

Hospital/Physician relationships are governed by complex and illogical laws and regulations. These laws include the **Federal Anti-Kickback Statute**, the **Federal Stark Law**, and, for tax-exempt hospitals, the tax laws and related tax-exempt bond financed space issues (neither of which are discussed here). Violations of these laws come with draconian consequences for both individuals and organizations. At a minimum, every financial relationship with a physician must be evaluated in the context of these laws. In most cases, the arrangement will need to be evaluated in context of applicable state laws and other laws as well.

<b><u>Stark and Anti-Kickback Laws</u></b>	<b><u>Penalties</u></b>	<b><u>Do's and Don't's</u></b>
<p>The <b>Federal Anti-kickback Statute</b> (the “AKS”) prohibits offering, soliciting, paying or receiving anything of value if even one purpose is intended to induce or reward referrals. The AKS (and similar state laws) looks to the intent of one or both of the parties when evaluating an arrangement.</p> <p>The AKS includes many “<u>safe harbors</u>”. If the payment or arrangement fits within a <u>safe harbor</u>, the arrangement may be permitted even if it appears inconsistent with the AKS prohibition. However, safe harbors are narrowly designed and, in practice, can be difficult to meet.</p>	<p style="text-align: center;"><b><u>AKS</u></b></p> <ul style="list-style-type: none"> <li>• <u>Criminal</u> – up to 5 years in prison and a \$25,000 fine for each violation</li> <li>• Medicare and Medicaid program exclusion* if convicted</li> <li>• <u>Civil</u> – possible Medicare and Medicaid program exclusion</li> </ul> <p style="text-align: center;">*Exclusion means the individual or entity cannot provide, order or supervise a service that would be paid for by a federally funded healthcare program. Practically this means the end of the ability to work in healthcare.</p>	<p style="text-align: center;"><b><u>Do</u> ☺</b></p> <ul style="list-style-type: none"> <li>• Have a written &amp; signed agreement in place prior to paying a physician or allowing the physician to provide services.</li> <li>• Have a written, signed agreement in place before renting space or leasing equipment to or from a physician.</li> <li>• Ensure that agreements between a physician or hospital have been reviewed by legal counsel or are documented using a template approved by legal counsel.</li> <li>• Treat every deal with a physician-owned company as if it is a deal with the physician.</li> <li>• Assume that every email and document is being read by the FBI and the FBI is listening to every phone call.</li> <li>• Immediately report suspected non-compliance to legal or appropriate compliance resource.</li> <li>• Ask questions if you have concerns.</li> </ul>
<p>The <b>Federal Stark Law</b> (“Stark”) prohibits referrals by a physician* to a hospital or other entity when there is a direct or indirect financial relationship between the physician (or immediate family member**) and the hospital or other entity. A financial relationship includes virtually all arrangements where something of value is exchanged between the parties. This includes payments for goods, services, equipment, space, and the provisions of other gift, discounts, free services or items, etc. Notably, an otherwise prohibited referral may be permitted if the financial relationship meets an applicable <u>Stark exception</u>. Financial relationships can be direct or indirect. Under Stark, there are three types of exceptions: (1) ownership exceptions; (2) compensation exceptions; and (3) services/global exceptions. In many cases, a written, signed agreement is required to qualify for an exception.</p> <p><small>*“Physician” means a doctor of medicine or osteopathy, a doctor of dental surgery, or dental medicine, a doctor of podiatric medicine, a doctor of optometry, or a chiropractor. **“Immediate family member” includes the physician's spouse, birth or adoptive parent, child, 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.</small></p>	<p style="text-align: center;"><b><u>Stark</u></b></p> <p><u>Hospitals (or other DHS entity)</u> – cannot bill Medicare for services ordered or performed by the physician, whether or not the services are related to the financial relationship in question</p> <ul style="list-style-type: none"> <li>➢ Hospital must repay amounts previously billed</li> <li>➢ Improper claims trigger False Claims Act exposure.</li> </ul> <p>False claim = repayment, damages of up to 3 times amount of overpayment, plus penalties of \$5,500 to \$11,000 per claim.</p> <p><u>Physicians</u> – Civil penalties and possible Medicare and Medicaid Program exclusion</p>	<p style="text-align: center;"><b><u>Don't Ever</u> ☹</b></p> <ul style="list-style-type: none"> <li>• Discuss the volume or value of referrals in the context of proposed or existing arrangements with physicians.</li> <li>• Offer to pay, make or increase payments, based on the value or volume of referrals.</li> <li>• Make a payment without a signed contract.</li> <li>• Allow a physician to begin to perform services without a signed contract.</li> <li>• Allow a physician to occupy space or use equipment without a signed contract.</li> <li>• Instruct or direct a subordinate to do something contrary to law/rules/policy.</li> </ul>

This document is for educational purposes only. For legal advice, consult **healthcare** legal counsel.

## Selected Exceptions/Safe Harbors

### STARK LAW EXCEPTIONS

#### 42 CFR 411.357 Exceptions to the referral prohibition related to compensation arrangements

For purposes of § 411.353, the following compensation arrangements do not constitute a financial relationship:

**(a) Rental of office space.** 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; 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.

(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.

**(b) Rental of equipment.** 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; 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.
- (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.

**(f) Isolated transactions.** Isolated financial transactions, such as a one-time sale of property or a practice, if all of the following conditions are met:

- (1) The amount of remuneration under the isolated transaction is—
  - (i) Consistent with the fair market value of the transaction; and
  - (ii) Not determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician or other business generated between the parties.
- (2) The remuneration is provided under an agreement that would be commercially reasonable even if the physician made no referrals to the entity.
- (3) There are no additional transactions between the parties for 6 months after the isolated transaction, except for transactions that are specifically excepted under the other provisions in § 411.355 through § 411.357 and except for commercially reasonable post-closing adjustments that do not take into account (directly or indirectly) the volume or value of referrals or other business generated by the referring physician.

**(p) Indirect compensation arrangements.** Indirect compensation arrangements, as defined at § 411.354(c)(2), if all of the following conditions are satisfied:

- (1)(i) The compensation received by the referring physician (or immediate family member) described in § 411.354(c)(2)(ii) is fair market value for services and items actually provided and not determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician for the entity furnishing DHS.
- (ii) Compensation for the rental of office space or equipment may not be determined 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 in the office space or to the services performed or business generated through the use of the equipment; 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.
- (2) The compensation arrangement described in § 411.354(c)(2)(ii) is set out in writing, signed by the parties, and specifies the services covered by the arrangement, except in the case of a *bona fide* employment relationship between an employer and an employee, in which case the arrangement need not be set out in a written contract, but must be for identifiable services and be commercially reasonable even if no referrals are made to the employer.
- (3) The compensation arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission.

### AKS SAFE HARBORS

#### 42 CFR 1001.952 Exceptions

The following payment practices shall not be treated as a criminal offense under section 1128B of the Act and shall not serve as the basis for an exclusion:

**(b) Space rental.** As used in section 1128B of the Act, "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 paragraph (b) of this section, 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.

**(c) Equipment rental.** As used in section 1128B of the Act, "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 paragraph (c) of this section, 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.

**(d) Personal services and management contracts.** As used in section 1128B of the Act, "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 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 paragraph (d) of this section, 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.

This document is for educational purposes only. For legal advice, consult **healthcare** legal counsel.