

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

Health Ethics Trust
Certification Course
May 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

2. 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 -21 OIG Advisory Opinions**
- **Special Fraud Alert: Speaker Program**
- **Certain OIG Work Plan Updates**
- **COVID Frequently Asked Questions (FAQs)**
- **OIG Report: The Pandemic & Hospitals**

5. HHS/CMS Hot Topics

- ❑ **HHS Advisory Opinion/Rules on the Use of Sub-regulatory Guidance**
- ❑ **HHS FCA Working Group**
- ❑ **Certain CMS Announcements & Rule 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 ^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	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.

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



Open Payments Program

➤ Medtronic USA, Inc. (Oct 2020)

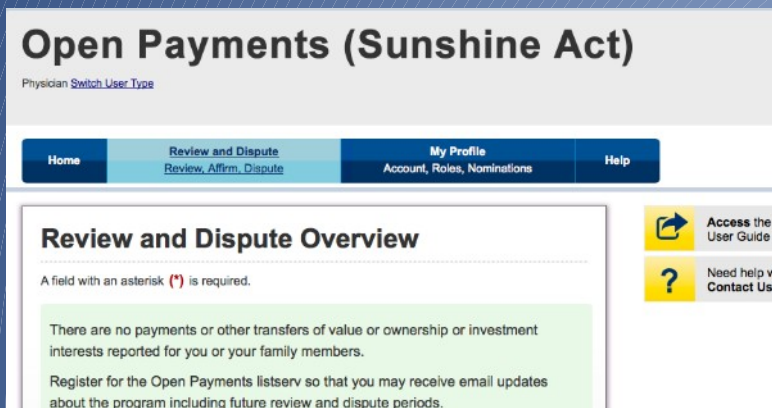
- ✓ \$9.2 million settlement
- ✓ Allegations include kickbacks to neurosurgeon (\$8.1 million) and Open Payments Program violations (\$1.11 million)
 - ✓ Carnival Brazilian Grill



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



Office of Inspector General “Hot Topics”

Advisory Opinions

2020-21 Advisory Opinions

Special Fraud Alert: Speaker Programs

AKS Final Rule PBMs

Certain 2021 OIG Work Plan Additions

OIG COVID FAQs

OIG Report: The Pandemic & Hospitals

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.”



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 (12-30-2020) regarding a program where a pharmaceutical manufacturer provides financial assistance for travel, lodging, and other expenses to certain patients prescribed the manufacturer's drug

OIG 2021 Advisory Opinions



- AO 21-01 (3-24-2021) regarding a free drug provided by a pharmaceutical manufacturer to certain patients to whom the manufacturer's drug has been prescribed.
- AO 21-02 (4-29-2021) regarding an investment by a health system, certain surgeons, and a management company in an ambulatory surgery center.

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

Certain OIG Work Plan Items

Announced or Revised	Agency	Title	Component	Report Number(s)	Expected Issue Date (FY)
April 2021	Centers for Medicare and Medicaid Services	Meeting the Challenges Presented by COVID-19: Nursing Homes	Office of Evaluation and Inspections	OEI-02-20-00490; OEI-02-20-00491; OEI-02-20-00492	2021, 2022
April 2021	Centers for Medicare & Medicaid Services	Skilled Nursing Facility Reimbursement	Office of Audit Services	W-00-21-35784	2022

OIG COVID FAQs

Can a federally qualified health center (FQHC) with a location in a rural area provide free space to a retail pharmacy that administers COVID-19 vaccinations to FQHC patients and the general public (including Federal health care program beneficiaries)?

Posted March 24, 2021

We recognize that effective and expeditious vaccine administration is crucial to the COVID-19 pandemic response and that individuals in rural areas may face heightened challenges in accessing vaccines. In the facts presented, the FQHC would provide the free use of space for the pharmacy to operate a vaccination clinic. The pharmacy would direct and operate all aspects of the vaccination clinic, including obtaining patient consents; administering COVID-19 vaccinations to individuals, some of whom may be Federal health care program beneficiaries; observing patients after vaccination and responding to any adverse reactions; and providing all items and services related to vaccine administration (e.g., staff and equipment). According to the FQHC, other than the free use of space, no remuneration would be exchanged between the parties. With respect to a patient of the FQHC who receives a vaccine administered by the pharmacy, the FQHC would maintain a record of vaccine administration within the patient's medical record.

OIG Report: The Pandemic & Hospitals

Hospitals Reported That the COVID-19 Pandemic Has Significantly Strained Health Care Delivery

03-23-2021 | OEI-09-21-00140 | [Complete Report](#)

SCOPE OF THE REVIEW

This review provides a national snapshot, from the perspective of front-line hospital administrators, on how responding to the COVID-19 pandemic has affected their capacity to care for patients, staff, and communities. This is not a review of the HHS response to the COVID-19 pandemic. We conducted our first pulse survey of challenges that hospitals reported facing in response to COVID-19 during the early weeks of the pandemic (March 23-27, 2020). This snapshot from 2021 provides HHS and other decisionmakers with updated information on hospital perspectives.

HHS & CMS “Hot Topics”

HHS Rule Restricting Use of
Sub-Regulatory Guidance

HHS FCA Working Group

Certain CMS Announcements
& 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

CMS Terminates Certain SNF COVID Waivers

Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850



Center for Clinical Standards and Quality/Quality, Safety & Oversight Group

Ref: QSO-21-17-NH

DATE: April, 8 2021

TO: State Survey Agency Directors

FROM: Director
Quality, Safety & Oversight Group

SUBJECT: Updates to Long-Term Care (LTC) Emergency Regulatory Waivers issued in response to COVID-19

Memorandum Summary

CMS continues to review the need for existing waivers issued in response to the Public Health Emergency (PHE). Over the course of the PHE, nursing homes have developed policies or other practices that we believe mitigates the need for certain waivers.

- **Therefore, CMS is announcing it is ending:**
 - The emergency blanket waivers related to notification of Resident Room or Roommate changes, and Transfer and Discharge notification requirements;
 - The emergency blanket waiver for certain care planning requirements for residents transferred or discharged for cohorting purposes.
 - The emergency blanket waiver of the timeframe requirements for completing and transmitting resident assessment information (Minimum Data Set (MDS)).

- **CMS is providing clarification and recommendations for Nurse Aide Training and Competency Evaluation Programs (NATCEPs)**

CMS Resumes Hospital Surveys

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850



Center for Clinical Standards and Quality

Ref: QSO-21-16-Hospitals

DATE: March 26, 2021

TO: State Survey Agency Directors

FROM: Directors, Quality, Safety & Oversight Group (QSOG) and Survey & Operations Group (SOG)

SUBJECT: Resuming Hospital Survey Activities Following 30-day Restrictions

Memorandum Summary

- ***CMS is lifting the previously extended 30-day survey suspension for hospitals. Survey activity will resume in accordance with Non-Long Term Care guidance issued in QSO-20-35-All.***
- ***Non-Immediate Jeopardy (IJ) Hospital Complaints* received during the survey suspension period beginning January 20, 2021, must be investigated within 45 days of date of this memo**
- ***Hospital Plans of Correction (POCs)* will be required for deficiencies cited on surveys performed on or after January 20, 2021.**
- ***Desk Reviews* are permitted of all open surveys cited at any level of noncompliance, except for unremoved IJ findings, which require an onsite revisit.**
- ***Onsite Revisits* are authorized and should resume as appropriate.**
- ***Open Enforcement Cases* that are not IJ will have at least 60 and up to 90 days to**

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

➤ Urgent Care Providers (April 2021)

- \$22.5 million settlement
- Allegations include that the urgent care provider and its management company falsely certified that certain urgent care visits were performed by providers who were credentialed to be Medicare, Medicaid and TRICARE when the services were actually performed by non-credentialed providers

➤ Comprehensive Pain Specialists & Owner (April 2021)

- \$4.1 million settlement
- Allegations include that the defendants submitted false claims for medically unnecessary and/or non-reimbursable testing and acupuncture.

➤ DME & Genetic Testing Services Enforcement Actions Continue (April 2021)

- 5 charged and 2 admit guilt in \$93 million health fraud scheme

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

➤ CareCloud Health (April 2021)

- ✓ \$3.8 million settlement
- ✓ Allegations include CareCloud provided existing clients cash equivalent credits, cash bonuses and percentage success payments to recommend it's EHR products to prospective clients



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



➤ 5 Charged in \$65M Nationwide Conspiracy (April 2021)

- Charges relate to orthotic brace orders using marketing call centers

Certain Enforcement Actions: Hospice

- Novus Hospice CEO (March 19, 2021)
 - Pled guilty and admitted for 4 years he filled Medicare and Medicaid for hospice services not provided, not directed by a medical professional or that were provided to patients who were not actually eligible for hospice care
- 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



Any Questions/Thoughts/Comments
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Comments
encouraged!

