LAW 7214: HEALTH CARE FRAUD AND ABUSE

Fall 2016

Summary and Syllabus

Vanderbilt University School of Law

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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. 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 21, 2016, and students will present their papers in class on November 28, 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:


Center for Medicare & Medicaid Services, [www.cms.gov](http://www.cms.gov)

TOPICS COVERED AND REQUIRED READING

1. August 22: 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:

2. August 29: The Anti-Kickback Statute
   
   • Review summary provided at:
   
   • 42 U.S.C. § 1320a-7b(b)
   
   • 42 C.F.R. § 1001.952
   
   • OIG Advisory Opinion No. 12-15, available at
   
   • Stark/AKS Comparison Chart, available at:
   
   • United States v. LaHue, 261 F.3d 993 (10th Cir. 2001)

3. September 5: The Physician Self-Referral Prohibition
   
   • Review summary provided at:
   
   • Excerpts from:
     
     
     • CMS Advisory Opinion No. 2011-01, available at:
4. **September 12: 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)

   C. Damages & Penalties
   
   - *United States v. Anchor Mortgage*, 711 F.3d 745 (7th Cir. 2013)

5. **September 19: Civil False Claims Act – Substantive Requirements (I)**

   A. Falsity & Causation
   

6. **September 26: 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)
B. Pleading Requirements for FCA Lawsuits


7. **October 3: 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


C. Parallel Proceedings

- *United States v. Stringer*, 535 F.3d 929 (9th Cir. 2008)

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 10: Administrative Enforcement

CMPs and Exclusion

- OIG Exclusion Statute, 42 U.S.C. § 1320a-7
- 42 C.F.R. §§ 1001.1-1001.3004

9. October 17: 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)

C. Compliance Programs


10. October 24: In Class Exercise – Healthcare Fraud Hypothetical

11. October 31: Overpayments, Self-Disclosures and Settlements

A. Overpayments

• 42 U.S.C. § 1128J(d)


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)


C. Settlements and Corporate Integrity Agreements

• FORBA Holdings LLC (“Small Smiles”) Settlement Agreement

• FORBA Holdings LLC (“Small Smiles”) Corporate Integrity Agreement
12. **November 7: 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)
      

   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 14: 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**