privacy protections of the HIPAA Privacy Rule. At the same time, individual demand to have easy access to their health information where and when they want it is increasing. This demand creates a challenge for HHS to create and promote better access for patients while reconciling the limits of existing privacy protections.

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Patient health information that falls outside of the typical framework covered by the Privacy Rule may be at risk of being misused. The Department's challenge is to keep up with changes in the health care industry and with non-traditional health care entities that may impact patient privacy. The Department has made progress by issuing guidance and frequently asked questions related to mobile apps, use of APIs, and working with the Federal Trade Commission to build a web-based tool for developers of health-related mobile apps.

6: Working Across Government To Provide Better Service to HHS Beneficiaries

CHALLENGE 6

RELEVANT OPDIVS

All HHS

KEY ELEMENTS

- Building and sustaining effective partnerships
- Managing greater integration and efficiency among HHS partners
- Ensuring that HHS and its partners are accountable for ongoing coordination

Big problems require big solutions. HHS faces some of the largest and most complex problems that challenge our Government and the American public. These problems commonly transcend a single HHS program. Often, HHS's mission is only one piece of a larger puzzle, and HHS shares responsibility with multiple entities, including other Federal departments, States, and industry partners. Nearly all HHS programs require strong partnership from multiple entities, within and outside of HHS. This coordination can add complexity to HHS's work but also provides greater gains, marshalling all available resources to improve the Nation's health and well-being.

The potential benefits of effective collaboration are great, both in ensuring program efficiency and providing better service to HHS beneficiaries and the public. HHS and the Administration recognize that complex issues require coordinated solutions and see the Department as a leader in forging these partnerships. The Administration pre-designated HHS as the Quality Service Management Office for grants management across Federal Government in response to its Cross-Agency Priority Goal 5 (Sharing Quality Services).[148] Pending final approval by OMB, HHS will be called upon to provide leadership and best practices to other Federal agencies in the area of grants management. Likewise, HHS responded to the Administration's 2017 directive to reorganize Government[149] to make it more efficient, effective and accountable through its *ReImagine HHS* effort. *ReImagine HHS* outlined several core objectives for the Department, including Optimizing Coordination across HHS. The *ReImagine HHS* initiative also laid out specific shifts in strategy across the Department, several of which highlight the need for greater coordination and information sharing across HHS and with partner agencies and Departments.[150] To achieve these goals and optimize its operations, HHS must prioritize coordination and work to identify opportunities, overcome barriers, and seek accountability and improved outcomes. The need for coordinated responses will only grow in the years to come as health care and other human services become more complex and intertwined with other Federal, State, and private-sector programs. For example, CMS estimates that national health expenditures will grow rapidly during 2020–2027, reaching nearly $6 trillion by 2027.[151] Given that much of this growth is expected to be in the Medicare and Medicaid programs, HHS will continue to lead in managing policy that affects publicly and privately funded health care. Coordination is so integral to success at HHS that it crosses many of the programs discussed in each TMC. Several TMCs highlight the broad and complex nature of HHS's work and the need to consider related issues outside of a single program or mission of a single agency. For example, the quality of care for HHS beneficiaries, described in TMC 3, is affected by not only the availability and quality of health

services but also human services such as child care and health care education. Likewise, delivery of quality care through Medicaid depends on accurate and complete data from States, as referenced in TMC 5.

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Building on HHS coordination efforts

Recent OIG work reveals the importance of effective and collaborative management within HHS and with HHS partners. In some areas, HHS has focused on collaboration and brought substantial gains, such as its extensive work within the Department and with law enforcement to combat opioid misuse and fraud. In other areas, HHS must work urgently to improve its coordination efforts, such as its management of ORR's UAC Program and programs to promote patient safety.

Confronting the opioid crisis

The need for coordinated responses will only grow in the years to come as healthcare and other human services become more complex and intertwined with other Federal, State, and private-sector programs.

Fighting the Nation's opioid epidemic is an example of a collaborative and coordinated activity across many Federal, State, and local agencies. HHS has multiple programs and offices involved in fighting the opioid epidemic: CDC sets opioid equivalent dosage guidelines; CMS gives guidance to providers on prescribing opioids; SAMHSA issues grants for OUD treatment; and OIG investigates and excludes providers who illegally prescribe and distribute opioids. (See TMCs 3 and 4 on HHS's efforts to combat the opioid epidemic.) HHS's external partners in the fight include the Department of Justice's (DOJ's) Criminal Division, the Federal Bureau of Investigation (FBI), the Drug Enforcement Administration (DEA), as well as State and local law enforcement agencies.

This is a collaborative effort for which HHS and its partners have enjoyed some success. For the first time in 30 years, the number of opioid-related deaths is decreasing.[152] In 2018, there was a significant decrease in the number of Part D beneficiaries who were prescribed opioids.[153] These improvements are due in part to better and more available anti-overdose drugs,[154] as well as aggressive law enforcement action to stop bad actors from providing opioids to people addicted to opioids.

A 2019 OIG study found that 36 percent of Medicare Part D beneficiaries in 5 Appalachian-region States received a prescription opioid in 2017; almost 49,000 beneficiaries received high amounts of opioids; and nearly 6,000 beneficiaries were at serious risk of opioid misuse (received extreme amounts of opioids or appeared to be doctor shopping).[155] OIG has worked with HHS, DOJ, and other law enforcement partners to prosecute people who illegally prescribe, dispense, or divert opioids. In October 2018, DOJ, in partnership with OIG, FBI, and DEA, launched the Appalachian Regional Prescription Opioid (ARPO) Strike Force.[156] As part of this Strike Force effort, OIG worked in cooperation with DEA, U.S. Attorneys, the FBI, and State Medicaid Fraud Control Units to investigate prescribing practices of physicians in the Appalachian Region.[157] These investigations have resulted in numerous indictments and arrests of doctors and nurse

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practitioners who were illegally prescribing opioids. In 2019, enforcement actions targeting the Appalachian Region yielded charges against 60 people, including 53 medical professionals, for allegedly illegally prescribing and distributing more than 32 million opioid pills to over 24,000 people.[158] In addition to taking bad providers off the street, the Strike Force team worked with CDC, DOJ, and State public health officials to ensure that patients received access to needed medical care and did not experience interruption of care due to the law enforcement operation.

The UAC Program

One of the most visible examples of HHS program activities requiring coordination and information sharing among multiple agencies is ORR's UAC Program. (See TMC 3 for more information.) HHS is not the only Department with responsibility for children served by the UAC Program. These children usually are referred to ORR by the DHS, Customs and Border Patrol, and transported to ORR-funded facilities by Immigration and Customs Enforcement. Much attention is focused on the lack of coordination between HHS and these DHS programs regarding the identification, transfer, case management, and placement of unaccompanied children, particularly unaccompanied children who were separated from their parents at the border.[159] Without strong and collaborative planning, coordination, and execution, HHS faces challenges in effectively providing care and identifying sponsors for these unaccompanied children. HHS must continue to improve its information gathering and communication practices to ensure that separated children are reunited with their families in a timely manner. Enhanced communication and cooperation with DHS, DOJ, and other Government partners are critical.

Emergency preparedness and response

Although assistance in responding to natural disasters and other public health emergencies is widely recognized as the responsibility of the Federal Emergency Management Agency (FEMA) within DHS and the Department of Housing and Urban Development (HUD), HHS provides important emergency preparedness and response services. (See TMC 4 for more on HHS's emergency preparedness challenges.) It is the lead Federal department responsible for providing medical support and coordination during public health emergencies, such as disease outbreaks.[160] Three OpDivs share this responsibility: Office of the Assistant Secretary for Preparedness and Response (ASPR), CDC, and CMS. ASPR coordinates HHS's response to public health emergencies with other Federal agencies, such as FEMA.[161] ASPR also coordinates and oversees Healthcare Coalitions, which are groups of providers and public health entities that work together to prepare for, respond to, and recover from emergencies and maintains the Strategic National Stockpile for vaccines, medicines, and supplies.[162] CDC conducts research about emergencies, provides critical guidance to providers, Government, and the public.[163] CMS oversees health care facilities participating in Medicare and Medicaid by requiring a set of minimum health and safety standards, including recently updated standards for emergency preparedness.[164, 165]

OIG studies have repeatedly identified the need for improved coordination in emergency preparedness and response, both within and outside the Department. A 2019 OIG report determined whether HHS's response efforts to the 2014 Ebola outbreak were effective and efficient and found that HHS (1) had no strategic framework in place to coordinate global health security at the international or departmental levels before the Ebola outbreak, (2) was not prepared to deploy the resources needed for such a large-scale

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international response, and (3) did not have in place internal or external communication channels for responding to an international public health emergency.[166] Similarly, a 2018 OIG report assessed hospital preparedness for infectious diseases in the years since the 2014 Ebola outbreak, and found that coordination between ASPR, CDC, and CMS was sometimes lacking.[167] Hospital administrators reported that their staff had difficulty interpreting guidance from multiple government entities and understanding their role in serving the public during a crisis.

Patient safety

As described in TMC 3, OIG has conducted extensive work regarding protecting the safety of patients undergoing medical care, including a 2008–2018 series of reports that found alarming rates of patient harm as the result of medical care.[168] HHS's responsibility for making health care safe and avoiding adverse events lies with CMS in overseeing facility compliance with health care standards and with the Agency for Healthcare Research and Quality (AHRQ) in conducting patient safety research and issuing guidance to providers. In these reports, OIG recommended that AHRQ and CMS work more closely together, and work with providers, to identify patient harm and develop technical assistance for the facilities and clinicians providing care. In response, AHRQ and CMS took action together, and with other HHS operating divisions, to develop new quality and safety measures and revise guidance to providers.

Federal Marketplace

Another example of a lack of coordination within HHS and with multiple stakeholders occurred during the roll-out of the Federal Marketplace under the *Patient Protection and Affordable Care Act of 2010*.[169] In a case study released in 2016, OIG found poor coordination and communication between the HHS Office of the Secretary (OS) and CMS contributed to the failed launch of the Federal Marketplace website HealthCare.gov.[170] The website project was transferred early in its development from a division within OS to CMS, and the transfer occurred without proper planning and coordination or a clear handoff of leadership. As the project progressed, CMS officials failed to adequately convey to OS that they were encountering deep and widespread problems with the policy, technology, and contracts associated with the website build.

As a result, the Department did not intervene and continued to plan for a website release date and functionality that CMS could not effectively meet. The website could not accommodate the volume of traffic it received and was plagued by performance problems in the first months of its operation. The OIG report identified lessons learned from this project and core management principles to apply to all Government programs, technological or otherwise: clear leadership; effective communication; willingness to adjust; and accountability for performance and meeting objectives. Attention to these areas helped CMS recover from the failed launch, develop a functioning system, and salvage the first open enrollment period. Better collaboration allowed CMS to leverage Departmental expertise and other resources, identify and address problems more quickly, make informed decisions, and provide clearer direction to the public. Going forward, CMS will continue to need close coordination with other Federal agencies and with States to ensure that marketplaces operate in accordance with requirements and meet emerging challenges.

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Indian Health Service

OIG found similar themes in a 2019 case study of the IHS closure and reopening of the Rosebud Hospital Emergency Department (ED), an IHS-run facility in South Dakota.[171] IHS has many partners in providing health care to AI/AN communities, including CMS (requiring that hospitals maintain basic standards), the AI/AN tribes, and the surrounding (often rural) communities. (See TMC 3 for more information on quality standards.) CMS found Rosebud Hospital was not in compliance with its ED standards, and CMS planned to terminate the hospital's certification to receive Medicare and Medicaid reimbursements. The hospital was unable to bring its ED operations back into compliance, so IHS closed the ED temporarily. The closure proved highly problematic for other hospitals in the area, in that IHS did not adequately notify them of the closure, and the hospitals were ill-prepared to receive Rosebud Hospital's emergency patients. After failed attempts to resolve the issues, IHS entered into a Systems Improvement Agreement with CMS and sought additional resources and support from the Department, including the Health Resources and Services Administration (HRSA). The Rosebud ED reopened following these collaborative efforts but has continued to struggle in maintaining compliance with CMS standards. The success of rural IHS services will depend on ongoing collaboration within and outside HHS, including Federal departments and agencies responsible for AI/AN programs, such as the Bureau of Indian Affairs in the Department of the Interior. A 2017 report by the Council of the Inspectors General on Integrity and Efficiency outlined management deficiencies that Inspectors General from HHS, Interior, and other Departments found in AI/AN programs, some of which were similar to Rosebud's problems with staffing and infrastructure.[172] (See TMC 3 for more on concerns regarding quality of care at IHS facilities.)

Improving coordination in ongoing and future multi-agency efforts

HHS cannot accomplish its mission to enhance and protect the health and well-being of all Americans without strong partnerships and improved coordination. As HHS continues to find solutions to the Department's many challenges, it should draw on its prior accomplishments and failures in coordinating complex, multi-agency projects and develop a roadmap for success. In developing this roadmap, HHS should focus on three key areas: (1) sustaining effective partnerships, (2) managing and planning for greater integration and efficiency among its partners, and (3) ensuring that all partners are accountable for ongoing coordination and information sharing.

To fully assess these areas, HHS must address some difficult questions: What information does HHS need from its partners? How do all entities develop a common plan and communicate effectively? What barriers to collaboration exist, including competing interests and practical issues such as IT compatibility? Which agency is responsible for which part, and how do agencies hold themselves and each other accountable?

After developing this path, HHS should aspire to leverage effective coordination to address problems and reach for new, ambitious goals, such as raising standards for health and well-being, improving holistic outcomes for beneficiaries served by multiple programs, and developing more effective preventive care and other health management programs. HHS recognizes the need for coordination and higher shared goals. Such goals are achievable and would allow HHS to best serve its mission and the American public.

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Department's Response to the Office of Inspector General

THE DEPUTY SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

To: Joanne Chiedi, Acting Inspector General

From: Eric D. Hargan, Deputy Secretary

Subject: FY 2019 Department's Response to the OIG Top Management and Performance Challenges

On behalf of the Department of Health and Human Services (HHS), thank you for the Office of Inspector General's (OIG) annual report identifying the top management and performance challenges facing the Department. The audits and investigations conducted by OIG during this past year strengthen the Department's efforts to ensure responsible stewardship of scarce taxpayer resources in the execution of HHS's mission.

The HHS mission is dynamic and far-reaching, and the evolving challenges are wide-ranging and complex. Senior leadership continues to appreciate OIG's independent perspective on HHS performance challenges and shares this valuable insight throughout the Department. Leadership at every level evaluates the risks and works diligently to prioritize resources and oversight efforts.

We are committed to addressing these challenges and adjusting to the evolving operating environment.

/Eric D. Hargan/

Eric D. Hargan
Deputy Secretary
November 13, 2019

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