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

Health Ethics Trust Certification Course August 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**
   - ❑ **Board Role & Responsibilities**

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**
   - **2021 OIG Advisory Opinions**
   - **Special Fraud Alert: Speaker Program**
   - **Certain OIG Work Plan Updates**
   - **COVID Frequently Asked Questions (FAQs)**

5. **HHS/CMS Hot Topics**
   - ❑ **HHS Advisory Opinion/Rules on the Use of Sub-regulatory Guidance**
   - ❑ **HHS FCA Working Group**
   - ❑ **Proposed Amendments to FCA**
   - ❑ **Certain CMS Announcements & Rule Changes**

Compliance Guidance

- Federal Sentencing Guidelines
- Office of Inspector General
- Department of Justice
- Board Duty & Responsibilities

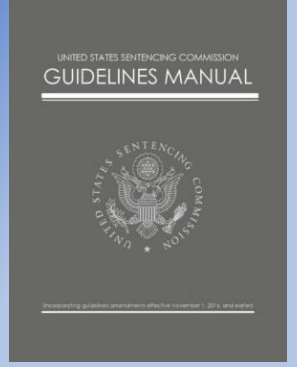
Compliance Guidance

Federal Sentencing Guidelines

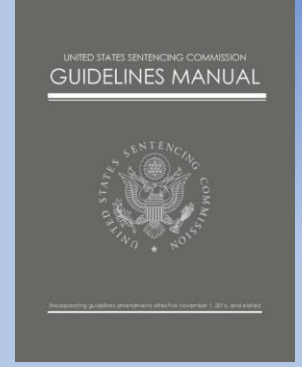
Federal Sentencing Guidelines

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)
	1	0–6	0–6	0–6	0–6	0–6	0–6
	2	0–6	0–6	0–6	0–6	0–6	1–7
	3	0–6	0–6	0–6	0–6	2–8	3–9
	4	0–6	0–6	0–6	2–8	4–10	6–12
Zone A	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
	9	4–10	6–12	8–14	12–18	18–24	21–27
Zone B	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
	12	10–16	12–18	15–21	21–27	27–33	30–37
Zone C	13	12–18	15–21	18–24	24–30	30–37	33–41
	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
Zone D	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.

Available at: https://www.ussc.gov/guidelines

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)

Available at: https://oig.hhs.gov/compliance/compliance-guidance/index.asp

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

Available at: https://oig.hhs.gov/compliance/compliance-guidance/index.asp

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-exiting 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

Board of Directors

Role & Responsibilities

A Board's Role and Responsibilities

The Board has 3 broad duties:

- The Duty of Care
- The Duty of Loyalty
- The Duty of Obedience to Purpose

Caremark:

"a duty to attempt in good faith to assure that a corporate information and reporting system, which the board concludes is adequate, exists, and . . . failure to do so under some circumstances may . . . render a director liable for losses caused by non-compliance with applicable legal standards."

A Board's Role and Responsibilities

Marchand:

". . . the board had no committee overseeing food safety, no full board-level process to address food safety issues, and no protocol by which the board was expected to be advised of food safety reports and developments. Consistent with this dearth of any board-level effort at monitoring, the complaint pleads particular facts supporting an inference that during a crucial period when yellow and red flags about food safety were presented to management, there was no equivalent reporting to the board and the board was not presented with any material information about food safety."

A Board's Role and Responsibilities

Corporate Integrity Agreements

"Board Compliance Obligations. The Board of Provider shall be responsible for the review and oversight of matters related to compliance with Federal health care program requirements and the obligations of this CIA. The Board must include independent (i.e., non-employee and non-executive) members. The Board shall, at a minimum, be responsible for the following: a. meeting at least quarterly to review and oversee Provider's compliance program, including but not limited to the performance of the Compliance Officer and Compliance Committee; b. submitting to the OIG a description of the documents and other materials it reviewed, as well as any additional steps taken, such as the engagement of an independent advisor or other third party resources, in its oversight of the compliance program and in support of making the resolution below during each Reporting Period;…"

A Board's Role and Responsibilities

HEAT PROVIDER COMPLIANCE TRAINING

TAKE THE INITIATIVE.

Cultivate a Culture of Compliance With Health Care Laws

A Toolkit for Health Care Boards

Promote Quality of Care

- Create a comprehensive policy and objectives to define your quality improvement and patient safety program. Ensure your stakeholders share a common vision of quality. To give your program real impact, incorporate its objectives into employee performance evaluations and incentive compensation.
- Establish a board quality committee and make quality of care a standing board agenda item.
- Ensure you have sufficient clinical expertise on the board. To address potential conflicts, some hospital boards recruit physicians who are not medical staff m
- Understand how management assesses the cre
- Implement conflict-of-interest policies to iden
- Use dashboards and benchmarks to measure t satisfaction. You should track how your orga "What gets measured is what gets done."

Evaluate the Compliance Program

- Ask questions that assess your compliance pr their strategy for improvement. Our website http://www.oig.hhs.gov/compliance/complian
- Protect the compliance officer's independence

"Driving for Quality in Acute Care: A Board of Directors Dashboard"
Government-Industry Roundtable

A Report on the Office of Inspector General and Health Care Compliance Association Roundtable on Hospital Board of Directors' Oversight of Quality of Care

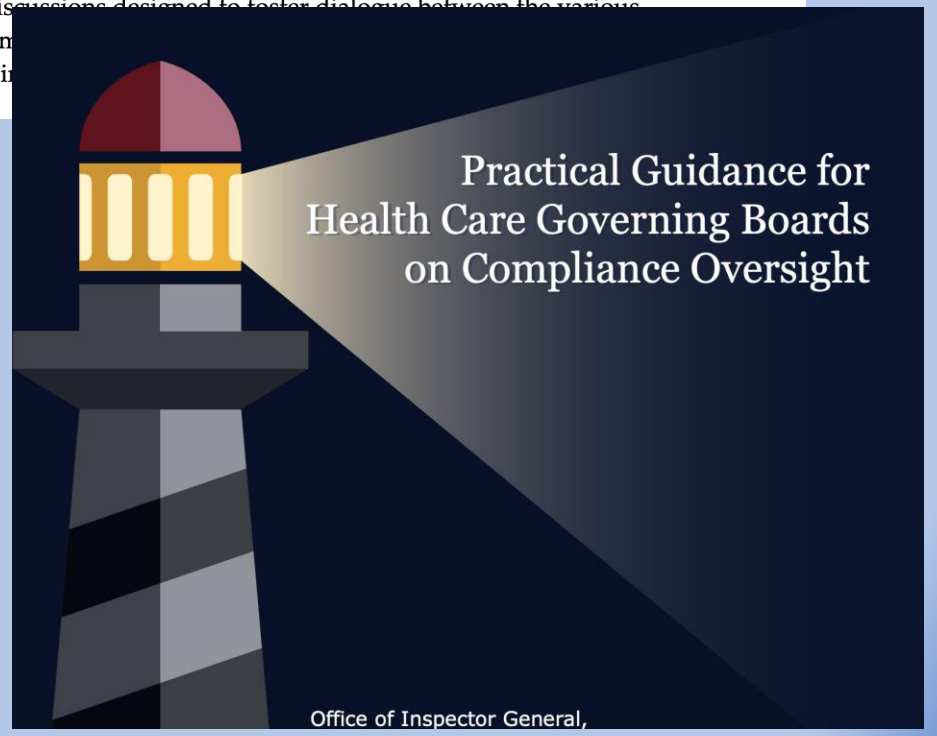
Introduction

On November 10, 2008, the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services and the Health Care Compliance Association (HCCA) co-sponsored a government-industry roundtable called Driving for Quality in Acute Care: A Board of Directors Dashboard. The meeting was the most recent in a series of government-industry dis
stakeholders that are con
es and requi

Health Lawyers' Public Information Series

THE HEALTH CARE DIRECTOR'S COMPLIANCE DUTIES: A Continued Focus of Attention and Enforcement

A Joint Publication from the Office of the Inspector General, U.S. Department of Health and Human Services and the American Health Lawyers Association



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 JUDGMENTS¹					RELATOR SHARE AWARDS²		
	NON QUI TAM	QUI TAM	NON³ 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

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

DOJ 2020 FCA Recoveries HHS

FY	NEW MATTERS°		SETTLEMENTS AND JUDGMENTS¹					RELATOR SHARE AWARDS²		
	NON QUI TAM	QUI TAM	NON³ 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

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DOJ 2020 FCA Recoveries HHS

FY	NEW MATTERS°		SETTLEMENTS AND JUDGMENTS¹					RELATOR SHARE AWARDS²		
	NON QUI TAM	QUI TAM	NON³ 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

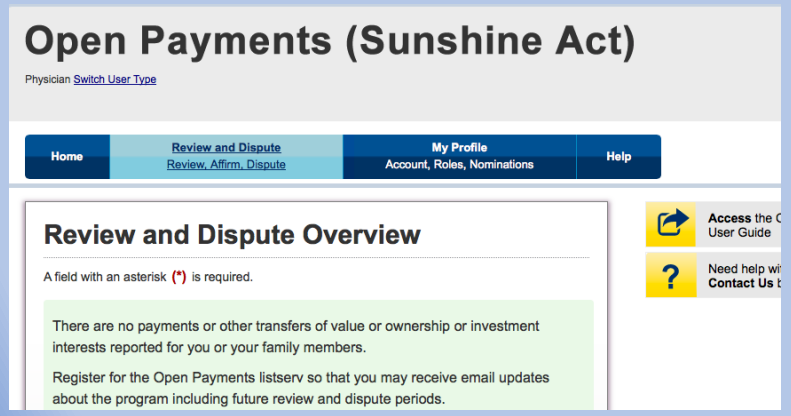
- Pandemic –Related Fraud
- Opioids
- Fraud Targeting Seniors
- Electronic Health Records
- Telehealth
- Cybersecurity

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



Open Payments Program

2022 Proposed Physician Fee Schedule

- PODs: provides definition and confirms reporting requirement
- Teaching Hospitals: add “context field”
- General Payments: remove ability to delay general payments
- Ownership Categories: 2 methods to report
- No report deletions; annual recertifications

Office of Inspector General "Hot Topics"

- Advisory Opinions
- 2021 Advisory Opinions
- Special Fraud Alert: Speaker Programs
- 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 2021 Advisory Opinions

- AO 21-10 (August 6, 2021) Regarding a dental provider's provision of free routine and emergency dental services to certain indigent residents of skilled nursing facilities and nursing facilities.

- AO 21-09 (July 19, 2021) Regarding the use of a "preferred hospital" network as part of Medicare Supplemental Health Insurance ("Medigap") policies, whereby an insurance company would contract with a preferred hospital organization to provide discounts on the otherwise-applicable Medicare inpatient deductibles for its policyholders and, in turn, would provide a premium credit of $100 off the next renewal premium to policyholders who use a network hospital for an inpatient stay.

- AO 21-08 (July 8, 2021) Regarding financial assistance for transportation, lodging, and meals provided by a pharmaceutical manufacturer to certain patients potentially eligible for treatment with the pharmaceutical manufacturer's drug.

- AO 21-07 (July 7, 2021) Regarding the use of a "preferred hospital" network as part of Medicare Supplemental Health Insurance ("Medigap") policies, whereby an insurance company would contract with a preferred hospital organization to provide discounts on the otherwise-applicable Medicare inpatient deductibles for its policyholders and, in turn, would provide a premium credit of $100 off the next renewal premium to policyholders who use a network hospital for an inpatient stay.

OIG 2021 Advisory Opinions

- AO 21-06 (June 29, 2021) Regarding a spinal implant manufacturer's proposal to offer its products to hospitals at a reduced price if the hospitals agree to assume certain duties related to the products.

- AO 21-05 (May 20, 2021) Regarding the use of a "preferred hospital" network as part of Medicare Supplemental Health Insurance ("Medigap") policies, whereby an insurance company would contract with a preferred hospital organization to provide discounts on the otherwise-applicable Medicare inpatient deductibles for its policyholders and, in turn, would provide a premium credit of $100 off the next renewal premium to policyholders who use a network hospital for an inpatient stay.

- AO 21-04 (May 19, 2021)Regarding the use of a "preferred hospital" network as part of Medicare Supplemental Health Insurance ("Medigap") policies, whereby an insurance company would contract with a preferred hospital organization to provide discounts on the otherwise-applicable Medicare inpatient deductibles for its policyholders and, in turn, would provide a premium credit of $100 off the next renewal premium to policyholders who use a network hospital for an inpatient stay.

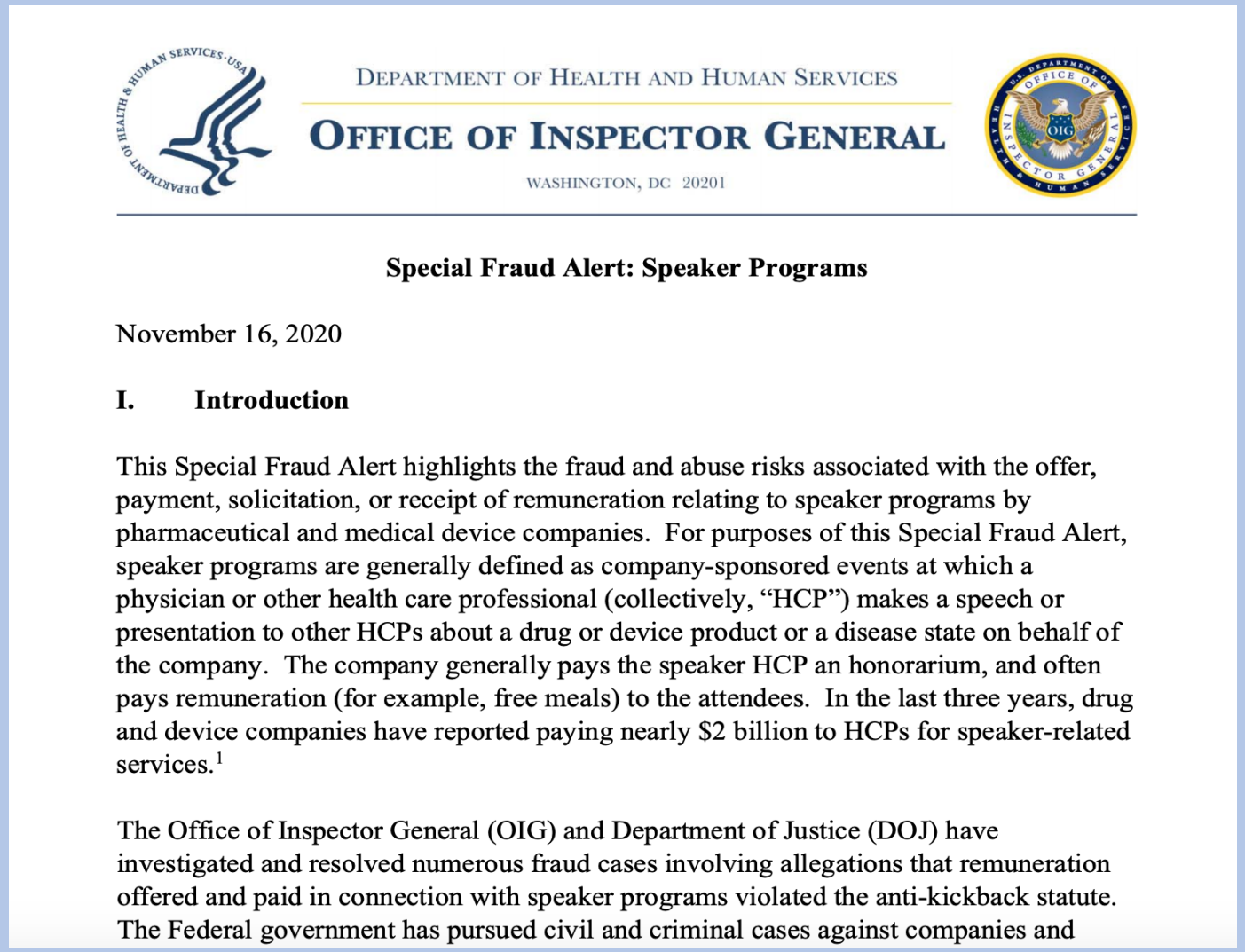
OIG 2021 Advisory Opinions

- AO 21-03 (May 17, 2021) Regarding the use of a "preferred hospital" network as part of Medicare Supplemental Health Insurance ("Medigap") policies, whereby an insurance company would contract with a preferred hospital organization to provide discounts on the otherwise-applicable Medicare inpatient deductibles for its policyholders and, in turn, would provide a premium credit of $100 off the next renewal premium to policyholders who use a network hospital for an inpatient stay.

- AO 21-02 (April 29, 2021) Regarding an investment by a health system, certain surgeons, and a management company in an ambulatory surgery center.

- AO 21- 01 (March 23, 2021) Regarding a free drug provided by a pharmaceutical manufacturer to certain patients to whom the manufacturer's drug has been prescribed.

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

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

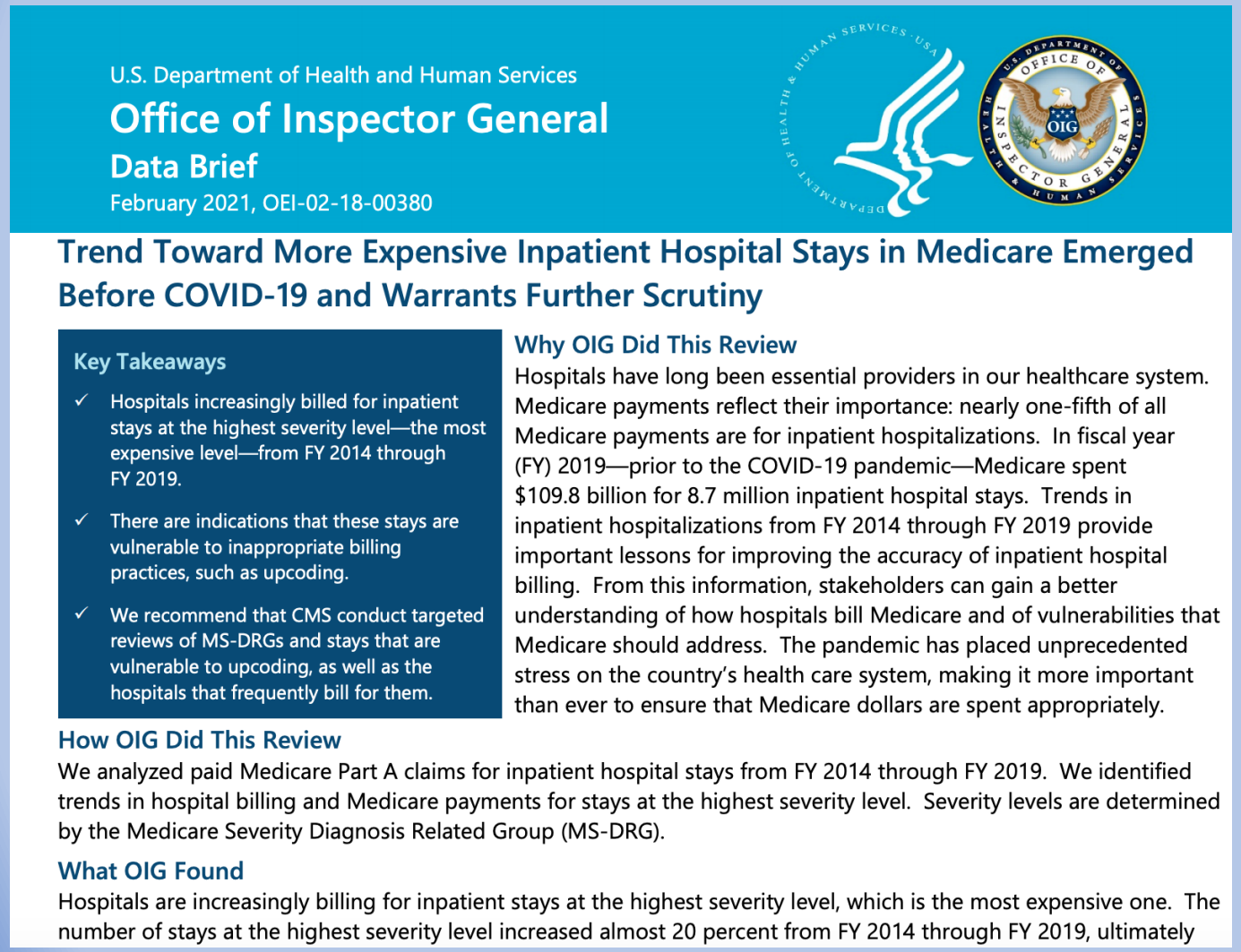
OIG COVID FAQs

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.

Certain OIG Reports



U.S. Department of Health and Human Services

Office of Inspector General

Data Brief

February 2021, OEI-02-18-00380

Trend Toward More Expensive Inpatient Hospital Stays in Medicare Emerged Before COVID-19 and Warrants Further Scrutiny

Key Takeaways

- ✓ Hospitals increasingly billed for inpatient stays at the highest severity level—the most expensive level—from FY 2014 through FY 2019.
- ✓ There are indications that these stays are vulnerable to inappropriate billing practices, such as upcoding.
- ✓ We recommend that CMS conduct targeted reviews of MS-DRGs and stays that are vulnerable to upcoding, as well as the hospitals that frequently bill for them.

Why OIG Did This Review

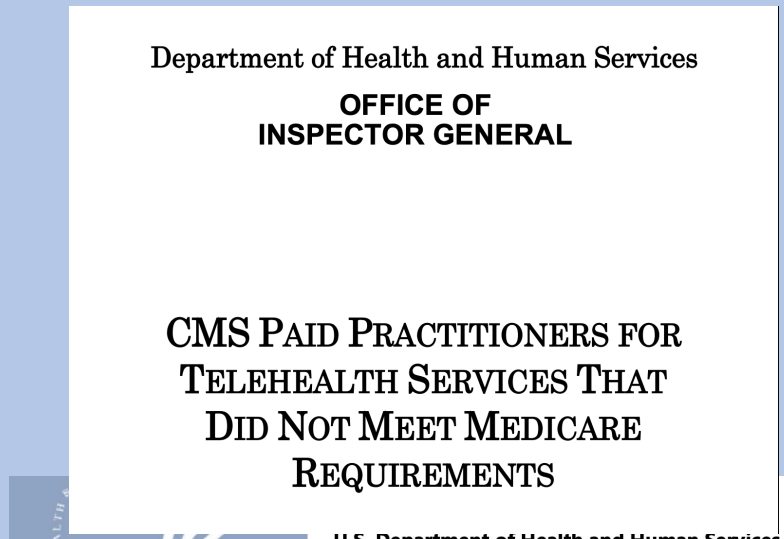
Hospitals have long been essential providers in our healthcare system. Medicare payments reflect their importance: nearly one-fifth of all Medicare payments are for inpatient hospitalizations. In fiscal year (FY) 2019—prior to the COVID-19 pandemic—Medicare spent $109.8 billion for 8.7 million inpatient hospital stays. Trends in inpatient hospitalizations from FY 2014 through FY 2019 provide important lessons for improving the accuracy of inpatient hospital billing. From this information, stakeholders can gain a better understanding of how hospitals bill Medicare and of vulnerabilities that Medicare should address. The pandemic has placed unprecedented stress on the country's health care system, making it more important than ever to ensure that Medicare dollars are spent appropriately.

How OIG Did This Review

We analyzed paid Medicare Part A claims for inpatient hospital stays from FY 2014 through FY 2019. We identified trends in hospital billing and Medicare payments for stays at the highest severity level. Severity levels are determined by the Medicare Severity Diagnosis Related Group (MS-DRG).

What OIG Found

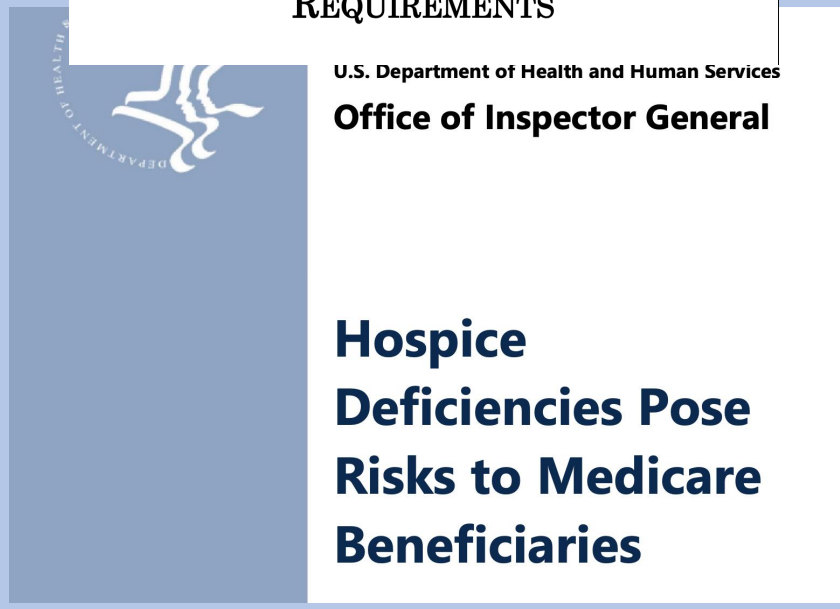
Hospitals are increasingly billing for inpatient stays at the highest severity level, which is the most expensive one. The number of stays at the highest severity level increased almost 20 percent from FY 2014 through FY 2019, ultimately



Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

CMS Paid Practitioners for Telehealth Services That Did Not Meet Medicare Requirements



U.S. Department of Health and Human Services

Office of Inspector General

Hospice Deficiencies Pose Risks to Medicare Beneficiaries

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

Proposals to Amend FCA

- Chuck Grassley with bi-partisan support introduces "False Claims Act Amendments of 2021
  - Proposed changes are in response to the *Escobar* case
  - Good for whistleblowers

- If a defendant tries to rebut materiality, the defendant will have a higher burden of proof than the government or the relator

- If government declines to intervene and moves to dismiss the case (1) whistleblower has strong tools to challenge, and (2) can charge for burdensome discovery

- Protects post-employment retaliation

- Administrative False Claims Act

CMS Terminates Certain SNF COVID Waivers

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

CENTERS FOR MEDICARE & MEDICAID SERVICES

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

CENTERS FOR MEDICARE & MEDICAID SERVICES

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*

CMS Budget Justification

- CMS requested a $50.5 million increase in funding in order to "conduct greater levels of medical review in FY 2022"
  - Goal is to decrease the amount of claims reviews that are overturned
    - Post-payment reviews of claims submitted during the PHE
      - Compliance challenge in applying flexibilities
  - Increase modeling to identify FW&A

CMS & Hospice Plan of Care

U.S. Department of Health and Human Services

Office of Inspector General

Hospice Deficiencies Pose Risks to Medicare Beneficiaries

mln Fact Sheet

Print-Friendly Version

KNOWLEDGE • RESOURCES • TRAINING

Creating An Effective Hospice Plan of Care

What's Changed?

CMS & Telehealth

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

CMS PAID PRACTITIONERS FOR TELEHEALTH SERVICES THAT DID NOT MEET MEDICARE REQUIREMENTS

MLN FACT SHEET

KNOWLEDGE • RESOURCES • TRAINING

Telehealth Services

Certain Enforcement Actions

- Stark & AKS
- Electronic Health Records
- Marketing
- Medicare Advantage

Certain 2020 FCA Recoveries

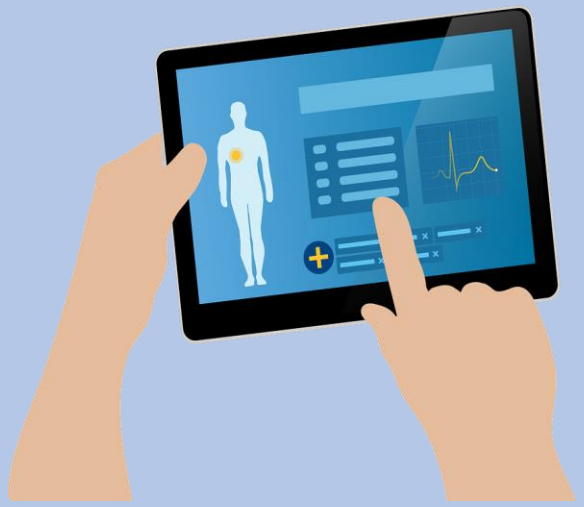
- Certain recoveries include:
  - $591 million Novartis Pharmaceuticals Company – involves speakers bureaus
  - $148 million combined from Novartis & Gilead Sciences – involves patient copayments
  - $145 million from Practice Fusion - involves EHR software
  - $41.6 million from UTC Laboratories – involves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

Certain Enforcement Actions

- Prime Healthcare Services & Two Doctors (July 2021)
  - $37.5 million settlement
  - Allegations include that Prime overpaid for a physician practice – was allegedly not commercially reasonable and exceeded fair market value - and entered into an employment agreement based on the volume or value of patient referrals
- Akron General Health System (July 2021)
  - $21.25 million settlement
  - Allegations include that health system paid compensation in excess of fair market value to area physician groups to secure patient referrals
- DME Enforcement Continues (Aug 10, 2021)
  - Telemedicine company owner indicted in scheme involving $784 million in allegedly false billings
  - Faces over 50 years in prison
  - Similar arrangement as those in Operation Brace Yourself

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: Medicare Advantage

- Kaiser Permanente (July 30, 2021)
  - Government intervened in 6 six complaints alleging that members of the Kaiser Permanente consortium violated the False Claims Act by submitting inaccurate diagnosis codes for its Medicare Advantage Plan enrollees in order to receive higher reimbursement

- Prior McA cases


Los Angeles Times

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Column: The government lawsuit against Kaiser points to a massive fraud problem in Medicare

Kaiser Permanente Medical Center on Sunset Blvd in Los Angeles: Government lawsuit accuses the nonprofit healthcare organization of massive Medicare fraud (Mel Melcon/Los Angeles Times)

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