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Anti-Referral and Anti-Kickback Laws: A Guide for Home Health Agencies and Hospices Operating in Texas

Prepared for the
Texas Association for Home Care & Hospice, Inc.

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Introduction

I. Introduction

Home health agencies and hospices are subject to many federal and state laws. Chief among these laws are those containing anti-referral and anti-kickback restrictions. These laws were adopted, generally speaking, to ensure patient protection (and the patient's freedom of choice) and to eliminate overpayment and the overutilization of resources. This guide focuses on what are generally considered the principal anti-referral and anti-kickback laws applicable to home health agencies and hospices operating in the state of Texas.

The practical effect of these principal laws is that each and every financial relationship between a home health agency or a hospice (on one hand) and any referral source or provider of health care services (on the other hand) should be scrutinized for compliance. For these purposes, a financial relationship is generally considered any compensation arrangement or ownership interest, in each case, whether direct or indirect, including through multiple levels of intermediaries, through multiple levels of contracts, and through family members. Examples of compensation arrangements include leases (whether for personal property or for real property) and personal services contracts (including those for medical director services or for management services). Examples of ownership interests include equity investments and many types of loans.

If a financial relationship does not comply with all of these principal laws, then a home health agency or hospice involved in the financial relationship may have significant criminal and civil exposure. Such exposure may range from: fines; revocation of one or more licenses, registrations, or certifications; civil penalties; and possibly even jail time. Additionally, it is not enough to confirm that a financial relationship complies with one of these principal laws. Instead, each of these principal laws is unique and must be evaluated on its own terms.

This guide is intended only as an overview of certain applicable federal and Texas laws. It is not intended to be a comprehensive analysis of each and every aspect of the law. Because of the generality of this guide and because interpretive guidance is still developing regarding the laws discussed in this guide, the information contained in this guide may not be applicable in all situations and may not, after the date of its presentation, even reflect the most current authority. Nothing contained in this guide should be relied or acted upon without the benefit of legal advice based upon the particular circumstances presented, and nothing in this guide is intended to be legal guidance or otherwise construed as developing any attorney-client relationship with the author.

Federal Laws

II. Federal Laws

There are at least three principal federal statutes containing anti-referral and anti-kickback restrictions. These statutes, as known by their common names, are: (1) the Stark Law (sometimes also referred to as Stark II); (2) the Anti-Kickback Law (sometimes also referred to as the Fraud and Abuse Statute); and (3) the Gifts to Beneficiaries Law. Each of these three statutes is discussed in the immediately following paragraphs.

A. Stark Law

1. Stark Law Discussion

The Stark Law prohibits a physician from referring a patient to an entity with which the physician (or an immediate family member of the physician) has a financial relationship for the furnishing of a designated health service. The Stark Law defines a “referral” as a request by a physician for any item or service paid for or by Medicare or Medicaid, including: a consultation with another physician; a test or procedure to be performed by another physician; and the establishment of a plan of care. Designated health services under the Stark Law include home health services; but, importantly, do not currently include hospice services. The relevant text of the Stark Law’s general prohibition can be found on [Pages 9-10](#). Additionally, the relevant text of selected Stark Law definitions can be found on [Pages 11-12](#).

Anyone receiving a payment in violation of the Stark Law must refund any amount so-received. Anyone presenting a claim for a service that he or she knows or should know is a violation of the Stark Law is subject to a penalty of up to \$15,000 per presentation. Also, anyone entering an arrangement in which he or she knows or should know is a violation of the Stark Law is subject to a penalty up to \$100,000 per arrangement. Finally, anyone violating the Stark Law is subject to having his or her Medicare/Medicaid certification revoked. The relevant text of the Stark Law sanctions can be found on [Page 13](#).

The Stark Law contains several exceptions that permit financial relationships which are otherwise prohibited by its plain language. In other words, a physician (or an immediate family member) is permitted to have a financial relationship with a home health agency and refer patients to the home health agency so long as the financial relationship complies with the applicable exceptions to the Stark Law. For example, the Stark Law contains an exception for ownership interests in a rural provider of designated health services so long as substantially all of the designated health services furnished by the rural provider are furnished to individuals residing in the rural area. There are certain qualifications as to what constitutes a “rural provider” and “substantially all” for this exception. The Stark Law also contains exceptions for certain contractual relationships, including: (1) the rental of office space; (2) the rental of equipment; (3) bona fide employment relationships; (4) personal service arrangements; and (5) non-monetary compensation up to \$300 (as such amount is adjusted annually by CMS). The relevant text of these exceptions, together with certain clarifying comments by the author, can be found on [Pages 14-21](#).

Importantly, in order to qualify for protection under an exception to the Stark Law, a financial relationship must strictly comply with each any every test and condition required by the applicable exception. The Stark Law does not care about, and is not dependent upon, whether the

parties to the financial relationship have any “bad” intent or otherwise intend to enter into a transaction in violation of the Stark Law. Instead, the Stark Law is what is considered a strict liability statute—in other words, if a financial relationship violates the Stark Law’s prohibitions in any way, then the parties to the financial relationship may have significant liability even if they believe they are acting in good faith and are, in fact, acting without any “bad” intentions.

2. Stark Law Comments

Immediately following are certain comments to the Stark Law provided by the author. Please note that these comments are also included within the content found at the links provided above. Most (if not all) of these comments are more helpful and provide more specific guidance when viewed in their applicable context, such as the statutes and regulations from which the comments derive. Therefore, it is recommended that the reader not rely solely on these comments but also carefully review the content provided in each of the links provided above:

- ***Comment: The Stark Law only applies to Medicare and Medicaid. Other federal health programs covered by the Anti-Kickback Law are not included within the Stark Law.***
- ***Comment: There are ten designated health services under the Stark Law, including home health services and occupational therapy services. Hospice services are not currently included as a designated health service.***
- ***Comment: The rural provider exception applies to non-Metropolitan Service Areas (as such areas are defined by the Federal government).***
- ***Comment: Percentage-based lease arrangements and per-click lease arrangements are no longer permissible under the Stark Law exceptions.***
- ***Comment: The bona fide employment exception may not apply to many situations, as Texas is a corporate practice of medicine state, meaning that non-physicians may not employ physicians.***
- ***Comment: The personal service arrangements exception provides a possible avenue by which home health agencies can utilize a physician’s services (such as medical director services, policy review services, and quality assurance services) in exchange for a services fee, and the physician can legally refer to the home health agency.***
- ***Comment: A home health agency may pay a physician a medical director fee so long as all of the specific items of the personal service arrangements exception are satisfied. This exception does not set a limit on the number of medical directors, but a home health agency is prohibited from having more medical directors than necessary to accomplish the commercially reasonable business purpose for having a medical director. In fact, the conditions for participation applicable to a home health agency do not require a medical director for certification purposes. Therefore, having multiple medical directors may be problematic, may be a red flag to a governmental regulator,***

and may lead to additional scrutiny. A legitimate business purpose never includes an inducement to make referrals.

- Comment: While the method for determining the fair market value hourly rate under the personal service arrangements exception is not explicitly specified in the regulations, it is recommended that the home health agency take all reasonable steps to confirm that the hourly rate is fair and reasonable in the home health agency's market and does not take into account the volume or value of referrals. It is further recommended that the home health agency document in writing the method it used to determine such hourly rate.
- Comment: Please note that the personal service arrangements exception requires "cross-referencing" of multiple personal service agreements or the maintenance of a "master list" listing all personal service agreements.
- Comment: The exception for non-monetary compensation up to \$300 does not permit the payment of any cash or any cash equivalent, such as a pre-paid gift card or credit card. In addition, non-monetary compensation can never be given as an inducement or a reward for referrals.
- Comment: There is an exception under the Stark Law for medical staff incidental benefits (not including cash or cash equivalents) that do not exceed \$25 and that meet certain other requirements. This exception is located at 42 C.F.R. 411.357(m). However, this exception is only available to hospitals and other facilities and health care clinics that have bona fide medical staffs. It is recommended that home health agencies proceed cautiously when attempting to operate under, or fit with, this exception.
- Comment: Under both non-monetary compensation exceptions (i.e., the \$300/\$25 exceptions), the compensation limits are adjusted each calendar year by CMS to the nearest whole dollar by the increase in the Consumer Price Index-Urban All Item (CPI-U) for the 12-month period ending the preceding September 30th. The CPI-U for the 12-month period ending September 30, 2009, decreased 1.3 percent. As the CPI-U decreased in the 12-month period ending September 30, 2009, the dollar value limits assigned by CMS to the non-monetary compensation and medical staff incidental benefits exceptions remained the same as they were in calendar year 2009. Thus, for the calendar year beginning January 1, 2010, the compensation limit for the exception at §411.357(k) remains \$355 per year, and the value of any medical staff incidental benefits to be furnished in compliance with the exception at §411.357(m) remains less than \$30 per occurrence of the benefit.

3. Stark Law Legal Materials

Stark Law: Prohibition

[Located at 42 U.S.C. § 1395nn(a)]

The relevant text of the Stark Law is:

(a) “Prohibition of certain referrals

(1) In general

Except as provided in subsection (b) of this section, if a physician (or an immediate family member of such physician) has a financial relationship with an entity specified in paragraph (2), then--

- (A) the physician may not make a referral to the entity for the furnishing of designated health services for which payment otherwise may be made under this subchapter [Medicare and Medicaid] ***[Comment: The Stark Law only applies to Medicare and Medicaid. Other federal health programs covered by the Anti-Kickback Law are not included within the Stark Law.]*** and
- (B) the entity may not present or cause to be presented a claim under this subchapter or bill to any individual, third party payor, or other entity for designated health services furnished pursuant to a referral prohibited under subparagraph (A).

(2) Financial relationship specified

For purposes of this section, a financial relationship of a physician (or an immediate family member of such physician) with an entity specified in this paragraph is--

- (A) except as provided in subsections (c) and (d) of this section, an ownership or investment interest in the entity, or
- (B) except as provided in subsection (e) of this section, a compensation arrangement (as

defined in subsection (h)(1) of this section) between the physician (or an immediate family member of such physician) and the entity . . .”

Stark Law: Definitions

[Located at 42 U.S.C. § 1395nn(h)]

The relevant text of certain Stark Law definitions is:

(h) “Definitions and special rules

For purposes of this section:

(1) Compensation arrangement; remuneration

(A) The term ‘**compensation arrangement**’ means any arrangement involving any remuneration between a physician (or an immediate family member of such physician) and an entity . . .

(B) The term ‘**remuneration**’ includes any remuneration, directly or indirectly, overtly or covertly, in cash or in kind.

...

(2) Employee

An individual is considered to be ‘**employed by**’ or an ‘**employee**’ of an entity if the individual would be considered to be an employee of the entity under the usual common law rules applicable in determining the employer-employee relationship . . .

(3) Fair market value

The term ‘**fair market value**’ means the value in arms length transactions, consistent with the general market value, and, with respect to rentals or leases, the value of rental property for general commercial purposes (not taking into account its intended use) and, in the case of a lease of space, not adjusted to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor where the lessor is a potential source of patient referrals to the lessee.

...

(5) Referral; referring physician

...

(B) Other items

Except as provided in subparagraph (C), the request or establishment of a plan of care by a physician which includes the provision of the designated health service constitutes a '*referral*' by a '*referring physician*.'

...

(6) Designated health services

The term '*designated health services*' means any of the following items or services:

...

- (I) Home health services. ***[Comment: There are ten designated health services under the Stark Law, including occupational therapy services. Hospice services are not currently included as a designated health service.]***

[Located at 42 C.F.R. § 411.351]

The relevant text of the definition of immediate family member is:

“411.351 Definitions.

Immediate family member or member of a physician's immediate family means husband or wife; birth or adoptive parent, child or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild.”

Stark Law: Sanctions

[Located at 42 U.S.C. § 1395nn(g)]

The relevant text of the Stark Law is:

(g) “Sanctions

(1) Denial of payment

No payment may be made . . . for a designated health service which is provided in violation of [the Stark Law].

(2) Requiring refunds for certain claims

If a person collects any amounts that were billed in violation of [the Stark Law], the person shall be liable to the individual for, and shall refund on a timely basis to the individual, any amounts so collected.

(3) Civil money penalty and exclusion for improper claims

Any person that presents or causes to be presented a bill or a claim for a service that such person knows or should know is for a service for which payment may not be made under paragraph (1) or for which a refund has not been made under paragraph (2) shall be subject to a civil money penalty of not more than \$15,000 for each such service . . .

(4) Civil money penalty and exclusion for circumvention schemes

Any physician or other entity that enters into an arrangement or scheme (such as a cross-referral arrangement) which the physician or entity knows or should know has a principal purpose of assuring referrals by the physician to a particular entity which, if the physician directly made referrals to such entity, would be in violation of this section, shall be subject to a civil money penalty of not more than \$100,000 for each such arrangement or scheme . . .

(5) Failure to report information

Any person who is required, but fails, to meet a reporting requirement of [the Stark Law] is subject to a civil money penalty of not more than \$10,000 for each day for which reporting is required to have been made . . .”

Stark Law Exception: Rural Providers

[Located at 42 U.S.C. 1395nn(d)(2)]

The relevant text of the Stark Law exception for rural providers is:

- (d) “. . . [t]he following . . . shall not be considered to be an ownership or investment interest described in subsection (a)(2)(A) of this section:

. . .

- (2) Rural providers

In the case of designated health services furnished in a rural area (as defined in section 1395ww(d)(2)(D) of this title) by an entity ***[Comment: The rural provider exception applies to non-Metropolitan Service Areas (as such areas are defined by the Federal government)]***, if--

- (A) substantially all of the designated health services furnished by the entity are furnished to individuals residing in such a rural area;
- (B) effective for the 18-month period beginning on December 8, 2003, the entity is not a specialty hospital . . . ; and
- (C) in the case where the entity is a hospital, the hospital meets the requirements of paragraph 3(D).”

Stark Law Exception: Rental of Office Space

[Located at 42 C.F.R. 411.357(a)]

The relevant text of the Stark Law exception for rental of office space is:

[Comment: Please note the comment below regarding a recent change in the Stark Law—percentage-based lease arrangements and per-click lease arrangements are no longer permissible under this Stark Law exception]

- (a) “Payments for the use of office space made by a lessee to a lessor if there is a rental or lease agreement that meets the following requirements:
- (1) The agreement is set out in writing, is signed by the parties, and specifies the premises it covers.

- (2) The term of the agreement is at least 1 year. To meet this requirement, if the agreement is terminated during the term with or without cause, the parties may not enter into a new agreement during the first year of the original term of the agreement.
- (3) The space rented or leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease or rental and is used exclusively by the lessee when being used by the lessee (and is not shared with or used by the lessor or any person or entity related to the lessor), except that the lessee may make payments for the use of space consisting of common areas if the payments do not exceed the lessee's pro rata share of expenses for the space based upon the ratio of the space used exclusively by the lessee to the total amount of space (other than common areas) occupied by all persons using the common areas.
- (4) The rental charges over the term of the agreement are set in advance and are consistent with fair market value.
- (5) The rental charges over the term of the agreement are not determined--
 - (i) In a manner that takes into account the volume or value of any referrals or other business generated between the parties; or
 - (ii) Using a formula based on--
 - (A) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed or business generated in the office space ***[Comment: Percentage-based payments are not allowed under this exception];*** or
 - (B) Per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee ***[Comment: Per-click payments are not allowed under this exception].***
- (6) The agreement would be commercially reasonable even if no referrals were made between the lessee and the lessor.
- (7) A holdover month-to-month rental for up to 6 months immediately following the expiration of an agreement of at least 1 year that met the conditions of paragraphs (a)(1) through (a)(6) of this section satisfies the requirements of paragraph (a) of this section, provided

that the holdover rental is on the same terms and conditions as the immediately preceding agreement.”

Stark Law Exception: Rental of Equipment

[Located at 42 C.F.R. 411.357(b)]

The relevant text of the Stark Law exception for rental of equipment is:

[Comment: Please note the comment below regarding a recent change in the Stark Law—percentage-based lease arrangements and per-click lease arrangements are no longer permissible under this Stark Law exception]

- (b) “Payments made by a lessee to a lessor for the use of equipment under the following conditions:
- (1) A rental or lease agreement is set out in writing, is signed by the parties, and specifies the equipment it covers.
 - (2) The equipment rented or leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease or rental and is used exclusively by the lessee when being used by the lessee and is not shared with or used by the lessor or any person or entity related to the lessor.
 - (3) The agreement provides for a term of rental or lease of at least 1 year. To meet this requirement, if the agreement is terminated during the term with or without cause, the parties may not enter into a new agreement during the first year of the original term of the agreement.
 - (4) The rental charges over the term of the agreement are set in advance, are consistent with fair market value, and are not determined—
 - (i) In a manner that takes into account the volume or value of any referrals or other business generated between the parties;
or

- (ii) Using a formula based on—
 - (A) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed on or business generated through the use of the equipment ***[Comment: Percentage-based payments are not allowed under this exception];*** or
 - (B) Per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee ***[Comment: Per-click payments are not allowed under this exception].***
- (5) The agreement would be commercially reasonable even if no referrals were made between the parties.
- (6) A holdover month-to-month rental for up to 6 months immediately following the expiration of an agreement of at least 1 year that met the conditions of paragraphs (b)(1) through (b)(5) of this section satisfies the requirements of paragraph (b) of this section, provided that the holdover rental is on the same terms and conditions as the immediately preceding agreement.”

Stark Law Exception: Bona Fide Employment Relationships

[Located at 42 C.F.R. 411.357(c)]

[Comment: This exception may not apply to many situations, as Texas is a corporate practice of medicine state, meaning that non-physicians may not employ physicians.]

The relevant text of the Stark Law exception for bona fide employment relationships is:

- (c) “Any amount paid by an employer to a physician (or immediate family member) who has a bona fide employment relationship with the employer for the provision of services if the following conditions are met:
 - (1) The employment is for identifiable services.
 - (2) The amount of the remuneration under the employment is--
 - (i) Consistent with the fair market value of the services; and
 - (ii) Except as provided in paragraph (c)(4) of this section, is not determined in a manner that takes into account (directly or

indirectly) the volume or value of any referrals by the referring physician.

- (3) The remuneration is provided under an agreement that would be commercially reasonable even if no referrals were made to the employer.
- (4) Paragraph (c)(2)(ii) of this section does not prohibit payment of remuneration in the form of a productivity bonus based on services performed personally by the physician (or immediate family member of the physician).”

Stark Law Exception: Personal Service Arrangements

[Located at 42 C.F.R. 411.357(d)]

[Comment: The personal service arrangements exception under the Stark Law provides a possible avenue by which home health agencies can utilize a physician’s services (such as medical director services, policy review services, and quality assurance services) in exchange for a services fee and the physician can legally refer to the home health agency.]

[Comment: A home health agency may pay a physician a medical director fee so long as all of the specific items of the personal service arrangements exception are satisfied. This exception does not set a limit on the number of medical directors, but a home health agency is prohibited from having more medical directors than necessary to accomplish the commercially reasonable business purpose for having a medical director. In fact, the conditions for participation applicable to a home health agency do not require a medical director for certification purposes. Therefore, having multiple medical directors may be problematic, may be a red flag to a governmental regulator, and may lead to additional scrutiny. A legitimate business purpose never includes an inducement to make referrals.]

[Comment: While the method for determining the fair market value hourly rate under the personal service arrangements exception is not explicitly specified in the regulations, it is recommended that the home health agency take all reasonable steps to confirm that the hourly rate is fair and reasonable in the home health agency’s market and does not take into account the volume or value of referrals. It is further recommended that the home health agency document in writing the method it used to determine such hourly rate]

The relevant text of the Stark Law exception for personal service arrangements is:

- (d) “Personal Service Arrangements.
- (1) General--Remuneration from an entity under an arrangement or multiple arrangements to a physician or his or her immediate family member, or to a group practice, including remuneration for specific physician services furnished to a nonprofit blood center, if the following conditions are met:
- (i) Each arrangement is set out in writing, is signed by the parties, and specifies the services covered by the arrangement.
- (ii) The arrangement(s) covers all of the services to be furnished by the physician (or an immediate family member of the physician) to the entity. ***[Comment: Please note that the personal service arrangements exception requires “cross-referencing” of multiple personal service agreements or the maintenance of a “master list” listing all personal service agreements.]*** This requirement is met if all separate arrangements between the entity and the physician and the entity and any family members incorporate each other by reference or if they cross-reference a master list of contracts that is maintained and updated centrally and is available for review by the Secretary upon request. The master list must be maintained in a manner that preserves the historical record of contracts. A physician or family member can ‘furnish’ services through employees whom they have hired for the purpose of performing the services; through a wholly-owned entity; or through locum tenens physicians (as defined at [42 C.F.R.] § 411.351, except that the regular physician need not be a member of a group practice).
- (iii) The aggregate services contracted for do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement(s).
- (iv) The term of each arrangement is for at least 1 year. To meet this requirement, if an arrangement is terminated during the term with or without cause, the parties may not enter into the same or substantially the same arrangement during the first year of the original term of the arrangement.
- (v) The compensation to be paid over the term of each arrangement is set in advance, does not exceed fair market value, and, except in the case of a physician incentive plan (as defined at [42 C.F.R.] § 411.351 of this subpart), is not

determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.

- (vi) The services to be furnished under each arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates any Federal or State law.
- (vii) A holdover personal service arrangement for up to 6 months following the expiration of an agreement of at least 1 year that met the conditions of paragraph (d) of this section satisfies the requirements of paragraph (d) of this section, provided that the holdover personal service arrangement is on the same terms and conditions as the immediately preceding agreement.”

Stark Law Exception: Non-Monetary Compensation up to \$300

[Located at 42 C.F.R. 411.357(k)]

[Comment: This exception for non-monetary compensation up to \$300 does not permit the payment of any cash or any cash equivalent, such as a pre-paid gift card or credit card. In addition, non-monetary compensation can never be given as an inducement or a reward for referrals.]

[Comment: There is also an exception under the Stark Law for medical staff incidental benefits (not including cash or cash equivalents) that do not exceed \$25 and that meet certain other requirements. This exception is located at 42 C.F.R. 411.357(m). However, this exception is only available to hospitals and other facilities and health care clinics that have bona fide medical staffs. It is recommended that home health agencies proceed cautiously when attempting to operate under, or fit with, this exception.]

[Comment: Under both exceptions (i.e., the \$300/\$25 exceptions), the compensation limits are adjusted each calendar year by CMS to the nearest whole dollar by the increase in the Consumer Price Index-Urban All Item (CPI-U) for the 12-month period ending the preceding September 30th. The CPI-U for the 12-month period ending September 30, 2009, decreased 1.3 percent. As the CPI-U decreased in the 12-month period ending September 30, 2009, the dollar value limits assigned by CMS to the non-monetary compensation and medical staff incidental benefits exceptions remained the same as they were in calendar year 2009. Thus, for the calendar year beginning January 1, 2010, the compensation limit for the exception at §411.357(k) remains \$355 per year, and the value of any medical staff incidental benefits to be furnished in compliance with the exception at §411.357(m) remains less than \$30 per occurrence of the benefit.]

The relevant text of the Stark Law exception for non-monetary compensation up to \$300 is:

- (k) “Non-monetary compensation.
 - (1) Compensation from an entity in the form of items or services (not including cash or cash equivalents) that does not exceed an aggregate of \$300 per calendar year...if all of the following conditions are satisfied:
 - (i) The compensation is not determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician.
 - (ii) The compensation may not be solicited by the physician or the physician’s practice (including employees and staff members).
 - (iii) The compensation arrangement does not violate the [Anti-Kickback Law] . . .”

B. Anti-Kickback Law

1. Anti-Kickback Law Discussion

The Anti-Kickback Law prohibits any person from knowingly and willfully soliciting, receiving, offering to pay, or paying any remuneration (including any kickback, bribe, or rebate) in return for (1) referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made under a federal health care program or (2) purchasing, leasing, ordering, or arranging any good, facility, service, or item for which payment may be made under a federal health care program. The relevant text of the Anti-Kickback Law can be found on [Pages 25-26](#). The Anti-Kickback Law applies to all federal health care programs, is not limited to Medicare or Medicaid, and equally applies to all persons (*i.e.*, it is not limited to certain types or providers or certain types of services).

The Anti-Kickback Law has been interpreted to cover and prohibit any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals (even if there are many other legitimate purposes of the remuneration). The relevant text of an advisory opinion by the Federal government regarding the broad nature of the Anti-Kickback Law can be found on [Page 27](#).

A violation of the Anti-Kickback Law is a criminal violation, and a person convicted under its provisions is guilty of a Felony and can be imprisoned for up to five years and fined up to \$25,000. The Anti-Kickback Law requires that anyone having knowledge of the receipt of Medicare or Medicaid dollars in violation of the statute notify the fiscal intermediary of the improper receipt and, if applicable, refund any improperly received funds. Conviction under the Anti-Kickback Law will lead to automatic exclusion from all federal health care programs, including Medicare and Medicaid, and the Federal government may impose civil monetary penalties on a party violating the Anti-Kickback Law.

Much like the Stark Law, the Anti-Kickback Law contains several exceptions that permit financial relationships which are otherwise prohibited by its plain language. An important distinction from the Stark Law, however, is how these exceptions work within the framework of the Anti-Kickback Law. More specifically, the exceptions to the Anti-Kickback Law are referred to as “safe harbors” and while complying with all of the elements of the applicable safe harbors will afford protection under the Anti-Kickback Law, the failure to strictly meet each and every element of the applicable safe harbors does not necessarily mean that a financial relationship is in violation of the Anti-Kickback Law.

While this may seem confusing when compared against the strict liability nature of the Stark Law (recall above how it was noted that the Stark Law is a strict liability statute and the parties’ “intent” does not matter), it is important to note that the Anti-Kickback Law is violated only if a person acts in a knowingly and willful manner. Thus, the safe harbors are merely guidelines for compliance; if a financial relationship does not fit squarely within the applicable safe harbors, then the parties to the financial relationship can nevertheless claim that they were not acting in a knowingly and willful manner in violation of the Anti-Kickback Law. This approach is not recommended, however. Conversely, it is strongly recommended that each financial relationship strictly comply with the applicable safe harbors to ensure protection from prosecution.

Many of the safe harbors to the Anti-Kickback law will sound familiar when compared against the Stark Law exceptions. Particularly, the Anti-Kickback Law has safe harbors for: (1) the rental of office space; (2) the rental of equipment; (3) personal services and management contracts; and (4) employees. The Anti-Kickback Law also has safe harbors for (5) investment interests (sometimes also referred to as the 60/40 rule); (6) referral services; (7) discounts; (8) waivers of beneficiary coinsurance and deductible amounts; and (9) price reductions offered to health plans and managed care organizations. The relevant text of these safe harbors, together with certain clarifying comments by the author, can be found on [Pages 28-37](#). Remember, just because a financial relationship complies with a Stark Law exception does not necessarily mean that the financial relationship complies with the Anti-Kickback Law or any of its safe harbors (and *vice versa*). Thus, a separate analysis of a financial relationship must be undertaken with respect to each and every applicable law.

2. Anti-Kickback Law Comments

Immediately following are certain comments to the Anti-Kickback Statute provided by the author. Please note that these comments are also included within the content found at the links provided above. Most (if not all) of these comments are more helpful and provide more specific guidance when viewed in their applicable context, such as the statutes and regulations from which the comments derive. Therefore, it is recommended that the reader not rely solely on these comments but also carefully review the content provided in each of the links provided above:

- ***Comment: The Anti-Kickback Law applies to all federal health care programs, including, among others, Medicare, Medicaid, the Federal Employees Health Benefit Plan, CHAMPUS, Indian Health Services, the Veterans Administration.***
- ***Comment: Home health agencies and hospices renting space in, or equipment from, assisted living facilities, hospitals, physician offices, and other providers must comply with the rental of office space safe harbor or the rental of equipment safe harbor (whichever is applicable). Please pay particular attention to items (5) and (6) of these safe harbors. The home health agency or hospice must be able to show that the space or equipment is needed for its business purpose and that the rental rate is at fair market value with no “kicker” for its proximity to potential referrals.***
- ***Comment: Please use particular caution when relying on the investment interest safe harbor, primarily since there is no analogous exception to the Stark Law for investment interests. In other words, a financial relationship may comply with this safe harbor but could still violate the Stark Law.***
- ***Comment: The investment interest safe harbor essentially caps investment interests of referring sources and service providers (among others) at 40%.***
- ***Comment: The investment interest safe harbor essentially caps revenue generated by a home health agency or hospice from referral sources (among others) at 40%.***

- *Comment: The safe harbor for discounts is very lengthy and complicated. Only a small portion of this safe harbor is reproduced in this guide. If you offer or receive, or intend to offer or receive, any discounts connected to any federal health care program, it is recommended that this safe harbor be reviewed in its entirety.*
- *Comment: Please note that the safe harbors relating to price reductions offered to health plans and managed care organizations refer to lengthy standards which must be met if a home health agency or hospice has a particular type of contract. Please read the entire section and its standards if you have such a contract.*

3. Anti-Kickback Law Legal Materials

Anti-Kickback Law: Prohibition

[Located at 42 U.S.C. § 1320a-7b(b)]

The relevant text of the Anti-Kickback Law is:

(b) **“Illegal remunerations**

(1) whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind--

(A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program
[Comment: A federal health care program includes, among others, Medicare, Medicaid, the Federal Employees Health Benefit Plan, CHAMPUS, Indian Health Services, the Veterans Administration], or

(B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than five years, or both.

(2) whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person--

(A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

- (B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than five years, or both.

- (3) Paragraphs (1) and (2) shall not apply to--
 - (A) a discount or other reduction in price obtained by a provider of services or other entity under a Federal health care program if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity under a Federal health care program;
 - (B) any amount paid by an employer to an employee (who has a bona fide employment relationship with such employer) for employment in the provision of covered items or services . . . ”

Anti-Kickback Law: Advisory Opinion

[OIG Advisory Opinion No. 01-5 (2001). Available at <http://oig.hhs.gov/fraud/docs/advisoryopinions/2001/ao01-05.pdf>]

The relevant text of the advisory opinion is:

“The [Anti-Kickback Law] makes it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce referrals of items or services reimbursable by Federal health care programs . . . Where remuneration is paid purposefully to induce referrals of items or services paid for by a Federal health care program, the [Anti-Kickback Law] is violated. By its terms, the [Anti-Kickback Law] ascribes criminal liability to parties on both sides of an impermissible ‘kickback’ transaction. For purposes of the [Anti-Kickback Law], ‘remuneration’ includes the transfer of anything of value, in cash or in-kind, directly or indirectly, covertly or overtly.

The [Anti-Kickback Law] has been interpreted to cover any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals . . . Violation of the [Anti-Kickback Law] constitutes a felony punishable by a maximum fine of \$25,000, imprisonment up to five years, or both. Conviction will also lead to automatic exclusion from Federal health care programs, including Medicare and Medicaid. Where a party commits an act described in [the Anti-Kickback Law], the OIG may initiate administrative proceedings to impose civil monetary penalties on such party . . .

This Office’s concern with the provision of goods and services for nominal or at below-market rates to actual or potential referral sources is longstanding and clear: such arrangements are suspect and may violate the [Anti-Kickback Law] if one purpose is to induce or reward referrals of Federal health care program business.”

Anti-Kickback Law Safe Harbor: Rental of Office Space

[Located at 42 C.F.R. § 1001.952(b)]

The relevant text of the safe harbor for the rental of office space is:

- (b) “Space rental. As used in [the Anti-Kickback Law], ‘remuneration’ does not include any payment made by a lessee to a lessor for the use of premises, as long as all of the following six standards are met--
- (1) The lease agreement is set out in writing and signed by the parties.
 - (2) The lease covers all of the premises leased between the parties for the term of the lease and specifies the premises covered by the lease.
 - (3) If the lease is intended to provide the lessee with access to the premises for periodic intervals of time, rather than on a full-time basis for the term of the lease, the lease specifies exactly the schedule of such intervals, their precise length, and the exact rent for such intervals.
 - (4) The term of the lease is for not less than one year.
 - (5) The aggregate rental charge is set in advance, is consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs.
 - (6) The aggregate space rented does not exceed that which is reasonably necessary to accomplish the commercially reasonable business purpose of the rental. Note that for purposes of [this safe harbor], the term fair market value means the value of the rental property for general commercial purposes, but shall not be adjusted to reflect the additional value that one party (either the prospective lessee or lessor) would attribute to the property as a result of its proximity or convenience to sources of referrals or business otherwise generated for which payment may

be made in whole or in part under Medicare, Medicaid and all other Federal health care programs.”

[Comment: Home health agencies and hospices renting space in assisted living facilities, hospitals, physician offices, and other providers must comply with this safe harbor. Please pay particular attention to items (5) and (6) of this safe harbor. The home health agency or hospice must be able to show that the space is needed for its business purpose and that the rental rate is at fair market value with no “kicker” for its proximity to potential referrals.]

Anti-Kickback Law Safe Harbor: Rental of Equipment

[Located at 42 C.F.R. § 1001.952(c)]

The relevant text of the safe harbor for the rental of equipment is:

- (c) “Equipment rental. As used in the [Anti-Kickback Law], ‘remuneration’ does not include any payment made by a lessee of equipment to the lessor of the equipment for the use of the equipment, as long as all of the following six standards are met--
- (1) The lease agreement is set out in writing and signed by the parties.
 - (2) The lease covers all of the equipment leased between the parties for the term of the lease and specifies the equipment covered by the lease.
 - (3) If the lease is intended to provide the lessee with use of the equipment for periodic intervals of time, rather than on a full-time basis for the term of the lease, the lease specifies exactly the schedule of such intervals, their precise length, and the exact rent for such interval.
 - (4) The term of the lease is for not less than one year.
 - (5) The aggregate rental charge is set in advance, is consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid or all other Federal health care programs.

- (6) The aggregate equipment rental does not exceed that which is reasonably necessary to accomplish the commercially reasonable business purpose of the rental. Note that for purposes of [this safe harbor], the term fair market value means that the value of the equipment when obtained from a manufacturer or professional distributor, but shall not be adjusted to reflect the additional value one party (either the prospective lessee or lessor) would attribute to the equipment as a result of its proximity or convenience to sources of referrals or business otherwise generated for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs.”

[Comment: Home health agencies and hospices renting equipment from assisted living facilities, hospitals, physician offices, and other providers must comply with this safe harbor. Please pay particular attention to items (5) and (6) of this safe harbor. The home health agency or hospice must be able to show that the equipment is needed for its business purpose and that the rental rate is at fair market value with no “kicker” for any business relationship with such potential referring lessor.]

Anti-Kickback Law Safe Harbor: Personal Services and Management Contracts

[Located at 42 C.F.R. § 1001.952(d)]

The relevant text of the safe harbor for personal services and management contracts is:

- (d) “Personal services and management contracts. As used in [the Anti-Kickback Law], ‘remuneration’ does not include any payment made by a principal to an agent as compensation for the services of the agent, as long as all of the following seven standards are met--
- (1) The agency agreement is set out in writing and signed by the parties.
 - (2) The agency agreement covers all of the services the agent provides to the principal for the term of the agreement and specifies the services to be provided by the agent.
 - (3) If the agency agreement is intended to provide for the services of the agent on a periodic, sporadic or part-time basis, rather than on a full-time basis for the term of the agreement, the agreement specifies exactly

the schedule of such intervals, their precise length, and the exact charge for such intervals.

- (4) The term of the agreement is for not less than one year.
- (5) The aggregate compensation paid to the agent over the term of the agreement is set in advance, is consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs.
- (6) The services performed under the agreement do not involve the counselling [sic] or promotion of a business arrangement or other activity that violates any State or Federal law.
- (7) The aggregate services contracted for do not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the services.

For purposes of [this safe harbor], an agent of a principal is any person, other than a bona fide employee of the principal, who has an agreement to perform services for, or on behalf of, the principal.”

Anti-Kickback Law Safe Harbor: Employees

[Located at 42 C.F.R. § 1001.952(i)]

The relevant text of the safe harbor for employees is:

- (i) “Employees. As used in [the Anti-Kickback Law], ‘remuneration’ does not include any amount paid by an employer to an employee, who has a bona fide employment relationship with the employer, for employment in the furnishing of any item or service for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs. For purposes of [this safe harbor], the term employee [means any individual who, under the usual common law rules applicable in determining the employer-employee relationship, has the status of an employee . . . pursuant to 26 U.S.C. § 3121(d)(2)].”

Anti-Kickback Law Safe Harbor: Investment Interests (aka the 60/40 Rule)

[Located at 42 C.F.R. § 1001.952(a)(2)]

[Comment: Please use particular caution when relying on this safe harbor, primarily since there is no analogous exception to the Stark Law for investment interests. In other words, a financial relationship may comply with this safe harbor but could still violate the Stark Law.]

The relevant text of the safe harbor for investment interests is:

- (a) “Investment interests. As used in [the Anti-Kickback Law], ‘remuneration’ does not include any payment that is a return on an investment interest, such as a dividend or interest income, made to an investor as long as all of the applicable standards are met within one of the following three categories of entities:

...

- (2) If the entity possesses investment interests that are held by either active or passive investors, all of the following eight applicable standards must be met--

- (i) No more than 40 percent of the value of the investment interests of each class of investment interests may be held in the previous fiscal year or previous 12 month period by investors who are in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity. (For purposes of paragraph (a)(2)(i) of this section, equivalent classes of equity investments may be combined, and equivalent classes of debt instruments may be

combined.) ***[Comment: This 40% standard has helped coin this safe harbor the 60/40 rule—i.e., it essentially caps investment interests of referring sources and service providers (among others) at 40%]***

- (ii) The terms on which an investment interest is offered to a passive investor, if any, who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity must be no different from the terms offered to other passive investors.
- (iii) The terms on which an investment interest is offered to an investor who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity must not be related to the previous or expected volume of referrals, items or services furnished, or the amount of business otherwise generated from that investor to the entity.
- (iv) There is no requirement that a passive investor, if any, make referrals to, be in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity as a condition for remaining as an investor.
- (v) The entity or any investor must not market or furnish the entity's items or services (or those of another entity as part of a cross referral agreement) to passive investors differently than to non-investors.
- (vi) No more than 40 percent of the entity's gross revenue related to the furnishing of health care items and services in the previous fiscal year or previous 12-month period may come from referrals or business otherwise generated from investors. ***[Comment: This other 40% standard has also helped coin this safe harbor the 60-40 rule—i.e., revenue generation by referral sources is capped at 40%]***
- (vii) The entity or any investor (or other individual or entity acting on behalf of the entity or any investor in the entity) must not loan funds to or guarantee a loan for an investor who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity if the investor uses any part of such loan to obtain the investment interest.
- (viii) The amount of payment to an investor in return for the investment interest must be directly proportional to the

amount of the capital investment (including the fair market value of any pre-operational services rendered) of that investor.”

Anti-Kickback Law Safe Harbor: Referral Services

[Located at 42 C.F.R. § 1001.952(f)]

The relevant text of the safe harbor for referral services is:

- (f) “Referral services. As used in [the Anti-Kickback Law], ‘remuneration’ does not include any payment or exchange of anything of value between an individual or entity (‘participant’) and another entity serving as a referral service (‘referral service’), as long as all of the following four standards are met--
- (1) The referral service does not exclude as a participant in the referral service any individual or entity who meets the qualifications for participation.
 - (2) Any payment the participant makes to the referral service is assessed equally against and collected equally from all participants, and is only based on the cost of operating the referral service, and not on the volume or value of any referrals to or business otherwise generated by either party for the referral service for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs.
 - (3) The referral service imposes no requirements on the manner in which the participant provides services to a referred person, except that the referral service may require that the participant charge the person referred at the same rate as it charges other persons not referred by the referral service, or that these services be furnished free of charge or at reduced charge.
 - (4) The referral service makes the following five disclosures to each person seeking a referral, with each such disclosure maintained by the referral service in a written record certifying such disclosure and signed by either such person seeking a referral or by the individual making the disclosure on behalf of the referral service--

- (i) The manner in which it selects the group of participants in the referral service to which it could make a referral;
- (ii) Whether the participant has paid a fee to the referral service;
- (iii) The manner in which it selects a particular participant from this group for that person;
- (iv) The nature of the relationship between the referral service and the group of participants to whom it could make the referral; and
- (v) The nature of any restrictions that would exclude such an individual or entity from continuing as a participant.”

Anti-Kickback Law Safe Harbor: Discounts

[Located at 42 C.F.R. § 1001.952(h)]

[Comment: This safe harbor is very lengthy and complicated. Only a small portion of this safe harbor is reproduced below. If you offer or receive, or intend to offer or receive, any discounts connected to any federal health care program, it is recommended that this safe harbor be reviewed in its entirety.]

The relevant text of the safe harbor for discounts is:

- (h) “Discounts. As used in [the Anti-Kickback Law], ‘remuneration’ does not include a discount, as defined in paragraph (h)(5) of this section, on an item or service for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs for a buyer as long as the buyer complies with the applicable standards of paragraph (h)(1) of this section; a seller as long as the seller complies with the applicable standards of paragraph (h)(2) of this section; and an offeror of a discount who is not a seller under paragraph (h)(2) of this section so long as such offeror complies with the applicable standards of paragraph (h)(3) of this section.

...

- (5) For purposes of this [safe harbor], the term discount ... does not include--

...

- (iv) A routine reduction or waiver of any coinsurance or deductible amount owed by a program beneficiary . . .”

Anti-Kickback Law Safe Harbor: Waiver of Beneficiary Coinsurance and Deductible Amounts

[Located at 42 C.F.R. § 1001.952(k)]

The relevant text of the safe harbor for waivers of beneficiary coinsurance and deductible amounts is:

- (k) “Waiver of beneficiary coinsurance and deductible amounts. As used in [the Anti-Kickback Law], ‘remuneration’ does not include any reduction or waiver of a Medicare or a State health care program beneficiary's obligation to pay coinsurance or deductible amounts . . .
- ...
- (2) If the coinsurance or deductible amounts are owed by an individual who qualifies for subsidized services under . . . [Medicaid] . . .”

Anti-Kickback Law Safe Harbors: Price Reductions Offered to Health Plans and Managed Care Organizations

[Located at 42 C.F.R. § 1001.952(m) and (t)]

The relevant text of the safe harbors for price reductions offered to health plans and managed care organizations is:

- (m) “Price reductions offered to health plans.
- (1) As used in [the Anti-Kickback Law], ‘remuneration’ does not include a reduction in price a contract health care provider offers to a health plan in accordance with the terms of a written agreement between the contract health care provider and the health plan . . . as long as both the health plan and contract health care provider comply with all of the applicable standards within one of the following four categories of health plans:
- (i) If the health plan is a risk-based health maintenance organization, competitive medical plan, or prepaid health plan . . . the contract health care provider must not claim

payment in any form from the Department or the State agency for items or services furnished in accordance with the agreement except as approved by CMS or the State health care program . . .

- (ii) If the health plan is a health maintenance organization, competitive medical plan, health care prepayment plan, prepaid health plan, or other health plan that has executed a contract or agreement with CMS or a State health care program to receive payment for enrollees on a reasonable cost or similar basis, the health plan and contract health care provider must comply with all of the following four standards . . .
 - (iii) If the health plan . . . is not paid on an at-risk, capitated basis, both the health plan and contract health care provider must comply with all of the following six standards . . .”
- (t) “Price reductions offered to eligible managed care organizations.
- (1) As used in [the Anti-Kickback Law], ‘remuneration’ does not include any payment between:
 - (i) An eligible managed care organization and any first tier contractor for providing or arranging for items or services, as long as the following three standards are met . . .”

[Comment: Please note that these safe harbors refer to lengthy standards which must be met if a home health agency or hospice has a particular type of contract. Please read the entire section and its standards if you have such a contract.]

C. Gifts to Beneficiaries Law

1. Gifts to Beneficiaries Law Discussion

The Gifts to Beneficiaries Law, which was created in 1996 as part of the HIPAA legislation, prohibits any person from offering or transferring to any Medicare or Medicaid beneficiary any remuneration that the person knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of Medicare or Medicaid payable items or services. The relevant text of the Gifts to Beneficiaries Law can be found on [Page 40](#). In 2002, the Federal government issued a special advisory bulletin that was designed to help the health care industry better understand the Gifts to Beneficiaries Law and its prohibition on furnishing inducements to Medicare and Medicaid beneficiaries. The text of the special advisory bulletin can be found on [Pages 41-44](#).

A violation of the Gifts to Beneficiaries Law may subject the violator to a civil money penalty of not more than \$10,000 for each item or service. In addition, the violator may be subject to an assessment of not more than three times the amount claimed for each such item or service or certain other treble damages. The Federal government may also exclude the violator from participation in any and all federal health care programs and direct the appropriate state agency or agencies to exclude the violator from participation in any and all state health care programs.

While the payment of cash or cash equivalents to a beneficiary is never permitted under the Gifts to Beneficiaries Law, the Federal government has determined that a beneficiary may be offered an inexpensive gift or gifts or services without violating the statute. For enforcement purposes, the Federal government has indicated that inexpensive gifts or services are those that have a retail value of no more than \$10 individually and no more than \$50 in the aggregate annually per patient. Cash or cash equivalents can never qualify as an inexpensive gift or service, regardless of the amount of such cash or cash equivalent.

Home health agencies and hospices may also find it beneficial and helpful to review the final rules regarding civil monetary penalties adopted by the Federal government with respect to the Gifts to Beneficiaries Law and published in the *Federal Register* on April 26, 2000. Specifically, the comments and guidance provided on pages 24407-24410 may be useful in providing services at health fairs or other screening services. Additionally, the Federal government has issued guidance relative to what types of gifts may or may not be considered acceptable. Links to this guidance, issued in the form of advisory opinions, can be found on [Page 45](#). Also, Texas Medicaid providers who contract with the Texas Department of Aging and Disability Services must also comply with the requirements found in Chapter 49 of Title 40 of the Texas Administrative Code regarding solicitation of clients.

2. Gifts to Beneficiaries Law Comments

Immediately following are certain comments to the Gifts to Beneficiaries Law provided by the author. Please note that these comments are also included within the content found at the links provided above. Most (if not all) of these comments are more helpful and provide more specific guidance when viewed in their applicable context, such as the statutes and regulations from which

the comments derive. Therefore, it is recommended that the reader not rely solely on these comments but also carefully review the content provided in each of the links provided above:

- ***Comment: For further direction from the Federal government regarding its special advisory bulletin, contact information has been provided by the Office of Inspector General: Vicki Robinson or Joel Schaer at 202.619.0335.***
- ***Comment: Gifts and free services to beneficiaries should not exceed the \$10 per item limit and the \$50 annual limit. The OIG will review these limits periodically and may adjust them for inflation if appropriate.***
- ***Comment: Home health agencies and hospices should have some process or criteria that establishes which program enrollees should not pay a co-pay.***

3. Gifts to Beneficiaries Law Legal Materials

Gifts to Beneficiaries Law: Prohibition

[Located at 42 U.S.C. § 1320a-7a(a)]

The relevant text of the Gifts to Beneficiaries Law is:

(a) “Improperly filed claims

Any person . . . that--

. . .

(5) offers to or transfers remuneration to any individual eligible for benefits under [Medicare or Medicaid] that such person knows or should know is likely to influence such individual to order or receive from a particular provider, practitioner, or supplier any item or service for which payment may be made, in whole or in part, under [Medicare or Medicaid]; . . .

(7) commits an act described in [the Anti-Kickback Law];

. . .

shall be subject, in addition to any other penalties that may be prescribed by law, to a civil money penalty of not more than \$10,000 for each item or service (or, . . . in cases under paragraph (7), \$50,000 for each such act . . .) In addition, such a person shall be subject to an assessment of not more than 3 times the amount claimed for each such item or service in lieu of damages . . . (or, in cases under paragraph (7), damages of not more than 3 times the total amount of remuneration offered, paid, solicited, or received, without regard to whether a portion of such remuneration was offered, paid, solicited, or received for a lawful purpose . . .) In addition the Secretary may make a determination in the same proceeding to exclude the person from participation in Federal health care programs . . . and to direct the appropriate State agency to exclude the person from participation in any State health care program.”

Gifts to Beneficiaries Law: Special Advisory Bulletin

[Offering Gifts and Other Inducements to Beneficiaries, OIG Special Advisory Bulletin (August 2002). Available at <http://oig.hhs.gov/fraud/docs/alertsandbulletins/SABGiftsandInducements.pdf>]

[Comment: For further direction from the Federal government regarding this special advisory bulletin, contact information has been provided by the Office of Inspector General: Vicki Robinson or Joel Schaer at 202.619.0335.]

The relevant text of the special advisory bulletin from the Federal government is:

“Under [the Gifts to Beneficiaries Law], enacted as part of Health Insurance Portability and Accountability Act of 1996 (HIPAA), a person who offers or transfers to a Medicare or Medicaid beneficiary any remuneration that the person knows or should know is likely to influence the beneficiary’s selection of a particular provider, practitioner, or supplier of Medicare or Medicaid payable items or services may be liable for civil money penalties (CMPs) of up to \$10,000 for each wrongful act. For purposes of [the Gifts to Beneficiaries Law], the statute defines ‘remuneration’ to include, without limitation, waivers of copayments and deductible amounts (or any part thereof) and transfers of items or services for free or for other than fair market value . . . The statute and implementing regulations contain a limited number of exceptions . . .

Offering valuable gifts to beneficiaries to influence their choice of a Medicare or Medicaid provider [which includes practitioners and suppliers, as defined in 42 C.F.R. 400.202: ‘Provider means . . . a home health agency . . . that has in effect an agreement to participate in Medicare . . .’] raises quality and cost concerns. Providers may have an economic incentive to offset the additional costs attributable to the giveaway by providing unnecessary services or by substituting cheaper or lower quality services. The use of giveaways to attract business also favors large providers with greater financial resources for such activities, disadvantaging smaller providers and businesses.

The Office of Inspector General (OIG) is responsible for enforcing [the Gifts to Beneficiaries Law] through administrative remedies. Given the broad language of the prohibition and the number of marketing practices potentially affected, this Bulletin is intended to alert the health care industry as to the scope of acceptable practices. To that end, this Bulletin provides bright-line guidance that will protect the Medicare and Medicaid programs, encourage compliance, and level the playing field among providers. In particular, the OIG will apply the prohibition according to the following principles:

- First, the OIG has interpreted the prohibition to permit Medicare or Medicaid providers to offer beneficiaries inexpensive gifts (other than cash or cash equivalents) or services without violating the statute. For enforcement purposes, inexpensive gifts or services are those that have a retail value of no more than \$10 individually, and no more than \$50 in the aggregate annually per patient.

- Second, providers may offer beneficiaries more expensive items or services that fit within one of the five statutory exceptions: waivers of cost-sharing amounts based on financial need; properly disclosed copayment differentials in health plans; incentives to promote the delivery of certain preventive care services; any practice permitted under the [Anti-Kickback Law] *[Comment: The Anti-Kickback Law has safe harbors for warranties; discounts; employee compensation; waivers of certain beneficiary coinsurance and deductible amounts; and increased coverage, reduced cost-sharing amounts, or reduced premium amounts offered by health plans.]*; or waivers of hospital outpatient copayments in excess of the minimum copayment amounts.

...

- Fourth, the OIG will continue to entertain requests for advisory opinions related to the prohibition on inducements to beneficiaries. However, as discussed below, given the difficulty in drawing principled distinctions between categories of beneficiaries or types of inducements, favorable opinions have been, and are expected to be, limited to situations involving conduct that is very close to an existing statutory or regulatory exception.

In sum, unless a provider's practices fit within an exception (as implemented by regulations) or are the subject of a favorable advisory opinion covering a provider's own activity, any gifts or free services to beneficiaries should not exceed the \$10 per item and \$50 annual limits. *[Comment: The OIG will review these limits periodically and may adjust them for inflation if appropriate.]*

In addition, valuable services or other remuneration can be furnished to financially needy beneficiaries by an independent entity . . . An example of such an arrangement is the American Kidney Fund's program to assist needy patients with end stage renal disease with funds donated by dialysis providers . . .

Elements of the Prohibition

Remuneration. [The Gifts to Beneficiaries Law] prohibits the offering or transfer of 'remuneration'. The term 'remuneration' has a well-established meaning in the context of various health care fraud and abuse statutes. Generally, it has been interpreted broadly to include 'anything of value.' The definition of 'remuneration' for purposes of [the Gifts to Beneficiaries Law] . . . affirms this broad reading . . .

The definition of 'remuneration' in [the Gifts to Beneficiaries Law] contains five specific exceptions:

- Non-routine, unadvertised waivers of copayments or deductible amounts based on individualized determinations of financial need or exhaustion of reasonable collection efforts . . . ***[Comment: Providers should have some process or criteria that establishes which program enrollees should not pay a co-pay.]***

...

- Incentives to promote the delivery of preventive care. Preventive care is defined in 42 CFR 1003.101 to mean items and services that (i) are covered by Medicare or Medicaid and (ii) are either pre-natal or post-natal well-baby services or are services described in the Guide to Clinical Preventive Services published by the U.S. Preventive Services Task Force (available online at <http://odphp.osophs.dhhs.gov/pubs/guidecps/>). Such incentives may not be in the form of cash or cash equivalents and may not be disproportionate to the value of the preventive care provided. (See 42 CFR 1003.101; 65 FR 24400 and 24409.)
- Any practice permitted under an [Anti-Kickback Law] safe harbor at 42 CFR 1001.952. ***[Comment: For example, the Anti-Kickback Law safe harbors exist for warranties; discounts; employee compensation; waivers of certain beneficiary coinsurance and deductible amounts; and increased coverage, reduced cost-sharing amounts, or reduced premium amounts offered by health plans. See 42 C.F.R. 1001.952(g), (h), (i), and (k).]***

...

[T]he OIG interprets the prohibition to exclude offers of inexpensive items or services, and no specific exception for such items or services is required. (See 65 FR 24400 and 24410.) The OIG has interpreted inexpensive to mean a retail value of no more than \$10 per item or \$50 in the aggregate per patient on an annual basis . . .

Inducement. [The Gifts to Beneficiaries Law] bars the offering of remuneration to Medicare or Medicaid beneficiaries where the person offering the remuneration knows or should know that the remuneration is likely to influence the beneficiary to order or receive items or services from a particular provider. The ‘should know’ standard is met if a provider acts with deliberate ignorance or reckless disregard. No proof of specific intent is required. (See 42 CFR 1003.101[], which states ‘[s]hould know or should have known means that a person, with respect to information--(1) [a]cts in deliberate ignorance of the truth or falsity of the information; or (2) [a]cts in reckless disregard of the truth or falsity of the information. For purposes of this definition, no proof of specific intent to defraud is required.’])

The ‘inducement’ element of the offense is met by any offer of valuable (*i.e.*, not inexpensive) goods and services as part of a marketing or promotional activity,

regardless of whether the marketing or promotional activity is active or passive. For example, even if a provider does not directly advertise or promote the availability of a benefit to beneficiaries, there may be indirect marketing or promotional efforts or informal channels of information dissemination, such as ‘word of mouth’ promotion by practitioners or patient support groups. In addition, the OIG considers the provision of free goods or services to existing customers who have an ongoing relationship with a provider likely to influence those customers’ future purchases.

Beneficiaries. [The Gifts to Beneficiaries Law] bars inducements offered to Medicare and Medicaid beneficiaries, regardless of the beneficiary’s medical condition. The OIG is aware that some specialty providers offer valuable gifts to beneficiaries with specific chronic conditions. In many cases, these complimentary goods or services have therapeutic, as well as financial, benefits for patients. While the OIG is mindful of the hardships that chronic medical conditions can cause for beneficiaries, there is no meaningful basis under the statute for exempting valuable gifts based on a beneficiary’s medical condition or the condition’s severity. Moreover, providers have a greater incentive to offer gifts to chronically ill beneficiaries who are likely to generate substantially more business than other beneficiaries.

Similarly, there is no meaningful statutory basis for a broad exemption based on the financial need of a category of patients. The statute specifically applies the prohibition to the Medicaid program—a program that is available only to financially needy persons. The inclusion of Medicaid within the prohibition demonstrates Congress’ conclusion that categorical financial need is not a sufficient basis for permitting valuable gifts. This conclusion is supported by the statute’s specific exception for non-routine waivers of copayments and deductibles based on individual financial need. If Congress intended a broad exception for financially needy persons, it is unlikely that it would have expressly included the Medicaid program within the prohibition and then created such a narrow exception.

Provider, Practitioner, or Supplier. [The Gifts to Beneficiaries Law] applies to incentives to select particular providers, practitioners, or suppliers. As noted in the regulations, the OIG has interpreted this element to exclude health plans that offer incentives to Medicare and Medicaid beneficiaries to enroll in a plan. (See 65 FR 24400 and 24407.) However, incentives provided to influence an already enrolled beneficiary to select a particular provider, practitioner, or supplier within the plan are subject to the statutory proscription (other than copayment differentials that are part of a health plan design). *Id.* In addition, the OIG does not believe that drug manufacturers are ‘providers, practitioners, or suppliers’ for the limited purposes of [the Gifts to Beneficiaries Law], unless the drug manufacturers also own or operate, directly or indirectly, pharmacies, pharmacy benefits management companies, or other entities that file claims for payment under the Medicare or Medicaid programs.”

Gifts to Beneficiaries Law: Advisory Opinions

Links to various advisory opinions from the Federal government are:

1. OIG Advisory Opinion No. 07-08: In this Opinion, the OIG discussed a durable medical equipment supplier's proposed arrangement to provide patients with a free in-home congestive heart failure assessment. OIG Advisory Opinion No. 07-08 (2007), *available at* <http://www.oig.hhs.gov/fraud/docs/advisoryopinions/2007/AdvOpn07-08A.pdf>.
2. OIG Advisory Opinion No. 06-20: In this Opinion, the OIG discussed a durable medical equipment supplier's practice of providing patients with free home oxygen until the patients qualify for Medicare coverage of oxygen, as well as the supplier's proposed arrangement to provide patients with a free overnight oximetry test. OIG Advisory Opinion No. 06-20 (2006), *available at* <http://www.oig.hhs.gov/fraud/docs/advisoryopinions/2006/AdvOpn06-20A.pdf>.
3. OIG Advisory Opinion No. 06-01: In this Opinion, the OIG a home health agency's practice of providing prospective customers with a free preoperative home safety assessment. OIG Advisory Opinion No. 06-01 (2006), *available at* <http://www.oig.hhs.gov/fraud/docs/advisoryopinions/2006/AdvOpn06-01A.pdf>.
4. OIG Advisory Opinion No. 07-16: In this Opinion, the OIG discussed a home health agency's practice of providing prospective orthopedic patients with free educational videos containing instructions for postoperative home-based convalescence. OIG Advisory Opinion No. 07-16 (2007), *available at* <http://www.oig.hhs.gov/fraud/docs/advisoryopinions/2007/AdvOpn07-16B.pdf>.
5. OIG Advisory Opinion No. 03-4: In this Opinion, the OIG discussed a proposed program by a provider of home health care services to provide free medical-alert pagers and pager monitoring service to homebound patients during the period such patients are receiving the company's home health services. OIG Advisory Opinion No. 03-4 (2003), *available at* <http://www.oig.hhs.gov/fraud/docs/advisoryopinions/2003/ao0304.pdf>.
6. OIG Special Advisory Bulletin: This Special Alert Bulletin from 2002 discusses various arrangements for services that are not compliant with the Civil Monetary Penalties Law. *Offering Gifts and Other Inducements to Beneficiaries*, OIG Special Advisory Bulletin (August 2002), *available at* <http://www.oig.hhs.gov/fraud/docs/alertsandbulletins/SABGiftsandInducements.pdf>.

Texas Law

III. Texas Law

A. Texas Law Discussion

The Texas anti-solicitation statute prohibits any person from knowingly offering to pay or agreeing to accept, directly or indirectly, overtly or covertly, any remuneration in cash or in kind to or from another for securing or soliciting a patient or patronage for or from a person licensed, certified, or registered by a Texas health care regulatory agency. We will refer to this anti-solicitation statute throughout this guide as the “Texas Anti-Solicitation Law.” The relevant text of the Texas Anti-Solicitation Law can be found on [Pages 49-50](#). The Texas Anti-Solicitation Law applies to all payers, including private payers, such as insurance companies. This is distinguished from the Stark Law, the Anti-Kickback Law, and the Gifts to Beneficiaries Law, which only apply to certain federal health care programs. Therefore, even if a home health agency or a hospice takes only private pay patients and does not accept any Medicare, Medicaid, or other federal health care program patients or funds, the Texas Anti-Solicitation Law still must be reviewed for compliance.

A violation of the Texas Anti-Solicitation Law is a Class A Misdemeanor and is punishable by up to one year in prison with a corresponding fine. If the accused has been previously convicted of a violation of the Texas Anti-Solicitation Law, or if the accused was employed by a federal, state, or local government at the time of the offense, however, then the offense is a Felony of the Third Degree and is punishable by up to ten years in prison with a corresponding fine. In addition, a violation of the Texas Anti-Solicitation Law is grounds for disciplinary action by the Texas regulatory agency that issued a license, certification, or registration to the person who committed the violation, and the violator is subject to a civil penalty of not more than \$10,000 for each day of violation and each act of violation.

When the Texas legislature adopted the Texas Anti-Solicitation Law, it did not adopt or create any safe harbors or exceptions to the law, as are found with the Stark Law and the Anti-Kickback Law. Instead, the Texas legislature inserted into the Texas Anti-Solicitation Law a statement that any payment, business arrangement, or payment practice permitted by the Anti-Kickback Law, or any regulation adopted under the Anti-Kickback Law, is permitted under the Texas Anti-Solicitation Law. Therefore, when determining whether a financial relationship violates or complies with the Texas Anti-Solicitation Law, it is recommended that the parties fit the financial relationship within the applicable safe harbors to the Anti-Kickback Law, thereby ensuring that the financial relationship will be safe from prosecution under the Texas Anti-Solicitation Law.

B. Texas Law Comments

Immediately following are certain comments to the Texas Anti-Solicitation Law provided by the author. Please note that these comments are also included within the content found at the links provided above. Most (if not all) of these comments are more helpful and provide more specific guidance when viewed in their applicable context, such as the statutes and regulations from which the comments derive. Therefore, it is recommended that the reader not rely solely on these comments but also carefully review the content provided in each of the links provided above:

- ***Comment: The Texas Anti-Solicitation Law is not limited to federal health care programs; instead, it applies to all payers.***

- *Comment: The Texas Anti-Solicitation Law does not have its own exceptions or safe harbors; instead, it relies on safe harbors promulgated under the Anti-Kickback Law*

C. Texas Law Legal Materials

Texas Anti-Solicitation Law: Prohibition

[Located at Texas Occupations Code §§ 102.001, .003, and .011]

The relevant text of the Texas Anti-Solicitation Law is:

“Sec. 102.001. Soliciting Patients; Offense.

- (a) A person commits an offense if the person knowingly offers to pay or agrees to accept, directly or indirectly, overtly or covertly any remuneration in cash or in kind to or from another for securing or soliciting a patient or patronage for or from a person licensed, certified, or registered by a state health care regulatory agency. ***[Comment: The Texas Anti-Solicitation Law is not limited to Federal health care programs; instead, it applies to all payers.]***
- (b) Except as provided by Subsection (c), an offense under this section is a Class A misdemeanor.
- (c) An offense under this section is a felony of the third degree if it is shown on the trial of the offense that the person:
 - (1) has previously been convicted of an offense under this section; or
 - (2) was employed by a federal, state, or local government at the time of the offense.”

“Sec. 102.003. Federal Law; Construction.

[The Texas Anti-Solicitation Law] permits any payment, business arrangement, or payment practice permitted by [the Anti-Kickback Law] or any regulation adopted under [the Anti-Kickback Law].” ***[Comment: The Texas Anti-Solicitation Law does not have its own exceptions or safe harbors; instead, it relies on safe harbors promulgated under the Anti-Kickback Law]***

“Sec. 102.010. Civil Penalties.

- (a) A person who violates this subchapter is subject to a civil penalty of not more than \$10,000 for each day of violation and each act of violation. In determining the amount of the civil penalty, the court shall consider:
 - (1) the person's previous violations;

- (2) the seriousness of the violation, including the nature, circumstances, extent, and gravity of the violation;
 - (3) whether the health and safety of the public was threatened by the violation;
 - (4) the demonstrated good faith of the person; and
 - (5) the amount necessary to deter future violations.
- (b) The attorney general or the appropriate district or county attorney, in the name of the state, may institute and conduct an action authorized by this section in a district court of Travis County or of a county in which any part of the violation occurs.
- (c) A penalty collected under this section by the attorney general shall be deposited to the credit of the general revenue fund. A penalty collected under this section by a district or county attorney shall be deposited to the credit of the general fund of the county in which the suit was heard.”

Examples of Prohibited Conduct

IV. Examples of Prohibited Conduct

1. Treating a hospital discharge planner to a “day of beauty” at a spa (regardless of dollar value) for the purpose of rewarding the discharge planner for referrals—

This financial relationship violates the Texas Anti-Solicitation Law and, if the patients involved are federal health care program beneficiaries, the Anti-Kickback Law. The Stark Law, and its exemption for non-monetary gifts, does not apply to this financial relationship because this financial relationship does not involve a physician or the physician’s staff.

2. Paying a physician any amount of money for a plan of care in exchange for the referral—

This financial relationship violates the Texas Anti-Solicitation Law and, if the patients involved are federal health care program beneficiaries, the Anti-Kickback Law and, if the patients involved are Medicare or Medicaid beneficiaries, the Stark Law.

3. Paying for space in an assisted living facility when there is really no commercial business justification for renting the space other than proximity to referrals, the rental rate exceeds fair market value, or the rent is tied to the number of referrals—

This financial relationship violates the Texas Anti-Solicitation Law and, if the patients involved are federal health care program beneficiaries, the Anti-Kickback Law.

4. Providing free blood sugar screenings at a health fair and, if the screening has a positive result, offering to contact the individual’s physician to arrange for home care services or informing the individual about the diabetes program that the home care agency offers—

This financial relationship violates the Texas Anti-Solicitation Law and, if the patients involved are federal health care program beneficiaries, the Anti-Kickback Law.

The following guidance was provided by the Federal government in final rules published April 26, 2000 [located at 65 Fed. Reg. 24,408]:

“We are similarly concerned about arrangements where an incentive to obtain covered preventive care services is, in reality, an incentive paid to patients to induce them to obtain other covered services. Any tie between provision of an exempt covered preventive care service and a covered service that is not preventive would vitiate the preventive care exception and might constitute a violation of section 231(h), the [Anti-Kickback Law], or other legal authorities.”

The same final rules make it clear that while “incentives to promote the delivery of preventive care” are permitted under the Gifts to Beneficiaries Law, they are generally limited to only those preventive services that are reimbursable by Medicare or Medicaid. So, for example, flu and pneumonia vaccinations provided by a Medicare home health agency would be permissible because the provider is reimbursed by the Medicare program to administer those vaccinations.

5. Having multiple medical directors without having a commercially reasonable business purpose for doing so or paying a medical director in excess of fair market value for the services performed—

This financial relationship violates the Texas Anti-Solicitation Law and, if the patients involved are federal health care program beneficiaries, the Anti-Kickback Law and, if the patients involved are Medicare or Medicaid beneficiaries, the Stark Law.

6. Providing physicians with free items or services that exceed \$300 in retail value in a year—

This financial relationship violates the Texas Anti-Solicitation Law and, if the patients involved are federal health care program beneficiaries, the Anti-Kickback Law and, if the patients involved are Medicare or Medicaid beneficiaries, the Stark Law.

Each home health agency and hospice must account for the value of free items and services given to providers (including the value of golf tournaments and dinners) to ensure that the total sum of these free items and services does not exceed \$300 annually (as adjusted by CMS) to any provider who refers a patient.

7. Having a formal or informal arrangement to provide free wellness check-ups to the residents in an ALF, Senior Center, or Adult Day Care Center—

This financial relationship violates the Texas Anti-Solicitation Law and, if the patients involved are federal health care program beneficiaries, the Anti-Kickback Law.

8. Holding a monthly raffle for physician offices where each office gets a number of tickets for the drawing based on the number of patients they refer to the home care agency or hospice—

This financial relationship violates the Texas Anti-Solicitation Law and, if the patients involved are federal health care program beneficiaries, the Anti-Kickback Law and, if the patients involved are Medicare or Medicaid beneficiaries, the Stark Law. If the prize involved was worth more than \$300, then the Stark Law would also be violated.