THE UTILIZATION AND QUALITY CONTROL

PEER REVIEW ORGANIZATION (PRO) PROGRAM:

AN EXPLORATION OF PROGRAM EFFECTIVENESS

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JANUARY 1989

CONTROL # OAI-01-88-00572

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EXECUTIVE SUMMARY

PURPOSE AND OBJECTIVES:

This is the third and final inspection report in a series assessing the performance of the Utilization and Quality Control Peer Review Organization (PRO) program. The purpose of this PRO inspection is to promote a better understanding of the PROs' mission and activities. This final report offers an exploration of the overall effectiveness of the PRO program, focusing on an assessment of both the PROs themselves and on the Health Care Financing Administration's (HCFA) oversight of them.

METHODOLOGY:

The inspection grew out of the Inspector General's desire to obtain a broad perspective on the PROs' performance during their second contract period (1986-88). 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.

MAJOR FINDINGS:

PRO-RELATED FINDINGS

MOST RESPONDENTS REGARDED THE PROS AS AT LEAST MODERATELY EFFECTIVE IN CARRYING OUT THEIR MISSION. The vast majority (83 percent) of respondents reported favorably on the PROs' effectiveness. The highest ratings came from the PRO CEOs, congressional staff, and hospital association representatives. Three of the 12 case study sites received consistently high effectiveness ratings. They differed in sizes and geographic locations but shared several characteristics, including high staff morale, relatively strong sanction referral records, relatively visible board chairmen and CEOs and strong communication links with external entities.

THE PROS REPORTED SOMEWHAT MORE EFFECTIVE RELATIONSHIPS WITH THEIR MEDICARE FISCAL INTERMEDIARIES (FIS) THAN WITH THEIR MEDICARE CARRIERS. Ninety-one percent of the PROS reported at least moderately effective relationships with their fiscal intermediaries and 70 percent reported similar levels of effectiveness with their carriers. Despite generally close working relationships between PROs and their FIs, some PRO and HCFA staff noted concerns about FIs failing to make timely payment adjustments based on the PROs' DRG determinations. Such concerns have been supported by a recent Office of Inspector General (OIG) audit which found that as of July 1987,

approximately 54,000 claims adjustments totaling about \$51 million remained unprocessed by the FIs. In addition, although the PROs have had rather limited interactions with their carriers, the need for stronger PRO, FI, and carrier coordination will increase as the PROs begin to review in non-hospital settings.

THE PROS VARY IN THE DEGREE TO WHICH THEIR REVIEW DECISIONS CONCUR WITH THOSE OF SUPERPRO. Because no acceptable range of disagreement between the PROs and SuperPRO has been established and no national trend analysis of variation among quality problems identified has been undertaken, it is impossible to assess a particular PRO's performance based on SuperPRO data. However, our analysis of PRO/SuperPRO variations within the PROs! second contract period reflected strong differences between PRO and SuperPRO determinations, with the exception of premature discharges, where both groups identified relatively few problems. Furthermore, comparison of PRO/SuperPRO differences within the first and second contract periods reflected that the PROs' use of generic quality screens appears to have had no effect in narrowing the margin of difference between PRO and SuperPRO determinations related to the identification of quality problems or the appropriate referral of cases to physician reviewers.

HCFA-RELATED FINDINGS

THERE HAS BEEN SIGNIFICANT IMPROVEMENT IN HCFA'S MANAGEMENT AND ADMINISTRATION OF THE PRO PROGRAM DURING THE SECOND CONTRACT PERIOD. Despite the problems enumerated in other findings of this report, HCFA has made important strides in improving the PRO program, as reflected in part by the fact that a majority of all respondents considered HCFA's management of the program at least "moderately effective" and noted an improvement in that oversight since the start of the program. Our interviews and review of HCFA materials confirm that HCFA has taken important steps to improve the program, particularly by broadening its communication efforts with both the PRO and external entity communities.

THE HCFA'S ABILITY TO ASSESS PRO PERFORMANCE HAS BEEN LIMITED BY THE LACK OF REFINEMENT AND INTEGRATION OF ITS EVALUATION TOOLS. Although we had hoped to assess PRO effectiveness by supplementing our interview-generated information with HCFA evaluation data, the inherent limitations of HCFA's evaluation tools made such analysis impossible. As currently structured, these tools have not been sufficiently integrated into a comprehensive, coordinated system for evaluating the PROs' performance. Our interviews and review of HCFA documents revealed both individual and collective problems with HCFA's three evaluation tools—the PRO Monitoring Protocol and Tracking System (PROMPTS-2), SuperPRO, and the PROs' ongoing data-reporting requirements.

The PROMPTS-2 has focused much more on process than outcome evaluation of the PROs and its format has failed to capture gradations in PRO performance.

The SuperPRO process appears duplicative of the medical review component of PROMPTS-2, and most respondents, including a number of HCFA regional office staff, noted uncertainty about how HCFA has used SuperPRO data. In addition, many PRO respondents complained about their lack of contact with SuperPRO reviewers and SuperPRO's limited use of local reviewers.

The PROs' ongoing reporting requirements have been cumbersome and complex, involving 23 separate reports, 90 percent of which must be submitted on a monthly or quarterly basis. Furthermore, in-depth data analysis has been limited. However, HCFA has recently taken steps to strengthen its data analysis capability and is planning to reduce the PROs' reporting requirements in the third contract cycle.

THE HCFA APPEARS TO HAVE GIVEN THE PROS INSUFFICIENT INFORMATION ON ITS CRITERIA FOR MAKING CONTRACT RENEWAL DECISIONS. Respondents cited a wide range of activities as most important to HCFA's evaluation of the PROS. Although the PROS' second scope of work requirements reflected greater emphasis on activities related to quality review, only 30 percent of all respondents cited such activities when asked to identify what HCFA has considered most important in evaluating PRO performance. Furthermore, within HCFA's scoring system for the PROS' second PROMPTS-2 evaluation, the numerical weights assigned to specific activities do not appear to be consistent with the relative importance of those activities within the second contract period.

THE USE OF 2-YEAR, FIXED-PRICE CONTRACTS APPEARS TO HAVE CREATED INEFFICIENCIES IN THE PRO PROGRAM. Seventy-eight percent of all respondents thought that the 2-year length of the PROs' contracts has been too short, especially given the ever-increasing responsibilities of the PROs. The short contract period has given the PROs little time for operational stability between contract renewal cycles and has hampered HCFA's planning and evaluation efforts. Therefore, we support the recent Onmibus Budget Reconciliation Act of 1987 (OBRA 1987) provision that lengthens the PRO contract period to 3 years and allows greater spacing between termination dates for the 54 PRO contracts.

Although fewer respondents directly noted the inefficiencies of fixed-price contracts, many complained about the delays inherent in HCFA's processing the large volume of PRO contract modifications, which have been a by-product of using fixed-price contracts for a rapidly changing program. HCFA has taken important steps to improve the timely processing of contract modifications and is intending to experiment with alternative contracting mechanisms for the third contract cycle.

THE HCFA'S SECOND SCOPE OF WORK HAS BEEN HIGHLY PRESCRIPTIVE AND APPEARS TO HAVE PROVIDED INSUFFICIENT INCENTIVES FOR PRO INITIATIVE. Many respondents criticized the highly detailed menu of PRO activities prescribed by HCFA, recommending that several of those activities should be de-emphasized or eliminated from the PROs' contract requirements. In determining the PROs' second scope of work, HCFA clearly had to balance competing forces for flexibility and uniformity. The HCFA appears to have developed the second and third scopes of work without adequate pilot testing of activities prior to full-scale implementation by all PROS. Several respondents also voiced concern about the PROS' current requirement to perform comparable levels of review at all hospitals regardless of their levels of performance.

THE DYNAMISM AND BROAD SCOPE OF THE PRO PROGRAM HAVE IMPAIRED HCFA'S ABILITY TO MANAGE IT. HCFA has had to implement a complex, ever-changing program which is of strong interest to Congress and the professional medical community. The HCFA's programmatic work load has included implementation of planning and evaluation systems, negotiation of 2 basic contracts and 1,300 contract modifications for 54 PRO areas, and coordination with other HCFA and outside entities. HCFA's large work load has been accompanied by frequent staff turnover at both the agency administration and program management levels.

Such pressures may have inhibited short-term planning, as reflected by HCFA's delay in implementing legislative mandates, and by its failure to incorporate policy changes into the PRO manual in a timely manner. Long-term planning may also have been compromised as evidenced by the fact that in our interviews and review of HCFA materials, we saw no indication of HCFA having a long-range perspective on future directions for the PRO program.

Although the PROs' responsibilities may have strengthened their role in protecting the integrity of the Medicare program, several respondents raised substantial and legitimate concerns that everincreasing PRO mandates could precipitate the program's implosion rather than facilitate its improvement.

RECOMMENDATIONS

Although HCFA has made important strides in the communications, contracting, and data areas, our findings suggest the need for HCFA to take the following actions in the areas of evaluation and planning:

o Improve coordination and integration of its evaluation tools (PROMPTS-2, SuperPRO and PRO data reports) to ensure comprehensive assessments of PRO performance. This might include:

- synchronizing the PROMPTS-2 review with the due dates of SuperPRO reports; and
- incorporating SuperPRO results into the PROMPTS-2 document along with data from PRO reports to maximize the comprehensiveness of the evaluation.
- Encourage consistency and objectivity in PRO renewal decisions by:
 - establishing rating standards for PROMPTS-2 and for acceptable ranges of variance for SuperPRO;
 - formally informing the PROs, regional office staff and review panel members of the weights to be assigned SuperPRO, HMO/CMP, cost/savings ratio factors; and
 - establishing a standing evaluation panel of HCFA regional and central office staff to review regional recommendations. Participation by PRO staff before closed session action would permit discussion of mutual questions and concerns.
- o Re-examine the purpose for and validity of the SuperPRO review process. This assessment should address such issues as:
 - whether SuperPRO uses appropriate reviewers and criteria to render valid judgments about local PRO decisions;
 - whether SuperPRO is intended to complement PROMPTS-2 medical review or to duplicate it;
 - whether SuperPRO is intended to validate PROMPTS-2 review decisions. If so, whether its sample size, criteria and record selection process permit valid comparison; and
 - whether there are better ways to use SuperPRO expertise, such as having SuperPRO perform on-site review and provide technical assistance to those PROs most consistently differing from SuperPRO in their review decisions or by having SuperPRO assess what types of quality problems that are being identified by PROs.
- Create forums for SuperPRO, HCFA and PRO discussions.
- Examine ways to streamline the SuperPRO process to minimize the administrative burden on PROs and to maximize its utility to HCFA, such as:

- reducing the sample size for small PROs;
- revising the schedule for reporting results to reduce time lag between PROMPTS-2 and SuperPRO reviews; and
- facilitating closer interactions between PRO and SuperPRO reviewers in resolving PRO/SuperPRO differences.

o Improve the PROMPTS-2 process by:

- developing standards for judging the manner of PRO performance, i.e., "Are PRO/provider relationships effective ...?", "Is the PRO successfully tracking problems ...?"; and
- establishing standards for rating "yes/no" acceptability of overall activity category based on number of "yes/no" ratings of subcategories;
- developing more outcome measures of PRO effectiveness through research and demonstrations.
- o Develop and release comparative PRO performance data to the PROs and other interested parties.
- Develop and distribute requirements, instructions, and policies in a more timely manner to allow sufficient leadtime for PRO implementation.
- o Improve the consistency in policy interpretation among PROs and HCFA staff by updating the PRO Manual on an on-going basis and by providing training and orientation sessions for both PROs and regional staff as needed.
- o Review the current roles of carriers, fiscal intermediaries and PROs to assess the appropriateness of the current distribution of responsibilities and assess the coordination of these entities, such as the timeliness of F.I. adjustments.
- o Strengthen long-range planning of future directions and appropriate roles for the PRO program by:
 - increasing the emphasis on research and demonstrations in such areas as review methodologies, patient outcome and severity measures and data system requirements;
 - exploring mechanisms to encourage PRO innovations and reduce the prescriptive nature of the current review requirements;

- exploring better long-term ways of structuring PROs' activities so they are cost-effective and complement the efforts of other review entities such as State medical licensure boards and hospital quality assurance committees. For instance, HCFA might explore the possibility of having SuperPRO responsible for making DRG determinations and have the PROs focus on quality review; and
- establishing an advisory group of PRO and other relevant entity representatives to provide input to HCFA on long-range planning issues.

COMMENTS ON DRAFT REPORT

We received written comments from the Health Care Financing Administration (HCFA), the Assistant Secretary for Planning and Evaluation (ASPE), and the American Hospital Association (AHA). The ASPE and AHA raised some questions but were basically positive about the report. The HCFA raised significant concerns about the basis for the findings and about many of the recommendations. See appendix XII for a complete presentation of the comments and of our response to them.

INTRODUCTION

The Office of Inspector General (OIG) recently completed an inspection of the Utilization and Quality Control Peer Review Organization (PRO) program. The primary purpose of this broadbased 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 back-ground for this inspection.)

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

This is the third and final report of a series summarizing the findings of our study. The first report focused on the PROs' quality review activities, and the second, on the PROs' sanction activities. This final report offers an exploration of the overall effectiveness of the PRO program, focusing 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 analysis of this qualitative data with available quantitative data.

Owing to our time constraints, the limitations of the study design, and the breadth of the PROs' activities, it is impossible to draw definitive conclusions about the program's overall effectiveness. Nevertheless, if, as one U.S. Senator noted, "reputation is a proxy for quality," this report should offer significant indications of the PROs' and HCFA's performance during the second contract period.

Our two previous reports included detailed explanations of the PRO program. To minimize repetition for readers, we have placed the detailed summary of the PRO program in appendix III of this report. Appendix III also includes a more detailed discussion of HCFA and its tools for evaluating the PROs, as well as an explanation of the responsibilities of HCFA's fiscal intermediaries and carriers and their interaction with the PROs. A chart of PRO activities during the second scope of work is included in appendix IV.

PRO DESCRIPTIVE DATA

In the course of our study, we learned that the PROs vary significantly in their structures and functions. The 44 organizations that have contracted with HCFA to carry out the requirements of the second scope of work in the 54 areas reflect the following patterns:

- o 86 percent conduct all reviews themselves, whereas 14 percent of them subcontract with other organizations;
- o 68 percent were previously Professional Standards Review Organizations (PSROs);
- o 84 percent are physician-sponsored and 16 percent are physician-access organizations;
- o 68 percent derive the large majority of their work from Medicare, whereas 5 percent of them spend less than 50 percent of their time on Medicare-related activities;
- o 73 percent reported conducting review activities for business entities, and 68 percent of them reported contracting with State Medicaid programs;
- o approximately 50 percent subcontract for their data processing, whereas the others maintain their own systems;
- o 61 percent reported "usually" performing on-site review; 20 percent reported "always" performing on-site rather than off-site review.

In addition, our 12 case study sites reflected the following variations in board composition and staff morale:

- o 75 percent had a clear separation between board and staff functions, whereas 25 percent of them had one person simultaneously serving as board chairman and medical director; and
- o 66 percent reported at least average staff morale, whereas 33 percent of them had at least some staff who reported low staff morale: board members tended to rate staff morale more highly than PRO staff. Most respondents reported that the key factors inhibiting stronger staff morale included the lack of competitive salaries, the high turnover in nurse reviewers, and the frustrations inherent in the shifting priorities of a quickly changing program.

The case sites also showed great variation in their quality review systems and relationships with external entities, which were highlighted in our first report on the PROs' quality review activities.²

LIST OF ABBREVIATIONS

AARP: American Association of Retired Persons

AMA: American Medical Association

BPO: Bureau of Program Operations, Health Care

Financing Administration

Carrier: Medicare Carrier

CEO: Chief Executive Officer

COBRA: Consolidated Omnibus Budget Reconciliation

Act of 1985

DRG: Diagnosis-Related Groups

EOMB: Executive Office of Management and Budget

FI: Medicare fiscal intermediary

HCFA: Health Care Financing Administration HSQB: Health Standards and Quality Bureau

GAO: U.S. General Accounting Office

OBRA 1986: Omnibus Budget Reconciliation Act of 1986 OBRA 1987: Omnibus Budget Reconciliation Act of 1987

OMB: Office of Management and Budget

PPS: Prospective Payment System

PRO: Utilization and Quality Control Peer Review

Organization

PROMPTS-2: Peer Review Organization Monitoring Protocol

and Tracking System for the PROs' Second Scope

of Work

PSRO: Professional Standards Review Organization

SuperPRO: SysteMetrics, Inc.

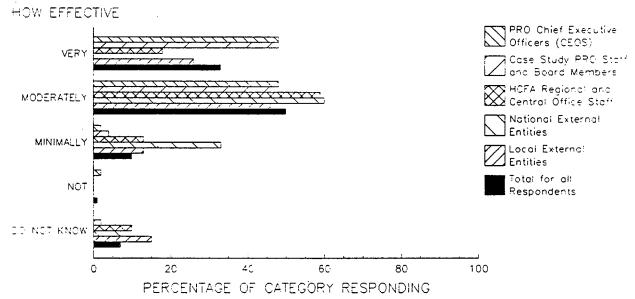
FINDINGS

PRO-RELATED FINDINGS

Most respondents regarded the PROs as at least moderately effective in carrying out their mission.

The vast majority (83 percent) of respondents reported favorably on the PROs' effectiveness (see figure I). Among the several groups interviewed, the strongest proponents of PRO effectiveness were the PRO CEOs, congressional staff, and hospital association representatives. The harshest criticism of PRO effectiveness came from some medical societies, national governmental review entities, and HCFA regional staff.

FIGURE I
PERCEPTIONS OF THE PROS' EFFECTIVENESS IN
CARRYING OUT THEIR MISSION



Source: OIG Inspection Interviews. Note: N= 208 respondents.

Of those respondents who viewed the PROs as effective, the major reasons cited for their assessments were, in descending order of frequency, as follows:

- o the PROs had a positive impact on the quality of patient care;
- o the PROs provided good educational information to the medical community;
- o the PROs had a positive influence on changing utilization patterns;
- o the PROs had a strong sentinel effect on physician and hospital practices.

The major reasons cited for low ratings of PRO effectiveness were, in descending order of frequency, as follows:

- o the PROs' educational efforts to change physician practices were inadequate;
- o the PROs operated with too many constraints;
- o the PROs had inadequate support from the medical community.

It is worth noting that a sizable number of both HCFA and national external entities mentioned that the effectiveness of individual PROs varied so widely that it was difficult or impossible to develop a composite picture of the PROs' overall effectiveness.

Our analysis of response patterns among our 12 case study sites revealed the following (see table 1, appendix X):

- The PRO CEOs and other staff tended to rate their own PRO as at least moderately effective. Only two PROs (sites E and K on table 1) had staff members who rated their PRO as minimally or not effective. In one case, the reason offered for that rating was the excessive difficulty the PRO had in recruiting physicians to review cases and the resultant difficulty in meeting HCFA's time frames. In the other case, the staff person noted that the PRO's ineffectiveness was due to the overly prescribed nature of its work and the lack of funding necessary to keep up with its requirements.
- o The hospital associations tended to give the PROs higher effectiveness ratings than did the other external entities. This is consistent with the fact that the case study sites usually had closer working relationships with the hospital associations than with the medical societies, or State medical licensure boards. In fact, a sizable number (45 percent) of the State medical licensure boards in our case study sites noted that they "did not know" the effectiveness of their PROs. This was consistent with our finding in our previous report on the PROs' quality review activities that most PROs have little interaction with their State medical licensure boards.
- In one quarter of our case study sites (sites A, G, and H), all respondents considered the PRO at least moderately effective. In all the other sites, at least one respondent rated the PRO less than moderately effective or "did not know" the PRO's effectiveness.

The three PROs that were consistently rated as at least moderately effective by all entities were of different sizes and

geographic locations. However, the three organizations shared the following characteristics:

- o high staff morale;
- o relatively strong sanction referral records;
- o contracts with State Medicaid and business entities in addition to the one with HCFA:
- o no subcontractors for review activities;
- o relatively visible board chairmen and CEOs who worked closely together;
- o communication links in place with most significant external entities, through either designated positions on their boards, active task forces, or advisory groups to the board.

The most striking indication of the PRO program's growth in stature was the fact that although many people we interviewed voiced particular concerns about the PROs, no one questioned the overall need for the program.

Many respondents noted that the PROs' effectiveness has been hampered by both internal and external constraints.

The most significant constraints mentioned in descending order of frequency included the following (see figure II):

Limited resources: insufficient money, staff, and time to carry out the PROs' myriad responsibilities. Most PRO and external entities believed that the PROs had inadequate funding for their activities, whereas most HCFA staff thought that the PROs had adequate funding. As noted by one U.S. Senator: "We recognize that the PROs have done their best to move beyond their original mandate for utilization review and to put greater emphasis on quality... (but) their efforts have been severely hampered by limited funds."4

Many PRO staff mentioned their difficulty in attracting and retaining good physician and nurse reviewers, the former because of medical community resistance and the latter because of an inability to provide competitive salaries and the lack of professional stimulation inherent in repetitive patient record review.

o HCFA's management: inadequate time frames, inconsistencies in interpretation among HCFA regional offices, and too prescriptive a process for carrying out the PROs' responsibilities. Many PROs voiced concern about the serious delays in HCFA's contract modification

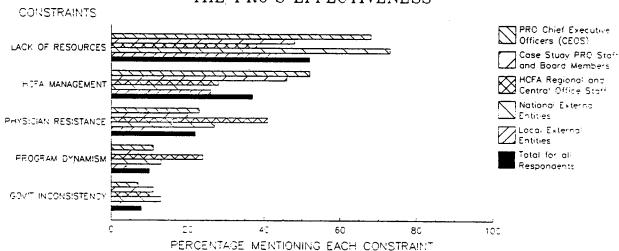
process and the corresponding need for PROs to undertake new responsibilities without the necessary funding. The American Medical Peer Review Association (AMPRA) conducted a PRO survey last year, which found that contract modification delays were posing serious cash-flow problems for several PROs. Since that time, HCFA has implemented a computerized tracking system for contract modifications, and Congress has mandated that HCFA must give notice to the PROs 30 days before requiring new activities.

In addition, concerns were raised by PROs and some HCFA staff themselves about both the lack of consistency in interpretation of PRO requirements and the extensive requirements for uniformity that HCFA places on the PROs for selecting cases for review.

- The PROs' lack of acceptance by the medical community: the PROs' difficulty in effecting change in practice patterns given their often adversarial relationships with the medical community.
- o Program's dynamism: the rapid pace of change in the program dictated by congressional action.
- o Inconsistent expectations: the PROs' mandate to be "all things to all people" and the sometimes conflicting messages the PROs have received from government oversight entities.

Other constraints mentioned included the PROs' lack of adequate interaction with external entities, and their extensive oversight by multiple government entities.

FIGURE II
PERCEPTIONS OF THE MAJOR CONSTRAINTS LIMITING
THE PRO'S EFFECTIVENESS



Sturce 0.3 Inspection interviews. Note 14= 195 respondents

Respondents reflected considerable consensus regarding the PROs' most and least useful HCFA-defined activities.

Of the five types of review that the PROs are required to perform on a given record (see categories A-E in appendix IV), generic quality screens and admission reviews were seen as the most likely tools for identifying quality problems. This was consistent with our previous report on the PROs' quality review activities, which noted that respondents saw those quality activities as the most important part of the PROs' mission.

On the other hand, no one found coverage review the most useful type of PRO review and a large majority of the PRO CEOs (82 percent) saw it as least useful. Many respondents mentioned that the PROs were less equipped to make coverage determinations than fiscal intermediaries, which are more versed in the intricacies of Medicare coverage requirements.

Among the 18 types of retrospective and prospective review mandated by HCFA (see activities 1-18, appendix IV), respondents found the following four most useful:

- o 3 percent random sample from each PPS hospital;
- o all readmissions within 15 days from a PPS acute care bed to any acute hospital (PPS or non-PPS) for inappropriate admissions;
- o performance of five objectives to eliminate adverse outcomes and reduce unnecessary admissions and procedures;
- o intensified review of hospitals that reach six cases or 5 percent trigger error rate.

Every respondent group rated the 3 percent random sample as most useful for identifying utilization problems and readmission review as most useful for identifying quality problems. However, it is worth noting that one third of the national external entities and one half of the local external entities had no opinions about the most and least useful activities.

Those types of review found least useful by respondents included:

- o all percutaneous lithotripsy claims in hospitals with extracorporeal shockwave lithotripters;
- o all cases identified by the Medicare code editor;
- o all cases referred by the fiscal intermediary for coverage issues;

- o 50 percent random sample of day and cost outliers;
- o preadmission review of pacemaker and four procedures proposed by a PRO that add up to 2.5 percent of statewide discharges;
- o all cases involving assistants at cataract surgery; and
- o all submitted claims adjustments resulting in a higherweighted DRG.

Percutaneous lithotripsy review was ranked as the least useful activity by a considerable margin. However, the other types of review listed as least useful were more equally ranked by respondents.

Respondents' rankings of the least useful review activities closely paralleled their rankings of those activities they thought should be de-emphasized or eliminated from their contracts. In addition to all the least useful activities previously outlined, a number of respondents also thought that the PROs' requirement to perform five objectives should be deemphasized or eliminated, although many respondents noted it as being a useful review. This indicates that there is greater discrepancy in perceptions about this activity than most others, which may be explained by the fact that since such objectives are PRO-defined, there is greater variation among the PROs in their implementation of that requirement.

Furthermore, a significant majority of PRO CEOs and staff noted that the five objectives and the day and cost outlier activities consumed more time than they warranted. On the other hand, they thought that the readmissions within 15 days and the 3 percent random sample review activities were worthwhile in spite of their being time-consuming. Nevertheless, several PRO CEOs and staff questioned their upcoming mandate to extend readmission review to 31 days.

It is important to note that HCFA has eliminated percutaneous lithotripsy review from the third scope of work and has decreased the percentage samples of day and cost outliers.

The PROs reported somewhat more effective relationships with their Medicare fiscal intermediaries than with their Medicare carriers.

A vast majority of PROs (91 percent) reported having at least moderately effective relationships with their local fiscal intermediaries (FIs). A smaller number (79 percent) reported similar levels of effectiveness with their carriers.

Our case study analysis revealed that most PROs had more interaction with their fiscal intermediaries than with their carriers. The FIs forward the Unibill tape to the PROs from which the PROs select cases for review. The FIs also make payment adjustments in response to cases in which the PRO makes DRG changes or denies an admission. In discussing their FI-related concerns, several PRO and a few HCFA staff mentioned concerns about the FIs' lack of timely payment adjustments and the lack of close coordination between the two respective HCFA components (Health Standards and Quality Bureau and the Bureau of Program Operations) responsible for the PROs and FIs. A few of the PRO CEOs from the case study sites noted that their relationships with the FIs were enhanced by regular meetings with the FIs and appropriate HCFA personnel.

A recently conducted and as yet unreleased OIG audit provides supporting evidence of the FIs' lack of timely adjustments. In that audit, the OIG's Office of Audit (OA) notes that as of July 1987, approximately 54,000 claims adjustments totaling about \$51 million remained unprocessed by the FIs. More than 40 percent of those unprocessed adjustments were pending at the FIs for over 90 days. The OA audit provides recommendations to HCFA for ways of improving the FIs' timeliness in making such adjustments.

Most PROs reported relatively little ongoing interaction with their carriers but found few problems with what existed. They anticipated having more interaction with them as they begin to conduct reviews in nonhospital settings. Accordingly, in our first inspection report, we noted the need for HCFA to facilitate a stronger link between the Medicare Part A and Part B data bases. 7

In its recent draft report, "Medicare Improving Quality of Care Assessment and Assurance," the General Accounting Office (GAO) highlighted the inadequate coordination among the PROs, FIs and carriers on issues related to quality. Just as we argued in our first inspection report that Medicare beneficiaries would be better served by closer coordination between the PROs and other entities such as licensure boards and hospital quality assurance committees, GAO recommended that HCFA "develop formal guidelines to coordinate the systematic and timely reporting by carriers and intermediaries to PROs of possible problems with the quality of care provided in ambulatory and post-hospital care settings identified in medical reviews."

There has been considerable variation among the PROs in the degree to which their review decisions have concurred with those of SuperPRO.

HCFA has contracted with SysteMetrics (more commonly referred to as SuperPRO) to biannually review a sample of records previously reviewed by each PRO (see appendix III for a fuller discussion). During the PROs' second contract period, the first 6 months of

which corresponded to the fourth SuperPRO cycle, SuperPRO validated the determinations made by the PROs regarding admission review, discharge review, DRG validations, quality review, and admission referrals (i.e., whether the PROs' nurse reviewers are referring appropriate cases to their physician reviewers).

Because no acceptable range of disagreement between the PROs and SuperPRO has been established and no national trend analysis of variation among identified quality problems has been undertaken, it is impossible to judge a particular PRO's performance based on SuperPRO data. However, an analysis of PRO/SuperPRO variation within the second contract period (cycle 4) reflected the following patterns (see table 2, appendix X, for a summary of the ranges and means of these differences):

- o the PRO and SuperPRO findings corresponded most closely in the area of premature discharge, where both groups found relatively few problems;
- o the largest average difference between PRO and SuperPRO findings was in the area of DRG changes and the widest range of differences was in the area of admission referrals;
- o SuperPRO generally found a greater frequency of problems in each area of review than did the PRO, with the following exceptions:
 - o one PRO found more quality problems;
 - o three PROs identified more cases for review by physicians (i.e., admission referrals); and
 - o one PRO found more cases of premature discharge.

These patterns were generally consistent across the 4 cycles of SuperPRO review and among our 12 case sites. Two additional considerations are worth noting. First, although HCFA required the PROs to use generic quality screens in the second contract period, their use appears to have had no effect in narrowing the margin between PRO and SuperPRO differences in either identifying quality problems or in determining when it is appropriate for a nurse reviewer to refer a case to a physician reviewer (i.e., physician referrals). A comparison of the PRO/SuperPRO differences across the four cycles (the first three of which correspond to the PROs' first contract period) reflected that the overall differences between the PRO and SuperPRO seem to have widened rather than narrowed in these two areas (see table 2.) More specifically, between the third and fourth SuperPRO cycles, the range of difference between PRO and SuperPRO findings related to quality problems and admission referrals has widened, although the average difference has remained relatively constant. may be explained by the PROs' variation in implementation of the generic quality screens noted in our first inspection report. 10

Second, in our case study analysis, we found no consistent association between perceptions of PRO effectiveness and PRO/SuperPRO agreement levels. Although one of the three PROs perceived by all respondent groups to be at least moderately effective also had consistently high agreement with SuperPRO, the other two reflected average differences with SuperPRO (see table 3, appendix X).

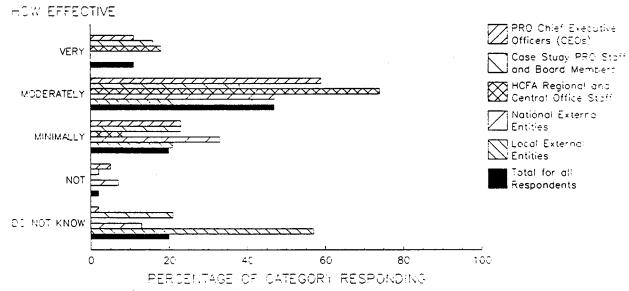
In response to the generally high discrepancy rates between PRO and SuperPRO, the PROs have complained that SuperPRO fails to employ local physicians to review PRO cases and that they have little if any opportunity to discuss differences with SuperPRO reviewers. A further discussion of SuperPRO issues will be included in the HCFA-related findings section of this report.

HCFA-RELATED FINDINGS

There has been significant improvement in HCFA's management and administration of the PRO program during the second contract period.

Despite the problems that are enumerated in other findings of this section, HCFA staff have made important strides in addressing PRO-related concerns as reflected by the fact that a majority of all respondents rated HCFA's management of the PRO program as at least "moderately effective." (see figure III). It is worth noting that HCFA received the highest ratings from those respondents most intimately involved with the PRO program--PRO and HCFA staff. Respondents from entities less involved in the implementation of the program rated HCFA's management less favorably.

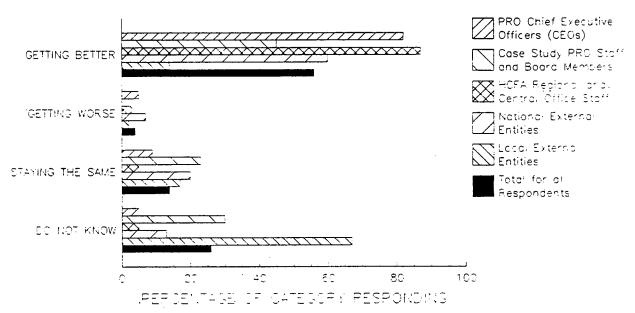
FIGURE III
PERCEPTIONS OF THE EFFECTIVENESS OF
HCFA'S MANAGEMENT



Sturte: 010 Inspection interviews Liste 1.= 196 respondents

Furthermore, a majority of respondents also thought that HCFA's oversight of the PRO program had been improving since the start of the PRO program (see figure IV). Again, those respondents closest to the PRO program tended to give HCFA the highest marks for improvement, but a sizable number (60 percent) of the national external entities also saw HCFA's management as improving.

FIGURE IV
PERCEPTIONS OF CHANGES IN HCFA'S OVERSIGHT



Source: 0.6 inspection interviews Note: N= 196 respondents.

Our conversations with respondents, coupled with our review of HCFA materials, disclosed that HCFA has increasingly emphasized greater consistency and stability in program operations and has intensified efforts to improve communications with the PRO community and national constituency groups. The HCFA's push to improve communication included at least three components. First, since 1986, HCFA has held periodic, high-level meetings with representatives of the PRO community and national constituency groups of providers, physicians, and beneficiaries to discuss issues related to the PRO program. These discussions have resulted in a formal PRO action plan that summarizes specific actions for improving program administration in such areas as communications, monitoring, and evaluation, and for improving the effectiveness of the PROs. Second, in September 1987, HCFA initiated its first national meeting with PRO staff and HCFA regional and central office staff. Third, senior HSQB staff now participate regularly in biweekly conference calls for all PROs convened by the American Medical Peer Review Association (AMPRA). In addition, HCFA's increasing emphasis on consistency and

effectiveness has led it not only to seek more input into policy-making from both the PROs and outside experts, but to undertake a number of research initiatives to strengthen the PRO program. Finally, it has taken measures to improve program operations by formalizing the policy interpretation process, allowing the PROs 30 days' advance notice of program changes and implementing a tracking system to monitor contract modifications.

The HCFA's success in improving communication with the PROs was indicated by the fact that 84 percent of the PRO CEOs and staff and 93 percent of the HCFA regional staff noted at least "moderately effective" relationships between the PROs and HCFA regional office staff. On the other hand, HCFA's central office staff either assigned lower ratings to the regional office/PRO relationships or offered no opinion of those relationships.

A smaller percentage (43 percent) of PRO CEOs and other PRO staff viewed their relationships with HCFA's central office as positively as those with regional office staff. In fact, many did not consider that they had enough of a relationship with HCFA central office staff even to comment upon it.

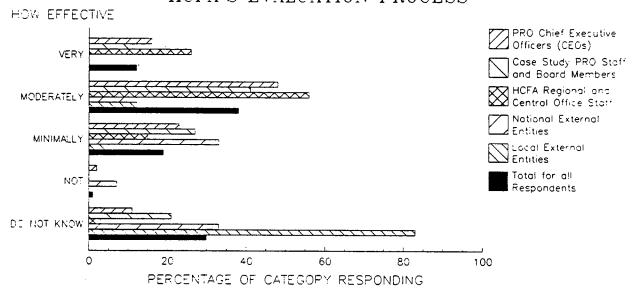
When asked for their observations on the changing nature of PRO-HCFA relations, 66 percent of PRO CEOs, 90 percent of HCFA central office staff and 48 percent of HCFA regional office staff reported that those relationships were "getting better." On the other hand, a small percentage (14 percent) of the PRO CEOs noted that their relationships with HCFA were "getting worse." Those individuals represented 6 PROs from 5 of the 10 HCFA regions. In explaining the reasons for the deteriorating relationships, all commented on the fact that the regional HCFA staff were "nit-picky" and offered inadequate technical assistance. The fact that only one HCFA region received more than one of these negative ratings suggests that the PROs' perceptions of HCFA's effectiveness may be largely influenced by their relationships with particular project officers.

The HCFA's ability to assess PRO performance has been limited by the lack of refinement and integration of its evaluation tools.

When we began this study, we expected to be able to draw definitive conclusions about PRO effectiveness by supplementing our interview-generated data with HCFA evaluation data. But, because of certain limitations inherent in HCFA's various tools, such an analysis has been impossible.

Although half of the total respondents thought that HCFA's process for evaluating the PROs was at least moderately effective, a quarter of the PRO CEOs rated the process as minimally or not effective (see figure V).

FIGURE V PERCEPTIONS OF THE EFFECTIVENESS OF HCFA'S EVALUATION PROCESS



Scurte: 013 inspection Interviews Nate: N= 196 respondents.

The HCFA employs three general tools for evaluating the PROs performance—the PRO Monitoring Protocol and Tracking System (more commonly referred to as PROMPTS-2), SuperPRO and periodic (monthly and quarterly) data reports (see appendix III for description). Our interviews and review of a sample of those documents revealed both individual and collective problems which will be summarized below.

PROMPTS-2

Both PRO and HCFA respondent groups rated the PROMPTS-2 as a more effective evaluation tool than SuperPRO (see table 4, appendix X). Sixty-two percent of respondents thought that the PROMPTS-2 was at least moderately effective. Not surprisingly, HCFA staff were more enthusiastic in their ratings of PROMPTS-2 than were the PROS.

Our interviews and review of the PROMPTS-2 protocol revealed the following concerns about PROMPTS-2:

o PROMPTS-2 has focused primarily on process versus outcome evaluation of the PROs' performance. As one HCFA official noted, "Outcome measures would be nice, but we don't have them. They must be developed."

- o PROMPTS-2's design encourages potential subjectivity and inconsistency among regional office reviewers because it lacks standards for determining PRO performance. Furthermore, it fails to capture gradations in PRO performance because it has only yes/no rating categories.
- The medical review component of PROMPTS-2, in which regional office staff draw a sample of records reviewed by the PRO and validate the PROs' judgments in these cases, is seen as problematic. Specifically, some respondents questioned the expertise of regional office medical reviewers and the validity of their determinations. Many others commented that the medical review element of PROMPTS-2 duplicates the SuperPRO process.

SuperPRO Review

The PRO CEOs and staff were the strongest critics of SuperPRO (see table 4, appendix X). Furthermore, while most HCFA staff considered SuperPRO a nationally consistent tool for validating medical decisions of all PROs, a number of HCFA regional office staff echoed the PRO respondents' uncertainty about how SuperPRO results have been used in evaluating the performance of individual PROs. In addition, our interviews and a review of SuperPRO data revealed the following concerns:

- The HCFA has not established guidelines for acceptable levels of PRO/SuperPRO discrepancies, thereby making it impossible to assess significant concerns. Nor has HCFA undertaken an analysis of those PROs with close or strongly disparate SuperPRO agreement levels. Only analysis computation of national average rates of PRO/SuperPRO disagreement has been made.
- o The HCFA has not undertaken any trend analysis of the types of quality problems identified by SuperPRO. 11
- o SuperPRO was viewed as unresponsive by many PROs because of the lack of contact between PRO and SuperPRO reviewers and the SuperPRO's limited use of local reviewers.
- The 6-month lag time between SuperPRO review and HCFA's receipt of SuperPRO reports has made it difficult for HCFA regional staff to integrate the findings into its own (PROMPTS-2) review of the PROs. For instance, SuperPRO cycle 4 reports were unavailable in time to integrate into the first PROMPTS-2 review.

The HCFA has required SuperPRO to sample approximately 400 records from every PRO's review area every 6 months regardless of size or general performance; several PROs have complained about the excessive staff resources involved in meeting such demands.

Despite the considerable concerns raised about the SuperPRO component, however, a recent study by the OIG corroborated SuperPRO rather than PRO rates of unnecessary admissions. ¹² In that review of 7,050 Medicare records from 239 hospitals, OIG found that 10.5 percent of the hospital admissions were unnecessary, as opposed to the 2 percent to 2.5 percent noted by the PROs.

Data Reporting

The data-reporting process used to monitor ongoing PRO performance has been problematic for both the PROs and HCFA since the beginning of the program. In the absence of HCFA-generated software and computer system specifications, the PROs have struggled on their own to develop and refine the sophisticated data systems required for timely and accurate reporting of their activities to HCFA.

The complexity and large volume of reports required by HCFA has complicated this process. For example, the 1-page Sanction Report (HCFA-545) has more than 12 pages of instructions. HCFA has required the PROs in the second contract cycle to submit 23 different reports, over 90 percent of which are submitted either monthly or quarterly. The PROs have also faced the added difficulty of being responsible for ever-changing reporting requirements called for either by HCFA or by new legislative mandates. The requirements changed significantly between the first and second contract periods, and the reporting process will change again for the third scope of work beginning in 1988. consequences have been PRO data reports that are frequently inaccurate and untimely and data that are inconsistently reported from PRO to PRO. Although nearly three-fourths of HCFA staff rated the PRO reports as being at least moderately useful, many voiced concerns about the quantity, quality, and complexity of the reported data. In-depth data analysis for the purposes of program planning and evaluation has been limited, in part because of the volume and unreliability of the reported data. Analysis has also been limited by HCFA's emphasis on addressing its immediate concerns for validating the accuracy of PRO reports and for remedying reporting problems. It is worth noting that HCFA has recently taken steps to strengthen its data analysis capability and is planning to reduce the PROs' reporting requirements in the third contract cycle.

Integration of Evaluation Tools

The PROMPTS-2 protocol, the SuperPRO process and the PROs' data reports have not been sufficiently integrated into a comprehensive, coordinated system for evaluating the PROs' performance. For instance, although the PROMPTS-2 protocol has been designed by HCFA to serve as the basis for monitoring and evaluating the PROs' performance, it has failed to incorporate systematically the disagreement rates of SuperPRO reviews to permit comparison with those of the HCFA regional office medical reviews. addition, although the medical review component of PROMPTS-2 appears to have duplicated SuperPRO activities, the time frames and sampling methodologies have not been complementary, thereby precluding potentially useful comparisons between the two. Furthermore, PROMPTS-2 has failed to integrate appropriate data report information. For instance, although PROMPTS-2 addresses the PROs' progress in achieving the quality objectives of their contracts, specific data related to the PROs' activities concerning quality of care problems, including sanctions, have not been incorporated into the evaluation document.

Implications for Contract Renewal Process

In the fall of 1987, HCFA issued guidelines to the regional offices, which were shared with the PROs, that outlined the process and scoring system to be used for evaluating PROs for renewal for the third contract period. The second PROMPTS-2 will serve as the basis for assessing PRO performance for contract renewals. In close-call situations, HCFA will utilize the results of SuperPRO review, the PROs' performance in HMO/CMP review, where applicable, and the PROs' cost/savings ratios as computed by HCFA. However, the evaluation guidelines failed to include either the weights or the criteria that HCFA reviewers will use when considering such factors.

The process to be followed by HCFA will begin with the preparation by regional offices of an evaluation package for each PRO consisting of the PROMPTS-2 review, including a total point score for performance, as well as a recommendation for either renewal or nonrenewal. Evaluation packages will be forwarded to central office panels for further review. According to HCFA staff, these panels will be ad hoc groups composed of approximately two central office staff and one staff person from a "neutral" regional office. Panel members will deliberate and make their decisions by telephone because of limited travel money and tight deadlines for decision making. Should the review panels not concur with regional office recommendations or should they make a recommendation for nonrenewal, a third level of review will be performed by senior HCFA managers, the project officer, and the regional branch chief.

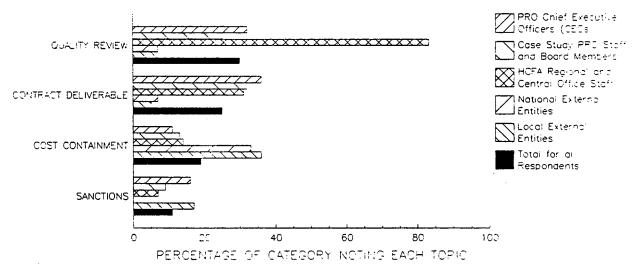
The review panels' lack of consistent membership coupled with the limitations of HCFA's evaluation tools make the renewal process for the third contract period vulnerable to inconsistencies in evaluation and decision making. It is worth noting that GAO¹³ recognized such inconsistencies in HCFA's renewal process for the second contract period, and HCFA assured GAO that proper internal controls had been instituted to avoid such problems in the future.

The HCFA appears to have given the PROs insufficient information on its criteria for making contract renewal decisions.

When asked to identify which of the PROs' activities have been most important to HCFA when evaluating the PROs' performance, respondents in all groups mentioned a wide range of activities. Eighty-three percent of HCFA staff named activities related to the PROs' quality review. In fact, HCFA staff mentioned quality review almost three times as often as any other activity. In contrast, only 32 percent of the PRO CEOs and 25 percent of other PRO staff identified quality review as being the most important activity to HCFA in evaluating PRO performance.

The PRO CEOs and staff most frequently noted the importance of fulfilling their contract deliverables. Most of the respondents from national and local external groups (33 percent and 36 percent, respectively) identified denials and cost containment activities as being the most important of the PROs' activities to HCFA. Less than 10 percent of the respondents from these two groups mentioned activities related to quality review (see figure VI).

FIGURE VI
PERCEPTIONS OF THE MOST IMPORTANT ACTIVITIES TO
HCFA IN EVALUATING PRO PERFORMANCE



Source: OR Inspection interviews thate. N= 186 respondents

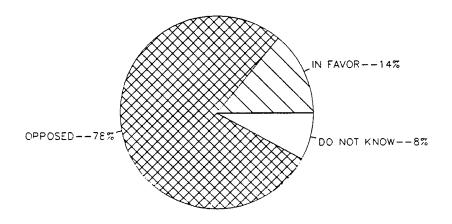
The striking variations and lack of consensus suggested by these responses may reflect the different perceptions that exist about the PROs' mission. However, they may also suggest that HCFA has not clearly and consistently articulated its priorities for assessing acceptable performance by the PROs. For example, the PROs' second scope of work requirements reflected an increased emphasis on activities related to quality review. Furthermore, as we mentioned in our first report, 14 most PROs identified quality review activities as the most important part of their mission. Yet the PROs did not often cite these activities as being the most important to HCFA in evaluating PRO performance.

Since our interviews of the late summer and early fall of 1987, HCFA has articulated priorities for evaluating the PROs! performance during their second contract periods. priorities are reflected in the numerical scoring systems to be used in the final PROMPTS-2 review, which will serve as the primary determinant in HCFA's decision to renew PROs' contracts. According to that scoring system, four categories of PRO activities -- those related to utilization (and other required review), to quality review, to data, and to management -- will each receive a maximum of 100 points, yielding an overall maximum of 400 points. Although that scoring system establishes priorities among the PROs' activities, the system also raises questions about possible inconsistencies and mixed messages sent to the For example, quality-related activities under that system can result in a maximum of 100 points, or 25 percent of the total score, which may be inconsistent with the heavy emphasis being placed on quality review by HCFA and the Congress. Similarly, community outreach activities, included in the management category, can result in only 15 points, or less than 4 percent of the total score, which seems inconsistent with HCFA's increased focus on those activities during the second contract period.

The use of 2-year, fixed-price contracts appears to have created inefficiencies in the PRO program.

Over three-fourths of all respondents believed the 2-year length of the PROs' contracts has been too short (see figure VII). Ninety-five percent of the PRO CEOs, 88 percent of HCFA staff, and 80 percent of national external groups thought that the PROs should have longer contract periods, with most respondents favoring a 3- to 4-year period. Respondents from all groups cited myriad problems with the 2-year contract period. Most were related to the undue pressure such a quick turnaround time has placed on the PROs and on HCFA, especially since the PROs have been given ever-increasing responsibilities since the start of the program.

FIGURE VII PERCEPTIONS OF THE SUITABILITY OF TWO-YEAR CONTRACTS FOR THE PRO PROGRAM



Fercent of Respondents Favoring and Opposing Two—Year Contracts

Sturce: Old Inspection Interviews.

For the PROs, the short contract period has given them very little time for operating between contract renewal cycles--some have equated it with running for Congress every 2 years. For HCFA, the short contract period has hampered opportunities for adequate planning and evaluation since it has had to start planning for the next scope of work after less than a year's experience with the current one. In addition, the final PROMPTS-2 must be conducted by the 17th month of the PROs' contracts in order for HCFA to evaluate for renewal and to meet the deadlines imposed by the contracting process. Moreover, the time lag inherent in the PROs' data reporting (PROs have up to 60 days to review records and 30 additional days to report to HCFA) has meant that the final 17-month PROMPTS-2 reviews may have been based on only 14 months of review activity by the PROs.

Finally, HCFA has had only a very short time within which to evaluate the majority of PRO contracts for renewal and to negotiate new ones for the next scope of work. Fifty-two of the 54 current PRO contracts expire within a 6-month period beginning June 30, 1988. During the 6 months preceding each expiration date, HCFA must evaluate each contractor's performance, seek competitive contract bids if necessary, review proposal(s) for the next scope of work and negotiate a contract before the beginning date of the next contract period. Moreover, with nine groups of PRO contracts expiring over a 6-month period and each group being at most a month apart, HCFA has had to deal

simultaneously with the requirements of several different groups, each of which may be at a different stage in the complicated evaluation/contracting process.

The recent OBRA 1987 legislation included a provision, supported by HCFA, to lengthen the contract period to 3 years and to allow for greater spacing between termination dates of the PROs' contracts. We believe these changes are critically important to improving the administration of the PRO program. They will afford HCFA more time both for evaluating the PROs' performance based on more months of actual review data and for the planning and analysis essential for developing subsequent scopes of work. They will also help alleviate the present administrative nightmare of having to evaluate for renewal so many PRO contracts within a short period of time.

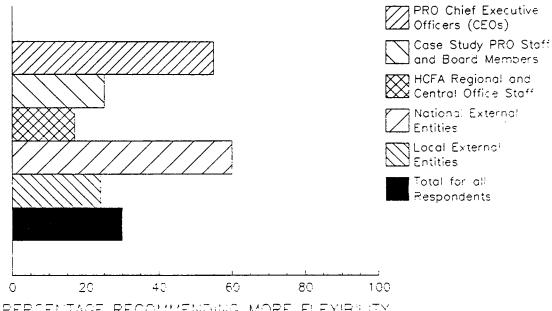
Although fewer respondents directly noted the inefficiencies of fixed-price contracting, many complained about a major by-product of using such contracts for a constantly changing program—the consequent need for frequent contract modifications. According to HCFA staff, by the fall of 1987, HCFA had made more than 1,300 modifications since the first contracts, with 700 of them occurring during the first 15 months of the second contract period.

The PROs have complained vehemently about the long periods of time involved in processing these contract modifications. During the past year, HCFA has initiated several measures to address these problems. Guidelines for the contract modification process, developed in cooperation with the PROs, were issued in September 1987. These guidelines detail the responsibilities of HCFA and the PROs as well as procedures and time frames for submission and review of contract modifications. In addition, the program and contracting components of HCFA responsible for the PRO program have clarified their respective roles and responsibilities and have instituted an automated tracking system to monitor the status of contract modification proposals. Furthermore, during our conversations with high ranking HCFA officials, they noted their intent to experiment with alternative contracting mechanisms with the third contract cycle.

The HCFA's second scope of work has been highly prescriptive and appears to have provided insufficient incentives for PRO initiative.

When asked for their recommendations for improving the PRO program, 30 percent of all respondents suggested that HCFA give the PROs greater flexibility in carrying out their review activities (see figure VIII). It is worth noting that 55 percent of PRO CEOs, 50 percent of the local medical associations, and 24 percent of the HCFA regional staff were among those suggesting such flexibility.

FIGURE VIII RESPONDENTS RECOMMENDING THE PROS BE ALLOWED MORE FLEXIBILITY IN PERFORMING THEIR REVIEWS



PERCENTAGE RECONMENDING MORE FLEXIBILITY

Source: OIG Inspection Interviews. Note: N= 211 respondents.

One of the major reasons cited for this recommendation was that HCFA has required the PROs to follow a closely prescribed menu of activities (as summarized in appendix IV) without adequate regard for whether the activities are productive in identifying either quality or utilization problems. This concern was reinforced by the fact that the PROs identified several activities as having limited or no effectiveness. While HCFA has either de-emphasized or eliminated two of those activities (day and cost outliers and percutaneous lithotripsy) in its third scope of work, it has retained the other five activities most often considered to be least effective: Medicare code editor, fiscal intermediary referrals, preadmission review of pacemaker and four procedures proposed by the PROs, review of cases involving assistants at cataract surgery, and claims adjustments resulting in higherweighted DRGs. In fact, in the third scope of work, HCFA has proposed to add further restrictions on the PROs' preadmission review by requiring the PROs to choose 8 from a list of 11 procedures determined by HCFA.

In our discussions with HCFA program staff, we learned that their process for determining both the second and third scopes of work was primarily an internal exercise with some input from the PRO community. Although HCFA staff reported using statistical

consultation in determining the sampling methodologies, we were unable to determine the reasons for the particular sampling percentages or trigger points included in the review activities (e.g., 50 percent sample of day and cost outliers or intensified review when hospital reaches six cases or 5 percent trigger error rate).

In determining the PROs' scope of work, HCFA has clearly had to balance competiting forces for flexibility and uniformity. While the PROs have pushed HCFA to allow them more latitude in determining their approaches to review, Congress has held HCFA accountable for maintaining national statistics on the PROs' activities. However, in reviewing the list of PRO activities (appendix IV) with HCFA staff, we learned that most of the specific requirements for particular types of review derived from HCFA itself. Many respondents cited the desirability of having HCFA conduct pilot tests prior to mandating universal review of activities by all PROs. In fact, HCFA is planning to undertake several pilot tests during the third scope of work. Nevertheless, it is also adding 100 percent review of nine additional DRGs without first establishing the value of that review.

Several HCFA central office staff noted that the PROs have been given latitude to focus on their areas of concern by carrying out their five objectives. However, many PROs commented that HCFA has made it very difficult to adjust those objectives when they have needed to do so.

Several respondents from each interview category also highlighted the need for the PROs to have greater flexibility to focus their review activities on troubled providers rather than performing equal levels of review at all hospitals in their area. The HCFA is planning to pilot test such an approach in the PROs' third scope of work.

All these restrictions on the PROs' scope of work seem at least somewhat to contradict the PRO legislation which stressed the need to give the PROs more latitude in decision making than PSROs had. As one medical society representative noted: "PROs are overwhelmed right now. HCFA needs to be more selective with the current [review] menu. The tooth of the comb is too fine." As observed by a PRO review director: "If unnecessary activities were eliminated, PROs could focus attention on areas with higher yield."

The dynamism and broad scope of the PRO program have impaired HCFA's ability to manage the program.

Review of the legislative history of the PRO program (see appendix III) reveals that, from the beginning, HCFA has had to implement and administer a complex, ever-changing program which is of strong interest to the Congress, the Administration, and

diverse national constituency groups. The PRO program has been caught in the cross-currents of debate over national health policy and of efforts by the Federal Government to ensure high quality health care while controlling health expenditures. Controversy over the necessity for and purposes of the PRO program both within the Federal Government and among various national constituency groups has surrounded the program from the beginning. The playing out of these various interests has resulted in a highly dynamic program characterized by multiple mandates, shifting emphases, and ever-increasing responsibilities.

The work load involved in implementing the PRO program has been enormous. Since the first contracts in 1984, HCFA has had to develop and implement management systems for planning, monitoring and evaluation, and data reporting and analysis. In addition, the requirements of the initial 1982 legislation as well as those of COBRA (1985) and OBRA (1986) have had to be translated into contract scope of work requirements for three contract cycles. (For a summary of COBRA and OBRA requirements, see appendix VI.) Two basic contracts have been negotiated for each of the 54 PRO areas, and, as noted earlier, more than 1,300 modifications to the basic contracts of the first two cycles have been required to keep up with changes in the program.

In carrying out its complex mission, HCFA's Health Standards and Quality Bureau (HSQB) staff have had to coordinate their activities with those of other entities. For example, HSQB staff have had to coordinate the contracting efforts with HCFA's Office of Management and Budget (OMB). In addition, HCFA has had a close association with the OIG, which has the authority for sanction determinations and performs contract audits for HCFA. And because the PRO program is funded through apportionment from the Medicare trust funds, the Executive Office of Management and Budget (EOMB) has been more directly involved in the administration of the PRO program than is usual for most government programs that are funded through appropriations.

HCFA's large work load has been accompanied by a high degree of instability in staff within and outside the bureau responsible for overseeing the program. Not only has the top leadership of HSQB and HCFA changed since the spring of 1986, but virtually all division director positions within HSQB were filled by new personnel at least once during the course of our study.

Given the pace of changes in both the work load and the staff, it is not surprising that HCFA's management of the PRO program presents a mixed picture. On the one hand, HCFA has been able to implement a complicated, evolving program and has made significant strides since the program's beginning. On the other hand, HCFA has often been criticized for being crisis-oriented and reactive rather than proactive in its management of the PRO

program. This criticism was reflected in the large number of respondents who identified a wide range of specific concerns related to HCFA's planning for and implementation of legislative requirements, as well as operational policies and procedures for the PRO program. Such concerns were expressed not only by the PROs and by local and national constituency groups but by HCFA staff themselves. As one HCFA manager commented, HCFA is "always reacting to crisis and having to do too much."

One manifestation of HCFA's problems has been its delay in implementing certain legislative mandates. For example, the provisions in COBRA 1985 requiring the PROs to secure second opinions for certain surgical procedures have yet to be implemented. On the other hand, timetables established by HCFA for the PROs to implement new requirements have sometimes been unrealistically short. For example, in late summer 1987, HCFA required the PROs to implement by October 1 the OBRA 1986 provision that PROs review beneficiaries' complaints about the quality of care in skilled nursing facilities (SNFs) and home health agencies (HHAs). Although HCFA subsequently extended the deadline, the review requirement was nonetheless retroactive to August 1987.

In addition, HCFA's instructions and guidelines to the PROs have sometimes been complex and unclear. For example, several PROs mentioned the confusing and cumbersome procedures for their review of hospital-issued notices of noncoverage. In addition, HCFA has failed to incorporate certain policy changes into the PRO Manual, which is its official reference for operating policies. A number of the PROs and regional office staff commented that HCFA policymakers have lacked sufficient appreciation of the programmatic and resource implications associated with the PROs' implementation of HCFA requirements. They cited as an example the lack of adequate pretesting of the generic quality screens. As one PRO staff person commented, "HCFA needs more upfront thinking and planning so the PROs won't always have to play catch up."

In addition to inadequate short-term planning, HCFA also appears to have inadequately identified long-term goals and strategies for the PRO program. In our interviews and review of HCFA materials, we saw no indication of HCFA having a long-range perspective on the PRO program. Preoccupied with keeping up with short-term demands of this complex, dynamic program, HCFA has been unable to address such long-term strategic issues as: What are future directions for the program? What role should PROs be playing 5 years from now? How can the PROs best affect the quality and utilization of health care? How can the impact of the PROs be maximized? That these questions be addressed is important for the long-term viability of the PRO program and for the ability of HCFA to influence its future directions.

As previously mentioned, Congress recently extended the contract period for the PRO program, which should help HCFA have more time for program planning. But OBRA 1987 also assigned new responsibilities to the PROs. Although the PROs' broad responsibilities reflect strong public concern for protecting the integrity of the Medicare program, several respondents raised substantial and legitimate concerns that ever-increasing PRO mandates could precipitate the program's implosion rather than facilitate its improvement.

RECOMMENDATIONS

Our review of the PRO program reflected that HCFA has already taken some important steps in strengthening its communication with the PROs and other external entities as well as in improving its contracting processes and data requirements. We commend these efforts and suggest that HCFA continue to strengthen communication between its regional and central office staff, its programmatic and contracting staff and between itself and the PRO and external entity communities. We also suggest that HCFA continue to reduce the volume and complexity of data required of the PROs, to improve the accuracy, timeliness, and consistency of that data and to develop strategies and increase resources to perform comprehensive data analysis.

Our inspection also highlighted several issues related to evaluation and planning that deserve more attention by HCFA. Those issues, along with our recommendations and rationales for those recommendations are included below.

EVALUATION-RELATED ISSUES AND RECOMMENDATIONS

Issues:

- Lack of integration of HCFA's evaluation tools.
- o Inadequate communication of evaluation criteria to the PROs.
- High degree of PRO/SuperPRO discrepancy.
- o Inefficient use of SuperPRO data.
- o Inadequate gradations and outcome measures within PROMPTS-2.

Recommendations:

The HCFA should:

- o Improve coordination and integration of its evaluation tools (PROMPTS-2, SuperPRO and PRO data reports) to ensure comprehensive assessments of PRO performance. This might include:
 - synchronizing the PROMPTS-2 review with the due dates of SuperPRO reports; and
 - incorporating SuperPRO results into the PROMPTS-2 document along with data from PRO reports to maximize the comprehensiveness of the evaluation.

- o Encourage consistency and objectivity in PRO renewal decisions by:
 - establishing rating standards for PROMPTS-2 and for acceptable ranges of variance with SuperPRO;
 - formally informing the PROs, regional office staff and review panel members of the weights to be assigned SuperPRO, HMO/CMP, and cost/savings factors; and
 - establishing a standing evaluation panel of HCFA regional and central office staff to review regional recommendations. Participation by PRO staff before closed session action would permit discussion of mutual questions and concern.

Reexamine the purpose for and the validity of the SuperPRO review process. This assessment should address such issues as:

- whether SuperPRO uses appropriate reviewers and criteria to render valid judgments about local PRO decisions;
- whether SuperPRO is intended to complement PROMPTS-2 medical review or to duplicate it;
- whether SuperPRO is intended to validate PROMPTS-2 review decisions. If so, whether its sample size, criteria and record selection process permit valid comparison; and
- whether there are better ways to use SuperPRO expertise, such as having SuperPRO perform onsite review and provide technical assistance to those PROs most consistently differing from SuperPRO in their review decisions or by having SuperPRO assess what types of quality problems are being identified by PROs.
- Create forums for SuperPRO, HCFA and PRO discussions.
- Examine ways to streamline the SuperPRO process to minimize the administrative burden on PROs and to maximize its utility to HCFA, such as:
 - reducing the sample size for small PROs;
 - revising the schedule for reporting results to reduce time lag between PROMPTS-2 and SuperPRO reviews; and
 - facilitating closer interactions between PRO and SuperPRO reviewers in resolving PRO/SuperPRO differences.

- o Improve the PROMPTS-2 process by:
 - developing standards for judging the manner of PRO performance, i.e., "Are PRO/provider relationships effective ...?", "Is the PRO successfully tracking problems . . . ?";
 - establishing standards for rating "yes/no" acceptability for overall activity category based on number of "yes/no" ratings of subcategories; and
 - developing more outcome measures of PRO effectiveness through research and demonstrations.
- O Develop and release comparative PRO performance data to the PROs and other interested parties.

Rationale:

As noted in the introduction to this report, the specific limitation of HCFA's evaluation tools has made it impossible for us or other parties to receive an integrated view of PRO performance. Because HCFA's evaluation system is central to its ability to assess the PROs, either individually or collectively, it should focus time and attention on strengthening its individual evaluation tools and integrating them more effectively.

PLANNING-RELATED ISSUES AND RECOMMENDATIONS

Issues:

- o Inadequate lead time for implementing new PRO activities.
- o Inconsistency among PROs and HCFA regional staff related to HCFA policy interpretations.
- o Lack of coordination and role clarity among the PROs, fiscal intermediaries and carriers.
- o Prescriptive nature of the PROs' review activities.
- Inadequate long-range planning by HCFA.

Recommendations:

The HCFA should:

Develop and distribute requirements, instructions, and policies in a more timely manner to allow sufficient leadtime for PRO implementation;

- o Improve the consistency in policy interpretation among PROs and HCFA staff by updating the PRO Manual on an on-going basis and by providing training and orientation sessions for both PROs and regional staff as needed; and
- o Review the current roles of carriers, fiscal intermediaries and PROs to assess the appropriateness of the current distribution of responsibilities and assess the coordination of these entities, such as the timeliness of F.I. adjustments.
- o Strengthen long-range planning of future directions and appropriate roles for the PRO program by:
 - increasing the emphasis on research and demonstrations in such areas as review methodologies, patient outcome and severity measures and data system requirements;
 - exploring mechanisms to encourage PRO innovations and reduce the prescriptive nature of the current review requirements;
 - exploring better long-term ways of structuring PROs' activities so they are cost-effective and complement the efforts of other review entities such as State medical licensure boards and hospital quality assurance committees. For instance, HCFA might explore the possibility of having SuperPRO responsible for making DRG determinations and having the PROs focus on quality review; and
 - establishing an advisory group for PRO and other relevant entity representatives to provide input to HCFA on long-range planning issues.

Rationale:

The PRO program has undergone enormous change since its beginning. The pace of the program, coupled with a lack of HCFA staff continuity has contributed to a lack of long-range planning by HCFA. However, now the program contract period has been extended to 3 years and PRO contracts will be staggered over the next 2 years. Therefore, HCFA staff should now have time to address more long-range planning issues. As mentioned earlier, HCFA has made important strides in improving communication with the PRO and external communities. It is imperative that such input also be sought in determining the future course of the PRO program.

APPENDIX I

ENDNOTES

- 1. From a speech given by Senator David Durenburger at the American Medical Peer Review Association conference on May 19, 1987.
- 2. The Utilization and Quality Control Peer Review Organization (PRO) Program: Quality Review Activities (Control #OAI-01-88-00570), Office of Analysis and Inspections, Office of Inspector General, Department of Health and Human Services, February 1988, pp. 17-18.
- 3. Ibid., pp. 18-20.
- 4. Senator John Heinz, "The PRO Funding Victory: Challenges and Growing Expectations," <u>The AMPRA Review</u> (The American Medical Peer Review Association), January/February 1988, p. 3.
- 5. Andrew Webber, "A PRO Report Card," <u>The Internist: Health Policy in Practice</u> (The American Society of Internal Medicine), July 1986, pp. 7-9.
- 6. Op. cit., OIG Report Control #OAI-01-88-00570, pp. 10-12.
- 7. Ibid., p. 26.
- 8. <u>Medicare Improving Quality of Care Assessment and Assurance</u>, Draft Report, U.S. General Accounting Office, December 30, 1987, p. 3-38.
- 9. Ibid. p. 3-31
- Op. cit., OIG Report Control #OAI-01-88-00570, pp. 14-15.
- 11. This issue was also raised in the previously cited GAO report, p. 4-30.
- 12. National DRG Validation Study of Unnecessary Admissions to Hospitals (Control #OAI-01-88-0080), Office of Analysis and Inspections, Office of Inspector General, Department of Health and Human Services, p. 4.
- 13. <u>Medicare Better Controls Needed for Peer Review</u>
 <u>Organizations' Evaluation</u>, U.S. General Accounting Office,
 GAO/HRD 88-13, October 1987.
- 14. Op. cit., OIG Report Control #OAI-01-88-00570, pp. 10-12.

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

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

Although several other entities had reviewed various elements of the PRO program (see appendix VII), no one had undertaken a broad evaluation. 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 and 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. Because of other OIG priorities, completion of the PRO inspection fieldwork was delayed until the fall of 1987.

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

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

Past Work

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

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

- o Inspection of Inappropriate Discharges and Transfers, March 1986, which concluded that many PROs had not effectively used the authorities or processes available to address poor quality of care associated with premature discharges and inappropriate transfer. The report included recommendations regarding HCFA's reporting and evaluation systems and suggested that the PROs be given authority to deny payments for substandard care.
- Report on Evaluation of California Medicare Review, 0 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 in 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 That report reinforced the recommendasanction cases. tions of the first report and also recommended that HCFA issue modifications to the PROs' fixed-price contracts to make only the PROs' incremental sanction costs reimbursable.

Current Work

- o The Region VII Office of Audit is conducting a national cost-benefit analysis of five types of PRO review including retrospective admission, DRG validation, day outlier, cost outlier, and preadmission. The audit is focusing on 14 PROs and is expected to be completed soon.
- 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. That PRO-related report is expected to be completed by this fall.

APPENDIX III

BACKGROUND OF THE PRO PROGRAM

Creation of the PRO Program

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

Peer Review Organizations (PROs) succeeded Professional Standards Review Organizations (PSROs) in the provision of Medicare peer review. The PSRO program had been established by Congress (in Part B of Title XI of the Social Security Act) in 1972 to ensure that health care services provided under the Medicare, the Medicaid, and the Maternal and Child Health and Crippled Children's programs were "medically necessary, conformed to appropriate professional standards, and were delivered in the most efficient and economical manner possible." 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. (For the complete PRO statute, see 42 U.S.C. Sec. 1320C.) The PRO legislation addressed concerns about the potential negative incentives of the prospective payment system (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.

In authorizing the Secretary of the Department of Health and Human Services to enter into contracts with PROs, Congress specified that such organizations must be composed of or have available to them a substantial number of licensed doctors of medicine or osteopathy who are practicing in the area. Hence, the PRO program is composed of both physician-sponsored and physician-access organizations.

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 Marianna 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 appendix.)

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 VII for a summary of PROrelated studies.) In response to these findings and general pressure from within and out 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 VIII 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 or 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; 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. (See appendix IV for a summary of PRO activities for the second contract period.)

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 V for a summary of the differences between the first and second scopes of work.)

COBRA and OBRA 1986 Provisions:

The PROs' responsibilities were substantially increased through provisions of the Consolidated Omnibus Budget Reconciliation Act of 1985 (P.L. 99-272, commonly referred to as COBRA) and the Omnibus Budget Reconciliation Act of 1986 (P.L. 99-509, commonly referred to as OBRA 1986). The COBRA legislation required the

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

Visibility and Vulnerability of the PRO Program

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

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

It is clear from my vantage point that PROs are quickly becoming all things to all people.... The Inspector General of the Department of Health and Human Services is searching vigorously for a policeman of the marketplace. The Executive Office of Management and Budget is looking hard for cost containment services, particularly to hold the line on Medicare admissions. The Medicare beneficiary community earnestly desires a protector of quality as the incentives of diagnosis related group (DRG) payment and capitated arrangements invite under-service. Health care consumers seek ready access to the information that review activities can generate. How else will a competitive marketplace 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

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 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 "grossly and flagrantly" violated or "substantially" failed in a "substantial number of cases" to comply with their statutory obligations to provide (1) services "economically and only when, and to the extent they are medically necessary," (2) services that are "of a quality which meets professionally recognized standards of health care," and (3) services that are properly documented. The Secretary may impose one of two

sanctions: (1) a monetary penalty for no more than the "actual or estimated cost of the medically improper or unnecessary services so provided" or (2) exclusion from the Medicare program for a specified period of time. (For detailed sanction provisions, see 42 U.S.C. Sec. 1320C-5.)

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

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

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.

The PROs' sanction procedures have precipitated ongoing debate among all parties associated with the PRO program. Organized medicine has argued vociferously that the PROs should provide physicians and providers with stronger due process protection. In response to such concerns, HCFA and the OIG held discussions last spring with the American Association of Retired Persons (AARP) and the American Medical Association (AMA) and developed sanction procedures that strengthened PRO notice procedures, clarified the role of an attorney for the physician or provider

at the PRO discussions, ensured that physicians or providers would be provided records of the PRO proceedings, and permitted expert witnesses to provide relevant medical evidence at the PRO discussions with the physician or provider.

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

As of December 31, 1987, the OIG had received 151 referrals from 38 of the 54 PRO areas. For a detailed discussion of sanction issues and statistics, see our recent report on the PROs' sanction activities.

Administration and Oversight of the PRO Program

The 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 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.

During the second contract period, HCFA has used three mechanisms for evaluating PRO performance. For ongoing monitoring of their activities, HCFA has required the PROs to submit over 20 separate reports, 90 percent of which are submitted either monthly or quarterly. For more overall evaluation of the PROs, HCFA employs the PRO Monitoring Protocol Tracking System (more commonly referred to as PROMPTS-2), which HCFA regional staff administer twice during the course of the contract period. PROMPTS-2 is structured to assess the PROs' performance in 17 different areas such as medical review activities, community outreach, data requirements, sanctions, and management internal control through a series of yes/no questions. As part of the PROMPTS process, HCFA regional office staff draw samples of cases reviewed by each PRO to validate the PROs' determinations.

In addition to the regional staff review of PRO determinations, HCFA has contracted with Systemetrics, Inc. (more commonly referred to as SuperPRO) since the PROs' first contract period to biannually re-review a sample of approximately 400 cases from each of the 54 PRO areas. In its blind re-review of these cases, SuperPRO uses the generic quality screens required by HCFA along with the PROs' individual criteria and then compares its determinations to those previously made by each PRO. More specifically, SuperPRO validates the PROs' admission review, discharge review, DRG determination, and quality review determinations and assesses the PROs' medical review criteria and the appropriateness of referrals made to PRO physician reviewers by their nurse reviewers. SuperPRO issues draft and final reports of its findings to HCFA and the PROs and regional HCFA staff are expected to follow-up on discrepancies identified between PRO and SuperPRO determinations.

The PROs' Relationship to HCFA's Fiscal Intermediaries and Carriers.

In addition to its contracts with the PROs, HCFA contracts with two other types of entities that are important to the PRO program. Fiscal intermediaries (FIs) process claims for services covered by Medicare Part A, including inpatient hospital, skilled nursing home, home health, and hospice services. Carriers process claims for services covered by Medicare Part B including physician, and laboratory and diagnostic services. Like the PROs, the carriers and FIs are both required to conduct utilization review activities, and the intermediaries are required to conduct quality-related reviews of skilled nursing facility and home health claims.

The PROs are dependent on the fiscal intermediaries to forward them the hospital billing information which triggers the PROs' selection of cases for review. The FIs are also expected to make appropriate payment adjustments based on the PROs' DRG determinations. In addition, the carriers are expected to make adjustments to physician billing in response to all hospital and skilled nursing facility denials forwarded to them by the FIs. As the PROs begin to conduct nonhospital reviews, their need for close coordination with the carriers will intensify.

Although the FIs and carriers are overseen by a different bureau within HCFA than the one responsible for the PROs, it is obviously important for HCFA to ensure the close coordination of these review entities.

ENDNOTES

- 1. <u>Federal Register</u>, 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 Report, 97-494 at 41.
- 3. "Examination of Quality of Care Under Medicare's Prospective Payment System," Hearing before the Committee on Finance, United States Senate, June 3, 1984, p. 44.
- 4. Andrew Webber, "A PRO Report Card," <u>The Internist: Health Policy in Practice</u> (The American Society of Internal Medicine), July 1986, pp. 7-9.
- 5. Material on the PROs' quality review process was taken from the <u>Congressional Research Service Report for Congress: The Peer Review Organization Program</u>, 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. The Utilization and Quality Control Peer Review Organization (PRO) Program: Sanction Activities (Control # OAI-01-88-00751), Office of Analysis and Inspections, Office of Inspector General, Department of Health and Human Services, March 1988.

APPENDIX IV

PRO ACTIVITIES

Second Scope of Work (1986-1988)

(A) DISCHARGE REVIEW -detect premature/

discharges

(B) GENERIC QUALITY SCREENS

- -discharge planning -medical stability at discharge -deaths
- -nosocomial infections
 -unacheduled return to surgery
 -trauma in hospital

(C) DRG VALIDATION

essure correct
PPS payments
-check physician
attestation
-requirements

(D) ADMISSION REVIEW

nedical medical necessity determine appropriateness (E) COVERAGE REVIEW

-identify noncovered items and services

RETROSPECTIVE

- 1. Review 3% random sample from each PPS hospital, including a 6 month report of short stays (1-2 days)
- 2. Review all cases referred by the Fiscal Intermediary for coverage issues
- 3. Review all cases identified by the Medicare Code Editor (9 ICD-9 codes)
- 4. Review all percutaneous lithotripsy claims in hospitals with extracorporeal shockwave lithotripters
- 5. Review all submitted claims adjustments resulting in a higher weighted DRG (review prior to payment)
- 6. Review 15% random sample of discharges from PPS exempt hospitals and swing bed units to which beneficiary directly admitted**
- 7. Review all transfers from PPS to other PPS hospitals
- 8. Review 50% random sample of day and cost outliers.
- 9. Conduct focused DRG reviews: 462,468,088
- 10. Review notices of non-coverage issued by PPS and non-PPS hospitals:

100% of cases where physician disagrees

- 100% of cases where patient disagrees
- 100% of cases of patient cost liability
- 10% random sample of remainder
- 11. Conduct Intensified Review when hospital reaches
 6 cases or 5% trigger error rate
- 12. Review 10% or 1200 discharges in quarter for validation of objectives****
- 13. Review all related readmissions within 15 days from a PPS acute care bed to any acute hospital (PPS or non-PPS) for inappropriate admissions
- 14. Review all cases with non-covered admissions
- 15. Perform 5 objectives to eliminate adverse outcomes (by generic screen, by provider/practitioner, and by DRG) and reduce unnecessary admissions and procedures (by provider/practitioner, and by DRG)
- 16. Review transfers to non-PPS, exempt distinct units of acute hospitals***:

50% random sample to swing beds

50% random sample to excluded alcohol/drug abuse unit 25% random sample to excluded rehabilitation unit To excluded psych unit:

100% of records showing invalid ICD-9 codes 100% of records showing organic brain conditions 10% random sample of remainder

PROSPECTIVE

- 17. Preadmission review of pacemaker and 4 procedures proposed by PRO that add up to 2.5% of statewide discharges*
- 18. Review all cases with assistants to cataract surgery to

OTHER ACTIVITIES

- 19. Develop profiles of data received on a quarterly basis to identify aberrant providers, practitioners
- 20. Implement community outreach/education programs
- 21. Implement HCFA approved intervention steps whenever quality issues are identified and take necessary corrective actions:

education intensified review sanction

- 22. Make waiver of liability determinations
- 23. Review HMOs and CMPs for quality and appropriateness of inpatient and outpatient services (COBRA/OBRA)
- 24. Review written complaints by beneficiaries concerning quality of care at hospitals, SNFs, home health agencies, and HMO/CMPs(OBRA)

PENDING ACTIVITIES

- Review ten surgical procedures on preadmission/ preprocedure basis to determine medical necessity (COBRA)
- Deny payment for substandard quality of care (COBRA)
- Review skilled nursing facilities and home health agencies for quality of care (OBRA)
- Provide information on specific cases or patterns of substandard care to state licensing, state certification, or national accreditation boards (OBRA)
- Review services provided in hospital outpatient departments and ambulatory surgery centers (OBRA)
- Conduct small area enalysis in at least twelve PRO areas (ORRA)
- Review all readmissions within 31 days to PPS and non-PPS hospitals for inappropriate admissions and review any intervening care provided in hospitals, skilled nursing facilities or outpatient departments, for contracts entered into after January 1,1967 (OBRA)

KEY

- Admission and coverage review only
- ** In lieu of DRG validation, review medical necessity and length of stay
- Review for appropriateness of transfer, admission and length of stay, as well as determining the medical necessity of length of stay. Do not perform DRG validation
- ***** Discontinued during the second scope of work

Note:

This chart was created by Region I DHHS/OIG/OAI in consultation with HCFA.

APPENDIX V

COMPARISON OF 1984 SCOPE OF WORK TO 1986 SCOPE OF WORK

Review Area	1984	<u>1986</u> *
Objec tives	3 Admission Objectives 5 Quality Objectives All proposed and vali- dated 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 pro- posed 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 extracorporeal shock wave lithotripter

Review Area	1984	<u>1986</u> *
Validation of Objectives	Not in contracts	Sample of one quarter's dis- charges to validate objective performance
Hospital Notices	100% where patient or physician dis-agrees. 100% where patient is liable.	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 coveragreview.

Source: HCFA

APPENDIX VI

SUMMARY OF RECENT PRO-RELATED LEGISLATIVE PROVISIONS

A. STATUS OF IMPLEMENTATION OF COBRA 1985 PROVISIONS

Assistants at Cataract Surgery

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

PRO Denials for Substandard Care

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

PRO 100 Percent Preprocedure Review

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

B. STATUS OF IMPLEMENTATION OF OBRA 1986 PROVISIONS

- 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 <u>Review of hospital denial notice</u>. 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.
- 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. Contracts have been awarded in those States where it is applicable. Review began July 1, 1987.
- The Secretary is to identify and make available to PROS methods of identifying those cases that are more likely than others to be associated with substandard quality of care, and to provide at least 12 PROS with data and data processing assistance to perform small-area analysis. Both provisions effective upon enactment. The first is an ongoing activity. The HCFA has contracted with the American Medical Review Research Center (AMRRC) for the small-area analysis which will utilize feedback from 12 pilot PROS. Information is presently being gathered.

- o <u>PRO boards must include at least one consumer</u>
 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 <u>PROs must respond to beneficiary complaints about poor quality care provided in all settings</u>. 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 regarding exchange of
 information with licensure boards. Clarifications
 regarding exchange with State Medicaid agencies have
 been published.
- 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.

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 programs. 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 and fiscal intermediaries of payment denials before offering providers or physicians the opportunity for reconsideration;
 - o publication in the <u>Federal Register</u> of the standards used for evaluating the PROs and any new

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

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

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

APPENDIX VII

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):

- "Strategies for Assessing Medicare Health Care 0 Quality," December 30, 1987: The study evaluated the systems for assessing quality of care in the Medicare program (i.e., carriers, intermediaries, and PROs) and identified short- and long-term strategies for measuring and monitoring quality of care. Among other suggestions, the GAO recommended that HCFA: review the PROs' methods for dealing with quality issues; evaluate the spheres of responsibilities of the PROs, FIs, and carriers to determine that their responsibilities are appropriately divided; require the PROs, FIs, and carriers to maintain data related to quality; require that patient diagnoses be recorded on Medicare outpatient Part B claims and develop HCFA data files of that Part B information; and develop a mechanism to allow SuperPRO to evaluate PRO cases that were selected through both the PROs' random sample and specific samples of hospital records.
- "Better Controls Needed for Peer Review Organizations' Evaluations," October 8, 1987: The study assessed HCFA's evaluation process for the 1986-88 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.

"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 1984-86 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):

"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:

Assurance in Medicare," July 1985: Study focused on the first scope of work for PROs' review of quality during the first 2 years of PPS. Rand recommended that the quality objectives in the 1984-86 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

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 Dantzler--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 final draft is expected by mid-June, 1988. (Eric Peterson--Team Leader)
- o At the request of the House Ways and Means Committee, the PEMD has designed a study to evaluate the PROs' handling of quality of care issues. Preliminary descriptive findings are expected in late 1988.

 (Jill Bernstein--Team Leader)
- The Human Resources Division (HRD), is undertaking a brief review of two aspects of the PRO program: an analysis of the lack of information exchange among PROs, Medicare carriers, State Medicaid agencies, and State licensure boards, as well as an analysis of OIG practices in imposing monetary penalties. The report is expected to be issued in the fall of 1988. 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 VIII

THE PROS WITH MORE THAN ONE CONTRACT*

Organization Name/Location	Addition PRO Areas Re	
Professional Review Organization for Washington Seattle, WA	Alaska Idaho	
West Virginia Medical Institute, Inc Charleston, WV	Delawa	re
Delmarva Foundation for Medical Care, Inc Easton, MD	Distri Columb	
Hawaii Medical Services Association Honolulu, HI	Guam/A	merican Samo
PEERVIEW, Inc	Kentuc	ky
Health Care Review, Inc	Maine	
Iowa Foundation for Medical Care West Des Moines, IA	Nebras	ka
New Hampshire Foundation for Medical Care Dover, NH	Vermon	t
Montana-Wyoming Foundation for Medical Care Helena, MT	Wyomin	9
*Note: Eight PROs hold two contracts; one	PRO holds three	contracts.

APPENDIX IX

MEMORABLE "PRO-ISMS"

We appreciated the candor and thoughtfulness with which individuals responded to our questions. 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 we heard that were related to the PRO program (i.e., "PRO-isms").

Regarding the PROs' effectiveness:

"This program stands almost alone as the buffer [against poor medical care] for the American public" (from a PRO medical director).

"We're spinning our wheels, we're not moving forward" (from a PRO CEO).

"I wish that I could tell you how effective [the PROs] are, but I don't know" (from a congressional staff person).

Regarding HCFA's evaluation methods:

"There's a lot more to a PRO than not getting a chart done in 30 days" (from a PRO staff member).

"They [HCFA] are starting to do some things right" (from a PRO staff member).

"They're looking at numbers and numbers only" (from a PRO staff member).

Regarding factors constraining PRO performance:

"Some [PRO] responsibilities are exercises in futility" (from a PRO CEO).

"The government is like a monstrous behemoth with its legs mired in the swamp" (a PRO medical director).

Regarding the length of the PRO-contract period:

"It's 4 years for the President" (from a PRO CEO).

"Give us time to get a little bit better [seated] in the saddle."

For other "PRO-isms" related to the PROs' sanction and quality review activities, see our previous two reports on those subjects.

CASE STUDY SITE	HOW EFFECTIVE	NUME PRO CEO	BER OF RESPO PRO Staff & Board	NDENTS HCFA RO	NOTING Hosp. Ass'n	EFFECTIV Medical Society	ENESS LEVEL Licensure Board	FI
Α	VERY MODERATELY	1	3 2	1 2	1	1	1	1
В	VERY MODERATELY MINIMALLY DO NOT KNOW	1	2	1 1 1	1	1	1	1
C	VERY MODERATELY MINIMALLY DO NOT KNOW	1	1 4	2	1	1	1	1
D	VERY MODERATELY MINIMALLY DO NOT KNOW	1	1 5	2	1	1	1	1
Ē	VERY MODERATELY MINIMALLY	1	2 1 1	1 2	1	1	ì	1
F	VERY MODERATELY MINIMALLY	1	4	2	1	1	1	1
G	VERY MODERATELY	1	2	3	1	1	1	î
H	VERY MODERATELY	1	3 1	2	1	1	1	1
Ī	VERY MODERATELY MINIMALLY DO NOT KNOW	1	3	1 1 1	1	1	1	1
J	VERY MODERATELY MINIMALLY DO NOT KNOW	1	1 5	2	1	1	NOT AVAILABLE	1
K	VERY MODERATELY MINIMALLY NOT DO NOT KNOW	1	2 1 1	3	1	1	1	1
·L	VERY MODERATELY DO NOT KNOW	1	3	3	1	1	1	<u> </u>

APPENDIX X

TABLE 2

SUPERPRO - PRO DISAGREEMENT RATES FOR FIRST FOUR CYCLES

	CYCLE	RANGE OF DIFFERENCES (1)	SIZE OF RANGE	AVERAGE DIFFERENCE(2) %
DRG CHANGES	4	3.7 - 20.0	16.3	10.6
	3	6.0 - 17.3	11.3	11.5
	2	1.3 - 16.6	15.3	9.9
	1	1.3 - 14.6	13.1	9.2
ADMISSION	4	-9.9 - 23.8	33.7	7.3
REFERRALS (3)	3	-1.8 - 25.7	27.5	7.4
• •	2	-2.4 - 20.1	22.5	6.5
	1	-8.5 - 15.6	24.1	7.1
NECESSITY	4	1.8 - 15.9	14.1	7.5
DENIALS	3	4.8 - 16.2	11.4	9.2
	2	1.9 - 16.8	14.1	7.8
	1	1.9 - 25	23.1	8.0
QUALITY	4	-1.5 - 19	20.5	4.8
PROBLEMS	3	-3.2 - 11.7	14.9	3.1
	2	-2.7 - 3.2	5.9	1.0
	1	0.0 - 11.2	11.2	2.2
PREMATURE DISCHARGES (4	4	-1.0 - 3.1	4.1	0.5

^{1:} Range of differences between the percentage of problems found by a PRO and SuperPRO when reviewing same cases.

Negative values mean PRO found more problems than SuperPRO.

^{2:} Average difference in percentage of problems found by PROs and by SuperPRO when reviewing same cases.

^{3:} Percent of cases referred to physician for further review.

^{4:} Data available only for cycle 4.

APPENDIX X TABLE 3 REVIEW DETERMINATIONS FOR 12 CASE STUDY SITES

CASE STUE SITE *A		PRO DIFF	1 1	DENIALS PRO DIFF \$ \$ 1.0 3.2 2.1 13.0 1.0 7.8	PROBLEMS PRO DIFF \$ \$ 14.9 2.1 7.3 0.2	PREMATURE DISCHARGE PRO DIFF 1.0 0.0
В	4	3.8 11.8	12.6 8.4	2.2 7.6	5.2 3.3	0.5 1.7
С	4	3.6 12.8	6.2 3.4	2.9 2.8	1.6 4.9	0.3 0
D	4 3 2 1	5.6 10.6 4.0 7.3	9.0 6.2 3.4 12.0 2.2 10.7 2.1 6.3	1.3 10.6 21.3 8.1	1.6 2.1 0.5 1.1	0.0 0.0
E	4 3 2 1	9.6 7.0	7.3 8.3 5.5 4.4 7.6 5.5 15.1 6.7	1.0 6.0 3.0 5.8 4.9 5.3 2.5 6.7	1.5 0.2	0.6 0.0
F	4 3 2 1	3.5 11.4	15.9 -0.5 9.8 5.9 15.1 6.3 7.2 4.3	4.5 5.3 6.8 6.6	0.5 3.5 1.3 2.2	0.5 0.5
*G	4 3 2 1	3.8 9.3	3.0 3.8 2.3 7.8 5.2 6.2 8.2 6.7	1.0 4.8 1.4 7.3	0.0 4.0	1.5 0.0
*H	4 3 2 1	4.7 14.6 3.9 14.7 5.4 11.0 3.1 8.1	8.8 12.4 11.1 6.0 9.7 0.6 9.1 1.3	3.1 8.3 2.1 3.0	0.0 2.1 0.3 0.5	0.3 1.4
I	4 3 2 1	8.1 22.0 0.8 17.3 1.1 16.6 2.1 14.6	15.7 6.3 4.3 16.0 2.4 14.5 3.4 10.4	2.5 6.8 1.1 12.8 0.8 8.2 1.3 4.8	0.0 3.0 0.0 4.8 0.5 1.5 0.0 1.6	0.0 0.0
J	4 3 2 1	3.2 11.4 4.1 9.6 2.5 8.4 4.9 8.7	13.6 11.7 1.3 17.5 6.8 11.1 6.7 13.9		5.4 3.5 0.3 4.8 3.2 1.0 1.8 3.1	2.0 0.3
K	4 3 2 1	1.1 14.3 2.1 16.5 12.8 7.7 2.3 12.6	0.8 7.3 8.3 9.0 12.5 4.0 8.6 4.8	0.0 5.6 5.2 6.7 9.0 5.9 3.8 6.3	1.7 3.3 1.3 4.9 3.4 3.2 1.3 2.8	0.0 0.0
L	4 3 2 1	7.0 8.6 1.3 11.1 5.7 9.7 2.9 7.8	12.5 1.8 10.6 3.9 9.0 11.8	1.6 5.7 3.1 7.2 2.7 7.4 2.6 10.9	0.6 8.5 0.0 5.7	0.3 0.2

All numbers are percentages. PRO: Percent of problems found by PRO. DIFF: Difference between percent of problems found by SuperPRO and PRO. A negative value means the PRO found more problems than SuperPRO. * PROs seen as at least moderately effective by all respondents groups.

APPENDIX X

TABLE 4

COMPARISON OF THE PERCEPTIONS OF THE EFFECTIVENESS OF SUPERPRO AND PROMPTS IN EVALUATING PRO PERFORMANCE

RESPONDENT GROUP	EVALUATION TOOL	Very	PERCENT NOT Moderately %	ING HOW EFF Minimally %		VE Don't Know %
PRO	PROMPTs	20	48	25	2 20	5
CEOs	SuperPRO	11	27	36		5
PRO	PROMPTs	11	30	23	4	32
Staff	SuperPRO	7	27	- 29	21	16
HCFA Regional	PROMPTs	34	55	10	0	0
Office	SuperPRO	24	48	10	10	10
HCFA Central	PROMPTs	40	30	10	0	20
Office	SuperPRO	30	50	10		10
Total for All	PROMPTs	21	41	20	2	16
Respondents	SuperPRO	14	33	26	17	15

APPENDIX XI

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 two-hour) interviews with a variety of people associated with the program. Those 211 individuals included the following:

- 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;
- 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);
- 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);
- 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);
- 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 firsthand perspective on the PROs' operations, we made 3- to 4-day site visits to at least 1 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 began only on July 1, 1987.

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

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

HCFA Region	PRO Area	<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

HCFA Region	PRO Area	<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 according to 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.

<u>Discussion</u> 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 usually coded all questions in a given file to maximize coding consistency. In addition, a different team member checked at least a 20 percent random sample of the files to ensure accuracy. As part of the PRO inspection team's quality control plan, the project leader assigned one team member to be the project's data coordinator. In addition to having primary responsibility for designing the PRO data base, that individual was also responsible for developing and enforcing data-related quality control procedures.

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

Other PRO-Related Data

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

Statistical Area (SMSA) as defined by the U.S. Bureau of Census. Information on the numbers of rural and urban physicians for 1985 was provided by the Public Health Service, Bureau of Health Professions. Information on the number of physicians eligible for Medicare reimbursement as of January 1, 1987 was obtained from HCFA, Bureau of Program Operations.

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

Methodological Considerations in Interpreting PRO Interview Data

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

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

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

APPENDIX XII

COMMENTS ON THE DRAFT REPORT AND OIG RESPONSE TO THE COMMENTS

Within the Department of Health and Human Services we received comments on the draft report from the Health Care Financing Administration (HCFA) and the Assistant Secretary of Planning and Evaluation (ASPE). In addition, we received comments from the American Hospital Association (AHA). In the sections that follow, we offer these comments, in full, and our response to them.

ASPE COMMENTS

Thank you for the opportunity to review the draft report entitled "The Utilization and Quality Control Peer Review Organization (PRO) Program: An Exploration of Program Effectiveness." My primary concern is that the document, although well-written and informative, needs to be expanded to incorporate more information on the third scope of work (1988-1990). Specifically:

- Page one of the report states that the study focused on "the implications of the changes in the PROs' scope of work from the first to second contract period." Since the report also discusses changes from the second to third contract period, this should be referenced in the Introduction.
- The last sentence on page 18 states that "HCFA is planning to reduce the PROs' reporting requirements in the third contract cycle." Some detail should be included on the nature of these changes. How will the contract cycle compare to the 23 reports required in the second cycle, 90 percent of which are submitted either monthly or quarterly.
- Appendices III, IV and V contain summaries and comparisons of the first and second scopes of work. These appendices should be expanded to include information on the third scope of work as well, particularly given that the body of the report includes discussion of third round requirements (e.g., pp. 24-25).

Finally, I have one minor suggestion with respect to the format of the report. Pages iv through vii of the executive summary list recommendations made by the OIG. Pages 29 through 32 of the report reiterate the same recommendations. Rather than repeat the same recommendations verbatim, I recommend that they be put

in the body of the report and then just summarized in the executive summary.

OIG RESPONSE

The comments for further information on the third scope of work and or HCFA changes concerning reporting requirements are well taken. In part, these are reflected in HCFA's comments. More detailed explanation, we think, is best offered in other forums. This report essentially focused on the second scope of work.

AHA COMMENTS

The following are the American Hospital Association (AHA) comments on OIG draft report entitled "The Utilization and Quality Control Peer Review Organization (PRO) Program: An Exploration of Program Effectiveness."

EXECUTIVE SUMMARY

My only comment is with the statement on page iii pertaining to PRO data reporting. The statement reads "However, HCFA has recently taken steps to strengthen its data analysis capability and is planning to reduce the PROs' reporting requirements in the third contract cycle." Based on my review of the PRO data chapter and in conversations with PRO data staff, it would appear that HCFA is increasing the PROs data requirements (i.e. inclusion of provider and beneficiary identifiers, and information pertaining to generic quality screens). A statement describing HCFA's expectations as a result of strengthening the PRO data capabilities would be helpful.

GENERAL COMMENTS

In general, the study was informative and easy to follow. The findings and recommendations presented in the study were quite accurate. The appendices provided useful background information about the PRO program. It would be helpful to the reader if some of the key requirements of the third scope of work could be included in the report.

OIG RESPONSE

Our response to the ASPE comments also applies to the AHA comments above. Additional, detailed explanations concerning HCFA's expectations and the third scope of work would provide helpful context to our report, but we feel are best provided by HCFA in other forums.

HCFA COMMENTS

We have reviewed the draft report on the effectiveness of the PRO program and we have two general comments:

- We are concerned that the findings are listed in the report as having been identified by the OIG. In fact, they were identified by HCFA and the recommendations, for the most part, were already under consideration by HCFA and were discussed with OIG staff during the inspection. We raised this concern in our comments on the OIG's draft report on Quality review Activities (the second in this series of reviews).
- Although the methodology for the review and its conclusion appear valid, the findings are based on questions presented to PRO representatives and other groups associated with the PROs. validity and reliability are suspect. Questions used in the survey were ambiguous and in some instances the analysis of the responses were not defined. For example, what definition or standard of "effectiveness" was used in presenting questions or evaluating responses? Are effective review activities those that result in a high number of denials, generate significant problem savings, identify substantial quality of care problems or meet some other undelineated criterion? In addition, there is no examination of variables such as familiarity with the system, philosophy of medical review, and association with HCFA and the PROs for each category of respondent.

Our response to the specific recommendations, as well as other general comments, are attached for your consideration. We have addressed the recommendations in the order in which they appear on pages iv through vii of the report.

OIG Recommendation

Improve coordination and integration of its evaluation tools (PROMPTS-2, SuperPRO and PRO data reports) to ensure comprehensive assessments of PRO performance. This might include:

 synchronizing the PROMPTS-2 review with the due dates of SuperPRO reports; and - incorporating SuperPRO results into the PROMPTS-2 document along with data from PRO reports to maximize the comprehensiveness of the evaluation.

HCFA COMMENTS

During the second Scope of Work, the PROMPTS-2 was designed primarily as a PRO monitoring and performance tracking system. HCFA employs a broad based PRO evaluation process that reviews a variety of indicators, including PROMPTS-2.

We do not feel that PROMPTS-2 should be evaluated separately from the corrective action plan (CAP) process. The combination of PROMPTS-2 and the CAPs process is keyed to compliance with contract requirements and the specifics of the PRO's own contract proposal. We are not surprised that the PRO's interviewed would characterize HCFA's insistence on contract compliance as "process oriented." We would expect the OIG to reject such a characterization of the routine monitoring that is prudently required with large, fixed-price federal contracts.

Finally, the SuperPRO contract for the third Scope of work will be recompeted and we are giving serious consideration to integrating SuperPRO findings with the PROMPTS-2.

OIG Recommendation

Encourage consistency and objectivity in PRO renewal decisions by:

- establishing rating standards for PROMPTS-2 and for acceptable ranges of variance for SuperPRO.
- formally informing the PROs, regional office staff and review panel members of the weights to be assigned SuperPRO, HMO/CMP, cost/savings ratio factors; and
- establishing a standing evaluation panel of HCFA regional and central office staff to review regional recommendations. Participation by PRO staff before closed session action would permit discussion of mutual questions and concerns.

HCFA COMMENTS

HCFA's criteria for contract renewal have always been:

- strict contract compliance;
- appropriate medical review determinations; and
- a fair price.

The final evaluation for contracts under the second Scope of Work takes into consideration regional office review and recommendations. The PROs and regional offices were formally notified as to what constitutes acceptable performance. We use evaluation panels to review regional office renewal recommendations to assure that performance standards are applied consistently on a national basis and to assure that all PROs are treated equally and fairly. As mentioned previously, we are developing SuperPRO standards and are currently planning the integration of SuperPRO and PROMPTS-2 during the next contract cycle.

As required by statute, HCFA will publish its evaluation criteria for the next contract cycle and will consider all comments received.

OIG Recommendation

Re-examine the purpose for and validity of the SuperPRO review process. This assessment should address such issues as:

- whether SuperPRO is intended to complement PROMPTS-2 medical review or to duplicate it;
- whether SuperPRO is intended to complement PROMPTS-2 review decisions. If so, whether its sample size, criteria and record selection process permit valid comparison; and
- whether there are better ways to use SuperPRO expertise, such as having SuperPRO perform onsite review and provide technical assistance to those PROs most consistently differing from SuperPRO in their review decisions or by having SuperPRO assess what types of quality problems are being identified by PROs.

HCFA COMMENTS

As discussed with OIG staff during the inspection, HCFA has already recognized the existence of significant variation in SuperPRO disagreement rates. We responded by establishing a system of rereviews of disagreements by regional and central office medical staff and consultant physicians.

SuperPRO was originally intended as an educational tool for PROs to identify and correct areas of performance where deficiencies exist. The regional offices use SuperPRO results to monitor PRO performance and establish CAPs. SuperPRO does not use local physicians and would not necessarily apply local practice patterns. If we have SuperPRO "make" the PROs conform to

national standards, the whole concept of local peer review would be lost.

As previously mentioned, we are reevaluating the SuperPRO process and are planning the incorporation of SuperPRO findings into the PROMPTS-2. While the report does not explain whether onsite review would occur at the PRO or at the health care facility, we believe that having SuperPRO go onsite would decrease the effectiveness and objectivity of SuperPRO review and would not be cost-effective.

OIG Recommendation

Create forums for SuperPRO, HCFA and PRO discussions.

HCFA COMMENTS

HCFA already maintains active liaison with the American Medical Peer Review Association (AMPRA), the industry group that represents the PRO contractors. HCFA and AMPRA representatives meet on a regular basis to provide an effective exchange of information. In addition, HCFA representatives attend various regional and topical meetings sponsored by AMPRA.

We conduct annual meetings with PRO Executive Directors and Medical Directors and routinely convene ad hoc industry task force groups when we need to implement new legislation/policy (e.g., industry on HHA, SNF, hospital outpatient review, etc.). Finally, we are considering the development of a regular forum of PRO, SuperPRO and regional office staff to consider SuperPRO issues.

OIG Recommendation

Examine ways to streamline the SuperPRO process to minimize the administrative burden on PROs and to maximize its utility to HCFA, such as:

- reducing the sample size for small PROs;
- revising the schedule for reporting results to reduce time lag between PROMPTS-2 and SuperPRO reviews; and
- facilitating closer interactions between PRO and SuperPRO reviewers in resolving PRO/SuperPRO differences.

HCFA COMMENTS

In preparation of the new Scope of Work for the next SuperPRO contract, we are considering changes to the SuperPRO model.

Areas currently under consideration include: refinement of sampling methodology; flexibility with respect to sample size, especially for smaller PROs; continued analysis of SuperPRO data; and effective ways to use SuperPRO findings, including integration with PROMPTS-2.

We are also considering having the regional offices act as the final authority to resolve disagreements between PROs and SuperPRO.

OIG Recommendation

Improve the PROMPTS-2 process by

- developing standards for judging the manner of PRO performance, i.e., "Are PRO/provider relationships effective...?", "Is the PRO successfully tracking problems...?";
- establishing standards for rating "yes/no" acceptability of overall activity category based on number of "yes/no" ratings of subcategories; and
- developing more outcome measures of PRO effectiveness through research and demonstrations.

HCFA COMMENTS

The evaluation of peer review, like peer review itself, can never be totally objective. HCFA has responded to criticisms of the first PROMPTS by making the PROMPTS-2 easier to complete, including "yes/no" answers where appropriate, and by taking steps to develop computer assisted analyses of PROMPTS-2 results. Ultimately, we believe that the effectiveness or success of the PRO, or the impact of subcategory ratings on category ratings, is best determined by the professional judgment and expertise of HCFA central and regional office staff. HCFA has emphasized regional office training, regional and central office communication, as well as the participation of senior HCFA management in evaluation decisions to ensure national consistency. PROMPTS-2 like the original PROMPTS protocol, is currently being reexamined based on regional office experience. HCFA is always open to suggestions that will simplify the completion of the PROMPTS, but still allow HCFA to take advantage of the considered judgment of regional office staff.

As we discussed in detail under our response to the long-term planning recommendation and have previously discussed with OIC personnel, we have already initiated pilot studies and research efforts to develop outcome measures of PRO effectiveness.

OIG Recommendation

Develop and release comparative PRO performance data to the PROs and other interested parties.

HCFA COMMENTS

We currently release PRO data reports on a regular basis and will continue to do so. We are also considering the development and release of other PRO performance data reports.

OIG Recommendation

Develop and distribute requirements, instructions, and policies in a more timely manner to allow sufficient lead time for PRO implementation.

HCFA COMMENTS

We recognize that there have been problems in this area in the past. We have already implemented procedures whereby PROs are given sufficient lead time (at least 30 days) prior to implementation of revised contract requirements.

In addition, OBRA 87 requires that we publish in the <u>Federal</u> <u>Register</u> any new policy or procedure that affects the performance of contract obligations at least 30 days before the policy or procedure becomes effective. It also requires that contract modifications requiring funding for these activities are negotiated prior to implementation.

OIG Recommendation

Improve the consistency in policy interpretation among PROs and HCFA staff by updating the PRO Manual on an on-going basis and by providing training and orientation sessions for both PROs and regional staff as needed.

HCFA COMMENTS

We agree that revisions to the PRO manual must be issued on a more timely basis. We have improved our performance in this area and will continue to do so. We also note that the third Scope of Work is considerably more detailed and should greatly assist PROs in the conduct of their contractual obligations. In addition, HCFA has emphasized PRO/regional office training to ensure national consistency. We have made improvements by having at least annual meetings to train regional office staff who in turn train the PROs. We also participate at AMPRA conferences and hold an annual conference for PRO executives.

OIG Recommendation

Review the current roles of carriers, fiscal intermediaries (FIs) and PROs to assess the appropriateness of the current distribution of responsibilities and assess the coordination of these entities, such as the timeliness of FI adjustments.

HCFA COMMENTS

There have been a variety of problems with the FI/PRO interface. In the current Scope of Work, the actual communications problems which existed in the first Scope of Work were corrected. The problems which exist with the processing of adjustments have been identified and analyzed. HCFA has established a joint effort, with representatives from the regional offices, FIs and PROs, which will provide a plan for correcting problem areas.

OIG Recommendation

Strengthen long-range planning of future directions and appropriate roles for the PRO program by:

- increasing the emphasis on research and demonstrations in such areas as review methodologies, patient outcome and severity measures and data system requirements;
- exploring mechanisms to encourage PRO innovations and reduce the prescriptive nature of the current review requirements;
- exploring better long-term ways of structuring PROs' activities so they are costeffective and complement the efforts of other review entities such as State medical licensure boards and hospital quality assurance committees. For instance, HCFA might explore the possibility of having SuperPRO responsible for making DRG determinations and have the PROs focus on quality review; and
- establishing an advisory group of PRO and other relevant entity representatives to provide input to HCFA on long-range planning issues.

HCFA COMMENTS

We believe that long-range planning has been strengthened. As we advised OIG staff, we believe that is important for the PROs to become involved in long-range planning efforts. In fact, several efforts already are underway. As part of their medical review, eight PROs are currently engaged in a special collection of

clinical data which will be linked with Medicare data on outcomes. This data will be used to assess the impact of interventions in six areas--coronary revascularization, cholecystectomy, prostatectomy, myocardial infarctions, heart failure and pulmonary disease--on mortality, morbidity, disability and cost.

HCFA also has developed and begun testing a method for collecting clinical data from PROs which can be linked to claims data. The clinical information will lead to the development of a Uniform Clinical Data set which will assist in the collection of the key data elements necessary for effectiveness research. This will result in HCFA having the capability to measure patient outcomes and, as a result, better evaluate the impact of peer review, direct future review activities and guarantee more effective PRO review.

Also, as cited elsewhere in the OIG report, HCFA will be conducting a number of pilot studies at the PROs directed at developing methodologies in a number of areas including the review of both utilization and quality of physician services. Finally, we are giving serious consideration to establishing appropriate technical advisory groups to complement our other industry liaison efforts.

It must be noted that much of PRO review is legislatively mandated. Also, if we were to allow greater flexibility to the PROs, we would have even more complaints about consistency State-to-State in both the types of reviews and the overall level of review, and the resulting data would not be comparable. We do not believe that having SuperPRO conduct DRG determinations would be cost-effective and it could have negative program results. We would have to pay for duplicating records for PROs (where applicable) as well as SuperPRO on a much larger basis and this would negate all our efforts for increased onsite review. Also, it is a much lower burden to have the PRO do the DRG validation while it is already reviewing the medical record than to pay both the PRO and SuperPRO to review the entire record.

GENERAL COMMENTS ON THE REPORT

Page 9

The least "useful" reviews listed are probably dependent on how the question was phrased and the respondent's idea of what the question meant. We have deleted percutaneous lithotripsy review as we found it non-effective (i.e., generated few denials or changes in DRGs). Conversely, the Medicare Code Editor review is the most effective review we have, with a large admission denial rate and a large amount of coding changes. The number of cases, however, is very small, thus not leading to a large amount of savings in the aggregate.

Page 10

The OIG indicates that outlier review and assistants at cataract surgery review are not "effective." In addition, OIG states that several PROs complained about extending review of readmissions to those occurring within 30 days. The OIG points out that HCFA should reassess the need for these reviews. The HCFA did not administratively decide to have PROs perform these reviews; these are legislatively mandated reviews.

Page 12

Last paragraph, line 9, we assume should be "physician referrals," not "admission referrals."

In the first paragraph OIG lists five activities which are considered least effective but does not cite whether these "least effective" activities are, in fact, ineffective (based upon data) or whether this is a conception based on misinformation on the part of the respondents. Also, in the last sentence of this paragraph, the OIG states that in the third Scope of Work we require PROs to choose from a list of 10 procedures determined by HCFA. Instead, we require the PROs to choose 8 from a list of 11 (2 additional ones are mandated for review). In addition, we do allow the PRO to "go outside the list" if it furnishes data to support the choices(s).

Page 25

The first full paragraph, last sentence, states that we are mandating review of 9 more DRGs without establishing the value of review. Seven of those codes are newborn codes and amount to 100 cases nationally. In analyzing the data, these cases are not truly "newborn" cases, and HCFA sees the need to "clean-up" the data (since Medicare does not pay for newborns).

Page 26

In paragraph 3, the OIG states that virtually all division director jobs changed in HSQB. Since the study was of the PRO program only, we assume the reference is to the two division director jobs in the Office of Program Review. At the time of the study, one Division Director retired and the other was promoted to Deputy Office Director.

Page 27

The first full paragraph discusses the fact that HCFA has not implemented the 100 percent review and opinion portions of COBRA. The 100 percent review will be implemented in the third Scope of Work as will the preadmission review of 10 procedures. We are

already in the process of issuing implementing regulations for full 100 percent review and the second opinion requirements.

Page 39

Bullet 5 is not accurate. PROs report on short stays separately but do not do any extra review. (We have made this comment before.)

Page 52

In bullet 4, the last sentence should be deleted. The MOUs were implemented on October 1, 1987. This is not one of the provisions to be implemented with the Scope of Work.

OIG RESPONSE

We are concerned with the general thrust of HCFA's response. First, we must disagree with HCFA's assertion that the findings in the report were identified by HCFA rather than the OIG. The findings are the result of an intensive, broadly based inquiry involving many sources outside of as well as within HCFA. If, at a general level, the OIG's findings tend to parallel observations and conclusions already reached by HCFA, they still, quite properly, are presented as OIG findings. Moreover, as is apparent in the report and in HCFA's response to it, the OIG and HCFA have a number of differences with respect to many of the specifics underlying the general findings and many of the implications flowing from them.

Second, we must emphasize that because a particular line of action is under consideration in HCFA does not necessarily mean it will be enacted or that an OIG recommendation in concert with it is inappropriate. We did have discussions with HCFA staff about the possible implications of our findings. At the time, those discussions seemed to reflect a good deal of agreement on the kind of actions that ought to be taken. In those instances where HCFA had already initiated action at the time our report was written, we strove to provide that information in the report itself.

Third, we must express concern about HCFA's observation that the "validity and reliability" of the findings "are suspect" and that the questions used in the survey were "ambiguous." We carefully explained our methodology in the report. The information in the report is limited, but represents the perspective of a carefully selected sample of respondents who are directly involved with the PRO program at various levels. We believe that their observations and opinions represent valuable feedback on the performance of the PRO program. We feel it is important for the Department to take into account the accumulated, operational wisdom that underlies this feedback.

With respect to the recommendations, we are concerned that HCFA did not convey a more positive response to our suggestions concerning the refinement and integration of evaluation tools. We feel that improvement in this area is vital to the continued improved performance of the PRO program. We are also concerned that HCFA did not respond to our call for strengthened long-range planning. Our frame of reference in making that recommendation involved HCFA itself, not the individual PROS. HCFA's response focused more narrowly on the PROS.