

HEALTH CARE FRAUD AND ABUSE AND STARK ISSUES

(719)

DePaul University College of Law

Health Law Institute

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WEEK 1 – JANUARY 12, 2009

I. OVERVIEW OF FRAUD AND ABUSE PROVISIONS

- A. Introduction
 - 1. Medicare
 - 2. Medicaid
- B. Excerpts from CMS Publication “Fraud & Abuse”
- C. Financial Inducements/Illegal Remuneration
 - 1. Criminal Provisions
 - 2. Civil Enforcement Provisions
- D. Self-Referral/Stark Act
- E. False Statements and False Claims
 - 1. Criminal Provisions
 - 2. Civil Provisions
 - 3. Civil Administrative Provisions
 - 4. Nature of False Claims
 - DOJ Press Release of Initial HCA Settlement
- F. Federal Health Care Program Exclusion Provisions
- G. Medicare Anti-Gouging Provision
- H. Settlements/Corporate Integrity Agreements

- I. HIPAA Fraud Provisions
 - *United States v. Whited*, 311 F.3d 259 (3d Cir.2002)
- J. PRO/QIO Actions
- K. EMTALA

WEEK 2 – JANUARY 19, 2009

II. REMUNERATION TO INDUCE REFERRALS

- A. Nature of Violation
- B. Purpose and Intent
 - *United States v. Universal Trade and Industries, Inc.* 695 F.2d 1151 (9th Cir. 1983).
 - *United States v. Greber*, 760 F.2d 68 (3rd Cir. 1985).
 - *United States v. Kats*, 871 F. 2d 105 (9th Cir. 1989)
 - *United States v. Bay State Ambulance*, 874 F. 2d 20 (1st Cir. 1989).
 - *United States v. McClatchey*, 217 F.3d 823 (10th Cir. June 13, 2000).
 - *United States v. LaHue*, 261 F.3d 993 (10th Cir. 2001)
 - *United States v. Shaw*, 2000 U.S. Dist. LEXIS 9347 (D. Mass. June 19, 2000)
 - *TAP Pharmaceuticals Superceding Indictment and Jury Instructions*
- C. Exclusion Provisions

WEEK 3 – JANUARY 26, 2009

- *Inspector General v. Hanlester Network*, CCH Medicare and Medicaid Guide ¶ 39,566 (DAB 1991).
- *Inspector General v. Hanlester Network*, CCH Medicare and Medicaid Guide ¶ 40,406B (DAB 1992).
- *Hanlester Network v. Shalala*, 51 F.3d 1390 (9th Cir. 1995)
- D. Use of Fraud and Abuse Principles to Void Contracts
 - *Polk County v. Peters*, 800 F. Supp. 1451 (E.D. Tex. 1992).

III. SAFE HARBOR REGULATIONS

A. Business Transaction Safe Harbors

1. Investment Interests

- Safe Harbor Language
- 1989 Preamble Language
- 1991 Preamble Language

2. Rental and Personal Services Arrangements

WEEK 4 – FEBRUARY 2, 2009

- Safe Harbor Language
- 1989 Preamble Language
- 1991 Preamble Language

3. Discount Safe Harbor

- Safe Harbor Language
- 1989 Preamble Language
- 1991 Preamble Language
- 1994 Clarification

B. Bona Fide Employment Arrangements

C. Purchase and Sale of Practices

D. Managed Care Safe Harbors

E. Investment in ASCs

F. Practitioner Recruitment

G. Referral Agreements for Specialty Services

H. Cooperative Hospital Service Organizations

I. Investment in Group Practices

J. Obstetrical Malpractice Insurance Subsidies

- K. Failure to Satisfy Safe Harbor
- L. 42 C.F.R. §1001.952

WEEK 5 – FEBRUARY 9, 2009

IV. OIG ADVISORY OPINIONS/INDUSTRY GUIDANCE

- A. Process for Obtaining Advisory Opinions
 - Preliminary Checklist for Advisory Opinion Requests
- B. Legal Significance of Advisory Opinions
- C. Considerations in Deciding to Seek Advisory Opinion
- D. Example Advisory Opinions
 - OIG Advisory Opinion 97-5
 - OIG Advisory Opinion 98-2
 - OIG Advisory Opinion 98-5
 - OIG Advisory Opinion 99-6
 - OIG Advisory Opinion 99-13
 - OIG Advisory Opinion 01-20
 - OIG Advisory Opinion 03-03
 - OIG Advisory Opinion 03-5
 - OIG Advisory Opinion 03-8
 - OIG Advisory Opinion 03-13
 - OIG Advisory Opinion 04-08
 - OIG Advisory Opinion 08-10

WEEK 6 – FEBRUARY 16, 2009

- E. OIG Fraud Alerts and Industry Guidance
 - 1. Joint Venture Arrangements
 - 2. Routine Waiver of Part B Copayments and Deductibles

3. Arrangements with Hospital-Based Physicians
4. Hospital Incentives to Physicians
5. Prescription Drug Marketing Schemes
6. Nursing Home Arrangements with Hospices
7. Services in Nursing Facilities
8. Home Health Fraud
9. Medical Supplies to Nursing Facilities
10. Physician Certification of Medical Necessity
11. Rental of Space in Physician Offices

F. OIG Voluntary Disclosure Protocol

CHAPTER IV APPENDIX: SUMMARY OF ADVISORY OPINIONS

WEEK 7 – FEBRUARY 23, 2009

V. STARK ACT AND REGULATIONS

A. Stark Act

- 42 U.S.C. §1395nn
- Designated Health Services
- *American Lithotripsy Society v. Thompson*, 215 F. Supp. 23 (D.C.D.C. 2002)
- Definitions of Financial Relationship/Compensation Arrangements
- Penalties

B. Specific Exceptions

C. Group Practice Definition

D. CMS Advisory Opinions

- Advisory Opinion No. CMS-AO-98-01
- Advisory Opinion No. CMS-AO-98-02

- Advisory Opinion No. CMS-AO-08-01
- E. Strict Liability and Implications of Non-Compliance With Stark Exceptions
- F. Pod Labs and the Anti-Markup Provision
- G. Application to Medicaid

CHAPTER V APPENDIX: 42 C.F.R. §§ 411.350 ET SEQ: STARK REGULATIONS

WEEK 8 – MARCH 2, 2009

VI. NATURE OF FALSE CLAIMS

- A. Nature of Violation
- B. Upcoding/Improper Coding.
 - *United States v. Larm*, 824 F.2d 780 (9th Cir. 1987).
 - *United States ex rel Stewart v. The Louisiana Clinic*, 2002 WL 1066745 (E.D.La. May 28, 2002)
- C. Cost Reports
 - *United States v. Whiteside*, 285 F.3d 1345 (11th Cir. 2002)
- D. Certification of Provider Status
 - *United States v. Syme*, 276 F.3d 131 (3rd Cir. 2002)
- E. Encouraging Claims For Non Covered Services
 - *United States ex rel Franklin v. Parke Davis*, 147 F. Supp. 39 (D. Mass. 2001)
 - *United States ex rel Franklin v. Parke Davis*, 2003 U.S. Dist. LEXIS 15754 (D. Mass. August 22, 2003)
 - *United States ex rel. Hess v. Sanofi-Synthelabo, Inc.*, (E.D. Mo. April 21, 2006)
- F. Actions Which Cost the Program Money
 - *OmniCare, Inc. To Pay \$49.5 Million To United States And 43 States To Settle Medicaid Prescription Drug Fraud Allegations*
- G. Failure to Deliver Quality Care

- *Anatomy Of A Nursing Home Case*, United States Attorneys' Bulletin September 2005
 - *United States v. Mercy Douglass Human Services Corporation* Complaint
 - *United States v. Mercy Douglass Human Services Corporation* Consent Order and Judgment
- H. Failure to Correct Errors/Refund Overpayments
- Payment for Non-Covered Services
 - Impact of Coding Audits
 - Failure to Audit
- I. Kickback and Stark Violations
- *Enforcement of Health Care Kickback Prohibitions Through the Civil False Claims Act: Recent Trends*, United States Attorneys' Bulletin September 2005
- J. Nature of Penalties/Excessive Fines Clause
- *Mayers v. Department of Health and Human Services*, 806 F. 2d 995 (11th Cir. 1986)
 - *United States v. Mayers*, 957 F.2d 858 (11th Cir. 1992)
 - *United States v. Mackby*, 261 F.3d 821 (9th Cir. 2001)

WEEK 9 – MARCH 9, 2009

VII. FALSE CLAIMS ACT/QUI TAM

- A. Nature of Penalties
- 31 U.S.C. § 3729
 - *Justice Department Recovers Over \$1 Billion in FY 2002*
- B. Qui Tam Provisions
- 31 U.S.C. § 3730
- C. Rights of Relator

- *United States ex rel. Stinson, Lyons, Gerlin & Bustamante, P.A. v. The Prudential Insurance Company*, 944 F. 2d 1149 (3rd Cir. 1991).
 - *United States ex rel. Cosens v. Yale-New Haven Hospital*, 2002 U.S. Dist. LEXIS 22469 (D.Conn. 2002).
- D. False Certifications
1. Certification of Provider Status
 - *United States v. Syme*, 276 F.3d 131 (3rd Cir. 2002)
 2. Implicit and Explicit Certification of Compliance
 - *Mikes v. Straus*, 274 F. 3d 687 (2nd Cir. 2001)
 - *United States ex rel. Swafford v. Borgess Medical Center*, 98 F. Supp. 2d 822 (W.D.Mich. 2000)
 - *United States ex rel. Obert-Hong v. Advocate Health Care*, 211 F. Supp. 2d 1045 (N.D.Ill. 2002)
 - *United States ex rel. Riley v. St. Luke's Episcopal History*, 355 F. 3d 370 (5th Cir. 2004)
 3. Part A Certifications
 4. Part B Certifications
 - CMS-1500 Certifications
 - *United States ex rel. Thompson v. Columbia/HCA Healthcare Corporation*, 125 F.3d 899 (5th Cir. 1997)
 - *United States ex rel. Barmak v. Sutter Corp and Orthologic Corp.*, 2002 U.S. Dist. LEXIS 8509 (S.D.N.Y. 2002)

WEEK 10 – MARCH 16, 2009

- D. Threshold Defenses
- *United States ex rel. Clausen v. Laboratory Corporation of America*, 290 F. 3d 1301 (11th Cir. 2002)
 - *United States ex rel. Karvelas, v. Melrose-Wakefield Hospital*, 360 F.3d 220 (1st Cir. 2004)
 - *United States v. St. Joseph's Regional Health Center*, 240 F. Supp. 882 (W.D. Ark. 2002)

- *In Re Cardiac Devices Qui Tam Litigation* , 221 F.R.D. 318 (D. Conn. May 12, 2004).
 - *United States v. Baylor University Medical Center*, 469 F.3d 263 (2nd Cir. 2006).
- E. Rights of Government/Settlement Issues
- *United States v. Health Possibilities, P.S.C.*, 207 F.3d 335 (6th Cir. March 22, 2000)
- F. States as Defendants
- *Vermont Agency of Natural Resources v. United States ex rel. Stevens*, 529 U.S. 765 (2000)

CHAPTER VII APPENDIX: FALSE CLAIMS ACT PROVISIONS

WEEK 11 -- MARCH 30, 2009

VIII. THE ETHICAL CHALLENGES OF IN-HOUSE COUNSEL AND COMPLIANCE OFFICERS

- A. Overview of Ethical Challenges for In-House Counsel and Compliance Officers
- B. Obligations of Compliance Officer
- C. Seven Essential Components of a Corporate Compliance Program
- D. OIG Guidelines for Corporate Compliance Programs
- Laboratory Compliance Guidelines
 - Hospital Compliance Guidelines
 - Small Physician Practice Guidelines
 - Pharmaceutical Company Guidance
- E. Ethical Obligations in Monitoring Compliance With OIG Corporate Integrity Agreements
- Frequently Asked Questions Related to OIG Corporate Integrity Agreements
 - OIG Checklist of CIA Compliance Reports
 - *United States v. Sulzbach* Complaint

CHAPTER VIII APPENDIX: EXAMPLE CORPORATE COMPLIANCE PROGRAM

WEEK 12—APRIL 6, 2009

IX. QIO REVIEW/EXCLUSION FROM FEDERAL HEALTH PROGRAMS

- A. QIO Review
 - CMS Report to Congress: Improving the Medicare Quality Improvement Organization Program
 - *Ritter v. Cohen*, 797 F.2d 119 (3rd Cir. 1986).
 - *Koerpel v. Heckler*, 797 F.2d 858 (10th Cir. 1986).
 - *Greene v. Bowen*, 639 F. Supp. 554 (E.D. Cal. 1986).
- B. Conditions of Participation

WEEK 13 – APRIL 13, 2009

X. PATIENT DUMPING/EMTALA

- *Abercrombie v. Osteopathic Hospital Founders Association*, 950 F.2d 676 (10th Cir. 1991).
- *Owens v. Nacogdoches County Hospital District*, 741 F. Supp. 1269 (E.D. Tex. 1990).
- *Foster v. Lawrence Memorial Hospital*, 1992 WL 2666888 (D. Kan. 1992).
- *In the Matter of Baby “K”*, 16 F. 3d 590 (4th Cir. 1994).
- *Bryan v. Rectors and Visitors of the University of Virginia*, 95 F. 3d 349 (4th Cir. 1996)
- *Roberts v. Galen of Virginia*, 525 U.S. 249 (1999)
- *Cherukuri v. Shalala*, 175 F. 3d 446 (6th Cir. 1999)
- *St. Anthony Hospital v. U.S. Dept. of Health and Human Services*, 309 F.3d 680 (10th Cir. 2002)
- How Far Do EMTALA Requirements Extend?
- 42 U.S.C. §1395dd

- CMS Clarifying Policies Related to the Responsibilities of Medicare-Participating Hospitals in Treating Individuals with Emergency Medical Conditions

WEEK 14 – APRIL 20, 2009

QUESTIONS AND REVIEW