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FACT SHEET

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FEDERAL ANTI-KICKBACK LAW AND REGULATORY SAFE HARBORS

Overview: *On the books since 1972, the federal anti-kickback law's main purpose is to protect patients and the federal health care programs from fraud and abuse by curtailing the corrupting influence of money on health care decisions. Straightforward but broad, the law states that anyone who knowingly and willfully receives or pays anything of value to influence the referral of federal health care program business, including Medicare and Medicaid, can be held accountable for a felony. Violations of the law are punishable by up to five years in prison, criminal fines up to $25,000, administrative civil money penalties up to $50,000, and exclusion from participation in federal health care programs.*

Because the law is broad on its face, concerns arose among health care providers that some relatively innocuous -- and in some cases even beneficial -- commercial arrangements are prohibited by the anti-kickback law. Responding to these concerns, Congress in 1987 authorized the Department to issue regulations designating specific "safe harbors" for various payment and business practices that, while potentially prohibited by the law, would not be prosecuted.

The Office of Inspector General has previously published 13 regulatory safe harbors, 11 in 1991 and two in 1992. A new final rule scheduled for publication in the Nov. 19, 1999, Federal Register *will establish eight new safe-harbor provisions and clarify six of the original 11 safe harbors published in 1991. These proposals were published in the Federal Register in 1993 and 1994 and have been significantly modified in response to voluminous public comments. Additionally, an interim final rule establishing a safe harbor for shared-risk arrangements is scheduled for publication in the Nov. 19, 1999,* Federal Register. *After publication of the two new rules, there will be a total of 23 anti-kickback safe harbors consolidated in the Code of Federal Regulations in 21 subparagraphs.*

SAFE HARBORS GENERALLY

Safe harbors immunize certain payment and business practices that are implicated by the anti-kickback statute from criminal and civil prosecution under the statute. To be protected by a safe harbor, an arrangement must fit squarely in the safe harbor. Failure to comply with a safe harbor provision does not mean that an arrangement is *per se* illegal. Compliance with safe harbors is voluntary, and arrangements that do not comply with a safe harbor must be analyzed on a case-by-case basis for compliance with the anti-kickback statute. Parties who are uncertain whether their arrangements qualify for safe harbor protection may request an advisory opinion. Instructions on how to request an advisory opinion are available on the Internet at http://oig.hhs.gov.

THE 13 EXISTING SAFE HARBORS

The 1991 safe harbors addressed the following types of business or payment practices: investments in large publicly held health care companies; investments in small health care joint ventures; space rental; equipment rental; personal services and management contracts; sales of retiring physicians' practices to other physicians; referral services; warranties; discounts; employee compensation; group purchasing organizations; and waivers of Medicare Part A inpatient cost-sharing amounts. The 1992 interim final safe harbors, which were finalized in 1996, addressed the following practices in managed care settings: increased coverage, reduced cost-sharing amounts, or reduced premium amounts offered by health plans to beneficiaries; and price reductions offered to health plans by providers.

THE NEW SAFE HARBORS

The preamble to the new final rule includes a summary of each proposal from 1993 and 1994, a summary of each new safe harbor, and the Office of Inspector General's response to public comments on each topic area. The new safe harbors address the following areas: investments in underserved areas; practitioner recruitment in underserved areas; obstetrical malpractice insurance subsidies for underserved areas; sales of practices to hospitals in underserved areas; investments in ambulatory surgical centers; investments in group practices; referral arrangements for specialty services; and cooperative hospital service organizations.

Investments in Ambulatory Surgical Centers (ASCs)

The original proposal protected only Medicare-certified ASCs wholly owned by surgeons. Many in the industry urged that the original proposal be broadened. The expanded final rule protects certain investment interests in four categories of freestanding Medicare-certified ASCs: surgeon-owned ASCs; single-specialty ASCs (e.g., all gastroenterologists); multi-specialty ASCs (e.g., a mix of surgeons and gastroenterologists); and hospital/physician-owned ASCs. In general, to be protected, physician investors must be physicians for whom the ASC is an extension of their office practice pursuant to conditions set forth in the safe harbor. Hospital investors must not be in a position to make or influence referrals. Certain investors who are not existing or potential referral sources are permitted. The ASC safe harbor does not apply to other physician-owned clinical joint ventures, such as cardiac catheterization labs, end-stage renal dialysis facilities or radiation oncology facilities.

Joint Ventures in Underserved Areas

Often health care ventures in medically underserved areas have difficulty attracting needed capital, and, often, the best available sources of capital are local physicians. Many underserved area ventures cannot fit in the existing safe harbor for small entity joint ventures because that safe harbor limits physician ownership and the revenues that can be derived from referrals from physician investors. The underserved area joint venture safe harbor relaxes several of the conditions of the existing joint venture safe harbor. The new safe harbor permits a higher percentage of physician investors -- up to 50 percent -- and unlimited revenues from referral source investors. The new safe harbor expands on the 1993 proposal by including joint ventures in underserved urban, as well as rural, areas. To qualify, a venture must be located in a medically underserved area, as defined by Department regulation, and serve 75 percent medically underserved patients.

Practitioner Recruitment in Underserved Areas

This safe harbor protects recruitment payments made by entities to attract needed physicians and other health care professionals to rural and urban health professional shortage areas (HPSAs), as designated by the Health Resources and Services Administration. The safe harbor requires that at least 75 percent of the recruited practitioner's revenue be from patients who reside in HSPAs or medically underserved areas or are members of medically underserved populations, such as the homeless or migrant workers. The safe harbor limits the duration of payments to three years. The safe harbor does not prescribe the types of protected payments, such

as income guarantees or moving expenses, leaving that determination to negotiation by the parties.

Because of the risk of disguised payments for referrals, the safe harbor does not protect payments made by hospitals to existing group practices to recruit physicians to join the group, nor does it protect payments to retain existing practitioners. Such arrangements remain subject to case-by-case review under the anti-kickback statute.

Sales of Physician Practices to Hospitals in Underserved Areas

This safe harbor protects hospitals in HPSAs that buy and "hold" the practice of a retiring physician until a new physician can be recruited to replace the retiring one. To qualify for safe harbor protection, the sale must be completed within three years, and the hospital must engage in good faith efforts to recruit a new practitioner.

Subsidies for Obstetrical Malpractice Insurance in Underserved Areas

This safe harbor protects a hospital or other entity that pays all or part of the malpractice insurance premiums for practitioners engaging in obstetrical practice in HPSAs. To qualify for protection, at least 75 percent of the subsidized practitioners' patients must be medically underserved patients.

Investments in Group Practices

This safe harbor protects investments by physicians in their own group practices, if the group practice meets the physician self-referral (Stark) law definition of a group practice. The safe harbor also protects investments in solo practices where the practice is conducted through the solo practitioner's professional corporation or other separate legal entity. The safe harbor does not protect investments by group practices or members of group practices in ancillary services' joint ventures, although such joint ventures may qualify for protection under other safe harbors.

Specialty Referral Arrangements Between Providers

The safe harbor protects certain arrangements when an individual or entity agrees to refer a patient to another individual or entity for specialty services in return for the party receiving the referral to refer the patient back at a certain time or under certain circumstances. For example, a primary care physician and a specialist to whom the primary care physician has made a referral may agree that, when the referred patient reaches a particular stage of recovery, the primary care physician should resume treatment of the patient. The safe harbor does not protect arrangements involving parties that split a global fee from a federal program. The safe harbor requires that referrals be clinically appropriate, rather than based on arbitrary dates or time frames.

Cooperative Hospital Services Organizations

This safe harbor protects cooperative hospital service organizations (CHSOs) that qualify under section 501(e) of the Internal Revenue Code. CHSOs are organizations formed by two or more tax-exempt hospitals, known as "patron hospitals," to provide specifically enumerated services, such as purchasing, billing, and clinical services solely for the benefit of patron hospitals. The safe harbor will protect payments from a patron hospital to a CHSO to support the CHSO's operational costs and payments from a CHSO to a patron hospital that are required by IRS rules.

CLARIFICATION OF EXISTING SAFE HARBORS

The new final rule clarifies aspects of the original safe harbors for large and small entity investments; space

rental; equipment rental; personal services and management contracts; referral services; and discounts. Many of the changes are technical in nature. The intent of the clarifications is to make the regulations easier for the industry to understand and apply to particular factual circumstances.

Withdrawal of Proposed "Sham" Transactions Rule

The Office of Inspector General elected not to adopt the "sham" transactions rule proposed in the 1994 proposed regulation. However, the preamble to the new rule makes clear that safe harbors only protect arrangements if the form and substance of the transaction conform to the safe harbor in which shelter is sought.

SHARED-RISK SAFE HARBORS

In 1996, Congress enacted a new exception to the anti-kickback statute for certain shared-risk arrangements and directed the Department to issue regulations through a negotiated rulemaking process. The negotiating committee, composed of industry and government representatives, issued a joint committee statement in January 1998 that describes the agreement reached by the committee and served as a guideline for the government's rulemaking. The interim final rule with comment period for the shared-risk exception is also scheduled for publication in the Nov. 19, 1999, *Federal Register.*

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