[Federal Register: December 19, 1994]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Publication of OIG Special Fraud Alerts

AGENCY: Office of Inspector General, HHS.
ACTION: Notice.

SUMMARY: This Federal Register notice sets forth the 5 previously-developed Special Fraud Alerts issued directly to the health care provider community by the HHS Office of Inspector General (OIG). In keeping with the OIG's goal and intent of publicizing its concern about possible widespread and abusive health care industry practices, and seeking wider dissemination of this information to the general public, we are republishing the main content of these Special Fraud Alerts in the Federal Register. This notice also serves to alert the general public of our intention to publish all future OIG Special Fraud Alerts in this same manner, in addition to the current method used to distribute this material to Medicare and State health care program providers.

FOR FURTHER INFORMATION CONTACT: Joel J. Schaer, Legislation, Regulations and Public Affairs Staff, (202) 619-0089.

SUPPLEMENTARY INFORMATION:

I. Background

The Use of Fraud Alerts by the OIG

Over the years, the OIG has used fraud alerts as a vehicle to identify fraudulent and abusive practices within the health care industry. The majority of these fraud alerts are disseminated internally to the OIG's Office of Investigations and other agencies within the Department. However, the OIG has also developed and issued Special Fraud Alerts intended for extensive distribution directly to the health care provider community.

Special Fraud Alerts

Since 1988, the OIG has issued 5 ``Special Fraud Alerts'' addressing specific trends of health care fraud and certain practices of an industry-wide character. Specifically, the OIG Special Fraud Alerts have served to provide general guidance to the health care industry on violations of Federal law (including various aspects of the anti-kickback statute), as well as to provide additional insight to the Medicare carrier fraud units in identifying health care fraud schemes.

In developing these Special Fraud Alerts, the OIG relies on a

number of sources, such as studies or management and program evaluations conducted by the OIG's Office of Evaluation and Inspections. In addition, the OIG may consult with experts in the subject field, including those within the OIG, other agencies of the Department, other Federal and State agencies, and from those in the health care industry.

The Nature of Past Special Fraud Alerts

For the most part, the OIG Special Fraud Alerts have been reserved for national trends in health care fraud and have addressed potential violations of the Medicare and State health care programs' anti-kickback statute. The Special Fraud Alerts have addressed the following topic areas that could violate the anti-kickback statute:

- Joint venture arrangements;
- Routine waiver of Medicare Part B copayments and deductibles;
- Hospital incentives to referring physicians;
- Prescription drug marketing practices;
- Arrangements for the provision of clinical laboratory services. II. Federal Register Publication of Special Fraud Alerts In the past, the OIG has always printed and distributed copies of these Special Fraud Alerts directly to all Medicare program providers. While the OIG Special Fraud Alerts have been designed to be available to all affected program providers, we believe it is useful to publicize these various issues and concerns involving potential abusive health care industry practices to a more widespread audience. For this reason, we are using this Federal Register notice as a vehicle to reprint the substance of the 5 previously-issued Special Fraud Alerts cited above. It is our intention to use this same Federal Register form for publishing future Special Fraud Alerts developed by the OIG. Because each of the previously-developed Special Fraud Alerts contained a similar brief narrative as to the nature of the OIG and a description of the Medicare and Medicaid anti-kickback statute, we will first summarize and set out this material in one section, as it is germane to all 5 subject issuances. Following that will be the main body and content of each of the Special Fraud Alerts. Lastly, we have provided the general information set forth in each of these Special Fraud Alerts addressing information on how to report information on suspected violations. The OIG Special Fraud Alerts A. General Background The Office of Inspector General was established at the Department of Health and Human Services by Congress in 1976 to identify and eliminate fraud, abuse and waste in Health and Human Services 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. To help reduce fraud in the Medicare and Medicaid programs, the OIG is actively investigating violations of the Medicare and Medicaid anti-kickback statute, 42 U.S.C. Section 1320a-7b(b). What Is the Medicare and Medicaid Anti-Kickback Law? Among its provisions, the anti-kickback statute penalizes anyone who knowingly and willfully solicits, receives, offers or pays remuneration in cash or in kind to induce, or in return for: A. Referring an individual to a person for the furnishing, or arranging for the furnishing, of any item or service payable under the Medicare or Medicaid program; or B. Purchasing, leasing or ordering , or arranging for or recommending purchasing, leasing or ordering, any goods, facility, service or item payable under the Medicare or Medicaid program. Violators are subject to criminal penalties, or exclusion from participation in the Medicare and Medicaid programs, or both. In

1987, section 14 of the Medicare and Medicaid Patient and Program Protection Act, PL 100-93, directed this Department to promulgate ``safe harbor'' regulations, in order to provide health care providers a mechanism to assure them that they will not be prosecuted under the anti-kickback statute for engaging in particular practices. The Department published 11 final ``safe harbor'' regulations on July 29, 1991 (42 CFR 1001.952, 56 FR 35952), and two more on November 5, 1992 (42 CFR 1001.952, 57 FR 52723). The scope of the anti-kickback statute is not expanded by the ``safe harbor'' regulations; these regulations give those in good faith compliance with a ``safe harbor'' the assurance that they will not be prosecuted under the anti-kickback statute. B. Special Fraud Alert: Joint Venture Arrangements (Issued August 1989) The 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. Of course, there may be legitimate reasons to form a joint venture, such as raising necessary investment capital. However, the Office of Inspector General believes that some of these joint ventures may violate the Medicare and Medicaid anti-kickback statute. Under these suspect joint ventures, physicians may become investors in a newly formed joint venture entity. The investors refer their patients to this new entity, and are paid by the entity in the form of ``profit distributions.'' These subject joint ventures may be intended not so much to raise investment capital legitimately to start a business, but to lock up a stream of referrals from the physician investors and to compensate them indirectly for these referrals. Because physician investors can benefit financially from their referrals, unnecessary procedures and tests may be ordered or performed, resulting in unnecessary program expenditures. The questionable features of these suspect joint ventures may be reflected in three areas: (1) The manner in which investors are selected and retained; (2) The nature of the business structure of the joint venture; and (3) The financing and profit distributions. Suspect Joint Ventures: What To Look For To help you identify these suspect joint ventures, the following are examples of questionable features, which separately or taken together may result in a business arrangement that violates the anti- kickback statute. Please note that this is not intended as an exhaustive list, but rather gives examples of indicators of potentially unlawful activity. Investor

- Investors are chosen because they are in a position to make referrals.
- Physicians who are expected to make a large number of referrals may be offered a greater investment opportunity in the joint venture than those anticipated to make fewer referrals.
- Physician investors may be actively encouraged to make referrals to the joint venture, and may be encouraged to divest their ownership interest if they fail to sustain an ``acceptable'' level of referrals.
- The joint venture tracks its sources of referrals, and distributes this information to the investors.
- Investors may be required to divest their ownership interest if they cease to practice in the service area, for example, if they move, become disabled or retire.
- Investment interests may be nontransferable. Business Structure

- The structure of some joint ventures may be suspect. For example, one of the parties may be an ongoing entity already engaged in a particular line of business. That party may act as the reference laboratory or DME supplier for the joint venture. In some of these cases, the joint venture can be best characterized as a ``shell."
- In the case of a shell laboratory joint venture, for example: --It conducts very little testing on the premises, even though it is Medicare certified. --The reference laboratory may do the vast bulk of the testing at its central processing laboratory, even though it also serves as the ``manager" of the shell laboratory. --Despite the location of the actual testing, the local ``shell" laboratory bills Medicare directly for these tests.
- In the case of a shell DME joint venture, for example: --It owns very little of the DME or other capital equipment; rather the ongoing entity owns them. --The ongoing entity is responsible for all day-to-day operations of the joint venture, such as delivery of the DME and billing. Financing and Profit Distribution
- The amount of capital invested by the physician may be disproportionately small and the returns on investment may be disproportionately large when compared to a typical investment in a new business enterprise.
- Physician investors may invest only a nominal amount, such as $500 to $1500.
- Physician investors may be permitted to ``borrow" the amount of the ``investment" from the entity, and pay it back through deductions from profit distributions, thus eliminating even the need to contribute cash to the partnership.
- Investors may be paid extraordinary returns on the investment in comparison with the risk involved, often well over 50 to 100 percent per year. C. Special Fraud Alert: Routine Waiver of Copayments or Deductibles Under Medicare Part B (Issued May 1991) To help reduce fraud in the Medicare program, the Office of Inspector General is actively investigating health care providers, practitioners and suppliers of health care items and services who (1) are paid on the basis of charges\1\ and (2) routinely waive (do not bill) Medicare deductible and copayment charges to beneficiaries for items and services covered by the Medicare program. ---------- \1\This fraud alert is not intended to address the routine waiver of copayments and deductibles by providers, practitioners or suppliers who are paid on the basis of costs or diagnostic related groups. The fact that these types of services are not discussed in this fraud alert should not be interpreted to legitimize routine waiver of deductibles and copayments with respect to these payment methods. Also, it does not apply to a waiver of any copayment by a Federally qualified health care center with respect to an individual who qualifies for subsidized services under a provision of the Public Health Service Act. ---------- What Are Medicare Deductible and Copayment Charges? The Medicare ``deductible" is the amount that must be paid by a Medicare beneficiary before Medicare will pay for any items or services for that individual. Currently, the Medicare Part B deductible is $100 per year. ``Copayment" (``coinsurance") is the portion of the cost of an item or service which the Medicare beneficiary must pay. Currently, the Medicare Part B coinsurance is generally 20 percent of the reasonable charge for the item or service. Typically, if the Medicare reasonable charge for a Part B item or service is $100, the Medicare beneficiary (who has met his [or her] deductible) must pay $20 of the physician's bill, and Medicare will pay $80. Why Is it Illegal for ``Charged-Based" Providers, Practitioners and Suppliers to Routinely Waive Medicare Copayment and Deductibles? Routine waiver of deductibles and copayments by charge-based providers, practitioners or suppliers is unlawful because it results in (1) false claims, (2) violations of the anti-kickback statute, and (3) excessive utilization of items and

services paid for by Medicare. A ``charge-based'' provider, practitioner or supplier is one who is paid by Medicare on the basis of the ``reasonable charge'' for the item or service provided. 42 U.S.C. 1395u(b)(3); 42 CFR 405.501. Medicare typically pays 80 percent of the reasonable charge. 42 U.S.C. 1395l(a)(1). The criteria for determining what charges are reasonable are contained in regulations, and include an examination of (1) the actual charge for the item or service, (2) the customary charge for the item or service, (3) the prevailing charge in the same locality for similar items or services. The Medicare reasonable charge cannot exceed the actual charge for the item or service, and may generally not exceed the customary charge or the highest prevailing charge for the item or service. In some cases, the provider, practitioner or supplier will be paid the lesser of his [or her] actual charge or an amount established by a fee schedule. A provider, practitioner or supplier who routinely waives Medicare copayments or deductibles is misstating its actual charge. For example, if a supplier claims that its charge for a piece of equipment is $100, but routinely waives the copayment, the actual charge is $80. Medicare should be paying 80 percent of $80 (or $64), rather than 80 percent of $100 (or $80). As a result of the supplier's misrepresentation, the Medicare program is paying $16 more than it should for this item. In certain cases, a provider, practitioner or supplier who routinely waives Medicare copayments or deductibles also could be held liable under the Medicare and Medicaid anti-kickback statute. 42 U.S.C. 1320a-7b(b). The statute makes it illegal to offer, pay, solicit or receive anything of value as an inducement to generate business payable by Medicare or Medicaid. When providers, practitioners or suppliers forgive financial obligations for reasons other than genuine financial hardship of the particular patient, they may be unlawfully inducing that patient to purchase items or services from them. At first glance, it may appear that routine waiver of copayments and deductibles helps Medicare beneficiaries. By waiving Medicare copayments and deductibles, the provider of services may claim that the beneficiary incurs no costs. In fact, this is not true. Studies have shown that if patients are required to pay even a small portion of their care, they will be better health care consumers, and select items or services because they are medically needed, rather than simply because they are free. Ultimately, if Medicare pays more for an item or service than it should, or if it pays for unnecessary items or services, there are less Medicare funds available to pay for truly needed services. One important exception to the prohibition against waiving copayments and deductibles is that providers, practitioners or suppliers may forgive the copayment in consideration of a particular patient's financial hardship. This hardship exception, however, must not be used routinely; it should be used occasionally to address the special financial needs of a particular patient. Except in such special cases, a good faith effort to collect deductibles and copayments must be made. Otherwise, claims submitted to Medicare mat violate the statutes discussed above and other provisions of the law. What Penalties Can Someone Be Subject to for Routinely Waiving Medicare Copayments or Deductibles? Whoever submits a false claim to the Medicare program (for example, a claim misrepresents an actual charge) may be subject to criminal, civil or administrative liability for making false statements and/or submitting false claims to the Government. 18 U.S.C. 287 and 1001; 31 U.S.C. 3729; 42 CFR 1320a-7a). Penalties can include imprisonment, criminal fines, civil damages and forfeitures, civil monetary penalties and exclusion from Medicare and the State health care programs. In addition, anyone who routinely waives copayments or deductibles can be criminally prosecuted under 42 U.S.C. 1320a-7b(b), and excluded from participating in Medicare and the State health care programs under the anti-kickback statute. 42 U.S.C. 1320a-7(b)(7). Finally, anyone who furnishes items or services to patient substantially in excess of the needs of such patients can be excluded from Medicare and

the State health care programs. 42 U.S.C. 1320a- 7(b)(6)(B). Indications of Improper Waiver of Deductibles and Copayments To help you identify charge-based providers, practitioners or suppliers who routinely waive Medicare deductibles and copayments, listed below are some suspect marketing practices. Please note that this list is not intended to be exhaustive but, rather, to highlight some indicators of potentially unlawful activity.

- Advertisements which state: ``Medicare Accepted As Payment in Full,'' ``Insurance Accepted As Payment in Full,'' or ``No Out-Of- Pocket Expense.''
- Advertisements which promise that ``discounts'' will be given to Medicare beneficiaries.
- Routine use of ``Financial hardship'' forms which state that the beneficiary is unable to pay the coinsurance/deductible (i.e., there is no good faith attempt to determine the beneficiary's actual financial condition).
- Collection of copayments and deductibles only where the beneficiary has Medicare supplemental insurance (``Medigap'') coverage (i.e., the items or services are ``free'' to the beneficiary).
- Charges to Medicare beneficiaries which are higher than those made to other persons for similar services and items (the higher charges offset the waiver of coinsurance.)
- Failure to collect copayments or deductibles for a specific group of Medicare patients for reasons unrelated to indigency (e.g., a supplier waives coinsurance or deductible for all patients from a particular hospital, in order to get referrals).
- ``Insurance programs'' which cover copayments or deductibles only for items or services provided by the entity offering the insurance. The ``insurance premium'' paid by the beneficiary is insignificant and can be as low as $1 a month or even $1 a year. These premiums are not based upon actuarial risks, but instead are a sham used to disguise the routine waiver of copayments and deductibles. D. Special Fraud Alert: Hospital Incentives to Physicians (Issued May 1992) Why Do Hospitals Provide Economic Incentives to Physicians? As many hospitals have become more aggressive in their attempts to recruit and retain physicians and increase patient referrals, physician incentives (sometimes referred to as ``practice enhancements'') are becoming increasingly common. Some physicians actively solicit such incentives. These incentives may result in reductions in the physician's professional expenses or an increase in his or her revenues. In exchange, the physician is aware that he or she is often expected to refer the majority, if not all, of his or her patients to the hospital providing the incentives. Why Is it Illegal for Hospitals to Provide Financial Incentives to Physicians for Their Referrals? The Office of Inspector General has become aware of a variety of hospital incentive programs used to compensate physicians (directly or indirectly) for referring patients to the hospital. These arrangements are implicated by the anti-kickback statute because they can constitute remuneration offered to induce, or in return for, the referral of business paid for by Medicare or Medicaid. In addition, they are not protected under the existing ``safe harbor'' regulations. These incentive programs can interfere with the physician's judgment of what is the most appropriate care for a patient. They can inflate costs to the Medicare program by causing physicians to overuse inappropriately the services of a particular hospital. The incentives may result in the delivery of inappropriate care to Medicare beneficiaries and Medicaid recipients by inducing the physician to refer patients to the hospital providing financial incentives rather than to another hospital (or non-acute care facility) offering the best or most appropriate care for that patient. Suspect Hospital Incentive Arrangements--What To Look For To help identify suspect incentive arrangements, examples of practices which are often questionable are listed [below]. Please note that this list is

not intended to be exhaustive but, rather, to suggest some indicators of potentially unlawful activity.

- Payment of any sort of incentive by the hospital each time a physician refers a patient to the hospital.
- The use of free or significantly discounted office space or equipment (in facilities usually located close to the hospital).
- Provision of free or significantly discounted billing, nursing or other staff services.
- Free training for a physician's office staff in such areas as management techniques, CPT coding and laboratory techniques.
- Guarantees which provide that, if the physician's income fails to reach a predetermined level, the hospital will supplement the remainder up to a certain amount.
- Low-interest or interest-free loans, or loans which may be ``forgiven'' if a physician refers patients (or some number of patients) to the hospital.
- Payment of the cost of a physician's travel and expenses for conferences.
- Payment for a physician's continuing education courses.
- Coverage on hospitals' group health insurance plans at an inappropriately low cost to the physician.
- Payment for services (which may include consultations at the hospital) which require few, if any, substantive duties by the physician, or payment for services in excess of the fair market value of services rendered. Financial incentive packages which incorporate these or similar features may be subject to prosecution under the Medicare and Medicaid anti-kickback statute, if one of the purposes of the incentive is to influence the physician's medical decision as to where to refer his or her patients for treatment. E. Special Fraud Alert: Prescription Drug Marketing Schemes (Issued August 1994) How Does the Anti-Kickback Law Relate to Prescription Drug Marketing Schemes? In recent years, prescription drug companies in the United States have increased their marketing activities among providers, patients and suppliers such as pharmacies. Many prescription drug marketing activities go far beyond traditional advertising and educational contacts. Physicians, suppliers and, increasingly, patients are being offered valuable, non-medical benefits in exchange for selecting specific prescription drug brands. Traditionally, physicians and pharmacists have been trusted to provide treatments and recommend products in the best interest of the patient. In an era of aggressive drug marketing, however, patients may now be using prescription drug items, unaware that their physician or pharmacist is being compensated for promoting the selection of a specific product. Prescription drugs supplied under one of these programs are often reimbursed under Medicaid. Among the specific activities, which the OIG has identified, are the following actual cases:
- A ``product conversion'' program which resulted in 96,000 brand-name conversions. In this scenario, for instance, Drug Company A offered a cash award to pharmacies for each time a drug prescription was changed from Drug Company B's product to Drug Company A's product. The pharmacies were induced to help persuade physicians, who were unaware of the pharmacies' financial interest, to change prescription.
- A ``frequent flier'' campaign in which physicians were given credit toward airline frequent flier mileage each time the physician completed a questionnaire for a new patient placed on the drug company's product.
- A ``research grant'' program in which physicians were given substantial payments for de minimis recordkeeping tasks. The physician administered the drug manufacturer's product to the patient and made brief notes, sometimes a single word, about the treatment outcome. Upon

completion of a limited number of such ``studies,'' the physician received payment from the manufacturer. If one purpose of any of these marketing schemes is to induce the provision of a prescription drug item reimbursable by Medicaid, then the criminal anti-kickback statute is implicated. There is no statutory exception or ``safe harbor'' to protect such activities. Thus a physician, pharmacy or other practitioner or supplier receiving payment under these activities may be subject to criminal prosecution and exclusion from participation in the Medicare and Medicaid programs. A marketing program that is illegal under the anti-kickback statute may pose a danger to patients because the offering or payment of remuneration may interfere with a physician's judgment in determining the most appropriate treatment for a patient. Further, where the patient is a Medicaid beneficiary, these drug marketing practices may increase the Federal government's costs of reimbursing suppliers for the products. The OIG is investigating various drug marketing schemes, and enforcing the anti-kickback laws where these practices affect the Federal health care programs. What To Look For Generally, a payment or gift may be considered improper under 42 U.S.C. 1320a-7b(b) if it is:

- Made to a person in a position to generate business for the paying party;
- Related to the volume of business generated; and
- More than nominal in value and/or exceeds fair market value of any legitimate service rendered to the payer, or is unrelated to any service at all other than referral of patients. OIG investigation may be warranted where one or more of the following features is present in prescription drug marketing activities:
- Any prize, gift or cash payment, coupon or bonus (e.g., airline discounts and related travel premiums), offered to physicians and/or suppliers (including pharmacies, mail order prescription drug companies and managed care organizations) in exchange for, or based on, prescribing or providing specific prescription products. These items are particularly suspect if based on value or volume of business generated for the drug company.
- Materials which offer cash or other benefits to pharmacists (or others in a position to recommend prescription drug products) in exchange for performing marketing tasks in the course of pharmacy practice related to Medicare or Medicaid. The marketing tasks may include sales-oriented ``educational'' or ``counseling'' contacts, or physician and/or patient outreach, etc.
- Grants to physicians and clinicians for studies of prescription products when the studies are of questionable scientific value and require little or no actual scientific pursuit. The grants may nonetheless offer substantial benefits based on, or related to, use of the product.
- Any payment, including cash or other benefit, given to a patient, provider or supplier for changing a prescription, or recommending or requesting such a change, from one product to another, unless the payment is made fully consistent with a ``safe harbor'' regulation, 42 CFR 1001.952, or other Federal provision governing the reporting of prescription drug prices. F. Special Fraud Alert: Arrangements for the Provision of Clinical Lab Services (Issued October 1994) How Does the Anti-Kickback Statute Relate to Arrangements for the Provision of Clinical Lab Services? Many physicians and other health care providers rely on the services of outside clinical laboratories to which they may refer high volumes of patient specimens every day. The quality, timeliness and cost of these services are of obvious concern to Medicare and Medicaid patients and to the programs that finance their health care services. Since the physician, not the patient, generally selects the clinical laboratory, it is essential that the physician's decision regarding where to refer specimens is based only on the best interests of the patient. Whenever a laboratory offers or gives to a source of referrals anything of value not paid for at fair market value, the inference may be made that the thing of value is offered to induce the referral of

business. The same is true whenever a referral source solicits or receives anything of value from the laboratory. By ``fair market value'' we mean value for general commercial purposes. However, ``fair market value'' must reflect an arms length transaction which has not been adjusted to include the additional value which one or both of the parties has attributed to the referral of business between them. The office of Inspector General has become aware of a number of practices engaged in by clinical laboratories and health care providers that implicate the anti-kickback statute in this manner. Below are some examples of lab services arrangements that may violate the anti- kickback statute. Provision of Phlebotomy Services to Physicians When permitted by State law, a laboratory may make available to a physician's office a phlebotomist who collects specimens from patients for testing by the outside laboratory. While the mere placement of a laboratory employee in the physician's office would not necessarily serve as an inducement prohibited by the anti-kickback statute, the statute is implicated when the phlebotomist performs additional tasks that are normally the responsibility of the physician's office staff. These tasks can include taking vital signs or other nursing functions, testing for the physician's office laboratory, or performing clerical services. Where the phlebotomist performs clerical or medical functions not directly related to the collection or processing of laboratory specimens, a strong inference arises that he or she is providing a benefit in return for the physician's referrals to the laboratory. In such a case, the physician, the phlebotomist, and the laboratory may have exposure under the anti-kickback statute. This analysis applies equally to the placement of phlebotomists in other health care settings, including nursing homes, clinics and hospitals. Furthermore, the mere existence of a contract between the laboratory and the health care provider that prohibits the phlebotomist from performing services unrelated to specimen collection does not eliminate the OIG's concern, where the phlebotomist is not closely monitored by his [of her] employer or where the contractual prohibition is not rigorously enforced. Lab Pricing at Renal Dialysis Centers The Medicare program pays for laboratory tests provided to patients with end stage renal disease (ESRD) in two different ways. Some laboratory testing is considered routine and payment is included in the composite rate paid by Medicare to the ESRD facility which in turn pays the laboratory. Some laboratory testing required by the patient is not included in the composite rate, and these additional tests are billed by the laboratory directly to Medicare and paid at the usual laboratory fee schedule price. The OIG is aware of cases where a laboratory offers to perform the tests encompassed by the composite rate at a price below fair market value of the tests performed. In order to offset the low charges on the composite rate tests, the ESRD facility agrees to refer all or most of its non-composite rate tests to the laboratory. This arrangement appears to be an offer of something of value (composite rate tests below fair market value) in return for the ordering of additional tests which are billed directly to the Medicare program. If offered or accepted in return for referral of additional business, the lab's pricing scheme is illegal remuneration under the anti-kickback statute. The statutory exception and ``safe harbor'' for ``discounts'' does not apply to immunize parties to this type of transaction, since discounts on the composite rate tests are offered to induce referral of other tests. See 42 CFR 1001.952(h)(3)(ii). Waiver of Charges To Managed Care Patients Managed care plans may require a physician or other health care provider to use only the laboratory with which the plan has negotiated a fee schedule. In such situations, the plan usually will refuse to pay claims submitted by other laboratories. The provider, however, may use a different laboratory and may wish to continue to use that laboratory for non-managed care patients. In order to retain the provider as a client, the laboratory that does not have the managed care contract may agree to perform the managed care work free of charge. The status of such

agreements under the anti-kickback statute depends in part on the nature of the contractual relationship between the managed care plan and its providers. Under the terms of many managed care contracts, a provider receives a bonus or other payment if utilization of ancillary services, such as laboratory testing, is kept below a particular level. Other managed care plans impose financial penalties if the provider's utilization of services exceeds pre- established levels. When the laboratory agrees to write off charges for the physician's managed care work, the physician may realize a financial benefit from the managed care plan created by the appearance that utilization of tests has been reduced. In cases where the provision of free services results in a benefit to the provider, the anti-kickback statute is implicated. If offered or accepted in return for the referral of Medicare or State health care plan business, both the laboratory and the physician may be violating the anti-kickback statute. There is no statutory exception or ``safe harbor'' to immunize any party to such a practice because the Federal programs do not realize the benefit of these ``free'' services. See 42 CFR 1001.952(h)(3)(iii). Other Inducements The following are additional examples of inducements offered by clinical laboratories which may implicate the anti-kickback statute:

- Free pick-up and disposal of bio-hazardous waste products (such as sharps) unrelated to the collection of specimens for the outside laboratory.
- Provision of computers or fax machines, unless such equipment is integral to, and exclusively used for, performance of the outside laboratory's work.
- Provision of free laboratory testing for health care providers, their families and their employees. When one purpose of these arrangements is to induce the referral of program-reimbursed laboratory testing, both the clinical laboratory and the health care provider may be liable under the statute and may be subject to criminal prosecution and exclusion from participation in the Medicare and Medicaid programs. G. Reporting Information What To Do If You Have Information About Suspect Activities or Arrangements If you have information about health care providers, practitioners, entities or other persons engaging in these types of activities or arrangements described above, contact any of the regional offices of the Office of Investigations of the Office of Inspector General, U.S. Department of Health and Human Services, at the following locations: ---------- Regions States served Telephone ---------- Boston..... MA, VT, NH, ME, RI, CT..... 617-565-2660 New York..... NY, NJ, PR, VI..... 212-264-1691 Philadelphia..... PA, MD, DE, WV, VA..... 215-596-6796 Atlanta..... GA, KY, NC, SC, FL, TN, AL, MS 404-331-2131 (No. District). Chicago..... IL, MN, WI, MI, IN, OH, IA, MO.... 312-353-2740 Dallas..... TX, NM, OK, AR, LA, MS (So. 214-767-8406 District). Denver..... CO, UT, WY, MT, ND, SD, NE, KS.... 303-844-5621 Los Angeles..... AZ, NV (Clark Co.), So. CA..... 714-836-2372 San Francisco..... No. CA, NV, AZ, HI, OR, ID, WA.... 415-556-8880 Washington, DC..... DC and Metropolitan areas of VA 202-619-1900 and MD. ---------- Dated: December 2, 1994. June Gibbs Brown, Inspector General. [FR Doc. 94-31157 Filed 12-16-94; 8:45 am] BILLING CODE 4150-04-P