SYLLABUS

Health Reform: A New Age of Regulatory Enforcement 2012 Summer Course June 11, 12, 13, 14 5:30 PM – 8:45 PM

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1. <u>Course description</u>: The Patient Protection and Affordable Care Act of 2010 (PPACA) significantly enhances the federal government's efforts to combat fraud, waste and abuse with respect to Medicare, Medicaid and other federally funded health care programs.

Fraud in the health care system is pervasive. Tens of billions of taxpayer dollars are lost each year to fraud and abuse in the nation's health care system. What is the government doing about it? Are these efforts working? Can they be improved upon?

This court will examine several of PPACA's "Transparency and Program Integrity" provisions, which are designed to augment the government's enforcement efforts. We will focus on the complex nature of the problem that PPACA is tasked to solve. The seminar is intended to be lively and interactive, with students coming to class ready to participate and discuss the materials as if they were the decision-makers.

2. Course Materials:

- a. There is no textbook. A reading list follows. Materials will be available via TWEN.
- b. An updated reading list will be provided in advance of the start date. The readings will not change materially, but the list may be modified or supplemented if there are important developments in the law.

- 3. <u>Attendance</u>: The seminar is scheduled to meet 4 times. You should attend and be prepared for each session. Attendance and participation in the class will be significant portions of your grade, so please take seriously the requirement to show up ready to go. If you must miss a class, please let us know in advance if at all possible.
- 4. <u>Preparation and Class Discussion</u>: If you come to class having read and thought about the materials, you will learn more and find the seminar more interesting. We do not expect to do all of the talking in the class, so please come prepared to discuss the materials, and to answer questions from us or from any other participant in the seminar.
- 5. <u>Electronics</u>: The use of laptops during the class is discouraged if your laptop will distract your attention from the course. As a courtesy, please turn your phones off before class and leave them off during class.
- 6. <u>Evaluation</u>: Your grade will be based upon class participation (40%) and a final examination (60%).
- 7. <u>Exam</u>: There will be a take-home, open-book final exam. Students may pick up their exam anytime between Thursday June 14th (after class) and Saturday June 23rd. Students will have 72 hours between the time they "pick-up" the exam online and the time they "return" it. The exam will account for 60% of a student's grade.
 - <u>Note 1</u>: Exams will be graded on both substance and drafting. They should be well-written and well-reasoned, not simply a recitation of course content.
 - Note 2: Per AR-105 (B)(8): A student who does not take a scheduled examination will receive a grade of "F" for that examination, unless properly excused. Failure to meet any course requirement can be the basis for a final grade of "F" in the class, unless properly excused.

READING LIST Health Reform: A New Age of Regulatory Enforcement

June 11: An Introduction to the Problem

Tristram Korten, How To Commit Medicare Fraud in Six Easy Steps, FAST COMPANY.COM (Nov. 14, 2011)

Tristram Korten, Cracking Down on \$70 Billion Worth of Medicare Fraud, FAST COMPANY.COM (Nov. 19, 2011)

Atul Gawande, What a Texas Town Can Teach Us About Health Care, THE NEW YORKER (June 1, 2009)

Julie E. Kass & John S. Linehan, Fostering Healthcare Reform Through a Bifurcated Model of Fraud & Abuse Regulation, 5 J. HEALTH & LIFE SCI. LAW 75 (2012)

Jay Weaver, Medicare Fraud Rampant in South Florida, MIAMI HERALD (Aug. 3, 2008)

Guest Speaker (prosecutor's perspective)

June 12: Anti-Kickback Statute and False Claims Act

42 U.S.C. §1320a-7b

31 USC §§3729-3733

PPACA Sections 6402 (enhanced integrity provisions), 6408 (enhanced penalties)

United States ex rel. Spetter, Jr. et al. v. Abbott Laboratories, Inc. et al., 10-cv-00006-SGW (W.D. Va.) (partially unsealed)

Corporate Integrity Agreement, Merck & Co., Inc. (2011) (skim pages 1-25)

June 13: Medicare Provisions, Stark Self-Disclosure Protocol, Exclusion

Guest Speaker (practitioner's perspective on Stark Self-Disclosure Protocol)

42 USC §1395nn

PPACA Sections 6401 (Provider screening and compliance programs), 6402 (enhanced integrity provisions), 6409 (self-disclosure protocol), 6502 (Medicaid exclusion)

Friedman v. Sebelius, Civ. 09-2028 (D.D.C. Dec. 12, 2010) (Mem. Op.) (Huvelle, J.)

U.S. ex rel. Drakeford v. Tuomey Healthcare, (4th Cir. Mar. 30, 2012)

U.S. v. Rogan, 517 F.3d 449 (7th Cir. 2008)

Corporate Integrity Agreement, Maxim Healthcare Services, Inc. (2011) (skim pages 1-23)

June 14: Physician Payment Sunshine Act and Other Transparency Provisions

PPACA Sections 6002-6005 (Physician Payment Sunshine Act)

Physician Payment Sunshine Act Proposed Regulations, 76 Fed. Reg. 78,742 (Dec. 19, 2011) (skim)

PROPUBLICA, Docs on Pharma Payroll Have Blemished Records, Limited Credentials (Oct. 18, 2010)

PROPUBLICA, In Minnesota, Drug Company Reports of Payments to Doctors Arrive Riddled With Mistakes (Dec. 10, 2010)

Additional Suggested Reading

Testimony of Lewis Morris, Chief Counsel, Office of Inspector General, DHHS (June 15, 2010)

U.S. v. Duran et al., No. 10-cr-20767, Sept. 9, 2011 (Government's Memorandum in Aid of Sentencing)

U.S. v. Abbott Labs, No. 06-cv-1769 (N.D. Tex. Oct. 1, 2010), U.S.'s Statement of Interest on Defendants' Motions To Dismiss

Jay Weaver, A Former Scam Artist Tells How It Works, MIAMI HERALD (Aug. 5, 2008)

Jay Weaver, Medicare Fraud Fugitives Evade Capture, MIAMI HERALD (Aug. 5, 2008)