Department of the Treasury is soliciting comments on the effectiveness of OFAC's licensing procedures for the exportation of agricultural commodities, medicine, and medical devices to Sudan and Iran. Pursuant to section 906(c) of the Trade Sanctions Reform and Export Enhancement Act of 2000 (Title IX of Pub. L. 106–387, 22 U.S.C. 7201 *et seq.*) (the ''Act''), OFAC is required to submit a biennial report to the Congress on the operation of licensing procedures for such exports.

DATES: Written comments should be received on or before January 10, 2007 to be assured of consideration.

ADDRESSES: Direct all written comments to the Licensing Division, Office of Foreign Assets Control, Department of the Treasury, 1500 Pennsylvania Avenue, NW., Washington, DC 20220.

FOR FURTHER INFORMATION CONTACT: Requests for additional information about these licensing procedures should be directed to the Licensing Division, Office of Foreign Assets Control, Department of the Treasury, 1500 Pennsylvania Avenue, NW., Washington, DC 20220, telephone: (202) 622–2480. Additional information about these licensing procedures is also available under the heading ''Other OFAC Sanctions Programs'' at *http://www.treas.gov/ofac.*

SUPPLEMENTARY INFORMATION: The current procedures used by OFAC for authorizing the export of agricultural commodities, medicine, and medical devices to Sudan and Iran are set forth in 31 CFR 538.523–526 and 31 CFR 560.530–533. Under the provisions of section 906(c) of the Act, OFAC must submit a biennial report to the Congress on the operation, during the preceding two-year period, of the licensing procedures required by section 906 of the Act for the export of agricultural commodities, medicine, and medical devices to Sudan and Iran. This report is to include:

(1) The number and types of licenses applied for;

(2) The number and types of licenses approved;

(3) The average amount of time elapsed from the date of filing of a license application until the date of its approval;

(4) The extent to which the licensing procedures were effectively implemented; and

(5) A description of comments received from interested parties about the extent to which the licensing procedures were effective, after holding a public 30-day comment period.

This notice solicits comments from interested parties regarding the effectiveness of OFAC's licensing procedures for the export of agricultural commodities, medicine, and medical devices to Sudan and Iran. Interested parties submitting comments are asked to be as specific as possible. All comments received on or before January 10, 2007 will be considered by OFAC in developing the report to the Congress. In the interest of accuracy and completeness, OFAC requires written comments. Comments received after the end of the comment period will be considered, if possible, but their consideration cannot be assured. OFAC will not accept comments accompanied by a request that part or all of the comments be treated confidentially because of their business proprietary nature or for any other reason. OFAC will return such comments when submitted by regular mail to the person submitting the comments and will not consider them. All comments made will be a matter of public record. Copies of the public record concerning these regulations may be obtained from OFAC's Web site (*http://www.treas.gov/ofac*). If that service is unavailable, written requests may be sent to: Office of Foreign Assets Control, U.S. Department of the Treasury, 1500 Pennsylvania Ave., NW., Washington, DC 20220, Attn: Merete Evans.

Effective September 21, 2004, Executive Order 13357 terminated the national emergency declared in Executive Order 12543 of January 7, 1986, with respect to the policies and actions of the Government of Libya and revoked Executive Orders 12543, 12544 of January 8, 1986, and 12801 of April 15, 1992 (all of which had imposed sanctions against Libya in response to the national emergency). Consequently, the prohibitions of the Libyan Sanctions Regulations, 31 CFR Part 550 (the ''LSR''), have been lifted, and all property and interests in property blocked under the LSR have been unblocked. Accordingly, specific licenses issued by OFAC for the export of agricultural commodities, medicine, and medical devices to Libya are no longer required pursuant to the LSR and, therefore, OFAC is not soliciting comments on its licensing procedures under that program. This termination of the Libya Sanctions does not, however, eliminate the need to comply with other provisions of law, including the Export Administration Regulations, 15 CFR parts 730 *et seq.*, which are administered by the U.S. Department of Commerce.

Approved: November 28, 2006.

Adam J. Szubin,

Director, Office of Foreign Assets Control.

[FR Doc. E6–21005 Filed 12–8–06; 8:45 am]

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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 anti-kickback statute (section 1128B(b) of the Social Security Act), 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 9, 2007.

ADDRESSES: Please mail or deliver your written comments to the following address: Office of Inspector General, Department of Health and Human Services, Attention: OIG–111–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–111–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 a.m. to 4:30 p.m.

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

SUPPLEMENTARY INFORMATION:

I. Background

A. 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 or reward business reimbursable under the Federal 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. OIG may also impose civil money penalties, in accordance with section 1128A(a)(7) of the Act (42 U.S.C. 1320a–7a(a)(7)), or exclusion from the Federal health care programs, in accordance with section 1128(b)(7) of the Act (42 U.S.C. 1320a–7(b)(7)).

Since the statute on its face is so broad, concern has been expressed for many years that some relatively innocuous commercial arrangements may be subject to criminal prosecution or administrative sanction. In 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, specifying various payment and business practices which, although potentially capable of inducing referrals of business reimbursable under the Federal health care programs, would not be treated as criminal offenses under the anti-kickback statute and would not serve as a basis for administrative sanctions. 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 will not be subject to liability under the anti-kickback statute or related administrative authorities.

Existing OIG safe harbors describing those practices that are sheltered from liability are codified in 42 CFR 1001.

B. OIG Special Fraud Alerts

OIG has also periodically issued Special Fraud Alerts to give continuing guidance to health care providers with respect to practices OIG finds potentially fraudulent or abusive. The Special Fraud Alerts encourage industry compliance by giving providers guidance that can be applied to their own practices. OIG Special Fraud Alerts are intended for extensive distribution directly to the health care provider community, as well as to those charged with administering the Federal health care programs.

In developing these Special Fraud Alerts, OIG has relied on a number of sources and has consulted directly with experts in the subject field, including those within OIG, other agencies of the Department, other Federal and State agencies, and those in the health care industry.

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, OIG is required to engage in a thorough review of the range of factual circumstances that may fall within the proposed safe harbor subject area so as to uncover potential opportunities for fraud and abuse. Only then can 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, OIG last published a **Federal Register** solicitation notice for developing new safe harbors and Special Fraud Alerts on December 9, 2005 (70 FR 73186). As required under section 205, a status report of the public comments received in response to that notice is set forth in Appendix F to the OIG's Semiannual Report covering the period April 1, 2006, through September 30, 2006.[1] OIG is not seeking additional public comment on the proposals listed in Appendix F at this time. Rather, this notice seeks additional recommendations regarding the development of proposed or modified safe harbor regulations and new Special Fraud Alerts beyond those summarized in Appendix F to the OIG Semiannual Report referenced above.

A. Criteria for Modifying and Establishing Safe Harbor Provisions

In accordance with section 205 of HIPAA, 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 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 other factors, including, for example, the existence (or nonexistence) of any potential financial benefit to health care professionals or providers that may take into account 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.

B. Criteria for Developing Special Fraud Alerts

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

A detailed explanation of justifications for, or empirical data supporting, a suggestion for a safe harbor or Special Fraud Alert would be helpful and should, if possible, be included in any response to this solicitation.

Dated: December 6, 2006.

Daniel R. Levinson,

Inspector General.

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[1] The OIG Semiannual Report can be accessed through the OIG Web site at *http://oig.hhs.gov/publications/semiannual.html.*