

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 10, 2004.

ADDRESSES: Please mail or deliver your written comments to the following address: Office of Inspector General, Department of Health and Human Services, Attention: OIG-81-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-81-N. Comments received timely will be available for public inspection as they are received, generally beginning approximately three 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. 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 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. The OIG may also impose civil money penalties, in accordance with section 1128A(a)(7) of the Act (42 U.S.C. 1320a-7(a)(7)), or 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. 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 will not be subject to any enforcement action under the anti-kickback statute or related administrative authorities.

To date, the OIG has developed and codified in 42 CFR 1001.952 a total of 22 final safe harbors that describe practices that are sheltered from liability.

B. OIG Special Fraud Alerts

The OIG has also periodically issued Special Fraud Alerts to give continuing guidance to health care providers with respect to practices the 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. 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 Federal health care 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, the OIG has issued 12 individual Special Fraud Alerts.

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 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 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 last published a **Federal Register** solicitation notice for developing new safe harbors and Special Fraud Alerts on December 9, 2002 (67 FR 72894). As required under section 205, a status report of the public comments received in response to that notice is set forth in appendix G to the OIG's Semiannual Report covering the period April 1, 2003 through September, 30, 2003.¹ The OIG is not seeking additional public comment on the proposals listed in appendix G 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 G to the OIG Semiannual Report referenced above.

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 affect 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 vary based on their

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