



Pennsylvania Bar Institute

24th Annual Health Law Institute Physician Year In Review

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Charles I. Artz, Esq.
Artz McCarrie Health Law

I. MEDICAL MARIJUANA REMAINS ILLEGAL UNDER FEDERAL LAW

- U.S. v. Bey, 341 F.Supp.3d (E.D. Pa. 2018)

Prescription of medical marijuana for pain management violated terms of supervised release/probation.

Conflict between the federal Controlled Substances Act and the Pennsylvania Medical Marijuana Act.

II. LEGITIMATE MEDICAL PURPOSE PROVISION IN CONTROLLED SUBSTANCES ACT NOT UNCONSTITUTIONALLY VAGUE

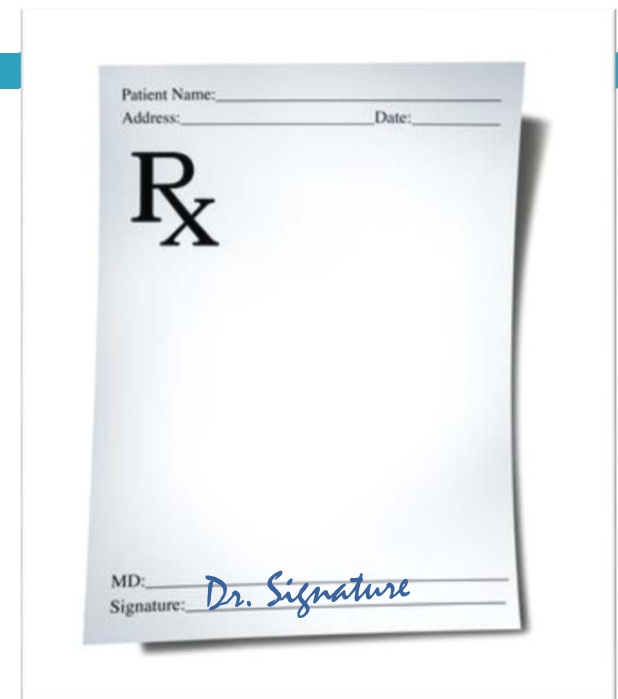
- U.S. v. Buckingham, (2018 WL 6570874) (N.D. Ala. 2018)
- Nine circumstances what physicians cannot do:
 1. Large quantity of controlled substances;
 2. Large numbers of Rx;
 3. Failing to physically examine patients;
 4. Fill Rx at different drug stores;
 5. Rx to patients delivering drugs to others;
 6. Inconsistent intervals with treatment;
 7. Using street slang;
 8. No logical relationship—drugs/condition;
 9. More than one prescription on single occasion/postdating.

Federal court held that the “legitimate medical purpose in the usual course of professional practice” provisions in the federal Controlled Substances Act are not unconstitutionally vague.

III. PRE-SIGNED BLANK PRESCRIPTIONS

- U.S. v. Delia, 906 F.3d 1212 (10th Cir. 2018)
 - Defendant physician signed pads of blank prescription forms for the clinic staff's use.

Compliance Point: Physicians should **never** pre-sign blank prescription pads for narcotics.



IV. FAILURE TO REPORT STOLEN CONTROLLED SUBSTANCES – LEGAL DUTY/POTENTIAL MALPRACTICE

DEA regulations require all individuals and entities registered with the DEA to notify the local DEA office, in writing, of the theft or significant loss of any controlled substances within one business day of discovery of such loss or theft.

21 C.F.R. §1301.76(b).

- ❑ Walters v. UPMC Presbyterian Shadyside, 187 A.3d 214 (Pa. 2018)
 - ❑ UPMC radiology technician engaged in the diversion and substitution of IV fentanyl.

VI. \$114 MILLION FALSE CLAIMS ACT VERDICT FAIR MARKET VALUE/ANTI-KICKBACK VIOLATIONS

- U.S. ex rel. Lutz v. BlueWave Healthcare Consultants, et al., (S.D.C. 2018)
 - Defendants filed Notice of Appeal of the \$114 Million judgment to the 4th Circuit U.S. Court of Appeals.
 - Briefing/Spring 2019

Marketing representatives and individuals found liable for violating the Anti-Kickback statute and False Claims Act for improper claims submitted to Medicare and TRICARE.

VII. STARK MRI NOTIFICATION FREEDOM OF CHOICE REQUIREMENTS

- U.S. ex rel. Richardson v. Lexington Foot & Ankle Center, (2018 WL 2709320) (E.D. Ken. 2018)
 - Violation of Imaging Disclosure requirements under 42 C.F.R. §411.356(b)(7).
 - Federal court dismissed case due to insufficient evidence.
 - Court granted whistleblower's motion to file a new, amended Complaint with more specifics relating to fraud.

The whistleblower alleged that the defendant provider violated the Stark regulations by self-referring MRIs and by placing written confirmation in patient records indicating third party MRI services were offered to patients when no such alternatives were actually offered.

VIII. STARK INDIRECT COMPENSATION ARRANGEMENTS FALSE CLAIMS ACT DISMISSAL

A whistleblower alleged that compensating physicians above the Medicare wRVU rate was a *per se* Stark violation and took into account the volume or value of internal referrals, thereby creating an Independent Compensation Arrangement.

- ❑ U.S. ex rel. Bookwalter v. UPMC, (2018 WL 1509064) (W.D. Pa. 2018)
 - ❑ Federal court dismissed the case with prejudice.
 - ❑ Must first establish that an ICA exists before proving applicability of an exception.

IX. SUBSTITUTE SIGNATURE ON PHYSICIAN CLAIMS FALSE CLAIMS ACT DECISION

- U.S. ex rel. Kelly v. Select Specialty Hospital,
(2018 WL 1568874)
(D. Del. 2018)
- Court cited U.S. ex rel. Emanuele v. Medicor Associates,
242 F.Supp.3d 409, 431
(W.D. Pa. 2017)

The whistleblower alleged the lack of physician signatures and the chief nursing officer's execution of medical practitioners' signatures on medical records constituted legally false claims.



X. MANUFACTURER CONSULTING AGREEMENTS POTENTIAL ANTI-KICKBACK/FALSE CLAIMS ACT LIABILITY

- U.S. ex rel. Bawduniak v. Biogen,
(2018 WL 1996829)
(D. Mass. 2018)

The whistleblower sued the pharmaceutical drug manufacturer under the FCA based upon “sham” consulting contracts and speaker fee arrangements.

XI. PURCHASED PHYSICIAN SERVICES/ POTENTIAL ANTI-KICKBACK VIOLATION

- U.S. ex rel. Piacentile v. Snap Diagnostics,
(2018 WL 2689270)
(N.D. Ill. 2018)

Whistleblower filed suit under the FCA alleging illegal kickbacks, bribes or rebates were paid by the defendant provider to treating physicians and independent sales representatives to induce patient referrals.

XII. ANTI-KICKBACK STATUTE – MORE MARKETING DECISIONS

- Carrel v. AIDS Healthcare Foundation, 898 F.3d 1267 (11th Cir. 2018) →

11th Circuit U.S. Court of Appeals

- Aff'd dismissal of AKB violation
- *Bona fide employees*

- U.S. ex rel. Perez v. Healthquest, No. 16-81147 (S.D. Fla. 2018) →

Fed. Gov't recovered \$1.5 Million

- Hired marketing staff as independent contractors NOT as *bona fide employees*

XIII. OUT-OF-NETWORK PHYSICIAN COMPENSATION ERISA/ANTI-ASSIGNMENT CLAUSE ENFORCED

- American Orthopedic & Sports Medicine v. Independence Blue Cross Blue Shield, 890 F.3d 445 (3rd Cir. 2018)



XIV. CHIROPRACTIC DELEGATION OF THERAPEUTIC EXERCISE, MANUAL THERAPY AND MASSAGE THERAPY PROHIBITED

- State Farm v. Cavoto,
197 A.3d 1209 (Pa. Super. 2018)
- **What may and may not be delegated?**

State Farm sued defendants, contending that delegation of therapeutic exercise, manual therapy, massage and other modalities was unlawful.

XV. MEDICAL NECESSITY FRAUD FALSE CLAIMS CASE REINSTATED

- U.S. ex rel. Polukoff v. St. Mark's Hospital/ Sherman Sorensen, M.D. et al.,
895 F.3d 730 (10th Cir. 2018)

The 10th U.S. Court of Appeals has held that health care providers can be subjected to fraud claims prosecuted under the FCA for failing to follow national association guidelines, even in the absence of NCD or LCD.

XVI. MEDICAL NECESSITY CRIMINAL FRAUD CONVICTION REINSTATED

- U.S. v. Paulus,
894 F.3d 267 (6th Cir. 2018)

Cardiologist charged with health care fraud and making false statements.

- Jury convicted physician.
- Federal district court granted motion for judgment of acquittal.
- Government appealed.
- U.S. Court of Appeals reversed judgment of acquittal and reinstated conviction.