

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**THE SANCTION REFERRAL AUTHORITY
OF PEER REVIEW ORGANIZATIONS**



APRIL 1993 OEI-01-92-00250

EXECUTIVE SUMMARY

PURPOSE

The purpose of this study is to assess the trends and problems associated with the Peer Review Organizations' use of their sanction referral authority.

BACKGROUND

Since their establishment in 1982, the Peer Review Organizations (PROs) have reviewed millions of inpatient medical records to confirm the necessity, quality, and appropriateness of care rendered to Medicare beneficiaries. One controversial aspect of the PROs' responsibilities has been their sanction referral authority, which requires them to recommend that the Office of Inspector General (OIG) sanction physicians and hospitals responsible for violating their Medicare obligations, as specified in section 1156(a) of the Social Security Act. If the OIG accepts a PRO's recommendation, it can sanction physicians and hospitals by excluding them from participating in Medicare and all State health care programs or by imposing a monetary penalty.

In this report, we provide an update on the extent to which the PROs have been using that authority and the difficulties they experience with it. We offer three options for policymakers to consider. We reviewed the PRO sanction referral data for FYs 1986 through 1992 and interviewed representatives of 10 PROs. Among those 10 were PROs that, during Fiscal Years 1990 and 1991, had made at least 1 referral leading to a sanction, PROs that had made referrals that were rejected by the OIG, and PROs that had made no referrals.

FINDINGS

PRO sanction referrals have dwindled.

- ▶ PRO sanction referrals to the OIG have fallen from a high of 72 in FY 1987 to a low of 12 in FY 1991 and 14 in FY 1992.
- ▶ PROs for seven States have never referred a physician or hospital for sanction. Twenty-three of the 43 PROs have referred no physician or hospital for sanction in FYs 1991 and 1992.
- ▶ OIG sanctions based on PRO referrals have fallen from a high of 50 in FY 1987 to a low of 6 in FY 1992. Only 1 monetary penalty has been imposed since FY 1988.

Three major factors account for the drop in sanction referrals.

- ▶ The statutory unwilling or unable requirement remains a significant barrier to sanction referrals. This requirement stipulates that even where physicians or hospitals have violated Medicare obligations, they cannot be sanctioned unless they have demonstrated an "unwillingness or lack of ability" to comply with those obligations.
- ▶ The PROs' negative experiences with the sanction process deter referrals. They see the process as costly, complex, and contentious, and are unsure that their recommendations will be upheld.
- ▶ The PROs see themselves increasingly as educators in addressing quality-of-care problems.

Despite dwindling referrals, all the PRO officials we interviewed believe that the sanction referral authority is important to achieving their mission because it gives them leverage with the medical community.

POLICY OPTIONS

Given our findings and the moribund state of the PROs' sanction referral authority, we believe the authority needs reexamining. In that light, we offer three options for consideration by the Department of Health and Human Services, the Congress, interest groups, and other concerned parties. The options are not mutually exclusive. Any of the three could be adopted separately, but in combination they could substantially strengthen protection for Medicare beneficiaries under the PRO program.

- ▶ *Repeal or substantially modify the unwilling or unable requirement.*
- ▶ *Increase the monetary penalty sanction substantially.*
- ▶ *Maintain PROs' sanction referral authority as it exists now, but mandate referrals to State medical boards when PROs confirm serious quality-of-care problems.*

COMMENTS

We received comments on the draft report from the Health Care Financing Administration (HCFA), Public Health Service (PHS), and Assistant Secretary for Planning and Evaluation (ASPE) within the Department. The American Medical Association (AMA), American Medical Peer Review Association (AMPRA), and American Association of Retired Persons (AARP) also provided comments. The full text of the comments and our responses to each appear in appendix C.

The HCFA and AMA oppose changes in the unwilling and unable requirement, while PHS, AMPRA, and AARP support its repeal or modification. The HCFA, PHS,

ASPE, AMPRA, and AARP support increases in the monetary penalty, while the AMA opposes it.

With regard to the third policy option, HCFA indicates it will consider this option in its development of regulations that govern the sharing of confidential information between PROs and State medical boards. The PHS sees merit in requiring PROs to report serious quality-of-care cases to State medical boards, but cautions that this option could require that State boards add to their investigatory and monitoring capacity. The ASPE does not support this proposal, citing the pending fourth scope of work, and a potential for parallel investigation by PROs and medical boards. The AMA supports this option conceptually for "serious quality-of-care problems that have been confirmed by the PRO following specialty-specific physician review and completion of due process rights at the PRO level." The AMPRA and AARP support mandating referrals to State medical boards when PROs confirm serious quality-of-care problems.

Each of the respondents, both within the Department and from outside organizations, expressed concerns that two of the options proposed in the draft report could have negative consequences: Elimination of the sanction referral authority and providing that authority directly to the PROs. In response to their comments, we eliminated these policy options from the final report.

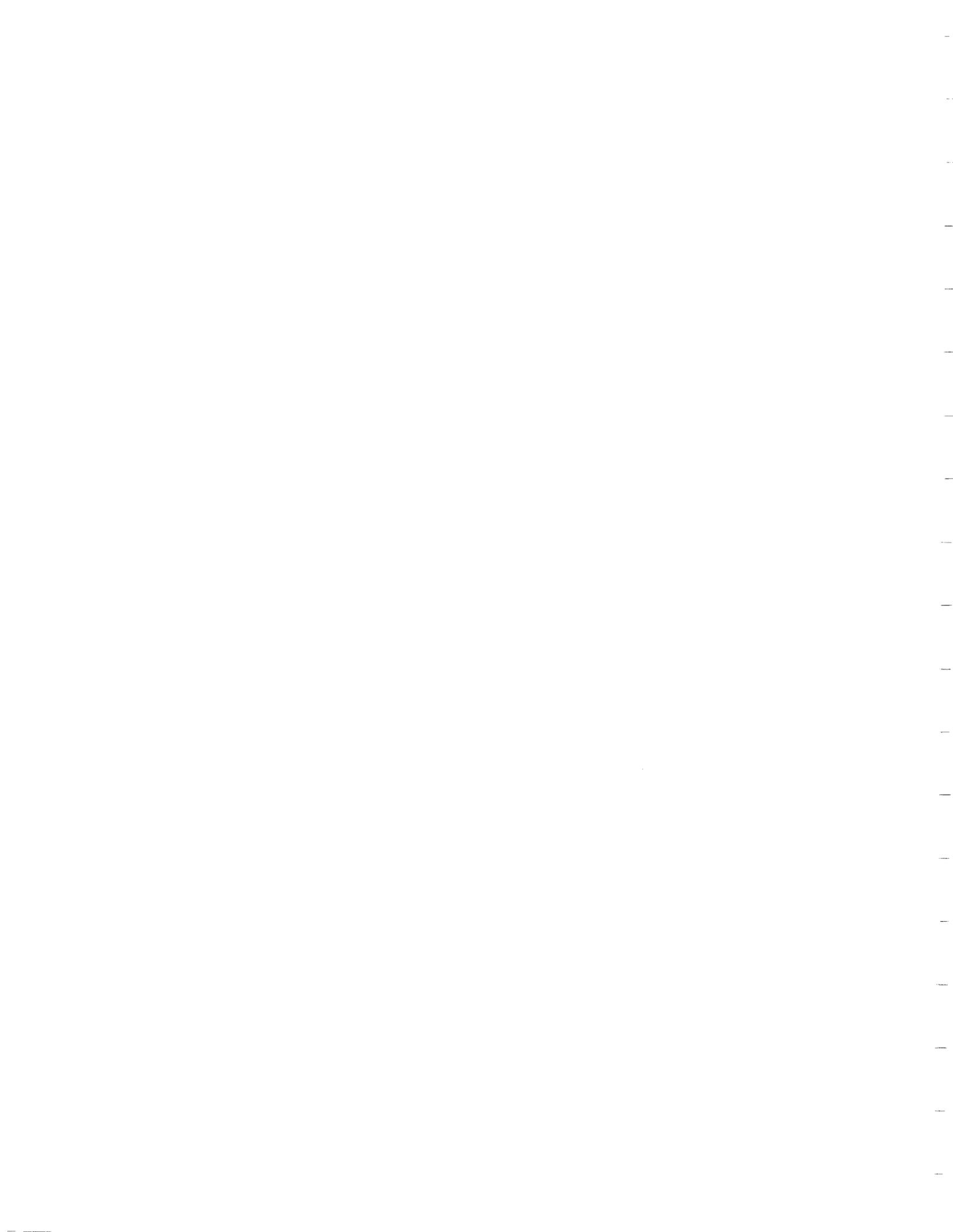


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INTRODUCTION

PURPOSE

The purpose of this study is to assess the trends and problems associated with the Peer Review Organizations' use of their sanction referral authority.

BACKGROUND

Since their establishment in 1982, the Peer Review Organizations (PROs) have reviewed millions of inpatient medical records to confirm the necessity, quality, and appropriateness of care rendered to Medicare beneficiaries. Although at first PROs functioned primarily as cost controllers, legislative, regulatory, and contractual changes have shifted their focus increasingly toward quality assurance.

The PROs' Sanction Referral Authority

One controversial aspect of the PROs' responsibilities has been their sanction referral authority. This authority requires the PROs to recommend that the Office of Inspector General (OIG) sanction physicians and hospitals in two instances. One involves physicians and hospitals who substantially violate their Medicare obligations in a substantial number of cases, as specified in section 1156(a) of the Social Security Act (see appendix A).¹ In this instance, the PRO must identify a pattern of inappropriate or unnecessary care. The other instance involves those who grossly and flagrantly violate their obligations, even in a single case. To find a gross and flagrant violation, the PRO must find that the violation placed the Medicare beneficiary in danger.

To make either type of referral to the OIG, the PRO must also provide a recommendation that supports that the physician or hospital "has demonstrated an unwillingness or lack of ability substantially to comply"² with the Medicare obligations (hereafter referred to as the unwilling or unable requirement). If willingness or ability to comply is demonstrated, then that physician or hospital cannot be sanctioned.

The Secretary of Health and Human Services, rather than the PROs, is authorized to impose sanctions against Medicare providers. The Secretary has delegated that authority to the OIG. Upon receiving a referral from a PRO, the Inspector General can accept, modify, or reject the PRO's recommendation. The Inspector General may exclude the physician or hospital from participating in Medicare for a period of time or may impose a monetary penalty that cannot exceed the cost of the medically unnecessary or improper services rendered.

Sanctioned physicians and hospitals can appeal their sanction to administrative law judges (ALJs) within the Department, who conduct hearings and can affirm, reverse, or modify the sanction imposed by the OIG. ALJ decisions can be appealed to the Departmental Appeals Board, and then to Federal district courts.

In a prior report, we addressed issues concerning the PROs' sanction referral authority.³ We noted the low level of sanction activity among the PROs, the conflict between the PROs' educational and enforcement roles, and problems with interpreting the regulations and providing adequate due process protection.

In this report, we provide an update on the extent to which the PROs have been using their sanction referral authority and any difficulties they continue to experience with it. We conclude the report with three options for policymakers.

Methodology

We draw on three sources of information for this study: (1) analysis of the PRO sanction data from FY 1986 through FY 1992 maintained by the OIG, (2) telephone interviews with staff from a purposive sample of 10 PROs⁴ and other groups interested in sanction activity, including regional staff from the Health Care Financing Administration (HCFA) and OIG, and representatives of the American Medical Peer Review Association, the American Medical Association, the American Hospital Association, and the American Association of Retired Persons, and (3) a review of the relevant literature. We chose the 10 PROs in such a way as to ensure that our sample contained PROs that, during FYs 1990 and 1991, had made at least 1 referral leading to a sanction, PROs that had made referrals that were rejected by the OIG, and PROs that had made no referrals.

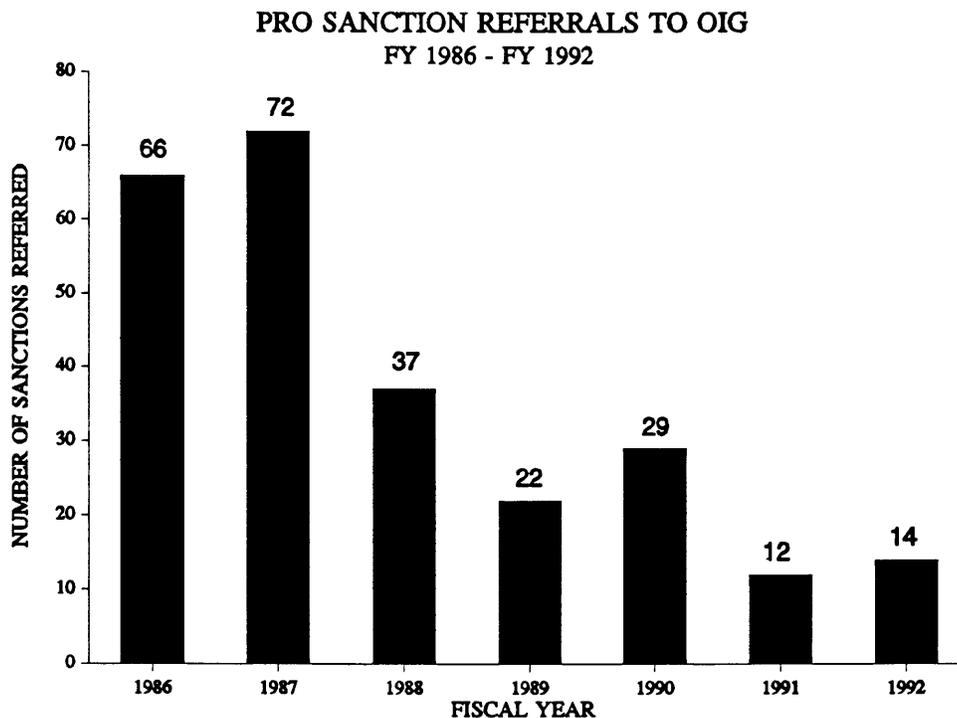
We conducted our review in accordance with the *Interim Standards for Inspections* issued by the President's Council on Integrity and Efficiency.

FINDINGS

PRO sanction referrals have dwindled.

- ▶ PRO sanction referrals to the OIG have fallen from a high of 72 in FY 1987 to a low of 12 in FY 1991 and 14 in FY 1992.

FIGURE 1



Source: Office of Investigations, Office of Inspector General

During the first 2 years of the program, the PROs referred 138 physicians⁵ and hospitals for sanction (figure 1). This was the peak level of activity. In the next five years, though the number of physicians in the United States rose steadily,⁶ the PROs used the sanction referral authority much less often. In fact, by FY 1992 they were hardly using it at all.

Throughout the seven-year period, the PROs have referred many more physicians than hospitals (see appendix B). All but 17 of the 252 PRO sanction referrals made between FYs 1986 and 1992 involved physicians. And all but 1 of the 55 referrals made in the last 3 fiscal years involved physicians.

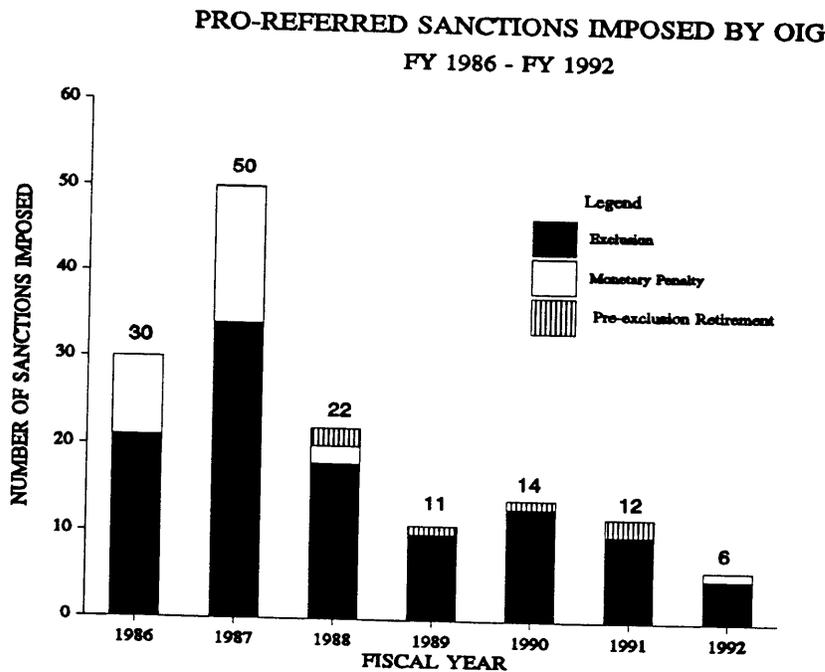
- ▶ PROs for seven States have never referred a physician or hospital for sanction. Twenty-three of the 43 PROs have referred no physician or hospital for sanction in FYs 1991 and 1992.

Four of the seven States with no PRO sanction referrals are in New England: Connecticut, Massachusetts, Rhode Island, and Vermont. The others are Alaska, Wyoming, and Hawaii.⁷

The 23 PROs⁸ that made no referrals in FYs 1991 or 1992 are responsible for States having more than 160,000 patient-care physicians.⁹ These States are scattered throughout the country.

- ▶ OIG sanctions based on PRO referrals have fallen from a high of 50 in FY 1987 to a low of 6 in FY 1992. Only 1 monetary penalty has been imposed since FY 1988.

FIGURE 2



Source: Office of Investigations, Office of Inspector General

The drop in OIG sanctions reflects the drop in the PRO sanction referrals on which the OIG actions are based. The peak of activity occurred in the earliest years of the PRO program (figure 2). And as with referrals, more physicians than hospitals have been sanctioned.¹⁰

Each year, exclusions have outnumbered monetary penalties (see appendix B), which are limited to Medicare's cost of that portion of the care deemed medically unnecessary or improper. The costs to the OIG and the PROs of pursuing monetary penalties usually have exceeded the amount of the fines. The fines have ranged from \$65.44 to \$17,512.11, but average less than \$5,000.¹¹ Exclusions have ranged from six months to permanent, with a mean length of three years.¹²

Three major factors account for the drop in sanction referrals.

- ▶ **The statutory unwilling or unable requirement remains a significant barrier to sanction referrals. This requirement stipulates that even where physicians or hospitals have violated Medicare obligations, they cannot be sanctioned unless they have demonstrated an "unwillingness or lack of ability" to comply with those obligations.**

In our 1988 study, we reported that the statutory unwilling or unable requirement was a major flaw that undermined the effectiveness of the PROs' sanction referral authority. Drawing on interviews with all the PROs, we noted that they were confused over what documentation was necessary to establish unwillingness or inability.¹³

Shortly after we issued that report, the Administrative Conference of the United States reached a similar conclusion based on its own review. In its 1989 report, it stated that the violations the PROs and the OIG find to be substantial or gross and flagrant "already serve as indicators of inability or unwillingness to comply." It added that the requirement calls for the PROs and OIG to "prove what amounts to a speculative negative" and is an "inappropriate" burden of proof.¹⁴

Despite an attempt to make the requirement more workable, it remains an obstacle. Congress, through the Omnibus Budget Reconciliation Act of 1990 (PL 101-508), attempted to clarify the unwilling or unable requirement. It specified that PROs could accept a physician's failure to participate in a corrective action plan (CAP)¹⁵ as a demonstrated unwillingness or inability to comply. Despite that clarification, PRO officials told us that as long as a physician agrees to a CAP, it remains exceedingly difficult to proceed with a sanction referral. One PRO official noted that a physician's lack of response to repeated calls and letters from the PRO was not considered evidence of unwillingness or inability.

The PROs' experiences with the unwilling or unable requirement have made them cautious in making sanction referrals. They remain keenly aware that it has accounted for more OIG rejections of PRO sanction referrals than any other reason. From FY 1986 to FY 1992, 42 of the 106 sanction referrals rejected by the OIG have been because of the unwilling or unable requirement (see appendix B). Among the 10 OIG-imposed sanctions that have been reversed by the ALJs, 3 were based on that requirement.

- ▶ **The PROs' negative experiences with the sanction process deter referrals. They see the process as costly, complex, and contentious, and are unsure that their recommendations will be upheld.**

PRO officials cited the high costs in staff, time, and funds in referring sanctions to the OIG. As they had in our earlier report,¹⁶ they noted contending with late and inadequate payments from the Health Care Financing Administration (HCFA) for sanction-related legal and expert witness fees. A PRO often spends many months preparing the referral, but receives supplemental reimbursement for legal fees only if and after a case is referred to the OIG.

Interpreting instructions governing the sanction referral process from HCFA and the OIG has also confused the PROs. For example, PRO officials cited HCFA's instruction "that corrective action plans (CAPs) be used in all but the most egregious situations."¹⁷ The PROs expressed uncertainty on how to interpret "egregious." That word never appears in the statute--which calls for CAPs only "if appropriate." They also noted that HCFA's requirement that they consider referring a physician or hospital for sanction based on a single quality-of-care problem conflicts with OIG guidance.

PRO officials cited frustrations with the due process protection, which were designed to balance the physicians' rights for due process and the beneficiaries' need for quality care. Although recognizing their importance, the PROs noted that ensuring those protection complicates the referral process. Because the due process requirements for gross and flagrant violations differ from those for substantial violations,¹⁸ referrals involving both types become even more complex. And with expert witnesses and attorneys involved, the process often becomes contentious.

From their experience with the sanction process over the years, the PROs understand that any of these factors can undermine the process. The OIG has rejected referrals not only on the ground of the unwilling or unable requirement but also on grounds that the PROs failed to follow regulatory requirements, such as those that guarantee due process¹⁹ (42 rejections). And finally, the OIG has rejected referrals based on insufficient medical evidence (20 rejections).²⁰ The ALJs have overturned OIG-imposed sanctions on similar grounds.²¹ Although most sanctions appealed to an ALJ (51 of 61) have resulted in some sanction being imposed, in many cases the sanction terms were reduced during settlement (see appendix B).

- ▶ **The PROs see themselves increasingly as educators in addressing quality-of-care problems.**

The thrust of the PRO program has been increasingly educational rather than punitive. The move toward a more educational focus began with a shift from utilization to quality review in the PROs' second contract period (1986-88).²² The third contract, which also stressed quality assurance, advanced this shift by adding

specific instructions for addressing quality-of-care problems with educational interventions. The HCFA has also expanded the use of educational CAPs over the years and now requires the PROs to use CAPs before making a sanction referral "in all but the most egregious situations."²⁴ And the PROs' educational slant is further bolstered in HCFA's discussion of its emerging Health Care Quality Improvement Initiative in the fourth scope of work:

In the Fourth SOW, HCFA begins a fundamental change in the way PROs carry out their responsibilities. PROs will place less emphasis on dealing with individual clinical concerns and focus more attention on helping physicians and providers improve the mainstream of care.²⁵

This shift toward education is in accordance with the continuous quality improvement movement emerging in the quality assurance field.²⁶ That movement stresses improving overall performance over identifying and correcting poor performers at the margin.

The PROs consider sanction referrals as failures of their educational efforts, which far outnumber their sanction activities. According to HCFA,²⁷ 4,140 physicians and 1,327 hospitals received educational interventions from the PROs during the third scope of work, while they issued just 464 sanction notices.²⁸

Despite dwindling referrals, all the PRO officials we interviewed believe that the sanction referral authority is important to achieving their mission because it gives them leverage with the medical community.

The PRO officials stress that the value of their sanction referral authority is twofold: (1) it is available when they need it to deal with those providing dangerously poor quality care, and (2) it provides a threat that gives the PROs clout with physicians and hospitals. When the PROs' preferred educational approaches fail, they need the "teeth" or "stick" that the sanction authority provides. That threat can be enough to convince a reluctant physician to cooperate with a CAP. Without the authority, the PRO officials question whether the medical community would take their interventions seriously enough. They believe it exerts a sentinel effect that contributes to their overall mission.

POLICY OPTIONS

As currently constituted, it is not at all clear that the PRO sanction referral authority is helping to protect the public from poor medical care. We do not advocate a target number of sanction referrals. Nevertheless, we are compelled to note that in FY 1992, when more than 400,000 physicians were practicing in the United States, the PROs made 14 sanction referrals.

PRO officials told us that the authority is important to achieving their overall mission. The basic reason, as we have indicated, rests with the threat that the authority carries. But as the medical community becomes more aware of just how infrequently the sanction authority is used, that threat is likely to seem remote, even to the most unskilled practicing physician.

We believe that the findings of this report identify a need to reexamine the PRO sanction referral authority. We do not make formal recommendations, but we offer three options as a starting point for discussion. The OIG has expressed support previously for each of these options.²⁹ Given the moribund state of the sanction referral authority, we believe that each option warrants serious consideration by the Department, the Congress, interest groups, and other concerned parties.

► *Repeal or substantially modify the unwilling or unable requirement.*

Upon finding that a physician has violated statutory obligations for participating in Medicare, the PRO could make a sanction referral, without having to provide additional evidentiary proof of unwillingness or inability. We recommended this in a prior report³⁰ and the OIG has developed a legislative proposal to delete the separate requirement of a determination of "unwillingness or lack of ability." This proposal is under review in the Department.

Pros: Would make the referral process less cumbersome. Would enable PROs to move more quickly on serious cases. Would base decisions on a physician's demonstrated ability and quality rather than speculation about future actions.

Cons: Could make PROs less eager to develop corrective action plans when appropriate. Could be seen as conflicting with PROs' educational and quality improvement orientation.

► *Increase the monetary penalty sanction substantially.*

Current law restricts monetary penalties to the cost involved for Medicare. These penalties could be increased to make them a more meaningful sanction. We recommended this in a prior report³¹ and the OIG has developed a legislative

proposal to authorize penalties of up to \$25,000 in lieu of exclusion. This proposal is under review in the Department.

Pros: Would provide an alternative to excluding a physician or hospital from participation in Medicare. Could help to reinforce the sanction threat. Could result in fewer appeals. Could help Government recover funds expended in sanctioning.

Cons: Could appear as an inadequate sanction. Could further discourage PROs from recommending exclusions when warranted.

► ***Maintain PROs' sanction referral authority as it exists now, but mandate referrals to State medical boards when PROs confirm serious quality-of-care problems.***

The PROs would continue to refer cases to OIG as they currently do. This authority would be supplemented with a mandate to refer physicians responsible for serious quality-of-care problems to State medical boards, which would then investigate and take whatever action was necessary.³² Likewise, PROs could refer hospitals to their State licensure agencies. We recommend such a mandate in our recent report *The Peer Review Organizations and State Medical Boards: A Vital Link*.³³

Pros: Adds its own threat apart from that of the sanction referral authority and its constraints. Allows PROs to concentrate more fully on their educational mission. Allows for increased State-level peer review. Recent experiences from Ohio suggest that the approach has potential.³⁴

Cons: Directs to State medical boards responsibility for reviewing quality of care in individual cases, not part of many boards' current practice. Could require additional investigatory and monitoring capacity. Raises possibility of PROs and boards taking conflicting approaches toward a physician. Could further discourage PROs from using their sanction referral authority. Board authority varies from State to State.

COMMENTS ON THE DRAFT REPORT

We received comments on the draft report from the Health Care Financing Administration (HCFA), Public Health Service (PHS), and Assistant Secretary for Planning and Evaluation (ASPE) within the Department. The American Medical Association (AMA), American Medical Peer Review Association (AMPRA), and American Association of Retired Persons (AARP) also provided comments. The full text of the comments and our responses to each appear in appendix C.

We have included updated figures on the number of sanctions imposed through Fiscal Year 1992, because the more recent data are available. In the draft report, the data were presented only through FY 1991. The FY 1992 data provide further support to our findings stated in the draft report.

We have omitted from the final report two policy options that appeared in the draft report--elimination of the sanction referral authority and providing that authority directly to the PROs. We agree with the comments we received from all of the respondents, both within the Department and from outside organizations, that adopting either of these options could have negative consequences.

We discuss the remaining three options here. We wish to stress that these options are not mutually exclusive. Any of the three could be adopted separately, but in combination they could substantially strengthen protection for Medicare beneficiaries under the PRO program.

- **Repeal or substantially modify the unwilling or unable requirement.**

The HCFA and AMA oppose changes in this requirement, while PHS, AMPRA, and AARP support its repeal or modification.

The unwilling and unable provision remains an obstacle to sanction referrals. Despite legislative changes in 1990 that attempted to clarify the definition of unwilling or unable, experience since then leaves little reason to believe that they have eased the problem. In FY 1991, PROs referred 12 cases for sanction, and in FY 1992 they referred 14 cases. In our interviews, the PROs themselves cited the provision as a continuing obstacle.

It is important that PROs have the capacity to use the sanction referral authority when it is appropriate to do so, in order to protect Medicare beneficiaries from harm. In those situations, the PROs should be able to move swiftly and effectively, without having to speculate on the future behavior of individual physicians. The evidence on the physician's past record should be sufficient to make this judgement.

- **Increase the monetary penalties substantially.**

The HCFA, PHS, ASPE, AMPRA, and AARP support this option, while the AMA opposes it.

This option has widespread support within the Department. Clearly, an increase in the monetary penalties is necessary if this is to become an effective sanction. As currently constituted, this provision is virtually meaningless. The amount of money involved is so small, that the threat of monetary penalties has little if any deterrent effect. Only one monetary penalty has been imposed since FY 1988.

- **Maintain PROs' sanction referral authority as it exists now, but mandate referrals to State medical boards when PROs confirm serious quality-of-care problems.**

The HCFA indicates it will consider this option in its development of regulations that govern the sharing of confidential information between PROs and State medical boards. The PHS sees merit in requiring PROs to report serious quality-of-care cases to State medical boards, but cautions that this option could have implications for the boards: it could require additional capacity for investigation and monitoring, and may not provide a uniform standard because States vary in their sanctions, authority, and practices. The ASPE does not support this proposal, citing the pending fourth scope of work, and a potential for parallel investigation by PROs and medical boards.

The AMA supports this option conceptually for "serious quality-of-care problems that have been confirmed by the PRO following specialty-specific physician review and completion of due process rights at the PRO level." The AMPRA and AARP support the option to require this information exchange.

This option would supplement the current provision that PROs provide information to State medical boards after they have made a sanction referral to the OIG. The option presented in this report advocates that PROs share case information with medical boards in serious quality-of-care cases before a formal recommendation for sanction. Still, these cases would not be minor problems--the case reporting would take place after a physician has interacted with PRO physicians and after PRO physicians have determined that this is a serious quality of care problem that requires attention. Once such a problem is confirmed, the PRO would be required to provide the case information to the State medical licensure board. The boards already receive information about physicians on malpractice claims and hospital adverse actions. It clearly makes sense for the boards to receive information from the PROs when they confirm serious quality-of-care problems after medical review.

The fourth scope of work contains substantial changes in the role of the PROs. Included among these changes, PROs will be required to develop written memoranda of agreement with State medical boards. The HCFA could provide guidance to the PROs on the timing

and content of this information exchange. The agency could specify that this information sharing take place at the point when the PROs have confirmed, after medical review, that a physician is responsible for medical mismanagement resulting in significant adverse effects on the patient. Should it determine that legislation is necessary to effect this change, HCFA could propose such legislation.

We recognize, as PHS has pointed out, that implementing this option could require additional resources and skills for many State boards. We have added these points in the text that discusses this option.

APPENDIX A

STATUTORY PROVISIONS

Obligations of Health Care Practitioners and Providers of Health Care Services; Sanctions and Penalties; Hearings and Review

[42 U.S.C. 1320c-5]

Sec. 1156. (a) It shall be the obligation of any health care practitioner and any other person (including a hospital or other health care facility, organization, or agency) who provides health care services for which payment may be made (in whole or in part) under this Act, to assure, to the extent of his authority that services or items ordered or provided by such practitioner or person to beneficiaries and recipients under this Act-

- (1) will be provided economically and only when, and to the extent, medically necessary;
- (2) will be of a quality which meets professionally recognized standards of health care; and
- (3) will be supported by evidence of medical necessity and quality in such form and fashion and at such time as may reasonably be required by a reviewing peer review organization in the exercise of its duties and responsibilities.

(b)(1) If after reasonable notice and opportunity for discussion with the practitioner or person concerned, and, if appropriate, after the practitioner or person has been given a reasonable opportunity to enter into and complete a corrective action plan (which may include remedial education) agreed to by the organization, and has failed successfully to complete such plan, any organization having a contract with the Secretary under this part determines that such practitioner or person has-

- (A) failed in a substantial number of cases substantially to comply with any obligations imposed on him under subsection (a), or
- (B) grossly and flagrantly violated any such obligation in one or more instances,

such organization shall submit a report and recommendations to the Secretary. If the Secretary agrees with such determination, and determines that such practitioner or person, in providing health care services over which such organization has review responsibility and for which payment (in whole or in part) may be made under this Act, has demonstrated an unwillingness or a lack of ability substantially to comply with such obligations, the Secretary (in addition to any other sanction provided under law) may exclude (permanently or for such period as the Secretary may prescribe) such

practitioner or person from eligibility to provide services under this Act on a reimbursable basis. In determining whether a practitioner or person has demonstrated an unwillingness or lack of ability substantially to comply with such obligations, the Secretary shall consider the practitioner's or person's willingness or lack of ability, during the period before the organization submits its report and recommendations, to enter into and successfully complete a corrective action plan. If the Secretary fails to act upon the recommendations submitted to him by such organization within 120 days after such submission, such practitioner or person shall be excluded from eligibility to provide services on a reimbursable basis until such time as the Secretary determines otherwise.

(2) A determination made by the Secretary under this subsection to exclude a practitioner or person shall be effective on the same date and in the same manner as an exclusion from participation under the programs under this Act becomes effective under section 1128(c), and shall remain in effect until the Secretary finds and gives reasonable notice to the public that the basis for such determination has been removed and that there is reasonable assurance that it will not recur.

(3) In lieu of the sanction authorized by paragraph (1), the Secretary may require that (as a condition to the continued eligibility of such practitioner or person to provide such health care services on a reimbursable basis) such practitioner or person pays to the United States, in case such acts or conduct involved the provision or ordering by such practitioner or person of health care services which were medically improper or unnecessary, an amount not in excess of the actual or estimated cost of the medically improper or unnecessary services so provided. Such amount may be deducted from any sums owing by the United States (or any instrumentality thereof) to the practitioner or person from whom such amount is claimed.

(4) Any practitioner or person furnishing services described in paragraph (1) who is dissatisfied with a determination made by the Secretary under this subsection shall be entitled to reasonable notice and opportunity for a hearing thereon by the Secretary to the same extent as provided in section 205(b), and to judicial review of the Secretary's final decision after such hearing as provided in section 205(g).

(5) Before the Secretary may effect an exclusion under paragraph (2) in the case of a provider or practitioner located in a rural health manpower shortage area (HMSA) or in a county with a population of less than 70,000, the provider or practitioner adversely affected by the determination is entitled to a hearing before an administrative law judge (described in section 205(b)) respecting whether the provider or practitioner should be able to continue furnishing services to individuals entitled to benefits under this Act, pending completion of the administrative review procedure under paragraph (4). If the judge does not determine, by a preponderance of the evidence, that the provider or practitioner will pose a serious risk to such individuals if permitted to continue furnishing such services, the Secretary shall not effect the exclusion under paragraph (2) until the provider or practitioner has been provided

reasonable notice and opportunity for an administrative hearing thereon under paragraph (4).

(6) When the Secretary effects an exclusion of a physician under paragraph (2), the Secretary shall notify the State board responsible for the licensing of the physician of the exclusion.

(c) It shall be the duty of each utilization and quality control peer review organization to use such authority or influence it may possess as a professional organization, and to enlist the support of any other professional or governmental organization having influence or authority over health care practitioners and any other person (including a hospital or other health care facility, organization, or agency) providing health care services in the area served by such review organization, in assuring that each practitioner or person (referred to in subsection (a)) providing health care services in such area shall comply with all obligations imposed on him under subsection (a).



APPENDIX B

OVERVIEW OF DATA FROM THE OFFICE OF INVESTIGATIONS

B-1. PRO Sanction Referrals to the OIG, FY 1986 through FY 1992

A. By Type of Violation

Type of Violation:	FY86	FY87	FY88	FY89	FY90	FY91	FY92	Total
Gross & Flagrant	46	60	27	17	24	11	9	194
Substantial	19	12	10	5	5	1	5	57
Lack of Documentation	1	0	0	0	0	0	0	1
Total	66	72	37	22	29	12	14	252

B. By Type of Provider

Type of Provider:	FY86	FY87	FY88	FY89	FY90	FY91	FY92	Total
Physicians (MD or DO)	60	66	34	21	29	12	13	235
Hospitals	6	6	3	1	0	0	1	17
Total	66	72	37	22	29	12	14	252

B-2. OIG Disposition of Referrals from PROs, FY 1986 through FY 1992

A. Sanctions Imposed by the OIG

Type of Sanction	FY86	FY87	FY88	FY89	FY90	FY91	FY92	Total
Exclusions	21	34	18	10	13	10	5	111
Monetary Penalties	9	16	2	0	0	0	1	28
Pre-exclusion Retirements*	0	0	2	1	1	2	0	6
Total	30	50	22	11	14	12	6	145

*Pre-exclusion retirement results from an agreement among the PRO, the physician, and the OIG that the physician retire from practice rather than be excluded. Because the retirement would not have occurred without the sanction referral, the OIG counts these as actions taken.

B. Referrals Rejected or Closed by the OIG without Sanction

Rejection Based On:	FY86	FY87	FY88	FY89	FY90	FY91	FY92	Total
Unwilling or Unable Requirement	0	19	11	4	4	2	2	42
Failed to Follow Regulatory Process	4	10	12	6	2	1	7	42
Lack of Medical Evidence	6	5	0	2	2	5	0	20
Closed Due to Physician's Death	2	0	0	0	0	0	0	2
Total	12	34	23	12	8	8	9	106

**B-3. Outcomes of Sanction Appeals to Administrative Law Judges
FY 1986 through FY 1991**

Total number appealed to the ALJ	61
Appeal withdrawn or settled**	32
OIG decision upheld (concurrence)	19
OIG decision overturned	10

**Cases withdrawn or settled resulted in a sanction.

Explanatory Note:

The data in Table B-1 are based on the date that a sanction referral was received by the OIG. The data in Table B-2 are based on the date on which a sanction was imposed. For example, a sanction referred by the PRO late in FY 1991 might not be acted on by the OIG until FY 1992. Consequently, the numbers of referrals and sanctions imposed in any single year are not equal, since they are referring to different actions.



APPENDIX C

DETAILED COMMENTS ON THE DRAFT REPORT

In this appendix we present the full comments on the draft report and the OIG response to each. The comments presented in this appendix are from:

	Page
The Health Care Financing Administration	C-2
The Public Health Service	C-11
The Assistant Secretary for Planning and Evaluation	C-17
The American Medical Association	C-22
The American Medical Peer Review Association	C-25
The American Association of Retired Persons	C-29

**Memorandum**

Date

William Tobey, Jr. · JAN 27 1993
William Tobey, Jr.

From

Acting Administrator

Subject

Office of Inspector General (OIG) Draft Report: "The Sanction Referral Authority of Peer Review Organizations," OEI-01-92-00250

To

Bryan B. Mitchell
Principal Deputy Inspector General

We have reviewed the subject report which assesses the trends and problems associated with the use of sanction referral authority by Professional Review Organizations (PROs). The PROs' sanction referral authority requires them to recommend that OIG sanction physicians and hospitals responsible for violating their Medicare obligations, as specified in section 1156(a) of the Social Security Act.

OIG found that the number of sanction referrals made by PROs annually have decreased. In fiscal year (FY) 1987, PROs referred 72 cases for possible sanction to OIG. This number dropped to a low of 12 in FY 1991. PROs for seven States have never referred a physician or hospital for sanction. In FYs 1990 and 1991, 24 of the 43 PROs did not refer any physicians or hospitals for sanction. OIG presented the following major factors that might account for the drop in the number of sanction referrals: the statutory "unwilling or unable requirement," PROs' negative experiences with the sanction process, and the PROs' emphasis on educational approaches to quality of care problems.

OIG presented five policy options to be considered:

- o Repeal or substantially modify the unwilling or unable requirement,
- o Increase the monetary penalty sanction substantially,
- o Eliminate the PROs' sanction referral authority,
- o Provide sanction authority directly to the PROs, and
- o Maintain PROs' sanction referral authority as it exists now, but mandate referrals to State medical boards when PROs confirm serious quality of care problems.

HCFA's specific comments on the options and our proposed solution to this problem are attached for your consideration.

Thank you for the opportunity to review and comment on this draft report. Please advise us whether you agree with our position on the options presented in the report at your earliest convenience.

Attachment

Comments of the Health Care Financing Administration (HCFA)
on the Office of Inspector General (OIG) Draft Report:
"The Sanction Referral Authority of Peer
Review Organizations," OEI-01-92-00250

Policy Option 1

Repeal or substantially modify the unwilling or unable requirement.

HCFA Response

HCFA disagrees with this policy option. Under section 1156(b)(1) of the Social Security Act (the Act), the Secretary of the Department of Health and Human Services is required to evaluate whether a provider has demonstrated an unwillingness or inability to correct a quality of care problem identified by a Peer Review Organization (PRO). We recognize that in past years the unwilling or unable requirement placed a burden on PROs because the PROs had to determine if a provider was unwilling or unable to correct a quality of care problem during the informal review process. However, we believe that section 4205 of the Omnibus Budget Reconciliation Act (OBRA) of 1990 has simplified the determination of the unwilling or unable requirement. PROs are now required to provide an opportunity to establish a corrective action plan (CAP) except when a CAP would not be appropriate. The practitioner's or provider's failure to comply with the CAP or correct the violations after implementation of a CAP would be sufficient evidence to support the PRO's determination of unwilling or unable.

Policy Option 2

Increase the monetary penalty sanction substantially.

HCFA Response

HCFA supports an increase in monetary penalty authority. However, in such cases, it is important that the impact on Medicare beneficiaries' health and well being be paramount in considering whether a physician should be allowed to continue practicing versus the imposition and collection of a monetary penalty.

Policy Option 3

Eliminate the PROs' sanction referral authority.

HCFA Response

HCFA does not agree with this option. PROs should retain their authority to recommend sanctions to the Secretary when educational efforts have failed. We believe the PROs' sanction referral authority is necessary for PROs to safeguard the health and well being of Medicare beneficiaries.

Policy Option 4

Provide sanction authority directly to the PROs.

HCFA Response

HCFA does not agree with this option. We believe that the sanction authority requirement would place a significant burden on PROs. A resulting effect could be that PROs would be less decisive in making sanction determinations knowing that they must impose them. We also believe that PROs would find it extremely difficult to achieve and maintain national consistency when imposing sanctions at a State level. We also believe that it would be inappropriate to cede to government contractors the authority to exclude individuals and institutions from a government program. For those reasons, HCFA believes that OIG should retain this authority for uniformity and consistency in imposing sanctions.

Policy Option 5

Maintain PROs' sanction referral authority as it exists now, but mandate referrals to State medical boards when PROs confirm serious quality of care problems.

HCFA Response

HCFA will consider this option. PROs currently have the authority to disclose confirmed quality of care problems to State medical boards. The current regulations at 42 CFR 476.138 allow PROs to provide relevant confidential information to State medical boards on their own initiative and require PROs to provide this information when the State medical board requests it. These regulations, however, do not address mandatory disclosures without a request from the State medical board. We are currently revising the PRO confidentiality regulations and will consider including the requirement of mandatory disclosure to State medical boards without a request. Furthermore, the Fourth Scope of Work (SOW) will require PROs to develop written memoranda of agreement with State medical boards on what type of information (including timeframes) to exchange with boards.

HCFA is also in the process of implementing further requirements for information exchanges between PROs and State/Federal licensing bodies. Section 4205(d) of OBRA 1990 added section 1154(a)(9)(B) to the Act. This provision requires information sharing with the appropriate State medical board after the PRO provides the physician with notice and opportunity for a hearing and has made a final (negative) decision. We are also developing regulations (HSQ-135-F) which will require a PRO to provide State/Federal licensing bodies with portions of any PRO sanction report forwarded to OIG which concerns practitioners that are subject to the State/Federal licensing body's jurisdiction. This will implement section 1160(b)(1)(D) of the Act.

HCFA's Solution

In the fourth round of PRO contracts, we are beginning a Health Care Quality Improvement Initiative. Under this initiative, PROs will analyze patterns of health care and patient outcomes. PROs will share this information with providers to help them identify ways to improve patient outcomes and the quality of care. Under this initiative, HCFA is emphasizing cooperative efforts at continuous quality improvement, rather than confrontation and punishment. We believe that sanctions should be imposed on providers only as a last resort to protect beneficiaries from poor quality care.

However, we believe that the PROs' sanction referral authority is necessary in cases where hospitals or physicians fail to cooperate with PROs to correct identified patterns of quality or utilization problems, or fail to improve their patterns of care despite repeated attempts to work with PROs through voluntary action plans.

The Fourth SOW includes an integrated strategy for actions that should be taken in such cases. PROs will have the choice of:

- o imposing a PRO-directed corrective action plan;
- o directly negotiating an action plan with the physician if a hospital fails to cooperate with a PRO to improve a physician's care;
- o referring the case to the HCFA regional office for an investigation of a hospital's possible noncompliance with its Medicare provider agreement;
- o referring a case of physician utilization problems to the carrier for prepayment review;
- o referring the case to the appropriate State medical board; or

- o beginning the sanction process.

Of the listed alternatives, PROs will be required to take the least disruptive intervention necessary to correct the patterns of concern.

General Comments

Entire Report

OIG should review the Fourth SOW before issuing the final of this report.

Pages i and 3 - 1st and 3rd bullets

Are 12 referrals what OIG agreed to exclude? Did PROs submit more than 12 cases?

Pages i and 4 - 2nd bullet

OIG should clarify the reference to "43 PROs." During fiscal years (FYs) 1990 and 1991, HCFA had 53 PRO contracts in place. It should be noted that some organizations have more than one PRO contract.

Pages i and 3 - Methodology

The explanation of the methodology should have included the number of sanction actions begun and closed at the PRO level. Also, the reasons why sanction actions were closed at the PRO level should also be included.

A PRO is not necessarily failing to utilize the sanction process simply because it is not recommending sanctions. A factor in the decreased number of referrals could be that PROs have been successful in "educating" practitioners/providers involved. The ability of a PRO to refer a practitioner/provider for sanction is an added incentive to the practitioner/provider to become "educated" during the informal review process by the PRO. Therefore, even if the PRO does not refer the practitioner/provider for sanction, the ability of the PRO to refer them for sanction may enable the PRO to correct many problems without actually utilizing their sanction referral authority.

Pages B - 1 - Appendix B - Clarify FY 1991

Were there 20 referrals by PROs (8 rejected and 12 excluded)?

Page 5

Page 6 - 1st full paragraph

The last sentence is inaccurate. PROs are paid for all costs they incur beginning with the issuance of a sanction notice. The final outcome of the case, the referral to OIG, does not affect their ability to recover their expenditures.

OIG RESPONSE TO HCFA COMMENTS

We disagree with HCFA that the 1990 amendments have simplified the determination of the unwilling or unable requirement. We believe that the evidence is clear--12 sanction referral cases in FY 1991 and 14 cases in FY 1992. In those situations when it is appropriate to use the sanction referral authority, the PROs need to be able to move swiftly to protect beneficiaries from harm. The past record of the physician, rather than speculation about future behavior, should be sufficient to make that judgement.

We welcome HCFA's support for increased monetary penalties, which we called for in 1988. We strongly agree that beneficiaries' health and well-being should be paramount in any sanction consideration.

We are encouraged that HCFA is willing to consider the option to mandate referrals to State medical boards when PROs confirm serious quality-of-care problems. The fourth scope of work contains substantial changes for the PROs, including a requirement that they develop written memoranda of agreement with State medical boards. We urge HCFA to take advantage of this opportunity to specify that this information sharing take place at the point when the PROs have confirmed, after medical review, that a physician is responsible for medical mismanagement resulting in significant adverse effects on the patient. Should it determine that legislation is necessary to effect this change, HCFA could propose such legislation.

Based on the concerns that HCFA and other parties raise, we have omitted from the final report the two policy options that would have eliminated the PROs' sanction referral authority and that would have provided that authority directly to the PROs.

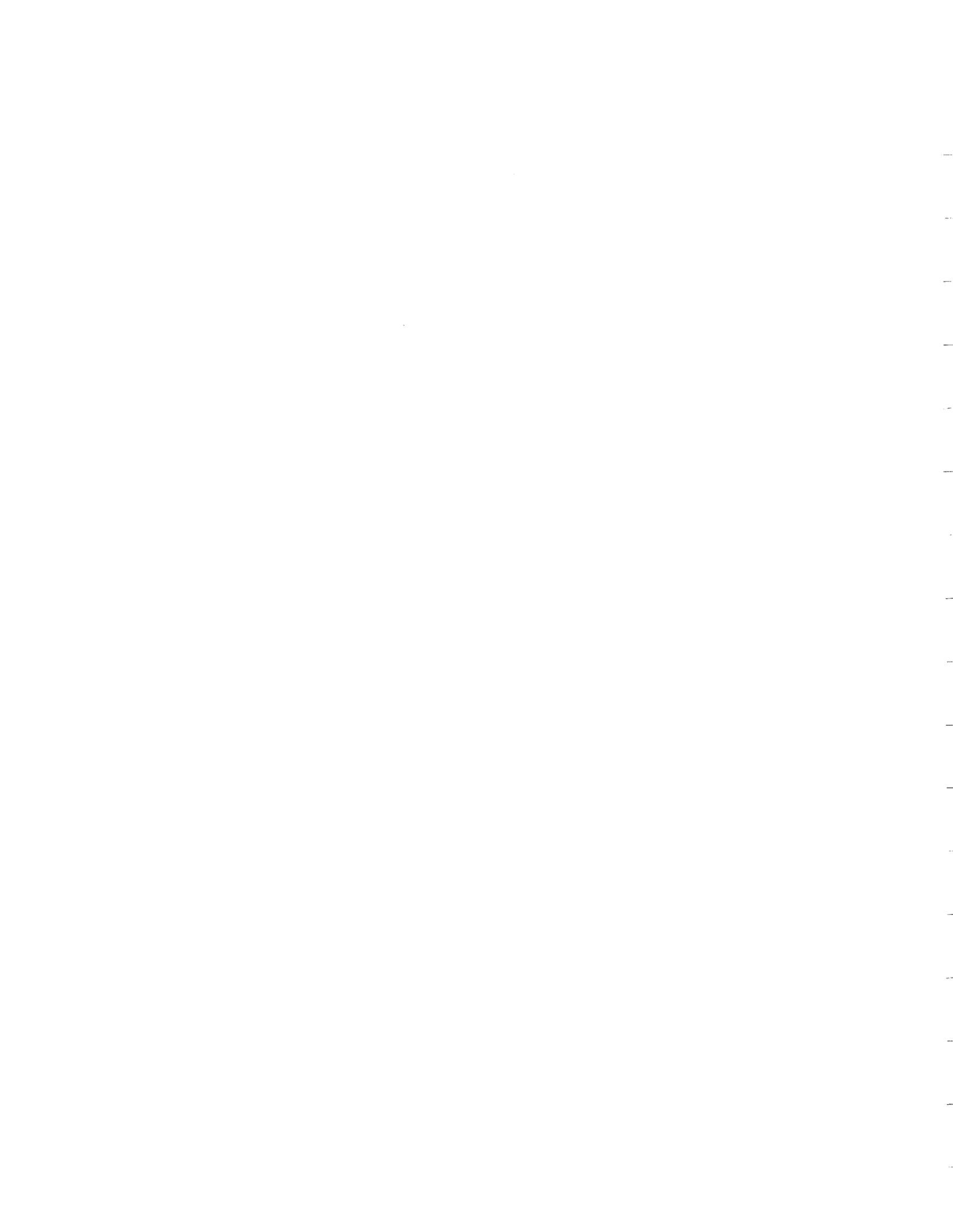
We will be watching HCFA's implementation of the fourth scope of work with great interest. It is clear from our review of the request for proposals for the fourth scope, that it contains substantial changes in the role of the PROs, with its focus on pattern analysis and information sharing as a way of improving overall patient outcomes and the quality of care. We applaud broad-based efforts to improve the quality of care for Medicare beneficiaries and for the population at large. Notwithstanding this new approach, the PROs continue to have a critical responsibility to protect the health and well-being of Medicare beneficiaries. This responsibility may call for taking action against individual physicians who practice in a manner that is harmful to the beneficiary.

We agree with HCFA that the threat of a sanction may enable the PRO to correct many problems. In this report, we are dealing with cases that were actually referred for sanction. As we indicate in the finding that appears on pages ii and 7, "Despite dwindling referrals, all the PRO officials we interviewed believe that the sanction referral authority is important to achieving their mission because it gives them greater leverage with the medical community."

The HCFA requests clarification on the number of referrals and exclusions. The PROs referred a total of 12 cases to the OIG for sanction in FY 1991. The OIG also sanctioned a total of 12 physicians in that fiscal year. It is only coincidental that the numbers are the same. The 8 rejections include cases that were submitted prior to that year.

The HCFA also questions our reference to 43 PROs, rather than 53 PRO contracts. While there are 53 PRO contracts in place, some PROs hold more than one contract. In fact, 3 of the 10 PROs with which we conducted our telephone interviews hold 2 contracts each, and one holds 3 contracts. We chose to count the organizations, rather than the contracts.

We also have modified the text on page 6 to reflect HCFA's suggested change.



DEPARTMENT OF HEALTH AND HUMAN SERVICES

NOV 27 1992

Assistant Secretary for Health

Office of Inspector General (OIG) Draft Report "The Sanction Referral Authority of Peer Review Organizations"

Acting Inspector General, OS

Attached are the Public Health Service (PHS) comments on the subject OIG report. Although the report contains no recommendations to PHS, we offer comments for your consideration regarding the policy options contained in the report.

/s/ James O. Mason

James O. Mason, M.D., Dr.P.H.

Attachment

CC:

ASH

ES/PHS

DASHMO

OM, Rm. 17-19, Parklawn

ORM, Rm. 17A-13, Parklawn

DFM, Rm. 17A-13, Parklawn

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PUBLIC HEALTH SERVICE (PHS) COMMENTS ON THE OFFICE OF
INSPECTOR GENERAL (OIG) DRAFT REPORT "THE SANCTION REFERRAL
AUTHORITY OF PEER REVIEW ORGANIZATIONS," OIG-01-92-00250

General Comments

This report provides a thorough and balanced overview of an important set of complex issues and options for addressing persistent problems with the Medicare Peer Review Organization (PRO) program's sanction referral authority. There are, from our perspective, two particularly difficult aspects of these problems.

First, the specific statutory and regulatory provisions of a very large Federal program such as Medicare creates special oversight requirements that extend beyond the general responsibilities of other medical peer review or professional regulations. It is unlikely that any other professional organization or State authority will enforce Medicare rules and regulations unless violation of those rules and regulations are clearly violations of professional standards of conduct or medical practice. For example, licensing boards may not have authority to take any action against physicians who consistently perform what Medicare or other insurers deem "unnecessary" tests.

Only the Medicare program can consistently ensure program integrity across all jurisdictions. Therefore, we believe that the Medicare program needs to maintain the authority to sanction providers, and that Medicare PROs, as well as carriers and intermediaries, should be able, at minimum, to formally refer providers to the OIG for possible sanction.

Second, dealing with cases of substandard care, or patterns of substandard care, is extremely difficult under any circumstances. While PHS is not opposed to requiring referral of "serious" quality of care cases to State medical boards, this alone will not solve the problem. The development of valid instruments for assessing the quality and appropriateness of medical decisions is underway, in the PHS and elsewhere, but as of now both the PROs and State medical review boards need better tools for evaluating poor performance by physicians so that decisions can consistently withstand appeals.

Because the sharp drop in sanction referrals occurred during a period of increased emphasis on PRO educational activities, it is difficult to discern what effect this educational activity may have had on the drop. It is not clear whether declines in sanction referrals have occurred because educational activities have been given a priority or whether PROs are simply overlooking sanction referrals. OIG might consider a

study of the quality of PROs' decision-making to provide education rather than sanction referral.

The Institute of Medicine completed a congressionally mandated study in 1990 entitled "Medicare: A Strategy for Quality Assurance." The study devoted considerable attention to the role of PROs and should probably be cited in the OIG report.

OIG Policy Options

The OIG offers five options for consideration by the Department of Health and Human Services (DHHS), the Congress, interest groups, and other concerned parties as follows.

- o Repeal or substantially modify the unwilling or unable requirement.
- o Increase the monetary penalty sanction substantially.
- o Eliminate the PROs' sanction referral authority.
- o Provide sanction authority directly to the PROs.
- o Maintain PROs' sanction referral authority as it exists now, but mandate referrals to State medical boards when PROs confirm serious quality-of-care problems.

The following sets forth the PHS comments on the policy options offered by OIG.

OIG Policy Option

- 1) Repeal or substantially modify the unwilling or unable requirement.

PHS Comments

The PHS supports this recommendation.

OIG Policy Option

- 2) Increase the monetary penalty sanction substantially.

PHS Comments

The PHS supports this recommendation.

OIG Policy Option

- 3) Eliminate the PROs' sanction referral authority.

PHS Comments

Although medical groups and the hospital industry would favor this option, this authority remains an important deterrent to poor quality and fraudulent care. It is this authority which makes the quality and educational corrective action plans work.

This option has broad implications for State medical boards. We suggest that the "cons" paragraph of the OIG report also indicate that this option might create pressures for State medical boards to increase their investigation and monitoring activities when State medical boards may not have the capacity for such an expansion. In addition, this option would lead to greater variation in approaches to investigating and applying sanctions.

OIG Policy Option

- 4) Provide sanction authority directly to the PROs.

PHS Comments

This option would exacerbate the variability that already exists within the PROs by having each PRO set its own standard. Under this option, the DHHS would have to have oversight to ensure some degree of uniformity.

OIG Policy Option

- 5) Maintain PROs' sanction referral authority as it exists now, but mandate referrals to State medical boards when PROs confirm serious quality-of-care problems.

PHS Comments

This option would provide the uniformity of a national standard and activate the State medical boards' safety mechanisms. In addition, this option could be modified to mandate the PROs to report individuals and institutions to the Federation of State Medical Boards to permit national surveillance and profiling, and national comparisons.

Although the report includes this policy option to make referrals to State medical boards, it does not indicate that the Federation of State Medical Boards was contacted to provide input.

Under the option of mandated referrals to State medical boards, it would be helpful to have a brief discussion of the

congruence of the PRO mission to review inappropriate and unnecessary care with the scope of authority of licensing bodies. The latter tend to focus on such issues as unethical behavior and physical/mental incompetence as, for example, in addiction problems, rather than on substandard care.

This option has broad implications for State medical boards. We suggest that the "cons" paragraph of the OIG report under this Policy Option also state that: (a) this option would require additional medical board capacity for investigation and monitoring, (b) medical board authority varies from State to State which would result in a variety of approaches to investigating and a variety of sanctions to be applied to physicians with similar problems, and (c) evaluating each single instance of poor quality of care would require an approach that is not currently part of most State medical boards' authority or practice.

Finally, we note that even if the PRO sanction referral authority is strengthened by elimination of the unwilling and unable requirement, and/or by increasing monetary penalties, there would continue to be merit in also requiring PROs to report serious quality of care problems to State medical boards.

OIG RESPONSE TO PHS COMMENTS

We appreciate PHS's positive response to this report. The PHS is playing an important leadership role, particularly in its efforts to develop valid instruments for assessing the quality and appropriateness of medical decisions, and by assisting in the development of tools that could assist State medical boards and PROs in evaluating poor performance by physicians.

The PHS finds merit in requiring PROs to report serious quality-of-care problems to State medical boards, but raises some important concerns about the boards' capacity and focus with respect to review of cases that involve quality-of-care problems. Despite limited resources, some States are beginning to address these problems. We have recently released a report that examines some of these initiatives, *State Medical Boards and Quality-of-Care Cases: Promising Approaches* (OEI-01-92-00050, February 1993).

The PHS also questions whether the decline in the number of sanction referrals occurred because of increased emphasis on educational activities. In this inspection, we did not examine the relationship between educational activities and the number of sanction referrals. In a previous report, however, we found that the educational value of PRO interventions was uncertain and that the interventions seldom reflect research findings concerning how physicians learn (*Educating Physicians Responsible for Poor Medical Care: A Review of the Peer Review Organizations' Efforts*, OEI-01-89-00020, February 1992).

Due to the concerns that PHS and other parties raise, we have omitted from the final report the two policy options that would have eliminated the PROs' sanction referral authority and that would have provided that authority directly to the PROs.

We also have added to the text points raised by PHS on the implications of referrals to State medical boards.



Washington, D.C. 20201

TO: Bryan Mitchell
Principal Deputy Inspector General

FROM: Assistant Secretary for
Planning and Evaluation

SUBJECT: OIG Draft Management Advisory Reports: "The Sanction Referral Authority of Peer Review Organizations" (OEI-01-92-00250) and "The Peer Review Organizations and State Medical Boards: A Vital Link" (OEI-01-92-00530)
-- COMMENTS

I offer the following comments on the two subject draft reports, which I have linked due to the interrelatedness of their recommendations.

In the first report, you reviewed the sanction referral authority of peer review organizations (PROs), of which referral to state medical boards is one element. You recommended several policy options for improvement, including a recommendation requiring that state medical boards be informed whenever a serious quality of care problem is confirmed through medical review; this is a lesser standard than is currently in place. In the second report, you specifically examined the low frequency with which PROs referred cases involving physicians cited for poor quality of care to state medical boards. You reiterated the recommendation concerning PRO-medical board contact contained in the first report.

I agree with the observations made in these reports that the formal sanction referral process is not often used. Nevertheless, I feel that the process is critical and, with improvements, some of which you propose in your reports, I believe it will play an important role in the primarily educational efforts of the PROs under the Fourth Scope of Work (SOW). I have the following comments about the findings, policy options and recommendations of your reports.

- o Repeal or substantially modify the unwilling or unable requirement. (Policy option 1, Report on the Sanction Referral Authority) I agree that the additional evidentiary hurdle for sanction of demonstrating that a physician is either unwilling or unable to comply with a corrective action plan is, at present, vague. The report is written from the perspective of complete repeal, however, and does not identify how the requirement could be meaningfully modified. I suggest that you clarify better why the recent legislative change -- defining a physician's failure to participate in a corrective action plan (CAP) as

demonstrated unwillingness or inability to comply -- is inadequate. Also, I urge you to clarify how due process protections would be preserved in the event that the requirement was modified or repealed.

- Increase the monetary penalty sanction substantially. (Policy option 2, Report on the Sanction Referral Authority) I agree that this is an important policy option, and believe that it would be a desirable alternative for the PROs, where patient safety would not be compromised.
- Eliminate the PROs' sanction referral authority. (Policy option 3, Report on the Sanction Referral Authority) This is a theoretical option only; without the ability to impose sanctions in the face of aberrant or poor quality behavior, PROs would have little clout in certain circumstances to influence physician behavior. I would oppose this proposal.
- Provide sanction authority directly to the PROs. (Policy option 4, Report on the Sanction Referral Authority) There are actually two alternatives to OIG administration of the sanctions process. The first is to decentralize and give the PROs the direct authority to impose sanctions. The second is to move the authority from OIG to HCFA. Decentralization would be undesirable for the reasons cited on page 10 of the Sanction Referral Authority report, with the additional concern that physician exclusion is too serious an outcome to cede without central review to the PROs, who are merely the contractual agents of the Federal Government.

The second alternative, having HCFA pursue the sanction actions, also may not be desirable, but the report does not provide sufficient information to evaluate whether the OIG has been too conservative in its choice of which cases to pursue, and whether this restraint -- rejecting, for example, 8 of 12 cases referred to it in FY 1991 -- is itself contributing to the dwindling number of cases proposed for sanctions by the PROs. It appears from the statistics in Appendix B that the PROs may be doing a better job at following the proper procedures for developing a solid case. No justification or explanation is provided, however, for the increasing rate of cases rejected by the OIG for lack of medical evidence from FY 1988 to 1991. Why is the OIG rejecting the medical advice of the PRO physicians? The report would be substantially strengthened by an objective evaluation of the cases the OIG rejected, and by the discussion of the second alternative.
- Maintain PROs' sanction referral authority as it exists now, but mandate referrals to State medical boards when PROs

confirm serious quality-of-care problems. (Policy option 5, Report on the Sanction Referral Authority and recommendation of report "The Peer Review Organizations and State Medical Boards: A Vital Link") I do not support this proposal for several reasons. I would agree that the PROs and the State medical boards (and hospital licensure authorities, etc.) should be in closer contact. The most recent versions of the PRO Fourth Scope of Work include requirements that each PRO develop memoranda of agreement (MOAs) with such entities, within 60 days after the effective date of its contract, for the purpose of mutual exchange of information and data. Such mutual exchange is far more likely to contribute to improvement of quality of care than a legislated requirement for unilateral action.

I understand that the provision of the 1990 Omnibus Budget Reconciliation Act requiring PROs to share case information with state medical boards has not been implemented because it is unclear. I understand that a technical correction to require the PROs to inform boards when a sanction recommendation is sent to the OIG has been sought but that it may not have been included among the OBRA technicals in the tax bill that will be sent to the President soon. If no action has been taken on the technical change, it should be advanced again in the next session.

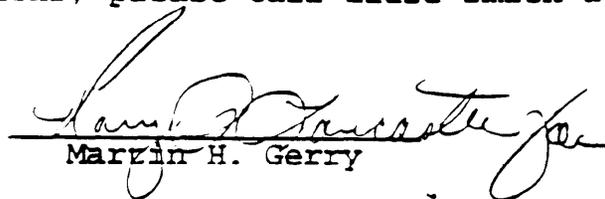
It is not clear how the OIG's proposal would differ from the technical correction being sought by HCFA. It would seem to require involvement of the state medical societies at an earlier stage, prior to issuance of the sanction recommendation to the OIG and prior to the physician having the full opportunity to review and respond to the concerns raised by a PRO. Except for clear instances where patients are in immediate danger, it does not seem fair or appropriate to essentially initiate a parallel investigation by the medical society until there has been confirmation of a problem. This is particularly a problem in those states that require all complaints made to the state medical society to be made public, including reports from the PROs. I do not object to such publicity where the physician has had ample opportunity to respond to the PRO and has been unwilling or unable to cooperate in the development and execution of a meaningful corrective action plan. However, such publicity is probably more useful as a potential sanction than as a context for obtaining physician cooperation for changed behavior.

Furthermore, it is curious that the OIG is calling for mandatory notification of the medical board prior to the issuance of the sanction recommendation to OIG. As noted above, the OIG refused to pursue 5 of 12 cases referred to it in FY 1991 because of inadequate medical

evidence from the PROs. The reports do not explain why it would be productive or appropriate to engage the state medical societies based on information that the OIG itself feels is inadequate to justify a sanction.

Finally, the first three tables of Appendix B of the report on the Sanction Referral Authority (sanctions referred to the OIG, referrals rejected by OIG, sanctions imposed by the OIG) do not agree and should be clarified. For FYs 1987, 1988, 1989 and 1991, the sum of the sanctions imposed and referrals rejected exceeds the sanctions referred (cases are resolved in a later year than they are referred?). Similarly, the totals for all years involved do not agree.

If you have any questions, please call Elise Smith at 690-6870.


Marrin H. Gerry

OIG RESPONSE TO ASPE COMMENTS

We appreciate the comments from ASPE. We agree that the additional evidentiary requirement imposed by the unwilling or unable provision is vague. We believe that the evidence is clear--12 sanction referral cases in FY 1991 and 14 cases in FY 1992. In those situations when it is appropriate to use the sanction referral authority, the PROs need to be able to move swiftly to protect beneficiaries from harm. The past record of the physician, rather than speculation about future behavior, should be sufficient to make that judgement.

We welcome ASPE's support for increased monetary penalties, which we called for in 1988.

Based on ASPE's concerns and those of other parties, we have omitted from the final report the two policy options that would have eliminated the PROs' sanction referral authority and that would have provided that authority directly to the PROs.

We believe that it is important to have in place memoranda of agreement between PROs and State medical boards regarding the exchange of information. Unless they require the exchange of meaningful and useful information, such memoranda, in and of themselves, may do little to address physicians with quality-of-care problems. It is clear that little information is exchanged at present. The option described in this report would require PROs to share information with the State medical boards only after they have confirmed serious quality-of-care problems through medical review involving the physician and the PRO physicians.

We are concerned that ASPE's comments may reflect some misunderstanding. We wish to clarify that this report refers strictly to the role of State medical boards, not to State medical societies.

We have also added text in appendix B in response to ASPE's request for clarification on the data.



American Medical Association

Physicians dedicated to the health of America



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October 22, 1992

Bryan B. Mitchell
Principal Deputy Inspector General
Department of Health and Human Services
Office of Inspector General
330 Independence Avenue, S.W.
Cohen Building, Room 5554
Washington, DC 20201

Dear Mr. Mitchell:

Thank you for providing the American Medical Association (AMA) with the opportunity to review and comment on the Office of Inspector General's (OIG) draft inspection report entitled "The Sanction Referral Authority of Peer Review Organizations." The AMA has reviewed the policy options set forth in the OIG's draft report and offers the following comments, taking into account the OIG's recent draft management advisory report entitled "The Peer Review Organizations and State Medical Boards: A Vital Link."

The AMA supports keeping the "unwilling or unable" clause in the PRO statute. By including the specific requirement that the Secretary of the Department of Health and Human Services demonstrate a physician's inability or unwillingness to comply with program obligations before being sanctioned, Congress expressed its belief that it would be inappropriate to exclude a physician or other provider from participation in the Medicare program unless the physician or provider was clearly unwilling or unable to comply with the program obligations.

The AMA opposes any legislative or regulatory change that would allow PROs to impose punitive monetary fines in excess of the actual or estimated costs of the medically unnecessary or inappropriate services provided. Accordingly, the AMA strongly opposes any effort to increase the monetary penalty beyond its current statutory limits.

With respect to the other policy options proposed by the OIG, the AMA favors the position that PROs should maintain the sanction referral authority as it currently exists. In addition, as indicated in my letter dated October 14 to you, the AMA conceptually supports the OIG's position that PROs should refer to state medical boards any serious quality-of-care problems that have been confirmed by the PRO following specialty-specific physician review and completion of due process rights at the PRO level. This policy option, which is consistent with Sections C.9.7 and C.9.8 in the PRO Fourth Scope of Work, would allow state medical boards to take action in response to the provision of care of allegedly questionable quality that may not meet the threshold required for a sanction referral under the PRO program.

As you know, the AMA is working to develop constructive and innovative approaches to enhance professional self-regulation. The AMA is working to establish closer relationships between state boards and state medical associations. For example, the AMA is actively pursuing with the Federation of State Medical Boards an arrangement whereby volunteer physicians from state

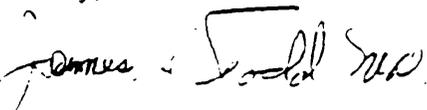
medical associations could perform part of the investigative and review functions on behalf of, and under the supervision of, the state boards. Such an arrangement should permit the boards to process a greater number of complaints.

At present, state medical associations that conduct peer review can take only limited action against physicians. The ultimate sanction that state medical associations can apply is revocation of membership in the association, which, of course, has limited effect on physicians who are not members of the association. Every practicing physician has a license, however, and medical associations can broaden the scope and increase the relevance of their peer review activities by assisting in the investigations of state boards. In turn, the actions of the state boards can be improved if PROs refer serious quality-of-care problems, confirmed by specialty-specific reviewers at the PRO level, to the state board for review.

In closing, the AMA favors the OIG's policy option of having PROs maintain their current sanction referral authority and, consistent with the PRO Fourth Scope of Work, refer to state medical boards any serious quality-of-care problems confirmed by the PRO following specialty-specific physician review and completion of due process rights at the PRO level.

Thank you again for providing the AMA with the opportunity to review and comment on your draft inspection report. We look forward to a continuing dialogue.

Sincerely,



James S. Todd, MD

OIG RESPONSE TO COMMENTS FROM THE AMA

We appreciate the AMA's comments. We acknowledge their opposition to changes in the unwilling or unable clause and to increased monetary penalties for medically unnecessary or inappropriate services.

Based on the concerns raised by the AMA and other parties, we have omitted from the final report the two policy options that would have eliminated the PROs' sanction referral authority and that would have provided that authority directly to the PROs.

We believe a full range of quality assurance approaches are required. One approach that would complement the efforts of the AMA and State medical societies is earlier information sharing between PROs and State medical boards. This exchange could take place when the PRO physicians have confirmed, after medical review, that a physician has been responsible for medical mismanagement resulting in significant adverse effects on the patient.





November 10, 1992

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Bryan B. Mitchell
Principal Deputy Inspector General
Department of Health & Human Services
Office of the Inspector General
Washington, DC 20201

Dear Mr. Mitchell:

Thank you for sending me a draft copy of the report, "The Sanction Referral Authority of Peer Review Organizations". AMPRA appreciates the opportunity to comment. Our remarks focus on the report's five policy options.

For several years now, the unwilling or unable standard - at the ALJ level - has been a difficult test to meet. Absent direction, ALJs varied widely in their interpretations, finding some physicians able because they possessed a medical degree and other willing even though they refused interaction at the PRO level.

Congress shared PRO concerns in OBRA 1990 and resolved to define the unwilling or unable standard to guide ALJ rulings. AMPRA recommended to Congress in 1990 and would still advocate deletion of the "unwillingness or lack of ability" language from the PRO statute. Short of deletion, AMPRA was supportive of a compromise position that tied the standard to a provider/practitioner's willingness and ability to implement and successfully complete a PRO directed corrective action plan within designated timeframes.

In essence, the language passed in OBRA 1990 simply clarified the law relating to PRO sanctions by providing that in determining whether a practitioner or person is "unwilling or unable", the Secretary shall consider the practitioner's or person's willingness or lack of ability, during the period before the PRO submits its report and recommendations, to enter into and successfully complete a corrective action plan. It is important to note that development of a course of corrective action is not mandatory in every instance. Indeed, the statutory change contained in OBRA 90 is prefaced by the clause, "if appropriate". AMPRA was supportive of this provision and worked with the Office of Inspector General and the Department of Health to assist in immediate communication to ALJs, practitioners/providers and peer review organizations.

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Regarding your second policy option, AMPRA recommended in 1990 and still maintains that the PRO statute should be amended to increase civil monetary penalties from the cost of the service in question to up to \$10,000. Present statute enables PROs to fine or exclude providers/practitioners for failure to comply with their Medicare obligations. The law stipulates that such civil monetary penalties should not be "an amount in excess of the actual or estimated cost of the medically improper or unnecessary services so provided." Often, the cost of actual service in question is minuscule and not an effective remedy to affect future physician behavior. Indeed, thousands of administrative dollars are spent by PROs in identifying and verifying a service that was improper or unnecessary.

AMPRA believes that PROs should have the flexibility to recommend higher penalties than the cost of the service in question and likewise, the Inspector General should be empowered with the authority to impose a fine of up to \$10,000. This position is also endorsed by the Administrative Conference of the United States. A higher threshold is needed to garner the attention of facilities/practitioners and to provide a meaningful alternative to exclusion from the Medicare program.

AMPRA opposes elimination of the PROs sanction referral authority. The PROs need sanction authority to: protect beneficiaries and as leverage to motivate providers to take action.

AMPRA also opposes providing sanction authority directly to the PROs. The government as the sponsor of Medicare should not abdicate their responsibility to make final decisions on sanction cases. Giving sanction authority directly to PROs would also conflict with the more educational role of PROs.

AMPRA supports that the existing provisions relating to the exchange of information between peer review organizations (PROs) and State medical licensing boards be amended to require information exchange earlier in the review process and to remove administratively burdensome procedural barriers to such information exchange. Absent these changes, AMPRA recommends repeal of the entire provision.

Once again, OBRA 90 included provisions relating to the exchange of certain types of information between peer review organizations (PROs) and medical licensing boards. Changes in these provisions are needed, including several technical corrections. H.R. 1555, a technical corrections bill passed by the House of Representatives at the end of 1991, includes a provision correcting

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several drafting errors in OBRA 1990. However, the bill did not alter the requirement that PROs notify State licensing boards only once they have submitted a formal sanctions recommendation to the Secretary and only after "notice and a hearing."

AMPRA continues to believe that PROs should notify State licensing boards about problematic care earlier in the process--i.e., after a first notice of proposed sanction is sent, the practitioner or person involved is offered an opportunity to discuss the matter with the PRO, and the PRO confirms that a problem exists. In addition, we believe that the provision requiring a PRO to hold a hearing before notifying the State licensing board is unnecessarily burdensome and not needed to afford adequate due process to affected practitioners and providers. AMPRA supports a peer discussion - not a legal proceeding.

AMPRA will continue to urge the Congress to modify the PRO statute in a manner consistent with these views. However, if such changes are not feasible, then AMPRA recommends repeal of the entire provision.

Thank you for the opportunity to comment on the draft report. We recognize, of course, that the multiple steps in the PRO adjudication process, designed to assure due process to all involved, are time-consuming and may require considerable effort on the part of physicians, patients and others. We welcome suggestions for making the process more efficient and less burdensome. If you have any questions please contact me.

Sincerely,



Andrew Webber
Executive Vice President

OIG RESPONSE TO AMPRA COMMENTS

We appreciate AMPRA's positive response to this report. We wish to acknowledge the organization's efforts over the years. The AMPRA has worked with the Department, the Congress, and the provider community to develop and improve methods for addressing quality-of-care problems.

In response to the concerns raised by AMPRA and other parties, we have omitted from the final report the two policy options that would have eliminated the PROs' sanction referral authority and that would have provided that authority directly to the PROs.



Bringing lifetimes of experience and leadership to serve all generations.

October 23, 1992

Bryan B. Mitchell
Principal Deputy Inspector General
Office of Inspector General
Department of Health and Human Services
330 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Comments on draft Peer Review
Organization reports

Dear Mr. Mitchell:

Horace Deets has asked me to respond to your letters of September 3 and 15, 1992. The Office of Inspector General -- in its two draft reports "The Sanction Referral Authority of Peer Review Organizations" and "The Peer Review Organizations and State Medical Boards: A Vital Link" -- has performed an important service for Medicare beneficiaries in assessing the current status of PROs' sanction activity and the degree of data exchange between PROs and medical licensure boards (MLBs).

Because the two reports have arrived in tandem and deal with complementary issues, we are responding in one letter.

In view of AARP's longstanding positions on PRO sanctions and PRO-MLB relations, we are distressed, although not surprised, by the OIG's findings. Through investigation, statistical analysis, and review of a Citizens Advocacy Center PRO-MLB survey, the findings confirm that 1) the PRO sanction authority has atrophied, and 2) the PRO-MLB data exchange, with one or two notable exceptions, has failed to develop -- this despite legislative efforts in 1990 to address problems concerning both those areas.

As the reports indicate, the PRO program -- moving into the fourth contractual scope of work -- is in the process of undergoing a shift in focus and methodology towards an educational, "continuous quality improvement" (CQI) model of interaction with doctors and hospitals. AARP has engaged in an extensive dialogue with HCFA with respect to this evolution. While supportive of the increased use of profiling and feedback mechanisms to improve the quality of care, we remain convinced that PROs must have an ongoing ability to identify and act upon serious threats to patient care arising from incompetent performance. PROs' ability to resort to sanction proceedings, as well as their ability to interact with licensure boards in appropriate cases, remain essential elements of PROs' mission to help protect patients.

PRO-MLB Interaction

As you point out in the draft report on PRO-MLB relations, the 1980s' effort to increase data exchange culminated in a 1990 legislative amendment. The origin of the amendment was an AARP-supported OIG recommendation that PROs send their boards all confirmed "first sanction" notices.¹ What emerged from Congress, however, was a confusing provision that is difficult to enforce and has left the largely lack-of-data-exchange situation essentially unchanged.

As we stated in our comment letter on your 1990 PRO-MLB report, the interests of patients require earlier rather than later PRO notification to the appropriate medical board of quality of care concerns. At that time we endorsed your "first sanction" notice recommendation and urged that it be expanded beyond sanctions-related information to include material, produced by PROs' quality review process, that indicates a serious quality problem.

Accordingly, we welcome your current recommendation that PROs be mandated to "provide case information to state medical boards when they have confirmed, after medical review, that a physician is responsible for medical mismanagement resulting in significant adverse effects on the patient." We would suggest that the proposal clearly indicate that it is in addition to the information exchange contemplated by the 1990 recommendation, and not a substitute. The goal is to ensure that PROs inform licensure boards not only about the most serious problem cases -- those potentially "sanctionable" under the statutory definitions of the PRO law -- but also about those other problem performance cases that, while very serious, are addressed solely through corrective action initiated according to PROs' contractual scope of work.

Although your draft recommendation is for additional legislative action, we suggest that the data sharing recommendation be stated in the alternative, i.e., HCFA should either pursue an amendment or use its rulemaking authority to achieve the desired result, whichever path appears to be the most expeditious.

As reported in the draft, there have been some impressive instances of voluntary exchange along the lines of the proposal, in Ohio, particularly, where the PRO has used

¹ Under Section 1156 of the PRO law, sanctions may be pursued based upon a physician's or provider's failure in "a substantial number of cases substantially to comply with" quality of care obligations, or a physician or provider "grossly and flagrantly" violating such obligation "in one or more instances."

its current discretionary authority under existing regulations to share material concerning all "level three" quality problem cases (the most serious cases).²

The OIG's recommendation for a new data exchange mandate does involve addressing some impediments. Not the least of these is the major transformation of the third scope of work's "Quality Intervention Plan (QIP)," which, by elimination of the current three levels of quality problems, necessitates development of a new "formula" for PRO-MLB information exchange. As of the release of the October 1 fourth scope of work document, the precise elements of the new "Quality Review Process," including the contents of a new "Physician Review Assessment Form" (PRAF) and the "weighing" system for identifying problems and instituting corrective action plans (CAPs), remained under development. In the ongoing process of fleshing out the fourth scope of work, AARP intends to seek a quality review system that could facilitate the kind of PRO-MLB exchange contemplated by the OIG's report and recommendation.

The PRO Sanction Referral Authority

The "moribund" nature of the PRO sanction referral authority is strikingly documented in your latest statistical findings.

Two of the three explanations -- the PROs' cumulative unhappy experience with the sanctions process and the increasing emphasis on educational approaches to quality of care problems -- appear well on target. As for the third, the statutory "unwilling or unable" requirement, we believe the 1990 legislative "fix"³, if properly construed and aggressively implemented, would, in fact, be a significant improvement. This is not to say that outright deletion of the requirement would not have been a better legislative

² Under the PRO data disclosure regulations, 42 C.F.R. 476.138 (a)(1)(ii) a PRO may provide "confidential" information to a state licensure body without a request.

³ The language of OBRA-90, which represented a compromise, was intended to remove the most objectionable features of the "unwilling or unable" requirement. The 1990 amendment defined the "unwilling or unable" standard in terms of a physician's failure to enter into and satisfactorily complete a corrective action plan (CAP). The PRO, however, was left with discretion in each case as to whether to offer a CAP. The result, as we read the revised section, is that a PRO's judgement that a sanctionable offense was such as to necessitate an immediate sanction recommendation would enable the Secretary to consider the "unwilling or unable" requirement constructively met and thereby move to implement the recommendation without fear of subsequent attack at the administrative hearing level.

In the early drafts of the fourth scope of work, HCFA, in our view, failed to accurately reflect this compromise approach by appearing to ignore PROs' case-by-case authority to decline to offer a CAP. The July and now October redrafts have been revised to embody the 1990 statutory sanctions language.

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outcome; the Administrative Conference of the United States urged this course in 1989, and AARP supported it.

The overall issue of PROs' use of their sanction authority, however, remains a critical one. Your draft report makes a major contribution towards our understanding of the background of the problem. The report makes a further contribution in its discussion of a number of possible "corrective" options ranging from outright elimination of the PRO sanction authority to maintenance of the status quo, supplemented by increased referrals to medical boards.

To begin with the negative: our current view is that neither elimination of PROs' referral authority nor provision of direct sanction authority to them would be in the public interest. On the one hand, we agree with the PROs that the existence of the authority, however sparingly used, is, in the words of your draft, "important to achieving their mission because it gives them leverage with the medical community." On the other hand, we believe it would be unwise to vest private peer review organizations with what we perceive to be a governmental (either federal or state) function, namely the power to actually impose financial penalties or actually remove practitioners from practice.

In our view the answer to the sanctions dilemma requires a combination of approaches. AARP is on record as favoring elimination of the "unwilling or unable" requirement (although, again, the 1990 compromise amendment, if properly implemented, could go far towards resolving that particular problem). The Association has also stated its support for a substantial increase in the available monetary penalty. As noted, these two recommendations have been pending for years and have not been enacted. Therefore, we believe there is a need for a new focus. Therefore, we endorse your fifth recommendation - to require PROs to send information to medical licensure boards - as a workable approach.

It is important, once and for all, to establish a good working relationship between PROs and licensure boards. The PRO program is clearly at a crossroads as it prepares to enter a new world of pattern analysis, outcomes research, educational feedback, and CQI activities. But as we have said in the past and continue to believe, there are some doctors and some institutions whose poor performance warrants close oversight and/or interruption. If PROs' new role is to further emphasize the educator over the sanctioner, then it is imperative that more information regarding such poor performance be directed to the entity that can act as disciplinarian -- the medical licensure board. In their recast role, PROs' ability, authority, and willingness to share information with boards in appropriate cases and on a timely basis will be essential to the overall fulfillment of their patient protection mission. At the same time we believe a very important additional element is the need for closer cooperation and coordination between HCFA and OIG in

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giving guidance to the PROs, facilitating their sanctions efforts, and enabling the Secretary to implement his statutory responsibilities. We trust that such coordination will accompany any approach that is adopted.

Conclusion

We appreciate the opportunity to respond to your two draft reports on aspects of the operation of the PRO program. Once again, the Office of Inspector General has focused on significant issues of concern to the Medicare population and contributed thoughtful recommendations. If you have any questions or we can be of further assistance, please contact Cheryl Matheis of our Federal Affairs Department (202/434-3770).

Sincerely,

A handwritten signature in black ink that reads "John Rother". The signature is written in a cursive style with a large initial "J".

John Rother
Director
Division of Legislation and Public Policy

OIG RESPONSE TO COMMENTS FROM AARP

We appreciate the AARP's positive response to the draft report. We agree that the ability of the PROs to resort to sanction proceedings remains an essential element of their mission.

With respect to AARP's comment about the 1990 legislative change in the unwilling or unable standard, we note that experience since that date leaves little reason to believe that the problem has eased. In FY 1991, PROs referred 12 cases for sanction, and in FY 1992 they referred 14 cases. The PROs themselves also cite the unwilling or unable provision as a continuing obstacle to their use of the sanction referral authority.

Based on the concerns raised by the AARP and other parties, we have omitted from the final report the two policy options that would have eliminated the PROs' sanction referral authority and that would have provided that authority directly to the PROs.

We agree that a good working relationship between PROs and medical boards is important. Enhanced information sharing between the two will not eliminate the need for the PROs to be involved in sanction activities. The PROs' ability to sanction physicians who violate their Medicare obligations needs to be maintained even as they move toward an increasing emphasis on education.

APPENDIX D

ENDNOTES

1. Medicare-reimbursed physicians and providers are required to comply with their statutory obligations to (1) provide services that are "economical and only when, and to the extent, medically necessary," (2) provide services that are "of a quality which meets professionally recognized standards of health care," and (3) provide services that are "supported by evidence of medical necessity and quality" (42 U.S.C. Sec. 1320c-5, section 1156 of the Social Security Act).
2. 42 U.S.C. Sec. 1320c-5.
3. Office of Inspector General, *The Utilization and Quality Control Peer Review Organization (PRO) Program: Sanction Activities*, OAI-01-88-00571, October 1988.
4. These 10 PROs held contracts for peer review in 15 States: Alabama, Iowa (holds contract for Nebraska), Michigan, New Jersey, New York, North Carolina (holds contract for South Carolina), Oregon, Pennsylvania, Rhode Island (holds contract for Maine), and Washington (holds contract for Alaska and Idaho).
5. The 235 sanction referrals against physicians since the inception of the PRO program involved 220 different physicians because the PROs referred some physicians more than once.
6. Based on 439,580 non-Federal patient-care physicians in 1986 and 471,692 in 1989, the most recent data available (American Medical Association, Division of Survey and Data Resources, *Physician Characteristics and Distribution*, 1990), Table A-8.
7. The PROs for the Virgin Islands, American Samoa, and Guam also have made no referrals.
8. The 23 PROs that made no sanction referrals in FYs 1991 and 1992 are Arizona, Colorado, Connecticut, Florida, Georgia, Hawaii (also holds the contract for American Samoa and Guam), Kansas, Louisiana, Massachusetts, Minnesota, Mississippi, Missouri, Montana (also holds the contract for Wyoming), New Hampshire (also holds the contract for Vermont), New Mexico, North Dakota, Oregon, Pennsylvania, Rhode Island (also holds the contract for Maine), South Dakota, Tennessee, Utah (also holds the contract for Nevada), and Virgin Islands. These PROs represent 26 States plus the Virgin Islands, American Samoa, and Guam.
9. Based on non-Federal, patient-care physicians as of January 1, 1989 (*Physician Characteristics and Distribution*, op. cit.).

10. From FYs 1986 through 1992, the Office of Inspector General has sanctioned 142 physicians and 3 hospitals (fined 2 and excluded 1).
11. Office of Inspector General, PRO Technical Information Memorandum No. 2, July, 1987. Also in an undated paper, "Due Process in the Peer Review Organization (PRO) Sanctions Activities."
12. Calculation based on the length of exclusion prior to any appeal actions and excluding three exclusions for an indefinite term and one permanent exclusion.
13. *The Utilization and Quality Control Peer Review Organization (PRO) Program: Sanction Activities*, op. cit.
14. Administrative Conference of the United States, Recommendation 89-1, "Peer Review and Sanctions in the Medicare Program" (Washington, DC: June 1989).
15. A corrective action plan (CAP) is the PRO's suggested method for correcting the violations the physician or hospital has made. The CAP can include coursework, refresher residencies, and reading assignments, among others.
16. *The Utilization and Quality Control Peer Review Organization Program: Sanction Activities*, op. cit.
17. Health Care Financing Administration, Directed Change Order (DCO) 91-4, "Implementation of a New Statutory Requirement Mandating the Use of Corrective Action Plans Prior to Recommending a Sanction Action."
18. The PRO is required to have at least two meetings with the physician before referring a sanction based on a substantial violation. One meeting is required before referring a sanction based on a gross and flagrant violation.
19. For example, the PROs failed to send the requisite number of written notices to the physician or hospital or failed to offer the requisite opportunities for meetings with the PRO.
20. The OIG rejected two referrals because the physicians died.
21. Of the 61 sanctions appealed to an ALJ from FY 1986 through FY 1991, 12 were overturned. The OIG appealed 2 of those sanctions overturned by the ALJ and won.
22. In a 1988 study, we found that the PROs considered their quality assurance activities to be more important than utilization review and to have received more focus during their second contract period (Office of Inspector General, *The Utilization and Quality Control Peer Review (PRO) Organization Program: Quality Review Activities*, OAI-01-88-00570, August 1988).
23. Directed Change Order (DCO) 91-4, op. cit.

24. Health Care Financing Administration, Request for Proposal, Fourth Scope of Work, (October 1, 1992), p. C-1.
25. G. R. Wilensky, "Medicare's PROs Change Their Focus, Broaden Their Mission," *Journal of the American Medical Association* 266, No. 20 (November 1991), p. 2810.
26. Health Care Financing Administration, *Results of the Peer Review Organization Review for the Third Scope of Work* (based on reports submitted through 4/30/91 and reviews completed through 3/31/91), July 25, 1991.
27. Sanction notices are written letters from the PRO to the physician or hospital responsible for the violation and indicate the start of the sanction process. Notices must cite the Medicare obligations violated, describe how the obligation was violated, cite the PROs' sanction referral authority, suggest a corrective action plan (at the PROs' discretion), invite submission of additional information, and review information on which the PRO based its decision.
28. See *The Utilization and Quality Control Peer Review Organization (PRO) Program: Sanction Activities*, op. cit., and *State Medical Boards and Medical Discipline* (OEI-01-89-00560, August 1990).
29. In our 1988 report, *The Utilization and Quality Control Peer Review Organization (PRO) Program: Sanction Activities*, as part of a series of recommendations to strengthen the PROs' sanction referral function, we called for congressional action to eliminate the unwilling or unable provision as a basis for a sanction referral. In 1989 the Administrative Conference of the United States made the same recommendation.
30. In our 1988 report we also called for the development of legislation to strengthen monetary penalties to make them an effective sanction. We recommended that a penalty of up to \$10,000 per violation be imposed for substandard, unnecessary, or uneconomical care.
31. State medical boards often are criticized as being ineffective quality assurance bodies. However, data from the Federation of State Medical Boards show that in calendar year 1991 they imposed 2,804 prejudicial actions against physicians, 959 of which involved a loss of license or license privileges, and 1,110 a restriction of license or license privileges.
32. Office of Inspector General, *The Peer Review Organizations and State Medical Boards: A Vital Link*, OEI-01-92-00530, April 1993.
33. From May 1990 until April 1992, the Ohio PRO referred 75 cases to the Ohio medical board. The board dismissed 13 of these without any active investigation and another 37 after conducting some investigation. The remaining 25 are in various stages of review, with 8 at an advanced stage involving the initiation of a formal action against a physician. For more information, see our companion report *Peer Review Organizations and State Medical Boards: A Vital Link*.

