REFRIGERATION AND AIR CONDITIONING—Continued

End-use	Substitute	Decision	Further information
	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.	
Ice skating rinks (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 and HCFC–22	Acceptable.	
Household refrigerators and freezers (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.	
Vending machines (retrofit and new)	KDD5 as a substitute for HCFC–22	Acceptable.	
Water coolers (retrofit and new)	RS–45 as a substitute for HCFC–22	Acceptable.	
	KDD5 as a substitute for HCFC–22	Acceptable.	
Residential dehumidifiers (retrofit and new)	RS–45 as a substitute for HCFC–22	Acceptable.	
	KDD5 as a substitute for HCFC–22	Acceptable.	
Household and light commercial air conditioning and heat pumps (retrofit and new).	RS–45 as a substitute for HCFC–22	Acceptable.	
	KDD5 as a substitute for HCFC–22	Acceptable.	
Motor vehicle air conditioning for buses and passenger trains.	KDD5 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

capable of inducing referrals of business under the Federal health care programs. Since July 29, 1991, OIG has 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 liability under the anti-kickback statute, the CMP provision for anti-kickback violations, or the program exclusion authority related to kickbacks. In giving the Department the authority to protect certain arrangements and payment practices from penalties 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 services. In the Health Centers Consolidation Act of 1996, Public Law 104–299, Congress consolidated the four then-existing Federal health center grant programs (the Migrant Health Center Program, the Community Health Center Program, the Health Care for the Homeless Program, and the Health Services for Residents of Public Housing Program) into a single program under section 330 of the Public Health Service (PHS) Act. *See* S. Rep. 104–186 (December 15, 1995). In the Health Care Safety Net Amendments of 2002, Public Law 107–251, Congress reauthorized and strengthened the health centers program. In 2005, the Federal health center programs supported 954 organizations that provided care to over 14 million patients at 3,745 health care service delivery sites.[2]

Section 330 grant recipients play a vital role in the health care safety net, providing cost effective care for communities with limited access to health care resources. All recipients of grants under section 330 are public, nonprofit, or tax-exempt entities. The health centers must serve ''a population that is medically underserved, or a special medically underserved population comprised of migratory and seasonal agricultural workers, the homeless, and residents of public housing.'' 42 U.S.C. 254b(a)(1). Health centers must be community based; to this end, a majority of a health center's governing board must be users of the center and must, as a group, represent the individuals being served by the center.[3] 42 U.S.C. 254b(k)(3)(H)(i). Health centers receiving section 330 grant funding must provide, either directly or through contracts or cooperative arrangements, a broad range of required primary health care services, including clinical services by physicians, and, where appropriate, physician assistants, nurse practitioners, and nurse midwives; diagnostic laboratory and radiological services; preventive health services; emergency medical services; certain pharmaceutical services; referrals to other providers (including substance abuse and mental health services); patient case management; services that enable individuals to use the services of the health center (*e.g.*, outreach, transportation, and translation services); and patient and community education services. 42 U.S.C. 254b(b)(1). They may also provide certain additional health services that are appropriate to serve the health needs of the population served by the health center. 42 U.S.C. 254b(b)(2). These additional health services may include mental health and substance abuse services; recuperative care services; environmental health services; special occupation-related health services for migratory and seasonal agricultural workers; programs to control infectious disease; and injury prevention programs.

Consistent with their mission and the terms of their PHS grants, section 330 grant recipients serve predominantly low-income individuals, including some beneficiaries of the Medicare and Medicaid programs. In 2005, 36 percent of patients treated by section 330 grant recipients were beneficiaries of a Medicaid program, 7.5 percent were beneficiaries of the Medicare program, and 2.3 percent were beneficiaries of another public insurance program.[4] Section 330 grant recipients also treat a substantial and growing number of uninsured patients. In 1996, section 330 grant recipients provided services to 3.2 million uninsured patients, and by 2005, this number had increased to 5.6 million, representing nearly 40 percent of patients treated at those centers during that year.[5]

Section 330 grant recipients must serve all residents of their ''catchment'' area regardless of the patient's ability to pay and must establish a fee schedule with discounts to adjust fees on the basis of ability to pay. 42 U.S.C. 254b(a)(1)(B) and 254b(k)(3)(G)(i). Section 330 grant recipients must also make and continue ''every reasonable effort to establish and maintain collaborative relationships with other health care providers in the catchment area of the center'' (42 U.S.C. 254b(k)(3)(B)), and must ''develop an ongoing referral relationship'' with at least one hospital in the area. 42 U.S.C. 254b(k)(3)(L).

Section 330 grant funds are intended to defray the costs of serving uninsured patients. Grant recipients are required to seek reimbursement from those patients who are able to pay all or a portion of the charges for their care (applying a schedule of fees and a corresponding schedule of discounts adjusted on the basis of the patient's ability to pay) or who have private insurance or public coverage, such as Medicare or Medicaid. The amount of a section 330 grant may not exceed the amount by which the costs of operation of the health center in such fiscal year exceed the total of: (i) State, local, and other operational funding provided to the health center; and (ii) the fees, premiums, and third-party reimbursements that the center may reasonably be expected to receive for its operations in such fiscal year. By statute, nongrant funds must be used to further the objectives of the recipient's section 330 grant.

Section 330 grant funding accounts for approximately 20 percent of revenue for health centers receiving such grants. The majority of health center funding derives from charges for patient services. On average, the largest source

[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); 66 FR 62979 (December 4, 2001); and 71 FR 45110 (August 8, 2006).

[2] HRSA Bureau of Primary Health Care, Uniform Data System: Calendar Year 2005 Data (available upon request at *http://www.bphc.hrsa.gov/uds/default.htm*).

[3] Health centers receiving grant funding to serve migratory and seasonal agricultural workers, homeless people, or residents of public housing may, upon a showing of good cause, obtain a waiver of this requirement. 42 U.S.C. 254b(k)(3)(H).

[4] HRSA Bureau of Primary Health Care, Uniform Data System: Calendar Year 2005 Data—Table 4: Users by Socioeconomic Characteristics (available upon request at *http://www.bphc.hrsa.gov/uds/default.htm*).

[5] HRSA Bureau of Primary Health Care, Uniform Data System: Calendar Year 2005 Data—UDS Trend Data for Years 1996 through 2005 (available upon request at *http://www.bphc.hrsa.gov/uds/default.htm*).

of revenue, 37 percent comes from Medicaid payments, 6.5 percent of health center revenues come from private third-party reimbursement, 6 percent from Medicare payments, and 6.5 percent from self-payments from patients. Remaining revenue comes from a mix of other Federal, State, local, and philanthropic sources.[6]

Frequently, health centers are provided with, or seek out, opportunities to enter into arrangements with hospitals or other providers or suppliers to further the health centers' patient care mission.[7] For example, providers or suppliers may agree to provide health centers with capital development grants, low cost (or no cost) loans, reduced price services, or in-kind donations of supplies, equipment, or space.

Some providers and suppliers expressed concern that remuneration offered to health centers might be viewed as suspect under the anti-kickback statute, because the health centers are frequently in a position to refer Federal health care program beneficiaries to the provider or supplier. Accordingly, Congress enacted section 431 of MMA to enable some health centers to conserve section 330 and other monies by accepting needed goods, items, services, donations, or loans for free or at reduced rates from willing providers and suppliers.

C. Section 431 of MMA

Section 431 of MMA amended the anti-kickback statute to create a new safe harbor for certain agreements involving health centers. Specifically, section 431(a) of MMA excludes from the reach of the anti-kickback statute any remuneration between: (i) A health center described under section 1905(l)(2)(B)(i) or 1905(l)(2)(B)(ii) of the Act; and (ii) an individual or entity providing goods, items, services, donations, loans, or a combination of these to the health center pursuant to a contract, lease, grant, loan, or other agreement, provided that such agreement contributes to the health center's ability to maintain or increase the availability, or enhance the quality, of services provided to a medically underserved population served by the health center.

In other words, Congress intended to permit health centers to accept certain remuneration that would otherwise implicate the anti-kickback statute when the remuneration furthers a core purpose of the Federal health centers program: ensuring the availability and quality of safety net health care services to otherwise underserved populations. As discussed in greater detail below, Congress limited the scope of the safe harbor to certain health centers engaged in arrangements involving specific types of identifiable remuneration.

In establishing regulatory standards relating to the safe harbor, Congress directed the Department to consider the following factors:

- Whether the arrangement results in savings of Federal grant funds or increased revenues to the health center. We believe this factor evidences Congress' intent that a protected arrangement directly benefit the health center economically and that the benefits of the arrangement primarily inure to the health center, rather than the individual or entity providing the remuneration.
- Whether the arrangement restricts or limits patient freedom of choice. We believe this factor evidences Congress' intent that protected arrangements not result in inappropriate steering of patients. Under the safe harbor, patients remain free to obtain services from any provider or supplier willing to furnish them.
- Whether the arrangement protects the independent medical judgment of health care professionals regarding medically appropriate treatment for patients. We believe this factor evidences Congress' intent to safeguard the integrity of medical decision-making and ensure it is untainted by direct or indirect financial interests. In all cases, the best interests of the patient should guide the medical decision-making of health centers and their affiliated health care professionals.

Section 431(b)(1)(B) of MMA provides that these three factors are ''among'' the factors the Department may consider in establishing the safe harbor standards. The statute authorizes the Department to include ''other standards and criteria that are consistent with the intent of Congress in enacting'' the health center safe harbor. Accordingly, we interpret the statute to permit us to consider other relevant factors and to establish other relevant safe harbor standards consistent with the anti-kickback statute and the health center safe harbor. Among the factors we have considered is whether arrangements would pose a risk of fraud or abuse to any Federal health care programs or their beneficiaries. We believe Congress intended to protect arrangements that foster an important goal of the section 330 grant program—assuring the availability and quality of needed health care services for medically underserved populations—without adversely impacting other Federal programs or their beneficiaries.

D. Summary of Proposed Safe Harbor

On July 1, 2005, we issued a notice of proposed rulemaking (70 FR 38081) to set forth standards related to the safe harbor described in section 431 of MMA, in which we proposed: (1) To protect remuneration in the form of goods, items, services, donations, loans, or a combination thereof provided by an individual or entity (hereinafter in this preamble ''Donor'') to a qualifying health center; (2) that remuneration must be medical or clinical in nature or relate directly to patient services provided by the health center as part of the scope of the health center's section 330 grant; and (3) importantly, that a protected arrangement must contribute to the ability of the health center to maintain or increase the availability, or enhance the quality, of services provided to a medically underserved population.

The proposed regulation proposed that protected arrangements must be pursuant to a comprehensive contract, lease, grant, loan, or other agreement that is written and signed by the parties, and the amount of the protected remuneration must not be conditioned on the volume or value of Federal health care program business generated between the parties. As we said in the notice of proposed rulemaking:

''In the unique and limited context of arrangements described in the proposed safe harbor, we would extend safe harbor protection to arrangements where only the methodology, and not the absolute value of the remuneration, is predetermined. For example, a health center might agree to pay a supplier a set hourly or per visit fee that is below fair market value for services furnished by the supplier to the health center, provided that the formula for

[6] HRSA Bureau of Primary Health Care, Uniform Data System: Calendar Year 2005 Data—Exhibit A: Total Revenue Received by BPHC Grantees (available upon request at *http://www.bphc.hrsa.gov/uds/default.htm*).

[7] Congress has previously recognized the importance of health center affiliations with hospitals and other health care service providers in promoting efficiency and quality of care. The Health Centers Consolidation Act expressly requires health centers to maintain collaborative relationships with other providers. With respect to integrated delivery systems, the Report states:

''The committee believes, based on expert testimony given at the May 14, 1995, hearing, that the development of integrated health care provider networks is key to preserving and strengthening access to community-based health care services in rural areas. Provider networks offer a number of advantages: They can work to ensure that a continuum of health care services is available, reduce the duplication of services, produce savings in administrative and other costs through shared services and an enhanced ability to negotiate in the health care market place, and recruit and utilize health professionals more effectively and efficiently.''

S. Rep. 104–186 at p. 11.

calculating the compensation (*e.g.*, $ × per hour or $ × per service) is fixed in advance and not conditioned on referrals to the supplier.'' 70 FR 38084.

We proposed that health centers must reasonably determine before entering into an agreement that the arrangement is likely to contribute to the health center's ability to maintain or increase the availability, or enhance the quality, of services provided to a medically underserved population. We also proposed that health centers would have to periodically re-evaluate agreements to ensure ongoing compliance with this benefit standard and terminate as expeditiously as possible any arrangements that are not reasonably expected to continue to meet the standard. We proposed that the initial determination and any re-evaluations should be contemporaneously documented.

Our proposed rule stated that health centers must not be required to refer patients to a particular provider or supplier. In addition, we proposed that Donors that offer to provide goods, items, or services must accept all referrals of patients from the health center who clinically qualify for the goods, items, or services, regardless of payor status or ability to pay. We proposed that protected arrangements could not be exclusive. The proposed rule also required health centers to provide effective notification to patients of their freedom to choose any willing provider or supplier and to disclose the existence and nature of protected arrangements.

We proposed to give health centers the option of requiring that a Donor that enters into a protected arrangement charge a referred health center patient the same rate it charges other similarly situated persons not referred by the health center or that the items or services be furnished to health center patients at a reduced rate or free of charge.

Finally, we proposed that an arrangement could not be protected under the safe harbor unless it complied with the requirements of the health center's section 330 grant funding.

E. Summary of Final Safe Harbor

1. Major Changes

We have modified the proposed rule in a number of areas in response to public comments. The substantial changes and clarifications being made in the final regulations include:

- Clarifying the definition of the term ''remuneration'' for purposes of the safe harbor;
- Eliminating the requirement that arrangements that do not comply with the safe harbor be terminated;
- Eliminating the requirement that arrangements must comply with all relevant requirements of the health center's section 330 grant funding;
- Consolidating and clarifying the documentation requirements;
- Clarifying that health centers do not need to develop set standards for determining whether an arrangement is expected to contribute meaningfully to services for underserved patients;
- Simplifying the safe harbor requirement pertaining to disclosures to patients;
- Clarifying health centers' freedom to refer patients; and
- Clarifying the conditions under which individuals and entities furnish separately billable goods, items, or services to health centers.

2. Final Safe Harbor Conditions

As discussed more fully in this preamble and regulations, the health center safe harbor protects remuneration in the form of goods, items, services, donations or loans (whether the donation or loan is in cash or in-kind), or a combination thereof provided by a Donor to a qualifying health center. Qualifying health centers are health centers described under section 1905(l)(2)(B)(i) or 1905(l)(2)(B)(ii) of the Act. Remuneration must be medical or clinical in nature or relate directly to services provided by the health center as part of the scope of the health center's section 330 grant. A protected arrangement must contribute to the ability of the health center to maintain or increase the availability of, or enhance the quality of, services provided to a medically underserved population.

Protected arrangements must be pursuant to a contract, lease, grant, loan, or other agreement that is written, signed by the parties, and covers all of the remuneration to be provided. The amount of the remuneration must be specified and not be conditioned on the volume or value of Federal health care program business generated between the parties.

Health centers must reasonably expect before entering into an agreement that the arrangement is likely to contribute to the health center's ability to maintain or increase the availability, or enhance the quality, of services provided to a medically underserved population as defined at 42 U.S.C. 254b(b)(3). Health centers must document the basis for their determination that the arrangement will yield such a benefit. Health centers must periodically re-evaluate agreements to ensure ongoing compliance with the benefit standard. These determinations must be contemporaneously documented.

Health centers must not be required to refer patients to a particular provider or supplier under the arrangement, and must be free to refer patients to any provider or supplier. In addition, Donors that offer to furnish goods, items, or services for health center patients must furnish those goods, items, or services to all health center patients who clinically qualify for them, regardless of payor status or ability to pay.

Health centers are required to provide effective notification to patients of their freedom to choose any willing provider or supplier and to disclose to patients, upon request, the existence and nature of the arrangement with the Donor.

The safe harbor makes clear that a health center may, at its option, require a Donor that enters into a protected arrangement to charge a referred health center patient the same rate it charges other similarly situated persons not referred by the health center or furnish items or services to health center patients at a reduced rate (where the discount applies to the total charge and not just the cost-sharing portion owed by an insured patient).

II. Summary of Public Comments and OIG Responses

In response to our proposed rulemaking, OIG received a total of nine timely filed comments from trade associations, hospitals, health centers, and other interested parties. We have divided the summaries of the public comments and our responses into three parts: general comments; comments on statutory elements; and comments on additional regulatory standards.

A. General Comments

All the commenters supported the establishment of a safe harbor for arrangements involving Federally Qualified Health Centers. While some commenters expressed their support for all of the regulatory standards in the proposed rule, other commenters took issue with one or more specific aspects of the proposal.

Comment: A trade association objected to the number of standards in the proposed regulation. The commenter suggested that the number of standards is too high and might dissuade parties from participating in safe harbored arrangements.

Response: As discussed in detail elsewhere in this preamble, we have reduced the number of standards from eleven in the proposed rule to nine in

the final rule. We do not believe that the regulatory standards should create an undue burden or otherwise chill participation in arrangements under the safe harbor.

Comment: Several commenters responded to the statement in the preamble to the proposed rule that OIG intended to monitor participants in safe harbored arrangements for compliance with billing rules, in order to guard against improper billing of Federal health care programs or inappropriate transfers of governmental funds. *See* 70 FR 38086. Two trade associations requested that we remove any mention of such monitoring, lest it discourage parties from participating in arrangements under this safe harbor. Another trade association suggested that, in return for safe harbor protection, it would be appropriate that health centers be monitored closely for compliance with the requirements of section 330 funding to determine whether the funding is used for its intended purpose. In particular, the commenter stated that it is important to ensure that any government benefits provided to health centers to serve uninsured patients are used to provide services to those patients and not diverted to subsidizing unrelated service lines.

Response: Our use of the term ''monitor'' may have inadvertently created the misimpression that parties to arrangements under this safe harbor would be subject to a higher level of scrutiny than parties to other arrangements. We clarify that we were referring simply to our usual and customary oversight authorities and practices. Participation in a safe harbored arrangement would not necessarily make parties a target of OIG attention or subject parties to heightened scrutiny; however, as providers who receive funding from Federal health care programs, health centers remain subject to our general oversight tools, including monitoring for proper billing and appropriate transfers of governmental funds. With that clarification, we do not believe that referencing our longstanding oversight authority should discourage participation in safe harbored arrangements. We agree with the last commenter and affirm our continued commitment to ensuring that Government funding is used for its intended purposes.

Comment: A trade association requested that we remove the proposed requirement at § 1001.952(w)(11), which would have required any safe harbored agreement to comply with all relevant requirements of the health center's section 330 grant funding. The commenter suggested that the requirement is unnecessary, because health centers already operate under an obligation to comply with all requirements of their section 330 grant funding. Moreover, the commenter observed that including this provision in the safe harbor regulations might chill a Donor's willingness to participate in safe harbored arrangements, if that Donor also becomes obligated to ensure that the arrangements comply with the terms of a health center's section 330 grant funding.

Response: We agree with this commenter and are eliminating the standard in the final rule. The remaining safe harbor conditions, in combination with health centers' existing obligations to comply with the requirements of their section 330 grant funding, should be sufficient to minimize any risk of fraud and abuse.

Comment: We received a comment from a health center network noting that the safe harbor only offers protection under the anti-kickback statute and does not offer protection under the physician self-referral law, section 1877 of the Act (commonly known as the ''physician self-referral law'' or ''Stark'' law). The commenter expressed concern that the need to comply with both statutes may prove burdensome for health centers, and suggested that the requirements of the two laws be consolidated.

Response: The commenter correctly notes that the safe harbor only protects arrangements under the anti-kickback statute, and, where applicable, parties would also need to comply with the physician self-referral law. An exception under the physician self-referral law is beyond the scope of this rulemaking. The anti-kickback statute and the physician self-referral law, while similar in that they both address abuses of the Medicare and Medicaid programs, are different in scope and application. Congress has made clear that the physician self-referral law and the anti-kickback statute are separate legal authorities, and compliance with one does not necessarily ensure compliance with the other. *See, e.g.*, H.R. Conf. Rep. No. 386, 101st Cong., 1st session 856 (1989).

B. Comments on Statutory Elements

1. Protected Health Centers

Comment: A trade association suggested we broaden the scope of the safe harbor to apply to arrangements involving other types of health centers that are similar to the health centers described in sections 1905(l)(2)(B)(i) and 1905(l)(2)(B)(ii) of the Act, except for the fact that they lack section 330 funding. These other facilities are often called ''look-alike'' facilities.

Response: We decline to adopt this suggestion. Congress specifically provided that the safe harbor should apply to the facilities described in sections 1905(l)(2)(B)(i) and 1905(l)(2)(B)(ii) of the Act and not to other types of facilities. Moreover, we believe the lack of section 330 funding, which entails a higher level of Government oversight, constitutes a significant distinction between section 330-funded health centers and look-alike facilities. Extending safe harbor protection to entities without such Government funding and such a level of oversight would pose a greater risk of fraud and abuse. We recognize that many look-alike facilities play important roles in the health care safety net, and we note that just because arrangements with look-alike facilities do not fall within the safe harbor does not mean they are necessarily illegal. The fact that the safe harbor does not apply simply means that such arrangements must be analyzed on a case-by-case basis to determine whether they violate the anti-kickback statute.

Comment: A trade association asked us to commit to considering the issuance of a regulatory safe harbor protecting arrangements involving look-alike facilities.

Response: We may consider this option in the future, depending on our experience with this safe harbor in practice.

2. Protected Remuneration

Comment: Several commenters sought clarification as to whether community benefit grants and other types of cash donations qualify as protected remuneration under this safe harbor. A trade association asked that we add language in § 1001.952(w)(2) that clarifies that donations and loans could include cash donations, such as community benefit grants, and are not limited to in-kind donations and loans. One commenter noted that some community benefit grants entail reconciliation provisions, which allow the donor (i) to augment the grant if grant funds fall short of actual health center expenditures or (ii) to determine the use of excess funds where grant funds exceed actual health center spending. Two trade associations requested clarification of the definition of ''remuneration'' and assurance that the definition includes community benefit grants or similar payments to health centers by public hospitals and health systems, even if the amount of

the payments are subject to reconciliation.

Response: The definition of ''remuneration'' at § 1001.952(w) would generally extend to community benefit grants or similar payments, even where such grants or payments are subject to a reconciliation provision. So long as the reconciliation methodology is fixed in advance and does not hinge on the volume or value of referrals from the health center to the Donor, funding subject to reconciliation could comply with the condition at § 1001.952(w)(1) and be protected remuneration under this safe harbor (provided all other safe harbor conditions are satisfied). Donations and loans need not be limited to in-kind goods or services, and indeed may be in monetary form. We have clarified the scope of § 1001.952(w) to make this point more explicit: ''As used in section 1128B of the Act, 'remuneration' does not include the transfer of any goods, items, services, donations or loans (*whether the donation or loan is in cash or in-kind*), or combination thereof from an individual or entity to a health center * * *'' (emphasis added).

Comment: A trade association suggested we expand the scope of the safe harbor to cover arrangements whereby the remuneration is provided not *to* the health center, but *from* the health center to an individual or entity related to the health center. The commenter said there are arrangements not covered by other safe harbors where a health center could provide payments or other forms of support to a provider that would result in improving the overall health outcomes of patients.

Response: Section 431 of MMA does not protect remuneration from a health center to an individual or entity. We believe it is clear that Congress intended the safe harbor to enhance the resources available to health centers in order to help them achieve their community benefit mission, and we decline to adopt the commenter's recommendation. We recognize that there may be beneficial arrangements where remuneration flows away from the health center that may not fit within a safe harbor; such arrangements would be evaluated on a case-by-case basis to ensure compliance with the anti-kickback statute. We note that some arrangements pursuant to which a health center provides remuneration to an individual or entity may qualify for other safe harbors, including, for example, the safe harbors for personal services, employees, practitioner recruitment, and electronic health records items a nd services. *See* §§ 1001.952(d), (i), (n), and (y).

Comment: A trade association noted that our proposed rule stated that section 431 ''only protects remuneration provided to a health center and does not protect remuneration provided to individuals affiliated with a health center * * *.'' 70 FR 38084. The commenter asked whether, for purposes of this safe harbor, remuneration to the health center could include funds provided by a hospital, if such funds were used to help recruit a physician to the health center.

Response: The donation described by the commenter raises the possibility of two scenarios: one in which the donation could be used to recruit a physician to the health center primarily for the benefit of health center patients, and one where it could be used to recruit a physician primarily for the benefit of the donor hospital. If the hospital made the donation of funds to the health center primarily for the benefit of health center patients, then its donation of funds for the purpose of supporting general physician recruitment by the health center could qualify for protection under this safe harbor, if all safe harbor conditions are satisfied. Conversely, we believe Congress did not intend the safe harbor to protect arrangements where the donation primarily creates a benefit to the Donor instead of to the health center. Likewise, this safe harbor would not protect an arrangement where a Donor used the health center as a conduit to transfer remuneration to a particular recruited physician; to transfer remuneration specifically for the purpose of recruiting a physician to join the Donor's medical staff, or to practice in the Donor's service area; or to transfer remuneration to existing group practices. The safe harbor does not protect remuneration provided by Donors to individuals affiliated with the health center. Section 431 evidences Congress' intent to protect the provision of certain remuneration ''to'' a health center. It does not protect remuneration transferred to an individual affiliated with a health center, nor does it protect remuneration transferred from a health center to an individual or entity. We note that, depending on the circumstances, such a recruitment arrangement between a health center and a physician may be eligible for protection under another safe harbor, such as the safe harbor for practitioner recruitment at § 1001.952(n). When evaluating arrangements with potential Donors for funds to support physician recruitment, health centers should consider whether the remuneration would be used for expenses commonly or typically borne by the health center, such that the arrangement results in measurable savings that will benefit a medically underserved population, or would be used to recruit a health care professional needed by the health center to serve a medically underserved population. If a recruited physician were to join the health center's medical staff, it would be some evidence that the benefit primarily runs to medically underserved populations served by the health center as opposed to the Donor.

Comment: We received several comments regarding the proposed regulatory text for § 1001.952(w)(2), which provides examples of ''patient services furnished by the health center as part of its section 330 grant'' in the parenthetical portion of the text, but does not similarly list examples of ''goods, items, donations, or loans.'' The commenters expressed concern that this suggested that only services could constitute protected remuneration. These commenters requested that the regulatory text also supply examples of protected goods, items, donations, and loans.

Response: The commenters misread proposed § 1001.952(w)(2). Goods, items, donations, and loans—and services—can indeed constitute protected remuneration under this safe harbor. In the interest of clarifying § 1001.952(w)(2) so that health centers and Donors do not interpret the scope of protected remuneration to be narrower than it actually is, we have deleted the term ''patient services furnished'' and replaced it with the term ''services provided.'' Section 1001.952(w)(2) now requires that goods, items, services, donations, or loans (or combination thereof) must either (i) Be medical or clinical in nature or (ii) relate directly to services provided by the health center in furtherance of its section 330 grant. The parenthetical list offers illustrative examples of the kind of services that meet the latter test and makes clear that such services need not be medical or clinical in nature. For example, goods, items, services, donations, or loans directly related to a health center's billing, administrative, social services, and health information functions can qualify. We note that the term ''medical or clinical in nature'' broadly covers all medical or clinical services (*e.g.*, physician services, nurse practitioner and physician assistant services, diagnostic services, therapeutic services, etc.); medical or clinical goods and items (*e.g.*, pharmaceuticals, knee braces, stethoscopes, x-ray machines, etc.); donations of money or other forms of remuneration that the health center can use to furnish medical or clinical

services or to acquire goods, items, or services that are medical or clinical in nature; and loans of money or other forms of remuneration that the health center can use to furnish medical or clinical services or to acquire goods, items, or services that are medical or clinical in nature.

Comment: A non-profit organization and several health centers submitted comments seeking clarification that the definition of remuneration at § 1001.952(w) would include pharmaceutical manufacturers' donations of pharmaceutical products to health centers with the intent that these products be used to treat patients of the health center. They requested that we amend § 1001.952(w) specifically to include donations of pharmaceutical products from pharmaceutical manufacturers, citing concerns that absent such an explicit acknowledgement, pharmaceutical manufacturers would refuse to donate to health centers.

Response: Nothing in § 1001.952(w) excludes donations of pharmaceuticals by pharmaceutical companies from protection by the safe harbor. To the contrary, as discussed in the preceding response, such donations are clearly within the meaning of the language ''goods * * * [that] are medical or clinical in nature'' in § 1001.952(w)(2). Pharmaceutical donations can play an important role in ensuring a health center safety net for vulnerable patients, and many arrangements between health centers and pharmaceutical companies may be eligible for protection. That said, we are not enumerating in the regulatory text any particular types of Donors. Whether something fits in the definition of protected ''remuneration'' at § 1001.952(w) turns on the nature of the remuneration, not on its source. By listing some Donors and not others, we might create a misimpression regarding the scope of the safe harbor.

Comment: A non-profit organization sought clarification that a health center's practice of purchasing discounted drugs by means of participation in the 340B Drug Pricing Program would not preclude that health center from receiving free drugs pursuant to a donation protected under this safe harbor.

Response: We confirm that this safe harbor could protect arrangements involving the donation of pharmaceuticals to health centers, including to health centers that participate in the 340B Drug Pricing Program.

3. Documentation Requirements

Comment: Several commenters supported our documentation requirements at proposed §§ 1001.952(w)(1) and (3) (consolidated at § 1001.952(w)(1) of the final rule). A trade association commented that the documentation requirements at proposed §§ 1001.952(w)(1) and (3) are inconsistent with statements in the preamble. According to the commenter, the use of the term ''written agreement'' in the proposed regulatory language implies that all arrangements between a health center and a Donor must be included in a single writing, while the preamble says that all such arrangements should be memorialized ''by one comprehensive writing or by means of multiple writings that cross-reference and otherwise incorporate the agreements between the parties.''

Response: For clarity and ease of application, we have combined the documentation requirements at proposed §§ 1001.952(w)(1) and (3) of the proposed rule into one requirement at § 1001.952(w)(1) in the final rule. We confirm that it may be satisfied by one comprehensive writing or by multiple writings that cross-reference and otherwise incorporate the agreements between the parties. We have revised the safe harbor to reflect this. We have also revised the safe harbor to provide the option of using a centralized master list in lieu of cross-referencing and incorporation of multiple agreements. The master list must be maintained centrally and in a manner that preserves the historical record of arrangements, kept up to date, and made available for review by the Secretary upon request. This flexibility should enhance the ability of Donors and health centers to use the safe harbor. The safe harbor does not require that all arrangements between a health center and a Donor be included in a single agreement that would qualify under the safe harbor.

Comment: A trade association sought clarification that the documentation requirements at proposed §§ 1001.952(w)(1) and (3) (§ 1001.952(w)(1) of the final rule) apply only to arrangements related to a safe harbored arrangement, and not to other interactions between the health center and the Donor that truly are unrelated to a safe harbored arrangement. The commenter believed that the documentation requirements imply that all arrangements between a health center and a Donor must be included in a single arrangement that would qualify under the safe harbor. The commenter suggested that only arrangements that ''require safe harbor protection'' should require documentation.

Response: The safe harbor does not require that all arrangements between a health center and a Donor be included in a single arrangement that would qualify under the safe harbor. The documentation standards at § 1001.952(w)(1) (§§ 1001.952(w)(1) and (3) in our proposed rule) require that the written documentation ''cover all goods, items, services, donations, or loans to be provided to the health center.'' In the interest of providing bright-line guidance with respect to what must be documented under § 1001.952(w)(1), we clarify that this paragraph requires the documentation of all arrangements for the transfer of goods, items, services, donations, or loans from a Donor to a health center. With respect to the commenter's assertion that certain arrangements ''require safe harbor protection,'' we note that, like all safe harbors, compliance with this safe harbor is voluntary and no arrangement requires safe harbor protection. Rather, arrangements must comply with the anti-kickback statute. Compliance with a safe harbor is one option for ensuring compliance with the anti-kickback statute.

4. Benefit to a Medically Underserved Population

Comment: A trade association asked us to clarify § 1001.952(w)(4) of the proposed rule (§ 1001.952(w)(3) of the final rule), which requires that arrangements protected under the safe harbor be reasonably expected to contribute meaningfully to the health center's ability to maintain or increase the availability, or enhance the quality of, services provided to a medically underserved population. Specifically, the commenter sought confirmation that, in order to contribute meaningfully, the arrangement need not result in a financial gain for the health center. The commenter asked us to consider the case of a health center that does not offer a particular service for its patients, but enters into an arrangement with a Donor for that service for free. The commenter observed that since the health center had not previously incurred expenses for the service, the new arrangement would not offer a financial gain to the health center. Another trade association requested confirmation that proposed § 1001.952(w)(4) would not necessarily require direct savings of section 330 funding and could be satisfied without a monetary benefit to the health center.

Response: We confirm that proposed § 1001.952(w)(4) (§ 1001.952(w)(3) of the final rule) does not require a

financial gain to the health center and does not require the direct savings of section 330 funding. Whether the condition is satisfied will depend on the specific facts and circumstances. As noted in the preamble to the proposed rule at 70 FR 38085, we believe health centers are well-situated in the first instance to make a reasonable determination whether an arrangement contributes meaningfully to the health center's ability to maintain or increase the availability, or enhance the quality of, services provided to a medically underserved population, and we believe health centers should have flexibility in making these determinations. In the preamble to the proposed rule at 70 FR 38085, we listed factors that are exemplars of the type that should be considered in making these determinations:

- Does the arrangement directly benefit a medically underserved population?
- Does the arrangement involve goods, items, or services of a type that are commonly or typically purchased by the health center, such that the arrangement results in measurable savings that will benefit a medically underserved population?
- If the arrangement involves a donation to the health center, would the donation result in the increased availability of an item, good, device, service, technology, or treatment needed by a medically underserved population but not previously available in sufficient quantities due to financial limitations?
- Does the health center need the donated items, goods, or services, or the loaned funds to satisfy the scope of its section 330 grant?

The arrangement described in the first commenter's example could contribute meaningfully, if it increased the availability of the service for the health center's medically underserved population. With respect to the second commenter, we observe that while an arrangement that conserves a health center's section 330 funding means the health center has more money available to provide or enhance services for a medically underserved population, there are many other ways that remuneration could maintain, increase, or enhance services for a medically underserved population without the direct savings of section 330 funding. For example, if an arrangement allowed a health center to begin delivering an important new clinical service, which the health center was not previously able to provide, a meaningful benefit to a medically underserved population would likely be achieved without a direct monetary gain to the health center.

Comment: A trade association had a concern regarding the significance of the list of factors in the preamble that we wrote ''should be considered'' in determining whether an arrangement would result in a meaningful benefit to a medically underserved population. *See* 70 FR 38085. The commenter asked for confirmation that the factors in the list are only examples, and that it is not necessary to satisfy all of the factors to demonstrate a meaningful benefit under proposed § 1001.952(w)(4) (§ 1001.952(w)(3) of the final rule).

Response: The factors listed in the proposed rule and noted in the preceding response are examples of ways to analyze the existence of a meaningful benefit, and the commenter correctly understood that it is not necessary to satisfy each exemplary factor to establish the existence of a meaningful benefit to a medically underserved population under § 1001.952(w)(3) of the final rule.

Comment: A trade association commented that our requirement at proposed § 1001.952(w)(4) that health centers apply ''reasonable, consistent, and uniform standards'' when determining whether an arrangement bestows a meaningful benefit for services provided to a medically underserved population provides insufficient guidance to health centers for structuring arrangements. The commenter also objected to the proposed requirement that health centers document evaluation of such standards. It expressed concern that these requirements would have a chilling effect on parties' participation in safe harbored arrangements, as parties would be unsure whether their standards would satisfy the requirements of the safe harbor. The commenter requested that we provide examples of acceptable standards and how to document them, or eliminate the requirement all together.

Response: We intended the language ''reasonable, consistent and uniform standards'' to give health centers flexibility in assessing benefits to a medically underserved population, while at the same time requiring accountability and providing safeguards against abuse. Upon further consideration and consistent with our original intent, we have determined that proposed § 1001.952(w)(4) (now § 1001.952(w)(3)) can be simplified. Under § 1001.952(w)(3) of the final rule, parties need not develop or apply any separate ''standards,'' nor document that they have applied them. They must, however, document the basis for the reasonable expectation of benefits to a medically underserved population prior to entering the arrangement. Parties may, as a matter of prudent business practice, develop standards that are reasonable, uniform, and consistently applied as part of the methodology they use in assessing the expected benefit to a medically underserved population. We have similarly changed the corresponding language in § 1001.952(w)(4) of the final rule, which concerns the reevaluation of arrangements. With respect to the commenter's concern that proposed § 1001.952(w)(4) (§ 1001.952(w)(3) in the final rule) will chill participation in the safe harbor, we note that our approach here is consistent with several existing safe harbors that provide parties with flexibility to determine how to satisfy key conditions (*e.g.*, how to determine fair market value). A health center can document its determination of a meaningful benefit to a medically underserved population, for example, by maintaining written or electronic records of the data and methodology used to assess the expected maintenance of, increase in, or enhanced quality of services to a medically underserved population and the outcome of such assessment. We believe that the documentation necessary to satisfy this requirement is consistent with that generally kept in the usual and customary course of a health center's business. For example, in many cases a health center's section 330 grant documents, in combination with the agreement required under § 1001.952(w)(1), may serve as the documentation of a sufficient benefit to a medically underserved population, to the extent they transparently document that a volume of items or services specified by the section 330 grant requirements will be provided under the agreement. Parties with concerns about their specific practices can avail themselves of OIG's advisory opinion process.

5. Periodic Re-Evaluation of Arrangements

Comment: A health network supported the requirement at proposed § 1001.952(w)(5) (§ 1001.952(w)(4) of the final rule) that parties periodically re-evaluate arrangements. The commenter stated that it seems reasonable and useful for health centers participating in these arrangements to re-evaluate agreements periodically and document such factors as fair market value of equipment or costs of providing services. A trade association requested that we eliminate the requirement that an arrangement that, upon reevaluation,

fails to meet the benefit standard be terminated. This commenter also asked us to clarify that continuation of such an arrangement would not automatically constitute a violation of the anti-kickback statute.

Response: We agree with these commenters. We have adopted the trade association's recommendation to eliminate the language in § 1001.952(w)(5) of the proposed rule that required noncompliant arrangements to be promptly terminated. We also confirm that a decision by a health center to continue participating in an arrangement that no longer satisfies the requirements of § 1001.952(w)(3) of the final rule will not necessarily give rise to a violation of the anti-kickback statute. Rather, the continuation of such an arrangement would fall outside of the safe harbor, and its legality under the anti-kickback statute would be determined on a case-by-case basis, based on all the facts and circumstances, including the intent of the parties. Finally, we agree with the commenter that, depending on the arrangement, it would be reasonable and useful for health centers participating in these arrangements to re-evaluate agreements periodically and document such factors as fair market value of equipment or costs of providing services.

C. Comments on Additional Regulatory Standards

1. General Comments

Comment: A trade association asserted that the regulatory standards OIG proposed in accordance with section 431 of MMA should be limited to the factors set forth in section 431 and should not include additional requirements. As discussed in our preamble to the proposed rule at 70 FR 38083, in addition to the standards established by Congress, section 431 of MMA authorizes OIG to add other standards or criteria consistent with Congress' intent in creating this safe harbor. The commenter stated that establishing additional safe harbor standards consistent with the anti-kickback statute contravenes the plain language of the statute and Congress' intent. The commenter asked that the regulatory standards created in accordance with section 431 not include additional requirements that health centers and their partners would have to meet to be consistent with the anti-kickback statute. Finally, the commenter contended that these standards wrongly ''reconsider'' whether the arrangements pose a risk of fraud and abuse. According to the commenter, by definition, all the arrangements described in the safe harbor pose a risk of fraud and abuse, which is why they require safe harbor protection in the first place.

Response: We agree with the commenter's view that the regulatory standards we create in accordance with section 431 must be consistent with the language of section 431, and we believe that our regulations meet that test. Section 431 explicitly requires us to consider health center resources, patient freedom of choice, and independent medical judgment; however, it further states that these factors are ''among'' those to be considered and that ''the Secretary may also include other standards and criteria that are consistent with the intent of Congress in enacting the exception established under this section.'' Every safe harbor is established to protect arrangements that otherwise implicate the anti-kickback statute. Therefore, we believe Congress charged the Secretary with promulgating regulations implementing the health center safe harbor in a manner that furthers beneficial health center arrangements without posing an undue risk of fraud and abuse under the anti-kickback statute. This approach is consistent with our longstanding approach to safe harbor rulemaking. For instance, in our preamble to the proposed rule for the first ten safe harbors we stated that: ''[w]e have attempted in these proposed regulations to permit physicians to freely engage in business practices and arrangements that encourage competition, innovation and economy. However, we have added criteria to each 'safe harbor' in order to reduce the potential for abuse.'' (50 FR 3088; January 23, 1989) Congress enacted section 431 in the context of this regulatory history. Moreover, we do not believe Congress intended to protect arrangements that pose significant risk to Federal health care programs or their beneficiaries. We believe our regulations directly and reasonably derive from the guidelines specifically enacted in section 431 and Congress' invitation to include other standards consistent with the establishment of the safe harbor. With respect to the commenter's final comment, historically, regulatory safe harbors were initiated in response to concerns that the anti-kickback statute covered some relatively innocuous commercial arrangements. (*See* 50 FR 3088; January 23, 1989 and 56 FR 35952; July 29, 1991) These safe harbors are meant to protect arrangements that do not pose undue risk for Federal health care programs or beneficiaries; they are not meant to protect arrangements that pose high risks to Federal health care programs.

2. Patient Freedom of Choice and Independent Medical Judgment

Comment: A trade association sought clarification that proposed §§ 1001.952(w)(6) and (8) (§§ 1001.952(w)(5) and (7) of the final rule) would permit a health center to select a single supplier of particular goods or services if the health center followed the procurement rules applicable to health centers set forth at 45 CFR 74.40 through 74.48. The commenter presented the scenario of a health center purchasing laboratory services where the health center has a choice of suppliers, which are equal in all respects except that one prospective supplier will offer free laboratory services for uninsured patients while the other will not. The commenter suggested that it may be appropriate for the health center to enter into an exclusive contract with the supplier that offers free services.

Response: Where a health center purchases or receives a particular good or service from a supplier, the health center may limit the number of suppliers with which it contracts, in keeping with health center procurement rules. Nothing in this safe harbor is to the contrary. We agree that in some circumstances it would be appropriate for a health center to contract with one supplier (*e.g.*, a single supplier of laboratory services), and that such an arrangement would not be likely to impinge unduly or significantly on the freedom of choice of patients seeking care at a section 330 health center. We have made clarifying revisions to § 1001.952(w)(5) of the final rule to reflect that a Donor may not require a health center to refer patients to a particular individual or entity. Nothing in this provision limits a health center's ability to contract with one supplier consistent with the procurement rules.

Similarly, proposed § 1001.952(w)(8) (§ 1001.952(w)(7) of the final rule) prohibits a Donor from requiring the health center to forego arrangements with other prospective Donors, but does not prohibit the health center from entering into an exclusive arrangement with a provider or supplier when the health center so chooses, and when it can do so in compliance with relevant procurement rules. In the commenter's example, a health center can accept the offer of free laboratory services for uninsured patients under the safe harbor, provided all other safe harbor conditions are met. We emphasize that this safe harbor is unique to Federally Qualified Health Centers. In general,

arrangements where a provider or supplier offers free or discounted items or services to a potential referral source that would otherwise incur out-of-pocket costs for such items or services pose a substantial risk of fraud under the anti-kickback statute. Nevertheless, Congress enacted a law that protects such arrangements in the health center context, where the remuneration inures to the benefit of a section 330 health center and its medically underserved patients, and where other appropriate safeguards are in place. Other similar arrangements outside the health center context are fundamentally different and pose substantial risk under the anti-kickback statute.

Comment: A trade association offered mixed reactions to proposed § 1001.952(w)(7) (§ 1001.952(w)(6) in the final rule), which provides that Donors who offer to provide goods, items, or services to health center patients cannot limit their acceptance of health center patient referrals based on a patient's insurance status. The commenter stated that asking Donors to accept all health center patients without regard to insurance status is a laudable goal, but expressed concern that this requirement would put prospective Donors at significant financial risk and could have a chilling effect on parties' willingness to participate in safe harbored arrangements. The commenter also stated that allowing Donors to ''impose reasonable limits on the aggregate volume or value of referrals it will accept'' might cause risk averse Donors to commit to serving a smaller number of health center patients than they otherwise would.

Response: We are mindful of the commenter's concerns and we believe that the regulations strike an appropriate balance between preserving health center patients' access to care, allowing prospective Donors to limit their risk, and reducing the risk of parties abusing the safe harbor by ''cherry picking'' lucrative patients from the health centers. We believe a requirement that Donors that offer to furnish goods, items, or services to health center patients should do so for all health center patients without regard to insurance status is essential to effectuating Congress' intent that the safe harbor promote arrangements that provide a benefit to the health centers and the medically underserved populations they serve. We are mindful that this requirement could discourage prospective Donors from participating in safe harbored arrangements absent a way for them to limit their risk, which is why we have provided a mechanism for Donors to set a reasonable cap on the volume or value of items or services they will provide. Furthermore, nothing in § 1001.952(w)(6) of the final rule precludes Donors from billing for such goods, items, or services in accordance with the Donor's usual billing practice (absent an agreement between the parties as provided for in § 1001.952(w)(9)). The safe harbor does not protect arrangements through which Donors limit their financial risk by cherry picking which health center patients will receive their goods or services based on the patient's insurance status. For example, if a physician were to offer physician services to a health center, he or she could not condition the offer on treating only patients who are Federal healthcare program beneficiaries. However, the physician could cap the number of hours he or she would work at the health center. Similarly, an end stage renal disease facility cannot offer to provide free dialysis for one uninsured health center patient for every four insured patients the health center refers to the facility. However, the facility could offer to provide a fixed number of dialysis treatments to the health center. Finally, we clarified that § 1001.952(w)(6) concerns goods, items, or services furnished by Donors to the health center, and not donations or loans.

Comment: A health system commenter asked if the requirements of proposed § 1001.952(w)(7) (§ 1001.952(w)(6) of the final rule) would apply to Donors providing remuneration in the form of loans or donations, since a patient cannot ''clinically qualify'' for a loan or donation.

Response: Proposed § 1001.952(w)(7) (§ 1001.952(w)(6) of the final rule) does not apply to Donors providing donations or loans to a health center. For clarity and consistency of meaning, we have replaced the term ''provide'' with the term ''furnish'' in § 1001.952(w)(6) of the final rule. As defined at 42 CFR 1000.10, ''[f]urnished refers to items or services provided or supplied, directly or indirectly, by any individual or entity.'' We have further clarified the subsequent language in this paragraph by conforming it to reflect that the term ''furnish'' refers to items or services provided or supplied, not referrals accepted. We believe these changes better distinguish between (i) Donors who furnish items or services for health centers patients (and may bill insurers separately for some of these items or services), who must comply with § 1001.952(w)(6) of the final rule if they want safe harbor protection, and (ii) Donors who provide health centers with donations or loans. We note that safe harbored donations or loans may not take into account the volume or value of Federal health care program referrals, in accordance with § 1001.952(w)(1).

3. Patient Notification

Comment: Two trade associations asked that we eliminate the patient notification requirement at proposed § 1001.952(w)(9) (§ 1001.952(w)(8) of the final rule). One commenter suggested that, if the requirement is retained, we distinguish providers of health care services from suppliers of goods and services since, in the commenter's opinion, it is less important to preserve patients' freedom of choice to select suppliers of health care goods and services. This commenter also questioned why this safe harbor requires patient notification when other safe harbors do not. Another trade association asserted that any patient notification requirement would be unworkable and would not significantly enhance patient freedom of choice.

Response: We disagree with the commenters and decline to eliminate the notification requirement. We will not draw a distinction between providers and suppliers for purposes of this subparagraph because preserving patient freedom of choice is important for both providers and suppliers of health care items and services (we note that physicians are ''suppliers'' for Medicare Part B purposes. 42 CFR 400.202. We believe a patient notification requirement is consistent with our specific charge from Congress to protect patient freedom of choice. Moreover, this is not the only safe harbor that requires patient notification. *See, e.g.*, 42 U.S.C. 1001.952(v). As we noted in the preamble to the proposed rule, transparency will help protect the informed decision-making of patients, enhancing their ability to act as prudent consumers of health care services and preserving freedom of choice. (70 FR 38086; July 1, 2005) That said, we have simplified the requirements. Under the final rule, health centers must notify patients of their freedom of choice and provide information regarding the existence and nature of arrangements under this safe harbor to patients upon request.

Comment: A trade association asked that we specify how to satisfy the patient notification requirement at proposed § 1001.952(w)(9) (§ 1001.952(w)(8) of the final rule). The commenter asked us to confirm that health centers would be allowed to notify patients strictly through broad

disclosures and that an acceptable notification method would be to direct patients to a posted written disclosure notice.

Response: We confirm that health centers can satisfy the notification requirement through broad disclosures. For example, directing patients to a written disclosure notice posted in a conspicuous place in the health center would be an acceptable disclosure method, provided that the written notice is reasonably calculated to provide effective notice and to be understood by the parties. However, since the most appropriate notification method is likely to vary from health center to health center, depending on the particular facts and circumstances, we believe it would be inappropriate for us to dictate a one-size-fits-all notification method to be used by all health centers. Accordingly, we further note that broad disclosures are not required. To further improve clarity, we replaced the general reference to arrangements under ''this paragraph'' with a specific cite to § 1001.952(w)(1).

4. Rates Charged to Health Center Referrals

Comment: We received several comments concerning proposed § 1001.952(w)(10) (§ 1001.952(w)(9) of the final rule), which gives health centers the option of requiring a Donor to charge a patient referred from the health center the same rate it charges other patients or a reduced rate. A trade association requested that the entire proposed provision be deleted from the safe harbor or, if retained, clarified as optional. The same trade association sought clarification that the provision would not preclude providers or suppliers from waiving or reducing cost sharing obligations for health center patients under the safe harbor at 42 CFR 1001.952(k).

Response: We emphasize that proposed § 1001.952(w)(10) (§ 1001.952(w)(9) of the final rule) describes an optional standard. We have revised § 1001.952(w)(9) of the final rule to make this elective clear. Health centers are not required to exercise this option, but they may choose to do so to ensure that Donors giving remuneration to a health center do not simply recoup the remuneration by overcharging health center patients. Our intent is to allow health centers to protect their patients from price gouging. (We note that a similar provision is included in the safe harbor for referral services at § 1001.952(f).) We added this provision to ensure that health centers can protect their patients from being charged prices higher than they would be charged in the absence of the health center's participation in the safe harbored arrangement. We are concerned, for example, that Donors might otherwise seek to recoup part of the cost of remuneration offered to a health center by charging health center patients inflated rates. We confirm that nothing in the provision would preclude hospitals and health centers from offering health center patients waivers or reductions of cost sharing obligations, as permitted in the safe harbor for waiver of beneficiary coinsurance and deductible amounts at § 1001.952(k). Moreover, health centers and other providers and suppliers can waive or reduce patients' cost sharing amounts based on individualized, good faith assessments of financial need. Section 1128A(i)(6)(A)(iii) of the Act.

Comment: A health system asked whether the regulatory language ''the same rate it charges other patients'' at proposed § 1001.952(w)(10) (§ 1001.952(w)(9) of the final rule) means the entity's customary charges (as defined at 42 CFR 413.13(a)) or the discounted rate the provider or supplier actually charges similarly situated patients.

Response: We clarify that ''the same rate it charges other patients'' refers to the rate the provider or supplier actually charges a patient similarly situated to a patient referred from a health center. We have changed the regulatory text at § 1001.952(w)(9) to reflect this clarification by inserting the words ''similarly situated'' after the word ''other.''

III. Regulatory Impact Statement

A. Regulatory Analysis

We have examined the impact of this rule as required by Executive Order 12866, the Unfunded Mandates Reform Act of 1995, the Regulatory Flexibility Act (RFA) of 1980, and Executive Order 13132.

Executive Order 12866

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulations are necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects; distributive impacts; and equity). A regulatory impact analysis must be prepared for major rules with economically significant effects (*i.e.*, $100 million or more in any given year).

This is not a major rule, as defined at 5 U.S.C. 804(2), and it is not economically significant since the overall economic effect of the rule is less than $100 million annually. This safe harbor is designed to allow health centers to enter into certain beneficial arrangements with individuals or entities providing goods, items, services, donations, loans, or a combination thereof to the health center. In doing so, this regulation would impose no requirements on any party. Health centers may voluntarily seek to comply with this provision so that they have assurance that participating in covered agreements will not subject them to liability under the anti-kickback statute. The safe harbor facilitates health centers' ability to provide important health care services to communities in need and helps these centers fulfill their mission as integral components of the health care safety net. We believe that the aggregate economic impact of this rule will be minimal and will have no effect on the economy or on Federal or State expenditures. To the extent that there is any economic impact, that impact will likely result in savings of Federal grant dollars.

Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995, Public Law 104–4, requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditures in any one year by State, local, or tribal governments, in the aggregate, or by the private sector, of $110 million. Since compliance with safe harbor requirements is voluntary, we believe that there are no significant costs associated with this safe harbor that will impose any mandates on State, local, or tribal governments or the private sector that would result in an expenditure of $110 million or more (adjusted for inflation) in any given year, and that a full analysis under the Unfunded Mandates Reform Act is not necessary.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) and the Small Business Regulatory Enforcement and Fairness Act of 1996, which amended the RFA, require agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, certain nonprofit organizations, and small governmental jurisdictions. Individuals and States are not included in the definition of a small entity. In accordance with the RFA, some of the health centers that may avail themselves of the protections of the safe harbor are considered to be small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. While this safe harbor may have an impact on small rural hospitals, we believe that the aggregate economic impact of this rule will be minimal, since it is the nature of the violation and not the size or type of the entity that would result in a violation of the anti-kickback statute. Moreover, the safe harbor should benefit small rural hospitals (and their patients) that have relationships with health centers by increasing their flexibility to engage in transactions involving goods, items, services, donations, and loans that result in conservation of Federal grant dollars and other funding without any risk under the anti-kickback statute. The safe harbor should effectively expand opportunities for health centers to engage in arrangements beneficial for fulfilling their mission. For these reasons, and because the vast majority of entities potentially affected by this rule do not engage in prohibited arrangements, schemes, or practices in violation of the law, we have concluded that this rule should not have a significant impact on a substantial number of small rural hospitals, and that a regulatory flexibility analysis is not required for this rulemaking.

Executive Order 13132

Executive Order 13132, Federalism, establishes certain requirements that an agency must meet when it promulgates a rule that imposes substantial direct requirements or costs on State and local governments, preempts State law, or otherwise has Federalism implications. In reviewing this rule under the threshold criteria of Executive Order 13132, we have determined that this rule would not significantly limit the rights, roles, and responsibilities of State or local governments. We have determined, therefore, that a full analysis under Executive Order 13132 is not necessary.

The Office of Management and Budget (OMB) has reviewed this rule in accordance with Executive Order 12866.

B. Paperwork Reduction Act

In accordance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (PRA), we are required to solicit public comments, and receive final OMB approval, on any information collection requirements set forth in rulemaking.

In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- Whether the information collection is necessary and useful to carry out the proper functions of the agency;
- The accuracy of the agency's estimate of the information collection burden;
- The quality, utility, and clarity of the information to be collected;
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

On July 1, 2005, we solicited comment under this section upon publication of the 60-day notice of proposed rulemaking (70 FR 38081). We will publish the 30-day **Federal Register** notice soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements following publication of this final rule.

For an arrangement to fall within the safe harbor it will have to fulfill the following documentation requirements: (1) It must be set out in writing (§ 1001.952(w)(1)(i)(A)); (2) the written agreement must be signed by the parties (§ 1001.952(w)(1)(i)(B)); (3) the written agreement must cover, and specify the amount of, all goods, items, services, donations, or loans provided by the individual or entity to the health center § 1001.952(w)(1)(i)(C)); (4) the health center must document its basis for its reasonable expectation that the arrangement will benefit a medically underserved population (§ 1001.952(w)(3)); and (5) the health center, at reasonable intervals, must re-evaluate the arrangement to ensure that it is expected to continue to benefit a medically underserved population, and must document the re-evaluation contemporaneously (§ 1001.952(w)(4)).

As required by section 3504(h) of the Paperwork Reduction Act of 1995, we will submit a copy of this document to OMB for its review and approval of these information collection requirements.

We believe that the documentation requirements necessary to enjoy safe harbor protection do not qualify as an added paperwork burden, because the requirements deviate minimally, if at all, from the information these entities would routinely collect in their normal course of business. The statute applies only to the health centers' receipt of goods, items, services, donations, or loans pursuant to a contract, lease, grant, loan, or other agreement. We believe it is usual and customary for health centers to memorialize contracts, leases, grants, loans, and other similar agreements in writing. Ensuring that such writings are comprehensive and that the actual business activities are accurately reflected by documentation are standard prudent business practices. The only documentation requirement of the safe harbor that potentially imposes an additional recordkeeping burden is the requirement that health centers document the statutorily mandated expected benefit to a medically underserved population. Since serving a medically underserved population is central to the underlying mission of the health centers and the section 330 grant program (and all health centers serve at least one such population), documentation of such benefit would seem to be a prudent business practice to ensure continued compliance, not only with the safe harbor, but also with the section 330 grant program.

We note that although we require health centers to provide effective notification to patients reminding patients of their freedom to choose any willing provider or supplier and to provide information about safe harbored arrangements to patients who inquire, these disclosures need not be in writing. Instead, we require that health centers provide patient disclosures in a manner reasonably calculated to provide effective notice and to be understood by the patient. The type of notice provided may vary depending on the health center and its patients. We believe the notification requirement will achieve the goal of protecting patients without imposing an added paperwork burden because the notice need not be written. Moreover, we believe the notification requirement will be consistent with health centers' existing interest in protecting their vulnerable patient populations.

It should be noted that compliance with a safe harbor under the Federal anti-kickback statute is voluntary, and no party is ever required to comply with a safe harbor. Instead, safe harbors merely offer an optional framework regarding how to structure business arrangements to ensure compliance with the anti-kickback statute. All parties remain free to enter into arrangements without regard to a safe harbor, so long as the arrangements do not involve unlawful payments for referrals under the anti-kickback statute.

List of Subjects in 42 CFR Part 1001

Administrative practice and procedure, Fraud, Grant programs—health, Health facilities, Health professions, Maternal and child health, Medicaid, Medicare.

■ Accordingly, 42 CFR part 1001 would be amended as set forth below:

PART 1001—[AMENDED]

■ 1. The authority citation for part 1001 continues to read as follows:

Authority: 42 U.S.C. 1302, 1320a–7, 1320a–7b, 1395u(j), 1395u(k), 1395y(d), 1395y(e), 1395cc(b)(2)(D), (E) and (F), and 1395hh; and sec. 2455, Pub.L. 103–355, 108 Stat. 3327 (31 U.S.C. 6101 note).

■ 2. Section 1001.952 is amended by republishing the introductory paragraph for this section and by adding a new paragraph (w) to read as follows:

§ 1001.952 Exceptions.

The following payment practices shall not be treated as a criminal offense under section 1128B of the Act and shall not serve as the basis for an exclusion:

* * * * *

(w) *Health centers.* As used in section 1128B of the Act, ''remuneration'' does not include the transfer of any goods, items, services, donations or loans (whether the donation or loan is in cash or in-kind), or combination thereof from an individual or entity to a health center (as defined in this paragraph), as long as the following nine standards are met—

(1) (i) The transfer is made pursuant to a contract, lease, grant, loan, or other agreement that—

(A) Is set out in writing;

(B) Is signed by the parties; and

(C) Covers, and specifies the amount of, all goods, items, services, donations, or loans to be provided by the individual or entity to the health center.

(ii) The amount of goods, items, services, donations, or loans specified in the agreement in accordance with paragraph (w)(1)(i)(C) of this section may be a fixed sum, fixed percentage, or set forth by a fixed methodology. The amount may not be conditioned on the volume or value of Federal health care program business generated between the parties. The written agreement will be deemed to cover all goods, items, services, donations, or loans provided by the individual or entity to the health center as required by paragraph (w)(1)(i)(C) of this section if all separate agreements between the individual or entity and the health center incorporate each other by reference or if they cross-reference a master list of agreements that is maintained centrally, is kept up to date, and is available for review by the Secretary upon request. The master list should be maintained in a manner that preserves the historical record of arrangements.

(2) The goods, items, services, donations, or loans are medical or clinical in nature or relate directly to services provided by the health center as part of the scope of the health center's section 330 grant (including, by way of example, billing services, administrative support services, technology support, and enabling services, such as case management, transportation, and translation services, that are within the scope of the grant).

(3) The health center reasonably expects the arrangement to contribute meaningfully to the health center's ability to maintain or increase the availability, or enhance the quality, of services provided to a medically underserved population served by the health center, and the health center documents the basis for the reasonable expectation prior to entering the arrangement. The documentation must be made available to the Secretary upon request.

(4) At reasonable intervals, but at least annually, the health center must re-evaluate the arrangement to ensure that the arrangement is expected to continue to satisfy the standard set forth in paragraph (w)(3) of this section, and must document the re-evaluation contemporaneously. The documentation must be made available to the Secretary upon request. Arrangements must not be renewed or renegotiated unless the health center reasonably expects the standard set forth in paragraph (w)(3) of this section to be satisfied in the next agreement term. Renewed or renegotiated agreements must comply with the requirements of paragraph (w)(3) of this section.

(5) The individual or entity does not (i) Require the health center (or its affiliated health care professionals) to refer patients to a particular individual or entity, or (ii) restrict the health center (or its affiliated health care professionals) from referring patients to any individual or entity.

(6) Individuals and entities that offer to furnish goods, items, or services without charge or at a reduced charge to the health center must furnish such goods, items, or services to all patients from the health center who clinically qualify for the goods, items, or services, regardless of the patient's payor status or ability to pay. The individual or entity may impose reasonable limits on the aggregate volume or value of the goods, items, or services furnished under the arrangement with the health center, provided such limits do not take into account a patient's payor status or ability to pay.

(7) The agreement must not restrict the health center's ability, if it chooses, to enter into agreements with other providers or suppliers of comparable goods, items, or services, or with other lenders or donors. Where a health center has multiple individuals or entities willing to offer comparable remuneration, the health center must employ a reasonable methodology to determine which individuals or entities to select and must document its determination. In making these determinations, health centers should look to the procurement standards for recipients of Federal grants set forth in 45 CFR 74.40 through 74.48.

(8) The health center must provide effective notification to patients of their freedom to choose any willing provider or supplier. In addition, the health center must disclose the existence and nature of an agreement under paragraph (w)(1) of this section to any patient who inquires. The health center must provide such notification or disclosure in a timely fashion and in a manner reasonably calculated to be effective and understood by the patient.

(9) The health center may, at its option, elect to require that an individual or entity charge a referred health center patient the same rate it charges other similarly situated patients not referred by the health center or that the individual or entity charge a referred health center patient a reduced rate (where the discount applies to the total charge and not just to the cost-sharing portion owed by an insured patient).

For purposes of this paragraph, the term ''health center'' means a Federally Qualified Health Center under section 1905(l)(2)(B)(i) or 1905(l)(2)(B)(ii) of the Act, and ''medically underserved population'' means a medically underserved population as defined in regulations at 42 CFR 51c.102(e).

* * * * *

Dated: May 8, 2007.

Daniel R. Levinson,

Inspector General.

Approved: June 27, 2007.

Michael O. Leavitt,

Secretary.

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