

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 8, 1999.

ADDRESSES: Please mail or deliver your written comments to the following address: Office of Inspector General, Department of Health and Human Services, Attention: OIG-31-N, Room 5246, Cohen Building, 330 Independence Avenue, S.W., Washington, D.C. 20201.

We do not accept comments by facsimile (FAX) transmission. In commenting, please refer to file code OIG-31-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, S.W., Washington, D.C., 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 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 purchasing, leasing, ordering, or arranging for 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-7b(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 13 final safe harbors that describe practices that are sheltered from liability. The OIG is also currently drafting a comprehensive safe harbor rule that intends to finalize certain proposals for new and clarified safe harbors that were published in the **Federal Register** in 1993 and 1994 (58 FR 49008, September 21, 1993 and 59 FR 37202, July 21, 1994). The OIG is also developing an interim final rule for the shared-risk exception to the anti-kickback statute (section 216 of HIPAA). This rule, which will set forth two new safe harbors, is being developed through the negotiated rulemaking process in accordance with the requirements of

HIPAA and the Federal Advisory Committee Act.

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, nine individual Special Fraud Alerts have been issued by the OIG and subsequently reprinted in the **Federal Register** on December 19, 1994 (59 FR 65372), August 10, 1995 (60 FR 40847), June 17, 1996 (61 FR 30623) and April 24, 1998 (63 FR 20415).

C. Section 205 of Public Law 104-191

In accordance with the Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191), the Department is now required to provide additional formal guidance regarding the application of the anti-kickback statute and the safe harbor provisions, as well as other OIG health care fraud and abuse sanctions. In addition to accepting and responding to requests for advisory opinions from outside parties regarding the interpretation and applicability of certain statutes relating to the Federal and State health care programs, 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 accordance with this requirement, the OIG has published notices in the **Federal Register** on December 31, 1996 (61 FR 69060) and on December 10, 1997 (62 FR 65049) soliciting such proposals.

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 concerning subject areas other than those to be addressed in the safe harbor rulemakings under development. In response to the 2 previously-issued **Federal Register** solicitation notices, the OIG received 32 timely-filed responses to the 1996 notice and 17 responses to the 1997 notice. A status report of these public comments for new and modified safe harbors is contained in Appendix G of the OIG's Semiannual Report for the period April 1, 1998 through September 30, 1998.¹ The OIG is currently taking these recommendations 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 Fraud Alerts beyond those summarized in Appendix G of the OIG Semiannual Report.

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 4, 1998.

June Gibbs Brown,

Inspector General.

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 54

[CC Docket No. 96-45; FCC 98-278]

Federal-State Joint Board on Universal Service

AGENCY: Federal Communications Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: Between September, 1997 and March, 1998, the Commission's Wireless Telecommunications Bureau and Common Carrier Bureau hosted a series of *ex parte* meetings with representatives of the wireless telecommunications industry. The Bureau's primary objective in hosting those meetings was to solicit proposals on methods by which wireless telecommunications providers might allocate between the intrastate and

interstate jurisdictions their end-user telecommunications revenues for purposes of the universal service reporting requirements. In this document, the Commission seeks comment on what amount of local usage, if any, eligible telecommunications carriers should be required to provide.

DATES: Comments are due on or before January 11, 1999 and reply comments are due on or before January 25, 1999.

Written comments by the public on the proposed information collections are due January 11, 1999. Written comments must be submitted by the Office of Management and Budget (OMB) on the proposed information collections on or before February 8, 1999.

ADDRESSES: Parties who choose to file by paper must file an original and four copies of each filing. All filings must be sent to the Commission's Secretary, Magalie Roman Salas, Office of the Secretary, Federal Communications Commission, 445 Twelfth Street, S.W., TW-A325, Washington, D.C. 20554. In addition to filing comments with the Secretary, a copy of any comments on the information collections contained herein should be submitted to Judy Boley, Federal Communications Commission, Room 234, 1919 M Street, N.W., Washington, DC 20554, or via the Internet to jboley@fcc.gov, and to Timothy Fain, OMB Desk Officer, 10236 NEOB, 725-17th Street, N.W., Washington, DC 20503 or via the Internet to fain_t@al.eop.gov.

FOR FURTHER INFORMATION CONTACT: Lori Wright, Attorney, Common Carrier Bureau, Accounting Policy Division, (202) 418-7400. For additional information concerning the information collections contained in this Further Notice of Proposed Rulemaking contact Judy Boley at 202-418-0214, or via the Internet at jboley@fcc.gov.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's document released on October 26, 1998. The full text of this document is available for public inspection during regular business hours in the FCC Reference Center, Room 239, 1919 M Street, N.W., Washington, D.C., 20554.

Initial Paperwork Reduction Act Analysis

1. This Further Notice of Proposed Rulemaking (Further Notice) contains a proposed information collection. The Commission, as part of its continuing effort to reduce paperwork burdens, invites the general public and the Office of Management and Budget (OMB) to comment on the information collections

¹ The OIG Semiannual Report can be accessed through the OIG web site at <http://www.dhhs.gov/progorg/oig/semann/index.htm>.