

Agency, Air Planning and Development Branch, 901 North 5th Street, Kansas City, Kansas 66101. Comments may also be submitted electronically or through hand delivery/courier by following the detailed instructions in the **ADDRESSES** section of the direct final rule located in the rules section of this **Federal Register**.

**FOR FURTHER INFORMATION CONTACT:** Tracey Casburn at (913) 551-7016, or by e-mail at [casburn.tracey@epa.gov](mailto:casburn.tracey@epa.gov).

**SUPPLEMENTARY INFORMATION:** In the final rules section of the **Federal Register**, EPA is approving the state's revision as a direct final rule without prior proposal because the Agency views this as a noncontroversial revision amendment and anticipates no relevant adverse comments to this action. A detailed rationale for the approval is set forth in the direct final rule. If no relevant adverse comments are received in response to this action, no further activity is contemplated in relation to this action. If EPA receives relevant adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed action. EPA will not institute a second comment period on this action. Any parties interested in commenting on this action should do so at this time. Please note that if EPA receives adverse comment on part of this rule and if that part can be severed from the remainder of the rule, EPA may adopt as final those parts of the rule that are not the subject of an adverse comment. For additional information, see the direct final rule which is located in the rules section of this **Federal Register**.

Dated: December 15, 2009.

**William Rice,**

*Acting Regional Administrator, Region 7.*

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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 March 1, 2010.

**ADDRESSES:** In commenting, please refer to file code OIG-114-N. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of three ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments on specific recommendations and proposals through the Federal eRulemaking Portal at <http://www.regulations.gov>. (Attachments should be in Microsoft Word, if possible.)

2. *By regular, express, or overnight mail.* You may send written comments to the following address: Office of Inspector General, Department of Health and Human Services, Attention: OIG-114-N, Room 5541, Cohen Building, 330 Independence Avenue, SW., Washington, DC 20201. Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By hand or courier.* If you prefer, you may deliver, by hand or courier, your written comments before the close of the comment period to Office of Inspector General, Department of Health and Human Services, Cohen Building, 330 Independence Avenue, SW., Washington, DC 20201. Because access to the interior of the Cohen Building is not readily available to persons without Federal Government identification, commenters are encouraged to schedule their delivery with one of our staff members at (202) 619-1343.

For information on viewing public comments, please see the **SUPPLEMENTARY INFORMATION** section.

**FOR FURTHER INFORMATION CONTACT:** Patrice Drew, Department of Health & Human Services, Office of Inspector General, Office of External Affairs, (202) 619-1368.

**SUPPLEMENTARY INFORMATION:**

*Submitting Comments:* We welcome comments from the public on recommendations for developing new or revised safe harbors and Special Fraud Alerts. Please assist us by referencing the file code OIG-114-N.

*Inspection of Public Comments:* All comments received before the end of the comment period are available for viewing by the public. All comments will be posted on <http://www.regulations.gov> as soon as possible after they have been received. Comments received timely will also be available for public inspection as they are received at Office of Inspector General, Department of Health and Human Services, Cohen Building, 330 Independence Avenue, SW., Washington, DC 20201, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone (202) 401-2206.

### 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 part 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 17, 2008 (73 FR 76575). As required under section 205, a status

report of the public comments received in response to that notice is set forth in Appendix D to the OIG's Semiannual Report covering the period April 1, 2009, through September 30, 2009.<sup>1</sup> OIG is not seeking additional public comment on the proposals listed in Appendix D 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 D 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 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 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

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

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 14, 2009.

**Daniel R. Levinson,**

*Inspector General.*

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## FEDERAL COMMUNICATIONS COMMISSION

### 47 CFR Parts 32, 36 and 54

[WC Docket No. 05-337; CC Docket No. 96-45; FCC 09-112]

### High-Cost Universal Service Support; Federal-State Joint Board on Universal Service

**AGENCY:** Federal Communications Commission.

**ACTION:** Further notice of proposed rulemaking.

**SUMMARY:** In this document, the Commission responds to the decision of the United States Court of Appeals for the Tenth Circuit in *Qwest Communications International, Inc. v. FCC* and seeks comment on certain interim changes to address the court's concerns and changes in the marketplace.

**DATES:** Comments are due on or before January 28, 2010 and reply comments are due on or before February 12, 2010.

**ADDRESSES:** You may submit comments, identified by WC Docket No. 05-337; CC Docket No. 96-45, by any of the following methods:

■ **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the instructions for submitting comments.

■ **Federal Communications Commission's Web Site:** <http://fjallfoss.fcc.gov/ecfs2/>. Follow the instructions for submitting comments.

■ **People with Disabilities:** Contact the FCC to request reasonable accommodations (accessible format documents, sign language interpreters, CART, etc.) by e-mail: [FCC504@fcc.gov](mailto:FCC504@fcc.gov) or phone: 202-418-0530 or TTY: 202-418-0432.

For detailed instructions for submitting comments and additional information on the rulemaking process, see the **SUPPLEMENTARY INFORMATION** section of this document.

**FOR FURTHER INFORMATION CONTACT:** Katie King, Wireline Competition Bureau, Telecommunications Access Policy Division, 202-418-7400 or TTY: 202-418-0484.