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 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.

In reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air 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 Clean Air 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.*).

Dated: June 21, 2005.

Ronald A. Kreizenbeck,

Acting Regional Administrator, Region 10.

[FR Doc. 05–13058 Filed 6–30–05; 8:45 am]

BILLING CODE 6560–50–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

41 CFR Parts 51–2, 51–3, and 51–4

[Docket No. 2004–01–01]

RIN 3037–AA00

Governance Standards for Central Nonprofit Agencies and Nonprofit Agencies Participating in the Javits-Wagner-O'Day Program

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Withdrawal of notice of proposed rulemaking.

SUMMARY: The Committee for Purchase From People Who Are Blind or Severely Disabled (The Committee), which is responsible for administering and overseeing the implementation of the Javits-Wagner-O'Day (JWOD) Act, published a notice of proposed rulemaking on November 12, 2004 (69 FR 65395) proposing to amend its regulations by requiring nonprofit agencies awarded Government contracts under the authority of the JWOD Act, as well as central nonprofit agencies designated by the Committee and nonprofit agencies that would like to qualify for participation in the JWOD Program, to comply with new governance standards. The Committee is now withdrawing this proposed rule for further study and will propose a new rule in the near future.

DATES: *Effective Date:* July 1, 2005.

FOR FURTHER INFORMATION CONTACT: G. John Heyer, General Counsel, by telephone at (703) 603–2121, by fax at (703) 603–0655, by e-mail at *jheyer@jwod.gov*, or by postal mail at Committee for Purchase From People Who Are Blind or Severely Disabled, 1421 Jefferson Davis Highway, Jefferson Plaza 2, Suite 10800, Arlington, VA 22202–3259.

SUPPLEMENTARY INFORMATION: The Committee proposed by notice of November 12, 2004 (69 FR 65395) to amend its regulations to require nonprofit agencies awarded Government contracts under the authority of the JWOD Act, as well as central nonprofit agencies designated by the Committee and nonprofit agencies that would like to qualify for participation in the JWOD Program, to comply with new governance standards, including limits on executive compensation. The Committee, by notice of December 3, 2004 (69 FR 70214), extended the comment period on the proposal to February 10, 2005. By the close of the comment period, the Committee had received 167 written comments, from Members of Congress, representatives of designated central nonprofit agencies, representatives of nonprofit agencies, and other interested persons. Six commenters supported the proposed rule in its entirety, and eight other commenters supported the proposed rule in part but requested changes to other parts of the rule. Commenters who objected to the proposed rule frequently offered more than one reason for their objections, including 90 who questioned the Committee's authority to propose the rule; 106 who claimed that the proposed rule is duplicative of efforts of other Governmental entities, such as the Internal Revenue Service, which also regulate nonprofit agencies participating in the Committee's JWOD Program; and 84 who claimed that the rule is a waste of limited resources for most JWOD Program participants, as the Committee admitted that the proposed rule is a response to actions by a small number of program participants. The Committee's analysis of the comments revealed 106 different objections, most made by a small number of commenters, in addition to requests for extension of the original comment period, which the Committee granted, and requests for public hearings on the proposed rule.

As a first step in analyzing the comments received on the proposed rule, the Committee re-examined its legal authority in light of the arguments made in the comments and concluded that the JWOD Act's general rulemaking authority provision (41 U.S.C 47(d)(1)(C)) does permit the Committee to propose a rule concerning governance standards and executive compensation for JWOD Program participants. There was nothing provided or referenced in the written comments which would explicitly and specifically prohibit the Committee from using its rulemaking authority to propose a rule of this nature.

However, the Committee believes that the number and nature of the other issues raised in the comments justify extensive study and revision of the rule. By withdrawing the proposed rule, the Committee will have the flexibility to make use of valuable insights it has received from reviewing the comments to craft a new rule or rules which will address its concerns without unintended consequences and excessive burdens on program participants. The Committee intends to propose a new rule or rules in this area by the end of the year.

Accordingly, the proposed rule of November 12, 2004 (69 FR 65395) is hereby withdrawn.

Dated: June 28, 2005.

Sheryl D. Kennerly,

Director, Information Management, Committee for Purchase From People Who Are Blind or Severely Disabled.

[FR Doc. 05–13118 Filed 6–30–05; 8:45 am]

BILLING CODE 6353–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Office of Inspector General

42 CFR Part 1001

RIN 0991–AB38

Medicare and State Health Care Programs: Fraud and Abuse; Safe Harbor for Federally Qualified Health Centers Under the Anti-Kickback Statute

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: In accordance with section 431 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Public Law 108–173, this proposed rule would establish regulatory standards for the new safe harbor under the Federal anti-kickback statute for certain goods, items, services, donations, and loans provided by individuals and entities to certain health centers funded under section 330 of the Public Health Service Act. Under this proposed safe harbor, the goods, items, services, donations, or loans must contribute to the health center's ability to maintain or increase the availability, or enhance the quality, of services available to a medically underserved population.

DATES: We will consider comments if we receive them at the appropriate address, as provided in the address section below by no later than 5 p.m. on August 1, 2005.

ADDRESSES: You may submit comments by any of the methods set forth below. In all cases, when commenting, please refer to file code OIG–67–P.

- Mail—Office of Inspector General, Department of Health and Human Services, Attention: OIG–67–P, Room 5246, Cohen Building, 330 Independence Avenue, SW., Washington, DC 20201.

Please allow sufficient time for us to receive mailed comments by the due date in the event of delivery delays.

- Hand delivery/courier—Cohen Building, 330 Independence Avenue, SW., Washington, DC 20201.

Because access to the Cohen Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in OIG's drop box located in the main lobby of the building.

- Federal eRulemaking Portal: *http://www.regulations.gov.* Include agency name and identifier RIN 0991–AB37.

Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. For information on viewing public comments, see section IV in the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Julie Taitsman, Office of Counsel to the Inspector General, (202) 619–0335.

SUPPLEMENTARY INFORMATION:

I. Background

A. The Anti-Kickback Statute and Safe Harbors

Section 1128B(b) of the Social Security Act (the Act) (42 U.S.C. 1320a–7b(b), the anti-kickback statute) provides criminal penalties for individuals or entities that knowingly and willfully offer, pay, solicit, or receive remuneration in order to induce or reward the referral of business reimbursable under any of the Federal health care programs, as defined in section 1128B(f) of the Act. The offense is classified as a felony and is punishable by fines of up to $25,000 and imprisonment for up to 5 years. Violations of the anti-kickback statute may also result in the imposition of a civil money penalty (CMP) under section 1128A(a)(7) of the Act (42 U.S.C. 1320a–7a(a)(7)) or program exclusion under section 1128(b)(7) of the Act (42 U.S.C. 1320a–7(b)(7)) and liability under the False Claims Act (31 U.S.C. 3729–33).

The types of remuneration covered specifically include, without limitation, kickbacks, bribes, and rebates, whether made directly or indirectly, overtly or covertly, in cash or in kind. In addition, prohibited conduct includes not only the payment of remuneration intended to induce or reward referrals of patients, but also the payment of remuneration intended to induce or reward the purchasing, leasing, or ordering of, or arranging for or recommending the purchasing, leasing, or ordering of, any good, facility, service, or item reimbursable by any Federal health care program.

Section 14 of the Medicare and Medicaid Patient and Program Protection Act of 1987, Public Law 100–93, specifically required the development and promulgation of regulations, the so-called ''safe harbor'' provisions, that would specify various payment and business practices that would not be treated as criminal offenses under the anti-kickback statute, even though they may potentially be capable of inducing referrals of business under the Federal health care programs. Since July 29, 1991, we have published in the **Federal Register** a series of final regulations establishing ''safe harbors'' in various areas.[1] These OIG safe harbor provisions have been developed ''to limit the reach of the statute somewhat by permitting certain non-abusive arrangements, while encouraging beneficial or innocuous arrangements.'' 56 FR 35952, 35958 (July 21, 1991).

Health care providers and others may voluntarily seek to comply with safe harbors so that they have the assurance that their business practices will not be subject to any enforcement action under the anti-kickback statute, the CMP provision for anti-kickback violations, or the program exclusion authority related to kickbacks. In giving the Department of Health and Human Services the authority to protect certain arrangements and payment practices under the anti-kickback statute, Congress intended the safe harbor regulations to be evolving rules that would be updated periodically to reflect changing business practices and technologies in the health care industry.

B. Section 330-Funded Health Centers

Beginning in the 1960s, Congress enacted various health center programs to assist the large number of individuals living in medically underserved areas, as well as the growing number of special populations with limited access to preventive and primary health care

[1] 56 FR 35952 (July 29, 1991); 61 FR 2122 (January 25, 1996); 64 FR 63518 (November 19, 1999); 64 FR 63504 (November 19, 1999); and 66 FR 62979 (December 4, 2001).