

VII. 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 state law as meeting Federal requirements and imposes no additional requirements beyond those imposed by state law. 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 pre-existing requirements under state law 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 state rule implementing a Federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the 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.

In reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Act. In this context, in the absence of a prior existing requirement for the

state to use voluntary consensus standards (VCS), EPA has no authority to disapprove a SIP submission for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a SIP submission, to use VCS in place of a SIP submission that otherwise satisfies the provisions of the Act. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. 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 52

Environmental protection, Air pollution control, Intergovernmental relations, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Authority: 42 U.S.C. 7401-7671q.

Dated: November 30, 2004.

George Pavlou,

Acting Regional Administrator, Region 2.

[FR Doc. 04-27170 Filed 12-9-04; 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 and State health care programs' 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 8, 2005.

ADDRESSES: Please mail or deliver your written comments to the following address: Office of Inspector General, Department of Health and Human Services, Attention: OIG-91-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-91-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-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. 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, 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 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 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 12, 2003 (68 FR 69366). 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, 2004 through September, 30, 2004.¹ 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 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.

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 24, 2004.

Daniel R. Levinson,

Acting Inspector General.

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DEPARTMENT OF HOMELAND SECURITY

Transportation Security Administration

49 CFR Part 1507

[Docket No. TSA–2004–19845]

RIN 1652–AA34

Privacy Act of 1974: Implementation of Exemptions

AGENCY: Transportation Security Administration (TSA), DHS.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: TSA proposes to exempt Transportation Security Intelligence Service (TSIS) Operations Files (DHS/TSA 011) from several provisions of the Privacy Act; to add 5 U.S.C. 552a(k)(1) as an authority to exempt the Personnel Background Investigation File System (DHS/TSA 004) from the provisions previously claimed for that system; and to add 5 U.S.C. 552a(j)(2) as an authority to exempt the Transportation Security Enforcement Record System (DHS/TSA 001) and the Internal Investigation Record System (DHS/TSA 005) from the provisions previously claimed for those two systems, to now include subsection (e)(3). Public comment is invited.

DATES: Submit comments by January 10, 2005.

ADDRESSES: You must identify the TSA docket number when you submit comments to this rulemaking, using any one of the following methods:

Comments Filed Electronically: You may submit comments through the docket Web site at <http://dms.dot.gov>. Please be aware that anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.).

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