

LAW 7214: HEALTH CARE FRAUD AND ABUSE

Fall 2017

Summary and Syllabus

Vanderbilt University School of Law

Matthew M. Curley
Bass Berry & Sims PLC
150 Third Avenue North, Suite 2800
Nashville, Tennessee 37201
615.742-7790
matthew.curley@law.vanderbilt.edu
mcurley@bassberry.com

Brian D. Roark
Bass Berry & Sims PLC
150 Third Avenue North, Suite 2800
Nashville, Tennessee 37201
615-742-7753
brian.roark@law.vanderbilt.edu
broark@bassberry.com

COURSE SUMMARY

Overview

This course is intended to cover the health care fraud and abuse laws and issues relating to the prosecution and defense of alleged wrongdoing under federal and state health care systems. This course will provide a basic overview of the laws governing healthcare providers, such as hospitals, physicians and physician practices, medical device and pharmaceutical manufacturers, clinical laboratories and nursing homes. The course also will cover the criminal and civil prosecution and defense of actions against such entities and individuals and the essential features of the major statutes in this area of the law including the federal civil False Claims Act, the Stark Act, the federal Anti-kickback Statute and the remedies and civil and criminal penalties available to governmental entities and civil litigants. This course will address voluntary and mandatory fraud and abuse compliance strategies and the practical compliance issues faced by health care providers.

Course Materials

There is no text for this course. The required reading materials primarily consist of statutes, regulations and case law, along with federal and state agency guidance and materials, articles, sample documents, and other photocopied materials. Materials will be provided on the Blackboard website or are available on-line. Reading packets also may be distributed in hard copy form before each class. See the reading assignments.

Students are expected to complete the assigned reading in advance of each class. Areas of focus for each of the assigned readings will be provided in advance of each class.

Student Outcomes and Assessment Measures

At the conclusion of this course, students will:

- Understand the primary federal fraud and abuse laws governing health care providers, including the civil False Claims Act, the Stark Law, the Anti-Kickback Statute, and the Civil Monetary Penalties Law
- Appreciate the differences and overlap of civil, criminal, and administrative enforcement authorities in the health care industry
- Be able to evaluate and discuss the policy implications underlying the health care fraud and abuse laws
- Recognize the fraud and abuse compliance challenges faced by different health care industries, including hospitals and health systems, physicians, pharmaceutical and device manufacturers, and long-term care companies

These outcomes will be measured by a written paper and through class participation in discussion and mock exercises.

Course Requirements and Grading

Regular class attendance is required. Excessive absences may result in automatic withdrawal from the course, exclusion from the final examination with a failing grade, or a reduction in grade, all at the discretion of the faculty member involved.

We request that no laptops be used during class.

Final Paper (75% of Grade). In lieu of a final exam, each student will choose a case from among a listing of health care fraud cases dealing with one or more of the issues that has been covered during the course. Students will write a paper discussing and analyzing the ruling in the assigned case and discussing the case in context with existing health care fraud laws covered during the course.

Papers should be written in case-note style, using endnotes instead of footnotes and using appropriate citation format. The papers must be a minimum of 15 pages and a maximum of 20 pages of text, excluding endnotes. NOTE: All papers must be completed by or before November 20, 2016, and students will present their papers in class on November 27, 2016. The in-class presentations will be approximately five minutes.

Class Participation/Required Reading (25% of Grade). Students are expected to attend all classes in their entirety, read the course materials in preparation for class discussion, participate actively in group discussions, mock exercises, and hypothetical factual scenarios, and complete any homework assignments the instructors may assign.

The required reading materials primarily consists of statutes, regulations and case law, along with federal and state agency guidance and materials, articles, sample documents and other photocopied materials. Materials will be provided on Blackboard or available on-line. Students are expected to complete the assigned reading in advance of each class. Areas of focus for each of the assigned readings will be provided in advance of each class. We request that no laptops be used during class.

Recommended Reading and Resources. While not required reading, the following materials are recommended resources covering the issues and topics discussed in this class:

Robert S. Salcido, *False Claims Act & the Healthcare Industry: Counseling & Litigation*, Second Edition (American Health Lawyers Association)

John T. Boese, *Civil False Claims and Qui Tam Actions*, Fourth Edition (Aspen Publishers)

Michal Loucks & Carol Lam, *Prosecuting and Defending Health Care Fraud Cases*, Second Edition (BNA Publishing)

Center for Medicare & Medicaid Services, www.cms.gov

U.S. Department of Health & Human Services, OIG, www.hhsoig.gov

TOPICS COVERED AND REQUIRED READING

1. August 21: Overview of Fraud and Abuse Laws

A. Delivery of Care and Reimbursement

B. Regulatory Framework

- “Avoiding Medicare Fraud & Abuse: A Roadmap for New Physicians,” Publication of the Department of Health and Human Services Office of Inspector General, available at:
https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/Avoiding_Medicare_Fraud_Physicians_FactSheet_905645.pdf

2. August 28: The Anti-Kickback Statute

- Review summary provided at:
<http://www.healthlawyers.org/hlresources/Health%20Law%20Wiki/Anti-Kickback%20Statute.aspx>
- 42 U.S.C. § 1320a-7b(b)
- 42 C.F.R. § 1001.952
- OIG Advisory Opinion No. 12-15, available at
<http://www.oig.hhs.gov/fraud/docs/advisoryopinions/2011/AdvOpn12-15.pdf>
- Stark/AKS Comparison Chart, available at:
<https://oig.hhs.gov/compliance/provider-compliance/training/files/StarkandAKSChartHandout508.pdf>
- *United States v. LaHue*, 261 F.3d 993 (10th Cir. 2001)

3. September 4: The Physician Self-Referral Prohibition

- Review summary provided at:
<http://www.healthlawyers.org/hlresources/Health%20Law%20Wiki/Stark.aspx>
- Excerpts from:
 - *U.S. ex rel. Drakeford v. Tuomey Healthcare Sys., Inc.*, 675 F.3d 394 (4th Cir. 2012), and 2015 WL 4036166 (4th Cir. Jul. 2, 2015)
 - *U.S. ex rel. Villafane v. Solinger*, 543 F. Supp. 2d 678 (W.D. Ky. 2008)
- CMS Advisory Opinion No. 2011-01, available at:
<https://www.cms.gov/PhysicianSelfReferral/Downloads/CMS-AO-2011-01.pdf>

4. September 11: The Civil False Claims Act

A. Statutory Framework

- 31 U.S.C. §§ 3729-3733
- False Claims Act Primer (to be provided)

B. Public Disclosure Bar & First to File Bar

- 31 U.S.C. § 3730(e)(4)
- *United States ex rel. Whipple v. Chattanooga-Hamilton Co. Hosp. Auth.*, 782 F.3d 260 6th Cir. 2015)
- *U.S. ex rel. White v. Gentiva Health Services, Inc.*, 2104 WL 2893223 (E.D. Tenn. June 25, 2014)

C. Damages & Penalties

- *United States v. Rogan*, 459 F. Supp. 2d 692 (N.D. Ill. 2006)
- *United States v. Anchor Mortgage*, 711 F.3d 745 (7th Cir. 2013)

5. September 18: Civil False Claims Act – Substantive Requirements (I)

A. Falsity & Causation

- *U.S. ex rel. Hutcheson v. Blackstone Med., Inc.*, 647 F.3d 377 (1st Cir. 2011)
- *Universal Health Servs., Inc. v. U.S. ex rel. Escobar*, 136 S.Ct. 1989 (2016)
- *U.S. ex rel. Martin v. Life Care Centers of America*, 2014 WL 4816006 (E.D. Tenn. Sep. 29, 2014)
- *U.S. ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235 (3d Cir. 2004)

6. September 25: Civil False Claims Act – Substantive Requirements (II)

A. Knowledge and Materiality

- *U.S. ex rel. Williams v. Renal Care Group, Inc.*, 696 F.3d 518 (6th Cir. 2012)
- *Universal Health Servs., Inc. v. U.S. ex rel. Escobar*, 136 S.Ct. 1989 (2016) (repeated from previous class)
- *United States v. Krizek*, 111 F.3d 934 (D.C. Cir. 1997)

B. Pleading Requirements for FCA Lawsuits

- *U.S. ex rel. Nathan v. Takeda Pharmaceuticals N.A., Inc.*, 707 F.3d 451 (4th Cir. 2013)

7. **October 2: Criminal Enforcement**

A. Applicable Criminal Statutes

- Health Care Fraud, 18 U.S.C. § 1347
- Criminal False Claims, 18 U.S.C. § 287
- False Statements, 18 U.S.C. § 1001
- Mail Fraud/Wire Fraud, 18 U.S.C. §§ 1341, 1343
- Obstruction, 18 U.S.C. §§ 1516, 1518

B. Prosecuting Business Organizations

- U.S. Attorney's Manual: Principles of Federal Prosecution of Business Organizations, 9-28.000, available at:
www.justice.gov/usao/eousa/foia_reading_room/usam/title9/28mcrm.htm
<http://www.justice.gov/opa/documents/corp-charging-guidelines.pdf>

C. Parallel Proceedings

- Memorandum of United States Attorney General Eric Holder: "Coordination of Parallel Criminal, Civil, Regulatory and Administrative Proceedings" (Jan. 30, 2012)
- *United States v. Stringer*, 535 F.3d 929 (9th Cir. 2008)
- *United States v. Scrushy*, 366 F. Supp. 2d 1134 (N.D. Ala. 2005)

C. Prosecuting Individuals

- Memorandum Regarding Individual Accountability for Corporate Wrongdoing (Sep. 9, 2015)

E. Sentencing and Deferred Prosecution Agreements

- *United States v. Allergan Inc.*, 10-CR-0375 (N.D. Ga.), Criminal Information
- *United States v. Allergan Inc.*, 10-CV-0375 (N.D. Ga.), United States Sentencing Memorandum

8. October 9: Administrative Enforcement

CMPs and Exclusion

- OIG Exclusion Statute, 42 U.S.C. § 1320a-7
- 42 C.F.R. §§ 1001.1-1001.3004
- Guidance for Implementing Permissive Exclusion Authority Under Section 1128(b)(15) of the Social Security Act, available at: http://oig.hhs.gov/fraud/exclusions/files/permissive_excl_under_1128b15_10192010.pdf
- Criteria for Implementing Permissive Exclusion Authority Under Section 1128(b)(7) of the Social Security Act, 62 Fed. Reg. 67,392 (Dec. 24, 1997)
- The Effect of Exclusion From Participation in Federal Health Care Programs Special Advisory Bulletin (September 1999), available at: http://oig.hhs.gov/exclusions/effects_of_exclusion.asp
- Synthes/Norian Corporation Divestiture Agreement (September 2010), available at: http://www.justice.gov/usao/pae/Pharma-Device/synthes_divestagrmt.pdf

9. October 16: Internal Investigations and Compliance Programs

A. Conducting Internal Investigations

B. Attorney-Client Privilege Considerations

- Preserving the Attorney-Client Privilege in Healthcare Fraud Investigations (to be provided)
- *U.S. ex rel. Frazier v. IASIS Healthcare Corp.*, 2012 U.S. Dist. LEXIS 6896 (D. Ariz. Jan. 10, 2012)
- *U.S. ex rel. Fair Laboratories Practices Assocs. v. Quest Diagnostics Inc.*, 2011 WL 1330542 (S.D.N.Y. Apr. 5, 2011)
- *U.S. ex rel. Fair Laboratories Practices Assocs. v. Quest Diagnostics Inc.*, 734 F.3d 154 (2d Cir. 2013)

C. Compliance Programs

- 2011 Federal Sentencing Guidelines Manual, Chapter 8, Part B, Section 2, available at http://www.ussc.gov/Guidelines/2011_guidelines/Manual_HTML/8b2_1.htm

- OIG Supplemental Compliance Program Guidance for Hospitals, 70 Fed. Reg. 4858 (January 31, 2005), available at: <http://www.oig.hhs.gov/fraud/docs/complianceguidance/012705HospSupplementalGuidance.pdf>

10. October 23: In Class Exercise – Healthcare Fraud Hypothetical

11. October 30: Overpayments, Self-Disclosures and Settlements

A. Overpayments

- 42 U.S.C. § 1128J(d)
- *U.S. ex rel. Kane v. Healthfirst, Inc.*, 2015 WL 4619686 (S.D.N.Y. Aug. 3, 2015)

B. OIG/CMS Self Disclosure Protocol

- HHS/OIG Publication of the OIG’s Provider Self-Disclosure Protocol (Apr. 17, 2013)
- Open Letter to Health Care Providers (Mar. 24, 2009)
- Open Letter to Health Care Providers (April 15, 2008)
- Open Letter to Health Care Providers (April 24, 2006)
- CMS Voluntary Self-Referral Disclosure Protocol, available at: https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Self_Referral_Disclosure_Protocol.html
- Report to the Congress: Implementation of the Medicare Self-Referral Disclosure Protocol, available at <http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/CMS-SRDP-Report-to-Congress.pdf>

C. Settlements and Corporate Integrity Agreements

- FORBA Holdings LLC (“Small Smiles”) Settlement Agreement
- FORBA Holdings LLC (“Small Smiles”) Corporate Integrity Agreement

12. November 6: Pharmaceutical & Device Issues

A. Government Oversight and Approval

B. Food Drug & Cosmetic Act

- 21 U.S.C. §§ 351-52
- Alerting the C-Suite: The Responsible Corporate Officer Doctrine (to be provided)

C. Off-Label Promotion & Defenses

- Misbranding Under the Food, Drug and Cosmetic Act: Promotion Guidelines, Off-Label Enforcement Trends and Defenses (to be provided)
- *United States v. Caronia*, 703 F.3d 149 (2d Cir. 2012)
- *Amarin Pharma, Inc. v. United States Food & Drug Admin.*, No. 15-cv-3588 (S.D.N.Y. Aug. 7, 2015)

D. Current Good Manufacturing Practices

- *United States v. SB Pharmco Puerto Rico, Inc.*, Final Information and Plea Agreement

E. Average Sales Price

- 42 C.F.R. § 414.800-04

13. November 13: Case Study

United States v. Lauren Stevens, No. 10-cr-0694 (D. Md.) (materials below to be provided)

- Indictment
- Memorandum Opinion dated March 23, 2011
- Defendant's Motion under Fed. R. Crim. P. 29 for Judgment of Acquittal
- United States' Initial Response to Defendant's Motion for Judgment of Acquittal
- Transcript of Hearing dated May 10, 2011

14. November 28: Discussion/Presentation of Final Papers