

required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by December 3, 2007. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition

for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

**List of Subjects 40 CFR Part 52**

Environmental protection, Air pollution control, Electric utilities, Intergovernmental relations, Nitrogen oxides, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur dioxide.

Dated: September 21, 2007.  
**J.I. Palmer, Jr.**,  
*Regional Administrator, Region 4.*

■ 40 CFR part 52 is amended as follows:

**PART 52—[AMENDED]**

■ 1. The authority citation for part 52 continues to read as follows:

*Authority:* 42 U.S.C. 7401 *et seq.*

**Subpart S—Kentucky**

■ 2. In § 52.920(c) Table 1 is amended under Chapter 51 by adding in numerical order the entries for "401 KAR 51.210," "401 KAR 51.220," and "401 KAR 51.230" to read as follows:

**§ 52.920 Identification of plan.**

\* \* \* \* \*  
 (c) \* \* \*

TABLE 1.—EPA APPROVED KENTUCKY REGULATIONS

State citation	Title/subject	State effective date	EPA approval date	Explanation
* * *	<b>Chapter 51 Attainment and Maintenance of the National Ambient Air Quality Standards</b>	* * *	* * *	* * *
401 KAR 51.210	CAIR NO <sub>x</sub> Annual Trading Program	2/2/2007	10/4/2007 [Insert citation of publication].	
401 KAR 51.220	CAIR NO <sub>x</sub> Ozone Season Trading Program	6/13/2007	10/4/2007 [Insert citation of publication].	
401 KAR 51.230	CAIR SO <sub>2</sub> Trading Program	2/2/2007	10/4/2007 [Insert citation of publication].	

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 82**

[EPA-HQ-OAR-2003-0118; FRL-8477-7]

RIN 2060-AG12

**Protection of Stratospheric Ozone: Notice 22 for Significant New Alternatives Policy Program**

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

**ACTION:** Determination of acceptability.

**SUMMARY:** This Determination of Acceptability expands the list of acceptable substitutes for ozone-depleting substances under the U.S. Environmental Protection Agency's (EPA) Significant New Alternatives Policy (SNAP) program. The determinations concern new substitutes for use in the refrigeration and air conditioning sector.

**DATES:** This action is effective on October 4, 2007.

**ADDRESSES:** EPA has established a docket for this action under Docket ID No. EPA-HQ-OAR-2003-0118 (continuation of Air Docket A-91-42). All electronic documents in the docket are listed in the index at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, i.e., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Publicly available docket materials are available either electronically at [www.regulations.gov](http://www.regulations.gov) or in hard copy at the EPA Air Docket (No. A-91-42), EPA/DC, EPA West, Room 3334, 1301 Constitution Avenue, NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the Air Docket is (202) 566-1742.

**FOR FURTHER INFORMATION CONTACT:** Margaret Sheppard by telephone at (202) 343-9163, by facsimile at (202)

343-2362, by e-mail at [sheppard.margaret@epa.gov](mailto:sheppard.margaret@epa.gov), or by mail at U.S. Environmental Protection Agency, Mail Code 6205J, 1200 Pennsylvania Avenue, NW., Washington, DC 20460. Overnight or courier deliveries should be sent to the office location at 1310 L Street, NW., 10th floor, Washington, DC 20005.

For more information on the Agency's process for administering the SNAP program or criteria for evaluation of substitutes, refer to the original SNAP rulemaking published in the **Federal Register** on March 18, 1994 (59 FR 13044). Notices and rulemakings under the SNAP program, as well as other EPA publications on protection of stratospheric ozone, are available at EPA's Ozone Depletion World Wide Web site at <http://www.epa.gov/ozone/> including the SNAP portion at <http://www.epa.gov/ozone/snap/>.

**SUPPLEMENTARY INFORMATION:**

- I. Listing of New Acceptable Substitutes
  - A. Refrigeration and Air Conditioning
- II. Section 612 Program
  - A. Statutory Requirements
  - B. Regulatory History

Appendix A—Summary of Decisions for New Acceptable Substitutes

### I. Listing of New Acceptable Substitutes

This section presents EPA's most recent acceptable listing decisions for substitutes in the refrigeration and air conditioning sector. For copies of the full list of ODS substitutes in all industrial sectors, visit EPA's Ozone Depletion Web site at <http://www.epa.gov/ozone/snap/lists/index.html>.

The sections below discuss each substitute listing in detail. Appendix A contains a table summarizing today's listing decisions for new substitutes. The statements in the "Further Information" column in the table provide additional information, but are not legally binding under section 612 of the Clean Air Act. In addition, the "further information" may not be a comprehensive list of other legal obligations you may need to meet when using the substitute. Although you are not required to follow recommendations in the "further information" column of the table to use a substitute, EPA strongly encourages you to apply the information when using these substitutes. In many instances, the information simply refers to standard operating practices in existing industry and/or building-code standards. Thus, many of these statements, if adopted, would not require significant changes to existing operating practices.

You can find submissions to EPA for the use of the substitutes listed in this document and other materials supporting the decisions in this action in docket EPA-HQ-OAR-2003-0118 at <http://www.regulations.gov>.

#### A. Refrigeration and Air Conditioning

##### 1. RS-45

###### *EPA's decision:*

RS-45[R-125/143a/134a/600a (63.2/18.0/16.0/2.8)] is acceptable for use in new and retrofit equipment as a substitute for hydrochlorofluorocarbon (HCFC)-22 in:

- Chillers (centrifugal, screw, reciprocating).
- Industrial process refrigeration.
- Industrial process air conditioning.
- Retail food refrigeration.
- Cold storage warehouses.
- Refrigerated transport.
- Commercial ice machines.
- Ice skating rinks.
- Household refrigerators and freezers.
  - Water coolers.
  - Residential dehumidifiers.
  - Household and light commercial air conditioning and heat pumps.

RS-45 is a blend of 18.0% by weight hydrofluorocarbon (HFC)-143a (1,1,1-trifluoroethane, CAS ID #420-46-2), 63.2% by weight HFC-125 (pentafluoroethane, CAS ID #354-33-6), 16.0% by weight HFC-134a (1,1,1,2-tetrafluoroethane, CAS ID #811-97-2, and 2.8% by weight R-600a (isobutane, 2-methyl propane, CAS ID #75-28-5). The American Society of Heating, Refrigerating, and Air-Conditioning Engineers (ASHRAE) has assigned this blend the designation R-434A. You may find the submission under Docket item EPA-HQ-OAR-2003-0118-0162 at [www.regulations.gov](http://www.regulations.gov).

*Environmental information:* The ozone depletion potential (ODP) of R-421A is zero. The global warming potentials (GWPs) of HFC-143a, HFC-125, HFC-134a, and isobutane are 3800, 3450, 1320, and less than 10, respectively (relative to carbon dioxide, using a 100-year time horizon (United Nations Environment Programme (UNEP) and World Meteorological Organization (WMO) *Scientific Assessment of Ozone Depletion: 2002*)). The atmospheric lifetimes of these constituents are 48.3, 29, and 14 years, and less than one year, respectively.

The contribution of this blend to greenhouse gas emissions will be minimized through the implementation of the venting prohibition under section 608 (c)(2) of the Clean Air Act (see 40 CFR part 82, subpart F). This section and EPA's implementing regulations prohibit venting or release of substitutes for class I or class II ODSs used in refrigeration and air conditioning and require proper handling, such as recycling or recovery, and disposal of these substances.

HFC-143a, HFC-125 and HFC-134a are excluded from the definition of volatile organic compound (VOC) under Clean Air Act regulations (see 40 CFR 51.100(s)) addressing the development of State implementation plans (SIPs) to attain and maintain the national ambient air quality standards. Isobutane is a VOC under Clean Air Act regulations.

*Flammability information:* While two of the blend components, isobutane and HFC-143a, are flammable, the blend as formulated and under worst case fractionated formulation scenarios is not flammable.

*Toxicity and exposure data:* HFC-143a has an 8 hour/day, 40 hour/week recommended acceptable exposure limit for the workplace from the manufacturer of 1000 ppm. HFC-125 and HFC-134a have 8 hour/day, 40 hour/week workplace environmental exposure limits (WEELs) of 1000 ppm established by the American Industrial Hygiene

Association (AIHA). Isobutane has an 8 hour/day, 40 hour/week threshold limit value (TLV) established by the American Conference of Governmental Industrial Hygienists (ACGIH) of 1000 ppm. EPA recommends that users follow all requirements and recommendations specified in the Material Safety Data Sheet (MSDS) for the blend and the individual components and other safety precautions common in the refrigeration and air conditioning industry. EPA also recommends that users of RS-45 adhere to the AIHA's WEELs and the ACGIH's TLV.

*Comparison to other refrigerants:* RS-45 is not an ozone depleter in contrast to HCFC-22, the ozone-depleting substance which it replaces. RS-45 is comparable to other substitutes for HCFC-22 in its lack of risk for ozone depletion. RS-45 has a GWP of about 3200, comparable to or lower than that of other substitutes for HCFC-22. For example, the GWP of R-407C is about 1700, the GWP of R-410A is about 2000, and the GWPs of R-404A and R-507 are about 3900. Flammability and toxicity risks are low, as discussed above. Thus, we find that RS-45 is acceptable because it does not pose a greater overall risk to public health and the environment than the other substitutes acceptable in the end uses listed above.

##### 2. KDD5

###### *EPA's decision:*

KDD5 is acceptable for use in new and retrofit equipment as a substitute for HCFC-22 in:

- Chillers (centrifugal, screw, reciprocating).
- Industrial process refrigeration.
- Industrial process air conditioning.
- Retail food refrigeration.
- Cold storage warehouses.
- Refrigerated transport.
- Commercial ice machines.
- Ice skating rinks.
- Household refrigerators and freezers.
  - Vending machines.
  - Water coolers.
  - Residential dehumidifiers.
  - Household and light commercial air conditioning and heat pumps.
  - Motor vehicle air conditioning (buses and passenger trains only).
  - Non-mechanical heat transfer.

The submitter of KDD5 has claimed its composition as confidential business information. You may find the submission under Docket item EPA-HQ-OAR-2003-0118-0157 at [www.regulations.gov](http://www.regulations.gov).

*Environmental information:* The ODP of KDD5 is zero. The average 100-year integrated GWP of this blend is in the

range of the GWPs for R-407C and R-410A. Some components of the blend are VOCs under Clean Air Act regulations addressing the development of State implementation plans (SIPs) to attain and maintain the national ambient air quality standards. 40 CFR 51.100(s).

The contribution of this blend to greenhouse gas emissions will be minimized through the implementation of the venting prohibition under section 608(c)(2) of the Clean Air Act (see 40 CFR part 82, subpart F). This section and EPA's implementing regulations prohibit venting or release of substitutes for class I or class II ODSs used in refrigeration and air conditioning and require proper handling, such as recycling or recovery, and disposal of these substances.

**Flammability information:** As formulated and under worst-case fractionated formulation scenarios, this blend is not flammable.

**Toxicity and exposure data:** The manufacturer's recommended 8-hr TWA workplace exposure limit for the blend is 995 ppm. A number of components of the blend have workplace exposure limits of 1000 ppm set by the manufacturer, the AIHA, or the ACGIH.

**Comparison to other refrigerants:** KDD5 is not an ozone depleter; thus, it poses a lower risk for ozone depletion than the ODSs it replaces. KDD5 has comparable or lower risk for ozone depletion than other substitutes for HCFC-22. KDD5 has a GWP comparable to or lower than that of other substitutes for HCFC-22. For example, the GWP of R-407C is about 1700, the GWP of R-410A is about 2000, and the GWPs of R-404A and R-507 are about 3900. Flammability and toxicity risks are low, as discussed above. We find that KDD5 is acceptable because it does not pose a greater overall risk to public health and the environment than the other substitutes acceptable in the end uses listed above.

### 3. R-428A

#### *EPA's decisions:*

*R-428A is acceptable for use in new and retrofit equipment as a substitute for R-502, HCFC-22, and refrigerant blends containing HCFC-22, including R-402A, R-408A, R-403B, and R-411B in:*

- Retail food refrigeration.
- Cold storage warehouses.
- Refrigerated transport.
- Commercial ice machines.
- Household refrigerators and freezers.

*R-428A is acceptable for use in new equipment as a substitute for R-403B in:*

- Industrial process refrigeration.

*R-428A is acceptable for use in new and retrofit equipment as a substitute for R-502 and HCFC-22 in:*

- Ice skating rinks.

R-428A is a blend of 77.5% by weight HFC-125 (pentafluoroethane, CAS ID #354-33-6), 20.0% by weight HFC-143a (1,1,1-trifluoroethane, CAS ID #420-46-2), 0.6% by weight R-290 (propane, CAS ID #74-98-6), and 1.9% by weight R-600a (isobutane, 2-methyl propane, CAS ID #75-28-5). A common trade name for this refrigerant is RS-52. You may find the submission under Docket item EPA-HQ-OAR-2003-0118-0155 at [www.regulations.gov](http://www.regulations.gov).

**Environmental information:** The ODP of R-428A is zero. For environmental information on HFC-125, HFC-143a and isobutane, see the section on environmental information above for RS-45. The 100-year integrated GWP of propane is generally considered to be less than 10, relative to CO<sub>2</sub>. The atmospheric lifetime of propane is less than one year.

The contribution of this blend to greenhouse gas emissions will be minimized through the implementation of the venting prohibition under section 608(c)(2) of the Clean Air Act (see 40 CFR part 82, subpart F). This section and EPA's implementing regulations prohibit venting or release of substitutes for class I or class II ODSs used in refrigeration and air conditioning and require proper handling, such as recycling or recovery, and disposal of these substances.

Isobutane and propane are VOCs under Clean Air Act regulations concerning the development of SIPs to attain and maintain the national ambient air quality standards. HFC-125 and HFC-143a are exempt from the definition of VOC under these regulations. 40 CFR 51.100(s).

**Flammability information:** While three components of the blend, HFC-143a, isobutane and propane, are flammable, the blend as formulated and under worst-case fractionated formulation scenarios, is not flammable.

**Toxicity and exposure data:** For information on the workplace exposure limits for HFC-125 and HFC-143a, see the section on toxicity and exposure data above for RS-45. Isobutane has an 8 hour/day, 40 hour/week threshold limit value (TLV) established by the American Conference of Governmental Industrial Hygienists (ACGIH) of 1000 ppm. Propane has an 8 hour/day, 40 hour/week TLV of 800 ppm established by the ACGIH. EPA recommends that users follow all requirements and recommendations specified in the MSDS for the blend and the individual

components and other safety precautions common in the refrigeration and air conditioning industry. EPA also recommends that users of R-428A adhere to the ACGIH's TLVs.

**Comparison to other refrigerants:** R-428A is not an ozone depleter in contrast to the ozone depleting substances which it replaces. R-428A has comparable or lower risk for ozone depletion than other substitutes for R-502. R-428A has a GWP of about 3500, comparable to or lower than that of other substitutes for HCFC-22 and R-502. For example, the GWP of R-407C is about 1700, the GWP of R-410A is about 2000, and the GWPs of R-404A and R-507 are about 3900. The flammability and toxicity risks are low, as discussed above. Thus, we find that R-428A is acceptable because it does not pose a greater overall risk to public health and the environment than the other substitutes acceptable in the end uses listed above.

## II. Section 612 Program

### A. Statutory Requirements

Section 612 of the Clean Air Act authorizes EPA to develop a program for evaluating alternatives to ozone-depleting substances. We refer to this program as the Significant New Alternatives Policy (SNAP) program. The major provisions of section 612 are:

- **Rulemaking**—Section 612(c) requires EPA to promulgate rules making it unlawful to replace any class I (chlorofluorocarbon, halon, carbon tetrachloride, methyl chloroform, and hydrobromofluorocarbon) or class II (hydrochlorofluorocarbon) substance with any substitute that the Administrator determines may present adverse effects to human health or the environment where the Administrator has identified an alternative that (1) reduces the overall risk to human health and the environment, and (2) is currently or potentially available.

- **Listing of Unacceptable/Acceptable Substitutes**—Section 612(c) also requires EPA to publish a list of the substitutes unacceptable for specific uses. We must publish a corresponding list of acceptable alternatives for specific uses.

- **Petition Process**—Section 612(d) grants the right to any person to petition EPA to add a substance to or delete a substance from the lists published in accordance with section 612(c). The Agency has 90 days to grant or deny a petition. Where the Agency grants the petition, it must publish the revised lists within an additional six months.

- **90-day Notification**—Section 612(e) directs EPA to require any person who

produces a chemical substitute for a class I substance to notify the Agency not less than 90 days before new or existing chemicals are introduced into interstate commerce for significant new uses as substitutes for a class I substance. The producer must also provide the Agency with the producer's unpublished health and safety studies on such substitutes.

- *Outreach*—Section 612(b)(1) states that the Administrator shall seek to maximize the use of federal research facilities and resources to assist users of class I and II substances in identifying and developing alternatives to the use of such substances in key commercial applications.

- *Clearinghouse*—Section 612(b)(4) requires the Agency to set up a public clearinghouse of alternative chemicals, product substitutes, and alternative manufacturing processes that are available for products and manufacturing processes which use class I and II substances.

*B. Regulatory History*

On March 18, 1994, EPA published the final rulemaking (59 FR 13044) that described the process for administering the SNAP program and issued our first acceptability lists for substitutes in the major industrial use sectors. These sectors include:

- Refrigeration and air conditioning;
- Foam blowing;

- Solvents cleaning;
- Fire suppression and explosion protection;
- Sterilants;
- Aerosols;
- Adhesives, coatings and inks; and
- Tobacco expansion.

These sectors comprise the principal industrial sectors that historically consumed the largest volumes of ozone-depleting compounds.

As described in this original rule for the SNAP program, EPA does not believe that rulemaking procedures are required to list alternatives as acceptable with no limitations. Such listings do not impose any sanction, nor do they remove any prior license to use a substance. Therefore, by this notice we are adding substances to the list of acceptable alternatives without first requesting comment on new listings.

However, we do believe that notice-and-comment rulemaking is required to place any substance on the list of prohibited substitutes, to list a substance as acceptable only under certain conditions, to list substances as acceptable only for certain uses, or to remove a substance from the lists of prohibited or acceptable substitutes. We publish updates to these lists as separate notices of rulemaking in the **Federal Register**.

The Agency defines a “substitute” as any chemical, product substitute, or alternative manufacturing process,

whether existing or new, intended for use as a replacement for a class I or class II substance. Anyone who plans to market or produces a substitute for an ODS in one of the eight major industrial use sectors must provide EPA with health and safety studies on the substitute at least 90 days before introducing it into interstate commerce for significant new use as an alternative. This requirement applies to substitute manufacturers, but may include importers, formulators, or end-users, when they are responsible for introducing a substitute into commerce.

You can find a complete chronology of SNAP decisions and the appropriate **Federal Register** citations from the SNAP section of EPA's Ozone Depletion World Wide Web site at <http://www.epa.gov/ozone/snap/chron.html>. This information is also available from the Air Docket (see **ADDRESSES** section above for contact information).

**List of Subjects in 40 CFR Part 82**

Environmental protection, Administrative practice and procedure, Air pollution control, Reporting and recordkeeping requirements.

Dated: September 7, 2007.

**Edward Callahan,**  
*Acting Director, Office of Atmospheric Programs.*

**Appendix A: Summary of Acceptable Decisions**

**REFRIGERATION AND AIR CONDITIONING**

End-use	Substitute	Decision	Further information
Centrifugal chillers (retrofit and new) .....	RS-45 as a substitute for HCFC-22 .....	Acceptable.	
	KDD5 as a substitute for HCFC-22 .....	Acceptable.	
Screw chillers (retrofit and new) .....	RS-45 as a substitute for HCFC-22 .....	Acceptable.	
	KDD5 as a substitute for HCFC-22 .....	Acceptable.	
Reciprocating chillers (retrofit and new) .....	RS-45 as a substitute for HCFC-22 .....	Acceptable.	
	KDD5 as a substitute for HCFC-22 .....	Acceptable.	
Industrial process refrigeration (retrofit and new) ....	RS-45 as a substitute for HCFC-22 .....	Acceptable.	
	KDD5 as a substitute for HCFC-22 .....	Acceptable.	
Industrial process refrigeration (new only) .....	R-428A as a substitute for R-403B .....	Acceptable.	
Industrial process air conditioning (retrofit and new)	RS-45 as a substitute for HCFC-22 .....	Acceptable.	
	KDD5 as a substitute for HCFC-22 .....	Acceptable.	
Retail food refrigeration (retrofit and new) .....	RS-45 as a substitute for HCFC-22 .....	Acceptable.	
	KDD5 as a substitute for HCFC-22 .....	Acceptable.	
	R-428A as a substitute for R-502, HCFC-22 and refrigerant blends containing HCFC-22, including R-402A, R-403B, R-408A, and R-411B.	Acceptable.	
Cold storage warehouses (retrofit and new) .....	RS-45 as a substitute for HCFC-22 .....	Acceptable.	
	KDD5 as a substitute for HCFC-22 .....	Acceptable.	
	R-428A as a substitute for R-502, HCFC-22 and refrigerant blends containing HCFC-22, including R-402A, R-403B, R-408A, and R-411B.	Acceptable.	
Refrigerated transport (retrofit and new) .....	RS-45 as a substitute for HCFC-22 .....	Acceptable.	
	KDD5 as a substitute for HCFC-22 .....	Acceptable.	
	R-428A as a substitute for R-502, HCFC-22 and refrigerant blends containing HCFC-22, including R-402A, R-403B, R-408A, and R-411B.	Acceptable.	
Commercial ice machines (retrofit and new) .....	RS-45 as a substitute for HCFC-22 .....	Acceptable.	
	KDD5 as a substitute for HCFC-22 .....	Acceptable.	

REFRIGERATION AND AIR CONDITIONING—Continued

End-use	Substitute	Decision	Further information
Ice skating rinks (retrofit and new) .....	R-428A as a substitute for R-502, HCFC-22 and refrigerant blends containing HCFC-22, including R-402A, R-403B, R-408A, and R-411B. RS-45 as a substitute for HCFC-22 .....	Acceptable. Acceptable.	
Household refrigerators and freezers (retrofit and new).	KDD5 as a substitute for HCFC-22 .....	Acceptable.	
	R-428A as a substitute for R-502 and HCFC-22 ... RS-45 as a substitute for HCFC-22 .....	Acceptable. Acceptable.	
Vending machines (retrofit and new) .....	KDD5 as a substitute for HCFC-22 .....	Acceptable.	
Water coolers (retrofit and new) .....	R-428A as a substitute for R-502, HCFC-22 and refrigerant blends containing HCFC-22, including R-402A, R-403B, R-408A, and R-411B. KDD5 as a substitute for HCFC-22 .....	Acceptable. Acceptable.	
Residential dehumidifiers (retrofit and new) .....	RS-45 as a substitute for HCFC-22 .....	Acceptable.	
Household and light commercial air conditioning and heat pumps (retrofit and new).	KDD5 as a substitute for HCFC-22 .....	Acceptable.	
Motor vehicle air conditioning for buses and passenger trains.	RS-45 as a substitute for HCFC-22 .....	Acceptable.	
Non-mechanical heat transfer .....	KDD5 as a substitute for HCFC-22 .....	Acceptable.	

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Office of the Secretary**

**Office of Inspector General**

**42 CFR Part 1001**

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

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

**ACTION:** Final rule.

**SUMMARY:** In accordance with section 431 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), this final rule sets forth a safe harbor under the anti-kickback statute to protect certain arrangements involving 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. 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:** *Effective Date:* These regulations are effective on December 3, 2007.

**FOR FURTHER INFORMATION CONTACT:** Spencer Turnbull, Office of Counsel to the Inspector General, (202) 619-0335.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

*Overview—Establishing New Safe Harbor for Arrangements Involving Federally Qualified Health Centers*

This final regulation establishes safe harbor protection under the anti-kickback statute for certain arrangements involving Federally qualified health centers. Section I of this preamble contains a brief background discussion addressing the anti-kickback statute and safe harbors; a discussion of section 330-funded health centers; a summary of the relevant MMA provisions; a summary of the proposed safe harbor; and a summary of the final safe harbor. Section II of this preamble sets forth a summary of the public comments and our responses to those comments.

**A. The Anti-Kickback Statute and Safe Harbors**

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 five years.

Violations of the anti-kickback statute may also result in the imposition of civil money penalties (CMPs) under section 1128A(a)(7) of the Act (42 U.S.C. 1320a-7a(a)(7)), 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 prohibited specifically include, without limitation, kickbacks, bribes, and rebates, whether made directly or indirectly, overtly or covertly, in cash or in kind. 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.

Because of the broad reach of the statute, concern was expressed that some relatively innocuous commercial arrangements were covered by the statute and, therefore, potentially subject to criminal prosecution. In response, Congress enacted section 14 of the Medicare and Medicaid Patient and Program Protection Act of 1987, Public Law 100-93 (section 1128B(b)(3)(E) of the Act), which specifically required the development and promulgation of regulations, the so-called "safe harbor" provisions, which 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