Federally Qualified Health Centers

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Practice Area: Health Law

On July 1, 2005, the Office of the Inspector General of the Department of Health and Human Services ("OIG") published a proposed safe harbor under the federal anti-kickback statute.[1] This safe harbor addresses donations, loans, and the furnishing of items, goods, and services to certain federally-funded health centers, including FQHCs and Indian health centers ("Health Centers").[2] The safe harbor protects arrangements in which entities and individuals (namely, hospitals, specialty physicians and other health care providers and suppliers) ("Affiliates"), furnish these sorts of loans, services and other items to Health Centers, if the arrangements meet certain safe harbor criteria. Congress required publication of the safe harbor in the Medicare Prescription Drug Improvement and Modernization Act of 2003.

This *Bulletin* briefly describes the proposed safe harbor criteria. These criteria are similar in intent to the OIG Advisory Opinion 01-03 obtained by von Briesen attorneys on behalf of a client, in which a hospital waived co-payments for Indian health center patients. A notable difference from that earlier Opinion is that the safe harbor imposes certain administrative tasks on the Health Center, which are discussed below.

Health Centers and their Affiliates may want to evaluate their current arrangements in light of the OIG's newly published criteria to determine whether current or future arrangements satisfy the requirements or if changes in their practices will be necessary. Health Centers should consider developing the infrastructure outlined in the safe harbor criteria to assess and accept discounted and free goods and services from Affiliates.

Background – the Anti-Kickback Statute
The anti-kickback statute makes it a felony to knowingly and willfully offer, solicit, pay or receive anything of value, directly or indirectly, in exchange for or to induce referrals of items or services reimbursable by Medicare or Medicaid. The OIG may impose civil money penalties or exclude a person or entity from participation in any federal or state health care program for violating the anti-kickback statute. However, an arrangement will not be subject to such sanctions if the arrangement meets the criteria of a safe harbor. Importantly, however, the failure to qualify for a safe harbor does not mean that an arrangement is illegal. Instead, arrangements that do not meet the safe harbor criteria should be reviewed on a case-by-case basis to ensure that they do not involve unlawful payments for referrals of Medicare or other federally-funded program patients.

The Proposed Safe Harbor
The safe harbor is intended to protect the transfer of goods, items, services, donations and/or loans to a Health Center if those items contribute to the availability and quality of "safety net" health care services to medically underserved populations; and to prevent parties from entering into agreements in exchange for referrals of patients to an Affiliate. The proposed safe harbor requires the following criteria be met when an Affiliate furnishes any of these items of value to a qualifying Health Center at other than fair market value.

- Under an arrangement with an Affiliate, the goods, services or other items furnished to a Health Center or supported by a loan or donation must be medical or clinical in nature, or relate directly to patient services (for example, billing services, administrative support, or translation services).
- The Health Center must reasonably expect the arrangement to contribute to a Health Center's ability to maintain or increase the availability of services to medically underserved populations or enhance the quality of such services. A Health Center's determination of whether the arrangement will "contribute meaningfully" must be made by applying reasonable, consistent, and uniform standards. A Health Center must document the basis for this expectation prior to entering into the arrangement. This documentation must be available to the Secretary of the Department of Health and Human Services. A Health Center must reevaluate each of its arrangements with its Affiliates annually (or more frequently) to ensure that the arrangement continues to "contribute meaningfully," as described above. Noncompliant arrangements must be promptly terminated, and may not be renewed or renegotiated in any manner that takes into account the volume or value of Federal health care program business between a Health Center and its Affiliate.
- If a Health Center has multiple Affiliates willing to offer items of value, the Health Center should employ a reasonable methodology to determine which partners to select, in accordance with the procurement standards for recipients of Federal grants.[3] An agreement between a Health Center and an Affiliate may not restrict a Health Center's ability to enter into arrangements with other Affiliates, lenders, or donors.
- When referring a patient to an Affiliate, a Health Center should provide "effective notification" to the patient of his or her right to choose any willing health care provider. In addition, a Health Center must disclose the existence and nature of its arrangement with an Affiliate to a patient at the time of the patient's initial referral, if the patient or any third-party payor (other than the Health Center) will pay for the Affiliate's services. The notification and disclosure must be "timely" and "in a manner reasonably calculated to be effective and understood by the patient."
- • An arrangement cannot require that a Health Center (or its affiliated health care professionals) refer patients to a particular Affiliate. In addition, an Affiliate must accept a Health Center's referrals of all patients who clinically qualify for services. Although an Affiliate may impose a reasonable limit on the total number of Health Center patient referrals, the Affiliate may not consider any individual patient's payor status or ability to pay when accepting a referral. An arrangement may require that an Affiliate charge a Health Center patient either the same rate the Affiliate charges its other patients or a reduced rate. If a reduced rate is charged, the discount must apply to the total charge, not just any costsharing portion owed by the patient.
- Finally, certain common safe harbor criteria must be met. The arrangement must be set out in writing, signed by all the parties, and cover all the items to be provided to a Health Center by the individual or entity. The written agreement must specify the amount (meaning a fixed sum, percentage or other fixed methodology) of the items to be provided to a Health Center. The amount may not vary based on the volume or value of Medicare or Medicaid program business generated between a Health Center and an Affiliate. In addition to these common safe harbor criteria, any agreement regarding an arrangement must comply with all relevant requirements of a Health Center's section 330 grant funding.

[1] See 70 Fed. Reg. 38081-38089.

[2] Not all federally-funded health centers qualify for the protection of the proposed safe harbor. The safe harbor covers only an entity which (i) is receiving a grant under section 330 of the Public Health Service Act, or (ii) is receiving funding from such a grant under a contract with the grant's recipient and meets the requirements to receive a grant under section 330 of such Act. These qualifying health centers include an outpatient health program or facility operated by a tribe or tribal organization under the Indian Self-Determination Act or by an urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act for the provision of primary health services. "Lookalike" health centers would not be covered by the proposed safe harbor.

[3] See 45 CFR 74.40 et seq. These requirements include creating a code of conduct applicable to employees, officers or agents; conducting alltransactions in a manner that promotes open and free competition, such as choosing the Affiliate most responsive to the Health Center's request for services; establishing and abiding by written procurement policies; documenting a cost and price analysis for each arrangement; creating a contract administration system; and including certain contract provisions in each arrangement, such as permitting HHS to inspect the Affiliate's books and records.
