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

QUALITY REVIEW ACTIVITIES



OFFICE OF INSPECTOR GENERAL
OFFICE OF ANALYSIS AND INSPECTIONS

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

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EXECUTIVE SUMMARY

PURPOSE AND OBJECTIVES:

The purpose of this inspection was to assess the performance of the Utilization and Quality Control Peer Review Organization (PRO) program and to promote a better understanding of the PROs mission and activities. Because of the major importance of the PROs' quality assurance activities to the integrity of the Medicare program, the inspection has paid particular attention to the processes by which the PROs identify and address quality of care issues, including their education and sanction activities.

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:

- RESPONDENTS CONSIDERED QUALITY REVIEW TO BE THE MOST CRITICAL ELEMENT OF THE PROS' MISSION AND THOUGHT IT HAS RECEIVED INCREASED EMPHASIS DURING THE SECOND CONTRACT PERIOD (1986-1988).
- GENERIC QUALITY SCREENS APPEAR TO BE USEFUL INSTRUMENTS FOR QUALITY REVIEW, BUT MAY BE IN NEED OF REFINEMENT. Screens provide the PRO program with national quality review procedures, but they have produced excessive referrals to physician advisers and may be inconsistently applied.
- THE PROS' QUALITY REVIEW EFFORTS ARE LIMITED BY A LACK OF CONSENSUS REGARDING THE DEFINITION OF QUALITY MEDICAL CARE, BY THE AMOUNT OF RESOURCES AVAILABLE FOR SUCH CARE, AND BY THE CURRENT LACK OF SOPHISTICATED TECHNOLOGY TO ASSESS QUALITY.
- THE PROS EXHIBIT GREAT VARIATION IN THEIR APPROACHES TO AND OUTCOMES OF QUALITY REVIEW. Some PROs identify many quality of care problems using the generic quality screens while others identify few, if any problems. The quality review processes among the 12 case study PROs showed variations in both the identification and the treatment of physicians and providers with quality of care problems.

- o THE PROS' IMPACT ON ENSURING HIGH-QUALITY CARE WOULD BE ENHANCED BY GREATER COORDINATION WITH OTHER HEALTH CARE ENTITIES, PARTICULARLY WITH THE STATE MEDICAL LICENSURE BOARDS. The sharing of important information has been limited by the PROs' confusion about their confidentiality restrictions under the Social Security Act and HCFA's failure to require PROs to report physician misconduct or incompetence to State Medical Boards.
- o MOST PROS ARE FINDING IT DIFFICULT TO PROVIDE EFFECTIVE OUTREACH TO MEDICARE BENEFICIARIES. Although most PROs viewed themselves as reasonably effective in this area, other national and local representatives were generally unaware of the PROs' outreach activities.
- o THE PROS WILL FACE SERIOUS CHALLENGES AND OBSTACLES IN REVIEWING CARE IN NONHOSPITAL SETTINGS. In addition to the normal learning curve, respondents anticipated that the PROs will face problems concerning adequate funding, guidance, data sources, review technology, coordination with skilled nursing facilities (SNFs) and home health agencies (HHAs), as well as resistance from the medical community.

RECOMMENDATIONS

QUALITY OF CARE

- o THE HCFA SHOULD:
 - WORK WITH THE PROS TO DEVELOP MORE CONSISTENT APPROACHES TO DEFINING AND ADDRESSING QUALITY OF CARE PROBLEMS;
 - WORK WITH THE PROS TO ENSURE MORE CONSISTENT REPORTING OF QUALITY INTERVENTION ACTIVITIES;
 - DEVELOP AND WIDELY DISSEMINATE INFORMATION ON THE FULL RANGE OF EDUCATIONAL CORRECTIVE ACTIONS BEING TAKEN BY THE PROS TO ADDRESS QUALITY OF CARE PROBLEMS;
 - CREATE MORE OPPORTUNITIES FOR THE PROS TO SHARE INFORMATION WITH EACH OTHER CONCERNING THEIR QUALITY REVIEW AND INTERVENTION APPROACHES; and
 - INTENSIFY ITS SUPPORT OF RESEARCH TO DEFINE AND ASSESS THE QUALITY OF MEDICAL CARE. IN ADDITION, HCFA SHOULD COLLECT AND INTEGRATE QUALITY-RELATED RESEARCH FINDINGS FROM ALL RELEVANT SOURCES AND DISSEMINATE THEM TO THE PROS.

GENERIC QUALITY SCREENS

o THE HCFA SHOULD:

ENSURE THAT ANY MAJOR MODIFICATIONS TO THE GENERIC QUALITY SCREENS ARE PILOT-TESTED BEFORE NATIONAL IMPLEMENTATION;

PROMOTE GREATER CONSISTENCY IN THE APPLICATION OF GENERIC SCREENS THROUGH ITS TRAINING EFFORTS AND OPERATIONAL INSTRUCTIONS; AND

SUPPORT THE DEVELOPMENT AND PILOT TESTING OF MORE EFFECTIVE AND LESS LABOR-INTENSIVE REVIEW METHODOLOGIES.

PROS' COORDINATION WITH OTHER ENTITIES:

- o THE HCFA SHOULD PROMOTE CLOSER WORKING RELATIONSHIPS BETWEEN THE PROS AND OTHER HEALTH CARE ENTITIES AND ENCOURAGE MORE SHARING OF INFORMATION ABOUT PHYSICIANS AND PROVIDERS WITH QUALITY OF CARE PROBLEMS. THESE EFFORTS SHOULD INCLUDE CLARIFICATION BY HCFA OF THE PROS' CONFIDENTIALITY RESTRICTIONS AND A REGULATORY REQUIREMENT THAT PROS REPORT INSTANCES OF PHYSICIAN MISCONDUCT OR INCOMPETENCE TO STATE MEDICAL LICENSURE BOARDS. THIS REPORTING REQUIREMENT WAS AGREED TO BY HCFA IN MARCH 1986 IN A BRIEFING ON THE OIG REPORT, "MEDICAL LICENSURE AND DISCIPLINE: AN OVERVIEW." THIS SHOULD BE ACCOMPLISHED THROUGH THE NOTICE OF PROPOSED RULEMAKING (NPRM) ON CHANGES TO PEER REVIEW ORGANIZATION REGULATIONS.

PROS' OUTREACH TO MEDICARE BENEFICIARIES

- o THE HCFA SHOULD SEEK WAYS TO STRENGTHEN THE BENEFICIARY OUTREACH EFFORTS OF THE PROS. IN THIS CONTEXT, IT SHOULD COORDINATE MORE CLOSELY WITH THE SOCIAL SECURITY ADMINISTRATION AND THE OFFICE OF HUMAN DEVELOPMENT SERVICES AND SHOULD PROVIDE MORE OPPORTUNITIES FOR THE PROS TO SHARE BEST PRACTICE APPROACHES WITH EACH OTHER.

REVIEW OF CARE IN NONHOSPITAL SETTINGS

o THE HCFA SHOULD:

WORK WITH THE PROS TO DELINEATE THE MOST SIGNIFICANT CONSTRAINTS THAT WILL BE FACED IN REVIEWING CARE IN NONHOSPITAL SETTINGS AND TO DEVELOP STRATEGIES FOR ADDRESSING THESE CONSTRAINTS; AND

SEEK WAYS TO IMPROVE THE AVAILABILITY OF DATA ON OUTPATIENT AND INPATIENT SERVICES PROVIDED TO THE MEDICARE POPULATION. IN THIS CONTEXT, IT SHOULD BUILD UPON DEMONSTRATION PROJECTS CURRENTLY UNDERWAY IN TEXAS AND MARYLAND TO LINK THE MEDICARE PART A (INPATIENT) AND PART B (OUTPATIENT) DATA FILES.

COMMENTS ON DRAFT REPORT

We received written comments from the Health Care Financing Administration, the Assistant Secretary for Planning and Evaluation, the American Association of Retired Persons and the American Hospital Association. All four entities reflected positive reactions to our recommendations but AHA raised some important methodological considerations which led us to modify two of our findings. In addition, HCFA and ASPE highlighted several steps that HCFA is planning to undertake in the third scope of work to address several of the concerns raised in our report. See appendix XI for a complete summary of the aforementioned comments, and our response to 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 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' quality assurance activities are of major importance to the integrity of the Medicare program, this inspection has paid particular attention to the processes by which the PROs identify and address quality of care issues.

This report summarizes the OIG's inspection findings related to the PROs' quality review activities. It is the first in a series of reports on the OIG's inspection of the PRO program. The second report will focus on the PROs' sanction activities and the third and final report will offer an explanation of the overall

effectiveness of the PRO program. That report will focus on an assessment of both the PROs themselves and HCFA's oversight of them. It is important to note that our assessment of the PRO program is based primarily on interviews with a wide variety of well-informed individuals closely associated with the PROs and HCFA. Wherever possible, we have supplemented our analyses of the qualitative data with available quantitative data.

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 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."¹ 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."²

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 (1984-86)

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 introduction.)

Second Scope of Work (1986-88)

During the first contract period, several entities, including the General Accounting Office, 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."³

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

COBRA and OBRA Provisions:

The PROs' responsibilities were substantially increased through provisions of the Consolidated Omnibus Reconciliation Act of 1985 (COBRA) and the Omnibus Reconciliation Act of 1986 (OBRA). 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. The OBRA 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 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 was 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?"⁴

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 a subsequent OIG 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.⁵

The Sanction Process

The Secretary of Health and Human Services is authorized to impose sanctions on Medicare-reimbursed physicians or providers if they have "gross 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. For offenses related to the first two obligations, the Secretary may impose one of two sanctions--either a monetary penalty for no more than the "actual or estimated cost of the medically improper or unnecessary services so provided" or exclusion from the Medicare program for a specified period of time. And for improper documentation, the Secretary may impose a sanction or exclusion.

The PRO must provide the practitioner or provider with "reasonable notice and opportunity for discussion" before making its recommendation to the Secretary (42 U.S.C. S 1320c-5(b)(1)). Under the regulations, 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 allegations of "substantial" violations, the physicians or providers are 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 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.⁶

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 an effort to address such concerns, the American Association of Retired Persons (AARP), the American Medical Association (AMA), the Health Care Financing Administration, and the Office of Inspector General drafted an agreement (hereafter referred to as the AARP/AMA/HCFA/OIG agreement) in May 1987 to standardize the PROs' due process 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 for ALJ review prior to the imposition of an exclusion for any physician or provider who is practicing in a "Health Manpower Shortage Area" (HMSA) or in a county with a population of 70,000 or less. 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 efficiency 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)
- 2 physicians expired
- 54 rejections by the OIG
- 8 cases still pending

A more thorough discussion of sanction issues and figures will be included in our forthcoming report on the sanction process.

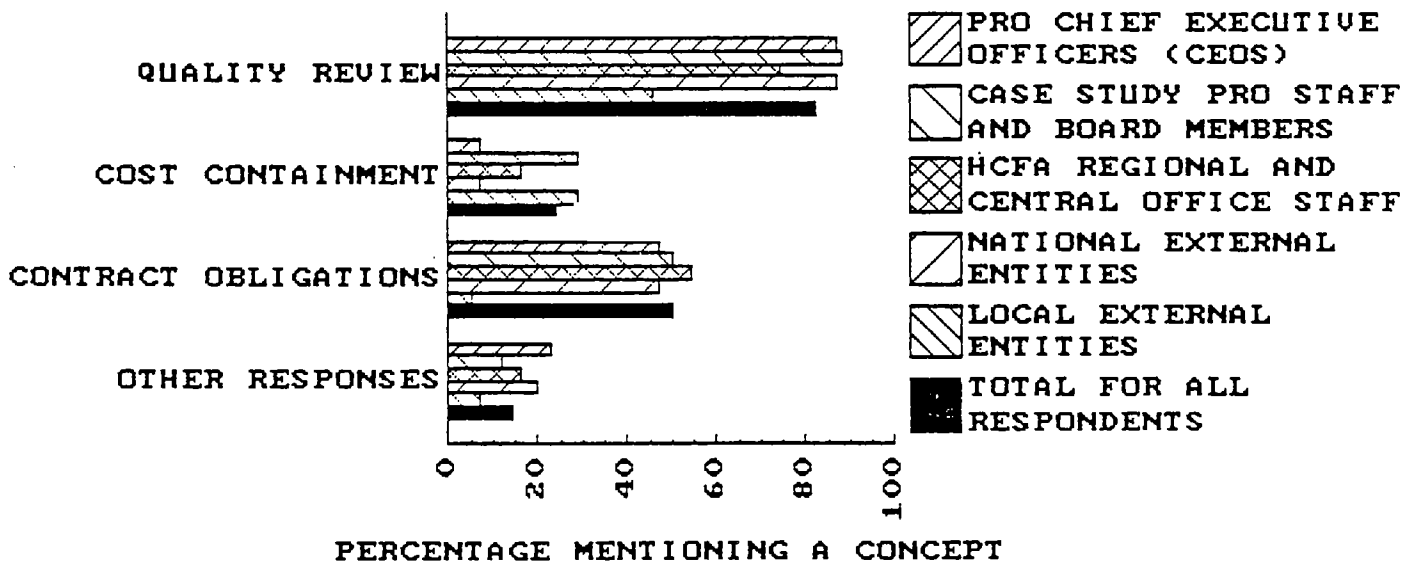
FINDINGS

Respondents considered quality review to be the most critical element of the PROs' mission and thought it has received increased focus during the second contract period (1986-1988).

The PRO program emerged at a time of record budget deficits and thereby had the inherent mandate to limit Government expenditures by eliminating incentives to deliver unnecessary care. However, the PROs were also expected to alleviate the public's concern that the PPS would precipitate a "deterioration in quality or an increase in negative patient outcomes."⁷ Hence, the PROs were the key instrument used by the Government to "exercise a degree of surgical precision vs. a meat ax approach when planning to eliminate waste while avoiding negative patient outcomes."⁸

An overwhelming majority of the PRO chief executive officers (CEOs), along with other groups interviewed, articulated the primary importance of quality review to the PROs' mission. (See figure I.)

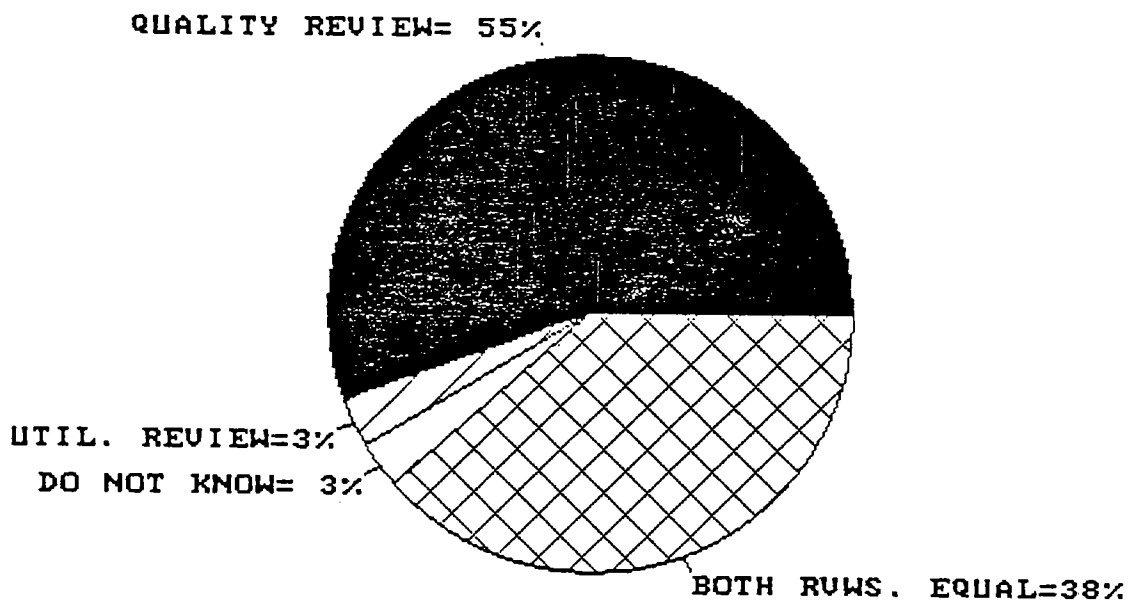
**FIGURE I
PERCEPTIONS OF THE PROS' PRIMARY MISSION**



Note: N= 188 respondents
Source: OIG Inspection Interviews

In addition, although the PROs and others were equally divided about whether the PROs' primary mission had changed since the start of the PRO program, the majority of those who noted such a change described it as a shift toward more quality review in the second contract period. Furthermore, a majority of respondents thought that quality review was more important than utilization review for carrying out the PROs' mission. (See figure II.) In particular, a vast majority (64 percent) of the PRO CEOs thought quality was more important than utilization review and most of the others (32 percent) thought that quality and utilization were equally important. While most other respondents shared similar high regard for quality review, a majority of HCFA staff thought that quality and utilization were equally important. The national external entities were equally divided between quality being more important than, and being as important as, utilization review. As reflected in figure II, only 3 percent of the total respondents described utilization review as being more important than quality review.

**FIGURE II
PERCEPTIONS OF THE IMPORTANCE OF QUALITY REVIEW
RELATIVE TO UTILIZATION REVIEW FOR PRO PROGRAM**



**% Noting Quality or Utilization
Review as More Important**

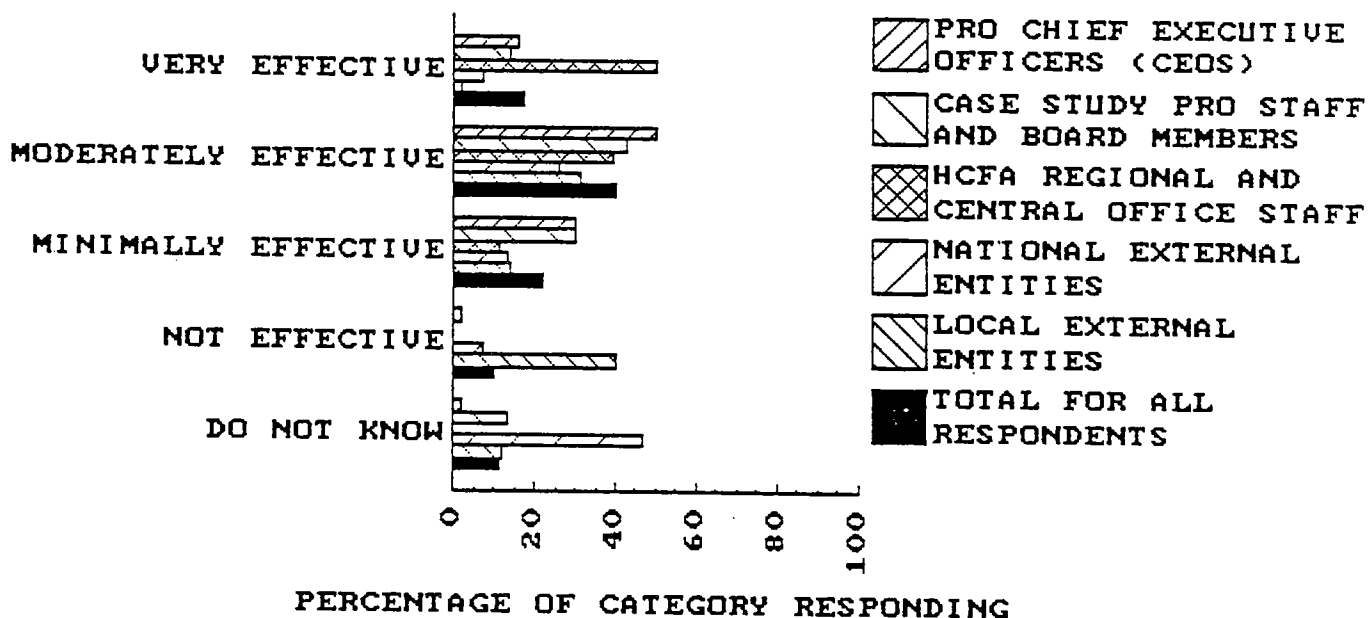
Note: N= 186 respondents.
Source: OIG Inspection Interviews.

Many of the respondents who viewed quality and utilization as equally important for the PRO mission highlighted the inappropriate dichotomy that exists in peoples' minds between the PROs' cost containment and quality monitoring activities. One Government official explained that "quality assurance and cost savings go hand in hand because any unnecessary admission that is avoided is also a potential quality problem avoided."

Generic quality screens appear to be useful instruments for quality review, but may be in need of refinement.

The HCFA required all PROs in their second contract period (1986-1988) to review all cases against a set of criteria (called generic quality screens) designed to identify potential quality problems. The generic quality screen process includes reviewing the following six elements: 1) adequacy of discharge planning, 2) medical stability at time of discharge, 3) deaths, 4) nosocomial infections, 5) unscheduled return to surgery, and 6) trauma suffered in hospitals. Two-thirds of the PRO CEOs thought that the screens have been at least moderately effective in identifying quality problems. A greater proportion (89 percent) of HCFA staff thought they were at least moderately effective. In fact, one HCFA staff person described the screens as "a stroke of genius." On the other hand, a majority of the local external entities, particularly State medical licensure board and American Association of Retired Persons (AARP) representatives, thought the generic screens were only marginally useful or not effective, and a sizable proportion of the national external entities (47 percent) noted that they "did not know" about the effectiveness of the generic quality screens. (See figure III.)

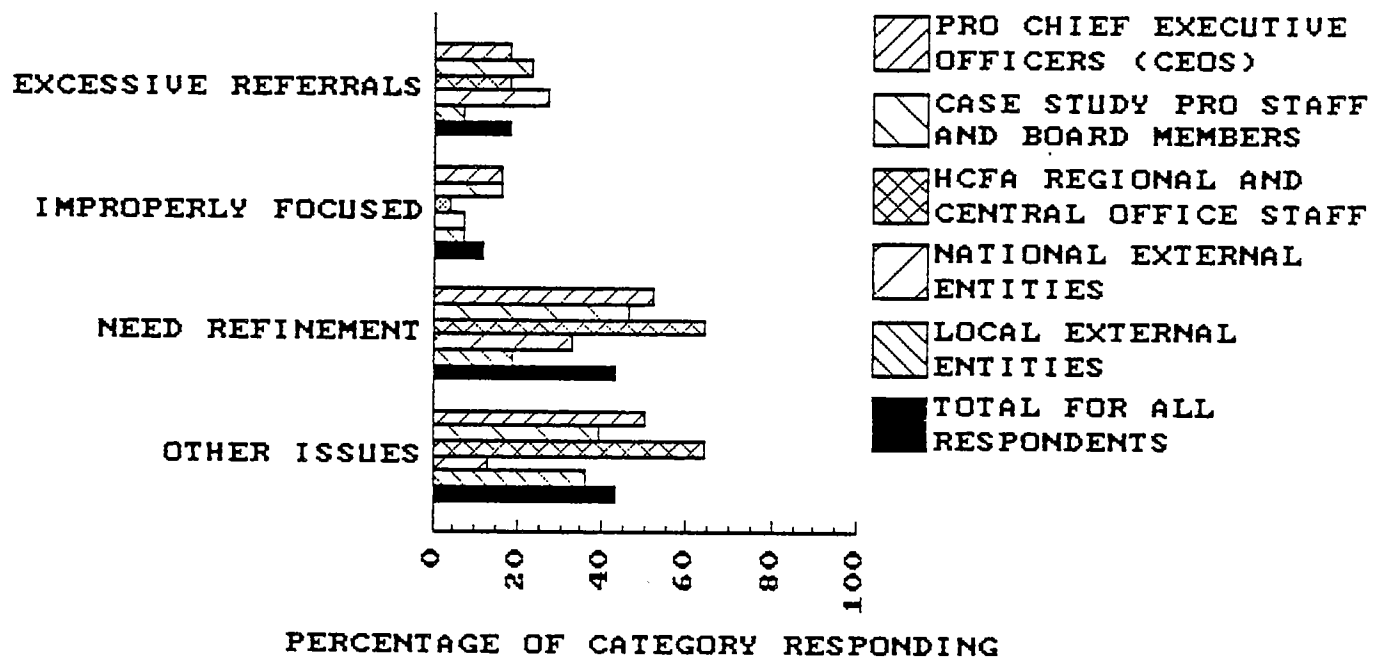
FIGURE III
PERCEPTIONS OF THE EFFECTIVENESS OF
GENERIC QUALITY SCREENS



Note: N=185 respondents
Source: OIG Inspection Interviews

A recent Ernst and Whinney telephone survey of the PROs and a sample of hospitals supported the value of the generic quality screens. The study's findings noted that "the survey participants strongly agreed the current generic quality of care screens are effective in flagging cases of suboptimal quality."⁹ Such sentiments were echoed by many of the respondents in the OIG inspection, who found the screens useful because they provide the PRO program with national quality review procedures and encourage reviewers to focus on quality. On the other hand, as reflected in figure IV, several respondents from each group noted a variety of problems with the screens.

FIGURE IV
CONCERNS REGARDING GENERIC QUALITY SCREENS



Note: N=185 respondents
Source: OIG Inspection Interviews

The concerns most frequently mentioned by respondents included that the screens have produced excessive referrals to physician advisers, have been improperly focused, and need refinement. The HCFA introduced the generic quality screens without pilot-testing them. Instructions for implementing the screens required nurse reviewers to refer all cases identified through the screens (screen failures) to physician advisers, regardless of whether the nurse reviewers thought that such cases merited a higher level of review. Hence, the screens produced many "false positives" (cases that were identified as potential quality problems but were subsequently dismissed by the physician reviewers), which proved expensive for the PROs, professionally

frustrating for both the nurse reviewers and the physician advisers, and caused much ill feeling in the medical community. In response to loud protests from the PRO and medical communities, HCFA has allowed the PRO nurse reviewers some discretion in using their "professional judgment" with cases identified by the generic quality screens.

Other problems indicated by respondents were that the screens lack flexibility for local use and that their interpretation and application are inconsistent among PROs. This inconsistency is also suggested by our recent analysis of the generic quality screen data reports that the PROs submit to HCFA. We analyzed those reports through July 30, 1987. Given the staggered start-up of the PROs and hence the variable number of months reflected in each PRO's aggregated totals as of July 30, 1987, we are unable to draw definitive conclusions from the data. However, the figures do reflect wide variations in both the percentages of cases that failed particular screens and the percentages that were later confirmed to be quality problems. The national ranges for each of the six screens are reflected in table 1 below:

TABLE 1

NATIONAL AGGREGATED PERCENTAGE RANGE OF GENERIC QUALITY SCREEN FAILURES AND CONFIRMED PROBLEMS (1986-1987)

<u>Screen Number</u>	<u>Range of Screen Failure¹</u>	<u>Range of Confirmed Problems²</u>
1	0.1 - 17.5%	0 - 100%
2	1.6 - 43.0%	0 - 69.0%
3	0.1 - 11.2%	0 - 63.8%
4	0.3 - 21.6%	0 - 98.8%
5	0.1 - 12.7%	0 - 73.1%
6	0.4 - 17.5%	5.5 - 82.6%

¹ Percentage of all records reviewed that failed the screen

² Percentage of screen failures that were subsequently confirmed as quality problems

Source: HCFA/HSQB/OMR, "Peer Review Organization Data Summary," July 1987.

Analysis of quality screen data for the 12 case study sites further supports the suggestion that a substantial variation exists among the PROs relative to their interpretation and application of the generic quality screens. (See appendix X.) Among the case study sites, generic quality screen #1 (adequacy of discharge planning) appears to be the most consistently applied and useful screen, given the relatively high percentages

of cases identified by most of the PROs that were subsequently confirmed as quality problems. Furthermore, analysis of the quality screen data for the case study sites identified one site ("C") as a particular outlier because of its consistently low percentages both of screen failures and of confirmed problems with five of the six screens.

Such analysis supports the value of the PROs using some standard generic quality screens in order for HCFA to compare and contrast their outcomes. However, analysis of the data also suggests that the current screens may need refinement.

The PROs' quality review efforts are limited by a lack of consensus regarding the definition of quality medical care, by the amount of resources available for such care, and by the current lack of sophisticated technology to assess quality.

Physicians must provide services and the PROs must evaluate them within an environment where differing and sometimes competing views of high-quality care coexist.¹⁰ One economic explanation of the recent reemergence of the debate about the quality of and resource allocations for medical care is that we are making a transition away from a seller's market (the relative scarcity of physicians and health facilities of the previous 2 decades) to a buyer's market (an abundance of physicians and health facilities). Hence, buyers of health care--businesses, Government, and individual consumers--are asserting their priorities for quality health care in both micro and macro contexts. In the micro context, the various buyers want their notions of quality incorporated into the individual care provided by physicians. In the macro context, they want "a voice in the money transfers made to providers per unit of service and in the use of resources in the treatment of illness."¹¹

The changing health care delivery environment is reflected in Secretary Bowen's recent article, "What Is Quality Care?" in which he tells physicians that in approaching quality of care:

"You must constantly weigh two matters. One is the enduring concern for patients as people that you bring with you as a physician, and the other, more public, is a recognition that your desire to extend the physicians' healing touch must be tempered by the limits of society's resources.... We who practice medicine have not until recently had to consider the public perspective. For us, it has always been the patient first, regardless of costs.... But now...events force a different and wider perspective on every practicing physician."¹²

One analysis of the differing views of what constitutes quality is summarized in table 2 below:

TABLE 2
DIFFERING VIEWS OF QUALITY

<u>Interested Party</u>	<u>High Priority Elements of Care</u>
Consumers	<ul style="list-style-type: none"> o Responsiveness to perceived care needs o Level of communication, concern, and courtesy o Degree of symptom relief o Level of functional improvement
Practitioners	<ul style="list-style-type: none"> o Degree to which care meets the current technical state-of-the-art o Freedom to act in the full interest of the patient
Purchasers	<ul style="list-style-type: none"> o Efficient use of funds available for health care o Appropriate use of health care resources o Maximum possible contribution of health care to reduction in lost productivity

Source: James Roberts, M.D. and James Prevost, M.D. "Using Outcome Indicators to Evaluate Quality of Care," The Internist: Health Policy in Practice, September 1987, p. 11.

Just as different views coexist about how to define quality, several perspectives also exist about how to measure it. The classic model for measuring quality, developed by Avedis Donabedian, focuses on three components: structure, process, and outcome. Structure includes such factors as whether a hospital has a regularly operating quality assurance committee and whether the physicians on staff are properly credentialed; process includes such factors as whether a physician or provider delivers care that conforms with generally recognized standards of quality; and outcome includes such factors as morbidity, mortality and patient satisfaction.¹³

All these factors interact in the measurement of quality. Several private entities are responding to the public's growing demand for quality assurance by developing new quality assessment

methodologies. For instance, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) is currently identifying key clinical indicators of quality in order to create a national data base of normative performance to which an organization can compare its own performance. Such data will be adjusted for difference in case mix. Other academic institutions and private companies have developed various computer programs to evaluate clinical outcomes. Although we have not evaluated their effectiveness, these new software systems include: the Medical Illness Severity Grouping System (MedisGroups), the Acute Physiology and Chronic Health Evaluation (APACHE II), the Computerized Severity Index (CSI), the Disease Staging and the Patient Management Categories (PMC).¹⁴

In the course of our interviews with PRO CEOs and staff, many voiced concerns about their lack of accessibility to the latest quality assessment technologies. The PROs' current case-by-case review of patient records is a highly labor-intensive process. Virtually all the case study sites are experiencing high turnover among nurse reviewers who constitute the backbone of the review process. In addition, several PROs, as well as national external entities, voiced the feeling that the PROs should be more in the forefront of quality assurance research--both in field testing severity measures and developing new quality assurance techniques. As one PRO medical director put it, "We should be the national leaders of quality assurance research."¹⁵

The PROs exhibit great variations in their approaches to and outcomes of quality review.

As previously stated, our analysis of HCFA's data reports through July 30, 1987, suggested that the PROs' interpretation and application of the generic quality screens were inconsistent. In addition, recent congressional testimony by Sidney Wolfe, M.D., Director of Public Citizens Health Research Group (PCHRG), reflected that the PROs vary in their provision of quality-related information to the public. Most of the PROs surveyed by PCHRG appeared to receive and process little or no requests for public information, while a few PROs appeared to be very active in providing such information.¹⁶

Our case study site visits enabled us to compare and contrast the PROs' processes for reviewing and addressing quality of care problems. We found great variation among the PROs' review systems regarding the following:

- o the number of severity levels (i.e., three to six);
- o the number of review layers (i.e., the number of different groups of individuals who review a given case);
- o the number and type of intervention steps and time frames between the identification of a quality problem and the potential sanctioning of a physician or provider;

- o the number of cases required to constitute a "substantial number of substantial violations;" and
- o the guidelines for determining what penalties (monetary penalty or exclusion) to recommend in sanction cases.

Furthermore, our analysis of HCFA's aggregated Quality Intervention (544J) Report for the 12 case study sites through September 30, 1987 suggested some interesting patterns. In general, the PROs reported using very little formal education as an intervention tool and relatively little intensified review. One State reported no new physicians with quality problems within four quarters, whereas another found 5,694 in the same time period. Most significantly, the two case study site PROs that had the most complicated quality review systems (in terms of layers of review) also were among the three least active PROs according to the 544J report. The variations in the PROs' reporting reflected either inconsistent interpretation of the report instructions or differences in their approach to quality review.

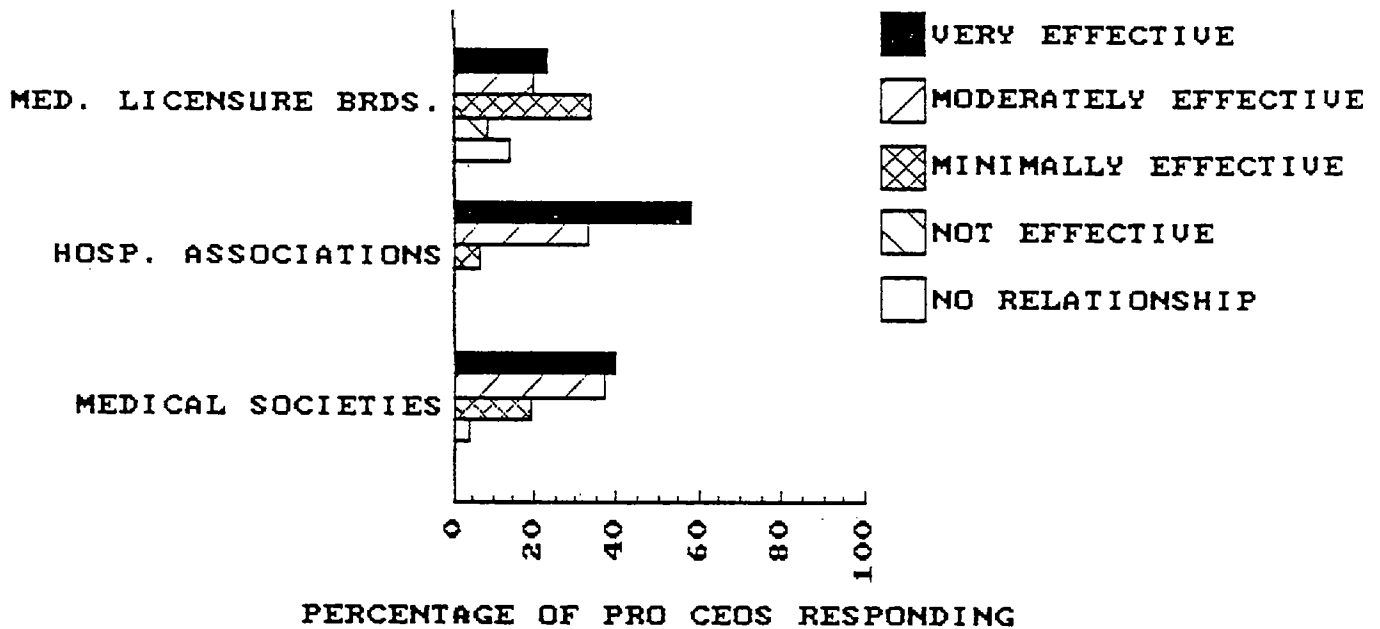
The PROs' impact on ensuring high-quality care would be enhanced by greater coordination with other health care entities, particularly with the State medical licensure boards.

PRO Relationships with State Medical Licensure Boards:

Sixty-seven percent of the 44 PRO CEOs noted a relatively poor working relationship (i.e., less than "moderately effective") with State medical licensure boards (See figure V) and 27 percent of them indicated that they needed clarification of their Federal confidentiality restrictions. Several CEOs noted that their wish to work more cooperatively with the State medical licensure boards is inhibited by their uncertainty about what information they are allowed to share with those boards. The HCFA has yet to release clarifying instructions (i.e., the confidentiality chapter of the PRO Manual) to the PROs on this issue.

In only one of the 12 case study States did the PRO and the State medical licensure board representatives agree that they had a "very effective relationship." In that particular best practice State, the close working relationship between the organizations was fostered by the cross-fertilization of personnel--two current medical licensure board staff were former PRO employees, and one physician on the State medical board also sat on the PRO board of directors. However, in every other case study site, at least one of the two organizations perceived a poor working relationship between the two organizations. Several PRO CEOs mentioned that they had referred sanction cases to their State medical board but had received no feedback.

FIGURE V
PRO CEOs' PERCEPTIONS OF EFFECTIVENESS OF
PRO RELATIONSHIPS WITH STATE EXTERNAL ENTITIES



Note: N=44 respondents
 Source: OIG Inspection Interviews

The continuing pattern of poor working relationships between the PROs and the State medical licensure boards is particularly disturbing in view of a previous OIG inspection report on State medical licensure boards which included recommendations for the boards to improve their working relationships with other review entities.¹⁷

PRO Relationships with Hospital Associations:

As reflected in figure V, the PRO CEOs perceived having much better relationships with their local hospital associations. Fifty-eight percent of the PROs thought that their relationships with their hospital associations were "very effective" and 33 percent thought that they were "moderately effective." Our case study site visits confirmed this pattern. In two sites, both the PRO and the hospital association rated their relationship as being "very effective." In both those States, hospital association board members sat on the PRO board. In eight of the 10 other States, the PROs and hospital associations ranked their relationships as at least "moderately effective." Despite their generally positive working relationships, several of the PRO and hospital association staff mentioned that the PROs had had problems with individual hospitals regarding the PROs' unwillingness to share information about particular physicians who had been identified as having quality problems.

PRO Relationships with Medical Societies:

The PROs' relationships with their respective State medical societies, as reflected in figure V, appear to be stronger than with the State medical licensure boards but less effective than with the hospital associations. Seventy-seven percent of the PRO CEOs reported at least moderately effective relationships with their medical societies. Again, our case study site visits supported the pattern reflected by the CEO interviews. Two case site PROs had "very effective" relationships with their respective medical societies. In both cases, the PROs were medical-society sponsored. In most of the remaining sites, the PROs had at least moderately effective relationships with the medical societies. Two States reported poor working relationships between the PRO and the State medical society; one of the two had a large number of sanction referrals and the other had none. Most PRO and medical society respondents mentioned that the major issues between their organizations focused on whether the PROs quality intervention procedures provided adequate physician and provider education and whether the PROs' sanction procedures provided physicians with adequate due process.

Importance of Communication Between PROs and External Entities:

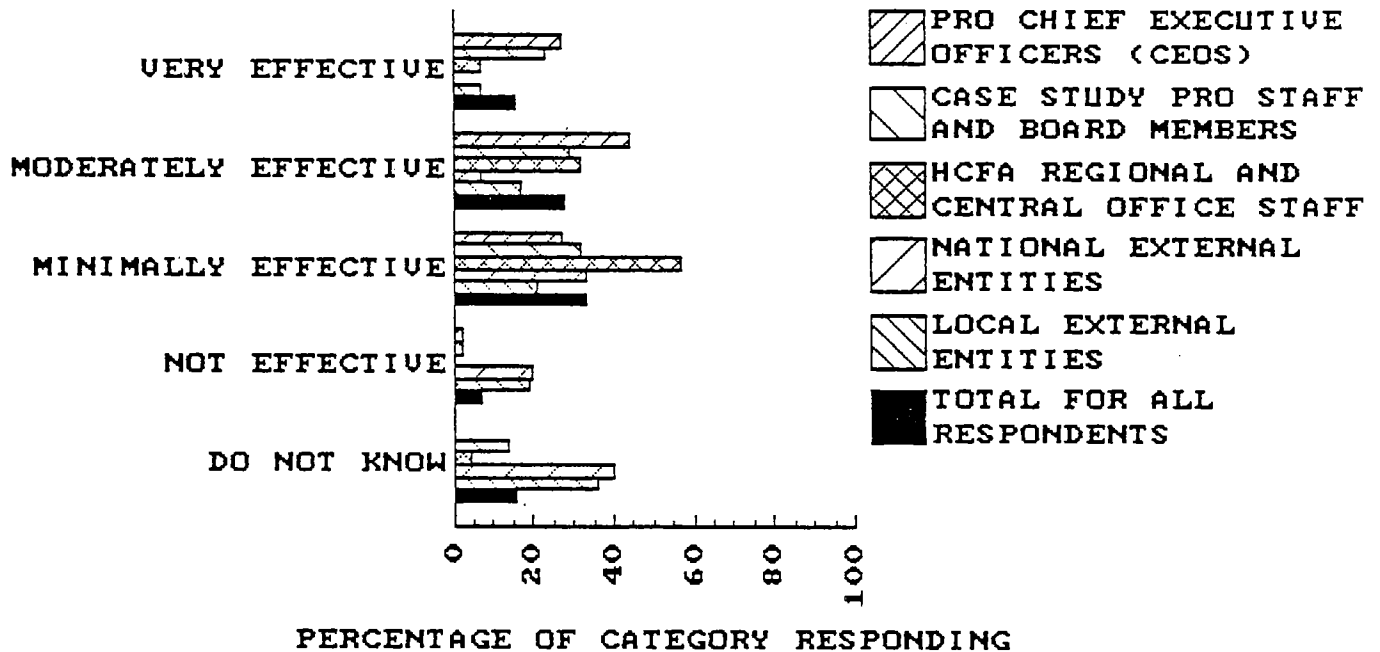
In comparing the 12 PRO case study sites, we found that greater coordination between the PRO and external entities seemed to be enhanced when the PRO initiated some formal ongoing communication link with that entity, either through representation on the PRO board or through regular issue-related meetings.

Implementation of the Medicare and Medicaid Patient and Program Protection Act of 1987 is intended, in part, to facilitate closer working relationships and greater information sharing between the PROs and other entities, especially State medical licensure boards. That legislation requires States to make available to the HHS Secretary information concerning adverse actions taken by State medical licensure boards against health care practitioners. It also requires that the HHS Secretary disseminate information on these actions to State medical licensure boards and to other State and Federal officials.

Most PROs are finding it difficult to provide effective outreach to Medicare beneficiaries.

Eighty-four percent of all PRO CEOs, 62 percent of HCFA staff, and 72 percent of the AARP representatives thought that the PROs had at least moderately effective relationships with beneficiary organizations. In addition, the vast majority of the PROs thought they were at least moderately effective in their outreach efforts to beneficiaries. (See figure VI.)

FIGURE VI PERCEPTIONS OF THE PROS' EFFECTIVENESS IN OUTREACH TO MEDICARE BENEFICIARIES



Note: N=185 respondents
Source: OIG Inspection Interviews

However, in contrast, a vast majority of the national and local external entities either thought the PROs were only minimally or less effective or "did not know" how effective the PROs were in their outreach efforts to beneficiaries. As one national entity representative said: "I know that if they were doing much in this area that I would have heard about it. And I haven't heard anything."

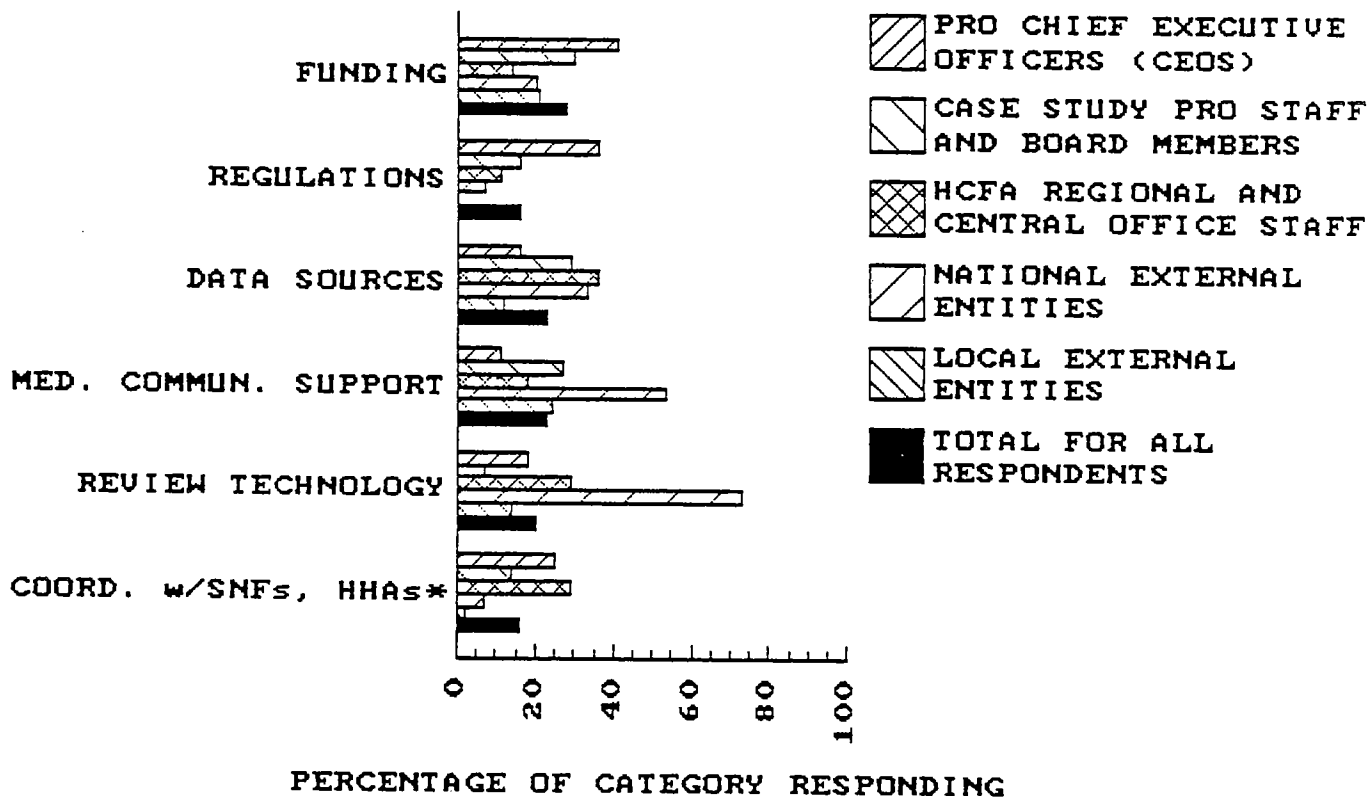
The major outreach activities mentioned by the PROs included speaking engagements, hot lines, radio spots, and newspaper articles. The major reasons cited for the PROs' relative lack of activities in this area included the PROs' limited resources and the fact that the elderly are a difficult population to reach effectively. In our case study visits, we observed three PROs with especially strong beneficiary outreach efforts. In all of those organizations, particular staff have been assigned to that function and have developed extensive video and written materials. They, along with consumer representatives on the PRO boards, hold ongoing meetings with beneficiaries. Although staff at one case study site raised questions about the rationality of the PROs having responsibility for beneficiary outreach, most PRO staff felt they could do more outreach activities if they were provided with the necessary resources and opportunities to share ideas with other PROs. Aside from the AARP, we heard of few other private or Government organizations providing information

to the beneficiaries about their local PROs. For instance, only 6 of the 44 PRO CEOs reported that their local Social Security offices distribute PRO-related information.

The PROs will face serious challenges and obstacles in reviewing care in nonhospital settings.

Seventy-five percent of all CEOs interviewed anticipate problems in reviewing care in nonhospital settings and the four other groups interviewed voiced similar levels of concern. Besides the normal learning curve associated with any new activity, the primary concerns anticipated by various groups are reflected in figure VII.

**FIGURE VII
EXPECTED PROBLEMS WITH REVIEW IN
NON-HOSPITAL SETTINGS**



N=185 respondents/Source:OIG Insp. Interviews
 *SNFs--Skilled nursing facilities
 *HHAs--Home health agencies

The PROs' major concerns focus on the lack of adequate funding, guidance (regulations) and data sources, as well as the lack of support that they anticipate from the medical community. In

addition, they voiced concern about their inability to link data on medical care provided to Medicare beneficiaries in hospital settings (Medicare Part A) with data on medical care provided to them in nonhospital settings (Medicare Part B).

The HCFA staff anticipated that the PROs' major problems in reviewing care in nonhospital settings would include (in descending order of frequency) the lack of adequate data sources and review technology for ambulatory settings as well as the inherent difficulties of coordinating with multiple skilled nursing facilities (SNFs) and home health agencies (HHAs). The national and local external entities anticipated that the PROs' major problems would include (in descending order of frequency) the lack of adequate review technology, the lack of support from the medical community, the lack of available data sources and the lack of funding.

In both our macro-level and case study interviews, individuals from all groups voiced concerns about the feverish pace at which the PRO program has moved. The PROs have been asked to do ever-increasingly complicated reviews without the time and technical assistance to do a credible job. As one PRO CEO staff person noted: "If you really want to help us do better, why don't you leave us alone for a while?"

RECOMMENDATIONS

Quality of Care

- o The HCFA should work with the PROs to develop more consistent approaches to defining and addressing quality of care problems.
- o The HCFA should work with the PROs to ensure more consistent reporting of quality intervention activities.
- o The HCFA should develop and widely disseminate information on the full range of educational corrective actions being taken by the PROs to address quality of care problems.
- o The HCFA should create more opportunities for the PROs to share information with each other concerning their quality review and intervention approaches.
- o The HCFA should intensify its support of research to define and assess the quality of medical care. In addition, HCFA should collect and integrate quality-related research findings from all relevant sources and disseminate them to the PROs.

Discussion:

The HCFA has an opportunity to build upon the work it has already undertaken in research related to quality of care. The PROs' quality review efforts are difficult and complex, and they have a limited track record. Implementation of the above recommendations will help the PROs learn from one another's experience and broaden the public's understanding of the PROs' quality review efforts.

Generic Quality Screens

- o The HCFA should ensure that any major modifications to the generic quality screens are pilot-tested before national implementation.
- o The HCFA should promote greater consistency in the application of generic screens through its training efforts and operational instructions.
- o The HCFA should support the development and pilot testing of more effective and less labor-intensive review methodologies.

Discussion:

Implementation of the generic quality screens was central to the PROs' quality of care review efforts. The HCFA has already taken steps to refine the screens. By also implementing the above recommendations, HCFA will help to avoid unnecessary expenditure of PRO resources and enhance the credibility of the PROs' quality review efforts.

PROs' Coordination with Other Entities

- o The HCFA should promote closer working relationships between the PROs and other health care entities and encourage more sharing of information about physicians and providers with quality of care problems. These efforts should include clarification by HCFA of the PROs' confidentiality restrictions and a regulatory requirement that PROs report physician misconduct or incompetence to State Medical Licensure Boards. This should be accomplished through the Notice of Proposed Rulemaking (NPRM) on changes to peer review organization regulations.

Discussion:

The PROs are one of several different types of entities responsible for ensuring quality of medical care. By encouraging PROs to work more cooperatively with other entities that share similar missions, the HCFA will help maximize the PROs' impact on quality of care.

PROs' Outreach to Medicare Beneficiaries

- o The HCFA should seek ways to strengthen the beneficiary outreach efforts of the PROs. In this context, it should coordinate more closely with the Social Security Administration and the Office of Human Development Services and should provide more opportunities for the PROs to share best practice approaches with each other.

Discussion:

An extensive network of Federally funded agencies provide services to the Medicare population. By coordinating with those agencies, the HCFA can help PROs gain better access to the Medicare population it is charged to serve. In addition, because relatively few PROs have had extensive experience with such outreach efforts, it is important to provide opportunities for the PROs to learn from each other's experiences.

Review of Care in Nonhospital Settings

- o The HCFA should work with the PROs to delineate the most significant constraints that will be faced in reviewing care in nonhospital settings and to develop strategies for addressing these constraints.
- o The HCFA should seek ways to improve the availability of data on outpatient and inpatient services provided to the Medicare population. In this context, it should build upon demonstration projects currently underway in Texas and Maryland to link the Medicare Part A (inpatient) and Part B (outpatient) data files.

Discussion:

The PROs' review of care in nonhospital settings will lead them into uncharted waters. To prepare for such broad and complicated responsibilities, the PROs will need to use lessons learned from their inpatient review efforts. Implementation of the above recommendations will help the PROs address the most critical concerns in their efforts to carry out effectively their expanded responsibilities.

APPENDIX I

ENDNOTES

1. Federal Register, Vol. 49, No. 39, February 27, 1984, p. 7202.
2. Tax Equity and Fiscal Responsibility Act of 1982, Commerce Clearing House, Inc. p. 37D. Senate Rept. 97-494 at 41.
3. "Examination of Quality of Care Under Medicare's Propective Payment System," Hearing before the Committee on Finance, United States Senate, June 3, 1984, p. 44.
4. Andrew Webber, "A PRO Report Card," The Internist: Health Policy in Practice, the American Society of Internal Medicine, July 1986, pp. 7-9.
5. 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.
6. 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.
7. Carole Magoffin, "Can PROs Uncover Quality Concerns?" Business and Health, the Washington Business Group on Health, July/August, 1986, p. 14.
8. Ibid., p. 15.
9. Ernst and Whinney National Office, 2000 National City Center, Cleveland, Ohio 44114, Tel. (216) 861-5000 ext. 5800, unpublished survey report.
10. James S. Roberts, M.D. and James Prevost, M.D., "Using Outcome Indicators to Evaluate Quality of Care," The Internist: Health Policy in Practice, the American Society of Internal Medicine, September, 1986, pp. 10-15. This thought-provoking article offers a definition of high-quality care that bridges diverse perspectives: "High quality care identifies accurately and fully the health care needs (educational, preventative, restorative and maintenance) of an individual or group and applies the resources (human and other) necessary to meet those needs in a timely manner as effectively as the practical state of the art allows."

11. Uwe Reinhardt, "Quality of Care in Competitive Markets," Business and Health, the Washington Business Group on Health, July/August, 1987, p. 7.
12. Otis Bowen, M.D., "What is Quality Care?" New England Journal of Medicine, Massachusetts Medical Society, June 18, 1987, p. 1578.
13. Arnold Milstein, David Nash and Jonathan Sands, "Auditing Quality of Care: An Employer Based Approach," Business and Health, the Washington Business Group on Health, July/August, 1987, p. 10.
14. For a detailed summary of the elements and costs of these computer packages, see Charles M. Jacobs, Alan Brewster, M.D. and James B. Couch, M.D., J.D., "Severity of Illness in the Cost/Quality Equation," The Internist: Health Policy in Practice, the American Society of Internal Medicine, September 1987, pp. 16-31.
15. The following research efforts have recently been undertaken and should provide some valuable quality-related information for the PRO community:
 - o The National Academy of Sciences is conducting a study to develop a strategy for reviewing and assuring the quality of care for Medicare beneficiaries; and
 - o The consulting firm of Lewin/IMC, under contract with the HHS Assistant Secretary for Planning and Evaluation is conducting two related studies. The first, "A Taxonomy and a Critical Review of Existing Quality of Care Guidelines" will critique existing systems for enhancing quality medical care. The second, "A Forward Plan for Expanding the Use of Quality of Care Guidelines" will develop a systematic plan for HHS to encourage the dissemination and application of clinically useful information on medical practices.
16. 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, U.S. House of Representatives, October 26, 1987.
17. Medical Licensure and Discipline: An Overview, Office of Analysis and Inspections, Office of Inspector General, Department of Health and Human Services, June 1986.

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 has had a close association with the PRO program since its inception. Among other activities, the OIG has conducted pre-award 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, policy makers, 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 pre-admission. 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 area (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 five hours with an average length of two 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 generally 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 assure 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 had responsibility 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. 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 (i.e., 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 "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 out-patient 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 two 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 is expected soon. (Herb Danzler--Project Leader).

- o At the request of the Senate Aging Committee, the Program Evaluation and Methodology Division (PEMD) is exploring how outcome data can be used to monitor quality of care. That study will include a review of how PROs use available data in their profiling of providers. A draft report is expected soon. (Eric Peterson--Team Leader).
- o At the request of the House Ways and Means Committee, the PEMD is also designing a study to evaluate the PROs' handling of quality of care issues. The study is still at the design stage. (Jill Bernstein--Team Leader)
- o At the request of the House Ways and Means Committee, the Human Resources Division (HRD), is undertaking a brief 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 analysis of the variation among PROs in their criteria for determining the appropriate sanction penalty (monetary penalty or exclusion) to recommend. The HRD is also contemplating an evaluation of HCFA's management of the PRO program. (Steven Fox--Project Leader)

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 Samo
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 present 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 of practitioner and/or review of 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 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/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 non-emergency 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

- o 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.
- o Review of hospital denial notice. Implemented on December 1, 1986, as required by the statute.
- o 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.
- o 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.
- o 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.
- o Review of HMOs/CMPs. The HCFA published a listing of States to be competitively bid in the Federal Register on January 5, 1987. RFP for those States was issued on March 9, 1987. Review began July 1, 1987.
- o The Secretary is to identify and make available to PROs methods of identifying those cases which 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 is planning to contract with the American Medical Review Research Center (AMRRC) for the small-area analysis which will utilize feedback from 12 pilot PROs.
- o 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.

- o 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.
- o 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.
- o 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

- o The Medicare and Medicaid Patient Program Protection Act of 1987 greatly expanded the sanction and civil monetary penalty authorities under the Medicare and Medicaid program. The bill also required the reporting of all disciplinary actions made by State medical licensure boards.
- o The recently enacted 1987 Omnibus Budget Reconciliation Act has made the following PRO changes:
 - o three-year PRO contracts with staggered expiration dates;
 - o a ban on informing Medicare beneficiaries of substandard quality payment denials before offering providers the opportunity for reconsideration;
 - o publication in the Federal Register of PRO work plans and evaluation techniques;
 - o a prohibition of automatic renewals of PRO contracts held by out-of-state groups, provided in-state physician groups wish to compete;

- o a ban on physicians billing Medicare patients for assigned claims denied for payment on grounds of substandard quality;
- o a requirement that PROs give special consideration to the needs of "remote rural areas" in setting review standards;
- o mandatory onsite review at 20 percent of rural hospitals in a review area;
- o mandatory meetings several times a year between PROs and hospitals' leadership;
- o assessment of access provided to Medicare enrollees in risk-sharing HMOs and mandatory beneficiary outreach;
- o a provision encouraging PROs to use physician specialists in initial review of psychiatric and rehabilitation cases;
- o demonstration projects assessing the educational value of video communications between academic medical centers and physicians treating patients in rural areas;
- o administrative law hearings for rural physicians or hospitals facing PRO-initiated exclusions from Medicare; and
- o a report to Congress on the sanctions "due process" reforms agreed to by HHS, the American Medical Association, and the American Association of Retired Persons.

Source: Medical Utilization Review, vol. 15 (no. 24), December 24, 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 about the PRO program (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 vs. 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 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).

APPENDIX X

TABLE OF NUMERIC QUALITY SCREENS:
PERCENT OF FAILURES AND CONFIRMED PROBLEMS (1906-1907),
BY SCREEN AND CASE STUDY SITE

PRO CASE STUDY SITE	SCREEN 1 REVIEWED FAILED	SCREEN 1 X REVIEWED PROBLEMS	SCREEN 2 X REVIEWED FAILED	SCREEN 2 X REVIEWED PROBLEMS	SCREEN 3 X REVIEWED FAILED	SCREEN 3 X REVIEWED PROBLEMS	SCREEN 4 X REVIEWED FAILED	SCREEN 4 X REVIEWED PROBLEMS	SCREEN 5 X REVIEWED FAILED	SCREEN 5 X REVIEWED PROBLEMS	SCREEN 6 X REVIEWED FAILED	SCREEN 6 X REVIEWED PROBLEMS	
A	34,792	6.6	96.6	36.2	17.4	2.2	10.4	14.0	24.3	1.3	2.9	6.7	23.4
B	44,575	2.3	100.0	7.2	30.2	1.1	9.5	5.7	21.3	0.9	29.2	7.9	41.0
C	124,642	0.3	29.0	1.6	23.7	0.2	14.9	1.2	57.5	0.2	9.7	1.2	33.0
D	24,302	0.2	100.0	17.0	31.9	0.1	31.3	6.6	21.7	0.0	29.2	3.4	40.5
E	6,140	0.5	75.0	15.5	19.1	1.0	10.3	11.7	36.4	0.9	19.3	3.1	29.6
F	80,624	0.6	40.5	4.8	32.0	3.3	13.4	2.5	42.7	0.6	15.6	2.1	37.6
G	171,007	12.5	99.9	11.0	21.5	1.4	22.2	5.0	57.9	1.0	19.6	4.0	31.9
H	14,300	3.4	100.0	10.9	19.7	1.1	15.5	7.4	31.7	0.9	22.0	1.7	35.0
I	3,502	3.9	100.0	8.9	9.0	1.4	4.0	9.3	2.0	1.5	3.9	6.0	32.4
J	162,019	0.3	77.0	2.0	34.5	0.4	22.4	1.6	00.0	0.3	15.5	1.0	45.2
K	31,449	0.7	100.0	18.3	17.6	0.7	23.4	2.6	90.0	0.4	6.9	6.5	27.7
L	35,571	8.2	97.2	6.4	4.0	1.6	2.4	0.0	4.1	1.2	3.6	3.9	14.8
TOTAL	733,163	4.1	97.1	8.0	22.1	1.1	15.7	4.1	42.5	0.6	16.0	3.2	32.9

KEY:

SCREEN 1: Adequacy of discharge planning
SCREEN 2: Medical stability of patient at discharge

SCREEN 3: Deaths

SCREEN 4: Nosocomial infections

SCREEN 5: Unscheduled return to surgery

SCREEN 6: Trauma suffered in the hospital

NOTE: "X Reviewed Failed" is the percentage of all records reviewed that failed the screen.

"X Failed Problems" is the percentage of screen failures that were subsequently confirmed as quality problems.

Source: HCFA/HSOB/DMR, "Peer Review Organizations Data Summary," July 1907.

APPENDIX XI

HCFA, ASPE, AARP AND AHA COMMENTS ON THE DRAFT REPORT AND OIG RESPONSES TO THE COMMENTS

We sent copies of the draft report to a wide array of entities who participated in our PRO study and received comments from the Administrator, Health Care Financing Administration, the Assistant Secretary of Planning and Evaluation, the Acting Executive Director, American Association of Retired Persons and the Executive Vice President, American Hospital Association. In the sections that follow, we offer their comments, either verbatim or in summary form, and our responses to the comments

HCFA COMMENTS

The following are HCFA's comments in full and our response to it:

General Comments

We have reviewed OIG's draft report regarding the effectiveness and utilization of quality care reviews conducted by the peer review organizations (PROs) and agree with its content. The report accurately reflects problems already identified by our Health Standards and Quality Bureau (HSQB). Planned and completed remedies, discussed by HSQB staff during the course of their interviews with OIG staff, appear as recommendations in the draft.

Our specific actions for each of the findings contained in the report are attached for your consideration.

Specific Comments

Quality of Care:

A task force made up of PRO physicians and central and regional office personnel has developed a model Quality Intervention Plan. Its use will be mandated in the new Scope of Work which was reviewed by OIG. This Plan prescribes the following quality review process:

1. Problem identification/timing of review
2. Determination of source of problem
3. Assignment of severity levels (The HCFA severity levels will be mandated.)
4. Notification of quality problems

5. Quarterly profiling and weighted severity scores
6. Quality interventions

We have pilot studies and research efforts underway which should assist us in assessing quality care in the future.

Generic Quality Screens:

A task force was set up by HSQB and during the period September through November 1987, meetings were held to develop consistent definitions for the hospital inpatient generic quality screens. The task force was comprised of representatives from each HCFA regional office, each PRO and central office staff. The revised generic quality screens are included in the new Scope of Work.

We have solicited PROs to participate in several different pilot studies. The PROs will be asked to develop review methodologies and submit to HCFA a study design which will include evaluation criteria.

Coordination with Other Entities:

Although we are restricted by law as to the amount of information we can share, we are attempting to remedy this situation. We have a regulation in process that will relax restrictions and provide for a larger exchange of information.

PROs' Outreach to Medicare Beneficiaries:

The current PRO Scope of Work requires PROs to describe the methods they use to implement programs such as hotlines, seminars, brochures, and consumer representation on PRO governing bodies. We collected and reviewed each of the PROs' community outreach plans and developed a model community outreach program. This model is included in the new Scope of Work.

Review of Care in Nonhospital Settings:

In preparation for starting review of Intervening care between hospital discharges, we worked with the PROs, as well as national associations, in developing the review requirements.

We have been working to provide the data needed to link outpatient and inpatient care. HCFA has developed the Medicare Automated Data Retrieval System (MADRS). The PRO is able to electronically query this system. The PRO will provide the two hospital stay dates and the MADRS will identify any intervening care. This system is currently being used by the Pennsylvania PRO. In addition, the HCFA demonstration projects, known as the Common Work File (CWF), are being expanded. In addition to combining the data from our carriers and intermediaries into

single files in Maryland and Texas, we will add additional jurisdictions to those files in FY 1988. We are also taking steps to assure that all Part A and Part B claims for beneficiaries assigned to CWFs, regardless of which contractor in the country actually processes the bills, are incorporated into the CWF. This will provide complete Medicare history and permit higher quality medical review. We are currently discussing how the CWF might best support PRO review functions. We also have plans to conduct several pilot studies to test alternatives for reviewing care in nonhospital settings.

Other Comments

Finally, we would like to suggest that pages 48 and 49, C., Other PRO-Relevant Legislation, be revised to incorporate the actual legislative language. Parts of this summary, which was prepared by Medical Utilization Review, are misleading and should be clarified.

OIG Response

We support the initiatives that HCFA has undertaken to address issues raised in our report. However, we reiterate our suggestion that HCFA "develop and widely disseminate information on the full range of educational corrective action being taken by the PROs to address quality of care problems." It is important for all relevant parties to know the breadth of activities other than sanctioning, in which the PROs engage.

Furthermore, we would like to highlight the importance of HCFA expeditiously developing the confidentiality regulation referred to in its comments. In addition, HCFA failed to address whether it is intending to require PROs to report instances of physician misconduct or incompetence to State medical licensure boards, which HCFA first agreed to in March 1986 in a briefing on the OIG report on medical licensure and discipline. If the intention of the PRO program is to protect Medicare beneficiaries from substandard medical practice, it is imperative that the PROs be given clear direction to maximize coordination with other review entities, especially State medical licensure boards and hospital quality assurance committees.

It is worth noting that, since HCFA responded to our draft report, it has informed PROs that "the physician-specific quality concern (i.e., one or more confirmed quality problems) may be disclosed by a PRO, with or without a specific request, to the hospital where the service in question was provided." As with the release of information to medical licensure boards, we believe that the PROs should be required to provide quality-related information to hospitals and that HCFA should issue the necessary regulations immediately. The PROs' confidentiality

restrictions have been a festering issue that is worthy of immediate attention.

Finally, while we commend HCFA's efforts to develop a model community outreach plan, we agree with the AHA's suggestion that HCFA clarify the purpose of the PROs' community outreach efforts.

ASPE COMMENTS

The Assistant Secretary for Planning and Evaluation echoed HCFA's comments regarding the model community outreach program which HCFA will be incorporating into the PROs' third scope of work. In addition, ASPE suggested that we revise our report to include reference to three quality-related studies that are currently underway, which should help address concerns cited in our report regarding the PROs' "failure to define and assess quality."

OIG Response

We appreciate ASPE's suggestion and have added an endnote to our report in order to include reference to these three quality-related studies. However, we would like to reiterate the importance of HCFA collecting and disseminating the findings of such research to the PROs so that they can integrate it into their review approach.

AARP COMMENTS

The following are AARP's comments in full and our response to them:

Thank you for the opportunity to comment on your draft report entitled "The Utilization and Quality Control Peer Review Organization Program: Quality Review Activities." The Association appreciates your leadership to safeguard quality in the Medicare program. We share your view that quality assurance is of major importance to the integrity of Medicare.

The Association is in general agreement with the content and overall thrust of the report's recommendations. The draft report's findings and recommendations, if carried out, will enhance the nation's ability to understand quality medical care and the role of the PROs in protecting it.

More specifically, the Association agrees with the series of recommendations that are aimed at bringing greater uniformity to the quality review process. In this connection, the report's findings on page twelve with respect to generic quality screens are particularly noteworthy. From a national perspective AARP continues to believe that mandating the screens was an important step forward in the evolution of quality of care review. At the

same time, we endorse the observation that the screens themselves are in need of refinement and greater consistency in application.

Moreover, a better understanding of what constitutes quality and how to measure and report it are critical elements of the unfinished agenda. PROs have a central role in the development of the health care quality assurance system for this country. PROs should be in the forefront of quality assurance research because they represent the Nation's commitment to quality in medical care; a strategy of both strengthening PROs and holding them increasingly accountable is obviously in the public interest.

The Association commends the report's recommendations that HCFA promote closer working relationships between the PROs and other health care entities, particularly state medical licensure boards. In an era of tight budgetary constraints the need to coordinate community services becomes even more important. Better coordination is essential among bodies charged with assuring that practitioners and providers of health care are competent. Yet, with few exceptions, in most of the country, professional societies, medical licensing boards, peer review organizations, etc., do virtually nothing to coordinate data resources, analysis, monitoring, and enforcement responsibilities on behalf of the public. The Association believes that greater coordination and communication between PROs and medical licensure boards is essential to the development of an efficient quality assurance system.

AARP would give greater prominence to the recommendation that HCFA improve the availability of data on outpatient and inpatient services. Parts A and B data must be linked so that policy makers have a better understanding of an entire episode of illness. In addition, Medicare contractors must begin to use common data processing systems so that measures are consistent and will yield comparisons of medical outcomes and provider behavior.

The Association is optimistic about the development of small area variation analysis as a tool for identifying both costs and quality problems in the health care system. Small area variation analysis is key to understanding both costs and quality in medical care. Describing these variations creates new ways to assess the delivery of medical care. Understanding the variations in medical practice suggests opportunities for reducing expenditures under Medicare and Medicaid without reducing the benefits of medical care. Moreover, the variations reveal the need to evaluate the outcomes of different approaches to treatment so that patients and physicians can better understand the significance of their choices in care.

Small area analysis of Medicare data begins this year. The research should be a routine function of HCFA with the data regularly reported to the public. PROs will have an important role in organizing the physician community to help explain the data and make judgments about what it means for both the costs and quality of medical care. The Association urges the OIG to help promote this important new tool.

We note your expression of caution with respect to the extension of PRO review to post-hospital settings. AARP strongly supported the Congressional decision in 1986 to mandate such review, and we continue to believe that the PRO mechanism is the best hope for creating a system that assures quality across the continuum of care. At the same time we acknowledge the concerns regarding untested review methodologies, data availability, and funding constraints. The Association seeks to work with all interested groups and HCFA to maintain the review direction and momentum established in OBRA '86, as well as a measured and sensible pace of implementation.

With respect to PROs' beneficiary outreach activities--a matter of obvious interest and concern to AARP--we welcome your highlighting the continued deficiencies in this area. We do perceive a growing desire within PROs to work with the beneficiary community to improve communication and understanding. We will continue to do as much as possible to contribute ideas and resources to this effort, as well as make the case for increased contract funds earmarked for this important purpose.

AARP was pleased to have participated in the survey phase of this project both at the national and state levels. We greatly look forward to reviewing your findings and recommendations in the remaining areas of the study. Thank you again for allowing the Association to comment on your draft report.

OIG Response

We appreciate AARP's support of the report, given its unique perspective on the PRO program. We would like to clarify that in our report the order of our recommendations to HCFA parallels the order of the findings to which they relate. Hence, the fact that our last recommendation relates to HCFA's need to improve the availability of data on outpatient and inpatient services, is no indication that we find it less important than other recommendations. We have modified the format of our recommendations in our executive summary to help clarify this fact.

AHA Comments

The following are the AHA's comments in full:

On behalf of its nearly 6,000 institutional members, the American Hospital Association appreciates this opportunity to comment on the draft report, "The Utilization and Quality Control Peer Review Organization Program: Quality Review Activities", which was prepared by the Inspector General's Office of Analysis and Inspections. This report sets for itself a very important task--assessment of PRO performance--which has not yet been publicly attempted. It is particularly timely, given the increases in PRO activity mandated by Congress in 1986, for HHS to step back and analyze the direction the program has taken and to evaluate its real and potential impact.

We have reviewed the report carefully, and agree with many of your recommendations. However, while the report does identify that there are differences among PROs, it provides little insight into why those differences occur or whether the existence of differences constitutes a problem in how the program functions.

Apparent differences in effectiveness and efficiency may be due to differences in each PRO's process of review, or they may be due to basic inefficiencies in the overall program structure. We offer some specific questions about the actual conduct of review in the detailed comments attached that might help to sort out the sources of the differences among PROs. With respect to program structure, HCFA may have condemned some PROs to inefficient and ineffective review by creating basically uniform contracts and structuring contract deliverables around anticipated provider behavior rather than on problems in the area identified by the PROs. We continue to feel that a great deal remains to be known about what is the most effective and efficient way to structure the PRO contracts and to conduct the review.

We also think it is important for HHS to give careful consideration to the effectiveness of PRO interventions, including sanctions, and to consider the extent to which the intervention is appropriate to the nature of the problem identified by the PRO. Education and consensus building may be more effective and appropriate than sanctions if the problems identified reflect a lack of knowledge of Medicare standards or lack of clearcut standards of care within the medical community.

Finally, we believe it is important to consider the overall effect of all PRO review, including utilization review, on the quality of care provided to Medicare patients, not just on the actual quality review efforts of the PROs. For example, what has been the effect of the PRO priority to shift medical treatment and surgery from an inpatient to an outpatient setting on the

health and safety of Medicare beneficiaries? This is something we do not know.

We look forward to future OIG reports which, we hope, will address some of the issues we have raised here. We hope these comments will provide some useful perspective.

In order to make the following comments easier to follow, they have been organized into two sections: first, general remarks about the purpose and methodology of the study and comments relating to the background discussion, and second, comments on specific findings. For ease of reference, we have for the most part used the subheadings that appear in the report.

The purpose of the study

Our chief concern has to do with the limited extent to which the research actually addresses the broad purpose announced at the beginning of the report. The research is intended to "assess the performance" of the PRO program and to "promote a better understanding of the PRO's mission and activities". Although many of the report's findings and recommendations seem quite reasonable, the research does not really address the outcomes of review and does not analyze differences in PRO review methods or interventions. The discussion of the PROs' quality review and intervention procedures on pp. 6-7 is not adequate. The analysis necessary to judge what makes some PROs more effective than others with respect to both their quality review processes and their chosen intervention strategies is simply not there.

As your review of the data reported by PROs on the use of generic quality screening shows, there is wide variation not only in the level of referrals to physicians for review but in the number of confirmed problems. This variation should lead to questions about what the PROs do differently to yield such different results. For example:

- o What kind of training do they provide to the nurse reviewers?
- o Do they vary in the level of instructions they give to the nurse reviewers who perform the initial screening of cases?
- o Do they vary in the extent to which they build a consensus for the standards of care among their physician reviewers?
- o Do they vary in their use of specialists to conduct the physician review?

- o Is a final decision about the quality of services made on the basis of a single physician's judgment, or is the physician reviewer's opinion bolstered by a second physician review, or by a quality committee review?
- o What sort of system does the PRO have--telephone, or mail?--to allow discussion to take place between the attending and reviewing physicians? Do the PROs vary in the way they perceive these discussions?
- o What sort of interventions have been tried? Have some been tried and failed?

These questions were not asked. As a consequence, the report identifies that there are differences between PROs but provides no insights on why those differences occur or whether the existence of differences constitutes a problem in how the program functions--either in how the contracts are structured or how the review is actually conducted.

The report mentions in passing (at the bottom of page 1) that subsequent reports will focus on the PROs' sanction process, on their overall activities and effectiveness, and on the HCFA oversight of the program. How does the current report fit in? Is it intended as background only? Clearly a report on "overall activities and effectiveness" would come closer to answering the questions we would have you ask. But if you would defer these questions to future reports, the language you use to describe the current project is inaccurate and should be changed.

If an overall assessment of PRO performance is contemplated, we would make two other general suggestions. First, it should address both the results and the processes of review. As with any kind of quality evaluation, whether of hospital performance or of PRO performance, outcomes should not be evaluated without looking at the processes involved. Observed differences in outcome must be accompanied by an evaluation of differences in process if they are going to deepen our understanding of what needs to be done differently to achieve better results.

Second, an evaluation of the results of PRO review should include not only a comparative assessment of the number of PRO findings of quality problems, but an evaluation of their appropriateness. In addition, if HHS really wants to assess the impact of PROs on the quality of care provided to Medicare beneficiaries, it must consider the effect of PRO utilization review: is the shift from inpatient to outpatient services always safe and effective? Is it better for the Medicare beneficiary?

The study's methods

A study's methods limit the conclusions that can legitimately be drawn from it. Because this study relies most heavily on interviews to evaluate the program, several of its findings reflect broad perceptions of PRO performance rather than PRO performance itself.

In several places, the language used to summarize the results of the research somewhat overstates the findings. For example, the study concludes, in its first finding, that "quality review is the most critical element of the PROs' mission and has received increased emphasis during the second contract period." It is certainly true that quality review has been given more emphasis in the second contract period, as shown by a comparison of the two scopes of work. But the research shows that quality is perceived as the most important function, not that quality review is the most critical element of the PROs' mission. Our perception is that quality has received more emphasis in the second contract period, but that the PRO workload is still predominantly concerned with utilization review. Therefore, it is questionable whether it can justly be said that "quality" is the most important function of the PRO program.

Similarly, in its analysis of the generic quality screens, the "finding" is that the generic screens are useful, but are in need of refinement in that they produce excessive referrals to physicians and may be inconsistently applied. While this may well be true, the research merely shows that this is the way the screens are perceived by PRO executive directors and others interviewed. This is our perception as well. But it would be nice to see these perceptions reinforced by some evidence.

Creation of the PRO Program

In the historical discussion on p. 2, you suggest that the PRO program was created simultaneously with the PPS. Although it is true that the PRO program might not have been implemented without the implementation of PPS, the PRO program was conceived and legislated as an administrative reform six months before PPS was passed in March 1983.

The PRO reforms were introduced with TEERA in September 1982. The PRO reforms streamlined program administration by creating statewide organizations and enhanced their accountability to HCFA by moving from a grant structure to performance-based contracts. The PPS legislation, passed in March 1983, gave a particular focus to PRO review, based on the fear that such a significant shift in provider payment might result in incentives to compromise the Medicare program in new ways. Quality review had always and continues to be concerned with poor "technical" quality. In addition, under cost-based per-diem payment, concern

focused on the quality implications of providing too many services; under PPS, a per case payment system, the quality concern shifted to the potential underprovision of services.

The initial scope of work, as you point out, was based on HCFA's anticipation that under PPS, Medicare expenditures were vulnerable to provider attempts to increase revenues by manipulating admissions. The first contracts therefore called for reductions of nearly 1.25 million admissions, nearly half of which were to be shifted from inpatient to outpatient care. During the second and third years of PPS, as length of stay declined, congressional interest turned to a perceived problem of "premature discharge", and the budget bills passed in 1986 contained several provisions enhancing PRO review of this aspect of quality of care. In the meantime, HCFA was preparing the scope of work for the 1986-1988 contracts. Admissions had begun to decline before PPS was implemented and continued to drop sharply despite the analysts' expectations that the opposite would happen in response to PPS. Consequently, HCFA apparently felt it could reduce the level of review of utilization problems in the 1986-88 contracts and shift some of its focus to "quality" concerns.

This historical overview raises an issue important to understanding the program: to what extent are the PRO contracts structured around problems identified by the PROs in the course of their review or through original research? To what extent is the structure of the review system dictated by hypotheses about the effect of the financing system on hospital behavior? And how sensitive has the program been to the political climate? As you point out on p. 6, HCFA has had to respond to a variety of competing pressures in implementing this program.

HCFA was forced to put a great deal of emphasis on the review of "premature discharge", because there was a growing public perception that this was becoming a problem under PPS. Yet HCFA-sponsored research by several PROs found that the actual level of premature discharge is quite small. We understand that forthcoming research by the OIG confirms this view. It remains to be seen whether this research will lead to significant change in future PRO contracts or whether the contracts will continue to be driven by the potential for problems under prospective payment even though that potential has not been realized.

An examination of this issue might demonstrate that the PRO program could be more effective and efficient if the PRO contracts were based more on identifying and resolving local problems than on testing perceptions about provider behavior. One of the great advantages of the contract structure created by the statute is the flexibility it gives HCFA to adapt each contract to the problems found in each state. What has been implemented, by contrast, is a very uniform program. We

recognize that such uniformity has its advantages--for example, in the consistency of information generated. HCFA may believe that it has sacrificed the principle of local determination for more efficient program administration and greater programmatic consistency, when, in fact, the choice to create a uniform contract may lead to much wasted effort and a less effective program.

The Sanction Process

As mentioned in your description of the sanction process on p. 7, sanctions are issued for violations of the provider's obligations to provide services which are (a) medically reasonable and appropriate; (b) provided economically; and (c) of appropriate quality. The appropriateness of a sanction thus hinges on the appropriateness of the determination that a violation of these obligations exists.

Is it appropriate for a sanction to be issued if there was no willful attempt to provide inappropriate care or to circumvent PPS? The sanction process, like all penalties, serves not only as retribution for an inappropriate action but as a deterrent to all those who might contemplate such actions. But one might wonder whether it is appropriate to sanction someone whose actions are unknowingly inappropriate. Certainly it is true that sanctions will not have a deterrent effect on anyone who is not willfully engaged in wrongdoing.

If the PROs are enforcing standards of care that all physicians and hospitals know beforehand, then penalties for failure to conform to those standards might be appropriate. But if the PROs are enforcing standards which are controversial, or which are different than those that prevail in the community, then the appropriate step is education and consensus development, not sanction. HCFA repeatedly assures the provider and practitioner communities that PROs are not attempting to change standards of practice. Let us assure you, this is not the way the PROs are perceived by providers. In its regulations governing the program, HCFA requires the PROs to use national criteria, norms, and standards rather than local standards, unlike the statute, whose emphasis is precisely the reverse. This emphasis of national over local criteria and norms would likely be confirmed by an analysis of the criteria sets used by PROs to conduct review.

Finally, as a factual matter, the statute allows for both monetary and exclusion sanctions, but does not allow monetary sanctions to be imposed for documentation violations. This needs to be sorted out on p. 7.

FINDINGS

Improvement in Quality Screens and the Process of Review

The discussion (p. 12-14) of the adequacy of the generic quality screens is misleading, since the research attempts to identify perceptions of their effectiveness rather than to establish just how sensitive (how well the screens correctly identify problems) and specific (to what extent the screens incorrectly identify as problems cases which are not problems) the screens are.

The comparison of screen failure and confirmed problem identification is particularly confused. The questions you need to address are (a) whether the screens allow quality problems to escape notice; and (b) whether the cases they identify are truly problematic. It has been well known that one of the biggest problems with the screens was the large number of unnecessary referrals to physician review ("false positives"). The American Medical Peer Review Association has made many suggestions for refinements to the screens that make them more accurate, and HCFA has adopted many of these suggestions.

There are two potential sources of variation: first, the amount of discretion granted to the nurse reviewer to identify "potential" problems; second, the judgment of the reviewing physician in confirming true problem cases. One PRO may refer few cases to physician review, but the ones referred may be the right cases (i.e., the ones reflecting real quality problems). Another PRO may refer many cases to physician review, but confirm problems in only a small portion. The two may identify the same percentage of confirmed cases in relation to overall cases reviewed, so the first PRO would appear to use the screens more efficiently than the second. You have (a) defined the percentage of confirmed cases in relation to screen failures rather than cases reviewed; and (b) expressed these as ranges without attempting to establish the relationship, if any exists, between screen failures and confirmed problems. The comparison of screen failures to confirmed cases as presented here is therefore not meaningful.

To truly assess the differences among PROs in the use of the screens, you have to investigate precisely how they conduct the initial screening and the final decisions. How much instruction do the PROs give the initial reviewer? How many physicians review a case to determine whether a confirmed problem exists? Do the PROs use specialists in a related field of medicine to make these determinations? The answers to these questions could provide useful insights into just how effective and appropriate the generic screens would be as the basis for the PRO quality review process. You point out in the discussion on pp. 17-18 that there is wide variation among PROs in their review processes and approaches to review but without any detail comparing the

differences in process to differences in result, it is difficult to say just what this shows about PRO performance.

The Definition of Quality and the Technology of Quality Review

The report concludes that PRO quality review is limited by a "lack of consensus regarding the definition of quality medical care", by the lack of available resources to provide such care, and by lack of sophisticated technology to assess quality. These conclusions are widely perceived to be true. However, this discussion, which covers very broad territory in a mere four paragraphs, contains an alarming confusion of key concepts.

First, it is certainly true that quality is multifarious, that is, that no single element will capture all the dimensions of quality. While it might be useful for HCFA to consider what purposes--whose interests--they hope to serve in doing this review, it is not at all clear that this is a particular handicap to the PROs. The PRO quality review function has been limited to determining whether a particular course of treatment can be considered to meet "appropriate standards of quality". The real handicap the PROs face is the lack of definition at the "micro" level--lack of consensus on what constitutes quality care in the individual instance--because these "appropriate standards" are not articulated.

Second, in discussing quality measurement, the report suggests that PRO access to severity of illness measures and "sophisticated quality assurance techniques" would eliminate some of the current labor-intensive, case-by-case review process. This is only partially true. These techniques can prove useful for more efficient screening to select cases for review. The generic quality screens require extensive chart review in the screening process, which is, indeed, time consuming. But there is no magic to the use of statistical techniques or a severity of illness measure. In the end, the basis of PRO quality assessment must remain the detailed review of medical records, because it is only by looking at the medical record that a judgment can be made about whether the care provided a particular patient was appropriate.

Relationships between PROs and other Health Care Entities

The study rated the PRO CEO's perceptions of the effectiveness of the PRO's relationship with other state health care organizations, including state medical licensure boards, hospital associations, and medical societies, and found that PROs generally believe their relationships with hospital associations and medical societies are good. While interesting observations, the interviews revealed two issues of importance to hospitals and physicians which didn't appear in the findings summary, but which are well worth pursuing.

With regard to hospitals, the PROs reported that hospitals had been troubled by the PROs' unwillingness to share information about particular physicians who had been identified as having quality problems. This has become an enormously important issue for hospitals.

HCFA argues that current regulations prohibit PROs from identifying physicians with confirmed quality problems to their hospital medical staffs. PRO regulations at Sec. 476.133 allow disclosure to an institution of information about its physicians only "to the extent that the information displays practice or performance patterns" of the physician within the hospital. HCFA contends that confirmation of a quality problem does not constitute "patterns" of performance, and therefore cannot be disclosed to the hospital. The institution is therefore notified only if the problem is so severe that a sanction recommendation is forwarded to the OIG or, indirectly, the PRO undertakes intensified review of the physician. Yet without proper notification, the hospital medical staff can not implement internal measures necessary to address the physician's practice problem.

The AHA has recommended that HCFA change these regulations to allow PROs to notify the hospital's medical staff whenever it discovers a quality problem with physician practice.

Better coordination with State medical review boards is certainly important when the PRO uncovers egregious quality problems that threaten the public health and safety. But it is equally important that PRO intervention begin early, while it is still possible to effect some change in practice, before invoking an investigation by the medical license boards.

Beneficiary Outreach

OIG found that PROs have trouble providing effective outreach to Medicare beneficiaries. This observation is not surprising given HCFA's failure to define what the purpose of this outreach is supposed to be. Is the outreach supposed to improve beneficiary understanding of Medicare coverage? Or increase beneficiary awareness of appeals mechanism for lodging a protest of a hospital notice of noncoverage? Or some other purpose? The OIG recommendation--that HCFA seek ways to strengthen beneficiary outreach efforts--should be made more specific: the best way for HCFA to strengthen PRO outreach programs is to clarify their purpose.

Review of Non-hospital Care

The study concludes, after interviewing HCFA staff and others, that the major obstacles to review of non-hospital settings will include lack of data, inadequate review technology, lack of

Second, consider whether PRO effectiveness and efficiency might be enhanced by making the structure of the review program conform more to local problems as determined by the PRO than by assumptions about provider behavior based on an analysis of the payment system.

Third, in evaluating differences in PRO effectiveness, consider both the level of effect and the appropriateness of the effect. It is important to look at the overall effect of all PRO review, including utilization review, on the quality of care provided to Medicare beneficiaries, not just on the actual quality review efforts of the PROs.

Finally, in evaluating PRO effectiveness, consider the range of alternative interventions at the PROs' disposal, and assess whether the interventions--including sanctions--are appropriately geared to the level of the problem identified.

OIG Response:

We appreciate the time and effort that the AHA put into crafting its detailed and thoughtful response to our draft report. The AHA has raised several important issues about the PRO program that are worthy of further exploration by both HCFA and other entities like ourselves.

In regard to the concerns raised about our study's methodological limitations, it is worth noting that although our assessment of the PRO program is based primarily on interviews with a wide variety of well-informed individuals closely associated with the PROs, wherever possible, we have supplemented our analysis of this qualitative data with available quantitative data. Unfortunately, as reflected in our third PRO inspection report, the limitations of available data hampered our ability to draw definitive conclusions about PRO effectiveness.

In response to legitimate methodological and format concerns raised by AHA, we have reworded our first two findings and altered the presentation of recommendations in the executive summary to correspond with the groupings in the text. We have also changed our introduction to better reflect the methodological limitations of the study, and to clarify how our three inspection reports fit together. In addition, we have included AHA's historical and sanction clarifications in the appropriate parts of the PRO background section of our report.

As reflected in our response to HCFA's comments, we also agreed with AHA's suggestions that HCFA clarify the purpose of community outreach and facilitate the PRO's release of quality-related information to hospitals. Furthermore, AHA's concerns about the prescriptive nature of the PRO contracts are addressed in our third PRO inspection report entitled: "The Utilization and

Quality Control Peer Review Organization (PRO) Program: An Exploration of Effectiveness" (OAI-01-88-00572).

Finally, while we appreciate AHA's careful criticism of our report and support of our recommendations, we take exception with its assessment that our PRO inspection "fails in any meaningful way to assess PRO performance." We believe that the three reports of this inspection provide more evaluative information about the PRO program than any other entity has compiled to date.