
**THE UTILIZATION AND QUALITY
CONTROL PEER REVIEW
ORGANIZATION (PRO) PROGRAM**

SANCTION ACTIVITIES



OFFICE OF INSPECTOR GENERAL
OFFICE OF ANALYSIS AND INSPECTIONS

OCTOBER 1988

Office of Inspector General

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This Report

Entitled "The Utilization and Quality Control Peer Review Organization (PRO) Program: Sanction Activities," this report examines the sanction process followed by the PROs and the OIG concerning those physicians and providers who have failed to meet the obligations required under Title XVIII of the Social Security Act. It is part of a broad-based study that examines the overall performance of the PRO program.

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THE UTILIZATION AND QUALITY CONTROL
PEER REVIEW ORGANIZATION (PRO) PROGRAM:
SANCTION ACTIVITIES

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EXECUTIVE SUMMARY

PURPOSE AND OBJECTIVES:

This is the second in a series of inspection reports assessing the performance of the Utilization and Quality Control Peer Review Organization (PRO) program. The purpose of this PRO inspection is to promote a better understanding of the PROs' mission and activities. The PROs' sanction authority is an essential element of their mission to protect Medicare beneficiaries from abuse and substandard care. This report focuses on a review of those activities within the context of the PROs' overall quality assurance efforts.

BACKGROUND:

The inspection grew out of the Inspector General's desire to obtain a broad perspective on the PROs' performance during their second contract period (1986-1988). To that end, we pursued three primary lines of inquiry: (1) interviews with 211 individuals associated with the PRO program, including all the PRO Chief Executive Officers (CEOs) and representatives of other Government, provider and consumer groups associated with the PROs, (2) site visits to 12 PROs selected for case study, and (3) review of pertinent literature and data bases.

FINDINGS:

- o SANCTION REFERRAL AUTHORITY STRENGTHENS THE PROS' ABILITY TO CARRY OUT THEIR OVERALL MISSION. The vast majority of respondents from all groups represented in this study articulated the importance of the PROs' sanction authority. Such authority gives the PRO program teeth and its sentinel effect "gets people's attention." This facilitates the PROs' efforts to correct substandard medical practices without actually having to recommend a sanction. The majority of respondents also thought that the sanction process will be further strengthened by the recent procedural changes that grew out of discussions held by the Health Care Financing Administration (HCFA) and the Office of Inspector General (OIG) with the American Association of Retired Persons (AARP) and the American Medical Association (AMA). Those revised PRO sanction procedures are expected to help ensure adequate due process for all physicians and providers.

- o THERE IS CONSIDERABLE VARIATION AMONG PROS IN THE NUMBER, QUALITY AND TYPE OF SANCTION RECOMMENDATIONS REFERRED. Most sanction activity has come from a relatively small number of PROs. Available data and evidence suggest that the level of the PROs' sanction activity may be related to their organizational philosophies, quality review systems, and

degrees of association with their local medical societies. However, more information is needed before drawing conclusions about the reasons for and implications of the PROs' variations in sanction activity.

- THE PROS' SANCTION REFERRAL AUTHORITY IS THE MOST CONTROVERSIAL ASPECT OF THEIR RESPONSIBILITIES. Despite the relatively small number of sanctions to date, the sanction process has engendered heated controversy, widespread publicity and extensive congressional attention because it pits the economic livelihood and due process rights of physicians and providers against the quality of care rights of Medicare beneficiaries.
- THE CURRENT SANCTION PROCESS APPEARS TO HAVE SERIOUS FLAWS THAT UNDERMINE ITS EFFECTIVENESS. These include:
 - the PROs' problems in referring acceptable sanction recommendations to the OIG which are due in part to difficulties in (1) interpreting statutory and regulatory definitions and requirements related to sanctions, and in (2) providing adequate documentation of physicians' or providers' "unwillingness or lack of ability" to comply with their obligations under Section 1156 of the Social Security Act;
 - the lack of clarity, consistency, and coordination of sanction guidelines and interpretations given to the PROs by HCFA and the OIG and by the lack of consistent sanction data collected by the two agencies;
 - the PROs' confusion and conflict inherent in their concurrent education and sanction enforcement roles; and
 - the current lack of viability of the monetary penalty as an alternative method of sanctioning a physician or provider.

Evidence suggests that such limitations may have had a chilling effect on the PROs' sanction activity over the last year.

- MOST RESPONDENTS THOUGHT THAT THE PROS' PROCESS FOR IDENTIFYING QUALITY OF CARE PROBLEMS IS FREE FROM SYSTEMIC BIAS AGAINST RURAL PHYSICIANS AND PROVIDERS. Nonetheless, evidence to date seems to suggest that rural physicians have been sanctioned at a higher rate than those in urban settings. There are several possible explanations for such an anomaly, including a bias in the PROs' sampling or review methodologies, or an inability or unwillingness of rural physicians and

providers to correct substandard medical practices identified by the PROs. The information necessary to determine why more rural than urban physicians have been sanctioned is currently unavailable.

RECOMMENDATIONS

In view of the issues raised by this report and by the OIG's experience with the sanction process, we offer two sets of recommendations: one directed to the Department of Health and Human Services (DHHS) in general and the other to HCFA in particular.

The Department

- o THE DEPARTMENT SHOULD SUBMIT A LEGISLATIVE PROPOSAL TO AMEND SECTION 1156 OF THE PRO STATUTE TO STRENGTHEN THE MONETARY PENALTY AS AN EFFECTIVE ALTERNATIVE SANCTION. THE LAW SHOULD BE AMENDED TO ALLOW FOR AN IMPOSITION OF A MONETARY PENALTY OF UP TO \$10,000 PER VIOLATION FOR SUBSTANDARD, UNNECESSARY, OR UNECONOMICAL CARE. Currently, the law provides that only the amount paid the physician or provider for rendering the care in question may be recouped as a penalty. This measure would address the PROs' concerns related to ensuring that they have a viable sanction measure short of exclusion available to them.
- o THE DEPARTMENT SHOULD SUBMIT A LEGISLATIVE PROPOSAL TO AMEND THE PRO STATUTE TO PROVIDE THAT THE FAILURE OF PHYSICIANS OR PROVIDERS TO COMPLY WITH THEIR PATIENT CARE OBLIGATIONS UNDER SECTION 1156, IN ITSELF, CONSTITUTES A SUFFICIENT BASIS FOR SANCTIONING. THUS, THE SEPARATE REQUIREMENT THAT, IN ORDER TO BE SANCTIONED, PHYSICIANS OR PROVIDERS MUST DEMONSTRATE AN "UNWILLINGNESS OR LACK OF ABILITY" TO COMPLY SUBSTANTIALLY WITH THEIR OBLIGATIONS TO MEDICARE BENEFICIARIES SHOULD BE DELETED. This change would eliminate the confusion over what constitutes "unwilling or unable."
- o THE OFFICE OF INSPECTOR GENERAL WILL PROPOSE A REGULATORY CHANGE TO CLARIFY THE PROFESSIONALLY-RECOGNIZED STANDARDS OF HEALTH CARE TO WHICH PHYSICIANS AND PROVIDERS ARE EXPECTED TO CONFORM. Such a change would help eliminate the confusion of some PROs and administrative law judges concerning what constitutes health care that meets professionally-recognized standards which physicians and providers are obligated to uphold.

The HCFA

- THE HCFA SHOULD EXPLORE AND DOCUMENT THE REASONS FOR THE CONSIDERABLE VARIATION IN SANCTION ACTIVITY AMONG THE PROS. Such efforts should clarify what, if any, impact such variations have on the PROs' protection of Medicare beneficiaries. As part of that effort, HCFA should carefully examine the impact of enacting Section 4095 of the 1987 Omnibus Budget Reconciliation Act (OBRA) that requires pre-exclusion hearings for physicians or providers "located in a rural health manpower shortage area (HMSA) or in a county with a population of less than 70,000." Our study suggests that enactment of this OBRA 1987 provision may further inhibit the PROs from making sanction referrals to the OIG due to the added complexity and delay it brings to the sanction process.

- THE HCFA SHOULD EXPLORE AND DOCUMENT THE REASONS FOR THE APPARENT HIGHER RATE OF SANCTION RECOMMENDATIONS PERTAINING TO PHYSICIANS PRACTICING IN RURAL VERSUS URBAN SETTINGS. AS PART OF THIS EFFORT, HCFA SHOULD STUDY PRO REVIEW PROCEDURES TO ENSURE THAT SANCTIONABLE ACTIVITIES BY URBAN PHYSICIANS ARE BEING IDENTIFIED WHEN APPROPRIATE. These actions by HCFA will help clarify whether physicians practicing in rural areas have greater problems effectively addressing quality problems through corrective actions or whether the system for identifying such physicians is somehow biased against them.

INTRODUCTION

The Office of Inspector General (OIG) has recently completed an inspection of the Utilization and Quality Control Peer Review Organization (PRO) program. The primary purpose of this broad-based study was to assess PRO performance and to promote a better understanding of the PROs' mission and activities. To that end, the study focused on the following factors:

- o the implications of the changes in the PROs' scope of work from the first to second contract period;
- o the major differences in perception among the PROs and other entities (e.g., health providers, consumers, Government officials, public interest advocates) regarding the PROs' mission and performance;
- o the significant variations that exist among PROs in carrying out their scope of work responsibilities;
- o the PRO practices that appeared to be exemplary; and
- o the potential weaknesses or vulnerabilities of the program.

(See appendix II for a more detailed explanation of the background for this inspection.)

In the course of this OIG inspection of PRO performance, we conducted in-depth interviews with a wide range of individuals associated with the PRO program, including all PRO chief executive officers (CEOs), and a sample of other PRO staff, as well as national and local external entities. We visited 12 of the 44 PROs who are conducting reviews in 16 of the 54 PRO jurisdictions: California, Colorado, Florida, Georgia, Indiana, Iowa, Massachusetts, New York, Oregon, Rhode Island, Texas, and West Virginia (for the Delaware PRO area). We created a computer file to store and sort information gathered from our interviews. In addition to this primary data, we collected and analyzed PRO-related performance data from HCFA and other entities. (See appendix III for a more detailed description of our methodology.)

Because the PROs' sanction activities are central to the protection of Medicare beneficiaries, this inspection included a review of those activities within the context of the PROs' overall quality assurance efforts. This report focuses on the processes followed by the PROs and the OIG to sanction physicians or providers who fail to meet their patient care obligations under Section 1156 of the Social Security Act.

This report is the second in a series of three reports of our inspection findings. The first report focused on the PROs'

quality review activities¹. That report noted that such quality review activities are central to the PROs' mission but have some operational problems that limit their effectiveness. To address some of those problems, we recommended that HCFA refine the generic quality screens and encourage the PROs to expand their outreach efforts to Medicare beneficiaries and to have closer coordination with other health care entities, particularly State medical licensure boards.

A subsequent report of this PRO inspection will focus on an overview of PRO performance, including a discussion of PRO effectiveness and of HCFA's oversight of the program.

BACKGROUND OF THE PRO PROGRAM

Creation of the PRO Program

The Utilization and Quality Control Peer Review Organization (PRO) program was created by the Peer Review Improvement Act of 1982, Title I, Subtitle C of the Tax Equity and Fiscal Responsibility Act of 1982, Public Law 97-248.

Peer Review Organizations (PROs) succeeded Professional Standards Review Organizations (PSROs) in the provision of Medicare peer review. The PSRO program had been established by Congress (in Part B of Title XI of the Social Security Act) in 1972 to ensure that health care services provided under the Medicare, the Medicaid, and the Maternal and Child Health and Crippled Children's programs were "medically necessary, conformed to appropriate professional standards, and were delivered in the most efficient and economical manner possible."² The PSRO program was a response to increasing Medicare and Medicaid costs and the failure of existing utilization and claims review mechanisms to deal with widespread inappropriate usage of health care services.

The congressional rationale for replacing the PSRO program with the PRO concept was based on the fact that the PSRO program had "been faced with certain structural problems: overregulation and too detailed specification in laws (had) restricted innovation in new approaches to review."³

The PRO legislation emphasized greater accountability by requiring PROs to have performance-based contracts with specific measurable objectives. The PRO legislation shortly preceded the Prospective Payment System (PPS) legislation and the PROs were expected to address concerns about the potential negative incentives of the PPS for increases in hospitalizations and reductions in the quality of care provided to Medicare beneficiaries. Compared with former cost-reimbursement systems, PPS gave hospitals much stronger incentives to increase Medicare

payments by increasing their number of admissions and to reduce costs by limiting services or discharging patients earlier. Hence, the PROs were charged with monitoring the system to protect against potential provider abuses such as unnecessary admissions, substandard care, and premature discharge.

The Secretary of the Department of Health and Human Services (HHS) was mandated legislatively to enter into PRO contracts with "physician sponsored" or "physician-access" organizations. A physician-sponsored organization is composed of a substantial number of physicians in the review area and is representative of those physicians. A physician-access organization has an adequate number of available physicians practicing medicine or surgery in the review area.

First Scope of Work (1984-1986)

The PRO program was implemented in 54 States and territories through 2-year, fixed-price contracts with "peer review organizations." Each of the 50 States, the District of Columbia, Puerto Rico, and the Virgin Islands was designated as a separate PRO area. Guam, American Samoa, the Northern Mariana Islands, and the Trust Territory of the Pacific Islands were designated a single PRO area.

The first contracts, which became effective over a 5-month period from July to November 1984, emphasized detection of inappropriate utilization and payments under the new PPS system. To that end, contract goals included reducing unnecessary admissions, ensuring that payment rates matched the diagnostic and procedural information contained in patient records, and reviewing patients transferred or readmitted within 7 days of discharge to determine whether readmission was for the same condition as the first hospital visit. In addition, each PRO contract included at least five objectives: reducing unnecessary readmissions because of substandard care during the prior admission, ensuring the provision of medical services critical to avoidance of unnecessary patient complications, reducing unnecessary surgery or other invasive procedures, reducing the risk of mortality, and reducing avoidable postoperative or other complications. The PROs were also expected to develop and analyze Medicare patient data to identify instances and patterns of poor quality.

When the PROs identified problems with given physicians or hospitals, they were expected to address those problems through education and consultation, intensified review, or denial of payment for care that was not reasonable or was provided in an inappropriate setting. The PROs were also authorized to recommend the sanction of physicians or providers in cases of a "substantial violation" in a "substantial number of cases" or a "gross and flagrant" violation even in a single case. Such cases were referred to the Inspector General's Office for review and

sanction determination. (A further discussion of the sanction process appears later in this background.)

Second Scope of Work (1986-1988)

During the first contract period, several entities, including the General Accounting Office (GAO), the Inspector General of the Department of Health and Human Services, and the Rand Corporation, studied the PROs' performance and recommended that their quality review be strengthened. (See appendix IV for a summary of PRO-related studies.) In response to these findings and general pressure from within and outside of the Department, HCFA strengthened the quality review requirements in the second PRO contracts which began in July 1986. In those new contracts, the 44 PROs that were responsible for review in the 54 PRO areas (see appendix V for a summary of PROs with more than one contract) had the following requirements:

- o review of readmissions to the same hospital within 15 days;
- o review of a sample of discharges to assess whether there was evidence of premature discharge or transfer;
- o review of hospitals with unexplained statistical outliers in the PRO data on high mortality rates or utilization patterns;
- o application of a standard set of quality-related criteria (called generic quality screens) to all cases selected for PRO review. These six generic quality screens included: adequacy of discharge planning, medical stability of patient at discharge, deaths, nosocomial infection, unscheduled return to surgery, and trauma suffered in the hospital;
- o special review of short hospital stays; and
- o development and implementation of community outreach programs.

Thus, the second scope of work intensified the PROs' review requirements. In addition to generic quality screens, all records selected for retrospective review for any reason were also subjected to admission review, DRG validation, coverage review, and discharge review.

The Senate Finance Committee staff in a background paper, "Quality and Access to Health Care Under Medicare's Prospective Payment System," noted that "these changes in the PRO review effort were designed to increase detection of premature discharges; to improve review of care in the hospital, particularly the

detection of situations where under-service may impact the quality of patient cases; and to improve the patients' understanding regarding their rights and appeals under the system."4

(See appendix VI for a summary of the differences between the first and second scopes of work.)

COBRA and OBRA 1986 Provisions:

The PROs' responsibilities were substantially increased through provisions of the Consolidated Omnibus Budget Reconciliation Act of 1985 (P.L. 99-272, commonly referred to as COBRA) and the Omnibus Budget Reconciliation Act of 1986 (P.L. 99-509, commonly referred to as OBRA 1986). The COBRA legislation required the implementation of preadmission review for 10 surgical procedures and preprocedure review of any cases involving assistants at cataract surgery. It also gave PROs the authority to deny payment for quality of care concerns, with the expectation that this authority would complement rather than conflict with the PROs' sanction authority. The OBRA 1986 legislation extended the PROs' review from only inpatient hospital settings to ambulatory and posthospital settings. Over the next several years, the PROs will be expected to review care delivered in hospital outpatient departments, ambulatory surgical centers, skilled nursing facilities, home health settings, and doctors' offices. In addition, in certain States, PROs are performing quality review of health maintenance organizations (HMOs) and competitive medical plans (CMPs). (See appendix VIII for a summary of COBRA and OBRA 1986 provisions.)

Visibility and Vulnerability of the PRO Program

As reflected in the legislative history, the scope of the PRO program significantly expanded after its inception. That expansion has been accompanied by extensive scrutiny from many oversight entities within Government and from provider and consumer groups outside Government. To date, Congress has held eight hearings related to the PRO program and numerous research and oversight entities have conducted PRO-related evaluations. (See appendix IV.)

The complex identity and inherent vulnerability of the PROs were summed up by one PRO spokesman:

"It is clear from my vantage point that PROs are quickly becoming all things to all people... The Inspector General of the Department of Health and Human Services is searching vigorously for a policeman of the marketplace. The Executive Office of Management and Budget is looking hard for cost containment services, particularly to hold the line on Medicare admissions. The Medicare beneficiary community earnestly desires a

protector of quality as the incentives of diagnosis related group (DRG) payment and capitated arrangements invite under-service. Health care consumers seek ready access to the information that review activities can generate. How else will a competitive market place work? Local practicing physicians remain wedded to a responsibility to monitor and evaluate their own practice behavior. All this and more for one fifth of 1 percent of the Medicare hospital trust fund (the PRO budget for a single year)... Can there be any doubt that PROs will surely fail on someone's scorecard?"⁵

Administration and Oversight of the PRO Program

The Health Care Financing Administration (HCFA) is responsible for administering and overseeing the PRO program through its Office of Medical Review in the Health Standards and Quality Bureau (HSQB). These functions are shared by central and regional office staff. The former group is responsible for establishing the operational and evaluation policies and mechanisms for the program and for negotiating the PRO contracts. The latter group is responsible for implementing program requirements and providing regular oversight and technical assistance to the PROs in their respective regions.

Since the inception of the PRO program, both HHS and HCFA leadership have changed. In response to substantial concerns raised about their predecessors' management of the program, the Secretary of HHS and the Administrator of HCFA have met periodically since 1986 with physician, hospital, consumer, and PRO representatives to hear their concerns about and suggestions for improving the PRO program. In response to those meetings, a "PRO action plan" has been developed to improve both HCFA's management of the program and the PROs' performance and effectiveness. The action plan has served as a resource for HCFA in its ongoing efforts to strengthen the PRO program.

The HCFA has faced numerous challenges in overseeing the PRO program. Like the PROs, HCFA has responded to competing expectations from within and outside the Government. For instance, HCFA has juggled pressures to make the PROs accountable for quantifiable outputs with those to give the PROs the proper flexibility to carry out their mission in an efficient and effective manner. In addition, HCFA has had to balance the expectation that additional PRO provisions (such as COBRA and OBRA) would be implemented quickly with the pressures to follow formal mechanisms. All the while allowances had to be made for the limitations of available quality review technology. The HCFA has also had to juggle its mandates to carry out congressional intent for the PRO program and to operate within the apportioned funding levels prescribed by the Executive Office of Management and

Budget. A more detailed description of HCFA's role in the PRO program will be included in our next inspection report.

The PROs' Quality Review and Intervention Procedures

As part of their ongoing quality assurance efforts, the PROs draw a sample of hospital records for a review of both quality and utilization elements. Those records are reviewed on a case-by-case basis, using six HCFA-generated generic quality screens and discharge criteria, as well as PRO-specific screens. The PROs employ nurse reviewers, or other health care professionals, to perform the initial review of records. They refer any potential quality cases to physician reviewers for final determination. The PROs also identify potential quality problems through "profiling," in which they use their data system to identify patterns of inappropriate care.

Once the PROs have determined that a quality problem exists, they are required to initiate corrective action which may include the following: intensified review, alternate timing of review, education, and sanctions.

Intensified review involves sampling a larger percentage of a particular physician's or provider's records (often 100 percent) in the subsequent quarter to verify whether or not the identified problem has continued. Intensified review may also be used after contact with the physician to ensure that the particular problem has been corrected.

Although most PRO review is done on a retrospective basis, the PRO may choose to alter the timing of that review to address particular problems. For instance, if a particular physician has a large number of unnecessary admissions, the PRO might initiate preadmission review of the physician's patients.

The PRO may also require that a doctor enroll in continuing medical education. This could include the physician's taking specialized courses or possibly retaining a physician consultant to review his or her cases.

If the PRO determines that corrective action has failed to address the quality problem adequately, the PRO is expected to recommend the physician or provider for sanction.⁶

The Sanction Process

The Secretary of Health and Human Services is authorized to impose sanctions on Medicare-reimbursed physicians or providers if they have "grossly and flagrantly" violated or "substantially" failed in a "substantial number of cases" to comply with their statutory obligations to provide (1) services which are provided "economically and only when, and to the extent they are medically

necessary," (2) services that are "of a quality which meets professionally recognized standards of health care," and (3) services that are properly documented. The Secretary may impose one of two sanctions: (1) a monetary penalty for no more than the "actual or estimated cost of the medically improper or unnecessary services so provided" or (2) exclusion from the Medicare program for a specified period of time. (For detailed sanction provisions, see 42 U.S.C. Sec. 1320C-5.)

The PRO must provide the practitioner or provider with "reasonable notice and opportunity for discussion" before making its recommendation to the Secretary. Under the regulations, (42 CFR part 1004) the provider or practitioner is entitled to an opportunity to submit additional information and/or meet with the PRO to discuss an allegation of "gross and flagrant" violation(s). With an allegation of "substantial" violations, the physician or provider is entitled to submit additional information and to receive two notices of potential violation and two opportunities to meet with the PRO. In either case, if the PRO recommends the imposition of a sanction, the physician or provider must be given 30 days' notice and an additional opportunity to submit written comments to the Secretary.

The Secretary has delegated the authority for sanction determinations to the Office of Inspector General (OIG). Upon receipt of the PRO's sanction recommendation, the Inspector General must determine whether he agrees with the recommendation and whether the physician or provider has "demonstrated an unwillingness or lack of ability substantially to comply with statutory obligations." The Inspector General may accept, reject, or modify the sanction recommendation forwarded by a PRO. In cases where the PRO has recommended exclusion, the OIG must act on that recommendation within 120 days or the exclusion automatically goes into effect pending final determination by the OIG.

Within the Office of Inspector General, the Office of Investigations is responsible for processing and reviewing each PRO sanction referral. If the OIG accepts the PRO's recommendation, the sanction goes into effect 15 days upon the relevant physician's or provider's receipt of the OIG sanction notification. The physician or provider may appeal the sanction to an administrative law judge (ALJ), who will conduct a de novo hearing to review the facts of the case. If dissatisfied with that appeal, the sanctioned party may then appeal to the Secretary's Appeals Council and may thereafter seek judicial review in court. (See appendix VII for a detailed description of the process for addressing a case of "gross and flagrant violation" versus a case of "substantial number of substantial violations.")

The peer review statute and implementing regulations related to the sanction process have attempted to balance the competing priorities to protect both the rights of Medicare beneficiaries

to receive high-quality care and the rights of physicians and providers to receive adequate due process. That delicate balance has meant that although a physician or provider has had an opportunity to have at least two administrative entities (the PRO and the OIG) review a case prior to the imposition of a sanction, the process has deferred a full evidentiary hearing until after the sanction has been imposed.⁷

The PROs' sanction procedures have precipitated ongoing debate among all parties associated with the PRO program. Organized medicine has argued vociferously that the PROs should provide physicians and providers with stronger due process protection. In response to such concerns, HCFA and the OIG held discussions last spring with the American Association of Retired Persons (AARP) and the American Medical Association (AMA) and developed certain sanction procedures that were incorporated into HCFA's PRO Manual. (See appendix X for a copy of the revised PRO sanction procedures.) The new PRO sanction instructions strengthened PRO notice procedures, clarified the role of an attorney for the physician or provider at the PRO discussions, ensured that physicians or providers would be provided records of the PRO proceedings, and permitted expert witnesses to provide relevant medical evidence at the PRO discussions with the physician or provider.

Over the last year, both organized medicine and Medicare beneficiaries from some affected communities have also argued that the sanction process has adversely affected rural communities since sanctioned physicians and providers have been excluded from the Medicare program pending their ALJ hearings. Such concerns led to a recent legislatively mandated requirement (Section 4095 of the Omnibus Budget Reconciliation Act of 1987, P.L. 100-203, commonly referred to as OBRA 1987) for ALJ review prior to the imposition of an exclusion for any physician or provider who is practicing in a "rural health manpower shortage area" (HMSA) or in a county with a population of 70,000 or less, unless it is determined that the physician or provider poses a "serious risk" to Medicare beneficiaries. In addition, Congress has directed the Secretary of HHS to conduct a year-end study of how the PROs' new standardized due process procedures have impacted the PRO program.

Like other aspects of the PRO program, the sanction process has been dynamic--changing as the PROs, the HCFA, and the OIG have gained more experience and as particular groups have highlighted its ambiguities and vulnerabilities. In addition to the aforementioned changes, the OIG has recently proposed changes in the use of monetary penalties. The current statutory formula for assessing monetary penalties is outdated given that the PROs' sanction provisions were enacted prior to the advent of the prospective payment system (PPS). For example, under PPS, it is almost impossible to determine what Medicare Part A costs are for

improper or unnecessary care. Hence, the monetary penalties imposed have generally been based on only Medicare Part B costs and have resulted in amounts as low as \$65.44. In response to that problem, the OIG issued a technical memorandum to all the PROs in July 1987 highlighting the lack of cost-effectiveness of monetary penalties and suggesting new guidelines for forwarding such recommendations to the OIG. In addition, the OIG submitted a legislative proposal to the Department in the Fiscal Year 1989 legislative process to modify the current monetary penalty provisions so that a penalty of up to \$10,000 would be set for each instance in which medically improper or unnecessary health care services were provided.

As of December 31, 1987, the OIG had received 151 referrals from 38 of the 54 PRO areas. The status of those cases is as follows:

- 61 exclusions (60 physicians and 1 facility)
- 26 monetary penalties (24 physicians and 2 facilities)
- 1 physician retired
- 2 physicians expired
- 53 rejections by the OIG
- 8 cases still pending

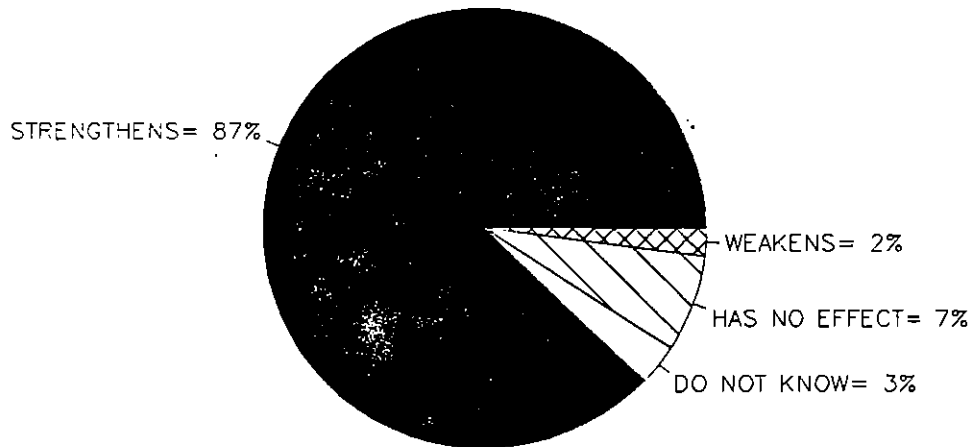
A more thorough discussion of sanction issues and statistics follows in the "Findings" section of this report.

FINDINGS

Sanction referral authority strengthens the PROs' ability to carry out their overall mission.

The vast majority (87 percent) of the 154 respondents who were asked to comment on the PROs' sanction authority thought that it strengthened the PROs' ability to carry out their mission. (See figure I.) As one national external entity representative noted, "It is a club that gets people's attention. Most individuals are good candidates for educational peer review, but you have to have a powerful weapon for the outliers."

FIGURE I
PERCEPTIONS OF THE EFFECT OF PROS' SANCTION
AUTHORITY ON PROS' ABILITY TO PERFORM MISSION



Note: N=154 respondents.
Source: OIG Inspection Interviews

It is worth noting that during our extensive interviews, none of the PRO CEOs flaunted their sanction statistics. In fact, most of them view sanctions as a step of last resort when other measures have failed. In addition, many of them mentioned that sanction authority gives the program teeth and that its sentinel effect "gets people's attention," thereby facilitating the PROS' efforts to correct substandard medical practices without actually having to recommend sanctions.

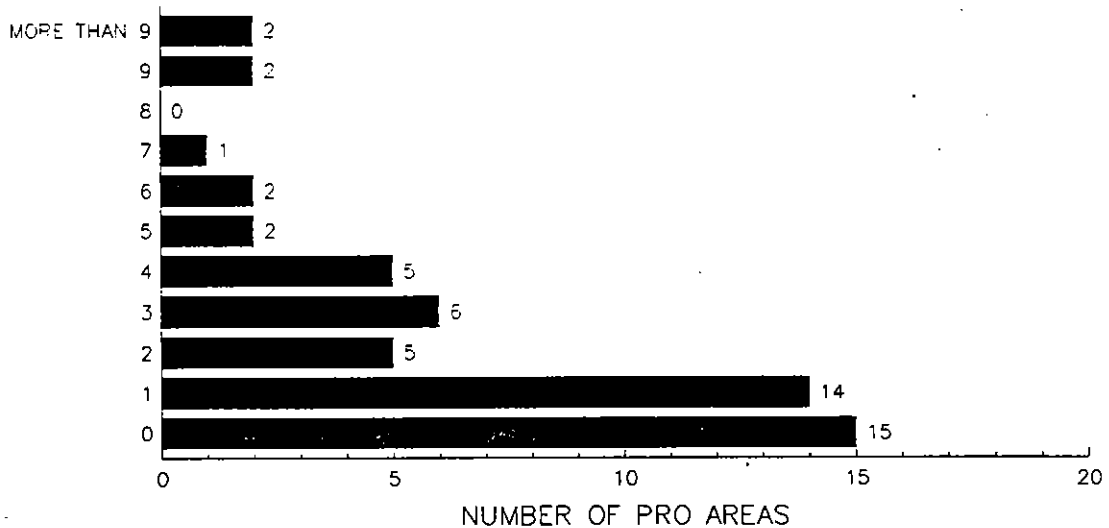
Approximately two-thirds of the PRO CEOs, and a corresponding percentage of other groups interviewed, thought that the revised PRO sanction procedures that grew out of discussions held by HCFA and the OIG with the AMA and AARP would strengthen the sanction process by improving cooperation between the PROs and the medical community. However, many PRO staff also mentioned that the new procedures are cumbersome and simply formalize their preexisting practices.

There is considerable variation among PROs in the number, quality, and type of sanction recommendations referred.

Through December 31, 1987, 35 of the 44 PROs had referred 151 sanction cases to the OIG from 38 of the 54 PRO areas. The OIG has accepted 87 of those recommendations, rejected 53 of them, and closed 3 cases because of physician death or retirement; eight cases are still pending. Our analysis of the distribution of sanction cases across PRO areas reflects that most sanction activity has come from a relatively small number of areas. In fact, 30 percent of the 54 PRO areas have made no sanction referrals to the OIG, and 44 percent of them have had no sanctions imposed by the OIG. (See figure II. For detailed analyses of sanction activity for each PRO area, see appendix XI.) It is worth noting that we attempted to use HCFA's data report on sanctions for our analysis. However, that report only included sanction activity within the PROs' second contract period and reflected inconsistencies with data obtained from the OIG's Office of Investigations. Therefore, in order to be consistent in our various analyses related to sanctions, we relied on data obtained from OIG/OI.

FIGURE II
SANCTION REFERRALS FROM 54 PRO AREAS TO
OFFICE OF INSPECTOR GENERAL, 1985-1987

NUMBER OF SANCTION REFERRALS



Source: OIG/ Office of Investigations.

The major reasons cited by the respondents for the PROs' differences in sanction activity included (in descending order of frequency) the PROs' variations in (1) their interpretation of when it is appropriate to sanction rather than to provide other corrective action, (2) their relative competence as

organizations, (3) their relative commitment to and comfort with having sanctions as a part of their responsibilities, and (4) their reticence versus their aggressiveness as organizations.

Our analysis of the interview responses, the quality review procedures and the sanction activity levels of our 12 case study sites suggests that the following factors may have contributed to stronger sanction records:

- o an organizational philosophy of "patient advocacy";
- o a relatively straightforward and minimally layered quality review process;
- o an organizational consensus about sanction-related definitions;
- o a degree of relative independence from the local medical society; and
- o a relatively large geographic area.

However, a more in-depth review of the factors affecting the PROs' variation in sanction activity is needed before any definitive conclusions can be drawn.

The PROs' sanction referral authority is the most controversial aspect of their responsibilities.

Given that approximately half a million physicians are involved in the Medicare program and that we are living in a time of increased quality assurance accountability, the level of sanction activity associated with the PRO program seems modest. In fact, several PRO areas with relatively large numbers of physicians show no sanction activity. (See appendix XI, table B.) Furthermore, according to recent congressional testimony, eight of the areas with no Medicare physician sanctions also have shown the lowest level of disciplinary actions taken by their respective State medical boards.⁸

Although the number of sanctions have been relatively low, they have engendered heated controversy, widespread publicity, and extensive congressional attention. Numerous newspapers (including The New York Times)⁹ have written front-page stories about PRO sanctions and several government, PRO, provider and consumer spokespersons have provided impassioned congressional testimony about the sanction process.

The sanction process is controversial because it embodies the inherent conflicts associated with the PROs' mandates to be "all things to all people."¹⁰ More specifically, the process pits the economic livelihood and due process rights of physicians and

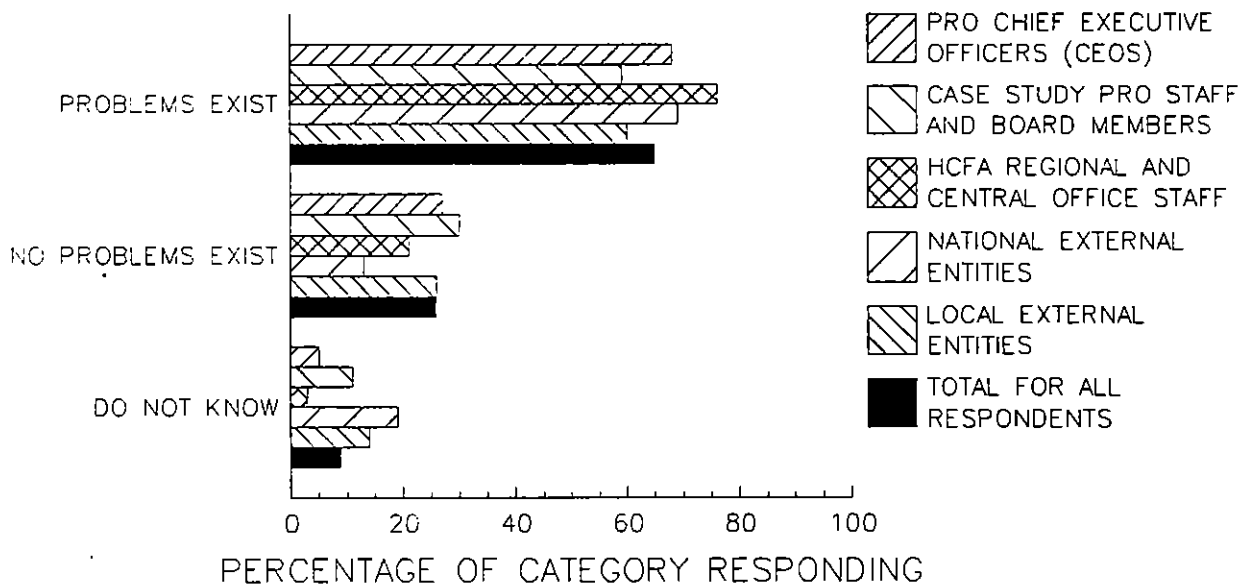
providers against the quality of care rights of Medicare beneficiaries and forces the PROs to simultaneously balance their educating and enforcing roles.

Several PRO CEOs voiced frustration about the disproportionate share of public attention that their sanction activities receive compared with their myriad other quality intervention efforts. Our discussions with various national and local external entities reinforced that little information about the PROs' quality intervention efforts reaches the public's attention. To address this concern, our recent report on the PROs' quality review activities recommended that HCFA "develop and widely disseminate information on the full range of educational corrective actions being taken by the PROs to address quality of care problems."¹¹

The current sanction process appears to have serious flaws that undermine its effectiveness.

Sixty-eight percent of the PRO CEOs and a similar level of other respondents thought that the current sanction process has problems. (See figure III.)

FIGURE III
PERCEPTIONS OF SANCTION PROCESS



Note: N=196 respondents.
Source: OIG Inspection Interviews.

A majority (59 percent) of the PRO CEOs noted difficulty in determining when it is appropriate to sanction a given physician or provider. Other major issues cited by the PROs (in descending order of frequency) were as follows:

- o the difficulty in interpreting the statutory and regulatory definitions of "gross and flagrant," and "substantial number of substantial violations";
- o the difficulty in understanding what support documentation is necessary to establish that a physician or provider is "unwilling or unable" to change;
- o the confusion over the appropriate method of handling one case of "gross and flagrant violation";
- o the lack of clarity, consistency, and coordination of sanction guidelines and interpretations given to the PROs by HCFA and the OIG;
- o the lack of clarity about the appropriate conditions for recommending a monetary penalty, given the OIG's recent determination that monetary penalties are often not cost-effective. The PROs, HCFA, and national external entities all voiced a strong desire for an intermediate measure short of exclusion to be incorporated into the sanction process. However, no consensus existed about the appropriate guidelines for imposing such a penalty (i.e., whether it is appropriate to issue a monetary "traffic ticket" for quality issues or just for fraudulent practices);
- o the frustration related to the OIG overturning a significant (37) percent of their sanction recommendations;
- o the frustrations related to the "cumbersomeness" of the due process procedures, including the PROs' perceived lack of preparation for and adequate representation at administrative law judge (ALJ) hearings, and the extensive time lag (average of 15 months) between the PROs' initial sanction referrals to the OIG and the ALJs' appeal determinations;
- o the lack of timely and adequate payment to the PROs for sanction-related work;
- o the confusion and conflict inherent in their concurrent education and sanction enforcement roles;

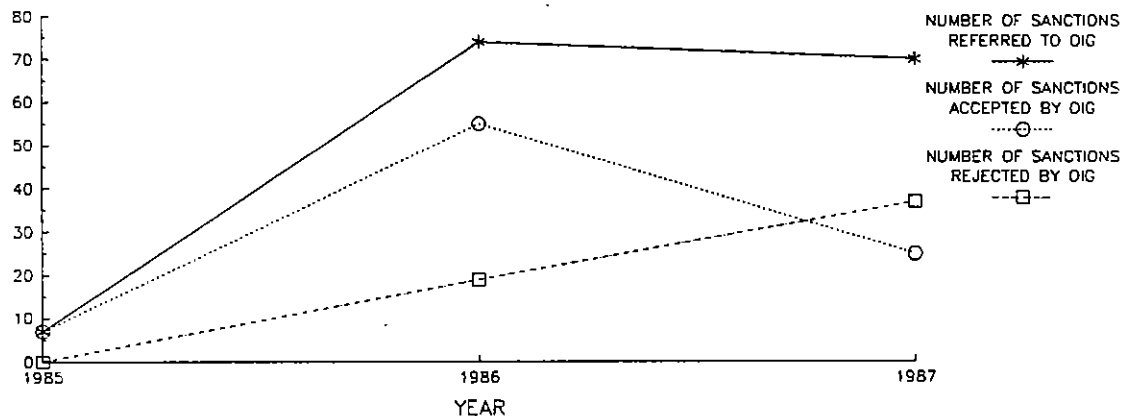
- o the confusion over their ability to share sanction and quality intervention information with other review entities (i.e., State medical boards, hospital quality assurance committees, etc.) given the confidentiality requirements of the Social Security Act, and
- o the limited medical review provided by the OIG in its evaluation of PRO sanction referrals.

The aforementioned issues were also raised by the other groups interviewed, although the frequency with which these issues were mentioned varied among the groups. The HCFA respondents focused most on the definitional concerns, the lack of coordination between HCFA and the OIG, and the cumbersomeness of the due process sanction procedures. The national and local external entities focused most on concerns about the PROs' confidentiality restrictions and on definitional concerns. They were the only groups who voiced considerable concern about what they perceived to be a lack of adequate due process in the sanction process.

In part, to address the PROs' confusion about their confidentiality requirements, our recent report on the PROs' quality review activities recommended that HCFA clarify those restrictions and require the PROs to report instances of "physician misconduct or incompetence to State medical licensure boards."¹²

The myriad limitations of the current sanction process may have influenced its use. Over the last year, the PROs' overall sanction referrals have decreased due, in large part, to the previously more active PROs submitting fewer sanction referrals. (See figure IV. For a detailed breakout of sanction activity for 1985, 1986, and 1987, by PRO area, see appendix XI, table C.)

FIGURE IV
SANCTION REFERRALS TO OIG, REJECTIONS AND ACCEPTANCES BY OIG IN 1985, 1986 AND 1987



Source: OIG/ Office of Investigations
Note: Eight cases referred in 1987 are still pending decision in the OIG.

The reduction in PRO referrals may mean that the PROs are successfully addressing all quality problems through the educational process. However, it may also reflect that because of the enormous financial and political costs PROs must endure to sanction a physician that they have simply concluded that the "juice just isn't worth the squeeze."

In addition to fewer PRO referrals, as reflected in figure IV, the OIG's rejection of PRO cases has increased substantially over time. Our Office of Investigations' analysis of the 53 rejections as of December 31, 1987 reflects the following reasons for such action:

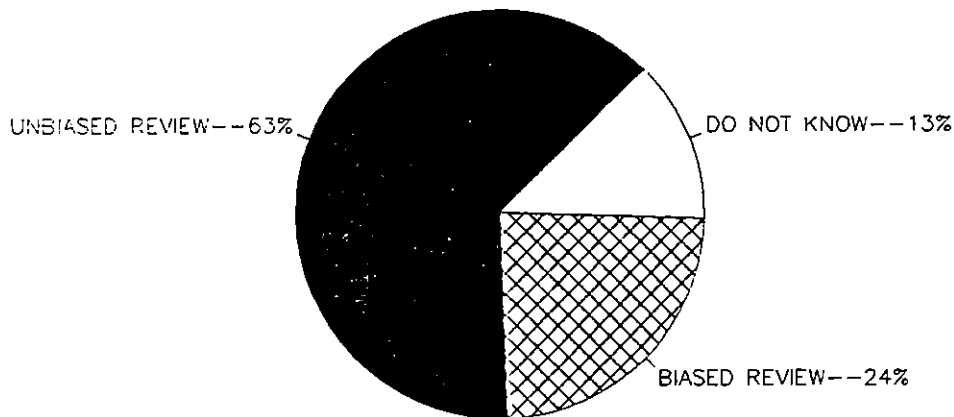
- 20 cases rejected because the PRO had failed to provide adequate information related to physicians' or providers' "unwillingness" or "inability" to meet their obligations under Section 1156 of the Social Security Act,
- 11 cases rejected because the PRO had failed to provide adequate medical evidence to support its recommendation, and
- 22 cases rejected because the PRO had failed to follow proper regulatory procedures for sanctions (as outlined in appendix VII).

If limitations of the sanction process have had a chilling effect on sanction activity, two recent developments are likely to exacerbate that effect. First, several ALJ decisions rendered over the last year have either reversed or limited the sanctions imposed by the OIG. However, in a number of these cases, the OIG is appealing those decisions to the Departmental Appeals Council. Second, OBRA 1987 includes a provision requiring ALJ review prior to exclusion from Medicare for any physician or provider located in a rural health manpower shortage area (HMSA) or in a county of less than 70,000 population. This provision dictates that such a physician or provider cannot be excluded without an opportunity to request a preliminary hearing to determine whether that physician's or provider's continued participation would place beneficiaries at risk. The preliminary hearing will be to determine the basis of the risk to patients. If the OIG prevails, the exclusion will be effectuated and remain in effect during the course of the appeal. If the physician or provider prevails, the exclusion will be stayed until a decision is rendered by the ALJ. Because an ALJ decision takes an average of 10 months from the time the case is forwarded to the ALJ by the OIG, this policy change is likely to intensify the PROs' frustrations with the length of the sanction process and therefore may make them less inclined to make sanction referrals.

Most respondents thought that the PROs' process for identifying quality of care problems is free from systemic bias against rural physicians and providers.

Sixty-three percent of the 185 respondents saw no bias in the PROs' process for identifying quality of care problems. A greater percentage of the PRO CEOs and staff found the system to be free from rural bias. They believe that any disproportionately greater sanctioning of rural physicians results both from the PROs' application of one standard of care to all physicians and providers and from the greater isolation of rural physicians from informal and formal quality assurance mechanisms (i.e., exchange with fellow physicians and active hospital quality assurance committees). (See figure V.)

FIGURE V
PERCEPTIONS OF BIAS AGAINST RURAL PHYSICIANS
AND PROVIDERS IN PRO QUALITY REVIEW PROCESS



Note: N=185 respondents.
Source: OIG Inspection Interviews.

Those respondents (24 percent) who did think the system is biased against rural physicians and providers generally attributed that bias to the PROs' 3 percent sampling methodology. They suggested that because the 3 percent sample is hospital--rather than physician--specific, a physician practicing in a small rural hospital is more likely to be reviewed by the PRO than one practicing in a large urban hospital because hospital discharges are distributed among fewer physicians. However, HCFA has

reviewed the sampling methodology and has concluded that it is free from bias.

Although there have been too few sanctions to draw definitive conclusions, our analysis of PRO-specific sanction data nevertheless suggests that rural physicians have been sanctioned at a higher rate than urban ones. Using the 1980 census data, we classified all sanctions according to whether the physicians' addresses fell within Standard Metropolitan Statistical Areas (SMSAs). Those falling within an SMSA were classified as urban and those falling outside were classified as rural. We also compared the percentage of rural and urban sanctions to the States' percentages of rural and urban physicians. (See appendix XI, table D.)

The reasons for the greater sanctioning of rural physicians are unclear. Although HCFA's instructions to the PROs for drawing a 3 percent random sample seem free from bias, perhaps there are problems with the PROs' application of that methodology. On the other hand perhaps the greater sanctioning of physicians results from the fact that physicians in rural areas are more isolated and therefore may find it more difficult to correct those substandard medical practices identified by the PROs.

Sanctions are the final step in a long process which includes a range of possible interventions by the PROs. Therefore, definitive conclusions about the potential systemic bias of the PROs' system for identifying quality of care problems cannot be drawn without analysis of the distribution of rural and urban physicians identified early in the process as having quality problems compared with the distribution of rural and urban physicians who have been subsequently sanctioned. Such information is currently unavailable.

RECOMMENDATIONS

This study has generated important insights concerning the factors that inhibit PROs from making more effective use of their sanction referral activity. In view of these insights, we in the Office of Inspector General have committed ourselves to two important lines of action. One is to increase the level of communication with the PROs to provide them guidance regarding their statutory and regulatory sanction requirements. Such increased communication, we expect, will provide the PROs greater opportunity to address sanction-related concerns such as definitional interpretations, compilation of necessary documentation and preparation for administrative hearings.

The other line of action is to increase the medical input involved in reviewing the PROs' sanction referrals to the OIG. We will do that by having a second level medical review in all

such cases. We have made arrangements with the Department of Army and the Social Security Administration to provide the additional input.

In addition, we have two sets of recommendations that, if carried out, will help PROs make more effective use of their sanction referral authority. One set is directed to the Department of Health and Human Services in general and the other to HCFA in particular.

The Department

- o The Department should submit a legislative proposal to amend Section 1156 of the PRO statute to strengthen the monetary penalty as an effective alternative sanction. The law should be amended to allow for an imposition of a monetary penalty of up to \$10,000 per violation for substandard, unnecessary, or uneconomical care. Currently, the law provides that only the amount paid the physician or provider for rendering the care in question may be recouped as a penalty. This measure would address the PROs' concerns related to ensuring that they have a viable sanction measure short of exclusion available to them.
- o The Department should submit a legislative proposal to amend the PRO statute to provide that the failure of physicians or providers to comply with their patient care obligations under Section 1156, in itself, constitutes a sufficient basis for sanctioning. Thus, the separate requirement that, in order to be sanctioned, physicians or providers must demonstrate an "unwillingness or lack of ability" to comply substantially with their obligations to medicare beneficiaries should be deleted. This change would eliminate the confusion over what constitutes "unwilling or unable."
- o The OIG will issue a regulatory change to clarify the professionally-recognized standards of health care to which physicians and providers are expected to conform. Such a change would help eliminate the confusion of some PROs and administrative law judges concerning what constitutes health care that meets professionally-recognized standards which physicians and providers are obligated to uphold.

The HCFA

- o The HCFA should explore and document the reasons for the considerable variation in sanction activity among the PROs. Such efforts should clarify what, if any, impact such variations have on the PROs' protection of Medicare beneficiaries. As part of that effort, HCFA should carefully examine the impact of enacting Section 4095 of the

beneficiaries. As part of that effort, HCFA should carefully examine the impact of enacting Section 4095 of the 1987 Omnibus Budget Reconciliation Act (OBRA) that requires pre-exclusion hearings for physicians or providers "located in a rural health manpower shortage area (HMSA) or in a county with a population of less than 70,000." Our study suggests that enactment of this OBRA 1987 provision may further inhibit the PROs from making sanction referrals to the OIG due to the added complexity and delay it brings to the sanction process.

- o The HCFA should explore and document the reasons for the apparent higher rate of sanction recommendations pertaining to physicians practicing in rural versus urban settings. As part of this effort, HCFA should study PRO review procedures to ensure that sanctionable activities by urban physicians are being identified when appropriate. These actions by HCFA will help clarify whether physicians practicing in rural areas have greater problems effectively addressing quality problems through corrective actions or whether the system for identifying such physicians is somehow biased against them.

APPENDIX I

ENDNOTES

1. The Utilization and Quality Control Peer Review Organizations (PRO) Program: Quality Review Activities, (Control # OAI-01-88-00570), Office of Analysis and Inspections, Office of Inspector General, Department of Health and Human Services, February 1988.
2. Federal Register, Vol. 49, No. 39, February 27, 1984, p. 7202.
3. Tax Equity and Fiscal Responsibility Act of 1982, Commerce Clearing House, Inc. p. 37D. Senate Report, 97-494 at 41.
4. "Examination of Quality of Care Under Medicare's Prospective Payment System," Hearing before the Committee on Finance, United States Senate, June 3, 1984, p. 44.
5. Andrew Webber, "A PRO Report Card," The Internist: Health Policy in Practice, the American Society of Internal Medicine, July 1986, pp. 7-9.
6. Material on the PROs' quality review process was taken from the Congressional Research Service Report for Congress: The Peer Review Organization Program, The Library of Congress, October 23, 1987, pp. 20-21.
7. Material for the description of the sanction process was taken from the transcript of Inspector General Richard Kusserow's testimony at a hearing before the Subcommittee on Intergovernmental Relations and Human Resources, Committee on Government Operations, United States House of Representatives, October 20, 1987.
8. Transcript of testimony of Sidney M. Wolfe, M.D., Director, Public Citizens Health Research Group before the Subcommittee on Health and the Environment, Committee on Energy and Commerce, United States House of Representatives, October 26, 1987, p. 4.
9. Robert Reinhold, "Quality-Care Reviews Hurting Rural Doctors," The New York Times, March 24, 1987.
10. Op. cit., Andrew Webber, p. 7.
11. Op. cit., Office of Inspector General, Control # OAI-01-88-00570, p. 24.
12. Ibid., p. 25.

APPENDIX II

BACKGROUND OF THE PRO INSPECTION

The Office of the Inspector General (OIG) is mandated by statute to provide leadership and coordination within the Department of Health and Human Services (HHS). The OIG is charged with ensuring the economy, efficiency, and effectiveness of HHS program operations.

Because of the PRO program's vital role in protecting both the quality of care of Medicare beneficiaries and the financial integrity of the Medicare program, the OIG has taken a keen interest in and had a close association with the PRO program since its inception. Among other activities, the OIG has conducted preaward audits of the PRO and SuperPRO contracts and of sanction cost estimates for HCFA and has made sanction determinations on cases referred by the PROs.

The impetus for this inspection of PRO performance grew out of the Inspector General's personal interest in gaining a broad perspective on the PROs' performance during the second scope of work.

Although several other entities had reviewed various elements of the PRO program (see appendix IV), no one had undertaken a broad evaluation of it. Hence, in the fall of 1986, the Inspector General asked the Office of Analysis and Inspections to conduct an inspection of the PRO program in the spring/summer of 1987. In addition, the OIG's Office of Investigations asked us to incorporate a review of the sanction process into our overall inspection. We designed the PRO inspection to integrate some original PRO data collection and analysis with other existing PRO-related data collected from primary and secondary sources. Due to other OIG priorities, completion of the PRO inspection field work was delayed until the fall of 1987.

We designed this PRO inspection to provide the Inspector General and other departmental officials, policymakers, and the public with a broad perspective on the PRO program and how it has changed over time.

In addition to this inspection, the OIG has done and continues to do other work related to the PRO program. The following is a summary of some key audits and inspections.

Past Work

- o Review of Financial Operations of Peer Review Organizations (Audit No. 14-62158), which concluded that most PROs made a sizable profit on their initial contracts and recommended administrative and fiscal procedures

for HCFA to incorporate into its management of the PRO program.

- o Inspection of Inappropriate Discharges and Transfers, March 1986, which concluded that many PROs had not effectively used the authorities or processes available to address poor quality of care associated with premature discharges and inappropriate transfer. The report included recommendations regarding HCFA's reporting and evaluation systems and suggested that the PROs be given authority to deny payments for substandard care.

- o Report on Evaluation of California Medicare Review, Inc. (CMRI) Price Proposal for Development of 43 Sanction Cases (Audit No. 09-61658), September 1986, which concluded that HCFA failed to include reimbursable sanction activities into its fixed-price contracts with the PROs. The report recommended that HCFA: (1) provide guidance to all PROs on the reporting of and accounting for sanction costs; (2) require all PROs to establish adequate cost accounting systems for summarizing the costs of sanction activities; (3) ensure all PROs develop and implement bid estimating procedures that more reasonably reflect the estimated costs of performing sanction activity; (4) ensure that all PRO contracts contain the necessary cost-reimbursement provisions required by the Federal acquisition regulations (FAR) before initiating any reimbursement of sanctions; and (5) require CMRI to provide an accounting of funds advanced for sanction activities and return any excess funds to the Federal Government. A subsequent report (Audit No. 09-8661662) was issued in May 1987 on CMRI's price proposals for its first 117 sanction cases. That report reinforced the recommendations of the first report and also recommended that HCFA issue modifications to the PROs' fixed-price contracts to make only the PROs' incremental sanction costs reimbursable.

Current Work

- o The Region VII Office of Audit is conducting a national cost-benefit analysis of five types of PRO review including retrospective admission, DRG validation, day outlier, cost outlier, and preadmission. The audit is focusing on 14 PROs and is expected to be completed before the spring of 1988.

- o The Office of Analysis and Inspections (OAI) is coordinating the national DRG Validation Study, an analysis of medical record data collected from 239 PPS

hospitals (for the period October 1, 1984 to March 31, 1985) for DRG validation and identification of quality of care problems. The OAI central office staff are coordinating the review but regional staff are responsible for analysis of the PRO-related data on DRG validation and quality. Those reports are expected to be completed by the spring of 1988.

APPENDIX III

METHODOLOGICAL NOTES

Summary of Interviews

Because we wanted to examine how both the PROs and HCFA viewed themselves and were viewed by others, we conducted in-depth (approximately 2-hour) interviews with a variety of people associated with the program. Those 211 individuals included the following:

- 44 PRO chief executive officers (i.e., all PRO CEOs as 8 of the 44 PROs manage 2 PRO areas and 1 PRO manages 3 areas;
- 56 other PRO staff and board members (i.e., the medical directors, program directors, review directors, board chairs, and consumer representatives from the 12 PROs selected for case study site visits);
- 16 national external entity representatives (i.e., the American Association of Retired Persons, the American Hospital Association, the American Medical Association, the American Medical Peer Review Association, and the Public Citizen Health Research Group as well as the Department of Health and Human Services, Executive Office of Management and Budget, and congressional committee staff);
- 54 local external entity representatives (i.e., State medical societies, medical licensure boards, hospital associations, fiscal intermediaries, and the American Association of Retired Persons chapters associated with the 12 PROs selected for case study site visits);
- 12 Health Care Financing Administration (HCFA) central office staff (i.e., from the Health Standards and Quality Review Bureau, the Office of Management and Budget, and the Bureau of Program Operations); and
- 29 HCFA regional office staff (i.e., all 10 Associate Regional Administrators for Health Standards and Quality, all 10 branch chiefs and a sample of the project officers in the Medical Review Branch).

Case Study Selection

In an effort to gain a first-hand perspective on the PROs' operations, we made 3- to 4-day site visits to at least one PRO from each of the 10 HCFA geographic regions. As part of that case study effort, we planned to compare those case study

assessments to HCFA's PRO-specific evaluation documents (i.e., PROMPTS and SuperPRO) for the second scope of work. Hence, we eliminated those PROs with a November 1, 1987 contract start date (i.e., Group 5 PROs) from the case study selection pool since we would be unable to obtain their corresponding HCFA evaluation documents in time for review. We also eliminated the Pennsylvania PRO from the selection pool since its second contract period only began on July 1, 1987.

We then drew a judgmental sample of the PROs based on the following criteria: size (as reflected by funding level), geographic location, and sanction activity level. We divided the PROs into four groups based on their Medicare contract awards (\$2.9 million or less, \$3-5.9 million, \$6-8.9 million, and \$9 million or more) and calculated the appropriate number of PROs to select from each funding category. That selection of particular PROs focused on ensuring a group of PRO sites with a distribution of geographic areas (i.e., at least one PRO from each of the 10 HCFA regions) and of sanction activity levels and with at least some representation of PROs that had both Medicare and Medicaid contracts.

The final group of 12 organizations selected for site visits in the 10 HCFA regions were as follows:

<u>HCFA Region</u>	<u>PRO Area</u>	<u>Organization</u>
1	Massachusetts	Massachusetts Peer Review Organization, Inc., Waltham, MA
1	Rhode Island	Health Care Review, Inc. Providence, RI
2	New York	Empire State Medical, Scientific and Educational Foundation, Inc. Lake Success, NY
3	Delaware	West Virginia Medical Institute, Inc. Charleston, WV
4	Florida	Professional Foundation for Health Care, Inc. Tampa, FL
4	Georgia	Georgia Medical Care Foundation Atlanta, GA

<u>HCFA Region</u>	<u>PRO Area</u>	<u>Organization</u>
5	Indiana	PEERVIEW, Inc. Carmel, IN
6	Texas	Texas Medical Foundation Austin, TX
7	Iowa	Iowa Foundation for Medical Care West Des Moines, IA
8	Colorado	Colorado Foundation for Medical Care Denver, CO
9	California	California Medical Review, Inc. San Francisco, CA
10	Oregon	Oregon Medical Professional Review Organization Portland, OR

In the case study selection process, we opted to choose PROs based on their individual contracts with HCFA, rather than combining multiple contracts held by one PRO for different PRO areas. We chose Delaware as a PRO site to visit, although the West Virginia PRO actually holds the contract for Delaware. Hence, we refer to the West Virginia PRO in listing the case study PROs but note parenthetically that discussions focused on the Delaware contract. On the other hand, our site visit to the Rhode Island PRO focused on its operation in that State, although the Rhode Island PRO also holds the PRO contract for Maine.

Discussion Guides

We designed seven separate but interrelated discussion guides to capture the perspectives of PRO executive directors, national external entities, other PRO board and staff, local external entities and HCFA central and regional office staff. The discussion guide questions were structured so that we could later compare responses within and across groups. All discussion guides grouped questions under three or four categories: PRO assessment, quality review and sanctions, HCFA oversight, and in some cases, descriptive material. The discussion guides included about equal numbers of closed and open-ended questions, but most of the closed questions had an open-ended probe following them.

Interview Approach

We conducted approximately half the 211 interviews by phone and the other half in person. For methodological consistency, we chose to interview all 44 PRO chief executive officers (CEOs) by

telephone and held subsequent additional on-site interviews with those CEOs associated with the 12 case study PRO sites. In addition to the 12 case study PRO sites, we conducted on-site rather than telephone interviews with most of the national and local external entities and with HCFA central office staff.

The primary PRO inspection team consisted of four individuals from Region I who conducted 95 percent of the telephone interviews and 80 percent of the on-site ones. Four additional field team members (two from Region I and two from OAI's central office) conducted the other interviews. At least two team members participated in each of the 12 PRO case study site visits. Inspection interviews ranged up to 5 hours with an average length of 2 hours. We informed all participants interviewed for this study that the confidentiality of their specific responses to questions would be maintained, unless otherwise cleared by them.

As part of our quality control plan, the project leader assigned one person to be the project's administrative coordinator. That individual developed and maintained a tracking system for all discussion guides, correspondence, supplementary materials, and a master schedule of team interviews.

Coding and Analysis

We designed three primary and six relational data files, using dBASE III PLUS, to store and tabulate interview responses. We developed codes for all questions and one team member usually coded all questions in a given file to maximize coding consistency. In addition, a different team member checked at least a 20 percent random sample of the files to ensure accuracy. As part of the PRO inspection team's quality control plan, the project leader assigned one team member to be the project's data coordinator. In addition to having primary responsibility for designing the PRO data base, that individual was also responsible for developing and enforcing data-related quality control procedures.

We used dBASE III PLUS to tabulate all interview data by respondent group (i.e., PRO CEOs, other PRO staff and board, HCFA, national external entities, and local external entities).

Other PRO-Related Data

In addition to interview data, we collected and analyzed other PRO-related data including HCFA's monthly and quarterly data summary reports for all PROs and HCFA's PROMPTS and SuperPRO reports for the 12 PRO case study sites. Because complete and accurate sanction data was unavailable from HCFA, the team used information provided by the OIG's Office of Investigations as a basis for its sanction data analysis. The team classified rural

and urban sanctions based on whether the particular physician's address fell within a Standard Metropolitan Statistical Area (SMSA) as defined by the U.S. Bureau of Census. Information on the numbers of rural and urban physicians for 1985 was provided by the Public Health Service, Bureau of Health Professions. Information on the number of physicians eligible for Medicare reimbursement as of January 1, 1987 was obtained from HCFA, Bureau of Program Operations.

We also collected and reviewed a wide array of other materials concerning PROs, including newspaper and journal articles, congressional hearings, and GAO, Library of Congress, OIG, and other studies and audits.

Methodological Considerations in Interpreting PRO Interview Data

The reader should keep three caveats in mind when reviewing this report. First, because we wanted to give as comprehensive a view of PROs as possible, we have integrated the case study data with the universal data. The case study data is generally used to amplify broader-based findings, and such data is always clearly labeled. Although we used a judgmental rather than random sampling methodology for choosing the case study sites, it is worth noting that those sites are broadly representative of PROs by size, geographic location, and sanction activity level.

A second caveat to keep in mind is that although we interviewed a total of 211 individuals, a given question may have been directed to only a subset of that universe. Therefore, in this report, we have sought to clarify the number of people responding to a given question by noting the universe of respondents (N=____) in all relevant summary tables and figures.

The third but perhaps most important consideration to highlight is that much of the information gathered in this study came from questions with both closed and open-ended parts (e.g., "Do you have any recommendations to the Federal Government regarding actions it might take that would help PROs be more effective in addressing quality of care issues?" Explain.) Because we chose not to distribute the discussion guides prior to the interviews, the open-ended questions required the respondent to spontaneously formulate his or her answers. Therefore, the percentages of people noting any particular answer vary much more than if the respondents had been presented with limited response options or had reviewed the discussion guides prior to the interviews.

APPENDIX IV

SUMMARY OF PRO-RELATED STUDIES

Because the PRO program is vital to the Medicare program and exists within a highly visible political arena, several entities have evaluated the program. The following is a summary of some key studies related to the PROs:

A. Past Studies

The Congressional Research Service (CRS):

- o "The Peer Review Organization Program," October 23, 1987: The study presented a summary of the legislative history, program features, and relevant issues of the PRO program. The CRS report was prepared at the request of the House Committee on Energy and Commerce, Subcommittee on Health and the Environment. It revised a prior report prepared at the request of the Senate Committee on Finance.

The General Accounting Office (GAO):

- o "Medicare: Improving Quality of Care Assessment and Assurance," May, 1988: This study assessed current systems for measuring and monitoring Medicare quality of care and reviewed quality assessment research and evaluation within the DHHS, analyzed its relationship to ongoing quality assessment functions, and assessed the need for long term changes. Among other suggestions, the GAO recommended evaluations of the methods PROs use to review medical records, the utility of current methods for establishing the PROs' quality of care contract objectives, and the quality of care in Medicare prepaid health plans. The GAO also recommended that formal guidelines be developed to coordinate the reporting of possible quality problems by carriers and intermediaries to PROs and HCFA; that studies be initiated to assess the strengths and weaknesses of the division of responsibilities among carriers, intermediaries and PROs for processing and screening Medicare claims data and performing medical reviews to identify quality of care problems and substandard providers and suppliers; that PROs, intermediaries and carriers document and report incidents of inaccurate data elements related to quality of care; and, that data used to evaluate PRO medical records include the information necessary to generate national estimates of quality problems.

- o "Medicare: Improved Patient Outcome Analyses Could Enhance Quality Assessment," June, 1988: This study explored how outcome data can be used to monitor quality of care and included a review of how PROs' use available data in their profiling of providers.
- o "Strategies for Assessing Medicare Health Care Quality," December 30, 1987: The study evaluated the systems for assessing quality of care in the Medicare program (i.e., carriers, intermediaries, and PROs) and identified short- and long-term strategies for measuring and monitoring quality of care. Among other suggestions, the GAO recommended that HCFA: review the PROs' methods for dealing with quality issues; evaluate the spheres of responsibilities of the PROs, FIs, and carriers to determine that their responsibilities are appropriately divided; require the PROs, FIs, and carriers to maintain data related to quality; require that patient diagnoses be recorded on Medicare outpatient Part B claims and develop HCFA data files of that Part B information; and develop a mechanism to allow SuperPRO to evaluate PRO cases that were selected through both the PROs' random sample and specific samples of hospital records.
- o "Better Controls Needed for Peer Review Organizations' Evaluations," October 8, 1987: The study assessed HCFA's evaluation process for the 1986-1988 contract awards and concluded that HCFA's process was fraught with inconsistent and inadequate documentation and improper application of instructions. Although GAO found no evidence of inappropriate contract decisions, it recommended that HCFA develop sufficient internal controls for PRO evaluation, provide better ongoing monitoring to the PROs and collect and use adequate cost and performance data to set each PRO's contract funding level.
- o "Reviews of Quality of Care at Participating Hospitals," September 15, 1986: The study was based on a survey of California, Florida, and Georgia PROs, and focused on the monitoring of inappropriate discharges and profiling of hospital and physician quality of care problems. The GAO recommended that HCFA require PROs to include quality of care review data available from the 1984-1986 contract period in their profiling of hospitals and physicians and that the PROs review the appropriateness of the discharge destinations as part of their discharge reviews to better ensure that patients needing skilled nursing care are allowed to remain in the hospital while awaiting placement.

The Prospective Payment Assessment Commission (PropAC):

- o "Report and Recommendations to the Secretary, U.S. Department of Health and Human Services," April 1, 1986: PropAC, which is an independent commission established by Congress to analyze and recommend changes in the prospective payment system, recommended in its second annual report that better information about PPS be provided to beneficiaries, hospitals, and physicians. PropAC also recommended that PRO review be extended to the overall episode of care, including skilled nursing facilities, home health care and outpatient surgery.

The Rand Corporation:

- o Kathleen N. Lohr, "Peer Review Organization: Quality Assurance in Medicare," July 1985: Study focused on the first scope of work for PROs' review of quality during the first 2 years of PPS. Rand recommended that the quality objectives in the 1984-1986 PRO contracts be broadened to include the use of generic screens and that quality review be given greater weight in the PRO review activities. Rand also recommended that the PROs' quality review be extended beyond the hospital to include the Medicare beneficiary's entire episode of care.

B. Current and Future Studies by the GAO

- o The Financial Integrity Act Group at GAO is currently reviewing the internal controls for payments by Medicare intermediaries. As part of that study, the group is assessing the effectiveness of the SuperPRO as a control mechanism for PRO performance. A draft report was issued July 22, 1988.
- o At the request of the House Ways and Means Committee, the PEMD is currently conducting a study to evaluate the PROs' effectiveness in handling of quality of care issues. Preliminary descriptive findings are expected in late 1988.
- o The Human Resources Division (HRD) is undertaking a review of two aspects of the PRO program: an analysis of the reasons for the lack of information exchange between the PROs and other quality review entities and an examination of the DHHS/OIG's criteria for accepting and rejecting PRO recommendations for monetary penalties.

See appendix II for a summary of the OIG's past and current work related to the PRO program.

APPENDIX V

THE PROS WITH MORE THAN ONE CONTRACT*

<u>Organization Name/Location</u>	<u>Additional PRO Areas Reviewed</u>
Professional Review Organization. for Washington Seattle, WA	Alaska Idaho
West Virginia Medical Institute, Inc. Charleston, WV	Delaware
Delmarva Foundation for Medical Care, Inc.. . . . Easton, MD	District of Columbia
Hawaii Medical Services Association Honolulu, HI	Guam/American Samoa
PEERVIEW, Inc.. Carmel, IN	Kentucky
Health Care Review, Inc.. Providence, RI	Maine
Iowa Foundation for Medical Care. West Des Moines, IA	Nebraska
New Hampshire Foundation for Medical Care Dover, NH	Vermont
Montana-Wyoming Foundation for. Medical Care Helena, MT	Wyoming

*Note: Eight PROs hold two contracts; one PRO holds three contracts.

APPENDIX VI

COMPARISON OF 1984 SCOPE OF WORK TO 1986 SCOPE OF WORK

<u>Review Area</u>	<u>1984</u>	<u>1986*</u>
Objectives	3 Admission Objectives 5 Quality Objectives All proposed and validated by PROs. Very limited areas for focusing objectives	5 Objectives Based on PRO data from first 90 days of generic quality screen review. HCFA-identified outliers. Broader objectives
Random Samples	5% Admission Sample DRG Sample ranging from 3% to 100% based on hospital discharge size	3% random sample (includes 1- and 2-day stays)
Preadmission Review	5 Procedures proposed by PRO	Pacemakers plus 4 procedures proposed by PRO
Pacemakers	100% retrospective	100% preadmission (see above)
Transfers	From PPS to another hospital, exempt unit, swing bed	Same but lower level of review
Readmissions	All readmissions within 7 days	All readmissions within 15 days
Medicare Code Editor	100% of 9 diagnoses	Same
Focused DRGs	468 (462 added during contract period)	468, 462, 088
Outliers	100% (reduced to 50% during contract period)	50%
Percutaneous Lithotripsy	Not in contracts	Review all claims for percutaneous lithotripsy in hospitals which have an extra-corporeal shock wave lithotripter

<u>Review Area</u>	<u>1984</u>	<u>1986*</u>
Validation of Objectives	Not in contracts	Sample of one quarter's discharges to validate objective performance
Hospital Notices	100% where patient or physician disagrees. 100% where patient is liable. 10% of remaining	Same
Specialty Hospital Review	Proposed by each PRO	15% of discharges
Admission Pattern Monitoring	Discontinued during contract	Not in Scope of Work
Intensified Review	Trigger: 2.5% or 3 cases (whichever is greater) of cases reviewed Review increased to: 100% or subsets	Trigger: 5% or 6 cases (whichever is greater) of cases reviewed. Review increased to: 50% or subsets (first quarter) 100% or subsets (two or more consecutive quarters)
Community Outreach	Not in contracts	All PROs to propose program
		*All cases reviewed are subject to generic quality screens, discharge review, admission review, DRG validation, and coverage review.

Source: HCFA

APPENDIX VII

SANCTION PROCEDURES FOR CASES OF GROSS AND FLAGRANT AND SUBSTANTIAL NUMBER OF SUBSTANTIAL VIOLATIONS

The following chart summarizes the steps that a PRO and the Department of Health and Human Services must follow in reviewing the health care services rendered to Medicare beneficiaries by individuals or entities and in determining whether statutory violations have occurred. Because of the extreme seriousness of "gross and flagrant violations," the two-tier review process treats those cases more expeditiously than cases of "substantial number of substantial violations."

SUBSTANTIAL VIOLATIONS IN A SUBSTANTIAL NUMBER OF CASES

Definition - A pattern of care has been provided that is inappropriate, unnecessary, or does not meet recognized professional standards of care, or is not supported by the necessary documentation of care, as required by the PRO.

42 C.F.R. Section 1004.1(b).

Step 1 - Written notice of a potential violation by the PRO. Subject has 20 days to request a meeting and/or submit additional material to explain, clarify, or resolve the potential violations.

42 C.F.R. Section 1004.40.

Step 2 - PRO review of additional material submitted and/or the meeting.

Step 3 - If the PRO determines that a violation has occurred, it attempts to develop a corrective action plan, which is agreed to by the provider or practitioner, to resolve the case.

GROSS AND FLAGRANT VIOLATION

Definition - A violation of an obligation has occurred in one or more instances which presents an imminent danger to the health, safety or well-being of Medicare beneficiary or places the beneficiary in high risk situations.

42 C.F.R. Section 1004.1(b).

Written notice of a potential violation by the PRO. Subject has 30 days to ask for a meeting and/or submit additional material to explain, clarify, or resolve the potential violations.

42 C.F.R. Section 1004.50.

PRO review of additional material submitted and/or the meeting. On the basis of additional information received, the PRO may affirm, modify, or reverse its determination.

42 C.F.R. Section 1004.50(c).

PRO proceeds to Step 6.

Step 4 - In those cases unresolved at Step 3, the PRO is to provide written notice to a provider or practitioner that possible violations have been identified. Subject has 30 days to request a meeting and/or submit additional material to explain, clarify, or resolve the potential violations.
42 C.F.R. Section 1004.50.

Step 5 - Second meeting between the PRO and the provider or practitioner and/or review or additional material submitted.

Step 6 - At the conclusion of the above process and following consideration of all the information presented by provider or practitioner, if the PRO comes to the conclusion that a violation has occurred which should be the subject of a sanction action by the Department, it is required to send its recommendation for imposition of a sanction and a supporting report to the OIG for independent review. The PRO must notify the individual or entity that there is an additional opportunity to submit information regarding the violations, and that this information should be sent to the OIG. 42 C.F.R. Sections 1004.60-80.

Step 7 - After reviewing the PRO's recommendations and any additional material submitted by the provider or practitioner, the OIG must determine: (1) whether the statutory and regulatory requirements have been complied with; (2) whether an adequate legal and medical basis exists for imposing a sanction; (3) the appropriate sanction to be imposed. The OIG can exercise one of several options. It can: (1) sustain the PRO's recommendation in its entirety; (2) alter the recommendation; or (3) reject the recommendation. If OIG fails to act within 120 days, an exclusion recommended by a PRO is automatically imposed.

The sanctions that the Secretary may impose on a provider or practitioner following a PRO's recommendation are either exclusion from participation in the Medicare program or, in lieu of exclusion, the imposition of a monetary penalty as a condition for continued eligibility to receive reimbursement under the Medicare program. 42 C.F.R. Section 1004.90.

Step 8 - A provider or practitioner who wishes to appeal the imposition of a sanction has the right to a formal administrative hearing in accordance with Section 205(b) of the Act. (42 U.S.C. 405(B)). This hearing, conducted in accordance with specified procedures (42 C.F.R. Part 405, Subpart 0), is de novo, and the

entire factual basis of the case is presented to a Departmental administrative law judge (ALJ). Each side may present evidence and witnesses, and each has the right to cross-examination. The ALJ is required to issue a decision sustaining, modifying, or dismissing the sanction, and setting forth findings of fact and conclusions of law. 42 C.F.R. Section 498.74.

Step 9 - Subsequent to the administrative hearing, review of the ALJ decision by the Departmental Appeals Council may be requested. 42 C.F.R. Sections 498.80-95.

Step 10 - After the Appeals Council renders a decision, a provider or practitioner has a right to request judicial review of the Department's decision, in accordance with Section 205(g) of the Act, 42 U.S.C. 405(g).

(Source: Summary taken from the transcript of Inspector General Richard P. Kusserow's testimony before The House Committee on Government Operations, Human Resources and Intergovernmental Relations Committee, October 20, 1987.)

APPENDIX VIII

SUMMARY OF RECENT PRO-RELATED LEGISLATIVE PROVISIONS

A. STATUS OF IMPLEMENTATION OF COBRA 1985 PROVISIONS

Assistants at Cataract Surgery

- o Provides that no Medicare payment may be made for an assistant surgeon at cataract surgery unless carrier or PRO approves use of assistant before procedure is performed. Also prohibits physician from knowingly and willfully billing Medicare beneficiary if he or she has not obtained prior approval and where presence of assistant surgeon has been found to be unnecessary.
- o Instructions for PRO review of this activity, effective with assistants proposed to be used after March 1, 1987, were issued to PROs on December 30, 1986, and review has been implemented.

PRO Denials for Substandard Care

- o Provides for denial of payment when a PRO determines that the quality of health care services rendered to a Medicare beneficiary fails to meet professionally recognized standards of health care. Also specifies that denials for care of substandard quality shall be made only on the basis of criteria which are consistent with guidelines established by the Secretary.
- o Formal rule-making process is being followed. Regulations are in the final stages of Departmental clearance and will be published soon.

PRO 100 Percent Preprocedure Review

- o Requires peer review on a preadmission/preprocedure basis of nonemergency cases for at least 10 surgical procedures. Second opinion will be required if PRO cannot make determination as to medical necessity of services.
- o Formal rule-making process will be followed. Proposed regulations are still in process of Departmental clearance.

B. STATUS OF IMPLEMENTATION OF OBRA 1986 PROVISIONS

- Review of services provided in hospital outpatient departments and ambulatory surgical centers. Effective for PRO contracts entered into or renewed on or after January 1, 1987. This provision has been implemented by the Pennsylvania PRO, which entered a new contract period on July 1, 1987. It will be implemented by other PROs as they enter their next contract periods.
- Review of hospital denial notice. Implemented on December 1, 1986, as required by the statute.
- FIs must provide PROs with "timely" monthly information, or hospitals will be required to provide such information directly to the PROs. Effective April 1, 1987.
- Review of at least a sample of readmissions occurring within 31 days of discharge and any intervening post-hospital care. Effective for contracts entered into or renewed on or after January 1, 1987. This provision has been implemented by the Pennsylvania PRO and will be implemented by the other PROs as they enter their next contract periods.
- A reasonable proportion of PRO funds must be allocated to review of quality of care provided in all settings. The HCFA has no plans for separate implementation of this provision. It will be implemented as part of other OBRA provisions.
- Review of HMOs/CMPS. The HCFA published a listing of States to be competitively bid in the Federal Register on January 6, 1987. Contracts have been awarded in those States where it is applicable. Review began July 1, 1987.
- The Secretary is to identify and make available to PROs methods of identifying those cases that are more likely than others to be associated with substandard quality of care, and to provide at least 12 PROs with data and data processing assistance to perform small-area analysis. Both provisions effective upon enactment. The first is an ongoing activity. The HCFA has contracted with the American Medical Review Research Center (AMRRC) for the small-area analysis which will utilize feedback from 12 pilot PROs. Information is presently being gathered.

- PRO boards must include at least one consumer representative. Effective with contracts entered into or renewed on or after January 1, 1987. Officially implemented with new contracts, but most PROs have already implemented this provision.
- PROs must respond to beneficiary complaints about poor quality care provided in all settings. Implemented October 1, 1987. PROs had already been required to respond to complaints referred to them and will continue to do so. Clarifying regulations in process.
- PROs will be required to share (when requested) information relating to substandard care with State licensure or certification bodies and with national accrediting bodies. Effective April 1, 1987. Clarifying regulations in process regarding exchange of information with licensure boards. Clarifications regarding exchange with State Medicaid agencies have been published.
- Hospitals, home health agencies, HMOs and skilled nursing facilities will be required to have agreements with PROs, under which costs of PRO review activities are to be paid by the Secretary to the PRO. Effective October 1, 1987. Will be implemented by the PROs as they enter their next contract periods.

Source: HCFA/HSQB/OMR.

C. Other PRO-Relevant Legislation

- The Medicare and Medicaid Patient Program Protection Act of 1987 greatly expanded the sanction and civil monetary penalty authorities under the Medicare and Medicaid programs. The bill also required the reporting of all disciplinary actions made by State medical licensure boards.
- The recently enacted 1987 Omnibus Budget Reconciliation Act has made the following PRO changes:
 - three-year PRO contracts with staggered expiration dates;
 - a ban on informing Medicare beneficiaries of substandard quality payment denials before offering providers the opportunity for reconsideration;
 - publication in the Federal Register of the standards used for evaluating the PROs and any new

policy or procedure that substantially affects the performance of contract obligations;

- o negotiation of appropriate contract modifications before implementation of additional review functions not included in the initial or renewed contract;
- o provisions by the Secretary of regular performance reports to each organization comparing its performance with other PROs';
- o a prohibition of automatic renewals of PRO contracts held by out-of-State groups, provided in-state physician groups wish to compete;
- o requirement that the hospital notify the Medicare patient when the hospital requests PRO review because the hospital and the attending physician do not agree that inpatient care is no longer necessary;
- o a ban on physicians billing Medicare patients for assigned claims denied for payment on grounds of substandard quality;
- o a requirement that PROs, in establishing review standards, take into account the special problems associated with delivering care in remote rural areas, the availability of service alternatives to inpatient hospitalization, and social factors that could adversely affect the safety or effectiveness of outpatient treatment;
- o mandatory onsite review at 20 percent of rural hospitals in a review area;
- o requirement that PROs offer for PRO physician to meet several times a year with medical and administrative staff of hospitals in their review area;
- o requirement that PROs publish and distribute to providers and practitioners, at least annually, a report describing the types of cases the PROs frequently determine involve inappropriate or unnecessary care, services rendered in an inappropriate setting, or substandard care;
- o assessment of access provided to Medicare enrollees in risk-sharing HMOs and CMPs and

mandatory beneficiary outreach to inform enrollees about the role of the PRO and their rights;

- o a provision encouraging PROs to use physician specialists in initial review of psychiatric and rehabilitation cases;
- o emphasis, when evaluating PRO performance, on the PROs' activities in educating providers and practitioners, particularly those in rural areas, about PRO review and criteria;
- o demonstration projects for the instruction and oversight of rural physicians, in lieu of imposing sanctions, through video telecommunications between Medicare teaching hospitals and rural hospitals;
- o entitlement of a provider or practitioner located in a rural health manpower shortage area, or in a county with a population of less than 70,000 to an administrative law judge hearing prior to being excluded from the Medicare program, to determine whether the provider or practitioner poses a serious risk to his or her patients;
- o a report to Congress to include an assessment of sanction due process reforms agreed to by HHS, the American Medical Association, and the American Association of Retired Persons, as well as physician and provider responses to the improved procedures and an assessment of the appropriate balance between procedural fairness and the need for ensuring quality medical care.

Source: Congressional Record--House, December 21, 1987.

APPENDIX IX

MEMORABLE "PRO-ISMS"

We appreciated the candor and thoughtfulness with which individuals responded to our questions about the PRO program. In an effort to share more of those diverse opinions than could be integrated into the main body of this report, we offer the following examples of memorable opinions that we heard related to the PROs' quality review and sanction activities (i.e. "PRO-isms"):

In regard to quality review:

"It's like feeding the hungry--everyone agrees it is important, but no one wants to go down to the mission and do it" (from a PRO CEO).

"Quality review is carried out too much and too long on the written record...the Government came in with a ball and chain and a meat ax" (from a medical community representative).

In regard to the generic quality screens:

"They're so good it's scary" (from a PRO medical director).

"They're so frustrating, they make me scream" (from a PRO medical director).

In regard to the PROs' upcoming review of care in nonhospital settings:

"They're invading the last bastion of individuality" (from a State medical board representative).

"They will see us like a lynching squad in the community and we will meet with hostility" (from a PRO board chair).

In regard to health care in rural versus urban settings:

"Just because you're out in the sticks, doesn't mean you treat people differently" (from a PRO CEO).

"You simply cannot practice the same medicine in Muleshoe, Texas as Dallas, Texas. You can call that two-tier medicine or whatever you want" (from a medical community representative).

In regard to the use of sanctions:

"It's important to remember that most doctors are competent most of the time and all doctors are incompetent some of the time" (from a medical community representative).

"Once you get a sanction in doctors' hands, their hearts and minds will follow" (from a HCFA representative).

"We have a moral obligation to underaccuse more than overaccuse" (from a PRO medical director).

"The only way to affect physicians is through their back pockets" (from a PRO board chair).

"They (sanctions) make us the most hated group in the State...but they (physicians) read their mail now" (from a PRO staff person).

"They require us to have a lot of intestinal fortitude" (from a PRO CEO).

Medicare

Peer
Review
Organization
Manual

ADVANCE COPY
OF FINAL ISSUANCE

Department of Health
and Human Services
Health Care Financing
Administration

Transmittal No. 15

Date MAY 1987

<u>NEW MATERIAL</u>	<u>REVISED PAGES</u>	<u>REPLACED PAGES</u>
Table of Contents Part 6	6-1 (1p.)	6-1 (1p.)
Section 6025	6-12 - 6-12.3 (4pp.)	6-11 - 6-12 (2pp.)
Table of Contents Part 12	12-1 (1p.)	12-1 (1p.)
Exhibits 2-3	12-7 - 12-8.4 (10pp.)	12-5 - 12-8 (4 pp.)
Exhibit 5	12-17 - 12-17.4 (5 pp.)	12-17 - 12-18 (2 pp.)
Exhibit 7	12-23 - 12-23.1 (2 pp.)	12-23 - 12-24 (2 pp.)

NEW PROCEDURES - EFFECTIVE DATE: May 12, 1987

Section 6025, Procedures for Discussions with Providers/Practitioners
Following the 30 Day Notice Letter Specified in 42 C.F.R. §1004.50.--This section defines the procedures the PRO is required to follow when holding discussions with providers/practitioners subsequent to sending the 30 day notice specified in 42 C.F.R. §1004.50.

Exhibits 2, 3, 5, 7, Model Letters.--These exhibits provide the PRO with model letters to use in the following instances:

- Exhibit 2 - Initial Sanction Notice of a Substantial Violation in a Substantial Number of Cases.
- Exhibit 3 - Second Sanction Notice of Substantial Violation in a Substantial Number of Cases.
- Exhibit 5 - Initial Sanction Notice of Gross and Flagrant Violation.
- Exhibit 7 - PRO Sanction - Model Final Notice of Sanction.

PROs ARE REQUIRED TO USE THESE MODEL LETTERS

6025. PROCEDURES FOR DISCUSSIONS WITH PROVIDERS/PRACTITIONERS
FOLLOWING THE 30 DAY NOTICE LETTER SPECIFIED IN 42 C.F.R. §1004.50

The meeting between the PRO and a provider or practitioner under 42 C.F.R. §1004.50 is intended to be a discussion between the members of the PRO and the provider or practitioner regarding the medical issues raised by the PRO. This medical dialogue is not designed to be a formal adversarial hearing, but it should afford the provider or practitioner a full and fair opportunity to present his/her views. The PRO has a crucial duty to protect Medicare patients and the Medicare program, but, given the serious nature of the sanction, it also has a duty to allow the provider or practitioner to understand the basis of the allegations and to provide an explanation of the challenged conduct. The purpose of the discussion is to allow the provider or practitioner to present his/her views regarding the care rendered to Medicare beneficiaries in the identified cases, to discuss those views with the PRO, and to respond to the PRO's initial determination that such care failed to comply with the statutory obligations of §1156 of the Social Security Act, 42 U.S.C. §1320c-5. It is also an opportunity for the provider or practitioner to address the issue whether the provider or practitioner has the ability and willingness to comply with such statutory obligations.

The discussion between the PRO and the provider or practitioner pursuant to 42 C.F.R. §1004.40 (following a 20-day notice) is intended to serve similar purposes to those discussed above. However, the discussion following the 20-day notice may, at the PRO's discretion, be more informal, since all providers and practitioners are entitled to a discussion under §1004.50, with the procedures set out in this section of the Manual, before a sanction can be recommended to the Office of Inspector General.

A full adversarial hearing before an administrative law judge, which is not limited to the record created before the PRO, is provided following the imposition of a sanction by DIG. At that time, the DIG, with the assistance of the recommending PRO, has the burden of proof, and the sanctioned provider or practitioner is entitled to such procedures as the right to request that the ALJ subpoena witnesses who are necessary for a full presentation of a case and require that they appear, bring documents, and testify. (See 42 C.F.R. Part 405, Subpart O.)

A. Notice.--Prior to a discussion with a provider or practitioner pursuant to 42 C.F.R. §1004.50 the PRO should insure that the provider or practitioner has been informed of the PRO's initial findings, including a clear statement of the factual bases for those findings, the purpose of the proposed meeting, the potential sanctions which may be imposed, the importance of the discussion of the PRO sanction process, and the procedures applicable to the meeting, including the availability of the procedures outlined in the model letters. The notice should inform the provider or practitioner that he/she should bring to the meeting all relevant documentation (including office records) regarding the cases in question, and a lawyer and/or witnesses, if desired. The written notice to be sent to the provider or practitioner pursuant to 42 C.F.R. §1004.50 should be sent by certified mail, return receipt requested.

NOTE: The model letters have been amended to conform with this section. See Exhibits 2, 3, 5 and 7.

B. Attorneys.--The provider or practitioner may have an attorney present at the discussion. The attorney will be permitted to counsel the provider or practitioner, assist the provider or practitioner in the presentation of his/her witnesses, ask for clarification of PRO procedures and questions posed to the provider or practitioner or expert witness, and present brief opening and closing statements. The attorney may ask questions designed to clarify the basis for the PRO's conclusions. The PRO, however, may control the scope, extent, and manner of questioning, as appropriate, if the questions are unproductive or irrelevant, are badgering, unduly prolonged, or otherwise inappropriate in tone or nature, or for any other appropriate reason.

C. Scheduling and Conduct of Meeting.

1. If a provider or practitioner requests a discussion pursuant to 42 C.F.R. §1004.50, the PRO should attempt to schedule the meeting within 30 days from the date of receipt of the request, unless the PRO, in its discretion, determines that good cause exists to postpone the meeting. In the case of availability of expert witnesses, "good cause" will require the provider or

practitioner to demonstrate that reasonable efforts have been made to have such witnesses available to testify within the 30 day period, but that a delay, of the minimum necessary duration, is justified. To aid in prompt preparation for the discussion, a provider or practitioner, directly or through counsel, may disclose patient records to potential expert witnesses without violating any non-disclosure requirements in the regulations.

2. The PRO shall seek to ensure that the objectivity and judgment of all physician-members of the panel making any final PRO determination of a violation under 42 C.F.R. §1004.60 shall not be affected by either personal bias against, or direct economic competition with, the subject provider or practitioner.
3. At the meeting, the PRO shall afford the provider or practitioner with the opportunity to present expert testimony in either oral or written form on the medical issues presented with the assistance of an attorney, but may reasonably limit the number of witnesses and length of such testimony, if such testimony is irrelevant or repetitive.
4. The PRO shall be required to prepare a record of the meeting and make a copy available to the provider or practitioner when the PRO's recommended sanction (if any) is sent to the DIG. The record shall include a verbatim transcript.
5. A physician who, at the last stage prior to the meeting between the PRO and the provider or practitioner, was solely or primarily responsible for making medical judgments and developing the record and initial findings to be used at the discussion shall not vote on the PRO's final determination about whether or not to recommend a sanction to the DIG. (This does not apply, for example, to a physician, such as a PRO medical director, who summarizes the views of other physicians in assembling the record and findings for use at the discussion.)
6. In the discretion of the PRO, it may be helpful for the physician referred to in paragraph 5 to be present at the meeting in order to have an efficient and full discussion of the issues relating to the sanction recommendation.
7. The PRO has no obligation to consider any additional information provided by the provider or practitioner subsequent to the meeting. However, prior to the end of the meeting with the PRO, if the provider or practitioner believes that additional documentation exists which relates to the cases or issues

discussed at the meeting, he/she may request an additional period of time, not to exceed 5 days, to submit the relevant information to the PRO. If the PRO concurs that the additional information to be provided by the provider or practitioner is relevant and necessary to the issues and cases discussed, it will grant an additional period of time, not to exceed 5 days from the date of the meeting, for the submission of this information. The provider or practitioner is always entitled to submit additional information to the Office of Inspector General, within the timeframes authorized by 42 C.F.R. §1004.60(b)(2).

D. Basis for Recommended Sanction.--If the PRO determines, after the discussion, that it will recommend a sanction to the OIG, it shall include as an attachment to the Final Sanction Notice to the provider or practitioner (exhibit 7), its own clear statement of the factual bases for each violation.

APPENDIX XI

INTRODUCTION TO TABLES A - D

This appendix consists of four tables presenting analyses of sanction data for the PRO areas (herein referred to as States). Each table includes detailed footnotes which explain and qualify the data as appropriate. The reader is cautioned about comparisons among the tables which may include different subsets of the sanction data.

The following caveats are particularly important:

- o While tables A and C include sanction data for doctors of medicine and osteopathy as well as for hospitals, tables B and D contain only sanction data for doctors. Therefore, the number of sanctions listed for each State will differ between the two sets of tables for those States that have referred hospitals for sanction.
- o As of December 31, 1987, several States had referred sanction cases that were still pending action by the OIG. Therefore, the sum of the cases accepted and rejected on table C will be less than the number of cases referred for sanction.
- o All tables include two cases in which the physician referred for sanction died prior to an OIG sanction determination. These cases have been reflected as "rejections" in the tables, but footnoted accordingly.
- o In tables B and D, the total numbers of physicians listed per State are different because: (1) they represent different time periods, (2) include different definitions of "physician", and (3) were obtained from different data sources. We chose to use both sources of physician data despite these limitations because they are the most current data available.
- o Because approximately 15 percent of the number of physicians per State listed in table B are limited license practitioners (chiropractors, podiatrists and optometrists), the ratios of sanction referrals and acceptances per 1000 physicians listed are underestimations of the actual ratios per 1000 medical doctors. It was necessary to use such aggregated data because figures including only medical doctors were unavailable.
- o The small numbers of sanction referrals and acceptances tend to inflate the numbers reflected in the "Percent" columns of tables A and D.

APPENDIX XI: TABLE A
NUMBER OF PRO SANCTION REFERRALS AND NUMBER AND PERCENT
OF OIG ACCEPTANCES, BY STATE, (1985-1987)

STATE	PRO REFERRALS (1)			OIG ACCEPTANCES (1)			PERCENT ACCEPTED BY OIG
	GF (2)	SNS (3)	TOTAL	GF	SNS	TOTAL	
Arizona	2.00	1.00	3.00	0.00	1.00	1.00	33.33
Arkansas	6.00	3.00	9.00	2.00	1.00	3.00	33.33
California	16.00	3.00	19.00	12.00	2.00	*****	73.68
Colorado	2.00	0.00	2.00	2.00	0.00	2.00	100.00
District of Columbia	1.00	0.00	1.00	0.00	0.00	0.00	0.00
Florida	2.00	1.00	3.00	2.00	0.00	2.00	66.67
Georgia (4)	1.00	1.00	2.00	0.00	1.00	1.00	50.00
Idaho	0.00	1.00	1.00	0.00	0.00	0.00	0.00
Illinois (4)	2.00	2.00	4.00	0.00	1.00	1.00	25.00
Indiana	0.00	1.00	1.00	0.00	1.00	1.00	100.00
Iowa	7.00	1.00	*9	3.00	1.00	*5	56.00
Kansas	3.00	2.00	5.00	2.00	1.00	3.00	60.00
Kentucky	3.00	4.00	7.00	1.00	1.00	2.00	28.57
Louisiana	1.00	0.00	1.00	0.00	0.00	0.00	0.00
Maine	0.00	1.00	1.00	0.00	1.00	1.00	100.00
Maryland	0.00	1.00	1.00	0.00	1.00	1.00	100.00
Michigan (4)	2.00	1.00	3.00	0.00	1.00	1.00	33.33
Minnesota	1.00	0.00	1.00	0.00	0.00	0.00	0.00
Mississippi	3.00	1.00	4.00	1.00	0.00	1.00	25.00
Missouri	2.00	1.00	3.00	0.00	1.00	1.00	33.33
Montana	1.00	0.00	1.00	0.00	0.00	0.00	0.00
Nevada	1.00	0.00	1.00	0.00	0.00	0.00	0.00
New Hampshire	1.00	0.00	1.00	0.00	0.00	0.00	0.00
New Jersey	3.00	1.00	4.00	2.00	0.00	2.00	50.00
New York	2.00	0.00	2.00	2.00	0.00	2.00	100.00
North Carolina (4)	3.00	1.00	4.00	1.00	0.00	1.00	25.00
North Dakota	0.00	1.00	1.00	0.00	0.00	0.00	0.00
Ohio	6.00	0.00	6.00	3.00	0.00	3.00	50.00
Oklahoma	1.00	2.00	3.00	1.00	0.00	1.00	33.33
Oregon	1.00	0.00	1.00	1.00	0.00	1.00	100.00
Pennsylvania	2.00	0.00	2.00	2.00	0.00	2.00	100.00
South Dakota	0.00	1.00	1.00	0.00	1.00	1.00	100.00
Tennessee (4)	3.00	0.00	3.00	1.00	0.00	1.00	33.33
Texas	23.00	0.00	23.00	20.00	0.00	*****	86.96
Utah (4)	0.00	1.00	1.00	0.00	0.00	0.00	0.00
Virginia	4.00	1.00	5.00	4.00	1.00	5.00	100.00
Washington	5.00	1.00	6.00	3.00	1.00	4.00	66.67
West Virginia	1.00	1.00	2.00	1.00	1.00	2.00	100.00
Wisconsin	3.00	1.00	4.00	2.00	0.00	2.00	50.00
TOTAL	*****36.00		*151	68.00	*****	*87	58.00

Source: OIG/ Office of Investigations.

- (1) Referrals and acceptances for hospitals and doctors of medicine and osteopathy through 12/31/87. Referrals include two cases (CA and MO) in which the physician died before OIG decision.
- (2) Gross and flagrant violations.
- (3) Substantial number of substantial violations.
- (4) States with cases pending decision in OIG as of 12/31/87.

* TOTAL referrals and acceptances greater than sum of GF and SNS cases because referred and accepted cases include one (IA) for lack of documentation.

Note: No sanctions referred for : Alabama, Alaska, American Samoa/ Guam, Connecticut, Delaware, Hawaii, Massachusetts, Nebraska, New Mexico, Puerto Rico, Rhode Island, South Carolina, Vermont, Virgin Islands, and Wyoming.

APPENDIX XI: TABLE B
NUMBER OF PHYSICIAN SANCTION REFERRALS, OIG ACCEPTANCES,
PER 1000 PHYSICIANS, BY STATE (1985-1987)

STATE	NUMBER OF PHYSICIANS (1)	NUMBER SANCTIONS REFERRED	REFERRALS PER 1000 PHYSICIANS	NUMBER SANCTIONS ACCEPTED	ACCEPTANCES PER 1000 PHYSICIANS
AR	5,816	8	1.38	3	0.52
IA	7,656	8	1.04	5	0.65
KS	5,549	5	0.90	3	0.54
MS	4,595	4	0.87	1	0.22
SD	1,375	1	0.73	1	0.73
WI	6,229	4	0.64	2	0.32
ND (3)	1,569	1	0.64	0	0.00
KY	11,266	7	0.62	2	0.18
ID	1,914	1	0.52	0	0.00
MT	1,977	1	0.51	0	0.00
WA	12,055	6	0.50	4	0.33
WV	4,110	2	0.49	2	0.49
TX	50,537	23	0.46	20	0.40
NV	2,280	1	0.44	0	0.00
OK	7,057	3	0.43	1	0.14
VA	11,922	5	0.42	5	0.42
NC (3)	10,644	4	0.38	1	0.09
UT	3,382	1	0.30	0	0.00
NJ	13,895	4	0.29	2	0.14
ME	3,507	1	0.29	1	0.29
TN (3)	10,614	3	0.28	1	0.09
AZ	7,346	2	0.27	0	0.00
GA (3)	7,612	2	0.26	1	0.13
OH	24,221	6	0.25	3	0.12
CO	10,625	2	0.19	2	0.19
MO (2)	11,743	2	0.17	1	0.09
CA (2)	92,000	15	0.16	12	0.13
OR	6,555	1	0.15	1	0.15
IL (3)	23,654	3	0.13	1	0.04
MI (3)	27,336	3	0.11	1	0.04
MD	9,521	1	0.11	1	0.11
LA	10,135	1	0.10	0	0.00
IN	10,256	1	0.10	1	0.10
MN	11,541	1	0.09	0	0.00
FL	38,285	2	0.05	2	0.05
PA	50,471	2	0.04	2	0.04
NY	56,899	2	0.04	2	0.04
AK	924	0	0.00	0	0.00
AL	7,271	0	0.00	0	0.00
CT	10,132	0	0.00	0	0.00
DC	9,729	0	0.00	0	0.00
DE	1,773	0	0.00	0	0.00
HI	2,746	0	0.00	0	0.00
MA	29,835	0	0.00	0	0.00
NB	2,718	0	0.00	0	0.00
NH	2,445	0	0.00	0	0.00
NM	2,519	0	0.00	0	0.00
RI	2,838	0	0.00	0	0.00
SC	8,593	0	0.00	0	0.00
VT	2,229	0	0.00	0	0.00
WY	698	0	0.00	0	0.00
TOTAL	660,599	139	0.21	84	0.13

(CONTINUED)

APPENDIX XI: TABLE B
NUMBER OF PHYSICIAN SANCTION REFERRALS, OIG ACCEPTANCES,
PER 1000 PHYSICIANS, BY STATE (1985-1987)

Source: OIG/ Office of Investigations and HCFA/ Bureau of Program Operations.

- (1) Includes doctors of medicine, and osteopathy, and a limited number of chiropractors, podiatrists and optometrists eligible for Medicare reimbursement as of 1/1/87. Physician data unavailable for American Samoa/Guam, Puerto Rico, and the Virgin Islands.
- (2) Sanction referrals for this state include one instance of physician death before OIG decision.
- (3) States with cases pending decision in OIG as of 12/31/87.

APPENDIX XI: TABLE C
NUMBER OF PRO SANCTION REFERRALS, OIG ACCEPTANCES,
AND REJECTIONS, BY STATE AND YEAR, (1985-1987)

STATE	PRO REFERRALS (1)			OIG ACCEPTANCES (1)			OIG REJECTIONS (1)		
	1985	1986	1987	1985	1986	1987	1985	1986	1987
Arizona	0	0	3	0	0	1	0	0	2
Arkansas	1	2	6	1	1	1	0	1	5
California	5	12	2	5	7	2	0	5	0
Colorado	0	2	0	0	2	0	0	0	0
Dist. of Columbia	0	1	0	0	0	0	0	1	0
Florida	0	1	2	0	1	1	0	0	1
Georgia(2)	0	1	1	0	1	0	0	0	0
Idaho	0	1	0	0	0	0	0	1	0
Illinois(2)	0	1	3	0	0	1	0	1	0
Indiana	0	1	0	0	1	0	0	0	0
Iowa	0	2	7	0	2	3	0	0	4
Kansas	0	2	3	0	2	1	0	0	2
Kentucky	0	3	4	0	1	1	0	2	3
Louisiana	0	1	0	0	0	0	0	1	0
Maine	0	1	0	0	1	0	0	0	0
Maryland	0	1	0	0	1	0	0	0	0
Michigan(2)	0	1	2	0	1	0	0	0	1
Minnesota	0	0	1	0	0	0	0	0	1
Mississippi	0	0	4	0	0	1	0	0	3
Missouri	0	3	0	0	1	0	0	2	0
Montana	0	0	1	0	0	0	0	0	1
Nevada	0	0	1	0	0	0	0	0	1
New Hampshire	0	1	0	0	0	0	0	1	0
New Jersey	0	0	4	0	0	2	0	0	2
New York	0	1	1	0	1	1	0	0	0
North Carolina(2)	0	1	3	0	1	0	0	0	2
North Dakota(2)	0	0	1	0	0	0	0	0	0
Ohio	0	2	4	0	2	1	0	0	3
Oklahoma	0	1	2	0	0	1	0	1	1
Oregon	0	1	0	0	1	0	0	0	0
Pennsylvania	0	1	1	0	1	1	0	0	0
South Dakota	1	0	0	1	0	0	0	0	0
Tennessee(2)	0	0	3	0	0	1	0	0	1
Texas	0	14	9	0	14	6	0	0	3
Utah (2)	0	0	1	0	0	0	0	0	0
Virginia	0	5	0	0	5	0	0	0	0
Washington	0	5	1	0	4	0	0	1	1
West Virginia	0	2	0	0	2	0	0	0	0
Wisconsin	0	4	0	0	2	0	0	2	0
TOTAL	7	74	70	7	55	25	0	19	37

Source: OIG/ Office of Investigations.

- (1) Referrals, acceptances and rejections for hospitals and doctors of medicine and osteopathy through 12/31/87. Rejections include two instances (CA and MO) of physician death before OIG decision.
- (2) States with referrals pending decision in OIG as of 12/31/87.

Note: No sanctions referred for: Alabama, Alaska, American Samoa/Guam, Connecticut, Delaware, Hawaii, Massachusetts, Nebraska, New Mexico, Puerto Rico, Rhode Island, South Carolina, Vermont, Virgin Islands, and Wyoming.

APPENDIX XI: TABLE D
 NUMBER OF RURAL AND URBAN PHYSICIANS, PRO PHYSICIAN SANCTION REFERRALS
 AND OIG ACCEPTANCES, BY STATE AND PERCENT RURAL, (1985-1987) (1)

STATE	NUMBER OF PHYSICIANS (2)			PRO REFERRALS (3)			OIG ACCEPTANCES (3)		
	RURAL	URBAN	% RURAL	RURAL	URBAN	% RURAL	RURAL	URBAN	% RURAL
AZ	714	5,812	11	0	2	0	0	0	0
AR	1,269	2,046	38	8	0	100	3	0	100
CA	1,653	62,029	3	7	8	47	5	7	42
CO	760	5,975	11	1	1	50	1	1	50
FL	1,106	22,554	5	0	2	0	0	2	0
GA (4)	1,948	7,868	20	2	0	100	1	0	100
ID	903	332	73	1	0	100	0	0	0
IL (4)	1,852	22,475	8	2	1	67	0	1	0
IN	1,455	6,825	18	1	0	100	1	0	100
IA	1,445	3,148	31	3	5	38	3	2	60
KS	1,227	3,047	29	5	0	100	3	0	100
KY	1,752	3,955	31	4	3	57	1	1	50
LA	942	7,024	12	1	0	100	0	0	0
ME	821	1,401	37	0	1	0	0	1	0
MD	467	13,271	3	0	1	0	0	1	0
MI (4)	1,820	19,428	9	3	0	100	1	0	100
MN	1,220	7,508	14	1	0	100	0	0	0
MS	1,596	1,533	51	4	0	100	1	0	100
MO	1,611	8,967	15	2	0	100	1	0	100
MT	789	389	67	0	1	0	0	0	0
NV	161	1,371	11	1	0	100	0	0	0
NJ	NA	(5)		2	2	50	1	1	50
NY	2,115	51,601	4	0	2	0	0	2	0
NC (4)	2,827	7,712	27	1	3	25	0	1	0
ND (4)	393	693	36	0	1	0	0	0	0
OH	2,089	19,920	9	1	5	17	0	3	0
OK	1,172	4,174	22	2	1	67	1	0	100
OR	1,166	4,262	21	0	1	0	0	1	0
PA	2,257	26,725	8	1	1	50	1	1	50
SD	606	352	63	1	0	100	1	0	100
TN (4)	1,320	7,275	15	1	2	33	1	0	100
TX	2,343	25,798	8	19	4	83	17	3	85
UT (4)	320	2,544	11	1	0	0	0	0	0
VA	1,786	9,379	16	5	0	100	5	0	100
WA	1,059	7,986	12	5	1	83	4	0	100
WV	1,799	1,524	54	2	0	100	2	0	100
WI	1,592	7,026	18	1	3	25	1	0	100
TOTAL	48,355	383,929	11	88	51	63	55	29	65

Sources: OIG/ Office of Investigations, PHS/ Bureau of Health Professions, and U.S. Bureau of Census.

- (1) Rural areas defined as outside Standard Metropolitan Statistical Areas (SMSAs) listed in 1980 Census data. Urban areas defined as within SMSAs.
- (2) Includes doctors of medicine and osteopathy practicing in 1985.
- (3) Referrals and acceptances only for doctors of medicine and osteopathy through 12/31/87. Referrals include two instances (CA and MO) of physician death before OIG decision.
- (4) States with referrals pending decision in OIG as of 12/31/87.
- (5) Data not available.

Note: No sanctions referred for: Alabama, Alaska, American Samoa/ Guam, Connecticut, D.C., Delaware, Hawaii, Massachusetts, Nebraska, New Hampshire, New Mexico, Puerto Rico, Rhode Island, South Carolina, Vermont, Virgin Islands, and Wyoming.

APPENDIX XII

COMMENTS ON OIG DRAFT REPORT AND OIG RESPONSE TO COMMENTS

We received comments on the draft report from the Administrator of the Health Care Financing Administration (HCFA); the Assistant Secretary for Management and Budget (ASMB); the Assistant Secretary for Planning and Evaluation (ASPE); the Director of Program Evaluation and Methodology of the U.S. General Accounting Office (GAO); the Executive Vice President of the American Medical Peer Review Association (AMPRA); and the President of the American Hospital Association (AHA).

We made a number of changes based on these comments. Most notably, we eliminated a recommendation calling for the Secretary to be granted sole responsibility for determining the type and extent of sanctions to be imposed following PRO determination that the care in question is sanctionable.

Below, we present each of the recommendations set forth in our draft report. After each recommendation, we present all the comments that were directed to that recommendation and then our response to the comments. Subsequently, we include additional comments by the reviewers and, once again, our response.

- o The Department should submit a legislative proposal to amend Section 1156 of the PRO statute to strengthen the monetary penalty as an effective alternative sanction by allowing an imposition of a monetary penalty of up to \$10,000 per violation for substandard, unnecessary, or uneconomical care.

HCFA Comments

We agree and we will assist the OIG in preparing such a legislative proposal.

AHA Comments

The AHA is opposed to any efforts to increase the monetary sanctions against physicians, hospitals, or other health care entities (hereafter referred to as "providers") for rendering care which is determined to be substandard, unnecessary or uneconomical. The AHA shares the desire that all patients receive high quality care rendered in an efficient manner, and recognizes that instances arise where medical and hospital services may be provided which are inappropriate in terms of quality or efficiency. It is our position, however, that monetary penalties, at any level, are an ineffective mechanism to insure compliance with PRO standards.

There is no showing in the report that monetary sanctions could be expected to have a positive effect on the program. In fact, according to page 16 of the report, the OIG has apparently not found monetary penalties to be cost effective. Education and monitoring to ensure compliance is the way to improve the quality of care. Monetary penalties should be used only to reimburse HCFA for services which were unnecessarily or poorly performed.

OIG Response:

The authority to impose a monetary penalty instead of an exclusion from participation in Medicare was enacted prior to the advent of the prospective payment system for hospitals. Accordingly, it is now difficult in many cases to determine the "actual or estimated cost" of substandard or unnecessary hospital-based services for the purpose of imposing a monetary penalty. Furthermore, because of the current statutory formula for assessing a monetary penalty, the amount of such penalty is frequently very small, appears to have little deterrent value, and is disproportionate to the Federal Government's cost in processing such a case. By authorizing a monetary penalty of up to \$10,000, Congress would allow for a viable alternative to exclusion from Medicare participation: the authority to impose monetary penalties commensurate with statutory violations.

- o The Department should submit a legislative proposal to amend the PRO statute to provide that the failure of physicians or providers to comply with their patient care obligations under Section 1156, in itself, constitutes a sufficient basis for sanctioning. Thus, the separate requirement that, in order to be sanctioned, physicians or providers must demonstrate an "unwillingness or lack of ability" to comply substantially with their obligations to Medicare beneficiaries should be deleted.

HCFA Comments

We agree and we will assist the OIG in preparing such a legislative proposal.

AHA Comments

The AHA is opposed to any efforts to weaken the standards used to determine whether providers should be sanctioned. Removing the "unwillingness or lack of ability" standard will result in a fundamental shift in the PRO program's emphasis: from education and corrective action to punishment. This is inconsistent with the fundamental purposes of the program and will serve to further weaken PRO credibility.

The report states that one reason to remove the "unwillingness or lack of ability to comply" standard is to "address the confusion relating to what constitutes 'unwilling or unable.'" We believe that this confusion would not exist however, if PROs were instructed to perform comprehensive fact finding of the particular situation, resulting in a report detailing all relevant facts, all discussions with witnesses and all conclusions reached, including whether the provider is "willing and able" to comply with the patient care obligations.

OIG Response:

Under the prior PRO statute, a failure to comply with the specified statutory violations was considered evidence of a practitioner's or provider's "unwillingness or lack of ability to comply" with these requirements. Accordingly, the Department did not have to make a separate independent finding on the unwillingness/inability issue. Under the current statutory structure, the "unwillingness or lack of ability" requirement makes it quite difficult, even with comprehensive fact finding as the AHA calls for, for PROs and administrative law judges to determine whether or not there is a sufficient basis for sanction. By eliminating this requirement Congress would, we still believe, allow for a more effective and efficient administration of the sanction authority set forth in the statute.

- o The Department should submit a legislative proposal re delegating to the Secretary the sole responsibility for determining the type and extent of sanctions to be imposed following a PRO determination that the care in question is sanctionable.

HCFA Comments

We believe that this recommendation would weaken the authority and credibility of PROs. The OIG study has not established that inconsistencies in the type and extent of sanctions are a problem. Redelegating this authority to the Secretary would only add an additional level to the sanction process and would not improve the consistency of decisions on whether or not to sanction.

ASMB Comments

We would appreciate seeing additional information on the resource and cost implications of the proposed legislation, for both the PROs and the Office of the Secretary, in the final report on sanction activities.

AHA Comments

The report argues that removing PRO input into the sanction process will alleviate the "inherent" frustration and conflict in the concurrent roles of the PROs as educators and enforcers. We disagree.

Local input is essential to the sanctioning process. PROs, familiar with the facts in issue and the provision of medical care in the relevant area, are in the best position to understand the particular situation and reach a conclusion about the seriousness of any offense. As such, they are best able to recommend any action which the OIG should take.

Further, we do not believe that removing the recommendation function would alleviate any perceived conflict between the PRO's educative role and enforcement role. PROs would still be viewed as policemen, even if they were not viewed as district attorneys.

Removing PRO input into the sanction decision will also fail to advance greater nationwide consistency in the application of sanctions. The current system vests final sanction authority with the OIG, which is free to reject PRO recommendations. Inconsistent application of sanctions, therefore, results from inconsistencies endemic in the OIG, not PROs. Measures to assure greater nationwide consistency in the application of sanctions can most appropriately be established by promulgating clear, consistent regulations which govern the sanctioning process and which can be understood and followed by all PROs and the OIG. Removing the recommendation function from PROs will only serve to remove vital input into the sanctioning process.

OIG Response:

In view of the points and concerns raised in the above comments, we have decided to eliminate this recommendation. While it would, we believe, tend to promote greater nationwide consistency in the application of sanctions, we recognize, as AHA notes, that it could remove an important local component to the sanctioning process.

- o The HCFA should explore and document the reasons for considerable variation in sanction activity among the PROs.

HCFA Comments

The changes to the next PRO scope of work should help to relieve some of the variation that the OIG has identified. To this end, we have mandated a national quality intervention plan that must be used by all PROs. The quality intervention plan will lead to more consistency and uniformity in PRO interventions. After we

have the new scope of work in place for a period of time, we will revisit this issue if the OIG, at that time, thinks it necessary.

We believe that the OIG is the best entity to study the impact of the Omnibus Budget Reconciliation Act (OBRA) of 1987 on sanction activities because OIG retains the responsibility for pre-exclusion hearings. We will be glad to cooperate in this endeavor.

AMPRA Comments

AMPRA supports but would appreciate reviewing study design.

AHA Comments

Throughout the report the OIG expresses concern regarding the variation in sanction activities among the PROs. The AHA supports further research into why this variation exists. Any proposal for legislative change should follow such research and suggested legislative changes contained in the report are, therefore, premature.

We suggest that one reason for any variations in sanction activity is lack of clarity with respect to what constitutes a sanctionable offense. As discussed below, the definition of "professionally recognized standards" is ambiguous. We believe that this and other flaws contained in the regulations and PRO Manual play a large part in the differing degrees of sanction activity at the local level.

We do not believe that the recent amendment contained in the OBRA of 1987, which requires pre-exclusion hearings for providers located in rural health manpower shortage areas or in counties with populations of less than 70,000, will further inhibit PROs from making sanction referrals. The report states that "[o]ur study suggests that enactment of the OBRA 1987 provision may further inhibit the PROs from making sanction referrals to the OIG due to the added complexity and delay it brings to the sanction process." (Report, p. iv) In fact, there is no data in the report to support this conclusion. We believe that should there be any reduction in sanction activities after the enactment of this provision, it is most likely because additional fact-finding has revealed that the particular offense is non-sanctionable. For this reason, we strongly urge pre-exclusion hearings for all providers, regardless of the geographic or demographic characteristics of the area.

As table A to appendix XI of the report indicates, the OIG rejects 42 percent of all sanction recommendations. This indicates that still further safeguards are necessary to protect providers from unnecessary subjection to the sanctioning process. Pre-exclusion hearings for all providers will serve this purpose.

OIG Response:

We have left this recommendation unchanged. For the reasons stated in the text, we regard it as important to understand more clearly the reasons behind the considerable variation in PRO sanction activity. Moreover, we continue to feel that the responsibility for studying this recommendation rests more directly with HCFA than OIG. The HCFA has the responsibility for developing and overseeing procedures concerning the identification of sanctionable activities. The OIG's responsibility is to respond to the referrals once sent to us and to render assistance that can facilitate the referral process.

- o The HCFA should explore and document the reasons for the apparent higher rate of sanction recommendations pertaining to physicians practicing in rural versus urban settings. As part of this effort, HCFA should study PRO review procedures to ensure that sanctionable activities by urban physicians are being identified when appropriate.

HCFA Comments

We have no reason to believe that PROs are not identifying sanctionable activities by urban physicians. We also disagree with your comment that the review (i.e., its sampling techniques) is biased against rural physicians.

The requirement that each PRO review a certain percentage of each hospital's Medicare admissions does not result in the PRO reviewing a greater percentage of each rural physician's Medicare admissions than a physician practicing in an urban hospital. The PROs currently select a hospital-specific 3 percent random sample. The random sampling (selection) technique used by PROs and required by HCFA does not discriminate against large or small, rural or urban hospitals. Over time, the sample would result in a 3 percent sample of discharges for each physician.

As in all random samples, chance plays a role in the actual cases selected. The likelihood of a physician appearing in a random sample is based solely upon the number of bills he or she submits and is not dependent upon the size of the hospital. It is possible that at a specific point in time, the cases selected could be more heavily weighted towards one physician while another physician may not have any cases in the sample. It is important to keep in mind, however, that this could occur whether the physician practices in a small rural hospital or in a large urban hospital. Thus, as the selection methodology is a purely random sample without inherent biases, there is no reason to assume that it discriminates against physicians with respect to the location of their practice.

The probability of identifying an inadequacy in a physician's practice increases only when more of that physician's cases are reviewed. Obviously, if the case load of a physician in a rural hospital is greater than that of a physician in an urban hospital, then the rural physician has more cases reviewed and thus stands a better chance of having a problem discovered--if indeed a problem exists. However, if a physician treats the same number of cases in an urban hospital, it would result in an equal number of cases being reviewed. Thus, the probability of identification of a problem is the same. If each physician treats fewer cases, then each physician has less chance of having a problem discovered simply because there are fewer cases reviewed, whether the setting is urban or rural. Frankly, we do not see this as giving advantage or disadvantage to urban or rural physicians. A physician only stands a better chance of having a problem identified or being subject to more review if he has a disproportionate number of cases in any setting. The thrust of review is to the number and type of cases. The important fact to note is that the protection afforded to the patients will always be the same, regardless of the number of admissions each physician has, because the review is directed to the number of total admissions or of admissions of a certain type.

We do not believe that the criteria used by PROs contribute to more rural physicians' cases failing the criteria than urban physicians' cases. The only criteria used by PROs are utilization criteria. We have begun an intensive review of the PROs' criteria sets. Our review, thus far, has not demonstrated that there is any inherent bias in the criteria. The criteria are used by medical review coordinators to screen potentially aberrant cases for intensive physician review.

For quality review, the PROs use HCFA's generic quality screens as the screening tool (i.e., criteria). If a case fails a generic quality screen, the case is referred to a PRO physician for review. As you know, PROs are required to use, for final determinations about quality and utilization, a physician who practices in a setting similar to the one in which the attending physician practices. In addition, the PRO criteria are further validated by HCFA's independent contractor, the "SuperPRO." The "SuperPRO" is an organization of health care professionals whose responsibility is to review the accuracy of PRO determinations and provide HCFA with an independent, professionally recognized evaluation of PRO medical determinations.

The OBRA of 1987 added certain provisions which should augment the PRO review process as it relates to rural areas. The amendments include provisions that require, if necessary, a change in the PRO standards in remote rural areas and a particular emphasis on education of rural physicians and providers.

As noted in the study, the actual number of sanctions recommended is too small to determine whether the apparent disproportion of rural sanctions represents anything more serious than a statistical artifact from a small sample. Given that the OIG was unable to identify a bias in the selection of PRO reviews and the numerous OBRA mandated changes related to the review of rural care and due process, any additional study of this issue would be premature and unlikely to reach reliable conclusions.

AMPRA Comments

AMPRA supports.

AHA Comments

The AHA is concerned about apparent disproportionate sanction activity for physicians practicing in rural settings. We support efforts to study whether the sanctioning process is somehow biased against rural providers and practitioners. We are not convinced, however, that urban providers and practitioners are somehow being reviewed in a more lenient manner, and that sanctions should be increased in these areas to bring them into line with a perceived "appropriate" level of sanctions in rural areas.

We also will continue to strive to achieve uniformity between the sanction regulations and the regulations that allow denial of payment for substandard care. This does not mean, however, that we are agreeing at this time to modify our position that the beneficiary has to have an adverse outcome before a denial for substandard care is effectuated.

OIG Response:

In response to the HCFA comments, we must note that we did not report that the process for reviewing quality of care problems is biased against rural physicians and providers. Indeed, we reported that a majority of the respondents felt that the review system was free of such bias.

However, on the basis of our analysis we did find and report that rural physicians have been sanctioned at a higher rate than urban ones. For the reasons stated in the report, we continue to feel that such an inquiry is warranted. Moreover, for the same reasons stated in response to the previous recommendation, we feel HCFA is best suited to initiate the inquiry.

- o A HCFA/OIG workgroup should be established to improve communications about the PRO quality of care review and sanction process.

HCFA Comments

While we agree with the recommendation, we do not agree with the group's charter as outlined in the draft report. We continue to believe that HCFA retains the responsibility for establishing the guidelines used by PROs in addressing quality of care problems. As in the past, we will continue to seek and analyze input from other sources (including the OIG) in defining and/or modifying these guidelines for the PROs.

AMPRA Comments

AMPRA strongly supports.

AHA Comments

The AHA is supportive of this effort directed towards improving the quality of care review and sanction process.

OIG Response:

Upon further consideration, we have withdrawn our recommendation for a formal HCFA/OIG work group. We believe that ongoing communication on the kind of issues stated in the recommendation is vital to the effective performance of the PRO program. However, after discussing the matter with HCFA and OIG representatives, it appears that improved communication can best be achieved in more informal ways, building on the links already in place.

- o The OIG should increase the number of regular meetings and other communications with the PROs to provide them guidance regarding their statutory and regulatory sanction requirements.

HCFA Comments

We agree with this recommendation and are ready to assist the OIG in arranging these meetings.

AMPRA Comments

AMPRA strongly supports. We are particularly interested in improving communications between PROs and HHS Department lawyers in preparing for administrative law hearings.

AHA Comments

The AHA supports this recommendation. We believe, however, that any policies developed to provide the PROs with guidance regarding their sanction responsibilities should be promulgated via the regulatory process to provide for input from interested parties.

OIG Response:

The OIG is committed to the meetings and communications called for in the recommendations. In this final report, this commitment is stated as part of the introduction to the recommendations rather than as a recommendation in itself.

- o The OIG should issue regulations that will clarify the scope of the PROs' authority to determine what constitutes professionally-recognized standards of health care within their jurisdictions.

HCFA Comments

We disagree. We believe that national standards such as those that would be developed by the OIG would need to be modified to take into account, for example, the setting in which the care was delivered, amount of resources available as support to the attending physician, etc. We think the guidelines proposed in our regulation regarding denials for substandard care will strengthen the authority for the PRO to determine what constitutes professionally-recognized standards of health care in its area.

GAO Comments

- o ...the tenuousness of the link between sanctions and health care quality makes the reader question whether the OIG should be involved, as you recommend, in issuing "regulations that will clarify the scope of the PROs' authority to determine what constitutes professionally-recognized standards of health care within their jurisdictions." Normally, this would seem to be a function of the relevant medical or professional community and the OIG's involvement, therefore, would have to be justified, I presume, on the grounds of knowledge that a stronger sanctions process would cure the quality problems that have been found. I would have felt more comfortable with the recommendation if such knowledge had been presented. As things stand, it seems to me that this recommendation can be seen as going beyond your data.

AMPRA Comments

AMPRA supports.

AHA Comments

The AHA supports any efforts which can be directed towards clarifying what constitutes "professionally-recognized standards of health care." Section 1154 of the Medicare Act (42 U.S.C. S 1320C-3 (a)(6)) provides some guidance on this issue. It states that PROs shall "apply professionally-developed norms of care, diagnosis, and treatment based upon typical patterns of practice within the geographic area served by the organization... taking into consideration national norms where appropriate." The statute further states that such norms shall take into account "differing but acceptable" modes of treatment, methods of organizing and delivering care and the type of health care facility under consideration.

We believe that any efforts to clarify the definition of "professionally-recognized standards of health care" must take into consideration regional variations in the provision of health care services. Such consideration is mandated by the PRO statute, and by case law interpreting the statute. See, e.g., Greene v. Bowen, 639 F. Supp. 554 (E.D. Cal. 1986). There, the court rejected the Department of Health and Human Service's position that the standard of care appropriate to a specific geographic area was irrelevant to the determination of a gross and flagrant violation.

Therefore, while we support efforts to clarify the definition of "professionally-recognized standard of health care," such clarification must take into account regional variations concerning methods of practice. The AHA stands ready to work with the OIG in developing requisite standards in this area.

OIG Response:

In response to the comments, we have revised the recommendation to make it clearer that what we are calling for is further clarity in the professionally-recognized standards of health care to which physicians and providers are expected to conform. We recognize that this is a complex issue calling for careful consideration but it is vital to provide further clarity on it. Toward that end, we are developing a specific regulatory proposal and will issue it shortly for review and comment.

- o The OIG should develop an independent medical advisory panel of outside medical experts that OIG physicians may consult with in reviewing the PROs' sanction referrals to the OIG.

HCFA Comments

We agree but believe that a PRO physician should be part of the panel, as he/she can best explain why the PRO is recommending the

sanction action (including an explanation of the local practice standards). If the OIG plans to use only a national panel, this would cause problems as far as local practice patterns are concerned. In addition, the panel would have to contain specialists in all fields and the specialists would have to be further divided into urban and rural groups.

AMPRA Comments

AMPRA strongly supports.

AHA Comments

The AHA supports this recommendation. We believe that an independent medical advisory panel will provide needed input into the sanctioning process, and will provide further expertise in evaluating situations referred by the PROs for sanction.

OIG Response:

Here again, as with the draft recommendation concerning meetings between the OIG and PROs, we have recast the recommendation as a statement appearing in our introduction to the recommendations.

Additional Comments by ASMB

My staff and I are finding the series of OIG reports on Peer Review Organizations (PROs) useful in helping us better understand the PROs' mission and activities. We are also impressed with the attention to detail and data quality control found in the methodology sections.

We recently reviewed the second draft report on sanction activities. We concur with the report, but would like to request that additional information on one of the recommendations be provided in the final report.

OIG Response:

The recommendation addressed by ASMB was the one calling for the Secretary to be granted sole responsibility for determining the type and extent of sanctions to be imposed following a PRO determination that the care in question is sanctionable. As noted earlier, we have eliminated that recommendation.

ASPE Comments

Thank you for the opportunity to review the draft report entitled "The Utilization and Quality Control Peer Review Organization (PRO) Program: Sanction Activities." My primary concern is one of format rather than substance. Specifically, over 50 percent of this approximately 60 page report consists of appendices which

give background information on PROs and which are exactly duplicative of the appendices in the OIG report we reviewed a few weeks ago on PRO quality review activities. This draft report on sanction activities is the second in a series of three inspection reports assessing the PRO program. Rather than issue three reports which are largely duplicative of each other, I recommend that the three reports be consolidated into one comprehensive report which assesses the entire PRO program. This seems preferable to reiterating the same 30 pages of background information in each of the three documents. Further, consolidating the reports makes particular sense given that the subject matters of the three reports are closely interrelated. For example, both the first report (on quality review activities) and this report (on sanction activities) discuss issues related to sharing information with State Medical Boards.

Additionally, I have two minor suggestions with respect to this report specifically:

- o On page iii, the third sentence of the first paragraph should be revised to refer to the "inability or unwillingness of rural physicians and providers to correct substandard medical practices identified by the PROs." This proposed change is in keeping with the statutory requirement that in order to be sanctioned, providers must demonstrate either an unwillingness or lack of ability to comply with their obligations to Medicare beneficiaries.
- o Pages iii, iv and v of the executive summary list recommendations made by the OIG with respect to the sanction process. Pages 21, 22, and 23 of the report reiterate the same recommendations verbatim, I recommend that they be put in the body of the report and then just summarized in the executive summary.

OIG Response:

We appreciate ASPE's concern about format. We issued separate reports rather than one comprehensive report because that approach enabled us to present our findings and recommendations in a more timely manner. Since each report was, therefore, a stand-alone piece, we decided to include the same background information in each.

For those reading all three reports, we recognize that this manner of presentation can be tedious. For that reason, in our third report, we have incorporated more of the background information into the appendices.

With respect to ASPE's two other suggestions, we have made the suggested addition in the recommendation concerning rural physicians and providers, but have chosen not to present a more abbreviated set of recommendations in the executive summary. Because the recommendations are somewhat complex, we feel that some explanation is important, even in the executive summary.

Additional GAO Comments

This letter responds to your request of April 5 for my comments on your draft report, "The Utilization and Quality Control Peer Review Organization (PRO) Program: Sanction Activities."

Overall, I found the paper interesting and useful. It was a good idea to take a discrete look at sanctions in the PRO program, I think, because it's always uncertain what emphasis will in fact be placed on deterrence mechanisms when they are housed together with service functions (e.g., when sanctions are located cheek by jowl with education, as in the PRO program; or with income maintenance, as in certain welfare programs; or with protection, as in some police programs). So it seems very worthwhile to examine this question separately.

However, because you're looking at sanctions separately, it becomes very important not to overestimate the value of deterrence (and underestimate the value of other factors) in creating quality. Can the case be made, as your report seems to assume it can, that there is a tight cause-and-effect relationship between sanctioning physicians or providers generally, and quality of care? To make that case, wouldn't we need to know more about (1) the actual distribution and kinds of quality-of-care problems that currently exist (so as to be able to infer whether sanctions could solve them) and (2) the actual effects of a strong sanctions process on (a) PRO performance and (b) quality of care? What we are given in the report is people's opinions that the sanctions process strengthens the PROs' ability to carry out their mission. But while I think most people would agree with this, it nonetheless provides only weak support for one of your recommendations.

Indeed, the tenuousness of the link between sanctions and health care quality makes the reader question whether the OIG should be involved, as you recommend, issuing "regulations that will clarify the scope of the PROs' authority to determine what constitutes professionally-recognized standards of health care within their jurisdictions." Normally, this would seem to be a function of the relevant medical or professional community and the OIG's involvement, therefore, would have to be justified, I presume, on the grounds of knowledge that a stronger sanctions process would cure the quality problems that have been found. I would have felt more comfortable with the recommendation if such

knowledge had been presented. As things stand, it seems to me that this recommendation can be seen as going beyond your data.

In the same way that this recommendation would have been bolstered by more documentation of the specific quality problems PROs have reported, I think your other recommendations would have been helped if more distinctions had been made among respondents in your presentations of data. In many cases, combining all the responses masks important information which thereby gets lost. The reader is interested not only in general results, but also wants to know, say, how the perceptions of PROs may differ from those of the various external entities (p. 12), or how respondents may vary in citing reasons for differences in sanction activity (pp. 13-14). Such a breakout was given in the report in one case (pp. 16-17) and differences between groups were important to understand. figure V especially (p. 19), should be desegregated and broken out by type of respondent.

Finally, two technical notes. First, you've probably corrected this already but there is some inconsistency in the presentation of the numbers (given first on p. 11) as the reader proceeds through the report. Second, you may want to update your description of our work on p. 33 by a reference to the final report, Medicare: Improving Quality of Care Assessment and Assurance, GAO/PEMD-88-10. This is scheduled to be published April 29. Also, you could update your reference to our PRO effectiveness work by saying that PEMD's evaluation of PRO quality and utilization review activities is underway and preliminary descriptive findings are expected in late 1988.

OIG Response:

We accept the caution about overestimating the value of sanctions and deterrence. We recognize that there is not necessarily a tight cause-and-effect relationship between sanction activity and quality of care. Indeed, we point out in the report that a reduction in PRO referrals may mean that the PROs are successfully addressing quality problems through the education process. It may also mean that the financial and political costs associated with sanctions are too high. Clearly, this is an area warranting further study.

On the matter of making more distinctions by type of respondent, we recognize that further detail of this kind can be useful. At the same time, we must impose some limitation in how much we include on one report. Where significant differences appeared among respondents, we did indicate those differences in the text.

On the two technical notes mentioned, we added brief clarifications that explain the inconsistencies in sanction data reported. Also in accord with GAO's suggestion, we have made updates to reflect the more recent GAO work.

Additional AMPRA Comments

On behalf of the American Medical Peer Review Association (AMPRA), I appreciate the opportunity to comment on your draft report entitled, "The Utilization and Quality Control Peer Review Organization (PRO) Program: Sanction Activities."

AMPRA concurs with the major findings of the report. We caution against drawing conclusions about the variation in the number of sanction recommendations by PROs until further study. The absence of a low number of sanction recommendations is not, in itself, an indicator of poor performance; it may indicate just the reverse. AMPRA appreciates the report's recognition of the problems PROs face in interpreting statutory and regulatory requirements, particularly the meaning of providers' "unwillingness or lack of ability" to comply with Medicare obligations. We are pleased that most respondents in the study agreed with AMPRA's long standing position that the PRO review process "is free from systematic bias against rural physicians and providers."

The report's recommendations are, on the whole, well conceived and may provide needed solutions to some remaining problems with the PRO sanction process.

OIG Response:

We agree on the need for further study on the reasons for the considerable variation in sanction activity among the PROs.

Additional AHA Comments

I want to thank you for the opportunity provided to the American Hospital Association (AHA) to comment on your draft report entitled "The Utilization of Quality Control Peer Review Organization (PRO) Program: Sanction Activities" (the report). The review activities of PROs are an issue of great concern to our members, and one which we are following closely. We agree that the PRO review process is an important tool to ensure the provision of efficient, quality medical care to Medicare beneficiaries.

In order for the PRO sanction process to achieve its objectives, however, it appears that a number of significant changes will be necessary. We agree with many of the findings and certain of the recommendations contained in the report, and believe that by raising the subject and providing a framework for discussion, it makes a useful contribution.

We have fundamental concerns and differences, however, with various of the positions and recommendations stated in the document. Chief among these concerns is the apparent lack of

sensitivity to the need for due process safeguards in the sanction process. Given the severe nature of the sanctions which may be imposed, the provision of such safeguards is essential. The report, however, appears to take the opposite view, seeking ways to relieve the "cumbersomeness of the due process procedure."

We are also concerned about what we perceive as an underlying thrust of the report--to increase sanction activity as a goal in itself. The AHA believes that PROs can review the provision of care in a manner which is not punitive to practitioners and providers rendering that care. The PRO program was established in large part to educate providers about ways to render efficient and high-quality medical services. PRO concerns echoed throughout the report regarding ways to emphasize this educative role are poorly served if PROs are urged to increase their sanction statistics at all costs.

The report puts forth what we consider to be the false notion that the PRO program can be improved by authorizing monetary penalties, centralizing important functions in the Office of Inspector General, and reducing procedural safeguards. We believe that each of these actions would be counterproductive.

Instead, the AHA believes the following to be essential for the improved performance of the PRO program:

- that the educative role of PROs be re-emphasized, including a restructuring of sanctions away from punitive measures and towards corrective action;
- that the authority to review cases and recommend sanctions be retained by the individual PROs; and
- that the PROs be given detailed guidelines in the form of regulations setting forth standards against which provider performance is judged, and detailing the due process procedures to be used throughout the review process.

These steps taken together will ensure that the reviews and sanctions are undertaken at the most appropriate level--the local PRO--where the familiarity with each case and situation is the greatest. They will provide both the PROs and those subject to review with a clear understanding of their duties and rights, and will enable the PROs to undertake progressive, remedial actions which can correct problems at an early stage, rather than waiting for them to reach major proportions. They will ensure that those institutions and persons coming to the attention of the OIG and facing potentially severe reprisals will receive rights and protection commensurate with the sanctions.

These and other recommendations, as well as the comments of the AHA to the recommendations made in the report, are contained in the attached document which is made a part of this letter.

We believe that the opportunity is now at hand to discuss a wide range of issues concerning PRO performance, and to initiate steps which will ultimately lead to improved patient care. We look forward to working cooperatively with you and the other interested parties in this regard.

OIG Response:

We agree on the importance of educational efforts. We also believe that there is an important role for sanctions if PROs are to do an effective job in protecting Medicare beneficiaries. Due process safeguards are vital in this process. At the same time, it is, we believe, quite legitimate and important to identify ways in which the sanction process can be carried out more efficiently and effectively.

It is important to recognize that the Section 1156 implementing regulations (42 C.F.R. Part 1004) have been drafted to assure adequate due process for providers and physicians while protecting the right of Medicare beneficiaries to receive high quality health care. The existing sanction procedures have been upheld, to date, by each U.S. Court of Appeals to review them. See Varandani vs. Bowen, 824-F. 2d 791 (9th Cir., 1987), Cassim vs. Bowen 824-F. 2d 791 (9th Cir., 1987), and Doyle vs. Secretary of Health and Human Services ---- F. 2d ---- (1st Cir., June 3, 1988). See also Koespel vs. Heckler, 797 F. 2d 858 (10th Cir., 1986) and Ritter vs. Cohen, 797 F. 2d 119 (3rd Cir., 1986).