PEER REVIEW ORGANIZATIONS:
QUALITY ASSURANCE IN MEDICARE

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In mid-1984, the Office of Technology Assessment (OTA) of the Congress of the United States initiated a detailed study of Medicare's Prospective Payment System (PPS). Special attention was directed at ways to assess the effects of PPS on cost, quality, and medical technology. To aid in its investigation and preparation of a final report (to be entitled *Medicare's Prospective Payment System: Strategies for Evaluating Cost, Quality, and Medical Technology*), OTA supported the preparation of a number of background papers, including this report.

Because PPS offers hospitals a vastly different set of incentives for delivering care than had obtained when cost-reimbursement was the norm, concerns for overuse (such as excessive lengths of stay) have diminished. Correspondingly, concerns for underprovision of services, and the attendant possibilities of harmful effects on the quality of patient care, have become more prominent. The current Medicare peer review system, Utilization and Quality Control Peer Review Organizations (commonly known as PROs), is the mechanism by which quality of care received by program beneficiaries is to be assured.

The PROs have many responsibilities in addition to monitoring quality of care. Further, implementation of the program has been slow and uneven. These factors prompted OTA to question (a) the degree to which PROs could be expected to be an effective quality assurance mechanism (in both the long- and short-run); (b) what barriers could be identified to their effectiveness in the quality arena; and (c) what policies or actions might reduce these barriers. This report addresses these three topics, drawing on materials available through the early part of 1985.

OTA submitted the first draft of this paper to review by numerous experts both within and outside the Department of Health and Human Services. The present version reflects revisions made in accordance with many helpful and insightful comments of those reviewers, although of course any errors of fact or interpretation remain the responsibility of the author. The steady support and assistance of Judith L. Wagner and Cynthia P. King, both of OTA, are also gratefully acknowledged.
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I. INTRODUCTION

BACKGROUND

During 1984-85, the Office of Technology Assessment (OTA) of the Congress of the United States conducted a study of Diagnosis-Related Groups (DRG) payment and medical technology. It addressed, among other topics, the technology-related impacts of the prospective payment system (PPS) on the Medicare program. The project required detailed investigation of the impact of PPS and DRG reimbursement on costs of care, access to care, and quality of care.

One important element of PPS for the Medicare program is Utilization and Quality Control Peer Review Organizations (commonly called PROs). PROs have several significant responsibilities for monitoring care delivered to Medicare beneficiaries, including controlling unnecessary admissions and validating diagnostic and procedure information on which DRG assignments are made. In addition, PROs are to assure the quality of care received by Medicare beneficiaries.

PPS and PROs are both new to Medicare. Financial incentives for hospitals now differ considerably from those inherent in cost reimbursement systems of paying for care. Quality concerns now relate more to underservice than to overservice. Further, PROs have a mission and an organizational structure quite dissimilar in some respects to the previous peer review program, Professional Standards Review Organizations (PSROs).

OTA asked three questions about PROs and the impact of PPS on patient care:

1. To what extent can the PROs be expected to be an effective quality assurance mechanism, in the short-run and in the long-run?

2. What are the barriers, if any, to their effectiveness with respect to quality of care?
3. What kinds of policies or actions might reduce these barriers?

The remainder of this background paper addresses these questions. Specifically, it:

1. Briefly reviews and summarizes the history of Federal peer review efforts, with special attention to effects on quality of care;
2. Describes PROs, with particular emphasis on the quality-of-care tasks they are expected to carry out;
3. Discusses the apparent advantages and drawbacks that PROs have as an effective quality assurance program;
4. Explores policy and evaluation issues that might foster the role of PROs as a successful quality-assurance program.

QUALITY ASSURANCE

The connections among PPS, PROs, and quality of care might be said to fall into the general domain of quality assurance. Quality assurance is a formal and systematic exercise whose goal is improving medical care practice and ultimately patient outcomes. It consists of identifying problems in medical care delivery, designing activities to overcome the problems, and carrying out follow-up monitoring to ensure that the corrective steps have been effective and that no new problems have been introduced.

As such, it necessitates articulating a usable definition of quality, establishing mechanisms to set professionally acceptable standards and criteria against which quality might be judged, creating systems by which to collect and analyze relevant data, disseminating findings to practitioners and other concerned individuals or officials, and implementing methods to initiate and follow up corrective actions. Quality assurance attempts to improve the effectiveness and efficiency of health care delivery by focusing on high effectiveness of care and appropriate use of health resources.
Concern with the quality of medical care is as old as the healing arts themselves, but active steps to assess and improve the quality of medical care have waxed and waned over the centuries [1-18]. As long as 30 years ago, physicians in private practice banded together in Foundations for Medical Care, especially in California, to review and monitor use and quality of care; these activities well antedated any formal government (certainly federal) concerns in these areas. Much of the credit for progress in the peer review area is owed to these pioneering efforts.

The 1960s saw a significant leap forward in more formal quality assurance enterprises. In creating Medicare in 1965, for example, Congress mandated hospital-based utilization review committees. A more ambitious effort was the Professional Standards Review Organizations (PSRO) program established in 1972, which was superceded a decade later by the PRO program. The next section of this paper describes Federal efforts in quality assurance in more detail.
II. PEER REVIEW AND QUALITY ASSURANCE

The largest programs of quality assurance in the United States have, not surprisingly, been sponsored by the Federal government. The purposes and organizational accomplishments of these programs are quite diverse, but experiences gained in past programs may shed some light on the potential for the current PRO program in the quality-assurance arena.

EXPERIMENTAL MEDICAL CARE REVIEW ORGANIZATIONS

Experimental Medical Care Review Organizations (EMCROs), which operated from 1970 to 1975, were voluntary associations of physicians that typically reviewed inpatient or ambulatory services paid for by Medicaid or Medicare. Their dual mission was to foster ways for physicians (mainly but not exclusively in relatively large geographic areas) to come together in a quality-assurance effort and to upgrade available methods for assessing and assuring quality of care. Although not so designed, they served in effect as prototypes of PSROs.

Rigorous evaluation of the EMCRO program was not possible, but various assessments [5,19-22] suggest that at least some EMCROs were able to improve existing quality-assurance methodologies and to identify and successfully attack problems in quality of care. Most importantly, EMCROs prompted the participation in quality-assurance efforts by physicians in private practice to a degree not previously seen. The EMCRO experience reinforced the view that quality assurance can be achieved through "local" peer review.

PROFESSIONAL STANDARDS REVIEW ORGANIZATIONS

Elements of the PSRO Program

Local peer review was at the heart of the Professional Standards Review Organization, or PSRO, program established by the Social Security Amendments of 1972 (P.L. 92-603). PSROs were to assure that services provided and paid for by the Medicare, Medicaid, and Maternal and Child Health programs were medically necessary and of a quality that met
locally determined professional standards, and that they were provided at the most economical level consistent with quality of care. For the last half of its operations, the program was administered by the Health Standards and Quality Bureau, Health Care Financing Administration, Department of Health and Human Services (HSQB/HCFA/DHHS). Table 1 provides a synopsis of legislation and program guidelines that guided the operation of the program.

At the height of the program, PSRO areas numbered 195; some were states, others as small as subdivisions of a city. On average, each PSRO covered about 1 million people, about 35 hospitals, and 2000 to 3000 physicians (although the range was large). PSROs were required to offer membership to all physicians in the relevant geographic area; by the end of the program, physician membership included more than half of the practicing physicians in areas of the country with a PSRO.

Congress primarily intended for the PSRO program to lower public expenditures on medical, especially inpatient, care because the Medicare cost-reimbursement system provided substantial incentives to overuse services (e.g., excessive lengths of stay and overutilization of ancillary services). Nonetheless, the legislators were certainly aware of the potential role PSROs would have in quality assurance. In the early years, the Federal executive branch and the medical profession emphasized the quality-of-care aspect of the program; in particular, physician leaders stressed the capability of peer review organizations to achieve quality assurance goals so as to gain acceptance locally.

Over the years, PSROs took on a variety of activities [13]. Medical Care Evaluation (MCE) studies, and later Quality Review Studies, were the mainstay of the quality-assurance efforts. Other tasks by some PSROs included long-term-care review, surgical review, ancillary services review, and ambulatory care review. In the last 2 to 3 years of the program, PSROs also did profile analysis, a more sophisticated form of retrospective review in which patient care data (aggregated by type of service, physician, institution, or patient characteristics) could be subjected to analyses specifically designed to uncover patterns of care that could then be compared with, e.g., past or present patterns in the region or with national patterns. Towards the end of the program, some PSROs carried out health services research projects as
Table 1

SELECTED ELEMENTS OF LEGISLATION OR PROGRAM GUIDELINES PERTAINING TO QUALITY ASSURANCE ACTIVITIES OF PSROs AND PROs

ACT OR EXECUTIVE INSTRUCTION AND PRINCIPAL FEATURES

P.L. 92-603: Social Security Amendments of 1972

Created the original PSRO program by which areawide nonprofit physicians groups would review services reimbursed by federal beneficiary programs (Medicare, Medicaid, and Maternal and Child Health).

PSROs on behalf of hospitals were to carry out utilization review and profile analyses and to do Medical Care Evaluation studies.

Hospitals that were willing to perform review functions "in house" and were capable of doing so effectively were to be delegated the responsibility by the PSRO.

Created an ambiguously phrased, multiple-source funding system of grants.

PSRO Transmittal No. 100 (1980)

Ordered that Quality Review Studies supercede Medical Care Evaluation Studies and that more emphasis be placed on improving quality of care, that a broader set of topics be considered, and that methods other than medical record audit be developed.

Title XXI, Chapter 3: Professional Standards Review Organizations (PSROs)

Made delegated review optional by allowing the PSRO to select which hospitals would be delegated review functions.

Required DHHS Secretary to specify PSRO requirements relative to assuring quality of care, lowering unnecessary utilization, and managing activities efficiently and to evaluate them on those grounds. Eased the mechanisms by which PSROs could be terminated.

Required only Medicare review services and made allowance to support only 75 percent of a State's costs attributable to review of Medicaid services.

Established the Utilization and Quality Control Peer Review Organization (PRO) program in place of PSROs. Major elements of the PRO program:

(a) allowed eligible organizations to be proprietary and to have a "sufficient" number of physicians to perform review;

(b) disallowed facilities and facility associations from participating, but allowed payor organizations (e.g., insurance companies or fiscal intermediaries), also referred to as physician-access organizations, to participate after 12 months (from enactment); physician-sponsored organizations are to have priority over physician-access organizations;

(c) replaced the old system of federal grants with a system in which the Secretary of DHHS enters into biennial contracts with PROs;

(d) made it easier to terminate such contracts than it was to terminate PSROs grants;

(e) consolidated PSRO areas unless the volume of activities (e.g., number of Medicaid plus Medicare admissions) or other factors warranted otherwise;

(f) improved the peer review organization's ability to sanction physicians or hospitals that do not comply with the obligation to provide services economically, and only when such services are medically necessary, and only of a quality that meets professional standards;

Title VI: Prospective Payments for Medicare Inpatient Hospital Services

Established prospective payment system (PPS) for Medicare hospitalizations based on diagnosis-related groups (DRGs)

Required that by October 1983 PPS hospitals must contract for review services with a PRO if one exists in the area and that by October 1984 hospitals must have such a contract as a condition for continued Medicare reimbursement.

Specified many review functions for PROs. See description of PSRO Transmittal No. 107 (below) for details.

Provided that the PRO be paid directly for review on the basis of a rate per review determined by the Secretary, all funding to come from the Trust Funds.
PSRO Transmittal No. 105 (1983)

Provided detailed instructions for Admission Pattern Monitoring (APM). This included requirements for designating hospitals as anomalies (hospitals that appear to have abnormal patterns or numbers of discharges or average lengths of stay relative to a rolling baseline period), according to specific formulae and a test statistic that gives the probability that a given observation (i.e., hospital discharge rate) is not an "outlier" relative to previous observations.

Specified steps PSROs would take to carry out and report on APM activities (Level I and Level II analyses).

PSRO Transmittal No. 107 (1984)

Provided detailed instructions on how PSROs were to conduct various types of admission review, validate DRG assignments, select samples of cases for review, report in detail on medical review activities, etc.

Specifically required reviews include the following:

(a) Admission review for all cases under review for any other reason, for a random 5-percent sample of admissions, and for any cases with certain principal diagnoses believed not to be indicative of a justified admission. Usually, if 2.5 percent of all admissions reviewed or three cases (in a calendar quarter) are found to be unnecessary, 100 percent of admissions are to be reviewed the following quarter.

(b) All transfers from PPS hospitals to various PPS-exempt units in acute hospitals (psychiatric, rehabilitation, alcohol/drug treatment, and swing beds) and all transfers from PPS hospitals to any other (PPS or non-PPS) hospital.

(c) All cases involving subsequent admissions to any acute hospital within 7 days of discharge from a PPS hospital, with more intensive review of those cases where the two confinements are related (medical record review to determine if the patient was prematurely discharged and institution of quality review studies in hospitals where a problem is identified).

(d) All cases of the insertion or reimplantation of permanent cardiac pacemakers, all cases of invasive procedures where patterns of abuse had previously been identified, and any case where a procedure was found not to be needed.

(e) all cases of day outliers, defined as those cases where the number of covered days exceeds the average length of stay in that DRG by the lower of [1] a fixed number of days or [2] a fixed number of standard deviations.
(f) all cases of cost outliers, defined as those that are not day outliers but do have charges that exceed the greater of [1] a fixed multiple of the applicable DRG payment rate or [2] some other fixed dollar amount.

(g) DRG validation to see if diagnostic and procedural information in the medical record substantiates the DRG assignment and if the admission was medically necessary and appropriate; this will be done on samples of specified sizes and on all cases of DRG 468 (the "all-other" grouping).

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**P.L. 93-369: Deficit Reduction Act of 1984**

Provided for continued funding of PSROs until PRO contracts are signed.

Changed provisions as to who could sit on a PRO governing board and as to what types of organizations were eligible to be a PRO.

Changed from October 1, 1984, to November 15, 1984, the date by which hospitals must have a signed agreement with a PRO as a condition for Medicare payment, and designated the latter as the first date on which payer organizations could qualify as PROs.

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Provided clarification and guidance for PROs to implement required review functions (except for PPS-exempt areas and states with approved waivers). This issuance revised several required activities, some of which raised the level of review while others decreased it. Major changes from PSRO/PRO Transmittal No. 107 include:

(a) Requires admission review of noncovered admissions with a covered level of care rendered during the stay.

(b) Reduced the level of day and cost outlier review (to a minimum of 50 percent sample of claims from each PPS hospital) but added a requirement that PROs review "fragmented" changes (those previously included in per diem charges) while reviewing cost outlier claims.

(c) Reduced the DRG validation sample size for small hospitals.

(d) Changed the "physician attestation" requirements effective October 1, 1984. The physician now certifies for each discharge that the narrative description of diagnoses and procedures was accurate and complete to the best of his or her knowledge. The hospital must keep on record a current signed acknowledgement (updated each October) that the physician has received the "notice to physicians" about penalties for misrepresentation, falsification or concealment of information pertinent to Medicare reimbursement to the hospital. The PROs must monitor hospitals' compliance with the attestation requirements.
well. Hospital utilization review, nonetheless, was the overriding concern of the entire program.

Impact of PSROs on Utilization

A number of program-wide evaluations were conducted over the years [23-30]. Of necessity, given the emphasis placed by PSROs on hospital review and decreasing unnecessary use of inpatient services, most of these evaluations focused on whether PSROs had been able to produce desired reductions in hospital stays and costs of Federal health programs—i.e., on how well they saved money. Quality assurance activities were given only secondary attention.

The evaluations were, in the aggregate, somewhat contradictory and incomplete. In general, the PSRO program probably saved about as many resources as it consumed (at least when the perspective is restricted to the Medicare program). The savings fell short of expectations, however. Calls for additional (or different) efforts to lower costs in the medical sector were increasingly heard.

Impact of PSROs on Quality of Care

External evaluations. In the mid-1970s, Private Initiative in PSRO conducted a three-year investigation (five case studies) of PSROs then in existence. The researchers concluded at that time that the potential for PSROs to improve the quality of inpatient care was limited [12].

A few years later, a narrative report from the American Association of Professional Standards Review Organizations (now the American Medical Peer Review Association) cited a wide range of improvements in acute inpatient, ambulatory, and long-term care [30]. A 1981-82 survey documented similar accomplishments.²

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¹Evaluations of individual PSROs for refunds of their annual grants was done by the DHHS regional offices (ROs). Such separate RO evaluations were never really aggregated into a program-wide evaluation for any particular year or funding cycle (although see the 1981 “national rankings” discussed below).

²Examples included: (a) decreasing services provided by "outlier" (very substandard) physicians (e.g., diagnosis, treatment, and medication of patients with cardiac, pulmonary, or renal failure); (b) improving the outcome of patients with the diagnosis of acute myocardial infarction (heart attack); (c) reducing the inappropriate use of
**Internal evaluations: The 1979 evaluation.** In 1979, HCFA's Office of Research, Demonstrations, and Statistics (which was not in the same organizational line as HSQB) conducted a ground-breaking program evaluation [29]. Although its principal topics concerned hospital use and expenditures, it represented a landmark effort to assess quality-of-care activities of this magnitude. In particular, the evaluators attempted to quantify quality-assurance efforts in a wide variety of clinical areas into a single impact measure.

The major outcome measure was change in a "variation rate" between an initial MCE audit and a reaudit, where variation rate is the proportion of patient records that did not meet a specific standard in some quality-of-care area. MCE studies in certain PSROs improved care for a range of conditions (e.g., pneumonia, asthma, and tonsillectomy and adenoidectomy) but had no effect on others (e.g., positive pathology reports in appendectomy). Most improvement was observed for problems involving higher levels of initial variation rates (rates greater than 10 percent).

The study also attempted to relate the benefits of MCE studies to the costs of conducting them plus the costs of changes in care secondary to the MCE studies. Measuring outcome as a weighted index of "health status months" ranging from 0 (death) to 1 (perfect well-being) and assuming that a health-month was worth $500-$1000, the study suggested that the benefits could far surpass costs.

**Internal evaluations: The 1981 national rankings.** By 1981, the milieu in which the PSRO program was operating, at least at the national level, had changed. In the spring of that year, HCFA conducted a "national ranking" of PSROs based on a set of "performance evaluation..."
criteria"; PSROs had to achieve a minimum score in at least 2 of 3 performance areas: (a) organization and program management; (b) process of review; and (c) impact or potential impact of review.

More complex and detailed criteria based on these performance areas were circulated (but not used) in 1982. The components of these criteria reflected a growing sophistication about how to evaluate such activities. Perhaps more important, they figure in procedures for evaluating and awarding PRO contracts (see below) and assessing PRO performance.

Regarding quality assurance, the criteria included specifications relating to Quality Review studies. Key factors included the prevalence of the problem under study, the extent to which it was resolved, and the severity of the problem. The degree of problem resolution was defined as the observed reduction in the problem (number of hospital discharges affected) adjusted to the rate of occurrence of the problem during a specific baseline period.

Severity (degree of actual adverse effect on patient wellbeing) was categorized as life-threatening, major loss of function, other adverse effects (e.g., complications or iatrogenic illness), and other patient care practices that may reflect or result in inappropriate patient care outcomes. This factor was codified into a 'Severity Index' used to evaluate PRO quality objectives according to the following numerical ratings: loss of life, 10; permanent loss of a major physical function, 7; unnecessary surgery or other invasive procedures or postoperative or other complications that do not cause death or permanent loss of function, 5; underutilization of services with significant potential for causing serious patient complications, 3; and other problems, 0 [31].

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3These evaluation criteria were based on the expectation that PSROs would have set specified quality objectives for themselves or carried out MCE or Quality Review studies (or delegated such studies to hospitals). A quality objective was defined as "... one which deals with medical patient care problems other than those due only to patient exposure to an inappropriate or unnecessary length of hospital stay or medical admission." Examples included unnecessary surgery or procedures, inappropriate drug therapy, avoidable post-operative complications, and omission or underutilization of necessary hospital services or care.
Conclusions. Despite the quality-of-care accomplishments noted above, concluding anything definitive about PSRO quality-assurance efforts is difficult [14]. Aggregating individual findings, interpreting them in a larger context, or doing more than rudimentary statistical analyses all present problems. Relating benefits from quality assurance to the costs of achieving such benefits or to the savings in medical resources is a second obstacle. Finally, Federal agencies paid little attention to evaluating PSRO quality-assurance functions before 1979, and organized medicine gave even less attention to PSRO attainments, so the body of evidence is slim.

Nonetheless, at least three points should be emphasized. First, PSROs had beneficial, not harmful, effects on quality of care, irrespective of their impacts on saving public monies. Second, the legacy of all peer review activities up to the early 1980s is a positive one. For instance, the methods for doing quality assessment and assurance improved greatly, as did the techniques for systematically evaluating quality-assurance organizations.

Most significant, however, is probably the change in the attitudes of the medical community during the 1970s. Physicians eventually were motivated to band together in the interests of improving quality of medical care. It was shown that they could, through peer review agencies, identify quality-of-care problems and effect measures to overcome them. The average physician came to accept the idea that length-of-stay review, medical record audit, and other peer review activities were here to stay. Perhaps most remarkably, this progress occurred in an environment almost wholly concentrated on controlling the costs of medical care.
III. LEGISLATION UNDERLYING THE PRO PROGRAM

INTRODUCTION

If the quality achievements of PSROs seem rather amorphous, the disappointment with other aspects of the program was not. The legislative and executive branches of the federal government came to regard the program as over-regulated and inflexible; certainly, the lack of meaningful effects on costs of care was discouraging. The stage was set for substantial modification of Federal peer review activities.

Two major pieces of legislation were instrumental in this: the Tax Equity and Fiscal Responsibility Act of 1982 (specifically, Title I, "Peer Review Improvement Act of 1982") and the Social Security Amendments of 1983. Some provisions of the Deficit Reduction Act of 1984 affected specific aspects of the program. Table 1 provides a synopsis of these acts and of selected HCFA transmittals (some for the PSRO program, which are operative for PROs as well). Section IV describes in more detail the elements of the PRO program set in place by this body of legislation.

TAX EQUITY AND FISCAL RESPONSIBILITY ACT

In replacing the PSRO program with PROs, TEFRA (P.L. 97-248) wrought major changes in the mission and structure of Federal peer review entities while retaining what were believed to be the best aspects of the old PSRO program. One major departure from the PSRO program was a different funding arrangement: PROs are financed with two-year, fixed price contracts; the total contract amount is to be derived from a set price per review. The total to be spent in the first two-year period was $339 million (payable from the Medicare HI Trust Fund).

1The amount is said to be about $12 per review (A. Webber, AMPRA, personal communication). In accordance with the law, it is based on the 1982 PSRO appropriation ($24.4 million) adjusted for inflation and nationwide implementation [33].
The PRO contracts are performance-based. Numerous quantitative objectives are negotiated between the PRO and HCFA to assure that impact is achieved in areas of high utilization. This presumably will make it easier to terminate inefficient organizations.

In another departure from the PSRO program, eligibility to be a PRO was extended to for-profit groups and payer organizations (e.g., insurers and fiscal intermediaries). In the first year "physician-sponsored" organizations (defined below) were to be given priority over "physician-access" ones in PRO contract competitions, and nonpayer organizations were given priority over payer organizations. In the event that no suitable contract could be negotiated with a priority organization, however, HCFA was allowed to contract with, say, a fiscal intermediary even in this first round.

TEFRA enhanced considerably the effectiveness of peer review organizations to deal with problems of high cost and overutilization in the Medicare program, in part by improving the organizations' ability to sanction providers.\(^2\) PROs now have a direct link to reimbursement. Basically, denials of payment made by the PRO will now take effect as issued, whereas PSROs could only recommend denials and such recommendations could be and often were overridden. Furthermore, PRO recommendations about sanctions against providers automatically become effective within 120 days if the Secretary of DHHS fails to act.

Moreover, TEFRA clearly meant for PROs to be less regulated by the central government (i.e., HCFA) than the PSRO program had been, precisely so that PROs could try to explore innovative and more efficient methods for the review of medical care. It further attempted to retain the sense and the reality of identifying and solving problems locally, even while consolidating PSRO areas into statewide PRO areas. Finally, although written in the pre-PPS era, the legislation clearly was drafted to allow a relatively straightforward transition of PROs into new review activities necessitated by the radical change in Medicare funding that was widely accepted as just a matter of time.

\(^2\)Other provisions of TEFRA directly attacked the problems of excessive costs and use, irrespective of the changes in the move from PSROs to PROs. Of course, the advent of PPS reversed hospitals' financial incentives and provided an impetus toward stringent cost-cutting and underprovision of services.
PROSPECTIVE PAYMENT IN THE SOCIAL SECURITY AMENDMENTS OF 1983

In response to continued escalation of medical care costs in the public sector, especially Medicare, Title VI of P.L. 98-21 (the Social Security Amendments of 1983) established the prospective payment system (PPS) for Medicare. After October 1983, hospital payments were to be based on the costs of treating patients classified into 468 diagnosis-related groups (DRGs). This "sweeping ... legislation reversed key economic incentives that have driven the behavior of hospitals since the Federal program for the elderly began [34]."

The crucial factor is that hospitals must attempt to live within a budget determined by prices established in advance on a cost-per-case basis, rather than rely on retrospective reimbursement of such costs.² PPS initially applies to all Medicare participating hospitals; exceptions are special hospitals such as psychiatric, rehabilitation, and long-term-care hospitals (or similar units in acute care hospitals), those in so-called waiver states (New Jersey, New York, Maryland, and Massachusetts) or exempted areas (Virgin Islands, Puerto Rico, Guam, American Samoa), and certain other hospitals designated by the Secretary of DHHS. Lohr and Marquis (and the articles and documents cited therein) provide a more detailed overview of the issues confronting Medicare as PPS became operational [35].

PROs were established as the peer review entities for Medicare, and the advent of PPS brought yet more changes for PROs: more visibility, considerable urgency to their implementation, and a great many required activities. On the assumption that implementation of PROs would proceed apace, the legislation required PPS hospitals to sign a contract with a PRO, if one existed in their area, by October 1983 and to have such a contract in force by October 1984 as a condition of Medicare payment.

PROs were also assigned a large number of mandatory review tasks. Most of these relate to monitoring changed behaviors of hospitals in accommodating to considerably different incentives under PPS; for

²The term PPS implies that payment is prospective, but this is misleading. Only the rates (DRG prices and hospital- or region-specific weights) are set prospectively; reimbursement is retrospective. This scheme differs substantively from prepayment as the term is understood for prepaid group practices or health maintenance organizations.
instance, length of stay is no longer a critical concern, but increased admissions are. Generally, the activities mandated for PROs favor attention to admissions and use of invasive procedures over those related explicitly to quality of care.

DEFICIT REDUCTION ACT OF 1984

Two provisions of this Act (P.L. 98-861) address concerns arising from delays in the implementation of PROs and about exclusion of providers from PRO boards. First, the Act provided for the continued funding of existing PSROs from the Medicare Hospital Insurance Trust Fund until such time as HCFA signed a contract with a PRO in the relevant area. Second, because of the substantial delays in promulgating certain regulations (e.g., definitions of PRO areas and eligible organizations) and issuing the necessary Request for Proposal (RFP), the time remaining before the October 1, 1984, deadline was believed insufficient for hospitals to negotiate contracts with local PROs and retain their eligibility for Medicare reimbursement; the Act extended the deadline to November 15, 1984. Finally, certain provisions permitted limited representation of providers on a PRO governing board and allowed entities associated with self-insured employers or with no more than one member affiliated with a health maintenance organization (HMO) to qualify as a PRO.

IMPLEMENTATION OF THE PRO PROGRAM

TEFRA and the PPS Title of the 1983 Social Security Amendments set the PRO program in motion, but the PRO program differed sufficiently from the old PSRO program that a variety of implementing regulations and program guidelines had to be drawn up and issued. Some proposed PRO activities were simply extensions of what PSROs were required to do pursuant to TEFRA (e.g., those relating to Admission Pattern Monitoring), and HCFA had issued PSRO transmittals detailing those tasks. (Where PSROs did not exist, Medicare fiscal intermediaries acted in their stead.) The more important (e.g., Transmittal 104, which later became 107, and Transmittal 105) are summarized in Table 1.
PRO regulations were very slow in coming. For instance, the final regulations regarding area designations and definitions of physician-sponsored and physician-access organizations did not appear until February 27, 1984. Although some professional associations thought that the public response time had been too short, a good deal of public comment surfaced about certain provisions. For example, the proposed regulations that required only a very small fraction of practicing physicians in a state to be members of a physician-sponsored organization prompted a good deal of reaction.

The final regulations about definitions of eligible organizations specified that a physician-sponsored organization must be composed of at least 10 percent of the physicians in the area; if it comprises 20 percent, it is considered "representative." These percentages are appreciably lower than the typical level of physician representation in the PSRO program. Physician-access organizations (which can be either proprietary or non-profit entities) need show only the ability to acquire the services of appropriate types and numbers of practicing physicians to ensure adequate peer review. This rather vague requirement was subsequently clarified at a "preproposal bidders conference"; physician-access PROs were to have only one physician in each of 21 generally recognized specialties available to perform reviews.

To carry out the contracting procedure, HCFA held a competition based on a formal Request for Proposal (RFP). Before issuing the final RFP, HCFA circulated a draft Scope of Work for comment and revision. These steps took far longer than originally foreseen, leading to considerable distress in the hospital and peer-review communities.

Described PRO areas number 54: all 50 states, the District of Columbia, Puerto Rico, Virgin Islands, and a combined area of Guam, American Samoa, the Northern Mariana Islands, and the Trust Territory of the Pacific Islands [36]. As noted above, however, 7 of these areas are not covered directly by the PPS Medicare legislation; they were not included in the main PRO solicitation but were given a separate solicitation somewhat later in the spring of 1984.
A number of persons testifying before the Senate Subcommittee on Health in February, 1984, [37] had alluded to delays already experienced and expressed concern that the October 1984 deadline for hospitals to have PRO contracts in force could not be met. As noted above, P.L. 98-861 extended the deadline to mid-November, 1984. Even at Senate Finance Committee hearings in July, some observers were still concerned that even the time extension to mid-November would not suffice to get all PRO contracts signed and all hospital-PRO contracts signed as well.

The final RFP (No. HCFA-84-015) appeared February 29, 1984, eighteen months after the TEFRA legislation was passed; proposals were due April 30, 1984 [31]. A preproposal conference for PPS states was held in Baltimore on March 19, 1984; prospective contractors who attended were able to obtain clarification of a number of issues not fully explained in the RFP.

In some cases of nonresponsive bids the RFP was reissued. Negotiations and resubmissions continued throughout the summer. By the end of July, 1984, 19 PRO contracts had been signed; by September, 31 contracts; by mid-October, 44; and by October 31, 51. All 54 contracts between HCFA and the PROs were signed before the mid-November deadline.

In several cases, one state is covered by another state's PRO: Alaska by the PRO in Washington State; Maine by the PRO in Rhode Island; Vermont by the New Hampshire organization; Wyoming by the Montana PRO; and the District of Columbia by a PRO based in Maryland. In such cases, the PRO may be a "physician-sponsored" organization for its own state and a "physician-access" organization for the other state. The contract in Idaho was awarded to a fiscal intermediary (Blue Cross) because no suitable proposal had been forthcoming from a nonpayer organization.

**IMPORTANT PRO REGULATIONS**

Major regulations affecting the PRO program were published in the early months of 1985. In January, regulations implementing sections of TEFRA and the 1984 Deficit Reduction Act that authorized Medicare reimbursement for health care services to eligible HMOs and competitive medical plans (CMPs) appeared. PROs became the review entities for these organizations [32, p. 1322].
Some features of HMOs and CMPs—unique records files rather than bills or insurance claims, for instance, as well as the fact that they offer Medicare beneficiaries a full range of ambulatory and inpatient care—raised issues not pertinent to the fee-for-service system, so HCFA envisioned that a special review strategy would be needed. The agency recommended that Medicare enrollees in each plan be traced over time to ensure that appropriate access to care was provided and that specific patient-provider encounters be sampled to ensure that the quality of care provided was adequate. The latter required that special methods be developed for selecting cases for review; such cases would be screened against specific, pre-established criteria. Thus, review activities for HMOs and CMPs are expected to be broader than those currently performed for PPS hospitals, because both inpatient and outpatient care will be scrutinized; in addition, innovative review and targeting strategies such as generic screening can be used.

In April, 1985, long-awaited final regulations governing the PRO program were published, two and a half years after enactment of the PRO legislation (TEFRA) [38]. The four primary topics covered by these regulations concerned (a) assumption of Medicare review functions and coordination with Medicaid, (b) imposition of sanctions on health care practitioners and providers of services, (c) acquisition, protection, and disclosure of information, and (d) reconsiderations and appeals.

The question of confidentiality and disclosure of patient-, provider-, or hospital-specific information had occasioned a great deal of debate. PRO regulations basically extended the confidentiality and information disclosure procedures of the PSRO program, providing public access to aggregate statistical information on institutions but maintaining strict confidentiality of data on practitioners (and patients). Some quality assurance information (such as medical review deliberations or decisions) is also considered confidential and not disclosable, although at its own discretion (and subject to specified procedures) a PRO may make public its interpretations and

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5One change from the PSRO program regulations mandates the use of Medicare provider identification numbers when PRO data are transferred to HCFA (through the PHDDS system described below).
generalizations about the quality of health care in an identifiable institution. In situations in which the public could identify a practitioner if an institution were identified, however, PROs cannot allow institutional data to be made public. The basic reasoning was that although all information in principle ought to be disclosed, practitioner data were too susceptible to misinterpretation and thus the potential harm to individuals--and to the peer review process--was too high to permit disclosure of medical review proceedings, votes, or decisions concerning individual practitioners.

In the proposed PRO regulations, DHHS had suggested that PRO data be disclosable to health researchers, at least under some restrictions. The final regulations, however, include a blanket proscription on research of such information to researchers. Finally, there are strict redisclosure provisions and prohibitions.
IV. BASIC ELEMENTS OF THE PRO PROGRAM

MANDATED ADMISSIONS REVIEW AND OTHER ACTIVITIES

Admissions and Procedures Review and Other Review Activities

Three admission objectives. The most important PRO efforts are
directed at admissions review (Table 2). Three are explicitly called
"Admission Objectives," and PROs were required to specify one or more
objectives with numerical goals in each of the three areas. These are
briefly described just below.

1. Reduce admissions for procedures that could be performed
effectively and with adequate assurance of patient safety in an
ambulatory surgical setting or on an outpatient basis. A typical
objective might be to reduce inappropriate or unnecessary admissions for
one (or several) specified procedures by 50 percent over the period of
the contract.¹

In the PRO RFP, HCFA had provided a suggested list of surgical
procedures deemed appropriate for the first admission objective. This
included release of carpal tunnel syndrome, certain biopsies (e.g., of
the breast), repair of unilateral inguinal hernia, certain gynecologic
procedures (e.g., dilation and curettage), and certain foot procedures
(e.g., removal of nail, nailbed, or nailfold). Some PROs identified
lens and intraocular procedures (e.g., cataract extractions) as suitable
candidates for this review activity; others proposed to use internally
developed, very lengthy lists of procedures deemed appropriate to be
done in ambulatory settings.

Most PROs proposed to circulate statements of medical criteria
establishing when outpatient treatment would be most appropriate for the
identified procedure and delineating when extenuating circumstances
might justify inpatient care. Generally, the primary methodology is

¹Information on this and other objectives described in this section
come from Peer Review Organization Objectives: A Synopsis, volume 1,
dated September 1984, which was put together by staff of HSQB/HCFA on
the basis of information contained in the final negotiated PRO
contracts. Volume 1 of this synopsis contained information on the first
31 contracts signed. Synopses for 20 remaining contracts were available
in the spring of 1985.
Table 2
MAJOR ACTIVITIES REQUIRED OF PROs

I. ADMISSION OBJECTIVES a

A. Reduce admissions for procedures that could be performed effectively and safely in an ambulatory surgical setting or on an outpatient basis.
B. Reduce the number of inappropriate or unnecessary admissions or invasive procedures for specific DRGs.
C. Reduce the number of inappropriate or unnecessary admissions or invasive procedures by specific practitioners or in specific hospitals.

II. OTHER REQUIRED ADMISSION OR UTILIZATION ACTIVITIES

A. Perform Admission Pattern Monitoring.
B. Review (before admission or before procedure) every elective case for five procedure-related DRGs (from a state-specific list of the top 20 procedures or procedure-specific DRGs for 1982).
C. Review admissions occurring within seven days of a discharge and deny all claims for inappropriate admissions.
D. Review every permanent cardiac pacemaker implantation or reimplantation procedure and deny payment for all that are unnecessary.
E. Review transfers from a PPS hospital to other hospitals or to specific PPS-exempt special units or swing beds.
F. Perform additional admission-related reviews in three distinct areas, including cases with specific principal diagnoses.
G. Review admissions to and days of care in non-PPS hospitals or units.
H. Carry out various other tasks relating to review and monitoring of hospital denials and notices of noncoverage.

III. OTHER REQUIRED REVIEW ACTIVITIES

A. DRG validation.
B. Review claims for day and/or cost outliers for necessity and appropriateness of admission and subsequent care.
C. Carry out special sets of reviews on DRGs 462 and 468.
D. Monitor denial notices that hospitals issue to Medicare beneficiaries to ensure that they do not mislead the patient (or family) or misstate the hospitals' authority or responsibility as to decisions to terminate care.
E. Monitor hospitals' compliance with the physician attestation requirements.

IV. QUALITY OBJECTIVES

A. Reduce unnecessary hospital readmissions resulting from substandard care provided during the prior admission.
B. Assure the provision of medical services which, when not performed, have "significant potential" (occurrence in 5 percent or more of cases) for causing "serious patient complications."
C. Reduce the risk of mortality associated with selected procedures and/or conditions requiring hospitalization.\(^b\)
D. Reduce unnecessary surgery or other invasive procedures.
E. Reduce avoidable postoperative or other complications.

\(^a\)See Table 1 for details on the PSRO transmittals related to these PRO activities.
\(^b\)In the early months of implementing the PRO program, this objective was called "Reduce avoidable deaths."
preadmission or preprocedure review of 100 percent of cases, sometimes followed by retrospective review of a random sample of cases to ensure necessity and appropriateness of admission and accuracy of information. Other PROs rely on retrospective review of all or a random sample of admissions. If an inpatient admission for the procedure or the procedure itself is found to be medically unnecessary, it will be denied. When problems persist, specific corrective action plans, such as prepayment review or rebuttal of waiver of liability,\(^2\) will be undertaken.

2. Reduce the number of inappropriate or unnecessary admissions or invasive procedures for specific DRGs. The diagnostic categories covered by this admission objective, which are specified by the PROs, range widely. Some PROs proposed to reduce one-day or two-day admissions across DRGs. Many identified DRGs associated with common procedures, such as lens and intraocular or cataract procedures, transurethral prostatectomy, cardiac pacemaker implants, and major joint or hip and femur procedures. Others focused on medical DRGs, such as various lung diseases (chronic obstructive pulmonary diseases; simple

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\(^2\)Waiver of liability is the concept that Medicare payments can and will be made to an institutional provider for certain uncovered or medically unnecessary services if the provider could not have known that payment would be disallowed (and assuming the provider was acting in good faith). During most of the PSRO program, PSROs had little effective way to combat this waiver-of-liability presumption, so payments to hospitals could continue even in the face of stringent denials. The PRO legislation markedly strengthened the power of PROs in the waiver-of-liability process.

Specifically, as long as total denial rates for Medicare claims do not reach certain levels, hospitals, skilled nursing homes, and home health agencies continue to receive payment even if the services are found later to be uncovered or unnecessary. Before March 1984, this "threshold" denial rate was 2.5 percent of all Medicare admissions. HCFA proposed in that month that waiver-of-liability procedures be changed in important ways. First, the PRO would have to make an individual finding in each denied case as to whether the hospital should have known the services were deniable. Second, the "threshold" denial rate was changed to 2.5 percent of Medicare admissions reviewed, effectively reducing the universe substantially. Thus, a much larger number of institutions faced the prospect of not qualifying for a favorable waiver of liability presumption than had previously been the case; this was thought by some to put small rural institutions especially at risk of payment denials.
pneumonia), medical back problems, or diabetes. Numerical goals were established on the basis of expected number of admissions and percentages of admissions believed likely to be avoidable or unnecessary according to past experience (e.g., during the PSRO program).

As with the first admission objectives, some PROs will institute primarily preadmission review, others retrospective review. Typically, a variety of corrective actions involving physician education, rebuttal of waiver of liability presumption, and sanctions are specified.

3. Reduce the number of inappropriate or unnecessary admissions or invasive procedures by specific practitioners or in specific hospitals. Almost by definition, goals articulated for this admission objective are more individualized than those specified above. Practitioners to be subjected to review may be identified because they were found (e.g., during PSRO review) to have excessive numbers of cases failing explicit review criteria or because they had too-high rates of performing certain procedures (e.g., pacemaker implants). Hospitals might be subject to this review if they had excessive numbers of short-stay admissions in the pre-PRO baseline period or simply excessive rates of unnecessary or inappropriate admissions generally.

The great majority of PROs opted to focus on hospitals, not physicians. The full range of review and sanction activities (e.g., preadmission and/or preprocedure review, retrospective review with revocation of waiver, etc.) was specified as the primary methodologies for this objective.

Other required activities. In addition, the PRO is expected to perform a number of other, more targeted review activities (Table 2). Some require review of all cases. Others require review of only a sample, but if a relatively small number of cases (called a "significant pattern" in some review tasks) is found to involve inappropriate or unnecessary admissions or services, the PRO must review all cases in the ensuing calendar quarter. The PRO has some leeway in how many cases it will actually have to review in the event a hospital has a significant pattern of unnecessary admissions. Nonetheless, the "trigger" for this full review is considered quite rigorous (2.5 percent or three cases, whichever is greater), so the expectation is that PROs will have to review very large
1. Perform Admission Pattern Monitoring (APM). APM is a complex set of activities designed by HCFA, instituted after TEFRA. It is intended to assure that Medicare discharges are appropriate in hospitals identified by HCFA as having significant increases in discharges per quarter (so-called "anomalies"). It is one of the more important activities PROs will undertake.

To carry out APM, PROs must validate reports of possible anomalies sent to them from HCFA, identify what problem(s) may be causing the increase in admissions, and, where necessary, take corrective action. HCFA identifies anomalies on the basis of "scores" measuring the reasonableness of the number of discharges for the period being reviewed and the reasonableness of the average length of stay for the period; hospital-specific scores lower than a criterion score of 1 prompt a required PRO review.4

2. Preadmission review of every elective case in five procedure-related DRGs. In the PRO RFP, HCFA specified a list of DRGs or DRG groups for preadmission review from which the PRO had to select at least five. These were state-specific lists of the top 20 surgical DRGs for Medicare patients in 1982. Almost invariably, at or near the top of these lists were lens procedures, major joint procedures, hip and femur procedures except major joints, major large and small bowel procedures, transurethral prostatectomy, and total cholecystectomy without common bile duct exploration. There was no special requirement or expectation that these types of procedures were being overused in the PRO area (i.e., HCFA did not validate overuse but just provided the data to prospective PROs).

3. Review admissions occurring within seven days of discharge. All cases involving admissions to any acute hospital (whether PPS or not) within seven calendar days of discharge from a PPS acute care facility numbers of cases during the course of the contract. This has occasioned concern that dollar amounts of the fixed-price PRO contracts will be too low, because there was no straightforward way for PROs to estimate the number of additional cases they might need to review when such triggers are tripped.

4As with certain other required activities, the total number of reviews that a PRO might actually have to do in this area during the contract period might be hard to estimate a priori.
are to be reviewed. If diagnostic data indicate that the two stays are not related, no further review is necessary, but if such data suggest the confinements could be related the PRO must review appropriate medical records to determine if the patient was prematurely discharged.

4. Review permanent cardiac pacemaker implantation or reimplantation cases. The medical records of every such case are to be reviewed.

5. Review transfers of patients from a PPS hospital to a different PPS hospital or to various PPS-exempt units or swing-beds within the same hospital. One hundred percent of cases are to be reviewed, with review based on medical records.

6. Perform additional admission-related reviews. A variety of "general" review activities intended to determine whether admissions are medically necessary and whether services were delivered in the most appropriate setting must be undertaken. First, PROs will perform admission review on 100 percent of cases under review for any other reason (e.g., outlier review or DRG validation). Second, they must review (at a minimum) a 5-percent random sample of admissions to validate diagnostic and procedure information and determine medical necessity and appropriateness. (This is not to be confused with DRG validation, which is described later.)

Third they must review 100 percent of cases with a specified principal diagnosis that HCFA considers a priori not indicative of a justified admission. Included in this activity, for example, would be cases with a principal diagnosis (in ICD-9-CM coding) of diabetes without mention of complications (whether or not insulin-dependent), benign hypertension, and elevated blood pressure without a diagnosis of hypertension.

Fourth, the PRO must review Medicare admissions to and days of care in certain types of hospitals and units that are not subject to PPS (in which both the fact of admission and length of stay would be important). Fifth, HCFA specified a set of tasks related to review and monitoring of hospital denials. These included procedures for issuing notices of

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5ICD-9-CM refers to the International Classification of Diseases, ninth revision, clinical modification. It is the most recent and sophisticated diagnostic coding system now in use.
noncoverage in situations where attending physicians do not concur in a
determination that a beneficiary no longer requires inpatient hospital
care; special procedures are outlined in cases when a beneficiary
remained in the hospital after he or she became (or might have become)
liable for payment.

**DRG Validation**

PROs must review the validity of diagnostic and procedure
information provided by the hospitals in their areas. The number of
cases reviewed is a sample of the universe of cases in the previous
calendar quarter. For instance, if the universe is up to 25 admissions,
al cases are reviewed; if it is between 151 and 400 admissions, 40
cases chosen randomly are reviewed; and if it is 1701 or more
admissions, a 3 percent random sample is reviewed. Rejecting the
diagnostic or procedure information in 2.5 percent of these admissions
(or three cases, whichever is greater) prompts an increase in the amount
of review to 20 percent or to a specified number of cases (according to
a HCFA sample size chart). In addition, all cases of DRG 468
("unrelated operating room procedures") are reviewed, as are all cases
of DRG 462 (relating to prosthesis fitting and certain types of
physical, speech, or rehabilitation therapy).

DRG validation will prove to be a critical assignment because
accurate designation of hospital case mix by DRGs is crucial for
adequate, but not excessive, prospective funding. It will be difficult
because of the problems associated with "validating" true diagnoses on a
broad range of patients when sample sizes are small (relative to the
number of DRGs) and because of the complexities and subjective aspects
of listing and sequencing diagnoses and procedures with the ICD-9-CM
coding system that is used for DRG assignment.

**Day and Cost Outlier Review**

PROs are responsible for retrospective review of "outliers," i.e.,
those cases that greatly exceed the length of stay or costs typically
associated with a given DRG. Day outliers are those that extend beyond
a fixed number of days or beyond 1.9 standard deviations from the mean
number of days, whichever is fewer. Cost outliers are those that are
not day outliers but that have charges that exceed a fixed multiple of the DRG PPS rate or some other fixed dollar amount, whichever is greater.

Fifty percent of day outliers must be reviewed, on either a prepayment or postpayment basis; if a "significant pattern" of cases with denied days is found, review increases to 100 percent for the next calendar quarter for that hospital. Fifty percent of cost outliers are to be reviewed prior to payment, but only when the hospital requests cost-outlier payment; as with day outliers, a significant pattern of charges denied triggers 100 percent review for the ensuing quarter. Day- or cost-outlier review is to determine the necessity and appropriateness of the admission, of all days of care, and of the services rendered. DRG validation is also routinely performed on these cases.

Quality of Care

PPS provides hospitals with a clear incentive to underserve patients. Smits voiced an early concern with underservice during the PSRO "contraction" period: [39] "The proposed legislation [referring to "procompetitive" bills before Congress], which is intended to give hospitals and health-care plans a competitive incentive to cut costs, also provides a strong incentive to do so by delivering substandard services or by forcing patients to underuse services. There appears to be little question that such a system would require monitoring of the quality of care."

The passage of time has not changed this judgment in the minds of many observers. In commenting on the draft PRO RFP [37:119], the American Hospital Association asserted that PRO objectives would be based on dollar targets, not medical needs of beneficiaries, resulting in "... a rationing of care ... [and] thereby increasing the probability that medically appropriate care will be denied by the PRO and jeopardizing essential services for Medicare beneficiaries...."

Problems with quality are thus seen to arise from PPS incentives that lead hospitals to discharge patients prematurely or provide less than needed amounts of diagnostic or therapeutic services or to admit patients for questionably indicated surgical procedures or invasive
diagnostic procedures. The rest of this section describes the measures that PROs are supposed to take to forestall or overcome such problems.

QUALITY ASSURANCE ACTIVITIES OF PROs

In developing the quality-assurance aspect of the PRO performance-based contract, HCFA undertook to balance two difficult goals. One was to specify in sufficient detail a set of required tasks that the agency could monitor against explicit milestones and numerical goals. The objective was to enable HCFA to make defensible judgments about the PROs' performance and to hold them more accountable than had been possible for most of the PSRO program.

The other goal was to allow as much latitude or flexibility as possible to the PROs to identify and attack "local" problems on which they could reasonably expect to have some impact. The idea was to avoid forcing PROs to study or work on issues mandated at the Federal level that might have little or no relationship to problems known to exist within the state.

Thus, as a condition of winning a PRO contract, prospective PROs had to propose one or more measurable objectives in each of five generic quality "areas" specified by HCFA in the RFP's Scope of Work (Table 2) [31]. Each area had to have at least one numerical objective proposed by the PRO, but the PRO was free to undertake more than one objective in any area where it felt there was a particular need for action. The areas were defined in the contract RFP for review in PPS areas as follows:

I. Reduce unnecessary hospital readmissions resulting from substandard care provided during the prior admissions;

II. Assure the provision of medical services which, when not performed, have significant potential for causing serious patient complications;

6Lohr et al. [40] discuss these points in more detail.

7Seven PRO geographic areas are "non-PPS" because they are in waiver states or exempt areas. Moreover, PROs in PPS states have review responsibilities for non-PPS facilities. The quality objectives for those PROs are essentially equivalent to those for the PPS areas, so no distinction is made in this discussion between PPS and non-PPS PROs.

8"Significant potential" is defined as "... occurrence in 5 percent or more of cases that are subject to the problem," and had to be
III. Reduce the risk of mortality associated with selected procedures
and/or conditions requiring hospitalization;*

IV. Reduce unnecessary surgery or other invasive procedures;

V. Reduce avoidable postoperative or other complications.

The impact of the interventions on quality of care is to be
assessed in terms of a measure incorporating the number of patients
affected by the problem described in the objectives and the severity of
the problem. (Specifically, the measure is the product of the number of
patients and severity.) The Severity Index (described above in the
section on national rankings of PSROs) is to be used in this
calculation.

HCFA recognized that review of unnecessary readmissions,
procedures, or patient complications that might be proposed for the
quality objectives could overlap with review required for admissions
within seven days, transfers, or pacemaker insertions, and that the
efficiency of review would be enhanced if the same patient records were
used and/or needed information was collected at the same time. Thus,
quality-of-care data could be collected at the same time as data for
other required reviews were collected; the only stipulation was that the
data had to be appropriate for the quality problem under investigation.

In describing each quality objective, PROs had to specify numerical
goals (typically as two-year totals). They also had to describe their
primary technical approach to the problem. Review approaches can
include, but are by no means limited to, preadmission review,
retrospective review, post-admission but pre-procedure review, and post-

*demonstrated "... through published research or ... data specific to the
problem." "Serious patient complications" are "... situations that
require clinical intervention to avert threats to the patient's life or
other adverse outcomes that extend a patient's stay or result in
additional morbidity or in physical limitation" [31].

*Initially this quality objective was denoted "reduce avoidable
death," which raised the ire of the medical community. Although HCFA
documents may contain the revised version of the objective, the first
round of PRO contracts uses the initial wording.
admission/post-procedure review. They also had to document ("validate" in contract terms) the importance of the objective with an analysis of historical patterns of inpatient care use.

As a general rule, the objectives are based on pre-PPS-era problems and data, and validating information is sometimes drawn from PSRO studies or other empirical data in other areas or states. Those for Objective No. I, however, tend to be based on PPS readmissions data.

EXAMPLES OF QUALITY OBJECTIVES

The rest of this section gives examples of the types of objectives proposed by the various PROs that had contracts signed by September 1984.\(^1\) They have been chosen simply as typical cases, with no attempt to characterize them as to importance or difficulty. The objective, the documentation, and the methodologies proposed are briefly summarized.

Quality Objective I: Reduce Unnecessary Readmissions Owing to Substandard Care in the Previous Admission

The South Carolina Medical Care Foundation (Columbia, South Carolina) detailed the following goals for this quality objective: "To reduce hospital readmissions resulting from substandard care provided during the prior admissions from 1543 cases (17 percent) to 908 cases (10 percent). The numerical goals for this objective were based on data for the first quarter of FY84 (i.e., the first PPS year); of a total of more than 33,000 Medicare discharges, about 2 percent resulted in readmissions. Of these about 17 percent were attributable to premature discharge. Similar findings were cited from Alabama. The South Carolina PRO concluded that, with retrospective quality review and other procedures, they would be able to reduce the 17-percent figure to 10 percent.

Their primary methodology involves reviewing 100 percent of all readmissions to assess (a) need for the second hospitalization, (b) possibility of premature discharge, and (c) quality of care during the first hospital stay. Questionable cases and any patterns of premature discharge will be submitted to a Quality Assurance Committee. If the

\(^1\) As with the admission objectives, this information is excerpted from volume 1 of Peer Review Objectives: A Synopsis or the later addendum.
Committee finds that patients are being prematurely discharged, it will meet with the physician in question; if the problem continues, the PRO will implement a concurrent prior-approval discharge procedure and, if necessary, initiate sanction proceedings.

Quality Objective II: Assure Provision of Necessary Medical Services

The objective statement of the Utah PRO (Utah Professional Review Organization, Salt Lake City) for this quality area was "to assure the provision of necessary medical services through improvement in measuring baseline renal function, calculating appropriate dosage, and monitoring serum concentration levels during the usage of aminoglycosides." Aminoglycosides are powerful antibiotics; their concomitant risks and a relatively narrow range between effective and possibly toxic levels require that dosage levels be calculated carefully and that use be monitored closely. Although the PRO could not precisely specify numerical goals, it was able to estimate that about half of all Medicare patients receiving aminoglycosides during hospitalizations were inadequately monitored. They proposed, therefore, to cut the rate of noncompliance with explicit monitoring criteria by 50 percent in the first year of the contract and by another 40 percent in the second year.

The strategy by which the PRO would attempt to effect this quality improvement involves educational interventions followed by corrective actions.\(^{11}\) Specifically, the PRO will first mail an educational packet containing information about the correct use and monitoring of these drugs to each physician in Utah. Using pharmacy logs and concurrent review, the PRO will identify every Medicare patient receiving aminoglycosides and review the relevant admission. (A physician committee will have defined criteria and data to be collected, will analyze information collected, and will intervene if problems surface.) Any physician with a pattern of inappropriate use or monitoring of these drugs will be required to have a second physician countersign all subsequent orders for these drugs. Further corrective actions could include sanction proceedings.

\(^{11}\)Distribution of such criteria to hospitals or physicians permits the PRO to assume that the provider could and should have known about appropriate elements of care in the given case. This has implications for instituting rebuttal or revocation of waivers of liability.
Quality Objective III: Reduce Avoidable Deaths

The New York PRO (Empire State Medical Scientific and Educational Foundation, Lake Success, New York) will pursue the following goal in this quality area: "To reduce by 514 the number of avoidable deaths with the diagnosis of pneumococcal, aspiration or bacterial pneumonia."

Information from New York State and three PSRO-area studies from the 1982-1984 period showed that about 20 percent of patients of Medicare age admitted with the principal diagnosis of pneumococcal, bacterial, or aspiration pneumonia died; of these, about 25 percent were found to be preventable. Assuming that about 1028 patients admitted per year with these diagnoses would die, then about 257 deaths can be expected to be avoidable (.25 x 1028 deaths). Because the objective covers two years, the total number of avoidable deaths to be reduced is 514.

The principal methodology involves intensive education of physicians about the signs and symptoms of pneumonia among elderly patients and about important preventive interventions. In addition, all deaths from these causes will be identified and reviewed. Findings will be compiled according to hospital and physician, and if patterns are identified the hospital will be so notified. Those hospitals will be required to report all admissions with a diagnosis of pneumonia and the PRO will undertake concurrent review of the identified cases. If the hospital or practitioner fails (over time) to meet quality standards as judged from the concurrent review, the PRO will initiate a sanction process.

Quality Objective IV: Reduce Unnecessary Surgery or Other Invasive Procedures

In West Virginia, the PRO (West Virginia Medical Institute, Inc., Charleston) proposed to reduce by 528 cases the incidence of unnecessary surgery or other invasive procedures, with special reference to selected gastrointestinal (GI) procedures (esophagoscopy, gastroscopy, small bowel endoscopy, fiberoptic colonoscopy, large bowel endoscopy, and proctosigmoidoscopy). Factors that prompted this objective included a significant rise in GI endoscopies, often in patients with at best
minimal indications and frequently without prior x-ray studies that are usually considered critical diagnostic services. In perhaps as many as one-quarter of patients receiving such GI procedures, the principal diagnoses were inappropriate or the procedure was otherwise apparently not indicated.

A multi-step approach to achieving this objective was outlined. It involves retrospective review of 20 percent of targeted cases and identification of aberrant providers. Preadmission review will be done on all endoscopy procedures; 100 percent of cases in which principal and/or secondary diagnoses do not correspond with principal/secondary procedures will also be analyzed. A variety of interventions will be employed, including continuing education and staff development courses, specific educational recommendations from a Quality Assurance Committee, corrective action plans, and sanctions if needed.

Quality Objective V: Reduce Avoidable Postoperative or Other Complications

The Connecticut PRO (Connecticut Peer Review Organization, Inc., Hartford) proposed to reduce by 30 percent (over two years) the number of post-operative urinary tract infections (of indwelling catheters) for patients receiving six procedures (abdominal hysterectomy, disc excision, total hip replacement, bowel resection, cholecystectomy, and repair of hip fracture). Their initial estimate of the decrease was from 1233 to 996, with a better estimate expected in the first quarter of the contract period.

The goal was based on review in one of the state's PSRO areas showing an 8.3 percent incidence of such infections; chart review showed that 15 of 55 patients with Foley catheters (27.2 percent) developed catheter-related infections. The PRO proposed to use retrospective chart review as their main data collection procedure. Interventions were scaled from written communications to intensified retrospective review, physician education, face-to-face meetings with providers, and finally other sanctions.
DATA REPORTING REQUIREMENTS OF PROs
Quality Objective Progress Report

PROs must comply with numerous requirements set forth in program
directives, including those dealing with instructions and forms to be
used to meet contract reporting specifications.\textsuperscript{12} For quality of care,
the most important form is "HCFA 513: Quality Objective Progress
Report." It is due quarterly (by calendar quarter) 75 days following
the end of the quarter and is submitted to the PRO Reports Coordinator
and the relevant HCFA Regional Office. Information from these reports
is used for administration and evaluation purposes.

Each Progress Report is to include all five quality objectives as
finally approved in the contracts. Apart from identifying information,
the Progress Report has essentially two main sections: Baseline
Environment and Milestone Impact.

In the Baseline Environment section, data are those from the PRO
contract used to establish the negotiated quality objectives. Data
elements include: (a) total number of cases (patients) subject to the
problem; (b) number of patients reviewed (of those in (a)) as provided
in the approved contract; (c) patients (of those in (b)) who prove to
have the problem; and (d) earliest and latest dates covered by the
records of the patients referred to in (b). In addition, the specific
review methodology used during the calendar quarter being reported on
must be given.

Milestone Impacts reflect reviews performed during the quarter
being reported on and include the following elements: (a) dates covered
by patient records reviewed; (b) total population subject to the
problem; (c) number of patients reviewed (of those in (b)); (d) number
of patients anticipated to have the problem (specified by HCFA based on
data from the PRO contract); and (e) actual number of patients who
proved to have the problem. The PRO must indicate whether its progress
toward the objective is "on target."

\textsuperscript{12}Information for this section is drawn from draft mimeo materials
on "The CORDT (Central Office and Regional Office Dispersed Terminal)
Network Reference Guide." This system is being developed by the
Division of Data Planning and Analysis, Health Standards and Quality
Bureau, HCFA.
If the answer is no (i.e., if the milestone figure is not on target with respect to the anticipated number), the PRO must explain the discrepancy fully as an attachment to the Progress Report. It must include a projection as to whether the next milestone (for the next calendar quarter) will be achieved and describe any change in strategy that the PRO proposes to accomplish the objective. Changes in review strategies require written amendments to the contract.

Other Reporting Forms

Numerous other PRO Federal reports are required, mostly every calendar quarter. The Acute Care Summary Report (Form 510) reflects the volume of discharges during the time period and is used to validate PHDDS reports (see below). The Specialty Hospital Review Report Summary (Form 511) provides information on admissions and continued stays in specialty hospitals (or equivalent distinct-part units of PPS hospitals). Forms 512 and 513 give information on the progress PROs are making with respect to specific contract objectives relating to admissions, procedures review, and quality of care. Form 514 collects data about reconsiderations of denial determinations, initiation of sanctions against providers, and review of DRG reassignments when so requested by the provider. Finally, Admission Pattern Monitoring (Levels I and II, respectively) is documented on Forms 517 and 518.

Form 516 (submitted monthly) is a report of medical review workload. It includes documenting the number of reviews identified and completed, denials, and cases paid under waiver of liability for the following: admission review, review of transfers, review of readmissions within 7 days, required procedure reviews (e.g., pacemakers; other invasive procedures), as well as day and cost outliers reviewed. Finally, Form 515 (completed semi-annually) documents the allocation of costs and manpower according to review activities carried out by the PRO.
Other Aspects of PRO Data

The Central Office and Regional Office Dispersed Terminal (CORDT) Network is being developed by HSQB to document, maintain, and update various automated systems and data bases that support HCFA-wide programs. Numerous data systems have been or are being developed for both the Medicare and Medicaid programs. Two are especially important for PROs.

PMIS. Supporting the Office of Medical Review (in HSQB) is the "Professional Standards Review Organizations Management Information System (PMIS)." With the advent of PROs, PMIS will serve as the information system. Modifications will be made as necessary to tailor it to the PRO program.

Perhaps the best-known element of the PMIS is the PSRO/PRO Hospital Discharge Data System (PHDDS), a tape file of information on Medicare hospitalizations. The following types of information are reported to the Federal level: demographic data, zip code of patient's residence, provider (hospital) number, dates of admission and discharge, type of admission (e.g., emergency, elective, etc.), source of admission (e.g., physician referral, transfer from another hospital, etc.), patient status (e.g., discharged to home, died, etc.), diagnoses (admitting, principal, secondary), procedures, main source of payment, total dollar amounts charged and paid, type of PRO review and action (e.g., preadmission/pre-procedure review and approval, admission review and denial, cost (or day) outlier review and approval/denial, etc.), and DRG(s) assigned. Not reported in the PHDDS system are any data or identifiers that would allow patients to be identified.

PHDDS data are reported on a calendar quarter basis. The file uses ICD-9-CM coding from 1980 through the present. Data from 1977 through 1979 use the HICDA-2 diagnostic coding system.¹³

The "PHDDS STAT file" is routinely developed from the PHDDS system; it essentially provides aggregate statistics for PRO areas, DHHS regions, and the nation. Data elements include year of discharge, total discharges and days of care, and statistical information (numbers,

¹³HICDA refers to the International Classification of Diseases, Adapted for Hospitals, second revision.
variances) about deaths in hospital, long-stay patients, and one-day and
two-day patients.

MRAS. The "Medical Review Admission System (MRAS)" includes the
Admission Pattern Monitoring System. Through APM, providers (hospitals)
are identified as being "anomalies" if they appear to have abnormal
(excessively high) admission patterns under prospective payment; lists
of anomalies are forwarded to the PRO for verification, analysis, and
resolution. MRAS also contains a wide variety of administrative data,
such as information on costs, physicians, and facilities and other
descriptive data about each PRO.

PERFORMANCE-BASED EVALUATION OF PROS

How PROs are to be evaluated is not entirely clear in public
documents. The draft RFP (September, 1983) specified that the
evaluation involve a "cost-benefit" calculation based on accomplishments
in admissions review, DRG validation, and outlier review. In addition,
the cost-benefit evaluation was to include an "admissions factor." This
was a complex measure based on how much impact a PRO had on changes in
admissions rates, as compared to increases or decreases in admissions
rates that the PRO area had had in the previous few years relative to
the national average. The cost-benefit computation would not include
quality-related activities, and how achievements in this arena were to
be incorporated into the overall evaluation methodology remained
unspecified. Some of these evaluation provisions were sharply
criticized in Senate hearings, because they appeared to downplay the
quality assurance component significantly [37].

The performance evaluation provisions in the final RFP (February
1984) specified that PROs will be evaluated in terms of (a) meeting
objectives and (b) dollar benefits to the government [31]. The elements
of this evaluation include: (a) a cost-benefit calculation for areas
where actual dollar benefits can be calculated (namely, admission
review, DRG validation, and outlier review); (b) measures of changes in
behavior, with specific attention to changes in hospital admission rates
in the PRO area compared to increases or decreases in the rates in a
"before" period; methods for making the before/after comparisons in
admissions rates were to be made available to the contractors at a later
time;\textsuperscript{14} and (c) meeting objectives or responsibilities in quality of care, sanctions, fraud, and abuse, and other areas for which no monetary benefit can be applied. Quality impact is to be measured as "the reduction between baseline period and contract evaluation in the product of the number of patients affected by the problem times the severity of the problem" (as severity was defined above).

These provisions were still being criticized well after the final RFP appeared. The American Medical Association, for instance, argued against the provision for evaluating PRO performance in changing admission behaviors. They believe that Congress did not intend for PROs "to be held responsible for changing the area's overall Medicare admission rates to meet arbitrary objectives" [41:117] and that it threatened to put PROs in the position of needing to deny more than inappropriate admissions.

Apart from the SuperPRO effort to validate PRO medical decisions (discussed in the next section), no plans were promulgated for a program-wide evaluation of PROs within the first few months of PRO operations. Presumably, such assessment could not take place until reasonably complete information on individual PRO's performance is available. The interim period should give HCFA ample opportunity to develop methods by which to aggregate PRO-specific information and to value appropriately the quality (and other nonmonetary) tasks.

\textsuperscript{14}This is the aspect of the evaluation that had involved the "admissions factor." Although the term "admission factor" and its precise definition were gone from the final Scope of Work, the essence of the idea remains.
V. QUALITY ASSURANCE POTENTIAL OF PROs

POTENTIAL ADVANTAGES

History of Quality Assurance

The cumulative experience of Federal peer review efforts in quality assurance is positive. PSROs were beginning to compile a good record in the quality area, and many current PROs were formerly PSROs or are amalgams of several substate PSROs. The operational expertise, professional relationships, and general goodwill amassed by the more successful PSROs should provide a helpful base as the PRO program gets underway. Related to this is the broad set of review methods that have been tried and refined over the past 15 years or so.

Attitudes of Medical Profession

The effect of the PRO program on "local peer review," as practiced in the EMCRO and PSRO programs, is uncertain. As an organized profession, physicians did not instantly embrace PSROs' quality assurance efforts; only after some years' experience did the medical community appear to support quality assurance and peer review. Local physician leaders may hesitate to press for their colleagues' active participation in PRO activities precisely because of the rather unceremonious termination of the PSRO program.

Further, requirements about the proportion of physicians in an area that must belong to the PRO for it to be accepted for a Federal contract were considerably relaxed relative to the PSRO program. For example, it was originally proposed that a physician-sponsored PRO need be composed of no more than 5 percent of the licensed physicians practicing in the PRO area; public comment was sufficiently negative that the final regulations raised the figure to 10 percent--still not very high. Moreover, possible competition for PRO contracts from insurers and fiscal intermediaries, which have different (lower) requirements for physician participation or from other types of physician-access entities, may further dampen enthusiasm for and dedication to peer review among those of the medical community who have spent years in the quality-assurance arena.
On the other hand, physicians have in fact great incentives to increase or at least maintain their participation in PROs: to preserve some control and influence in the Medicare program, to prevent nonphysician entities such as insurers from becoming PROs, and to continue to press the quality-assurance aspects of the program. A large majority of PROs, for instance, have the support of the relevant medical society [42].

Moreover, some factors in the implementation of PROs suggest that local emphasis has not been overly compromised. In many large states, the "parent" PRO has initiated subcontracts with "regional" PROs, which are often existing substate PSROs. PROs are allowed to delegate quality-assurance activities to individual hospitals.¹ Since the aspect of PRO responsibilities about which practicing physicians predictably will be most concerned is quality of care, the ability to involve physicians at the most dispersed level (e.g., local hospitals) should serve as a powerful incentive for continued support of the program.

Consequently, the attitude of the medical community may be more positive than negative [43]. Hospitals' medical staffs recognize that "... physician peer review offers perhaps the best prospect for a viable transition into the Medicare prospective payment system despite its constraints" [37:139]. Working to make PROs effective may be seen as one good way to preserve the traditional fee-for-service system in the nation as well as to forestall imposition of a de facto "quota" system in Medicare (or all) admissions.

¹PROs are authorized to delegate only quality review, unlike PSROs, which could and did delegate a variety of utilization review and quality activities to hospitals. Some observers, not surprisingly including the American Hospital Association, have criticized this stand as being wasteful of a considerable reservoir of review capabilities. This would probably become even more the case as hospitals improve their computer-based medical record and billing systems [43].

It should be noted that PROs are allowed, not required, to delegate quality review, and they retain ultimate responsibility for meeting their quality objectives. Because the PROs could reclaim review authority in the event of poor performance, hospitals desiring to take on such delegated tasks have an incentive to do a good job.
Visibility and Importance of Quality Issue

More visibility and importance may come to be attached to quality issues under PPS than was true with cost-reimbursement. By implication, therefore, quality might eventually receive more attention under PROs than PSROs, a view explicitly taken by HCFA [44:3].

The intent of Congress is widely perceived to have been to use PROs partly as a balance to the emphasis on dollar savings inherent in the changing financing environment. Widespread concern among professional groups and representatives of the elderly over the possible threat to quality of care as PPS begins to take effect also contributes to the visibility of the issue.

The reaction to the draft PRO RFP illustrates this point. HCFA had proposed that PROs specify only one quality objective (from among the five areas noted above). Witnesses at Senate Finance Committee hearings in February, 1984, were very critical of what they saw as a downgrading of quality-assurance issues. For instance, "... PROs may be the only mechanism for monitoring and maintaining quality of care under the new DRG system. HCFA has given no indication of support for any other mechanisms by which to monitor quality of care. Yet the PRO program as is currently being developed by HCFA appears inadequate to assure the maintenance of quality care" [37:105].

It should be emphasized, however, that HCFA recognized from the beginning that they had thought through their approach to quality assurance less well than they had designed other aspects of the PRO program (e.g., Admission Pattern Monitoring). In disseminating the draft RFP, HCFA explicitly asked for help from the medical and hospital communities on ways to improve the quality objectives. Quality objectives had been tentatively defined in terms of "significant outcome-oriented improvements in patient care quality"; i.e., they were to deal with the most urgent problems that had significant or lasting effects on patient well being. Reviewers were specifically requested to provide suggestions for alternative definitions of these concepts (e.g., severity, serious patient complications) that would aid in the development of the entire quality focus for PROs.
In the end, the final RFP required PROs to specify objectives in each of the five areas noted above. The precise wording of the objective areas (e.g., reduce avoidable postoperative complications) in the final RFP was nearly identical to the initial wording. Thus, the process of issuing and revising the draft RFP strengthened the quality review component of PRO requirements, even if it did not appreciably change the content.

Some members of Congress evidently remained skeptical, however. For instance, the Medicare Quality Assurance Reform Act of 1985, introduced by the Chairman of the House Select Committee on Aging in April, 1985, was explicitly intended to upgrade the current system by, among other things, requiring PROs to spend "... at least as much effort and resources for quality assurance as for cost containment." Further, it would have established a "national Council on Quality Assurance" and extended PRO responsibilities to all services covered by Medicare.

Interest from other affected parties. Representatives of Medicare beneficiaries, or the elderly more generally, have taken more (or more prompt) interest in the PRO program than they did in the PSRO program. One concern is how Medicare beneficiaries might play a role in PROs, perhaps by being appointed to PRO boards or banding together as advisory committees to PROs. Questions to be considered in this regard include how to identify appropriate citizen representatives, what formal or advisory functions such consumer representatives would fulfill, and how to optimize the contribution they could make to the PROs' activities.

The American Association of Retired Persons (AARP) is working with the PRO national association (American Medical Peer Review Association, or AMPRA) in a pilot project that will place a consumer representative (an AARP member) on PRO boards in seven states. The proposed Medicare Quality Assurance Act would also have established a consumer advisory board for each state served by a PRO.

Similarly, business groups have a substantial interest in the PRO program. This stems mainly from the enhanced activities of PROs (compared to PSROs) in private review (see below), since presumably few businesses have a large stake (except in a broad social sense) in the effectiveness of PROs in their Medicare capacities. Although businesses
have utilization review and cost containment as their principal review concerns [45], they are sensitive to the issue of not endangering quality of care, so the capacities of PROs in this arena should be of considerable interest to business coalitions around the nation.

In sum, a variety of groups outside the hospital sector are taking a much closer look at the current Federal peer review system--and at both the utilization and quality-assurance aspects--than had been true heretofore. Greater understanding of the capabilities and potential of PROs among the citizenry at large can only work to the benefit of the program.

Private Review

The PRO legislation provided a considerable incentive for these organizations to pursue activities in private review--the arrangements by which PROs will conduct utilization and quality review for states, insurance companies, and employers [46]. Providers must agree to release patient information so that a PRO can do similar review functions under any contract it may have with a private or public agency that pays for health care in the same area. Assuming patient consent (which is required), any hospital that does not provide the information runs the risk of losing its rights to Medicare reimbursement.

The effects of these provisions will take some time to be felt. Widening the base of information about levels of quality of care in various hospitals cannot help but be useful to quality-assurance purposes. Furthermore, private review contributes more generally to the long-run stability of the PRO program, which in turn should strengthen its role in quality assurance.

POTENTIAL DISADVANTAGES

Despite many positive aspects of the PRO program, a number of potential limitations to its viability as a quality-assurance mechanism for the Medicare program were identified at the start of the program. Some are short-run problems, such as simply getting the many required activities under way. Others may pose longer range threats to the program. Problems noted by various observers included the following:
-- PROs have been assigned a large number of mandatory review tasks that are also new activities (e.g., outlier review, DRG validation); implementing them in a timely and effective manner may force PROs to skimp on the attention they can give to quality review.

-- The quality objectives (as well as the overall set of requirements placed on PROs) may be excessively narrow or inflexible.

-- The quality (or other) objectives are effectively quotas for limiting Medicare hospitalizations irrespective of whether the admission is appropriate or inappropriate.

-- Payer organizations, such as fiscal intermediaries and insurers, may not be as well equipped or disposed to emphasize quality concerns as are the physician-sponsored PROs.

-- Evaluation procedures and the weight to be given to quality assurance are vague.

-- If PPS has its intended effects on hospital use, a number of secondary (albeit unintended) effects might be experienced, including hospital closure and poorer quality of care in other settings.

Timing

The sheer number of administrative tasks PROs must undertake in the first weeks of the contract period may hamper their short-run efforts in the quality-assurance area. For example, PROs had to negotiate agreements with all hospitals in their states by mid-November, 1984, as well as negotiate agreements with all fiscal intermediaries in their area within 45 days of their effective contract date.

PROs also had to develop, by the end of the first 45 days, patient profiles, physician profiles, hospital profiles, DRG profiles, and diagnosis/procedure profiles. These profiles were to show various data and rates of admissions pertinent to monitoring admissions. With respect to quality of care, the only major task required within the equivalent time period was to submit a detailed description of the explicit written outcome criteria to be used in initial quality reviews.

Over time, the reporting burden is considerable. Several detailed reports on admission review, outlier review, and quality objectives are due quarterly; detailed medical review workload reports, monthly. In
fact, according to some, "... the PRO program has as much as and maybe more paperwork ... as the PSRO program" [47]. Costs (e.g., salaries, fringe benefits, travel, etc.) as reported to HCFA will be monitored more closely. Failure to submit the many deliverables specified by contract could result in financial penalties.

Inflexibility

The argument that the PRO program is overly prescriptive is widely voiced [41, 42, 47-51]. It stems from the following factors.

Central office direction. HCFA specified the five quality-objective areas a priori, and then required that prospective PROs undertake an objective in each area regardless of whether it was seen as truly important in the state. Further, the numerical goals eventually agreed upon in the contracts may be unrealistic--essentially reflecting what HCFA may have wanted from the PRO rather than what was the true state of affairs in the PRO area. Finally, very detailed instructions for other tasks such as APM are derived directly from PSRO transmittals, an irony not lost on some who believed that the PSRO program had been overly regulated. The obvious implication is that quality-of-care review could come to be equally tightly run from the Federal level.

HCFA, for its part, could argue that it was diligent in getting PROs to propose ambitious goals precisely to underscore the seriousness with which it viewed the quality-assurance aspects of the program. Furthermore, requiring the peer review entities to set specific quantifiable objectives that could be monitored over time was not a complete departure from the past, because the PSRO program had been in the year or so before TEFRA. Nevertheless, the charge that the program as a whole, including the quality assurance aspects, is overly prescriptive and regulated is not likely to go away. That this criticism was very telling in bringing the PSRO program to an end does not bode well for PROs.

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2 A rather colorful quote from the head of the Kentucky PRO makes essentially this point (quoted by Weiss [52]): "It really wasn't a negotiation as such.... They [HCFA] bring you in, beat you up, tell you how much you're going to get and what you're going to do, and send you home.... A very clever ploy ... in the sense that they could then claim they did not come up with those numbers themselves. But the real question is would they have signed the contract if we didn't agree to those numbers?" The implicit answer was "no."
Narrow quality objectives. Current objectives are, on the face of it, rather narrow, even though they will occasion a great deal of review activity. They do not concern negative patient outcomes that fall short of death or major complications or attend to problems of poor or substandard care delivered during a hospital stay, unless the care was so poor that it necessitated a second admission or resulted in a significant complication or setback. (They also do not apply to problems encountered if Medicare beneficiaries are kept out of the hospital altogether.)

The Severity Index (see above) that HCFA uses to judge impact in the quality-of-care area gives no credit for looking at any problem other than death, actual permanent loss of a major physical function, actual unnecessary procedures or actual complications, or underuse of services that may bring about life-threatening situations or other adverse outcomes that extend a patient's stay or result in additional morbidity (presumably while still in the hospital). Under these contract specifications, therefore, some of the quality-related problems that the PSROs detected and undertook to correct (e.g., improving control of pain, improving use of medications) generally may become less attractive targets of the PRO's quality assurance efforts. Furthermore, even if PROs are allowed to renegotiate quality objectives, discovered problems may be difficult to fit into the current set of objectives.

Where the major quality-of-care problems will arise with prospective payment remains to be seen. Many of them will probably fall short of the extremes implicit in these quality objectives. For instance, patients may be prematurely discharged with levels of medications not fully adjusted to maintenance levels (e.g., medicines to avoid heart failure, insulin dosages to control blood sugar levels). PROs can effectively detect and correct such problems. Given the present quality-objective areas and the weights in the Severity Index, however, it is hard to see how they would be rewarded for trying to do so.

Tried and true methods. Proposed review methods are fairly commonplace, despite the apparent Congressional intention that PROs be given some leeway to develop creative, innovative approaches to quality
review. Having to specify quality objectives at the outset and to
describe intended review methods—as part of performance-based
contracting—seems to have hamstrung PROs in trying new strategies.

One innovative approach that might have been given a wider trial is
"generic screening" of medical records to identify potential quality
problems at an early stage. "Generic" or "occurrence" screening means
different things to different people. Essentially it grows out of
efforts at risk management and is typically designed to provide early
identification of hospital-based adverse events and patterns of
substandard care that may have malpractice liability implications. The
meaning for PROs is a little different, because the focus would be more
on quality of care per se than detecting potentially litigable cases in
individual hospitals.

In this context, for example, PROs might mount a screening program
based on "generic" criteria—i.e., those that can be applied to a wide
range of medical and surgical problems. Such criteria could include,
for instance, readmission within three months of any emergency-room or
day-surgery care, unanticipated transfers from general to special units,
cardiac or respiratory arrest, injury to organ or body part during an
invasive procedure, or unexplained return to the operating room. Some
PROs may have specified one or another of these specific topics as
warranting their attention, but not as part of an overall generic
screening approach.

Such review is usually retrospective (at best it could only be
concurrent with the hospitalization) and is obviously based on medical
record review. Moreover, it is highly unpredictable as to output, since
different criteria might turn up quite different problems in different
hospitals. Clearly, it would be harder to specify numerical goals for
improvements in quality like those now required (e.g., reduce the risk
of death by "x" percent or for "n" cases), but it should not be
completely beyond the capability of HCFA and the PROs to devise mutually
acceptable performance-oriented, generic-screening objectives.
Nonetheless, this is one innovative approach to quality review that PROs
appear not to be in a good position to mount at the moment.³

³Interestingly, occurrence screening as a quality-assurance system
has been undergoing testing or phasing-in in a number of Army, Navy, or
Other questions about quality objectives. Apart from the limitations of the quality objectives just described, there seems to be little to criticize, especially if they are viewed as the first step. Some concerns were raised about the objective to "reduce avoidable deaths." This objective (now, "reduce the risk of mortality ...") was seen as having substantial legal problems related to malpractice liability, which would complicate dealing with it as a public issue. A few deaths might patently be preventable or avoidable, but most will be borderline; defining precisely what really constitutes an avoidable death could present a considerable problem. Furthermore, although the medical profession can be presumed always to have striven to reduce avoidable deaths, the idea of addressing it as an explicit quality assurance topic is new. Consequently, the reliability and validity of the data on which numerical goals for this objective were based could probably be questioned. Finally, aggressive work on the other (or different) quality objectives could well decrease avoidable deaths while permitting more attention to be given to quality problems of lesser severity but considerably greater prevalence.

Objectives or Quotas?

The Secretary of DHHS has emphatically stated "... these specific [admission] objectives are not 'quotas'. All admission objectives focus only on unnecessary and inappropriate care, not on reductions in overall admissions. PROs will deny no admissions that are necessary and appropriate based on local and regional standards of practice for the PRO area."[54:35] The final PRO RFP specified that PROs are expected to deny only inappropriate and unnecessary admissions (or admissions for unnecessary procedures).

The perception remains, however, that HCFA has quotas or ceilings for Medicare admissions in mind.[55] This may arise partly from lingering distress over the draft RFP's Scope of Work, which said that PROs would have to undertake one or more efforts to reduce admissions (overall, for specific DRGs, or for specific practitioners or providers)

Air Force hospitals [53]. In some quarters it is regarded as a highly effective and useful technique.
with no reference to inappropriate admissions. In the final RFP, this wording was changed. However, the performance-evaluation section continues to state that PROs will be "evaluated by reference to changes in hospital admission behavior" with no explicit reference to inappropriateness. The worry expressed by some is simply that, in order to meet contract objectives, PROs will deny appropriate as well as inappropriate admissions [41].

This controversy does not directly concern the PRO quality assurance tasks per se. The problem it poses is more one of appearance. If the PROs are seen to be the mechanism by which inpatient care is to be rationed, then the possible hostility to them from both providers and Medicare beneficiaries could undermine the good that they can do in the quality area.

**Eligible Organizations**

Congressional intent in establishing PROs was clearly to "foster peer review, not intermediary review" [56]. HCFA and the Office of Management and Budget [57], however, at one time or another apparently preferred to see all review activities handled by fiscal intermediaries (FIs). Payer organizations will be eligible to compete directly for PRO contracts in the second contract period. Even in the first period, if no non-payer organization was found suitable, FIs or other payer organizations could be awarded contracts (as noted earlier, one was). At the outset of the program, however, some observers remained concerned that the input of practicing physicians into quality review would eventually be substantially curtailed, with bad effects on quality of care."

Whether these concerns would be borne out in the event of transfer of PRO contracts to fiscal intermediaries is uncertain, for several reasons. As the PSRO program drew to a close, FIs took over all review activities, including medical review, in all areas of the country not

"Statements from physicians active in peer review over the years reflect the intensity of this concern. For example: "1... Payer organizations, including Blue Cross, will be eligible. That is the last thing doctors want. The patient gets short-changed unless someone who is competent to make decisions about their care is in charge.... The only reason you need peer review is to ensure quality care"" [quoted in 33].
covered by a PSRO. No particular charge has ever been leveled that they showed themselves to be either incompetent at the task or inconsiderate of quality of care for patients.

Further, the FIs most likely to become PROs are probably Blue Cross/Blue Shield Plans--hospital/physician organizations that could probably be expected to take more account of patients' interests than some other insurers might. BC/BS plans are more "local" than nationwide carriers and may have developed longer-standing relationships with professional and institutional providers that would simplify the logistics of PRO review. Finally, they have expressed interest in cooperative arrangements (e.g., subcontracts) with PROs [58].

Conceding beforesometimes that a shift from non-payer (and presumably) physician-sponsored to payer-organization PROs would essentially cut physicians in local private practice out of any influence in the quality-assurance aspects of PROs underestimates the power that physicians can muster to make their voices heard. Furthermore, quality assurance is the one element of the program that can (and probably will) be delegated to hospitals. Arguably, if large FIs take over PRO responsibilities, the input from physicians at the local level on quality issues could be enhanced. The basic point, however, is that this is likely to remain an issue, and its resolution lies at least a couple of years ahead.

The Evaluation Puzzle

The question of what sort of emphasis HCFA will really put on quality assurance by the PROs remains valid as long as the evaluation criteria are not forthcoming. The concern that holding down admissions and expenditures generally will take precedence over maintaining or improving quality of care has a good foundation: the emphasis on cost-control rather than quality of care in the major PSRO evaluations. The present evaluation criteria do not offer much comfort for those who would like to see quality assurance be valued at least as highly as admission control.

A related problem is the timing of evaluations. HCFA has an obligation to determine if the public's funds are being well spent in this endeavor, so an evaluation cannot be delayed indefinitely. Too early an evaluation, however, might give an incomplete or inaccurate review of the accomplishments (or lack of them) of the PRO program.
On October 29, 1984, HCFA issued the so-called SuperPRO RFP; because of dissatisfaction with the original responses to it, the RFP was essentially reissued in the spring of 1985 with proposals due by May 3. A $3.3 million two-year contract was awarded in June [59]. The main SuperPRO tasks will be to validate medical determinations made by PROs.\textsuperscript{5} Practicing physicians, registered nurses, and medical records personnel will sample PRO determinations and advise HCFA of the correctness of PRO review. Thus, although this may be a significant assessment effort, it does not constitute a full program evaluation.

The conclusion remains, then, that at the heart of the long-range success of PROs as a quality-assurance program lie several questions about how and when HCFA evaluates the PRO program. The topic is further discussed in Section VI.

\textbf{Other Facets of the Program}

\textbf{Physician attestation.} Physicians were initially quite disturbed about the "physician attestation" issue [42]. Final PRO regulations require physicians to sign a statement certifying that the narrative description of the principal and secondary diagnoses and the major procedures is accurate and complete to the best of his or her knowledge. Physicians must also acknowledge annually a notice of penalties (stating that any physician who misrepresents, falsifies, or conceals essential information would be subject to fine, imprisonment, or civil penalty), and hospitals must keep a record of these acknowledgements.\textsuperscript{6}

One problem with the physician attestation statement is technical and only indirectly related to quality of care. The ultimate \textit{sequencing} of primary and secondary diagnoses or procedures (important for DRG assignment, for example) is performed by medical record abstractors and is driven in part by ICD-9-CM rules; it is a complex task when done as

\textsuperscript{5}One contemporary description had it, however, that "... the SuperPRO will serve as a police force to monitor PRO aggressiveness in carrying out utilization review" [59:4].

\textsuperscript{6}Originally, the regulations would have placed the penalty notice \textit{within} the certifying statement (kept in the patient's record) and thus required physicians to acknowledge the penalty provisions each time he or she discharged a Medicare patient.
a basis for completing a Medicare claim or assigning a DRG, and it may not "match" the sequence in which a physician might list diagnoses or procedures. Medical record professionals can sequence the clinical data as long as the physician attests to the data, but the physician attestation statement may be sufficiently ambiguous as to put physicians in some inadvertent jeopardy as a side effect of DRG validation.

More to the point, physicians object in principle to being required to sign such statements. Apart from the negative implications about the provider's integrity, the statement can be read as asking physicians to attest to something (in this case, especially a diagnosis) that they perhaps cannot know for certain. Again, although not directly germane to quality of care, this type of issue casts the PRO program in a negative light in the minds of many physicians.

**Local medical practice.** A second issue has to do with whether HCFA really intends to foster "local" peer review. Some observers have speculated that the PRO contracting system is a more powerful means for the Federal government to enforce "national" standards of care (than had been available under the old PSRO grants) [60]. Certainly the reference in the draft PRO Scope of Work to using national rates of admissions as an evaluation criterion could have been viewed as evidence against the local emphasis. Such national standards have always been opposed by some members of the medical community precisely because they are seen as infringing on physicians' response to local needs.

One vocal critic of the PRO program has suggested that members of the medical community should "direct their energies elsewhere" (than being involved with a PRO contractor), with a strong reaffirmation that a better approach would be "working with others who share our community commitment to preserve the best possible standards of health care for those who live here."[61] Although some may view this as an extreme stand, it will probably persist in some quarters, if PROs are perceived as weakening local practice patterns.

Over the longer run, however, this emphasis on local medical practice may be muted by factors having little to do with the Medicare program or peer review per se. Efforts by medical specialty associations to establish guidelines of good practice for their members (e.g., in specifying appropriate timing of preventive screening tests)
are one example. The trend toward diffusion of medical and surgical specialists into smaller and more rural communities is another [62,63]. The phenomenon of Consensus Development Conferences (sponsored by the National Institutes of Health) is a third [64,65]. Finally, enormous variations in per-capita use of certain procedures and services are known to exist, and they are not well explained by characteristics or needs of patients or by the level or type of medical care resources in the community. "Local practice style" is coming to be seen as an unsatisfactory justification for such huge differences in use of services [66,67]. Thus, national "standards of practice" may evolve quite independently of government action or peer review policies.

Effects of PPS

PPS may have short- and long-term effects on the quality of care received by Medicare beneficiaries, and those effects may be good or harmful. Among the latter, apart from impacts on and within the acute short-stay hospital [40], are problems with care provided post-discharge from skilled nursing homes or home health agencies and ambulatory care for patients who can be presumed to have been kept out of the hospital altogether. These points are briefly discussed below.

Hospital closures. The effects of the Medicare prospective payment system on the financial picture of hospitals will take some time to be felt, but some experts believe that the threat of hospital closures is a real one. This is not directly related to the quality-assurance aspects of the PRO program, of course. However, if PROs are very aggressive and successful in curtailing admissions and affecting DRG assignments, then some hospitals may eventually experience occupancy rates or reimbursements below those necessary to stay open.

If such hospitals are unsuccessful in finding ways to improve efficiency or underwrite costs (e.g., by moving into nonmedical enterprises), or if they really bear a disproportionate share of unreimbursed care (e.g., because they are inner city hospitals with large numbers of self-pay or charity cases), they may close. If no alternative facilities are nearby, it could be argued that such closures reduce quality of care for all patients who would have otherwise used the closed hospitals. This might be especially true for certain types of patients, such as elderly poor persons.
Care from other non-hospital providers: A second problem concerns the likely effects of PPS in promoting early, if not premature, discharge. More patients will be receiving some post-admission care in nursing homes, home health agencies (HHAs), or physicians' offices. Empirical evidence (e.g., from professional associations concerned with home health care, occupational therapy, and the like) suggests that the caseloads of nursing homes and HHAs are more severely ill relative to the pre-PPS period; presumably the same is true of patients discharged home who must now obtain some services in doctors' offices that they previously would have had during the last part of a hospital stay.

The quality-of-care ramifications of these phenomena are enormous. Care in nursing homes is known to be suboptimal in many cases [68, 69]; it is not likely to improve in circumstances of increased numbers of patients who are more seriously ill. The record of quality of care from HHA personnel is basically unknown. Two decades of research on the quality of care in ambulatory settings documents many problems even with the "ordinary" patient [9-12], so one cannot be too sanguine about the level of care in those settings for newly discharged elderly patients.

PROs are at the moment not required to review the quality of care from such providers. Thus, they may (or may not) compile a good record in quality assurance in the acute hospital setting, but they will not have addressed quality-of-care concerns throughout the duration of an episode of illness. It seems unlikely that a second or complementary program would be developed to take on such review. Thus, if the PRO program were not eventually expanded to include quality-assurance activities directed at these settings, Medicare beneficiaries could experience a decline in the quality of their overall medical care without any mechanism in place for even detecting the decline.
VI. FUTURE ACTIONS AND POLICIES

CONGRESSIONAL OVERSIGHT

Congressional leaders who pushed to replace the PSRO program with the PRO program wished to promote local peer review, to give such agencies the flexibility to identify and attack problems of concern to their communities and states, and to underscore that quality of medical care in the Medicare program should not be compromised. Hearings in February and July, 1984, were useful in highlighting important and legitimate concerns about the implementation of the PRO program, especially, as it happens, those related to quality of care [37, 41, 42, 48, 49, 54, 70]. Some observers believe that the February hearings in particular were instrumental in getting HCFA finally to issue crucial regulations.

Some problems with the PRO program remain, as outlined in the last section. Others, as yet unforeseen, are sure to arise. The success of Congressional hearings is instructive, therefore, and suggests that periodic oversight in this forum will be amply repaid.

CLARIFICATION OF PROGRAM ADMINISTRATION

Evaluation Issues

Two dimensions to PRO evaluations should be clarified: (1) How the performance of individual PROs will be measured, and (2) when and how the entire program will be assessed. In both cases, the issue of how much weight is given to the quality-assurance objectives will be critical to the success of PROs in ensuring the quality of care delivered to Medicare beneficiaries.

Evaluation of individual PRO contracts. Individual PRO contracts must be renegotiated within two years of the date on the contract. This timetable calls for action as soon as possible on several points. Timely promulgation of the evaluation procedures is important.

First, it is not clear whether new RFPs will be issued or whether contracts will be renegotiated on the basis of the 1984 RFP, with quality and other objectives updated as necessary. Although legally
HSQB may be able just to review (i.e., renegotiate and renew) the current contract within the 1984 RFP, it may not wish to do so. Reissuing an RFP and requiring completely new bids from all interested competitors gives HCFA great leverage over the current contractors. It also allows them to survey the market again and especially to look carefully at the payer organizations (FIs and insurers) as PROs.

Thus, a second question is whether (and, if so, how much) preference will be given to physician-sponsored organizations. Congress stated (somewhat ambiguously) that such organizations were to be accorded "priority" over physician-access organizations but did not specify how much preference.

Under such circumstances, one option might be to revise the distribution of points or the number of bonus points given to such bidders in the next round of contract awards. Another might be to award a PRO contract to any physician-sponsored organization that meets minimum requirements, regardless of whether a physician-access organization has a higher score. Although this may restrict competition between, say, current peer review entities and payer organizations, it does not restrict competition among prospective physician-sponsored organizations.

FIs and insurers can do a good job on the admission and other non-quality-related requirements of PROs; the main uncertainty lies in how well they can protect quality of care. Despite this concern, HCFA may still wish to open the market up to all bidders, within the constraint of according priority to physician-sponsored entities. In this regard, the current point and bonus distribution might be retained, but a number of extra protections might be built into any contract awarded to, say, an FI. For instance, HCFA might be able to include in any such contract special requirements about the amount of local physician participation in quality reviews the FI would have to maintain.

The success of the PROs in the quality area will be tied directly to what it is "worth" in the evaluation process. The quality objectives, taken together, must be valued at least as much as cost containment and admission control, or they will be short-changed. If PROs come to suspect that quality of care concerns will be downgraded, as they were in the PSRO program, they will target their scarce
resources elsewhere, on matters that will stand them in better stead at the time of contract renewals. To ensure that quality of care is not relegated to second priority requires prompt action on HCFA’s part to issue more detailed evaluation criteria that place all the emphasis needed on the quality objectives.

**Evaluation of the entire PRO program.** A strong case can be made that PROs will be more valuable in the longer run in the quality assurance area than they can possibly be in the next two or so years. Given the incentives to underservice inherent in the PPS approach to financing, the elderly (indeed the nation) must have a viable quality assurance organization watching over the Medicare program.

PPS itself may not have much attributable effect on quality of care for several years. Initially, PPS impacts on quality may be small because many useful efficiencies can be put into place; they may even enhance the outcomes for Medicare beneficiaries. However, as the slack in the system is taken up, PPS may begin to pose a real threat to patient outcomes: continued constraints on resources may well force economies that are not consistent with maintaining quality of care. That is when careful nurturing of the PRO program and forceful promotion of the quality-assurance aspects of its mandate will begin to pay off. That these problems may arrive sooner for hospitals with marginal financial reserves or other difficulties (e.g., being in areas of high labor and nonlabor costs of inputs to hospital care) argues for continued emphasis on devolving peer review activities down to the smallest "local" level consistent with efficient operations.

Second, PROs cannot really be expected to have much effect in the quality area during their first two years of operation precisely because it is the first two years. Thus, rigorous program-wide evaluations may be biased toward the negative if they are done immediately.

Furthermore, the methods for measuring quality-of-care accomplishments are less well developed than those for assessing cost-control or utilization effects. Substantial progress in this area was made in the last evaluations of the PSRO program, but further efforts to

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1Certainly the outcomes of the early PSRO evaluations, which were done when fewer that half of the PSROs were fully implemented, give pause to the idea that any definitive program-wide evaluation should be mounted early in the PRO program.
refine these methods and develop valid quantitative measures are needed. This is especially true because the goal-driven nature of the quality-assurance objectives and great variety of review methods proposed for these objectives may make those earlier methods not fully applicable today.

The next year or so might be most profitably put to refining the techniques that would be applied to a program-wide evaluation. Any evaluation done in that period should be explicitly seen as an aid to improving the design, structure, and financing of the program, not as an up-or-down vote on the program as a whole.

QUALITY OBJECTIVES

Perhaps the most common criticism of the quality assurance aspects of the PRO program has been the idea that, in trying to promote local identification of problems simultaneously with implementing performance-based contracts, HCFA has inadvertently designed an inflexible and unrealistic system. The criticism has a good deal of validity, and doubtless more responsiveness and creativity could be fostered. The following do not exhaust the possible steps that will be needed or might be considered.

Contract Renegotiations and Renewals

The ways in which quality objectives might be renegotiated should be clarified. The American Hospital Association (AHA), for instance, asserts that "... the contracts provide that only ... HCFA, 'at its option,' can initiate a re-evaluation of contract objectives if [they] ... are unrealistic or inappropriate" [70:96]. HCFA promises not to be "... rigid or inflexible if we learn, during ... the contract, that the numbers [meaning numerical goals] should be modified. We are always ready to renegotiate with the PROs if we or they learn, for example, that they have overstated the nature of a particular problem, or if they have identified a more pressing problem ..."[54:35].

This process can occur in two ways. First, if a PRO is appreciably ahead of schedule in some admission or quality objective, HCFA can request that it write a stronger objective. Alternatively, if the PRO cannot make appropriate progress toward an objective, it can go to HCFA
with new information to indicate that the original objective had a faulty basis [44]. HCFA's position may not entirely answer the AHA charge, however. Thus, it should be made more explicit, perhaps as a prominent part of the contract, that PROs have a right to initiate changes in their quality objectives and that HCFA has a concomitant obligation to consider the changes objectively.

Some commentators have noted that "... flexible objectives may help dispel the belief, widespread in the health care industry, that fixed quantified objectives impose quotas on hospital use.... [But] if PROs were prohibited from adjusting numerical objectives downward when current information justified [it], many people might conclude that the federal government had set fixed, predetermined limits on hospital inpatient use" (71:343). Thus, the issue of revising contract objectives during a contract year is inextricably tied to the (bigger) issue of whether contract objectives are truly goals or quotas. Presumably, how HCFA conducts contract renegotiations in the first contract period will convey much about the latter issue.

**Broadening the Quality Objectives**

The scope, definition, and number of quality objectives can be broadened. For instance, some larger number of objective areas, such as ten, could be defined. Five of these might be the current set. Of the other five, some might target inpatient care review for problems less serious but more prevalent than those the current objectives address; one might incorporate generic or occurrence screening techniques as a means of detecting emerging problems.

Further, changes in the current weighting schemes might be contemplated. For example, different weights might be given to the ten different objectives, depending on a variety of criteria such as seriousness of the outcomes or prevalence of the problem. PROs would then be allowed to pick any combination of objectives that summed to at least some minimum total weight. One or a few might be made mandatory. In all cases, HCFA could express objectives in ranges instead of setting specific numeric goals.
In short, there are many ways that more flexibility and responsiveness might be brought into the quality-assurance dimensions of the PRO program; the above illustrate only a few. The breadth and depth of the criticism leveled at the program on these grounds calls for remediation at the earliest possible moment.

In revising this part of the program, however, two considerations should be kept in mind. The first is that among the PROs are many with a good deal of experience from the PSRO days; that expertise should be extensively tapped. Ample time should be allowed for public comment, including that of PROs, on proposed regulations or future RFPs.

The second is that other divisions within HCFA, such as the Office of Research and Demonstrations, are greatly concerned with the effects of PPS on quality of care for Medicare beneficiaries. Their knowledge and expertise should also be brought to bear in identifying and defining quality problems to which PROs should be required to give high priority.

**Quality of Care Outside the Hospital**

As noted above, one major area of concern is quality of care provided by personnel from home health agencies and long-term-care facilities: the caseloads will grow, patients will be on average sicker, nursing home care is known to be suboptimal in many cases, and the methods to evaluate such care are poorly developed. Medicare beneficiaries have a great deal to lose if the quality of care in these settings is not monitored aggressively. The validity of quality-assurance efforts on behalf of Medicare beneficiaries can be called into question if the responsibility of the PROs stops at the hospital door.

PROs have a great deal to offer in ensuring that quality of care does not fall below acceptable standards in these settings. Serious consideration should be given to allowing PROs to take on this responsibility. This might be done as an additional set of quality objectives. Such review might be allowed to substitute for one or two of the current hospital-oriented objectives.

Midway through the first year of PRO operations, explicit consideration was being given to extending PRO quality-assurance
activities to other non-acute or ambulatory settings. As hospitals adapt to PPS by unbundling services to the outpatient sector, the questions become whether patients are harmed when care is provided in these different ways. The first such area of attention was surgery that is shifted from the inpatient to the outpatient setting (i.e., in hospital-based or free-standing surgical centers). HCFA hoped to test such review by the start of FY 1986 [72].

Quality assessment in all these settings is not easy. Among the first steps needed is to develop standards and criteria applicable to them and to improve methods for efficient review. This area might be an excellent one for application of "occurrence screening" as a trigger for more complete review. The fundamental need, however, is the need for all parties to undertake more thorough planning of the important role that PROs might play in non-hospital quality assurance.

FINANCIAL CONSIDERATIONS FOR THE PROGRAM

Costs of Review for PROs. Attention should be directed at several other possible barriers to effective quality assurance by the PROs. The first is costs of review. PROs may indeed review many more medical records than they initially plan on, because of the inherent difficulty of predicting in advance how many cases they would have to review (counting all the admission, outlier, DRG validation, and quality requirements). Given that the fixed price budgets are computed on the basis of a cost per review, it is easy to see that budgets may be too tight.

One of the main objectives of the PRO program is precisely to put them at some financial risk, so that they have every incentive to be efficient. Furthermore, PROs can legitimately use the review of one record for more than one purpose. In the early stages, however, the risk may be inadvertently excessive. Hence, careful attention should be given to the true financial costs of all these activities, and adjustments made to contracts in justifiable circumstances.

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2The activities that PROs will perform in reviewing both inpatient and outpatient care in HMOs and CMFs were briefly noted in an earlier section.
In addition, HCFA has made numerous adjustments to PRO performance requirements in the first six months or so of the program (as detailed, for instance, in Transmittal No. IM 85-2); some of these modifications increase the level of review; others decrease the workload. The PRO national association noted that although program revisions of this sort may be unquestionably needed, they are costly in terms of time and resources required to retrain staff, change computer or data systems, and the like.[73] PRO representatives thus called for some assurance from HCFA that PROs suffering demonstrable adverse financial impacts would be awarded additional funds.

Finally, it should be clear that PROs cannot be expected to take on additional tasks, such as review of care from SNFs or surgical care in free-standing centers, without additional funding. In the early years, such activities might be financed on a trial basis among only selected PROs, rather than across the board.

Costs to Hospitals. Part of the cost of review may be shifted from the PROs to individual hospitals. In some cases, the PRO cannot or will not maintain an on-site reviewer; hospitals then become liable for the costs of reproducing medical records and transmitting them to the PRO offices. Although eventually some hospitals may be able to make medical record data available to the PROs by computer tapes, in the immediate future this is not a likely possibility.

Costs of medical record reproduction are supposedly built into DRG prices, but whether the amount of records to be reproduced was adequately projected when the 1983 DRG prices were calibrated is questionable. Some estimates place the total number of records that PROs will need to review at 25 to 33 percent of all Medicare records, others at 50 percent; at anything approaching those levels, the potential burden on hospitals becomes heavy. This may be especially true for rural hospitals, small hospitals, and those with large Medicare patient loads. Thus, some thought should be given to how adequately and fairly to compensate hospitals that face substantial costs in this area.
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