



NATIONAL ASSOCIATION OF  
Community Health Centers

## **ISSUE BRIEF**

**Medicare/Medicaid Technical Assistance #91:**

# **The Final Health Center Safe Harbor Rule: What Is It and What Does It Mean for You?**

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On October 4, 2007, the Office of Inspector General (“OIG”) at the Department of Health and Human Services (“DHHS”) issued the long-anticipated final rule establishing regulatory standards for the Statutory Health Center Safe Harbor<sup>1</sup>, which was enacted by Congress as part of the Medicare Prescription Drug, Improvement and Modernization Act of 2003. The Health Center Safe Harbor protects from prosecution under the federal anti-kickback statute (42 U.S.C. §1320a-7b, the “Statute”) certain arrangements between health centers that receive grant funds under Section 330 of the Public Health Service Act (“health centers”) and other providers / suppliers of goods, items, services, donations and loans that could otherwise violate the Statute. To be protected, the arrangement 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.

The final Health Center Safe Harbor rule represents the culmination of almost fifteen (15) years of advocacy by NACHC, Primary Care Associations (“PCAs”), and individual health centers for an anti-kickback safe harbor to protect arrangements between health centers and other providers that could result in enhanced care or expansion of services for the health centers’ low-income patients. In the past, health centers frequently would turn down opportunities for reduced or free services to benefit their underserved populations for fear that the OIG would view the arrangement as remuneration to the health center in exchange for Medicare or Medicaid referrals to the provider offering the services. By protecting certain types of arrangements that previously were questionable under the federal anti-kickback statute, the Health Center Safe Harbor will enable health centers to save millions of dollars annually, which, in turn, can be used to provide care to a greater number of uninsured and underserved patients.

This Issue Brief:

- Reviews the basics of the federal anti-kickback statute;
- Provides a historical perspective of the Health Center Safe Harbor;
- Summarizes the requirements of the final Health Center Safe Harbor rule; and
- Explores the opportunities the final Health Center Safe Harbor rule may provide to health center grantees.

Please note that this Issue Brief is intended only to provide the reader with an overview of the Health Center Safe Harbor and does not (and is not intended to) offer health centers definitive advice on potential or existing arrangements (nor should it be used in lieu of obtaining such advice). In addition, readers should keep in mind that the OIG has repeatedly noted that nonconformance with any safe harbor does not automatically make the arrangement illegal. Rather, such an arrangement must be evaluated on its merits to determine whether the Statute is violated.

### **The Basics of the Federal Anti-Kickback Statute**

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<sup>1</sup> See 72 *Fed Reg* 56632 (October 4, 2007), as codified at 42 C.F.R. § 1001.952(w).

The purpose of the Statute is to discourage arrangements which could result in higher costs to the federal government or negatively impact beneficiaries of federal health care programs, such as the Medicaid and Medicare programs, by compromising care. In particular, the Statute forbids any person or entity from knowingly or willfully soliciting or receiving “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 health care program.

In analyzing the application of the Statute, it is important to understand the meaning of some of the key terms in the definition.

- “**Knowingly and willfully**” indicates that the Statute is an “intent-based” law. That is to say, in order to be found in violation of the Statute, the government must demonstrate that the person or entity (*e.g.*, a health center) knows or has reason to know that what he/she/it is doing constitutes prohibited conduct and yet he/she/it nevertheless continues to engage in the activity (*i.e.*, the person or entity specifically intends to engage in an unlawful arrangement).<sup>2</sup>
- “**Remuneration**” is defined broadly to include the transfer of anything of value in exchange for referrals of patients or business which are paid for in whole or in part by federal health care programs, including monetary savings through the use of discounts, rebates and free goods and/or services. Further, the Statute has been interpreted to cover any arrangement where even one purpose of the remuneration was to induce referrals or other business.

Violation of the Statute can result in serious consequences for health centers, including both civil and criminal penalties, as well as suspension and exclusion from federal health care programs.

- **Criminal liability.** If a party to an anti-kickback transaction is found criminally liable for a violation of the Statute, the party could face a felony conviction punishable by a maximum fine of \$25,000, imprisonment up to five years, or both.
- **Civil penalties.** In addition to criminal penalties, a party to an anti-kickback transaction 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.
- **Administrative proceedings.** The OIG also can initiate an administrative proceeding to suspend or exclude an individual or entity engaged in an anti-

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<sup>2</sup> It is interesting to note that courts are split as to the breadth of knowledge required to prove a violation of the Statute. Some courts require the government to demonstrate that the individual or entity has knowledge that the conduct constitutes an intentional violation of the Statute, while others require only that the individual/entity knows that the conduct itself is unlawful (without specific knowledge of the Statute). Regardless, to prove a violation of the Statute, the government must show some form of purposeful activity.

kickback transaction from participating in any federal health care program (*e.g.*, Medicare, Medicaid, Section 330 grant funding) for a defined period of time or indefinitely, depending on the nature of the suspension / exclusion.

Due to the broad application of the Statute, and the serious consequences if an individual or entity is found in violation, there are countless business practices and other arrangements that health care providers engage in that require a substantive legal analysis to ensure that there is no prohibition under the Statute. However, in recognition of the fact that not all financial arrangements between providers intentionally induce referrals, both Congress (through statute) and the DHHS OIG (through regulation) have approved certain “benign” business practices and arrangements that they have deemed to present a low risk of fraud and abuse. Arrangements that meet the requirements of these “safe harbors” are exempted from scrutiny under the 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 which do not fit squarely within any safe harbor may still be permissible so long as the arrangement does not violate the statutory intent.

Prior to the Health Center Safe Harbor, health centers have relied on qualifying their business practice and arrangements under a number of other safe harbors, including the safe harbors for:

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

As stated above, 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 Statute. Notwithstanding, a common element in several (but not all) of these safe harbors is the requirement that payments made as part of the arrangement reflect the “fair market value” for the goods and/or services involved.

Typically, this requirement presents unique challenges for health centers, which, by virtue of their missions to improve and expand access and availability of services provided to underserved populations, often seek no-cost or reduced-cost arrangements with other providers and vendors in order to “stretch” the health centers’ scarce resources. While entering into such cost-saving arrangements may fulfill a health center’s mission, it may also expose the health center (and its partner) to prosecution under the Statute. In particular, because the health center would otherwise have to use its grant funds to cover the full cost of these arrangements, the savings could be viewed as

“remuneration” or a benefit / payment to the health center in exchange for federal health care program business.

To ensure the continued ability to execute cost-saving arrangements, for years, health centers have sought a safe harbor to protect their unique relationships with community providers, thereby allowing them to expand health care and related services to the constantly growing underserved populations residing within their communities without the threat of prosecution. These efforts are summarized below.

## **The Health Center Safe Harbor: A Historical Perspective**

### ***The Early Years: Pre-Statutory Safe Harbor***

To understand the origin and development of the Health Center Safe Harbor, one would have to go back nearly fifteen (15) years. As early as 1993, NACHC submitted a proposal to DHHS advocating for a new safe harbor designed to protect from anti-kickback prosecution certain arrangements between health center grantees and other providers or vendors, provided that the covered arrangement maintains or enhances accessibility, availability and/or quality of services health centers provide to medically underserved populations.

The rationale for the safe harbor was simple – while Section 330 grant funds are used by the health center to cover the uncompensated costs of rendering services to uninsured and underinsured patients, often these funds are insufficient to meet the needs of the health centers’ medically underserved communities. To address those critical needs, health centers need the ability to supplement scarce resources with assistance from other providers in the community, as well as vendors, without fear of exposure under the anti-kickback statute.

This proposal was re-submitted to DHHS in 1997, 1999 and 2001, in response to the OIG’s annual solicitation of proposals for new and revised safe harbors. However, an applicable safe harbor rule was not promulgated. Thus, NACHC sought federal legislation.

### ***The Statutory Health Center Safe Harbor***

The goal of a statutory safe harbor was realized upon the enactment of the Medicare Prescription Drug, Improvement and Modernization Act of 2003.<sup>3</sup> The Statutory Health Center Safe Harbor included in that legislation exempted from the definition of remuneration prohibited by the Statute:

any remuneration between a health center entity... and any individual or entity providing goods, items, services, donations, loans, or a combination

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<sup>3</sup> Section 431(a) of the Medicare Prescription Drug, Improvement and Modernization Act amended Section 1128B(b)(3) of the Social Security Act [42 U.S.C. §1320a-7(b)(3)] by adding a new subparagraph (H), referred to herein as the Statutory Health Center Safe Harbor.

thereof, to such health center entity pursuant to a contract, lease, grant, loan or other agreement, if such agreement contributes to the ability of the health center entity to maintain or increase the availability, or enhance the quality, of services provided to a medically underserved population served by the health center entity.

The legislation provided that DHHS establish standards relating to the safe harbor, which would take into consideration factors demonstrating that the arrangement between the health center and the other party:

- Results in savings of Federal grant funds or increased revenues to the health center;
- Does not restrict or limit an individual's freedom of choice; and
- Protects a health care professional's medical judgment regarding medically appropriate treatment.

DHHS also was permitted to consider and include other standards and criteria consistent with Congress' intent in enacting the health center safe harbor legislation. On its face, this safe harbor differed significantly from other statutory and regulatory safe harbors in that it applied exclusively to one type of provider - health centers receiving funds under Section 330 of the Public Health Service Act. No other health care provider, including Federally Qualified Health Center "Look-Alike" entities, can qualify under the statutory Health Center Safe Harbor.<sup>4</sup>

### *The Proposed Health Center Safe Harbor Rule*

On July 1, 2005, the OIG issued a proposed rule to establish regulatory standards for the statutory Health Center Safe Harbor, as directed by Congress. The proposed rule included eleven (11) requirements, many of which were a source of concern for NACHC and health center grantees nationwide. In particular, the requirements were significantly more restrictive than NACHC had anticipated based upon its previous conversations with the OIG. Further, the proposed rule lacked specific standards to guide health centers in satisfying the requirements, which, in turn, could create potential uncertainty regarding the legal sufficiency of arrangements. In response, NACHC submitted substantial comments, voicing its apprehension regarding whether the rule would effectively "chill" otherwise legitimate arrangements and activities, rather than encourage them.

### **Requirements of the Final Health Center Safe Harbor Rule**

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<sup>4</sup> In its response to comments on the proposed rule, the OIG declined to broaden the scope of the rule to include FQHC Look-Alike entities, for the following reasons: (1) Congress specifically limited the safe harbor to exclude FQHC Look-Alike entities; and (2) the FQHC Look-Alikes' lack of Section 330 funding, which necessitates a higher level of oversight by the government, could pose a greater risk of fraud and abuse. For the complete response, please see the final rule at 72 *Fed. Reg.* 56632, 56636 (October 4, 2007).

On October 4, 2007, the OIG published the final rule establishing regulatory standards for the statutory Health Center Safe Harbor.<sup>5</sup> In both the preamble to the final rule and the rule itself, it is apparent that the OIG favorably addressed many of the concerns raised by NACHC in its response to the proposed rule, including:

- Modifying and clarifying provisions which NACHC believed would have a “chilling effect” on potential partners, including: (1) clarifying that the preamble reference to the OIG’s efforts to monitor the parties to safe-harbored arrangements refers to its usual and customary oversight and not to a higher level of scrutiny; and (2) deleting a proposed requirement that the agreement comply with all relevant Section 330-related requirements.
- Clarifying that the scope of protected “remuneration” includes: (1) goods, items, donations, services, *etc.*, related to both patient and administrative services provided under the health center’s scope of project; and (2) community benefit grants and similar payments, even if such payments are subject to reconciliation and thus not set in advance (provided that the reconciliation methodology is fixed in advance and does not vary based on the value or volume of referrals).
- Simplifying a proposed requirement for determining whether the arrangement maintains or increases services to the underserved by allowing health centers to document the basis for their expectations without establishing consistent, uniform measurements.
- Simplifying a proposed disclosure requirement by requiring health centers to disclose the arrangement to patients who inquire about it, but not requiring disclosure every time the center makes a referral to an individual/entity that is a party to the arrangement.

The final rule includes eight requirements. In order for a health center arrangement to be protected by the safe harbor, **it must satisfy all 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, as noted above, 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

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<sup>5</sup> See 72 Fed Reg 56632 (October 4, 2007), as codified at 42 C.F.R. § 1001.952(w).



under the health center's scope of project, including billing services, administrative and technology support, and enabling services.

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.

The final rule also includes an optional standard, under which a health center can require the entity or individual providing it with discounted or no charge goods, items, services, *etc.*, to charge a referred patient either the same rate the entity/individual charges other similarly situated patients, or a reduced rate that applies to the total charge (and not just cost-sharing amounts for insured patients). By choosing this option, health centers can prevent the entity/individual from recouping the amount of the discount provided to the health center from the health center's patients by overcharging them for services or items furnished directly to the patients.<sup>6</sup>

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<sup>6</sup> Please note that under certain circumstances, health centers and hospitals are allowed to waive or reduce co-payments and deductibles under the existing cost-sharing safe harbor set forth at 42 C.F.R. § 1001.952(k). The preamble to the final Health Center Safe Harbor rule clarifies that the final rule's requirement that any reduced rate charged to patients must apply to the total patient charge and not solely

## **Opportunities the final Health Center Safe Harbor Rule May Provide to Health Center Grantees**

As discussed above, the final Health Center Safe Harbor rule is a much welcome legal development for health centers that, by virtue of their missions, are always searching for new ways to improve access to care for the populations they serve by securing cost-effective arrangements with other members of the health care community. Whereas prior to the Health Center Safe Harbor many of those arrangements or collaborations could have triggered anti-kickback liability, they 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.<sup>7</sup>

### ***Monetary and In-Kind Donations***

Prior to the Health Center Safe Harbor, donations (monetary and in-kind) from entities conducting business or having referral relationships with health centers could have triggered scrutiny under the Statute. However, because of the Safe Harbor, the donation potentially could be exempt from the Statute's scrutiny if the arrangement satisfies the requirements of the health Center Safe Harbor rule. Thus, the following types of arrangements, for example, may no longer raise anti-kickback concerns:

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to cost-sharing amounts owed by insured patients does not preclude health centers from utilizing the cost-sharing safe harbor or from waiving cost-sharing amounts based on individualized determinations of need (as permitted by Section 1128A(i)(6)(A)(iii) of the Social Security Act).

<sup>7</sup> Recently, the Centers for Medicare and Medicaid Services ("CMS") issued its long-awaited final rule implementing Stark III, which restricts the ability of physicians to refer to organizations with which they have a compensation arrangement or an ownership interest for the provision of certain designated health services ("DHS"). See 72 Fed Reg. 51012 (September 5, 2007), amending 42 C.F.R. Parts 411 & 424.

In general, to be exempted from the referral restriction, compensation arrangements must satisfy certain requirements including fair market value payments. Under prior rules, only the health center (and not the physicians employed by the health center) had a compensation relationship with an entity with which it conducts business. Thus, if the arrangement between the health center and the entity included below fair market value payments, Stark would not have precluded the health center's physicians from referring to the entity for DHS.

However, under the newly promulgated "stand in the shoes" provision, physicians employed by certain "physician organizations" and other physician practices will be deemed to "stand in the shoes" of their employers, so that the physicians themselves would be considered to have compensation arrangements with the health center's business partners. If the arrangement between the health center and its partner includes below fair market value payments, the physicians would be prohibited from referring patients to the partner for DHS. Since many below fair market value deals are exactly what the Health Center Safe Harbor is intended to protect, there was concern that the new Stark III rules would limit the Safe Harbor's usefulness.

NACHC is happy to report that CMS has stated that health centers are not considered "physician organizations" or other types of physician practices subject to the "stand in the shoes" provision. Accordingly, the question of whether below market arrangements protected by the Safe Harbor could trigger Stark violations under the new Stark III rules has been put to rest with a definitive "no."

- An arrangement under which a clinical lab company that has a business relationship with a health center donates certain lab supplies to the health center.
- An arrangement under which a hospital that receives referrals from a health center makes a monetary donation to a health center, such as a community benefit grant.

### ***Low-Cost Leases and Purchase Agreements***

In many instances, health centers will negotiate lease or purchase agreements with other health care entities (*e.g.*, hospitals, private physician practices) for goods or services furnished to the health center at below fair market value rental or purchase payments, or loans from such entities at below market interest rates. Previously, these types of arrangements raised serious anti-kickback concerns if the other health care entity also conducted business or had referral relationships with the health center, since the savings to the health center which resulted from the arrangement could be viewed as the remuneration to the health center from the provider in exchange for the health center's referral of Medicare and Medicaid patients to the provider. Under the Health Center Safe Harbor, however, these arrangements could qualify for protection. Accordingly, the following types of arrangements, for example, may no longer be scrutinized under the Statute:

- An arrangement under which a health center's hospital partner, in an effort to help the health center with some of its costs, offers the health center clinic space at below fair market value.<sup>8</sup>
- An arrangement under which a health center purchases additional OB/GYN clinical capacity from a local physician practice for a cost that is below fair market value.
- An arrangement under which a health center purchases equipment from a durable medical equipment supplier at below fair market value.

Please note that if any of the aforementioned arrangements are offered to the health center at no-cost, they could be protected by the Health Center Safe Harbor as "in-kind" contributions.

### ***Low-Cost (or No-Cost) Referral Arrangements***

In other instances, health centers may negotiate referral arrangements with other health care entities for services provided and charged directly to the health centers' uninsured patients at below fair market value rates. Similar to the lease and purchase agreements

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<sup>8</sup> It's important to note that an arrangement under which the health center leases space and/or equipment to a specialty or ancillary services provider that co-locates the services in the health center's facility at below market value would not be covered under the Health Center Safe Harbor because the other provider, not the health center, is receiving the benefit.

noted above, in the past, these types of arrangements have raised serious anti-kickback concerns if the other health care entity also conducted business or had referral relationships with the health center. While the health center was not receiving the discounted services directly, if it was obligated under its grant or otherwise, to provide the services and, therefore, had to pay the full cost to secure the services, the reduced or free costs of services could have been viewed as remuneration in the form of savings to the health center. Under the Health Center Safe Harbor, these arrangements could qualify for protection. Thus, the following type of arrangement, for example, may no longer be scrutinized or determined to be problematic under the Statute:

- An arrangement under which a health center refers patients to a radiology department that agrees to provide services to the health center's uninsured patients at no-cost or based on the center's discounted fee schedule without charging the balance to the health center.

#### ***Low Interest, No Interest or Forgivable Loans***

Health centers may receive offers of low interest, no interest or forgivable loans from other health care entities (*e.g.*, hospitals, private physician practices) to assist in the construction or renovation of buildings, the purchase of equipment, or other similar activities. While in the past, these types of arrangements have raised serious anti-kickback concerns, they may now be protected under the Health Center Safe Harbor provided that the arrangement contributes meaningfully to the provision of care to underserved populations (and meets the other Safe Harbor requirements).

#### ***Practitioner Recruitment Assistance***

Traditionally, arrangements under which a hospital that receives referrals from a health center offers to assist a health center in recruiting practitioners to the health center's area by providing assistance such as payments for travel and moving expenses and salary guarantees have been subject to scrutiny under the Statute. These forms of assistance may be protected under the Health Center Safe Harbor provided that the assistance is given to the health center and not the individual practitioner (and the other requirements of the Safe Harbor are satisfied).

#### **Conclusion**

The long-awaited final Health Center Safe Harbor rule is a much welcome legal development for health centers that are always searching for new ways to improve access to care for the populations they serve by securing cost-effective arrangements with other members of the health care community. For some health centers, such arrangements offer the promise of savings that can be used to enhance expand services. For others, these arrangements may be necessary for the health center's survival in an increasingly costly health care environment with limited available resources.

In the past, entering into such cost-saving arrangements could fulfill a health center's mission, while potentially exposing the health center (and its partner) to prosecution under the Statute. Now, the Health Center Safe Harbor protects the ability of health centers and their partners to execute these unique cost-saving arrangements, thus, allowing health centers to expand health care and related services to the constantly growing underserved populations residing within their communities without the threat of prosecution.

Effectively, the Health Center Safe Harbor Rule (both on its face and in the preamble to the rule) offers health centers a multitude of opportunities to expand their programs in a world where additional federal grant funds are in short supply. Notwithstanding, given the potential legal implications if all requirements are not sufficiently met (as well as the fact that as a new rule, it has not yet been "tested"), it is advisable for health centers and their partners to have legal counsel take a close look at "safe-harbored" arrangements prior to implementation.

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