
**AAHOMECARE CODE OF BUSINESS ETHICS
SUPPORTING CITATIONS**

I) Interactions with Patients

A) Products and Services:

- 1) 42 C.F.R. § 424.57 (c) (1), requires a supplier to certify that it operates in compliance with applicable Federal and State licensure requirements.
- 2) Centers for Medicare and Medicaid Services (CMS) DMEPOS Quality Standards (“Quality Standards”), August 2006. Section I. A. 4., requires suppliers to comply with Medicare laws and payment policies; Section II. A., requires suppliers to determine patient needs via an intake process and communication with the prescribing physician.
- 3) 42 C.F.R. § 424.57 (c) (16), requires suppliers to disclose the supplier standards to beneficiaries, including information on payment policies such as warranties, inexpensive or routinely purchased, repairs of rental items; Office of Inspector General (“OIG”) Compliance Program Guidance for the DMEPOS Industry (“DMEPOS Model Compliance Plan”), 64 Fed. Reg. 363868, 36378 (July 6, 1999), recommends that suppliers inform beneficiaries with respect to their financial responsibility for items and services.
- 4) Quality Standards, I. D. 2., requires the supplier to inform the physician or other healthcare team member if it is unable to furnish the item that was ordered.
- 5) 45 C. F. R. Parts 160 and 164, Standards for Privacy of Individually Identifiable Health Information, establish standards for maintaining the privacy of patient health records; Quality Standards, I. G., requires that suppliers maintain the integrity, security, and privacy of company information.

B) Continuum of Care

- 1) Quality Standards, II. A. –D., require suppliers to communicate with the physician during intake and to perform patient follow-up that is consistent with the type of equipment the beneficiary uses. Additional quality standards establish specific standards for respiratory equipment and power mobility devices (“PMDs”).
- 2) 42 C.F.R. § 424.57 (c) (19), requires a supplier to maintain a complaint resolution protocol; Quality Standards I. E., requires suppliers to implement performance management processes and track patient satisfaction.

C) Gifts to Patients

- 1) OIG Advisory Opinions Nos. 06-01; 06-20; and 07-08, address the provision of free goods and services to Medicare beneficiaries. Generally, providing free equipment or services to beneficiaries with an expectation that the beneficiary will select a supplier or remain on services with the supplier constitutes an improper inducement.
- 2) 42 U. S. C. § 1320a-7a (5) prohibits offering remuneration to influence a Medicare beneficiary's choice of supplier. OIG Special Advisory Bulletin: Offering Gifts and Other Inducements to Beneficiaries, August 2002, permits gifts of "modest value" to beneficiaries. OIG interprets this to mean that gifts cannot exceed \$10.00 for any one item with an aggregate limit of \$50.00 annually. <http://www.oig.hhs.gov/fraud/docs/alertsandbulletins/SABGiftsandInducements.pdf>,

D) Gifts to Non-Profit Organizations or Charities Representing or Advocating for Patients.

- 1) Gifts or donations to legitimate charitable organizations or educational institutions must not be earmarked for use by a specific referral source or a patient or individual identified by the referral source or the provider making the gift or donation. See OIG Special Advisory Opinions 97-01 and 02-01 stating that providers maybe the source of funding for a patient advocacy organization, provided that the organization makes an independent determination on who receives the funds.

E) Health Fairs

- 1) See generally the discussion under paragraph D above. The prohibitions on offering or giving inducements to beneficiaries apply in the context of health fairs. Suppliers may provide items of nominal value, *i.e.*, \$10.00 an item and no more \$50.00 annually, consistent with the limits established by the OIG.

II) Interaction with Payers

A) Billing Policies and Procedures

- 1) Generally, the false claims act prohibits presenting false and fraudulent claims for payment by the government. See 31 U.S.C. 3729. Civil money penalties (CMPs) and administrative sanctions may also be imposed for the submission of false claims. 42 U. S. C. 1320a-7(a). Activities that may constitute false claims include, knowingly billing government programs for items and services that were not furnished; knowing misrepresenting the quality of an item or service as superior to what was actually furnished, knowingly misrepresenting the frequency or level

of the service or item furnished as greater than what was furnished; or knowingly misrepresenting that the item or service was properly ordered consistent with applicable documentation guidelines (such as relying on a forged order or CMN).

B) Complying with Applicable Federal and State Laws and Regulations

- 1) 42 C. F. R. § 424.57 (c) requires suppliers to certify that they operate in compliance with applicable Federal and State laws and regulations.
- 2) OIG Special Advisory Bulletin, The Effect of Exclusion from Participation in Federal Health Care Programs, September 1999, <http://oig.hhs.gov/fraud/docs/alertsandbulletins/effected.htm>. No Federal program payment may be made for items or services furnished by excluded individuals, or ordered by an excluded physician. This prohibition applies even if the payment is made to someone other than excluded person or entity.
- 3) 42 C. F. R. § 424.57 (c), and § 424.500 - § 424.555 establish standards for enrollment and reenrollment in the Medicare program.
- 4) 42 U. S. C. § 1395 m (17) and 42 C. F. R. § 424.57 (c) establish prohibitions on certain telemarketing activities by DMEPOS suppliers. The OIG has published two special fraud alerts addressing the DMEPOS telemarketing prohibition, See Telemarketing by Medical Equipment Suppliers, March 2003 and January 2010, <http://www.oig.hhs.gov/fraud/docs/alertsandbulletins/Telemarketingdme.pdf>.
- 5) See also CMS FAQs identifying the types of phone contact with beneficiaries that are prohibited, <http://www.cms.gov/MedicareProviderSupEnroll/Downloads/DME%20Supplier%20Telemarketing%20FAQs.pdf>.

C) Ensuring Ongoing Compliance

- 1) See Generally, OIG Model Compliance Plan for the DMEPOS Industry, 64 Fed. Reg. 36372 (July 6, 1999). Section 6401(a) (7) of the Patient Protection and Affordable Care Act of 2010 (PPACA) amends the Social Security Act (SSA) to require that providers implement compliance plans as a condition of enrollment in the Medicare program. Section 6402 of the PPAC adds a new provision to the SSA to require providers to refund an overpayment within 60 days of the date the overpayment was identified.

III) Interactions with Referral Sources

A) Sales and Promotional Meetings

- 1) 42 U. S. C. §1320a-7b prohibits offering or soliciting any remuneration for the purpose of inducing the referral of patients or for the furnishing, or arranging for

the furnishing or for the purchasing, leasing, ordering, or recommending the purchasing, leasing, or ordering of an item or service. The statute has been interpreted to cover arrangements even when only one purpose (i.e., not the primary purpose) of the arrangement was to induce referrals. See United States v. Kats, 871 F. 2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68(3d Cir.), cert. denied, 474 U. S. 988 (1985).

- 2) OIG Compliance Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 2371 (May 5, 2003). The OIG recognizes the legitimate purposes of meals and other promotional activities in conjunction with sales meetings, but the OIG views lavish meals and entertainment as possible inducements. DMEPOS suppliers are strongly advised to confer with their counsel before offering meals or entertainment to physician referral sources in particular.
- 3) 42 C. F. R. § 411.357, establishes a limited exception for nonmonetary compensation from a referral source to a physician who prescribes a designated health service (DHS) such as DMEPOS or outpatient prescription drugs. The annual limit for nonmonetary compensation is \$300.00 (adjusted for inflation – but providers must use CMS’ inflation adjusted amounts). Compliance with this exception, however, does not preclude a finding that the nonmonetary compensation was an improper inducement under the anti-kickback statute.

B) Provision of Services and Information

- 1) OIG Advisory Opinion 98-16, stating that a provider that locates its employee on the premises of a referral source could violate the anti-kickback law if the employee relieves the referral source of some of its obligation to provide discharge services to patients.
- 2) OIG Advisory Opinion 08-20 reiterates that if a supplier’s employee is located at a hospital, the supplier could be at risk of offering illegal inducements if that employee relieves the hospital of any of its administrative obligations.
- 3) OIG Model compliance guidance for pharmaceutical manufacturers identifies the provision of support services and information that have value beyond the manufacture’s product as a risk area.
- 4) OIG Advisory Opinion 06 -16, held that a marketing program funded by a DME manufacturer and a program involving assistance with Medicare billing could constitute a kickback if intended to induce referrals.

C) Supporting Third Party Educational Conferences

- 1) 42 C. F. R. § 411.357 (o), allows institutions (such as hospitals) to provide compliance training to their physicians. However, programs that provide CMEs to physicians, do not qualify for this exception unless the program is designed to provide compliance training. CMS views the provision of CMEs to physicians as remuneration subject to the reach of the Stark law.
- 2) OIG compliance program for pharmaceutical manufacturers identifies educational programs sponsored by manufacturers as a risk area. The risk can be addressed according to the OIG by separating sales and marketing staff from participating in the education grants. The content of the education program should be determined by the independent sponsor of the program.

D) Arrangements with Consultants

- 1) Relationships with consultants should be structured to fit within a safe harbor and/or, if the consultant is a physician, an exception to the prohibition on physician self referrals under the Stark law and regulations. The OIG model compliance plan for pharmaceutical manufacturers clarifies that lavish entertainment, gifts, and other “perks” bestowed on consultants can constitute improper inducements under the anti-kickback laws (these perks would also exceed the Stark exception limits).

E) Gifts

- 1) The Stark regulations establish an annual limit of \$ 300.00 (adjusted for inflation) on nonmonetary compensation to physicians. Complying with this limit does not assure compliance with the anti-kickback laws.

F) Grants and Other Charitable Donations

- 1) Gifts or donations to legitimate charitable organizations or educational institutions must not be earmarked for use by specific referral source or a patient or individual identified by the referral source. See OIG Special Advisory Opinions 97-01 and 02-01 stating that providers maybe the source of funding for a patient advocacy organization, provided that the organization makes an independent determination on who receives the funds.

IV) Interaction with Vendors

- A) 42 U. S. C. §1320a-7b prohibits offering or soliciting any remuneration for the purpose of inducing the referral of patients or for the furnishing, or arranging for the furnishing or for the purchasing, leasing, ordering, or recommending the

purchasing, leasing, or ordering of an item or service. The statute has been interpreted to cover arrangements even when only one purpose (i.e., not the primary purpose) of the arrangement was to induce referrals. See United States v. Kats, 871 F. 2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68(3d Cir.), cert. denied, 474 U. S. 988 (1985).

- B)** OIG Advisory Opinion 06 -16, states that a marketing program funded by a DME manufacturer and a program involving assistance with Medicare billing could constitute a kickback if intended to induce referrals. DMEPOS provider policies should address risk areas in their interaction with vendors. These include the use of sample or demonstration products or soliciting free services from vendors that could serve as unlawful inducements.