LAW 772: HEALTH CARE FRAUD AND ABUSE

Fall 2013

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 Requirements and Grading

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 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 15, 2013, and students will present their papers in class on November 18, 2013. 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 and mock exercises, 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 the OAK/Online Access to Knowledge website and publicly-available on-line or through other resources available to students (e.g., LexisNexis/Westlaw). Students are expected to complete the assigned reading in advance of each class. In advance of each class, students will be informed as to the particular entries in the required reading that will be emphasized during the following class and whether certain readings may be skimmed or omitted.
**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 19: Overview of Fraud and Abuse Laws
   
   A. Delivery of Care and Reimbursement
   
   B. Regulatory Framework
     
     • “A Roadmap for New Physicians, Avoiding Medicare and Medicaid Fraud and Abuse, Publication of the Department of Health and Human Services Office of Inspector General”
     
     Available at:  

2. August 26: 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
     
     • Hanlester Network v. Shalala, 51 F.3d 1390 (9th Cir. 1985)
     
3. **September 2: The Physician Self-Referral Prohibition**

   - 42 U.S.C. § 1395nn
   - 42 C.F.R. §§ 411.350-411.389 (skim)

4. **September 9: The Civil False Claims Act**

   **A. Statutory Framework**
   - 31 U.S.C. §§ 3729-3733

   **B. Amendments & History**

   **C. Damages & Penalties**
   - *United States ex rel. Feldman v. Van Gorp*, 679 F.3d 78 (2d Cir. 2012)
   - *United States v. Anchor Mortgage*, 711 F.3d 745 (7th Cir. 2013)

   **D. Qui Tam Relators**
   
     **1. Public Disclosure Bar**
     - 31 U.S.C. § 3730(e)(4)

     **2. Original Source**
     - *U.S. ex rel. Davis v. Dist. of Columbia*, 679 F.3d 832 (D.C. Cir. 2012)
5. September 16: Civil False Claims Act – Substantive Requirements

A. Causation

• United States ex rel. Hutcheson v. Blackstone Med., Inc., 647 F.3d 377 (1st Cir. 2011)

B. Falsity

• Amicus Brief of the United States, United States ex rel. Hutcheson v. Blackstone Med., Inc.
• U.S. ex rel. Mikes v. Straus, 274 F.3d 687 (2d Cir. 2001)

C. Knowledge

• United States ex rel. Williams v. Renal Care Group, 696 F.3d 518 (6th Cir. 2012)
• United States ex rel. Hays v. Hoffman, 325 F.3d 982 (8th Cir. 2003)

6. September 23: Civil False Claims Act – Substantive Requirements

A. Materiality

• United States ex rel. Williams v. Renal Care Group, 696 F.3d 518 (6th Cir. 2012)
• United States ex rel. Hobbs v. Medquest Assocs., 711 F.3d 707 (6th Cir. 2013)
• U.S. ex rel. Drakeford v. Tuomey Healthcare Sys., Inc. – Various Pleadings

B. Pleading Requirements for FCA Lawsuits

7. September 30: Pharmaceutical & Device Issues

A. Government Oversight and Approval

B. Food Drug & Cosmetic Act

• 21 U.S.C. §§ 331-337, 351-52
• United States v. Park, 421 U.S. 658 (1975)

C. Off-Label Promotion & Defenses

• 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. § 414.804

F. Adulterated/Counterfeit Drugs

• U.S. v. Nissar, No. 4:12-CR-0009 (E.D. Mo.), Sentencing Memorandum

8. October 7: Prosecuting Healthcare Fraud Cases

A. Medicare Fraud Strike Force

• The Department of Health and Human Services and The Department of Justice Health Care Fraud and Abuse Control Program Annual Report for Fiscal Year 2011


B. Prosecuting Business Organizations


C. Parallel Proceedings


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


D. 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
9. **October 14: Internal Investigations and Defense of Cases**

A. Conducting Internal Investigations

- *United States v. Ruehle*, 583 F.3d 600 (9th Cir. 2009)

B. Attorney-Client Privilege Considerations

- *U.S. ex rel. Frazier v. IASIS Healthcare Corp.*: Selected Pleadings
- *United States v. Kovel*, 296 F.2d 918 (2d Cir. 1961)

C. Compliance Programs


D. In-Class Exercise: Interviewing Witnesses

10. **October 21: In Class Exercise – Healthcare Fraud Hypothetical**
11. October 28: Case Resolution

A. Administrative Enforcement

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

B. OIG/CMS Self Disclosure Protocol

- 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 4: Case Study & Common Fraud Schemes**

A. Case Study: *United States v. Lauren Stevens*, No. 10-cr-0694 (D. Md.)
   - 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

B. Common Fraud Schemes

1. Billing for Services Not Rendered
   - *United States v. O’Brien*, 14 F.3d 703 (1st Cir. 1994)

2. Billing for More Expenses Services Than Rendered (a/k/a “upcoding”)

3. Fragmenting Claims/Unbundling

13. **November 11: Common Fraud Schemes Continued**

A. Billing for Medically Unnecessary Services
   - *United States v. Khan*, 53 F.3d 507 (2d Cir. 1995)

B. Kickbacks and Self-Referrals
   - *United States v. Lipkis*, 770 F.2d 1447 (9th Cir. 1985)
   - *United States v. Ogba*, 526 F.3d 214 (5th Cir. 2008)

C. Lack of Physician Supervision/Billing for Care Provided by Unlicensed Staff

14. **November 18: Discussion/Presentation of Final Papers**