



1

Enforcement and Compliance for General Counsel and Compliance Officers

◆ Speakers

- ▶ **John Kelly**
Member, Bass, Berry & Sims PLC

- ▶ **Lisa Adkins**
Vice President Compliance/ Chief Compliance Officer, Children's National Hospital





- ▶ **Shannon Sumner**
Principal/Chief Compliance Officer, PYA

BASS BERRY + SIMS_{PC}





2

HCF Statistics

2017

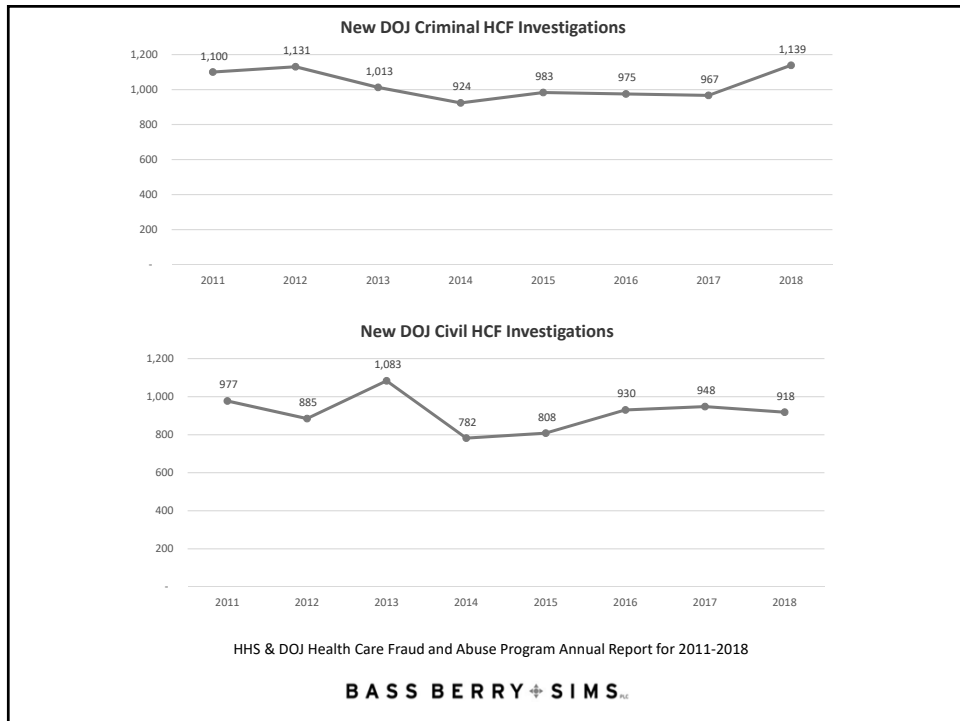
<p>HCF recoveries of \$2.6 billion. ROI of \$4 for every \$1 spent.</p> 	<p>Opened 967 criminal investigations and filed charges in 439 cases against 720 defendants.</p> 	<p>Opened 948 civil investigations with 1,048 matters pending at end of year.</p> 	<p>Exclusion of 3,224 individuals and entities and 551 payment suspensions.</p> 
---	--	---	---

2018

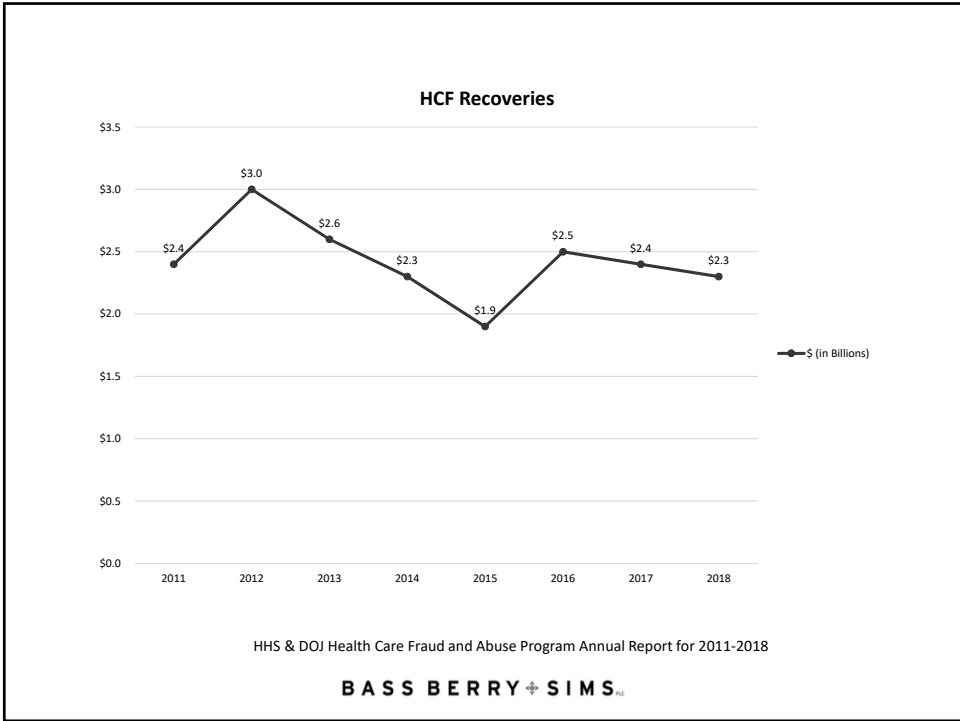
<p>HCF recoveries of \$2.3 billion. ROI of \$4 for every \$1 spent.</p> 	<p>Opened 1,139 criminal investigations and filed charges in 572 cases against 872 defendants.</p> 	<p>Opened 918 civil investigations with 1,203 matters pending at end of year.</p> 	<p>Exclusion of 2,712 individuals and entities and 551 payment suspensions.</p> 
---	--	---	---

BASS BERRY + SIMS

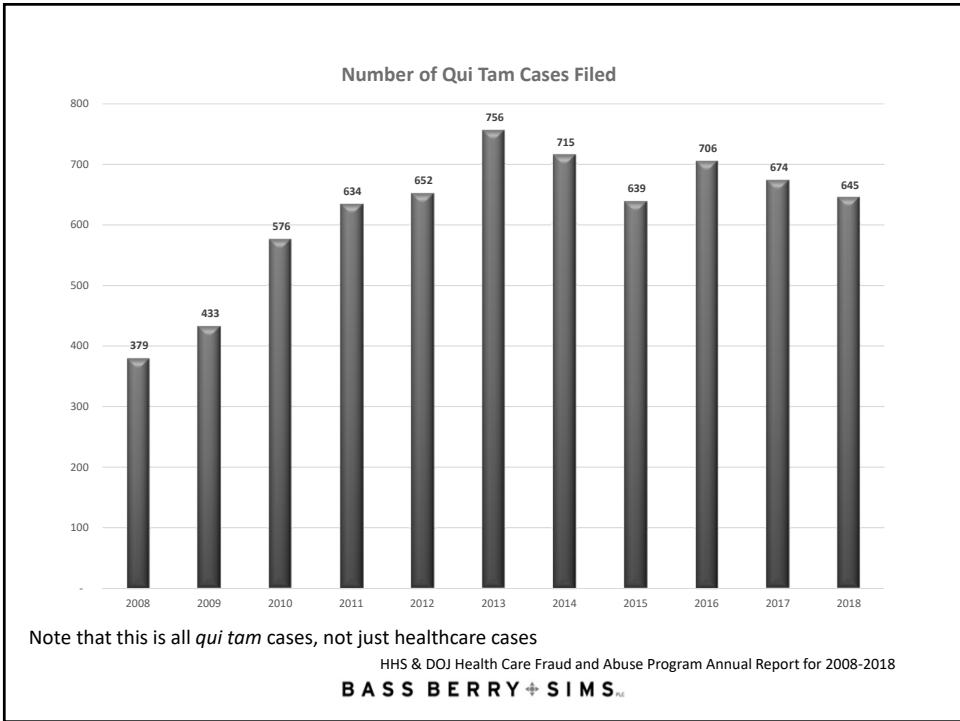
3



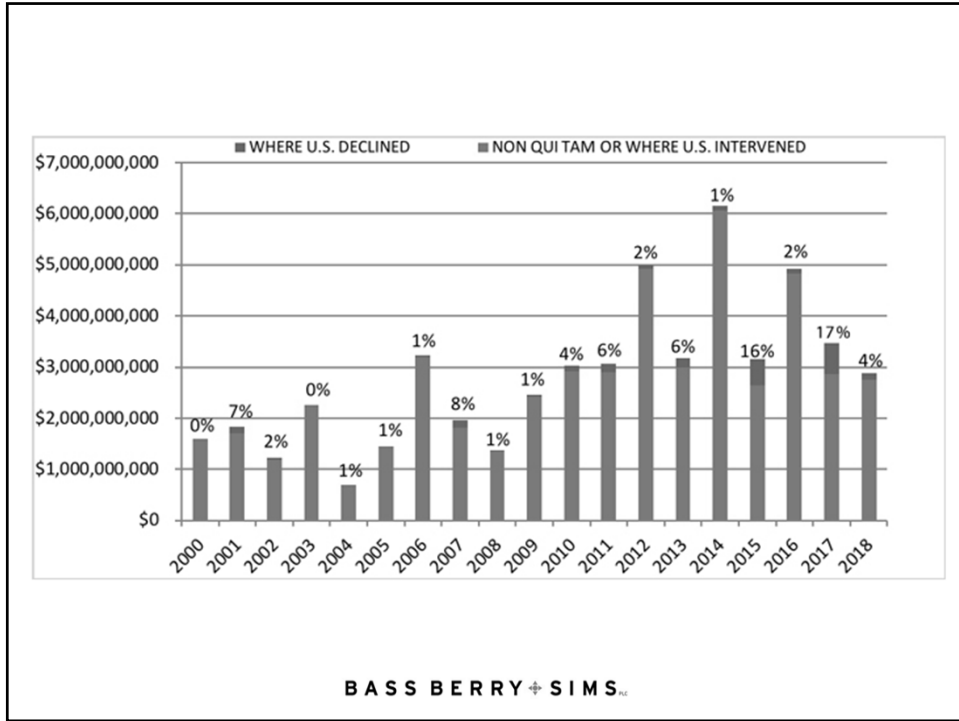
4



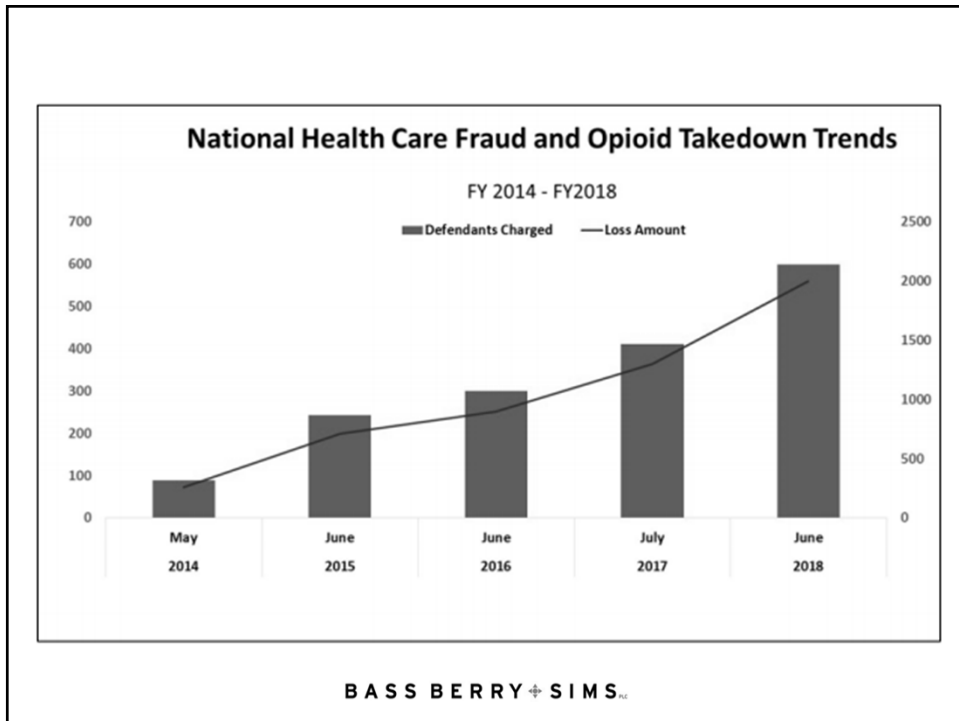
5



6



7



8

Key DOJ Pronouncements

BASS BERRY + SIMS[®]

9

DOJ Dismissal Authority

◆ Granston Memo

- ▶ January 10, 2018
- ▶ 7 factors DOJ should consider when deciding whether to dismiss non-intervened *qui tam* actions under 31 U.S.C. 3730(c)(2)(A):
 - Curbing meritless actions
 - Preventing parasitic or opportunistic lawsuits
 - Preventing interference with agency policies and programs
 - Controlling litigation brought on behalf of federal government
 - Safeguarding classified information
 - Preserving governmental resources
 - Addressing egregious procedural errors
- ▶ Now incorporated into DOJ Policy Manual (Section 4-4.111)

BASS BERRY + SIMS[®]

10

DOJ Dismissal Authority

- ◆ Post-Granston Memo
 - ▶ DOJ has sought dismissal of 30+ non-intervened cases
- ◆ Court review of dismissals
 - ▶ **Swift v. United States (D.C. Cir.)**
 - US is real party in interest in FCA cases
 - DOJ's right to dismiss is essentially unfettered
 - ▶ **Sequoia Orange v. Baird-Neece Packing Corp. (9th Cir.)**
 - Court must conduct limited judicial review to ensure government's decision to dismiss is not fraudulent, arbitrary, or abuse of power
 - DOJ must identify a valid purpose for dismissal and show a "rational relation" between dismissal and accomplishing that purpose

BASS BERRY + SIMS[®]

11

Updated and Revised DOJ Policies

- ◆ Justice Manual 9-28.700 incorporates revised principles of Yates Memo
- ◆ Evaluation of Corporate Compliance Programs (April 2019)
 - ▶ Expanded list of sample topics and questions
 - ▶ Greater detail for what prosecutors should look for in compliance programs
- ◆ New FCA Cooperation Policy – Justice Manual 4-4.112 (May 2019)
 - ▶ Spells out 11 forms of voluntary cooperation and four potential remedial measures
 - ▶ Lacks concrete details on benefits of cooperation

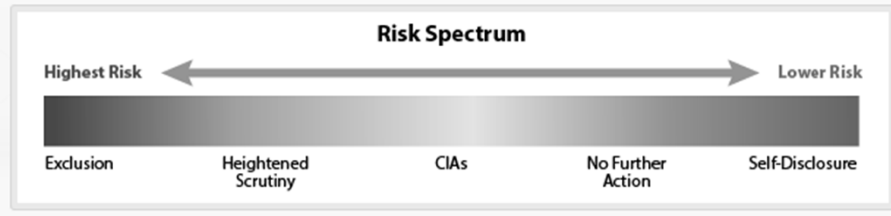
BASS BERRY + SIMS[®]

12

CMS Role in HCF Settlements

Fraud Risk Indicator

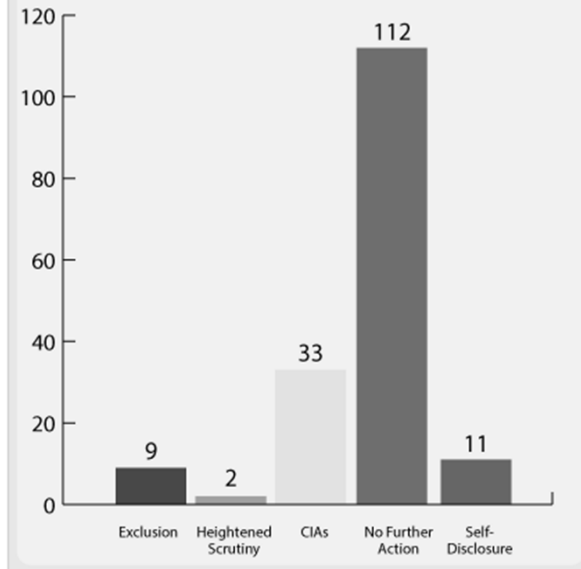
OIG assessment of future risk posed by persons who have allegedly engaged in civil healthcare fraud.



BASS BERRY + SIMS

13

False Claims Act Settlements on the Risk Spectrum FY 2019 Q1-Q3



14

High Risk – Heightened Scrutiny

Parties are in the High Risk category, and subject to heightened scrutiny, because they pose a significant risk to Federal healthcare programs and beneficiaries. This is because, although OIG determined that these parties needed additional oversight, they refused to enter [Corporate Integrity Agreements](#) (CIAs) sufficient to protect Federal healthcare programs. Parties in the High Risk category that reached settlements finalized on October 1, 2018 or later will be listed below.

Provider	Date Settled	City/State	Press Release
Ridgeview Rehab & Nursing Center	05-13-2019	Chicago, Illinois	Link
ImmediaDent of Indiana, LLC & Samson Dental Partners, LLC	10-31-2018	various cities in Indiana and Leawood, Kansas	Link

BASS BERRY + SIMS[®]

15

FCA Developments

BASS BERRY + SIMS[®]

16

FCA Statute of Limitations

❖ *Cochise Consultancy, Inc. et al. v. U.S. ex rel. Hunt*,
No. 18-315 (U.S.)

- ▶ Under the FCA, cases must be brought either:
 - Within six years of the alleged FCA violation or
 - Within three years after material facts “are known or reasonably should have been known by the official of the United States charged with responsibility to act in the circumstances, but in no event more than 10 years after the date on which the violation is committed, whichever occurs last.”

BASS BERRY + SIMS[®]

17

FCA Statute of Limitations

❖ *Cochise Consultancy, Inc. et al. v. U.S. ex rel. Hunt*,
No. 18-315 (U.S.)

- ▶ Relator’s case was filed seven years after the alleged fraud but within three years of his telling federal agents about the alleged fraud.
- ▶ Trial court ruled government knowledge SOL was applicable only in intervened cases.
- ▶ The Eleventh Circuit reversed and held that the government knowledge SOL applies in declined cases, effectively extending the SOL for relator to 10 years.

BASS BERRY + SIMS[®]

18

FCA Statute of Limitations

◆ *Cochise Consultancy, Inc. et al. v. U.S. ex rel. Hunt*, No. 18-315 (U.S.)

- ▶ Supreme Court ruled 9-0 that “government knowledge” statute of limitations applies regardless of whether US intervenes
- ▶ Will lead to expanded discovery on what the US knew and when

BASS BERRY + SIMS[®]

19

Medical Necessity

◆ *U.S. ex rel. Polukoff v. St. Mark’s Hospital* (10th Cir. 2018)

- ▶ Relator alleged cardiologist performed unnecessary patent foramen oval (PFO) closures
- ▶ District court dismissed for failure to plead objectively false claims.
 - “[M]edical judgments and conclusions about which reasonable minds can differ cannot be false’ for purposes of an FCA claim.”
 - Physician’s certification that a PFO closure was “reasonable and necessary” could not be false under the FCA absent “a regulation that clarifies the conditions under which [the government] will or will not pay for a PFO closure.”

BASS BERRY + SIMS[®]

20

Medical Necessity

- ◆ ***U.S. ex rel. Polukoff v. St. Mark's Hospital*** (10th Cir. 2018)
 - ▶ Tenth Circuit reversed district court's ruling, explaining that "it is possible for a medical judgment to be 'false or fraudulent'" under the FCA.
 - ▶ "Doctor's certification to the government that a procedure is 'reasonable and necessary' is 'false' under the FCA if the procedure was not reasonable and necessary under the government's definition of the phrase" found in the Medicare Program Integrity Manual.
 - Recognized this holding "might expose doctors to more liability under the FCA" but noted the Supreme Court "has already addressed those concerns" in *Escobar*
 - ▶ Petition for cert filed January 14, 2019

BASS BERRY + SIMS[®]

21

Medical Necessity

- ◆ ***United States v. Paulus*** (6th Cir. 2018)
 - ▶ Defendant cardiologist indicted for performing unnecessary cardiac cath and stent placements
 - ▶ In 2017, following conviction on 11 of 16 counts, district court granted motion for judgment of acquittal: the "evidence presented at trial failed to show that the degree of stenosis is an objective fact, subject to proof or disproof."
 - ▶ Sixth Circuit overturned this ruling and reinstated the jury's findings
 - "The degree of stenosis is a fact capable of proof or disproof," and "[i]t is up to the jury – not the court – to decide whether the government's proof" which included "a phalanx of experts" – "is worthy of belief."
 - "[T]he court may not enter a judgment of acquittal merely because it doubts the persuasiveness of the government's expert testimony."

BASS BERRY + SIMS[®]

22

Retention of Overpayments

- ◆ ***U.S. ex rel. Hernandez-Gil v. Dental Dreams, LLC*** (D.N.M. 2018)
 - ▶ Relator, former employee, alleged defendant dental practice retained overpayments in violation of FCA
 - Management informed of billing practices but refused to allow investigation or audit
 - “[I]t would cost too much money”
 - ▶ District court denied summary judgment motion
 - Reasonable jury could infer defendant “*knew* it received overpayments and took no steps to investigate, quantify, report, or return overpayments”
- ◆ Reasonably investigate potential overpayments even when no overpayments specifically identified

BASS BERRY + SIMS[®]

23

Physician Remuneration

- ◆ ***William Beaumont Hospitals*** (E.D. Mich.)
 - ▶ Detroit health system agreed to pay \$84.5M to settle allegations that it violated AKS and Stark by providing physicians with excessive pay and low-cost or free office space
 - ▶ Physician contracts were a “mess”
 - ▶ Medical directorships duplicative of work compensated under other contracts
 - ▶ Medical directorships with four cardiologists paid each \$500,000 or more despite the physicians being in full-time medical practice.
 - After group made clear it was considering moving their practice to a competing health system, Beaumont allegedly increased medical director payments to between \$671,304 and \$734,218 per doctor, even though the duties performed by the directors did not change.
 - ▶ “Devastating” report from FTI Consulting was ignored

BASS BERRY + SIMS[®]

24

Physician Remuneration

- ◆ ***U.S. ex rel. IIRT, LLC v. Sightline Health LLC***, No. 16-cv-3203 (N.D. Tex.)
 - ▶ Cancer center operator agreed to pay \$11.5 million to settle claims it violated the AKS by encouraging physicians to invest in JV that leased facilities to cancer clinic
 - ▶ Doctors were allegedly promise a cut of profits generated by any patient referred through profit distribution of leasing company

- ◆ ***U.S. ex rel. Derrick v. Hoffman-La Roche***, No. 14-cv-4601 (N.D. Ill.)
 - ▶ Court denied motion to dismiss in declined qui tam alleging that Roche forgave debt owed by Humana to get its diabetes product back on formulary
 - ▶ Relator alleges that Roche paid rebates to Humana that were not owed leading to debt that parties allegedly settled for negotiated amount

BASS BERRY + SIMS

25

Physician Remuneration

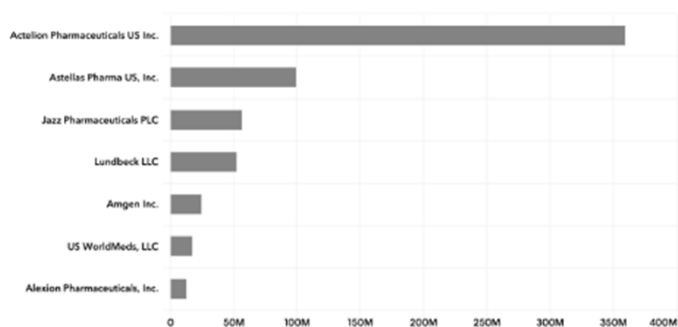
Case / Entity	Alleged Improper Remuneration	Settlement Amount
<i>U.S. ex rel. Johnson v. Post Acute Med. LLC</i> (M.D. Pa.)	Medical directorship fees	\$13.17 million
<i>U.S. v. Insys Therapeutic Inc.</i> (C.D. Cal.)	Sham speaking engagements	\$150 million
<i>U.S. ex rel. Thomas v. Lincare</i> (S.D. Ill.)	Waived co-pays	\$5 million
<i>U.S. ex rel. Prose v. Reliant Rehabilitation</i> (N.D. Tex.)	Nurse practitioners for free of charge or below-market rates	\$6.1 million
Kalispell Regional Healthcare System (D. Mont.)	Full-time pay to physicians for part-time work	\$24 million
<i>California v. AbbVie</i> (Sup. Ct. Cal.)	“Classic”: money, meals, liquor, vacation, gifts “Sophisticated”: software & marketing assistance for physician practices	N/A

26

Patient Assistance Programs

Charitable Donation Settlements

Settlements Effective June 1, 2018 - May 31, 2019



Source: Bloomberg Law Health Care Fraud Analytics

Bloomberg Law

BASS BERRY + SIMS_{PC}

27

Travel Act

- ❖ Even where there is no Medicare/Medicaid reimbursement, DOJ is increasingly using Travel Act to extend HCF enforcement to commercial insurance
- ❖ Forest Park Medical Center
 - ▶ Physician-owned hospital in Dallas
 - ▶ No Medicare/Medicaid reimbursement

BASS BERRY + SIMS_{PC}

28

Department of Justice

U.S. Attorney's Office

Northern District of Texas

SHARE 

FOR IMMEDIATE RELEASE

Thursday, September 12, 2013

Physician-Owned Hospital Agrees To Resolve Its Civil And Criminal Liability For Benefiting From Illegal Kickbacks To Physicians

DALLAS - Forest Park Medical Center, LLC (FPMC), a North Texas physician-owned hospital, paid over \$258,000 to settle allegations that it violated the civil False Claims Act, announced U.S. Attorney Sarah R. Saldaña of the Northern District of Texas. The United States contends that a FPMC representative paid illegal kickbacks to area physicians to obtain referrals for Tricare patients, a federally funded health care program, in violation of the federal law, between 2008 and 2012. Based on the same allegations, FPMC entered into a Non-Prosecution Agreement with the United States and agreed to certain conditions, as well as a federally imposed monitor for not more than 24 months. FPMC fully cooperated with the investigation, and by settling civilly and criminally, did not admit any wrong-doing or liability.

FPMC, located in Dallas, did not seek reimbursement from any federal sources such as Medicare and Medicaid, but only commercial payors and self-pay. Federal and State law usually limits the amount of compensation paid to physicians and their ability to refer certain patients under federally-insured

29

military retirees and their dependents. The United States contends such payments were unlawful kickbacks for the referral of federal health care program patients in violation of the federal Anti-Kickback Statute between January 1, 2008, and October 31, 2012. The United States initiated the investigation in response to numerous complaints.

In the Non-Prosecution Agreement, FPMC acknowledged the United States has sufficient evidence to seek an indictment for the offering and payment of illegal kickbacks in violation of federal law. In return for the non-prosecution of the hospital, FPMC selected and retained an independent monitor to address any compliance issues and the United States' concerns regarding the allegations of illegal conduct. The monitor will be in place for not more than 24 months and will review and evaluate inpatient and outpatient claims submitted to all payors, not just federal programs. FPMC also agreed to cooperate with the United States' ongoing investigation into certain individuals. No persons were released under the civil and criminal agreements. The United States' investigation remains ongoing.

U.S. Attorney Saldaña praised the efforts of the investigating agencies, including the Defense Criminal Investigative Services; FBI; Department of Labor, EBSA; Office of Inspector General of the Office of Personnel Management; and FDA-CI.

"This civil and criminal resolution spares the honest employees and investors of FPMC, while holding the hospital accountable for allowing an environment where its representatives paid illegal kickbacks for referrals," said U.S. Attorney Saldaña. "This outcome imposes well-deserved measures that we expect will ensure FPMC becomes fully compliant with federal and private health care program requirements. Whether physician-owned, not-for-profit or for-profit, the Department of Justice expects, and requires, all providers to be trustworthy and abide by the law," Saldaña continued.

The case was handled by Assistant U.S. Attorneys Sean McKenna, Errin Martin and Lynette Wilson, and Special Assistant U.S. Attorney Glenn Harrison.

30

Case 3:16-cr-00516-JJZ - Document 1 Filed 11/16/16 Page 1 of 44 PageID 1

ORIGINAL **SEALED** CLERK OF DISTRICT COURT
IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION 2016 NOV 16 PM 2:26

UNITED STATES OF AMERICA
v.
ALAN ANDREW BEAUCHAMP (01)
RICHARD FERDINAND TOUSSAINT, JR. (02)
WADE NEAL BARKER (03)
WILTON MCPHERSON BURT (04)
ANDREA KAY SMITH (05)
CARLI ADELE HEMPEL (06)
KELLY WADE LOTER (07)
JACKSON JACOB (08)
DOUGLAS SUNG WON (09)
MICHAEL BASSEM RIMLAWI (10)
DAVID DAESUNG KIM (11)
WILLIAM DANIEL NICHOLSON IV (12)
SHAWN MARK HENRY (13)
MRUGESHKUMAR KUMAR SHAH (14)
GERALD PETER FOOX (15)
FRANK GONZALES JR. (16)
ISRAEL ORTIZ (17)
IRIS KATHLEEN FORREST (18)
ANDREW JONATHAN HILLMAN (19)
SEMYON NAROSOV (20)
ROYCE VAUGHN BICKLEIN (21)

DEPUTY CLERK _____
CRIMINAL NO.
TO BE FILED UNDER SEAL
3-16CR-0516D

INDICTMENT

The Grand Jury charges:
At all times material to this Indictment, unless otherwise specified:
General Allegations

1. Forest Park Medical Center Dallas (FPMC) was a physician owned, surgical hospital located at 11990 North Central Expressway, Dallas, Texas. It opened in March

31

FPMC Indictment

- ❖ Three-pronged conspiracy
 - ▶ Maximize reimbursement by refusing to join payer networks
 - ▶ Maximize patient volume by paying bribes and kickbacks
 - ▶ Hide scheme by laundering bribes through sham arrangements
 - Management support and marketing arrangements

BASS BERRY + SIMS^{PC}

32

FPMC Indictment

- (1) Conspiracy to pay and receive health care bribes and kickbacks
- (2) Violation of Anti-Kickback Statute
- (3) Violation of Travel Act (18 U.S.C. § 1952) and Texas Commercial Bribery Statute
 - - Makes it illegal to travel or use mail in interstate commerce with the intent to promote or facilitate any “unlawful activity,” which includes bribery
- (4) Money Laundering

BASS BERRY + SIMS[®]

33

Questions?

BASS BERRY + SIMS[®]

34