control devices? What were the costs of the engine models?

(g) How much did control devices cost for different horse-powered engines?

(h) Did mine operators have to modify the exhaust system to apply the DPM control? What were the costs for doing so?

(i) What are the advantages, disadvantages, and relative costs of different DPM control devices?

(j) What types of DPM control devices are commercially available and how much do these devices cost?

(k) What are the engineering costs of the DPM control devices?

(l) What current reductions in EC levels are mine operators experiencing from having installed DPM control devices? What is the experience with filtration efficiencies?

(m) What has been the experience of mine operators with the useful life of DPM filters?

(n) Is there any information available with DPM control filters in non-mining industries or in other countries?

(o) What has been the experience of mine operators with DPM filters? Did filters fail or did they perform as the manufacturer predicted? If they failed, what were the causes of filter failure? What could be done to prolong the life of DPM filters?

(p) Do mine operators have any technical data on their experience with using cabs with filtered breathing air?

(q) Have you experienced increases in NO_2 when using any of the following: (1) A base-metal catalyzed filter; (2) a non-catalyzed filter; or (3) platinum-based catalyzed filter?

(r) What effect do high altitudes have on the ability of the DPM control device to reduce DPM exposures?

(s) What costs did mine operators incur for filters that were regenerated off board?

(t) What costs did mine operators incur for filters that were regenerated on board?

(u) Would active regeneration be feasible for your mine; such as off-board filter regeneration in an oven, or on-board electrical regeneration?

(v) What are the costs to mine operators for new engines and venting for filter ovens?

(w) Would fuel additives used to facilitate regeneration be feasible?

(x) Are there any significant technologies for controlling DPM when EC is the surrogate?

9. *Paperwork Burden Issues.*

What paperwork and other costs will you incur if changes are made to the DPM standard, particularly development of a written program for use of administrative controls, use of respiratory protection, and for development of a control plan?

Dated: September 20, 2002.

Dave D. Lauriski,

Assistant Secretary of Labor for Mine Safety and Health.

[FR Doc. 02–24370 Filed 9–20–02; 4:22 pm]

BILLING CODE 4510–43–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

42 CFR Part 1001

RIN 0991–AB16

Medicare and State Health Care Programs: Fraud and Abuse; Safe Harbor Under the Anti-Kickback Statute For Waiver of Beneficiary Coinsurance and Deductible Amounts

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

ACTION: Notice of proposed rulemaking.

SUMMARY: This proposed rule would expand the existing safe harbor for certain waivers of beneficiary coinsurance and deductible amounts to benefit the policyholders of Medicare SELECT supplemental insurance. Specifically, the amended safe harbor would protect waivers of coinsurance and deductible amounts under Part A or Part B of the Medicare program owed by beneficiaries covered by a Medicare SELECT supplemental insurance policy issued in accordance with section 1882(t)(1) of the Social Security Act (the Act), if the waiver is in accordance with a price reduction agreement covering such policyholders between the Medicare SELECT issuer and the provider or supplier offering the waiver and the waiver is otherwise permitted under the Medicare program.

DATES: To assure consideration, public comments must be delivered to the address provided below by no later than 5 p.m. on October 25, 2002.

ADDRESSES: Please mail or deliver your written comments to the following address: Department of Health and Human Services, Office of Inspector General, 330 Independence Avenue, SW., Room 5246, Attention: OIG–729–P, Washington, DC 20201.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file OIG–729–P.

FOR FURTHER INFORMATION CONTACT: Vicki L. Robinson, Senior Counsel, 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 Act (42 U.S.C. 1320a–7b(b)) provides criminal penalties for individuals or entities that knowingly and willfully offer, pay, solicit, or receive remuneration (*i.e.*, anything of value, in cash or in kind) in order to induce or reward the referral of business reimbursable by a Federal or State health care program. Violations of the 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)).

The statute has been in existence since 1977 and applies broadly to all kinds of health care providers and suppliers. Payments tied to referrals corrupt the health care system, increasing the risks of overutilization of items and services, increased costs to the Federal health care programs, inappropriate steering of patients, and unfair competition.

In response to concerns that the statute technically covered some relatively innocuous commercial arrangements, subjecting them to criminal prosecution, Congress enacted section 14 of the Medicare and Medicaid Patient and Program Protection Act of 1987, Public Law 100–93, which specifically required the development and promulgation of the ''safe harbor'' provisions. The safe harbor regulations specify various payment and business practices that, although potentially capable of inducing referrals of business reimbursable under the Federal health care programs, would not be treated as criminal offenses under the anti-kickback statute. Since July 29, 1991, we have published in the **Federal Register** a series of final regulations establishing safe harbors for various business practices.[1]

Health care providers and others may voluntarily comply with these provisions to ensure that their business practices are not subject to any enforcement action under the anti-kickback statute, including the CMP provision for anti-kickback violations and the program exclusion authority related to kickbacks. In giving the

[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).

Department 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. Safe Harbor Regarding Waiver of Beneficiary Coinsurance and Deductible Amounts in Accordance With an Agreement between a Hospital and a Medicare SELECT Issuer

On July 29, 1991, the Department published final regulations (56 FR 35952) that included, among other provisions, a safe harbor for the waiver or reduction of coinsurance or deductible amounts (cost-sharing amounts) for inpatient hospital services reimbursed under the prospective payment system (42 CFR 1001.952(k)(1)). For full or partial waivers to be protected, three standards had to be met: (1) The hospital could not claim waived amounts as bad debt or otherwise shift the cost of the waivers; (2) the hospital could not discriminate in offering waivers or reductions based on the patient's reason for admission; and (3) the waivers or reductions could not result from an agreement between the hospital and a third-party payer. The Department concluded that waivers of cost-sharing amounts for inpatient hospital services that complied with these standards would not increase costs to the Medicare program, shift costs to other payers, or increase patient demand for inpatient hospital services.

On November 5, 1992, the Department issued an interim final rule (57 FR 52723) modifying the safe harbor to accommodate the waiver or reduction of inpatient hospital cost-sharing amounts made in accordance with a contract between the hospital and a Medicare SELECT issuer. Unlike conventional Medicare supplemental insurance policies, which must by law cover cost-sharing amounts for most Medicare services provided by qualified providers or suppliers, a Medicare SELECT issuer may contract selectively with providers or suppliers to waive cost-sharing amounts it would otherwise have to pay on behalf of policyholders, subject to certain conditions to ensure access, coverage, and quality. In other words, Medicare SELECT is similar to a preferred provider network; enrollees may receive reduced supplemental benefits (e.g., less coverage of Medicare cost-sharing) if they use an out-of-network provider. Under the 1992 modified safe harbor, Medicare SELECT issuers can enter into contracts with hospitals to waive or reduce inpatient hospital cost-sharing amounts for Medicare SELECT enrollees, provided the other requirements of the safe harbor are met. On January 25, 1996, the Department published final regulations (61 FR 2122) that included the amendments to the safe harbor made by the interim final rule.

II. Provisions of the Proposed Modification to the Rule

This proposed rule modification would add a new subsection to 42 CFR 1001.952(k) to supplement the current safe harbor to include waivers of cost-sharing amounts for Part A or Part B services for Medicare SELECT policyholders in accordance with an agreement between the Medicare SELECT issuer and a provider or supplier, *provided that the waivers are otherwise permitted under applicable Medicare program laws, regulations, and policies.* This new subsection has the limited purpose of making clear that Medicare SELECT waivers, when implemented in accordance with the safe harbor conditions, will not violate the anti-kickback statute. However, the scope of acceptable waivers under the Medicare SELECT program is within the purview of the Centers for Medicare and Medicaid Services (CMS). For example, should CMS pay exclusively based on charges (*e.g.*, no fee schedule, cap, composite rate, or prospective payment) for any fee-for-service Medicare service, we expect that CMS would not authorize routine waivers of cost-sharing amounts for those services, including waivers for Medicare SELECT beneficiaries. In short, this safe harbor will make it easier for CMS to change or expand the scope of the Medicare SELECT program.

In 1996, we specifically declined to protect waivers of cost-sharing amounts for other than hospital inpatient services. That decision was based on several reasons, including: (1) The expanded waivers were not necessary or essential to the operation or development of Medicare SELECT provider networks; (2) there was a possibility that the waivers could lead to overutilization of services and, consequently, increased costs to the Medicare program; and (3) the waivers could raise potential issues under the False Claims Act (31 U.S.C. 3729).

There have been several developments since our decision in 1996 to limit protection to waivers of hospital inpatient cost-sharing amounts for Medicare SELECT enrollees. In particular, an extensive study of the Medicare SELECT demonstration determined that the absence of a safe harbor under the anti-kickback statute for waivers of Part B cost-sharing amounts was a major impediment to expanding the Medicare SELECT networks beyond hospitals.[2] In addition, Congress made the Medicare SELECT program permanent, giving Medicare beneficiaries a wider choice of Medicare supplemental insurance coverage plans.[3] Also during the intervening period, there has been a significant movement away from cost-based and charge-based reimbursement methodologies in the Medicare program and a concomitant increase in prospective payment methodologies. Finally, there has been an increase in consumer preference for flexible managed care arrangements, such as preferred provider plans.

In light of these intervening events, we have reconsidered our earlier decision to limit the safe harbor for Medicare SELECT waivers of cost-sharing amounts to hospital inpatient services. First, the detailed evaluation of the Medicare SELECT demonstration determined that a major shortcoming of the plans was that they were almost exclusively limited to hospital networks—a direct result of the absence of broader safe harbor protection for other suppliers and providers. Given that Congress has demonstrated its support for the Medicare SELECT program by making it permanent, we should try to maximize the program's chances for success to the extent practical.

Second, we believe the expansion of the safe harbor to cover all otherwise permitted waivers of cost-sharing for Medicare services covered by a Medicare SELECT program will benefit the public by providing more choice in coverage and pricing for the Medicare supplemental insurance market. To the extent the safe harbor results in reduced expenditures for the issuer, it will also be likely to reduce the price of supplemental insurance coverage for beneficiaries who purchase Medicare SELECT policies. We understand that CMS intends that issuers will pass on a significant share of savings to beneficiaries; beneficiaries may either realize those savings in cash or purchase a policy that has greater coverage than they might otherwise be able to afford.

Third, we do not believe that the expansion of the safe harbor would result in a substantial overutilization or inappropriate utilization of Medicare services by enrollees. It is well

[2] *See* ''Impact of Medicare SELECT on Cost and Utilization in 11 States,'' *Health Care Financing Review,* Fall 1997.

[3] Public Law 104–18.

established that any Medicare supplemental insurance coverage increases utilization, by virtue of removing discrete beneficiary cost-sharing obligations. The increase in utilization occurs with the shifting of cost-sharing obligations from a beneficiary to an insurer regardless of whether the insurer pays the cost-sharing obligations or enters into an agreement with a provider to waive cost-sharing amounts. If a beneficiary already has supplemental coverage, a waiver of cost-sharing amounts does not pose any additional risk of increased utilization.

Notwithstanding this proposed safe harbor, Medicare SELECT issuers, providers, and suppliers would still need to comply with all applicable Medicare program laws, regulations, and policies regarding payment and cost-sharing waivers.

III. Regulatory Impact Statement

A. Regulatory Analysis

We have examined the impacts of this proposed rule as required by Executive Order 12866, the Unfunded Mandates Reform Act of 1995, and the Regulatory Flexibility Act of 1980 (RFA) (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is 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 ($100 million or more in any given year). Since this proposed regulation will not have a significant effect on program expenditures and as there are no additional substantive costs to implement the resulting provision, we do not consider this to be a major rule. The provisions in this proposed rule will permit individuals and entities to engage freely in competitive business practices and arrangements. Parties may voluntarily comply with safe harbor provisions to ensure that business practices are not subject to any enforcement actions under the anti-kickback statute. The current safe harbor has resulted in Medicare SELECT preferred provider networks being limited to hospitals. The proposed safe harbor will facilitate the creation of significantly broader Medicare SELECT provider networks, making Medicare SELECT a more attractive insurance option. Moreover, we understand that CMS intends that broader Medicare SELECT networks will lead to savings for beneficiaries who purchase Medicare SELECT policies, either in the form of lower premiums or the ability to purchase a more comprehensive policy than they could otherwise afford.

Additionally, in accordance with the Unfunded Mandates Reform Act of 1995, we believe that there are no significant costs associated with these safe harbor guidelines that would impose any mandates on State, local, or tribal governments, or on the private sector that will result in an expenditure of $110 million or more, adjusted for inflation, in any given year. Further, in reviewing this rule under the threshold criteria of Executive Order 13132, Federalism, we have determined that this rule will not significantly affect the rights, roles, and responsibilities of States, and that a full analysis under these Acts is not necessary.

Further, in accordance with the RFA, and the Small Business Regulatory Enforcement and Fairness Act of 1996, which amended the RFA, we are required to determine if this proposed rule will have a significant economic effect on a substantial number of small entities and, if so, to identify regulatory options that could lessen the impact. For purposes of the RFA, small entities include small businesses, nonprofit organizations and Government agencies. Most hospitals (and most other providers) are small entities, either by nonprofit status or by having revenues of $5 million to $25 million or less annually. For purposes of the RFA, most other providers and suppliers that contract with Medicare SELECT issuers are considered to be small entities. Individuals and States are not included in the definition of a small entity. 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 providers. This analysis must conform to the provisions of section 603 of the RFA.

While these proposed safe harbor provisions may have an impact on small entities and rural providers, we believe that the aggregate economic impact of this proposed rulemaking will be minimal, since it is the nature of the conduct and not the size of the entity that results in a violation of the anti-kickback statute. Moreover, the proposed safe harbor may benefit some providers by increasing their flexibility to enter into Medicare SELECT provider agreements without risk under the anti-kickback statute. The safe harbor should effectively expand opportunities for providers to enter into preferred provider arrangements that they find beneficial. For these reasons and because the vast majority of individuals and entities potentially affected by this proposed regulation do not engage in prohibited arrangements, schemes, or practices in violation of the law, we are not preparing analyses for either the RFA or section 1102(b) of the Act, because we have determined, and we certify, that this proposed rule would not have a significant impact on a substantial number of small entities, or a significant impact on the operations of a substantial number of small rural providers.

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

B. Paperwork Reduction Act

Under the Paperwork Reduction Act (PRA) of 1995, we are required to provide a 60 day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to OMB for review and approval. In order to evaluate fairly whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA required that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our 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.

We are soliciting public comment on each of these issues with respect to the proposed safe harbor, which contains information collection requirements.

We believe the burden associated with these requirements is exempt in accordance with 5 CFR 1320.3(b)(2), because the requirements are consistent with the usual and customary business practices of issuers, providers, and suppliers, and because the time, effort, and financial resources necessary to comply with the requirements would be incurred by issuers, providers, and suppliers in the normal course of their business activities. Specifically, the safe harbor requires that: (i) The offer to waive cost-sharing amounts be part of a price reduction agreement in a contract for the furnishing of items and services to a Medicare SELECT beneficiary between the provider or supplier and the Medicare SELECT issuer; and (ii) the beneficiary must be covered by a Medicare supplemental insurance

policy that complies with the terms of section 1882(t)(1) of the Act. The network contracts and the insurance policies are prepared in the normal course of business and are usual and customary business practices for parties engaged in arrangements that would be covered by the safe harbor.

Comments on these information collection activities should be sent to the following address within 60 days following the **Federal Register** publication of this proposed rule: 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 October 25, 2002, in Room 5518, Office of Counsel to the Inspector General, at 330 Independence Avenue, SW., Washington, DC on Monday through Friday of each week (Federal holidays excepted) between the hours of 9 a.m. and 4 p.m., (202) 619–0089.

Because of the large number of items of correspondence we normally receive on **Federal Register** documents published for comment, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and will respond to the comments in the preamble of the 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 is proposed to 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 text, by revising the introductory text of paragraph (k), and by adding a paragraph (k)(3) 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:

* * * * *

(k) *Waiver of beneficiary coinsurance and deductible amounts.* As used in section 1128B of the Act, ''remuneration'' does not include any reduction or waiver of a Medicare or a State health care program beneficiary's obligation to pay coinsurance or deductible amounts as long as all of the standards are met within one of the following three categories of health care providers:

* * * * *

(3) If the coinsurance or deductible amounts are owed by an individual who is a beneficiary under title XVIII of the Act for items or services for which Medicare pays under parts A or B, the provider or supplier must comply with both of the following two standards—

(i) The provider or supplier must not later claim the amount reduced or waived as bad debt for payment purposes under Medicare or otherwise shift the burden of the reduction or waiver onto Medicare, a State health care program, other payers, or individuals.

(ii) The offer of the provider or supplier to reduce or waive the coinsurance or deductible amounts must be part of a price reduction agreement in a contract for the furnishing of items or services to a beneficiary of a Medicare supplemental policy issued under the terms of section 1882(t)(1) of the Act and the waiver must otherwise be permitted under applicable Medicare program laws, regulations, and policies.

* * * * *

Dated: August 13, 2002.

Janet Rehnquist,

Inspector General.

Approved: August 21, 2002.

Tommy G. Thompson,

Secretary.

[FR Doc. 02–24344 Filed 9–24–02; 8:45 am]

BILLING CODE 4150–04–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 02–2281, MB Docket No. 02–280, RM–10558]

Television Broadcast Service; Blanco, TX

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: The Commission requests comments on a petition filed by Univision Television Group, Inc., proposing the substitution of channel 17 for channel 52+ at Blanco, Texas. TV Channel 17 can be allotted to Blanco, Texas, with a zero offset at coordinates 29–42–58 N. and 98–30–39 W. Since the community of Blanco is located within 275 kilometers of the U.S.-Mexico border, concurrence from the Mexican government must be obtained for this allotment.

DATES: Comments must be filed on or before November 12, 2002, and reply comments on or before November 27, 2002.

ADDRESSES: Federal Communications Commission, 445 12th Street, SW., Room TW–A325, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve the petitioner, or its counsel or consultant, as follows: Scott R. Flick, Brendan Holland, Shaw Pittman LLP, 2300 N Street, NW., Washington, DC 20037–1128 (Counsel for Univision Television Group, Inc.).

FOR FURTHER INFORMATION CONTACT: Pam Blumenthal, Media Bureau, (202) 418–1600.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Notice of Proposed Rule Making, MB Docket No. 02–280, adopted September 13, 2002, and released September 18, 2002. The full text of this document is available for public inspection and copying during regular business hours in the FCC Reference Information Center, Portals II, 445 12th Street, SW., Room CY–A257, Washington, DC 20554. This document may also be purchased from the Commission's duplicating contractor, Qualex International, Portals II, 445 12th Street, SW., Room CY–B402, Washington, DC 20554, telephone 202–863–2893, facsimile 202–863–2898, or via e-mail *qualexint@aol.com*.

Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

Members of the public should note that from the time a Notice of Proposed