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

Accordingly, the proposed rule of November 12, 2004 (69 FR 65395) is hereby withdrawn.

Dated: June 28, 2005.

Sheryl D. Kennerly,

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

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

BILLING CODE 6353–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Office of Inspector General

42 CFR Part 1001

RIN 0991–AB38

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

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

ACTION: Notice of proposed rulemaking.

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

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

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

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

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

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

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

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

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

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

SUPPLEMENTARY INFORMATION:

I. Background

A. The Anti-Kickback Statute and Safe Harbors

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

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

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

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

B. Section 330-Funded Health Centers

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

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

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 2003, the Federal health center programs supported 890 organizations that provided care to over 12 million patients at 3,600 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 (Internal Revenue Code section 501(c)(3) corporations) 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)(l). 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)(l). 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 2003, 36 percent of patients treated by section 330 grant recipients were beneficiaries of a Medicaid program, 7 percent were beneficiaries of the Medicare program, and 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 2003, this number had increased to 4.9 million, representing 39 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)(l)(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. In general, section 330 grant funds help make up for shortfalls in health center revenues. Thus, 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 25 to 30 percent of revenue for health centers receiving such grants. The majority of health center funding derives from charges for patient services. On average, approximately 6.2 percent of health center revenues come from private third-party reimbursement, 35.5 percent from Medicaid payments, 5.5 percent from Medicare payments, and 5.9 percent from self-payments from patients.[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

[2] Bureau of Primary Health Care, ''Section 330 Grantees Uniform Data System: Calendar Year 2003 Data'' (available at *http://www.bphc.hrsa.gov/uds/data.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 the requirement. 42 U.S.C. 254b(k)(3)(H).

[4] Bureau of Primary Health Care, ''Section 330 Grantees Uniform Data System: Calendar Year 2003 Data''—Table 4: Users by Socioeconomic Characteristics (available at *http://www.bphc.hrsa.gov/uds/data.htm*).

[5] Bureau of Primary Health Care, ''Section 330 Grantees Uniform Data System: Calendar Year 2003 Data''—UDS Trend Data for Years 1996 through 2003 (available at *http://www.bphc.hrsa.gov/uds/data.htm).*

[6] Bureau of Primary Health Care, ''Section 330 Grantees Uniform Data System: Calendar Year 2003 Data''—Exhibit A: Total Revenue Received by BPHC Grantees (available at *http://www.bphc.hrsa.gov/uds/data.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.

in-kind donations of supplies, equipment, or space.

Some providers and suppliers have 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 amends 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, *i.e.*, 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 exception to certain health centers engaged in arrangements involving specific types of identifiable remuneration.

Section 431(b) of MMA requires the Department to promulgate regulatory standards relating to the new safe harbor. In establishing the standards, 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's 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's 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's 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. Section 431(b)(1) of MMA. 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 statue and the health center exception. 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.

II. Provisions of the Proposed Rule

This proposed rule would establish standards for a safe harbor under the anti-kickback statute that would protect certain remuneration provided by an individual or entity to certain health centers funded under section 330 of the PHS Act when all safe harbor conditions are satisfied.

A. Statutory Elements

1. Protected Health Centers

The health center safe harbor would be limited to health centers described under section 1905(l)(2)(B)(i) or 1905(l)(2)(B)(ii) of the Act. These sections describe health centers that satisfy all requirements for a section 330 grant and: (i) Directly receive such a grant; or (ii) receive such grant funding under contract with a grant recipient. For the purposes of these regulations, the facilities described in sections 1905(l)(2)(B)(i) and 1905(l)(2)(B)(ii) of the Act are referred to as ''health centers.'' These health centers are two of the four types of Federally qualified health centers (FQHCs) described in section 1905(l)(2)(B) of the Act. Congress excluded from safe harbor protection the two other types of FQHCs described in sections 1905(l)(2)(B)(iii) and 1905(l)(2)(B)(iv) of the Act. Although these or other ''look-alike'' facilities might qualify for section 330 grant funding, they do not actually receive section 330 grant funding and are not similarly subject to Government oversight inherent in the grant approval and administration processes. We note that arrangements involving these other types of facilities that do not qualify for safe harbor protection are not necessarily unlawful under the anti-kickback statute; rather, such arrangements must be evaluated on a case-by-case basis for compliance with the anti-kickback statute.

2. Protected Remuneration

Section 431(a)(3) of MMA defines the scope of protected remuneration as ''goods, items, services, donations, loans, or a combination thereof'' provided by an individual or entity to a qualifying health center.[8] Other forms of remuneration fall outside the scope of the safe harbor. To ensure that protected arrangements further the purposes of the safe harbor, we would require that the remuneration must be medical or clinical in nature or relate directly to patient services furnished by the health center as part of the scope of the health center's section 330 grant (including, for example, billing services, administrative support services, technology support, and enabling services, such as case management, transportation, and translation services).

We interpret section 431 of MMA as applying to remuneration provided by an individual or entity to the health center. Section 431 of MMA does not protect remuneration from a health

[8] We note that the ''Stark law'' (section 1877 of the Act, 42 U.S.C. 1395nn) will apply to financial relationships between a health center and a physician who refers Medicare or Medicaid patients to the health center for ''designated health services'' (defined in the statute at 42 U.S.C. 1395nn(h)(6) and in the regulations at 42 CFR 411.351). All such arrangements must fit in a Stark law exception. *See generally* 42 U.S.C. 1395nn and 42 CFR part 411.

center to an individual or entity. Any such arrangements must be evaluated on a case-by-case basis to ensure compliance with the anti-kickback statute.[9] This interpretation is consistent with: (i) The statutory requirement that the remuneration contribute to the health center's ability to maintain or increase the availability or quality of services provided to medically underserved populations; and (ii) the factors set out in section 431(b), including, specifically, the factor at section 431(b)(i) related to the economic benefit to the health center.

Moreover, section 431(a)(3) of MMA makes clear that the health center exception only protects remuneration provided to a health center and does not protect remuneration provided to individuals affiliated with a health center, such as board members, physicians or other health care professionals, administrators, or others. Where remuneration results in personal gain for an individual in a position to influence the referral or award of business, there is an elevated risk of fraud or abuse.

Similarly, the exception, by its terms, does not protect remuneration offered by providers and suppliers to patients of the health center. Where the remuneration inures to the financial benefit of the patient, rather than the economic benefit of the health center, we believe the existing prohibitions on offering inducements to Federal health care program beneficiaries apply.[10] These existing prohibitions are intended to prevent unscrupulous providers and suppliers from luring vulnerable patients to receive unnecessary, substandard, or overpriced services.[11] Notwithstanding, we make the following observations:

- Remuneration, such as reduced charges or free services, offered by providers and suppliers to uninsured patients is not prohibited by the Federal fraud and abuse laws, except in the unusual circumstances where a patient is a potential source of referrals of Federal health care program business (for example, the patient is an uninsured referring physician or an uninsured spouse or child of a referring physician).[12]
- Providers and suppliers may waive the cost-sharing amounts for Federal health care program patients who have financial need, provided the provider or supplier does not routinely waive copayments; the waivers are not offered as part of an advertisement or solicitation; and the copayments are waived only after a good faith individualized determination of financial need or the failure of reasonable collection efforts.[13]

To further ensure transparency and untainted medical decision-making, we would require that the goods, items, services, donations, or loans to be provided under a protected arrangement must be specified and fixed in advance in the agreement between the parties in the form of a fixed amount or sum, fixed percentage, or other fixed methodology.[14] The fixed amount or sum, fixed percentage, or other methodology must not be conditioned on the volume or value of Federal health care program business generated between the parties. Requiring that the remuneration (or methodology for determining the remuneration) be fixed in advance would prevent the parties from subsequently adjusting the nature or quantity of the remuneration based on the volume or value of Federal health care program referrals generated by the health center. In addition, the requirement that the remuneration be fixed in advance and not conditioned on referrals would help protect the independent medical judgment of health care professionals.

3. Documentation Requirements

Section 431(a)(3) of MMA specifies that protected arrangements be ''pursuant to a contract, lease, grant, loan, or other agreement.'' To enable the parties and the government to verify compliance with the safe harbor, we would require that the agreement: (i) Be in writing; (ii) be signed by the parties; and (iii) cover all the goods, items, services, donations, and loans provided by the individual or entity to the health center. These requirements would be satisfied by one comprehensive writing or by means of multiple writings that cross-reference or otherwise incorporate other agreements between the parties. These proposed documentation conditions are consistent with other safe harbors at 42 CFR 1001.952. Moreover, we believe these proposed documentation practices are consistent with existing prudent business practices of health centers. Importantly, the conduct of the arrangement must comport with the terms of the written agreement.

4. Benefit to a Medically Underserved Population

Section 431(a)(3) of MMA requires that a protected arrangement 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 served by the health center.'' This benefit to a medically underserved population is a critical factor distinguishing the safe harbored conduct from many otherwise potentially abusive arrangements.

Under existing program rules, health centers serve: (i) Populations that are medically underserved; or (ii) special medically underserved populations comprised of migratory and seasonal agricultural workers, homeless people, and residents of public housing. 42 U.S.C. 254b(a)(1). The term ''medically underserved population'' means ''the population of an urban or rural area designated by the Secretary as an area with a shortage of personal health services or a population group designated by the Secretary as having a shortage of such services.'' 42 U.S.C. 254b(b)(3)(A). The Secretary bases such determinations on the health status of the population, as well as its ability to access and pay for needed services. Accordingly, for purposes of this safe harbor, we would define ''medically underserved population'' with reference

[9] We note that some such arrangements may fit in other available safe harbors, such as the safe harbors for personal services and management contracts, employees, or practitioner recruitment, 42 CFR 1001.952(d), (i), and (n).

[10] These prohibitions are the CMP law against offering inducements to Medicare or Medicaid beneficiaries, section 1128A(a)(5) of the Act, and the anti-kickback statute. Exceptions to section 1128A(a)(5) of the Act are set forth at section 1128A(i)(6) of the Act.

[11] In August 2002, we issued a Special Advisory Bulletin on ''Offering Gifts and Other Inducements to Beneficiaries'' (available on our web site at *http://www.oig.hhs.gov/fraud/docs/alertsandbulletins/SABGiftsandInducements.pdf*) that explains our concerns regarding improper beneficiary inducements and our interpretation of the existing prohibitions.

[12] In February 2004, we issued a guidance document on discounts for patients who cannot afford to pay their hospital bills (available on our web site at *http://www.oig.hhs.gov/fraud/docs/alertsandbulletins/2004/FA021904hospitaldiscounts*).The analytical framework contained in this guidance would apply similarly to discounts offered to uninsured patients by other types of providers or suppliers.

[13] *See, e.g.*, section 1128A(i)(6) of the Act; Special Fraud Alert, ''Routine Waiver of Part B Co-payments/Deductibles'' (available on our Web site at *http://www.oig.hhs.gov/fraud/docs/alertsandbulletins/121994.html*); Special Advisory Bulletin, ''Offering Gifts and Other Inducements to Beneficiaries'' (*id.* at fn. 9). We also note that the anti-kickback statute allows health centers to waive copayments under a special exception at 42 U.S.C. 1320a–7b(b)(3)(D); 42 CFR 1001.952(k)(2).

[14] In the unique and limited context of arrangements described in this 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 calculating the compensation (*e.g.*, $ × per hour or $ × per service) is fixed in advance and not conditioned on referrals to the supplier.

to the existing definition at 42 U.S.C. 254b(b)(3)(A) and the corresponding regulations at 42 CFR 51c.102(e). All health centers that qualify for section 330 funding serve at least one medically underserved population.

While the statute requires that a protected arrangement benefit a medically underserved population served by the health center by maintaining or increasing the availability or quality of services provided to the medically underserved population, Congress established no specific methodology for determining whether this benefit standard is satisfied. Having considered various options, we have concluded that Congressional intent would best be served by assessing whether an arrangement would result in the required benefit based upon the particular facts and circumstances. We believe health centers are well situated in the first instance to make a reasonable determination whether an arrangement will increase the availability, or enhance the quality, of services provided to a medically underserved population.

We do not interpret the statute as protecting arrangements in which the benefit to the health center and the medically underserved population it serves is merely incidental or where the arrangement primarily benefits the donor (*e.g.*, through referrals of Federally billable business) rather than the health center. An incidental benefit to a medically underserved population tangentially related to an arrangement would not suffice to protect an arrangement under this proposed safe harbor. Accordingly, the proposed regulations would require that the arrangement must 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.

In determining whether an arrangement would result in a meaningful benefit to a medically underserved population, the following factors, among others, should be considered:

- Does the arrangement directly benefit a medically underserved population (*e.g.*, additional services of physicians or allied health professionals at the health center)?
- 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? It is important to note that this safe harbor only protects arrangements involving remuneration that helps the health center fulfill its section 330-grant mission (including, for example, transportation and other enabling services that help patients access the services available from the health center), but does not protect remuneration that does not further the health center's mission (*e.g.*, unnecessary office space, superfluous supplies, or expired medications).

These factors are illustrative, not exhaustive, of relevant considerations. No one factor would be dispositive in determining whether an arrangement confers the benefit required for safe harbor protection. We are soliciting public comments on methods for establishing that an arrangement will confer the requisite benefit to a medically underserved population.

Health centers would be required to take reasonable and verifiable steps to ensure that all arrangements meaningfully contribute to the quality or availability of services the center provides to a medically underserved population. Specifically, to qualify for safe harbor protection, the health center would have to:

- Reasonably determine before entering into the 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 to a medically underserved population. Health centers would have to apply reasonable, consistent, and uniform standards for determining this benefit to all proposed arrangements involving similar items, goods, services, loans, or donations. Assuming there is a reasonable and documented expectation of sufficient benefit at the onset of an agreement, the arrangement would not lose its safe harbor protection retroactively if the expected benefit were not, in fact, realized for reasons beyond the control of the parties.
- Periodically re-evaluate agreements to ensure ongoing compliance with the benefit standard and terminate as expeditiously as possible any arrangements that are not reasonably expected to continue to meet the standard. Re-evaluation would need to be conducted at reasonable intervals not to exceed one year, applying reasonable, consistent, and uniform standards. Terminated agreements would not be able to be renegotiated in a manner that is conditioned on the volume or value of Federal health care program referrals. Similarly, arrangements would not be able to be renewed unless the health center reasonably expected the benefit to a medically underserved population standard to be satisfied in the next agreement term.
- Document the initial determination and any re-evaluations contemporaneously. The nature of the documentation would need to be reasonable under the circumstances. Acceptable documentation might include, for example, an estimate of the value of the remuneration exchanged in the particular arrangement and its usefulness to the health center. For example, for an arrangement involving donated equipment, the health center might document the fair market value of the donated equipment or the expenses the health center would have otherwise incurred to purchase or lease similar equipment, as well as the extent to which accepting the donated equipment would increase the quantity or quality of services provided to health center patients. Similarly, for an arrangement involving a monetary donation, the health center might document the amount of the donation and the estimated health care services to be purchased or furnished with the funds. The health center would need to make this documentation available to the Secretary upon request.

We think it likely that many of these steps are those that a prudent health center would otherwise take when evaluating an offer from an individual or entity.

B. Additional Regulatory Standards

Section 431(b) of MMA authorizes us to add additional standards or criteria consistent with Congress's intent in creating an exception under the anti-kickback statute for certain arrangements involving health centers. As discussed above, Congress set forth specific factors that we must consider when establishing safe harbor standards.

1. Freedom of Choice and Independent Medical Judgment

Section 431(b) of MMA directs us to consider the impact of a health center's arrangement on patient freedom of choice and the independent medical judgment of health care professionals.

As these two factors are related, we will address them together. In identifying these two factors, Congress emphasized an important patient protection function of the anti-kickback statute: Preventing both the corruption of medical judgment by financial incentives and improper steering of patients. We are proposing in the safe harbor regulation the following standards intended to ensure that protected arrangements do not impair patient freedom of choice or the independent medical judgment of health care professionals:

- First, under the arrangement, health centers must not be required to refer patients to a particular provider or supplier, and there must be no restrictions on the health center's or its health care professionals' freedom to refer patients to any provider or supplier. For example, a protected arrangement could not require a health center to refer a certain number or proportion of its patients, or a particular category of patients, to a particular provider or supplier.
- Second, individuals and entities 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. The provider or supplier may impose reasonable overall limits related to the resources it will devote to health center patients. For example, a provider can cap the aggregate number of health center patients it has the capacity to treat, but it cannot determine that it will only treat health center patients who are Medicare beneficiaries. This standard is intended to prevent providers or suppliers in an arrangement with a health center from ''cherry picking'' particular types of health center patients. In addition, this standard helps ensure that health centers remain free to refer patients based on the patient's health care needs.
- Third, the protected arrangement cannot be exclusive. The individual or entity cannot 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 providers or suppliers willing to offer comparable remuneration, the health center must employ a reasonable methodology to determine which prospective partners to select and must document its determination. In making these determinations, health centers should look to the procurement standards for recipients of Federal grants. *See* 45 CFR 74.40 *et seq.*
- Fourth, health centers must provide effective notification to patients of their freedom to choose any willing provider or supplier. Moreover, a health center must disclose the existence and nature of a protected arrangement: (i) To any patient who inquires; and (ii) to any patient referred to an individual or entity that is a party to the protected arrangement for the furnishing of separately billable items or services (*i.e.,* an item or service for which the patient or a third-party payor, rather than the health center, may be obligated to pay). Such disclosure need only be made to a patient the first time the patient is referred to the particular individual or entity. This 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. The health center must provide required patient disclosures in a timely fashion and in a manner reasonably calculated to provide effective notice and to be understood by the patient. The appropriate disclosure method will necessarily vary depending on the individual characteristics of the health center and its patients. We are electing not to require broader disclosure to patients of all relationships covered by the safe harbor, because we do not believe broader disclosure would be an effective means of preserving health center patients' freedom of choice and, in some situations, might be confusing to the patients served by the health center. Notwithstanding, health centers would be encouraged to consider whether broader disclosure would benefit their patients and, if so, how best to convey useful information to patients. We note that, in many situations, it may be feasible for health centers to provide the required notice through posting lists of arrangements in conspicuous places in the health center and directing patients to those postings.

2. Additional Standards To Prevent Abuse of Federal Health Care Programs and To Protect Patients

As noted above, in accordance with our authority under section 431(b)(1) of MMA to consider other factors and to add additional standards and criteria, we have also considered whether arrangements between health centers and individuals or entities may pose a risk of abuse to Federal health care programs other than the section 330 grant program, such as Medicare or Medicaid, or to beneficiaries. To safeguard these programs and their beneficiaries, we propose adding the following standards to the safe harbor:

- First, the health center may elect to require that an individual or entity 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 (where the discount applies to the total charge and not just to the cost-sharing portion owed by an insured patient). This condition would apply when the individual or entity is billing patients or third parties, rather than the health center, for the items or services.
- Second, no arrangement may enjoy protection under this safe harbor unless it complies with the requirements of the health center's section 330 grant funding.

We further note that providers and suppliers who furnish items and services to Federal health care program patients referred by a health center must comply with all Federal and State laws, including, without limitation, relevant Federal health care program rules governing billing and claims submission. We are concerned that some providers and suppliers may seek to recoup amounts donated to a health center through improper billing of Federal health care programs or inappropriate transfers of governmental funds. We will give further consideration to this potential problem in the final regulations. Once the final regulations are promulgated, we intend to monitor participants in the safe-harbored arrangements for compliance with billing rules.

We are soliciting public comments on these standards, as well as any other standards or criteria that should be included in this safe harbor to achieve its purpose of protecting beneficial, low-risk arrangements.

III. Regulatory Impact Statement

A. Regulatory Analysis

We have examined the impact of this proposed rulemaking 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 proposed 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 final regulations, once promulgated, so that they have assurance that participating in covered agreements will not subject them to any enforcement actions under the anti-kickback statute. The safe harbor would facilitate health centers' ability to provide important health care services to communities in need and help these centers fulfill their mission as integral components of the health care safety net. As such, we believe that the aggregate economic impact of this rulemaking would be minimal and would have no effect on the economy or on Federal or State expenditures. To the extent that there is any economic impact, that impact would 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 proposed safe harbor that would 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. Pursuant to 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 proposed safe harbor may have an impact on small rural hospitals, we believe that the aggregate economic impact of this rulemaking would 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 rulemaking do not engage in prohibited arrangements, schemes, or practices in violation of the law, we have concluded that this proposed 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 proposed rule would not significantly limit the rights, roles, and responsibilities of State or local governments. We have determined, therefore, that a full analysis under these Acts is not necessary.

The Office of Management and Budget (OMB) has reviewed this proposed 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.

This proposed safe harbor would impose some minimal information collection requirements on health centers. Specifically, for an arrangement to fall within the proposed safe harbor it would have to fulfill the following documentation requirements: (1) It must be in writing; (2) the written agreement must be signed by the parties; (3) the written agreement must cover all the goods, items, services, donations, and loans provided to the health center; and (4) the health center must document a potential benefit to a medically underserved population. However, these 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. As recipients of Federal grant money, these health centers are already obligated to comply with the administrative requirements, including certain documentation requirements, outlined in 45 CFR part 74. 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 all health centers serve at least one such population) and the section 330 grant program, documentation of such benefit would seem to be a prudent business practice to ensure continued compliance not only with the proposed safe harbor but also with the section 330 grant program.

Under certain circumstances, we would require health centers to provide effective notification to patients, disclosing the existence of arrangements protected under this safe harbor and reminding patients of their freedom to

choose any willing provider or supplier. Disclosures would not need to be in writing; rather, we would 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 this notification requirement would achieve the goal of protecting patients without imposing a significant additional administrative burden on health centers. Moreover, we believe the notification requirement would 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.

Thus, we believe that the documentation requirements necessary to enjoy safe harbor protection would not qualify as an added paperwork burden in accordance with 5 CFR 1320.3(b)(2), because the requirements are consistent with the usual and customary business practices of health centers and because the time, effort, and financial resources necessary to comply with the requirements would largely be incurred by health centers in the normal course of their business activities. With respect to the patient notification requirement, we do not believe the requirement would impose an added paperwork burden because the notice need not be written. Furthermore, the notice would only need to be provided in a limited number of circumstances and the requirement is consistent with the health centers' ongoing mission to protect vulnerable patients.

We are specifically soliciting public comments with respect to these requirements. Comments on these requirements should be sent to the following address within 60 days following the **Federal Register** publication of this interim final rule:

HHS OIG Desk Officer, Office of Management and Budget, Room 10235, New Executive Office Building, 725 17th Street, NW., Washington, DC 20053, FAX: (202) 395–6974.

IV. Public Inspection of Comments and Response to Comments

Comments will be available for public inspection beginning on July 15, 2005 in Room 5518 of the Office of Inspector General at 330 Independence Avenue, SW., Washington, DC on Monday and through Friday of each week (Federal holidays excepted) between the hours of 8 a.m. and 4 p.m., (202) 619–0089. Because of the large number of comments we normally receive on regulations, we cannot acknowledge or respond to comments individually. However, we will consider all timely and appropriate comments when determining whether to revise this interim final rule.

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 would continue 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 would be amended by republishing the introductory paragraph for this section and by adding a new paragraph (w) 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, loans, or combination thereof from an individual or entity to a health center (as defined in this paragraph), as long as the following eleven standards are met—

(1) The transfer is made pursuant to a contract, lease, grant, loan, or other agreement that is set out in writing, signed by the parties, and covers all the goods, items, services, donations, and loans to be provided by the individual or entity to the health center.

(2) The goods, items, services, donations, or loans are medical or clinical in nature or relate directly to patient services furnished 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 written agreement specifies and sets forth the amount of goods, items, services, donations, or loans to be provided to the health center (where such amount may be a fixed sum, fixed percentage, or set forth by a fixed methodology), and the amount is not conditioned on the volume or value of Federal health care program business generated between the parties.

(4) 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. Health centers must apply reasonable, consistent, and uniform standards when making the determination. The documentation must be made available to the Secretary upon request.

(5) 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)(4) of this section. The health center must apply reasonable, consistent, and uniform standards when making the re-evaluation, and must document the re-evaluation contemporaneously. The documentation must be made available to the Secretary upon request. Noncompliant arrangements must be promptly terminated. Terminated agreements must not be renegotiated in a manner that is conditioned on the volume or value of Federal health care program business generated between the parties. Similarly, arrangements must not be renewed or renegotiated unless the health center reasonably expects the standard set forth in paragraph (w)(4) of this section to be satisfied in the next agreement term. Renewed or renegotiated agreements must comply with the requirements of paragraph (w)(4) of this section.

(6) The health center (and its affiliated health care professionals) must not be required to refer patients to a particular individual or entity, and the health center (and its affiliated health care professionals) must be free to refer patients to any provider or supplier.

(7) Individuals and entities that offer to provide goods, items, or services to health center patients must accept all referrals of 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 referrals it will accept.

(8) 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 prospective partners to select and must document its determination. In making these determinations, health centers should look to the procurement standards for recipients of Federal grants. *See* 45 CFR 74.40 *et seq*.

(9) 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 arrangement under this paragraph to any patient who inquires and upon the initial such referral, to any patient referred to an individual or entity that is a party to the arrangement for the furnishing of separately billable items or services (*i.e.*, an item or service for which the patient or a third-party payor, rather than the health center, may be obligated to pay). The health center must provide required patient disclosures in a timely fashion and in a manner reasonably calculated to be effective and understood by the patient.

(10) Under the arrangement, the health center may elect to require that the individual or entity charge a referred health center patient the same rate it charges other 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).

(11) The agreement must comply with all relevant requirements of the health center's section 330 grant funding. 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: January 31, 2005.

Daniel R. Levinson,

Acting Inspector General.

Approved: March 2, 2005.

Michael O. Leavitt,

Secretary.

[FR Doc. 05–13049 Filed 6–30–05; 8:45 am]

BILLING CODE 4150–01–P