Fraud and Abuse Considerations for Contracting in the Health Care Industry: Introductory Guidance

Background

In order to provide health care services, health centers are required to enter into a variety of agreements with individuals and organizations. Such agreements can be categorized into several types, including: procurement contracts for the purchase of property, equipment, and supplies; agreements with other health care providers regarding the provision of health care services; and agreements with third party payors and managed care organizations. The following compliance issues can arise in these arrangements.

Suspension / Debarment

Health centers may not contract with or provide sub-awards to organizations or individuals that are debarred, suspended or otherwise excluded from or ineligible for participation in federal assistance programs or activities.[1]

Organizations or individuals that are suspended, debarred, declared ineligible, or voluntarily excluded from eligibility for covered transactions by any federal department or agency cannot, during the period of suspension, debarment, or exclusion, receive HHS grants or be paid from HHS grant funds, whether under a primary or lower-tier transaction. Because individuals who have been debarred, suspended, declared ineligible or who have been voluntarily excluded from covered transactions may not receive federal funds for a specified period of time, charges made to HHS grants for such individuals (e.g., salary) are unallowable.[2]

Additionally, individuals or organizations that have been debarred, suspended, declared ineligible or who have been excluded from participating in federal and state health care programs, including Medicare and Medicaid, may not be reimbursed using federal or state health care program funds for claims submitted for health care services rendered. Accordingly, health centers may not employ or contract with any individuals or entities that have been debarred, suspended, declared ineligible or excluded if the health center would be compensating the individual or organization with funds received from Medicare or Medicaid.[3]

The Civil Monetary Penalties Law imposes penalties on any person (including individuals and organizations) that "arranges or contracts (by employment or otherwise) with an individual or

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1 45 C.F.R. § 74.13.

2 HHS *Grants Policy Statement* (Jan 1, 2007) at I-13.

3 For more on screening Individuals Affiliated with the Health Center, see U.S. Dept. of Health and Human Services, Office of Inspector General, *Special Advisory Bulletin on the Effect of Exclusion from Participation in Federal Health Care Programs* (May 8, 2013).

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entity that the person knows or should know is excluded from participation in a federal health care program … for the provision of items or services for which payment may be made under such a program."[4]

The Federal Anti-Kickback Statute

The purpose of the Federal Anti-Kickback Statute[5] is to prevent fraudulent or abusive arrangements that could result in higher costs to the Federal Government or compromise the quality of care provided to beneficiaries of federal and state health care programs such as the Medicaid and Medicare programs. In particular, the Anti-Kickback Statute prohibits any person or entity from knowingly or willfully soliciting or receiving (or offering or paying) remuneration directly or indirectly, in cash or in kind, to induce patient referrals or the purchase or lease of equipment, goods or services, payable in whole or in part by a federal or state health care program.

Violations of the Anti-Kickback Statute can occur even if the intent to induce referrals or a purchase / lease is only one of several reasons or purposes for the arrangement. Moreover, the Patient Protection and Affordable Care Act of 2010, P.L. 111-148 (the "Health Reform Law") modified the intent requirement to codify that a person need not have actual knowledge of the Anti-Kickback Statute or specific intent to commit a violation of the Anti-Kickback Statute in order to violate the Anti-Kickback Statute. Violations of the Anti-Kickback Statute can result in serious consequences for health centers, including both civil and criminal penalties, as well as suspension and exclusion from participating in federal or state health care programs.

- ***Criminal liability***. If a party to a transaction is found criminally liable for a violation of the Anti-Kickback Statute, including a guilty plea or a plea of nolo contendere, the party could face a maximum fine of $25,000, imprisonment up to five years, or both.

- ***Civil penalties***. In addition to criminal penalties, a party to a transaction found to violate the Anti-Kickback Statute could face civil penalties of up to $50,000 for each improper act and damages of up to three times the amount of remuneration at issue.

- ***False Claims Act liability.*** Claims submitted to federal or state health care programs that result from a violation of the Anti-Kickback Statute constitute false claims under the Federal Civil False Claims Act, leading to additional civil penalties.[6]

- ***Administrative proceedings***. The Department of Health and Human Services ("DHHS"), Office of Inspector General ("OIG") can initiate an administrative

4 42 U.S.C. § 1320a–7a.
5 42 U.S.C. §1320a-7b.
6 For more information regarding the Federal False Claims Act, see Coding, documentation, and billing: Introductory guidance.

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proceeding to suspend or exclude an individual or entity found to have violated the Anti-Kickback Statute from participating in any federal or state health care program (e.g., Medicare, Medicaid, grant funding under Section 330 of the Public Health Service Act ("Section 330")) for a defined period of time or indefinitely.

A series of statutory and regulatory "safe harbors" have been established to protect certain business practices and arrangements that the OIG has deemed to present a low risk of fraud and abuse.[7] Arrangements that meet the requirements of these "safe harbors" are exempted from scrutiny under the Anti-Kickback Statute.

In order to qualify for one of the statutory or regulatory safe harbors, a health care entity must meet all of the requirements of the specific safe harbor under which it is attempting to qualify. Arrangements that do not fit squarely within any safe harbor may still be permissible so long as the arrangement does not violate the statutory intent—each arrangement is judged on a case-by-case basis. Further, parties to arrangements that do not meet the requirements of a particular safe harbor under the Anti-Kickback Statute may seek an advisory opinion from the OIG. In general, OIG advisory opinions are binding only on the OIG and the party or parties seeking the opinion. This limitation notwithstanding, the opinions often provide insight into the OIG's thinking on enforcement matters.

Safe harbors commonly utilized by health centers include:

- Employment arrangements;
- Personal services and management contracts;
- Equipment and space rental;
- Waivers of co-insurance and deductible amounts;
- Discounts;
- Referral arrangements (both general and specialty);
- Practitioner recruitment;
- Sale of practice; and,
- Risk sharing arrangements.

While each of these safe harbors has its own set of requirements that a health center must meet in order to qualify for protection from the Anti-Kickback Statute, common elements in several include:

1. A signed, written contract for a term of not less than one year that specifies the premises, equipment or services to be provided; and,
2. Total aggregate compensation that is set in advance, reflects the "fair market value" for the goods and/or services involved and does not vary based on volume or value of referrals or business (direct or indirect) generated between the parties.

[7] See 42 U.S.C. §1320a-7b; 42 C.F.R. § 1001.952.

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An arrangement that provides for discounts on items or services can be "safe harbored" if, among other requirements, the discount represents "a reduction in the amount a buyer (who buys either directly or through a wholesaler or a group purchasing organization) is charged for an item or service based on an arms-length transaction." Transactions that would not qualify as a "discount" include warranties, cash payments or a reduction in price applicable to one buyer but not to Medicare or Medicaid.

In 2007, the OIG issued the final rule establishing regulatory standards for the "Federally-Funded Health Center Safe Harbor."[8] The Federally-Funded Health Center Safe Harbor protects certain arrangements between health centers that receive grant funds under Section 330 and providers / suppliers of goods, items, services, donations and loans from prosecution under the Anti-Kickback Statute.

The Federally-Funded Health Center Safe Harbor by definition only applies to transactions involving Section 330-funded health centers. Nonetheless, the OIG has acknowledged that arrangements involving types of facilities that do not qualify for Federally- Funded Health Center Safe Harbor protection (e.g., health center look-alikes) are not necessarily unlawful under the Anti-Kickback Statute; rather, such arrangements must be evaluated on a case-by-case basis for compliance with the Anti- Kickback Statute.[9] In general, such arrangements must contribute to the health center's ability to maintain or increase the availability, or enhance the quality, of services provided to the health center's medically underserved patients.

For a health center arrangement to be protected by the Federally-Funded Health Center Safe Harbor, it must satisfy each of the following eight requirements:

1. ***Written agreement***: The arrangement must be codified in a written agreement signed by the parties, which covers and specifies the amount of all goods, items, services, donations, loans, etc., provided to the health center. The amount may be based on a fixed sum or a fixed percentage, or may be established by a fixed methodology. Further, there may be multiple agreements between the parties so long as the agreements reference each other or cross-reference a centrally located master list.

2. ***Scope of goods and services***: The goods, items, services, donations, loans, etc., must be medical or clinical in nature or relate directly to any services provided under the health center's scope of project, including billing services, administrative and technology support, and enabling services.

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[8] *Medicare and State Health Care Programs: Fraud and Abuse; Safe Harbor for Federally Qualified Health Centers Arrangements under the Anti-Kickback Statute*, 72 Fed. Reg. 56632 (Oct 4, 2007); 42 C.F.R.§ 1001.952(w).

[9] See id.

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3. ***Meaningful contribution to services provided to underserved populations***: The health center must have a reasonable expectation that the arrangement will contribute meaningfully to services to the underserved. The health center must document its basis for the expectation prior to entering the arrangement.

4. ***Re-evaluation of the arrangement***: The health center must periodically (at least annually) re-evaluate the arrangement to ensure that it continues to meet the original expectation, and must document the re-evaluation at the time it is conducted.

5. ***Protection of independent professional judgment***: The arrangement must not require or restrict the health center in making referrals it deems appropriate.

6. ***Provision of services regardless of ability to pay***: Any goods, items, and/or services offered to the health center (and, ultimately, to its patients) at no charge or at reduced rates must be furnished to all health center patients who clinically qualify for them, regardless of payor status or ability to pay. The entity or individual furnishing the goods, items and/or services may reasonably limit the aggregate amount it will furnish, provided that the limitation is not based on payor status or ability to pay.

7. ***No restrictions on contracting with other entities***: The arrangement must not restrict the health center's ability to contract with other providers / suppliers, and the health centers must employ a reasonable selection methodology (e.g., procurement standards).

8. ***Patient freedom of choice and disclosure of the arrangement***: The health center must effectively notify patients of their freedom to choose any willing provider / supplier, as well as disclose the existence and nature of the arrangement to any patient who inquires.

Health centers should note that many states have enacted their own anti-kickback laws and that a transaction that is protected under a federal safe harbor is not necessarily protected from state anti-kickback laws. Protection under the federal safe harbor may influence the evaluation by state enforcement agencies.

Physician Self-Referral Prohibition (Stark Law)

The federal physician self-referral prohibition ("Stark Law")[10] prohibits a physician (defined as doctors of medicine, osteopathy, dental surgery, dental medicine, podiatry, optometry and chiropractors) from referring patients for a "designated health service" payable under Medicare

[10] See 42 U.S.C. §1395nn.

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or Medicaid to a health care entity if the physician (or an immediate family member) has a direct or indirect financial relationship with the entity.[11]

The "designated health services" subject to the Stark Law are:

1. Clinical laboratory services;
2. Physical therapy, occupational therapy, and outpatient speech-language pathology services;
3. Radiology and certain other imaging services,
4. Radiation therapy services and supplies;
5. Durable medical equipment and supplies;
6. Parenteral and enteral nutrients, equipment, and supplies;
7. Prosthetics, orthotics, and prosthetic devices and supplies;
8. Home health services;
9. Outpatient prescription drugs; and,
10. Inpatient and outpatient hospital services.

The statute is designed to discourage over-utilization of Medicare and Medicaid services that may occur if a physician is in a position to personally benefit from making referrals for a covered service.

Although the Stark Law addresses the referral practices of physicians, unless certain exceptions apply, it operates by prohibiting the health care entity that provides a designated health service pursuant to a prohibited referral from billing Medicare and by denying payment to a state Medicaid agency of the federal share for a service covered by Medicaid. As a result, claims for payment or reimbursement for designated health services related to the prohibited referral relationship will not be paid or reimbursed by federal or state health care programs such as Medicare and Medicaid. Further any such claims that are submitted may be considered false claims under the Federal False Claims Act.[12]

Accordingly, the Stark Law can affect a health center's ability to bill for designated services provided to a patient when the referring physician (or an immediate family member of the physician) has a financial relationship with the health center. In addition, co-payments or similar amounts collected from patients, if associated with a prohibited referral, must be refunded.

If an entity has a financial relationship with a physician, it may identify an exception under the statute or regulations that applies to the circumstance in order to avoid the prohibition.[13] A

[11] For purposes of the Stark Law, a "financial relationship" with a health care entity includes both an "ownership or investment interest" in the entity and a "compensation arrangement" with the entity.

[12] For more information regarding the Federal False Claims Act, see Coding, documentation, and billing: Introductory guidance.

[13] See 42 C.F.R. §§ 411.355 – 357.

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physician is deemed to "stand in the shoes" of his or her physician organization and have a direct compensation arrangement with an entity furnishing designated health services if:

1. The only intervening entity between the physician and the entity furnishing designated health services is his or her physician organization; and
2. The physician has an ownership or investment interest in the physician organization.

While Federally-Qualified Health Centers may share some characteristics with physician medical practices, for purposes of the Stark Law, they[14] are not "physician organizations"[15] and thus, health center physicians do not "stand in the shoes" of the health center.

Because the Stark Law would otherwise prevent necessary types of financial arrangements, there are many exceptions. Commonly utilized exceptions include:

- Group practices;
- Investments;
- Equipment rentals;
- Bona fide employment relationships;
- Personal services arrangements; and,
- Rental of office space

Similar to the Anti-Kickback Statute safe harbors, arrangements must meet all of the requirements of the Stark Law exception. For example, the key elements of the exceptions for bona fide employment relationships and personal services arrangements are:

1. The services covered by the employment relationship or the personal services arrangement are specified and identifiable;
2. The compensation to be paid is set in advance, does not exceed fair market value, is provided pursuant to an agreement which would be commercially reasonable even if no referrals were made to the employer / contractor, and except in the case of a physician incentive plan, is not determined in a manner that takes into account the volume or value of any referrals or other business (direct or indirect) generated between the parties; and,
3. The relationship or arrangement meets such other requirements as DHHS may impose by regulation as needed to protect against program or patient abuse.

Further, with respect to personal services arrangements, the arrangement must meet additional requirements including:

[14] As defined at 42 C.F.R. § 405.2401(b).
[15] As defined at 42 C.F.R. § 411.351.

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1. The arrangement must be set out in writing and signed by both parties and must cover all of the services to be provided by the physician (or an immediate family member of such physician) to the entity;
2. The aggregate services contracted for must not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement;
3. The term of the arrangement must be for at least 1 year; and,
4. The services to be performed under the arrangement must not involve the counseling or promotion of a business arrangement or other activity that violates any state or federal law.[16]

Many states have enacted laws that place significant limitations on physician "self- referrals" where the services are covered under state health care programs. As a general matter, state self-referral laws are frequently more stringent than the federal standards. Accordingly, health centers that are concerned that certain features of their proposed arrangements may violate the Stark Law should consult qualified legal counsel to determine whether the arrangement is permissible under both federal and state law.

Antitrust Law

The formation of joint ventures may result in potential legal exposure under federal antitrust law.[17] In general, federal antitrust laws prohibit activities among competitors and potential competitors that are considered inherently "anti-competitive" or which are deemed to be anti-competitive when balanced against their potential pro-competitive effects. Activities deemed to be inherently anti-competitive (i.e., per se anti-competitive) include price fixing, boycotting, market allocation agreements, and other forms of collusive behavior. While these activities are per se examples of antitrust law violations, other activities, such as mergers, consolidations and joint ventures, require a careful analysis of the particular facts and circumstances to the law to determine whether potential anti-competitive effects outweigh potential pro-competitive effects. This type of analysis is referred to as the "rule of reason."

State antitrust laws generally mirror the federal statutes. However, relevant state antitrust laws should be researched independently to determine whether they contain more stringent requirements. In addition, many states have enacted statutes that provide immunity from antitrust prosecution for certain joint venture activities between health care providers that would control health care costs and improve the quality of, and access to, health care services.

[16] 42 C.F.R. § 411.357(c) and (d).
[17] See the Sherman Act, 15 U.S.C. §§ 1-7 and the Clayton Act, 15 U.S.C. §§ 12-27.

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Advice and Recommendations[18]

Many health centers enter into informal ("handshake") arrangements with other parties. In most states, a contract term is not enforceable unless it is in writing and part of a contract document. Generally, verbal agreements will not be enforced. Additionally, in order to meet the requirements of Anti-Kickback Statute safe harbors and Stark Law exceptions, contracts must be in writing. Accordingly, it is always advisable to put all agreements in writing, regardless of the complexity (or lack thereof) of the arrangement.

In reducing an agreement to writing, it is best to deal with uncertainty before the contract is signed. Never assume that the other party knows what is intended by a potentially ambiguous provision or that the parties can work out the details after the contract has been executed. Consider that both parties have an incentive to clarify a matter before an agreement is signed, rather than afterwards so as to avoid costly disputes. In addition, all contracts should include terms requiring the party with which the health center is contracting to comply with the health center's Compliance Program and should specify that the contract is intended to comply with the limitations of the Anti-Kickback Statute and Stark Law, as applicable.

Suspension and Debarment

Because of the prohibitions applicable to ineligible persons, prior to employing, contracting or otherwise affiliating with an individual or entity, a health center should screen all potential Board member, officer, employee, contractor, vendor, agent or other individual with which it may affiliate against the exclusion databases. When a health center contracts with an entity for services to be performed by individuals employed, contracted or otherwise affiliated with that entity, the health center should require the entity to screen its Board members, officers, employees, contractors, vendors, agents, and other individuals with which it affiliates, and promptly report the identification of an excluded individual to the health center.

The government does not provide notice to employers, contractors or other affiliates that it intends to exclude an individual or entity that is employed or otherwise contracted with it. The Authors recommend that health centers conduct screening of the exclusion databases prior to hiring or entering into a relationship with a person or entity and on a monthly basis thereafter. Screening on a monthly basis is important for two reasons:

1. The OIG updates its List of Excluded Individuals and Entities (LEIE) on a monthly basis. If a health center checks only once or twice a year, then there is a possibility that the health center has compensated an excluded individual or entity for one or

[18] The Authors of these materials include attorneys at the law firm of Feldesman Tucker Leifer Fidell LLP. The advice and recommendations consist of general guidance based on federal law and regulations and do not necessarily apply to all health centers under all facts and circumstances. Further, these materials do not replace, and are not a substitute for, legal advice from qualified legal counsel.

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more months. Because a health center can be fined at up to three times the amount paid to an excluded individual or entity, health centers can face high fines for relatively short periods of time for compensating an excluded individual or entity.

2. In 2009, the Centers for Medicare and Medicaid Services ("CMS") instructed state Medicaid programs to require providers to search the LEIE monthly "to capture exclusions and reinstatements that have occurred since the last search."[19] Consequently, some states now require Medicaid providers to check the exclusions database monthly.

The authors recommend that health centers establish a policy and procedure for screening all individuals affiliated with the health center.

Federal Anti-Kickback Statute

It is particularly important for health centers that enter into arrangements with third parties with whom they generate business payable by federal health care programs to consider the implications of the Federal Anti-Kickback Statute. Often, health centers' "partners" with "deeper pockets" will propose to discount fees for certain services / items (or provide free services / items) to help subsidize the cost of the services provided to uninsured, low income patients. While well-meaning, prior to the Federally-Funded Health Center Safe Harbor, many of those arrangements or collaborations could have triggered Anti-Kickback liability.

However, under the Federally-Funded Health Center Safe Harbor, the arrangements may now be permissible, thus improving health centers' ability to provide a full continuum of health care and related services to their patients while saving money and extending scarce resources. In turn, these savings can be used to further enhance services and support additional otherwise uncompensated care. The following are examples of previously problematic arrangements that could be permissible, provided that the requirements of the Federally-Funded Health Center Safe Harbor are met:

- Monetary and in-kind donations from entities conducting business or having referral relationships with the health center, including donations of space and equipment and provision of community benefit grants.

- Below market value or no-cost leases and purchase agreements with other health care entities for space, equipment, supplies, and other goods and items, as well as clinical and administrative services, furnished to the health center.

- Below market rate, no interest or forgivable loans from other health care entities (or entities with whom the health center does business) to assist in the construction or

[19] Centers for Medicare and Medicaid Services, *State Medicaid Director Letter 09-001* (Jan 16, 2009)

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renovation of buildings, the purchase of equipment or other similar activities related to the operation of the health center.

- Low-cost or no-cost referral arrangements with other health care entities for services which the health center is obligated to provide, but are provided and charged directly to the health centers' uninsured patients.

- Practitioner recruitment assistance from a hospital that receives referrals from the health center, provided that the assistance is given to the health center and not the individual practitioner (and the other requirements of the Federally-Funded Health Center Safe Harbor are satisfied).

Physician Self-Referral Prohibition (Stark Law)

Generally, physicians must be careful when referring to hospitals or other providers of designated health services to ensure that such referrals are not prohibited as a result of any financial interests. Because physicians do not stand in the shoes of Federally-Qualified Health Centers, the Stark Law prohibitions generally do not apply to health center referrals to other health care providers. Nonetheless, health centers should be aware of the Stark Law prohibitions and should consider state anti-referral laws during their contracting processes.

Examples of scenarios under which a relationship that may be prohibited under the Stark Law could arise include, but are not limited to:

- A health center enters into a compensation relationship with a physician:
  - Who is not a bona fide employee of the health center;
  - Who refers patients to the health center for designated health services; and
  - Whose compensation arrangement does not meet a Stark Law exception.
- A health center physician refers patients to a clinical laboratory, a durable medical equipment supplier or a physical therapy provider (DHS) that is owned by his or her spouse. Though such a relationship may not be a technical violation of the Stark Law for the health center, it may be prohibited for the referring physician.

As a matter of good practice, the Authors suggest that health centers ensure that their relationships with their clinicians are appropriately categorized and documented as bona fide employees or contractors.

Antitrust Law

Affiliation arrangements involving the participation of potentially competing health care providers in the same market or service area should be carefully evaluated to determine whether the collaboration could result in unacceptable levels of market power or other antitrust concerns. For example, a collaboration that seeks to increase access for all populations to a continuum of

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health care services by establishing a shared referral system or appointment schedule and linking providers in the area without shared financial risk may lead to antitrust problems as collaborations without financial integration may be viewed as anti-competitive.

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