

to prevent loss of propeller control because of hardening or blocking of the control cable, which could result in the inability to control propeller pitch and inability to feather the

propeller. Such failure could lead to loss of airplane control.

(d) *What actions must I accomplish to address this problem?* To address this

problem, you must do the following, unless already accomplished:

Actions	Compliance	Procedures
Install a thermal protection sleeve on the propeller control cable.	Within the next 100 hours time-in-service (TIS) after the effective date of this AD or within the next 3 calendar months after the effective date of this AD, whichever occurs first, unless already done.	Do this installation following the ACCOMPLISHMENT INSTRUCTIONS of Socata Service Bulletin SB 70-084, dated September 2000, and the applicable maintenance manual.

(e) *Can I comply with this AD in any other way?* You may use an alternative method of compliance or adjust the compliance time if:

(1) Your alternative method of compliance provides an equivalent level of safety; and
 (2) The Manager, Small Airplane Directorate, approves your alternative. Send your request through an FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Small Airplane Directorate.

Note 1: This AD applies to each airplane identified in paragraph (a) of this AD, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (e) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if you have not eliminated the unsafe condition, specific actions you propose to address it.

(f) *Where can I get information about any already-approved alternative methods of compliance?* Contact Karl Schletzbaum, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64016; telephone: (816) 329-4146; facsimile: (816) 329-4090.

(g) *What if I need to fly the airplane to another location to comply with this AD?* The FAA can issue a special flight permit under sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate your airplane to a location where you can accomplish the requirements of this AD.

(h) *How do I get copies of the documents referenced in this AD?* You may get copies of the documents referenced in this AD from SOCATA Groupe AEROSPATIALE, Customer Support, Aerodrome Tarbes-Ossun-Lourdes, BP 930—F65009 Tarbes Cedex, France; or the Product Support Manager, SOCATA—Groupe AEROSPATIALE, North Perry Airport, 7501 Pembroke Road, Pembroke Pines, Florida 33023. You may look at these documents at FAA, Central Region, Office of the Regional Counsel, 901 Locust, Room 506, Kansas City, Missouri 64106.

Note 2: The subject of this AD is addressed in French AD 2000-430(A), dated November 15, 2000.

Issued in Kansas City, Missouri, on December 7, 2000.

Larry E. Werth,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

42 CFR Part 1001

Solicitation of New Safe Harbors and Special Fraud Alerts

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Notice of intent to develop regulations.

SUMMARY: In accordance with section 205 of the Health Insurance Portability and Accountability Act (HIPAA) of 1996, this annual notice solicits proposals and recommendations for developing new and modifying existing safe harbor provisions under the Federal and State health care programs' anti-kickback statute, as well as developing new OIG Special Fraud Alerts.

DATES: To assure consideration, public comments must be delivered to the address provided below by no later than 5 p.m. on February 12, 2001.

ADDRESSES: Please mail or deliver your written comments to the following address: Office of Inspector General, Department of Health and Human Services, Attention: OIG-51-N, Room 5246, Cohen Building, 330 Independence Avenue, SW., Washington, DC 20201.

We do not accept comments by facsimile (FAX) transmission. In commenting, please refer to file code OIG-51-N. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 5541 of the Office of Inspector General at 330 Independence Avenue, SW.,

Washington, DC, on Monday through Friday of each week from 8:00 a.m. to 4:30 p.m.

FOR FURTHER INFORMATION CONTACT: Joel Schaer, (202) 619-0089, OIG Regulations Officer.

SUPPLEMENTARY INFORMATION:

I. Background

A. The OIG Safe Harbor Provisions

Section 1128B(b) of the Social Security Act (the Act) (42 U.S.C. 1320a-7b(b)) provides criminal penalties for individuals or entities that knowingly and willfully offer, pay, solicit or receive remuneration in order to induce business reimbursed under the Federal or State health care programs. The offense is classified as a felony, and is punishable by fines of up to \$25,000 and imprisonment for up to 5 years. The OIG may also impose administrative sanctions or exclude violators from the Federal or State health care programs.

The types of remuneration covered specifically include kickbacks, bribes, and rebates, whether made directly or indirectly, overtly or covertly, or in cash or in kind. In addition, prohibited conduct includes not only remuneration intended to induce referrals of patients, but remuneration intended to induce the arranging for or the purchasing, leasing or ordering of any good, facility, service, or item paid for by Federal or State health care programs.

Since the statute on its face is so broad, concern has been expressed for many years that some relatively innocuous commercial arrangements are technically covered by the statute and are, therefore, subject to criminal prosecution. As a response to the above concern, the Medicare and Medicaid Patient and Program Protection Act of 1987, section 14 of Public Law 100-93, specifically required the development and promulgation of regulations, the so-called "safe harbor" provisions, designed to specify various payment and business practices which, although potentially capable of inducing referrals of business under the Federal and State health care programs, would not be treated as criminal offenses under the

anti-kickback statute (section 1128B(b) of the Act; 42 U.S.C. 1320a-7(b)) and would not serve as a basis for a program exclusion under section 1128(b)(7) of the Act; 42 U.S.C. 1320a-7(b)(7). The OIG safe harbor provisions have been developed “to limit the reach of the statute somewhat by permitting certain non-abusive arrangements, while encouraging beneficial and innocuous arrangements” (56 FR 35952, July 29, 1991). Health care providers and others may voluntarily seek to comply with these provisions so that they have the assurance that their business practices are not subject to any enforcement action under the anti-kickback statute or program exclusion authority.

To date, the OIG has developed and codified in 42 CFR 1001.952 a total of 21 final safe harbors that describe practices that are sheltered from liability. The OIG is also currently developing a final safe harbor rule addressing ambulance restocking arrangements.

B. OIG Special Fraud Alerts

In addition, the OIG has also periodically issued Special Fraud Alerts to give continuing guidance to health care providers with respect to practices the OIG regards as unlawful. These Special Fraud Alerts serve to notify the health care industry that the OIG has become aware of certain abusive practices that the OIG plans to pursue and prosecute, or to bring civil and administrative action, as appropriate. The Special Fraud Alerts also serve as a tool to encourage industry compliance by giving providers an opportunity to examine their own practices. The OIG Special Fraud Alerts are intended for extensive distribution directly to the health care provider community, as well as those charged with administering the Medicare and Medicaid programs.

In developing these Special Fraud Alerts, the OIG has relied on a number of sources and has consulted directly with experts in the subject field, including those within the OIG, other agencies of the Department, other Federal and State agencies, and those in the health care industry. To date, ten individual Special Fraud Alerts have been issued by the OIG and subsequently reprinted in the **Federal Register**.¹

¹ See 59 FR 65372 (December 19, 1994); 60 FR 40847 (August 10, 1995); 61 FR 30623 (June 17, 1996); 63 FR 20415 (April 24, 1998); and 64 FR 1813 (January 12, 1999). The OIG has also issued three Special Advisory Bulletins—64 FR 37985 (July 14, 1999); 64 FR 52791 (September 30, 1999); and 64 FR 61353 (November 10, 1999).

C. Section 205 of Public Law 104-191

Section 205 of Public Law 104-191 requires the Department to develop and publish an annual notice in the **Federal Register** formally soliciting proposals for modifying existing safe harbors to the anti-kickback statute and for developing new safe harbors and Special Fraud Alerts.

In developing safe harbors for a criminal statute, the OIG is compelled to engage in a complete and thorough review of the range of factual circumstances that may fall within the proposed safe harbor subject area so as to uncover all potential opportunities for fraud and abuse. Only then can the OIG determine, in consultation with the Department of Justice, whether it can effectively develop regulatory limitations and controls that will permit beneficial and innocuous arrangements within a subject area while, at the same time, protecting the Federal health care programs and their beneficiaries from abusive practices.

II. Solicitation of Additional New Recommendations and Proposals

In accordance with the requirements of section 205 of Public Law 104-191, the OIG is continuing to study safe harbor and Special Fraud Alert proposals submitted in response to the annual solicitations. Some of those suggestions have been addressed in the safe harbor rulemakings published on November 19, 1999 (64 FR 63504 and 64 FR 63518) or are already under development. The OIG last published a **Federal Register** solicitation notice for developing new safe harbors and Special Fraud Alerts on December 10, 1999 (64 FR 69217). The OIG received 17 timely-filed responses from a cross-section of organizations, associations and other interested parties. In response to that and previously-issued **Federal Register** solicitation notices, a status report of the public comments received for new and modified safe harbors is set forth in Appendix G to the OIG's Semiannual Report covering the period April 1, 2000 through September, 30, 2000.² OIG is currently taking the recommendations listed in the appendix under advisement and is not seeking additional public comment on those proposals at this time. Rather, this notice seeks additional recommendations from affected provider, practitioner, supplier and beneficiary representatives regarding the development of proposed or modified safe harbor regulations and new Special

² The OIG Semiannual Report can be accessed through the OIG web site at <http://www.dhhs.gov/oig/semann/index.htm>.

Fraud Alerts beyond those summarized in the appendix to the OIG Semiannual Report referenced above.

Criteria for modifying and establishing safe harbor provisions

In accordance with the statute, we will consider a number of factors in reviewing proposals for new or modified safe harbor provisions, such as the extent to which the proposals would effect an increase or decrease in—

- Access to health care services;
- The quality of care services;
- Patient freedom of choice among health care providers;
- Competition among health care providers;
- The cost to Federal health care programs;
- The potential overutilization of the health care services; and
- The ability of health care facilities to provide services in medically underserved areas or to medically underserved populations.

In addition, we will also take into consideration the existence (or nonexistence) of any potential financial benefit to health care professionals or providers that may vary based on their decisions whether to (1) order a health care item or service, or (2) arrange for a referral of health care items or services to a particular practitioner or provider.

Criteria for Developing Special Fraud Alerts

In determining whether to issue additional Special Fraud Alerts, we will also consider whether, and to what extent, those practices that would be identified in new Special Fraud Alerts may result in any of the consequences set forth above, and the volume and frequency of the conduct that would be identified in these Special Fraud Alerts.

A detailed explanation of justifications or empirical data supporting the suggestion, and sent to the address indicated above, would prove helpful in our considering and drafting new or modified safe harbor regulations and Special Fraud Alerts.

Dated: December 7, 2000.

June Gibbs Brown,

Inspector General.

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