

reimbursement received from the federal health care programs. By agreeing effectively to provide services it could otherwise provide in its own right for less than the available reimbursement, the Manager/Supplier is providing the Owner with the opportunity to generate a fee and a profit. The opportunity to generate a fee is itself remuneration that may implicate the anti-kickback statute.

C. Indicia of a Suspect Contractual Joint Venture

To help identify the suspect contractual joint ventures that are the focus of this Special Advisory Bulletin, we describe below some characteristics, which, taken separately or together, potentially indicate a prohibited arrangement. This list is illustrative, not exhaustive.

New Line of Business. The Owner typically seeks to expand into a health care service that can be provided to the Owner's existing patients. As illustrated in Part A, examples include, but are not limited to, hospitals expanding into DME services, DME companies expanding into the nebulizer pharmacy business, or nephrologists expanding into the home dialysis supply business.⁴

Captive Referral Base. The newly-created business predominantly or exclusively serves the Owner's existing patient base (or patients under the control or influence of the Owner). The Owner typically does not intend to expand the business to serve new customers (*i.e.*, customers not already served in its main business) and, therefore, makes no or few *bona fide* efforts to do so.

Little or No Bona Fide Business Risk. The Owner's primary contribution to the venture is referrals; it makes little or no financial or other investment in the business, delegating the entire operation to the Manager/Supplier, while retaining profits generated from its captive referral base. Residual business risks, such as nonpayment for services, are relatively ascertainable based on historical activity.

Status of the Manager/Supplier. The Manager/Supplier is a would-be competitor of the Owner's new line of business and would normally compete for the captive referrals. It has the capacity to provide virtually identical services in its own right and bill insurers and patients for them in its own name.

Scope of Services Provided by the Manager/Supplier. The Manager/

Supplier provides all, or many, of the following key services:

- Day-to-day management;
- Billing services;
- Equipment;
- Personnel and related services;
- Office space;
- Training;
- Health care items, supplies, and services.⁵

In general, the greater the scope of services provided by the Manager/Supplier, the greater the likelihood that the arrangement is a contractual joint venture.

Remuneration. The practical effect of the arrangement, viewed in its entirety, is to provide the Owner the opportunity to bill insurers and patients for business otherwise provided by the Manager/Supplier. The remuneration from the venture to the Owner (*i.e.*, the profits of the venture) takes into account the value and volume of business the Owner generates.

Exclusivity. The parties may agree to a non-compete clause, barring the Owner from providing items or services to any patients other than those coming from Owner and/or barring the Manager/Supplier from providing services in its own right to the Owner's patients.

As noted above, these factors are illustrative, not exhaustive. The presence or absence of any one of these factors is not determinative of whether a particular arrangement is suspect. As indicated, this Special Advisory Bulletin is not intended to describe the entire universe of suspect contractual joint ventures. This Bulletin focuses on arrangements where substantially all of the operations of a new line of business are contracted out to a would-be competitor. Arrangements involving the delegation of fewer than substantially all services, or delegation to a party not otherwise in a position to bill for the identical services, may also raise concerns under the anti-kickback statute, depending on the circumstances.

The Office of Inspector General (OIG) was established at the Department of Health and Human Services by Congress in 1976 to identify and eliminate fraud, abuse, and waste in the department's programs and to promote efficiency and economy in departmental operations. The OIG carries out this mission through a nationwide program of audits, investigations, and inspections.

⁵ The Manager/Supplier may also provide marketing services, although in many instances no such services are required since the Owner generates substantially all of the venture's business from its existing patient base.

The Fraud and Abuse Control Program, established by the Health Insurance Portability and Accountability Act of 1996 (HIPAA), authorized the OIG to provide guidance to the health care industry to prevent fraud and abuse and to promote the highest level of ethical and lawful conduct. To further these goals, the OIG issues Special Advisory Bulletins about industry practices or arrangements that potentially implicate the fraud and abuse authorities subject to enforcement by the OIG.

Dated: March 27, 2003.

Dennis J. Duquette,

Acting Principal Deputy Inspector General.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; National Institute of Diabetes and Digestive and Kidney Diseases Information Clearinghouses Customer Satisfaction Survey

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 to provide opportunity for public comment on proposed data collection projects, the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), the National Institutes of Health (NIH), will publish periodic summaries of proposed projects to be submitted to the Office of Management (OMB) for review and approval.

Proposed Collection

Title: NIDDK Information Clearinghouses Customer Satisfaction Survey. **Type of Information Request:** EXTENSION. The OMB control number 0925-0480 expires July 31, 2003. **Need and Use of Information Collection:** NIDDK is conducting a survey to evaluate the efficiency and effectiveness of services provided by NIDDK's three information clearinghouses: National Diabetes Information Clearinghouse, National Digestive Diseases Information Clearinghouse, National Kidney and Urologic Diseases Information Clearinghouse. The survey responds to Executive Order 12862, "Setting Customer Service Standards," which requires agencies and departments to identify and survey their "customers to determine the kind and quality of service they want and their level of satisfaction with existing service." **Frequency of Response:** On occasion.

⁴ These examples are illustrative only. This list is not intended to suggest that other analogous ventures are not equally suspect.