§ 165.110 [Amended]

2. In § 165.110(a)(1), remove the words ''two miles'' and add, in its place, the words ''one mile''.

Dated: April 3, 2000.

J.R. Whitehead,

Captain, U.S. Coast Guard, Captain of the Port, Boston, Massachusetts.

[FR Doc. 00–10848 Filed 5–1–00; 8:45 am]

BILLING CODE 4910–15–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 62

[OK–19–1–7453b; FRL–6582–2]

Approval and Promulgation of State Plans for Designated Facilities and Pollutants: Oklahoma

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: We propose to approve the section 111(d) Plan submitted by the Oklahoma Department of Environmental Quality on November 17, 1999, to implement and enforce the Emissions Guidelines (EG) for existing Hospital/Medical/Infectious Waste Incinerators (MWI). The EG require States to develop plans to reduce toxic air emissions from all MWIs. In the final rules section of this **Federal Register**, we are approving the State Plan as a direct final rule without prior proposal because we view this as a noncontroversial amendment and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this rule, no further activity is contemplated in relation to this rule. If we receive adverse comments, the direct final rule will be withdrawn, and all public comments received will be addressed in a subsequent final rule based on this proposed rule. We will not institute a second comment period on this action. Any parties interested in commenting on this action should do so at this time. Please see the direct final notice of this action located elsewhere in today's **Federal Register** for a detailed description of the Oklahoma State Plan.

DATES: Comments must be received by June 1, 2000.

ADDRESSES: You should address comments on this action to Lt. Commander Mick Cote, EPA Region 6, Air Planning Section (6PD–L), 1445 Ross Avenue, Suite 1200, Dallas, Texas 75202. Copies of all materials considered in this rulemaking may be examined during normal business hours at the following locations: EPA Region 6 offices, 1445 Ross Avenue, Suite 700, Dallas, Texas 75202, and at the Oklahoma Department of Environmental Quality offices, 707 North Robinson, Oklahoma City, Oklahoma 73101–1677.

FOR FURTHER INFORMATION CONTACT: Lt. Commander Mick Cote at (214) 665–7219.

List of Subjects in 40 CFR Part 62

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

Dated: March 31, 2000.

Jerry Clifford,

Acting Regional Administrator, Region 6.

[FR Doc. 00–10762 Filed 5–1–00; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

42 CFR Part 1003

RIN 0991–AB04

Medicare and State Health Care Programs: Fraud and Abuse; Civil Money Penalty Safe Harbor To Protect Payment of Medicare Supplemental Insurance and Medigap Premiums for ESRD Beneficiaries

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

ACTION: Notice of proposed rulemaking.

SUMMARY: In accordance with section 5201 of the Omnibus Consolidated and Emergency Supplemental Appropriations Act for Fiscal Year 1999, this proposed rule would set forth in the OIG's civil money penalty provisions in 42 CFR part 1003 a new safe harbor for unlawful inducements to beneficiaries to provide protection for independent dialysis facilities that pay, in whole or in part, premiums for Supplementary Medical Insurance (Medicare Part B) or Medicare Supplemental Health Insurance policies (Medigap) for financially needy Medicare beneficiaries with end-stage renal disease (ESRD). This safe harbor would specifically establish various standards and guidelines that, if met, would result in the particular arrangement being protected from civil sanctions under section 1128A(a)(5) of the Social Security Act.

DATES: To assure consideration, public comments on this proposed rule must be delivered to the address provided below by no later than 4:30 p.m. on July 3, 2000.

ADDRESSES: Please mail or deliver your written comments to the following address: Office of Inspector General, Department of Health and Human Services, Attention: OIG–699–P, Room 5546, Cohen Building, 330 Independence Avenue, S.W., Washington, D.C. 20201. We do not accept comments by facsimile (FAX) transmission. In commenting, please refer to code OIG–699–P.

FOR FURTHER INFORMATION CONTACT: Julie Kass (202) 205–9501 or Joel Schaer (202) 619–0089, Office of Counsel to the Inspector General.

SUPPLEMENTARY INFORMATION:

I. Background

A. Section 1128A(a)(5) of the Social Security Act

The Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104–191, amended the Social Security Act (Act) to prohibit providers from offering patients any inducement to order or receive items or services from a particular provider, practitioner or supplier. Specifically, section 231(h) of HIPAA established a new provision—section 1128A(a)(5) of the Act—to provide for the imposition of a civil money penalty (CMP) against any person who:

> Offers or transfers remuneration to any individual eligible for benefits under [Medicare or Medicaid] that such person knows or should know is likely to influence such individual to order or receive from a particular provider, practitioner, or supplier any item or service for which payment may be made, in whole or in part, under [Medicare or Medicaid].

Section 231(h) of HIPAA also created a new section 1128A(i)(6) of the Act to define the term ''remuneration'' for purposes of the new CMP. The section defines ''remuneration,'' in relevant part, as ''transfers of items or services for free or for other than fair market value.'' Remuneration does not include certain enumerated practices, including waivers of coinsurance and deductible amounts, if the waiver: (1) Is not advertised; (2) is not routinely offered; and (3) is made following an individualized good faith assessment of financial need or is made after reasonable efforts to collect the coinsurance or deductible amounts have failed. There is no exception for the payment of Medicare Part B or Medigap insurance premiums on behalf of beneficiaries even when the same criteria are met.

On October 21, 1998, Congress enacted the Omnibus Consolidated and Emergency Supplemental Appropriations Act for Fiscal Year 1999 (OCESAA), Public Law 105–277. Section 5201 of OCESAA specifically authorized the Secretary to issue regulations establishing ''safe harbors'' under section 1128A(a)(5) of the Act for payment practices that would otherwise run afoul of the statute. (In addition to this provision, the Secretary is vested with the authority to issue advisory opinions providing legal and regulatory guidance to providers under this section.) With respect to the payment of Medicare Part B and Medigap premiums for ESRD patients, Congress required any exception to be established through a rulemaking process and limited it to the two-year period beginning on the date the final rule is promulgated. In addition, if the Secretary promulgates a safe harbor for ESRD premiums, Congress required the Comptroller General of the United States to conduct a study of any disproportionate impact on specific issuers of Medigap insurance policies due to adverse selection in enrolling Medicare ESRD beneficiaries. The Comptroller report would include a recommendation as to whether the time limit on the safe harbor should be extended.

B. End-Stage Renal Disease and Medicare's Dialysis Benefit

End-stage renal disease is a chronic disease that requires regular renal replacement therapy, such as dialysis treatments, as well as regular monitoring of laboratory values, diet and medication. In addition to irreversible renal failure, ESRD patients commonly suffer from certain co-morbid conditions, such as diabetes, anemia, hypertension and congestive heart failure. Without ongoing dialysis treatment or a transplant, ESRD is a fatal condition. End-stage renal disease affects a disproportionate share of minority populations that also have a higher than average incidence of poverty.

In 1978, Congress amended title 11 of the Act to create a special Medicare benefit under Public Law 95–292 for eligible individuals with ESRD (or dependents of those who are eligible). In accordance with section 226A of the Act, eligible persons are entitled to benefits under Medicare Part A and are eligible to enroll under Part B of the Medicare program. End-stage renal disease benefits include all Part A and Part B items and services covered under the Medicare program, and ESRD beneficiaries are subject to all the regular deductible, premium and coinsurance provisions of Part A and Part B.

Medicare pays a composite rate to dialysis facilities for each dialysis treatment. The composite rate includes: (1) Medically necessary dialysis equipment, (2) home dialysis support services, (3) all necessary dialysis supplies, (4) routine ESRD-related laboratory tests and (5) all dialysis services furnished by the dialysis facility's staff. Certain other ESRD services, such as non-routine laboratory tests, may be paid to the facility outside of the composite rate.

Medicare Part B payments generally cover 80 percent of the composite rate. End-stage renal disease patients are responsible for the remaining 20 percent coinsurance and any deductibles. Typically, ESRD patients are responsible for approximately $5,000 per year in coinsurance for their dialysis treatments alone. This amount does not include the cost of coinsurance associated with hospital and physician services. In addition, ESRD patients must pay for a number of related drugs that are not covered by Medicare. On average the cost of Medigap insurance can range from approximately $1,200 to $3,600, depending on what the policy covers.

C. Effects of Section 1128A(a)(5) on the ESRD Population

After the enactment of HIPAA, representatives of a number of ESRD providers informed the OIG that many ESRD providers had been paying for Medicare Part B premiums and Medigap policies for financially needy patients who could not afford to purchase such insurance. Under the new statutory CMP provision, the OIG concluded that such premium subsidies could be unlawful in many circumstances, and dialysis providers subsequently suspended the purchase of Medigap policies and payment of Medicare Part B premiums for their patients. However, some providers entered into arrangements with nonprofit organizations that agreed to pay premiums on behalf of needy ESRD patients.

To date, in accordance with statutory authority under section 1128D(b) of the Act, the OIG has issued three advisory opinions approving the payment by unrelated entities of insurance premiums for financially needy ESRD patients. In the first opinion, the American Kidney Fund (AKF)—a *bona fide* section 501(c)(3) charitable and educational organization—and a number of dialysis providers established an arrangement whereby providers make contributions to the AKF which, in turn, independently screens candidates for financial need and then pays Medicare Part B and Medigap premiums on behalf of qualifying patients [1]. We have indicated that this system does not violate the CMP provision because the dialysis providers are not making payments to patients or on their patients' behalf, and there is no ''pass through'' of specific payments to specific patients. The two other advisory opinion requests, which were also approved, involved a State-funded program and a Statewide program modeled on the AKF arrangement. [2]

Providers claim that these new premium payment programs are unwieldy, create delays and uncertainty for beneficiaries, and create unnecessary paperwork and bureaucracy. In addition, the provider community has indicated that the risks to the Medicare and Medicaid programs and to the patients do not appear to differ significantly from when dialysis providers paid the premiums directly.

II. Provisions of the Proposed Rule

We are proposing an exception to section 1128A(a)(5) of the Act for independent dialysis facilities, as defined in 42 CFR 413.174, that pay for Medicare Part B and Medigap premiums for financially needy ESRD patients when:

- The payment is not advertised;
- The dialysis facility does not routinely make payments for such policies; and
- The dialysis facility makes a good faith determination that the individual is financially needy.

Protection would not extend to the payment of Medicare Part B or Medigap premiums on behalf of any other beneficiaries (*i.e.,* beneficiaries without ESRD) or by any other provider, conduct which section 1128A(a)(5) of the Act specifically prohibits.

The OIG is concerned that by offering to provide financial assistance to ESRD patients as part of an advertisement or solicitation, providers might influence a beneficiary's choice of provider. Therefore, to fit within the proposed exception, independent dialysis facilities would have to refrain from advertising any offer to make such payments. Without advertising the payment of premiums, the likelihood increases that ESRD patients will have selected their dialysis provider prior to receiving the offer of payment for Medicare Part B or Medigap premiums.

Moreover, we believe that it is inappropriate for health care providers

[1] See OIG Advisory Opinion 97–1.

[2] See OIG Advisory Opinions 97–2 and 98–17.

to pay Medicare Part B or Medigap premiums *routinely* on behalf of ESRD beneficiaries, rather than to make payment decisions on a case-by-case basis. In this proposed rule, we are not specifying any particular method of determining financial need, since what may constitute ''financial need'' will vary depending on various factors and circumstances. What is important is that providers make determinations of financial need on an individualized, case-by-case basis in accordance with a reasonable set of income guidelines uniformly applied in all cases. The guidelines should be based on objective criteria and appropriate for the applicable locality. We believe that it is not appropriate to apply inflated income guidelines that result in waivers of copayments for persons not in genuine financial need.

Limited applicability. Despite the similarity of the criteria for the proposed payment of premium safe harbor to the statutory criteria for the waiver of copayment exception, we wish to emphasize that the proposed regulatory protection would apply *only* to payments by independent dialysis facilities that have no hospital, physician or other provider or supplier ownership. While waivers of copayments are themselves suspect, the payment of insurance premiums by a provider or supplier who is paid on a fee-for-service basis significantly increases the incentive for overutilization and other abuse.

In the case of dialysis, providers are paid a prospectively fixed payment for the dialysis services provided to each patient. Thus, there is less incentive to overutilize or provide unnecessary services, notwithstanding the additional insurance coverage. By contrast, we believe that a provider or supplier that is treating a patient with a chronic condition on a fee-for-service basis has a strong incentive to recoup its outlay for the premium by providing additional services. In the case of a hospital-based dialysis facility or independent dialysis facility in which a hospital, physician or other provider or supplier has an ownership interest, we are concerned that these providers or suppliers would have the same incentive as other providers or suppliers paid on a fee-for-service basis, especially given the substantial amount of health care services required by ESRD patients for co-morbid conditions. Accordingly, we are excluding from this proposed exception hospital-based dialysis facilities and independent dialysis facilities, owned in whole or in part by a hospital, physician or other provider or supplier paid on a fee-for-service basis, and seek specific comments on this exclusion from the exception. We are also concerned with the potential impact of adverse selection on the Medigap insurance market, and seek specific comments concerning the potential effects this provision may have on Medigap plans.

III. Regulatory Impact Statement

Executive Order 12866, the Unfunded Mandates Reform Act and the Regulatory Flexibility Act

The Office of Management and Budget (OMB) has reviewed this proposed rule in accordance with the provisions of Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and has determined that the rulemaking does not meet the criteria for a significant regulatory action. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when rulemaking is necessary, to select regulatory approaches that maximize net benefits, including potential economic, health and equity effects. The Unfunded Mandates Reform Act (Public Law 104–4) requires that agencies prepare an assessment of anticipated costs and benefits on any rulemaking that may result in an expenditure by State, local or tribal government, or by the private sector of $100 million or more in any given year. In addition, under the Regulatory Flexibility Act, if a rule has a significant economic effect on a substantial number of small businesses, the Secretary must specifically consider the economic effect of a rule on small business entities and analyze regulatory options that could lessen the impact of the rule.

Executive Order 12866

Executive Order 12866 requires that all regulations reflect consideration of alternatives, costs, benefits, incentives, equity and available information. Regulations must meet certain standards, such as avoiding unnecessary burden. We believe that this proposed rule would have no significant economic impact. The proposed safe harbor provision being set forth is designed to permit individuals and entities to freely engage in business practice and arrangements that encourage competition, choice and economy. In doing so, the rule would impose no requirements on any party. Independent dialysis facilities may voluntarily seek to comply with this proposed provision so that their business practice is not subject to enforcement actions under the civil money penalty statute. Any aggregate economic effect of this safe harbor rule would be minimal, allowing independent dialysis facilities to do directly what some dialysis facilities are already allowed to do indirectly through the AKF (in accordance with OIG Advisory Opinion 97–1). As such, we believe that the aggregate economic impact of this proposed safe harbor rule would be minimal and would have no effect on the economy or on Federal or State expenditures.

Unfunded Mandates Reform Act

Additionally, in accordance with the Unfunded Mandates Reform Act of 1995, since there are no significant costs associated with this proposed safe harbor guideline that would impose any mandates on State, local or tribal governments, or the private sector that would result in an expenditure of $100 million or more in any given year, we have determined that a full analysis under the Act is not necessary.

Regulatory Flexibility Act

In accordance with Regulatory Flexibility Act (RFA) of 1980, and the Small Business Regulatory Enforcement Act of 1996, which amended the RFA, we have determined that this proposed rule would have no significant economic effect on a substantial number of small entities. While this proposed safe harbor may have an impact on some small entities, we believe that the aggregate economic impact of this rulemaking should be minimal, since it is the nature of a violation and not the size of the entity that determines whether the OIG will pursue a sanction action. Since this proposed safe harbor would offer individuals and entities greater flexibility in their business arrangements, we believe that the proposed regulations should not have a significant economic impact on a number of small business providers, and that a regulatory flexibility analysis is not required for this rulemaking.

IV. Public Inspection of Comments

Comments will be available for public inspection beginning on May 16, 2000 in Room 5518 of the Office of Inspector General at 330 Independence Avenue, SW., Washington, DC, on Monday through Friday of each week from 8:00 a.m. to 4:30 p.m., (202) 619–0089. Because of the large number of comments we normally receive on regulations, we cannot acknowledge or respond to them individually. However, we will consider all timely and appropriate comments when developing the final rule.

List of Subjects in 42 CFR Part 1003

Administrative practice and procedure, Fraud, Grant programs—health, Health facilities, Health

professions, Maternal and child health, Medicare, Medicaid, Penalties.

Accordingly, 42 CFR part 1003 would be amended as set forth below:

PART 1003—[AMENDED]

1. The authority citation for part 1003 would be revised to read as follows:

Authority: 42 U.S.C. 1302, 1320–7, 1320a–7a, 1320b–10, 1395u(j), 1395u(k), 1395dd(d)(1), 1395mm, 1395nn, 1395ss(d), 1396b(m), 11131(c), 11137(b)(2).

2. Section 1003.101 would be amended by:

a. Republishing the introductory text; and

b. Amending the definition of *renumeration* by revising the introductory text and paragraphs (3) and (4), and by adding a new paragraph (5).

§ 1003.101 Definitions.

For purposes of this part:

* * * * *

Remuneration, as set forth in § 1003.102(b)(12) of this part, is consistent with the definition contained in section 1128A(i)(6) of the Act, and includes the waiver of coinsurance and deductible amounts (or any part thereof) and transfers of items or services for free or for other than fair market value. The term ''remuneration'' does not include—

* * * * *

(3) Differentials in coinsurance and deductible amounts as part of a benefit plan design (as long as the differentials have been disclosed in writing to all beneficiaries, third party payers and providers), to whom claims are presented;

(4) Incentives given to individuals to promote the delivery of preventive care services where the delivery of such services is not tied (directly or indirectly) to the provision of other services reimbursed in whole or in part by Medicare or an applicable State health care program. Such incentives may include the provision of preventive care, but may not include—

(i) Cash or instruments convertible to cash; or

(ii) An incentive the value of which is disproportionately large in relationship to the value of the preventive care service (*i.e.,* either the value of the service itself or the future health care costs reasonably expected to be avoided as a result of the preventive care); or

(5) Any payments for Supplementary Medical Insurance (Medicare Part B) or Medicare Supplemental Health Insurance (Medigap) premium amounts (or any parts thereof) by an independent dialysis facility, as defined in § 413.174 of this title, that is not owned in whole or in part by a hospital, physician, or other provider or supplier paid on a fee-for-service basis, as long as all of the following three standards are met —

(i) The payment is not offered as part of any advertisement or solicitation;

(ii) The facility does not routinely make payments for such premiums; and

(iii) The facility makes the payment for such premiums only after determining in good faith that the individual on behalf of whom such payment is made is in financial need.

* * * * *

Dated: August 9, 1999.

June Gibbs Brown,

Inspector General.

Approved: September 2, 1999.

Editorial Note: This document was received at the Office of the Federal Register on April 25, 2000.

Donna E. Shalala,

Secretary.

[FR Doc. 00–10695 Filed 5–1–00; 8:45 am]

BILLING CODE 4152–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 00–831; MM Docket No. 99–282; RM–9710]

Radio Broadcasting Services; Littlefield, AZ

AGENCY: Federal Communications Commission.

ACTION: Proposed rule; denial.

SUMMARY: This document denies a petition for rule making filed by Mountain West Broadcasting proposing the allotment of FM Channel 265C to Littlefield, Arizona, as a first local aural transmission service, for failure to establish that locality is a *bona fide* community for allotment purposes. See 64 FR 51286, September 22, 1999. With this action, the proceeding is terminated.

ADDRESSES: Federal Communications Commission, Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Nancy Joyner, Mass Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Report and Order, MM Docket No. 99–282, adopted April 5, 2000, and released April 14, 2000 . The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC's Reference Information Center (Room CY–A257), 445 Twelfth Street, SW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, International Transcription Service, Inc., 1231 20th Street, NW., Washington, D.C. 20036, (202) 857–3800.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Federal Communications Commission.

John A. Karousos,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 00–10756 Filed 5–1–00; 8:45 am]

BILLING CODE 6712–01–P