

approval of WDNR's PSD SIP to not cover the applicability of PSD to GHG-emitting sources below the Tailoring Rule thresholds, is no longer necessary. In this proposed action, EPA is also proposing to amend 40 CFR 52.2572 to remove this unnecessary regulatory language.

## VI. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the CAA and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a "significant regulatory action" subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Public Law 104-4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the state, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

### List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, and Reporting and recordkeeping requirements.

Dated: December 17, 2012.

**Susan Hedman,**

*Regional Administrator, Region 5.*

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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 (HIPAA), 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 ensure consideration, public comments must be delivered to the address provided below by no later than 5 p.m. on February 26, 2013.

**ADDRESSES:** In commenting, please refer to file code OIG-121-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>.
2. *By regular, express, or overnight mail.* You may send written comments to the following address: Patrice Drew,

Office of Inspector General, Congressional and Regulatory Affairs, Department of Health and Human Services, Attention: OIG-121-N, Room 5541C, 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 Patrice Drew, Office of Inspector General, Department of Health and Human Services, Cohen Building, Room 5541C, 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) 619-1368.

For information on viewing public comments, please see the Supplementary Information section.

**FOR FURTHER INFORMATION CONTACT:** Patrice Drew, Congressional and Regulatory Affairs Liaison, Office of Inspector General, (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-121-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 from 9:30 a.m. to 5 p.m. To schedule an appointment to view public comments, phone (202) 619-1368.

### 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 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, section 14 of the Medicare and Medicaid Patient and Program Protection Act of 1987, Public Law 100-93 § 14, the Act, § 1128B(b), 42 U.S.C. 1320a-7b(b), specifically required the development and promulgation of regulations, the so-called "safe harbor" provisions, specifying various payment and business practices that, 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. The OIG safe harbor regulations are found at 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 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 the Health Insurance Portability and Accountability Act of 1996

Section 205 of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104-191 § 205, the Act, § 1128D, 42 U.S.C. 1320a-7d, 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 HIPAA, OIG last published a **Federal Register** solicitation notice for developing new safe harbors and Special Fraud Alerts on December 29, 2011 (76 FR 89104). As required under section 205, a status report of the public comments received in response to that notice is set forth in Appendix F.<sup>1</sup> 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 new or modified safe harbor regulations and new Special Fraud Alerts beyond those summarized in Appendix F.

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.

#### A. Criteria for Modifying and Establishing Safe Harbor Provisions

In accordance with section 205 of HIPAA, we will consider a number of

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

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 health care 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 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 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.

Dated: December 20, 2012.

**Daniel R. Levinson,**  
*Inspector General.*

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## FEDERAL COMMUNICATIONS COMMISSION

### 47 CFR Part 54

[WC Docket No. 10-90; FCC 12-138]

#### Connect America Fund

**AGENCY:** Federal Communications Commission.

**ACTION:** Proposed rule.

**SUMMARY:** In this document, the Federal Communications Commission seeks comment in this Further Notice of Proposed Rulemaking on potential modifications to the rules governing Connect America Phase I incremental support to further accelerate the deployment of broadband facilities to