

# Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 62

[KS 0145-1145; FRL-7120-3]

#### Approval and Promulgation of State Plans for Designated Facilities and Pollutants; Control of Emissions From Hospital/Medical/Infectious Waste Incinerators; State of Kansas

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** EPA proposes to approve a revision to the state of Kansas' section 111(d) plan for controlling emissions from existing hospital/medical/infectious waste incinerators.

In the final rules section of the **Federal Register**, EPA is approving the state's submittal as a direct final rule without prior proposal because the Agency views this as noncontroversial 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 If EPA receives relevant adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed action.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.

**DATES:** Comments on this proposed action must be received in writing by January 18, 2002.

**ADDRESSES:** Comments may be mailed to Wayne Kaiser, Environmental Protection Agency, Air Planning and

Development Branch, 901 North 5th Street, Kansas City, Kansas 66101.

**FOR FURTHER INFORMATION CONTACT:** Wayne Kaiser at (913) 551-7603.

**SUPPLEMENTARY INFORMATION:** See the information provided in the direct final rule which is located in the rules section of the **Federal Register**.

Dated: December 7, 2001.

**James B. Gulliford,**

*Regional Administrator, Region 7.*

[FR Doc. 01-31239 Filed 12-18-01; 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 of 1996, this annual notice solicits proposals and recommendations for developing new and modifying existing safe harbor provisions under the 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 19, 2002.

**ADDRESSES:** Please mail or deliver your written comments to the following address: Office of Inspector General, Department of Health and Human Services, Attention: OIG-61-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-61-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 8:00 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 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 propose the imposition of civil money penalties, in accordance with section 1128A(a)(7) of the Act (42 U.S.C. 1320a-7a), or exclusions 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 are not subject to any enforcement

action under the anti-kickback statute or related administrative authorities.

#### *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 businesses. 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.

#### *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 14, 2000 (65 FR 78124). 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, 2001 through September, 30, 2001.<sup>1</sup> The 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.

#### *Criteria for Modifying and Establishing Safe Harbor Provisions*

In accordance with section 205, 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;

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

- 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 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 Alerts.

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: December 4, 2001.

**Janet Rehnquist,**

*Inspector General.*

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