

Guidelines and Regulations Affecting Healthcare Vendors

Patient Care

American Council of Surgeons (ACS) *Statement on Health Care Industry Representatives in the Operating Room* Supplier must wear a time sensitive means of identification at all times in the OR, be orientated to the particular healthcare facility, should be trained in HIPAA compliance and appropriate OR conduct and attire, and must receive education concerning infectious disease, blood borne pathogens, occupational safety, aseptic technique, and other applicable practices relating to the operation. (www.facs.org)

The Association of Peri-Operative Registered Nurses (AORN) *The Role of the Health Care Industry Representative in the Perioperative/Invasive Procedure Setting* "It is important that the health care industry representative understands how to safely work in the operating room to assist the perioperative team in maintaining the patient's safety, right to privacy, and confidentiality when a health care industry representative is present during a surgical procedure."
(<http://www.aorn.org/PracticeResources/AORNPositionStatements/>)

The Joint Commission "The standards in the human resource chapter apply to direct, contract, and volunteer personnel providing patient care and/or services on behalf of an organization, regardless of whether the contracted organization is accredited." These standards include verified education, training, orientation, health status, and other items.
(http://www.jointcommission.org/AccreditationPrograms/Hospital/Standards/09_FAQs/HR/Human_Resource_Standards.htm)

Centers for Disease Control *Immunization of Health-Care Workers* These recommendations outline a variety of immunization guidelines for health care workers ranging from physicians to volunteers.
(<http://www.cdc.gov/mmwr/preview/mmwrhtml/00050577.htm>)



Guidelines and Regulations Affecting Healthcare Vendors

Business Practices

Department of Health and Human Services Office of Inspector General (HHS/OIG) List of Excluded Individuals and Entities (42 U.S.C. 1320a–7a) Establishes categories of parties excluded from payment by any Federal health care program for any items or services from an excluded individual or entity. This payment prohibition applies to the excluded person, anyone who employs or contracts with the excluded person, any hospital or other provider where the excluded person provides services, and anyone else. Providers have an affirmative duty to check the program exclusion status of individuals and entities (List of Excluded Individuals and Entities (LEIE)) prior to entering into employment or contractual relationships or run the risk of Civil Monetary Penalties if they fail to do so. The list includes over 40,000 entries and is updated monthly. CMPs are delineated as up to \$10,000 for each item or service furnished by the excluded party as well as up to three times the amount claimed. (<http://oig.hhs.gov/fraud/exclusions.asp>)

Federal False Claims Act (31 U.S.C. ss3729 et seq.) Prohibits conspiring to defraud the government by getting a false claim paid, presenting a false claim for payment or approval, or using a false record to avoid or decrease any obligation to pay the Government. Allows for penalties of \$5,500 to \$11,000 per claim, treble damages and costs of civil action brought to recover.

State False Claim Laws Deficit Reduction Act of 2005 Section 6031 and Section 1909 of the Social Security Act create financial incentives for states to enact state Medicaid false claims acts similar to the Federal False Claims Act. States receive 10% of recoveries. States with FCA laws: California, Florida, Hawaii, Illinois, Indiana, Louisiana, Massachusetts, Michigan, Nevada, New York, Tennessee, Texas and Virginia.

Federal Anti-kickback Statute (section 1128B(b) of the Social Security Act) Civil and criminal penalties for an individual or entity that knowingly and willfully requests, solicits, gives or pays any remuneration, overtly or covertly, to induce a referral, purchase or lease of any good or service which may be paid under a Federal health care program, including Medicare. Safe harbor protection requires strict compliance with all applicable conditions set out in the relevant safe harbor. Criminal fines up to \$25000 per offense and/or 5 years imprisonment, Administrative fines, exclusion from Medicare/Medicaid programs, and civil penalties up to \$50,000 plus treble damages. (http://www.ssa.gov/OP_Home/ssact/title11/1128B.htm)

Physician Self-Referral/Stark Law (section 1877 of the Social Security Act) Prohibits hospitals from submitting—and Medicare from paying—any claim for a “designated health service” (DHS) if the referral of the DHS comes from a physician with whom the hospital has a prohibited financial relationship. This is true even if the prohibited financial relationship is the result of inadvertence or error. In addition, hospitals and physicians that *knowingly* violate the statute may be subject to CMPs and exclusion from the Federal health care programs. A knowing violation of the Stark law may also give rise to liability under the False Claims Act. (<http://oig.hhs.gov/fraud/complianceguidance.asp>)



Incentive for Self-Reporting Where the hospital discovers evidence of misconduct, the hospital should promptly report the existence of misconduct to the appropriate Federal and State authorities. Prompt reporting will be considered a mitigating factor by the OIG in determining administrative sanctions, if appropriate. (<http://oig.hhs.gov/fraud/complianceguidance.asp>)

General Services Administration (GSA) Excluded Party List Those excluded from Federal procurement and reciprocal programs. Any penalties or liability for doing business with an excluded party depends on the violation that led to ineligibility. (<http://www.epls.gov/>)

Department of Treasury Office of Foreign Asset Control (OFAC): Prohibits any transaction with persons on the specially designated nationals list. Maximum civil penalty is the greater of \$250,000 or an amount that is twice the amount of the transaction that is the basis of the violation. (<http://www.treas.gov/offices/enforcement/ofac/programs/terror/terror.shtml> and http://www.treas.gov/offices/enforcement/ofac/civpen/penalties/interim_pol_11272007.pdf)