QUALITY IMPLANT COALITION BACKGROUNDER

OIG Special Fraud Alert on PODs: Soon to Be The Latest in a Long History of Associated Enforcement Actions?

Since the Office of Inspector General (OIG) began issuing Special Fraud Alerts in 1989, it has created only fourteen such warnings to industry. **In each case**, OIG or Department of Justice (DOJ) enforcement proceedings and penalties were associated with the Fraud Alert. This history should be a flashing red light to those who have invested in (for physicians) or who deal with (for hospitals, Ambulatory Surgical Centers, and manufacturers) a POD, in light of OIG's recent Special Fraud Alert warning that such dealings are "inherently suspect" under the Anti-Kickback Law.

Special Fraud Alert	Sample Enforcement Actions[1]
Joint Venture Arrangements August 1989 Focused on "joint ventures" between individuals in referring-treating relationships.	• ***Hanlester (1995):*** Following years of litigation, the Ninth Circuit held that investment interests violated the Anti-Kickback Law if they were intended to induce referrals, and upheld a finding that a partnership that established joint venture laboratories with referring physicians and one of the promoters violated the Anti-Kickback Law. Separately, a company that managed the joint venture laboratories agreed to a $1.5 million settlement.[i] • ***T^2 (1994):*** Provider of infusion therapy and lithotripsy agreed to pay a $500,000 penalty and stop establishing joint ventures with referring physicians.[ii] • ***RadiationCare (1994):*** Company that established radiation therapy joint ventures with physician-investors paid $2,000,000 to settle claims, and agreed not to engage in such relationships with referring physicians.[iii]
Routine Waiver of Copayments or Deductibles Under Medicare Part B May 1991 Warned practitioners and suppliers that it is unlawful to routinely waive deductible or copayment charges.	• ***National Medical Systems (1995):*** Durable Medical Equipment (DME) supplier agreed to pay $1.5 million to settle claims, including that it regularly waived copayments and co-insurance deductibles for Medicare patients. [iv] • ***Advanced Care Associates (1996):*** Medical equipment supplier paid more than $4 million and entered a 3-year compliance program to settle allegations that supplier, among other things, routinely billed Medicare for lymphedema pumps and sleeves for which it never collected copayments.[v]
Hospital Incentives to Physicians May 1992 Stated that it is unlawful for hospitals to provide incentives to physicians for referrals, including payment of incentives each time a referral is made; free or significantly discounted office space or equipment; and free training for physicians' staff in	• ***National Medical Enterprises (1994):*** Specialty hospital chain pled guilty and paid $379 million for making unlawful payments to physicians, including free or discounted office space, income guarantees and money for support personnel.[vi] • ***Baptist Medical Center (1997):*** Hospital agreed to pay $17.5 million to settle claims that it provided kickbacks to physicians in the form of a hospital employee to provide financial and administrative management services, and sham consulting agreements. The physicians were sentenced to prison.[vii]

[1] Examples of enforcement actions are provided for illustrative purposes. Generally, other enforcement actions also addressed the issues covered by the Special Fraud Alerts.

Special Fraud Alert	Sample Enforcement Actions[1]
management, CPT coding and laboratory techniques.	
Prescription Drug Marketing Schemes August 1994 Addressed improper prescription drug marketing schemes where physicians, pharmacists, suppliers, and/or patients are offered non-medical benefits for selecting specific prescription drug brands.	• ***Ayerst Laboratories (1993):*** Drug company paid $830,000 to settle claims that it made improper payments to physicians for filling out questionnaires on patients newly prescribed the company's drug.[viii] • ***Hoffman-LaRoche (1994):*** Drug company agreed to pay $450,000 to settle claims that it offered and paid physicians for research of minimal value to induce physicians to order the company's drug.[ix] • ***Miles (1994):*** Drug company entered a settlement for $605,000 regarding allegations it paid pharmacists to provide counseling services to patients newly prescribed a drug, despite the fact that pharmacists were already expected to counsel patients.[x]
Arrangements for the Provision of Clinical Lab Services October 1994 Cautioned against clinical laboratories inducing referrals by offering or giving anything of value, such as 1) providing a phlebotomist to perform services not directly related to the collection or processing of lab specimens; 2) performing tests at a composite rate below fair market value; and 3) waiving the charges to managed care patients, if the free services benefit the provider.	• ***SmithKline (1996):*** Clinical laboratory agreed to pay $325 million to settle claims, including that it provided physicians with standard groups of tests, resulting in claims for non-medically necessary tests; referral sources and managed care patients with free or discounted tests; and clients with on-site phlebotomists and equipment.[xi] • ***Spectra (1996):*** Clinical testing laboratory agreed to pay $10,154,400 to settle claims that, among other things, the laboratory provided kickbacks to induce referrals, such as phlebotomists to work in clients' offices, discounted tests at below fair market value, free computers, and free or discounted tests for certain parties.[xii] • ***LifeChem (2000):*** Specialty laboratory owner agreed to pay $486 million to settle claims that it provided illegal inducements to dialysis facilities in the form of composite rate tests provided below fair market value, free or discounted tests for certain patients, and entertainment.[xiii]
Home Health Fraud June 1995 Highlighted fraudulent practices in the home health care industry, including: 1) submitting claims for home health visits that were not made or were made to ineligible beneficiaries; 2) filing cost reports with costs that are not reasonable, necessary for the maintenance of the health care entity and related to patient care; 3) paying or receiving kickbacks for Medicare or Medicaid referrals; and 4) marketing uncovered or unneeded services to beneficiaries.	• ***First American Health Care (1996):*** Home health provider agreed to pay $255 million to settle allegations regarding billing for costs that were not reasonable, necessary for the maintenance of the health care entity and related to patient care.[xiv] • ***Olsten (1999):*** Home health company agreed to pay $51 million, and its subsidiary pled guilty to conspiracy, mail fraud and violating the Anti-Kickback statute and agreed to pay $10.08 million to settle civil and criminal allegations, which included that the company had billed Medicare for unallowable costs such as management fees; and for home health visits to ineligible beneficiaries.[xv] • ***Tender Loving Care (2000):*** Home health company paid $1.4 million to settle allegations that it, among other things, included unallowable costs in cost reports, such as kickbacks to doctors for referrals, fictitious or excessive vehicle mileage expenses, and exaggerated or false lease costs for equipment and office supplies.[xvi] • ***Tenet (2002):*** Hospital that provided home health services

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	agreed to pay $29 million to settle allegations that it had, among other things, billed for non-reimbursable costs such as acquisition costs, and for services not rendered.[xvii]
Medical Supplies to Nursing Facilities August 1995 Identified fraudulent activities in the provision and billing of medical supplies to nursing facilities, including 1) submitting claims for non-medically necessary supplies and equipment; 2) submitting claims for items not provided; 3) submitting duplicate bills for supplies; and 4) providing kickbacks, such as free non-covered medical products, for referrals.	• ***Staco (1995):*** Owner of a medical supply company pled guilty, paid $1.9 million in restitution and $5,000 in fines, and with his partner agreed to pay $656,000 to settle civil claims that his company had "systematically billed Medicare for useless and unnecessary items sold to nursing home residents."[xviii] • ***Aiello (1996):*** Nursing home owner was sentenced to 11-18 years in prison, ordered to pay $3.2 million in restitution and fined $300,000 for billing Medicare for medical supplies that were never ordered or supplied to nursing home residents.[xix]
Fraud and Abuse in the Provision of Services in Nursing Facilities May 1996 Warned against fraud in providing health care services to nursing facility residents, focusing on claims for services that were either not rendered or not provided as claimed, and false claims designed to circumvent coverage limitations.	• ***Dreyfuss (2000):*** Physician pled guilty, paid $733,000 in fines and restitution, and agreed to pay $2 million to settle allegations, including that he billed Medicare and Medicaid for services provided to nursing home residents that were not provided, were not medically necessary, or were not as complex as claimed.[xx] • ***National Healthcare Corporation (2000):*** Nursing home operator agreed to pay $27 million to settle claims that company inflated Medicare cost reports by, among other things, overstating time nursing staff spent with patients and billing for therapy provided by personnel who do not actually provide therapy.[xxi]
Fraud And Abuse In Nursing Home Arrangements With Hospices March 1998 Warned against arrangements between nursing home and hospice industries that involve inducements to influence a nursing home's hospice selection.	• ***Detroit Nursing Home (1998):*** Owner of nursing homes pled guilty to accepting kickbacks from a hospice for recommending the hospice to his nursing homes' staff, and agreed to pay restitution, which was predicted to possibly exceed $700,000.[xxii] • ***Kirschenbaum (1999):*** Former hospice owner agreed to pay roughly $22 million to settle civil claims that, among other things, the hospice paid nursing homes $10 for every new hospice patient.[xxiii]
Physician Liability For Certifications In The Provision Of Medical Equipment And Supplies And Home Health Services January 1999 Warned physicians against signing medical necessity certifications knowing they are false or without regard for accuracy.	• ***Florida Physician (2003):*** Physician was sentenced to 60 months in prison and fined $4.1 million for signing certificates of medical necessity and issuing unnecessary prescriptions without examining the patient in return for $100 payments per prescription from a DME company.[xxiv] • ***Missouri Group of Six (2003):*** Co-defendants were ordered to pay $526,000 restitution, and four were sentenced to prison for a scheme in which owners of residential care facilities and home health agencies referred patients from the residential care facilities to a doctor in exchange for a certification that patients were homebound and eligible for home health services.[xxv]

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Rental of Space in Physician Offices By Persons or Entities to Which Physicians Refer February 2000 Described illegal rental practices that can arise when physicians rent space to persons or entities to which the physician-landlords refer.	• ***Tampa Physician (2001):*** Physician agreed to enter a 5-year integrity agreement and pay $150,000 to resolve claims that in return for referrals to a clinical laboratory he received kickbacks that included space rental payments above fair market value.[xxvi] • ***New Port Richey Physician (2001):*** Physician agreed to pay $70,000 to settle claims that in return for the physician received space rental payments above fair market value, as well as payments for employee salaries.[xxvii] • ***Zephyrhills Physician (2001):*** Physician agreed to pay $95,000 to settle claims that the physician received kickbacks in the form of space rental payments above fair market value in exchange for referrals to a mobile diagnostics services.[xxviii]
Telemarketing By Durable Medical Equipment Suppliers March 2003 Warned that it is generally unlawful for DME suppliers to make or use a third party to make unsolicited calls to Medicare beneficiaries regarding furnishing covered items. **Telemarketing by Durable Medical Equipment Suppliers (updated)** January 2010 Clarified the prohibition on telemarketing by DME suppliers and by third parties on behalf of DME suppliers.	• ***Girgis and Company (2004):*** Medicare suppliers pled guilty, were sentenced to probation and home detention and were excluded from the program for activities which included the improper use of telemarketers to call Medicare beneficiaries.[xxix] • ***Matrix, Diabetics (2009):*** Former owners and officers of a DME company agreed to pay $260,000 to settle claims arising from the use of telemarketing firms to make unsolicited marketing calls to Medicare beneficiaries, and the company's submission of claims for those marketed items.[xxx]

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[i] Hanlester Network v. Shalala, 51 F.3d 1390 (9th Cir. 1995); *Smithkline Lab To Pay Record $1.5-Million Fine: Health Care: The Firm Allegedly Violated a Federal Law That Prohibits Payments to Doctors to Encourage Referrals of Medicaid and Medicare Patients*, Los Angeles Times, Dec. 29, 1989, http://articles.latimes.com/1989-12-29/business/fi-1231_1_health-care-programs.

[ii] Shalala v. T2 Medical, No. 1-94-CV-2549-ODE, 1994 WL 686949 (N.D. Ga. 1994). *See also* Press Release, U.S. Department of Justice, T2 Medical, Inc., Agrees to Pay $500,000 and Discontinue Improper Practices in Settlement with Government (Sept. 26, 1994), http://www.justice.gov/opa/pr/Pre_96/September94/548.txt.html.

[iii] Shalala v. RadiationCare, No. 1:94-CV-3339-RCF, 1995 U.S. Dist. LEXIS 749 (N. D. Ga. 1995); *Radiation Care Inc. Agrees to Pay $2 Million to Settle Kickback Allegations*, 5 BHLR 1452 (Dec. 23, 1994).

[iv] U.S. Department of Justice, *Selected Cases* (Oct. 27, 1997), http://www.justice.gov/opa/health/hcf2.htm. *False Billing: Two Providers Pay Close to $2 Million to Settle Billing Fraud Allegations,* 4 BHLR 48 D9 (Dec. 14, 1995).

[v] Press Release, U.S. Department of Justice, Medical Supplier Pays U.S. $4 Million to Settle Medicare Claims (Jun. 19, 1996); U.S. Department of Justice, *Selected Cases* (Oct. 27, 1997), http://www.justice.gov/opa/health/hcf2.htm.

[vi] *See NME to Pay $379 Million in Penalties Under Settlement with Federal Agencies*, 3 BHLR 27 (Jul. 7, 1994); Michael Booth, *Kickbacks Net Hospital Major Fine*, Denver Post (Jun. 30, 1994); Allen R. Myerson, *Hospital Chain Sets Guilty Plea*, N.Y. Times (Jun. 29, 1994); Steven R. Reed, *Official of Hospital Chain Admits Nationwide Fraud*, New Orleans Times Picayune (Jun. 29, 1994).
[vii] *See* U.S. v. LaHue, 261 F.3d 993 (10th Cir. 2001); Superseding Indictment, U.S. v. Anderson et al., No. 98-20030-JWL (D. Kan. 1998); Press Release, U.S. Department of Justice, Missouri Hospital Pays U.S. $17.5 Million For Medicare Fraud (Sept. 18, 1997).
[viii] Settlement Agreement between United States and Ayerst Laboratories, Inc., Jul. 29, 1993 (on file with author). *See also* Press Release, U.S. Department of Justice, New York Lab Pays U.S. $830,000 to Settle Medicaid Dispute (Jul. 29, 1993).
[ix] Office of Inspector General, Fact Sheet on Settlement Agreement with Hoffman-LaRoche, Inc., New Jersey, Sept. 2, 1994.
[x] *See* Assurance of Discontinuance/Assurance of Voluntary Compliance, In the Matter of Miles, Inc., para. 7, Mar. 31, 1994 (on file with author). *See also* Settlement Agreement Between Miles Inc. and The Commonwealth of Massachusetts Department of the Attorney General, Jun. 30, 1994 (on file with author); Press Release, Massachusetts Office of the Attorney General, Drug Company Pays $200,000 to Settle Kickback Claims (Jun. 30, 1994).
[xi] *Chapter 1820: Clinical Laboratories, in* Health Care Program Compliance Guide 208-209 (BNA, 2000).
[xii] *Id*.
[xiii] *Id.*
[xiv] Press Release, U.S. Department of Justice, U.S. Recovers $255 Million for Medicare Rip-Off by First American Health Care (Oct. 18, 1996).
[xv] Press Release, U.S. Department of Justice, Olsten Corporation and a Subsidiary Agree to Pay $61 Million in Criminal Fines and Civil Damages (Jul. 19, 1999).
[xvi] Press Release, U.S. Department of Justice, National Home Health Care Services Firm Pays $1.4 Million for Medicare Fraud, (Sept. 5, 2000, http://www.justice.gov/opa/pr/2000/September/514civ.htm.
[xvii] Press Release, U.S. Department of Justice, Tenet Hospital in Florida Pays U.S. $29 Million to Resolve False Claims Act Allegations (Jul. 17, 2002).
[xviii] U.S. Department of Justice, *Selected Cases* (Oct. 27, 1997), http://www.justice.gov/opa/health/hcf2.htm.
[xix] *False Claims: Calif. Nursing Home Operator Sentenced To Prison; Mich. Indictments Announced*, 5 BHLR 4 D19 (Jan. 25, 1996).
[xx] Press Release, U.S. Department of Justice, Michigan Physician to Pay U.S. $2 million for Overcharging Medicare & Medicaid Health Programs (Dec. 27, 2000).
[xxi] Press Release, U.S. Department of Justice, Tennessee-Based National Healthcare Corporation Settles Medicare Fraud Case for $27 Million (Dec. 15, 2000), http://www.justice.gov/opa/pr/2000/December/699civ.htm.
[xxii] U.S. Department of Justice, *Health Care Fraud Report, Fiscal Year 1998*, http://www.justice.gov/dag/pubdoc/health98.htm (last visited Apr. 19, 2013).
[xxiii] Douglas Frantz, *Hospice Boom is Giving Rise to New Fraud*, N.Y Times, May 10, 1998, http://www.nytimes.com/1998/05/10/us/hospice-boom-is-giving-rise-to-new-fraud.html?pagewanted=all&src=pm; Matt O'Connor, *Ex-Hospice Owner Oks Fraud-case Deal*, Chicago Trib., Sept. 24, 1999, http://articles.chicagotribune.com/1999-09-24/news/9909240211_1_health-care-fraud-case-false-billings-fraud-charges.
[xxiv] Office of Inspector General, *Criminal and Civil Enforcement – February 2003 Criminal Enforcement Report*, https://oig.hhs.gov/reports-and-publications/archives/enforcement/criminal/criminal_archive_2003.asp (last visited Apr. 19, 2013).
[xxv] *Id.*
[xxvi] Office of Inspector General, *Archives - Kickback and Physician Self-Referral*, https://oig.hhs.gov/reports-and-publications/archives/enforcement/kickback_archive.asp (last visited Apr. 3, 2013).
[xxvii] *Id.*
[xxviii] *Id.*
[xxix] Program Exclusions, 69 Fed. Reg. 55639 (2004); Transcript of Sentencing, United States of America v. Diab, No. 02-367-03 (D. D.C. 2004); Transcript of Sentencing, United States of America v. Saleh, No. 02-

367 (D. D.C. 2004); Transcript of Sentencing, United States of America v. Dimitri A. Girgis, No. 02-367 (D. D.C. 2004); Criminal Docket, United States v. Abdelkhalek Elbagdad, No. 00-367 (D.D.C. 2004).

[xxx] Office of Inspector General, *False and Fraudulent Claims*, https://oig.hhs.gov/fraud/enforcement/cmp/false_claims.asp (last visited Apr. 3, 2013).