

procedure by submitting written comments in accordance with the instructions outlined earlier in this notice.

V. Statutory and Executive Order Reviews

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this proposed action is not a "significant regulatory action" and therefore is not subject to review by the Office of Management and Budget. For this reason, this action is also not subject to Executive Order 13211, "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001). This proposed action merely proposes to approve a redesignation to attainment and imposes no additional requirements beyond those imposed by state law. Redesignation of an area to attainment under section 107 of the Clean Air Act is an action that affects the attainment status of a geographical area and does not impose any new regulatory requirements on sources. Accordingly, the Administrator certifies that this proposed rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Because this rule proposes to approve a redesignation to attainment and does not impose any additional enforceable duty beyond that required by state law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4).

This proposed rule also does not have tribal implications because it will not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). This action also does not have Federalism implications because it does not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This action merely proposes to approve a redesignation to attainment and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act. This proposed rule also is not subject to Executive Order 13045 "Protection of Children from

Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997), because it is not economically significant.

Section 12(d) of the National Technology Transfer Advancement Act (NTTAA) of 1995, Public Law 104-113, section 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards (VCS) in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impracticable. VCS are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by VCS bodies. This action does not involve technical standards. Therefore, EPA did not consider the use of any VCS. This proposed rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

List of Subjects in 40 CFR Part 81

Air pollution control, National parks, Wilderness areas.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: November 28, 2005.

Robert E. Roberts,

Regional Administrator, Region 8.

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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 7, 2006.

ADDRESSES: Please mail or deliver your written comments to the following

address: Office of Inspector General, Department of Health and Human Services, Attention: OIG-101-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-101-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 any enforcement action under the anti-kickback statute or related administrative authorities.

To date, 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

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. To date, 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, 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 10, 2004 (69 FR 71766). 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, 2005, through September 30, 2005.¹ 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 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 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: November 30, 2005.

Daniel R. Levinson,

Inspector General.

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DEPARTMENT OF DEFENSE

48 CFR Parts 208, 252, and 253 and Appendix B to Chapter 2

[DFARS Case 2003–D072]

Defense Federal Acquisition Regulation Supplement; Required Sources of Supply

AGENCY: Department of Defense (DoD).

ACTION: Proposed rule with request for comments.

SUMMARY: DoD is proposing to amend the Defense Federal Acquisition Regulation Supplement (DFARS) to update text addressing acquisitions made through Government supply sources. This proposed rule is a result of a transformation initiative undertaken by DoD to dramatically change the purpose and content of the DFARS.

DATES: Comments on the proposed rule should be submitted in writing to the address shown below on or before February 7, 2006, to be considered in the formation of the final rule.

ADDRESSES: You may submit comments, identified by DFARS Case 2003–D072, using any of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.
- *Defense Acquisition Regulations Web Site:* <http://emissary.acq.osd.mil/dar/dfars.nsf/pubcomm>. Follow the instructions for submitting comments.
- *E-mail:* dfars@osd.mil. Include DFARS Case 2003–D072 in the subject line of the message.
- *Fax:* (703) 602–0350.
- *Mail:* Defense Acquisition Regulations Council, Attn: Ms. Robin Schulze, OUSD (AT&L) DPAP (DAR), IMD 3C132, 3062 Defense Pentagon, Washington, DC 20301–3062.

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