

ATTACHMENT 1.—LIST OF SUDS KNOWN TO BE REPROCESSED OR CONSIDERED FOR REPROCESSING—Continued

	Medical specialty	Device type	Regulation No.	Class	Product code	Risk 1,2,3,3*	Critical/semi-critical/non-critical	Premarket exempt
227 ..	Surgery	Scissor Tips	878.4800, 884.4520, 874.4420	I	LRW, HDK, HDJ, JZB, KBD GEX	2	C	Y
228 ..	Surgery	Laser Fiber Delivery Systems	878.4810 874.4500 886.4390 884.4550 886.4690	II	EWG LLW HQF HHR HQB	1	C	N

1 = low risk according to RPS

2 = moderate risk according to RPS

3 = high risk according to RPS

3* = high risk due to neurological use

Dated: April 23, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES**Office of Inspector General****Publication of OIG Special Advisory Bulletin on Contractual Joint Ventures****AGENCY:** Office of Inspector General (OIG), HHS.**ACTION:** Notice.

SUMMARY: The OIG periodically develops and issues guidance, including Special Advisory Bulletins, to alert and inform the health care industry about potential problems or areas of special interest. This **Federal Register** notice sets forth the recently issued OIG Special Advisory Bulletin addressing certain contractual joint venture arrangements.

FOR FURTHER INFORMATION CONTACT: Vicki Robinson or Joel Schaer, Office of Counsel to the Inspector General, (202) 619-0335.

SUPPLEMENTARY INFORMATION:**Special Advisory Bulletin: Contractual Joint Ventures (April 2003)****Introduction**

This Special Advisory Bulletin addresses certain complex contractual arrangements for the provision of items and services previously identified as suspect in our 1989 Special Fraud Alert on Joint Venture Arrangements.¹ While

much of the discussion in the 1989 Special Fraud Alert focused on investor referrals to newly formed entities, we observed that:

[t]he Office of Inspector General has become aware of a proliferation of arrangements between those in a position to refer business, such as physicians, and those providing items or services for which Medicare or Medicaid pays. Some examples of the items or services provided in these arrangements include clinical diagnostic laboratory services, durable medical equipment (DME), and other diagnostic services. Sometimes these deals are called "joint ventures." *A joint venture may take a variety of forms: it may be a contractual arrangement between two or more parties to cooperate in providing services, or it may involve the creation of a new legal entity by the parties, such as a limited partnership or closely held corporation, to provide such services.* (Emphasis added.)

Notwithstanding that caution, the Office of Inspector General (OIG) is concerned that contractual joint venture arrangements are proliferating.²

A. Questionable Contractual Arrangements

The federal anti-kickback statute, section 1128B(b) of the Social Security Act (the Act), prohibits knowingly and willfully soliciting, receiving, offering, or paying anything of value to induce referrals of items or services payable by a federal health care program. Kickbacks

are harmful because they can (1) distort medical decision-making, (2) cause overutilization, (3) increase costs to the federal health care programs, and (4) result in unfair competition by freezing out competitors unwilling to pay kickbacks. Both parties to an impermissible kickback transaction may be liable. Violation of the statute constitutes a felony punishable by a maximum fine of \$25,000, imprisonment up to 5 years, or both. The OIG may also initiate administrative proceedings to exclude persons from the federal health care programs or to impose civil money penalties for kickback violations under sections 1128(b)(7) and 1128A(a)(7) of the Act.

This Special Advisory Bulletin focuses on questionable contractual arrangements where a health care provider in one line of business (hereafter referred to as the "Owner") expands into a related health care business by contracting with an existing provider of a related item or service (hereafter referred to as the "Manager/Supplier") to provide the new item or service to the Owner's existing patient population, including federal health care program patients. The Manager/Supplier not only manages the new line of business, but may also supply it with inventory, employees, space, billing, and other services. In other words, the Owner contracts out substantially the entire operation of the related line of business to the Manager/Supplier—otherwise a potential competitor—receiving in return the profits of the business as remuneration for its federal program referrals.

Some examples of potentially problematic contractual arrangements include the following:

¹ The 1989 Special Fraud Alert was reprinted in the **Federal Register** in 1994. See 59 FR 65372 (December 19, 1994). The Special Fraud Alert is

also available on our Web page at <http://oig.hhs.gov/fraud/docs/alertsandbulletins/121994.html>.

² The kinds of contractual arrangements addressed in this Special Advisory Bulletin are sometimes referred to as "joint ventures" or "contractual joint ventures" or may be referenced by other terminology. For purposes of the analysis set forth in this Bulletin, a "joint venture" is any common enterprise with mutual economic benefit. The application of this Bulletin is not limited to "joint ventures" that meet technical qualifications under applicable state or common law.