

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.

[FR Doc. 03-10626 Filed 4-29-03; 8:45 am]

BILLING CODE 4150-01-P

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.

Affected Public: Individuals or households; clinics or doctor's offices.

Type of Respondents: Physicians, nurses, patients, family.

Type of respondents	Number of respondents	Frequency of response	Estimated average response time	Estimated annual burden hours
Patients/Family	3,600	1.00	0.167	600
Phys. Asst.	7,200	1.00	0.167	1,200
Physicians	1,200	1.00	0.167	200
Totals	12,000	2,000

The annual reporting burden is as follows: *Estimated Number of Respondents:* 12,000; *Estimated number of Responses per Respondent:* 1; *Estimated Average Burden Hours Per Response:* 0.167; and *Estimated Total Annual Burden Hours Requested:* 2,000. The annualized cost to respondents is estimated at \$39,000. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

Request for Comments

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection reports and instrument, contact Kathy Kranzfelder, Project Officer, NIDDK Information Clearinghouses, NIH, Building 31, Room 9A04, MSC2560, Bethesda, MD 20852. You may also submit comment and data by electronic mail (e-mail) at kranzfeldk@hq.nidDK.nih.gov.

Comments Due Date: Comments regarding this information are best

assured of having their full effect if received within 60 days following the date of this notice.

Dated: April 24, 2003.

Barbara Merchant,

Executive Officer, NIDDK.

[FR Doc. 03-10598 Filed 4-29-03; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Aggression Prevention Among High-Risk Early Adolescents

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

Proposed Collection

Title: Aggression Prevention Among High-Risk Early Adolescents Study. *Type of Information Collection Request:* NEW. *Need and Use of Information Collection:* This study will assess the efficacy of an in-school, group-mentoring intervention designed to foster academic engagement and prevent aggressive and deviant behavior among early adolescents (approximately ages 11-12). The primary objectives of the study are to determine if participation in a weekly group-mentoring program throughout 6th grade significantly impacts adolescents' attitudes and behaviors regarding school engagement

and aggression above and beyond educational materials for youth and parents. The findings will provide valuable information concerning: (1) The efficacy of in-school group-mentoring programs for improving youth attitudes, expectations, intent/motivation, and social competence; and (2) the extent to which such improvement increases academic engagement and decreases aggressive and deviant behavior among high-risk youth. *Frequency of Response:* six times over three years for 6th graders (*i.e.*, fall and spring of 6th, 7th, and 8th grades), four times over three years for 6th grade parents (*i.e.*, fall of 6th grade and spring of 6th, 7th, and 8th grades), and two times over one year for 7th and 8th graders (fall and spring of school year). *Affected Public:* For the pilot, incoming 6th graders from an inner city Baltimore middle school and their parents who agree to participate. For the main trial, two successive cohorts of incoming 6th grade students from two inner city Baltimore middle schools and their parents. Additionally, one cohort of 7th and 8th graders will be surveyed in the Fall and Spring of the first school year of the main trial. *Type of Respondents:* Early adolescents and parents. The annual reporting burden is as follows: *Estimated Number of Respondents:* 1280 early adolescents and 400 parents; *Estimated Number of Responses per Respondent:* six for early adolescents who enter study as 6th graders, two for youth who enter as 7th or 8th graders, and four for parents; *Average Burden Hours Per Response:* 1.0 for youth and 0.5 for parents; and *Estimated Total Annual Burden Hours Requested:* 2,187. The annualized cost to respondents is estimated at: \$32,805 (based on \$15 per hour). There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.