EPA is limiting the duration of this approval to 18 months following promulgation by EPA of the section 112(g) rule.

3. Program for Delegation of Section 112 Standards as Promulgated

EPA is promulgating approval under section 112(l)(5) and 40 CFR section 63.91 of NDEP's program for receiving delegation of section 112 standards that are unchanged from federal standards as promulgated. EPA is approving NDEP's delegation mechanism for part 70 and non-part 70 sources.

III. Administrative Requirements

A. Docket

Copies of NDEP's submittal and other information relied upon for the final interim approval, including public comment letters received and reviewed by EPA on the proposal, are contained in docket number NV–DEP–95–1–OPS maintained at the EPA Regional Office. The docket is an organized and complete file of all the information submitted to, or otherwise considered by, EPA in the development of this final interim approval. The docket is available for public inspection at the location listed under the **ADDRESSES** section of this document.

B. Executive Order 12866

The Office of Management and Budget has exempted this action from review under Executive Order 12866 review.

C. Regulatory Flexibility Act

The EPA's actions under section 502 of the Act do not create any new requirements, but simply address operating permit programs submitted to satisfy the requirements of 40 CFR part 70. Because this action does not impose any new requirements, it does not have a significant impact on a substantial number of small entities.

D. Unfunded Mandates

Under Section 202 of the Unfunded Mandates Reform Act of 1995 (''Unfunded Mandates Act''), signed into law on March 22, 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a federal mandate that may result in estimated costs to state, local, or tribal governments in the aggregate; or to the private sector, of $100 million or more. Under Section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule. EPA has determined that the approval action promulgated today does not include a federal mandate that may result in estimated costs of $100 million or more to either state, local, or tribal governments in the aggregate, or to the private sector. This federal action approves pre-existing requirements under state or local law, and imposes no new federal requirements. Accordingly, no additional costs to state, local, or tribal governments, or to the private sector, result from this action.

List of Subjects in 40 CFR Part 70

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

Authority: 42 U.S.C. sections 7401–7671q.

Dated: December 1, 1995.

Felicia Marcus,

Regional Administrator.

* * * * *

Part 70, title 40 of the Code of Federal Regulations is amended as follows:

PART 70—[AMENDED]

1. The authority citation for part 70 continues to read as follows:

Authority: 42 U.S.C. 7401, et seq.

2. Appendix A to part 70 is amended by adding paragraph (a) to the entry for Nevada:

Appendix A to Part 70—Approval Status of State and Local Operating Permits Programs

* * * * *

The following state program was submitted by the Nevada Division of Environmental Protection:

(a) *Nevada Division of Environmental Protection:* submitted on February 8, 1995; interim approval effective on January 11, 1996; interim approval expires January 12, 1998.

* * * * *

[FR Doc. 95–30261 Filed 12–11–95; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

42 CFR Part 1004

RIN 0991–AA73

Health Care Programs: Fraud and Abuse; Revisions to the PRO Sanctions Process

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

ACTION: Final rule.

SUMMARY: This final rule revises and updates the procedures governing the imposition and adjudication of program sanctions predicated on recommendations of State Utilization and Quality Control Peer Review Organizations (PROs). These changes are being made as a result of statutory revisions designed to address health care fraud and abuse issues and the OIG sanctions process. In addition, this final rule sets forth new appeal and reinstatement procedures for practitioners and other persons excluded by the OIG based on a PRO recommendation.

EFFECTIVE DATE: December 12, 1995.

FOR FURTHER INFORMATION CONTACT:

Joe J. Schaer, Office of Management and Policy, (202) 619–3270

Joanne Lanahan, Office of Civil Fraud and Administrative Adjudication, (410) 786–9609.

SUPPLEMENTARY INFORMATION:

I. Background

A. The PRO Sanctions Process

Section 1156 of the Social Security Act imposes specific statutory obligations on practitioners and other persons to furnish necessary services to Medicare and State health care program beneficiaries that meet professionally recognized standards, and authorizes the Secretary—based on a PRO's recommendation—to impose sanctions on those who fail to comply with these statutory obligations.

Under the PRO sanctions process, no practitioner or other person is recommended for an exclusion or a monetary penalty until the practitioner or other person has an opportunity to provide additional information and have an extensive discussion with the PRO. After the receipt of a recommendation from a PRO, the OIG excludes or imposes a monetary penalty only after a careful review of all submitted documents and a separate determination that the practitioner or

other person (1) violated the statutory obligations to render medically necessary and appropriate care or failed to provide evidence of medical necessity and quality, and (2) was unwilling or unable to comply with these obligations. A practitioner or other person who is excluded from Medicare and any State health care programs, or assessed a monetary penalty, on the basis of a PRO finding is entitled to administrative and judicial review after such sanction is assessed.

B. Summary of Recent Statutory Changes

A number of recent statutory changes have resulted in revisions to section 1156 of the Act—

Public Law 100–93: Section 6 of the Medicare and Medicaid Patient and Program Protection Act extended the obligation to provide appropriate and medically necessary care that meets professionally recognized standards of quality, and the obligation to ensure that the care is appropriately documented, to encompass *all* health care services for which payment may be made under the Act, and not just Medicare. In addition, the exclusion authority under section 1156 of the Social Security Act was extended to encompass violations occurring in, and exclusions from, the State health care programs.

Public Law 100–203: Section 4095 of the Omnibus Budget Reconciliation Act (OBRA) of 1987 provided that an exclusion of a practitioner or other person who practices in a county of less than 70,000 people or in a rural health professional shortage area (HPSA) cannot be effectuated until an opportunity for a preliminary administrative hearing is provided and, if requested, the administrative law judge (ALJ) determines that the practitioner or other person will pose a serious risk to beneficiaries if permitted to continue furnishing services during the appeals process.

Public Law 101–508: Section 4205 of OBRA 1990 set forth new statutory requirements for PROs, where appropriate, to offer a corrective action plan (CAP) to practitioners and other persons prior to making a finding; and, in determining whether a practitioner or other person is willing and able to comply with his or her obligations, require the Secretary to consider whether they entered into and successfully completed a CAP prior to the PRO's submission of a recommendation and report to the Secretary.

Public Law 103–432: Section 156 of the Social Security Act Amendments of 1994 set forth the requirement that if a PRO, after reasonable notice and opportunity for discussion with the physician or practitioner concerned, finds that the physician or practitioner has furnished services in violation of section 1156(a) of the Act and determines that the physician or practitioner should enter into a CAP under section 1156(b)(1), the PRO will notify the State board(s) responsible for the licensing or disciplining of the physician or practitioner of its finding and of any action taken as a result of the finding. (See discussion regarding § 1004.70 under the Response to the Public Comments section regarding use of the term ''physician and practitioner.'')

II. Summary of the Proposed Regulations

On February 28, 1994, the OIG published a notice of proposed rulemaking in the Federal Register that set forth a comprehensive rewrite of 42 CFR part 1004 consistent with the statutory revisions and other proposed procedures and recommendations. The proposed regulations were specifically designed to revise and update the administrative procedures for the imposition and adjudication of the PRO sanctions process. The proposed regulations addressed revisions in three broad areas: (1) Procedural changes resulting from the OBRA 1990 provisions, (2) the establishment of preliminary hearings for practitioners and other persons in rural areas or counties, and (3) an alternative sanctions notification process.

A. The OBRA 1990 Provisions Relating to PRO's

Among other things, the proposed regulations provided for—

- The elimination of the procedural distinction between ''substantial'' violations and ''gross and flagrant'' violations.
- The use of any violations of the obligations identified during a CAP period in support of the PRO's recommendation regarding a practitioner's or other person's unwillingness or inability to comply with statutory obligations.[1]
- The inclusion of a provision that no physician member of the PRO panel may be in direct competition with, or have a substantial bias for or against, the practitioner or other person being considered for sanction.
- The revision of § 1004.30(e) by setting forth instructions to PROs on the actions to be taken when a physician relocates after receiving a sanction notice.
- The inclusion of any prior problems that any State health care program has had with a practitioner or other person as an additional factor to be considered by the OIG in imposing an exclusion.

B. Preliminary Hearings

The proposed regulations also set forth provisions to allow a practitioner or other person in specified rural areas or counties of a specified population to request a preliminary hearing when notified by the OIG of an exclusion from participation in the Medicare program resulting from a PRO recommendation. The preliminary hearing would be solely on the issue of whether such practitioner's or other person's continued participation in the program during the appeal to an ALJ would place program beneficiaries at serious risk.

Entitlement to such a preliminary hearing would apply to practitioners and other persons for whom an exclusion is proposed who practice in a rural HPSA for their specialty or in a county with a population of less than 70,000. A practitioner's or other person's practice was considered to be where over 50 percent of his, her or its services were rendered. The proposed regulations provided that a practitioner's or other person's request for a preliminary hearing must be received within 15 days of receipt of an OIG exclusion notice.

C. Sanctions Notification Process

The proposed regulations set forth an alternative sanctions notification process that would allow sanctioned practitioners and other persons the option of informing all their patients *directly* of the sanction action taken against them. If they selected this option and complied with its requirements in a timely fashion, sanctioned practitioners and other persons would be exempted from current requirement for public notice.

Under this proposed option, practitioners and other persons would be required to certify to the Department that they have taken action to inform all their patients of the sanction and, in the case of exclusion, that they would notify new patients before furnishing services. Each sanctioned practitioner or other person opting for this alternative notice procedure would have to alert both existing patients and all new patients through written notification based on a suggested, non-mandatory model that would be provided by the OIG. For

[1] If a PRO decides to use any of the violations identified during a corrective action plan as a basis for a pending recommendation for sanction, instead of a basis to support unwillingness or inability, the PRO must send out a notification on these violations in accordance with § 1004.40.

those sanctioned practitioners or other persons not electing this alternative method or failing to return the required certification form within the proposed 30-day period, the OIG would follow its standard procedure for public notification.

III. Response to the Public Comments

As a result of the proposed rulemaking published on February 28, 1994, the OIG received a total of 12 timely-filed public comments from various practitioners and providers, medical and professional associations, third party payers, peer review organizations and other interested parties.

Set forth below is a summary of those comments and our response to the issues and concerns raised.

Section 1004.1—Scope and Definitions

Comment: Three commenters stated that the term ''gross and flagrant'' was confusing, and as currently defined, has been erroneously interpreted to permit the Department and the PROs to focus on the outcome of the procedure and not on the degree of the violation. The commenters believed that under the existing definition the PROs have been given broad authority to arbitrarily determine that any given quality concern is potentially sanctionable, and that this, in turn, has lead to the initiation of the sanction process in some questionable cases.

Response: We believe it is important to retain the present definition and classification for the term ''gross and flagrant'' so that the severity of the violation can be demonstrated. While we have considered alternative definitions for defining this term, we believe that the current classification adequately and properly reflects the severity of the violation of the obligation(s) and the risk to the patient(s) which has already been identified. As to one commenter's suggestion that the patient must be ''harmed'' before a violation can be considered gross and flagrant, we disagree. We believe that a gross and flagrant violation includes those situations where a patient is placed in danger or in a high-risk situation, whether or not the patient is harmed. Thus, we are retaining the current definition.

Comment: While agreeing that there needs to be a definition for the term ''pattern of care,'' one commenter was concerned that the definition for ''substantial violation in a substantial number of cases''—which encompasses the requirement that there be an inappropriate pattern of care—has been interpreted to support a finding of a substantial violation exclusively on the basis of multiple allegations of treatment deficiencies in a single patient. The commenter believes this is unfair since, while a physician's course of treatment with respect to one patient may be alleged to be negligent, the treatment of a single individual does not indicate the ''pattern'' of professional negligence that the law was designed to address.

Response: We agree with the commenter's concern and have revised the definition of ''pattern of care'' in substantial violation cases to mean that the care under question has been demonstrated in more than 3 instances, which must involve different *admissions.* Under this revised definition, the instances could involve the same patient but reflect problems with the treatment occurring at different times. This is in contrast with the definition of gross and flagrant violations in which multiple violations may be found within the same admission.

Comment: One commenter objected to our defining the term ''practice area'' as ''the location where over 50 percent of the practitioner's or other person's patients are seen,'' and requested that the definition be deleted. The commenter believed that a practitioner who has *any* amount of practice in a rural area should be entitled to a preliminary hearing on the issue of whether that person's continued participation during the appeal of the exclusion would place program beneficiaries at serious risk.

Response: We are rejecting this comment since we believe it is not consistent with the statutory provision and congressional intent in providing for such preliminary hearings. If Congress wanted to extend the right to a preliminary hearing to *all,* or virtually all, practitioners and other persons, it would have done so in the statutory language. Rather, the statute and these regulations are targeted only to those who ''practice'' in a HPSA or a county with a population of less than 70,000, and not those who may occasionally see a patient in a rural area. In order to carry out the intent of the statutory provision, we believe that the definition for the term ''practice area'' is appropriate, fair and reasonable.

Section 1004.40—Action on Identification of a Violation

Comment: While several commenters strongly supported the OIG's proposal to eliminate the distinction between ''substantial'' violations and ''gross and flagrant'' violations, one commenter believed that the elimination of this distinction would result in less due process by removing the physician's right to receive two notices and two hearings for any violation.

Response: As noted in the proposed rule, the second meeting in substantial violation cases has proven simply to be a repeat of the initial or 20-day meeting. This, in turn, has increased the risk of serious patient harm due to this procedural delay. Experience has shown that this dual meeting process has tended to be cumbersome, time-consuming and confusing to both the physician responding to substantial violations issues and the physician members of the PRO's sanction panel. The OIG believes that this approach to eliminating the violations' distinction will serve program beneficiaries well while still continuing to provide adequate due process to all practitioners and other persons.

Comment: One commenter strongly agreed with the additional safeguards under § 1004.40 that state that the notice must contain information regarding the meeting, that an attorney may represent the practitioner, and that the attorney may make opening and closing remarks, ask clarifying questions at the meeting and assist the practitioner in presenting testimony of expert witnesses who may appear on behalf of the practitioner. However, the commenter believed that the notice should also contain a provision stating that the attorney may also cross-examine any physician or other expert who provided evidence upon which the PRO relied in identifying a potential violation under § 1004.10.

Response: We do not agree with the commenter's recommendation under § 1004.40 that notice should also include a provision that would allow attorney cross-examination. The meeting between the PRO and the practitioner or other person is not a formal adversarial hearing or trial. Rather, this meeting serves only as a medical dialogue to afford the practitioner or other person an opportunity to discuss medical issues.

Comment: Under § 1004.40, when a PRO identifies a violation, it must send a notice to the practitioner or provider identifying the specific concerns. One commenter stated that, while traditionally it has been up to the provider or practitioner to initiate a CAP before the PRO would consider it, this rule change places the obligation on the PRO to initiate resolution through a CAP. The commenter questioned whether the absence of a CAP in the notice constituted a determination by the PRO that the case cannot, at that

time, be resolved with a CAP, and opined that if a CAP is *not* considered appropriate, perhaps the notice should state this along with the reasons why. The commenter also wanted the practitioner or provider to be given an opportunity to submit additional information within 15 days of receipt of notice without, at the same time, having to decide to request a meeting.

Response: With regard to the use of a CAP, we believe that there are times when the PRO will not know if, or what type of, a CAP is appropriate until they have met with or heard from the practitioner or other person in response to the letter. We are, therefore, dissuaded by the comment raised. With regard to the commenter's second point, before the PRO sends out a notice under this regulatory process, the practitioner or other person is given at least one and, in most instances, two opportunities to present clarifying information. Therefore, we do not believe that another opportunity such as that proposed by the commenter would be necessary.

Comment: One commenter indicated concern with the proposed language in § 1004.40(b)(5) that stated the PRO must advise the practitioner or other person of ''the sanction that the PRO could recommend to the OIG *if the violation continues*'' (italic added). The phrase ''if the violation continues'' is not contained in the current ''gross and flagrant'' notice, and the commenter believed that the use of these words in the regulations would prevent an exclusion recommendation by the PRO in the most egregious of circumstances if the PRO cannot document that the violation continues. The commenter specifically recommended that this phrase be deleted.

Response: We agree with the commenter and are deleting this wording from § 1004.40(b)(5).

Section 1004.50—Meeting With a Practitioner or Other Person

Comment: Several commenters strongly agreed with the codification of the requirement that no physician member of the PRO panel may be in direct competition with, or have a substantial bias against, the practitioner or other person being considered for sanction. One commenter urged, however, that this section be expanded to include specific reference to the right of the practitioner's attorney to cross-examine any reviewing physician who has made recommendations to the PRO regarding the quality of care rendered by the practitioner under review. The commenter also raised concern over the lack of a requirement that physicians providing expertise to the PRO in regard to the sanction investigation or other proceedings be in the same specialty as the practitioner under review.

Response: As discussed above, we do not believe that it is necessary that the physician's attorneys have the opportunity to cross-examine physician panel members. The meeting between the PRO and the physician or other person is *not* a formal adversarial hearing or trial. Rather, it is intended to remain merely a medical dialogue designed to afford the practitioner or other person an opportunity to discuss medical issues. With respect to the suggestion that the medical professional providing expertise be of the same or closely related specialty and be practicing in similar circumstances to the practitioner under review, we believe that proposed section (d) of this section satisfies this specific concern. Specifically, § 1004.50(d) states that at least one member of the PRO panel meeting with the practitioner or other person should practice in a similar geographic area, and at least one member of the panel must be in the same specialty. Both requirements can be met by a single individual.

Comment: One commenter asked that the composition of the sanctions panel be expanded to include persons trained and experienced in ''hospital issues'' before any hospital can be appropriately subject to a sanction.

Response: Since the obligations with regard to any violation involve medical quality of care issues, necessary services and medical documentation, we remain unclear as to what unique ''hospital issues'' are involved. As set forth, we believe that the changes contained in the rulemaking adequately remove any bias from addressing the pertinent issues in the ongoing sanction process.

Comment: Section 1004.50(g) provides that, when a practitioner or other person requests a meeting with the PRO, ''[t]he PRO may allow the practitioner or other person 5 working days after the meeting to provide the PRO additional relevant information that may affect its decision * * *.'' One commenter suggested that 5 working days was not adequate time for a practitioner to provide additional information to the PRO, and that 14 days would be a more reasonable amount of time.

Response: We believe that the 5-day period granted to provide additional information after the meeting is adequate. We believe that the practitioner or other person has been afforded several opportunities up to this point to provide additional information, and that 5 days, consistent with the American Medical Association (AMA) understanding, is sufficient in this instance.

Comment: One commenter indicated that the terms ''determination,'' ''decision'' and ''finding'' are used interchangeably in §§ 1004.40 and 1004.50, and requested that the terms ''determination'' and ''decision'' be eliminated and the term ''finding'' be used consistently throughout.

Response: We agree with the commenter's concern, and to be consistent throughout these sections, we are deleting the terms ''decision'' and ''determination'' by a PRO and inserting the word ''finding'' in its place.

Section 1004.60—PRO Finding of a Violation

Comment: One commenter requested that we specifically clarify the term ''issue'' in this section, and specify when it has been resolved since no clear distinction is made between a ''issue,'' a ''determination'' and a ''finding.'' In addition, the commenter asked that the last sentence in § 1004.60(a) be eliminated and a new sentence to paragraph (b) stating that ''(T)he PRO may, on the basis of the additional information, modify either its finding or recommendation or close the case.''

Response: While we have agreed to replace the term ''issue'' with the word ''finding,'' there remain numerous ways for a ''finding'' to be resolved by a PRO and believe it would not be appropriate in these regulations to attempt to attempt further clarification of this term. With regard to the commenter's second point, we have agreed instead to modify the language in paragraph (a). As revised, the language in § 1004.60(a) will state that ''(I)f the finding has been resolved to the PRO's satisfaction, the PRO may modify its initial finding or recommendation or close the case.''

Section 1004.70—PRO Action on Final Finding of a Violation

Comment: A commenter stated that in § 1004.70(c) the word ''physician'' should be replaced with the phrase ''physician or other person'' to be consistent with other references found elsewhere in these regulations.

Response: We agree that a revision to this section is appropriate. In addition, a technical correction is being made over language in section 1154(a)(9)(B) of the Act resulting from Pub. L. 103–432. With regard to the requirement that the PRO notify licensure boards for practitioners *other than physicians* when it submits a report and recommendation to the OIG, section 1154(a)(9)(B) of the Social Security Act, as recently amended by Pub. L. 103–

432, provides that if a PRO finds that a ''physician or practitioner has furnished services in violation of section 1156(a) and the organization determines that the physician or practitioner should enter into a corrective action plan under section 1156(b)(1), the organization shall notify the State board or boards responsible for the licensing or disciplining of the physician or practitioner of its finding and of any action taken as a result of the finding.''

The Secretary may require by regulation that the PRO notify appropriate licensure boards for non-physician practitioners when those practitioners are found in violation. Accordingly, we are revising § 1004.70(c) to include notification by the PRO of appropriate licensure boards when it sends a report to the OIG regarding a physician or other person.

Section 1004.100—Acknowledgement and Review of Report

Comment: While a number of respondents concurred with the content of this section, one commenter stated that if the OIG believes that a particular sanction recommendation is not warranted, procedures should be in place for the OIG to discuss the matter with the PRO before making a final decision. Accordingly, the commenter requested that we add a provision requiring the OIG physician advisor to communicate with one or more of the physicians on the PRO panel.

Response: We disagree with the need for this added requirement. We believe such communication on the part of the OIG physician advisor could raise specific concerns of due process. There would be no clear way for the practitioner or other person to be made aware of the questions raised and the responses made by the PRO through such communication. In addition, since the PRO has provided all the documentation on which it has based its recommendation, we believe that it is unnecessary for such discussion to occur prior to the OIG making a decision.

Section 1004.110—Notice of Sanction

Comment: Two commenters strongly opposed any alternative notification process for sanctions. One of the commenters indicated that an option of allowing the physician to notify privately both his or her existing and new patients does not adequately protect the public interest. While acknowledging the OIG's concerns that the current public notification may not be effectively reaching all of the physician's patients, the commenter stated that the same risk exists with private notification and, therefore, suggested that private notification be mandatory and that it be used in addition to the current public notification process.

Response: We believe that the present public notification process has not yielded the most effective results of informing affected parties and program beneficiaries of a specific sanction action taken under the program. As a result of preliminary discussions with the AMA, the American Association of Retired Persons (AARP) and the Health Care Financing Administration, we believe that this approach, with built-in safeguards such as the certification of patient notice, would afford both the provider community and the patient community with an alternative for disseminating information regarding program sanctions. By definition, this alternative approach will offer a second options for public notification. Any effort to require both newspaper publication *and* direct notice to a physician's patients would, in effect, not offer an alternative as we have contemplated, but rather impose an additional layer of burden on the practitioner or other person. Our intent is for such notice to be both effective and cost-efficient, and we believe that this approach will meet those objectives. In addition, as indicated in the preamble to the proposed rule, where the OIG receives reliable evidence that a practitioner or other person has not adequately informed his, her or its new and existing patients of the sanction, the OIG reserves the right to follow existing procedures for public notification. Failure by the practitioner or other person to comply with the alternative method of notification once he, she or it has elected to do so will be adversely considered by the OIG at the time of application for reinstatement.

Comment: While supportive of the alternative notification process, two commenters requested that the regulations also include a requirement that the OIG receive a copy of the notice sent to each patient to determine its adequacy, or include in the regulations certain minimum requirements for the content of such notice. One commenter recommended that if providers are allowed to create their own letters, then it should be required that the letters be reviewed and approved first by the OIG prior to the provider sending them to the patients.

Response: We believe that the requirements that were set forth in proposed § 1004.110(d) with regard to patient notification and certification are adequate. As indicated, the OIG will provide the sanctioned practitioner or other person a suggested model letter designed to address the nature of the sanction, as well as the exclusion's effective date and duration. In turn, the practitioner or other person is to specifically certify to the OIG that the information provided is truthful and accurate. Failure to properly inform one's patients and return to the required certification to the OIG within 30 days, or the obtaining of reliable evidence by the OIG that the practitioner or other person failed to adequately inform patients of the sanction, will result in the publication of a public notice and will be considered an aggravating factor at the time of the practitioner's or other person's application for reinstatement. As a result, we do not believe that the use of additional OIG staff time in reviewing such individuals letters is necessary.

Comment: In order to have each practitioner or other person in full compliance with the alternative notification approach, one commenter asked that the term ''all existing patients'' be cleared defined. In addition, the commenter questioned how notice to a new patient presenting himself or herself for emergency care would be handled, and whether such required notice would impede the provision or quality of care to such patients.

Response: We agree that the term ''all existing patients'' could be interpreted in different ways. In doing so, we believe it is necessary to balance our intent of assuring that proper notice is provided to the largest possible spectrum of program beneficiaries that may be affected by this sanction, without insurmountable burdens being placed on practitioners and other persons to contact their affected patient base. For this reason, we have agreed to define the term ''all existing patients'' to include *all* patients currently under active treatment with the practitioner or other person, as well as *all* patients who have been treated by the practitioner or other person within the last three years. We believe that this definition will provide adequate notification of the sanction to those most likely to be affected by it while assuring that this alternative approach remains a viable, effective option.

Patients being treated in an emergency situation could be notified verbally at the point they seek treatment, and since excluded physicians and others can be paid for emergency services, we do not believe this to result in a significant quality of care problem.

Comment: One commenter believed that effective monitoring and validation of timely and complete compliance with this notice option by the OIG would be very difficult. A second commenter stated that monitoring this option should include a signed statement of completion by the sanctioned provider and a follow-up mail survey of a sample of patients to determine if the requirements were met.

Response: The issue of ensuring that direct patient notification is enforced was given full consideration during the development of the alternative notification process. Specifically, we do not foresee expending and designating an excessive amount of staff time to directly monitor the alternative notification process. Rather, when the OIG learns through patient complaints or other methods that the practitioner or other person has not fully complied, it will at that point taken an action to remedy the situation, such as pursuing penalties for the filing of a false statement.

Comment: One commenter recommended that since PRO activity relates only to Medicare patients, the alternative notification process should be limited to Medicare patients only.

Response: Our rationale for selecting notification to all patients rests with the statutory requirement for ''reasonable notice to the *public*'' (underlining added). U.S.C. 1320c–5(b)(2). We believe that such proper public notice would not be met by having sanctioned parties limit notice to only their program-eligible patients. This selected option is designed to protect both Medicare program beneficiaries and future beneficiaries, and to ensure that the statutorily-required notice to the public of a sanction action is as effective as possible. As a result, in an effort to achieve proper notification and public awareness in an effective manner, we have opted to require that alternative notification be given to *all* patients.

Comment: While supportive of the alternative sanctions notification process, one commenter believed that the requirement that hospitals post a sign ''in all affiliated entities'' needs to be clarified to indicate what would be required of a hospital electing this alternative approach.

Response: We agree with the commenter over the need to define this term. Accordingly, we are defining in § 1004.110(d)(1)(i) the term ''in all affiliated entities'' to encompass all entities and properties which provide services and in which the hospital has a direct or indirect ownership interest of 5 percent or more and any management, partnership or control of the entity.

Comment: One commenter was concerned with the timeframes provided for in § 1004.110(b). That section provides that ''the sanction is effective 15 days from the date of receipt of the notice. The date of receipt is presumed to be 5 days after the date on the notice, unless there is a reasonable showing to the contrary.'' The commenter believed that in order for the provisions of this rule to be consistent, the effective date of a sanction should be 30 days from the date of the receipt of the notice in order to allow the sanctioned practitioner's patients adequate time to make other arrangements.

Response: Section 1156(b)(2) of the Social Security Act requires the effective date of the sanction to be consistent with section 1128(c) of the Act. Therefore, we are retaining the effective date as 20 days from the date of notice.

Section 1004.140—Appeal Rights

Comment: The proposed regulations provided that a request for a preliminary hearing must be received within 15 days of receipt of an OIG exclusion notice. Two commenters indicated that they did not believe 15 days is sufficient time to request a preliminary hearing, with one of these commenters suggesting that providers be given 30 days, rather than 15 days, to request such a preliminary hearing of a sanction.

Response: The OIG's concern remains with the protection of program beneficiaries and with decisions being reached in a timely and efficient manner. Accordingly, we believe that since the practitioner or other person continues to participate in the program until the time period for requesting a preliminary hearing has expired or a decision is made after a preliminary hearing, this process must be expeditious. Since all notices of exclusion under § 1004.110 are sent by overnight mail, we continue to believe that 15 days is sufficient time to request a preliminary hearing when desired.

Comment: The proposed regulations provided for a preliminary hearing prior to exclusion ''if the location where services are rendered to over 50 percent of the practitioner's or other person's patients at the time of the exclusion notice is in a rural HPSA or in a county where the population is less than 70,000.'' Citing that it is contrary to the public's interest to impose a specific, quantitative requirement on the amount of services that a practitioner provides in a rural area as a condition for eligibility for a hearing, one commenter disagreed with limiting the right to a preliminary hearing to physicians where over 50 percent of their practice is located in such a rural area.

Further, a second commenter indicated that they believe it would be difficult in many instances for the PRO to determine where 50 percent of the practitioner's practice is located.

Response: Section 1156(a) of the Act specifically limits the right to a preliminary hearing to those physicians who practice in a county with a population of less than 70,000 or those practicing in a HPSA. The statutory language was intentionally limiting and did not provide the right to such a hearing to every practitioner or other person who may occasionally provide a service in a rural HPSA. We believe that the ''over 50 percent'' standard is reasonable and is in keeping with the statutory intent.

Comment: One commenter believed that there should be an additional regulatory requirement that the OIG notify the PRO when a sanction appeal is made. The commenter believed that they should have this knowledge so that they can participate with and assist the OIG through the administrative appeal process.

Response: The OIG does not receive specific notification when a sanction is being appealed and, therefore, it cannot routinely notify the PRO of such action. In most cases, it is the Regional Counsel's office that notifies the PRO so that it can prepare the defense of the practitioner's or other person's exclusion action.

IV. Technical Revisions to 42 CFR Part 1004

In addition to the public comments received on the proposed rulemaking, the OIG received a number of internal technical comments from two of the Department's Regional Counsel's offices. These comments and recommendations for change were designed to further clarify specific aspects of the regulatory language set forth in 42 CFR part 1004, and are technical, non-substantive and editorial in nature. We have adopted a number of these suggestions and have incorporated them into the revised text for part 1004 set forth below.

V. Regulatory Impact Statement

The Office of Management and Budget has reviewed this final rule in accordance with the provisions of Executive Order 12866. As indicated above, the revisions contained in this final rule are intended to revise and update administrative procedures governing the imposition and adjudication of program sanctions, based on PRO recommendations, against practitioners and other persons who

violate the statute. We believe that the great majority of practitioners and other persons do not engage in such prohibited activities and practices, and that the aggregate economic impact of these provisions should, in effect, be minimal, affecting only those who have engaged in prohibited behavior in violation of statutory intent. As such, these regulations should have no direct effect on the economy or on Federal or State expenditures.

In addition, in accordance with the Regulatory Flexibility Act (5 U.S.C. 601 through 612), the Secretary certifies that this final rulemaking will not have a significant economic impact on a substantial number of small entities. While some sanctions and penalties may have an impact on small entities, we do not anticipate that a substantial number of these small entities would be significantly affected by this rulemaking. Therefore, we have determined, and the Secretary certifies, that this final rule should not have a significant economic impact on a number of small business entities.

List of Subjects in 42 CFR Part 1004

Administrative practice and procedure, Health facilities, Health professions, Medicare, Peer Review Organizations, Penalties, Reporting and recordkeeping requirements.

Part 1004 is revised to read as follows:

PART 1004—IMPOSITION OF SANCTIONS ON HEALTH CARE PRACTITIONERS AND PROVIDERS OF HEALTH CARE SERVICES BY A PEER REVIEW ORGANIZATION

Subpart A—General Provisions

Sec.
1004.1 Scope and definitions.

Subpart B—Sanctions Under the PRO Program; General Provisions

1004.10 Statutory obligations of practitioners and other persons.
1004.20 Sanctions.

Subpart C—PRO Responsibilities

1004.30 Basic responsibilities.
1004.40 Action on identification of a violation.
1004.50 Meeting with a practitioner or other person.
1004.60 PRO finding of a violation.
1004.70 PRO action on final finding of a violation.
1004.80 PRO report to the OIG.
1004.90 Basis for recommended sanction.

Subpart D—OIG Responsibilities

1004.100 Acknowledgement and review of report.
1004.110 Notice of sanction.

Subpart E—Effect and Duration of Exclusion

1004.120 Effect of an exclusion on program payments and services.
1004.130 Reinstatement after exclusion.

Subpart F—Appeals

1004.140 Appeal rights.

Authority: 42 U.S.C. 1302 and 1320c–5.

Subpart A—General Provisions

§ 1004.1 Scope and definitions.

(a) *Scope.* This part implements section 1156 of the Act by—

(1) Setting forth certain obligations imposed on practitioners and providers of services under Medicare;

(2) Establishing criteria and procedures for the reports required from peer review organizations (PROs) when there is failure to meet those obligations;

(3) Specifying the policies and procedures for making determinations on violations and imposing sanctions; and

(4) Defining the procedures for appeals by the affected party and the procedures for reinstatements.

(b) *Definitions.* As used in this part, unless the context indicates otherwise—

Dentist is limited to licensed doctors of dental surgery or dental medicine.

Economically means the services are provided at the least expensive, medically appropriate type of setting or level of care available.

Exclusion means that items and services furnished or ordered (or at the medical direction or on the prescription of a physician) by a specified health care practitioner, provider or other person during a specified period are not reimbursed under titles V, XVIII, XIX, or XX of the Social Security Act and all other Federal non-procurement programs.

Gross and flagrant violation means a violation of an obligation has occurred in one or more instances which presents an imminent danger to the health, safety, or well-being of a program patient or places the program patient unnecessarily in high-risk situations.

Health care service or services means services or items for which payment may be made (in whole or in part) under the Medicare or State health care programs.

Health professional shortage area (HPSA) means an area designated by the Secretary and defined in 42 CFR 5.2.

Metropolitan Statistical Area means an area as defined by the Executive Office of Management and Budget.

Obligation means any of the obligations specified at section 1156(a) of the Act.

Other person means a hospital or other health care facility, an organization or an agency that provides health care services or which payment may be made (in whole or in part) under the Medicare or State health care programs.

Pattern or care means that the care under question has been demonstrated in more than three instances, each of which involved different admissions.

Pharmacy professional is a term limited to individuals who are licensed or registered to provide pharmaceutical services.

Podiatric professional is a term limited to licensed doctors of podiatric medicine.

Practice area means the location where over 50 percent of the practitioner's or other person's patients are seen.

Practitioner means a physician or other health care professional licensed under State law to practice his or her profession.

Primary medical care professional is a term limited to:

(i) Licensed doctors of medicine and doctors of osteopathy providing direct patient care who practice in the fields of general or family practice, general internal medicine, pediatrics, obstetrics and gynecology, surgery, and any other specialty that is not accommodated by the remaining specialty HPSA designator, or

(ii) Those facilities where care and treatment is provided to patients with health problems other than mental disorders.

Pro area means the geographic area subject to review by a particular PRO.

Provider means a hospital or other health care facility, agency, or organization.

Psychiatric professional is a term limited to licensed doctors of medicine who limit their practice to psychiatry or to those facilities where care and treatment is limited to patients with mental disorders.

Rural means any area outside an urban area.

Rural health professional shortage area means any health professional shortage area located outside a Metropolitan Statistical Area.

Sanction means an exclusion or monetary penalty that the Secretary may impose on a practitioner or other person as a result of a recommendation from a PRO.

Serious risk includes situations that may involve the risk of unnecessary treatment, prolonged treatment, lack of treatment, incorrect treatment, medical complication, premature discharge, physiological or anatomical impairment, disability, or death.

State health care program means a State plan approved under title XIX, any

program receiving funds under title V or from an allotment to a State under such title, or any program receiving funds under title XX or from an allotment to a State under such title.

Substantial violation in a substantial number of cases means a pattern of providing care, as defined in this section, that is inappropriate, unnecessary, or does not meet recognized professional standards of care, or is not supported by the necessary documentation of care as required by the PRO.

Urban means a Metropolitan Statistical Area as defined by the Executive Office of Management and Budget.

Vision care professional is a term limited to licensed doctors of medicine who limit their practice to ophthalmology and to doctors of optometry.

Subpart B—Sanctions Under the PRO Program; General Provisions

§ 1004.10 Statutory obligations of practitioners and other persons.

It is the obligation of any health care practitioner or other person who furnishes or orders health care services that may be reimbursed under the Medicare or State health care programs to ensure, to the extent of his or her or its authority, that those services are—

(a) Provided economically and only when, and to the extent, medically necessary;

(b) Of a quality that meets professionally recognized standards of health care; and

(c) Supported by evidence of medical necessity and quality in the form and fashion and at such time that the reviewing PRO may reasonably require (including copies of the necessary documentation and evidence of compliance with pre-admission or pre-procedure review requirements) to ensure that the practitioner or other person is meeting the obligations imposed by section 1156(a) of the Act.

§ 1004.20 Sanctions.

In addition to any other sanction provided under law, a practitioner or other person may be—

(a) Excluded from participating in programs under titles V, XVIII, XIX, and XX of the Social Security Act; or

(b) In lieu of exclusion and as a condition for continued participation in titles V, XVIII, XIX, and XX of the Act, if the violation involved the provision or ordering (or at the medical direction or the prescription of a physician) of health care services that were medically improper or unnecessary, required to pay an amount not in excess of the cost of the improper or unnecessary services that were furnished or ordered (and prescribed, if appropriate). The practitioner or other person will be required either to pay the monetary assessment within 6 months of the date of notice or have it deducted from any sums the Federal government owes the practitioner or other person.

Subpart C—PRO Responsibilities

§ 1004.30 Basic responsibilities.

(a) The PRO must use its authority or influence to enlist the support of other professional or government agencies to ensure that each practitioner or other person complies with the obligations specified in § 1004.10.

(b) When the PRO identifies situations where an obligation specified in § 1004.10 is violated, it will afford the practitioner or other person reasonable notice and opportunity for discussion and, if appropriate, a suggested method for correcting the situation and a time period for a corrective action in accordance with §§ 1004.40 and 1004.60.

(c) The PRO must submit a report to the OIG after the notice and opportunity provided under paragraph (b) of this section and, if appropriate, the opportunity to enter into and complete a corrective action plan (CAP) if the PRO finds that the practitioner or other person has—

(1) Failed substantially to comply with any obligation in a substantial number of admissions; or

(2) Grossly and flagrantly violated any obligation in one or more instances.

(d) The PRO report to the OIG must comply with the provisions of § 1004.80.

(e) If a practitioner or other person relocates to another PRO area prior to a finding of a violation or sanction recommendation, and the originating PRO—

(1) Is able to make a finding, the originating PRO must, as appropriate, close the case or forward a sanction recommendation to the OIG; or

(2) Cannot make a finding, the originating PRO must forward all documentation regarding the case to the PRO with jurisdiction, and notify the practitioner or other person of this action.

(f) The PRO must deny payment for services or items furnished or ordered (or at the medical direction or on the prescription of an excluded physician) by an excluded practitioner or other person when the PRO identifies the services or items. It must report the findings to the Health Care Financing Administration.

§ 1004.40 Action on identification of a violation.

When a PRO identifies a violation, it must—

(a) Indicate whether the violation is a gross and flagrant violation or is a substantial violation in a substantial number of cases; and

(b) Send the practitioner or other person written notice of the identification of a violation containing the following information—

(1) The obligation(s) involved;

(2) The situation, circumstances or activity that resulted in a violation;

(3) The authority and responsibility of the PRO to report violations of any obligation under section 1156(a) of the Act;

(4) A suggested method for correcting the situation and a time period for corrective action, if appropriate;

(5) The sanction that the PRO could recomment to the OIG;

(6) The right of the practitioner or other person to submit to the PRO within 30 days of receipt of the notice additional information or a written request for a meeting with the PRO to review and discuss the finding, or both. The date of receipt is presumed to be 5 days after the date on the notice, unless there is a reasonable showing to the contrary. The notice will also state that if a meeting is requested—

(i) It will be held within 30 days of receipt by the PRO of the request, but may be extended for good cause;

(ii) The practitioner or other person may have an attorney present; and

(iii) The attorney, if present, will be permitted to make opening and closing remarks, ask clarifying questions at the meeting and assist the practitioner or other person in presenting the testimony of expert witnesses who may appear on the practitioner's or other person's behalf; and

(7) A copy of the material used by the PRO in arriving at its finding except for PRO deliberations, as set forth in § 476.139 of this part.

§ 1004.50 Meeting with a practitioner or other person.

If the practitioner or other person requests a meeting with the PRO—

(a) The PRO panel that meets with the practitioner or other person must consist of a minimum of 3 physicians;

(b) No physician member of the PRO panel may be in direct economic competition with the practitioner or other person being considered for sanction;

(c) The PRO must ensure that no physician member of the PRO panel has

a substantial bias for or against the practitioner or other person being considered for sanction;

(d) At least one member of the PRO panel meeting with the practitioner or other person should practice in a similar area, e.g., urban or rural, and at least one member of the panel must be in the same specialty (both requirements could be met by a single individual);

(e) If the practitioner or other person has an attorney present, that attorney will be permitted to make opening and closing remarks, ask clarifying questions and assist the practitioner or other person in presenting the testimony of expert witnesses who may appear on the practitioner's or other person behalf;

(f) The physician who recommends to the PRO that a practitioner or other person be sanctioned may not vote on that recommendation at the meeting;

(g) The PRO may allow the practitioner or other person 5 working days after the meeting to provide the PRO additional relevant information that may affect its finding; and

(h) A verbatim record must be made of the meeting and must be made available to the practitioner or other person promptly.

§ 1004.60 PRO finding of a violation.

(a) On the basis of any additional information received, the PRO will affirm or modify its finding. If the PRO affirms its finding, it may suggest in writing a method for correcting the situation and a time period for corrective action. This CAP could correspond with, or be a continuation of, a prior CAP or be a new proposal based on additional information received by the PRO. If the finding has been resolved to the PRO's satisfaction, the PRO may modify its initial finding or recommendation or close the case.

(b) The PRO must give written notice to the practitioner or other person of any action it takes as a result of the additional information received, as specified in § 1004.70.

(c) At least one member of the PRO participating in the process which resulted in a recommendation to the OIG that a practitioner or other person be sanctioned should practice in a similar geographic area, e.g. urban or rural, and at least one member of the panel must be in the same medical specialty. Both requirements can be met by a single individual. In addition, no one at the PRO who is a participant in such a finding may be in direct economic competition with, or have a substantial bias for or against, that practitioner or other person being recommended for sanction.

§ 1004.70 PRO action on final finding of a violation.

If the finding is not resolved to the PRO's satisfaction as specified in § 1004.60(a), the PRO must—

(a) Submit its report and recommendation to the OIG;

(b) Send the affected practitioner or other person a concurrent final notice, with a copy of all the material that is being forwarded to the OIG, advising that—

(1) The PRO recommendation has been submitted to the OIG;

(2) The practitioner or other person has 30 days from receipt of this final notice to submit any additional written material or documentary evidence to the OIG at its headquarters location. The date of receipt is presumed to be 5 days after the date on the notice, unless there is a reasonable showing to the contrary; and

(3) Due to the 120-day statutory requirement specified in § 1004.100(e), the period for submitting additional information will not be extended and any material received by the OIG after the 30-day period will not be considered; and

(c) Provide notice to the State medical board or to other appropriate licensing boards for other practitioner types when it submits a report and recommendations to the OIG with respect to a physician or other person whom the board is responsible for licensing.

§ 1004.80 PRO report to the OIG.

(a) *Manner of reporting.* If the violation(s) identified by the PRO have not been resolved, it must submit a report and recommendation to the OIG at the field office with jurisdiction.

(b) *Content of report.* The PRO report must include the following information—

(1) Identification of the practitioner or other person and, when applicable, the name of the director, administrator or owner of the entity involved;

(2) The type of health care services involved;

(3) A description of each failure to comply with an obligation, including specific dates, places, circumstances and other relevant facts;

(4) Pertinent documentary evidence;

(5) Copies of written correspondence, including reports of conversations with the practitioner or other person regarding the violation and, if applicable, a copy of the verbatim transcript of the meeting with the practitioner or other person;

(6) The PRO's finding that an obligation under section 1156(a) of the Act has been violated and that the violation is substantial and has occurred in a substantial number of cases or is gross and flagrant;

(7) A case-by-case analysis and evaluation of any additional information provided by the practitioner or other person in response to the PRO's initial finding;

(8) A copy of the CAP that was developed and documentation of the results of such plan or an explanation of why such the CAP will be used to support the PRO's recommendation regarding inability or unwillingness in accordance with § 1004.80(c)(6) and not as a basis for the sanction;

(9) The number of admissions by the practitioner or other person reviewed by the PRO during the period in which the violation(s) were identified;

(10) The professional qualifications of the PRO's reviewers; and

(11) The PRO's sanction recommendation.

(c) *PRO recommendation.* The PRO must specify in its report—

(1) The sanction recommended;

(2) The amount of the monetary penalty recommended, if applicable;

(3) The period of exclusion recommended, if applicable;

(4) The availability of alternative sources of services in the community, with supporting information;

(5) The county or counties in which the practitioner or other person furnishes services; and

(6) A recommendation, with supporting documentation, as to whether the practitioner or other person is unable or unwilling substantially to comply with the obligation that was violated and the basis for that recommendation.

§ 1004.90 Basis for recommended sanction.

The PRO's specific recommendation must be based on documentation provided to the OIG showing its consideration of—

(a) The type of offense involved;

(b) The severity of the offense;

(c) The deterrent value;

(d) The practitioner's or other person's previous sanction record;

(e) The availability of alternative sources of services in the community; and

(f) Any other factors that the PRO considers relevant, such as the duration of the problem.

Subpart D—OIG Responsibilities

§ 1004.100 Acknowledgement and review of report.

(a) *Acknowledgement.* The OIG will inform the PRO of the date it received the PRO's report and recommendation.

(b) *Review*. The OIG will review the PRO report and recommendation to determine whether—

(1) The PRO has followed the regulatory requirements of part 1004;

(2) A violation has occurred; and

(3) The practitioner or other person has demonstrated an unwillingness or lack of ability substantially to comply with an obligation.

(c) *Rejection of the PRO recommendation*. If the OIG decides that a sanction is not warranted, it will notify the PRO that recommended the sanction, the affected practitioner or other person, and the licensing board informed by the PRO of the sanction recommendation that the recommendation is rejected.

(d) *Decision to sanction*. If the OIG decides that a violation of obligations has occurred, it will determine the appropriate sanction by considering—

(1) The recommendation of the PRO;

(2) The type of offense;

(3) The severity of the offense;

(4) The previous sanction record of the practitioner or other person;

(5) The availability of alternative sources of services in the community;

(6) Any prior problems the Medicare or State health care programs have had with the practitioner or other person;

(7) Whether the practitioner or other person is unable or unwilling to comply substantially with the obligations, including whether he, she or it entered into a CAP—where such plan was deemed appropriate by the PRO—prior to the PRO's recommendation and, if so, whether he, she or it successfully completed such CAP; and

(8) Any other matters relevant to the particular case.

(e) *Exclusion sanction*. If the PRO submits a recommendation for exclusion to the OIG, and a determination is not made by the 120th day after actual receipt by the OIG, the exclusion sanction recommended will become effective and the OIG will provide notice in accordance with § 1004.110(f).

(f) *Monetary penalty*. If the PRO recommendation is to assess a monetary penalty, the 120-day provision does not apply and the OIG will provide notice in accordance with § 1004.110 (a)–(e).

§ 1004.110 Notice of sanction.

(a) The OIG must notify the practitioner or other person of the adverse determination and of the sanction to be imposed.

(b) The sanction is effective 20 days from the date of the notice. Receipt is presumed to be 5 days after the date on the notice, unless there is a reasonable showing to the contrary.

(c) The notice must specify—

(1) The legal and factual basis for the determination;

(2) The sanction to be imposed;

(3) The effective date and, if appropriate, the duration of the exclusion;

(4) The appeal rights of the practitioner or other person;

(5) The opportunity and the process necessary to provide alternative notification as set forth in paragraphs (d) and (e) of this section; and

(6) In the case of exclusion, the earliest date on which the OIG will accept a request for reinstatement.

(d) *Patient notification*. (1)(i) The OIG will provide a sanctioned practitioner or other person an opportunity to elect to inform each of their patients of the sanction action. In order to elect this option, the sanctioned practitioner or other person must, within 30 calendar days from receipt of the OIG notice, inform both new and existing patients through written notification—based on a suggested (non-mandatory) model provided to the sanctioned individual by the OIG—of the sanction and, in the case of an exclusion, its effective date and duration. Receipt of the OIG notice is presumed to be 5 days after the date of the notice, unless there is a reasonable showing to the contrary. Within this time period, the practitioner or other person must also sign and return the certification that the OIG will provide with the notice. For purposes of this section, the term ''all existing patients'' includes all patients currently under active treatment with the practitioner or other person, as well as all patients who have been treated by the practitioner or other person within the last 3 years. In addition, the practitioner or other person must notify all prospective patients orally at the time such persons request an appointment. If the sanctioned party is a hospital, it must notify all physicians who have privileges at the hospital, and must post a notice in its emergency room, business office and in all affiliated entities regarding the exclusion. In addition, for purposes of this section, the term ''in all affiliated entities'' encompasses all entities and properties in which the hospital has a direct or indirect ownership interest of 5 percent or more and any management, partnership or control of the entity.

(ii) The certification will provide that the practitioner or other person—

(A) Has informed each of his, her or its patients in writing that the practitioner or other person has been sanctioned, or if a hospital, has informed all physicians having privileges at the hospital that it has been sanctioned;

(B) If excluded from Medicare and the State health care programs, has informed his, her or its existing patients in writing that the programs will not pay for items and services furnished or ordered (or at the medical direction or on the prescription of an excluded physician) by the practitioner or other person until they are reinstated, or if a hospital, has provided this information to all physicians having privileges at that hospital;

(C) If excluded from Medicare and State health care programs, will provide prospective patients—or if a hospital, physicians requesting privileges at that hospital prior to furnishing or ordering (or in the case of an excluded physician, medically directing or prescribing) services—oral information of both the sanction and that the programs will not pay for services provided and written notification of the same at the time of the provision of services;

(D) If excluded from Medicare and State health care programs and is an entity such as a hospital, has posted a notice in its emergency room, business office and in all affiliated entities that the programs will not pay for services provided; and

(E) Certifies to the truthfulness and accuracy of the notification and the statements in the certification.

(2) If the sanctioned practitioner or other person does not inform his, her or its patients *and* does not return the required certification within the 30-day period, or if the sanctioned practitioner or other person returns the certification within the 30-day period but the OIG obtains reliable evidence that such person nevertheless has not adequately informed new and existing patients of the sanction, the OIG—

(i) Will see that the public is notified directly of the identity of the sanctioned practitioner or other person, the finding that the obligation ha been violated, and the effective date and duration of any exclusion; and

(ii) May consider this failure to adhere to the certification obligation as an adverse factor at the time the sanctioned practitioner or other person requests reinstatement.

(3) If the sanctioned practitioner or other person is entitled to a preliminary hearing in accordance with § 1004.140(a) and requests such a preliminary hearing, and if the administrative law judge (ALJ) decides that he, she or it poses a risk to program beneficiaries, the sanctioned practitioner or other person would have 30 days from the date of receipt of the ALJ's decision to provide certification to

the OIG in accordance with § 1004.110(d)(1). The date of receipt is presumed to be 5 days after the date of the ALJ's decision, unless there is a reasonable showing to the contrary.

(e) Notice of the sanction is also provided to the following entities as appropriate—

(1) The PRO that originated the sanction report;

(2) PROs in adjacent areas;

(3) State Medicaid fraud control units and State licensing and accreditation bodies;

(4) Appropriate program contractors and State agencies;

(5) Hospitals, including the hospital where the sanctioned individual's case originated and where the individual currently has privileges, if known; skilled nursing facilities, home health agencies, and health maintenance organizations and Federally-funded community health centers where the practitioner or other person works;

(6) Medical societies and other professional organizations; and

(7) Medicare carriers and fiscal intermediaries, health care prepayment plans and other affected agencies and organizations.

(f) If an exclusion sanction is effectuated because a decision was not made within 120 days after receipt of the PRO recommendation, notification is as follows—

(1) As soon as possible after the 120th day, the OIG will issue a notice to the practitioner or other person, in compliance with the requirements of paragraph (c) of this section, affirming the PRO recommendation or modifying the recommendation based on the OIG's review of the case, and that the exclusion is effective 20 days from the date of the notice; and

(2) Notice of the sanction is also provided as specified in paragraph (e) of this section; and

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Subpart E—Effect and Duration of Exclusion

§ 1004.120 Effect of an exclusion on program payments and services.

The effect of an exclusion is set forth in § 1001.1901 of this chapter.

§ 1004.130 Reinstatement after exclusion.

(a) A practitioner or other person who has been excluded in accordance with this part may apply for reinstatement at the end of the period of exclusion. The OIG will consider any request for reinstatement in accordance with provisions of §§ 1001.3001 through 1001.3005 of this chapter.

(b) The OIG may also consider a practitioner's or other person's compliance with the certification obligation in § 1004.110(d) at the time of reinstatement.

Subpart F—Appeals

§ 1004.140 Appeal rights.

(a) *Right to preliminary hearing.* (1)(i) A practitioner or other person excluded from participation in Medicare and any State health care programs under section 1156 of the Act may request a preliminary hearing if the location where services are rendered to over 50 percent of the practitioner's or other person's patients at the time of the exclusion notice is in a rural HPSA or in a county with a population of less than 70,000.

(ii) Unless the practitioner's or other person's practice meets the definition for psychiatric professional, vision care professional, dental professional, podiatric professional or pharmacy professional, the HPSA used by the OIG for determination of entitlement to a preliminary hearing will be the HPSA list for primary medical care professional.

(iii) Information on the population size of a county in order to determine entitlement to a preliminary hearing will be obtained by the OIG from the responsible officials of that county.

(2)(i) A request for a preliminary hearing must be made in writing and received by the Departmental Appeals Board (DAB) no later than the 15th day after the notice of exclusion is received by a practitioner or other person. The date of receipt of the notice of exclusion by the practitioner or other person is presumed to be 5 days after the date appearing on the notice, unless there is a reasonable showing to the contrary.

(ii) A request for a preliminary hearing will stay the effective date of the exclusion pending a decision of the ALJ at the preliminary hearing, and all the parties informed by the OIG of the exclusion will be notified of the stay.

(iii) A request for a preliminary hearing received after the 15-day period has expired will be treated as a request for a hearing before an ALJ in accordance with paragraph (b) of this section.

(iv) If the practitioner or other person exercises his, her or its right to a preliminary hearing, such a hearing must be held by the ALJ in accordance with paragraph (a)(3)(i) of this section unless the OIG waives it in accordance with paragraph (a)(6)(i) of this section.

(v) The ALJ cannot consolidate the preliminary hearing with a full hearing without the approval of all parties to the hearing.

(3)(i) The preliminary hearing will be conducted by an ALJ of the DAB in a city that the ALJ deems equitable to all parties. The ALJ will conduct the preliminary hearing and render a decision no later than 45 days after receipt of the request for such a hearing by the DAB. Unless there is a reasonable showing to the contrary, date of receipt by the DAB is presumed to be 5 days after the date on the request for a preliminary hearing or, if undated, the date of receipt will be the date the DAB actually received the request. A reasonable extension to the 45-day period of up to 15 days may be requested by any party to the preliminary hearing and such a request may be granted upon concurrence by all parties to the preliminary hearing. Such request must be received no later than 15 days prior to the scheduled date of the preliminary hearing.

(ii) The only issue to be heard and decided on by the ALJ at the preliminary hearing, based on the preponderance of the evidence, is whether the practitioner's or other person's continued participation in the Medicare and State health care programs during the appeal of the exclusion before an ALJ would place program beneficiaries at serious risk. The ALJ's decision is to be based on the preponderance of the evidence.

(iii) In the interest of time, the ALJ may issue an oral decision to be followed by a written decision.

(iv) In those cases where the ALJ has stayed an exclusion after a preliminary hearing, a full hearing must be held and a decision rendered by the ALJ within 6 months. If, for any reason, the request for a full hearing before the ALJ is withdrawn or dismissed, the practitioner or other person will be excluded effective 5 days after the notice of the withdrawal or dismissal is received in the OIG headquarters.

(4) The preliminary hearing decision is not appealable or subject to further administrative or judicial review.

(5) A practitioner or other person found at the preliminary hearing not to place program beneficiaries at serious risk, but later determined to have been properly excluded from program participation after a full hearing before an ALJ, is not entitled to have the exclusion stayed further during an appeal to the DAB. Exclusions in such instances will be effective 5 days after receipt of the ALJ decision in the OIG headquarters.

(6)(i) After notice of a timely request for a preliminary hearing, the OIG may determine that the practitioner's or other person's continued program participation during the appeal before

the ALJ will not place program beneficiaries at serious risk and waive the preliminary hearing. Under these circumstances, the exclusion will be stayed pending the decision of the ALJ after a full hearing. the hearing must be held, and a decision reached, within 6 months.

(ii) If the OIG decides to waive the preliminary hearing, the request for the preliminary hearing will be considered a request for a hearing before the ALJ in accordance with paragraph (b) of this section.

(b) *Right to administrative review.* (1) A practitioner or other person dissatisfied with an OIG determination, or an exclusion that results from a determination not being made within 120 days, is entitled to appeal such sanction in accordance with part 1005 of this chapter.

(2) Due to the 120-day statutory requirement specified in § 1004.100(e), the following limitations apply—

(i) The period of time for submitting additional information will not be extended.

(ii) Any material received by the OIG after the 30-day period allowed will not be considered by the ALJ or the DAB.

(3) The OIG's determination continues in effect unless reversed by a hearing.

(c) *Rights to judicial review.* Any practitioner or other person dissatisfied with a final decision of the Secretary may file a civil action in accordance with the provisions of section 205(g) of the Act.

Approved: October 23, 1995.

June Gibbs Brown,

Inspector General.

[FR Doc. 95–30130 Filed 12–11–95; 8:45 am]

BILLING CODE 4150–04–M

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No. 95–76; RM–8611]

Radio Broadcasting Services; Homestead and North Miami Beach, FL

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This document substitutes Channel 239C2 for Channel 239C1 at Homestead, Florida, reallots the channel to North Miami Beach, Florida, and modifies the license for Station WXDJ(FM) accordingly, in response to a petition filed by New Age Broadcasting, Inc. *See* 60 FR 31278, June 14, 1995. The coordinates for Channel 239C2 at North Miami Beach, Florida, are 25–42–55 and 80–09–17. With this action, this proceeding is terminated.

EFFECTIVE DATE: January 22, 1996.

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

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Report and Order,* MM Docket No. 95–76, adopted November 24, 1995, and released December 6, 1995. The full text of this Commission decision is available for inspection and copying during normal business hours in the Commission's Reference Center (Room 239), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractors, International Transcription Services, Inc., 2100 M Street, NW., Suite 140, Washington, DC 20037, (202) 857–3800.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Part 73 of title 47 of the Code of Federal Regulations is amended as follows:

PART 73—[AMENDED]

1. The authority citation for part 73 continues to read as follows:

Authority: Secs. 303, 48 Stat., as amended, 1082; 47 U.S.C. 154, as amended.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under Florida, is amended by removing Channel 239C1 and adding Channel 239C2 at Homestead, removing Channel 239C2 at Homestead and adding North Miami Beach, Channel 239C2.

Federal Communications Commission.

John A. Karousos,

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

[FR Doc. 95–30218 Filed 12–11–95; 8:45 am]

BILLING CODE 6712–01–F

47 CFR Part 73

[MM Docket No. 90–163; RM–7170]

Radio Broadcasting Services; Bay St. Louis and Poplarville, MS

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This document reallots Channel 300C from Poplarville, Mississippi to Bay St. Louis and modifies the license for Station WZKX(FM) accordingly, in response to a petition filed by Dowdy and Dowdy Partnership. See 55 FR 1913, April 3, 1990. The coordinates for Channel 300C at Bay St. Louis, MS are 30–44–48 and 89–03–30. With this action, this proceeding is terminated.

EFFECTIVE DATE: January 22, 1996.

FOR FURTHER INFORMATION CONTACT: Arthur D. Scrutchins, Mass Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Report and Order,* MM Docket No. 90–163, adopted November 25, 1995, and released December 6, 1995. The full text of this Commission decision is available for inspection and copying during normal business hours in the Commission's Reference Center (Room 239), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractors, International Transcription Services, Inc., 2100 M Street, NW., Suite 140, Washington, DC 20037, (202) 857–3800.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Part 73 of title 47 of the Code of Federal Regulations is amended as follows:

PART 73—[AMENDED]

1. The authority citation for part 73 continues to read as follows:

Authority: Secs. 303, 48 Stat., as amended, 1082; 47 U.S.C. 154, as amended.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under Mississippi, is amended by removing Channel 300C from Poplarville, Mississippi and adding Bay St. Louis, Channel 300C.

Federal Communications Commission.

John A. Karousos,

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

[FR Doc. 95–30219 Filed 12–11–95; 8:45 am]

BILLING CODE 6712–01–F

DEPARTMENT OF ENERGY

48 CFR Part 970

RIN 1991–AB08

Acquisition Regulation; Legislative Lobbying Cost Prohibition

AGENCY: Department of Energy (DOE).

ACTION: Final rule.

SUMMARY: The Department amends the Department of Energy Acquisition Regulation (DEAR) to clarify its