

aggregate; or to the private sector, of \$100 million or more. Under section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule.

EPA has determined that the proposed action does not include a Federal mandate that may result in estimated costs of \$100 million or more to either State, local, or Tribal governments in the aggregate, or to the private sector. This Federal action proposes to approve pre-existing requirements under State or local law, and imposes no new requirements. Accordingly, no additional costs to State, local, or Tribal governments, or to the private sector, result from this action.

#### *E. Executive Order 13132, Federalism*

*Federalism* (64 FR 43255, August 10, 1999) revokes and replaces Executive Orders 12612 (*Federalism*) and 12875 (*Enhancing the Intergovernmental Partnership*). Executive Order 13132 requires EPA to develop an accountable process to ensure “meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.” “Policies that have federalism implications” is defined in the Executive Order to include regulations that 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.” Under Executive Order 13132, EPA may not issue a regulation that has federalism implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by State and local governments, or EPA consults with State and local officials early in the process of developing the proposed regulation. EPA also may not issue a regulation that has federalism implications and that preempts State law unless the Agency consults with State and local officials early in the process of developing the proposed regulation.

This proposed rule will 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, because it 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 Clean Air Act. Thus, the requirements of section 6 of the Executive Order do not apply to this rule.

#### *F. Executive Order 13175, Coordination With Indian Tribal Governments*

Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000), requires EPA to develop an accountable process to ensure “meaningful and timely input by Tribal officials in the development of regulatory policies that have Tribal implications.” This proposed rule does not have Tribal implications, as specified in Executive Order 13175. It will not have substantial direct effects on Tribal governments, 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. Thus, Executive Order 13175 does not apply to this rule.

#### *G. Executive Order 13045, Protection of Children From Environmental Health Risks and Safety Risks*

EPA interprets Executive Order 13045 (62 FR 19885, April 23, 1997) as applying only to those regulatory actions that concern health or safety risks, such that the analysis required under section 5-501 of the Executive Order has the potential to influence the regulation. This rule is not subject to Executive Order 13045, because it proposes to approve a State rule implementing a Federal standard.

#### *H. Executive Order 13211, Actions That Significantly Affect Energy Supply, Distribution, or Use*

This rule is not subject to Executive Order 13211, “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) because it is not a significant regulatory action under Executive Order 12866.

#### *I. National Technology Transfer and Advancement Act*

Section 12 of the National Technology Transfer and Advancement Act (NTTAA) of 1995 requires Federal agencies to evaluate existing technical standards when developing a new regulation. To comply with NTTAA,

EPA must consider and use “voluntary consensus standards” (VCS) if available and applicable when developing programs and policies unless doing so would be inconsistent with applicable law or otherwise impractical.

The EPA believes that VCS are inapplicable to this action. Today’s proposed action does not require the public to perform activities conducive to the use of VCS.

#### **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 *et seq.*

Dated: December 2, 2009.

**Laura Yoshii,**

*Acting Regional Administrator, Region IX.*

[FR Doc. E9-30854 Filed 12-28-09; 8:45 am]

**BILLING CODE 6560-50-P**

## **ENVIRONMENTAL PROTECTION AGENCY**

### **40 CFR Parts 52 and 70**

[EPA-R07-OAR-2008-0895; FRL-9096-5]

### **Approval and Promulgation of Implementation Plans and Operating Permits Program; State of Iowa**

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

**ACTION:** Proposed rule.

**SUMMARY:** EPA proposes to approve revisions to the Iowa State Implementation Plan (SIP) and Iowa Operating Permits Program submitted by the State on November 18, 2008. The purpose of these revisions is to update existing air quality rules; make corrections, clarifications and improvements; add information with regard to control of fugitive dust; clarify the opacity limit for incinerators; update Prevention of Significant Deterioration (PSD) permitting requirements, and add rules for temporary operation of small generators during periods of disaster. EPA is approving the SIP provisions pursuant to section 110 of the CAA. EPA is approving the state operating permits revisions pursuant to section 502 of the CAA and implementing regulations.

**DATES:** Comments on this proposed action must be received in writing by January 28, 2010.

**ADDRESSES:** Submit your comments, identified by Docket ID No. EPA-R07-OAR-2008-0895, by mail to Tracey Casburn, Environmental Protection

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.*

[FR Doc. E9-30776 Filed 12-28-09; 8:45 am]

**BILLING CODE 6560-50-P**

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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