S. Hrg. 99-249

PEER REVIEW ORGANIZATIONS

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON FINANCE
UNITED STATES SENATE

NINETY-NINTH CONGRESS

FIRST SESSION

APRIL 19, 1985

Printed for the use of the Committee on Finance

U.S. GOVERNMENT PRINTING OFFICE

49-351 O WASHINGTON : 1985

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STATUS OF MEDICARE UTILIZATION AND QUALITY CONTROL PEER REVIEW ORGANIZATION PROGRAM

FRIDAY, APRIL 19, 1985

U.S. SENATE,
SENATE COMMITTEE ON FINANCE,
SUBCOMMITTEE ON HEALTH,
Washington, DC.

The subcommittee met, pursuant to notice, at 9:47 a.m., in room SD-215, Dirksen Senate Office Building, the Honorable David Durenberger (chairman) presiding.

Present: Senators Durenberger, Long, Baucus, and Mitchell.

[The press release announcing the hearing and background material on the PRO program follow:]

[Press Release No. 85-017: Apr. 3, 1985]

FINANCE COMMITTEE SETS HEARINGS ON PEER REVIEW ORGANIZATIONS

Senator Bob Packwood (R-Oregon), Chairman of the Senate Committee on Finance, announced today the scheduling of a hearing to review the status of the three-year-old Medicare Utilization and Quality Control Peer Review Organization (PRO) program.

The hearing it to be conducted by the Committee on Finance's Subcommittee on Health. Subcommittee Chairman David Durenberger (R-Minnesota) will preside at the Friday, April 19, 1985, hearing.

The hearing will begin at 10:30 a.m. in Room SD-215 in the Dirksen Senate Office Building.

Senator Packwood said the purpose of the hearing is to review the status of the implementation of the PRO program, which was created by the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA).

"Although it has been almost three years since the PRO program was created," Senator Packwood said, "the Secretary of the Department of Health and Human Services (HHS) has not finalized all of the regulations under which the peer review organizations must operate.

"The reason for the delay is one of the aspects of program implementation that our hearing on April 19 will address," Packwood said.

Other aspects include the Health Care Financing Administration (HCFA) evaluation of existing PROs, the negotiation of revised targets and objectives and the initiation of 100 percent review in the event a hospital loses its liability presumption.

The Committee on Finance's Subcommittee on Health will hear testimony from HCFA, but Senator Packwood also is soliciting requests to testify from the PRO community, Medicare providers and other interested parties.

A PRO is usually composed of a number of doctors of medicine and osteopathy practicing in a given geographic area or must have available to it a sufficient number of licensed, practicing physicians to perform review functions.

Hospitals must have agreements with a PRO before they can receive payments from Medicare, Senator Packwood pointed out.

THE PEER REVIEW ORGANIZATION (PRO) PROGRAM

Background Paper

Prepared for the Use of the Members of
The Committee on Finance

April 1985

THE PEER REVIEW ORGANIZATION PROGRAM

The "Tax Equity and Fiscal Responsibility Act of 1982" (commonly referred to as TEFRA) provided for the establishment of a Utilization and Quality Control Peer Review Organization Program to replace the existing Professional Standards Review Organization (PSRO) program. The legislation required the Secretary of Health and Human Services (HHS) to enter into performance-based contracts with physician-sponsored or physician-access organizations known as Peer Review Organizations (PROs) The Secretary has contracted with 54 PROs nationwide.

The "Social Security Amendments of 1983" (as amended by the "Deficit Reduction Act of 1984") required hospitals to have agreements with PROs by November 15, 1984, as a condition for receiving Medicare payments under the new prospective payment system. PROs and hospitals have entered into these agreements; in certain instances, hospitals are operating under informal oral arrangements while working out the details of their formal agreement.

On February 1, 1984, the Subcommittee on Health held a hearing to explore the reasons for apparent delays in implementation of the PRO program. On July 31, 1984, the Subcommittee held a hearing on whether the performance criteria being included in PRO contracts were reasonable, responsive to local problems, and achievable.

I. BRIEF OVERVIEW OF HISTORY OF LEGISLATION

A. The "Tax Equity and Fiscal Responsibility Act of 1982"

The "Tax Equity and Fiscal Responsibility Act of 1982" (commonly referred to as TEFRA) requires the Secretary to enter into performance-based contracts with peer review organizations. A PRO is defined as an entity which either: (1) is composed of a substantial number of licensed doctors of medicine and osteopathy practicing in the area, or (2) has available to it sufficient numbers of such physicians so that adequate review of medical services can be assured.

The legislation requires the Secretary to designate the geographic areas which are to be served by a PRO, with each State generally designated as a single area. The Secretary is required to enter into a contract with a peer review organization for each geographic area. PRO contracts are for an initial period of 2 years, renewable biennially.

The Secretary is required to include in the contract negotiated objectives against which the organization's performance will be judged. PROs may review, subject to the provisions of the contracts, the professional activities of physicians, other practitioners, and institutional and non-institutional providers in rendering services to Medicare beneficiaries. The review is to focus on the necessity and reasonableness of care, quality of care, and the appropriateness of the setting. The determinations of the peer review organizations are binding for purposes of determining whether Medicare benefits should be paid unless an appeal is successful or the

waiver-of-liability provision is applicable. Provisions are made for sanctions against health care providers and practitioners who follow a pattern of rendering unnecessary or poor quality services. Sanctions are subject to appeal.

B. The "Social Security Amendments of 1983" (P.L. 98-21)

The "Social Security Amendments of 1983" authorized the establishment of the Medicare prospective payment system. This legislation requires hospitals receiving payments under the new system to enter into an agreement with a PRO under which it will review: (1) the validity of diagnostic information provided by the hospitals; (2) the completeness, adequacy, and quality of care provided; (3) the appropriateness of admissions and discharges; and (4) the appropriateness of care provided to patients designated by the hospital as outliers. Hospitals are required to enter into such agreements by October 1, 1984 (subsequently changed to November 15, 1984), as a condition for receiving Medicare payments. Where a PRO contract between the Secretary and a PRO is terminated after October 1, 1984, hospitals would not be penalized for the six-month period during which the Secretary is required to enter into a new contract.

C. The Deficit Reduction Act of 1984 (P.L. 98-369)

The "Deficit Reducation Act of 1984" (commonly referred to as DEFRA) contained four provisions further modifying the new PRO program. The first provision would permit limited representation of providers on a PRO board. Specifically, up to 20 percent of the members of a PRO governing board could be affiliated with providers. The second provision would permit entities whose board members include a representative of a self-insured employer to

qualify as a PRO; in addition, an organization which has no more than one member affiliated with a health maintenance organization would not be classified as a payer organization and would therefore be permitted to qualify as a PRO.

The third provision would fund PSROs which were still in existence until a contract was signed with a new PRO. Payments would be made from the Medicare trust fund.

Finally, the Act delayed from October 1, 1984, to November 15, 1984, the date by which hospitals were required to have an agreement with a PRO. Similarly, November 15, 1984, was the first date on which a payer organization could qualify as a PRO.

II. IMPLEMENTATION OF THE PRO PROGRAM

A. Area Designation

The final notice and regulation establishing geographic areas and organizational qualifications for Peer Review Organizations, respectively, were published in the Federal Register on February 27, 1984.

The notice established geographic areas throughout the United States for contracts under the PRO program. All States, the District of Columbia, the Virgin Islands, and Puerto Rico are designated as separate PRO areas. Guam, American Samoa, and Northern Mariana Islands are designated as a single PRO area. In order to address local medical needs, a statewide PRO could subcontract with substate organizations. It could also establish criteria and standards to be applied to specific locations or facilities in its area.

B. Eligible Organizations

The final regulations defined organizations which were eligible to become PROs. In order to compete for a contract, an organization must be either a physician-sponsored organization or a physician-access organization and must demonstrate the ability to perform review. Physician-sponsored organizations must be composed of a "substantial" number of the combined population of licensed doctors of medicine and osteopathy practicing in the review area and be "representative" of these physicians. A physician-access organization is one which must have available to it a sufficient number of licensed practicing physicians in the area to perform review functions.

Any organization accepted as a PRO must be able to perform review. As a general standard, it must have acceptable utilization and quality review plans and resources sufficient to carry out those plans.

C. PRO Contracting Process

The law requires the Secretary to enter into PRO contracts for the review of the quality, necessity, reasonableness and appropriateness of health care services furnished under Medicare. These contracts, which are for an initial period of two years and renewable biennially, must specify objectives to be achieved over the contract period. The organization's performance will be judged against these objectives.

On February 28, 1984, the Health Care Financing Administration (HCFA) published a notice advising potential bidders of the availability of the Request for Proposals (RFP) which formed the basis of the contracts for the new PROs. The RFP contained the Scope of Work, the Technical Proposal instructions and the Business Proposal instructions. The bidders were instructed that their proposals should be in two parts: a "Technical Proposal" and a "Business Proposal." A point system for evaluating the proposals was specified.

The Business Proposal would contain information on the cost and pricing data supplied by the bidder. Information on salaries, fringe benefits, data collection costs and arrangements with subcontractors would be included.

The Technical Proposal would include the following information: the eligibility of the organization to participate; an understanding of the background (law, regulations) which prompted the proposed contract in addition to an understanding of the scope and purpose of peer review; a description of the proposed objectives to be achieved and the required review activities;

a description of the offeror's experience in conducting peer review; a description of the educational background, professional experience, and qualifications of the personnel of the organization; and finally a description of the management plan to be put into place by the organization.

Also contained in the RFP is a section entitled "Description and Scope of Work." Contained therein are detailed requirements that the organization must address in its bid. The following is a summary of the criteria contained in the Scope of Work:

1. Admissions

These objectives establish the improvement that the organization proposes to achieve. One or more objectives are required in each of the following areas:

- o Admissions Objective 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.
- o Admissions Objective 2. Reduce the number of inappropriate or unnecessary admissions or invasive procedures for specific diagnosis related groups (DRG's); and
- o Admissions Objective 3. Reduce the number of inappropriate or unnecessary admissions or invasive procedures by specific practitioners or in specific hospitals.

In addition, the contractor shall perform all of the following review activities:

- o Review, prior to hospital admission, every elective case proposed for five procedure-related DRGs or DRG groups from among those designated by HCFA;
- o Review admissions occurring within seven days of a discharge and deny all claims for inappropriate admissions;
- o Review every permanent cardiac pacemaker implantation or reimplantation procedure and deny payment for those that are unnecessary;

- For every pacemaker reimplantation, obtain warrenty information necessary to identify pacemaker costs reimbursable to Medicare (requirement subsequently eliminated--FDA now maintains national registry).

- Review transfers from a hospital subject to PPS to either another hospital or to a PPS-exempt psychiatric, rehabilitation, or alcohol detoxification unit or to a swing-bed within the same hospital; and deny all claims for inappropriate admissions resulting from those transfers;

- Perform admission pattern monitoring;

- Perform admission review according to specific instructions prepared by HCFA;

- Review Medicare admissions to and days of care in specialty hospitals and distinct part psychiatric, alcohol detoxification and rehabilitation units; and

- Perform review and monitoring of hospital denials in accordance with the specifications prepared by HCFA.

2. Quality Objectives

At least one quality objective is required in each of the following areas:

- Quality Objective 1. Reduce unnecessary hospital readmissions resulting from substandard care provided during the prior admission;

- Quality Objective 2. Assure the provision of medical services which, when not performed, have "significant potential" for causing "serious patient complications;"

- Quality Objective 3. Reduce avoidable deaths;

- Quality Objective 4. Reduce unnecessary surgery or other invasive procedures; and

- Quality Objective 5. Reduce avoidable postoperative or other complications.

3. DRG Validation

The contractor shall assure that Medicare payments under PPS are correct by identifying whether the diagnostic and procedural information reported by

hospitals and which resulted in a DRG assignment matches the diagnostic and procedural information contained in patient records. [The contractor is required to conform to PSRO Transmittal #107, governing required review under prospective payment.]

4. Outlier Review

The contractor shall review every case involving day and/or cost outliers for necessity and appropriateness of admission and subsequent care. [The contractor is required to conform to PSRO Transmittal #107 governing required review under prospective payment. Outlier review requirements were modified subsequently.]

5. Other Requirements

In addition to these criteria, the contractor must also comply with special review requirements:

a. Waiver of Liability--The contractor shall make determinations under the waiver of liability provisions contained in the law. If the services are found not to be appropriate or necessary, and if notification has been made to the hospital, payment shall not be made.

b. Subcontracting--The PRO may subcontract with other organizations to perform those aspects of the Scope of Work that lend themselves to localized performance of review WITH THE FOLLOWING IMPORTANT EXCEPTION: the contractor may not subcontract review with an organization which is affiliated with a hosptial, or with an association of such facilities in its area except for quality review. The contractor shall be responsible for the performance of all contractual obligations and shall not be relieved of any responsibility in the event of nonperformance by its subcontractors.

c. Admission Pattern Monitoring (APM)--The contractor shall participate in a HCFA admission pattern monitoring system to assure that the Medicare discharges are appropriate in those hospitals identified by HCFA as having significant increases in quarterly discharges. The contractor shall perform APM in accordance with the specifications.

d. Peer Review--Physicians must be used to review the care provided by their peers. Additionally, the contractor shall use board certified or board eligible physicians or dentists in the appropriate specialty to make reconsideration determinations for the contractor. Other health care practitioners can be consulted where appropriate.

e. Criteria--PRO's would be required to use explicit written criteria based on typical patterns of practice in the geographic area. Where such norms would not be effective in achieving contract objectives, regional, or national norms could be used.

f. Data--PROs would be allowed leeway in choosing methods of obtaining data. PROs would be required to negotiate a memorandum of understanding with the fiscal intermediary (FI). FI data would be available free of charge to the PRO. The PRO could negotiate with the FI to purchase additional data elements not presently collected. Confidentiality of PRO-specific data would be protected.

g. External Relationships, i.e., Relationships with Providers and Third-Party Payors

(1) The contractor shall assume review in hospitals, (including denial determinations) in its area according to the timetable negotiated with HCFA and included in its contract and shall comply with all requirements concerning relationships with hospitals specified in regulation.

(2) Confidentiality and disclosure requirements must be maintained as provided for in the law.

h. Sanctions--The contractor shall be responsible for initiating sanction recommendations as appropriate.

i. Abuse Issues--The contractor shall make available to HCFA the medical expertise necessary to render medical necessity or quality of care decisions on cases referred by Medicare contractors, the DHHS' Office of the Inspector General, or HCFA, and shall provide written evaluations of all cases submitted within 45 days of the receipt of the case.

j. Reconsiderations--The contractor shall provide a reconsideration, as a result of its own medical necessity or appropriateness of care denial determination, upon the request of a beneficiary or legal representative, practitioner, or provider.

D. PPS Regulations

On January 3, 1984, the Secretary issued final regulations implementing the prospective payment system provision of the "Social Security Amendments of 1983." These regulations specified that hospitals are required to have an agreement with a PRO beginning October 1, 1984. This was later modified by the "Deficit Reduction Act of 1984," moving the date to November 15, 1984. Under the agreement, the PRO is required to review on an ongoing basis: 1) the appropriateness of the hospital's admissions, admission patterns, discharges, lengths of stay, transfers, and servies furnished in outlier cases; 2) the validity of the hosptial's diagnostic and procedural information; and 3) the completeness, adequacy, and quality of the services furnished in that hospital.

The regulations require HCFA to monitor hospital discharge rates. If these rates increase significantly, a report will be sent to the medical review entity (generally a PRO) for analysis. If the entity finds a pattern of unnecessary or inappropriate admissions, it must intensify medical review activities in that hospital.

The January regulations contained certain provisions relating to physician attestation of the diagnosis and procedures performed. Final rulemaking, issued August 31, 1984, modified these requirements. Under the August regulations, a physician must certify that the narrative descriptions of the principal and secondary diagnosis and the major procedures performed are accurate and complete to the best of his/her knowledge. In addition, the hospital must have on file a signed acknowledgment that the physician has received a notice stating that anyone who misrepresents, falsifies, or conceals essential information would be subject to fine, imprisonment, or civil penalty. The acknowledgment must be signed once a year.

The medical review entity is required to review, at least every three months, a random sampling of discharges to validate the diagnosis related groups (DRGs) to which inpatient cases are assigned. If the information attested to by the physician is inconsistent with the hospital's DRG assignment, appropriate assignments (and payment recalculations) must be made.

The PPS regulations specify that HCFA can deny payment when a medical review entity finds that a hospital has misrepresented admissions, discharge, or billing information or has taken an action that results in the unnecessary admission of an individual entitled to Part A benefits, unnecessary multiple admissions of an individual, or other inappropriate medical or other practices. These decisions may be appealed. Sanction determinations with respect to patterns of inappropriate admissions and billing practices for the purpose of circumventing the DRG system are to be made by the Inspector General.

E. PRO Contracts

HCFA completed the PRO contracting process November 9, 1984. Fifty four contracts were signed at a total cost of $301,594,306. The majority of contracts went to PSROs or PSRO-related groups. In two States (Nebraska and New York) medical societies were chosen as contractors. In one State (Idaho), the fiscal intermediary was selected. PRO contracts focus on review of inpatient hospital services.

On August 6, 1984, HCFA issued a program directive outlining the contents of PRO agreements with hospitals. All hospitals were required to sign such agreements with PROs by November 15, 1984. In certain instances, hospitals are operating under informal oral agreements while working out the details of their formal agreement.

The following is a brief overview of admissions and quality objectives contained in PRO contracts:

- Admission Objective 1 (reducing admissions for procedures that can safely be performed in an ambulatory surgical setting or on an outpatient basis) - Most common targets are capal tunnel, cataract and lens, endoscopy, dilation and curettage, foot, cystoscopy, and gastroscopy procedures.

- Admission Objective 2 (reducing inappropriate or unnecessary admissions or invasive procedures) - Admissions for esophagitis or gastroenteritis, medical back problems, lens procedures, and chronic obstructive pulmonary diseases are most commonly cited targets.

- Admission Objective 3 (reducing inappropriate or unnecessary admissions by specific practitioners or specific hospitals)- Majority of PROs will concentrate on specific hospitals.

- Quality Objective 1 - Focuses on reducing unnecessary admissions due to substandard care in previous admissions.

- Quality Objective 2 (assuring the provision of medical services that when not performed have "significant potential" for causing serious patient complication) - Generally concentrates on pharmaceuticals that should be given in specific circumstances, such as heparin, prophylactic antibiotics, and aminoglycosides.

- Quality Objective 3 (reducing the risk of mortality associated with selected procedures and/or conditions requiring hospitalization) - PRO will be focusing primarily on reducing deaths from myocardial infarctions by improving emergency protocols.

- Quality Objective 4 (reducing unnecessary surgery or other invasive procedures) - Transurethral prostatectomy is most commonly cited target.

- Quality Objective 5 (reducing avoidable postoperative complications) - Urinary tract infections and complications of cholecystectomy are most common targets.

The estimated nationwide impact targets for admissions objectives are:

- 595,000 inappropriate inpatient procedures shifted to outpatient settings;

- 290,000 fewer unnecessary admissions or procedures; and

- 425,000 fewer unnecessary admissions by specific hospitals or physicians.

The estimated nationwide impact of quality objectives is:

- o 84,000 fewer admissions because of substandard care;
- o 38,000 fewer unnecessary invasive procedures;
- o 32,000 fewer complications; and
- o 6,000 fewer mortalities.

F. Medical Review

In March 1985, HCFA issued interim program manual instructions for medical review procedures. These guidelines are basically a revision of PSRO transmittal #107, which governed required review activities under prospective payment. Several changes are included in the instructions which affect small and rural hospitals.

1. DRG Validation

PROs are responsible for conducting DRG validations to ascertain that the diagnostic and procedural information that led to the DRG assignment is substantiated by the medical record. The instructions reduce the sample size of cases for DRG validation in small hospitals. The new required sample size is as follows:

Universe	Sample Size	Reject Level
1-25	10	
26-90	19	2.5 percent
91-150	25	or 3 cases
151-400	30	whichever
401-900	45	is greater
901-1700	50	
1701 or more	3 percent	

When a significant pattern of errors is identified (defined as errors on 2.5 percent or 3 cases, whichever is greater), intensified review is required. DRG validation sample reviews are conducted quarterly onsite at the hospital.

In the case of hospitals with 360 or fewer Medicare discharges for the last fiscal year, the DRG validation must be performed onsite at the hospital at least once a year. The other three quarterly reviews may be performed with records submitted to the PRO (offsite) or onsite, at the PRO's discretion. The instructions revise the policy on notifying hospitals of specific cases to be included in the onsite DRG validation review. The new policy requires notification of two working days (rather than no more than 24 hours) prior to such review.

The instructions also add sections explaining requirements for physician attestation for DRG adjustment bills.

2. Outlier Review

PROs are required to review atypical cases known as "outliers." These are cases that have an extremely long length of stay or extraordinarily high costs. The interim manual instructions reduce the level of review required for day and cost outliers from 100 percent to 50 percent of cases. When a significant pattern of cases with denied days (for day outliers) or denied charges exceeding $500 (for cost outliers) has been identified, the PRO is required to increase its review for the next quarter to 100 percent. A significant pattern occurs when 2.5 percent of the total reviews completed during the quarter or three cases, whichever is greater, are found to have either denied days or denied charges exceeding $500. If denials fall below the threshold in the subsequent quarter, the PRO may return to the 50 percent sampling procedure.

3. Other Provisions

The instructions also include several additional changes. Incorporated in the manual is the policy on review of noncovered admissions with a covered level of care rendered during the stay.

The instructions specify preadmission and preprocedure review and verification requirements. Cases subject to such review which are not identified to the PRO in a timely fashion for preadmission or preprocedure review, are subject to 100 percent retrospective payment review.

The instructions also outline documentation requirements for PROs. PROs are required to document and retain a record of all initial denial determinations and changes as a result of DRG validation for 6 years. The PRO is further required to retain its records and documentation of required review activities for the duration of the contract period.

The interim program manual instruction does not apply to the territories or to States with approved waivers of the PPS system (i.e., Maryland, Massachusetts, New Jersey, or New York). There will be a separate issuance for these States and territories.

III. ISSUES

A. Delay in Issuance of Regulations

In April 1984, the Department issued proposed rule-making concerning data confidentiality and sanctions. Proposed rule-making concerning review procedures and reconsiderations and appeals were issued in July 1984. In January 1985, final regulations on these four subjects were transmitted by the Department to the Office of Management and Budget (OMB). The final rules as transmitted to the OMB were similar in substance to the proposed rule-making though they contained a number of technical modifications. Final regulations were issued April 17, 1985.

The failure to issue final regulations prompted the American Hospital Association (AHA) to file suit on January 29, 1985, in the United States District Court for the District of Columbia. The suit was filed against the Secretary for failure to comply with the Administrative Procedures Act in implementing the PRO program. The suit contends that the Department acted arbitrarily in setting up PROs. It notes that the Department has failed to issue a complete set of regulations to carry out the requirements of law and that PSRO Transmittals, PRO contract provisions, and PRO program directives govern many aspects of the programs's operation. The AHA suit challenges the lack of public accountability as reflected in the fact that contracts have been let for a program on which public comments have not been incorporated in the form of final regulations. The suit further declares that the Secretary's

refusal to act upon the AHA's petition for rulemaking (dated October 10, 1984), is arbitrary and capricious.

B. Waiver of Liability

Under current Medicare law, payment may be made to an institutional provider of services for certain uncovered or medically unnecessary services furnished to an individual, if the provider could not have known that payment would be disallowed for such items or services. Hospitals, skilled nursing facilities, and home health agencies participating in Medicare are presumed to have acted in good faith, and therefore receive payment for services later found to be uncovered or unnecessary, if their total denial rate on Medicare claims is less than certain prescribed levels.

A hospital or home health agency must have a denial rate that does not exceed 2 1/2 percent and a skilled nursing facility must have a rate that does not exceed 5 percent. The denial rate is determined by the percentage of days or visits billed by the provider as covered which are later determined to be noncovered when the bill is reviewed. The denial rate, which was previously based on the total number of cases, is now based on the number of cases reviewed. Facilities are now more likely to hit the trigger and therefore lose their favorable waiver status. This is expected to result in additional program savings since fewer payments will be made for uncovered or medically unnecessary services.

On February 12, 1985, the Department issued proposed rulemaking which would end the favorable presumption status for providers. Under the proposed rules, payment could be made on an individual case basis only if the provider could show that it did not know or could not be expected to know that services were uncovered or unnecessary. A provider would be deemed to have knowledge

that payment could not be made for noncovered items or services if it had been notified previously of a pattern of inappropriate utilization of a similar or reasonably comparable service and had not taken corrective action after passage of a reasonable time period.

The Department, in the preamble accompanying the proposed rule-making, indicated that continued use of an administrative presumption to determine provider liability is no longer justified. It noted that implementation of the prospective payment system for hospitals should significantly lower the volume of claims involving length of stay denials. Intermediaries and PROs would therefore be in a better position to review specific PPS denials. The preamble also cited the March 1983 GAO report which recommended moving to case by case determinations.

The proposed rule-making has generated a number of negative comments. The AHA, in its comments on the regulations, indicated that the proposed rules appear to be based on the incorrect assumption that the same criteria and procedures can be used to establish knowledge for all retroactive denials subject to a waiver determination. However the AHA states that there is a substantive difference between determining knowledge when the denial was based on a definitive coverage policy appliable to all patients, or when the denial was based on general medical review criteria which identifies when care is appropriate, not when it is not appropriate. The AHA thus feels it is essential to retain a certain favorable presumption or margin of tolerance that recognizes the providers' obligations to provide care to beneficiaries when the need is uncertain.

The American Medical Peer Review Association (AMPRA) also notes that while the proposed rule-making eliminates the criteria for a favorable waiver presumption, it does not eliminate the waiver of liability or the provider's

right to appeal a waiver determination. However, AMPRA notes that under the proposed rule, the PRO would be required to define patterns of inappropriate utilization.

C. Rural Hospitals

It has been suggested that a large burden of PRO review has fallen on small and rural hosptials. One complaint has been that hospitals have been required to mail records to the PRO. This issue was partially addressed in the recent manual instructions which allow PRO's to perform quarterly on-site reviews at small hospitals.

Another issue relates to the relative proportion of rural hospitals which have exceeded the review trigger (2.5 percent or 3 cases, whichever is greater) and are thus subject to expanded medical review. PRO review in rural hospitals has identified a number of cases not meeting medical necessity criteria for inpatient admissions. In many instances this can be attributed to the absence of alternative health care facilities in the immediate area capable of providing services on an outpatient basis. Services previously provided on an inpatient basis near the patient's home may now in some cases be transfered to an outpatient facility located at a considerable distance. Some physician reviewers may therefore have to balance the preferences and needs of individual patients with the performance goals of PRO contracts.

Rural hospitals have also expressed concern that they may lose their favorable presumption status under the waiver of liability provision as a result of only a few inappropriate admissions.

D. Pennsylvania Contract

In October 1984, the Department entered into a contract with the Pennsylvania Peer Review Orgnaization (PaPRO) to serve as the PRO for the State. The organization has experienced a number of performance problems. Through the end of January 1985, it had conducted reviews on only 18 percent of the cases necessary to maintain a current level of review. The organization delayed signing a data processing subcontract, delayed sending out performance criteria to hospitals, and failed to validate performance objectives contained in its contract. Some of the problems have been attributed to difficulties in obtaining data from one of its fiscal intermediaries, Western Pennsylvania Blue Cross, and in hiring staff.

Despite efforts to develop a corrective action plan, the organizaiton was facing a backlog of 53,000 claims in mid-March. On March 20, 1985, the Department issued a Notice of Intent to Terminate. However, if PaPRO takes specific actions including eliminating its backlog, it could forestall the termination action.

PaPRO has informed the Department that it intends to stay in the program, make the requisite corrections, and avail itself of the procedures specified in the law for organizaions receiving termination notices. These procedures require the Secretary to "provide the organization with an opportunity to provide data, interpretations of data, and other information pertinent to its performance under the contract." The data is to be reviewed by a panel appointed by the Secretary and the findings submitted to the Secretary and made availalble to the organization. The Secretary may accept or not accept the panels' findings. The Secretary may, with the concurrence of the organization, modify the scope of the contract. The Secretary

may terminate the contract upon 90 days after the panel has submitted a report or earlier if the organization so agrees. The law does not make provision for assigning review (or backlogged review) to another entity during termination procedings.

E. Super PRO

In March 1985, HCFA issued a notice advising potential bidders of the availability of the Request for Proposal (RFP) for a medical evaluation team for the PRO program. This entity is sometimes referred to as a Super PRO. HCFA is seeking an independent, professionally recognized organization of physicians, registered nurses, registered records administrators or other health professionals to assess the accuracy of medical determinations made by PRO's. The assessments are to focus on admissions review and DRG validations. The major concern of Super PRO review will be the quality of PRO decision making. The Super PRO is to sample PRO decisions to determine whether peer review is being delivered in a fair, medically defensible manner and that review is not endangering the health of any Medicare beneficiary.

The current RFP is the second round in the Super PRO bidding process. The scope of work outlined in the previous RFP was considered too broad. As a result, the bids received exceeded the budget and were significantly different in their proposed plans of operation. The current bid is intended to appeal to a wider variety of organizations. The earliest date to let a Super PRO contract is May 1985. There is some concern that the Super PRO will have insufficient time to evaluate PRO performance prior to the start of the PRO contract renewal process and that it would therefore not have much input in that process. However, the major evaluation of individual PRO performance is expected to be conducted by HCFA regional offices.

F. Targets

The PRO contracts contain quantifiable objectives relating to certain goals such as reducing the number of admissions, and shifting inpatient procedures to outpatient settings.

When the legislation creating these new peer review organizations was discussed, there was considerable discussion concerning how an arrangement for peer review might be designed so as to address different quality and utilization problems in different communities. As a result of this concern, emphasis was placed on contract negotiations targeted on documented problems in that specific community. Also of concern was the ability of the Government to judge the effectiveness of these new organizations. There had been a great deal of difficulty in evaluating the former PSROs because of the lack of measurable criteria. The response to this problem was to require by law that the contracts with the new organizations "contain negotiated objectives against which the organization's performance will be judged, and negotiated specifications for use of regional norms, or modifications thereof, based on national norms for performing review functions under the contract."

At the Committee's July 1984 hearing, several witnesses expressed concerns relating to the bases for the objectives, the appropriateness of the objectives chosen, and the willingness of HCFA to alter these objectives if they prove to be inappropriate. The Department responded to these concerns by emphasizing that performance-based objectives are flexible targets which can be renegotiated where circumstances warrent. The Department reports that as of mid-March certain modifications had been made in parts of objectives in individual contracts. However, requests had not been received for significant modifications in the targets.

G. Manual Instructions

HCFA issued interim manual instructions on medical review in March 1985, subsequent to the negotiation of the PRO budgets. The accompanying statement indicated that the net result of the changes is estimated to be a 5 percent reduction in total workload cost over the remainder of the contract period. However, AMPRA has suggested that the changes to the fixed price contracts may actually increase costs. Some problem areas cited are reprogramming necessitated by changes in data requirements for transfers and readmissions, notification of potential third party liability, and requirements for review of noncovered items or services.

The AHA notes that the manual instructions address many of the concerns previously identified by the AHA. However, it has identified some remaining problem areas, including the fact that hospitals must still bear the cost of sending records to the PRO (though the volume has been substantially reduced) and the concern that some of the preadmission review requirements seem unreasonable.

H. Preadmission Screening

Before a PRO denies an admission under preadmission review, the attending physician must be given an opportunity to comment. If the PRO decides that denial is appropriate, it must notify the beneficiary, provider, attending physician and fiscal intermediary. If, despite the denial, the beneficiary is subsequently admitted to the hospital, payment may not be made for the admission unless the PRO decision is overturned during the reconsideration or appeals process.

Some physicians have questioned what they should do when a denial determination has been made but they feel the patient should be hospitalized. They note that the physician is ultimately liable for the care of the patient. Cases subject to initial denial determinations may be overturned during the appeals process. Further, as physicians gain experience with the review criteria, fewer cases may be subject to such disagreements.

I. Other Issues

PRO review is currently restricted to review of inpatient hospital services. It has been suggested that the program should gradually expand its scope of review into other settings. PROs are not reviewing outpatient services which are expected to increase in response to the PPS system. Further, while PROs are reviewing necessity of inpatient admissions for certain surgical procedures, they are not reviewing the medical necessity of such services when performed in other settings such as ambulatory surgical centers.

United States Senate
WASHINGTON, D.C. 20510

Senator Dole will be submitting an opening statement for the Health Subcommittee Hearing of April 19, 1985 on Peer Review Organizations.

STATEMENT

OF

SENATOR DAVE DURENBERGER

SENATE FINANCE COMMITTEE HEARING

ON

PEER REVIEW ORGANIZATIONS

APRIL 19, 1985

THE PURPOSE OF TODAY'S HEARING IS TO TAKE A READING ON THE PROGRESS IN IMPLEMENTING THE PEER REVIEW ORGANIZATION PROGRAM (PRO PROGRAM) FOR MEDICARE. THIS PROGRAM, ESTABLISHED IN TEFRA TO REPLACE THE OLD PSROs WENT INTO EFFECT LAST YEAR.

THE PRO PROGRAM WAS DESIGNED WITH THE PROBLEMS OF THE PSRO EXPERIENCE IN MIND. IT WAS GIVEN THE SAME DUAL GOALS AS THE PSROs OF MONITORING UTILIZATION OF HEALTH CARE SERVICES BY MEDICARE BENEFICIARIES AND ASSURING THAT BENEFICIARIES RECEIVE HIGH QUALITY CARE. BUT, THE NEW PRO PROGRAM WAS GIVEN A CLEARER DIRECTION AS TO THE INVOLVEMENT OF PHYSICIANS AND REQUIREMENTS FOR ACCOUNTABILITY. THE PROs WERE ALSO CONCEIVED AS AGENCIES WHICH WOULD SERVE THE PRIVATE AS well AS THE PUBLIC SECTOR.

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WE WANTED THEM TO CONTRACT WITH PRIVATE EMPLOYERS, PAYERS AND OTHERS WHO REQUIRE UTILIZATION AND QUALITY REVIEW FOR THE HEALTH CARE SERVICES THEY PURCHASE.

IT IS NOT A SIMPLE PROCESS TO DEVELOP AND IMPLEMENT A PROGRAM WITH SUCH BROAD GOALS. THERE WERE DELAYS IN START-UP, AND THE TRANSITION PERIOD TO THE NEW PRO PROGRAM WE LIVED THROUGH LAST YEAR WAS NOT EASY. IT WAS ESPECIALLY DIFFICULT GIVEN THE NATURAL MISTRUST BY PROVIDERS AND BENEFICIARIES OF THE FEDERAL GOVERNMENT.

AS I TRAVELED AROUND MINNESOTA AND THE REST OF THE COUNTRY LAST YEAR, I HEARD A LOT OF COMPLAINTS ABOUT THE NEW PROGRAM. THE RURAL HOSPITALS SAW BURDENSOME REVIEW REQUIREMENTS. THE PHYSICIANS SAW PRE-ADMISSION SCREENING AS A THREAT TO THEIR JUDGEMENT AND TO THE BEST INTEREST OF THEIR PATIENTS. PROVIDERS COMPLAINED ABOUT THE PERFORMANCE CRITERIA IN THE PRO CONTRACTS. AND NO ONE BOTHERED TO TELL MEDICARE BENEFICIARIES WHAT EITHER DRG OR PRO MEANT TO THEM.

THE OBJECTIVE TODAY IS TO DETERMINE HOW FAR WE HAVE COME, WHERE WE ARE GOING, AND HOW BETTER WE CAN GET THERE.

DATA SHOWS US THAT LENGTH OF HOSPITAL STAYS FOR MEDICARE PATIENTS IS DOWN THROUGHOUT THE COUNTRY. THIS IS TO BE EXPECTED BECAUSE OF THE INCENTIVES IN THE NEW DRG SYSTEM FOR MEDICARE AND BECAUSE OF OTHER PRESSURES ON HOSPITAL USE. ADMISSIONS FOR MEDICARE BENEFICIARIES ARE ALSO DOWN. PART OF THE CREDIT FOR THIS SUCCESS CAN BE ATTRIBUTED TO THE PRO PROGRAM.

ON THE OTHER HAND, THE ANECDOTAL HORROR STORIES, ABOUT PREMATURE DISCHARGE OF MEDICARE PATIENTS FROM THE HOSPITALS MOUNT. LAST WEEK I READ A LENGTHY LOS ANGELES TIMES STORY CITING ABUSIVE EARLY HOSPITAL DISCHARGE. THIS STORY WAS BASED ON A HANDFUL OF CASES AND IT MADE IT APPEAR THAT THE EXPERIENCES CITED WERE REPRESENTATIVE OF THE NORM.

I HAVE A FEELING THESE INCIDENTS ARE ISOLATED. BUT, WE DON'T KNOW FOR SURE, AND THE FEDERAL GOVERNMENT HAS A RESPONSIBILITY TO ASSURE THEY ARE NOT REPRESENTATIVE. PROS ARE MEDICARE'S VEHICLE TO ASSURE QUALITY. THEREFORE, IT IS CRITICAL WE EXPLORE WHAT THE PROGRAM CAN DO TO RESPOND TO THE ISSUE OF SUFFICIENT CARE, AS WELL AS, THE APPROPRIATE USE OF HOSPITAL SERVICES. THE GAO HAS DONE SOME PRELIMINARY WORK IN THIS AREA. BUT, HCFA AND THE PROS MUST BE OUR EARLY WARNING SYSTEM FOR PROBLEMS.

IT IS ALSO CLEAR THE THE PROS HAVE BEEN SUCCESSFUL AT MOVING A NUMBER OF SURGICAL PROCEDURES FROM THE INPATIENT TO OUTPATIENT SETTING. THIS CHANGE IS POSITIVE. BUT, IT IS CRUCIAL THAT HCFA AND THE PROS MONITOR THIS INCREASED USE OF THE OUTPATIENT SETTING. I AM PARTICULARLY CONCERNED THAT SOME PROCEDURES IN THE HOSPITAL OUTPATIENT DEPARTMENTS MAY HAVE HIGHER REIMBURSEABLE COSTS THAN THE SAME PROCEDURE ON THE INPATIENT SIDE. AND, WOULD LIKE TO KNOW WHAT HCFA PLANS TO DO ABOUT THESE VARIATIONS IN PAYMENT.

WE ARE NOT TOO FAR FROM THE END OF THE FIRST PRO CONTRACTING PERIOD. IT IS TIME TO EXAMINE HOW HCFA IS ASSESSING PRO PERFORMANCE AND ADJUSTING THE GOALS FOR THE PROGRAM. IT IS IMPORTANT WE DETERMINE WHAT ISSUES CONCERNING ASSESSMENT AND PERFORMANCE ARE MANAGERIAL AND CAN BE HANDLED THROUGH THE REGULATORY PROCESS. AND, WHAT ISSUES WILL REQUIRE THE CONGRESS TO LEGISLATE CHANGES IN THE PROGRAM.

IT IS FORTUNATE THAT THE REGULATIONS GOVERNING THE PROGRAM HAVE FINALLY BEEN PUBLISHED. HCFA'S PLANS FOR THE OPERATION OF THE PROGRAM ARE NOW ON THE TABLE. WE SHOULD BE ABLE AFTER TODAY TO MOVE FORWARD WITH SETTLING THE MAJOR CONCERNS OF ALL THOSE INVOLVED IN THE PROGRAM THE CONGRESS, THE HOSPITALS AND PHYSICIANS, THE PROS AND THE MEDICARE BENEFICIARIES.

THERE IS NO QUESTION THAT MEDICARE IN ITS CURRENT FORM NEEDS A REVIEW PROCESS TO ASSURE APPROPRIATE HOSPITAL USE AND QUALITY OF CARE. IN DEVELOPING THE REVIEW MECHANISM TWO YEARS AGO, THE ONLY QUESTION WAS WHETHER THE MEDICAL PROFESSIONALS WOULD BE RESPONSIBLE FOR THE OVERSIGHT OF MEDICARE HOSPITAL CARE OR WHETHER THE INTERMEDIARIES WOULD. NOT EVERYONE IS COMPLETELY SATISFIED WITH THE PROGRAM, THERE ARE MANY KINKS STILL TO WORK OUT, BUT I WOULD ARGUE THAT CAROLYN DAVIS AND HER COLLEAGUES AND THE PROS, WITH FEW EXCEPTIONS, HAVE DONE A YEOMAN'S DUTY IN MAKING THIS PROGRAM WORK IN A RELATIVELY SHORT TIME. CONGRESS DECIDED THE PEER ORIENTED APPROACH WAS THE BEST ONE, AND I FIRMLY BELIEVE THE PRO PERFORMANCE TO DATE HAS BORNE THIS OUT. BUT STOCKMAN'S OMB WILL CONTINUE TO SNIFF FOR ANY EXCUSE TO DUMP PEER REVIEW.

So I want to be sure our first two start-up years are successful, the regulations completed, and the preparation for more innovative second round PRO contracting underway.

One of the major issues raised in the regulations printed yesterday was the provision allowing the release of aggregate hospital data by the PROs. This data offers a potentially useful resource for the provider and consumer alike. Consumer choice, in the health care marketplace obviously depends on having sufficient information. And my support for consumer choice is well known.

I would, however, like to caution that raw medical data can be as much an obstacle as a help to understanding quality in health care. Information can be misleading and misinterpreted if released in an inappropriate form. For example, high death rates for one hospital may be a meaningful indicator of a problem, while at another institution it may merely be in the nature of the complex specialty services that a hospital provides.

SO INFORMATION MUST BE APPROPRIATE TO ITS USE AND FOR ITS USERS. ~~USES~~. EVENTUALLY, HEALTH PLANS WILL USE THEIR EXPERTISE TO PLACE THEIR BENEFICIARIES WITH THE HIGHEST QUALITY AND MOST EFFICIENT PROVIDERS. PLANS WILL NEED INFORMATION TO MAKE THESE DECISIONS AND WILL KNOW HOW TO USE IT. UNTIL THEN, WE NEED TO PROCEED CAREFULLY IN UTILIZING INFORMATION WE MAY NOT FULLY UNDERSTAND.

IN CONCLUSION, I WOULD LIKE TO STRESS THE POINT THAT PAYMENT UNDER MEDICARE FOR INPATIENT HOSPITAL CARE BY DRGS AND THE IMPLEMENTATION OF THE HMO/COMPETITIVE MEDICAL PLAN OPTION HAS FUNDAMENTALLY CHANGED THE MEDICARE PROGRAM.

THE INCENTIVES INHERENT IN BOTH NEW PAYMENT AND DELIVERY MODELS TEND TO DOWNPLAY THE USE OF EXPENSIVE HOSPITAL SERVICES. IT IS IMPORTANT AS WE ASSESS THE PRO PROGRAM THAT WE MAKE SURE IT IS GEARED TO THE CHANGING NATURE OF THE HEALTH CARE SYSTEM AND THE REQUIREMENTS OF THE UTILIZATION REVIEW DON'T OUTWEIGH THE QUALITY ASSURANCE ASPECT OF ITS RESPONSIBILITIES.

Statement of Senator George J. Mitchell
Senate Finance Subcommittee on Health
Oversight Hearing
Peer Review Organization Program
April 19, 1985

Mr. Chairman, I thank you for your continued interest in the Peer Review Organization Program, and your commitment to Congressional oversight of its progress and problems. I share your interest in the program and have become aware of some of the concerns which have arisen from its implementation in my home State of Maine.

The intent of Congress in passing legislation authorizing the Peer Review Organization Program was to review the quality, necessity, reasonableness and appropriateness of health care services furnished under Medicare. It was intended to serve a quality control function for a health care system undergoing dramatic change as a result of the new Prospective Payment System.

Recent reports released by the General Accounting Office and the Senate Special Committee on Aging indicate that Medicare patients may be being discharged from hospitals "quicker and sicker" since the implementation of the DRG system. We do not yet know how accurate this data is, or how

widespread such practices are. But in light of this information, it is more important than ever to assure that the PRO performs its intended function in assuring quality of care for the nation's elderly.

I support the concept of peer review. It is important for physicians and other health care professionals to be monitored and evaluated by their peers as a means of assessing their performance and working to improve the quality of care being offered to Medicare patients. This Committee has a responsibility to monitor the PRO Program to assure that the intent of Congress is being carried out.

I look forward to hearing testimony from Dr. Davis and hope that this Committee can work with the Health Care Financing Administration to resolve some of the issues of concern raised by health care professionals regarding the implementation of the Peer Review Organization.

Senator DURENBERGER. The hearing will come to order.

The purpose of today's hearing is to take a reading on the progress in implementing the Peer Review Organization Program for Medicare, the program established in TEFRA to replace the old PSRO and that went into effect last year, designed to put the problems of the PSRO experience in mind and was given the same dual goals of the PSRO. But the new PRO program was given a clearer direction as to the involvement of physicians and the requirements for accountability.

The PRO's were also conceived as agencies which would serve the private as well as the public sector. We wanted them to contact with private employers, payers and others, who require utilization quality review for the health care services they purchase.

It is not a simple process to develop and implement a program with such broad goals. There were delays in startup; the transition period of the new program we lived through last year wasn't easy. It was especially difficult given the natural mistrust by providers and beneficiaries of anything involving the Federal Government—especially if you are going to send them all out with sweatshirts. [Laughter]

As I traveled around Minnesota and the rest of the country last year, I heard a lot of complaints about the new program. Rural hospitals saw burdensome review requirements; the physicians saw preadmission screening as a threat to their judgment of the best interests of their patients; providers complained about the performance criteria in the PRO contract; and no one bothered to tell Medicare beneficiaries what either DRG or PRO meant to them.

The objective today is to determine how far we've come, where we are going, and how better we can get there. Data shows us that length of hospital stays for Medicare patients is down. This is to be expected, because of the incentives in the new DRG system and other pressures.

Admissions for Medicare beneficiaries are also down. Part of the credit can be attributed to the PRO Program. On the other hand, anecdotal horror stories like the one that I read, on the front page of the Los Angeles Times last week continue to cite abusive early hospital discharge. Usually they are based on a handful of cases and made to appear that experiences cited were representative of the norm, and hopefully we will talk about that today.

But we don't know for sure whether those are isolated incidents, and the Federal Government has a responsibility to the Medicare beneficiaries to assure that they are not representative.

PRO's are Medicare's vehicle to assure quality; therefore, it is critical that we explore what the program can do to respond to the issue of sufficient care as well as appropriate use of hospital services.

It is clear that the PRO's have been successful at moving a number of surgical procedures from inpatient to outpatient. This change is positive, but it is crucial that HCFA and the PRO's monitor this increased use of an outpatient setting.

I am particularly concerned that some procedures in the hospital outpatient department may have higher reimbursable costs than the same procedure on the inpatient side, and I would like to know

what HCFA plans to do about these variations in payment. I would like to know about it before we adopt our budget resolution.

We are not too far from the end of the first PRO contracting period, so it is also time to examine how HCFA is assessing PRO performance and adjusting the goals for the program. It is important we determine what issues concerning assessment and performance are managerial and can be handled through the regulatory process, and what issues if any will require the Congress to legislate changes in the program.

It is fortunate that the regulations governing the programs have finally been published. [Laughter.]

HCFA's plans for the operation of the program are now on the table; we should be able, after today, to move forward with settling the major concerns of all of those involved in the program—the Congress, hospitals, physicians, pros, and Medicare beneficiaries.

There is no question that Medicare in its current form needs a review process to assure appropriate hospital use and quality care. In developing the review mechanism 2 years ago, the only question was whether the medical professionals would be responsible or whether intermediaries would.

Not everyone is completely satisfied with the program—there are many kinks still to work out—but I would argue that Carolyne Davis, and her colleagues, and the pros, with few exceptions, have done a yeomen's duty in making the program work in a relatively short time.

Congress decided the peer-oriented approach was the best one. I firmly believe the PRO performance to date has borne this out. but Dave Stockman's OMB will continue to sniff for any excuse to dump peer review; so I want to be sure our first two startup years are successful, the regulations completed, and the preparation for more innovative second-round PRO contracting underway.

One of the major issues raised in the regulations printed yesterday was the provision allowing the release of aggregate hospital data by the PRO's. This data offers a potentially useful source for the provider and consumer alike. I would like to caution, however, that raw medical data can be as much an obstacle as a help to understanding quality in health care. Information can be misleading and misinterpreted if released in an inappropriate form. So, information must be appropriate to its use and for its users.

Eventually, health plans will use their expertise to place beneficiaries with the highest quality and most efficient providers. Plans will need information to make these decisions and will know how to use them. Until then, we need to proceed carefully in utilizing information we may not fully understand.

So, with that, George, do you have a statement?

Senator MITCHELL. I have a very brief statement, Mr. Chairman.

I thank you for your continued interest in the Peer Review Organization Program and your commitment to congressional oversight of its progress and problems. I share your interest in the program. I have become aware of some of the concerns which have arisen from its implementation in my home State of Maine and in other areas.

The intent of Congress in passing legislation authorizing the Peer Review Organization Program was to review the quality, ne-

cessity, reasonableness, and appropriateness of health care services furnished under Medicare. It was intended to serve a quality control function for a health care system undergoing dramatic change, in part as a result of the new prospective payment system.

Recent reports released by the General Accounting Office and the Senate Special Committee on Aging indicate that Medicare patients may be being discharged from hospitals quicker and sicker since the implementation of the DRG system. We do not yet know how widespread such practices are; but in light of this information it is more important than ever to assure that the PRO performs its intended function in assuring quality of care for our Nation's elderly.

I support the concept of peer review. It is important for physicians and other health care professionals to be monitored and evaluated by their peers as a means of assessing their performance and working to improve the quality of care being offered to Medicare patients.

This committee has the responsibility to monitor the PRO Program to assure that the intent of Congress is being carried out.

I look forward to hearing testimony from Dr. Davis and the other witnesses. I hope this committee can work with the Health Care Financing Administration to resolve some of the issues of concern raised by some health care professionals regarding the implementation of the PRO Program.

Thank you, Mr. Chairman.

Senator DURENBERGER. Thank you, George.

Carolyne, welcome. Your full statement will be made part of the record.

STATEMENT OF CAROLYNE K. DAVIS, PH.D., ADMINISTRATOR, HEALTH CARE FINANCING ADMINISTRATION, ACCOMPANIED BY PHILIP NATHANSON, DIRECTOR, HEALTH STANDARDS AND QUALITY BUREAU, HEALTH CARE FINANCING ADMINISTRATION

Dr. DAVIS. Thank you, Mr. Chairman.

First of all, I would like to introduce Mr. Phil Nathanson. He is the Director of the Health Standards and Quality Bureau, on my left.

As you know, the PRO legislation did challenge us to create a strong and effective quality and utilization review program, and I think despite the usual problems that accompany the early stages of the implementation of such an ambitious program, I believe we have met the challenge.

I would just like to share with you this morning our progress and some of the problems we have encountered, how we are going about solving those, and where we think we will go in the future.

To begin with, we completed the contracting process on November 9 with 54 peer review organization contracts signed at a total cost of about $302 million over a 2-year period.

I am also pleased to report that as of April 17 all four regulations implementing the PRO Program were published in final, and these regulations put in place the final regulatory authorities of the PRO Program. I think that will facilitate completion of the im-

plementation stage itself. Generally, however, I think that the implementation is progressing on schedule and that the PRO's all seem to be performing reviews.

The fiscal intermediaries and the hospital agreements are being successfully negotiated, although there are some PRO's that are still experiencing a few problems finalizing written agreements with hospitals. However, obtaining access to hospitals for review hasn't been a problem, even in those cases.

I believe the most common implementation problems have been in the exchange of data between the peer review organization and the fiscal intermediaries, and we believe that most of those problems have now been resolved. But, like any new program, we are making changes as we gain in our operating experience.

As the PRO's have discovered imperfections in their own systems or weaknesses or areas that could be enhanced, we have negotiated changes in those review systems. In fact, we have already renegotiated 36 objectives in 25 different PRO's, and we are currently negotiating others.

There has been some concern that the standard review activities that we ask the peer review organizations to carry out, in addition to their objectives, were quite intensive and burdensome for some providers, especially for the small and rural hospitals. And so, in March we issued instructions which reduced the review of outliers from 100 percent to 50 percent and reduced the DRG validation for hospitals with under 1,600 discharges per year, which will mean that the burden for the review will be decreased in these small rural hospitals by approximately 30 percent.

Because the PRO Program is still relatively new, however, and we have only a few months of data, it is too soon to make any definitive statements about the total PRO impact; but the evidence that we do have is that the PRO's in fact seem to be doing their job.

For example, in Alabama they reported a reduction of over 11,000 unnecessary admissions in 11 different DRG's. Alabama is one of the PRO's that is under 100 percent preadmission review.

In Minnesota, also, during the first 6 months of performance the PRO reports reductions in unnecessary admissions for over 3,600 lens procedures and about 1,200 medical back problems.

Those are just anecdotal evidences, but they are clear evidence.

I do want to stress that all the admission objectives focus only on inappropriate and unnecessary care, and not on a reduction in overall admissions.

The PRO's simply are not denying admissions that do prove to be necessary and appropriate based upon their local and regional standards of practice that are decided by medical people within the peer review area itself.

We do expect much of the effect of the PRO's to be sentinel, resulting from an improvement in physician awareness of more efficient medical treatment. In fact much of the initial quarter's work in terms of the peer review organizations dealt with the implementation of educational programs with the various hospital physician staffs.

We are closely monitoring what the PPS impact is in terms of the PRO review and what that means to the Medicare patients.

We have required the PRO's to submit monthly and quarterly reports on their review activities and on their progress toward meeting the objectives, and these reports are analyzed and validated onsite by inspections once every quarter from our regional offices.

In addition, we are also soliciting a proposal for a super PRO to evaluate the PRO performance. Those proposals are due by May 3, and we intend to award a contract by the end of June.

We will be using our onsite regional evaluations as well as the super PRO analysis and available national data in order to assess the effectiveness of the individual PRO performances and to make determinations as to the renewal of the 2-year contracts.

As the process of implementation continues, we are discovering areas where the current peer review system may need to be tightened and other areas where perhaps additional review is appropriate.

We are beginning to plan for some possible review for outpatient surgery performed in hospitals and ambulatory surgical centers. We will be working with the experts from the hospital community, the ambulatory surgical settings and groups that are involved in medical review in order to determine the best review approach.

Another area of concern for us is the fact that there is a time lag of several weeks to several months between the occurrence of what could be an inappropriate transfer and its review by the PRO. We intend to conduct a series of pilot projects to test the feasibility and the cost of a concurrent review of discharges and transfers in order to determine if there is anything other than an occasional problem. We will be looking at ways of targeting and focusing the review in order to make it cost effective.

One area that has been recently added to the PRO mandate is the quality review of hospitalization in HMO's. We have been working with the industry to develop a review system that will emphasize the quality of care, and I believe we have an agreement on such a system. We are going to be developing criteria using physicians that are familiar with the HMO concept and operations to review HMO care. Our goal is to begin that type of review no later than October of this year.

I think, in summary, Mr. Chairman, I am personally convinced that the efforts that we have outlined are making a positive difference, both for the beneficiaries in terms of improvement in the quality of care as well as in our efforts to contain health care costs.

With that, I would be happy to answer your questions.

[Dr. Davis' written prepared statement follows:]

STATEMENT OF CAROLYNE K. DAVIS, PH.D.

INTRODUCTION

MR. CHAIRMAN AND MEMBERS OF THE SUBCOMMITTEE, I AM PLEASED TO BE HERE TODAY TO BRING YOU UP-TO-DATE ON OUR IMPLEMENTATION OF THE PEER REVIEW ORGANIZATION (PRO) PROGRAM. I AM ACCOMPANIED THIS MORNING BY MR. PHILIP NATHANSON, DIRECTOR OF THE HEALTH STANDARDS AND QUALITY BUREAU. THE PRO LEGISLATION AS DRAFTED BY YOUR SUBCOMMITTEE AND PASSED BY THE CONGRESS, PROVIDED THE DEPARTMENT WITH THE CHALLENGE OF CREATING A STRONG, EFFECTIVE QUALITY AND UTILIZATION REVIEW PROGRAM. DESPITE THE USUAL PROBLEMS THAT ACCOMPANY THE INITIAL STAGES OF IMPLEMENTING SUCH AN AMBITIOUS PROGRAM, I BELIEVE WE HAVE MET THE CHALLENGE. I BELIEVE THAT WE ARE IMPLEMENTING THE PROGRAM IN A MANNER THAT IS IN KEEPING WITH BOTH THE LETTER AND SPIRIT OF THE LAW AND I COMMEND YOUR CONTINUED INTEREST AND SUPPORT. I WOULD LIKE TO SHARE WITH YOU THIS MORNING OUR PROGRESS, SOME OF THE PROBLEMS WE'VE ENCOUNTERED, HOW WE ARE SOLVING THEM, AND WHERE WE EXPECT TO GO IN THE FUTURE.

CURRENT STATUS

I AM PLEASED TO REPORT THAT SINCE I LAST TESTIFIED BEFORE THIS COMMITTEE ON PROS WE HAVE MADE GREAT

PROGRESS IN THE IMPLEMENTATION OF THE PROGRAM. WE COMPLETED THE PRO CONTRACTING PROCESS ON NOVEMBER 9, 1984, WITH 54 PRO AREA CONTRACTS SIGNED AT A TOTAL COST OF $301,594,306 OVER A TWO YEAR PERIOD. FORTY-FOUR OF THE CONTRACTS WERE AWARDED TO PHYSICIAN SPONSORED ORGANIZATIONS, 10 TO ORGANIZATIONS WITH PHYSICIAN ACCESS. OF THESE ORGANIZATIONS, 2 ARE AWARDED TO STATE MEDICAL SOCIETIES (NEBRASKA AND NEW YORK), 3 ARE TO FOR PROFIT ORGANIZATIONS AND IN ONE STATE (IDAHO) THE FISCAL INTERMEDIARY IS PERFORMING THIS FUNCTION. AT THIS TIME ALL 54 PROS ARE IN VARYING STAGES OF IMPLEMENTATION.

I AM ALSO PLEASED TO REPORT THAT AS OF APRIL 17 ALL FIVE REGULATIONS FURTHER IMPLEMENTING THE PRO PROGRAM HAVE BEEN PUBLISHED IN FINAL. THESE REGULATIONS PUT IN PLACE THE FINAL REGULATORY AUTHORITIES OF THE PRO PROGRAM AND WILL FACILITATE COMPLETION OF THE IMPLEMENTATION STAGE. BRIEFLY, THESE REGULATIONS ARE:

- AREA DESIGNATION AND DEFINITION OF ELIGIBLE ORGANIZATIONS -- DESIGNATING 54 PRO AREAS AND REQUIRING ELIGIBLE ORGANIZATIONS TO BE EITHER "PHYSICIAN-SPONSORED" OR "PHYSICIAN ACCESS."

- o CONDUCT OF REVIEW AND MEDICAID RELATIONSHIPS WITH PROs -- OUTLINING THE RELATIONSHIP BETWEEN PROs, FISCAL INTERMEDIARIES, PROVIDERS AND BENEFICIARIES; PROVIDING THAT STATES MAY CONTRACT WITH PROS FOR PERFORMANCE OF MEDICAL AND UTILIZATION REVIEW FUNCTIONS;

- o RECONSIDERATION AND APPEALS -- SETTING FORTH POLICIES AND PROCESSES BY WHICH PRO'S DETERMINATIONS WILL BE SUBJECT TO RECONSIDERATION AND FURTHER APPEALS;

- o CONFIDENTIALITY -- SETTING FORTH RULES GOVERNING THE PROTECTION AND DISCLOSURE OF INFORMATION GENERATED BY A PRO AND ACCESS TO THE INFORMATION BY OTHERS; AND

- o SANCTIONS -- DEFINING THE SANCTION PROCESS UNDER PROs AND IMPLEMENTING PORTIONS OF SECTION 143 OF TEFRA THAT IMPOSE OBLIGATIONS ON HEALTH CARE PRACTITIONERS AND PROVIDERS; REQUIRING PROs TO REPORT VIOLATIONS OF SUCH OBLIGATIONS AND AUTHORIZING THE SECRETARY TO MAKE DECISIONS, BASED ON A PRO'S RECOMMENDATIONS, TO IMPOSE SANCTIONS ON PRACTITIONERS OR PROVIDERS WHO HAVE NOT MET THEIR OBLIGATIONS.

IMPLEMENTATION

GENERALLY, PRO IMPLEMENTATION IS PROGRESSING ON SCHEDULE AND ALL PROS ARE PERFORMING REVIEW. FISCAL INTERMEDIARIES (FIS) AND HOSPITAL AGREEMENTS ARE BEING SUCCESSFULLY NEGOTIATED ALTHOUGH SOME PROS, INCLUDING MINNESOTA AND NEW JERSEY, ARE EXPERIENCING SOME PROBLEMS FINALIZING WRITTEN AGREEMENTS WITH HOSPITALS. OBTAINING ACCESS TO THE HOSPITALS FOR REVIEW, HOWEVER, HAS NOT BEEN A PROBLEM AND WE ARE CONTINUING TO MONITOR THIS SITUATION CLOSELY. WE EXPECT THAT NOW THAT FINAL REGULATIONS HAVE BEEN ISSUED, ALL HOSPITALS WILL COMPLY WITH THE AGREEMENT REQUIREMENT WITHIN 60 DAYS.

THE MOST COMMON IMPLEMENTATION PROBLEMS HAVE BEEN IN EXCHANGING DATA BETWEEN PROS AND FISCAL INTERMEDIARIES. SOME PROS HAVE EXPERIENCED DELAYS IN RECEIVING DATA BECAUSE OF PROGRAMMING PROBLEMS THAT TOOK LONGER THAN WE EXPECTED TO CORRECT. IN SUCH INSTANCES, SOME REVIEW ACTIVITIES WERE DELAYED. WE BELIEVE MOST OF THESE PROBLEMS ARE BEING RESOLVED. WE ARE MONITORING THE DATA EXCHANGE CLOSELY AND ARE WORKING WITH INDIVIDUAL PROS AND FIS.

A FEW AREAS SEEM TO BE EXPERIENCING REVIEW PROBLEMS, EITHER WITH SLOWNESS TO IMPLEMENT REVIEW COMPLETELY OR WITH LACK OF AGGRESSIVENESS IN REVIEW DECISIONS. WHERE THIS OCCURS, WE ARE ASKING FOR CORRECTIVE ACTION PLANS, AND WILL NOT HESITATE TO WITHHOLD FUNDS OR PURSUE TERMINATION ACTION WHEN SUCH ACTIONS ARE WARRANTED.

AS IN ANY NEW PROGRAM, WE ARE MAKING CHANGES AS WE GAIN OPERATING EXPERIENCE. ONE OF THE CONCERNS EXPRESSED BY THIS COMMITTEE AND ELSEWHERE WAS THAT WE WOULD BE TOO RIGID IN ASSURING THAT THE PROS MEET THEIR NUMERICAL OBJECTIVES. HOWEVER, AS THE PROS HAVE DISCOVERED IMPERFECTIONS IN THEIR SYSTEMS, WEAKNESSES OR AREAS THEY COULD ENHANCE, WE HAVE NEGOTIATED CHANGES IN THEIR REVIEW SYSTEMS. WE HAVE ALREADY NEGOTIATED 36 REFINEMENTS IN THE OBJECTIVES OF 25 PROS, AND ARE CURRENTLY NEGOTIATING OTHERS.

FOR EXAMPLE, WE ARE NEGOTIATING REFINEMENTS IN THE OBJECTIVES OF THE RHODE ISLAND PRO AS A RESULT OF THEIR FURTHER STUDY AND VALIDATION OF THEIR DATA. SIMILAR REFINEMENTS OF OBJECTIVES ARE BEING NEGOTIATED IN MAINE, WHERE BASELINE DATA FOR THE DEVELOPMENT OF OBJECTIVES WERE EXTREMELY LIMITED.

AND IN MONTANA AND WYOMING, REFINEMENT NEGOTIATIONS ARE ALSO UNDERWAY. THE NEW JERSEY PRO IS IN THE PROCESS OF REPLACING ITS OBJECTIVES ON THE RISK OF MORTALITY WITH A NEW OBJECTIVE WHICH WE FEEL HAS FAR GREATER POTENTIAL (TO DECREASE THE RISK OF MORTALITY ASSOCIATED WITH CONGESTIVE HEART FAILURE). SO FAR, WE HAVE DISAPPROVED ONLY THREE REQUESTS FOR MODIFICATION.

WE AT HCFA CONTINUE TO WORK WITH THE PROS IN THE DEVELOPMENT AND EXECUTION OF AN EFFECTIVE AND EFFICIENT REVIEW SYSTEM WITH MEANINGFUL OBJECTIVES. TOWARDS THIS END, WE WILL CONTINUE TO BE FLEXIBLE.

ANOTHER CONCERN OF THIS COMMITTEE, MR. CHAIRMAN, WAS THAT THE STANDARD REVIEW ACTIVITIES WE ASKED THE PROS TO CARRY OUT IN ADDITION TO THEIR OBJECTIVES WERE QUITE INTENSIVE AND BURDENSOME FOR SOME PROVIDERS, PARTICULARLY FOR SMALL AND RURAL HOSPITALS. WE PROMISED THAT WHERE WE COULD DO SO WITHOUT COMPROMISING THE EFFECTIVENESS OF REVIEW, WE WOULD REDUCE THE BURDEN. WE HAVE DONE SO. WE ISSUED INSTRUCTIONS IN MARCH WHICH:

- o REDUCE OUTLIER REVIEW FROM 100 PERCENT TO 50 PERCENT; AND

- REDUCE DRG VALIDATION FOR HOSPITALS WITH UNDER 1600 DISCHARGES PER YEAR, WHICH MEANS THAT THE BURDEN FOR REVIEW WILL BE DECREASED FOR THESE HOSPITALS.

IMPACT

BECAUSE THE PRO PROGRAM IS STILL RELATIVELY NEW AND WE ONLY HAVE A FEW MONTHS OF DATA, IT IS TOO EARLY TO MAKE DEFINITIVE STATEMENTS ABOUT PRO IMPACT. IN ADDITION, IT IS STILL TOO EARLY TO SEPARATE OUT THE EFFECTS OF PROS PER SE FROM THE EFFECTS OF REIMBURSEMENT, DEMOGRAPHIC, AND OTHER CHANGES. THE EVIDENCE WE DO HAVE, HOWEVER, IS THAT PROS IN FACT ARE DOING THE JOB. OVERALL, THE PRO PROGRAM OBJECTIVES ARE BEING MET, AND THE PROS ARE HAVING THEIR EXPECTED IMPACT.

FOR EXAMPLE:

- IN MINNESOTA, DURING THE FIRST 6 MONTHS OF PERFORMANCE, THE PRO REPORTS REDUCTIONS IN UNNECESSARY ADMISSIONS FOR OVER 3600 LENS PROCEDURES AND ALMOST 1200 MEDICAL BACK PROBLEMS;

- o ALABAMA REPORTS A REDUCTION OF OVER 11,000 UNNECESSARY ADMISSIONS IN 11 DIFFERENT DRGs;

- o IN KENTUCKY, A REDUCTION OF MORE THAN 21,000 INAPPROPRIATE OR UNNECESSARY ADMISSIONS IS REPORTED.

I WANT TO STRESS THAT ALL ADMISSION OBJECTIVES FOCUS ONLY ON INAPPROPRIATE AND MEDICALLY UNNECESSARY CARE, NOT ON REDUCTIONS IN OVERALL ADMISSIONS. PROs ARE DENYING NO ADMISSIONS THAT ARE NECESSARY AND APPROPRIATE BASED ON LOCAL AND REGIONAL STANDARDS OF PRACTICE FOR THE PRO AREA. IT SHOULD BE NOTED THAT ADMISSIONS FOR THOSE UNDER AGE 65 ARE DROPPING AT A FASTER RATE THAN THAT FOR THE AGED.

WE EXPECT MUCH OF THE EFFECT OF PROs TO BE SENTINEL, RESULTING FROM AN IMPROVEMENT IN PHYSICIAN AWARENESS OF MORE EFFICIENT MEDICINE TREATMENT TECHNIQUES. EVIDENCE THAT THIS IS WORKING IS CLEAR IN DATA WHICH SHOWS THAT IN THE FIRST QUARTER OF FY 1985 PROs HAD DENIAL RATE OF 2.3 PERCENT WHILE THE DROP IN THE MEDICARE ADMISSION RATE WAS 4.9 PERCENT.

BECAUSE OF THE NATURE OF QUALITY REVIEW, WHICH MAKES IT MORE DIFFICULT TO MEASURE, I CANNOT PROVIDE YOU WITH SPECIFIC NUMBERS ON HOW PROS ARE MEETING THEIR QUALITY OBJECTIVES. THESE NUMBERS WILL BE GENERATED BY RETROSPECTIVE STUDIES WHICH ARE TO BE COMPLETED BY THE PROS AROUND THEIR 15TH MONTH OF OPERATION. WE ARE, HOWEVER, MONITORING PROS ON THE SPECIFIC MILESTONES FOR THEIR QUALITY OBJECTIVES TO ASSURE THAT IMPLEMENTATION HAS OCCURRED AND THAT THE AGREED UPON INTERVENTIONS ARE TAKING PLACE. WE ARE ALSO MONITORING A SAMPLE OF THE CASES REVIEWED BY PROS TO ASSURE THAT QUALITY PROBLEMS WERE ADDRESSED. IT IS MY BELIEF, SUPPORTED BY THE ON-SITE MONITORING BY HCFA THAT SIGNIFICANT QUALITY ASSURANCE ACTIVITIES ARE TAKING PLACE AND WILL RESULT IN IMPRESSIVE IMPACT.

IN ADDITION TO AREA-SPECIFIC QUALITY AND ADMISSION OBJECTIVES, THERE ARE OTHER AREAS IN WHICH WE EXPECT SIGNIFICANT IMPACT. PROS ARE REVIEWING THE MEDICAL RECORDS OF READMISSIONS WITHIN 7 DAYS OF DISCHARGE AND TRANSFERS TO ASSURE NOT ONLY PROPER UTILIZATION, BUT ALSO TO DETERMINE THAT HIGH QUALITY CARE IS NOT BEING COMPROMISED. ALSO, FIS REVIEW ALL TRANSFERS TO HOSPITAL BASED SKILLED NURSING FACILITIES (SNF) AND

30 PERCENT OF ALL TRANSFERS TO NONHOSPITAL BASED SNFS TO ASSURE GOOD QUALITY CARE AND PROPER UTILIZATION. FEWER THAN 200 SUCH CASES HAVE BEEN REFERRED TO THE REGIONAL OFFICES SO FAR. THIS NUMBER IS INSUFFICIENT TO INDICATE ANY PATTERNS. HOWEVER, WE ARE CURRENTLY DEVELOPING DIRECTIONS FOR SPECIFIC REVIEW AND INTERVENTION OF CASES REPRESENTING POOR CARE, INCLUDING PREMATURE DISCHARGE.

MONITORING

PLEASE BE ASSURED MR. CHAIRMAN, THAT WITH THESE RAPID CHANGES OCCURING IN THE HEALTH CARE SYSTEM, WE ARE CLOSELY MONITORING WHAT PPS AND PRO REVIEW MEANS TO THE MEDICARE PATIENT. PROS ARE REQUIRED TO SUBMIT MONTHLY AND QUARTERLY REPORTS ON THEIR REVIEW ACTIVITY AND OBJECTIVE PROGRESS. THESE REPORTS ARE ANALYSED AND VALIDATED ON-SITE.

IN ADDITION, WE ARE AGAIN SOLICITING PROPOSALS FOR A "SUPER PRO" TO EVALUATE PRO PERFORMANCE. WE INTEND TO AWARD A CONTRACT TO AN ORGANIZATION WHICH WILL PROVIDE PRACTICING PHYSICIANS, REGISTERED NURSES AND MEDICAL RECORDS PERSONNEL TO SAMPLE PRO DETERMINATIONS AND ADVISE HCFA REGARDING THE CORRECTNESS OF THE PRO REVIEW. PROPOSALS ARE DUE BY

MAY 3RD AND WE HOPE TO HAVE AWARDED A CONTRACT BY THE END OF JUNE.

BOTH THE ON-SITE REGIONAL EVALUATIONS AND THE SUPER PRO ANALYSES WILL BE UTILIZED TOGETHER WITH AVAILABLE NATIONAL DATA TO EVALUATE THE EFFECTIVENESS OF INDIVIDUAL PRO PERFORMANCE AND TO MAKE A DETERMINATION AS TO THE RENEWAL OF THEIR 2 YEAR CONTRACTS.

FUTURE DIRECTION

ANY IMPLEMENTATION STAGE OF A NEW PROGRAM PROVIDES AN ARENA OF LEARNING FOR ALL PARTICIPANTS. AS THE PROCESS OF IMPLEMENTING PROS CONTINUES, WE ARE DISCOVERING AREAS OF CURRENT REVIEW WHICH NEED TO BE TIGHTENED AND OTHER AREAS IN WHICH ADDITIONAL REVIEW IS APPROPRIATE.

FOR EXAMPLE, ONE CONCERN WE HAVE IS THE SHIFT OF SOME PROCEDURES FROM THE INPATIENT TO THE OUTPATIENT OR AMBULATORY SETTING. THIS SHIFT IS TOTALLY IN ACCORD WITH AND OFTEN THE RESULT OF PPS, PRO REVIEW, AND THE GOAL OF REDUCING INAPPROPRIATE HOSPITAL ADMISSIONS. HOWEVER, THE SHIFT DOES RAISE ISSUES OF THE QUALITY OF CARE SINCE PROS ARE NOT REQUIRED TO REVIEW

OUTPATIENT PROCEDURES. WE ARE, THEREFORE, BEGINNING TO PLAN FOR SOME POSSIBLE ADDITIONAL REVIEW FOR OUTPATIENT SURGERY AS PERFORMED IN HOSPITALS AND AMBULATORY SURGICAL CENTERS. WE PLAN TO BRING TOGETHER EXPERTS FROM THE HOSPITAL COMMUNITY, THE AMBULATORY SURGERY SETTING AND GROUPS INVOLVED IN MEDICAL REVIEW (PROS, FIS, BLUE CROSS/BLUE SHIELD, PRIVATE INSURERS AND BUSINESS GROUPS) TO HELP US DEVELOP A REVIEW APPROACH, WITH A POSSIBLE TEST OF SUCH REVIEW BEGINNING IN THE NEXT FISCAL YEAR.

ANOTHER AREA OF CONCERN IS THE TIME LAG OF SEVERAL WEEKS TO SEVERAL MONTHS BETWEEN THE OCCURRENCE OF A INAPPROPRIATE TRANSFER -- AND ITS REVIEW BY THE PRO. I SHOULD MAKE IT CLEAR, MR. CHAIRMAN, THAT WE DON'T SEE ANY EVIDENCE OF MAJOR PROBLEMS WITH PREMATURE DISCHARGE OR INAPPROPRIATE TRANSFER -- BUT WE ARE FINDING INDIVIDUAL CASES. WHILE RETROSPECTIVE REVIEW IS USEFUL FOR IDENTIFYING PROBLEM PRACTITIONERS OR PROVIDERS (AND ALLOWING PROS TO TARGET THEM FOR INTENSIFIED REVIEW, EDUCATIONAL INTERVENTION AND SANCTIONS IF NEEDED), IT DOES NOT ADDRESS THE PROBLEM OF INAPPROPRIATE CARE GIVEN TO THE BENEFICIARY INVOLVED IN THE ORIGINAL INAPPROPRIATE DISCHARGE OR TRANSFER, NOR DOES IT ADDRESS ANY INAPPROPRIATE CARE

RENDERED BY THE PRACTITIONER OR PROVIDER IN THE INTERIM. THEREFORE, WE INTEND TO CONDUCT A SERIES OF PILOT PROJECTS TO TEST THE FEASIBILITY AND COST OF CONCURRENT REVIEW OF DISCHARGES AND TRANSFERS. WE WILL BE LOOKING FOR WAYS OF TARGETING AND FOCUSING THE REVIEW TO MAKE IT COST-EFFECTIVE.

AN AREA RECENTLY ADDED TO THE PRO MANDATE IS QUALITY REVIEW OF HOSPITALIZATION IN HEALTH MAINTENANCE ORGANIZATIONS (HMOs). NEW HMO REGULATIONS PUBLISHED JANUARY 10, 1985 ENCOURAGE ENROLLMENT OF MEDICARE BENEFICIARIES IN HMOs. BECAUSE OF THIS ENCOURAGEMENT, WE FEEL THAT MORE HMOs WILL CHOOSE TO PARTICIPATE IN MEDICARE AND THAT MORE SERVICES WILL MOVE TO THE HMO ARENA. WE HAVE BEEN WORKING CLOSELY WITH THE INDUSTRY TO DEVELOP A REVIEW SYSTEM WHICH WILL EMPHASIZE QUALITY OF CARE. THE INDUSTRY HAS PRESENTED US WITH A PROPOSAL AND WE ARE IN AGREEMENT ON THE BROAD OUTLINE. WE WILL BE DEVELOPING CRITERIA USING PHYSICIANS FAMILIAR WITH THE HMO CONCEPT AND OPERATIONS TO REVIEW HMO CARE, WITH THE GOAL OF BEGINNING REVIEW NO LATER THAN OCTOBER OF THIS YEAR.

I AM FIRMLY CONVINCED, MR. CHAIRMAN, THAT THESE EFFORTS WHICH I HAVE OUTLINED FOR YOU THIS MORNING

ARE CLEARLY MAKING A POSITIVE DIFFERENCE BOTH FOR OUR BENEFICIARIES IN THE QUALITY OF HEALTH CARE AND IN OUR EFFORTS TO CONTAIN HEALTH CARE COSTS. I BELIEVE THAT PROS ARE MEETING THE CHALLENGE THAT THIS COMMITTEE INITIATED AND CONGRESS MANDATED. CLEARLY, WE ARE STILL LEARNING AND IMPROVING AS OUR EXPERIENCE WITH PROSPECTIVE PAYMENT AND MEDICAL REVIEW GROWS.

BUT THIS I ASSURE YOU, AS I HAVE IN THE PAST, THE HEALTH CARE FINANCING ADMINISTRATION HAS SET A HIGH PRIORITY ON DEVELOPING AND IMPLEMENTING AN EFFECTIVE MEDICAL REVIEW SYSTEM IN ORDER TO PRESERVE AND GUARANTEE THE QUALITY OF CARE IN A COST-EFFECTIVE ENVIRONMENT.

I WILL BE PLEASED TO ANSWER ANY QUESTIONS YOU MIGHT HAVE.

Senator DURENBERGER. All right. Thank you.

Carolyne, would you first give me some idea of the regulations? How you use regulations or what you are working under by way of some proscriptions on regulations? I have the impression that the Department only wants to go to the regulatory process once a year, or something like that. I don't know where I heard that.

Dr. DAVIS. We are not currently working on any others. It does take close to a year from the time that you publish an NPRM, analyze the results, and then publish the final.

Senator DURENBERGER. You are not working on any others right now?

Dr. DAVIS. No, except we are beginning now to think through our process for how we would go about involving the communities in terms of a new scope of work for the next round of contracts. Admittedly, they are about 15 months away; but we need to begin to work with our various industry representatives, hospitals, physicians, and peer review groups, talking about how we would develop a scope of work, and then we would publish that as an NPRM for further comments.

Senator DURENBERGER. I just want to understand the way it works down there. The reality is not that it takes a year to get all of this stuff into regulatory form, but you sort of set yourself up like the IRS does, to tax people on an annual income rather than some other form.

So otherwise, as of right now, your answer might be, "Well there are three or four things we would like to have in regulations that we will have in next year's regulations." You are saying that there isn't anything in this set of regulations that you want to go to other than what you have just described. Correct?

Dr. DAVIS. That is the only thing that I believe we are looking at at the moment. The activities that I referred to in terms of expansion relates to quality review in the HMO area and also ambulatory surgery review. Those are the two areas that we are looking at now, and we need to do some pilot testing in that area prior to making a decision as to whether or not we would need regulations to move forward. If we do, of course, we would move to do so.

Senator DURENBERGER. All right.

Let me now ask you about the whole objectives area. And I was pleased to see in your statement that you have been more flexible—that isn't the right word, but realistic, maybe, is a good word—than a lot of people expected. You have turned down only three requests for modification.

I am sure that is going to be pleasing to George. I take it they have got one in the works in Maine someplace.

But I just wanted to ask you a couple of questions that focus on the revisions and the goal setting for future years.

You talked about the Super Pro. You don't select a Super Pro until June. It seems to me you have to renegotiate contracts, when? By the end of the year or something like that? How is the Super Pro going to get its work done?

Mr. NATHANSON. Well, Senator, we expect the Super Pro to begin its work over the summer and to begin generating reports to us in the fall. The time we have to enter into renegotiation is probably about 3 months before the contracts are going to expire, which is

not until spring of 1986 in some cases and not until the summer of 1986 in others.

We plan to have two good reports from the Super Pro on the validity of the approach that the PRO is taking before we have to negotiate those contracts.

Senator DURENBERGER. All right.

Can you describe for me what you believe the most essential elements of this Super Pro are? I mean, obviously it is not just a statistics gathering organization. Hopefully it is going to tell you how to perhaps somewhat more realistically set up a contract based on outcomes of some kind. Do you want to answer my question?

Mr. NATHANSON. We primarily want the Super Pro to take a sample of the judgments that the PRO's are making about medical necessity and appropriateness. That is really the function of the Super Pro. In other words, they are going to pull off say 400 cases that a Pro has adjudicated, and then they will look at the criteria set that the PRO has used. And they will say, "Did they follow their criteria set? Is this reasonable? In fact, is their criteria set reasonable?" That is one of the things they will give us input on if they think there is a problem with that.

In terms of our coming to grips with whether we should change the scope of work or change the way that we go about setting objectives, as Dr. Davis indicated, over the summer we are going to start working informally with the hospitals, with the physicians, with the PRO's themselves and with others to think through what we have done so far and to see if there is a better way to do this.

We do plan, once again, to publish our scope of work formally and to get comments on it before we award the new contracts. So we will get lots of input and lots of suggestions about how to improve this.

We certainly don't think that we have it figured out all by ourselves, or that we can't make it better. We believe we can make it better.

Senator DURENBERGER. I have to be sure I understand what the Super Pro is. The Super Pro evaluates the performance under the existing contracts.

Mr. NATHANSON. That is right.

Senator DURENBERGER. Does it also provide you, then, with some help out of that process in structuring a new set of contracts?

Mr. NATHANSON. Well, we have not asked it formally to do that. In other words, that isn't part of what we asked it to do. I think that certainly it will be inevitable that we will get good information out of that process and that we will get good information from the folks that do it that will help us when we reformulate, but it is not a formal part of their requirement.

Senator DURENBERGER. Is there a requirement that there be some medical community, public, other kinds of involvement in the Super Pro process?

Mr. NATHANSON. No; we have looked at the Super PRO exclusively or primarily as an independent validation by physicians of the physician judgments of the PRO.

Senator DURENBERGER. Do you mean there are going to be physicians in the Super Pro? Is that a requirement?

Mr. NATHANSON. Yes.

Senator DURENBERGER. All right.

You talked about medical judgment and admissions, or something like that. As you reset the PRO objectives for the next round, can you describe for us, even though it is somewhat difficult according to your statement to do, can you describe for us either a new emphasis on quality or perhaps some new set of quality measurements that you might be able to incorporate into the contract? Is that one of your goals, to come up with that?

Dr. DAVIS. Well, clearly we will still be focusing heavily on quality, and the quality outcomes are very important.

We will need to take a look at what the impact is in relationship to the goals that they have set out; but I think it is very clear, for example in the area of hospital acquired infections—that is clearly an area that we will continue to want to work on in order to improve quality. And the whole area of looking at various procedures in terms of avoiding complications, reducing mortality rates will all continue.

Obviously we will have new goals in terms of the outcome measures themselves, but I see every reason for us to continue to focus on improving the quality of care.

Senator DURENBERGER. How would you describe your or HCFA's current relationship with the PRO's out there?

Dr. DAVIS. Well, they might better answer that than I; but from my perception I think it is quite a cordial relationship. We have been flexible, we have been engaging in discussions when they ask for changes in their objectives.

Mr. NATHANSON. Could I add something?

Senator DURENBERGER. Sure.

Mr. NATHANSON. We have been informally meeting with different PRO's and with the trade association AMPRA to get input into what we do. In fact, earlier this week we met with them on the new medical review instructions.

We are going to continue to have a fairly regular process of getting input directly from the PRO's on things that we do, so we think it's good.

Senator DURENBERGER. All right.

Now, on the issue of the A-services being shifted to B, I guess in the first year of the PRO implementation I heard all of the usual complaints about—well, you know what they are.

But now that everybody is trying to be very superefficient in this whole system, I started hearing a lot about the fact that we ought to be much more concerned than we appear to be about what is going on in either the outpatient hospital or the outpatient-someplace-else setting. Is there currently some role for the individual PROs in providing you information on that subject? And if so, are they being compensated in some way to help you do that kind of work?

Dr. DAVIS. At this moment we are simply beginning our discussions. We became aware of the need to look in this area, and we are now in the task force mode of talking with them about how we would go about structuring, either some pilots or movement into this particular area. So it is a little bit premature for us to be able to say anything other than that we are very aware of the need, now that we are beginning to see some significant movement from

inpatient to outpatient, for us to structure some review in this area. And we will move to aggressively try to implement review in that area.

Senator DURENBERGER. You know that very shortly we have to make some tough decisions on budget changes, and somehow I have the feeling—and I am going to ask this question when we get to the ophthalmologist at the end of this day somewhere—but I really do have the feeling that we found economies in part A and we are losing it in some areas over there in part B. And I would sure love to put a figure, maybe not for this fiscal year but for next fiscal year and the following year, in our budget for that.

Would you encourage me to explore that sort of thing now? And if so, could you give me any kind of a dollar dimension as to what it might be?

Dr. DAVIS. We would be happy to provide a figure at a later point in time for that. I can't give you a figure right now, because I think it is a little premature. I don't think we know how much that kind of review would cost, whether it would be something we could substitute for some of what we are now doing in terms of the inpatient, or whether we need to have a very clear alternative.

Senator DURENBERGER. Well, that's the review. To pin it down, I would like to know what you learn from sitting there looking at those computers all the time, and attending all those diagnosis-related group meetings. You know more than I know about what is going on out there, because I see some of your people out in the field who are very knowledgeable. I am just curious to know if you would disagree with me when I say we ought to be putting some Medicare savings in a couple of those outyears for cutting back on some of the Part B reimbursement.

Dr. DAVIS. No. I certainly believe that. I don't make the final decisions in relationship to where budget allocations go, but outpatient care is clearly an area where, if we don't move to do some review, we could be losing savings over time.

Senator DURENBERGER. All right.

George?

Senator MITCHELL. Thank you, Mr. Chairman.

Dr. Davis, do you agree that the primary intent of Congress in creating the PRO program was to establish a mechanism to assure quality control in services provided to Medicare patients?

Dr. DAVIS. Yes, absolutely.

Senator MITCHELL. Has HCFA complied with that primary intent of Congress, or has it rather had cost containment as its primary objective in establishing the PRO program?

Dr. DAVIS. No, sir. I think that you can have both improvement in terms of quality of care and cost containment at the same time. Let me use an example:

It is very clear that when you enter into a hospital there is a potential for picking up some hospital-acquired infections. To the degree that individuals don't have to go to the hospital and are treated in an outpatient area, ambulatory surgery or perhaps even in the physicians' offices, then I think that can represent an improvement in terms of quality of care, because the patient is not exposed.

Now, granted, all hospitals don't have serious infection problems, but there can be an unneeded exposure. So I think that when we look at the fact that we are attempting to move some areas from inpatient to outpatient, that is appropriate not only from cost effectiveness but also from the quality aspect.

Senator MITCHELL. Well, my question did not suggest nor would I suggest that the two are mutually exclusive. The question, rather, was: Which objective has been primary in HCFA's implementation of the PRO program?

Let me say that I think there is substantial indication that the cost-containment objective has been primary, and I want to ask you whether that is true.

Dr. DAVIS. I think that is not true; I think I would respectfully disagree. And the reason why it may seem that way is that our early data has concentrated mostly on what has happened in relationship to the preadmission reviews. If you are doing preadmission reviews as every one of the PROs are doing in at least five objective areas or five diagnoses, that is the earliest data that we get. It takes a while for us to gather the data and to come up with the impact on quality. It probably takes about 6 months before you begin to see the data coming in in terms of the impact on the quality objectives. So our earliest types of published data relates more to what has been accomplished in relationship to the movement from the inpatient to the outpatient setting.

But I would submit that we have five quality objectives, and those five quality objectives speak to the issue of reducing unnecessary readmissions due to substandard care, to also reducing the unnecessary invasive types of procedures, to preventing complications in the hospital, and to reduction in mortality rates.

Now, it seems to me that if we can accomplish those, that we will have done a very, very admirable job of improvement of quality of care. And I believe that all of the hospitals and all of the physicians involved are dedicated towards reaching those, but it takes us longer to see any data that will prove that those are indeed happening.

Senator MITCHELL. Is it not true that the principal basis on which contracts were awarded in individual states was on the what someone has referred to as "arbitrary quotas" for inpatient admission reduction?

Dr. DAVIS. No, sir, that is simply not true. We did ask for measurable objectives, because we found that in the past, if you looked at the history of the old PSRO program, some were very good and some weren't. And we thought that the reason why they weren't was because we had no way to assess whether or not they had been doing a good job, because we didn't have any knowledge of what they were specifically trying to accomplish.

So we spoke to that by asking for quantifiable objectives. I believe that was in the legislation, too. The only way I know that you can quantify an objective is to ask for some kind of a goal, a numerical goal. Those clearly are goals, and in fact as I said earlier the peer review organizations are now coming back and reassessing whether or not they can reach those. And in some cases, in at least 25 cases, we have renegotiated with them, and we have other ones continuing now in terms of renegotiation.

Senator MITCHELL. Were there instances in which one applicant sought greater admission reductions than another and was not awarded the contract?

Dr. DAVIS. Our contracting process was an overall evaluation process that was composed of a point system. Approximately 25 percent was related to the overall price, and about 75 percent was related to the technical aspects of how they had framed their objectives, whether or not their data base was appropriate for those objectives. In some cases we felt that some peer review organizations could accomplish more; in other cases we felt that they were overly ambitious and we reduced their objectives.

Senator MITCHELL. When you say "accomplish more," do you mean a greater reduction in admissions?

Dr. DAVIS. No. What I mean is, we had one organization—which shall remain nameless—that indicated that they had no problems at all in their state, and therefore they saw no need to submit any quantified objectives. We took a dim view of that, obviously.

Senator MITCHELL. Well, of course that is the extreme example.

Dr. DAVIS. It is an extreme example.

Senator MITCHELL. And that was one applicant who wasn't awarded it. But there has been a lot of comment, a lot written about, on the view that this is being used as a cost-containment mechanism principally, that the applicant which promised the deepest reductions in admissions and therefore could exhibit the greatest amount of savings was, in all or most instances, chosen on that basis, and that in fact the congressional intent, the primary intention of Congress in establishing quality PRO mechanisms, has become a secondary objective of the Health Care Financing Administration.

Dr. DAVIS. I would categorically deny that. I am very strongly of the opinion that we very definitely looked at the entire proposal, and it did not get an award based simply on whether or not the individual PRO was going to go deeper, as you say, into that type of admissions.

But definitely that was not it, and I will be happy to submit for the record examples of how our process actually worked.

Senator MITCHELL. I would like to have that.

Dr. DAVIS. Fine.

Senator MITCHELL. With a specific view to proving or disproving the suggestions that have been made by others.

[The information follows:]

The process which HCFA utilized to evaluate PRO proposals was a meticulous, and thorough panel review of all technical areas. This technical evaluation was performed in conformance with standard contracting procedures in that the business proposal was not reviewed until after a proposal had been found technically acceptable. The technical evaluation gave equal balance to the areas of admission and quality objectives. If a PRO proposal did not have adequate objectives in both areas, the proposal was not considered acceptable. This means that a PRO was required to have fully developed, validated, and monitorable objectives for the 3 admissions areas and also in each of the 5 quality areas.

As a result of the panel review, many proposals were eliminated from consideration without regard to the amount of money and despite the fact that some promised significant cost savings.

Specifically, in one major western state we received 3 proposals. All 3 of these proposals were initially rejected and rebid when proposals were resolicited. All 3 organizations submitted new proposals. Only one of these proposals was considered ac-

ceptable despite the fact that one of the proposals was considered acceptable despite the fact that one of the proposals rejected promised greater cost savings. It was the review panel's determination that the objectives, especially in the quality area lacked significance and aggressiveness. (Privacy Act precludes giving proprietary information on losing proposals).

Similar situations occurred in two other States in the Midwest. In each of these two situations again 3 proposals were received and in both instances the determining factor was in the acceptability of the quality objectives.

I would also like to add, that, in most instances, the objectives were agreed upon prior to the negotiation of funds. It was primarily in the negotiation of funding that the magnitude of the targets were discussed. HCFA, attempting to negotiate the best deal for the government, pushed organizations to the optimal level of their capability to reduce medically unnecessary and inappropriate admissions. However, HCFA also, with numerous contracts, actually requested the organization to lower targets where the proposed impact or methodology was considered unrealistic or too aggressive.

Senator MITCHELL. Would you describe briefly the regulations regarding the release or prohibition of release of data for research purposes?

Dr. DAVIS. Yes. I think you are referring to the confidentiality regulations we have.

Senator MITCHELL. Yes. Well, let me put it more directly. One of the statements that we received that will be made later this morning by Willis B. Goldbeck, of the Washington Business Group on Health, states on pages 4 and 5—this is on page 5 at the conclusion of a section that begins on page 4:

By denying access to PRO data for researchers, HCFA is perpetuating the status quo in which malpractice lawyers determine what is inappropriate and general revenues that pay 75 percent of Part B costs are drained by lab tests constituting defensive medicine.

Do recent regulations address that? And if so, in what way?

Dr. DAVIS. We indicated that the PRO would not release that information at all in the final regulation. There was a lively debate before that decision was finally made, but it was finally decided that we would not release that information. It had the potential for breaching some confidentialities, so it was finally decided that it would not be done.

Senator MITCHELL. Are you familiar with the Maine Medical Assessment Program?

Dr. DAVIS. Yes.

Senator MITCHELL. You are? That is a program which has utilized admissions data in a nonregulatory framework by physicians themselves, and which appears to, at least based on the early results, be having dramatic positive effects in reduction of certain admissions and procedures, and therefore of course in cost of payment. That would not be possible without the kind of data that makes it for the first time possible for a physician to see where in a spectrum of other physicians he or she stands with respect to the decision on when certain admissions and procedures should occur.

If you are aware of it, do you regard that as a positive step and something that we should try to do in other areas? And if that is so, would not this type of data be useful?

Dr. DAVIS. Well, clearly, our preliminary discussions that we had indicate that there is interest in that. It is too soon for me to say whether or not I think it is appropriate that we would want to use the same system nationwide. But I think there is interest, at least

as we have talked to the Peer Review Organization, in testing that further. I think I would like to defer a final judgment until we have had a little more experience, as we have talked through it.

Senator MITCHELL. I guess I still don't understand why you made the decision not to release the data. Would you restate that and perhaps clarify it a little bit?

Dr. DAVIS. I simply said that the final decision was not to release the data.

Senator MITCHELL. Right. And I asked you why did you make that decision? I understand what your decision is; I am asking you why you made it, what is the reason for it?

Mr. NATHANSON. Well, the issue really got to how much control over redisclosure the PRO would have should it disclose it to a research organization.

When we compared the amount of control that a PRO would have over that to some other areas where we had not permitted disclosure, we really felt that although the goal was laudable of allowing researchers to get access to this data, that in fact it was simply a little too risky.

You always have to do a balancing act of the public good in getting the data as opposed to the risk of harm of redisclosure. The data is very sensitive, and when that balancing was done the decision was that the public good was more on the side of protecting the data than it was of disclosure.

Senator MITCHELL. What is the risk? Why would it be harmful?

Mr. NATHANSON. The risk is that the data that we are talking about is data that contains practitioner-specific information; that is to say, information about individual physicians that contains judgments about their practice patterns, that contains findings about problems that individual physicians may have had.

The chairman in beginning his discussion told us his concerns about the release of data generally, just aggregate statistical data, let alone detailed data about practice patterns of individual physicians.

Senator MITCHELL. Are you suggesting that it could not be released in a form that doesn't identify the individual physicians?

Mr. NATHANSON. That can be released, and that is releaseable. We are only talking about data that could identify that is not releaseable.

Senator MITCHELL. Thank you.

Senator DURENBERGER. Thank you both very much. We appreciate it.

Dr. DAVIS. Thank you, Mr. Chairman.

Senator DURENBERGER. Our next witness is Dr. Howard Strawcutter, President of the American Medical Peer Review Association, Washington, DC, accompanied by Dr. John Graham, AMPRA board member and former chairman of the board of the Minnesota Foundation for Health Care Evaluation in Minneapolis.

Gentlemen, your statement abstract will be made part of the record. Your printed statement, you may proceed to summarize it. And we will be using the little green light that turns yellow in 4 minutes and red in 1 thereafter.

STATEMENT OF HOWARD STRAWCUTTER, M.D., PRESIDENT, AMERICAN MEDICAL PEER REVIEW ASSOCIATION, WASHINGTON, DC, ACCOMPANIED BY JOHN GRAHAM, M.D., AMPRA BOARD MEMBER AND FORMER CHAIRMAN OF THE BOARD OF THE MINNESOTA FOUNDATION FOR HEALTH CARE EVALUATION, MINNEAPOLIS, MN

Dr. STRAWCUTTER. Thank you, Senator. I am Howard Strawcutter. I practice urology in Lumberton, NC, and I also serve as president of the American Medical Peer Review Association.

We appreciate your interest, your continued interest, in this project, and we appreciate the opportunity to be here to speak with you today.

In essence, the PRO's are up and running. The contracting process was difficult but has been completed, and as has been noted the regulations are now official.

There have been some startup problems, as might be expected. For example, if you take two large entities like the Fiscal Intermediaries and the Physician Review Organizations with the new data relationships, there are bound to be some problems. But I think the general attitude has been one of positive cooperation, and the problems have been dealt with in that way. There are still some little glitches.

As far as the utilization review process is concerned, we are confident that we are making good progress there. Admissions, as you have noted, are actually down in contrast to the projection of increased admissions under the prospective payment system. Some of this may be an initial shock effect that may not persist, but at least it certainly continues in that lower range now, partly beca.. of the PSRO activity that preceded our PRO activity, with conti ued review process.

We are confident about our progress in utilization review. Now, as far as quality assurance, we perhaps have a little less confidence.

I think the most effective quality-assurance mechanism is the actual peer pressure and peer-contact relationship. Unfortunately, that is not measurable, not quantifiable. Where we run into some problems with our quality assurance program is when we try to quantitate this. Our objectives or efforts at attempting to select quantifiable objectives, may have produced some problems for us.

Certainly base-line data is a subject to question. This is an area that certainly needs considerable research. AMPRA, along this line, has recently established a Medical Review Research and Education Center for the purpose of exploring this. Now, we are more than a little disappointed that—data will not be released and not be available to this research activity. We think this is something that should be corrected soon in order to expand that research capability.

We have a little problem, it appears, with the concept of fixed-price objective-based contracts. Coming from PSRO where we were burdened with process evaluation and analysis, we looked forward to the concept of an objective-based contract with opportunity for innovation in achieving those objectives. The problem is that the contract calls for the opportunity for "technical modifications". We

are obliged to comply with manuals and directives. And these get back to the old "process" attitude of PSRO.

We perhaps are in a situation of having the worst of both worlds. We are facing the "process" evaluation as well as the "objective" evaluation. Some of these things do impact on price. The way it is set up, it is a technical modification, not a negotiable element, if it does not affect price. But the determination as to whether it affects price is by decree.

I would like to yield to my colleague Dr. Graham, who can talk a little bit more about how this translates into the local activities.

Senator DURENBERGER. John, while you are speaking, would you try to incorporate into your comments, again looking at it from—well I guess we can't call you a "typical local PRO" because you are stuck with me out there. But would you try to incorporate into your comments some suggestions to us and/or the people, if there are any left here, from HCFA about what different kinds of objectives and how they approach the objective-setting process differently then you they approach either in renewing your contract or in contracting with somebody else?

Dr. GRAHAM. That is an opportunity I think I welcome.

I am Jack Graham, former chairman of the Board of the Foundation of Health Care Evaluation, currently a member of the board of AMPRA, practicing obstetrician and gynecologist in the Twin Cities for 15 years, and I currently hold the job of director of medical affairs at Fairview Southdale Hospital. I mention that, because I believe this has allowed me to look at PRO implementation from a variety of directions wearing a variety of hats.

I too want to thank you for the opportunity to testify this morning, and we appreciate your continued support of physician peer review.

We share the comments of Dr. Strawcutter. I don't wish to reiterate those, but would like to focus some on program evaluation.

As an organization familiar with the Peer Review Improvement Act, Mr. Chairman, and as one of the first PSROs in the country, I am a little concerned that the past with respect to PSRO may become prologue with regard to PRO. By that I mean, the PSRO was judged as a failure, but a failure by what standards? I would submit that the PSRO program suffered not from a failure to meet expectations but a failure to have those expectations articulated. And I am concerned that history may repeat itself.

PRO's, I believe, are pawns in a political war, if you will, being fought between those whose concern is bottom line, cost, and those whose concern is care. And I am concerned that until a winner in that war is finally declared, the PRO's really will not know how they will be judged. And I think this creates vulnerability in the program. It creates, I believe, program vulnerability.

As originally conceived, the measures of success were to be spelled out in performance-based contracts. The message there? "We'll look at your outcomes." As the quarterly evaluations have progressed, however, the focus has been heavily weighted toward process. Are we now to understand that it is our process that will be evaluated and not our outcomes, or is it both? And if it is both, how are we going to weight those?

Until this situation can be straightened out, I think two things will occur: We will continue to see what we call "scope of work creep," and it will be impossible for the PRO's to realistically set priorities and allocate resources.

Senator DURENBERGER. Do you mean HCFA asks more? The "scope of work creep" means they are asking you to do more?

Dr. GRAHAM. That is correct.

There are, I think, policy vulnerabilities. I think the Foundation for Health Care Evaluation points with some pride to the results from our first quarter. Admissions targeted for decline have fallen 57.9 percent. That is, by the way, 32.2 percent greater than what our objectives called for. Total Medicare admissions in Minnesota have dropped 19.3 percent as compared to the year prior to PRO implementation. And yet, the Office of Management and Budget tells AMPRA, "We don't think you are making any impact at all." I am wondering if it is possible——

Senator DURENBERGER. Stockman said that to me yesterday, "This whole thing we have been doing," he said, "hasn't accomplished anything."

Dr. GRAHAM. We are concerned that we might meet our goals in those performance-based contracts only to have been judged useless. And if we are useless, does that mean that the review of quality is useless?

I would submit that quality can be defined, and it can be measured, and it is measured by standards. And unless we have a quantifiable, definable, responsible physician-review organization looking at those standards, the standards become idiosyncratic and in fact become no standards at all.

I would submit that there is a very vital role for physician-directed peer review in any prospective payment system.

And finally, let me speak to what I call clinical vulnerability. I think this may be the most important aspect of all, because I think it gets at our very humanity.

When efforts to reduce hospital admissions result in rigidity, an interpretation of criteria of medical necessity—the compassionate link that I think is so important to the practice of medicine—is severed. And I would like to cite a case in point.

The Foundation for Health Care recently approved the admission of a 79-year-old psychotic woman who lived alone. Her judgment was markedly impaired, and in fact she was found at home surrounded by rotting garbage. She was malnourished, had abnormal lab findings. Her psychiatrist admitted her with the approval of the foundation, stabilized her, transferred her to a nursing home. The foundation was then told by HCFA that this was an inappropriate admission because it constituted a "social admission."

As Director of Medical Affairs I have watched families make the agonizing decision to withdraw life support from a member of their family, only to have that agony further compounded by the delivery of a denial letter because the patient no longer qualifies for an acute-care setting.

Hospitals, physicians, the PROs, and I believe HCFA all suffer because there is ambiguity of expectations.

I spoke earlier of a war. I think unless there is a clear, unequivocal, and universally understood set of expectations by which the

PROs will be judged, that the providers and the patients will become the refugees of that war.

Thank you, Senator.

[AMPRA's written testimony follows:]

OVERSIGHT HEARING

ON THE

PEER REVIEW ORGANIZATION PROGRAM

BEFORE THE SENATE FINANCE COMMITTEE

SUBCOMMITTEE ON HEALTH

APRIL 19, 1985

Presented by: Howard Strawcutter, M.D.
President
AMERICAN MEDICAL PEER REVIEW ASSOCIATION

Mr. Chairman, I am Howard Strawcutter, M.D., President of the American Medical Peer Review Association (AMPRA) and a practicing physician from Lumberton, North Carolina. AMPRA represents physician-based medical review organizations including Peer Review Organizations (PROs) under contract to Medicare. On behalf of our members, I want to express our appreciation for your continuing support for the PRO program and for providing us this opportunity to report on our progress to date.

On Wednesday of this week, two and one half years after enactment of the PRO statute, final regulations governing the PRO program were published. AMPRA is thankful that the PRO program has finally achieved official program status. These regulations will help legitimize the peer review effort in the wider health care community and help clarify many issues surrounding medical review policy and process. We are also hopeful that the regulations now signal the Administration's commitment to a physician directed medical review program that will help assure the quality of patient care rendered to Medicare beneficiaries.

Overall, we believe our progress in moving from 141 area-wide PSROs to fully operational state-wide PROs has been a major achievement. The long delays in the implementation of the program, the complexity and newness of the contracting process, and the implementation of new review methodologies and new relationships with hospitals and fiscal intermediaries, all posed significant challenges to our membership. We have tried to approach these challenges in a constructive manner, and we have found, on the whole, that HCFA, fiscal intermediaries, hospitals and physicians have proceeded in good faith.

While it is still early to properly gauge the impact of physician directed review, we have witnessed a number of significant changes in the statistics that measure performance of the Medicare program. The rate of increase in benefit payments under Part A has moved from 10.9 percent in FY 1983 to 8.9 percent in FY 1984. Medicare average length of stay in hospitals subject to the prospective payment system (PPS) in FY 1984 was 7.5 days--a decline of 2 full days from the FY 1983 average. Perhaps most surprising, however, is that Medicare hospital admissions actually declined 1.7 percent in FY 1984 as compared to FY 1983.

These data are impressive and suggest a period of transition for our health care delivery system. While many analysts are seeking to explain the meaning and causes of these emerging trends, we believe that the PRO program can be credited for some of the changing patterns of hospital use by Medicare beneficiaries. Even though most PRO's were not operational until last fall, their predecessor organizations--Professional Standards Review Organizations (PSRO's)--were conducting reviews of care in hospitals subject to PPS beginning October 1, 1983. There are, undoubtedly, many factors that influence hospital utilization under prospective payment, but we strongly believe that the decline in hospital admission rates--contrary to the financial incentives under PPS--can, in large measure, be attributed to the work of physician directed review organizations.

A dramatic example of PRO impact is provided by recent Medicare data on lens procedures. DRG 39, Lens Procedure, was reported by HCFA in October, 1984, as the second most frequent DRG from bills submitted by PPS

hospitals. In their March, 1985, report, DRG 39 had fallen to fifth place in frequency among all DRG's. In a majority of states, PROs have selected lens procedure as an objective to move from the inpatient to outpatient setting. Preadmission review programs have been employed to encourage this desired change in medical practice.

Another example of PRO impact at this early stage is the experience of New York state, where the PRO review system is disallowing 13.9 percent of Medicare payments to hospitals in New York City and 10.6 percent for the rest of the state. This compares to a 3 percent disallowance rate state-wide prior to November 1, 1984. The main target of the disallowances are additional days that have been found not to be medically necessary under New York's per diem hospital payment system.

In turning our attention to quality of care under Medicare prospective payment, it is more difficult to reach conclusions at this juncture. AMPRA has heard from PROs that their review to date has not uncovered any patterns of quality compromises. Still, individual instances of premature discharge, inappropriate readmissions and poor clinical management have been detected. AMPRA is hopeful that the Medicare prospective payment system, by encouraging more efficiency in medical care delivery, may improve the quality of patient care through reduced patient exposure to unnecessary services and care provided in inappropriate facilities.

While the PRO quality assurance program outlined by the Health Care Financing Administration is a start towards the development of an effective quality assurance program, it must be greatly expanded in the

years ahead. Such an expanded effort must necessarily include added resources to permit PRO review of hospital services on a concurrent review basis; Medicare Part B services; Competitive Medical Plans (CMPs) and Health Maintanence Organizations (HMOs). In addition, development of the instruments and methodologies of quality assurance must become a priority for public and private research if we are to have some confidence that our programmatic efforts will yield results. This must include the development of an integrated data system to track patient episodes of illness over time (i.e. merger of Medicare Part A & B), patient outcome measures, severity of illness indices, generic quality screens, clinical trials, and clinical decision analysis.

AMPRA was most disappointed to read in the final regulations that PROs would not be permitted to release PRO data for research purposes. AMPRA had hoped that through its newly established Research and Education Center, PRO data could be merged centrally for quality review studies. AMPRA recommends that changes in the final regulations be considered immediately by Congress and the Administration.

I would now like to discuss operational and administrative issues surrounding the PRO program. AMPRA members have recently begun to voice some concerns regarding HCFA's interpretation of fixed priced contracts. As you remember, Mr. Chairman, the PRO statute instructed the use of fixed price contracts rather than the grant system, as was previously employed in administering Professional Standards Review Organizations. The intent was to provide PROs a degree of predictability in their work effort and a clearer indication of performance expectations.

Subsequent to fixed price contract awards, HCFA has announced, through a series of PRO directives and manuals, revisions to the original scope of work. AMPRA does not dispute the need for program modifications. In fact, we are presently working with HCFA through AMPRA initiated groups to communicate our concerns and assist the Department in revisions that will help ensure program success. We must observe, however, that any modification is costly in terms of the time and resources necessary to carry out the changes. There are staff to be retrained and data systems to be reprogrammed. Moreover, some of the changes involve the imposition of new burdens that were not anticipated under the original contracts.

The effect of these changes will be, on balance, an increase in the workload on PROs without any adjustment to the fixed-price contracts negotiated last fall. We are concerned that our resources may not be sufficient for these additional tasks, and we would like some assurance from HCFA that PROs that can demonstrate adverse financial impact be provided additional funds to carry out their mandates.

Mr. Chairman, as AMPRA has testified before you in the past, we remain concerned about the proscriptive nature of the mandated PPS review plan. We believe this approach is often arbitrary, burdening good hospital performers with unnecessary monitoring, while not granting PRO physicians and staff the discretion to concentrate activities on identified problem areas or institutions. At the very least, PROs should be allowed to reduce or even eliminate required review activities in the event that appropriate provider behavior is demonstrated. It is time to reward the

good performers and target our energies where the payoff is greatest. We will be working with HCFA on developing review strategies and program modifications that can best accomplish this goal.

Mr. Chairman, a fundamental issue concerns the character of the evaluation process. How will PRO performance be measured? From the outset, we have been anxious about the potential for evaluations based on conformance with process requirements. In this program, there are a very large number of operational protocols and routines in place. It would be tempting--as in the case with PSRO evaluations--to construct an assessment instrument that relied on documentation of the operating characteristics of the PRO. This would be inappropriate, in our view, and would overlook the more relevant aspect of performance--outcome results.

AMPRA can appreciate the need to concentrate on process details in the early stages of the program. We do recommend and anticipate, however, a movement in the direction of an evaluation methodology focused on outcome performance. Such a basis for performance measurement more adequately reflects the dictates of the PRO statute. We believe that HCFA should be more interested in how PROs are meeting contract objectives and whether these objectives may need modification or revision, rather than strict PRO adherence to process instructions.

Mr. Chairman, we have offered a number of observations and recommendations concerning the operation of the PRO program to date. In concluding, we would like to suggest some future issues that need to be addressed as the

program matures. Some of these matters are under review now, and others should be added to our agenda.

With the anticipated growth in the enrollment of Medicare beneficiaries in health maintenance organizations and competitive medical plans, there is a need to plan for medical review of the quality of care in these new delivery entities. In order to address these issues, AMPRA has participated in an informal work group with representatives of the HMO industry and with HCFA.

We are excited about the prospects of this activity, particularly because it can greatly enhance our capabilities to carry out medical review outside the inpatient hospital setting. It can teach us the best means for tracking quality of care, taking account of the full ranges of services offered in the HMO or CMP. We believe this effort can be important as a precursor to outpatient review in general. As might be expected with such an ambitious undertaking, there will need to be additional financial resources, but we believe this to be an investment that will pay great dividends.

In another area for future work, we would like to proceed with the development of a more comprehensive and valid quality review program. Our existing quality review program is hampered by the absence of good base-line data, and by the fact that compromises in quality are only ascertained long after the discharge of the patient. We believe the use of quality screening criteria can identify potential cases of

compromised care. Armed with this information, PROs could, on a limited basis, begin a program of concurrent hospital review. This could provide the opportunity for intervention on behalf of a specific patient to prevent a premature discharge or other action that might impair the recovery of the patient.

Finally, we are all aware of the growing volume of services being provided to Medicare beneficiaries outside of the inpatient setting. Many of these new sites are not affilitated with hospitals, and many of them fall outside the jurisdiction of existing regulatory bodies or review organizations. We believe strongly that now is the time to begin planning for medical review of non-acute care facilities and ambulatory health centers. Many forces are promoting an expansion of services in these settings. As we strive to promote the most cost-effective delivery of health services, we must be equally diligent in assuring that it is of high quality.

Again, Mr. Chairman, we want to express our continuing gratitude for your interest and support of the PRO program. Your vision and commitment to physician-based peer review has had a positive influence on the thousands of physicians and other professionals who are working in PROs. We want you to know also that we remain committed to an effective and fair medical review program on behalf of our peers and the patients we all serve.

TESTIMONY OF THE
FOUNDATION FOR HEALTH CARE EVALUATION
SUBCOMMITTEE ON HEALTH
UNITED STATES SENATE FINANCE COMMITTEE
APRIL 19, 1985

Mr. Chairman, I am John Graham, M.D., past Chairman of the Foundation for Health Care Evaluation, member of the Board of Directors of the American Medical Peer Review Association and medical director of Fairview Southdale Hospital. With me is Julie Sanderson, R.N., Director of the Foundation's PRO program. We represent and speak on behalf of the Foundation. Our testimony has been coordinated with that of AMPRA.

The Foundation is the PRO for Minnesota and with its subsidiary, MedTrac, has conducted over 3 million peer reviews since 1971. We conduct peer review in 48 states. On behalf of our 3,000 physician members, 700 of whom are actively engaged in peer review, I want to thank you for your commitment to peer review. The last time I testified before this committee was when you were authoring the Peer Review Improvement Act. We appreciate this return engagement to share insights gleaned from implementing that legislation.

We agree with the positions of the American Medical Peer Review Association. AMPRA's advocacy for peer review has been effective and sensitive to the issues we face in the field. As cited by Dr. Strawcutter, the national results of PRO on admissions, targeted DRG's and disallowances have been impressive. We agree with AMPRA in saying that validating quality assurance objectives and improving quality assurance methods are important implementation concerns. We also concur with AMPRA's concerns over the prescriptiveness of program guidelines and over the phenomenon we label "scope of work creep." We want to stress that despite these concerns, PRO implementation has proceeded surprisingly well, in most instances. PRO is a complex program and HCFA, providers, intermediaries and PROs have worked cooperatively to put it in place. Rather than recapping or adding to Dr. Strawcutter's testimony on these matters, we have chosen to focus solely on the problem of PRO program evaluation. We see this as the existential issue for PRO.

As an organization directly familiar with the intent of the Peer Review Improvement Act, Mr. Chairman, and as one of the first PSROs in the nation, we fear that past, with respect to PSRO, may be prologue with respect to PRO. Let me explain. The political verdict on PSROs was ultimately negative. The scientific verdict remains unclear. However, our judgement is that the PSRO program suffered not from a failure to meet expectations, but from a failure to articulate what those expectations were. In the early months of PRO implementation, we are distressed to see some parallels.

I would like to share a story with you. Recently, we had an inspection by the regional office of HCFA. The team comes quarterly to look for the consistency and validity of our review determinations. Parenthetically, this type of assessment is similar in design, though not in scope, to the "Super-PRO" idea. Of the dozens of patient records HCFA reviewed, one comes to life. We had approved the medical necessity of admitting a 79 year old woman. The woman lived alone. Her history indicated impaired judgement. In fact, she was found sleeping on the floor of her home, surrounded by rotting garbage. She was malnourished and had abnormal laboratory findings. A psychiatrist admitted her, stabilized her and transferred her to a nursing home. HCFA's reviewers judged the admission inappropriate for lack of medical necessity and called her use of the hospital a "social admission." Such differences of opinion between the PRO and HCFA are not common; but not isolated. Our nurses and physicians perceive that the compassionate link so integral to the practice of medicine is severed when efforts to reduce hospital admissions result in rigidity in interpreting the criteria of medical necessity.

Let me make it perfectly clear that there are no good guys or bad guys in this story. Our disputes with HCFA have not been over what is the humane and proper thing to do, they are over what a PRO is supposed to do. Both we and HCFA suffer from ambiguity over expectations. How shall we be judged? That is the question.

At a policy level we see the issues as these:

- To what extent can or should norms, standards and criteria of medical care be routinized, nationalized, objectified?
- How are we as a society to balance cost containment with quality?

Lest these issues seem too abstract, let me suggest that our PRO makes 400 decisions a day, which practically speaking, answer these issues for Medicare beneficiaries. Do we instruct our reviewers to go by the book or exercise judgement? How are they to make the complex trade-offs between costs and quality? How would Congress have us answer these questions? The Administration?

One of the fundamental intents of the PRO Improvement Act was to make it easier to distinguish success from failure in PRO performance. Certainly the contracting mechanism was a step in the right direction. However, in implementation we have witnessed more ambiguity than clarity. There simply is no clear plan for evaluating PROs.

The assessments we have undergone to date have focused on review process rather than outcome. Indeed, though it is a physician peer review program, a physician has never reviewed any of the Foundation's review decisions. In this and in our reading of the "Super-PRO" request for proposal, we might logically conclude that the expectation is that medical decisions can be routinized. The scope of work for "Super-PRO" confines the evaluation to: validating determinations made by the PRO; validating the medical criteria used by non-physician reviewers; verifying that non-physicians properly apply the criteria for referral to physician review; and, identifying quality issues which should have been addressed by the PRO. Certainly, these are important performance characteristics. But, all but the last imply a focus on process not outcome. Does this mean that PROs should focus on dotting the i's and crossing the t's of review methodology?

We know that as a federal contractor we will be assessed on our ability to attain contracted objectives, especially in reduced admissions. AMPRA has eloquently described the significant changes in Medicare admission rates which have occurred. Yet, Mr. David Kleinberg, Deputy Associate Director of the Executive Office of Management and Budget, doesn't buy AMPRA's impact claims. He suggests that the declines would have occurred regardless of PRO, prompted alone by prospective payment. What are we to read in this message - that we may attain success but still be judged to have been useless?

As AMPRA has pointed out, the scope of work is creeping upward, without recompense, in such areas as coordination of benefits and denials due to reasons other than medical necessity determinations. Does this mean that a sort of adjunctive role to the fiscal intermediary is what will be valued?

Finally, our everyday experience tells us that the most important, unique and long-lived mission of PRO lies in quality assurance. While this role is generally accepted, like motherhood and apple pie, the commitment seems taken for granted. Let me assure you that the quality of care objectives in the contracts reflect only a fraction of a PROs current work in quality assurance. We have barely scratched the surface in terms of the need for this activity. There is no clear-cut approach to assess this beyond the few contracted objectives.

Rather than belaboring the point, suffice it to say that we view the fundamental problem of PRO implementation as the same one which haunted the PSRO program: No one has summarized what is expected of us nor how we shall be judged. Let us be clear again. Defining expectations and designing ways of measuring PRO performance is not just the responsibility of HCFA. Indeed, as we shall suggest later, HCFA could have admirable contractor compliance monitoring and the PRO program might still be beset by the problems which plagued PSRO. This is a problem which is no one's fault; yet, everyone's. We do not want a reprise of PSROs demise. There is too much at stake, too much invested, too many opportunities ahead, to let that happen.

We know that PROs can be successful along multiple dimensions. Although we may quibble over details, the Foundation and HCFA agree that we've done a proficient job with respect to dotting the i's and crossing the t's aspect of PRO performance. Benefitting from our PSRO experience, we were up to speed and up to snuff, more or less, according to plan. In preliminary results shared with Phil Nathanson some weeks ago, we also showed that a PRO could be ahead of target on the objectives. In the first quarter of operations, we were able to reduce admissions in those area targets for decline by 57.9% from the preceding year, 35.2% greater than our objectives called for. Overall, Medicare admissions in Minnesota have dropped 19.3% from the year preceding PRO implementation. Also, we have been able to encompass the subtle additions to our scope of work. We agree, however, with Dr. Strawcutter that continuing to take on these additional roles without additional resources may be taxing the goose who can lay the golden egg - enriching at first; ultimately, impoverishing. Finally, we have had some important results in the quality of care dimension of our role. We can produce dozens of examples where patterns of substandard care have improved. Thus, we know that in our case, and for many PROs, we have a good start at covering all the bases associated with the diverse, ambiguous, even conflicting, expectations placed on us.

However, for us and for the national PRO program, there must be a better way to go. We recommend that Congress require the National Peer Review Council to develop and promulgate a plan for evaluating PROs and peer review, generally. This should be based upon the input of PROs, the Administration, Congress, providers and representatives of the beneficiaries. The plan must be more extensive in scope and far more sensitive than "Super-PRO" or other assessments now being discussed. In our view, monitoring contract compliance is only one outcome of such evaluation. The limitations of "Super-PRO" and other assessments planned by HCFA are inherent to their definition of purpose. There is nothing, per se, "wrong" with HCFA's approach, within the context of measuring contractor compliance. However, we are certain that HCFA will agree that there are broader issues involved which are simply beyond the ken of evaluations planned.

Our perspective on evaluation is that it is the essential ingredient in peer review, not just PRO, accountability. Further, when we think of evaluation, we do so in the context of planning and developing and not merely deciding. We need insight into what precisely is expected of us. Put another way, the policy issues posed at the outset of this testimony about standardization of medical care and balancing costs and quality concerns, need to be operationalized. They never were under PSRO. PSRO ended with a debate as to whether the program was mainly a cost cutter or mainly a quality enhancer. PRO begins with this legacy. It can be both. Without the guidance of an evaluation agenda, however, PRO will not know how to set its sights or track its record. Congress must ensure that a comprehensive evaluation plan is produced and that adequate funding is available for this purpose.

In our view the evaluation plan must:

- Involve HCFA, but not be limited to HCFA, in design and execution.
- Represent a long term commitment; be a series of studies on many facets of performance under varying conditions.
- Combine a national flavor with the organizational and regional flexibility inherent in peer review.
- Represent an explicit statement of the expectations of PROs - expectations which are the consensus of decision makers in Congress, the Administration, the provider community and among beneficiaries.
- Comprehensively and rigorously measure performance against these expectations.
- Direct itself both to past impact and future plans. In the jargon of the evaluator, address both summative (did it meet the expectation) and formative (why not and what can be done about it?) dimensions.
- Look beyond PRO to the results, failures and expectations of peer review, generally.

We believe that the PRO program can survive with delayed or flawed regulations, questions over what should or shouldn't be tacked onto the fixed price contract and even limitations in the scope and methods of review such as those discussed by Dr. Strawcutter. This does not belittle the importance of such implementation concerns. We do not believe that the PRO program can long endure without an evaluation approach along the lines suggested above. Early on, the PRO program has to break out of the pattern which befell PSRO, a pattern of mixed, changing and implicit expectations and fuzzy means of assessing them.

One has only to have attended a few hearings of this committee over the years to appreciate how crucial this is. We don't want to return a year or two hence and still hear: "We say it worked; they say it didn't; and by the way, what was it supposed to do?" (or some variation on that theme). The evaluation protocols we are talking about won't be quick, simple or cheap. So, if we care about this program, we better start building and agreeing to them, now.

We believe that, properly done, evaluation will not only undergird the accountability of the program, it will provide the most important path through which the program will build into the future. We share the enthusiasm of AMPRA for potential PRO roles in HMO/CMP review; review outside of the hospital in ambulatory or long term care settings; and, the potential to enhance the methods through which the quality of patient care may be maintained or improved. But, we hear the skeptics whispering in the wings, "better prove that you can handle what you've got before you bite off a bigger chunk." We also know that in programmatic and administrative terms, some PROs are unprepared for a larger or more sophisticated review system. The use of shared, national evaluation data can be both the response to the critics and the building blocks of the PRO program of the future. Some of what we see as important future roles, such as beneficiary education, may be stillborn unless they are both confirmed by evaluation and informed by it.

Expectations. What are they? How shall we be judged? The PRO program is at the cutting edge of sweeping changes in health care. It shares with medicine itself a job which entails hundreds or thousands of daily decisions, some gravely consequential; methods which are part art and part science; conflicting expectations; and a commitment to patient welfare. We know that you understood these things when you gave preference to physician organizations.

We are confident that peer review has a unique role in helping to answer the questions we posed at the outset of our testimony. It is helping to reduce practice variations but in a way which doesn't inappropriately force standardization. Peer review is balancing society's cost and quality conundrum but with sensitivity as to how far one can push, without harm. This occurs daily across the country in hundreds of thousands of peer reviews. But, as we have seen with PSRO, peer review is fragile. The public is only willing to let the "foxes guard the chicken coop" so long as the foxes have "impact data." Conversely, the "foxes" need constant reassurance that they are doing the right thing and doing the thing well. Physicians active in peer review earn both the esteem and enmity of their colleagues. The former outweighs the latter and sustains commitment only when peer reviewers are judged to have made a difference. Peer review must grow to match the technical, organizational and financial sophistication of health care. So, for the internal integrity and development of PRO and for its external acceptance, we must have a national evaluation plan to which all can commit.

The Foundation, Julie and I appreciate your attention. We would be pleased to elaborate in person or in writing on the themes expressed in this testimony.

Senator DURENBERGER. Now having said that, would both of you take a minute to address how you would set those expectations if you were sitting there in Carolyne Davis' sweatshirt? [Laughter.]

I mean, we really ought to be thinking now about what do they do this fall when you all go back in again. How would you set more outcome-related objectives rather than process objectives? How would you do that in a quality setting where we know it is somewhat difficult? What are your thoughts on that?

Dr. STRAWCUTTER. Our main concern at the moment is not that those objectives that have been set are maybe not the best, but they are a good PRO shot. And the next time they will be a little bit better—that sort of concept.

Where we have a problem is with the process assessment that is being added in addition to that. The original concept was, we set objectives for a price and encourage innovation to accomplish those objectives. Now, it is appropriate that there be some monitoring of progress, but in order to monitor that progress it appears that there have to be parameters established to watch, to monitor. And as you establish more and more parameters, you get more and more actual process measurement being inserted into the evaluation system. And it is that type of process evaluation that is a problem.

As far as negotiating a new generation, better objectives, I think that could be done. But that is not the immediate problem; the immediate problem is the intervening drift toward the old process evaluation of the PSRO program replacing the intended innovation in the PRO program.

Senator DURENBERGER. Do either of you see any value in allowing the public to peek inside this process, as we sort of set new contract objectives? Why not allow some public comment on this as well?

Dr. GRAHAM. Senator, as you know, the Council of Community Hospitals in the Twin Cities already releases hospital-specific aggregate cost data. The public is privy to that, and I think the effect overall has been positive. I do share the concern about the release of physician-specific data, at least at this stage in the program, because the numbers probably wouldn't allow the kinds of judgment that the public probably would make. But I am not blanket-opposed to the release of data, and I am not opposed to providing the public the opportunity to make informed choices based on data. The job of those that release that data is to be sure that the data is accurate and that the conclusions that might be drawn are valid conclusions. Those are not easy decisions to make.

Senator DURENBERGER. What are your experiences from your work with peer-review and the prospective payment system with the shifts that are taking place in procedures from inpatient to outpatient and the adequacy of our review of what is going on in outpatient settings?

Dr. GRAHAM. Well, first of all both hospitals and physicians are, if you will, unbundling their services, and there is a clear shift to the outpatient versus the inpatient setting; I don't think there is any question about that.

I don't know of any system that adequately reviews outpatient procedures. Free-standing surgicenters are, for example, not subject

to joint commission review, as opposed to our hospitals' surgery centers.

I don't believe there is data to allow anyone to know whether this shift in site has had any beneficial effect on cost. I think until HCFA looks at its bottom line at the end of the year, only to find that "Yes, the site is different but the costs have been the same, will we know whether there has been any saving."

There isn't any effective system currently to review outpatient procedures. I am certainly sympathetic to AMPRA's belief that outpatient procedures, the outpatient setting, if you will, is a valid point of view. As procedures move to the outpatient setting, quality remains a question that ought to be answered.

Senator DURENBERGER. You use the ambulatory setting, but is there any question about what the outpatient procedure done within the hospital is going to raise with you the same suggestion about quality, as there is in the accreditation process for the hospital, as "hospital", or whatever? Have you any idea what happens? I take it the billings are done on the lower-of-cost or charges, so that we are not picking up any efficiencies. The hospitals are probably picking up some money when they move from part A to part B within the hospital. Wouldn't that be the case?

Dr. STRAWCUTTER. I would think; and as far as the review is concerned, as we move people out of the hospital, we in essence move them out of review. And that is the situation we are in right now.

Senator DURENBERGER. But the same thing is true within the hospital as "hospital." If you move them from part A to part B, they are outside the review process as well.

Dr. STRAWCUTTER. That's right, they are outside the review process then, and we don't know what is happening.

Senator DURENBERGER. I have used my time.

George?

Senator MITCHELL. Thank you, Mr. Chairman.

Do you—and I will ask this question of both of you and you can answer in turn—do you believe that HCFA has implemented the intent of Congress, the primary intent of Congress, which was to establish a quality-control mechanism? Or has it subordinated that intent to cost-containment?

Dr. STRAWCUTTER. If I might respond to that, from the standpoint of the PRO's, they are physician organizations, and as physicians they instinctively deal with quality of medical care.

Senator MITCHELL. They are not all physician organizations; they are physician-access organizations.

Dr. STRAWCUTTER. That's right. There is one non-physician-based organization. There are—I forget—three, four that are physician-access. The rest are physician sponsored.

But there are physicians doing the review.

Senator MITCHELL. Which is the one, incidentally?

Dr. STRAWCUTTER. In the State of Idaho, I believe, the PRO contract has gone to a Blue Cross organization.

Senator MITCHELL. Right. OK.

Dr. STRAWCUTTER. But the bulk certainly are physicians organizations and they are physician-review decisions, peer-review decisions. And physicians, as I say, instinctively address quality issues. And I might say also that historically physicians are not that en-

amored of the Federal Government to go down the line making decisions that they would try to impose, simply to meet a Federal quota. They have not had that relationship generally with the Federal Government.

Senator MITCHELL. No, they are no different from anybody else. Most people only enjoy their relationship with the Federal Government when it benefits them, and they don't like it when it doesn't.

Dr. STRAWCUTTER. So that quality issue, as I say, as long as it is a physician-review program and physician decisions, there is an element of quality there. The problem is, that is not a measureable one. And it's where we try to develop some means to measure and quantify that quality relationship, that we get into problems. I think that probably has not been done very well. I don't know how it could be done better. I think with more research we could find ways to do that better, to quantify it better.

Dr. GRAHAM. I think your question spoke to how effectively or dedicated, if you will, was HCFA in their implementing the quality direction that they seem to have been given.

I think the problem there is that HCFA serves many masters, if you will. They serve and try to serve the desires of the Congress; they are also under the scrutiny of the Office of Management and Budget. And I think it is this dichotomy of message that they struggle with that has impacted at the local PRO in terms of, "What are we here for? Are we here to cut the bottom line in terms of cost? Or are we here to assure quality as prospective payment is implemented?" I am not sure that the fault rests entirely with HCFA.

Senator MITCHELL. Well, you have really identified the crux of the problem, and it is interesting that you would suggest—and I don't know whether you mean this or not—that Congress and OMB are equal entities and that HCFA serves the both of them. [Laughter.]

I have never thought of it that way, and I don't know many Members of Congress who think of it that way; although there are undoubtedly many people at OMB who think of it that way. [Laughter.]

The fact is that it is a triangle, but it has turned the other way around. And Congress is here and OMB and HCFA are at another level. And that's the problem. It is difficult. There is a tension. There is a continuing tension between quality control and cost containment.

Dr. GRAHAM. It was not my intention to create an inaccurate metaphor.

Senator MITCHELL. No, I caught that.

But I think you very accurately, perhaps inadvertently, described what the situation is and therefore what the problem is.

Senator DURENBERGER. Tell him it wasn't inadvertent, Jack. [Laughter.]

Dr. GRAHAM. Thank you, Senator.

Senator MITCHELL. Thank you, Mr. Chairman; I see my time is up.

Senator DURENBERGER. Thank you both very much. I appreciate your testimony and your ongoing help.

Dr. STRAWCUTTER. Thank you.

Dr. GRAHAM. Thank you.

Senator DURENBERGER. The next witnesses are a panel consisting of Dr. William Felts, who is a member of the executive committee on legislation of the AMA; Mr. Jack Owen who is executive vice president of the American Hospital Association; and Dr. William Gilbert, a member of the committee on Federal legislation of the American Academy of Opthalmology in Washington.

Welcome, gentlemen. Your statements will be made part of the record in full, and you each have 5 minutes to summarize those statements, and in your summary you now have in mind some of the interests of the members of the subcommittee as reflected in our questions to previous witnesses, and if you want to anticipate some of our questions you may do that as well. Dr. Felts, you may go first.

STATEMENT OF WILLIAM FELTS, M.D., VICE CHAIRMAN OF THE COUNCIL ON LEGISLATION, AMERICAN MEDICAL ASSOCIATION, WASHINGTON, DC

Dr. FELTS. Mr. Chairman and members of the committee, I am William Felts. I am vice chairman of the AMA's council on legislation. Accompanying me is Tom Wolff of the AMA's department of Federal legislation. Parenthetically, I am also a past president of the National Capital Medical Foundation, which served as the PSRO for the District of Columbia.

In testimony before this committee on two occasions in 1984, the American Medical Association expressed its firm support for medical peer review that focuses on quality assurance. We wish to reiterate that support.

The AMA actively assisted State medical societies in their efforts to become PROs, and we are pleased to report that nine State medical societies secured such contracts. An additional 34 State societies supported the bid of the organization that was awarded the contract for their State.

We are also very pleased that all the PRO contracts except one were awarded to physician organizations. We believe strongly that professional direction and support is vital to the success of the PRO Program.

Because of our strong commitment to ensuring that the PRO program emphasize quality assurance, the AMA undertook a major effort to develop an appropriate proposal in response to the request for a proposal for the so-called Super PRO contract. We were quite disappointed that HCFA decided to cancel this RFP, because HCFA stated that it did not accurately describe the Government's needs.

Despite the problems involved with that first RFP, the AMA remains strongly interested in securing the Super PRO contract. To this end we have reviewed the recently released second Super PRO RFP, and yesterday the AMA Board of Trustees approved the submission of another proposal. We are hopeful that this time a contract will be awarded and that we will be selected as the contractor. Too much time has already elapsed without a formal structure in place to review the performance of the PRO's.

Even should we not be successful in securing the Super PRO contract, we will continue to be actively involved in the PRO Program.

In accordance with our longstanding interest in promoting medical peer review and quality of care, the AMA has developed a plan to monitor the PRO Program. The monitoring plan involves the collection of information concerning the impact of the program on patients, physicians, and hospitals, as well as on the quality and cost of medical care. Through mailings to hospital chiefs of staff and to State, county, and specialty societies we have asked physicians to inform us of relevant experiences both positive and negative which they feel are attributable to this program. We believe that this monitoring plan will provide useful information concerning the effect of the program on the quality of patient care in the country. We will be keeping you informed of our findings.

The AMA continues to have a number of concerns relating to the PRO Program. We are very concerned as to whether PRO's are adequately performing their quality-assurance function as intended by the Congress. The Social Security Amendments of 1983 provide that PRO's are to review the completeness, adequacy, and quality of hospital inpatient services provided as well as the appropriateness of discharges.

The General Accounting Office recently released a preliminary report referred to by Senator Mitchell on the impact of the Medicare prospective payment system on posthospital long-term care. It found evidence that Medicare patients are being discharged from hospitals after shorter lengths of stay and in a poorer state of health than prior to PPS.

While shorter lengths of stay may be indicative of increased efficiency, we are concerned that in the process quality of care may be compromised. Because of the strong economic incentive for underprovision of inpatient services inherent in the PPS system, PRO's have a vitally important role to play in assuring high quality care for Medicare beneficiaries.

In light of the GAO report, we believe that PRO's should place increased emphasis on ensuring that Medicare patients receive all medically necessary services and are not discharged from the hospital prematurely. Increased emphasis on concurrent review may be desirable.

It is important to remember that premature discharges can be costly as well as quality of care problems. Patients who are discharged prematurely often are referred to nursing homes or require home health services resulting in additional costs to the Medicare Program that would not have been incurred had the patient remained in the hospital.

We also are very concerned over provisions in the PRO contracts that establish objectives for reducing specified types of services, including admissions by specified amounts. We appreciate that HCFA has stated that PRO contract objectives are intended to be goals rather than quotas. However, in practice, these objectives may have the effect of encouraging an administratively pressured PRO to deny appropriate as well as inappropriate admissions in order to meet its contract objectives.

We are pleased that the final PRO rules concerning confidentiality, sanctions, reconsiderations, and appeals, and PRO-review functions have finally been published. We believe, however, that it is unreasonable for HCFA to delay publishing proposed rules for

many months, establish only a 30-day comment period on them, and then wait an additional 8 and 11 months to finally issue the rules. Unfortunately, this is how HCFA implemented these four rules.

The delay in publication created a considerable amount of uncertainty among physicians, hospitals, and PRO's concerning a number of issues. For example, confusion existed for some time concerning whether a PRO should discuss a proposed denial determination with the attending physician before such a determination is made.

Mr. Chairman, we commend this committee for holding this hearing and for its close oversight of the PRO program. Without doubt the committee's oversight activities for the past 15 months have greatly facilitated implementation of the program. We urge you to continue to closely monitor the program and the Super PRO contracting process to ensure that the implementation process is fully responsive to the development and continuation of quality care.

I will be very happy to answer any questions that members of the committee might pose.

Thank you.

[Dr. Felts' written testimony follows:]

STATEMENT

of the

AMERICAN MEDICAL ASSOCIATION

to the

Subcommittee on Health
Committee on Finance
United States Senate

Presented by

William Felts, M.D.

Re: Implementation of the Peer Review Organization Program

April 19, 1985

Mr. Chairman and Members of the Committee:

My name is William Felts, M.D., and I am a member of the Executive Committee of the AMA's Council on Legislation. Accompanying me is Thomas Wolff, a legislative attorney in the AMA's Department of Federal Legislation. The American Medical Association is pleased to have this opportunity to testify before this Committee concerning the implementation of the Peer Review Organization (PRO) program.

Mr. Chairman, in testimony before this Committee on two occasions in 1984 the AMA expressed its firm support for medical peer review that focuses on quality assurance. We wish to reiterate our strong support for medical peer review that emphasizes quality assurance.

PRINCIPAL POINTS IN THE STATEMENT

of the

AMERICAN MEDICAL ASSOCIATION

to the

Subcommittee on Health
Committee on Finance
United States Senate

Presented by

William Felts, M.D.

Re: Implementation of the Peer Review Organization Program

April 19, 1985

- The AMA strongly supports medical peer review that emphasizes quality assurance.
- The AMA is involved in an effort to become the designated contractor to review the accuracy and quality of the medical determinations made by PROs.
- The AMA has developed a plan to monitor the impact of the PRO program on patients, physicians and hospitals, as well as on the quality and cost of medical care.
- The AMA is very concerned regarding whether PROs are adequately performing their quality assurance function as intended by Congress. We believe that PROs should place increased emphasis on ensuring that Medicare patients receive all medically necessary services and are not discharged from the hospital prematurely.
- The AMA continues to be very concerned over provisions in PRO contracts that establish objectives of reducing specified types of services by a specified amount.
- The AMA remains concerned about the manner in which HCFA will be evaluating PRO performance based on changes in admission behavior in the PRO area.

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AMA Activities

The AMA actively assisted state medical societies in their efforts to become PROs. In addition to earlier conferences sponsored by the AMA, the AMA in March 1984, after the PRO request for proposals was released, held an additional seminar to assist medical society representatives in drafting a responsive PRO proposal. The AMA also developed a PRO contract proposal manual to further assist state medical society bidders in preparing their PRO bid and provided other informal assistance.

The AMA is pleased to report that nine state medical societies secured PRO contracts and an additional 34 state societies supported the bid of the organization that was awarded the contract for their state. We are also very pleased that all PRO contracts except one were awarded to physician organizations. We believe strongly that professional direction and support is vital to the success of the PRO program.

Because of our strong commitment to ensuring that the PRO program emphasize quality assurance, the AMA is attempting to become the designated contractor to review the accuracy and quality of the medical determinations made by PROs. We undertook a major effort to develop an appropriate proposal in response to the request for proposal (RFP) for the so-called Super-PRO contract. We were thus extremely disappointed when HCFA decided to cancel the Super-PRO RFP, particularly since HCFA stated that the RFP did not accurately describe the government's needs.

Despite the problems involved with the first RFP, the AMA remains strongly interested in securing the Super-PRO contract. To this end we have reviewed the recently released second Super-PRO RFP and intend to

submit another proposal. We are hopeful that this time a contract will be awarded and that we will be selected as contractor. Too much time has elapsed already without a formal structure in place to review the performance of the PROs.

Even if we are not successful in securing the Super-PRO contract, we will continue to be actively involved in the PRO program. In accordance with our long-standing interest in promoting medical peer review and quality of care, the AMA has developed a plan to monitor the PRO program. The monitoring plan involves the collection of information concerning the impact of the PRO program on patients, physicians and hospitals, as well as on the quality and cost of medical care. Through mailings to hospital chiefs of staff and to state, county and specialty societies, we have asked physicians to inform us of relevant experiences, both positive and negative, which they feel are attributable to the PRO program.

We have expressed particular interest in obtaining information concerning changes in length of stay, admission and discharge policies, preadmission certification procedures, utilization and quality review results, administrative relations between hospitals and physicians and PROs, any demonstrable impact that PRO review may have on the cost or quality of care, and the results of any PRO activities to review patients other than Medicare beneficiaries.

We believe that our PRO monitoring plan will provide useful information concerning the effect of the PRO program on the quality of patient care in the country. We will keep you informed of our findings.

AMA Concerns

The AMA continues to have a number of concerns with the PRO program. These concerns are detailed below.

Quality of Care

The AMA is very concerned regarding whether PROs are adequately performing their quality assurance function as intended by Congress. The Social Security Amendments of 1983 (P.L. 98-21) provide that PROs are to review the completeness, adequacy and quality of hospital inpatient services provided, as well as the appropriateness of discharges. The General Accounting Office recently released a preliminary report on the impact of the Medicare prospective payment system (PPS) on post-hospital long-term care. The report found evidence that Medicare patients are being discharged from hospitals after shorter lengths of stay and in a poorer state of health than prior to PPS.

While shorter lengths of stay may be indicative of increased "efficiency" by hospitals, we are concerned that in the process quality of care may be compromised. The AMA believes that because of the strong economic incentive for underprovision of inpatient services inherent under the PPS system, PROs have a vitally important role to play in assuring high quality care for Medicare beneficiaries. In light of the GAO report, we believe that PROs should place increased emphasis on ensuring that Medicare patients receive all medically necessary services and are not discharged from the hospital prematurely.

It is important to remember that premature discharges are a cost as well as a quality of care problem. Patients who are discharged prematurely often are referred to nursing homes or require home health services resulting in additional costs to the Medicare program that would not have been incurred had the patient remained in the hospital.

Contract Objectives

The AMA also continues to be very concerned over provisions in PRO contracts that establish objectives of reducing specified types of services, including admissions, by a specified amount. For example, some PRO contracts include objectives to reduce certain surgery admissions by 25%.

The AMA recognizes that HCFA has stated that PRO contract objectives are intended to be goals rather than quotas. However, in practice these objectives may have the effect of encouraging an overzealous PRO to deny appropriate as well as inappropriate admissions in order to meet its contract objectives.

Evaluation Criteria

Similarly, we are still concerned about the manner in which HCFA will be evaluating PRO performance based on changes in admission behavior in the PRO area. That is, the admission rate for the PRO area during the contract period will be compared to the admission rate before the contract went into effect. We understand that PROs are mandated by law to deny inappropriate admissions -- which is as it should be. However, we believe that Congress did not intend that PROs be held responsible for changing the area's Medicare admission rates to meet arbitrary

objectives. In sum, it is inappropriate to evaluate a PRO based on a function Congress did not intend it to perform. The danger is that the PRO is encouraged to deny more than clearly inappropriate admissions.

PRO Final Rules

The AMA is pleased that final PRO rules concerning confidentiality, sanctions, reconsiderations and appeals, and PRO review functions have finally been published. We believe, however, that it is unreasonable for HCFA to delay publishing proposed rules for many months, establish only a 30-day comment period for the proposals and then wait eight months or longer to issue final rules. Unfortunately, this is how HCFA implemented these four rules.

The delay in publishing these final rules created a considerable amount of uncertainty among physicians, hospitals and PROs concerning a number of important issues. For example, confusion existed for some time concerning whether PROs should discuss a proposed denial determination with the attending physician before any determination is made.

AMA Proposed Amendments to the PRO Law

The AMA continues to believe that changes to the PRO law are desirable in order to ensure an effective program. We have drafted a series of amendments which we believe would improve the PRO law. A list of these amendments is attached to our statement.

Conclusion

The AMA commends the Committee for holding this hearing and for its close oversight of the PRO program. Without doubt this Committee's oversight activities over the past 15 months have greatly facilitated implementation of the PRO program. We urge the Committee to continue to monitor closely this program and the Super-PRO contracting process to ensure that the program is fully responsive to the development and continuation of quality care.

Mr. Chairman, the AMA appreciates the opportunity to testify here today. I will be happy to answer any questions members of the Committee may have.

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January 1985

DRAFT BILL TO AMEND THE PEER REVIEW ORGANIZATION LAW

This bill would amend the Peer Review Organization law as follows:

(1) Section 1152(1)(A)* does not define the words "substantial" and "representative" for determining whether an entity is a physician organization for purposes of priority treatment. The amendment would define "substantial" to mean at least 25% of the physicians engaged in the practice of medicine or surgery in the PRO area. The amendment would define "representative" to mean geographically representative.

(2) Section 1152(1)(B) which establishes criteria for non-physician PROs would be amended to require that the licensed doctors of medicine or osteopathy who perform review for the entity be directly engaged in patient care.

(3) Section 1153(b)(1) does not state criteria for the Secretary in choosing between two competing physician organizations. The amendment would state that if more than one qualified physician organization desires to contract, priority must be given to the organization that has the greatest percentage of area physicians and is most geographically representative of physicians in the area.

(4) Section 1153(b)(2)(A) provides that the Secretary cannot contract with an entity that makes payments to health care practitioners or providers for at least twelve months after the Secretary begins to enter into contracts. The amendment would extend the time during which the Secretary could contract only with a physician organization from twelve to thirty-six months.

(5) Section 1153(c) fails to reinstate the priority for physician organizations as the area PRO after the termination of a PRO contract. The amendment would require the Secretary to give contracting priority to a physician organization for the first twelve months after a contract between the Secretary and a PRO is terminated for any reason.

(6) Section 1153 fails to give a PRO the right to renegotiate its agreement with the Secretary after the first year based on its experience under the contract. The amendment would add a new provision specifying a PRO's right to renegotiation after one year.

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*All Section references are to the Social Security Act

(7) Section 1153(c)(7) and 1154(a)(6) refer to national and regional norms of practice for a PRO to use in evaluating services. These sections would be amended to specifically provide that PROs are to ascertain and develop appropriate guidelines as opposed to norms. In drawing up the guidelines, the PROs should utilize the expertise of national, state and county medical associations and specialty societies. However, the guidelines should also reflect local practice patterns. The amendment would also state that the guidelines are to serve as guides only and should not be substituted for the judgment of individual physicians.

(8) Section 1153(d)(2) allows the Secretary absolute discretion to accept or reject the findings of panels appointed to review the performance of a PRO before a PRO can be terminated. The amendment would require the Secretary to accept the panel's findings unless the Secretary shows good cause for not doing so and issues a written opinion detailing his reasons.

(9) Section 1153(d)(3) provides that the panel reviewing a PRO's performance must consist of not more than five people each of whom is a member of a PRO. The amendment would require that at least two of the five members of the panel must be physicians directly engaged in patient care.

(10) Section 1153(f) prohibits judicial review of a determination by the Secretary to terminate a PRO contract. The amendment would provide for judicial review in the event that the Secretary terminates a PRO contract to ensure that adequate grounds for termination exist.

(11) Section 1154 gives all PROs the authority to conduct pre-admission review. The amendment would deny PROs that are not physician-composed organizations the authority to perform such review. It would allow physician-composed PROs to conduct focused pre-admission review under certain limited circumstances.

(12) Section 1154 allows the Secretary to require PROs to perform blanket pre-admission review for specified procedures. The amendment would specifically preclude the Secretary from doing so.

(13) Section 1154(a)(7)(C) allows PROs to examine the pertinent records of any practitioner or provider of health care services who provides services for which the PRO has review responsibility. The amendment would grant PROs the authority to examine only the pertinent records kept in a hospital not records kept in a physician's private office.

(14) Section 1154(a)(7)(D) authorizes PROs to inspect a physician's office if care is rendered to Medicare patients there. The amendment would prohibit PROs from inspecting a physician's office and would also deny PROs the authority to review services provided there.

(15) Section 1155 of the Act provides that a beneficiary who receives an adverse reconsideration determination from a PRO is entitled to a hearing by the Secretary if the amount in controversy is $200 or more and to judicial review of an adverse decision by the Secretary if the amount in controversy is $2,000 or more. The amendment would give practitioners the additional right to review by an independent panel of local physicians of any adverse reconsideration determination. The amendment would also provide that a practitioner who receives an adverse determination by a panel or a provider who receives an adverse reconsideration would be entitled to a hearing and judicial review if the threshold amounts are reached.

(16) Section 1156(b)(1) states that if the Secretary fails to act upon the recommendations submitted by a PRO for sanctions against a practitioner within 120 days after receiving them, the practitioner shall be excluded from eligibility to provide services to Medicare beneficiaries on a reimbursable basis until the Secretary determines otherwise. The amendment would provide that all sanctions recommended by a PRO must be accepted or rejected by the Secretary within 120 days.

(17) Under Section 1156(b)(2), the Secretary could provide notice to the public that sanctions have been imposed on a practitioner before the practitioner has exhausted his right-to-appeal. The amendment would provide that the Secretary shall not provide notice to the public that sanctions have been imposed against a practitioner until the practitioner has exhausted his opportunity for judicial review of the Secretary's decision.

(18) Section 1157(c) provides that physicians will not be held civilly liable if they exercise due care and act in compliance with professionally developed norms of care and treatment applied by a PRO. This provision would be repealed because it would probably have the effect of pressuring practitioners to adhere to the norms.

(19) The PRO law provides only for review of services for which payment may be made under Medicare and Medicaid. The amendment would provide for review of care delivered through federal medical programs under the Veterans Administration.

Senator DURENBERGER. Thank you very much.
Jack?.

STATEMENT OF JACK W. OWEN, EXECUTIVE VICE PRESIDENT, AMERICAN HOSPITAL ASSOCIATION, WASHINGTON, DC

Mr. OWEN. Thank you very much, Mr. Chairman.

My name is Jack Owen, and I am the executive vice president of the American Hospital Association. I guess the most important thing I learned this morning was that we have a new phrase to replace 'DRG creep.' It is now called 'scope of work creep.' So we are glad to hear that.

I think we should take into account as we listen to the testimony here today from HCFA of effect of PROs on the PPS program, the Prospective Payment System Program, that it already has had a decided effect on admissions and the lengths of stay. Our statistics show that as of December 1984, this fiscal year, admissions were down in this country 4 percent, over-65 admissions are down 2.9 percent, and there has been a 5.6 percent decline in the length of stay.

You have to keep in mind that PROs were not in effect while this was happening. So some of the things that we are seeing occur really have no relationship to the PROs.

Our concern primarily is one of quality, and that is, are the PROs looking at quality and not just the cost? I am concerned because, as I said before to this committee, as I read Carolyne Davis's testimony on page 5, she cites and I am quoting her, that one of the problems is "a lack of aggressiveness by the PROs," and states, "We will not hesitate to withhold funds or pursue termination action." That to me doesn't sound like an educational program but one that has a lot more authority to go after PROs on the basis of nothing other than program cost.

At the same time, we are pleased with what HCFA has done in actions regarding rural hospitals, for instance. The reduction of outlier review and the reduction of the DRG validation is very good, and we want to applaud what they are doing there.

I have four quick points I would like to bring up—five points, actually—that I think will express our concerns that he outlined in my written statement.

First, the PRO objectives and review criteria. The problems that we see in it, again, seem to be cost. And cost can't be the only consideration. There must be a consideration of quality. I think that is what Congress envisioned when they formed this program. The objectives were formulated with no public participation. And despite the fact that HCFA stated the goals are flexible targets, that view is not supported in PRO contracts or formal instructions to PROs and certainly the quote I took from Carolyne's testimony.

On the oversight of PRO determination, we feel strongly about this, that the providers can only have PRO decisions reconsidered. There is no real opportunity for an appeal. The beneficiaries also have no opportunity to appeal. So, although the Super PRO is going to maybe be a good oversight mechanism—we are not sure, because that hasn't been implemented yet. There is really no way

to appeal either for the beneficiary or the provider. We think that should be taken care of.

On the third point, public accountability, the long delays in issuing final regulations which Dr. Felts mentioned was a problem, and the limited time period for public comments are subjects of great concern.

On the centralization of review, again, we have discovered—Congress has discovered and the administration has discovered—that in the health care field the use of an incentive system has brought some very good results in health care. And yet we see no kind of incentive system in the PRO program. The current program doesn't provide rewards or incentives for those hospitals that have effective inhouse utilization; the contracts do not allow PRO discretion to reduce or review of specific hospitals or physicians with low denial rate.

We think there ought to be some incentives established for hospitals with good track records and effective utilization review programs.

And lastly, the waiver of liability. The waiver of liability probably has more hospitals concerned than anything else in the PRO program. And here, HCFA proposes to eliminate the provider's right to earn a favorable presumption in a waiver of liability termination.

Under the proposed new policy, waiver determinations have been made on a case-by-case basis, and application of the waiver would be denied under a much broader interpretation of the provider's knowledge of the situation.

Here is a case where medicine is an art, not that much of a science. And we heard Dr. Graham explain briefly about a patient who was admitted in Minnesota. We find these cases all around the country, where the decision has to be made by a phvsician to admit that patient, and then the Monday-morning quarterback or the judge with hindsight can say, "Well, you shouldn't have admitted him," and deny that particular case. We think something has to be done to make sure that this is corrected, because those decisions are decisions that have to be made on the spot, not 3 or 4 days or 1 week later.

That concludes my remarks. I will be happy to answer any questions. We believe in the PRO program. The Hospital Association supports it. We think that the quality assurances must be part of the program and not only just a cost program.

Thank you.

[Mr. Owen's Written Testimony Follows:]

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STATEMENT OF THE AMERICAN HOSPITAL ASSOCIATION
BEFORE THE
SUBCOMMITTEE ON HEALTH
OF THE
COMMITTEE ON FINANCE
UNITED STATES SENATE

ON

IMPLEMENTATION OF THE PEER REVIEW ORGANIZATION PROGRAM

April 19, 1985

SUMMARY

The American Hospital Association (AHA) supports the development of an effective utilization review program focused on the quality and appropriateness of care provided under Medicare. However, the Association continues to have fundamental objections to the Peer Review Organization (PRO) program as implemented by the Department of Health and Human Services (HHS) in response to the Peer Review Improvement Act of 1982 (part of the Tax Equity and Fiscal Responsibility Act, P.L.97-248).

The AHA's concerns center on the program's objectives; timing of issuance of regulations; lack of notice and minimal opportunity for public comment on new requirements; lack of independent validation of PRO determinations; and

centralization of review, with costs shifted from the PRO to the hospital. The AHA is also concerned about the proposed changes to Medicare's related waiver of liability rules.

In view of these concerns, the Association recommends that there be full, open communication among the Health Care Financing Administration (HCFA), PROs, beneficiaries and providers; assurance of due process in the formulation of policy and the conduct of review; maintenance of an adequate beneficiary appeals mechanism; flexible review procedures that recognize appropriate, as well as inappropriate, provider behavior; and retention of a modified favorable presumption under the waiver of liability rules.

GENERAL COMMENTS

Mr. Chairman, I am Jack W. Owen, executive vice president of the AHA, which represents over 6,100 hospitals and health care institutions, as well as more than 38,000 personal members. I appreciate this opportunity to once again comment on implementation of the PRO program, and to share the AHA's concerns on proposed changes to Medicare's waiver of liability rules. There has been a great deal of activity on this issue since the Subcommittee's oversight hearing last July, but little has changed in terms of the substantive and fundamental problems that the program faces.

Hospital Perspectives

The AHA's primary concern is that individuals in the communities served by its hospitals get the care that they need. Toward that end, the AHA supports

development of an effective utilization review program that focuses on both quality and appropriateness of care. The Association strongly backs the use of physician-sponsored peer review to evaluate medical care provided to Medicare patients. However, the AHA does not support:

- use of objectives negotiated between HCFA and PRO applicants without adequate validation and opportunity for public comment;

- a utilization review program that refuses to acknowledge the uncertain nature of the practice of medicine or the variable needs of individual patients; or

- a utilization review program that does not sufficiently recognize and reward provider performance and effectiveness in managing the quality and appropriateness of care they provide.

The AHA continues to be particularly concerned about the following aspects of PRO program implementation:

- the basis for, and use of, PRO objectives;

- the lack of adequate oversight or independent validation of PRO determinations;

- the extent to which the PRO program has been implemented without issuance of regulations and with minimal opportunity for public review and comment;

- the extent to which PRO review requirements are imposed without adequate or timely notice to providers, PROs, and beneficiaries to allow for orderly implementation; and

- the extent to which review is being centralized and the cost of review shifted from PROs to hospitals.

Prior to exploring these points, it seems useful to review hospital performance, especially how hospitals are responding to incentives established by Medicare prospective pricing.

Current Industry Performance

The PRO program was created as part of a broader strategy to contain the rate of increase in Medicare expenditures. Rising utilization has accounted for a substantial part of the increase in Medicare expenditures over the past decade. Hospitals have supported the adoption of the Medicare prospective pricing system (PPS) and have responded forcefully and positively to its incentives, as well as to the incentives of new, competitively oriented financing systems in the private sector.

During calendar year 1984, total hospital expenses rose 4.5 percent, less than one-third the rate of increase of two years ago (15.8 percent) and less than one-half the 1983 rate (10.2 percent). Inpatient expenses in 1984 increased only 3.2 percent. The dramatic slowing of the rate of increase in costs is largely the result of three factors. First, admissions have declined sharply

for both the over-65 and under-65 populations. Total admissions declined 4.0 percent in 1984, after not changing in 1982 and declining 0.5 percent in 1983. While admissions of patients under 65 years of age declined more sharply in 1984 (4.5 percent), the change in admissions of patients over 65 was also dramatic. After rising steadily for more than a decade, over-65 admissions declined 2.9 percent in 1984.

The second factor contributing to the slower increase in hospital expenses in 1984 was a continued decline in average length of stay. While lengths of stay have declined for many years, the long-term trend recently has accelerated. In 1984, length of stay of patients under 65 was 3.6-percent lower than the previous year. Length of stay of patients over 65 declined 7.6 percent between 1983 and 1984.

The combined effects of shorter stays and fewer admissions has been a sharp reduction in hospital inpatient census.

The third major factor responsible for slower growth of expenses is a reduction in hospital employment made possible both by the lower census and by staffing efficiency improvements. Total full-time equivalent employees increased at rates of 3.7 and 1.4 percent in 1982 and 1983 respectively. In 1984, full-time equivalent employment declined 2.3 percent. Because admissions and length of stay declined, the number of staff hours per admission continued to rise, but at a lower rate of increase, 0.5 percent in 1984 compared to 3.4 percent in 1982 and 1.4 percent in 1983. This lower rate

of growth is remarkable considering that admissions that have been eliminated are probably lower-intensity cases.

The significance of these trends is readily apparent. In 1984 hospital expenses rose at the lowest rate in years, and Medicare expenditures increased at the lowest rate since the inception of the program. Undoubtedly, some additional reform measures can be undertaken to reduce the growth in Medicare expenditures while maintaining quality. However, actions must not be taken merely to save more money without regard to effect. And actions must not be taken in a crisis atmosphere with limited opportunity for discussion of the short- and long-term implications of policy changes.

SPECIFIC PRO IMPLEMENTATION ISSUES

PRO Objectives and Review Criteria

The recent performance of the hospital industry is strong evidence that incentives are powerful tools for containing Mediare costs. However, when Medicare is evaluated, cost is not the only factor that should be taken into account. More important are the needs of the growing Medicare population and the nature of the system required to meet those needs, now and in the future.

These considerations are particularly relevant to the establishment of PRO goals and objectives. Last July, public uneasiness about PRO objectives was high. PRO contract objectives were negotiated with no formal public participation, and contract bidders may well have been put in the position of

proposing unrealistic objectives without clearly identifying specific problems or appropriate solutions. HCFA has publicly stated that the contract objectives are "flexible targets" for cutting "unnecessary" Medicare admissions, but such flexibility is reflected neither in PRO contracts nor in formal instructions to PROs and HCFA regional offices. HCFA's approach to the first six-month evaluation is a critical opportunity for demonstration of how these contract objectives will be used, particularly because HCFA has not released evaluation criteria.

The AHA believes measurable goals are essential if program administrators, hospitals, physicians, beneficiaries, and the public are to understand the direction in which the program is headed. However, the Association is concerned about lack of clarity in the origin, structure, and use of PRO objectives, and the absence of a structured process to reevaluate and revise objectives based on actual experience, rather than on inadequate information, inadequate review standards, and anticipated behavior.

The AHA believes that legitimate PRO objectives should meet several criteria:

- All objectives should be based on quality of care and medical considerations, rather than on financial considerations.

- Objectives should reflect local needs and circumstances, including the age and sex of the population served, local standards of medical practice, and the range of services available in individual communities.

- Objectives should be based on identified problems, and should address only utilization demonstrated to be unnecessary or inappropriate.

- Objectives should take into account the many medically related social factors that affect utilization patterns, such as ability of patients to travel to receive services and availability of support for patients at home.

While some PRO contract objectives may meet these criteria, others do not. Several characteristics of negotiated PRO objectives are troublesome:

- Methods used to establish objectives have never been specified publicly. However, HCFA's compendium of PRO objectives and validation methods provides some insights. Many PRO objectives are based on simple comparisons of national and local use rates without studies documenting the nature, source, or quantity of inappropriate utilization in the PRO's area (e.g., Kentucky, Alabama, Tennessee, Nebraska, and Missouri).

  Other PRO objectives are based on: (1) limited physician-opinion polls and undocumented expectations (e.g., Georgia, Missouri, Oregon, South Carolina, Alabama, and Arkansas); (2) extrapolations of exceptionally small sample studies (e.g., Pennsylvania, Vermont, and South Carolina); or (3) out-of-state studies covering other Medicare populations and providers (e.g., Texas, New Hampshire, Wyoming, and South Carolina). Most often, validation summaries indicate merely that the objective was

"determined" by the PRO on the basis of "available data," without any real indication of how the objective was formulated. National utilization rates can be used appropriately only to identify potential problem areas. Specific achievable objectives should be based only on valid local studies that confirm the existence and scope of a problem and identify its causes.

Furthermore, each PRO has at least one objective aimed at reducing admissions by specific physicians or at specific hospitals. Even if identified hospitals work with their PROs to reduce or eliminate unnecessary utilization, it is possible that the objectives will not be met if the hospitals' shares of total discharges rise because of effective competition with other hospitals, or for other reasons, such as care to patients injured in natural disasters. Any attempt to apply these objectives inappropriately would violate several federal laws, including, at a minimum, Medicare statutes.

- Studies used by PROs to set objectives were not made available for public comment prior to negotiations, even though PRO contracts could have been structured to provide opportunities for public review and discussion of proposed objectives. Full public review of PRO program goals and objectives is essential. It is increasingly clear that the Administration, in implementing PROs, is seeking to establish a PRO program that changes local medical practice standards rather than a program that reviews care based on such standards. Though this goal

may be legitimate in some cases, given variations in many practice patterns, HCFA and PROs have given neither adequate time nor study to this issue.

Most important, the existence of this goal and its implications have not been communicated explicitly to beneficiaries or providers. For example, about 600,000 of the 1.25 million admission reductions targeted in PRO objectives are to be achieved by shifting inpatient surgery to outpatient care. The impact of this objective must be conveyed to beneficiaries. The use of ambulatory rather than inpatient surgery may be appropriate for many younger adults but inappropriate for older Medicare beneficiaries and those who live alone or are disabled. Reassurances must be provided regarding continued beneficiary access to inpatient care if ambulatory surgery is ill-advised or unavailable. Hospitals and beneficiaries must be given clear answers to questions on their rights and alternatives if a beneficiary wants or needs to have a procedure performed on an inpatient basis and the PRO will authorize only an ambulatory procedure. Another major consideration is the possible lack of available ambulatory services. Therefore, steps should be taken to ensure that such services are available to patients.

- The PRO contracts were negotiated in an extremely short time, due largely to the passage of nearly 18 months between enactment of the Peer Review Improvement Act and issuance of a Request for Proposals

(RFP). Nevertheless, the contracts provide that only HCFA, "at its option," can initiate a reevaluation of contract objectives if it appears that the objectives agreed to during the initial negotiation are unrealistic or inappropriate. Despite data limitations for development of the objectives, the contracts do not provide an option to PROs to reopen discussions on objectives, much less include a universal requirement for reevaluation and refinement of objectives based on actual experience. These problems can be solved, if HHS is willing to observe its legal obligations. Opportunities for public review and comment can be built into PRO contracts and procedures. PROs can be given an opportunity to revise inappropriate objectives if more intensive study of potential problem areas reveals new information. HHS can require not only the careful wording of PRO objectives but also rigorous documentation of problems, to avoid placing PROs in the potentially untenable position of trying to meet an objective based on faulty premises.

It must be kept in mind that PRO review criteria are driven by objectives set in their contracts, not by local practice standards. If the underlying objectives are flawed or unrealistic and PROs are bound to meet them, the result will be overly restrictive or inappropriate review outcomes.

Oversight of PRO Determinations

The potential for degeneration of the PRO program into a budget-cutting tool remains because of the lack of adequate safeguards against inappropriate PRO

actions. HCFA claims that the PRO statute precludes provider appeals of PRO decisions, allowing only requests that the PRO reconsider its original decision. Beneficiaries have the right to appeal beyond PROs, but in January 1984, HCFA issued an administrative decision prohibiting hospitals and other providers from assisting beneficiaries in lodging such appeals. These policies severely limit the ability of beneficiaries and providers to obtain an objective third-party examination of PRO decisions.

HCFA's planned SuperPRO, which is to monitor quality and equity of PRO medical review decisions, may provide, at best, a limited safeguard, depending on how it is structured, the extent to which its activities are open to public scrutiny, and how well it is funded. As yet, HCFA's SuperPRO contract has not been let. A revised Request for Proposals was just issued and the AHA was pleased to see that the Scope of Work was expanded to require at least some validation of each PRO's medical review criteria. However, delays in implementing the SuperPRO mean that at least half of the first two-year contract cycle will have passed before the SuperPRO begins work.

Public Accountability

One of the most troubling aspects of the PRO program has been HHS' delay in publishing implementing regulations. In delaying publication of critical regulations, in limiting public comment periods to 30 days, and in implementing important policies outside the rulemaking process, HHS apparently has undervalued the benefit that can be derived from public comment in shaping

sound public policy. This approach precludes a smooth and workable transition to a review program:

- with sensible and practical policies;
- with national goals addressed in full recognition of local conditions and without sacrificing community needs;
- with delivery or receipt of needed services not disrupted by "surprise" new policies implemented without adequate notice to hospitals, physicians, or beneficiaries; and
- with PROs not faced with daily uncertainties regarding their ability to fulfill their contractual commitments.

This situation represents a serious breach of HHS' obligations to provide for public accountability and to meet specific requirements of the Administrative Procedures Act.

Specifically, the PRO program has been implemented without issuance of final regulations governing conduct of review, the reconsideration and appeal process, sanctions procedures, or acquisition and disclosure of data by PROs. Notices of Proposed Rulemaking (NPRMs) on acquisition and disclosure of data as well as the sanctions process were not issued until April 1984, almost 20 months after passage of the Peer Review Improvement Act. NPRMs on conduct of

review and the reconsideration and appeals process were not issued until July 1984. Although PROs have been in operation for more than nine months in some states, final regulations were not published until Wednesday of this week (April 17) and do not become effective until mid-May.

Because of continued delays, on October 10, 1984, the AHA filed a petition for rulemaking on all substantive PRO policies. A copy of the petition, detailing the Department's practices to that date and AHA's objections and requests for HHS action, is being sent to the committee under separate cover for review and incorporation into the record. Lack of response to the petition led the AHA to file suit against the Department on January 29, 1985, in an attempt to compel proper adherence to the Administrative Procedures Act.

The lack of adequate rulemaking has resulted in a variety of problems, principally the lack of a consistent policy framework to guide PROs, providers, and beneficiaries. Even when policies are adopted, informal channels used to communicate them leave many interested parties uninformed until a problem arises, often resulting in payment denials for administrative violations even though the PRO determined that care was medically necessary. Although HCFA staff and many PROs are generally responsive in addressing problems as they arise, this ad hoc approach to policymaking is inefficient and often destructive to working relationships. It also results in multiple individual decisions, rather than a solid conceptual framework for the program.

Without such a framework, numerous implementation problems have arisen that result directly from either an absence of appropriate policy or from conflicts

with other Medicare policies. During 1984, HCFA attempted to limit provider authority to issue the notices of noncoverage to beneficiaries as required by the waiver of liability rule, thereby severely restricting hospitals ability to exercise effective utilization control. HCFA has recognized the problem and corrected this policy in early 1985, but other problems remain. Beneficiaries and hospitals still are confused about partial Medicare coverage under Part B when the patient chooses inpatient over outpatient treatments for necessary--but not acute-level--services. Meanwhile, because of the delay in issuing final regulations governing the relationships between hospitals, PROs, and Medicare fiscal intermediaries, it is unclear how HCFA plans to resolve a backlog of thousands of unreviewed cases. In Pennsylvania, for example, the PRO faces possible termination for nonperformance because payment to hospitals has been delayed on all claims that require PRO review prior to payment.

Furthermore, many PRO program guidelines have been written in the context of the PPS rules, which has left PROs substantially without guidance on review of services provided in exempt psychiatric and rehabilitation hospitals and units, and for all review performed in the four waivered states and three U.S. jurisdictions exempt from the Medicare PPS. The recent issuance of comprehensive PRO Manual instructions for performing review applies exclusively to PPS hospitals. Many issues resolved in states under PPS remain unresolved in these situations.

Finally, the delay of final regulations has created severe problems in executing hospital-PRO agreements. Hospitals were given little opportunity

last fall for meaningful negotiation of PRO agreements because they had no definitive HCFA statement of their rights under the PRO program, only the PRO's interpretation of their obligations. Most, if not all, hospital PRO agreements probably will have to be renegotiated after the final regulations are fully analyzed. HCFA includes in the rules requirements governing hospital-PRO agreements that must be executed in writing within 60 days of publication. PROs and hospitals already are constrained in their negotiations by the many procedural requirements HCFA has written into their contracts. Additional requirements about what should be in the hospital-PRO agreements further bias negotiations and limit mutually satisfactory resolution of local operational problems. This is in stark contrast to the kind of flexibility envisioned by the PRO Act.

The AHA is committed, in good faith, to establishment of effective working relationships between hospitals and PROs. In July 1984, we distributed to all member hospitals a special briefing on the PRO program, including a discussion of constructive ways of approaching development of a hospital/PRO agreement. We have been providing assistance to hospitals and their state associations in resolving implementation problems and developing basic agreements with their PROs. The AHA will continue to use its full resources to disseminate information and provide implementation assistance. However, the AHA cannot accept HHS' continuing disregard of administrative procedures. It is clear that HHS and the Office of Management and Budget have unilaterally decided how the PRO program will be implemented and appear to be entrenching those decisions in PRO contracts. By using the contracting process in this way, HHS

has effectively deprived hospitals, whose activities are regulated by these contracts, of the opportunity for meaningful comment that the law guarantees. The deprivation is no less for beneficiaries.

Centralization of Review

The PRO program as it has emerged over the past several months is a highly centralized and formulistic program. It provides few rewards for those hospitals that have effective in-house utilization management, and in its current form will not yield the level of efficiency or cost-effectiveness contemplated by Congress.

Despite flexibility granted by the statute, every PRO contract includes a HCFA-specified review plan that focuses on specific DRGs or types of admissions and requires an overall minimum review of 25 percent to 30 percent of each hospital's Medicare admissions. The contracts do not allow PRO discretion to reduce review of specific hospitals or physicians with consistently low denial rates. If a specific hospital or physician provides care for a large volume of patients in a targeted DRG or procedure, the review volume is high, even if the denial rate is negligible. Such inflexibility forces PROs into inefficient review patterns and penalizes providers with low denial rates because of the types of services they provide.

In negotiating PRO contracts, HCFA insisted that PROs perform the majority of their review off-site rather than on-site by reducing travel allowances under the contracts. HCFA then compounded the problem by prohibiting payment to

hospitals for increased costs of photocopying and mailing of medical records needed to support off-site review. Moreover, safeguards for these medical records when they are outside the direct control of hospitals are inadequate. The shift to extensive off-site review has reduced the educational value of peer review by reducing opportunity for face-to-face discussions among hospitals, physicians, and PRO reviewers. In addition, the true cost of PRO review is camouflaged and will be understated in later evaluations of HCFA's implementation approach. Hospitals have been burdened with significant PRO review costs that are not reflected in payment rates, and their performance in achieving low denial rates will not be rewarded by any reduction in review volume and associated cost burdens.

These problems can be solved, given a commitment to make a locally based peer review program operate effectively. A Medicare program that encourages and rewards development of strong hospital-based systems would better serve Medicare beneficiaries than one that removes incentives to make utilization review a central part of hospitals' internal management structure.

Waiver of Liability

Finally, the Subcommittee has asked that witnesses at this hearing comment on HCFA's recently proposed revisions to the Medicare waiver of liability regulations. HCFA's proposal to eliminate a provider's right to earn a favorable presumption in waiver of liability determinations has triggered vigorous public debate of several fundamental issues involved in medical decision-making and the performance expected of Medicare providers.

In general, Medicare covers services that are medically reasonable and necessary and that are provided in an appropriate setting or level of care. Medicare coverage policies establish the services and general conditions under which services will be covered. PROs establish more specifically the conditions under which services will be covered through the process of medical review. Because medical practice standards are constantly evolving and vary among areas, and because individual patient needs differ and are not always certain, the specific services that will be considered "reasonable and necessary" are not always absolutely clear. It is obviously unfair to refuse payment for services that were believed, at the time, to be necessary by the provider if the provider and the beneficiary did not know that the services were not consistent with Medicare or PRO coverage policies. Recognizing this, Congress created the waiver of liability giving some benefit of doubt in difficult treatment situations. Under the waiver of liability, payment will be denied only if two conditions are met:

- The services were not consistent with coverage policies, including necessity as defined by the PRO; and

- The hospital knew or should have known of the coverage policies, including medical necessity criteria.

Historically, HCFA has relied on a "favorable presumption" to establish a provider's eligibility for application of the waiver. Under this policy, if the number of cases found to be unnecessary was less than a very small

percentage of total cases, it was presumed that the provider was acting in good faith and payment was made under the waiver.

In the 1982 amendments, Congress clarified the waiver of liability policy. Under the amendment, provider knowledge of coverage guidelines can be established by issuance of a notice identifying a utilization pattern inconsistent with coverage guidelines. The AHA supports this provision, believing that such notices are a means of both changing unnecessary utilization patterns and minimizing risk of nonpayment. These objectives can be achieved, however, only when such pattern notices are sufficiently precise to allow identification of cases that are part of the pattern.

Under the proposed new policy, waiver determinations would be made on a case-by-case basis, and application of the waiver would be denied if there were any evidence of knowledge, including general PRO or HCFA guidelines, transmittals, pattern notices issued by PROs, or PRO interpretations of current medical practice standards. Medical decision-making is fraught with uncertainty, and it often is impossible for providers to know before they provide a service how their decisions will be judged when the judges have the advantage of hindsight. The science of medicine is not precise enough to set rigid performance standards, particularly when many medical decisions are made under difficult conditions. Because of this uncertainty, the medical review criteria used by PROs are intended to screen out and approve those admissions for which the care provided definitely was necessary and appropriate. The criteria merely serve to identify those cases requiring a judgment based on

the patient's unique medical condition. For example, the majority of cases that initially fail the screening process are subsquently found to be necessary and appropriate upon further review. Consequently, the criteria do not, by themselves, allow a physician to determine if an admission will be considered "necessary."

If the applicability of review criteria to a beneficiary's medical condition is uncertain at the time when an admitting or treatment decision must be made, PROs should be required to judge the care on the basis of whether the provider's decision was reasonable under the circumstances--that is, whether the decision not to treat presented greater risk than the decision to treat. If PROs are not required to do so, the effect of PRO review and the waiver rule is to make hospitals and physicians financially liable for care that does not comply with a PRO's definition of "necessary and appropriate" and, at the same time, to require that providers violate that definition when a patient's need for the services is uncertain.

The AHA believes clarification of the waiver of liability policies is essential. Recognizing the uncertainty that pervades medical practice, the AHA believes that continuation of a favorable presumption is essential in a modified form to reflect the effects of the PPS and PRO programs. Specifically, the AHA believes that those hospitals that have a good review record (as demonstrated by a very low number of denials) should receive payment except when there are explicit national coverage policies excluding certain services from coverage or when there has been a preadmission review finding that the admission is unnecessary.

In addition, any notices concerning patterns of inappropriate utilization must be sufficiently precise to allow a provider to identify when services will not be covered before they are provided. Broadly worded notices are not useful if many patients covered by the notice will, in fact, need acute hospital treatment. Finally, it is essential that all medical necessity determinations be made from the perspective of the physicians faced with the admitting or treatment decision. It is unfair to allow the PRO to determine if an admission was appropriate based on information produced during the hospital stay. If it was necessary to admit the patient to obtain the information on which the PRO's determination is based, then, by definition, the admission was necessary.

Due to the nature and complexity of the waiver of liability, it is not a rule that should be treated lightly or that should be revised without adequate opportunity for public debate. HCFA's proposed revisions do not represent mere procedural changes, as characterized by the published notice and as suggested by the extremely short 30-day public comment period. Furthermore, the published preamble discussion did not reflect the administrative changes that were made last year and for which there was no opportunity for public comment, nor did it dispel the confusion generated by those changes. In fact, the lack of specificity in both the proposed rule and its preamble has resulted in many conflicting interpretations of the proposed policy, adding to the confusion about an already complex set of procedures and policies.

Consequently, the AHA has recommended to HCFA that the proposed rules be republished as a notice of proposed rulemaking with a more complete and

informative discussion of the purpose of the waiver and the substance of the proposed revisions.

CONCLUSIONS AND RECOMMENDATIONS

The AHA fully supports establishment of a properly developed and cost-effective Medicare utilization review program and is eager to work toward that end with both HHS and Congress. In doing so, the Association emphasizes that the only factors that should be considered in developing such a program are clinical and the only question that should be asked is whether the services provided to individual patients are necessary and appropriate from a quality-of-care standpoint.

Ultimately, physicians and hospitals are responsible for the appropriate treatment of individual patients. PROs cannot substitute for the professional judgments of physicians. They do not bear the legal and ethical responsibilities of hospitals and individual physicians for ensuring quality of care. Consequently, physicians and hospitals must be integral parts of the PRO program and must participate in developing PRO objectives, review criteria, and procedures. This cooperation clearly was intended when the Peer Review Improvement Act was written. Only if there is a partnership can the needs of Medicare beneficiaries be met.

Positive incentives should be established for hospitals and physicians with good review records by allowing flexible review procedures and delegation of

those functions for which a hospital has demonstrated the effectiveness of its in-house program. The Peer Review Improvement Act, written and initiated by this Subcommittee, was designed to provide PROs with this flexibility and the capacity to establish peer review programs that recognize appropriate, as well as inappropriate, provider behavior.

At this time, AHA believes the most important steps that need to be taken are:

- timely promulgation of regulations and policies under which the PROs will conduct review, including provisions that more clearly define provider and PRO rights and responsibilities;

- clarification of the requirement that hospitals and PROs maintain a written agreement that governs conduct of review in each hospital, including the addition of a statement of the PRO's obligation to negotiate the mechanics of review procedures and a mediation process when attempts to negotiate an agreement break down;

- notification and public comment procedures on all significant PRO program directives affecting conduct of review to provide both accountability and adequate time to comply with revised policies; and

- a formal process for obtaining independent validation of PRO determinations, including the ability of a provider to obtain judicial review of PRO actions when, taken in their totality, they indicate the

PRO is being unreasonable or is failing to provide adequate opportunity for hospitals to respond to PRO policies and determinations.

Thank you very much for giving me the opportunity to present the views and recommendations of the American Hospital Association. The Association hopes that an effective PRO program--focused on fair and efficient review of the quality and appropriateness of care--will be implemented. The AHA believes that such a program will benefit the Medicare program, providers and beneficiaries alike.

Senator DURENBERGER. Thank you very much.
Dr. Gilbert.

STATEMENT OF WILLIAM GILBERT, M.D., MEMBER, COMMITTEE ON FEDERAL LEGISLATION, AMERICAN ACADEMY OF OPHTHALMOLOGY, WASHINGTON, DC

Dr. GILBERT. Mr. Chairman, members of the committee, my name is William Gilbert. I am an ophthalmologist in private practice in Chevy Chase, MD. Today I am presenting testimony on behalf of the American Academy of Opthalmology, a national organization which represents 13,000 physicians, or 90 percent of those who specialize in medical and surgical treatment of the eye.

The Academy has been monitoring the implementation of the Medicare prospective payment system and the State Peer Review Organization Program. A majority of PROs have negotiated goals with the Health Care Financing Administration to reduce the rate of inpatient cataract surgery. The goals range from a 5-percent reduction in Kentucky to a 95-percent reduction in Maryland. Tables summarizing state-by-state goals are attached in my testimony, and I request that they be made a part of the hearing record.

Senator DURENBERGER. Without objection, they will be.

Dr. GILBERT. We take issue with the state PROs who have contracted with HCFA to turn cataract surgery into an exclusively outpatient procedure. There will always be those exceptions that will need hospitalization. Four States have goals to reduce inpatient admissions for cataract surgery by 90 to 95 percent. Other States which have lower goals are still moving agressively as if implementing a 90- to 95-percent goal.

The majority of PROs wrote into their contracts an implementation process which would first educate and seek cooperation from physicians. Despite these contract promises, some PROs have started with the 'stick' and not the 'carrot,' informing hospitals and physicians that cataract surgery will be subjected to a 100-percent pre-admission screening, retrospective review, or both.

In some cases hospitals have been notifying the Medicare patients that they might be at full risk for payment for their hospitalization if they are admitted as an inpatient. This is a source of additional stress and confusion for the patient and a burden for the physician, who might be required to fight as the patient's advocate when he or she judges that an inpatient stay is necessary for the safe and successful completion of surgery and to assure the quality of care.

For example, we can provide anecdotal evidence of persons who have been denied inpatient admission despite the physicians' recommendations, including a 93- year-old woman with only finger-counting vision, and many one-eyed patients who would have no useful vision during the immediate post-operative healing period because of poor vision in the second eye.

In order to implement the ambitious review of cataract admissions, PROs developed screening criteria to be utilized by the PRO's' nursing or clerical personnel. Few if any of these criteria sets have been field tested to study their viability as to patient

needs and their potential effect on the choice of surgical settings, the resources utilized, or the patient's outcome.

One-third of these PRO criteria sets do not include any test for determining inpatient versus outpatient surgery. Of the PROs we examined that do have specific admission criteria, half of these require the patient to have extremely severe current general medical or ophthalmic conditions such as kidney failure or a recent heart attack before the patient may be granted an inpatient admission.

Only six PROs permit additional factors to be considered, such as appropriate post-operative care and travel distance to available outpatient facilities.

Finally, although PROs claim that the screening criteria is only a tool and not a standard of care, a significant number leave the physician with little choice other than to accept narrowly-defined diagnostic and treatment criteria. We would consider this cookbook medicine, exactly what HCFA promised it would not be in the business of providing with PROs.

Congress should urge HCFA to resist the temptation of such encroachments on medical practice which insist on specific procedures or devices for treating particular diseases or conditions. Aware of the concern over the PRO screening guidelines, the Academy of Ophthalmology has established a process for developing minimal guidelines for cataract surgery as well as other ophthalmologic procedures.

HCFA has noted that PROs have been successful in meeting their goals. During testimony this morning, Dr. Davis used cataract surgery as an example of the influence of PROs, and she has on other testimony on April 1. Our recent data showed cataract surgery dropping from second place in frequency of patient admissions to sixth place. We suggest another interpretation: In view of the fact that half of the PROs had not signed contracts with HCFA until November, it is possible that Dr. Davis's numbers reflect an earlier push by the hospitals toward outpatient cataract surgery—one, to reduce the impact of the new Prospective Payment DRG System; two, to compete with freestanding surgicenters. Should a PRO be rewarded contract renewals for outcomes over which it had little influence?

We urge Congress to insist on an open process and to continue to monitor it closely for the negotiation for revised contract goals.

This concludes my prepared remarks. I would also request that the Academy's new paper on "Cataract Surgery in the 1980's" be included in the hearing's record.

Senator DURENBERGER. It depends on how big it is. We will make it part of the file of the hearing, for sure.

Dr. GILBERT. It gives examples as to why physicians should continue to have freedom to exercise professional judgment regarding choice of settings and resources for surgical medical care to meet individual patients' needs.

Thank you. I will be glad to answer any questions.

Senator DURENBERGER. Thank you.

[Dr. Gilbert's written testimony and the tables summarizing State-by-State goals follow:]

TESTIMONY
OF THE
AMERICAN ACADEMY OF OPHTHALMOLOGY

ON

MEDICARE PEER REVIEW ORGANIZATIONS

PRESENTED TO THE

SENATE FINANCE COMMITTEE

SUBCOMMITTEE ON HEALTH

APRIL 19, 1985

My name is William Gilbert, M.D. I am an ophthalmologist in private practice in Chevy Chase, Maryland. Today, I am presenting testimony on behalf of the American Academy of Ophthalmology, a national organization which represents 13,000 physicians, or 90% of those who specialize in the medical and surgical treatment of the eye.

The Academy has been monitoring the implementation of the Medicare prospective payment system and the State Peer Review Organization program. A majority of PROs have negotiated goals with the Health Care Financing Administration to reduce the rate of inpatient cataract surgery. The goals range from a 5 percent reduction in Kentucky to a 95 percent reduction in Maryland, and from 300 cases in Wyoming to 51,064 cases in Florida. Tables summarizing state-by-state goals are attached to my testimony, and I request they be made a part of the hearing record.

The Academy questions the process for establishing these goals and the means for implementing them. We request that the process be more open to public scrutiny. We join with the American Medical Association in urging the issuance of regulations and the establishment of a national review mechanism, the so-called "super PRO", to monitor the activities of the state PROs.

We take issue with the state PROs who have contracted with HCFA to turn cataract surgery into an exclusively outpatient procedure. There will always be those exceptions that will need hospitalization. Four states have goals to reduce inpatient admissions for cataract surgery by 90 to 95 percent: Connecticut, Maine, Maryland, and New Jersey. Other states which have lower goals, such as Missouri (a 10 percent reduction in admissions) are moving aggressively, as if implementing a 90-95 percent goal. In Missouri, a subcontractor for the PRO wrote to hospitals in late September notifying them that it would review and

deny all claims for inpatient cataract surgery (and a list of other outpatient procedures) from the start of its contract, weeks earlier, unless the patient had an extreme medical condition warranting inpatient care.

The majority of PROs wrote into their contracts an implementation process which would first educate and seek cooperation from physicians. Then, if inpatient admission rates were not reduced after a time, the PRO would take a more active stance, issuing denials, etc. Despite these contract promises, PROs have started with the "stick", not the "carrot", informing hospitals and physicians that cataract surgery will be subjected to 100 percent pre-admission screening, retrospective review, or both.

Conducting a one hundred percent review of any procedure requires a significant cost in personnel and resources, both for the reviewer and the physician, not to mention the delay and inconvenience to the patient. In some cases, hospitals have been notifying the Medicare patients that they might be at risk of full payment for their hospitalization if they are admitted as an inpatient. This is a source of additional stress for the patient, and a burden for the physician who may be required to fight as the patient's advocate when he or she judges that an inpatient stay is necessary for the safe and successful completion of the surgery, and to assure the quality of care.

For example, we can provide anecdotal evidence of persons who have been denied inpatient admission despite the physician's recommendation, including a 93 year-old woman with only finger-counting vision, and many "one-eyed" patients who would have no useful vision during the immediate post-operative healing period.

There is a possibility of double-jeopardy, too. If the pre-screening permits an inpatient admission, the PROs, during a retrospective review of cases may yet deny the claim. An example might be a patient who is admitted because of potential complications during surgery. If no complications arise, this case might be denied after the fact as not having needed an inpatient stay.

In order to implement the ambitious review of cataract admissions, PROs developed screening criteria to be utilized by the PRO's nursing or clerical personnel. Few, if any, of these criteria sets have been field tested to study their viability and their potential effect on the choice of surgical settings, the resources utilized or the patient's outcome. The Academy has collected screeing criteria from 18 PROs. One third (6) of these PRO criteria sets do not include any test for determining inpatient v. outpatient surgery. Of the PROs we examined that do have specific admission criteria (12), half of these (6) require the patient to have extremely severe concurrent general medical or ophthalmic conditions, such as renal failure or a recent heart attack, before the patient may be granted an inpatient admission.

It is unusual for an ophthalmologist to perform cataract surgery on such unstable patients. However, there are many relatively healthy patients who may have less severe conditions for whom an inpatient admission provides an extra margin of safety and insures quality of care. Each patient presents unique needs. Yet only six PROs permit consideration of additional factors, such as appropriate post-operative care and travel distance to available outpatient facilities.

Finally, although the PROs claim that the screening criteria is only a tool, not a standard of care, a significant number (7) include consideration of particular diagnostic procedures. Indeed, the PRO for Montana and Wyoming declares in its criteria: "In the case of a

patient with a history of retinal tears or detachment in either eye, the procedure of choice is an extracapsular extraction." The same PRO lists indications for insertion of an intraocular lens in its criteria, as well. We would consider this "cookbook" medicine, exactly what HCFA promised would not be the business of PROs. Congress should urge HCFA to resist the temptation of such encroachments on medical practice which insist on specific procedures or devices for treating particular diseases or conditions.

Aware of the concern over the PRO screening guidelines, the American Academy of Ophthalmology has established a process for developing minimum guidelines for cataract surgery, as well as other ophthalmic procedures. To date, the Academy has polled its membership for input on draft cataract surgery guidelines, and expects to finalize them soon.

HCFA has noted that the PROs have been successful in meeting their goals. During recent testimony to a House Subcommittee (House Ways and Means Subcommittee on Health, April 1, 1985), Dr. Carolyne Davis used cataract surgery as an example of the influence of PROs. Her recent data showed cataract surgery dropping from second place in frequency of inpatient admissions to sixth place. We suggest another interpretation in view of the fact that half of the PROs had not signed contracts with HCFA until November. It is possible that Dr. Davis' numbers reflect an earlier push by the hospitals toward outpatient cataract surgery: (1) to respond to the impact of the new prospective payment/DRG system; and (2) to compete with free-standing surgi-centers. Should a PRO be rewarded (contract renewal) for outcomes over which it had little influence?

This raises a final concern: the negotiation of revised contract goals. Will a PRO's apparent "success" in reducing inpatient admissions for cataract surgery lead to ambitious and unrealistic goals in reducing admissions for other ophthalmic surgery? Will the PROs be required to seek broader input in drafting their new goals? We urge Congress to insist on an open process, and to continue to monitor it closely.

This concludes my prepared remarks. I would also request that the Academy's new paper on "Cataract Surgery in the 1980's" be included in the hearings record. It is a concise review of the state- of-the art of cataract surgery, and the impressive changes which have occurred in the last five years.

I would be happy to answer your questions.

STATE PEER REVIEW ORGANIZATIONS

WITH NUMERICAL GOALS TO REDUCE

INPATIENT CATARACT SURGERY

State	Admissions No. of Cases		Percent Reduction
Arizona	1,777	or	80%
California	27,544	or	40%
Colorado	-		55%
Connecticut	4,123	or	90%
Delaware	-		35%
Florida	51,064		-
Georgia	5,396	or	25%
Iowa	642		-
Kansas	-		10%
Kentucky	306	or	5%
Maine	-		90%
Maryland	-		95%
Michigan	16,448	or	65%
Minnesota	5,928		-
Missouri	-		10%
Montana	1,078		50%
New Hampshire	-		27%
New Jersey	-		90%
New Mexico	674		15%
North Carolina	Reduce avoidable deaths by 108 cases or 25%		
Oregon	2,364		-
Pennsylvania	-		70%
South Carolina	-		50%
South Dakota	785	or	77.4%
Virginia	-		25%
Washington	3,618	or	59%
Wisconsin	-		16.6%
Wyoming	300	or	50%

PEER REVIEW ORGANIZATIONS
ADMISSION REDUCTION GOALS UNDER THE
MEDICARE PROSPECTIVE PAYMENT SYSTEM

STATE	No. of OPHTHAL (1)	1982 DRG 39 DISCHARGES (2)	PEER REVIEW ORGANIZATIONS CONTRACT GOALS (3)
Alabama	134	7,889	Reduce admissions for DRG 39 among other "outpatient" procedures.
Alaska	19	Not Available	Reduce admissions from 13.17 per thousand to 6.58 per thousand for selected procedures appropriate for outpatient/same-day settings.
Arizona	168	4,800	Reduce admissions by 6074 for 65 "outpatient" procedures. "Cataracts comprise the large majority." DRG 39 & 42.
Arkansas	95	4,979	Reduce admissions for DRG 39 by 80% or 1,777.
California	1,541	34,430	(1) Reduce admissions for cataract extraction by 27,544 cases, representing a 40% reduction; (2) Reduce by 50 cases, avoidable post-operative complications, in targeted operative areas, including ophthalmic operations.
Colorado	183	4,804	At least 55% of DRG 39 could be performed on outpatient basis. Reduce DRG 39 & 42.
Connecticut	195	3,371	Reduce admissions by 90% for DRG 39, lens procedures, from 5,073 to 950.
Delaware	23	-	Reduce cataract surgery & other "outpatient" procedures by 35%.
District of Columbia	91	2,872	(1) Reduce 4,889 admissions for 150 procedures, including lens extractions; (2) Reduce unnecessary surgery for 4 procedures by 360 cases, including "other extracapsular extraction of lenses" (ICD code 13.59).

(continued)

STATE	No. of OPHTHAL (1)	1982 DRG 39 DISCHARGES (2)	PEER REVIEW ORGANIZATIONS CONTRACT GOALS (3)
Florida	649	17,797	Reduce cataract surgery by 51,064 inpatient admissions.
Georgia	226	9,118	Reduce admissions for DRG 39 by 25% or 5,396 cases.
Hawaii	54	-	-
Idaho	31	-	-
Illinois	500	18,989	Eliminate 31,930 "nonacute admissions involving an ambulatory procedure".
Indiana	182	1,791	Reduce lens and 5 other procedures by 16,918 admissions.
Iowa	90	5,964	Reduce lens procedures (DRG 39) by 642 admissions.
Kansas	83	4,826	Reduce DRG 39 admissions by 10%.
Kentucky	115	5,691	Reduce unnecessary procedures-DRG 39 by 5% or 306 cases.
Louisiana	196	6,791	Reduce admissions by 1,138 over 2 years for 8 procedures including DRG 39, 40 & 42.
Maine	53	Not Available	Reduce by 90% or from 2300 to 230 admissions for selected ambulatory procedures, including: cataract extraction (13.19), iridectomy (12.14), and discission lens (13.2).
Maryland	253	Not Available	(1) Reduce by 95% or 16,146 admissions for selected ambulatory procedures including: iridectomy (12.14); cataract extraction (13.19, 13.2, 13.41, 13.43, 13.59); and "other disorders-eye" (DRG 47). (2) Reduce mortality in selected elective procedures by 75 deaths or 50%, including lens extraction (13.19).

(continued)

STATE	No. of OPHTHAL (1)	1982 DRG 39 DISCHARGES (2)	PEER REVIEW ORGANIZATIONS CONTRACT GOALS (3)
Massachusetts	342	Not Available	Reduce by 93.4% or 7,474 admissions for 155 selected elective procedures that can be performed in an ambulatory setting.
Michigan	370	11,925	Reduce by 65% or 16,448 cases unnecessary admissions for lens extractions (DRG 39).
Minnesota	201	8,295	Reduce DRG 39 admissions by 5,928.
Mississippi	86	4,645	Reduce by 9,133, unnecessary admission for 13 procedures including cataract extraction,
Missouri	219	11,841	Reduce by 7,096 or 10% admissions for 20 procedures, including DRG 39,
Montana	41	1,286	Reduce by 1,078 admissions for DRG 39, or 50%.
Nebraska	64	Not Available	None relating to ophthalmic surgery.
Nevada	33	1,154	Reduce by 5% or 764 admissions in 8 DRGs, including DRG 39, Cataract surgery.
New Hampshire	40	1,280	-Overall reduction of "outpatient" procedures by 27%. -Reduce unnecessary procedures by 112 for 5 procedures including cataract extraction.
New Jersey	376	Not Available	(1) Reduce admissions by 90% or 7,128 cases for lens extraction (DRG 39) and hernia repair which can be performed on an ambulatory basis; (2) Reduce unnecessary cataract surgery (DRG 39) by 5 to 8%.
New Mexico	57	2,124	Reduce DRG 39 by 15%, or 674 cases.

(continued)

STATE	No. of OPHTHAL (1)	1982 DRG 39 DISCHARGES (2)	PEER REVIEW ORGANIZATIONS CONTRACT GOALS (3)
New York	1,119	-	Reduce by 7,460 admissions for procedures which can be performed in an outpatient setting.
North Carolina	233	11,335	Reduce 9 DRGs by 13,204 admissions, including DRG 39 & 42 (combined DRG 39 & 42); reduce available deaths for DRG 39 by 108 or 25%.
North Dakota	23	2,499	Reduce admissions for DRG 39 & one other procedure by 1,923.
Ohio	419	18,408	Reduce by 95% or 17, 405 admissions that can be performed on outpatient basis, including cataract extraction (13.1-13.59, 13.69).
Oklahoma	106	6,521	Reduce by 77% or 24,881 admissions for 183 selected surgical procedures that could be performed as outpatient.
Oregon	158	4,828	Reduce DRG 39 from 5,749 to 3,385 admissions (by 2,364 in calendar 1985 & 1,520 in 1st half 1986).
Pennsylvania	561	14,259	(1) Reduce by 79% or 13,398 admissions for 33 procedures, including "after cataract excision" (13.65); (2) Reduce by 70% or 19,843 admissions for 6 procedures, including cataract surgery (DRG 39).
Rhode Island	56	1,288	Reduce cataract extraction, iridectomy, enucleation plus 40 other procedures by 1127 admissions.
South Carolina	98	4,410	Reduce DRG 39 admissions by 50%.
South Dakota	22	1,482	Reduce by 77.4% or 785 admissions for lens procedures (DRG 39).

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STATE	No. of OPHTHAL (1)	1982 DRG 39 DISCHARGES (2)	PEER REVIEW ORGANIZATIONS CONTRACT GOALS (3)
Tennessee	189	2,764	Reduce by 25.6% admissions for 76 procedures including: Blepharoptosis repair, entropion/ectropion repair, cryotherapy cornea lesion, excision eye lesion.
Texas	650	Not Available	(1) Reduce by 50% or 30,291 admissions for selected procedures that can be performed on an outpatient basis; (2) Reduce by 40% or 1,478 unnecessary procedures for 6 DRGs, including blepharoplasty (DRG 40).
Utah	72	1,611	Reduce from 21% to 12% admissions for "outpatient" procedures including cataracts and lens insertions.
Vermont	34	831	(1) Reduce by 263 admissions for procedures that can be performed as outpatient; (2) Reduce by 60 admissions for unnecessary surgery in 5 categories, including cataract extraction.
Virginia	247	4,804	(1) Reduce by 20.6% or 8,702 admissions for 54 selected procedures which can be performed on an outpatient basis, including blepharoplasty (8.70); (2) Reduce by 25% unnecessary procedures in 6 DRGs, including lens procedures (DRG 39).
Washington	209	6,878	Reduce by 59% or 3,618 admissions for cataract surgery (DRG 39).
West Virginia	73	3,531	Reduce by 3,498 admissions for cataract and 35 other procedures.
Wisconsin	216	8,108	Reduce by 16.6% admissions for 51 "outpatient" procedures, including: Entropion/ectropion repair, trabeculectomy, iridectomy & cataract extraction.

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STATE	No. of OPHTHAL. (1)	1982 DRG 39 DISCHARGES (2)	PEER REVIEW ORGANIZATIONS CONTRACT GOALS (3)
Wyoming	15	-	Reduce DRG 39 by 50% or 300 admissions; reduce unnecessary DRG 39 procedures by 5%.

Notes:

(1) Number of ophthalmologists as reported by the American Academy of Ophthalmology, 1983.

(2) 1982 discharges for cataract surgery (DRG 39) under Medicare, from Health Care Financing Administration sources, 1983.

(3) Peer Review Organization contract goals, relating to ophthalmic procedures, from Health Care Financing Administration published contract summaries. Contract summaries were not available for Hawaii or Idaho.

March 1985

Senator DURENBERGER. Dr. Felts, let me start with you, because the AMA has an application in for this Super PRO contract, and you can probably tell from the questions I have been asking that I have two concerns: One, that the evaluation of the existing PRO contracts by HCFA be fair, and I guess that is what the whole Super PRO contract is designed to do; the other is that, while we have some time and a little experience we ought to be looking a little more carefully at setting up more realistic objectives for the next round and, from what I have heard here today and certainly from your testimony, that we find better ways to work quality into those objectives.

Would you give us some observations? Do you have some problems with the way you have watched the Super PRO contracting process work? And then do you have some thoughts on what objectives we might use in the next round?

Dr. FELTS. Mr. Chairman, I think that the revised Super PRO RFP is more reasonable and certainly better focused on the reality of what can be accomplished within a reasonable price range than was the original RFP. There are some lingering concerns, however, in that it is a fixed price contract and thus puts the contractor at financial risk.

This is the first time that an effort of this sort has been attempted. For that reason, there are a number of unknown factors and, perhaps even unknown expenses that cannot be completely anticipated.

I was somewhat concerned at Dr. Davis' response to your earlier question in which she stated that formal input by the Super PRO into the contract specifications for the renewals would not be a part of the charge to that organization. Our concern is tempered, however, by the feeling that there would be a reasonable dialog that would influence that process. I can certainly appreciate HCFA's need to not be encumbered with a formal mechanism that would become an obstacle to awarding PRO contracts. However it is vitally important that the quality issue and the experience from review of the content of the current contracts be very heavily considered in the renegotiation process. It is very important that there be enough flexibility in the program to ensure that individual patient needs are safeguarded.

Senator DURENBERGER. Can you tell us briefly what some state medical societies are doing on variations in practice style across the country? Obviously this is not just because of the things that John Wennberg has written about, and so forth, but for a variety of reasons now that the hospitals and physicians are being provided some incentives to practice more conservative medicine there seems to be more activity generally in that area.

George had us listen to the folks from Maine the other day, the Maine Medical Society, and some of the work they are doing in the State of Maine. What generally is going on across the country, if you know, that would be helpful to us?

Dr. FELTS. My response to that question is generic rather than specific. The state medical societies are contacting many individual hospitals and medical staffs of hospitals concerning apparent disparities in practice patterns as they have emerged. They are en-

couraging physicians within the hospital to analyze why these disparities exist and whether the reasons are adequate or not.[1]

Data can be very deceptive in that regard. Certainly, some hospitals, some areas, draw patients that have more severe indices of illness than others. The comorbidity factors that have been alluded to earlier certainly draw into certain hospitals, and certain specialities within individual hospitals. In that way, the data can be distorted.

The activities of the association and the State medical societies are basically to begin to try to devise the answers to why these disparities exist. If the answers are not adequate, then we will encourage the medical societies and hospitals to institute educational programs to correct them.

Senator DURENBERGER. Jack, can I ask you a question about quality objectives and so forth, the emphasis on quality?

We have been talking here this morning about the charge of the PRO's and quality in general, their capacity, their financial ability to work in that area, the fact that some things are now being done on an outpatient basis that were not earlier, that the farther you get them away from a hospital the less quality assurance there might be. Do you have some thoughts for us on how to build the quality objectives into the next round of peer review?

Mr. OWEN. Yes, we do, Senator. In my testimony from page 7 there is some more specific information. But, basically we are saying that we ought to be looking at what is happening locally—the age, the sex, the type of patients that the hospital is working with, the PRO is working with. They all have a bearing on how that patient will be treated. And I think it was brought up here a minute ago that you can't just say that all patients are going to be treated on an outpatient basis because they have a specific diagnosis—there are going to be some that are going to have to be treated as inpatients.

We also think that quality assurance, audits, and so forth have been going on in hospitals for a long time, and that PRO's should utilize those hospitals and medical staffs who have done a good job, who can demonstrate that they have a good audit committee and medical review committee, and just audit them rather than continuing to look at them as if they are as bad as the guy down the street.

And we feel strongly that utilization patterns ought to be one way to start to look at the problem. When somebody falls out of a pattern, then you begin to educate him and bring him back in. We don't see that occurring; everybody is just looking at gross, kind of quantitative figures at this point in time, and I think—well put by a doctor here—that a lot of this was occurring before the PRO's ever even got started. And I think that is the issue that we are going to have to be facing in the coming year. It is, with that already happening and that squeezing out of the system, what is the PRO going to be looking at?

Senator DURENBERGER. Dr. Gilbert, one of the things that is coming along that is new, and part of it exists in the DRG system,

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[1] It is also important to remember that much of Dr. Wennberg's work has been suported by medical societies including those in Maine and Iowa.

is preadmission screening. And in your testimony you point out the double jeopardy that PRO's put the providers in when they perform both the preadmission screening and the retrospective review on the same case.

What would you propose as a solution to this problem?

Dr. GILBERT. Well, I think we perhaps need to better define our criteria, have more input by physicians in the specialties in their own fields, to define the criteria for admission.

It is true that it is physicians that are working on this, but we need to have more dialog between the various subspecialties so that the physicians that are most familiar with the vicissitudes of a particular course or the complications that can occur can have input into establishing the guidelines. I think that is one thing that we need. We need to have more dialog among ourselves.

The regulations came through late in the summer, and we found ourselves scrambling to be able to provide input to modify the regulations.

Senator DURENBERGER. All right.

Max, do you have questions?

Senator BAUCUS. Gentlemen, as I hear you, you generally agree that PRO's help to provide some check on maybe excessive—if that's the proper term—procedures in some cases. You also seem to agree that PRO's try to find the right balance between quality and cost.

When I listen to you, though, I hear lots of theoretical problems; I don't hear too many anecdotes or actual instances where a PRO made a gross error, and where someone was denied treatment altogether or denied what would amount to quality treatment.

Dr. Gilbert, you mentioned one instance of a 93-year-old woman who had very poor eyesight and was denied inpatient procedure, but I would like to hear more anecdotes. I want to hear more examples, actual instances, where there has been some outrageous application of a PRO guideline, and so forth.

And the second question I have is, have you seen cases where a patient was incorrectly denied inpatient hospital care? Where you disagreed with the decision for the patient to receive outpatient care? Or do you think that even though there are some problems, that probably the outpatient procedure was by and large adequate?

Mr. OWEN. Well, let me start off, if you want, with lots of letters.

Senator BAUCUS. I want it from your own personal experience, right now. Give me some examples.

Mr. OWEN. Well, what is happening out in the field on the hospital side of it is the denials. I hear lots of anecdotal material where a patient comes in, is taken care of, and then the PRO says that the case is denied, and the hospital is left holding the bag. They have taken care of the patient, and they do not get paid for it. There is a great deal of that occurring. I don't have them specifically by names, but I know there isn't a hospital that I have talked to in the past 3 months in any part of the country that hasn't run into this; it's a big problem.

One of the other problems is the waiver of liability, which says in effect that the hospital has been doing a good job, and now by changing this waiver of liability what they have done is said that you almost need a 100-percent perfect record. The physician can

never make a mistake and admit a patient, because if you have three cases you lose your waiver of liability. There isn't anybody who is that perfect in a field, that is an art and not a science, where you have to make decisions about people coming in.

These things are occurring on a regular basis right now. We have tried to look at it as an educational process as much as possible, although there are many hospitals which feel at this point that it has gone beyond education.

Senator BAUCUS. I understand what you are saying, and obviously we should do our very best to be certain that there is this right balance with falling costs; there is no doubt about that. But I am just telling you, as I listen to you and listen to the testimony generally, I hear a lot of objections that tend to be in the nature of theory, and which may be very valid, but are still theoretical. I tend not to hear precise examples that say, "Hey, here is a really outrageous example that really happened here." And there may or may not be those examples, but I'd like to know.

I don't get a lot of mail from the folks at home giving me outrageous examples. I get lots of mail on recordkeeping and logkeeping requirements, the folks objecting to the IRS. But I don't get a lot of mail from people saying, "The PRO's decision here is outrageous."

Dr. GILBERT. Our academy can supply you with case examples. My own work happens to be of the nature that I'm still doing types of surgery for which admission is usual. But we are talking about elderly infirm people with arthritis that can easily become disoriented, that may not have social support systems. These are the kinds of patients that come to cataract surgery.

Is it good quality that such a patient should have to get up at 4:30 in the morning to have an outpatient procedure?

Senator BAUCUS. What is the difference in cost between inpatient and outpatient cataract procedures, on the average in your practice, at least in this area, in the D.C. metropolitan area?

Dr. GILBERT. I can't readily give you that information.

Senator BAUCUS. Just a rough guess—what is your rough guess as to what the difference would be?

Dr. GILBERT. I can't give you that, either. But I am sure that our academy members, our staff members, can supply that information for you promptly.

Senator BAUCUS. You can't give me a rough idea?

Dr. GILBERT. My reason for not being able to give you a rough idea is that it happens that my practice is mainly retinal detachment work. And so I don't have the occasion to monitor that type of material in my own practice.

Senator BAUCUS. Probably there is quite a significant cost differential, wouldn't you expect, between inpatient and outpatient cataract procedures?

Dr. GILBERT. Certainly there is a difference in cost.

Senator BAUCUS. So the question is to try to balance the difference in cost with the quality of care, given the particular circumstances of a particular patient.

Dr. GILBERT. I did have a comment to make about your question. The process as it is designed is not designed to define definitions of quality, to chart those differences in quality, to record them and to have a method of reporting them. And so when we are told that we

hear things in general but not in the specific, you have to recognize that the system as it is organized now doesn't address that in a careful enough manner to allow that kind of reporting. So the conclusions are anecdotal, including the conclusions that it is all working very well.

Senator BAUCUS. I just encourage you to do what you are doing; it is good. I am just trying to keep the eye on the ball here and make sure the procedure is working properly.

But I must say again that from my personal point of view it would help to see some more concrete examples of what some of the problems are. Thank you.

[The information follows:]

AMERICAN ACADEMY OF OPHTHALMOLOGY

CATARACT SURGERY IN THE 1980'S

Submitted January, 1985, by the Committee on Ophthalmic Procedures Assessment for consideration by the Board of Directors of the American Academy of Ophthalmology, in response to a request by the Academy's Office of Governmental Relations for a document regarding current practice of cataract surgery in the United States and changes since 1980.

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INTRODUCTION

In recent years there have been many advances in cataract surgery. Technological developments together with refined surgical techniques have yielded a procedure which usually produces excellent visual results with few complications.

This document reviews the definition and types of cataracts. The evolution of surgical techniques is outlined with emphasis on changes in the management of cataracts over the past four years. The impact of these changes on the safety, effectiveness, and quality of care will be discussed. Finally, predictions regarding future developments and trends in cataract surgery are offered.

CATARACT: DEFINITION

The lens of the eye is a transparent, crystalline structure located behind the iris and pupillary space. Its purpose is to focus light on the retina to produce clear visual images. It is supported by fine ligaments which suspend it from the ciliary body. The lens is a unique structure because it has no blood vessels and is transparent. It is approximately the size of an aspirin tablet, but enlarges and yellows with aging.

CATARACT SURGERY - 4

A cataract may be defined as any opacity or cloudiness of the lens that prevents a clear image from forming on the retina. Cataracts most commonly develop as part of the normal aging process ("senile" cataracts), but they are sometimes congenital or developmental. Cataracts may also be acquired as a result of trauma, toxins, or metabolic defects.[1] Depending on the location and size of an opacification, light rays passing through the lens may be blocked or scattered. Scattering results in blurred vision and bothersome glare. At present, the only method of eliminating a cataract is by surgical removal.

Opacities may occur in any part of the lens, but most commonly occur in the central core or nucleus in association with aging. This type of cataract, called a "nuclear" cataract, generally progresses slowly over a period of many years, and patients often retain good near (reading) vision until the cataracts become dense. However, patients with nuclear cataracts have blurred distance vision and are often bothered by ghost images, glare, and halos around lights.

Opacification beneath the posterior capsule of the lens ("posterior sub-capsular" cataract) is particularly disabling when it is centrally located. This type of cataract may progress rapidly (over a period of months), near vision is affected early, and glare is often produced. In addition, a patient with this type of cataract may be able to see quite well in dim light and yet be

functionally blind in normal or bright light because the constricted pupil prevents light rays from passing around the central opacity.

OPTIONS FOR OPTICAL REHABILITATION

Following removal of a cataract, light passes freely to the retina, but the light rays are not in focus. Aphakia is the term used for the condition of an eye after surgical removal of a cataract, and an optical device must be used in order to restore good visual function. Four options are currently available to the aphakic patient: spectacles, contact lenses, intraocular lenses, or keratorefractive surgery.

Aphakic Glasses

Thick aphakic spectacles for the correction of aphakia may be safe as far as the eyes are concerned, but they produce significant visual distortions: peripheral vision is greatly reduced, images are magnified by 25-30 percent, and spatial orientation is altered. Because the lenses are much thicker in the center than on the edges, objects "swim" and change shape as the patient looks across the field of gaze. These optical problems commonly cause a feeling of insecurity and can even lead to accidents.

Because of the visual distortions associated with aphakic glasses, most patients are initially extremely unhappy, even after an excellent surgical result. Patients whose vision was poor preoperatively may be happy with a 20/20 result, but a person able to see 20/70 prior to surgery is often less happy with 20/20 aphakic spectacle vision following cataract surgery.

Also, aphakic spectacles are not suitable for binocular visual correction following cataract surgery in only one eye because the 25-30 percent image magnification on the retina with the aphakic spectacle causes confusion when compared with the normal image size in the opposite eye. The use of aphakic spectacles is currently limited to patients who do not qualify for implantation of an intraocular lens and who are unable to tolerate a contact lens.

Contact Lenses

Compared with spectacle lenses, contact lenses provide a much more natural means of visual rehabilitation following cataract surgery. Objects are magnified by only about 7 percent and peripheral vision is practically normal. The main disadvantages of contact lenses are that many elderly patients do not possess the manual dexterity necessary to handle them and the eye may become intolerant of the contact lens or develop hypersensitivity reac-

tions to the lens or to the contact lens solutions.[1] One of the common age-related changes in the human eye is decreased production of one or more components of the tears, and good tear production is essential for the use of contact lenses.

Recently, high water content contact lenses have become available which can remain in the patient's eye for extended periods of time. These lenses are more convenient for elderly patients, but are associated with an increased incidence of corneal infections and vascularization of the cornea.[1] Often a family member must be instructed regarding the removal and care of the contact lens should an emergency arise which the patient is unable to manage.

Wearing contact lenses requires periodic ophthalmic follow-up, and most types of soft contact lenses must be replaced yearly. It is estimated that over a period of 20 years contact lenses are approximately three times as expensive as intraocular lenses for the correction of aphakia.[2]

Intraocular Lenses

Intraocular lenses provide the most natural vision available following cataract surgery, with minimal magnification and normal peripheral vision. These lenses require no manipulation by the patient and do not need to be replaced. The intraocular lens has

proven to be the single greatest advance for the visual rehabilitation of the patient with cataracts, and its use has profoundly affected the practice of ophthalmology.

Even now research is continuing into new forms of intraocular lenses. Lenses with ultraviolet light absorbers are already available. Pliable and compressible materials are being investigated. Many ophthalmologists envision the ultimate goal to be to replace the clouded material of the natural lens with a clear moldable material placed within the natural lens capsule.

Keratorefractive Procedures for Aphakia

Keratomileusis ("sculptured cornea") and keratophakia ("corneal lens") are surgical procedures used to modify corneal curvature in order to correct the large refractive errors produced by removal of the cataractous lens.[3] Keratomileusis is an operation wherein part of the patient's cornea is removed and placed on a lathe for reshaping. When the desired shape of the cornea is achieved, the corneal button is resutured to the patient's globe.[4] In keratophakia a partial thickness corneal button is obtained from a donor cornea and sutured between the layers of the patient's cornea.

Both of these procedures require sophisticated, expensive equipment, and both procedures can be difficult to master. A simplified variation of these techniques is epikeratophakia, wherein a pre-lathed donor graft is sutured onto the surface of the cornea after removal of the superficial corneal layer.[5] In other procedures, synthetic plastic implants are inserted within a split-thickness pocket produced in the patient's cornea.[6]

Presently, although the above keratorefractive procedures may find application in selected cases (especially in infants and children), it is doubtful that they will replace intraocular lenses as the preferred method for correction of aphakia in the foreseeable future.

CURRENT PATIENT MANAGEMENT

Significant technological advances (particularly intraocular lenses) have provided superior methods for the correction of aphakia, and these advances, together with refined surgical techniques, have led to high-quality, rapid visual restoration following cataract surgery. The excellent visual results obtained have resulted in a change in the indications for cataract surgery with patients becoming less reluctant to undergo surgery, and surgeons less reluctant to recommend it.

Indications for Cataract Surgery

The most common indication for surgical removal of a cataract is the need to improve vision.[7] However, it may at times be necessary to remove a cataract to facilitate visualization of the interior of the eye in order to diagnose and/or treat other ocular diseases; for example, to examine the retina in a patient with glaucoma, diabetic retinopathy, retinal detachment, or some other condition which requires visual monitoring or treatment. It also may be necessary to remove a cataract because of cataract-induced ocular diseases. It is impractical to assign a particular level of visual acuity as a requirement or prerequisite for cataract surgery; rather the decision to perform cataract extraction should be made by the surgeon and patient based on the patient's visual needs, occupation or avocation, desired activity level (including walking or driving), mode of living or ability to function in a given environment, need for binocular vision, and general health.[1,8]

The visual needs of "elderly" Americans have changed dramatically over recent years; few of those 65 and older are content to sit in front of a television screen or in a rocking chair outside a nursing home. The vast majority desire to remain functionally active, which includes the ability to drive an automobile. In many states a driver must have a visual acuity of 20/40 or better in order to qualify for an unrestricted driver's license.

Patients in the working age group may have their livelihood threatened by decreased visual acuity caused by a cataract, and it is not uncommon for surgery to be performed in these patients at a visual level of 20/40 or 20/50. (Many of these middle-aged patients have posterior subcapsular cataracts which profoundly affect near vision.) In deciding when to operate, surgeons usually ask their patients to consider whether their present level of vision is sufficient for them to function adequately on a daily basis. Those patients who feel strongly that they are not able to function adequately for visual reasons are offered cataract surgery.

Preoperative Evaluation

Prior to performing cataract surgery it is important to determine the general health of the patient in order to identify any systemic disease which may influence the decision to operate or the technique used in surgery. Bronchitis, marked obesity, heart disease, diabetes mellitus, or the use of a number of systemic medications such as immunosuppressive agents or anticoagulants are important factors which the surgeon must consider.[1] In order to evaluate the patient's general health, the patient's general physician is often asked to perform a medical examination with appropriate laboratory tests. Cataract surgery usually lasts less than one hour under

local anesthesia, using mild sedation and causing minimal stress to the patient. Under certain circumstances, however, general anesthesia may be required.

Ocular Examination

Prior to surgery, a complete ocular history and examination of the eye is essential in order to determine the presence of coexisting ocular disease and the likelihood that surgery will significantly improve the patient's visual acuity. The ocular examination generally includes, as a minimum, functional exam, slit lamp exam, intraocular pressure measurement, and retinal examination (ocular media permitting).

Modern technology has produced a large number of tests which can help the surgeon predict what level of visual acuity the patient might expect to obtain following cataract surgery. Such tests include: Amsler grid testing, photostress testing, light projection discrimination, color perception, the flying corpuscle entoptic phenomenon,[9] the Haidinger brush test, laser interference fringe testing[10], potential acuity meters[11], electroretinography, and the visual evoked potential. In eyes with opaque cataracts where it is impossible to evaluate the retina by visual means, B-scan ultrasonography permits assessment of the structures of the eye using

sound waves. These tests improve the quality and safety of cataract surgery by allowing the patient and surgeon to more accurately assess the risk/benefit ratio.

A determination of the health of the corneal endothelium is important prior to surgery because of the essential role of endothelial cells in pumping fluid out of the cornea to maintain its transparency. Because endothelial cells do not regenerate, and any intraocular surgical procedure results in an obligatory loss of a number of these cells, examination can help to determine whether the functional reserve of the corneal endothelium is sufficient to tolerate cataract surgery. Specular microscopy is a method of photographing these cells under high magnification. This technique has been invaluable in monitoring the safety of new techniques,[12,13] and in judging whether a patient's cornea will be able to withstand surgery without a concurrent corneal transplant. It is also possible, though less accurate, to evaluate the status of the corneal endothelium using the slit lamp biomicroscope located in many eye surgeon's offices. Such evaluation helps in assessing the risk/benefit ratio and informs the surgeon when special precautions are needed intraoperatively.

The technology associated with intraocular lenses has resulted in a highly predictable optical result for the cataract patient, and current standards mandate an accurate preoperative calculation of the proper intraocular lens power. This calculation is based on measurement of the length of the eye by A-scan ultrasonography, and measurement of the curvature of the cornea by keratometry. Using these measurements, the physician can accurately calculate the proper intraocular lens which will be required to produce the desired postoperative focus of the eye.

Setting of Surgery

Traditionally, cataract surgery has been performed as an inpatient procedure. In the past several years it has been clearly demonstrated that in some instances cataract surgery may be safely and effectively performed in an outpatient setting.[14] Outpatient surgery may be performed in the outpatient department of a hospital, in an ambulatory surgical center, or in an office-based surgical facility. Regardless of the location of the facility, its design and construction are governed by state regulations which vary from state to state.

Because modern cataract surgery uses highly specialized microsurgical techniques, many types of sophisticated equipment are required which are not customarily found in a general operating facility. Specially trained personnel must care for this equip-

ment. In addition, highly trained and specialized assistants are essential in the surgical suite, as well as the usual reception, communication, and bookkeeping personnel.

In addition to providing facilities for elective care such as cataract surgery, the general hospital must maintain facilities and staff for emergencies and for care of the seriously ill. Most hospitals utilize spreading techniques to distribute the cost of these facilities. Thus, although the hospital environment provides an optimal backup system for handling complications which may occur during cataract surgery, the cost of this backup support is substantial and may not be justified for the healthy patient who is unlikely to experience complications. The ambulatory surgical center is able to operate more cost efficiently because it is not required to maintain the expensive services provided by the hospital. Hospitals may be forced to compete with such centers for ambulatory surgery by reducing or eliminating the availability of standby services for healthy patients.

Performing cataract surgery as an outpatient procedure requires the patient to have a good support system at home, the ability to recognize serious complications at home, and transportation to allow return for appropriate follow-up visits on the day following surgery and thereafter in the immediate postoperative period.

In contrast with many other patients undergoing surgery, patients undergoing cataract surgery are in an age group where concurrent illnesses are frequent. Inpatient surgery may be necessary because of the need for complex general medical and nursing care, multiple ocular conditions or procedures, or the patient's general medical status. For example, patients with significant systemic illnesses such as pulmonary or heart disease should probably have cataract surgery performed as inpatients. Hospitalization may likewise be considered for certain groups of patients requiring general anesthesia such as children, mentally retarded patients, and adults who are very senile, easily disoriented, or extremely apprehensive. In addition, some patients are better served by inpatient surgery if they cannot obtain appropriate postoperative care during the first 48 hours after surgery on an outpatient basis. Elderly patients who live in remote areas, have little or no support at home, or have no reliable means of transportation may be better served by hospitalization for cataract surgery. Hospitalization also may be required following planned outpatient surgery because of ocular or systemic intra-
operative or postoperative complications. Finally, patients who have no useful vision in the unoperated eye may be more safely managed in an inpatient setting, while the operated eye is patched in the immediate postoperative period.

EVOLUTION OF SURGICAL TECHNIQUES

Surgical techniques for cataract extraction have evolved in conjunction with advancing technology and with better awareness of the complications associated with each technique.

Extracapsular Cataract Extraction in the 1930's

In extracapsular cataract extraction, the anterior capsule of the lens is removed, the hard lens nucleus is expressed, and ideally, all remaining soft cortical fragments are removed. The posterior capsule is meticulously cleaned and left intact.

The extracapsular method of cataract extraction was popular in the 1930's, but at that time it was necessary to wait until the cataract was mature (ripe), with liquified cortex, before operating, because no reliable method was available for removing the soft cortical portion of the lens.[8] The moderate amounts of soft, opaque lens material left behind often caused a serious inflammatory reaction which resulted in the formation of a dense membrane, leaving the patient with poor vision.

Intracapsular Cataract Extraction

The introduction of the intracapsular technique in the late 1930's represented a great advance in cataract surgery because the entire lens was removed within the lens capsule, leaving no fragments behind which could form a dense membrane. Significant advances such as the use of the enzyme alpha-chymotrypsin (used to lyse the ligaments holding the lens in place),[15] cryoextraction,[16] and finer sutures and needles[17] all combined to significantly improve the optical success of cataract extraction.

Phacoemulsification

In the late 1960's a procedure was developed for removing a cataract through a 3 mm incision.[18,19] This technique involved the use of a high frequency ultrasonically-driven vibrating needle to fragment the hard nucleus of the lens into small particles. The fragmented material was then aspirated through the hollow vibrating needle as irrigating fluid flowed into the eye through a sleeve. The 3 mm incision allowed rapid rehabilitation and continues to be widely used especially in younger patients (where the nucleus is soft). In certain cases, however, a hard nucleus may not fragment readily, and the nuclear fragments may damage delicate intraocular tissues.[14]

Phacoemulsification required the surgeon to learn a completely new method of surgery, and the outcome of the surgery became largely dependent upon the proper performance of the machinery. The growing popularity of intraocular lenses in the United States in the early 1970's lessened the advantage of the phacoemulsification procedure because the 3 mm incision had to be extended to 7 mm in order to allow insertion of the implant. Today, however, pliable intraocular lenses which will fit through a 3 mm or smaller incision are being developed. Phacoemulsification continues to be used regularly by many surgeons.

Modern Extracapsular Cataract Surgery

In the early 1970's extracapsular cataract extraction was resurrected by the development of irrigation/aspiration devices which enabled the cataract surgeon to remove the entire contents of the cataractous lens, leaving only the clear posterior capsule intact. Soft cortical fragments which were a problem earlier can now be aspirated through small cannulas. Irrigation/aspiration systems are currently available in manual, finger-operated models as well as automated electrically powered devices. Both types of systems have their advocates and are widely utilized today.

A major factor in the development of phacoemulsification and other extracapsular techniques was the introduction of the surgical microscope. Surgery that was formerly done with the unaided eye or with loupes could now be accomplished under high magnification with directed illumination. The microsurgical development of cataract surgery and intraocular lens implantation has been among the most remarkable events in all of medicine.

Related Technological Advances

Wound Closure Materials and Techniques

Wound closure has always been a major consideration in the successful outcome of cataract surgery. Technology has produced a variety of ultra-sharp needles, and extremely fine sutures, which are essential to the success of modern cataract surgery. If a cataract wound is sutured either too loosely or too tightly, the cornea assumes an elliptical shape rather than a spherical shape, resulting in astigmatism and blurred vision, even in an otherwise perfect operation.

Intra-operative keratometers have been developed to facilitate better wound closure.[20] These instruments are used to detect or measure corneal astigmatism produced during wound closure so that the sutures can be tightened or loosened appropriately. The desirability of obtaining good wound closure without inducing astigmatism is evident in the number of surgical keratometers, surgical techniques, and wound closure materials specifically designed for this purpose.

Pressure-lowering Devices

Preoperative reduction of the intraocular pressure is generally accepted as an important factor in reducing the incidence of complications during cataract surgery.[21] Simple devices such as a rubber ball pressed against the eye, or slightly more sophisticated devices such as an adjustable, inflatable balloon, held in place on the eye by a head band, have proved invaluable in lowering intraocular pressure prior to surgery. These mechanical devices have largely replaced pharmacologic attempts at lowering intraocular pressure.[21]

Long-acting Local Anesthetics

Uncomplicated cataract surgery is a relatively short procedure, requiring about one hour to perform. Local anesthetics such as

lidocaine are capable of producing good anesthesia for this period of time and have been available for many years, but the preoperative use of mechanical pressure-lowering devices requires the anesthetic agent to be administered earlier but still remain effective throughout the procedure. Newer, longer-acting anesthetics such as bupivacaine are now commonly used in cataract surgery. These longer-acting local anesthetics produce up to 12 hours of anesthesia, having the additional advantage of providing a less painful postoperative period.[22]

Viscoelastic Substances

Viscoelastic materials are high molecular weight, high viscosity compounds with elastic properties. They are used during surgery to protect delicate intraocular structures such as the corneal endothelium and to maintain the normal shape of the eye, while affording excellent visualization for intraocular manipulations such as the insertion of intraocular lens implants.[23-25] Viscoelastic substances were introduced for use in cataract surgery in the early 1980's. They have added a significant margin of safety to the many types of cataract procedures.[23,24] Viscoelastic substances are used in as many as 90% of cataract operations in many areas of this country.

YAG Lasers

In extracapsular cataract extraction, the posterior capsule is left intact for a variety of reasons. It provides support for certain types of intraocular lens implants and serves as a barrier to the forward displacement of vitreous in the eye. About 40 percent of posterior capsules will opacify over a period of from 6 months to 5 years postoperatively with an accompanying decrease in visual acuity. Until recently, cutting this membrane to improve vision required another invasive surgical procedure.[26] The introduction of the Neodymium:YAG laser in the United States in July, 1982, provided a safer, more controlled means for the discission (opening) of the opaque posterior capsule without requiring repeat surgical incision of the eye.[27,28] Thus a patient with an opacified posterior capsule, a so-called "second cataract," may now have the visual obstruction eliminated in a matter of minutes as an outpatient or office procedure.

COMPLICATIONS FROM CATARACT SURGERY

Retinal Detachment

It has long been recognized that the incidence of retinal detachment increases following cataract surgery,[29] but until recently, incidence rates were available only for intracapsular extraction procedures. Studies have now indicated that extracapsular cataract extraction may be associated with a significantly lower incidence of retinal detachment than intracapsular extraction.[30,31] In a recent study, the incidence of retinal detachment following extracapsular extraction with an intact posterior capsule was 0.58% in the ten-year period following surgery, while the incidence increased ten-fold if the posterior capsule was violated.[31]

Cystoid Macular Edema

Cystoid macular edema is an accumulation of fluid within the macula (that tiny portion of the retina responsible for seeing fine detail). Despite recent surgical advances in cataract extraction techniques, cystoid macular edema remains one of the most common postoperative complications resulting in temporary, and occasionally permanent, visual impairment.[32] Extracapsular cataract

extraction, however, appears to be associated with a lower rate of cystoid macular edema as compared with intracapsular extraction.[33-39]

Harmful Effects of Intraocular Lenses

As part of the healing process which occurs following removal of a cataract with insertion of an intraocular lens, portions of the implant which are in direct contact with soft tissues inside the eye usually become imbedded within those tissues. In the vast majority of cases implants are well tolerated and this "healing-in" process actually stabilizes the implant. Rarely, however, the implant may cause a low-grade, chronic inflammation within the eye. Many surgeons now feel that if the supporting elements of the posterior chamber lens are inserted within the relatively inert capsular bag, this potential problem can be avoided altogether.[40,41]

In the past, insertion of poorly manufactured intraocular lenses produced inflammatory reactions, intraocular bleeding, and reduced visual acuity.[32,42,43,44] Strict quality control measures during the past few years have largely eliminated these problems.

Avoiding damage to the endothelial cell layer (those cells which are responsible for maintenance of the cornea in a clear, dehydrated state) continues to be an important priority both intraoperatively

and in the evaluation of the safety of different types of intraocular lenses and contact lenses.[12,13] Studies have shown that posterior chamber lens implants are associated with a significantly lower rate of ongoing endothelial cell loss as compared with other types of intraocular lenses.[45,46]

Complications of Contact Lenses

Many elderly patients are unable to tolerate or manage contact lenses, and with fitting, replacement, and long-term care costs, contact lenses are considerably more expensive in the long run than intraocular lenses.[2] Aside from these issues, contact lenses, especially extended wear contact lenses, are associated with an increased risk of vision-threatening corneal problems including corneal ulcers.[47] Recently some kinds of contact lenses have even been shown to induce abnormalities in the endothelial cell layer of the cornea.[48] Contact lenses, therefore, may not prove to be as attractive an alternative to intraocular lenses as originally believed.

Retinal Damage from Ultraviolet Light

The human crystalline lens filters out much of the ultraviolet light entering the eye, and there is growing speculation that the aphakic individual may be susceptible to retinal damage from short-wavelength UV light entering the eye following cataract surgery.[49] Although evidence for such damage is not conclusive, many surgeons recommend UV-absorbing spectacles following cataract surgery. Intraocular lenses are available with UV-absorbing capability, but until such time as this type of intraocular lens can be shown to pose no additional potential for complications, the use of UV-absorbing spectacles may be the preferred method for filtering the unwanted rays.

TRENDS IN CATARACT SURGERY

The increasing popularity of outpatient cataract surgery in private surgical centers makes the total annual number of cataract operations performed in the United States difficult to ascertain. National estimates are available, however, for cataract procedures performed on patients discharged from short-stay, non-federal hospitals,[50,51] which constitute 95% of all hospital discharges in the United States.[52] These estimates are based on data from the

Hospital Discharge Survey[50] conducted by the National Center for Health Statistics, and from the Hospital Record Study[51] conducted by the Commission on Professional and Hospital Activities.

While these studies are not strictly comparable, and both are subject to sampling and non-sampling errors, their findings show similar trends in cataract surgery. The overall number of cataract extraction procedures increased by over one-third from 1980 to 1983 in both surveys (Table 1). The increase in cataract surgery reflected a greater number of extracapsular extractions, which was over three times higher in 1983 than in 1980. In contrast, the number of intracapsular extractions declined slightly over the same time period. One of the great advantages of extracapsular surgery is that it enables the surgeon to minimize postoperative complications by using posterior chamber intraocular lenses, and the trend towards extracapsular surgery is paralleled by a similar increase in the number of posterior chamber intraocular lenses being inserted.[53]

While the total number of cataract operations performed in the United States is not known, accurate intraocular lens usage data are available from the U.S. Food and Drug Administration because intraocular lens manufacturers and distributors are required to report the number and type of lenses being implanted. During 1983, 631,000 intraocular lenses were implanted in the United States, and the FDA estimates that over 80% of the lenses implanted at the time of cataract surgery are of the posterior chamber variety.[52] By

comparison, in 1980 only 229,000 intraocular lenses were implanted, and only about one-third of these were posterior chamber lenses (Figures 1 and 2).

When compared with the FDA figures, data from the Hospital Records Study and the Hospital Discharge Survey tend to underestimate the number of intraocular lenses being implanted because these latter two studies do not include procedures performed in federal hospitals or among outpatients. However, the remarkable trend towards extracapsular surgery with the use of posterior chamber lenses is evident in all three studies: more than 70% of all cataract operations in the United States currently involve the use of an intraocular lens, and this percentage continues to increase.[54]

The increased rate of cataract surgery in the United States is due in part to a liberalization of indications for cataract surgery. A major factor in this liberalization stems from the fact that patient and physician anticipate and expect excellent visual results following the procedure. Intraocular lenses (and to a lesser degree, extended-wear contact lenses) have greatly reduced the patient's reluctance for cataract surgery. In the past, many patients ultimately adjusted to the distortion accompanying spectacle correction of aphakia, but many were quite disappointed with the results. A patient trading 20/200 phakic vision for 20/20 aphakic vision was usually reasonably happy with the results; not so

with the patient able to see 20/70 preoperatively. Similarly, monocular cataracts were often tolerated until they became so dense that peripheral vision was severely impaired; it was not possible to provide correction for monocular aphakia with the use of aphakic glasses. Contact lenses and intraocular lenses have eliminated both of these problems, restoring near-normal functional vision, and this may have contributed to the public's acceptance and desire for earlier surgery.

Until recently, many eye surgeons took a conservative approach to intraocular lens implantation. Surgery was limited to elderly patients and often only to a single eye.[55,56] Now, however, with the excellent visual restoration and paucity of complications, patients and surgeons alike have adopted a more confident approach to lens implantation.[57]

The increased access to health care provided by the government and third-party payers has also contributed to the increased numbers of cataract operations being performed.

SUMMARY; PREDICTIONS FOR THE FUTURE

In recent years better methods for preoperative evaluation, more reliable surgical techniques, and the excellent results from cataract surgery have led to its being performed earlier and more widely.[58,59] A person living a normal life span is more likely to undergo a cataract operation than any other major surgical procedure, and no other operation in medical practice is as frequently dramatically successful.[8] This trend towards an increased rate of cataract surgery is likely to continue, considering the increasing numbers of elderly people, changes in their lifestyles, and the success with which these procedures can be performed. In addition, increased numbers of diabetic patients with retinopathy are now surviving in the population. Many such patients can benefit from retinal photocoagulation, but cataracts may need to be removed earlier than otherwise in these patients in order to monitor the progress of the retinopathy and permit laser photocoagulation when necessary.

Because extracapsular cataract extraction, as compared with intracapsular surgery, is associated with fewer postoperative complications such as cystoid macular edema and retinal detachment, it is likely that extracapsular cataract surgery will continue to increase

in popularity. It has become obvious, even to the most skeptical eye surgeon, that intraocular lenses are the most practical and effective means for the correction of aphakia in most patients.

With continued advances in intraocular lens designs and refinement of surgical techniques, it is anticipated that in the future only the exceptional cataract patient will not be a candidate for an intraocular lens.

Recent developments such as viscoelastic materials and longer acting anesthetics will likely gain wider acceptance, and the bulk of cataract procedures will probably be performed as outpatient surgery. It remains to be seen whether most of the surgery will be performed in hospitals, in ambulatory surgical centers, or in office-based surgical units. It does seem evident, however, that some patients will still require hospitalization for cataract surgery.

New technologies and surgical techniques will undoubtedly continue to influence greatly the way cataract surgery is performed in the United States. For example, the development of soft, flexible intraocular lenses may cause a resurgence of interest in phacoemulsification, because these lenses may be collapsed and inserted through a 3 mm opening. As stated earlier, it is uncertain whether

keratorefractive procedures will replace intraocular lenses as the preferred method for the correction of aphakia.

Finally, medications have been developed which retard or prevent the development of cataracts in diabetic laboratory animals.[60,61] It is tempting to speculate that eventually such agents may become available for the prevention of cataracts in the general population. Even if such were the case, however, many years would elapse before the need for cataract surgery would diminish, simply because of the large number of individuals with cataracts already present in the population.

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TABLE 1

Number (in thousands) of operations on lens, by type of procedure, for inpatients discharged from short-stay nonFederal hospitals, from 1980 to 1983, as estimated by the Hospital Discharge Survey (HDS) and the Hospital Record Study (HRS)*

Type of procedure	1980		1981		1982		1983	
ICO-9-CM code	HDS	HRS	HDS	HRS	HDS	HRS	HDS	HRS
Extraction of lens								
13.1 Intracapsular	352	310	366	274	n/a†	330	276	234
13.2-13.5 Extracapsular	105	95	160	150	n/a†	268	325	347
13.6 Other	10	10	15	14	n/a†	20	29	16
Total extractions	467	415	541	438	599	618	630	597
Insertion intraocular lens								
13.7 Insertion prosthetic lens	191	164	297	242	418	427	516	512

* Data obtained from the Hospital Discharge Survey, National Center for Health Statistics and from the Hospital Record Study.

† n/a = not available

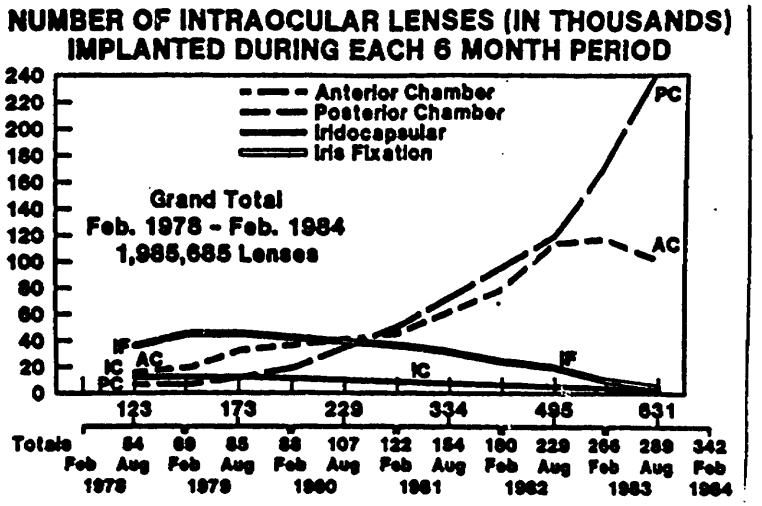

Fig. 1. (Stark et al.) Number of intraocular lenses (in thousands) implanted for each six-month period since February, 1978.

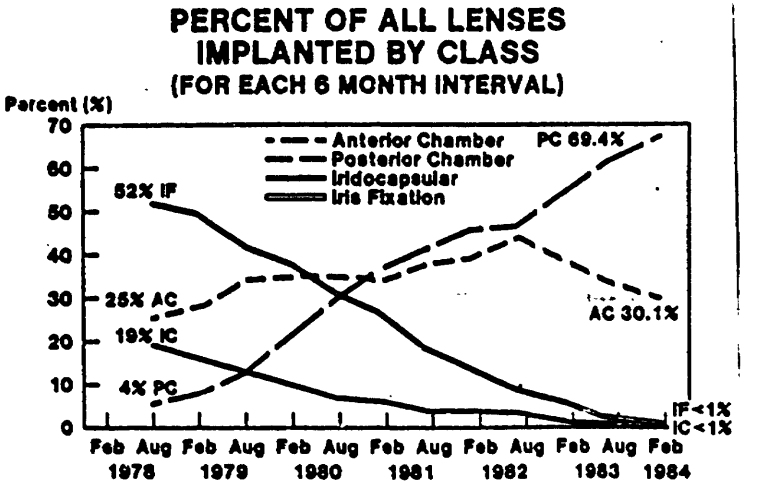

Fig. 2. (Stark et al.) Percentage of all intraocular lenses implanted by class, for each six-month period since February, 1978.

Senator DURENBERGER. Gentlemen, along that line, I haven't asked a question yet, and this may be the most appropriate group in which to ask it, that one of the disappointing things to me, and I'm sure it was to Max as we watched this develop, was the lack of information and education. I mean, we in effect dumped on the hospitals and the doctors—without thinking about it, I guess—the obligation to explain to all of those folks out there what was going on.

Can you make some observations about how you carried that out and what the current situation is? Do we need more information going out to the Medicare beneficiaries about what is going on particularly on preadmission screening and that sort of thing? What is the status of that right now? Or is that a question none of you feel competent to answer?

Mr. OWEN. Well, let me just comment briefly on it. I think that you are absolutely right, Senator, that we did a good job of explaining to the beneficiary that it wasn't going to cost him any more, that it was no different as far as they were concerned whether it was a DRG prospective payment system or the old cost reimbursement.

What we didn't tell him was that we were going to be treating him differently. And I think if you look at the GAO study that Senator Heinz had, the perception of the people because they were sent home faster—it didn't say that the hospitals did anything wrong particularly; I mean, they had to let them go faster. But what we are seeing develop is a transition patient, a patient that isn't quite as able to go home as he was in the past, but he is not quite a nursing home patient either. And that whole area right in there of explaining to the patient what this new system means and what it means when you are denied by PRO, and what it means when you are going to have to pay if you are denied or if you want to do this, we have not done a good job.

I think neither HCFA, Congress, hospitals, or perhaps physicians—although I will let Dr. Felts speak about that—have done probably as much in the educational portion of it as we should have.

Senator DURENBERGER. Well, all I see—and obviously I am going to go back to the AMA now and to the Docs—because what we get back, what you see in the newspapers, is doctors blaming me, the DRG's, or whatever for this, that, or the other thing.

Now, I don't think that is standard practice for a physician. I think most physicians are going to undertake the responsibility to explain what is going on because it is in the interests of their patients. But we see an awful lot of negative feedback coming from it. And if there is something we should be doing—I guess I am asking the question: What should we be doing?

Dr. Felts.

Dr. FELTS. Well, Senator, I am not sure of the answer as to what you should be doing. However, I think that it is accurate that physicians have been placed in a position of being forced to attempt to teach patients and patients' families about the meaning of a very complicated governmental program that has been imposed from the top down rather abruptly. The DRG system has intricacies with which many physicians are not as yet adequately familiar. Thus it

has been the case of the blind teaching the blind in some instances, or attempting to do so. The recipients of those teaching endeavors often do not want to hear or appreciate that type restriction, because it is taking away or gives visions of taking away a benefit that they previously enjoyed.

The mechanism by which this could be better explained to the public, it seems to me, is one that does have a governmental responsibility to it, because it is a governmentally derived program.

I think I can assure you that the medical profession is willing to assist in that, but I don't think we should be left with the burden alone.

Senator DURENBERGER. Now, that sounds to me like an AMA response. [Laughter.]

Now give me your "I'm the best physician around, and I was just waiting for an opportunity to save my patients some money by doing something better" kind of a response. [Laughter.]

Dr. FELTS. Well, I think I have always been willing to try to save my patients some money by doing something better, Senator.

Senator DURENBERGER. I guess the point is, we are in this together, and some of the physicians are going to explain that you can do an in-and-out on a hernia; you don't have to stay a couple of days like we used to. And others are going to say, 'Well, it's because of the Government that I have to do this, and/or some will try to combine it, if they have enough information to explain the combination of the two. It is a mutual responsibility, because while it looks regulatory and it looks like we are imposing something, really this whole process is designed to give the good physician—and that's why I asked you that practice pattern or the practice-style question earlier—to give the good physician an opportunity to make some money under this system and to do better by their patients. It really isn't designed just as it appears to be, to save a bunch of money.

Dr. FELTS. I am sympathetic with that, and I completely agree with it. I think that most physicians genuinely want to see this DRG approach work.

Senator DURENBERGER. Dr. Gilbert.

Dr. GILBERT. We don't really just treat the cataracts; we treat patients that have cataracts. And we are treating whole patients. It sounds like a cliche, but that is really what it is all about.

If the types of nurturing and support that came out of a hospital setting are taken away, what mechanisms do we have for substitutes? What financing mechanisms are available to provide less intensive followup ancillary care?

These are the ideas that come to my mind. What arrangements do we have for the utilization of less-scaled facilities or professional people to provide nursing support in the home setting?

It raises a whole concept of considering how we are going to have a new type of more complete delivery systems. Perhaps those are the areas that you are beginning to explore.

Senator DURENBERGER. If the doctor has a patient that he believes has symptoms that ought to be at least examined, diagnosed, and perhaps treated in the hospital, and there is a contact made with the PRO, and there is a denial of admission, is the doctor

denied under our system the right to admit that or request admission of that patient at a hospital?

Dr. GILBERT. We labor under the concern that, as my colleagues have said to me, "Who is responsible? Who is liable for the complications that might occur if we stick to the instruction that we have had?"

Senator DURENBERGER. But the instruction doesn't say you can't.

Dr. GILBERT. No, the patient can be admitted. But the anxiety rests with the physician. The physician is left with anxiety, and perhaps the patient, as to who may have the financial burden of an admission that has been disqualified on those grounds. That conflict exists. The physician feels that it is necessary for the best patient care. The patient is admitted. And it may be determined in retrospect that that just wasn't so.

Senator DURENBERGER. Early on I heard a lot of stories as I traveled the rural part of my State from doctors who were telling me, "I got a call at midnight from a patient that really sounded sick. So I checked out to see whether they could be admitted, and they couldn't. So I said, 'I'll see you at 8 in the morning.' And by 8 in the morning they were dead," and that sort of thing.

Those physicians want to blame me and the DRG system for the fact that they can't stay in bed. You know, they want to send the person over to the hospital and let the hospital take care of them for 8 hours so they can get a good night's sleep under the old system of medicine. And I am supposed to take the responsibility for that. I don't know that I have that responsibility. I have a responsibility for adequately reimbursing the individual involved, the patient involved and the providers.

But at the point of having to make a decision with regard to a patient, that is still between you as the doctor and the patient, isn't it? And with the hospital involved also. Am I correct in that?

Dr. GILBERT. The responsibility is left to us, but the economics come into play. We would like to have the people that make the economic decisions in on our professional opinions. I think that is what we are talking about. We would like to have our professional opinions respected as being insightful and being in the best interests of our patients. We would not like to feel that economic considerations are at odds with those professional opinions.

Senator DURENBERGER. Which is exactly why the Senator from Montana and the Senator from Minnesota fight to keep the "peer" in peer review in this whole process. And it is exactly why we have these hearings so often, to make sure that HCFA and other people continue to understand what our joint commitment is, as you say, to the patient and not to DRG-39.

Dr. FELTS. Senator, if I might supplement that response, I think the answer to your question is "Yes", the responsibility is with the physician and with the patient and his family. The patient certainly can be admitted. It does impose the anxiety upon both the patient and his family and the physician about the coverage for that admission if the pre-admission request is denied.

There is also a mechanism whereby a physician or patient can have the PRO reconsider its initial denial determination. This involves additional time and delay for the patient. However, I have

not heard any horror stories concerning the reconsideration process.

Senator DURENBERGER. All right.

That is very good testimony, and I do have some other questions, and Max may too, that we would submit to you in writing.

I appreciate your testimony today very much.

Dr. FELTS. Thank you.

Dr. GILBERT. Thank you.

Senator DURENBERGER. Our final witness is Bill Goldbeck, Willis B., president of the Washington Business Group on Health, Washington, DC

Are you going to come up with some explanation of your appearance?

Mr. GOLDBECK. Absolutely not.

Senator DURENBERGER. I mean, she had a sweatshirt; you've got a necktie.

Mr. GOLDBECK. She has more style. [Laughter.]

STATEMENT OF WILLIS B. GOLDBECK, PRESIDENT, WASHINGTON BUSINESS GROUP ON HEALTH, WASHINGTON, DC.

Mr. GOLDBECK. I appreciate the chance to come back and revisit this subject with you and your work on it. It is certainly interesting to reflect on the last several years and recognize that the PRO Program has survived a tremendous amount of opposition from those who are here today, and the recent testimony now supporting its continued existence.

We have been delighted with the progress of HCFA in the last few months, as reflected in the regulations that now allow access to privatepay data, and to substantiate the relationship between privatepay and Medicare data, and the release of institution comparative information.

Specific to several of the points that you and HCFA must now consider, we support HMO review; we urge that the evolution of PRO reach the point where physician aggregate data is also made available publicly, ambulatory review and disclosure established, and then we move toward the outcomes—standards, research—that was implied in your questions concerning variations on the work of John Windberg and others.

Certainly the research confidentiality question is important, as exemplified in our statements. And lastly, in response to one of the points you most recently made concerning education, yes, I think it would be tremendously valuable if the Department or the Government, generally speaking, were to launch a campaign to truly inform Americans of all ages of the advantages and the necessity of these kinds of review.

It was sort of ironic to hear the AMA saying that they thought that was a governmental responsibility, since they also opposed even a release of a list of cancer specialists as being inappropriate governmental education of the public. I am not quite sure where all these tradeoffs are, but we would certainly feel it was appropriate for the Government to do more in the educational vein.

I would like to speak specifically to several of the concerns that have come up today.

The quality/cost debate and Senator Mitchell's hierarchy. The fact of the matter is, from the standpoint of HCFA of course, OMB is considerably on top, because you don't get to them without going through OMB—I don't get to you without going through OMB.

We certainly are told in our dealings with OMB that the evaluation is by and large going to be a cost assessment of the "economic efficacy of the Peer Review Organizations." So, that is a legitimate problem. It is one that won't go away.

We feel very strongly that from our standpoint and our support of PRO, we will support PRO if the cost issue is moot. We will support PRO if in fact it costs somewhat more to have higher quality medical care for retirees and for the senior citizens and ultimately for the entire population, because that is the objective. But we should not confuse that support with the fact that we aren't going to make the decision. And that's the reality with which we all ought to cope.

It seems to me that to fail to connect the costs and recognize that it is the biggest threat to quality in many respects, because unless we do something to control costs, that is the biggest threat to access. And the absence of access is ultimately the biggest loss of quality.

On the Super PRO issue, our organization would be very disturbed if the Government was to contract with the Washington Business Group on Health to establish the standards of ethics and performance for American business. We would be equally disturbed if you were to contract with the AMA to establish the standards of every PRO on the specific performance and measurements of a particular case of case determinants. That is really not the concept of the PRO, it seems to me, nor can I imagine why you would contract with an organization that has opposed the development of this institution every step of the way and opposes the very national standards that are implicit in that kind of review of determinants.

Further, it seems to me that when we talk about objective criteria or the objective target, the objectives themselves, of the PRO Program, this is a dynamic that ought never to be locked into place. It is not only that the baseline data is inherently flawed, as it always is anytime you impose new standards on old information. Of course, the baseline is flawed. That is a reality; that is not something that serves us any purpose to talk about much further.

There are not national norms, mostly because we have never invested in the research, and because every professional organization in the country desires to avoid national norms.

It is a problem that is going to have to be addressed at all times and not have a solution sought. There should always be targets, there should always be objectives, and they should never be locked in place.

The convenience and social factors it seems to me are one of the stickiest areas and really do deserve a lot of thought, although I doubt if any of the medical Peer Review Organizations are by training or certainly by the budgets of their contracts in a position to determine parental responsibility, home standards, housing, and transportation as a criteria for the acceptability of a particular determinant by another doctor.

Whether or not it is a terrible imposition to have people have to get up at 4:30 in the morning to get surgery seems to me to be relatively easy to correct. Have doctors do surgery at a reasonable time of day. This is not an issue of medical peer review or quality care; this is just an economic issue.

So, let me close by saying unequivocably we support this program. It needs modification. Hopefully it will always need modification. Otherwise, it will be time to get rid of it as being too stultified.

There is a uniform public-private interest here. This is not a Medicare-versus-private-sector interest, and that is extremely important. We are attempting to achieve a balance between the impact, positive or negative, of competition and where that relates to review, quality, and costs, and how those interrelate.

The final assessment of PRO's in each subsequent year must be on a realistic basis. PRO's will never be the solution for costs or quality in America. They can't be graded accordingly. But a responsible strategy for medical care in American cannot exist without review.

Thank you very much.

[Mr. Goldbeck's written testimony follows:]

PREPARED STATEMENT OF WILLIS B. GOLDBECK

As President of the Washington Business Group on Health, it is my pleasure to present this distinguished committee with the concern and interests of many of our nation's largest purchasers of medical care.

Historically, business was not an active or well informed participant in the development of Medicare. Its involvement has increased over the last decade, however, and led to some of the private sector stipulations that were incorporated in the Peer Review Improvement Act of 1982. I want to commend you, Senator Durenberger, for your incessant oversight of that act and its implementation and to encourage you to sustain your involvement in the PRO program as it evolves. Let me outline a few broad remarks to portray the Medicare Prospective Payment System (PPS) that influences and drives the PRO program.

1. The need for a financially sound, well designed Medicare program has never been greater. Peer review is critical to this end. All changes to Medicare should be considered not as methods to preserve what was, or systems for producing short term savings, but rather as efforts to make Medicare fit the real needs of our aging population for the years to come.

2. For those of us who advocate a more market forces oriented medical system, preservation of access to quality care for those without the economic means to enter the market is essential. The greatest threat to a successful transition to market forces are the current increases in poverty, the uninsured and

inappropriate underservice of patients by dollar-driven providers. PROs can help protect us from deterioration into a two-tiered system.

3. Medicare can become a greater contributor to the market by purchasing care from high quality efficient providers. PRO data will assist us in identifying those institutions. Simply reducing benefits and giving providers of all types the economic incentives to underserve will result in short term savings and long term political pressures for new governmental programs.

4. Medicare, declared prematurely bankrupt last year, is being prematurely hailed as solvent this year. It is time we were given an honest assessment. In actuality, do the PROs rightfully deserve credit for curtailing utilization increases? Solvency is being achieved by drastically shifting program costs to beneficiaries and employers. Solvency for the future is predicated upon freezing fees for providers who were promised an orderly phase-in of the Prospective Payment System, and by (according to the White House study group) borrowing billions from the same Social Security program which two years ago was borrowing from Medicare. Government is playing an accounting game in which the losers will always be the elderly and the taxpayer. In that same vein, insufficient funds for PROs will compromise their effectiveness and limit their domain.

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5. The drive to achieve deficit reduction from Medicare should be balanced by reforms that make Medicare inherently more efficient and programmatically more in tune with real needs. To do so involves risk taking, experimentation, new types of research and new outlays for services which hold the promise of long term cost effectiveness. In the utilization review area, this means investing in a data base, with the requisite standardization of data elements that will facilitate PRO review of outpatient settings.

Equally important to the objectives of PROs is an investment in the development of outcome standards that would reduce the variation in physician practice patterns. The criteria adopted by PROs this year in compliance with the contracting process administered by HCFA were based on historical data. If history misrepresents or fails to account for recent developments in medical technology and treatment, we will base our expectations on artifacts and PRO objectives will not necessarily represent optimal treatment patterns. More importantly, physicians will be permitted to prolong the practice of defensive medicine due to lack of consensus, leading to unnecessary testing and utilization.

As an advocate of utilization review and its integral role in the management of health care costs for public and private payers, I offer the following comments on the PRO implementation process.

- Physician-based peer review remains the most appropriate form of utilization review. Where physicians refuse to participate, or do not use the system for constructive improvements, alternative providers of review services must be accepted.

- Though PROs are not meant to gain monopoly power for private review, we should facilitate every opportunity to stimulate review of private sector patients by PROs. The change in Section 476.41(b) of the recently released regulations accomplishes this objective. Improving the quality of care provided by practitioners is a societal goal which benefits public and private payers alike.

- With respect to the release of PRO information requested by researchers, HCFA has contradicted itself and thus obviated a potentially valuable resource for ameliorating quality health care for Medicare beneficiaries. If PROs are mandated to "meet professionally accepted standards of patient care quality" then researchers will need to access PRO data in order to establish those standards. The practice

of medicine, until now, has defied the setting of standards of excellence. Medicare patients would be more enlightened if, upon admission, they could base their expectations on standards. By denying access to PRO data for researchers, HCFA is perpetuating the status quo in which malpractice lawyers determine what is inappropriate and general revenues that pay 75 percent of Part B costs are drained by lab tests constituting defensive medicine.

- Sections 476.120(g) and (h) represent the culmination of an objective pursued by business for the last several years. By disclosing aggregate statistical information, PROs will contribute to the education of the American health care consumer. This educational process is a valuable investment, for it allows the government to begin to relate to Medicare beneficiaries as participants in a systematic overhaul of medical care. By empowering beneficiaries to become more knowledgeable of their caretakers, we are proceeding down a road which will also require the elderly to become better attuned to their health status and those lifestyle behaviors that increase their health risks.

The Congress should be mindful of the responsibilities for paper pushing that we are imposing on the PROs. While on the

one hand, we want to encourage the dissemination of information that will lead to a fuller understanding of the efficient and inefficient institutions in a community; we most assuredly do not seek to compromise the PRO assessment of providers by overburdening them with unbudgeted information dissemination responsibilities. The answer is not to decrease disclosure, rather it is to fund the PROs at an adequate level to accomplish this public objective.

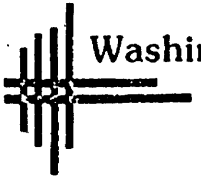
I raise this as a suggestion to sensitize the Congress on this issue. Meeting requests for data, though philosophically laudable could prove to be a costly use of our resources. We may need to devote additional monies to offset these demands.

PROs have embarked on a critical path. Is is the successful management of utilization and unit price under the PPS that will make the system work. We cannot afford to let utilization and quality issues go unchecked. Now, PROs purview will extend beyond the inpatient, fee-for-service sector to HMOs and CMPs. In order to lay the groundwork for an effective review mechanism for HMOs and CMPs. the government must address the current abyss of standardized data elements that will handicap review efforts in the outpatient setting. Without agreement on procedure codes and practitioner visit coding, efforts to assess quality of care will founder in costly, labor-intensive, untargeted, random chart review.

In essence, by committing to do HMO review without standardized data elements, HCFA is thrusting PROs into the very same situation that was the undoing of the PSROs - costly review in which the benefits barely outweigh the costs. Surely the Congress is capable of acting prospectively to avoid this inevitable recreation of the PSRO saga.

In assessing the operations of the PRO in their first year, I urge the Congress to adhere to realistic expectations. PROs have become our police force to sustain the high quality of medical care to which we have become accustomed. Isolated aberrations from the standards cannot be mistaken for the norm. Quality issues tend to insight inflammatory rhetoric. To carefully, responsibly, and objectively, assess the review performed by PROs, we owe Medicare beneficiaries and their agents a commitment to swift reaction in redressing wrongs, but not overreaction that could indict the entire review industry.

I thank this subcommittee for the opportunity to appear before you and share our perceptions of the PRO program.



Washington Business Group on Health

POSITION PAPER

PEER REVIEW

Position

The Washington Business Group on Health (WBGH) supports both interim funding for the existing Professional Standard Review Organizations (PSROs) and full program funding for the Peer Review Organizations (PROs) starting October 1, 1984.

Background

For the past eight years, the WBGH has supported the PSRO program as one essential element of quality assurance and cost management. We were directly involved with developing the Peer Review Improvement Act which, through Senator Durenberger's leadership, became law. Many of our members have contracts with PSROs for private review. Medicare and the government's cost control objectives benefit significantly from this private cooperation with the public program.

The WBGH

The WBGH is a membership organization representing the health policy interests of major employers. We are committed to working with the nation's other major purchaser, government, and with the high quality providers whose partnership is essential for a successful peer review program. A membership list and brief description of our program is attached.

Issue Analysis

In order to be effective, health care cost management strategies implemented by purchasers of care - be they business or government - must focus on capacity, financing, and utilization. No strategy can have a demonstrable impact on the growth of health care costs if any of these three components is ignored. It is on that premise that the Washington Business Group on Health posits the following statements on peer review.

1) Utilization review, initiated to monitor the use of medical services, has been largely developed by PSROs. Created by federal legislation in 1972, these PSROs have refined their efforts over the last 10 years and now stand as the most capable group of review entities to assume the roles and responsibilities delineated in the Peer Review Improvement Act of 1982. Although there are PSROs that have failed in their mission, many boast a responsible record of intervening to identify unnecessary and inappropriate use of medical services in hospitals. An additional byproduct of effective review is a community-wide change in physician behavior. Often referred to as the sentinel effect, this response to information that circulates among physicians, alerting them to a monitoring process, results in a higher standard of practice and improved quality of care for all citizens.

2) The Congress asserted its belief in medical peer review when it approved the inclusion of the Peer Review Improvement Act in the Tax Equity and Fiscal Responsibility Act (TEFRA) passed in August, 1982. A number of deficits that were part of the original PSRO program were eliminated in this carefully crafted piece of legislation that benefitted from the input of insurers, providers, PSROs, and the business community.

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3) In passing the prospective payment system (PPS) for hospitals last spring, the Congress reaffirmed a need for peer review. Since health care costs are a product of utilization and price, holding down prices through prospective payments does not ensure a concomitant check on utilization or total costs. For the PPS to succeed in stemming increases in total health care costs for Medicare and private purchasers, an effective utilization review system is imperative.

4) An effective utilization review system - designed to evaluate the necessity, appropriateness, and quality of medical care services provided in hospital settings - must contain the following components: access for all purchasers to appropriate data; a working relationship with providers and purchasers; an ability to target review to specific diagnoses, medical procedures, providers, or groups of patients; performance standards by which savings can be measured; and a variety of review approaches including pre-admission, concurrent, and retrospective analysis.

5) By allocating no interim funds for PSROs, the Congress would undercut the very organizations that it designated as instrumental in checking non-appropriate Medicare and Medicaid utilization under the PPS. If that responsibility is turned over to fiscal intermediaries (FIs), several considerations should be noted:

- FIs have no experience in preadmission testing which is the most likely area for gaming by hospitals intent on maximizing revenues under the new system.
- By law, FIs cannot qualify until October 1985 for the new PRO contracts, by virtue of their association with the financing of hospital care.
- For the FIs to succeed in assuming the responsibilities of PSROs, a cooperative relationship between FIs and commercial insurers would be essential. Since FIs and commercial insurers are competitors in the same insurance market, the expectation of a cooperative arrangement is overly optimistic.
- The performance of fiscal intermediaries as retrospective claims reviewers has hardly been reassuring. Large companies have elected to self insure against health care expenditures for a number of reasons, one of them being dissatisfaction with the utilization controls and data systems of the insurance carriers. The private sector's retraction from intermediaries is a message that should not be lost on the Administration and the Congress.

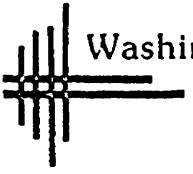
6) Defunding PSROs will threaten the integrity of private peer reveiw, a recent but notable development initiated by business seeking to adopt the strengths of peer review that yield reduced utilization and cost savings. Most PSROs cannot survive without funds from both public and private sources. The loss of federal funding jeopardizes the fiscal viability of these entities that have been saving significant sums of money for government and business.

7) Lessening the commitment to a system of peer review for Medicare will waste the considerable investment of tax dollars already expended on the development and refinement of this system.

Conclusion

The Washington Business Group on Health, as a representative of our nation's largest employers has been an ardent advocate for peer review. We are keenly aware of the integral rle for effective review in managing health care costs and, for that reason, strongly support the Peer Review Improvement Act and the modest but necessary funding that will maintain PSROs until the implementation of designated Peer Review Organizations on October 1, 1984. Without those funds, the new PPS will be more difficult to manage cost-effectively, and consequently, the fiscal demise of the Medicare Trust Funds will be

expedited. Ironically, at the same time, private employers which learned the benefits of peer review from witnessing PSRO intervention in Medicare cases will continue to benefit through private review contracts. Nevertheless, these very same employers will lose as taxpayers due to the increased cost to Medicare resulting from decreased review in this program.



Washington Business Group on Health

May 15, 1984

Carolyne K. Davis, Administrator
Health Care Financing Administration
Department of Health & Human Services
HSQ 110-P
P.O. Box 26678
Baltimore, MD 21207

RE: Proposed PRO regs

Dear Dr. Davis:

The issue of practitioner-specific quality information is of great import to the business community. Purchasers can benefit greatly from provider-specific information without committing breaches of patient confidentiality or misuse of data. In fact, as the agent for employees, making intelligent and informed decisions on sharing data could easily enhance the level of care for employees needing to select providers. Abuse of data is a sensitive subject and one which the great majority of employers treat with utmost security and respect. It is in fact an insult to the responsible majority of purchasers to prohibit any sharing of practitioner-identified information. This is not meant to contradict HCFA's concern that unwarranted freedom of access to practitioner-identified information may lead to abuses; but suitable safeguards can be established by practitioner-dominated PRO boards. Hence, the WBGH supports a less prescriptive approach for the following reasons:

- Purchasers need a larger sample size than their work force from which to make informed decisions on use of providers.
- A number of data-sharing relationships have already been established between purchasers and PSROs with no adverse outcomes (N.B.: The Iowa Foundation for Medical Care). These precedents prove that the process can be managed responsibly at the local level.
- Utilization data is a manifestation of quality of care for all payers, not just Medicare. Solutions to the health care cost and quality problem cannot be designed irrespective of the private sector. There is an implied presumption that physicians, hospitals, and Medicare fiscal intermediaries can behave conscientiously when in possession of practitioner-specific information; whereas employers cannot. There is no evidence to support this contention; in fact, business representatives handle the confidential health data of their employees daily.

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- Data-sharing decisions cannot be made unilaterally. Cooperative relationships between purchasers and providers ensure a strong likelihood of appropriate management of this kind of data. On the other hand, in communities where PROs vie between contentious adversaries, mishandled data potentially could increase discord and undermine progress. The decision of sharing practitioner-specific information, therefore, is most logically left up to the discretion of each PRO, based on an appreciation and understanding of its jurisdiction.

Recommendation: The WBGH recommends that disclosure of practitioner-identified information be decided by each PRO board based on the merits of local issues and historical relationships. Disclosure arrangements should be required for PRO designation. No PRO should be prohibited from sharing this kind of data; while at the same time, no PRO should be required to release practitioner-specific information. Resolution of standards and protocols for appropriate data sharing, in fact, will make communities more involved in utilization review programs, increase the likelihood for effective and concomitant private review, and underscore the recognition that involvement of all purchasers in health care problems is preferable.

Sincerely,

Willis B. Goldbeck
President

WBG:mra

Washington Business Group on Health

August 14, 1984

HCFA/DHHS
Attn: HSQ - 110- P
309 G HHH Bldg.
200 Independence Ave., S.W.
Washington, D.C. 20201

RE: 42CFR 466.88b "Records on non-Medicare Program Patients"

We are writing to express total opposition to the proposed regulation which would make PRO access to private paying patients' records dependent upon approval by either a facility or practitioner.

To be clear:

1.) P.L.97-248 explicitly encourages PROs to seek private contracts. The proposed regulation subverts this aspect of the law.

2.) Neither facilities nor practitioners should ever have authority over access to medical records by a PRO, regardless of source of reimbursement.

3.) As the administrator of Medicare, HCFA would never accept such a restriction. Then why should private payers be burdened with this requirement.

The PRO program is designed to protect consumers and taxpayers, not providers. Just as we have urged that full disclosure be required of physicians as well as hospitals, we now must urge you to remove any restriction for PROs that wish to contract with private purchasers. Such efforts should not be contingent on the discretion of a practitioner or facility.

This regulation is contrary to the Administration's expressed desire to facilitate private sector initiatives in medical care cost management. Utilization review, from the perspective of quality enhancement and cost reductions is needed for all payers. The PROs should never make a decision based upon the source of payment, only on the appropriateness of the care rendered.

Under HCFA's leadership, the PRO contracts are demanding major changes in utilization patterns. We are one of the few groups which has publically defended HCFA's approach. However, if your regulations undercut a strong, equal role for PRO review of private pay patients, we can only anticipate that the reductions in inappropriate admissions, infections, unnecessary surgery and even avoidable deaths will only be afforded to Medicare beneficiaries and not private patients. In fact, the data base from which a PRO determines inappropriate use of medical resources will shrink and providers for private patients will be exempt from the improved quality expectations imposed by HCFA. Moreover, the risk of hospitalization and substandard care may increase for the 50,000,000 employees, retirees, and dependents covered by our member companies while being better controlled for Medicare patients. Such a result would be wrong by every standard: ethically, medically, and economically.

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This is not a complex issue. We share your interest, and that of Congress, in having minimal government regulation, increased market forces, and efficacious cost management. The PRO program can play a responsible , balanced role. However, to be effective, there must be equal access to all classifications of patients, regardless of source of payment.

We are asking for nothing more than what the law provides: equal use of the PRO program for those private purchasers which want to enter into review contracts. This objective is good for quality of care, good for cost management, and will enhance each PRO's ability to meet its obligations to HCFA and the American taxpayers.

Respectfully submitted,

Willis B. Goldbeck
President

WBG/eam

cc: WBGH membership

Senator DURENBERGER. Bill, the PRO's really aren't—well I was going to say they weren't invented by Government. Maybe they were. But by the time we went from PSRO to PRO, there were a lot of private employers and third party payers in this country that were utilizing Peer Review Organizations to provide services for either their insured or their employees and accessing them to the provider system.

And you well know, because you helped us with it, that one of our objectives in putting this legislation together was to enccurage more of that, and more professionalism in the area of peer review, so that everybody else would use them for other purposes.

I wonder if you wouldn't comment on whether or not we are stultifying that possibility because of this sort of uncertainty that all of the 54 PRO's are under right now? They don't know if they are going to be alive or dead, or hit by Dave Stockman or the local Blue Cross, or somebody like that. So what impact is that having on building professionalism within some of these organizations? Are they being utilized? My impression is that to the degree they are being used by private employers, that they aren't being utilized maybe for some of the things they might do better or do very well.

Would there be an apprehension on the part of the private employers to use them, on the theory that if we get in and make a commitment with Jack Graham and his organization in Minnesota, that once he has got enough private business, HCFA, Stockman, Durenberger, somebody, will say, "Ha-ha. Let's do some cost shifting." And we will cut back on what we pay for peer review services for Medicare and force him to sort of load that on the private sector?

That is a couple or three questions that have occurred to me that you might have some answers to.

Mr. GOLDBECK. Well, trying to start at the reverse end, I guess, we are getting reasonably good at dealing with your cost shifting. So this will not be a new event if it takes place. And I don't think there is an absolute price on peer review.

The point is to have the peer review. There are some great advantages to the private sector—having the same institution reviewing all classifications of patients, as long as the data is made available.

I think you will see a distinct increase in the amount of review done through PRO's by private sector firms over the next 2 years. I think there are very clear reasons why there has not been a great leap forward in the last 6 months, and they begin with the fact that the contracts weren't signed until just a few months ago. They then move to the fact that the original PRO draft regulations explicitly would have made access to private pay patient data dependent upon the approval of the individual provider and institution. That would be enough to stop anybody from looking toward the PRO for private review, if everthing has got to be adjudicated on a case-by-case institution basis.

Fortunately, and to the surprise of a rather large number of people, that was stricken in the final regulations, and the final regulations are really the first time that we have the Government, in the form of the administration and certainly with congressional endorsement, prodding, some might say, stipulating now that private

review is important, is to be done by the PRO's in effect, if you read those regulations, and a PRO does not attempt to do private review—it would really be a bad mark—rather than the other way around. That is a reversal of the history.

So, I think you are going to see a lot more comfort and certainty over the next few years, and I don't think there is going to be a major concern as to whether OMB will change the rules down the way. That is a constant battle, and it is a constant battle on a lot more things than PRO.

Senator DURENBERGER. Now, I am not going to be one of the folks that does the cost shifting on this one, and that sort of thing, because I am one of the folks that would like to push this on the private employers. But I am apprehensive that they don't want to take on their employees.

I mean, one of the things that we are doing well in the Medicare side, of course, is preadmission screening, and we are kind of tough, as we were just talking about here before—scaring the hell out of the doctors, in effect, in a lot of cases, and people are dying, and/or have maybe in some of the cases, because of the way a doctor acted. Now, there is no way that very many employers I know would have the nerve to really put this same kind of preadmission screening thing in effect in this country, or to tell their employees, "No, you can't go here. No, you can't go there."

Now, I sense that it is sort of starting out there a little bit. Is there something that we should or could be doing to encourage more employers to utilize some of these other elements of the peer review process?

Mr. GOLDBECK. Yes. Two points in response to your comment and question.

In terms of your comment, I think it is important to recognize that the employers over the last half dozen years have been establishing preadmission review requirements, formal precertification requirements, long before the PRO program came into existence. That has been growing every single year.

There is an important economic distinction between an employee and a Medicare patient, because the classic at need Medicare patient may not have any other recourse of a place to go or a way to get care, and so if there is a Medicare denial it can be more severe on a Medicare patient than for instance an employee my age. If I don't like the employer's stipulations, I have the right to buy care outside my insurance system. So there is a distinction there.

Senator DURENBERGER. Not without a job. Are you going to switch your employer?

Mr. GOLDBECK. Pardon me?

Senator DURENBERGER. You have to switch your employer to do that.

Mr. GOLDBECK. No, no, no. You were questioning whether the employers could force the employee to only follow the proscription of the system. I am saying they can't force the employee. They can put in tough rules, but the employee always has the legal right to buy care outside and submitting a claim; whereas, a Medicare patient may not have anywhere near as much economic flexibility.

You don't have to switch employers to do that, and there are plenty of cases where employees choose to use a different doctor, to

not use a preferred provider, where an employee who is in an HMO chooses to use care elsewhere.

Senator DURENBERGER. But they are only doing that because we and the employers are paying for it. I mean, there are very few, other than the chairman of the board at General Motors, who are going to go outside their company-paid, government-paid, totally tax-subsidized health plan.

Mr. GOLDBECK. It has not been a major issue so far. And all I can tell you is, certainly you are right that employers obviously are not looking for major fights with employees. By the same token, the best way to sell a pre-certification program is on the quality issue and not on the cost issue, to establish the differences in infection rates, as you pointed out earlier, and the other kinds of things that come about as a result of avoidance of unnecessary and inappropriate care.

Senator DURENBERGER. Now, if we can have pre-admission screening requirements for Medicare, why couldn't we, say, condition the tax benefits of employee health insurance on pre-admission screening as part of the benefits in a health plan.

Mr. GOLDBECK. Well, No. 1, you can.

Senator DURENBERGER. Right.

Mr. GOLDBECK. No. 2, it is in concert with the trend although not yet the majority. It would seem to me that of the many things you have to do, pushing that hard on something that is already progressing along rather well is not necessarily your highest priority. It wouldn't bother a lot of firms, because they already have it in place.

I think you asked the specific question: Is there something you can do to stimulate more—both quantitatively and qualitatively, meaning more severe, I gather—private review? And I think that there is. I think the more the PRO Program is required to release a public disclosure of physician and institution-specific comparative information, the more you make it possible for a pre-admission or a pre-certification program of any kind, public or private, to be based on fact and real hard information rather than on more global rhetoric, generalizations, and less outcomes and standards based. That is the single largest thing you can do. It will help both the private and public sectors tremendously.

Senator DURENBERGER. Max.

Senator BAUCUS. Thank you, Mr. Chairman.

I have a slight question. On page 2 of your prepared statement in paragraph 4, you say that Medicare has borrowed from the trust fund. I am just curious—when did Medicare borrow?

Mr. GOLDBECK. It is not. I said that that refers to the White House study on the solvency of Medicare, which they now do not wish to have formally released. But that stipulated that to remain solvent Medicare would have to be borrowing some couple of hundred billion dollars from the Social Security Trust Fund over the next 30 years.

Senator BAUCUS. But I just want to establish—has Medicare borrowed?

Mr. GOLDBECK. No, not past tense. No, sir. That was a prescription for solvency, including that borrowing.

Senator BAUCUS. What White House study group was this?

Mr. GOLDBECK. It was the White House study group that was chaired by William Roper.

Senator BAUCUS. When was that?

Mr. GOLDBECK. It was basically over the course of the past year. I can look up the dates—it was roughly 8 weeks ago, or thereabout, that the report on their activities was, shall we say, made available to some. And then, upon public discussion, it was formally withdrawn by the White House. But the analysis was nonetheless there.

Senator BAUCUS. I was curious about that statement, because a few years ago or a year or two ago all of us were very concerned that Medicare was going to go belly-up——

Mr. GOLDBECK. Yes, Senator.

Senator BAUCUS [continuing]. In about 1985 or 1986, and each year more reports come out which show that Medicare, the Hospital Insurance Trust Fund, is really in a lot better financial shape than a lot of people thought. The latest estimate I see is the late 1990's—the mid to late 1990's—as a possible date. So I just wanted to get the facts straight here. Medicare has not been borrowing.

Mr. GOLDBECK. No, no, not in that sense at all.

Senator BAUCUS. And there is no intention that I am aware of that it either has or needs to in the near future.

Mr. GOLDBECK. I think it is important, if we are going to look at the future solvency of Medicare——

Senator BAUCUS. The future is a long way off. It is hard to predict what the world is going to be like in the 5 years preceding the year 2000. I mean, that is very difficult to predict.

Mr. GOLDBECK. It is, indeed. I think there are a few certainties, though. One is the rate of growth of the elderly population is no longer a mystery, and the impact that that can have if we don't make certain reforms within the system. I think it is important to note, at least we have tried to make this point because we feel it is important, that a lot of the ability to make Medicare solvent is because of a lot more of the costs being borne by other people and a lot of changes in the program itself. It isn't making the old Medicare solvent; it is really a new Medicare with very different kinds of assistance for the elderly.

Senator BAUCUS. Thank you.

Senator DURENBERGER. Bill, thank you very much. I appreciate your testimony, as always.

And all the other witnesses, we express our appreciation to you for your continued interest in peer review.

As I indicated earlier, there will be some additional questions propounded to some of the witnesses. And you can elaborate on your testimony.

Thank you all very much for being here. The hearing is adjourned.

[Whereupon, at 11:53 a.m., the hearing was concluded.]

[By direction of the chairman the following communications were made a part of the hearing record:]

Statement of the

AMERICAN MEDICAL CARE AND REVIEW ASSOCIATION

Mr. Chairman, my name is Gaylord C. Weeks. I am a practicing physician from Oregon City, Oregon, and I am the current President of the American Medical Care and Review Association, or AMCRA.

AMCRA is the national organization which represents physician practitioners and member health plans that now sponsor a variety of community-based options for providing quality health care through cost-effective, alternative delivery systems. AMCRA includes in its membership: individual practice association-type health maintenance organizations (or IPA/HMOs), preferred provider organizations (PPOs), and foundations for medical care (FMCs). The Association's present membership includes organizations that represent over 54,000 participating physicians and which have a combined enrollment of more than 2,800,000.

AMCRA members are concerned about the Government's peer review programs from several different perspectives--as individual practitioners who serve Medicare patients, as physician members of competitive health care delivery systems who know the importance of effective review programs to the success of such plans. But we also speak from much more specific knowledge about the workings of Medicare's peer review program, since the Association also numbers among its members several of the PROs that have contracts with HCFA in implementing the current program. On behalf of AMCRA, I am pleased, therefore, to have an opportunity to present our views and comments specifically about Medicare's utilization and quality control peer review organization programs.

Mr. Chairman, our health maintenance organizations and their related bretheren in the Medicare program--the competitive medical

plans--have long recognized the absolute importance of utilization management programs to the success of any health care delivery system. We know this to be especially true for the alternative delivery systems that make up the membership of AMCRA.

Quality assurance has long been a part of the HMO and CMP world, if for no other reason than self-preservation. As in any other business, if the word gets out that one of our plans provides patients with a poor quality product; enrollments will fall, private purchasers of care in the community will not sign contracts with us to care for their employees and dependents, and patients and physicians alike will turn to others to obtain the health care they require.

Good physicians and other providers of services are not really interested in being associated with any organization that is known to provide poor quality care. Quality control and the means to monitor the provision of any service are essential parts of any successful business activity--including the provision of health care. IPA/HMO physicians are particularly concerned about quality assurance. Most of them generate only a portion of their practice income from IPA/HMO enrollments. They certainly don't want to impair the other parts of their practice by being associated with a less than quality program.

Quality assurance is also important to alternative delivery systems for obvious economic reasons. Because of the way in which HMOs and CMPs are paid--i.e., on the basis of a fixed capitated payment per enrollee--such organizations are very much concerned about the provision of services that are truly medically necessary, that are provided at the appropriate level of care, and that meet recognized standards of quality. Health delivery systems that accept

capitation payments cannot succeed financially unless they employ their resources in a cost effective manner consistent with the provision of a quality product. Peer review is an integral part of this resource management process. All of this is by way of saying, Mr. Chairman, that the physicians and member plans of AMCRA firmly believe in the value of quality assurance--for patients, for practitioners and for quality health care delivery programs on which both depend.

We also strongly believe it to be in the public interest for the Federal Government to obtain the benefits of quality assurance mechanisms for its health programs for the aged, the disabled and the poor. We commend you and the members of the Committee on Finance who have steadily recognized the need for and who have supported the development of workable review mechanisms as part of the Medicare and Medicaid programs. We are also very pleased that implementing PRO regulations have now been finalized and published by HCFA.

In preparing these remarks, we solicited the views of our PRO members about Medicare's implementation of the peer review program. Let me say at the outset that each of our PRO members continues to express strong support for the goals and objectives set out for the program by the 1982 Amendments. At the same time, however, representatives from each of the PROs who are members of our Association also expressed serious concerns about a number of operational problems associated with implementation of the review program during the last year or so.

Some of our PRO members are especially alarmed by what they see as an increasing bureaucratic interest in peer review only in "bottom

line" expenditure terms. The importance of peer review must be in its focus on quality and utilization issues, and not only on cost containment objectives. There can be no room in a program of peer review for a system of quotas intended only to ration the provision of health services provided to the aged and the poor. We hope that HCFA will exercise flexibility when the need to renegotiate contract objectives is demonstrated.

Some of our members are also concerned about the hodgepodge of bureaucratic rules and requirements that can seriously impair the ability of PROs to accomplish the objectives which we believe you, and other members of Congress, expected from the 1982 Peer Review Improvement Act.

Let me describe some of the implementation problems as we have come to see them.

Unnecessarily Prescriptive Rules and Detail. In our view, the Health Care Financing Administration's (HCFA's) management of the PRO program has been far more prescriptive and administratively burdensome than Congress ever intended. We all recognize the many complexities that need attention in the design of a peer review process that is national in its scope, yet responsive to the medical practice circumstances and resource constraints at the local community level. But, in our view, HCFA has been unnecessarily rigid and concerned more with the form than the substance or purpose of good peer review. The level of detail prescribed by the agency sometimes defies any rationale at all--from the standpoint of good quality care or sound health care economics.

Lack of Accurate and Timely FI Data. PROs across the country appear to have spent an inordinate amount of time attempting to obtain complete, accurate and timely data from the fiscal intermediaries. The error rates in the data eventually received has also been so high as to make the data suspect in its application. Nevertheless, the PRO is being held responsible for implementing actions based on denial rates calculated from such poor data collection. HCFA must invest greater management and financial resources in the area of data collections and distribution, if effective review is to be carried out in a timely fashion.

Additional PRO Workloads Without Additional Resources. The PROs have been asked to take on a series of new responsibilities, many of which are being transferred from the fiscal intermediaries, such as: calculating waiver statistics, monitoring the accuracy of FI data, and identifying and notifying the FI's of transfers billed out of sequence. More recently, PROs have received instructions to undertake new areas of review, such as review of claims where hospitals have requested reclassification of a case into a higher DRG or requirements that PRO's report on the provision of non-covered services. Each of these kinds of additional tasks, however, are to be carried out without adequate modifications in PRO fixed-price contracts.

Lack of HCFA Responses to PRO Suggestions. Delays of several months are common in HCFA's response to PRO requests for assistance. PROs need quick responses to effectively deal with specific problem areas.

For example, HCFA might provide such quick response by establishing a coding hotline to provide an objective review of PRO coding decisions

disputed by hospital-financed coding personnel. PROs rarely, if ever at all, have an opportunity to review or comment upon draft PRO instructions, before being told that implementation is "to be effective upon receipt."

We would offer some of the following suggestions to improve--in a constructive way--the climate in which the Medicare peer review organization now operates:

- HCFA should encourage and, where appropriate, accept alternative PRO review plans; many PROs perform a broad range of other private and public review and are uniquely positioned to bring their expertise to bear to their Medicare workloads--HCFA could benefit from this expertise if the PROs are permitted to do the job in a flexible manner.
- HCFA must make the provision of accurate and timely FI data a major program priority and commit the resources needed to resolve problems in this area.
- HCFA should establish a coding task force, so that PROs would have a reliable source of coding expertise to review their decisions where challenged by hospital personnel.
- HCFA should establish a process to permit pre-issuance reaction and comments from PROs on new or revised peer review policies and directives; and,
- HCFA should give immediate attention to creation of a mechanism to assure that regional office policy decisions and clarifications are consistent among the regions and with the agency's overall position on peer review matters.

Mr. Chairman, we wish the Committee to know of our strong belief in peer review and in the role of the PRO to meet the needs of the Federal Government for an effective quality control program. We appreciate very much this opportunity to convey our support of the program and to share our views on its implementation.

Statement of the American Society of Internal Medicine

For the Record

of the

Senate Finance Committee Hearings

on the Implementation of the Utilization

and Quality Control Peer Review Organization (PRO) Program

April 19, 1985

The American Society of Internal Medicine (ASIM), an organization representing more than 18,000 physicians who are specialists in internal medicine, takes this opportunity to offer its views on the implementation of the Peer Review Organization (PRO) program. The Society has had an historical commitment to physician-directed peer review. In 1966, one month after the establishment of the Medicare program, the ASIM House of Delegates went on record to encourage internists to serve as members of utilization review committees. Since that time, ASIM has co-sponsored conferences, testified before Congress and set an example of membership involvement in physician-directed peer review.

Following implementation of the Peer Review Improvement Act of 1982, which mandated the establishment of Utilization and Quality Control Peer Review Organizations to replace the former Professional Standards Review Organizations (PSROs), ASIM again reaffirmed its commitment to physician-directed peer review. The Society testified before Congress and submitted comments on several sets of proposed regulations to the Department of Health and Human Services (DHHS). In addition, ASIM developed a step-by-step guide to help internists become actively involved with the formulation and operation of their state PROs. As a result, ASIM members are presently on the boards of

directors for several state PROs and are actively involved with many of the PRO review committees. ASIM's Board of Trustees recently established a PRO Task Force to help evaluate the functioning of the PRO program.

As a result of this involvement and commitment to physician-directed peer review, ASIM would like to offer its comments on the initial implementation of the PRO program. Specifically, the Society believes there presently is some confusion by beneficiaries, physicians and hospitals about certain administrative elements of the program. Further, ASIM believes that the quality review aspect of peer review needs refinement in order to better ensure quality health care under the prospective payment system.

Administrative Problems with the Peer Review Organizations

ASIM welcomes the recent release by DHHS of the final PRO regulations. However, the Society regrets there was an extended delay in the publication of these rules. Several administrative problems might otherwise have been avoided if final regulations regarding denial determinations, sanctions, liability and other administrative issues had been published. We recognize that many of these problems may be rectified with publication of the final regulations but did want to share with the committee some of the experiences of ASIM members. While such problems are not endemic of peer review, they have created uncertainty, confusion and distrust among hospitals, physicians and patients. To alleviate these problems, ASIM encourages the committee to closely monitor some of the following areas that have been particularly frustrating for ASIM members:

1. Patients have received PRO denial notices without their attending physician first being consulted. Section 1154(a)(3) of the Peer Review Improvement Act states that: "in the case of practitioners and providers of services, the organizations shall provide an opportunity for discussion and review of the determination." Mr. Philip Nathanson, director of the Health Standards and Quality Bureau for the Health Care Financing Administration (HCFA) has clarified this provision for ASIM by stating, in writing, "The intent of this provision is clearly that the PRO physician discuss a pending denial determination with the patient's attending physician. Therefore, PROs must follow this requirement, despite the current lack of interpretory regulations." Without final publication of the regulations implementing this provision, many PROs mistakenly believed this requirement did not apply to them Consequently, they have sent denial notices to patients without first discussing the proposed denial with the attending physician.

This practice created two problems. One, it did not afford physicians the opportunity to discuss their reasons for admitting a patient to the hospital. By not discussing the details and intricacies of individual cases with the attending physician, many of the PRO determinations were based on incomplete information. Also, by issuing a denial without first discussing the case with the physician, many of the PROs have undermined Medicare patients' trust in their physicians. Many Medicare patients have been shocked, confused and angered by these denials--problems that could have been prevented had physicians been given the opportunity to discuss a proposed denial with the patient prior to their notification.

At ASIM's urging, HCFA did issue a transmittal, IM 85-1, on February 1985, informing PROs that they must discuss all pending denials with the attending physicians before notifying the beneficiary of the initial denial determination. Despite this clarification, ASIM has received several complaints from internists that these procedures are still not being followed.

2. Some PROs have used misleading language in issuing PRO rulings. It has been brought to the Society's attention that some PROs have told patients that the medical care received was "substandard." This language--not mandated by DHHS in the proposed or final regulations--has been used by PROs when they inform Medicare beneficiaries of a denial determination concerning their medical care. ASIM believes that such negative characterizations of the medical care received by Medicare patients are both unwarranted and unfair under the PRO program. The PRO quality and utilization criteria were established, in part, to outline what the government would pay for under the Medicare program. Since there is an honest difference in professional opinion as to what constitutes quality medical care, ASIM believes that PRO denial language should not be worded in a manner that results in patients questioning the medical value of the care they receive. We would be happy to work with HCFA in developing more appropriate language. For example, the Society suggests that PROs, when issuing denial notices, simply state that the procedure or service does not meet Medicare's criteria for coverage.

3. The proposed regulations have caused confusion about who bears the financial liability for denied hospital care. The absence of final PRO

regulations has resulted in confusion about who is financially liable for denied claims. Hospitals have been uncertain about the circumstances under which they can properly bill Medicare patients for PRO denied care. After some initial confusion, hospitals learned that they can bill patients for denied care only after they have formally issued a "notice of non-coverage." However, patients and physicians were not adequately instructed as to how they can appeal such notices in a timely manner. Since much of the PRO review takes place retrospectively, many patients receive denial notices months after they have left the hospital. To further complicate the matter, PROs have not adequately been informed by HCFA as to how they can determine whether or not hospitals have properly issued their "notices of non-coverage." This has created tension among providers, practitioners and beneficiaries because they are often unsure about who is financially liable for medical care found by the PRO to not have met the Medicare criteria for coverage.

4. The preadmission review requirement has created administrative burdens for physicians. As part of their contract with HCFA, each PRO must conduct preadmission review for elective procedures under at least five selected DRGs or DRG groups. Many ASIM members have experienced administrative difficulties associated with this requirement. Lack of enough telephone lines to handle calls from physicians, insufficient PRO staff and inefficient handling of records are some of the problems encountered by internists seeking preadmission certification for their patients. These administrative headaches, unfortunately, undermine the value of preadmission review and subject some patients to unnecessary and, in some cases, unpleasant delays in receiving appropriate medical care. The

Society encourages Congress to ensure that the PROs receive sufficient funding so they can adequately accomplish the tasks mandated by Congress.

PRO Structural Concerns That Affect Quality

Since the Peer Review Improvement Act was passed, ASIM and other medical groups have expressed concern that the PRO program has focused too heavily on cost containment rather than quality review. To alleviate some of these concerns, HCFA added several additional quality review criteria to the PROs' scope of work. However, preliminary studies of the prospective payment system (PPS) indicates that the quality side of peer review needs closer scrutiny.

Because ASIM members have expressed concern about the negative effects PPS may have on the quality of health care, the Society is currently surveying internists about their experiences under the system. Specifically, the Society is concerned that physicians may be pressured by hospital to release patients prematurely and that the quality of hospital support services, i.e., nurses, lab technicians, etc., will be diminished. To verify these concerns, ASIM is developing an extensive, scientific survey of internists' experiences under PPS.

In the meantime, the General Accounting Office (GAO) has issued a preliminary report (GAO/PHD-85-8) at the request of Senator John Heinz (R-PA), which supports some of the problems indicated in the ASIM survey. At each of six sites visited by the GAO, health care personnel expressed concern about the quality of care received by Medicare patients. The GAO found the following problems under the PPS diagnosis related groups (DRGs):

- Patients are being discharged from hospitals after shorter lengths of stay and in poorer states of health than prior to DRGs.

- Beneficiaries are upset and confused about their Medicare benefits. Many patients are being told improperly that they have to leave the hospital because their Medicare/DRG coverage has run out.

- It is not clear that post-hospital providers--including nursing homes, home health, community services--are equipped to deal with these sicker patients.

- The demand for post-hospital care is expected to increase under DRGs--yet there is already a shortage of nursing home beds for Medicare patients and limited coverage for services under home and community health programs in many areas.

- Greater demand for non-hospital services that Medicare covers, such as skilled nursing home care and home health, will mean an increase in costs. This cost-shifting from hospitals to community-based programs will mean more dollars out-of-pocket for Medicare beneficiaries.

As the impact of DRGs on the quality of care becomes more evident, the Society believes HCFA should remain flexible in allowing peer review organizations to renegotiate their PRO objectives. ASIM is pleased that HCFA has responded to utilization and quality concerns by renegotiating the objectives for 25 PROs. Most of the PROs bid for their review contracts in a very competitive

atmosphere and may have established unfeasible goals. Many of these PROs were also hindered in realistically developing their criteria because they lacked adequate data. Since data did not exist for most of the DRGs, PROs often had to use hospital records to extrapolate, as best they could, their utilization and quality objectives. Carolyne Davis, PhD, Administrator for HCFA has indicated that the Administration is willing to renegotiate these criteria. ASIM believes that this is essential if quality care under the PRO and PPS programs is to be preserved.

ASIM believes PROs should place greater emphasis on the quality component of peer review. Internists are concerned that the quality criteria under the PRO program are proscriptive measures designed primarily to contain health care costs. The Soiety believes that if quality health care is to be properly preserved under the Medicare program, HCFA will need to refine its quality objectives in terms that enhance not only the cost aspect of health care but also place strong emphasis on preserving the quality of patient care.

Conclusion

In conclusion, ASIM would like to reaffirm its support for physician-directed peer review. The administrative problems with the PRO program that were outlined earlier in our testimony, while serious, can reasonably be remedied through clearer regulations and procedures. The Society believes that the recent release of the final PRO regulations will certainly contribute to this end. However, ASIM also believes that Congress will need to closely monitor the program to further ensure that the PRO program properly balances the utilization and quality aspects of peer review.

In the coming months, ASIM believes that it is essential for Medicare to place more of an emphasis on the quality side of peer review. The commitment of HCFA to renegotiate utilization and quality objectives of PROs is a positive step in this direction. ASIM would further urge the Administration to consider other ways to move quality review away from its present proscriptive measures that are designed largely for cost containment purposes. With the support of Congress, the Society believes that these changes will help the medical community operate efficiently while providing quality health care under the peer review program.

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