subject to OMB review under the Paperwork Reduction Act of 1980 (44 U.S.C. 3501, et seq.).

List of Subjects in 40 CFR Part 22

Administrative practice and procedures, Clean Air Act, Environmental protection, Penalties.

Dated: July 8, 1991.

William K. Reilly,

Administrator.

For the reasons set out in the preamble, 40 CFR part 22 is proposed to be amended as follows:

PART 22—[AMENDED]

1. The authority citation for part 22 is revised to read as follows:

Authority: 15 U.S.C. 2615; 42 U.S.C. 7413(d), 7524(c), 7545(d), 7547(d), 7601 and 7607(a); 7 U.S.C. 136(l) and (m); 33 U.S.C. 1319, 1415 and 1418; 42 U.S.C. 6912, 6928 and 6991(e); 42 U.S.C. 9609; 42 U.S.C. 11045.

2. Section 22.01 is amended by revising paragraph (a)(2) to read as follows:

§ 22.01 Scope of these rules.

(a) * * *

(2) The assessment of any administrative penalty under sections 113(d)(l), 205(c), 211(d) and 213(d) of the Clean Air Act, as amended (CAA) (42 U.S.C. 7413(d)(1), 7524(c), 7545(d) and 7547(d)).

* * * * *

3. Section 22.34 is revised to read as follows:

§ 22.34 Supplemental rules of practice governing the administrative assessment of civil penalties under title II of the Clean Air Act.

(a) *Scope of these Supplemental rules.* These Supplemental rules shall govern, in conjunction with the preceding Consolidated Rules of Practice (40 CFR part 22), all proceedings to assess a civil penalty conducted under sections 205(c), 211(d), and 213(d) of the Clean Air Act, as amended (42 U.S.C. 7524(c), 7545(d), and 7547(d)). Where inconsistencies exist between these Supplemental rules and the Consolidated Rules (§§ 22.01 through 22.32), these Supplemental rules shall apply.

(b) *Issuance of Notice.* (1) Prior to the issuance of an administrative penalty order assessing a civil penalty, the person to whom the order is to be issued shall be given written notice of the proposed issuance of the order. Such notice shall be provided by the issuance of a complaint pursuant to § 22.13 of the Consolidated Rules of Practice.

(2) Notwithstanding § 22.15(a), any answer to the complaint must be filed with the Hearing Clerk within thirty (30) days after service of the complaint.

(c) *Subpoenas.* (1) The attendance of witnesses or the production of documentary evidence may be required by subpoena. The Presiding Officer may grant a request for a subpoena upon a showing of:

(i) The grounds and necessity therefor, and

(ii) The materiality and relevancy of the evidence to be adduced. Requests for the production of documents shall describe with specificity the documents sought.

(2) Subpoenas shall be served in accordance with § 22.05(b)(1) of the Consolidated Rules of Practice.

(3) Witnesses summoned before the Presiding Officer shall be paid the same fees and mileage that are paid in the courts of the United States. Fees shall be paid by the party at whose instance the witness appears. Where a witness appears pursuant to a request initiated by the Presiding Officer, fees shall be paid by EPA.

4. Add a new section 22.43 to read as follows:

§ 22.43 Supplemental rules of practice governing the administrative assessment of civil penalties under section 113(d)(1) of the Clean Air Act.

(a) *Scope of these Supplemental rules.* These Supplemental rules shall govern, in conjunction with the preceding Consolidated Rules of Practice (40 CFR part 22), all proceedings to assess a civil penalty conducted under section 113(d)(1) of the Clean Air Act (42 U.S.C. 7413(d)(1)). Where inconsistencies exist between these Supplemental rules and the Consolidated Rules (§§ 22.01 through 22.32), these Supplemental rules shall apply.

(b) *Issuance of Notice.* (1) Prior to the issuance of an administrative penalty order assessing a civil penalty, the person to whom the order is to be issued shall be given written notice of the proposed issuance of the order. Such notice shall be provided by the issuance of a complaint pursuant to § 22.13 of the Consolidated Rules of Practice.

(2) Notwithstanding § 22.15(a), any answer to the complaint must be filed with the Regional Hearing Clerk within thirty (30) days after service of the complaint.

(c) *Subpoenas.* (1) The attendance of witnesses or the production of documentary evidence may be required by subpoena. The Presiding Officer may grant a request for a subpoena upon a showing of:

(i) The grounds and necessity therefor, and

(ii) The materiality and relevancy of the evidence to be adduced. Requests for the production of documents shall describe with specificity the documents sought.

(2) Subpoenas shall be served in accordance with § 22.05(b)(1) of the Consolidated Rules of Practice.

(3) Witnesses summoned before the Presiding Officer shall be paid the same fees and mileage that are paid in the courts of the United States. Fees shall be paid by the party at whose instance the witness appears. Where a witness appears pursuant to a request initiated by the Presiding Officer, fees shall be paid by EPA.

[FR Doc. 91-17237 Filed 7-19-91; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

42 CFR Parts 417, 431, 434, and 1003

RIN 0991-AA44

Medicare and State Health Care Programs: Fraud and Abuse; Civil Monetary Penalties and Intermediate Sanctions for Certain Violations by Health Maintenance Organizations and Competitive Medical Plans

AGENCY: Office of the Secretary, Office of Inspector General (OIG) and the Health Care Financing Administration (HCFA), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would implement sections 9312(c)(2), 9312(f), and 9434(b) of Public Law 99-509, the Omnibus Budget Reconciliation Act of 1986; section 7 of Public Law 100-93, the Medicare and Medicaid Patient and Program Protection Act of 1987; section 4014 of Public Law 100-203, the Omnibus Budget Reconciliation Act of 1987; sections 224 and 411(k)(12) of Public Law 100-360, the Medicare Catastrophic Coverage Act of 1988; and section 6411(d)(3) of Public Law 101-239, the Omnibus Budget Reconciliation Act of 1989. These provisions broaden the Secretary's authority to impose intermediate sanctions and civil monetary penalties on health maintenance organizations (HMOs) and other prepaid health plans contracting under Medicare or Medicaid that (1) substantially fail to provide an enrolled individual with required medically necessary items and services; (2) engage in certain marketing, enrollment, reporting, or claims payment abuses; or

(3) in the case of Medicare, employ or contract with, either directly or indirectly, an individual or entity excluded from participation in Medicare. The provisions also condition Federal financial participation (FFP) in certain State payments on the State's exclusion of certain entities excluded (or excludable) from Medicare. This rulemaking is intended to significantly enhance the protections for Medicare beneficiaries and Medicaid recipients enrolled in a HMO, CMP, or other contracting organization under titles XVIII and XIX of the Social Security Act.

DATES: To assure consideration, comments must be mailed and delivered to the address provided below by September 20, 1991.

ADDRESSES: Address comments in writing to: Office of Inspector General, Department of Health and Human Services, Attention: LLR-10-P, room 5246, 330 Independence Avenue, SW., Washington, DC 20201.

If you prefer, you may deliver your comments to room 5551, 330 Independence Avenue SW., Washington, DC. In commenting, please refer to file code LLR-10-P. Comments received timely will be available for public inspection, beginning approximately two weeks after publication, in Room 5551, 330 Independence Avenue SW., Washington, DC on Monday through Friday of each week from 9 a.m. to 5 p.m., (202) 619-3270.

FOR FURTHER INFORMATION CONTACT:

Zeno W. St. Cyr, II, Legislation, Regulations, and Public Affairs Staff, OIG, (202) 619-3270

or

Jean D. LeMasurier, Office of Prepaid Health Care, HCFA, (202) 619-2070

or

Ann Page, Medicaid Bureau, HCFA, (301) 966-5364.

SUPPLEMENTARY INFORMATION:

I. Background

A. Introduction

Prepaid health plans, such as health maintenance organizations (HMOs), competitive medical plans (CMPs), and health insuring organizations (HIOs) are entities that provide enrollees with comprehensive, coordinated health care in a cost-efficient manner. Payment for these plans is generally made on a prepaid, capitation basis. The goal of prepaid health care delivery is to control health care costs while at the same time providing enrollees with affordable, coordinated, quality health care services. Titles XVIII and XIX of the Social Security Act (the Act) authorize contracts with prepaid health plans for the provision of covered health services to Medicare beneficiaries and Medicaid recipients.

B. Medicare

Section 1876 of the Act provides for Medicare payment at predetermined rates to eligible organizations that have entered into risk contracts with HFCA, or for payment of reasonable costs to eligible organizations that have entered into cost contracts. Eligible organizations include HMOs that have been federally qualified under title XIII, section 1310(d) of the Public Health Service Act, and CMPs that meet the requirements of section 1876(b)(2) of the Act.

Medicare enrollees of organizations with risk contracts are required to receive covered services only through the organization, except for emergency services and urgently needed out-of-area services. In the case of a cost contract, the Medicare beneficiary may also receive services outside the organization, with Medicare paying for the services through the general Medicare fee-for-service system. If an HMO or CMP fails to comply with a contract provision, the Secretary may decide not to renew or to terminate the contract. Regulations governing non-renewal of a contract are found at 42 CFR 417.492, and regulations governing termination of a contract are at 42 CFR 417.494.

C. Medicaid

Section 1903(m) of the Act contains requirements that apply to State Medicaid contracts for the provision, on a risk basis, either directly or through arrangements, of at least certain specified services ("comprehensive services"). HCFA regulations at 42 CFR part 434 implement the requirements in section 1903(m), and contain other requirements applicable to Medicaid contracts generally. Section 434.70 provides that HCFA may withhold Federal matching payments, known as Federal financial participation (FFP), for State expenditures for services provided to Medicaid recipients when either party to a contract substantially fails to carry out the terms of the contract.

D. New Legislation

1. The Omnibus Budget Reconciliation Act of 1986

Section 9312(c)(2) of Public Law 99-509, the Omnibus Budget Reconciliation Act of 1986 (OBRA 86), added section 1876(f)(3) of the Act. This provision authorizes the Secretary to suspend enrollment of Medicare beneficiaries by an organization, or to suspend payment to the organization for individuals newly enrolled, after the date the Secretary notifies the organization of noncompliance with the requirement in section 1876(f)(1) that limits enrollment to no more than 50 percent Medicare beneficiaries and Medicaid recipients. Prior to OBRA 86, HCFA's only recourse against an organization for noncompliance with any contract provisions was to non-renew or initiate termination of the contract. The new authority provides alternative remedies that may be used in lieu of or in addition to contract non-renewal or termination for organizations that do not comply with the 50/50 enrollment composition requirement.

Additionally, sections 9312(f) and 9434(c) of OBRA 86 added sections 1876(i)(6) and 1903(m)(5) of the Act. These provisions authorize a civil monetary penalty not greater than $10,000 for each instance of failure by an organization with a Medicare risk contract, or an organization that contracts under Medicaid, to provide required medically necessary items or services to Medicare or Medicaid enrollees, if the failure adversely affects (or has the likelihood of adversely affecting) the enrollee.

2. The Medicare and Medicaid Patient and Program Protection Act of 1987

Section 7 of Public Law 100-93, the Medicare and Medicaid Patient and Program Protection Act of 1987 (MMPPPA), added section 1902(p) of the Act which grants States the authority to exclude individuals or entities from participation in their Medicaid programs for any of the reasons that constitute a basis for exclusion from Medicare under section 1128, 1128A, or 1866(b)(2) of the Act. In addition, section 7 of MMPPPA established a new condition that States must meet in order to receive Federal Medicaid matching funds, known as Federal financial participation (FFP), for payments to HMOs or entities furnishing services under a waiver approved under section 1915(b)(1) of the Act. The new authority conditioned FFP upon a State's providing that it will exclude from participation, as an HMO or an entity furnishing services under a section 1915(b)(1) waiver, any entity that could be excluded under section 1128(b)(8) of the Act (i.e. any individual or entity against whom criminal or civil penalties have been imposed. FFP is also conditioned upon a State excluding an entity that has, directly or indirectly, a substantial contractual relationship with

an individual or entity that is described in section 1128(b)(8)(B) of the Act.

3. The Omnibus Budget Reconciliation Act of 1987

Section 4014 of the Omnibus Budget Reconciliation Act of 1987 (OBRA 87), Public Law 100-203, provides the Department with increased penalty amounts and greater statutory authority and flexibility to take action against HMOs or CMPs that commit certain abuses. This authority also may be exercised in addition to or in lieu of initiating contract termination proceedings. Section 4014 of OBRA 87 amends section 1876(i)(6) of the Act by authorizing the Secretary to impose civil monetary penalties, suspend enrollment, and suspend payments for newly enrolled individuals in the case of an organization with a Medicare contract (both risk and cost contract) that he determines has (1) failed substantially to provide required medically necessary items and services to Medicare enrollees, if the failure adversely affects (or has the likelihood of adversely affecting) the enrollee; (2) imposed premiums on Medicare enrollees in excess of permitted premium amounts; (3) acted to expel or refused to re-enroll an individual in violation of section 1876; (4) engaged in any practice which can reasonably be expected to deny or discourage enrollment (except as permitted under section 1876) by Medicare enrollees whose medical condition or history indicates a need for substantial future medical services; (5) misrepresented or falsified information provided under section 1876 to the Secretary, an individual, or any other entity; or (6) fails to comply with the requirements of section 1876(g)(6)(A) regarding prompt payment of claims. Under OBRA 87, the maximum allowable civil monetary penalty that can be imposed for each determination of a violation was increased to $25,000, or $100,000 in the case of a HMO or CMP determined to have committed acts in (4) above or for misrepresenting or falsifying information furnished to the Secretary under section 1876.

4. The Medicare Catastrophic Coverage Act of 1988

The Medicare Catastrophic Coverage Act of 1988 (MCCA), Public Law 100-360, amended sections 1876 and 1903(m) of the Act by adding new civil monetary penalty authority for violations occurring within the Medicare program, and by applying the OBRA 87 HMO and CMP intermediate sanction and civil monetary penalty authority to the Medicaid program.

Section 224 of MCCA amended section 1876(i)(6)(B)(i) of the Act. In addition to other civil monetary penalties, in cases where Medicare enrollees are charged more than the allowable premium, section 224 imposes a penalty which doubles the amount of excess premium charged by the HMO or CMP. The excess premium amount is deducted from the penalty and returned to the Medicare enrollee. Section 224 also imposes a $15,000 penalty for each individual not enrolled when it is determined that the HMO or CMP engaged in any practice which denied or discouraged enrollment (except as permitted under section 1876) by Medicare enrollees whose medical condition or history indicated a need for substantial future medical services.

Section 411(k)(12) of MCCA amended section 1903(m)(5) of the Act by providing the Secretary with authority to impose civil monetary penalties on contracting organizations, and to deny payments for new enrollees of contracting organizations, in cases where he determines that an organization has (1) failed substantially to provide required medically necessary items and services to Medicaid enrollees, if the failure adversely affects (or has the likelihood of adversely affecting) the enrollee; (2) imposed premiums on Medicaid enrollees in excess of premium amounts permitted under title XIX; (3) discriminated among individuals in violation of the provisions of section 1903(m)(2)(A)(v), including expelling or refusing to re-enroll an individual or engaging in any practice which could reasonably be expected to deny or discourage enrollment (except as permitted under section 1903(m)) by Medicaid recipients whose medical condition or history indicates a need for substantial future medical services; or (4) misrepresented or falsified information provided under section 1903 to the Secretary, State, an individual, or any other entity.

Under the amendments to section 1903(m)(5) made by MCCA, the maximum allowable civil monetary penalty that can be imposed for each determination of a violation is increased to $25,000, or $100,000 in the case of a deterination that a contracting organization has (1) violated the provisions of section 1903(m)(2)(A)(v) by expelling or refusing to re-enroll an individual or by engaging in a practice which denied or discouraged enrollment (except as permitted under section 1903(m)) by Medicaid recipients whose medical condition or history indicated a need for substantial future medical services; or (2) misrepresented or falsified information furnished to the Secretary or State under section 1903(m).

Additionally, in cases where Medicaid enrollees are charged more than the allowable premium, section 411(k)(12) of MCCA amended section 1903(m)(5) to authorize imposition of an additional penalty which doubles the amount of excess premium charged by the contracting organization, with the excess premium amount deducted from the penalty and returned to the Medicaid enrollee. Imposition of an additional $15,000 penalty is authorized for each individual not enrolled when it is determined that the contracting organization has violated the provisions of section 1903(m)(2)(A)(v) by expelling or refusing to re-enroll an individual or by engaging in any practice which denied or discouraged enrollment (except as permitted under section 1903(m)) by Medicaid recipients whose medical condition or history indicated a need for substantial future medical services.

5. The Omnibus Budget Reconciliation Act of 1989

Public Law 101-239, the Omnibus Budget Reconciliation Act of 1989 (OBRA 89), amended sections 1876 and 1902(p) of the Act by providing the Secretary with an additional civil monetary penalty and intermediate sanction authority for violations occurring within the Medicare program, and an additional intermediate sanction authority for violations involving the Medicaid program.

Section 6411(d)(3)(A) of OBRA 89 amended section 1876(i)(6)(A) of the Act by authorizing the Secretary to restrict enrollment in, suspend payment to, and impose a civil monetary penalty against an organization with a risk contract that (1) employs or contracts with any individual or entity excluded from Medicare participation under sections 1128 or 1128A of the Act for the provision of health care, utilization review, medical social work, or administrative services; or (2) employs or contracts with any entity for the provision of such services (directly or indirectly) through an excluded individual or entity. The maximum allowable civil monetary penalty that may be imposed for each determination of a violation of this nature is $25,000.

Section 6411(d)(3)(B) of OBRA 89 amended section 902(p)(2) of the Act to condition FFP in payments to HMOs, or to entities furnishing services under a section 1915(b)(1) waiver, upon the State's barring the following entities from participation as HMOs or section

2925(b)(1) waiver participants: (1) Any organization that employs or contracts with any individual or entity excluded from Medicaid participation under sections 1128 or 1128A of the Act for the provision of health care, utilization review, medical social work, or administrative services; or (2) any organization that employs or contracts with any entity for the provision of such services (directly or indirectly) through an excluded individual or entity.

II. Provisions of the Proposed Regulation

These proposed regulations would amend 42 CFR part 417, subpart C; part 431, subpart B; part 434, subparts C, D, E, and F; and part 1003 specifically by establishing intermediate sanctions and civil monetary penalties which may be imposed on contracting organizations that substantially fail to provide an enrollee with required medically necessary items and services, or that engage in certain marketing, enrollment, reporting claims payment, employment, or contracting abuses.

A. Intermediate Sanctions

1. Medicare

HCFA proposes to incorporate the Medicare intermediate sanction provisions of OBRA 86, OBRA 87, MCCA, and OBRA 89 into agency regulations largely without substantial modifications. These changes would be added to 42 CFR part 417, subpart C under a new § 417.495, "Sanctions against the organization." Under these proposed regulations, if HCFA determines that a violation subject to an intermediate sanction has occurred, HCFA may provide, in lieu of contract termination proceedings, written notice to the organization describing the nature of the violation and a proposed intermediate sanction. The intermediate sanction would either (1) require that the HMO or CMP suspend applications for enrollment from Medicare beneficiaries or (2) provide that payments to the HMO or CMP be suspended for individuals who apply for enrollment after a date specified by HCFA. HCFA would also forward any determination that a violation has occurred to the Office of the Inspector General (OIG), which may impose a civil monetary penalty in addition to, or in lieu of, any intermediate sanctions that may be imposed by HCFA.

In general, HCFA would base any intermediate sanction notice on the nature, scope, severity and duration of the violation as well as the threat to patient health and safety. The organization's prior contract performance would also be considered when a determination is made.

The organization would have 15 days after receiving the notice to provide evidence that no violation has occurred, or to submit other pertinent information. If timely submitted, this evidence or information would be reviewed by a HCFA official who did not participate in the initial decision. Upon reaching a decision after reconsideration, the organization would receive notice of such determination accompanied by a brief written decision setting forth the factual and legal basis for the sanction. The effective date of the sanction would be 15 days after the organization receives notice of HCFA's initial decision to impose a sanction, unless the organization timely seeks reconsideration of that decision. If the organization timely seeks reconsideration, the sanction would be effective on the date the organization receives notice of HCFA's final decision on review, unless HCFA determines that the organization's conduct poses a serious threat to an enrollee's health and safety, in which case the effective date would be the date of notice of the initial determination.

The intermediate sanction would remain in effect until HCFA was satisfied that the problem was corrected and was not likely to recur. The organization's written response and HCFA's final determination would be provided to the Office of Inspector General (OIG).

We have not in these proposed regulations provided for further administrative review of a decision to impose intermediate sanctions. We would be interested in receiving comments on the question of whether such further administrative review would be useful or advisable, and, if so, what form it should take.

2. Medicaid

Unlike the Medicare program, the Medicaid program is administered by State governments, pursuant to Federal statutory and regulatory requirements, and a Medicaid "State plan" approved by HCFA. State governments thus are responsible for contracting with HMOs and other prepaid health plans, as well as monitoring such contracts. In the case of Medicaid contracts, therefore, we believe that States are in the best position to monitor for the violations discussed above, to make determinations as to whether a violation has occurred, and to recommend intermediate sanctions based upon the nature of the violation. HCFA therefore is proposing to rely upon States to perform, in the first instance, the same monitoring and sanction functions in the Medicaid program that HCFA will perform in the Medicare program. Each State would be required to set forth, in its State plan, procedures for: (1) Monitoring for violations; (2) determining whether a violation has occurred; and (3) recommending intermediate sanctions in accordance with these regulations.

The proposed Medicaid regulations would be set forth in 42 CFR part 431 and subparts C, D, E, and F of 42 CFR part 434. Under proposed § 434.63(c), States would be responsible for monitoring for the violations described in section 1903(m)(5)(A) of the Act. Under a proposed new § 434.67, States would be responsible for (1) making determinations as to whether a section 1903(m)(5)(A) violation has been committed by an HMO, (2) making a recommendation to HCFA as to whether an intermediate sanction should be imposed, and (3) reviewing evidence or information submitted by HMOs that wish to contest the imposition of intermediate sanctions. Under § 434.67(b)(1), a State determination that a violation has occurred would be sent to HCFA for review, and would become "the Secretary's" determination, for purposes of section 1903(m)(5)(A), if HCFA declines to reverse or modify the State finding within 15 days. Under § 434.67(g), a violation determination that is adopted as HCFA's would be forwarded to OIG for consideration of civil money penalties pursuant to the same process that applies to Medicare contracts.

Under § 434.67(b)(2), a State recommendation to HCFA that an intermediate sanction be imposed similarly would become "the Secretary's" determination, for purposes of section 1903(m)(5)(B)(ii), unless HCFA informs the States within 15 days that it disagrees with the recommendation. If a State's recommendation that a sanction be imposed becomes "the Secretary's" determination, the State would be required under § 434.67(c) to notify the HMO of this determination, and of its effect on payments to the HMO. In order to ensure that the intermediate sanction in section 1903(m)(5)(B)(ii) has its intended impact on the HMO found to have committed the violation, proposed §§ 434.22 and 434.42 would require that comprehensive risk contracts require that State payment for new enrollees be denied whenever Federal payment for such enrollees is denied pursuant to section 1903(m)(5)(B)(ii).

Under § 434.67(c), an HMO would have 15 days to provide the State with evidence that no violation has occurred,

or to submit other pertinent information. Under § 434.67(d), timely submitted evidence or other information would be reviewed by a State official who did not participate in the initial decision. Upon reaching a decision after reconsideration, the State would prepare a brief written decision setting forth the factual and legal basis for the decision. This decision would then be forwarded to HCFA, and constitute HCFA's determination if HCFA does not reverse or modify the decision within 15 days.

Under § 434.67(f), the effective date of the sanction would be, as appropriate, one of the following:

(1) In situations where the HMO does not timely appeal for a reconsideration, the date the HMO received notice of the Secretary's determination to impose sanctions; or

(2) When a timely appeal is made, the date the HMO received notification from the State of the reconsideration decision on review; or

(3) When HCFA, in consultation with the State agency, determines that the HMO's conduct poses a serious threat to an enrollee's health and safety, a date prior to an issuance of the decision under (1) or (2).

In all cases, it would be effective with respect to enrollees that apply for enrollment after the effective date of the sanction. The intermediate sanction would remain in effect until HCFA, in consultation with the State, was satisfied that HMO violation was corrected and was not likely to recur. The HMO's written submission and the final determination on review would also be forwarded by HCFA to OIG.

Under § 434.67(h), HCFA would retain concurrent authority to perform independently, at its discretion, the monitoring and sanction functions assigned to the States by these proposed rules.

Section 434.67(i) would require the State to document, in its State plan, a plan for monitoring for violations specified in § 434.67(a) and for implementing the provisions found in § 434.67 (b) through (g).

We have not in these proposed regulations provided for further administrative review by States or HCFA of decisions to impose intermediate sanctions under section 1903(m)(5)(B)(ii). We would be interested in receiving comments on the question of whether such further administrative review would be useful or advisable, and, if so, what form it should take.

Finally, proposed §§ 431.55 and 434.80 would implement the provision in section 1902(p) which establishes a new condition for FFP in payments to HMOs or entities furnishing services under a waiver approved under section 1915(b)(1) of the Act. These proposed regulations would implement the provision in section 902(p)(2) conditioning such FFP on the State's providing that it will "exclude from participation," as an HMO or an entity furnishing services under a section 1915(b)(1) waiver, any entity that (a) could be excluded under section 1128(b)(8) of the Act; (b) has, directly or indirectly, a substantial contractual relationship with an individual or entity that is described in section 1128(b)(8)(B) of the Act; or (c) employs or contracts with any individual or entity excluded from Medicaid participation under sections 1128 or 1128A of the Act for the provision of health care, utilization review, medical social work, or administrative services, or any organization that employs or contracts with any entity for the provision of such services (directly or indirectly) through an excluded individual or entity. "Substantial contractual relationship" is defined, at § 431.55(i)(2), to mean any contractual relationship that provides for administrative, management, or provision of medical services or the establishment of policies or operational support related to these activities. Section 431.55(i)(3) would require the State to submit, as part of its 1915(b)(1) waiver request, assurances that the entities described above are excluded from participation in the waiver program.

B. Civil Monetary Penalties

Under these proposed regulations, after HCFA determines that a contracting organization has committed a violation under § 1876(i)(6)(A) or 1903(m)(5)(A), information pertaining to the violation will be provided to the OIG. The OIG may then impose a civil monetary penalty in addition to or in lieu of other remedies available under law. The OIG may impose a civil monetary penalty of up to $25,000 for each determination that a contracting organization (1) failed substantially to provide required medically necessary items and services to Medicare or Medicaid enrollees, if the failure adversely affects (or has the likelihood of adversely affecting) the enrollee; (2) imposed premiums on Medicare or Medicaid enrollees in excess of permitted premium amounts; (3) acted to expel or refuse to re-enroll a Medicare beneficiary in violation of section 1876 of the Act; (4) misrepresented or falsified information provided under sections 1876 or 1903(m) of the Act to an individual, or any other entity; or (5) failed to comply with the requirements of section 1876(g)(6)(A) of the Act regarding prompt payment of claims. A civil monetary penalty of up to $25,000 may also be imposed for each determination that a contracting organization with a Medicare risk contract (1) employs or contracts with any individual or entity excluded from participation in Medicare under sections 1128 or 1128A of the Act for the provision of health care, utilization review, medical social work, or administrative services; or (2) employs or contracts with any entity for the provision of such services (directly or indirectly) through an excluded individual or entity.

A civil monetary penalty of up to $100,000 may be imposed for each determination that a contracting organization has (1) misrepresented or falsified information provided to the Secretary under section 1876 of the Act, or provided to the Secretary or State under section 1903(m) of the Act; (2) engaged in any practice which could reasonably be expected to result in denying or discouraging enrollment (except as permitted under section 1876) by Medicare beneficiaries whose medical condition or history indicates a need for substantial future medical services; or (3) violated the provisions of section 1903(m)(2)(A)(v) of the Act, including expelling or refusing to re-enroll an individual or engaging in any practice which could reasonably be expected to result in denying or discouraging enrollment (except as permitted under section 1903(m)) by Medicaid recipients whose medical condition or history indicated a need for substantial future medical services.

In cases where Medicare or Medicaid enrollees are charged more than the allowable premium, an additional penalty which doubles the amount of excess premium charged by the contracting organization will be imposed. The excess premium amount will be deducted from the penalty and returned to the enrollee. A $15,000 penalty will be imposed for each individual not enrolled when it is determined that a contracting organization has committed a violation described in section 1876(i)(6)(A)(iv) or section 1903(m)(5)(A)(iii) (i.e. expelling or refusing to re-enroll a Medicaid recipient or engaging in any practice which effectively denied or discouraged enrollment (except as permitted under sections 1876 or 1903) by Medicare beneficiaries or Medicaid recipients whose medical condition or history indicated a need for substantial future medical services).

Contracting organizations assessed civil monetary penalties under this regulation would be permitted to request a hearing before an Administrative Law Judge in accordance with the procedures currently set forth in 42 CFR part 1003.

C. Factors To Be Considered in Levying Civil Monetary Penalties

The following factors would be set forth in 42 CFR 1003.106 to consider in determining civil monetary penalty amounts:

- The nature of the appropriate item or service not provided and the circumstances under which it was not provided. It would be considered a mitigating circumstance if, where more than one violation exists, the appropriate items or services not provided were (1) few in number, or (2) of the same type and occurred within a short period of time. It would be considered an aggravating circumstance if such items or services were of several types and occurred over a lengthy period of time, or if there were many such items or services (or the nature and circumstances indicate a pattern of such items or services not being provided).
- The degree of culpability of the contracting organization. It would be considered a mitigating circumstance if the violation was the result of an unintentional, unrecognized error, and corrective action was taken promptly after discovery of the error.
- The seriousness of the adverse effect that resulted or could have resulted from any failure to provide required care. It would be considered an aggravating circumstance if the failure to provide required care was attributable to an individual or entity that the contracting organization is expressly prohibited by law from contracting or employing.
- The harm to the enrollee which resulted or could have resulted from the provision of care by an individual or entity that the contracting organization is expressly prohibited by law from contracting or employing. It would be considered an aggravating factor if the contracting organization knowingly or routinely engages in the prohibited practice of contracting or employing, either directly or indirectly, individuals or entities excluded from the Medicare program under sections 1128 or 1128A of the Act.
- The harm to the enrollee which resulted or could have resulted from expulsion or refusal to re-enroll by the contracting organization. It would be considered an aggravating factor if the contracting organization knowingly or routinely engages in any discriminatory or other prohibited practice which has the effect of denying or discouraging enrollment by individuals whose medical condition or history indicates a need for substantial future medical services.
- The nature and seriousness of the misrepresentative or fallacious information furnished by the contracting organization, under sections 1876 or 1903(m) of the Act, to the Secretary, State, enrollee, or any other entity.
- The history of prior offenses by the contracting organization or the principals of the contracting organization. It would be considered an aggravating circumstance if at any time prior to determination of the current violation or violations, the contracting organization or any of its principals was convicted on criminal charges or held liable for civil or administrative sanctions in connection with a program covered by this part or any other public or private program of payment for medical services. The lack of prior liability for criminal, civil, or administrative sanctions by the contracting organization, or the principals of the contracting organization, would not necessarily be considered a mitigating circumstance in determining civil monetary penalty amounts.
- Other such matters as justice may require.

Comments are specifically welcomed on the application of these criteria, and on the inclusion of other specific aggravating and mitigating factors to be considered in levying civil monetary penalties under this provision.

D. Alternatives Considered

The proposed regulations provide for a single determination made by HCFA to be the basis for both the intermediate sanctions and civil monetary penalties. However, the Department considered requiring separate determinations for the intermediate sanctions applied by HCFA and the civil monetary penalties imposed by OIG. The single determination approach was adopted because the Department believes it to be consistent with statutory intent that there be one determination by the Secretary which can result in various remedies. In addition, dividing the determination authority between different components within the Department would be inefficient and could result in less consistency and coherence. HCFA is delegated authority for actions under sections 1876 and 1903(m) of the Act and, with the exception of States in the case of Medicaid, is most directly involved in the operational activities of contracting organizations. To assure that the intermediate sanction and civil monetary penalty processes are coordinated, the proposed regulation includes a stipulation that all determinations made by HCFA will be routinely communicated to the OIG.

Consideration was also given to having HCFA, as opposed to States, monitor for violations by Medicaid contracting HMOs. However, State Medicaid Agencies already have the authority, personnel, and procedures established to monitor provisions of such contracts. Therefore, it is believed that State Agencies are the more appropriate entity to monitor for the specified violations and to implement certain activities related to intermediate sanctions.

III. Regulatory Impact Statement

A. Executive Order 12291

Executive Order 12291 (E.O. 12291) requires us to prepare and publish a regulatory impact analysis for any proposed rule that meets one of the E.O. criteria for a "major rule"; that is, that would be likely to result in—

- An annual effect on the economy of $100 million or more;
- A major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or
- Significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

This proposed rule would implement sections 9312(c)(2), 9312(f) and 9434(b) of Public Law 99-509; section 4014 of Public Law 100-203; sections 224 and 411(k)(12) of Public Law 100-360; and section 6411(d)(3) of Public Law 101-239. This proposed rule would broaden the Secretary's authority to impose intermediate sanctions and civil monetary penalties on HMOs, CMPs or other contracting organizations that (1) fail substantially to provide required medically necessary items and services to Medicare beneficiaries or Medicaid enrollees or (2) practice certain marketing, enrollment, reporting or claims payment abuses.

These provisions are the result of statutory changes and serve to clarify Departmental policy with respect to the imposition of intermediate sanctions and civil monetary penalties. We believe the majority of providers and practitioners do not engage in the prohibited activities and practices discussed in these proposed regulations.

In addition, we believe these proposed regulations would have a deterrent effect upon providers and practitioners. Therefore, we expect that the aggregate economic impact would be minimal, affecting only those engaged in the prohibited behavior in violation of statutory intent.

This proposed rule does not meet the $100 million criterion, nor do we believe that it meets the other E.O. 12291 criteria. Therefore, this proposed rule is not a major rule under E.O. 12291, and an initial regulatory impact analysis is not required.

B. Regulatory Flexibility Act

We generally prepare a regulatory flexibility analysis that is consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612) unless the Secretary certifies that a proposed rule would not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, we consider all HMOs, CMPs and other contracting organizations to be small entities.

In addition, section 1102(b) of the Act requires the Secretary to prepare a regulatory impact analysis if a proposed rule may have a significant impact on the operations of a substantial number of small rural hospitals. Such an analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital which is located outside of a Metropolitan Statistical Area and has fewer than 50 beds.

We do not have data to assist us in estimating the number of contracting organizations that would be affected by these proposed regulations or the magnitude of any penalties that would be imposed. As discussed under E.O. 12291, we believe any impact would be minimal because the majority of providers and practitioners engaged in prohibited activities would be few. In addition, this rule largely conforms our regulations to the Act.

Since we have determined, and the Secretary has certified, that this proposed rule would not result in a significant economic impact on a substantial number of small entities or on the operations of a substantial number of small rural hospitals, we are not preparing analyses for either the RFA or small rural hospitals.

IV. Paperwork Reduction Act

This proposed rule contains no information collection requirements; therefore, it does not qualify under the provisions of the Paperwork Reduction Act of 1980.

List of Subjects

42 CFR Part 417

Administrative practice and procedure; Health Maintenance Organizations (HMO); Medicare; Reporting and recordkeeping requirements.

42 CFR Part 431

Grant programs—Health; Health facilities; Medicaid; Privacy; Reporting and Recordkeeping requirements.

42 CFR Part 434

Grant programs—Health; Health Maintenance Organizations (HMO); Medicaid; Reporting and recordkeeping requirements.

42 CFR Part 1003

Administrative practice and procedure; Fraud; Grant programs—Health; Health facilities; Health Professions; Maternal and Child Health; Medicaid; Medicare; Penalties.

A. 42 CFR part 417 would be amended as set forth below:

PART 417—HEALTH MAINTENANCE ORGANIZATIONS, COMPETITIVE MEDICAL PLANS, AND HEALTH CARE PREPAYMENT PLANS

1. The authority citation for part 417 would be revised to read as follows:

Authority: 31 U.S.C. 9701, 42 U.S.C. 300e through 300e–17, 1302, 13951(a)(1)(A), 1395x(s)(2)(H), 1395hh, 1395kk, 1395mm, and 1395m note.

2. The table of contents for part 417, subpart C, would be amended by adding new § 417.495 to read as follows:

* * * * *

Subpart C—Health Maintenance Organizations and Competitive Medical Plans

* * * * *

417.495 Sanctions against the organization.

* * * * *

Subpart C—Health Maintenance Organizations and Competitive Medical Plans

3. In subpart C, a new § 417.495 would be added to read as follows:

§ 417.495 Sanctions against the organization.

(a) *Basis for application of sanctions.* HCFA may apply intermediate sanctions specified in paragraph (d) of this section, as an alternative to termination, if HCFA determines that an organization with a contract under this part—

(1) Fails substantially to provide medically necessary items and services that are required to be provided to an individual covered under the contract, and the failure has adversely affected (or has substantial likelihood of adversely affecting) the individual;

(2) Imposes premiums on individuals enrolled under this part in excess of premiums permitted;

(3) Acts to expel or to refuse to re-enroll an individual in violation of the provisions of this part;

(4) Engages in any practice that would reasonably be expected to have the effect of denying or discouraging enrollment (except as permitted by this part) with the organization by eligible individuals whose medical condition or history indicates a need for substantial future medical services;

(5) Misrepresents or falsifies information that is furnished—

(i) To HCFA under this part;

(ii) To an individual or to any other entity under this part;

(6) Fails to comply with the requirements of section 1876(g)(6)(A) of the Act relating to the prompt payment of claims;

(7) Fails to meet the requirement in section 1876(f)(1) of the Act that not more than 50 percent of the organization's enrollment may be Medicare beneficiaries and Medicaid recipients; or

(8) Has a Medicare risk contract and—

(i) Employs or contracts with individuals or entities excluded from participation in Medicare under sections 1128 or 1128A of the Act for the provision of health care, utilization review, medical social work, or administrative services; or

(ii) Employs or contracts with any entity for the provision of such services (directly or indirectly) through an excluded individual or entity.

(b) *Notice of intermediate sanction.* Prior to applying the sanctions specified in paragraph (d) of this section, HCFA will send a written notice to the organization stating the nature and basis of the proposed sanction. A copy of the notice (other than a notice for the violation described in paragraph (a)(7) of this section) will be forwarded to the OIG at the same time that it is sent to the organization. HCFA will allow the organization 15 days after the date it receives the notice to provide evidence that the organization has not committed an act or failed to comply with a requirement described in paragraph (a) of this section, as applicable.

(c) *Informal reconsideration.* If the organization submits a timely response to HCFA's notice of intermediate sanction, HCFA will conduct an informal reconsideration that includes:

(1) Review of the evidence by a HCFA official who did not participate in the initial decision to impose a sanction; and

(2) If the decision to impose a sanction is affirmed on review, forwarding to the organization a concise written decision setting forth the factual and legal basis for the decision.

(d) *Intermediate sanctions.* If HCFA determines that an organization has committed a violation described in paragraph (a) of this section and this determination is affirmed on review in the event the organization timely contests the determination under paragraph (b) of this section, HCFA may—

(1) Require the organization to suspend new applications for enrollment from Medicare beneficiaries after the effective date in paragraph (e)(1) of this section; or

(2) Suspend payments to the organization for any individuals who apply for enrollment after the effective date in paragraph (e)(1) of this section.

(e) *Effective date and duration of intermediate sanctions.* (1) Intermediate sanctions will be made effective 15 days after the date that the organization is notified of the decision to impose the sanctions, unless the organization timely seeks reconsideration under paragraph (c) of this section, in which case the intermediate sanction generally will be effective on the date the organization is notified of HCFA's decision under paragraph (c)(2) of this section.

(2) If HCFA determines that the organization's conduct poses a serious threat to an enrollees' health and safety, the intermediate sanction may be made effective on a date prior to issuance of HCFA's decision under paragraph (c)(2) of this section.

(3) The sanction will remain in effect until HCFA notifies the organization that HCFA is satisfied that the basis for applying the sanction has been corrected and is not likely to recur.

(f) *Termination by HCFA.* As an alternative to the sanctions described in paragraph (d) of this section, HCFA may decline to renew an organization's contract in accordance with § 417.492(b), or terminate its contract in accordance with § 417.494(b).

(g) *Civil monetary penalties.* If HCFA determines that an organization has committed an act or failed to comply with a requirement described in paragraph (a) of this section (with the exception of the violation described in paragraph (a)(7) of this section), HCFA will convey such determination to the Office of Inspector General. In accordance with the provisions of 42 CFR part 1003, the OIG may impose civil monetary penalties on the organization in addition to or in lieu of the intermediate sanctions imposed by HCFA.

B. 42 CFR part 431 would be amended as set forth below:

PART 431—STATE ORGANIZATION AND GENERAL ADMINISTRATION

1. The authority citation for part 431 would be revised to read as follows:

Authority: 42 U.S.C. 1302, 1396(a)(4), 1396a(p)(2), and 1396b.

2. In subpart B, § 431.55 would be amended by revising paragraph (a) and adding new paragraph (h) to read as follows:

§ 431.55 Waiver of other Medicaid requirements.

(A) *Statutory basis.* Section 1915(b) of the Act authorizes the Secretary to waive the requirements of section 1902 of the Act to the extent he or she finds proposed improvements or specified practices in the provision of services under Medicaid to be cost-effective, efficient, and consistent with the objectives of the Medicaid program. Sections 1915 (e), (f), and (h) of the Act prescribe how such waivers are to be approved, continued, monitored, and terminated. Sections 1916 (a)(3) and (b)(3) of the Act specify the circumstances under which the Secretary is authorized to waive the requirement that cost-sharing amounts be nominal. Section 1902(p)(2) of the Act conditions FFP in payments to an entity under a section 2925(b)(1) waiver on the State's provision for excluding certain entities from participation.

* * * * *

(h)(1) FFP in payments to an entity furnishing services under a waiver approved under section 1915(b)(1) is available only if the agency provides that it will exclude from participation as such any entity that—

(i) Could be excluded under section 1128(b)(8) of the Act;

(ii) Has a substantial contractual relationship, either directly or indirectly as defined in § 431.55(h)(2), with an individual described in section 1123(b)(8)(B) of the Act; or

(iii) Employs or contracts with—

(A) Any individual or entity excluded from Medicaid participation under sections 1128 or 1128A of the Act for the provision of health care, utilization review, medical social work, or administrative services; or

(B) Any entity, directly or indirectly, for the provision through an excluded individual or entity of such services described in paragraph (h)(1)(iii)(A) of this section.

(2) A *substantial contractual relationship* is any contractual relationship which provides for one or more of the following services:

(i) The administration, management, or provision of medical services;

(ii) The establishment of policies pertaining to the administration, management or provision of medical services; or

(iii) The provision of operational support for the administration, management, or provision of medical services.

(3) The agency must submit, as part of its section 1915(b)(1) waiver request, assurances that the entities described in paragraph (h)(1) of this section are excluded from participation under an approved waiver.

C. 42 CFR part 434 would be amended as set forth below:

PART 434—CONTRACTS

1. The authority citation for part 434 would be revised to read as follows:

Authority: 42 U.S.C. 1302, 396(a)(4), 1396a(p)(2), and 1396b.

2. The table of contents for part 434 would be amended by adding new § 434.22 to subpart C, 434.42 to subpart D, 434.67 to subpart E, and 434.80 to subpart F to read as follows:

* * * * *

Subpart C—Contracts With HMOs and PHPs: Contract Requirements

* * * * *

434.22 Application of intermediate sanctions to comprehensive risk contracts.

* * * * *

Subpart D—Contracts with Health Insuring Organizations

* * * * *

434.42 Application of intermediate sanctions to comprehensive risk contracts.

* * * * *

Subpart E—Contracts With HMOs and PHPs: Medicaid agency responsibilities

* * * * *

434.67 Sanctions against HMOs with comprehensive risk contracts.

* * * * *

Subpart F—Federal Financial Participation

* * * * *

434.80 Conditions for FFP in contracts with HMOs.

* * * * *

Subpart C—Contracts with MOs and PHPs: Contract requirements

3. In Subpart C, a new § 434.22 would be added as follows:

§ 434.22 Application of intermediate sanctions to comprehensive risk contracts.

A risk comprehensive contract must provide that payments provided for under the contract will be denied for new enrollees when, and for so long as, payment for such enrollees is denied by HCFA pursuant to § 434.67(e).

Subpart D—Contracts With Health Insuring Organizations

4. In subpart D, a new § 434.42 would be added as follows:

§ 434.42 Application of intermediate sanctions to comprehensive risk contracts.

A risk comprehensive contract must provide that payments provided for under the contract will be denied for new enrollees when, and for so long as, payment for such enrollees is denied by HCFA pursuant to § 434.67(e).

Subpart E—Contracts With HMOs and PHPs: Medicaid Agency Responsibilities

5. Subpart E, § 434.63 would be revised to read as follows:

§ 434.63 Monitoring procedures.

The agency must have procedures to—

(a) Monitor enrollment and termination practices;

(b) Insure proper implementation of the contractor's grievance procedures; and

(c) Monitor for violations of the requirements specified in § 434.67 and the conditions necessary for FFP in contracts with HMOs, specified in § 434.80.

Subpart E—Contracts With HMOs and PHPs: Medicaid Agency Responsibilities

6. In Subpart E, new § 434.67 would be added to read as follows:

§ 434.67 Sanctions against HMOs with comprehensive risk contracts.

(a) *Basis for application of sanctions.* The agency may recommend that the intermediate sanction specified in paragraph (e) of this section be imposed if the agency determines that an HMO with a comprehensive risk contract—

(1) Fails substantially to provide medically necessary items and services that are required under law or under the contract to be provided to an individual covered under the contract, and the failure has adversely affected (or has substantial likelihood of adversely affecting) the individual;

(2) Imposes premiums on individuals covered under the contract in excess of premiums permitted;

(3) Engages in any practice that discriminates among individuals on the basis of their health status or requirements for health care services, including expulsion or refusal to re-enroll an individual, or any practice that could reasonably be expected to have the effect of denying or discouraging enrollment (except as permitted by section 1903(m) of the Act) by eligible individuals whose medical condition or history indicates a need for substantial future medical services; or

(4) Misrepresents or falsifies information that is furnished—

(i) To HCFA or the State agency under section 1903(m); or

(ii) To an individual or to any other entity under section 1903(m).

(b) *Effect of an agency determination.* (1) When the agency determines that an HMO with a comprehensive risk contract has committed one of the violations identified in paragraph (a) of this section, the agency must forward this determination to HCFA. This determination becomes HCFA's determination for purposes of section 1903(m)(5)(A) of the Act, if HCFA does not reverse or modify the determination within 15 days.

(2) When the agency decides to recommend imposition of the intermediate sanction specified in paragraph (e) of this section, this recommendation becomes HCFA's decision, for purposes of section 1903(m)(5)(B)(ii) of the Act, if HCFA does not reject this recommendation within 15 days.

(c) *Notice of intermediate sanction.* If a determination to impose intermediate sanctions becomes HCFA's determination pursuant to paragraph (b)(2) of this section, the agency must send a written notice to the HMO stating the nature and basis of the proposed sanction. A copy of the notice will be forwarded to the OIG at the same time that it is sent to the organization. The agency will allow the HMO 15 days after the date it receives the notice to provide evidence that the HMO has not committed an act or failed to comply with a requirement described in paragraph (a) of this section, as applicable.

(d) *Informal reconsideration.* (1) If the HMO submits a timely response to the agency's notice of intermediate sanction, the agency will conduct an informal reconsideration that includes—

(i) Review of the evidence by an agency official who did not participate in the initial recommendation to impose a sanction; and

(ii) A concise written decision setting forth the factual and legal basis for the decision.

(2) The agency decision under paragraph (d)(1)(ii) of this section will be forwarded to HCFA and will become HCFA's decision if HCFA does not reverse or modify the decision within 15 days. The agency will send the HMO a copy of HCFA's decision under this subparagraph.

(e) *Intermediate sanction.* If a HCFA determination that a HMO has committed a violation described in paragraph (a) of this section is affirmed on review under paragraph (d) of this section, or is not timely contested by the HMO under paragraph (c) of this section, then HCFA, based upon the recommendation of the agency, may deny payment for new enrollees of the HMO pursuant to section 1903(m)(5)(B)(ii) of the Act. Under §§ 434.22 and 434.42, this denial of payment by HCFA for new enrollees automatically results in a denial of agency payments to the HMO for the same enrollees. A "new enrollee" is defined as an enrollee that applies for enrollment after the effective date in paragraph (f)(1) of this section.

(f) *Effective date and duration of intermediate sanction.* (1) Unless an HMO timely seeks a reconsideration pursuant to paragraph (d) of this section or HCFA determines the violation poses a serious threat to enrollees health or safety, intermediate sanctions will be made effective 15 days after the date that the HMO is notified of the HFCA decision to impose the sanction pursuant to paragraph (c) of this section. If the HMO seeks reconsiderations under paragraph (d) of this section, the intermediate sanction generally will be effective on the date the organization is notified of HCFA's decision under paragraph (d)(1)(ii) of this section.

(2) If HCFA, in consultation with the agency determines that the HMO's conduct poses a serious threat to an enrollees' health and safety, the intermediate sanction may be made effective on a date prior to issuance of the decision under paragraph (d)(1)(ii) of this section.

(3) The sanction will remain in effect until HCFA, in consultation with the agency, is satisfied that the basis for applying the sanction has been corrected and is not likely to recur.

(g) *Civil monetary penalties.* If a determination that an organization has committed a violation under paragraph (a) of this section becomes HCFA's determination under paragraph (b)(1) of this section, HCFA will convey such determination to the Office of Inspector General. In accordance with the provisions of 42 CFR Part 1003, the OIG may impose civil monetary penalties on

the organization in addition to or in lieu of the intermediate sanctions imposed under this section.

(h) HCFA retains the right to independently perform the functions assigned to the agency in paragraphs (a) through (f) of this section.

(i) *State Plan Requirements.* The State Plan must include a plan to monitor for violations specified in paragraph (a) of this section and for implementing the provisions of this section.

Subpart F—Federal Financial Participation

7. In subpart F, a new § 434.80 would be added to read as follows:

§ 434.80 Condition for FFP in contracts with HMOs.

FFP in payments to an HMO is available only if the agency provides that it will exclude from participation as such an entity any entity that—

(a) Could be excluded under section 1128(b)(8) of the Act;

(b) Has a substantial contractual relationship, either directly or indirectly as defined in § 431.55(h)(2), with an individual described in section 1128(b)(8)(B) of the Act; or

(c) Employs or contracts with—

(1) Any individual or entity excluded from Medicaid participation under section 1128 or 1128A of the Act for the provision of health care, utilization review, medical social work, or administrative services; or

(2) Any entity, directly or indirectly, for the provision through an excluded individual or entity of such services described in paragraph (c)(1) of this section.

PART 1003—CIVIL MONEY PENALTIES AND ASSESSMENTS

D. 42 CFR part 1003 would be amended as set forth below:

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

Authority: 42 U.S.C. 1302, 1320a-7, 1320a-7a, 1395mm, 1395ss(d), 1395u(j), 1395u(k), 1396b(m), 11131(c) and 1137(b)(2).

2. Section 1003.100 would be amended by revising paragraphs (a) and (b)(1) to read as follows:

§ 1003.100 Basis and purpose.

(a) *Basis.* This part implements sections 1128(c), 1128A, 1842(j), 1842(k), 1876(i)(6), 1882(d), and 1903(m)(5) of the Social Security Act, and sections 421(c) and 427(b)(2) of Public Law 99-660 (42 U.S.C. 1320a-7(c), 1320a-7a, 1395mm, 1395ss(d), 1395u(j), 1395u(k), 1396b(m), 11131(c) and 11137(b)(2)).

(b) *Purpose.* This part—

(1) Establishes procedures for imposing:

(i) Civil money penalties and assessments against persons who have submitted certain prohibited claims under the Medicare, Medicaid, or the Maternal and Child Health Services Block Grant programs;

(ii) Civil money penalties against persons who fail to report information concerning medical malpractice payments or who improperly disclose, use, or permit access to information reported under Part B of Title IV of Public Law 99-660, and regulations specified in 45 CFR Part 60; and

(iii) Civil money penalties against contracting organizations that substantially fail to provide an enrollee with required medically necessary items and services, or that engage in certain marketing, enrollment, reporting, claims payment, employment or contracting abuses;

* * * * *

3. Section 1003.101 would be amended by adding, in alphabetical order, definitions for the terms "adverse effect," "contracting organization," and "enrollee" to read as follows:

§ 1003.101 Definitions.

For purposes of this part:

* * * * *

Adverse effect means medical care has not been provided and the failure to provide such necessary medical care has presented an imminent danger to the health, safety, or well-being of the patient, or has placed the patient unnecessarily in a high-risk situation.

* * * * *

Contracting organization means a public or private entity, inclusive of a health maintenance organization (HMO), competitive medical plan (CMP), or health insuring organization (HIO) which meets the requirements of section 1876(b) or is subject to the requirements in section 1903(m)(2)(A) of the Social Security Act, and which has contracted with the Department or a State to provide medical items and services to Medicare beneficiaries or Medicaid recipients.

Enrollee means an individual who is eligible for Medicare or Medicaid, and who enters into an agreement to receive medical items and services from a contracting organization that contracts with the Department under titles XVIII or XIX of the Social Security Act.

* * * * *

4. Section 1003.102 would be amended by revising paragraph (b) to read as follows:

§ 1003.102 Basis for civil money penalties and assessments.

* * * * *

(b) The OIG may impose a penalty against:

(1) Any person whom it determines in accordance with this part:

(i) Has presented or caused to be presented a request for payment in violation of the terms of:

(A) An agreement to accept payments on the basis of an assignment under section 1842(b)(3)(B)(ii) of the Act;

(B) An agreement with a State agency not to charge a person for an item or service in excess of the amount permitted to be charged; or

(C) An agreement to be a participating physician or supplier under section 1842(h)(1); or

(ii) Is a non-participating physician under section 1842(j) of the Act and has knowingly and willfully billed individuals enrolled under part B of title XVIII of the Act, during the statutory period of the freeze, for actual charges in excess of such physicians, actual charges for the calendar quarter beginning on April 1, 1984.

(iii) Is a physician who has knowingly and willfully—

(A) Billed for services as an assistant at surgery during a routine cataract operation, or

(B) Included in his or her bill the services of an assistant at surgery during a routine cataract operation; and has not received prior approval from the appropriate Peer Review Organization or Medicare carrier for such services based on the existence of a complicating medical condition.

(2) Any contracting organization that HCFA determines has committed an act or failed to comply with the requirements set forth in §§ 417.495(a) and 434.70(c)(1) of this title.

5. Section 1003.103 would be amended by adding a new paragraph (c) to read as follows:

§ 1003.103 Amount of penalty.

* * * * *

(c)(1) The OIG may, in addition to or in lieu of other remedies available under law, impose a penalty of up to $25,000 for each determination by HCFA that a contracting organization has:

(i) Failed substantially to provide an enrollee with required medically necessary items and services, if the failure adversely affects (or has the likelihood of adversely affecting) the enrollee;

(ii) Imposed premiums on enrollees in excess of amounts permitted under section 1876 or title XIX of the Act;

(iii) Acted to expel or to refuse to re-enroll a Medicare beneficiary in violation of the provisions of section 1876 of the Act, and for reasons other than the beneficiary's health status or requirements for health care services;

(iv) Misrepresented or falsified information furnished to an individual or any other entity under section 1876 or 1903(m) of the Act; or

(v) Failed to comply with the requirements of section 1876(g)(6)(A) of the Act, regarding prompt payment of claims.

(2) The OIG may, in addition to or in lieu of other remedies available under law, impose a penalty of up to $25,000 for each determination by HCFA that a contracting organization with a contract under section 1876 of the Act:

(i) Employs or contracts with individuals or entitles excluded from participation in Medicare, under sections 1128 or 1128A of the Act, for the provision of health care, utilization review, medical social work, or administrative services; or

(ii) Employs or contracts with any entity for the provision of such services (directly or indirectly) through an excluded individual or entity.

(3) The OIG may, in addition to or in lieu of other remedies available under law, impose a penalty of up to $100,000 for each determination that a contracting organization has:

(i) Misrepresented or falsified information furnished to the Secretary under section 1876 of the Act, or to the State under section 1903(m) of the Act; or

(ii) Acted to expel or to refuse to re-enroll a Medicare beneficiary or Medicaid recipient because of the individual's health status or requirements for health care services, or engaged in any practice that would reasonably be expected to have the effect of denying or discouraging enrollment (except as permitted by section 1876 or 1903(m) of the Act) with the contracting organization by enrollees whose medical condition or history indicates a need for substantial future medical services.

(4) In cases where enrollees are charged more than the allowable premium, the OIG will impose an additional penalty equal to double the amount of excess premium charged by the contracting organization. The excess premium amount will be deducted from the penalty and returned to the enrollee.

(5) The OIG will impose an additional $15,000 penalty for each individual not enrolled when it is determined that a contracting organization has committed a violation described in paragraph (c)(3)(ii) of this section.

(6) For purposes of paragraph (c) of this section, a violation is defined as each incident where a person has committed an act or failed to comply with a requirement set forth in § 417.495(a) or § 434.67(a), as determined by HCFA.

6. Section 1003.106 would be amended by revising paragraph (a)(1), redesignating paragraph (a)(2) as paragraph (a)(3), and adding new paragraph (a)(2) to read as follows:

§ 1003.106 Determinations regarding the amount of the penalty and assessment.

(a)(1) In determining the appropriate amount of any penalty or assessment under § 1003.103(a), (b) and (c)(1)–(3), the OIG will consider:

(i) The nature of the claim or request for payment and the circumstances under which it was presented;

(ii) The degree of culpability of the person or contracting organization submitting the claim or request for payment;

(iii) The history of prior offenses of the person or contracting organization submitting the claim or request for payment;

(iv) The financial condition of the person or contracting organization presenting the claim or request for payment; and

(v) Such other matters as justice may require.

(2) In determining the appropriate amount of any penalty under § 1003.103(b)(4), the OIG will consider:

(i) The nature and scope of the required medically necessary item or service not provided and the circumstances under which it was not provided;

(ii) The degree of culpability of the contracting organization;

(iii) The seriousness of the adverse effect that resulted or could have resulted from the failure to provide required medically necessary care;

(iv) The harm which resulted or could have resulted from the provision of care by a person that the contracting organization is expressly prohibited, under sections 1876(i)(6) or 1903(p)(2) of the Act, from contracting or employing;

(v) The harm which resulted or could have resulted from the contracting organization's expulsion or refusal to re-enroll a Medicare beneficiary or Medicaid recipient;

(vi) The nature of the misrepresentation or fallacious information furnished by the contracting organization to the Secretary, State, enrollee, or other entity under sections 1876 or 1903(m) of the Act;

(vii) The history of prior offenses by the contracting organization, or principals of the contracting organization, including whether at any time prior to determination of the current violation or violations the contracting organization or any of its principals was convicted of a criminal charge, or was held liable for civil or administrative sanctions in connection with a program covered by this part or any other public or private program of payment for medical services; and

(viii) Such other matters as justice may require.

* * * * * *

Dated: October 26, 1990.

Bryan Mitchell,

Acting Inspector General, Department of Health and Human Services.

Dated: October 4, 1990.

Gail R. Wilensky,

Administrator, Health Care Financing Administration.

Approved: April 3, 1991.

Louis W. Sullivan,

Secretary, Department of Health and Human Services.

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No. 91-211, RM-7548]

Radio Broadcasting Services; Tallulah, LA

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: The Commission requests comments on a petition by Sharing, Inc., licensee of Station KBYO(FM), Channel 285A, Tallulah, Louisiana, seeking substitution of Channel 283C3 for Channel 285A and modification of its authorization accordingly. Channel 283C3 can be allotted to Tallulah in compliance with the Commission's minimum distance separation requirements at Station KBYO(FM)'s present transmitter site. The coordinates for Channel 283C3 at Tallulah are North Latitude 32-24-10 and West Longitude 91-04-00. In accordance with § 1.420(g) of the Commission's Rules, we will not accept competing expressions of interest in use of Channel 283C3 at Tallulah or require Sharing, Inc., to demonstrate the availability of an additional equivalent class channel.

DATES: Comments must be filed on or before September 6, 1991, and reply