

RECENT GUIDANCE FOR COMPLIANCE PROFESSIONALS: FROM DOJ TO OIG TO CMS

**Health Ethics Trust
Certification Course
February 2021**

Agenda

1. Compliance Guidance

- Federal Sentencing Guidelines
- Office of Inspector General (OIG)
 - Compliance Guidance
- Department of Justice (DOJ)
 - A Brief Look at Prior DOJ Guidance
 - A Brief Look at the 2019 Changes
 - 2020 Changes

3. Department of Justice

- FY 2020 FCA Recoveries
- Inability-to-Pay Memo
- Civil Division 2021 Enforcement Priorities
- Open Payments Program



Agenda

4. Office of Inspector General (OIG) Hot Topics

- **Advisory Opinions - General**
- **2020 OIG Advisory Opinions**
- **Special Fraud Alert: Speaker Program**
- **Certain OIG Work Plan Updates**
- **COVID Frequently Asked Questions (FAQs)**

6. HHS/CMS Hot Topics

- ❑ **HHS Advisory Opinion/Rules on the Use of Sub-regulatory Guidance**
- ❑ **HHS FCA Working Group**
- ❑ **Certain Physician Fee Schedule Changes**



Compliance Guidance

Federal Sentencing
Guidelines

Office of Inspector General

Department of Justice

**Compliance
Guidance**

Federal Sentencing Guidelines

Federal Sentencing Guidelines

SENTENCING TABLE
(in months of imprisonment)

Offense Level	Criminal History Category (Criminal History Points)						
	I (0 or 1)	II (2 or 3)	III (4, 5, 6)	IV (7, 8, 9)	V (10, 11, 12)	VI (13 or more)	
Zone A	1	0-6	0-6	0-6	0-6	0-6	
	2	0-6	0-6	0-6	0-6	1-7	
	3	0-6	0-6	0-6	0-6	2-8	
	4	0-6	0-6	0-6	2-8	4-10	6-12
	5	0-6	0-6	1-7	4-10	6-12	9-15
	6	0-6	1-7	2-8	6-12	9-15	12-18
	7	0-6	2-8	4-10	8-14	12-18	15-21
	8	0-6	4-10	6-12	10-16	15-21	18-24
Zone B	9	4-10	6-12	8-14	12-18	18-24	21-27
	10	6-12	8-14	10-16	15-21	21-27	24-30
	11	8-14	10-16	12-18	18-24	24-30	27-33
Zone C	12	10-16	12-18	15-21	21-27	27-33	30-37
	13	12-18	15-21	18-24	24-30	30-37	33-41
Zone D	14	15-21	18-24	21-27	27-33	33-41	37-46
	15	18-24	21-27	24-30	30-37	37-46	41-51
	16	21-27	24-30	27-33	33-41	41-51	46-57
	17	24-30	27-33	30-37	37-46	46-57	51-63
	18	27-33	30-37	33-41	41-51	51-63	57-71
	19	30-37	33-41	37-46	46-57	57-71	63-78
	20	33-41	37-46	41-51	51-63	63-78	70-87
	21	37-46	41-51	46-57	57-71	70-87	77-96
	22	41-51	46-57	51-63	63-78	77-96	84-105
	23	46-57	51-63	57-71	70-87	84-105	92-115
	24	51-63	57-71	63-78	77-96	92-115	100-125
	25	57-71	63-78	70-87	84-105	100-125	110-137
	26	63-78	70-87	78-97	92-115	110-137	120-150
	27	70-87	78-97	87-108	100-125	120-150	130-162
	28	78-97	87-108	97-121	110-137	130-162	140-175
	29	87-108	97-121	108-135	121-151	140-175	151-188
	30	97-121	108-135	121-151	135-168	151-188	168-210
	31	108-135	121-151	135-168	151-188	168-210	188-235
	32	121-151	135-168	151-188	168-210	188-235	210-262
	33	135-168	151-188	168-210	188-235	210-262	235-293
34	151-188	168-210	188-235	210-262	235-293	262-327	
35	168-210	188-235	210-262	235-293	262-327	292-365	
36	188-235	210-262	235-293	262-327	292-365	324-405	
37	210-262	235-293	262-327	292-365	324-405	360-life	
38	235-293	262-327	292-365	324-405	360-life	360-life	
39	262-327	292-365	324-405	360-life	360-life	360-life	
40	292-365	324-405	360-life	360-life	360-life	360-life	
41	324-405	360-life	360-life	360-life	360-life	360-life	
42	360-life	360-life	360-life	360-life	360-life	360-life	
43	life	life	life	life	life	life	



Federal Sentencing Guidelines

- **8B2.1.** (a) To have an effective compliance and ethics program, for purposes of subsection (f) of §8C2.5 (Culpability Score) and subsection (b)(1) of §8D1.4 (Recommended Conditions of Probation - Organizations), an organization shall—
 - (1) exercise due diligence to prevent and detect criminal conduct; and
 - (2) otherwise promote an organizational culture that encourages ethical conduct and a commitment to compliance with the law.

- Such compliance and ethics program shall be reasonably designed, implemented, and enforced so that the program is generally effective in preventing and detecting criminal conduct. The failure to prevent or detect the instant offense does not necessarily mean that the program is not generally effective in preventing and detecting criminal conduct.

**Compliance
Guidance**

**Office of
Inspector
General**

OIG Compliance Guidance Documents

- 09-30-2008 Supplemental Compliance Program Guidance for Nursing Facilities (73 Fed. Reg. 56832; September 30, 2008) Compliance Program Guidance for Nursing Facilities (65 Fed. Reg. 14289; March 16, 2000)
- 01-31-2005 Supplemental Compliance Program Guidance for Hospitals (70 Fed. Reg. 4858; January 31, 2005) Compliance Program Guidance for Hospitals (63 Fed. Reg. 8987; February 23, 1998)
- 05-05-2003 Compliance Program Guidance for Pharmaceutical Manufacturers (68 Fed. Reg. 23731; May 5, 2003)
- 03-24-2003 Compliance Program Guidance for Ambulance Suppliers (68 Fed. Reg. 14245; March 24, 2003)
- 10-05-2000 Compliance Program Guidance for Individual and Small Group Physician Practices (65 Fed. Reg. 59434; October 5, 2000)

OIG Compliance Guidance Documents

- 03-16-2000 Compliance Program Guidance for Nursing Facilities (65 Fed. Reg. 14289; March 16, 2000)
Supplemental Compliance Program Guidance for Nursing Facilities (73 Fed. Reg. 56832; September 30, 2008)
- 10-05-1999 Compliance Program Guidance for Hospices (64 Fed. Reg. 54031; October 5, 1999)
- 07-06-1999 Compliance Program Guidance for the Durable Medical Equipment, Prosthetics, Orthotics, and Supply Industry (64 Fed. Reg. 36368; July 6, 1999)
- 12-18-1998 Compliance Program Guidance for Third-Party Medical Billing Companies (63 Fed. Reg. 70138; December 18, 1998)
- 08-24-1998 Compliance Program Guidance for Clinical Laboratories (63 Fed. Reg. 45076; August 24, 1998)
- 08-07-1998 Compliance Program Guidance for Home Health Agencies (63 Fed. Reg. 42410; August 7, 1998) IG Remarks

**Compliance
Guidance**

**Department of
Justice**

A Brief Look at Prior DOJ Guidance

- 2017 – DOJ Fraud Section publishes Evaluation of Corporate Compliance Programs (ECCP) containing import topics and sample questions it uses when evaluating the effectiveness of corporate compliance programs
- DOJ’s “Principles of Federal Prosecution of Business Organizations” include “Filip Factors”
 - One factor is the existence and effectiveness of the corporation’s pre-existing compliance program as well as remedial efforts to implement an effective corporate compliance program or to improve an existing one.



A Brief Look at Prior DOJ Guidance

- 11 Sections:
 1. Analysis and Remediation of Underlying Conduct
 2. Senior and Middle Management
 3. Autonomy and Resources
 4. Policies and Procedures
 5. Risk Assessment
 6. Training and Communications
 7. Confidential Reporting and Investigation
 8. Incentives and Disciplinary Measures
 9. Continuous Improvement, Periodic Testing and Review
 10. Third Party Management
 11. Mergers & Acquisitions



A Brief Look at the 2019 Changes

- Expands DOJ Guidance to beyond the Fraud Section to DOJ's entire criminal division
- Focuses on 3 areas of corporate compliance:
 - Risk assessments – CCP must be proportionate to identified risks
 - Culture of compliance - Entities must demonstrate financial, practical and philosophical support for compliance
 - Continuous compliance program improvement – Entities should continually review, reassess and improve their CCP
- Effect on False Claims Act (FCA) Guidance



A Brief Look at the 2019 Changes

- There are 3 Fundamental Questions prosecutors must ask when evaluating the effectiveness of a Corporate Compliance Program (CCP):
 - (1) Is the compliance program well designed?
 - (2) Is the compliance program being implemented effectively?
 - (3) Does the compliance program work in practice?



The 2020 Changes

□ Is the program being implemented effectively?



□ Is the program adequately resourced and empowered to function effectively?

The 2020 Changes

- Some important questions that will be asked:
 - Why did the entity set up the program the way it did and has it evolved over time?
 - Are the risk assessments “snapshots” of the entity or based on continuous access to operational data which are periodically reviewed?
 - Have these periodic reviews resulted in updates to policies, procedures and controls?
 - Do the assessments incorporate “lessons learned”?
 - Are the entity’s policies and procedures in a searchable format?
 - Does the entity use technology for measuring the reporting and tracking of compliance hotline calls and other compliance complaints?
 - Is there an evaluation of training effectiveness and can employees raise questions?
 - Are third parties being used and why?
Is there oversight of third parties?



Additional Compliance Guidance

- Corporate Integrity Agreements
 - E.g., Novartis
- Government Take-Downs
 - E.g., “Operation Rubber Stamp”
 - \$4.5 billion kickback scheme involving telemedicine & marketing schemes
- FIFA Bribery Scheme & Deferred Prosecution Agreement (DPA)
 - “breathtaking effort”
 - “Immediately took a cooperative tack”
 - “Model” compliance behavior
- DOJ Antitrust Division looking for “Gold Standard Compliance Program”
 - Strength of compliance program could lead to DPAs
 - Such a program has not yet been found



**Department
of
Justice
“Hot
Topics”**

**FY 2020
False Claims Act (FCA) Recoveries**

Inability-to-Pay Memo

**Civil Division 2021 Enforcement
Priorities**

Open Payments Program

DOJ 2020 FCA Recoveries: Overview

FY	NEW MATTERS°		SETTLEMENTS AND JUDGMENTS ¹					RELATOR SHARE AWARDS ²		
	NON QUI TAM	QUI TAM	NON ³ QUI TAM	QUI TAM			TOTAL QUI TAM AND NON QUI TAM	WHERE U.S. INTERVENED OR OTHERWISE PURSUED	WHERE U.S. DECLINED	TOTAL
			TOTAL	WHERE U.S. INTERVENED OR OTHERWISE PURSUED	WHERE U.S. DECLINED	TOTAL				
2006	70	385	1,712,459,257	1,491,105,499	22,711,363	1,513,816,862	3,226,276,119	219,976,072	5,647,836	225,623,908
2007	129	365	564,826,844	1,251,726,955	160,246,894	1,411,973,849	1,976,800,693	194,463,212	4,616,899	199,080,111
2008	160	379	312,193,480	1,103,918,516	12,678,936	1,116,597,452	1,428,790,932	208,432,587	2,997,615	211,430,202
2009	133	433	470,685,686	1,964,005,251	33,776,480	1,997,781,730	2,468,467,417	249,567,135	9,684,147	259,251,282
2010	143	576	641,956,368	2,279,055,248	109,778,613	2,388,833,862	3,030,790,230	379,518,436	30,915,991	410,434,427
2011	125	634	241,365,995	2,656,802,414	173,888,703	2,830,691,117	3,072,057,112	525,035,022	49,041,606	574,076,628
2012	146	655	1,608,112,862	3,305,495,169	90,248,343	3,395,743,512	5,003,856,374	424,922,456	24,861,743	449,784,199
2013	101	757	188,376,772	2,797,819,362	200,298,056	2,998,117,418	3,186,494,190	509,210,518	50,123,937	559,334,455
2014	101	717	1,676,608,226	4,390,062,989	90,378,451	4,480,441,440	6,157,049,665	698,148,606	17,388,000	715,536,607
2015	117	640	738,442,487	1,898,041,298	516,735,695	2,414,776,993	3,153,219,480	344,293,369	138,977,377	483,270,746
2016	151	708	1,929,502,680	2,925,761,886	108,298,069	3,034,059,956	4,963,562,635	524,323,092	29,658,600	553,981,692
2017	148	681	280,997,308	2,547,523,870	602,682,052	3,150,205,922	3,431,203,229	402,226,569	135,360,010	537,586,579
2018	124	648	767,115,453	2,002,311,672	135,228,037	2,137,539,709	2,904,655,162	304,353,498	37,505,357	341,858,856
2019	148	638	844,282,697	1,944,200,113	295,029,620	2,239,229,732	3,083,512,430	290,889,677	74,734,067	365,623,744
2020	250	672	545,330,030	1,493,082,692	193,042,132	1,686,124,824	2,231,454,855	258,458,873	50,957,253	309,416,126

DOJ 2020 FCA Recoveries HHS

FY	NEW MATTERS ^o		SETTLEMENTS AND JUDGMENTS ¹					RELATOR SHARE AWARDS ²		
	NON QUI TAM	QUI TAM	NON ³ QUI TAM	QUI TAM			TOTAL QUI TAM AND NON QUI TAM	WHERE U.S. INTERVENED OR OTHERWISE PURSUED	WHERE U.S. DECLINED	TOTAL
			TOTAL	WHERE U.S. INTERVENED OR OTHERWISE PURSUED	WHERE U.S. DECLINED	TOTAL				
2006	18	216	1,050,520,714	1,227,114,221	16,229,540	1,243,343,761	2,293,864,475	163,167,984	3,921,996	167,089,981
2007	25	199	465,052,993	929,615,846	152,456,640	1,082,072,486	1,547,125,480	157,860,623	2,497,177	160,357,799
2008	60	231	162,972,022	1,005,797,375	6,852,571	1,012,649,946	1,175,621,969	192,433,605	1,522,164	193,955,770
2009	35	279	240,061,424	1,368,411,522	30,283,452	1,398,694,974	1,638,756,398	155,440,550	8,669,822	164,110,372
2010	42	385	546,963,732	1,955,805,336	16,366,232	1,972,171,568	2,519,135,301	335,084,132	4,639,804	339,723,936
2011	38	417	178,287,545	2,183,142,674	88,291,393	2,271,434,067	2,449,721,612	446,890,505	24,055,563	470,946,068
2012	26	417	557,273,967	2,510,255,899	37,838,668	2,548,094,567	3,105,368,534	281,818,575	10,598,793	292,417,368
2013	27	504	61,354,329	2,554,768,951	119,260,369	2,674,029,320	2,735,383,649	471,187,353	28,526,451	499,713,804
2014	32	471	88,054,490	2,281,424,137	75,322,326	2,356,746,462	2,444,800,952	384,850,880	13,397,186	398,248,066
2015	26	426	160,758,915	1,492,103,005	476,983,065	1,969,086,070	2,129,844,985	272,916,832	133,240,640	406,157,471
2016	71	504	97,354,415	2,552,354,452	75,145,688	2,627,500,141	2,724,854,556	464,035,400	20,481,847	484,517,247
2017	55	495	32,627,357	1,668,286,326	446,222,506	2,114,508,832	2,147,136,189	293,218,456	123,637,553	416,856,009
2018	60	447	568,069,015	1,869,893,723	97,390,606	1,967,284,329	2,535,353,343	279,232,883	27,091,647	306,324,530
2019	57	450	695,838,735	1,653,431,829	273,861,598	1,927,293,427	2,623,132,161	231,894,034	68,633,815	300,527,849
2020	117	456	400,572,626	1,279,826,331	179,271,783	1,459,098,113	1,859,670,739	213,946,531	47,786,925	261,733,456



DOJ 2020 FCA Recoveries HHS



FY	NEW MATTERS ^o		SETTLEMENTS AND JUDGMENTS ¹					RELATOR SHARE AWARDS ²		
	NON QUI TAM	QUI TAM	NON ³ QUI TAM	QUI TAM			TOTAL QUI TAM AND NON QUI TAM	WHERE U.S. INTERVENED OR OTHERWISE PURSUED	WHERE U.S. DECLINED	TOTAL
			TOTAL	WHERE U.S. INTERVENED OR OTHERWISE PURSUED	WHERE U.S. DECLINED	TOTAL				
TOTAL	1,199	8,541	7,882,140,113	33,338,924,092	2,154,021,731	35,492,945,824	43,375,085,937	5,454,106,615	532,510,661	5,986,617,277

Available at: <https://www.justice.gov/opa/press-release/file/1354316/download>

DOJ Civil Division Inability-to-Pay Memo



U.S. Department of Justice


Civil Division

Office of the Assistant Attorney General

Washington, D.C. 20530

September 4, 2020

MEMORANDUM FOR ALL CIVIL DIVISION EMPLOYEES

FROM: ETHAN P. DAVIS 
ACTING ASSISTANT ATTORNEY GENERAL
CIVIL DIVISION

SUBJECT: Assessing an Entity's Assertion of an Inability to Pay

The Civil Division brings civil claims on behalf of the United States that provide for the recovery of money or property, including damages and penalties. Although the Division may litigate these claims to final judgment, the Division also may agree to resolve them, either before or after judgment is entered, through settlement. In seeking to resolve a claim for money, a party may assert that it is unable to satisfy the payment sought by the Division. This memorandum provides guidance and an analytical framework for the Division to assess an assertion of an inability to pay an otherwise appropriate amount to resolve potential civil liability.¹

I. General Policy Regarding Inability to Pay

The Assistant Attorney General is authorized to compromise claims for money when any entity, including an individual, corporation, limited liability company, partnership, sole proprietorship, or estate, offers the maximum it has the ability to pay. *See* 28 C.F.R.

DOJ Civil Division Enforcement Priorities

Acting Assistant Attorney General Brian M. Boynton February 17, 2021

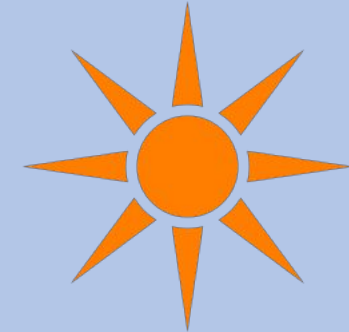
- Pandemic –Related Fraud
- Opioids
- Fraud Targeting Seniors
- Electronic Health Records
- Telehealth
- Cybersecurity



Open Payments Program

□ Medtronic USA, Inc. (Oct 2020)

- ✓ \$9.2 million settlement
- ✓ Allegations include kickbacks to neurosurgeon (\$8.1 million) and Open Payments Program violations (\$1.11 million)
- ✓ Carnival Brazilian Grill



The Sunshine Act

□ Charlene Keller Fullmer (Feb 2021)

- Reportedly stated that Open Payments Program violations may be included in global settlements and that DOJ may make more proactive use of Open Payments data

A screenshot of the Open Payments (Sunshine Act) website. The page title is "Open Payments (Sunshine Act)" with a sub-link "Physician Switch User Type". The navigation bar includes "Home", "Review and Dispute" (with sub-links "Review", "Affirm", "Dispute"), "My Profile" (with sub-links "Account", "Roles", "Nominations"), and "Help". The main content area is titled "Review and Dispute Overview" and contains a message: "There are no payments or other transfers of value or ownership or investment interests reported for you or your family members." Below this, it says "Register for the Open Payments listserv so that you may receive email updates about the program including future review and dispute periods." On the right side, there are two yellow buttons: "Access the User Guide" and "Need help with Contact Us".

Office of Inspector General “Hot Topics”

Advisory Opinions

2020 Advisory Opinions

Special Fraud Alert: Speaker Programs

AKS Final Rule PBMs

Certain 2021 OIG Work Plan Additions

OIG COVID FAQs



OIG's Advisory Opinions

“In accordance with section 1128D(b) of the Social Security Act (42 U.S.C. 1320a-7d(b)) and 42 CFR part 1008, OIG issues advisory opinions about the application of OIG's fraud and abuse authorities to the requesting party's existing or proposed business arrangement. As required by the statute, these advisory opinions are being made available to the public through this OIG Web site.

One purpose of the advisory opinion process is to provide meaningful advice on the application of the anti-kickback statute and other OIG sanction statutes in specific factual situations. Please note, however, that advisory opinions are binding and may legally be relied upon only by the requestor. Since each opinion will apply legal standards to a set of facts involving certain known persons who provide specific statements about key factual issues, no third parties are bound nor may they legally rely on these advisory opinions.”

<https://oig.hhs.gov/compliance/advisory-opinions/index.asp>

OIG 2020 Advisory Opinions



- AO 20-01 (01-13-2020) regarding a hospital's provision of discounted training to a specified fire department's personnel at the hospital's facility

- AO 20-02 (01-22-2020) regarding financial assistance for travel, lodging, and other expenses provided by a pharmaceutical manufacturer to certain patients prescribed the manufacturer's drug

- AO 20-03 (07-01-2020) regarding an arrangement under which a discount medical plan organization ("DMPO") pays chiropractors and chiropractic clinics a fee for each new DMPO member referred by the chiropractor or chiropractic clinic

- AO 20-04 (07-24-2020) regarding a charitable organization's proposal to purchase or receive donations of unpaid medical debt owed by qualifying patients from certain types of health care providers and then forgive that debt

- AO 20-05 (09-23-2020) regarding a pharmaceutical manufacturer's proposal to provide cost-sharing assistance directly to Medicare beneficiaries who are prescribed either of two formulations of its drug

OIG 2020 Advisory Opinions



- AO 20-06 (12-23-2020) regarding a management company's provision of below fair market value Medicaid enrollment application assistance services to certain individuals and affiliated skilled nursing facilities' payments for those services in particular circumstances regarding a hospital's provision of discounted training to a specified fire department's personnel at the hospital's facility
- AO 20-07 (12-28-2020) regarding a web-based platform where health care facilities and clinicians would, in particular circumstances, remit to patients and the patients' payors a portion of the claims for certain services for which payment may be made by the Medicare program as a secondary payor
- AO 20-08 (12-30-2020) regarding a federally qualified health center's proposal to offer gift cards to incentivize certain pediatric patients to attend rescheduled preventive and early intervention care appointments
- AO 20-09 (12-32-2020) regarding a program where a pharmaceutical manufacturer provides financial assistance for travel, lodging, and other expenses to certain patients prescribed the manufacturer's drug

Special Fraud Alert: Speaker Programs



DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201



Special Fraud Alert: Speaker Programs

November 16, 2020

I. Introduction

This Special Fraud Alert highlights the fraud and abuse risks associated with the offer, payment, solicitation, or receipt of remuneration relating to speaker programs by pharmaceutical and medical device companies. For purposes of this Special Fraud Alert, speaker programs are generally defined as company-sponsored events at which a physician or other health care professional (collectively, “HCP”) makes a speech or presentation to other HCPs about a drug or device product or a disease state on behalf of the company. The company generally pays the speaker HCP an honorarium, and often pays remuneration (for example, free meals) to the attendees. In the last three years, drug and device companies have reported paying nearly \$2 billion to HCPs for speaker-related services.¹

The Office of Inspector General (OIG) and Department of Justice (DOJ) have investigated and resolved numerous fraud cases involving allegations that remuneration offered and paid in connection with speaker programs violated the anti-kickback statute. The Federal government has pursued civil and criminal cases against companies and

OIG Discount Safe Harbor Changes

- November 30, 2020 Final Rule

- Amends Discount Safe Harbor to eliminate protection for drug discounts and rebates offered by pharmaceutical manufacturers to pharmacy benefit managers (PBMs), Medicaid MCOs, and Medicare Part D sponsors

- Creates 2 new safe harbors:
 - Point-of Sale Safe Harbor
 - PBM Service Fees Safe Harbor

Certain OIG Work Plan Items

February 2021	Centers for Medicare and Medicaid Services	Audits of Medicare Part B Laboratory Services During the COVID-19 Pandemic	Office of Audit Services	W-00-21-35867
February 2021	Centers for Medicare & Medicaid Services	Use of Telehealth to Provide Behavioral Health Services in Medicaid Managed Care	Office of Evaluation and Inspections	OEI-02-19-00400; OEI-02-19-00401; OEI-02-19-00402
February 2021	Centers for Medicare and Medicaid Services	Audit of Home Health Services Provided as Telehealth During the COVID-19 Public Health Emergency	Office of Audit Services	W-00-21-35864
January 2021	ASA	Audit of HHS Sole Source Contracts Awarded for COVID-19 Testing	Office of Audit Services	W-00-21-59453
January 2021	OS	Hospital Experiences Responding to the COVID-19 Pandemic: February 2021 Pulse Surveys	Office of Evaluation and Inspections	OEI-09-21-00140

OIG COVID FAQs

FAQs–Application of OIG's Administrative Enforcement Authorities to Arrangements Directly Connected to the Coronavirus Disease 2019 (COVID-19) Public Health Emergency

Last Updated: 02-17-2021

The Office of Inspector General (OIG) recognizes that, in the current public health emergency resulting from the outbreak of the COVID-19, the health care industry must focus on delivering needed patient care.¹ As part of OIG's mission to promote economy, efficiency, and effectiveness in HHS programs, we are committed to protecting patients by ensuring that health care providers have the regulatory flexibility necessary to adequately respond to COVID-19 concerns. Therefore, OIG is accepting inquiries from the health care community regarding the application of OIG's administrative enforcement authorities, including the Federal anti-kickback statute and civil monetary penalty (CMP) provision prohibiting inducements to beneficiaries (Beneficiary Inducements CMP).² If you have a question regarding how OIG would view an arrangement that is directly connected to the public health emergency and implicates these authorities, please submit your question to OIGComplianceSuggestions@oig.hhs.gov. In your submission, please provide sufficient facts to allow for an understanding of the key parties and terms of the arrangement at

HHS & CMS “Hot Topics”

HHS Rule Restricting Use of
Sub-Regulatory Guidance

HHS FCA Working Group

Certain CMS Rule Changes

HHS: Use of Sub-Regulatory Guidance



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Office of the General Counsel
Washington, D.C. 20201

ADVISORY OPINION 20-05 ON IMPLEMENTING *ALLINA* DECEMBER 3, 2020

The Office of the General Counsel (“OGC”) has received questions regarding the steps the Department of Health and Human Services (“HHS” or “the Department”) is taking to comply with the Supreme Court’s decision in *Azar v. Allina Health Services*, 139 S. Ct. 1804 (2019) that the Department must use notice-and-comment rulemaking in certain circumstances where the Administrative Procedure Act (“APA”) does not require such rulemaking. In this Advisory Opinion, OGC clarifies what the public can expect the Center for Medicare to do in order to satisfy *Allina*’s requirements regarding notice-and-comment rulemaking.

This advisory opinion sets forth the current views of the Office of the General Counsel.¹ It is not a final agency action or a final order. Nor does it bind HHS or the federal courts. It does not have the force or effect of law.

I. Meaning of “Substantive Legal Standard”

The Supreme Court in *Allina* held that under Social Security Act Section 1871, any Medicare issuance that establishes or changes a “substantive legal standard” governing the scope of benefits, payment for services, eligibility of individuals to receive benefits, or eligibility of individuals, entities, or organizations to furnish services, must go through notice-and-comment rulemaking. *See also* Social Security Act § 1871(a)(2). The Court declined to define the term “substantive legal standard,” other than to conclude it is not coterminous with the APA term

HHS FCA Working Group

FOR IMMEDIATE RELEASE

December 4, 2020

Contact: HHS Press Office

202-690-6343

media@hhs.gov

HHS Announces False Claims Act Working Group to Enhance Efforts to Combat Fraud and Focus Resources on Bad Actors

Today, the Department of Health and Human Services (HHS) announced the creation of a False Claims Act Working Group (Working Group) that enhances its partnership with the Department of Justice (DOJ) and the HHS Office of Inspector General (OIG) to combat fraud and abuse by identifying and focusing resources on those who seek to defraud the American taxpayers. HHS regulates over a third of the United States economy. In 2020, HHS provided over \$1.5 trillion in grants and other payments to public and private recipients, including for healthcare items and services. In addition, HHS is one of the largest government contractors, paying over \$170 billion in 2020 to thousands of contractors. In combating COVID-19, HHS has administered unprecedented levels of taxpayer support for private individuals and organizations.

“Fraud on the federal government is not a victimless crime. Every dollar that goes to fraudsters is a dollar not being used for the important work that HHS programs do for the American people, including

Certain Provisions in CMS 2021 Final Physician Fee Schedule Rule

□ Non-Physician Practitioners

- Pharmacists may provide services on an incident-to basis
- NPPs may supervise diagnostic tests
- Physicians and NPPs may review and verify medical record notes



□ Telehealth

- Until 12/31/2021 or the end of the PHE, direct supervision can be provided using real-time, interactive audio-visual technology
- Until 12/31/2021, certain audio-only assessments are permitted
- Nursing facility subsequent care visits were reduced from once every 30 days to once every 14 days
- New permanent telehealth services



Certain Provisions in CMS 2021 Final Physician Fee Schedule Rule

□ E/M Codes

- Coding based solely on medical decision making (MDM) or based solely on time
- Changes apply to outpatient E/M office visits (99202 – 99215)
- Changes do not apply to inpatient services
- Documentation of histories and assessments should continue



Certain Enforcement Actions

Pharmaceutical Companies

Electronic Health Records

Marketing

Yates & Individual
Accountability



Certain 2020 FCA Recoveries



- Certain recoveries include:
 - \$591 million Novartis Pharmaceuticals Company – involves speakers bureaus
 - \$148 million combined from Novartis & Gilead Sciences – involves patient copayments
 - \$145 million from Practice Fusion - involves EHR software
 - \$41.6 million from UTC Laboratories – involves genetic testing
 - \$37 million from ResMed – involves DME
 - \$13 combined from four foundations – involves patient assistance programs



Certain Enforcement Actions: Pharma

□ Novartis (July 2020) (2 actions)

- \$678 combined million settlement
- Allegations include that Novartis operated a sham speakers program pursuant to which it paid over \$100 million to physicians to induce them to prescribe certain drugs

□ Gilead (Sept 2020)

- \$97 million settlement
- Allegations included that Gilead used CVC as a conduit to pay the copayments of thousands of Medicare patients taking Letairis



Certain Enforcement Actions: EHR

□ Practice Fusion (Jan 2020)

- ✓ \$11.5 million civil settlement
- ✓ \$26 million+ criminal fines
- ✓ Deferred prosecution
- ✓ Allegations included kickbacks from opioid and pharma companies
 - ✓ Misrepresenting software capabilities
 - ✓ Meaningful use payments



□ Athenahealth, Inc. (Jan 2021)

- ✓ \$18.25 million settlement
- ✓ Allegations include the Athena provided lavish gifts and payments to increase sales
 - ✓ Concierge Event program
 - ✓ Client Lead Generation program

Certain Enforcement Actions: Marketing

□ Epsilon Data Management (Jan 2021)

- \$150 million settlement to resolve criminal charge for selling millions of individuals' information to perpetrators of elder fraud
- Entered into a DPA and agreed to implement significant compliance measures to safeguard consumers' data and prevent sales to those engaged in fraudulent or deceptive marketing

□ McKinsey & Company (Feb 2021)

- \$573 million settlement
- Global consulting firm
- Relating to advice provided on opioid marketing and sales strategies



Certain Enforcement Actions: Yates

- Owner of Texas Chain of Hospice Companies (Dec. 16, 2020)
 - 20 year prison sentence & \$120 million in restitution
 - Allegations included telling thousands of patients with long-term incurable illnesses that they had less than 6 months to live and enrolling them in hospice programs

- Owner of Providence Home Health and Providence Hospice (Dec. 10, 2020)
 - \$1.05 million settlement; 5-year exclusion
 - Allegedly paid kickbacks for referrals of Medicare patients
 - Payments to medical director allegedly exceeded FMV
 - Allegedly identified a physician who was said to have been the attending physician – but he was incarcerated at the time

- Owner of Brace Companies (Nov. 16, 2020)
 - Pled guilty; \$16.5 million pay-back
 - Faces up to 5 years in prison and up to \$250,000 in fines



Any Questions/Thoughts/Comments
Lynn Barrett, Esq., CCP, CHE
Lynn@blhealthlaw.com

