Healthcare Fraud Enforcement From The Trenches:

The Top Government Enforcement Priorities in the Healthcare Space

Scott Grubman

Chilivis Cochran (Atlanta GA)

Todd Swanson

U.S. Attorney's Office (M.D. GA.)

2

Enforcement Trends

Enforcement Trends

3

I. **Opioid Fraud & Abuse**

II. **Stark & AKS**

III. **EHR Fraud**

IV. **Telehealth/Telemedicine**

Enforcement Trends

4

FY	NEW MATTERS[2]		SETTLEMENTS AND JUDGMENTS[3]					RELATOR SHARE AWARDS[4]		
	NON QUI TAM	QUI TAM	NON QUI TAM	QUI TAM			TOTAL QUI TAM AND NON QUI TAM			
			TOTAL	WHERE U.S. INTERVENED OR OTHERWISE PURSUED	WHERE U.S. DECLINED	TOTAL		WHERE U.S. INTERVENED OR OTHERWISE PURSUED	WHERE U.S. DECLINED	TOTAL
2008	60	231	162,972,022	962,461,088	6,852,571	969,313,659	1,132,285,682	185,933,162	1,522,164	187,455,327
2009	34	279	238,061,424	1,368,411,522	30,283,452	1,398,694,974	1,636,756,398	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	25	415	557,273,967	2,504,859,295	37,838,668	2,542,697,964	3,099,971,931	280,962,860	10,598,793	291,561,653
2013	27	504	61,354,329	2,553,768,951	119,260,369	2,673,029,320	2,734,383,649	470,977,353	28,526,451	499,503,804
2014	32	470	88,054,490	2,281,871,362	66,322,326	2,348,193,688	2,436,248,178	384,433,366	10,877,186	395,310,552
2015	2	426	154,748,714	1,491,545,193	472,604,555	1,964,149,748	2,118,898,462	272,895,421	132,218,688	405,114,108
2016	6	503	97,579,302	2,442,433,633	72,945,688	2,515,379,321	2,612,958,623	436,863,321	20,481,847	457,335,168
2017	5	491	32,627,357	2,064,232,084	380,259,107	2,444,491,192	2,477,118,549	250,287,440	32,548,144	282,835,584
TOTAL	960	7,177	6,159,874,424	28,782,313,222	1,521,955,836	30,304,269,058	36,464,143,482	4,649,339,989	294,366,914	4,943,706,903

Source: DOJ Civil Division Fraud Statistics

5

Opioid Fraud & Abuse

Opioid Fraud & Abuse

6

- **July 2017:** National healthcare fraud takedown
  - Over 400 charged
  - Over 1/3 related to prescribing opioids & other dangerous narcotics

Opioid Fraud & Abuse

7

- **August 2017:** DOJ Announces Opioid Fraud & Abuse Detection Unit
  - Use of data to identify & prosecute individuals that are contributing to opioid epidemic
    - Outlier physicians
    - Patient deaths w/in 60 days of opioid RX
    - Avg. age of prescriptions
    - Outlier pharmacies
  - 12 AUSAs for 3 year term
  - MDFL, EDMI, NDAL, EDTN, DNEV, EDKY, DMD, WDPA, SDOH, EDCAL, MDNC, SDWV

Opioid Fraud & Abuse

8

- **September 2017:** 41 State AGs announce joint investigation of manufacturers & distributors of opioids.
- **January 2018:** AG Sessions announces DEA surge to focus on pharmacies and prescribers who dispense unusual or disproportionate amount of drugs.
- **Feb. 2018:** New Jersey AG announces creation of new office within AG Office dedicated exclusively to opioid issues.

Opioid Fraud & Abuse

9

- **Feb. 27, 2018:** DOJ announces creation of **Prescription Interdiction & Litigation (PIL) Task Force**.
  - PIL will "aggressively deploy and coordinate all available criminal and civil law enforcement tools to reverse the tide of opioid overdoses in the United States, with a particular focus on opioid manufactures and distributors."
  - PIL will use all criminal & civil tools available to hold distributors such as **pharmacies, pain mgmt. clinics, drug testing facilities, and individual physicians** accountable for unlawful actions.

Opioid Fraud & Abuse

10

- **CDC Guideline for Prescribing Opioids for Chronic Pain**
  - Nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain. Clinicians should consider opioid therapy **only if expected benefits for both pain and function are anticipated to outweigh risks to the patient**. If opioids are used, they should be **combined with nonpharmacologic therapy and nonopioid pharmacologic therapy**, as appropriate.
  - Before starting opioid therapy for chronic pain, **clinicians should establish treatment goals with all patients, including realistic goals for pain and function, and should consider how opioid therapy will be discontinued if benefits do not outweigh risks**. Clinicians should continue opioid therapy only if there is clinically **meaningful improvement** in pain and function that outweighs risks to patient safety.
  - Before starting and periodically during opioid therapy, clinicians should discuss with patients **known risks and realistic benefits** of opioid therapy and patient and clinician responsibilities for managing therapy.

Opioid Fraud & Abuse

11

- **CDC Guideline for Prescribing Opioids for Chronic Pain**
  - When starting opioid therapy for chronic pain, clinicians should **prescribe immediate-release opioids** instead of extended-release/long-acting (ER/LA) opioids.
  - When opioids are started, clinicians should prescribe the **lowest effective dosage**. Clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when considering increasing dosage to ≥50 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to ≥90 MME/day or carefully justify a decision to titrate dosage to ≥90 MME/day.
  - Long-term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should **prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than seven days will rarely be needed.**
  - **Clinicians should evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy for chronic pain or of dose escalation**. Clinicians should evaluate benefits and harms of continued therapy with patients every 3 months or more frequently. If benefits do not outweigh harms of continued opioid therapy, clinicians should optimize other therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids.

Opioid Fraud & Abuse

12

- **CDC Guideline for Prescribing Opioids for Chronic Pain**
  - **Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk factors for opioid-related harms.** Clinicians should incorporate into the management plan strategies to mitigate risk, including considering offering naloxone when factors that increase risk for opioid overdose, such as history of overdose, history of substance use disorder, higher opioid dosages (≥50 MME/day), or concurrent benzodiazepine use, are present.
  - **Clinicians should review the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP) data** to determine whether the patient is receiving opioid dosages or dangerous combinations that put him or her at high risk for overdose. Clinicians should review PDMP data when starting opioid therapy for chronic pain and periodically during opioid therapy for chronic pain, ranging from every prescription to every 3 months.
  - When prescribing opioids for chronic pain, clinicians should use **urine drug testing** before starting opioid therapy and consider urine drug testing at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs.
  - Clinicians should **avoid prescribing opioid pain medication and benzodiazepines concurrently** whenever possible.
  - Clinicians should offer or arrange **evidence-based treatment** (usually medication- assisted treatment with buprenorphine or methadone in combination with behavioral therapies) for patients with opioid use disorder.

13

Stark & AKS

Stark & AKS

14

- Stark Law:
  - **The Rule:** If physician (or immediate family member) has financial relationship with entity (e.g. hospital), physician may **not** make referral to entity for designated health service ("DHS") and entity may **not** submit claims for such services.
  - Applies to Medicare and Medicaid
  - Strict liability (no intent required)
  - Can lead to FCA liability, CMPs, exclusion

Stark & AKS

15

- **AKS:**
  - Prohibits **knowingly & willfully** paying, offering, soliciting or receiving remuneration in return for FHP referral
  - **Criminal**, civil & administrative remedies (including damages + penalties + exclusion)
  - Predicate to FCA liability
  - Feb. 9, 2018: Bipartisan Budget Act increase penalties from $25K to $100K per violation, and increases maximum prison time from 5 to 10 years.

Stark & AKS

16

- **Pacific Alliance (June 2017)**
  - Pacific Alliance Medical Center and parent companies agree to pay **$42M** to resolve alleged Stark/AKS/FCA violations, brought in a whistleblower suit by manager of hospital.
  - Suit alleged improper payments to referring physician in forms of (1) above-FMV office space rental payments; and (2) marketing arrangements that allegedly provided undue benefit to physicians' practices.

Stark & AKS

17

- **MediSys Health Network (Sept. 2017)**
  - N.Y. hospital pays **$4M** to resolve whistleblower suit filed by physician, alleging various Stark violations.
  - Whistleblower alleged that hospital violated Stark by, among other things, offering below-FMV rent for offices including free janitorial services, utilities, stationary, collection of medical waste, subsidized parking for patients, phone, fax, and pager services.

Stark & AKS

18

- **21st Century Oncology (Dec. 2017)**
  - 21st Century Oncology agrees to pay **$26M** to resolve FCA *qui tam* as well as self-disclosure related to EHR attestation
  - *Qui tam* brought by former Interim VP of Financial Planning
  - Allegations involved overcompensation of referring physicians

Stark & AKS

19

- **Pine Creek Medical Ctr. (Dec. 2017)**
  - Pine Creek Medical Ctr. (Dallas) agrees to pay **$7.5M** to resolve FCA *qui tam* alleging payment of kickbacks to physicians in exchange for surgical referrals in form of marketing services.
  - Remuneration included hospital paying for advertisements on behalf of physicians in local & regional publications, as well as radio and TV advertising, pay-per-click advertising campaigns, billboards, website upgrades, business cards, etc.

Stark & AKS

20

- **Jan 2018:** Two California urologists pay $1.085M to resolve allegations that they billed for IGRT services that were referred and billed in violation of Stark & AKS.
  - This included both referrals from other urologists who were receiving lease payments for IGRT equipment, as well as their own referrals to billing entity (which they owned).
  - Previously, "lessee urologists" agreed to pay $900K to resolve matter.

21

EHR-Related Fraud & Abuse

Technology in Fraud and Abuse

22

- **Meaningful Use Fraud**
  - **May 2017:** eClinicalWorks agrees to pay $155M to resolve FCA lawsuit alleging that ECW misrepresented the capabilities of its software and paid kickbacks to certain customers in exchange for promoting its product.
    - Govt. alleged that ECW falsely obtained meaningful use certification by concealing certain information from certifying entity.

Technology in Fraud and Abuse

23

- **Meaningful Use Fraud**
  - **Dec. 2017:** 21st Century Oncology (Fl.) agrees to pay **$26M** to settle allegations that it violated FCA by submitting falsified meaningful use attestations:
    - Practice self-disclosed that it submitted false MU attestations through EHR software.
    - Also reported that employees falsified data about how EHR was used, created untrue software utilization reports, and superimposed EHR vendor logos on reports.

24

Telehealth & Telemedicine

Telehealth & Telemedicine

25

- **CMS reimburses for telehealth services only if very specific requirements met**
  - **Originating Site:** This is location of beneficiary at time of service. Beneficiaries eligible for telehealth only if they are presented from originating site located in a county outside of an MSA or a rural HPSA located in a rural census tract.
    - Must also be an authorized original site, which includes a **physician office, hospital, CAH, community health center, SNF, rural health clinic, FQHC**.
    - Check address eligibility: https://datawarehouse.hrsa.gov/tools/analyzers/geo/Telehealth.aspx.
    - Telephone and/or Skype is not sufficient.

Telehealth & Telemedicine

26

- **CMS reimburses for telehealth services only if very specific requirements are met**
  - **Eligible Practitioners:** Physicians, PAs, NPs, nurse-midwives, CNSs, CRNAs, clinical psychologists, CSWs, registered dietitian or nutritional professional.
  - **Telehealth Services:** Must use an interactive audio & video telecommunications system that permits real-time communication b/t provider and beneficiary.

Telehealth & Telemedicine

27

- **CMS reimburses for telehealth services only if very specific requirements met**
  - **Telehealth Services:** Only certain services are covered (check CMS website for telehealth list).
  - Use Place of Service code 02.
  - Originating sites can bill for facility fee using HCPCS code Q3014. This is a separately billable Part B payment.

Telehealth & Telemedicine

28

- **July 2016:** Connecticut physician and practice group agree to pay $36K in first reported FCA matter related to telehealth.
  - *Qui tam* complaint alleges that group billed Medicare for services provided over the phone and didn't qualify for telehealth.

Telehealth & Telemedicine

29

- **October 2017:** OIG supplements work plan and announces that it will audit Medicare claims paid for telehealth services to ensure compliance with CMS requirements.

Telehealth & Telemedicine

30

- **Feb. 2018:** DOJ files FCA suit against Patient Care America (PCA) compounding pharmacy (FL).
  - One of the allegations is that PCA and its marketers paid telemedicine doctors to prescribe compounded medication without seeing the patients, and sometimes paid the patients themselves to accept the prescriptions.

31

FCA Updates

FCA Updates

32

DOJ memoranda under new administration

FCA Updates

33

Post-*Escobar* case law

34

Proactive Compliance Tips

Proactive Compliance Tips

35

- Build an effective compliance program:

(1) Implement written policies, procedures & standards of conduct
(2) Designate a compliance officer and compliance committee
(3) Conduct effective training & education
(4) Develop effective lines of communication
(5) Conduct internal monitoring and auditing
(6) Enforce standards through well-publicized disciplinary guidelines
(7) Respond promptly to detected offenses and undertake corrective action

Seven Fundamental Elements of an Effective Compliance Program (HHS-OIG)

Proactive Compliance Tips

36

- Take all concerns **seriously**
- Do **not** retaliate against concerned employees
- Seek the advice of **competent healthcare counsel**
- Consider **self-disclosure** when appropriate

Questions?

37

Scott Grubman
(404) 262-6505
sgrubman@cclblaw.com

Todd Swanson
(478) 621-2718
Todd.Swanson@usdoj.gov