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OIG Annual Solicitation of Safe Harbor Proposals

On December 28, 2012, The Office of Inspector General (OIG) issued its annual solicitation of proposals and recommendations to facilitate the development of new, or modification of, existing *safe harbors* under the *Federal Anti-Kickback Statute* (AKS).[1] The OIG is required under §205 of the *Health Insurance Portability and Accountability Act of 1996* (HIPAA) to annually request suggestions for the improvement of the AKS.[2] While these suggestion periods rarely result in significant change to the AKS, they offer providers and other interested parties an opportunity to express concerns regarding AKS safe harbors.

The AKS, enacted in 1972, makes it a felony for any person (physician, allied health professional, or paraprofessional with a Medicare provider number) to "*knowingly and willfully*" solicit or receive, or to offer or pay, any "*remuneration*", *directly or indirectly*, in exchange for the referral of a patient for a healthcare service paid for by a federal healthcare program.[3] Violations of the *Anti-kickback Statute* are punishable by up to five years in prison, criminal fines up to $25,000, or both.[4] While, there is no precise measure of healthcare fraud, the federal government estimates that abuse of the Medicare and Medicaid systems puts beneficiary health at risk, and cost these programs approximately $65 billion in 2010.[5] A 2012 study, by the RAND Corporation, estimated the cost of fraud and abuse in the Medicare and Medicaid Program to be as high as $98 billion in 2011.[6]

In a continuing effort to address concerns regarding the broad reach of the AKS,[7] but still protect the Medicare and Medicaid systems from abuse,[8] OIG instituted *safe harbors* that shielded certain business and financial practices that are perceived to be at a low risk of fraud from prosecution, so long as they fall within the parameters defined under the specific safe harbor. These parameters are reviewed yearly by the OIG in an effort to remain pertinent within the current healthcare environment.[9]

Currently, there are 25 AKS safe harbors.[10] Since 1991, OIG has made only ten changes to its safe harbor provisions, eight of which came in 1999 in an effort to clarify the initial provisions.[11] Safe harbor provisions can also be amended through other regulations, e.g., the 2007 modification to the Medicare Prescription Drug, Improvement, and Modernization Act created a safe harbor to protect certain arrangements involving loans, goods, and services between individuals and entities and health centers funded under the Public Health Service Act.[12]

In response to the OIG's last annual solicitation, published December 29, 2011,[13] the OIG considered four of the seven proposals received. The four proposals it considered included: (1) making the safe harbor for electronic health records (EHR) arrangements permanent; (2) creating a new safe harbor protecting certain motivational incentives offered to patients by Federally Qualified Health Centers (FQHCs); (3) modifying the safe harbor for waiver of beneficiary coinsurance and deductible amounts to extend protection to reductions or waivers offered to American Indians and Alaskan Natives eligible for Indian Health Service services; and, (4) creating a new safe harbor protecting exchanges or transfers of value among Indian healthcare providers, or to American Indians and Alaskan Natives eligible for or receiving services from that provider.[14]

The three proposals not considered by the OIG were: (1) the creation of a new safe harbor protecting remuneration associated with the distribution of durable medical equipment by physicians certified by the American Board of Sleep Medicine; (2) the creation of a new safe harbor protecting free continuing medical education programs offered by hospitals to physicians; and, (3) the modification of the safe harbor for referral services, or sources, to allow payments to entities serving as referral services to be based on the volume or value of referrals with respect to patients seeking dental services. The OIG noted that each proposal not considered would need to be addressed on a case by case basis, and new overarching safe harbors would either not be appropriate, or would be beyond the OIG's scope of authority.[15]

The OIG has stated that for the proposals submitted in response to the 2012 solicitation, the agency is evaluating those that may, "*...affect an increase or decrease in: Access to health care services, The quality of services, Patient freedom of choice among health care providers, Competition among health care providers, The cost to Federal health care programs, The potential overutilization of the health care services, and The ability of health care facilities to provide services in medically underserved areas or to medically underserved populations*."[16]

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The most recent annual notice also solicited suggestions regarding OIG Fraud Alerts, which provide guidance to healthcare providers and encourage industry compliance related to practices that the OIG finds potentially fraudulent or abusive.[17] When determining whether an additional fraud alert is justified, the OIG examines to what extent the practice being addressed may result in violation of the AKS, as well as, the anticipated volume and frequency of the practice.[18] The OIG publishes fraud alerts relatively infrequently, typically publishing one every few years.[19]

Comments regarding either the AKS safe harbors, or OIG fraud alerts, must be received by 5:00pm on February 26, 2013. As the healthcare transactional environment remains tumultuous and new integration models emerge within the U.S. healthcare delivery system, providers and their professional advisors must be certain to stay abreast of continuing regulatory developments and pronouncements by the OIG related to the AKS and other fraud and abuse regulations.

1 "Solicitation of New Safe Harbors and Special Fraud Alerts" Federal Register, Vol. 77, No., 249, December 28, 2012, p. 76434. The federal anti-kickback statute is section 1128B(b) of the Social Security Act.
2 "HHS Inspector General Seeks Input on Safe Harbors, Special Fraud Alerts, Health Law Reporter, Vol. 22, No. 13, January 3, 2013.
3 "Criminal Penalties for Acts Involving Federal Health Care Programs" 42 U.S.C.A. §1320a-7b(b).
4 *Ibid*.
5 "Fact Sheet – Medicare, Fraud & Abuse: Prevention, Detection, and Reporting" U.S. Department of Health and Human Services Center for Medicare & Medicaid Services, November 2012, p. 1; "Health Policy Brief: Eliminating Fraud and Abuse" By T.R. Goldman, Health Affairs, July 31, 2011, p. 1.
6 "Eliminating Waste in US Health Care" By Donald M. Berwick and Andrew D. Hackbarth, Journal of the American Medical Association, Vol. 307, No. 14, April 11, 2012, p. 1514.
7 77 FR 249, p. 56633
8 "Anti-Kickback Statute" American Health Lawyers Association, 2011, http://www.healthlawyers.org/hlresources/Health%20Law%20Wiki/Anti-Kickback%20Statute.aspx (Accessed 1/8/13). See also 77 FR 249, p. 76435.
9 "Anti-Kickback Statute" American Health Lawyers Association, 2011, http://www.healthlawyers.org/hlresources/Health%20Law%20Wiki/Anti-Kickback%20Statute.aspx (Accessed 1/8/13). See also 77 FR 249, p. 76435.
10 "Exceptions"42 C.F.R. 1001.952(a)-(x) (October, 1, 2009).
11 "Group Purchasing and HME Providers: Analysis of Discounts, Rebates, and other Issues of 'Safe Harbor'" By Mark J. Higley, VGM Management Ltd., 2003.
12 77 FR 249, p. 56633.
13 "Solicitation of New Safe Harbors and Special Fraud Alerts: Notice of intent to develop regulations" Federal Register, Vol. 76, No. 250, December 29, 2011, p. 81904.
14 "Office of Inspector General: Semiannual Report to Congress" Fall 2012, Appendix F, p. 91- 92.
15 *Ibid*.
16 77 FR 249, p. 81558.
17 77 FR 249, p. 76434-76435.
18 77 FR 249, p. 81558.
19 "Special Fraud Alerts" Office of Inspector General, https://oig.hhs.gov/compliance/alerts/index.asp (Accessed 1/29/2013).

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Robert James Cimasi, MHA, ASA, FRICS, MCBA, AVA, CM&AA, serves as Chief Executive Officer of **HEALTH CAPITAL CONSULTANTS** (HCC), a nationally recognized healthcare financial and economic consulting firm headquartered in St. Louis, MO, serving clients in 49 states since 1993. Mr. Cimasi has over thirty years of experience in serving clients, with a professional focus on the financial and economic aspects of healthcare service sector entities including: valuation consulting and capital formation services; healthcare industry transactions including joint ventures, mergers, acquisitions, and divestitures; litigation support & expert testimony; and, certificate-of-need and other regulatory and policy planning consulting.

Mr. Cimasi holds a Masters in Health Administration from the University of Maryland, as well as several professional designations: Accredited Senior Appraiser (ASA – American Society of Appraisers); Fellow Royal Intuition of Chartered Surveyors (FRICS – Royal Institute of Chartered Surveyors); Master Certified Business Appraiser (MCBA – Institute of Business Appraisers); Accredited Valuation Analyst (AVA – National Association of Certified Valuators and Analysts); and, Certified Merger & Acquisition Advisor (CM&AA – Alliance of Merger & Acquisition Advisors). He has served as an expert witness on cases in numerous courts, and has provided testimony before federal and state legislative committees. He is a nationally known speaker on healthcare industry topics, the author of several books, the latest of which include: "*Accountable Care Organizations: Value Metrics and Capital Formation*" [2013 - Taylor & Francis, a division of CRC Press], "*The Adviser's Guide to Healthcare*" – Vols. I, II & III [2010 – AICPA], and "*The U.S. Healthcare Certificate of Need Sourcebook*" [2005 - Beard Books]. His most recent book, entitled "*Healthcare Valuation: The Financial Appraisal of Enterprises, Assets, and Services*" will be published by John Wiley & Sons in the Fall of 2013.

Mr. Cimasi is the author of numerous additional chapters in anthologies; books, and legal treatises; published articles in peer reviewed and industry trade journals; research papers and case studies; and, is often quoted by healthcare industry press. In 2006, Mr. Cimasi was honored with the prestigious "*Shannon Pratt Award in Business Valuation*" conferred by the Institute of Business Appraisers. Mr. Cimasi serves on the Editorial Board of the Business Appraisals Practice of the Institute of Business Appraisers, of which he is a member of the College of Fellows. In 2011, he was named a Fellow of the Royal Institution of Chartered Surveyors (RICS).

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